



K162569

510(k) Notification (21 CFR 807.90(e)):

FDA Center for Devices and Radiological Health
 Document Mail Center, W066-0609
 10903 New Hampshire Ave.
 Silver Spring, MD 20993-0002

FDA/CDRH/DCG
 SEP 15 2016
 RECEIVED

To Whom it May Concern:

This cover letter is to notify you of the intention of Biotech Lubricants Limited, Petersfield, GU31 4AT, U.K to introduce into interstate commerce, for commercial distribution, by way of this bundled, Traditional 510(k), the following three (3) new personal lubricant devices:

Proposed Device 1:

| | New Device 1 | Predicate Device |
|------------------------------------|---|---|
| Panel: | Obstetrics/Gynecology | Obstetrics/Gynecology |
| Device Classification Name: | Lubricant, Patient, Latex compatible | Lubricant, Patient, Latex compatible |
| Common Name: | Personal Lubricant | Personal Lubricant |
| Proprietary Name: | YES [®] water-based Personal Lubricant | Aloe Cadabra Personal Lubricant (K124044) |
| Classification Code: | NUC | NUC |
| Regulation Number: | 884.5300 | 884.5300 |

Proposed Device 2:

| | New Device 2 | Predicate Device |
|------------------------------------|---|--|
| Panel: | Obstetrics/Gynecology | Obstetrics/Gynecology |
| Device Classification Name: | Lubricant, Patient, Latex compatible | Lubricant, Patient, Latex compatible |
| Common Name: | Personal Lubricant | Personal Lubricant |
| Proprietary Name: | YES [®] oil-based Personal Lubricant | LifeStyles Luxe Premium Personal Lubricant (K122477) |
| Classification Code: | NUC | NUC |
| Regulation Number: | 884.5300 | 884.5300 |

Proposed Device 3:

| | New Device 3 | Predicate Device |
|------------------------------------|--------------------------------------|---|
| Panel: | Obstetrics/Gynecology | Obstetrics/Gynecology |
| Device Classification Name: | Lubricant, Patient, Latex compatible | Lubricant, Patient, Latex compatible |
| Common Name: | Personal Lubricant | Personal Lubricant |
| Proprietary Name: | YES [®] Vaginal Moisturizer | Aloe Cadabra Personal Lubricant (K124044) |
| Classification Code: | NUC | NUC |
| Regulation Number: | 884.5300 | 884.5300 |

BioCity Nottingham, Pennyfoot Street,
 Nottingham, NG1 1GF, United Kingdom
 Registered Office: The Mills, Canal Street, Derby, DE1 2RU

3-1

Offices throughout the United States and Europe
 +44 115 921 6200 | www.maetrics.co.uk
 Registration: England 04530358 VAT No. GB 755 9433 94


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This submission contains methods, data and analysis of these data which the Sponsor considers "Trade Secret", commercially privileged and confidential. In accordance with 21 CFR §20.61, this information may not be disclosed to the public in accordance with Freedom of Information (FOI) Act. This submission follows the format suggested in the FDA's Guidance for Industry and FDA Staff: Format for Traditional and Abbreviated 510(k)'s dated August 12, 2005.

The eCopy is an exact duplicate of the paper copy.

If you have any questions, I can be contacted at either +44 115 921 6200, or by email at jshepperson@maetrics.com.

Best regards,

 31/08/2016

John Shepperson.

Senior Associate,
Maetrics,
BioCity Nottingham,
Pennyfoot Street,
Nottingham.
NG1 1GF.
United Kingdom.

End of Cover letter



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| | |
|--|--|
| DEPARTMENT OF HEALTH AND HUMAN SERVICES FOOD AND DRUG ADMINISTRATION MEDICAL DEVICE USER FEE COVER SHEET | PAYMENT IDENTIFICATION NUMBER: (b)(4) Write the Payment Identification number on your check. |
| A completed cover sheet must accompany each original application or supplement subject to fees. If payment is sent by U.S. mail or courier, please include a copy of this completed form with payment. Payment and mailing instructions can be found at: http://www.fda.gov/oc/mdufma/cover sheet.html | |
| 1. COMPANY NAME AND ADDRESS (include name, street address, city state, country, and post office code) BIO TECH LUBRICANTS LTD 2 Venture Road Southampton Science Park Chilworth Southampton Hampshire SO16 7NP GB 1.1 EMPLOYER IDENTIFICATION NUMBER (EIN) | 2. CONTACT NAME Sarah Brooks 2.1 E-MAIL ADDRESS sarah@biotechlubricants.com 2.2 TELEPHONE NUMBER (include Area code) 01730-261224 2.3 FACSIMILE (FAX) NUMBER (Include Area code) |
| 3. TYPE OF PREMARKET APPLICATION (Select one of the following in each column; if you are unsure, please refer to the application descriptions at the following web site: http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm345263.htm) Select an application type: | |
| <input checked="" type="checkbox"/> Premarket notification(510(k)); except for third party <input type="checkbox"/> 513(g) Request for Information <input type="checkbox"/> Biologics License Application (BLA) <input type="checkbox"/> Premarket Approval Application (PMA) <input type="checkbox"/> Modular PMA <input type="checkbox"/> Product Development Protocol (PDP) <input type="checkbox"/> Premarket Report (PMR) <input type="checkbox"/> 30-Day Notice | 3.1 Select a center <input checked="" type="checkbox"/> CDRH <input type="checkbox"/> CBER 3.2 Select one of the types below <input checked="" type="checkbox"/> Original Application <u>Supplement Types:</u> <input type="checkbox"/> Efficacy (BLA) <input type="checkbox"/> Panel Track (PMA, PMR, PDP) <input type="checkbox"/> Real-Time (PMA, PMR, PDP) <input type="checkbox"/> 180-day (PMA, PMR, PDP) |
| 4. ARE YOU A SMALL BUSINESS? (See the instructions for more information on determining this status) <input checked="" type="checkbox"/> YES, I meet the small business criteria and have submitted the required qualifying documents to FDA <input type="checkbox"/> NO, I am not a small business 4.1 If Yes, please enter your Small Business Decision Number: SBD165326 | |
| 5. FDA WILL NOT ACCEPT YOUR SUBMISSION IF YOUR COMPANY HAS NOT PAID AN ESTABLISHMENT REGISTRATION FEE THAT IS DUE TO FDA. HAS YOUR COMPANY PAID ALL ESTABLISHMENT REGISTRATION FEES THAT ARE DUE TO FDA? <input type="checkbox"/> YES (All of your establishments have registered and paid the fee, or this is your first device and you will register and pay the fee within 30 days after entering into an operation that requires you to register and submit device listing information.) <input checked="" type="checkbox"/> NO (If you currently market a medical device and your establishment is required to register and submit device listing information, FDA will not accept your submission until you have paid all fees due to FDA. See http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/RegistrationandListing/ucm053165.htm for additional information) | |

6. IS THIS PREMARKET APPLICATION COVERED BY ANY OF THE FOLLOWING USER FEE EXCEPTIONS? IF SO, CHECK THE APPLICABLE EXCEPTION.

- | | |
|---|---|
| <input type="checkbox"/> This application is the first PMA submitted by a qualified small business, including any affiliates | <input type="checkbox"/> The sole purpose of the application is to support conditions of use for a pediatric population |
| <input type="checkbox"/> This biologics application is submitted under section 351 of the Public Health Service Act for a product licensed for further manufacturing use only | <input type="checkbox"/> The application is submitted by a state or federal government entity for a device that is not to be distributed commercially |

7. IS THIS A SUPPLEMENT TO A PREMARKET APPLICATION FOR WHICH FEES WERE WAIVED DUE TO SOLE USE IN A PEDIATRIC POPULATION THAT NOW PROPOSES CONDITION OF USE FOR ANY ADULT POPULATION? (If so, the application is subject to the fee that applies for an original premarket approval application (PMA).

- YES NO

PAPERWORK REDUCTION ACT STATEMENT

Public reporting burden for this collection of information is estimated to average 18 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to the address below.

Department of Health and Human Services, Food and Drug Administration, Office of Chief Information Officer, 8455 Colesville Road, COLE-14-14253 Silver Spring, MD 20993-0002
 [Please do NOT return this form to the above address, except as it pertains to comments on the burden estimate.]

8. USER FEE PAYMENT AMOUNT SUBMITTED FOR THIS PREMARKET APPLICATION

(b)(4)

06-Jul-2016

Please wait...

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Windows is either a registered trademark or a trademark of Microsoft Corporation in the United States and/or other countries. Mac is a trademark of Apple Inc., registered in the United States and other countries. Linux is the registered trademark of Linus Torvalds in the U.S. and other countries.

**510(k) Notification (21 CFR 807.90(e)):**

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| Proprietary Name: | YES [®] water-based Personal Lubricant | Aloe Cadabra Personal Lubricant (K124044) |
| Classification Code: | NUC | NUC |
| Regulation Number: | 884.5300 | 884.5300 |

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Best regards,

 31/08/2016

John Shepperson.

Senior Associate,
Maetrics,
BioCity Nottingham,
Pennyfoot Street,
Nottingham.
NG1 1GF.
United Kingdom.

End of Cover letter



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Registered Office: The Mills, Canal Street, Derby, DE1 2RJ

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+44 115 921 6200 | www.maetrics.co.uk
Registration: England 04530358 VAT No. GB 755 9433 94

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Form Approved: OMB No. 0910-0120

Expiration Date: January 31, 2017

See PRA Statement below.

Indications for Use

510(k) Number (if known)

Device Name

YES® oil-based Personal Lubricant, YES® water-based Personal Lubricant, YES® Vaginal Moisturizer

Indications for Use (Describe)

Device Name: YES® oil-based Personal Lubricant

Indications for Use:

A personal lubricant, for vaginal and penile application, intended to moisturize and lubricate, to enhance the ease and comfort of intimate sexual activity and supplement the body's natural lubrication. YES® oil-based Personal Lubricant is not compatible with natural rubber latex, polyurethane or polyisoprene condoms.

Device Name: YES® water-based Personal Lubricant

Indications for Use:

A personal lubricant, for vaginal and penile application, intended to moisturize and lubricate, to enhance the ease and comfort of intimate sexual activity and supplement the body's natural lubrication. YES® water-based Personal Lubricant is compatible with natural rubber latex, polyurethane or polyisoprene condoms.

Device Name: YES® Vaginal Moisturizer

Indications for Use:

A personal lubricant, for vaginal and penile application, intended to moisturize and lubricate, to enhance the ease and comfort of intimate sexual activity and supplement the body's natural lubrication. YES® Vaginal Moisturizer is compatible with natural rubber latex, polyurethane or polyisoprene condoms.

Type of Use (Select one or both, as applicable)

 Prescription Use (Part 21 CFR 801 Subpart D) Over-The-Counter Use (21 CFR 801 Subpart C)**CONTINUE ON A SEPARATE PAGE IF NEEDED.**

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

Section 5: 510(k) Summary

In accordance with 21 CFR 807.87(h) and 21 CFR 807.92 the 510(k) Summary for YES[®] oil-based Personal Lubricant, YES[®] water-based Personal Lubricant, and YES[®] Vaginal Moisturizer is provided below:

Device Common Name: Personal Lubricant

Device Proprietary Names: YES[®] oil-based Personal Lubricant
YES[®] water-based Personal Lubricant
YES[®] Vaginal Moisturizer

Sponsor: Biotech Lubricants Limited,
Ramshill,
Petersfield,
GU31 4AT,
United Kingdom

Official Correspondent: John Shepperson, Maetrics
BioCity Nottingham.
Pennyfoot Street,
Nottingham.
NG1 1GF.
United Kingdom.
Phone: +44 115 921 6200
Email: jshepperson@maetrics.com

Date Prepared: May 3, 2016

Classification Regulation: 884.5300

Classification Name: Condom

Panel: Obstetrics/Gynecology

Product Code: NUC

Predicate Device: K124044 Aloe Cadabra Personal Lubricant (Seven Oaks Ranch Inc)
K122477 Lifestyles Luxe Premium Personal Lubricant (Ansell Healthcare Product LLC)

Indications for Use:

YES[®] oil-based Personal Lubricant: A personal lubricant, for vaginal and penile application, intended to moisturize and lubricate, to enhance the ease and comfort of intimate sexual activity and supplement the body's natural lubrication. YES[®] oil-based Personal Lubricant is not compatible with natural rubber latex, polyurethane or polyisoprene condoms.

YES[®] water-based Personal Lubricant: A personal lubricant, for vaginal and penile application, intended to moisturize and lubricate, to enhance the ease and comfort of intimate sexual activity and supplement the body's natural lubrication. YES[®] water-based Personal Lubricant is compatible with natural rubber latex, polyurethane or polyisoprene condoms.

YES[®] Vaginal Moisturizer: A personal lubricant, for vaginal and penile application, intended to moisturize and lubricate, to enhance the ease and comfort of intimate sexual activity and supplement the body's natural lubrication. YES[®] water-based Personal Lubricant is compatible with natural rubber latex, polyurethane or polyisoprene condoms.

Device Descriptions:

YES[®] oil-based Personal Lubricant: A non-sterile, non-condom compatible oil-based personal lubricant formulated to supplement the body's natural lubricating fluids when vaginal dryness causes discomfort. It is neither a contraceptive nor a spermicide. The formulation is a cream coloured non-staining, thick paste that melts at body temperature.

YES[®] water-based Personal Lubricant: A non-sterile condom compatible high viscosity water-based personal lubricant formulated to supplement the body's natural lubricating fluids when vaginal dryness causes discomfort. It is neither a contraceptive nor a spermicide. The formulation is a lightly opaque, non-staining, non-greasy natural liquid gel.

YES[®] Vaginal Moisturizer: A non-sterile condom compatible personal lubricant formulated to supplement the body's own natural lubricating fluids to provide personal moisturization when vaginal dryness causes discomfort. It is neither a contraceptive nor a spermicide. The formulation is a lightly opaque, non-staining, non-greasy natural liquid gel.

Technological Characteristics:

YES[®] oil-based Personal Lubricant: As an oil-based or oil containing lubricant the proposed device and the predicate devices are substantially equivalent. The plant based oils and butters in the proposed device are all GRAS. Testing per ASTM D7661, ASTM D3492, and ASTM D6324 indicated that the device is not compatible with polyurethane condoms. Additionally, as with other predicate devices containing natural or mineral oils this device is not compatible with natural rubber latex or polyisoprene condoms. The device is labeled "not compatible with natural rubber latex, polyurethane or polyisoprene condoms."

YES[®] water-based Personal Lubricant: A water-based gel with similar formulation to the predicate device. Testing per ASTM D7661, ASTM D3492, and ASTM D6324 indicated that the device is compatible with natural rubber latex, polyurethane and polyisoprene condoms.

YES[®] Vaginal Moisturizer: A water-based gel with similar formulation to the predicate device. The viscosity is slightly more viscous than YES[®] water-based Personal Lubricant. Testing per ASTM D7661, ASTM D3492, and ASTM D6324 indicated that the device is compatible with natural rubber latex, polyurethane and polyisoprene condoms.

Biocompatibility Testing:

Testing for cytotoxicity, vaginal irritation, sensitization, and systemic toxicity in accordance with ISO 10993-5, ISO 10993-10 and ISO 10993-11 was conducted for all three devices. All three devices indicated device biocompatibility.

Condom Compatibility Testing:

YES[®] oil-based Personal Lubricant: Condom compatibility testing was performed on polyurethane condoms per ASTM D7661, ASTM D3492, and ASTM D6324. Test results indicate that the device is not compatible with polyurethane condoms. Additionally, as with other predicate devices containing natural or mineral oils, natural or mineral oils are not compatible with natural rubber latex or polyisoprene condoms. The device is labeled "not compatible with natural rubber latex, polyurethane or polyisoprene condoms."

YES[®] Vaginal Moisturizer and YES[®] water-based Personal Lubricant: Testing per ASTM D7661, ASTM D3492, and ASTM D6324 indicated that the devices are compatible with natural rubber latex, polyurethane and polyisoprene condoms. The devices are labeled "compatible with natural rubber latex, polyurethane or polyisoprene condoms."

Shelf Life: YES[®] oil-based Personal Lubricant, YES[®] water-based Personal Lubricant, and YES[®] Vaginal Moisturizer have a two-year shelf life based on the results of a real time aging study in accordance with the International Council For Harmonisation (ICH) Guidelines – Q1A(R2) – Stability Testing of Drug Substances and Products.

Conclusion:

YES[®] oil-based Personal Lubricant, YES[®] water-based Personal Lubricant, and YES[®] Vaginal Moisturizer have the same intended use and basic technological characteristics as the predicate devices. Biocompatibility and performance testing demonstrate that these devices raise no new issues of safety or effectiveness. Therefore, these lubricants are substantially equivalent to the predicate devices.

End of Section 5

Section 6: Truthful and Accurate Statement

[As Required by 21 CFR 807.87(k)]

I certify that, in my capacity as Managing Director of Bio-Tech Lubricants Ltd, I believe to the best of my knowledge, that all data and information submitted in the premarket notification are truthful and accurate and that no material fact has been omitted.



(Signature)

Sarah Brooks

(Typed Name)

July 18, 2016

(Date)

Section 7: 510k Class III Summary and Certification

This section does not apply. All devices in this 510(k) submission are Class II.

End of Section 7

Section 8: Financial Certification or Disclosure Statement

This section does not apply. There is no information submitted in this 510(k) from clinical studies, it is a Class II device and no financial certification and/or a disclosure statement is required.

End of Section 8

Department of Health and Human Services
Food and Drug Administration
STANDARDS DATA REPORT FOR 510(k)s
(To be filled in by applicant)

This report and the Summary Report Table are to be completed by the applicant when submitting a 510(k) that references a national or international standard. A separate report is required for each standard referenced in the 510(k).

TYPE OF 510(K) SUBMISSION

Traditional Special Abbreviated

STANDARD TITLE ¹

ISO 10993-5 Biological Evaluation of Medical Devices - Part 5: Tests for In Vitro Cytotoxicity

Please answer the following questions

Yes No

Is this standard recognized by FDA ²?

FDA Recognition number³ # 2-153

Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?

Is a summary report ⁴ describing the extent of conformance of the standard used included in the 510(k)?
If no, complete a summary report table.

Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device?

Does this standard include acceptance criteria?
If no, include the results of testing in the 510(k).

Does this standard include more than one option or selection of tests?
If yes, report options selected in the summary report table.

Were there any deviations or adaptations made in the use of the standard?.....
If yes, were deviations in accordance with the FDA supplemental information sheet (SIS)⁵?

Were deviations or adaptations made beyond what is specified in the FDA SIS?.....
If yes, report these deviations or adaptations in the summary report table.

Were there any exclusions from the standard?
If yes, report these exclusions in the summary report table.

Is there an FDA guidance ⁶ that is associated with this standard?.....
If yes, was the guidance document followed in preparation of this 510k?

Title of guidance: _____

¹ The formatting convention for the title is: [SDO] [numeric identifier] [title of standard] [date of publication]

² Authority [21 U.S.C. 360d], <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Standards/default.htm>

³ <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm>

⁴ The summary report should include: any adaptations used to adapt to the device under review (for example, alternative test methods); choices made when options or a selection of methods are described; deviations from the standard; requirements not applicable to the device; and the name and

address of the test laboratory or certification body involved in conformance assessment to this standard. The summary report includes information on all standards utilized during the development of the device.

⁵ The supplemental information sheet (SIS) is additional information which is necessary before FDA recognizes the standard. Found at <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm>

⁶ The online search for CDRH Guidance Documents can be found at <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm>

| EXTENT OF STANDARD CONFORMANCE SUMMARY REPORT TABLE | | |
|---|--|--|
| STANDARD TITLE ISO 10993-5 Biological Evaluation of Medical Devices - Part 5: Tests for In Vitro Cytotoxicity | | |
| CONFORMANCE WITH STANDARD SECTIONS* | | |
| SECTION NUMBER | SECTION TITLE Complete test report included in Section 18 | CONFORMANCE? <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A |
| TYPE OF DEVIATION OR OPTION SELECTED ♦ | | |
| DESCRIPTION | | |
| JUSTIFICATION | | |
| SECTION NUMBER | SECTION TITLE | CONFORMANCE? <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A |
| TYPE OF DEVIATION OR OPTION SELECTED ♦ | | |
| DESCRIPTION | | |
| JUSTIFICATION | | |
| SECTION NUMBER | SECTION TITLE | CONFORMANCE? <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A |
| TYPE OF DEVIATION OR OPTION SELECTED ♦ | | |
| DESCRIPTION | | |
| JUSTIFICATION | | |
| SECTION NUMBER | SECTION TITLE | CONFORMANCE? <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A |
| TYPE OF DEVIATION OR OPTION SELECTED ♦ | | |
| DESCRIPTION | | |
| JUSTIFICATION | | |
| <p>* For completeness list all sections of the standard and indicate whether conformance is met. If a section is not applicable (N/A) an explanation is needed under "justification." Some standards include options, so similar to deviations, the option chosen needs to be described and adequately justified as appropriate for the subject device. Explanation of all deviations or description of options selected when following a standard is required under "type of deviation or option selected," "description" and "justification" on the report. More than one page may be necessary.</p> <p>♦ Types of deviations can include an exclusion of a section in the standard, a deviation brought out by the FDA supplemental information sheet (SIS), a deviation to adapt the standard to the device, or any adaptation of a section.</p> | | |
| <p>This section applies only to requirements of the Paperwork Reduction Act of 1995.</p> <p>*DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.*</p> <p>The burden time for this collection of information is estimated to average 1 hour per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:</p> <div style="display: flex; justify-content: space-between;"> <div style="width: 45%;"> <p>Department of Health and Human Services Food and Drug Administration Office of Chief Information Officer Paperwork Reduction Act (PRA) Staff PRAStaff@fda.hhs.gov</p> </div> <div style="width: 45%; text-align: right;"> <p><i>"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number."</i></p> </div> </div> | | |

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TYPE OF 510(K) SUBMISSION

Traditional Special Abbreviated

STANDARD TITLE ¹

ANSI/AAMI/ISO 10993-10 Biological evaluation of medical devices - Part 10: Tests for irritation and skin sensitization

Please answer the following questions

Yes No

Is this standard recognized by FDA ²?

FDA Recognition number ³ # 2-173

Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?

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⁴ The summary report should include: any adaptations used to adapt to the device under review (for example, alternative test methods); choices made when options or a selection of methods are described; deviations from the standard; requirements not applicable to the device; and the name and

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| EXTENT OF STANDARD CONFORMANCE SUMMARY REPORT TABLE | | |
|---|--|--|
| STANDARD TITLE ANSI/AAMI/ISO 10993-10 Biological evaluation of medical devices - Part 10: Tests for irritation and skin sensitization | | |
| CONFORMANCE WITH STANDARD SECTIONS* | | |
| SECTION NUMBER | SECTION TITLE Complete test report included in Section 18 | CONFORMANCE? <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A |
| TYPE OF DEVIATION OR OPTION SELECTED ♦ | | |
| DESCRIPTION | | |
| JUSTIFICATION | | |
| SECTION NUMBER | SECTION TITLE | CONFORMANCE? <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A |
| TYPE OF DEVIATION OR OPTION SELECTED ♦ | | |
| DESCRIPTION | | |
| JUSTIFICATION | | |
| SECTION NUMBER | SECTION TITLE | CONFORMANCE? <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A |
| TYPE OF DEVIATION OR OPTION SELECTED ♦ | | |
| DESCRIPTION | | |
| JUSTIFICATION | | |
| * For completeness list all sections of the standard and indicate whether conformance is met. If a section is not applicable (N/A) an explanation is needed under "justification." Some standards include options, so similar to deviations, the option chosen needs to be described and adequately justified as appropriate for the subject device. Explanation of all deviations or description of options selected when following a standard is required under "type of deviation or option selected," "description" and "justification" on the report. More than one page may be necessary. | | |
| ♦ Types of deviations can include an exclusion of a section in the standard, a deviation brought out by the FDA supplemental information sheet (SIS), a deviation to adapt the standard to the device, or any adaptation of a section. | | |
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Department of Health and Human Services
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STANDARDS DATA REPORT FOR 510(k)s
(To be filled in by applicant)

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TYPE OF 510(K) SUBMISSION

Traditional Special Abbreviated

STANDARD TITLE ¹

ANSI/AAMI/ISO 10993-11 Biological evaluation of medical devices - Part 11: Tests for systemic toxicity

Please answer the following questions

Yes No

Is this standard recognized by FDA ²?

FDA Recognition number³ # 2-118

Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?

Is a summary report ⁴ describing the extent of conformance of the standard used included in the 510(k)?
If no, complete a summary report table.

Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device?

Does this standard include acceptance criteria?
If no, include the results of testing in the 510(k).

Does this standard include more than one option or selection of tests?
If yes, report options selected in the summary report table.

Were there any deviations or adaptations made in the use of the standard?.....
If yes, were deviations in accordance with the FDA supplemental information sheet (SIS)⁵?

Were deviations or adaptations made beyond what is specified in the FDA SIS?.....
If yes, report these deviations or adaptations in the summary report table.

Were there any exclusions from the standard?
If yes, report these exclusions in the summary report table.

Is there an FDA guidance ⁶ that is associated with this standard?.....
If yes, was the guidance document followed in preparation of this 510k?

Title of guidance: _____

¹ The formatting convention for the title is: [SDO] [numeric identifier] [title of standard] [date of publication]

² Authority [21 U.S.C. 360d], <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Standards/default.htm>

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| EXTENT OF STANDARD CONFORMANCE SUMMARY REPORT TABLE | | |
|---|--|--|
| STANDARD TITLE ANSI/AAMI/ISO 10993-11 Biological evaluation of medical devices - Part 11: Tests for systemic toxicity | | |
| CONFORMANCE WITH STANDARD SECTIONS* | | |
| SECTION NUMBER | SECTION TITLE Complete test report included in Section 18 | CONFORMANCE? <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A |
| TYPE OF DEVIATION OR OPTION SELECTED ♦ | | |
| DESCRIPTION | | |
| JUSTIFICATION | | |
| SECTION NUMBER | SECTION TITLE | CONFORMANCE? <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A |
| TYPE OF DEVIATION OR OPTION SELECTED ♦ | | |
| DESCRIPTION | | |
| JUSTIFICATION | | |
| SECTION NUMBER | SECTION TITLE | CONFORMANCE? <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A |
| TYPE OF DEVIATION OR OPTION SELECTED ♦ | | |
| DESCRIPTION | | |
| JUSTIFICATION | | |
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TYPE OF 510(K) SUBMISSION

Traditional Special Abbreviated

STANDARD TITLE ¹

ASTM D3492-08 Standard Specification for Rubber Contraceptives (Male Condoms)

Please answer the following questions

Yes No

Is this standard recognized by FDA ²?

FDA Recognition number ³ #9-56

Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?

Is a summary report ⁴ describing the extent of conformance of the standard used included in the 510(k)?
If no, complete a summary report table.

Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device?

Does this standard include acceptance criteria?
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If yes, report options selected in the summary report table.

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If yes, were deviations in accordance with the FDA supplemental information sheet (SIS) ⁵?

Were deviations or adaptations made beyond what is specified in the FDA SIS?.....
If yes, report these deviations or adaptations in the summary report table.

Were there any exclusions from the standard?
If yes, report these exclusions in the summary report table.

Is there an FDA guidance ⁶ that is associated with this standard?.....
If yes, was the guidance document followed in preparation of this 510k?

Title of guidance: _____

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| EXTENT OF STANDARD CONFORMANCE SUMMARY REPORT TABLE | | |
|---|--|--|
| STANDARD TITLE ASTM D3492-08 Standard Specification for Rubber Contraceptives (Male Condoms) | | |
| CONFORMANCE WITH STANDARD SECTIONS* | | |
| SECTION NUMBER 1 | SECTION TITLE Scope | CONFORMANCE? <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No <input type="checkbox"/> N/A |
| TYPE OF DEVIATION OR OPTION SELECTED ♦ Omission of sections | | |
| DESCRIPTION Annex A2 and Appendix X.1 were applied | | |
| JUSTIFICATION The standard applies to manufacture of NRL condoms. The testing of the appropriate sections was performed on personal lubricants as indicated in ASTM D7661. | | |
| SECTION NUMBER X1.4.2.1 | SECTION TITLE Ring Specimen Preparation | CONFORMANCE? <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A |
| TYPE OF DEVIATION OR OPTION SELECTED ♦ Option - type of condom | | |
| DESCRIPTION Smooth surface condoms were used for testing. | | |
| JUSTIFICATION ASTM D7661 stipulates the use of smooth surface condoms. | | |
| SECTION NUMBER | SECTION TITLE | CONFORMANCE? <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A |
| TYPE OF DEVIATION OR OPTION SELECTED ♦ | | |
| DESCRIPTION | | |
| JUSTIFICATION | | |
| <p>* For completeness list all sections of the standard and indicate whether conformance is met. If a section is not applicable (N/A) an explanation is needed under "justification." Some standards include options, so similar to deviations, the option chosen needs to be described and adequately justified as appropriate for the subject device. Explanation of all deviations or description of options selected when following a standard is required under "type of deviation or option selected," "description" and "justification" on the report. More than one page may be necessary.</p> <p>♦ Types of deviations can include an exclusion of a section in the standard, a deviation brought out by the FDA supplemental information sheet (SIS), a deviation to adapt the standard to the device, or any adaptation of a section.</p> | | |
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TYPE OF 510(K) SUBMISSION

Traditional Special Abbreviated

STANDARD TITLE ¹

ASTM D6324-11 Standard Specifications for Male Condoms Made from Polyurethane

Please answer the following questions

Yes No

Is this standard recognized by FDA ²? Yes No

FDA Recognition number ³ #N/A

Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)? Yes No

Is a summary report ⁴ describing the extent of conformance of the standard used included in the 510(k)? Yes No
If no, complete a summary report table.

Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device? Yes No

Does this standard include acceptance criteria? Yes No
If no, include the results of testing in the 510(k).

Does this standard include more than one option or selection of tests? Yes No
If yes, report options selected in the summary report table.

Were there any deviations or adaptations made in the use of the standard?..... Yes No
If yes, were deviations in accordance with the FDA supplemental information sheet (SIS) ⁵? Yes No

Were deviations or adaptations made beyond what is specified in the FDA SIS?..... Yes No
If yes, report these deviations or adaptations in the summary report table.

Were there any exclusions from the standard? Yes No
If yes, report these exclusions in the summary report table.

Is there an FDA guidance ⁶ that is associated with this standard?..... Yes No
If yes, was the guidance document followed in preparation of this 510k? Yes No

Title of guidance: _____

¹ The formatting convention for the title is: [SDO] [numeric identifier] [title of standard] [date of publication]

² Authority [21 U.S.C. 360d], <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Standards/default.htm>

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| EXTENT OF STANDARD CONFORMANCE SUMMARY REPORT TABLE | | |
|--|---|--|
| STANDARD TITLE ASTM D6324-11 Standard Specifications for Male Condoms Made from Polyurethane | | |
| CONFORMANCE WITH STANDARD SECTIONS* | | |
| SECTION NUMBER 1 | SECTION TITLE Scope | CONFORMANCE? <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A |
| TYPE OF DEVIATION OR OPTION SELECTED ♦ Omission of non-applicable sections specific to polyurethane condoms and not testing with lubricant were omitted. | | |
| DESCRIPTION Annex 3 and Annex 7 were applied in place of ASTM D3492 as referenced in ASTM D7661. | | |
| JUSTIFICATION Only sections necessary for application to ASTM D7661 were required. | | |
| SECTION NUMBER A.3.4.2.1 | SECTION TITLE Smooth Surface Condoms | CONFORMANCE? <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A |
| TYPE OF DEVIATION OR OPTION SELECTED ♦ Option of condom type | | |
| DESCRIPTION Test methods give options of condom types. Smooth surface condoms were chosen for testing. | | |
| JUSTIFICATION Satisfies requirements of ASTM D7661. | | |
| SECTION NUMBER A.3.4.1.4 | SECTION TITLE Condom Preparation | CONFORMANCE? <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No <input type="checkbox"/> N/A |
| TYPE OF DEVIATION OR OPTION SELECTED ♦ Adjust method for dressing removal | | |
| DESCRIPTION Replace wiping dressing from sample, with laying flat on non-abrasive cloth and patting dry with another cloth. | | |
| JUSTIFICATION Alternate method creates less stress on the condom, ensuring less chance of damage to condom and ring while removing dressing. | | |
| <p>* For completeness list all sections of the standard and indicate whether conformance is met. If a section is not applicable (N/A) an explanation is needed under "justification." Some standards include options, so similar to deviations, the option chosen needs to be described and adequately justified as appropriate for the subject device. Explanation of all deviations or description of options selected when following a standard is required under "type of deviation or option selected," "description" and "justification" on the report. More than one page may be necessary.</p> <p>♦ Types of deviations can include an exclusion of a section in the standard, a deviation brought out by the FDA supplemental information sheet (SIS), a deviation to adapt the standard to the device, or any adaptation of a section.</p> | | |
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TYPE OF 510(K) SUBMISSION

Traditional Special Abbreviated

STANDARD TITLE ¹

ASTM D7661-10 Standard Test Method for Determining Compatibility of Personal Lubricants with Natural Rubber Latex Condoms

Please answer the following questions

Yes No

Is this standard recognized by FDA ²?

FDA Recognition number ³ #9-67

Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?

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Does this standard include acceptance criteria?
If no, include the results of testing in the 510(k).

Does this standard include more than one option or selection of tests?
If yes, report options selected in the summary report table.

Were there any deviations or adaptations made in the use of the standard?.....
If yes, were deviations in accordance with the FDA supplemental information sheet (SIS) ⁵?

Were deviations or adaptations made beyond what is specified in the FDA SIS?.....
If yes, report these deviations or adaptations in the summary report table.

Were there any exclusions from the standard?
If yes, report these exclusions in the summary report table.

Is there an FDA guidance ⁶ that is associated with this standard?.....
If yes, was the guidance document followed in preparation of this 510k?

Title of guidance: _____

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| EXTENT OF STANDARD CONFORMANCE SUMMARY REPORT TABLE | | |
|---|---|--|
| STANDARD TITLE ASTM D7661-10 Standard Test Method for Determining Compatibility of Personal Lubricants with Natural Rubber Latex Condoms | | |
| CONFORMANCE WITH STANDARD SECTIONS* | | |
| SECTION NUMBER All | SECTION TITLE | CONFORMANCE? <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A |
| TYPE OF DEVIATION OR OPTION SELECTED ♦ Adjustment to include additional material type | | |
| DESCRIPTION Standard used to test both natural rubber latex and polyisoprene condoms | | |
| JUSTIFICATION No standard exists for testing polyisoprene condoms | | |
| SECTION NUMBER 7.1.2 | SECTION TITLE Sampling Overview, Sample Groups and Sample Size | CONFORMANCE? <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No <input type="checkbox"/> N/A |
| TYPE OF DEVIATION OR OPTION SELECTED ♦ Adapted to remove lubricant from pre-lubricated samples. | | |
| DESCRIPTION Unroll pre-lubricated condoms and lay flat on a non-abrasive cloth. Pat with another non-abrasive cloth to remove excess lubricant. Invert condom and pat inner surface with a non-abrasive cloth. | | |
| JUSTIFICATION Non-lubricated polyisoprene condoms not available for purchase. | | |
| SECTION NUMBER | SECTION TITLE | CONFORMANCE? <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A |
| TYPE OF DEVIATION OR OPTION SELECTED ♦ | | |
| DESCRIPTION | | |
| JUSTIFICATION | | |
| <p>* For completeness list all sections of the standard and indicate whether conformance is met. If a section is not applicable (N/A) an explanation is needed under "justification." Some standards include options, so similar to deviations, the option chosen needs to be described and adequately justified as appropriate for the subject device. Explanation of all deviations or description of options selected when following a standard is required under "type of deviation or option selected," "description" and "justification" on the report. More than one page may be necessary.</p> <p>♦ Types of deviations can include an exclusion of a section in the standard, a deviation brought out by the FDA supplemental information sheet (SIS), a deviation to adapt the standard to the device, or any adaptation of a section.</p> | | |
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STANDARD TITLE ¹

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Please answer the following questions

Yes No

Is this standard recognized by FDA ²?

FDA Recognition number ³ #9-67

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Were deviations or adaptations made beyond what is specified in the FDA SIS?.....
If yes, report these deviations or adaptations in the summary report table.

Were there any exclusions from the standard?
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Is there an FDA guidance ⁶ that is associated with this standard?.....
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⁶ The online search for CDRH Guidance Documents can be found at <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm>

| EXTENT OF STANDARD CONFORMANCE SUMMARY REPORT TABLE | | |
|---|---|--|
| STANDARD TITLE ASTM D7661-10 Standard Test Method for Determining Compatibility of Personal Lubricants with Natural Rubber Latex Condoms | | |
| CONFORMANCE WITH STANDARD SECTIONS* | | |
| SECTION NUMBER 9.6 | SECTION TITLE Tensile Test | CONFORMANCE? <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A |
| TYPE OF DEVIATION OR OPTION SELECTED ♦ Adapted the standard to conform to FDA requested testing of lubricant on polyurethane condoms. | | |
| DESCRIPTION Used procedures specified in ASTM D6324-11 in place of ASTM D3492 where indicated in D7661. | | |
| JUSTIFICATION Standard for testing lubricants on polyurethane condoms does not exist. | | |
| SECTION NUMBER 9.2.2 | SECTION TITLE Ring Specimens | CONFORMANCE? <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A |
| TYPE OF DEVIATION OR OPTION SELECTED ♦ Adapted the standard to conform to FDA requested testing of lubricant on polyurethane condoms. | | |
| DESCRIPTION Used procedures specified in ASTM D6324-11 in place of ASTM D3492 where indicated in D7661. | | |
| JUSTIFICATION Standard for testing lubricants on polyurethane condoms does not exist. | | |
| SECTION NUMBER 10.6 | SECTION TITLE Procedure for Airburst Testing | CONFORMANCE? <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A |
| TYPE OF DEVIATION OR OPTION SELECTED ♦ Adapted the standard to conform to FDA requested testing of lubricant on polyurethane condoms. | | |
| DESCRIPTION Used procedures specified in ASTM D6324-11 in place of ASTM D3492 where indicated in D7661. | | |
| JUSTIFICATION Standard for testing lubricants on polyurethane condoms does not exist. | | |
| <p>* For completeness list all sections of the standard and indicate whether conformance is met. If a section is not applicable (N/A) an explanation is needed under "justification." Some standards include options, so similar to deviations, the option chosen needs to be described and adequately justified as appropriate for the subject device. Explanation of all deviations or description of options selected when following a standard is required under "type of deviation or option selected," "description" and "justification" on the report. More than one page may be necessary.</p> <p>♦ Types of deviations can include an exclusion of a section in the standard, a deviation brought out by the FDA supplemental information sheet (SIS), a deviation to adapt the standard to the device, or any adaptation of a section.</p> | | |
| <p>This section applies only to requirements of the Paperwork Reduction Act of 1995.</p> <p>*DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.*</p> <p>The burden time for this collection of information is estimated to average 1 hour per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:</p> <div style="display: flex; justify-content: space-between;"> <div style="width: 45%;"> <p>Department of Health and Human Services Food and Drug Administration Office of Chief Information Officer Paperwork Reduction Act (PRA) Staff PRAStaff@fda.hhs.gov</p> </div> <div style="width: 45%; text-align: right;"> <p><i>"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number."</i></p> </div> </div> | | |

| EXTENT OF STANDARD CONFORMANCE SUMMARY REPORT TABLE | | |
|---|--|--|
| STANDARD TITLE ASTM D7661-10 Standard Test Method for Determining Compatibility of Personal Lubricants with Natural Rubber Latex Condoms | | |
| CONFORMANCE WITH STANDARD SECTIONS* | | |
| SECTION NUMBER 7.1.2 | SECTION TITLE Sampling Overview, Sample Groups and Sample Size | CONFORMANCE? <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No <input type="checkbox"/> N/A |
| TYPE OF DEVIATION OR OPTION SELECTED ♦ Adapted pre-lubricated samples to meet requirement for non-lubricated samples. | | |
| DESCRIPTION Unroll pre-lubricated condoms and lay flat on a non-abrasive cloth. Pat with another non-abrasive cloth to remove excess lubricant. Invert condom and pat inner surface with a non-abrasive cloth. | | |
| JUSTIFICATION Non-lubricated polyurethane condoms are not available for purchase. | | |
| SECTION NUMBER 7.2.1.4 | SECTION TITLE Sampling Overview, Sample Groups, and Sample Size | CONFORMANCE? <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No <input type="checkbox"/> N/A |
| TYPE OF DEVIATION OR OPTION SELECTED ♦ Adapted standard for polyurethane | | |
| DESCRIPTION Substituted PEG 200 in place of Mineral Oil | | |
| JUSTIFICATION Mineral oil would not have the same effect on polyurethane as it does on latex and determined that a lower molecular weight PEG was more suitable for polyurethane. | | |
| SECTION NUMBER | SECTION TITLE | CONFORMANCE? <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A |
| TYPE OF DEVIATION OR OPTION SELECTED ♦ | | |
| DESCRIPTION | | |
| JUSTIFICATION | | |
| SECTION NUMBER | SECTION TITLE | CONFORMANCE? <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A |
| TYPE OF DEVIATION OR OPTION SELECTED ♦ | | |
| DESCRIPTION | | |
| JUSTIFICATION | | |

* For completeness list all sections of the standard and indicate whether conformance is met. If a section is not applicable (N/A) an explanation is needed under "justification." Some standards include options, so similar to deviations, the option chosen needs to be described and adequately justified as appropriate for the subject device. Explanation of all deviations or description of options selected when following a standard is required under "type of deviation or option selected," "description" and "justification" on the report. More than one page may be necessary.

♦ Types of deviations can include an exclusion of a section in the standard, a deviation brought out by the FDA supplemental information sheet (SIS), a deviation to adapt the standard to the device, or any adaptation of a section.

Section 10: Executive Summary

This is a Traditional, Bundled, 510(k) Submission of three (3) Proposed Devices.

Common Name: Personal Lubricant

Product Code: NUC

Device Class: II

Regulation Number: 884.5300

Proposed Devices:

| Proprietary Names | Description | Intended Use | Technology |
|---|---|--|---|
| YES [®] Water-based Personal Lubricant | A non-sterile, condom compatible, water-based personal lubricant. | Personal lubricants, for vaginal or penile application, intended to moisturize and lubricate, to enhance the ease and comfort of intimate sexual activity and supplement the body's natural lubrication. | Water-based, natural, plant thickeners not glycerin based. Slightly hypo-to iso osmotic |
| YES [®] oil-based Personal Lubricant | A non-sterile, non-condom compatible, oil-based personal lubricant. | | Oil-based, natural plant oils, butters & bees wax. |
| YES [®] Vaginal Moisturizer | A non-sterile, condom compatible, water-based personal lubricant. | | Water-based, natural, plant thickeners not glycerin based. Iso osmotic |

Technological Characteristics:

The three proposed devices are proprietary formulations; however, the products have no exceptional technological characteristics. YES[®] water-based Personal Lubricant and YES[®] Vaginal Moisturizer consist of water-soluble natural plant based ingredients and YES[®] oil-based Personal Lubricant consists of natural plant based oils, butters and bees wax. All ingredients in all three proposed devices are NF, USP, or GRAS food ingredients.

Indications for Use:

All three proposed devices have the same intended use; Personal lubricants, for vaginal and penile application, intended to moisturize and lubricate, to enhance the ease and comfort of intimate sexual activity and supplement the body's natural lubrication.as their predicates.

Device Comparison Tables

| YES[®] water-based Personal Lubricant | | |
|---|---|--|
| 510(k) # | | K124044 |
| Device name | YES [®] water-based Personal Lubricant | Aloe Cadabra Personal lubricant |
| Manufacturer | Bio-tech Lubricants Ltd | Seven Oaks Ranch, Inc. |
| Classification | 884.5300 | 884.5300 |
| Product code | NUC | NUC |
| Description | Personal Lubricant | Personal Lubricant |
| Indications for use | YES [®] water-based Personal Lubricant is a personal lubricant, for vaginal and penile application, intended to moisturize and lubricate, to enhance the ease and comfort of intimate sexual activity and supplement the body's natural lubrication. This product is compatible with NRL, Polyisoprene and polyurethane condoms. | Aloe Cadabra lubricants, are personal lubricants for penile and/or vaginal application, intended to moisturize and lubricate, to enhance the ease and comfort of intimate sexual activity and supplement the body's natural lubrication. This product is compatible with NRL and Polyisoprene condoms. This product is not compatible with polyurethane condoms. |
| Over-the-counter use | YES | YES |
| Biocompatible | YES | YES |
| Non-sterile | YES | YES |
| Packaging Materials | Plastic / PE | Plastic / PE |
| Contains plant extracts | YES | YES |
| Contains preservatives | YES | YES |

| YES[®] oil-based Personal Lubricant | | |
|---|--|---|
| 510(k) # | | K122477 |
| | YES [®] oil-based personal lubricant | LifeStyles Luxe Premium Personal Lubricant |
| Manufacturer | Bio-tech Lubricants Ltd | Ansell Healthcare Products, LLC |
| Classification | 884.5300 | 884.5300 |
| Product code | NUC | NUC |
| Description | Personal Lubricant | Personal Lubricant |
| Indications for use | YES [®] oil-based personal lubricant is a personal lubricant, for vaginal and penile application, intended to moisturize and lubricate, to enhance the ease and comfort of intimate sexual activity and supplement the body's natural lubrication. This product is not compatible with NRL, polyurethane or Polyisoprene condoms. | LifeStyles Luxe Premium Personal Lubricant Is a personal lubricant, for penile and/or vaginal application, intended to moisturize and lubricate, to enhance the ease and comfort of intimate sexual activity and supplement the body's natural lubrication. This product is compatible with natural rubber latex, polyurethane, and Polyisoprene condoms. |
| Over-the-counter use | YES | YES |
| Biocompatible | YES | YES |
| Non-sterile | YES | YES |
| Packaging Materials | Plastic / PE | Plastic / PE |
| Contains plant extracts | YES | No |
| Contains preservatives | No - Product cannot support microbial growth | No - Product cannot support microbial growth |

| YES[®] Vaginal Moisturizer | | |
|--|---|--|
| 510(k) # | | K124044 |
| | YES [®] VM (Vaginal Moisturizer) | Aloe Cadabra Personal lubricant |
| Manufacturer | Bio-tech Lubricants Ltd | Seven Oaks Ranch, Inc. |
| Classification | 884.5300 | 884.5300 |
| Product code | NUC | NUC |
| Description | Personal Lubricant | Personal Lubricant |
| Indications for use | YES [®] VM (Vaginal Moisturizer) is a personal lubricant, for vaginal and penile application, intended to moisturize and lubricate, to enhance the ease and comfort of intimate sexual activity and supplement the body's natural lubrication. This product is compatible with NRL, polyurethane and Polyisoprene condoms. | Aloe cadabra lubricants, are personal lubricants for penile and/or vaginal application, intended to moisturize and lubricate, to enhance the ease and comfort of intimate sexual activity and supplement the body's natural lubrication. This product is compatible with NRL and Polyisoprene condoms. This product is not compatible with polyurethane condoms. |
| Over-the-counter use | YES | YES |
| Biocompatible | YES | YES |
| Non-sterile | YES | YES |
| Packaging Materials | Plastic / PE, pre-filled applicators | Plastic / PE |
| Contains preservatives | YES | YES |

Non-Clinical Performance Data

This table summarizes the results of the non-clinical performance data. Detailed results are included in Sections 14, 15, and 18 of this 510(k) submission.

Detailed results included in Sections 14, 15 and 18 have been tested (b)(4) [redacted]
 [redacted]
 [redacted] This is a business decision and is no risk to the safety and effectiveness of the device. The legal manufacturer declares that where a test report has [redacted] (b)(4) the test results are identical for YES[®]. These results were submitted in K (b)(4) [redacted]

- YES[®] water-based Personal Lubricant is identical to A [redacted] (b) water-based Personal Lubricant.
- YES[®] oil-based Personal Lubricant is identical to [redacted] (b) oil-based Personal Lubricant.
- YES[®] Vaginal Moisturizer is identical to [redacted] (b) Vaginal Moisturizer.

| | |
|---|---|
| Proposed Devices | Condom compatible (ASTM D7661, ASTM D3492, and ASTM D6324) |
| YES [®] water-based Personal Lubricant | YES |
| YES [®] oil-based Personal Lubricant | No |
| YES [®] Vaginal Moisturizer | YES |
| Proposed Devices | Stability & Packaging Testing |
| YES [®] water-based Personal Lubricant | 2 years |
| YES [®] oil-based Personal Lubricant | |
| YES [®] Vaginal Moisturizer | |
| Proposed Devices | Osmolality Testing |
| YES [®] water-based Personal Lubricant | (b)(4) [redacted] |
| YES [®] oil-based Personal Lubricant | No water, N/A |
| YES [®] Vaginal Moisturizer | (b)(4) [redacted] |
| Proposed Devices | Preservative Efficacy |
| YES [®] water-based Personal Lubricant | Pass |
| YES [®] oil-based Personal Lubricant | Water assay level does not support microbial growth. |
| YES [®] Vaginal Moisturizer | Pass |
| Proposed Devices | Toxicology Assessment (ISO 10993-10) |
| All three Devices | No safety concerns |
| Proposed Devices | Cytotoxicity Testing (ISO 10993-5) |
| All three Devices | Biocompatible |

Biocompatibility Testing:

Biocompatibility testing was completed according to USP 34<87> (ISO 10993-5), ISO 10993-10, and ISO 10993-11 for YES® Vaginal Moisturizer and YES® oil-based Personal Lubricants. (b) (4) . The test results indicated that devices are non-toxic and non-irritating for their intended use.

Performance Testing – Bench:

YES® Vaginal Moisturizer was tested according to ASTM D7661, ASTM D3492, and ASTM D6324. (b) (4) . Testing demonstrated that YES® Vaginal Moisturizer and YES® water-based Personal Lubricant are compatible with Natural Rubber Latex (NRL), Polyisoprene, and Polyurethane condoms.

YES® oil-based Personal Lubricant was tested on polyurethane condoms according to ASTM D7661, ASTM D3492 and ASTM D6324 at the request of FDA. Condom compatibility testing on NRL or Polyisoprene condoms was not required because it is known that most oil-based lubricants are not condom compatible. Test results indicated that YES® oil-based Personal Lubricant is not compatible with polyurethane condoms.

Performance Testing – Animal:

Performance testing on animals is not required for this device.

Performance Testing – Clinical:

Clinical performance testing is not required for this device.

Conclusion:

(b)(4)

1. The Intended Use of the proposed devices are identical to predicate devices.
2. The Technological Characteristics are similar to predicate devices.
3. The Non-Clinical condom compatibility testing to ASTM D7661, ASTM D3492, and ASTM D6324 indicates the proposed devices exhibit the same properties as predicate devices.
4. Biocompatibility testing according to USP 34<87< (ISO 10993-5), ISO 10993-10 and ISO 10993-11 have demonstrated that the proposed devices do not present any new issues regarding biocompatibility.

Substantial Equivalence Determination:

We conclude that the three proposed devices are substantially equivalent to their predicate devices in intended use and technological characteristics. Biocompatibility and performance testing raised no new concerns regarding safety, and efficacy.

End of Section 10

Section 11: Device Description

Proprietary Name: YES®

Common Name: Personal Lubricant

Product Code: NUC

Device Class: II

Regulation Number: 884.5300

Narrative Description

YES® personal lubricants are non-sterile personal lubricants and are available in three variations; YES® Oil-based Personal Lubricant, YES® Water-based Personal Lubricant, and YES® Vaginal Moisturizer.

YES® Oil-based Personal Lubricant (YES® OB)

- is a non-sterile, oil-based, slightly opaque, non-staining personal lubricant formulated to supplement the body's own natural lubricating fluids to provide personal lubrication when vaginal dryness causes discomfort.
- are packed in three different sizes of tube (1.4 fluid ounce, 2.7 fluid ounce and 4.7 fluid ounce).
- is not compatible with condoms. YES® oil-based has been tested on polyurethane condoms (See Section 18) and proven to be not compatible.

YES® Water-based Personal Lubricants (YES® WB)

- are non-sterile, water-based, (b)(4) lightly cloudy (not water white) in appearance. It is formulated to supplement the body's own natural lubricating fluids to provide personal moisturization when vaginal dryness causes discomfort.
- are packed in four different sizes of tube (1.7 fluid ounce, 2.6 fluid ounce, 3.4 fluid ounce, and 5.1 fluid ounce, and one size of prefilled single-use applicators (.17 fluid ounce). The prefilled applicators provide added convenience and are sufficient for a single use only.
- are compatible with latex, polyurethane and polyisoprene condoms as demonstrated in the Condom Compatibility Testing in Section 18.

YES® Vaginal Moisturizer (YES® VM)

- is a non-sterile, water-based, slightly opaque, non-greasy, non-staining vaginal gel formulated to act as a long-lasting moisturizer for vaginal dryness. The prefilled applicators provide added convenience in application and are sufficient for a single use only. YES® VM is formulated to supplement the body's own natural lubricating fluids to provide personal moisturization when vaginal dryness causes discomfort.
- are packed in one size of tube (3.4 fluid ounce) and one size of prefilled single-use applicators (0.17 fluid ounce).
- has a very similar formulation to YES® water-based, the only major difference is (b)(4)
[REDACTED]
[REDACTED] the increased viscosity is for ease of application whilst the slightly lowered pH is to help elevated vaginal pH caused by vaginal dryness, return to typical pH levels, and so promote vaginal health.
- is compatible with latex condoms as demonstrated in Section 18.

Indications for Use

YES® oil-based Personal Lubricant: A personal lubricant, for vaginal and penile application, intended to moisturize and lubricate, to enhance the ease and comfort of intimate sexual activity and supplement the body's natural lubrication. YES® oil-based Personal Lubricant is not compatible with natural rubber latex, polyurethane or polyisoprene condoms.

YES® water-based Personal Lubricant: A personal lubricant, for vaginal and penile application, intended to moisturize and lubricate, to enhance the ease and comfort of intimate sexual activity and supplement the body's natural lubrication. YES® water-based Personal Lubricant is compatible with natural rubber latex, polyurethane or polyisoprene condoms.

YES® Vaginal Moisturizer: A personal lubricant, for vaginal and penile application, intended to moisturize and lubricate, to enhance the ease and comfort of intimate sexual activity and supplement the body's natural lubrication. YES® Vaginal Moisturizer is compatible with natural rubber latex, polyurethane or polyisoprene condoms.

Principals of Operation

The YES® product line is a gel-like, formulary product, which provides supplemental lubrication to male and female genitalia.

Composition:

YES® Oil-based Personal Lubricant (YES® OB)

| Ingredients: YES Oil-based Personal Lubricant | | | | | |
|---|--|--|--|-----|--|
| (b)(4) | | | | (b) | |
| | | | | (4) | |
| | | | | | |
| | | | | | |
| | | | | | |
| | | | | | |
| | | | | | |

| Specifications: YES® Oil-based Personal Lubricant | |
|---|--|
| (b)(4) | |
| | |
| | |
| | |
| | |

| Specifications: YES® Oil-based Personal Lubricant | |
|---|--|
| (b)(4) | |
| | |
| | |
| | |
| | |
| | |
| | |
| Check specifications ± 20% above values | |

* (b)(4)

| Product Specifications: YES® Oil-based (Additional for Shelf-life testing only) | |
|---|---------------|
| Attribute | Specification |
| (b)(4) | |

YES® Water-based Personal Lubricant (YES® WB)

(b)(4)

| Ingredients: YES® Water-based Personal Lubricant | | | | | |
|--|--|--|--|--------|--|
| (b)(4) | | | | (b)(4) | |
| | | | | (4) | |
| | | | | | |
| | | | | | |
| | | | | | |
| | | | | | |
| | | | | | |
| | | | | | |
| | | | | | |

| Ingredients: YES® Water-based Personal Lubricant | | | | | |
|---|------------------|-----------------|--------------|--------------|--------------|
| Ingredient/Component | INCI Name | Function | CAS # | % W/W | Grade |
| [REDACTED] | [REDACTED] | (b)(4) | [REDACTED] | [REDACTED] | [REDACTED] |
| [REDACTED] | [REDACTED] | [REDACTED] | [REDACTED] | [REDACTED] | [REDACTED] |

| Product Specifications: YES® Water-based personal lubricant. | |
|---|------------|
| (b)(4) | [REDACTED] |
| [REDACTED] | [REDACTED] |
| [REDACTED] | [REDACTED] |
| [REDACTED] | [REDACTED] |
| [REDACTED] | [REDACTED] |
| [REDACTED] | [REDACTED] |
| [REDACTED] | [REDACTED] |
| [REDACTED] | [REDACTED] |
| [REDACTED] | [REDACTED] |
| [REDACTED] | [REDACTED] |
| [REDACTED] | [REDACTED] |
| [REDACTED] | [REDACTED] |
| [REDACTED] | [REDACTED] |
| [REDACTED] | [REDACTED] |
| [REDACTED] | [REDACTED] |

[REDACTED]

| Product Specifications: YES® Water-based (Additional for Shelf-life testing only) | |
|--|------------|
| (b)(4) | [REDACTED] |
| [REDACTED] | [REDACTED] |
| [REDACTED] | [REDACTED] |

YES® Vaginal Moisturizer (YES® VM)

| Ingredients: YES® Vaginal Moisturizer | | | | | |
|---------------------------------------|------------|------------|------------|------------|------------|
| Ingredient/ | [Redacted] | [Redacted] | [Redacted] | (b) | [Redacted] |
| [Redacted] | [Redacted] | [Redacted] | [Redacted] | (4) | [Redacted] |
| [Redacted] | [Redacted] | [Redacted] | [Redacted] | [Redacted] | [Redacted] |
| [Redacted] | [Redacted] | [Redacted] | [Redacted] | [Redacted] | [Redacted] |
| [Redacted] | [Redacted] | [Redacted] | [Redacted] | [Redacted] | [Redacted] |
| [Redacted] | [Redacted] | [Redacted] | [Redacted] | [Redacted] | [Redacted] |
| [Redacted] | [Redacted] | [Redacted] | [Redacted] | [Redacted] | [Redacted] |
| [Redacted] | [Redacted] | [Redacted] | [Redacted] | [Redacted] | [Redacted] |
| [Redacted] | [Redacted] | [Redacted] | [Redacted] | [Redacted] | [Redacted] |
| [Redacted] | [Redacted] | [Redacted] | [Redacted] | [Redacted] | [Redacted] |
| [Redacted] | [Redacted] | [Redacted] | [Redacted] | [Redacted] | [Redacted] |
| [Redacted] | [Redacted] | [Redacted] | [Redacted] | [Redacted] | [Redacted] |

| Specifications: YES® Vaginal Moisturizer | |
|--|------------|
| (b)(4) | [Redacted] |
| [Redacted] | [Redacted] |
| [Redacted] | [Redacted] |
| [Redacted] | [Redacted] |
| [Redacted] | [Redacted] |
| [Redacted] | [Redacted] |
| [Redacted] | [Redacted] |
| [Redacted] | [Redacted] |
| [Redacted] | [Redacted] |
| [Redacted] | [Redacted] |
| [Redacted] | [Redacted] |
| [Redacted] | [Redacted] |
| [Redacted] | [Redacted] |
| [Redacted] | [Redacted] |

[Redacted]

| Product Specifications: YES® Vaginal Moisturizer (Additional for Shelf-life testing only) | |
|--|------------|
| (b)(4) | [REDACTED] |
| [REDACTED] | [REDACTED] |
| [REDACTED] | [REDACTED] |

CONFIDENTIAL

Physical Description:YES® Oil-based Personal Lubricant Packaging

YES® oil-based personal lubricants are available in three (3) HDPE flip-top tubes. The individual tubes are packaged into cartons.

| Model # | Container Size | Container Type | Material | Units per Case |
|---------|--------------------|----------------|----------|----------------|
| OB40C | 40ml / 1.4 fl. oz. | Tube | HDPE | 12 |
| OB80C | 80ml / 2.7 fl. oz. | Tube | HDPE | 12 |
| OB140C | 140ml/ 4.7 fl.oz. | Tube | HDPE | 12 |

YES® Water-based Personal Lubricant Packaging

YES® Water-based personal lubricants are available in four (4) HDPE flip-top tube sizes and one (1) HDPE single-use applicator. The individual bottles are packaged into cartons, and the single-use applicators are packaged six (6) to a carton. An “Instructions for Use” leaflet is also included in the carton with the single-use applicators.

| Model # | Container Size | Container Type | Material | Units per Case |
|---------|-----------------------------|-----------------|----------|----------------|
| WB50C | 50ml/ 1.7 fl.oz. | Tube | HDPE | 12 |
| W75C | 75ml/ 2.6 fl. oz. | Tube | HDPE | 12 |
| WB100C | 100ml / 3.4 fl. oz. | Tube | HDPE | 12 |
| WB150C | 150ml / 5.1 fl. oz. | Tube | HDPE | 12 |
| WB5AC6 | 5ml / 0.17 fl. oz. (6/pack) | Single use tube | HDPE | 6 |

YES® Vaginal Moisturizer Packaging

YES® Vaginal Moisturizer is available in one (1) HDPE flip-top tube size and one (1) HDPE single-use applicator. The individual tubes are packaged into cartons, and the single-use applicators are packaged six (6) to a carton and an “Instructions for Use” leaflet is included in the carton.

| Model # | Container Size | Container Type | Material | Units per Case |
|---------|--------------------------|---------------------------------------|----------|----------------|
| VM100C | 100ml / 3.4 fl. oz. | Tube | HDPE | 12 |
| VM5AC6 | 5ml / 0.17fl oz (6/pack) | Single use tube/pre-filled applicator | HDPE | 6 |

YES® water-based personal lubricants Carton for 75ml (2.6 fl. oz) HDPE flip-top tubes. Code W75C.

- Product Carton Dimensions in mm/inches.
 - Height = 160 mm/ 6.30 inches.
 - Width = 45 mm/ 1.97 inches.
 - Depth = 40 mm/ 1.57 inches.

YES® water-based personal lubricants Carton for 100ml (3.4 fl. oz) HDPE flip-top tubes. Code WB100C.

- Product Carton Dimensions in mm/inches.
 - Height = 150 mm/ 5.91 inches.
 - Width = 50 mm/ 1.97 inches.
 - Depth = 50 mm/ 1.97 inches.

YES® water-based personal lubricants Carton for 150ml (5.1 fl. oz) HDPE flip-top tubes. Code WB150C.

- Product Carton Dimensions in mm/inches.
 - Height = 190 mm/ 7.48 inches.
 - Width = 50 mm/ 1.97 inches.
 - Depth = 50 mm/ 1.97 inches.

YES® water-based personal lubricants Carton for 5 ml Single-use tubes. Code WB5AC6.

- Product Carton Dimensions in mm/inches.
 - Height = 145 mm/ 5.71 inches.
 - Width = 90 mm/ 3.54 inches.
 - Depth = 50 mm/ 1.97 inches.

YES® Vaginal Moisturizer Carton for 100ml (3.4 fl. oz) HDPE flip-top tubes. Code VM100C.

- Product Carton Dimensions in mm/inches.
 - Height = 150 mm/ 5.91 inches.
 - Width = 50 mm/ 1.97 inches.
 - Depth = 50 mm/ 1.97 inches.

YES® Vaginal Moisturizer Carton for 5ml (0.17 fl. oz) Single-use tubes. Code VM5AC6.

- Product Carton Dimensions in mm/inches.
 - Height = 150 mm/ 5.71 inches.
 - Width = 50 mm/ 3.54 inches.
 - Depth = 50 mm/ 1.97 inches.

Section 12: Substantial Equivalence

This is a Traditional, Bundled, 510(k) Submission of three (3) Proposed Devices.

Common Name: Personal Lubricant

Product Code: NUC

Device Class: II

Regulation Number: 884.5300

| Proposed Device: | Predicate Device: |
|---|--|
| YES [®] oil-based Personal Lubricant | LifeStyles Luxe Premium Personal Lubricant (K122477) |
| YES [®] Water-based Personal Lubricant | Aloe Cadabra Personal Lubricant (K124044) |
| YES [®] Vaginal Moisturizer | Aloe Cadabra Personal Lubricant (K124044) |

Device Comparison Tables

| YES[®] water-based Personal Lubricant | | |
|---|---|--|
| 510(k) # | | K124044 |
| Device name | YES [®] water-based Personal Lubricant | Aloe Cadabra Personal lubricant |
| Manufacturer | Bio-tech Lubricants Ltd | Seven Oaks Ranch, Inc. |
| Classification | 884.5300 | 884.5300 |
| Product code | NUC | NUC |
| Description | Personal Lubricant | Personal Lubricant |
| Indications for use | YES [®] water-based Personal Lubricant is a personal lubricant, for vaginal and penile application, intended to moisturize and lubricate, to enhance the ease and comfort of intimate sexual activity and supplement the body's natural lubrication. This product is compatible with NRL, Polyisoprene and polyurethane condoms. | Aloe Cadabra lubricants, are personal lubricants for penile and/or vaginal application, intended to moisturize and lubricate, to enhance the ease and comfort of intimate sexual activity and supplement the body's natural lubrication. This product is compatible with NRL and Polyisoprene condoms. This product is not compatible with polyurethane condoms. |
| Over-the-counter use | YES | YES |
| Biocompatible | YES | YES |
| Condom Compatible | Natural Rubber Latex (NRL), Polyisoprene, and Polyurethane condoms | Natural Rubber Latex (NRL), Polyisoprene and NOT compatible with Polyurethane condoms |
| Non-sterile | YES | YES |
| Packaging Materials | Plastic / PE | Plastic / PE |
| Contains plant extracts | YES | YES |
| Contains preservatives | YES | YES |

| YES[®] oil-based Personal Lubricant | | |
|---|--|---|
| 510(k) # | | K122477 |
| | YES [®] oil-based personal lubricant | LifeStyles Luxe Premium Personal Lubricant |
| Manufacturer | Bio-tech Lubricants Ltd | Ansell Healthcare Products, LLC |
| Classification | 884.5300 | 884.5300 |
| Product code | NUC | NUC |
| Description | Personal Lubricant | Personal Lubricant |
| Indications for use | YES [®] oil-based personal lubricant is a personal lubricant, for vaginal and penile application, intended to moisturize and lubricate, to enhance the ease and comfort of intimate sexual activity and supplement the body's natural lubrication. This product is not compatible with NRL, polyurethane or Polyisoprene condoms. | LifeStyles Luxe Premium Personal Lubricant Is a personal lubricant, for penile and/or vaginal application, intended to moisturize and lubricate, to enhance the ease and comfort of intimate sexual activity and supplement the body's natural lubrication. This product is compatible with natural rubber latex, polyurethane, and Polyisoprene condoms. |
| Over-the-counter use | YES | YES |
| Biocompatible | YES | YES |
| Condom Compatible | No (non-silicone oil-based products are known to be NOT compatible with NRL, polyisoprene or polyurethane condoms) | YES |
| Non-sterile | YES | YES |
| Packaging Materials | Plastic / PE | Plastic / PE |
| Contains plant extracts | YES | YES |
| Contains preservatives | No - Product cannot support microbial growth | No - Product cannot support microbial growth |

| YES[®] Vaginal Moisturizer | | |
|--|--|--|
| 510(k) # | | K124044 |
| | YES [®] VM (Vaginal Moisturizer) | Aloe Cadabra Personal lubricant |
| Manufacturer | Bio-tech Lubricants Ltd | Seven Oaks Ranch, Inc. |
| Classification | 884.5300 | 884.5300 |
| Product code | NUC | NUC |
| Description | Personal Lubricant | Personal Lubricant |
| Indications for use | YES [®] VM (Vaginal Moisturizer) is a personal lubricant, for vaginal application, intended to moisturize and lubricate, to enhance the ease and comfort of intimate sexual activity and supplement the body's natural lubrication. This product is compatible with NRL, polyurethane and Polyisoprene condoms. | Aloe cadabra lubricants, are personal lubricants for penile and/or vaginal application, intended to moisturize and lubricate, to enhance the ease and comfort of intimate sexual activity and supplement the body's natural lubrication. This product is compatible with NRL and Polyisoprene condoms. This product is not compatible with polyurethane condoms. |
| Over-the-counter use | YES | YES |
| Biocompatible | YES | YES |
| Condom Compatible | Natural Rubber Latex (NRL), Polyisoprene, and Polyurethane condoms | Natural Rubber Latex (NRL), Polyisoprene, and NOT compatible with Polyurethane condoms |
| Non-sterile | YES | YES |
| Packaging Materials | Plastic / PE, pre-filled applicators | Plastic / PE |
| Contains preservatives | YES | YES |

Conclusion:

The avoidance of ingredients known to irritate the mucosal tissues such as glycerin and glycols; and their replacement with plant derived gums, oils and butters of known beneficial properties to the mucosa mean that rather than just saying "this difference does not negatively affect the safety, efficacy or intended use of the proposed devices," we expect "these differences to positively affect the safety and the efficacy of these three proposed devices" when compared to the predicate devices.

1. The Intended Use of the proposed devices are identical to predicate devices.
2. The Technological Characteristics are similar to predicate devices.
3. The Non-Clinical condom compatibility testing to ASTM D7661, ASTM D3492, and ASTM D6324 indicates the proposed devices exhibit the same properties as predicate devices. Although the oil-based product is not condom compatible like the silicone predicate; it is commonly known and accepted that oil-based products will break down NRL condoms.
4. Biocompatibility testing according to USP 34<87< (ISO 10993-5), ISO 10993-10 and ISO 10993-11 have demonstrated that the proposed devices do not present any new issues regarding biocompatibility.
5. (b)(4)

(b)(4)

Substantial Equivalence Determination:

We conclude that the three proposed devices are substantially equivalent to their predicate devices in intended use and technological characteristics. Biocompatibility and performance testing raised no new concerns regarding safety, and efficacy.

End of Section 12

Section 13: Proposed Labeling / YES[®] Labels

21 CFR Part 807.87(e)

YES[®] Water-based Personal Lubricant

| Description | Size | Container Type | Model No. |
|---|--------------------|-----------------------|------------------|
| YES [®] Water-based Personal Lubricant | 0.17 fl.oz (5 ml). | Carton /Applicator | WB5AC6 |
| YES [®] Water-based Personal Lubricant | 1.7 fl.oz (50ml). | Carton/ Tube | WB50C |
| YES [®] Water-based Personal Lubricant | 2.6 fl.oz (75ml). | Carton/ Tube | W75C |
| YES [®] Water-based Personal Lubricant | 3.4 fl.oz (100ml). | Carton/ Tube | WB100C |
| YES [®] Water-based Personal Lubricant | 5.1 fl.oz (150ml). | Carton/ Tube | WB150C |
| YES [®] Water-based Personal Lubricant | n/a | Instructions For Use | n/a |

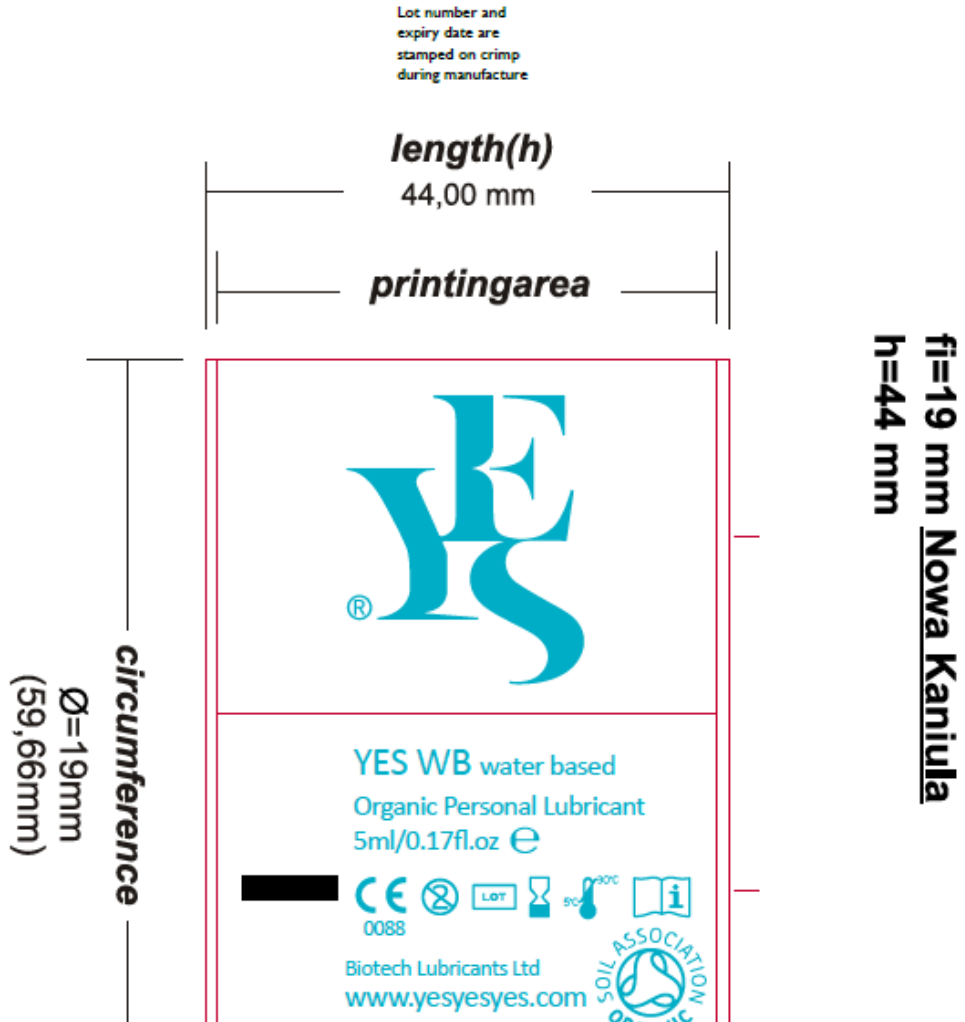
YES[®] Oil-based Personal Lubricant

| Description | Size | Container Type | Model No. |
|---|--------------------|-----------------------|------------------|
| YES [®] Oil-based Personal Lubricant | 1.4 fl.oz (40 ml) | Carton/ Tube | OB40C |
| YES [®] Oil-based Personal Lubricant | 2.7 fl.oz (80 ml) | Carton/ Tube | OB80C |
| YES [®] Oil-based Personal Lubricant | 4.7 fl.oz (140 ml) | Carton/ Tube | OB140C |
| YES [®] Oil-based Personal Lubricant | n/a | Instructions For Use | n/a |

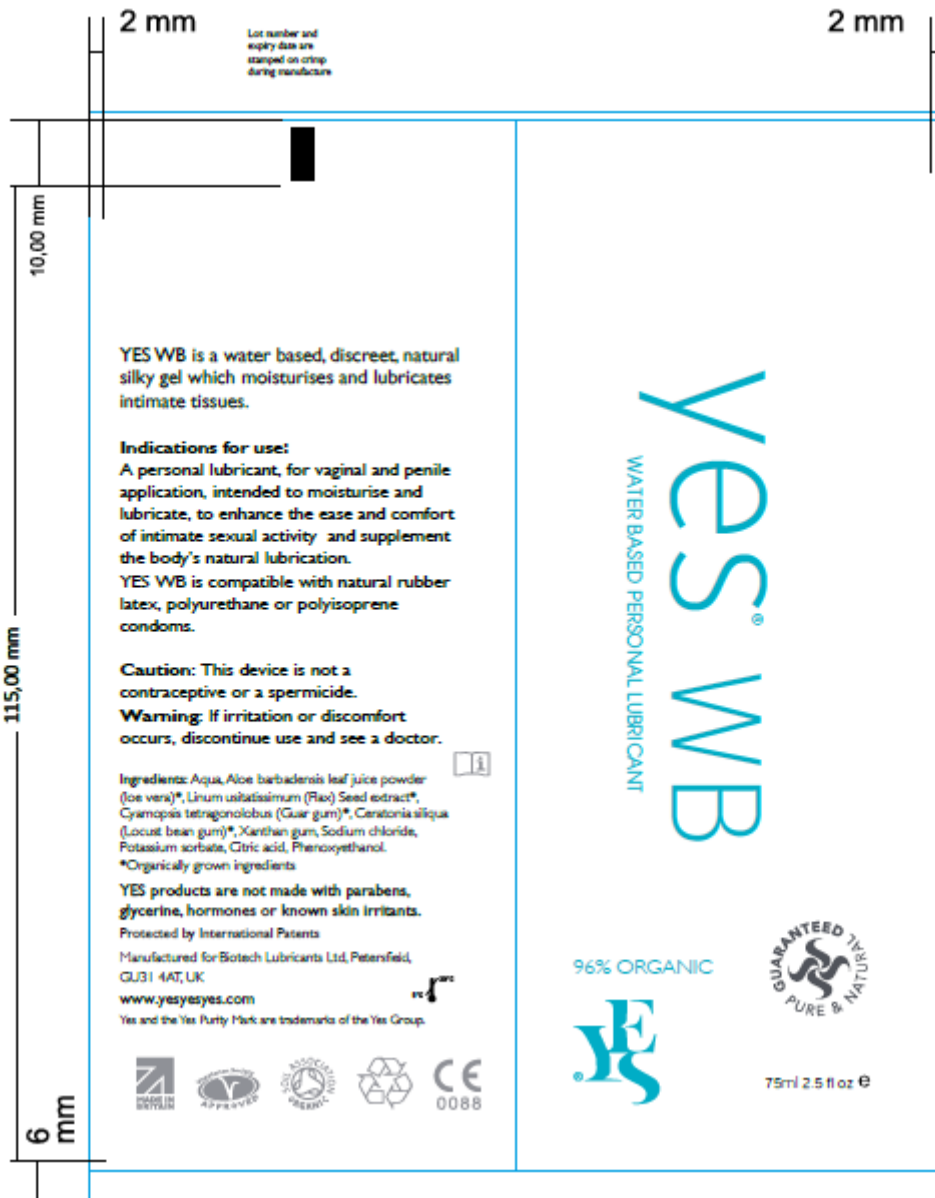
YES[®] Vaginal Moisturizer

| Description | Size | Container Type | Model No. |
|--------------------------------------|--------------------|-----------------------|------------------|
| YES [®] Vaginal Moisturizer | 0.17 fl.oz (5 ml) | Carton /Applicator | VM5AC6 |
| YES [®] Vaginal Moisturizer | 3.4 fl.oz (100 ml) | Carton/ Tube | VM100C |
| YES [®] Vaginal Moisturizer | n/a | Instructions For Use | n/a |

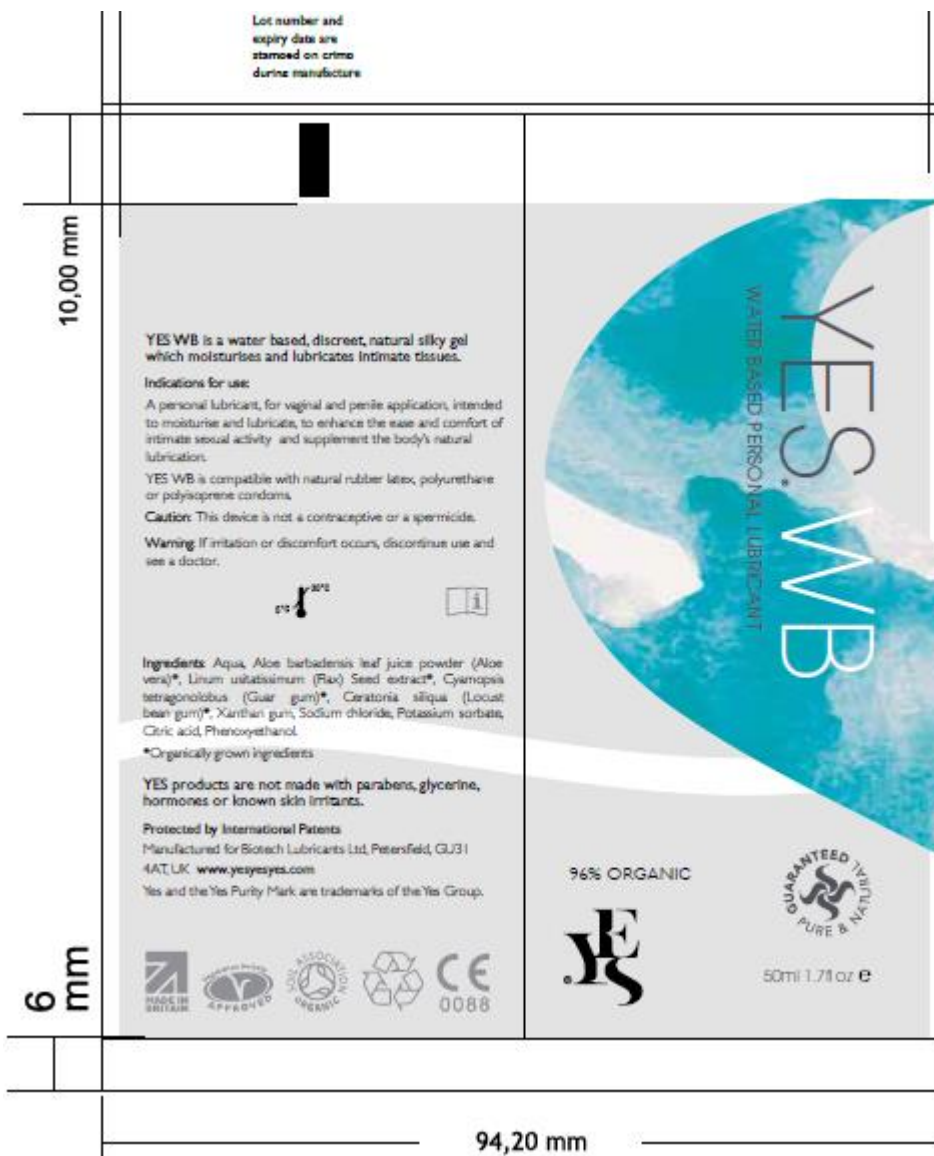
YES[®] water-based 5ml / .17 fluid ounce applicator label.



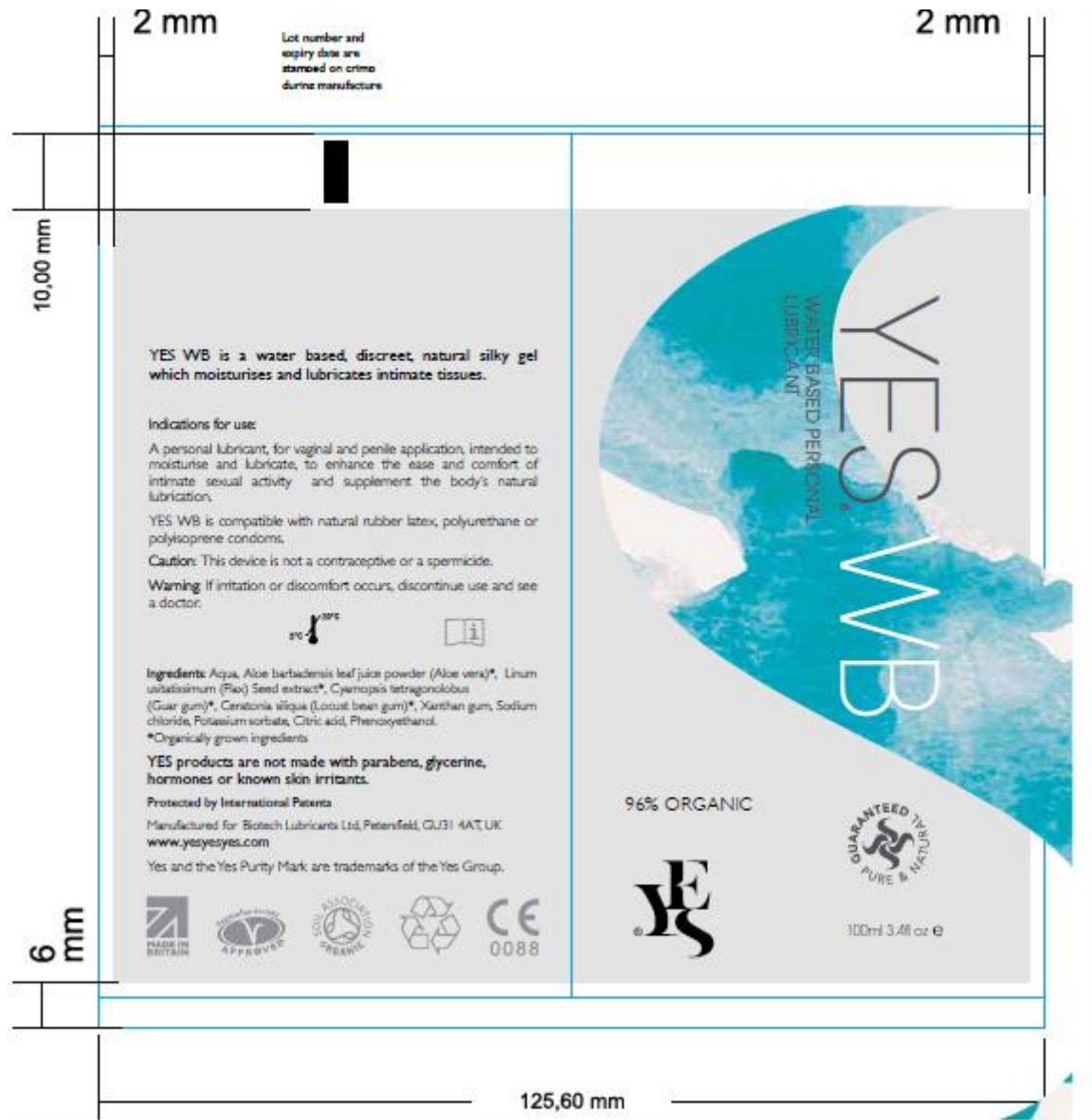
YES[®] water-based 75ml / 2.6 fluid ounce tube label.



YES® water-based 50ml / 1.7 fluid ounce tube label.



YES® water-based 100ml / 3.4 fluid ounce tube label.



YES® water-based 150ml / 5.1 fluid ounce tube label.




YES® water-based 150ml / 5.1 fluid ounce tube label (Zoom-View of Principal Display Panel).


YESWB is a water based, discreet, natural, certified organic, silky gel which moisturises and lubricates intimate tissues.

Indications for use: A personal lubricant, for vaginal and penile application, intended to moisturize and lubricate, to enhance the ease and comfort of intimate sexual activity and supplement the body's natural lubrication. YES™ water based Personal Lubricant is compatible with natural rubber latex, polyurethane or polyisoprene condoms.






Ingredients: Aqua, Aloe barbadensis leaf juice powder (Aloe vera)*, Linum usitatissimum (Flax) Seed extract*, Cyamopsis tetragonolobus (Guar gum)*, Ceratonia siliqua (Locust bean gum)*, Xanthan gum, Sodium chloride, Potassium sorbate, Citric acid, Phenoxylethanol.
*Organically grown ingredients

YES products are not made with parabens, glycerine, hormones or known skin irritants. 

Caution: This device is not a contraceptive or a spermicide.
Warning: If irritation or discomfort occurs, discontinue use and see a doctor.

Protected by International Patents
Manufactured for Biotech Lubricants Ltd, Petersfield, GU31 4AT, UK
www.yesyesyes.com 

Yes and the Yes Purity Mark are registered trademarks of the Yes Group.

YES® water-based 5 ml / 0.17 fluid ounce applicator carton label (Zoom view of Principal Display Panel).

YES AWARD WINNING NATURAL INTIMACY PRODUCTS CREATED WITH LOVING CARE TO NURTURE PRECIOUS HUMANS AND CHERISH OUR ENVIRONMENT.

YES WB IS A WATER BASED NATURAL INTIMATE LUBRICANT AND VAGINAL MOISTURISER IN SIX CONVENIENT PRE-FILLED APPLICATORS.

YES WB IS A DISCREET, NATURAL, SILKY GEL WHICH MOISTURISES AND LUBRICATES INTIMATE TISSUES.

- enables discreet and hygienic delivery of the right amount to the right place
- for pleasure and ease in love-making
- moisturises and soothes dry and sensitive vaginal tissues
- pH balanced for the vagina
- free of known skin irritants, fragrances, colour, taste and residue
- hypoallergenic formulated to minimise the risk of allergies

YES products are not made with parabens, glycerine, hormones or known skin irritants.

Ingredients: Aqua, Aloe barbadensis leaf juice powder (Aloe vera)*, Linum usitatissimum (Flax) Seed extract*, Cymopsis tetragonolobus (Guar gum)*, Ceratonia siliqua (Locust bean gum)*, Xanthan gum, Sodium chloride, Potassium sorbate, Citric acid, Phenoxyethanol. *Organically grown ingredients

Certified 96% organic by The Soil Association, Bristol, UK.

Indications for use: A personal lubricant, for vaginal and penile application, intended to moisturise and lubricate, to enhance the ease and comfort of intimate sexual activity and supplement the body's natural lubrication. YES WB water based Personal Lubricant is compatible with natural rubber latex, polyurethane or polyisoprene condoms.

Tamper-proofed tubes for your protection

Caution: This device is not a contraceptive or a spermicide.

Warning: If irritation or discomfort occurs, discontinue use and see a doctor.

Please read full details & directions for use inside.

GUARANTEED 100% PURE & NATURAL

YES WB

APPLICATORS
WATER BASED PERSONAL LUBRICANT

ORGANIC
6x5ml 0.17 fl oz e
single use applicators

YES

YES® is proud to be planet friendly. All our packaging is recyclable, sustainably sourced where available and all our products are certified organic.

Protected by International Patents

Manufactured for Biotech Lubricants Ltd, Petersfield, GU31 4AT, UK

24/7 care line +44 (0)8456 448 813
Email hello@yesyesyes.org

www.yesyesyes.com

Yes and the Yes Purty Mark are registered trademarks of the Yes Group.

MADE IN BRITAIN
NATURAL FACTORY APPROVED
CE 0088

SOIL ASSOCIATION ORGANIC

GUARANTEED 100% PURE & NATURAL

YES

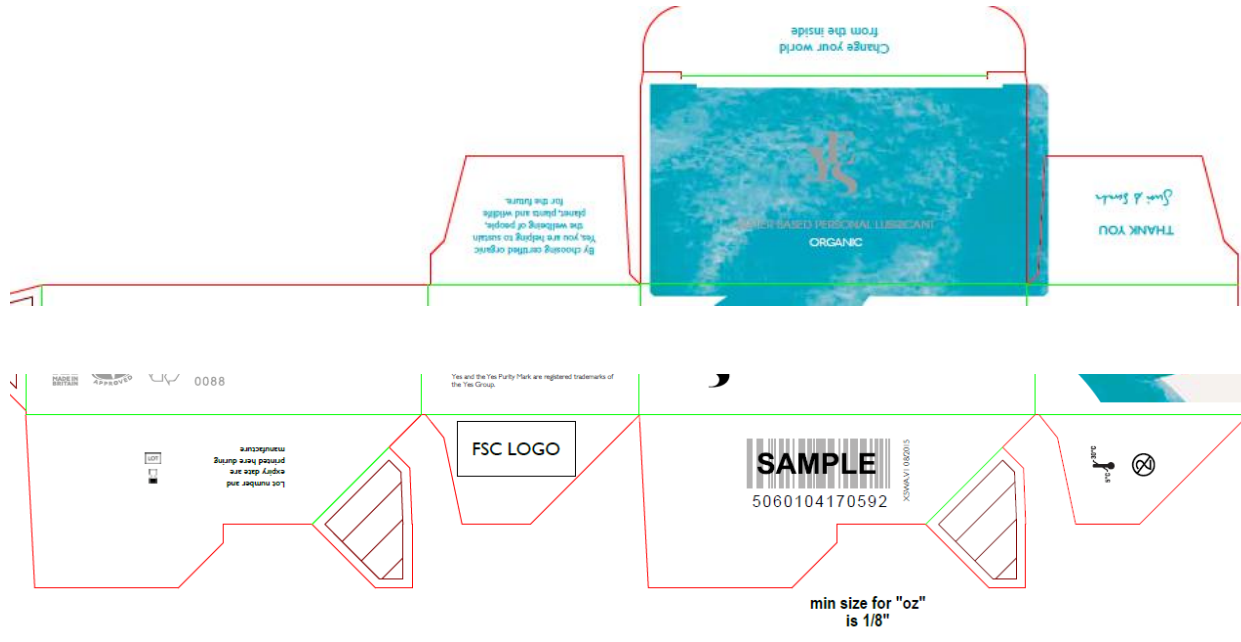
ORGANIC
6x5ml 0.17 fl oz e
single use applicators

YES

APPLICATORS
WATER BASED PERSONAL LUBRICANT

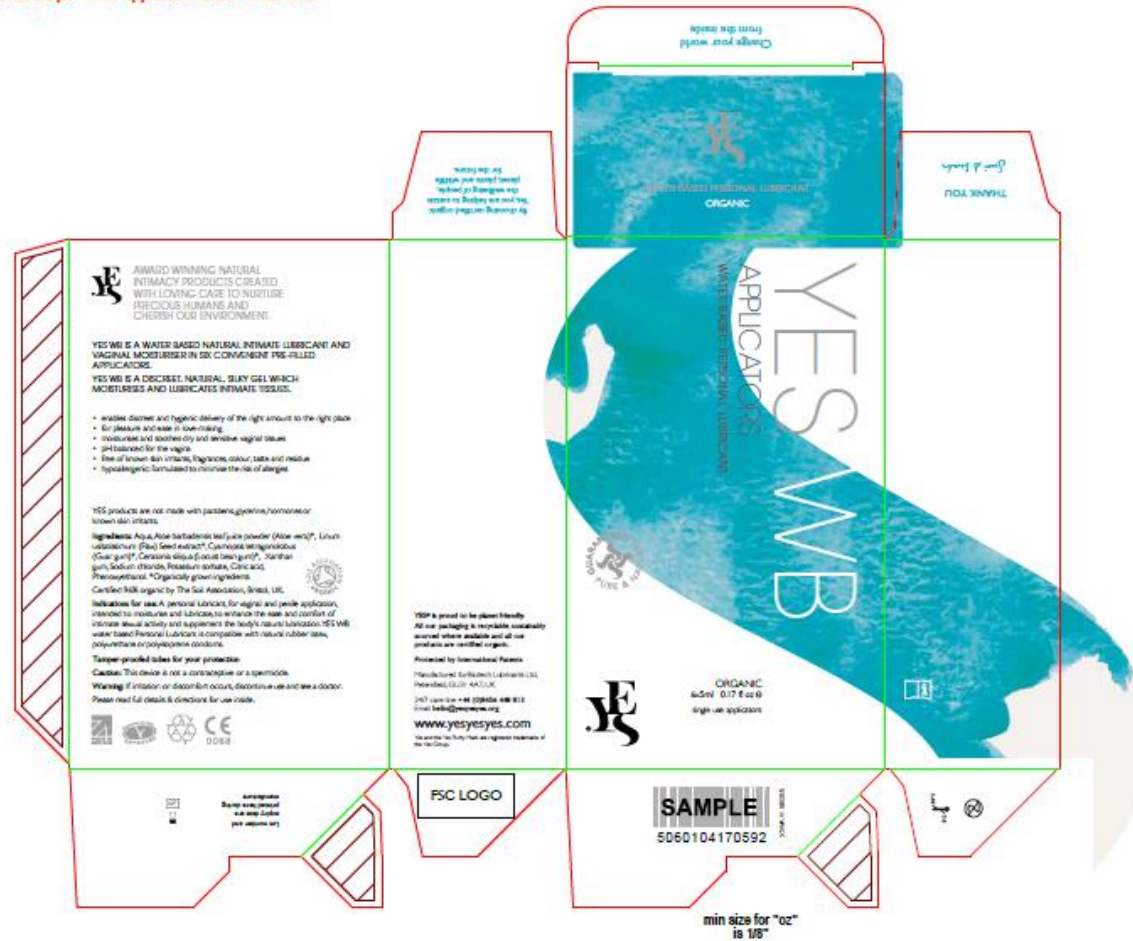
YES WB

YES[®] water-based 5 ml / 0.17 fluid ounce applicator carton label (Zoom view of Ends).



YES® water-based 5 ml / 0.17 fluid ounce applicator carton label.

YESWB 6x5ml pre-filled Applicator Carton Final Draft



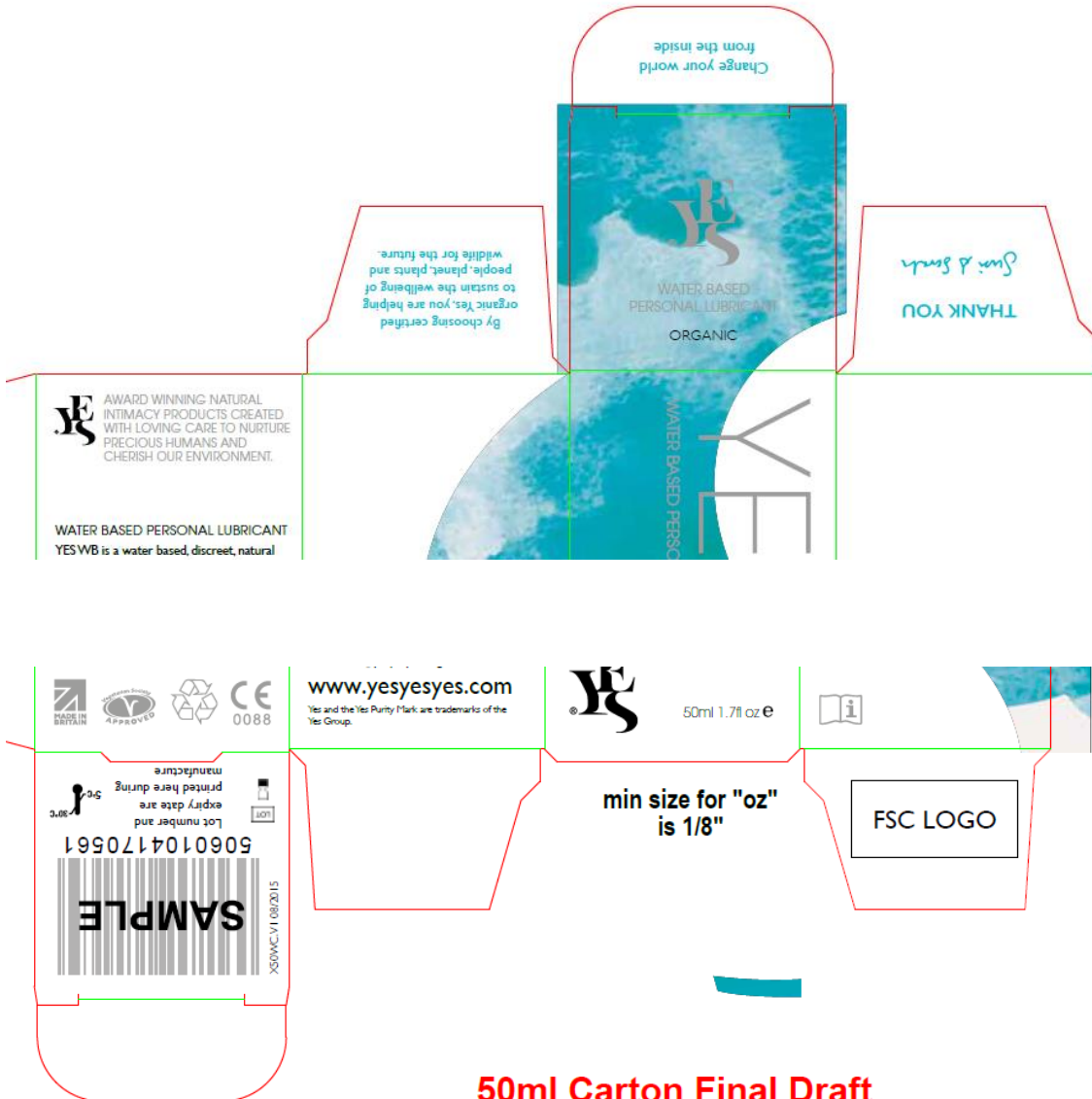
YES[®] water-based 50 ml / 1.7 fluid ounce tube carton label.

YesWB_50ml Carton and Tube Labels Final Draft



50ml Carton Final Draft

**YES® water-based 50 ml / 1.7 fluid ounce tube carton label (Top and bottom sections).
Identical information is displayed on other sized tube cartons.**



50ml Carton Final Draft

YES® water-based 50 ml / 1.7 fluid ounce tube carton label (Zoom View of Principal Display Panel).



YES[®] water-based 100 ml / 3.4 fluid ounce tube carton label.

YesWB_100ml Carton and Tube Labels Final Draft



100ml Carton Final Draft

YES® water-based 100 ml / 3.4 fluid ounce tube carton label (Zoom View of Principal Display Panel).

WATER BASED PERSONAL LUBRICANT

YES WB is a water based, discreet, natural silky gel which moisturises and lubricates intimate tissues.

- enhances sexual pleasure and sensitivity
- no smell, no taste, no stinging
- condom and toy compatible
- pH balanced for the vagina
- rapidly relieves dryness and discomfort
- gynaecologist recommended (see website)
- hypoallergenic formulated to minimise the risk of allergies

YES products are not made with parabens, glycerine, hormones or known skin irritants.

Ingredients: Aqua, Aloe barbadensis leaf juice powder (Aloe vera)*, Linum usitatissimum (Flax) Seed extract*, Cyamopsis tetragonolobus (Guar gum)*, Ceratonia siliqua (Locust bean gum)*, Xanthan gum, Sodium chloride, Potassium sorbate, Citric acid, Phenoxyethanol.

*Organically grown ingredients

Certified 96% organic by The Soil Association, Bristol, UK.



Indications for use: A personal lubricant, for vaginal and penile application, intended to moisturise and lubricate, to enhance the ease and comfort of intimate sexual activity and supplement the body's natural lubrication. YES WB water based Personal Lubricant is compatible with natural rubber latex, polyurethane or polyisoprene condoms.

Caution: This device is not a contraceptive or a spermicide.

Warning: If irritation or discomfort occurs, discontinue use and see a doctor.

Please read full details & directions for use inside.








WATER BASED PERSONAL LUBRICANT

YES WB

ORGANIC
personal lubricant



YES

100ml 3.4fl oz e



YES® is proud to be planet friendly.
All our packaging is recyclable, sustainably sourced where available and all our products are certified organic.

Protected by International Patents

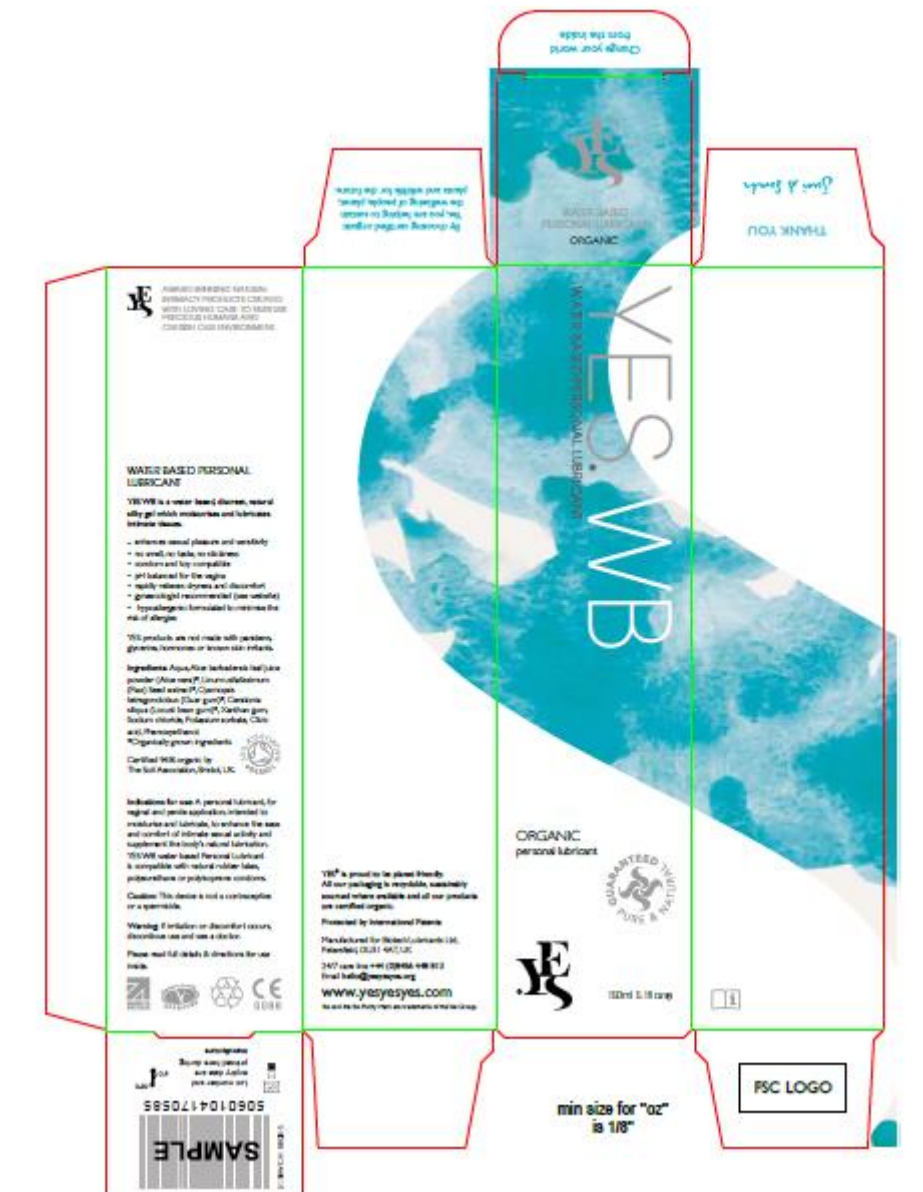
Manufactured for Biotech Lubricants Ltd, Petersfield, GU31 4AT, UK

24/7 care line +44 (0)8456 448 813
Email hello@yesyesyes.org

www.yesyesyes.com

Yes and the Yes Purity Mark are trademarks of the Yes Group.

YES[®] water-based 150 ml / 5.1 fluid ounce tube carton label.



YES® water-based 150 ml / 5.1 fluid ounce tube carton label (Zoom View of Principal Display Panel).

WATER BASED PERSONAL LUBRICANT

YES WB is a water based, discreet, natural silky gel which moisturises and lubricates intimate tissues.

- enhances sexual pleasure and sensitivity
- no smell, no taste, no stickiness
- condom and toy compatible
- pH balanced for the vagina
- rapidly relieves dryness and discomfort
- gynaecologist recommended (see website)
- hypoallergenic formulated to minimise the risk of allergies

YES products are not made with parabens, glycerine, hormones or known skin irritants.

Ingredients: Aqua, Aloe barbadensis leaf juice powder (Aloe vera)*, Linum usitatissimum (Flax) Seed extract*, Cymoposis tetragonolobus (Guar gum)*, Ceratonia siliqua (Locust bean gum)*, Xanthan gum, Sodium chloride, Potassium sorbate, Citric acid, Phenoxethanol.

*Organically grown ingredients

Certified 96% organic by The Soil Association, Bristol, UK.



Indications for use: A personal lubricant, for vaginal and penile application, intended to moisturise and lubricate, to enhance the ease and comfort of intimate sexual activity and supplement the body's natural lubrication. YES WB water based Personal Lubricant is compatible with natural rubber latex, polyurethane or polyisoprene condoms.

Caution: This device is not a contraceptive or a spermicide.

Warning: If irritation or discomfort occurs, discontinue use and see a doctor.

Please read full details & directions for use inside.








ORGANIC
personal lubricant

YES® is proud to be planet friendly. All our packaging is recyclable, sustainably sourced where available and all our products are certified organic.

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Email hello@yesyesyes.org

www.yesyesyes.com

Yes and the Yes Purty Mark are trademarks of the Yes Group.




150ml 5.1 fl oz e



YES® oil-based 140 ml / 4.7 fluid ounce tube carton label (Zoom View of Principal Display Panel).

**PLANT-OIL BASED
PERSONAL LUBRICANT**

YES OB is a luxurious plant-oil based natural lubricant, whose rich oils and butters nourish and condition skin, giving lasting lubricity and comfort.

- dual purpose intimate lubricant and massage oil
- perfect for prolonged love-making
- natural plant-oil based alternative to silicone lubricants
- safe for use with silicone toys
- hypoallergenic formulated to minimise the risk of allergies
- richly nourishing, providing soothing relief
- gynaecologist recommended (see website)
- YES OB is NOT condom compatible

YES products are not made with parabens, glycerine, hormones or known skin irritants.

Ingredients: Helianthus annuus (Sunflower) seed oil*, Butyrospermum parkii (Shea) butter*, Prunus dulcis (Sweet almond) oil*, Cera alba (Bees wax)*, Theobroma cacao (Cocoa) seed butter*, Tocopherol (Vitamin E).

*Organically grown ingredients

Certified 99.8% organic by The Soil Association, Bristol, UK



Indications for use: A personal lubricant, for vaginal and penile application, intended to moisturise and lubricate, to enhance the ease and comfort of intimate sexual activity and supplement the body's natural lubrication. YES OB plant-oil based Personal Lubricant is not compatible with natural rubber latex, polyurethane or polyisoprene condoms.

Caution: This device is not a contraceptive or a spermicide.

Warning: If irritation or discomfort occurs, discontinue use and see a doctor.

Please read full details & directions for use inside.



YES® is proud to be planet friendly. All our packaging is recyclable, sustainably sourced where available and all our products are certified organic.

Manufactured for Biotech Lubricants Ltd, Petersfield, GU31 4AT, UK

24/7 care line +44 (0)8456 448 813
Email hello@yesyesyes.org

www.yesyesyes.com

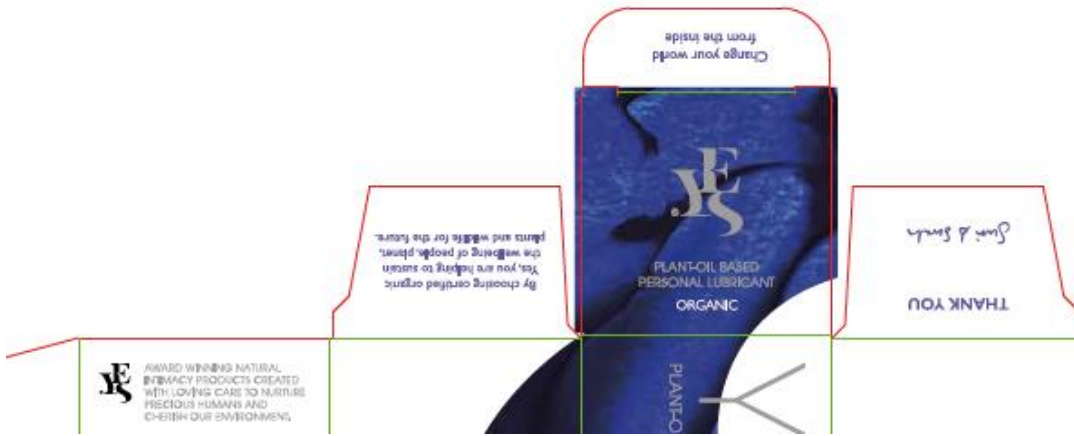


ORGANIC
personal lubricant



140ml 4.7 fl oz e

**YES[®] oil-based 140 ml / 4.7 fluid ounce tube carton label (Top and bottom of Carton).
All YES[®] oil-based tube carton labels for all sizes contain identical information on the
top and bottom sections.**



YES[®] oil-based 140 ml / 4.7 fluid ounce tube carton label.

YesOB_80ml Carton and Tube Labels Final Draft



YES[®] oil-based 140 ml / 4.7 fluid ounce tube label.



YES® oil-based 140 ml / 4.7 fluid ounce tube label (Zoom View of Principal Display Panel).

YES OB is a luxurious plant-oil based natural lubricant, whose rich oils and butters nourish and condition skin, giving lasting lubricity and comfort. This device is not a contraceptive or a spermicide. YES OB is NOT condom compatible.

Indications for use:
A personal lubricant, for vaginal and penile application, intended to moisturise and lubricate, to enhance the ease and comfort of intimate sexual activity and supplement the body's natural lubrication.

YES OB is NOT compatible with natural rubber latex, polyurethane or polyisoprene condoms.

Caution: This device is not a contraceptive or a spermicide.







Warning: If irritation or discomfort occurs, discontinue use and see a doctor.

Ingredients: Helianthus annuus (Sunflower) seed oil*, Butyrospermum parkii (Shea) butter*, Prunus dulcis (Sweet almond) oil*, Cera alba (Bees wax)*, Theobroma cacao (Cocoa) seed butter*, Tocopherol (Vitamin E).
*Organically grown ingredients

YES products are not made with parabens, glycerine, hormones or known skin irritants.

Manufactured for Biotech Lubricants Ltd, Petersfield, GU31 4AT, UK
www.yesyesyes.com

Yes and the Yes Purity Mark are trademarks of the Yes Group.



YES® oil-based 80 ml / 2.7 fluid ounce tube carton label (Zoom View of Principal Display Panel).

| | | |
|---|---|--|
|  <p>INTIMACY PRODUCTS CREATED WITH LOVING CARE TO NURTURE PRECIOUS HUMANS AND CHERISH OUR ENVIRONMENT.</p> <p>PLANT-OIL BASED PERSONAL LUBRICANT</p> <p>YES OB is a luxurious plant-oil based natural lubricant, whose rich oils and butters nourish and condition skin, giving lasting lubricity and comfort.</p> <ul style="list-style-type: none"> • dual purpose intimate lubricant and massage oil • perfect for prolonged lovemaking • natural plant-oil based alternative to silicone lubricants • safe for use with silicone toys • hypoallergenic: formulated to minimise the risk of allergies • richly nourishing providing soothing relief • gynaecologist recommended (see website) • YES OB is NOT condom compatible <p>YES products are not made with parabens, glycerine, hormones or known skin irritants.</p> <p>Ingredients: Helianthus annuus (Sunflower) seed oil*, Butyrospermum parkii (Shea) butter*, Prunus dulcis (Sweet almond) oil*, Cera alba (Bees wax)*, Theobroma cacao (Cocoa) seed butter*, Tocopherol (Vitamin E). *Organically grown ingredients</p> <p>Certified 99.8% organic by The Soil Association, Bristol, UK</p>  <p>Indications for use: A personal lubricant, for vaginal and penile application, intended to moisturise and lubricate, to enhance the ease and comfort of intimate sexual activity and supplement the body's natural lubrication. YES OB plant-oil based Personal Lubricant is not compatible with natural rubber latex, polyurethane or polyisoprene condoms.</p> <p>Caution: This device is not a contraceptive or a spermicide.</p> <p>Warning: If irritation or discomfort occurs, discontinue use and see a doctor.</p> <p>Please read full details & directions for use inside.</p>  |  <p style="writing-mode: vertical-rl; transform: rotate(180deg);">PLANT-OIL BASED PERSONAL LUBRICANT</p> <p style="font-size: 4em; font-weight: bold; text-align: center;">YES OB</p> <p>ORGANIC personal lubricant</p> <p>YES® is proud to be planet friendly. All our packaging is recyclable, sustainably sourced where available and all our products are certified organic.</p> <p>Manufactured for Biotech Lubricants Ltd, Petersfield, GU31 4AT, UK</p> <p>24/7 care line +44 (0)8456 448 813 Email hello@yesyesyes.org</p> <p>www.yesyesyes.com</p>  |  <p>80ml 2.7fl oz e</p> |
|---|---|--|

YES® oil-based 80 ml / 2.7 fluid ounce tube label (Zoom View of Principal Display Panel).



YES OB is a luxurious plant-oil based natural lubricant, whose rich oils and butters nourish and condition skin, giving lasting lubricity and comfort. This device is not a contraceptive or a spermicide. YES OB is NOT condom compatible.

Indications for use:
A personal lubricant, for vaginal and penile, application intended to moisturise and lubricate, to enhance the ease and comfort of intimate sexual activity and supplement the body's natural lubrication.

YES OB is NOT compatible with natural rubber latex, polyurethane or polyisoprene condoms.

Caution: This device is not a contraceptive or a spermicide.






Warning: If irritation or discomfort occurs, discontinue use and see a doctor.

Ingredients: Helianthus annuus (Sunflower) seed oil*, Butyrospermum parkii (Shea) butter*, Prunus dulcis (Sweet almond) oil*, Cera alba (Bees wax)*, Theobroma cacao (Cocoa) seed butter*, Tocopherol (Vitamin E).
*Organically grown ingredients

YES products are not made with parabens, glycerine, hormones or known skin irritants.



Manufactured for Biotech Lubricants Ltd, Petersfield, GU31 4AT, UK
www.yesyesyes.com
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PLANT-OIL BASED PERSONAL LUBRICANT

YES
OB

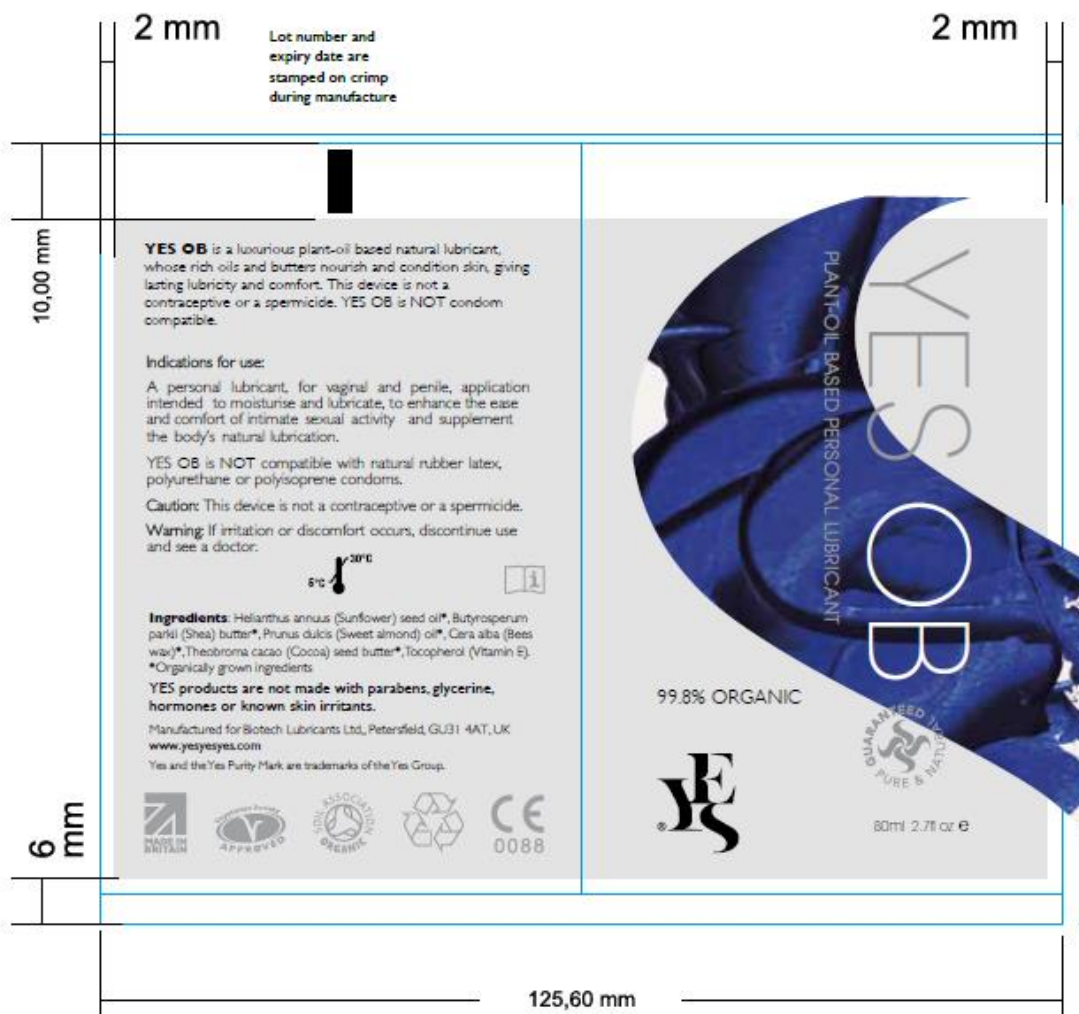
99.8% ORGANIC

80ml 2.7fl oz e

mm

YES® oil-based 80 ml / 2.7 fluid ounce tube label.












YES® oil-based 40 ml / 1.4 fluid ounce tube carton label (Zoom View of Principal Display Panel).

| | | |
|---|---|--|
| <p>PLANT-OIL BASED PERSONAL LUBRICANT YES OB is a luxurious plant-oil based natural lubricant, whose rich oils and butters nourish and condition skin, giving lasting lubricity and comfort.</p> <ul style="list-style-type: none"> • dual purpose intimate lubricant and massage oil • perfect for prolonged love-making • natural plant-oil based alternative to silicone lubricants • safe for use with silicone toys • hypoallergenic: formulated to minimise the risk of allergies • richly nourishing, providing soothing relief • gynaecologist recommended (see website) • YES OB is NOT condom compatible <p>YES products are not made with parabens, glycerine, hormones or known skin irritants. Ingredients: Helianthus annuus (Sunflower) seed oil*, Butyrospermum parkii (Shea) butter*, Prunus dulcis (Sweet almond) oil*, Cera alba (Bees wax)*, Theobroma cacao (Cocoa) seed butter*, Tocopherol (Vitamin E). *Organically grown ingredients Certified 99.8% organic by The Soil Association, Bristol, UK</p> <p>Indications for use: A personal lubricant, for vaginal and penile application, intended to moisturise and lubricate, to enhance the ease and comfort of intimate sexual activity and supplement the body's natural lubrication. YES OB plant-oil based Personal Lubricant is not compatible with natural rubber latex, polyurethane or polyisoprene condoms.</p> <p>Caution: This device is not a contraceptive or a spermicide.</p> <p>Warning: If irritation or discomfort occurs, discontinue use and see a doctor.</p> <p>Please read full details & directions for use inside.</p> <p>MADE IN BRITAIN APPROVED  CE 0088</p> | <p>YES OB PLANT-OIL BASED PERSONAL LUBRICANT</p> <p>YES® is proud to be planet friendly. All our packaging is recyclable, sustainably sourced where available and all our products are certified organic.</p> <p>Manufactured for Biotech Lubricants Ltd, Petersfield, GU31 4AT, UK 24/7 care line +44 (0)8456 448 813 Email hello@yesyesyes.org www.yesyesyes.com Yes and the Yes Purity Mark are trademarks of the Yes Group.</p> | <p>ORGANIC personal lubricant</p> <p>GUARANTEED 100% PURE & NATURAL</p> <p>YES</p> <p>40ml 1.4fl oz e</p> <p></p> |
|---|---|--|

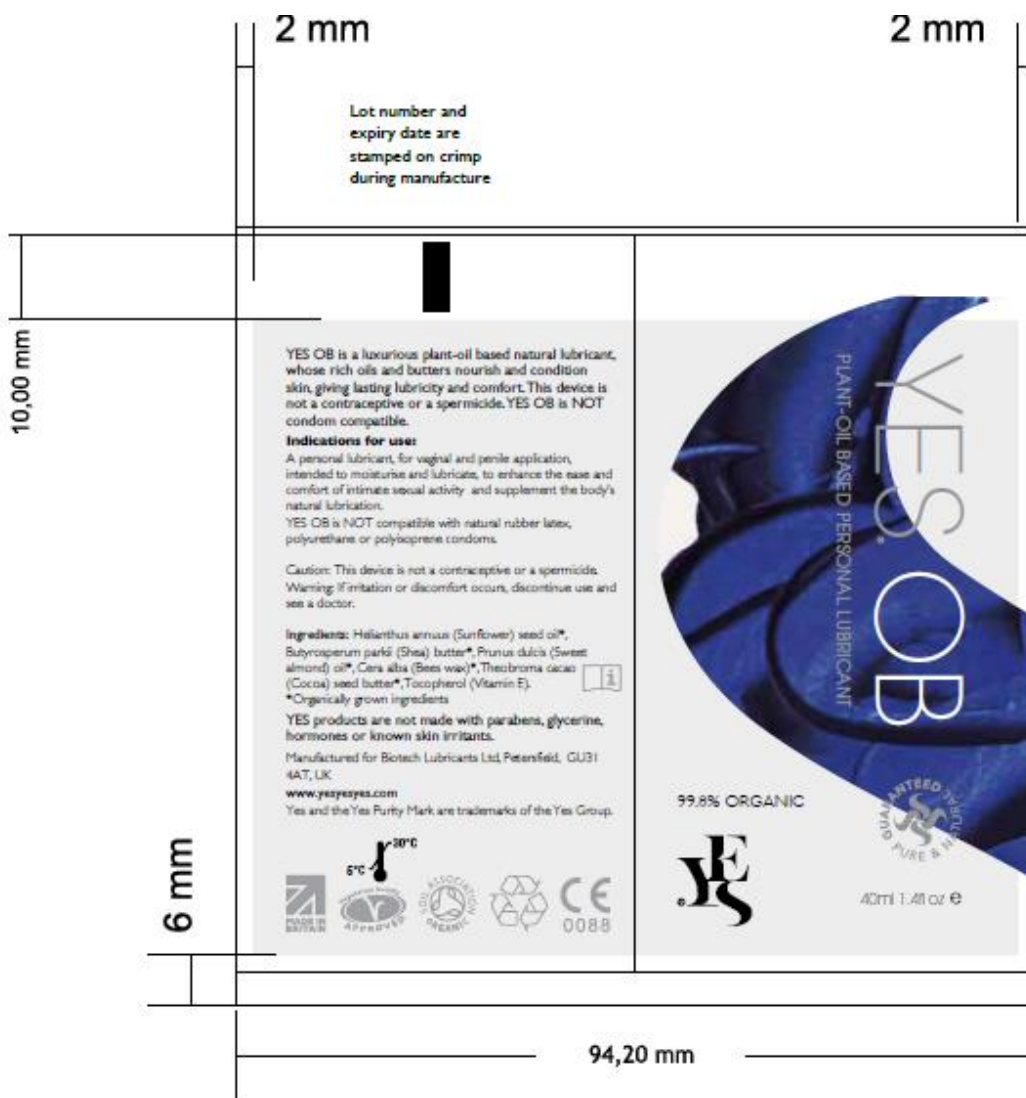
YES[®] oil-based 40 ml / 1.4 fluid ounce tube carton label.



YES® oil-based 40 ml / 1.4 fluid ounce tube label (Zoom View of Principal Display Panel).

| | |
|--|--|
| <p>YES OB is a luxurious plant-oil based natural lubricant, whose rich oils and butters nourish and condition skin, giving lasting lubricity and comfort. This device is not a contraceptive or a spermicide. YES OB is NOT condom compatible.</p> <p>Indications for use: A personal lubricant, for vaginal and penile application, intended to moisturise and lubricate, to enhance the ease and comfort of intimate sexual activity and supplement the body's natural lubrication. YES OB is NOT compatible with natural rubber latex, polyurethane or polyisoprene condoms.</p> <p>Caution: This device is not a contraceptive or a spermicide. Warning: If irritation or discomfort occurs, discontinue use and see a doctor.</p> <p>Ingredients: Helianthus annuus (Sunflower) seed oil*, Butyrosperum parkii (Shea) butter*, Prunus dulcis (Sweet almond) oil*, Cera alba (Bees wax)*, Theobroma cacao (Cocoa) seed butter*, Tocopherol (Vitamin E). </p> <p>*Organically grown ingredients</p> <p>YES products are not made with parabens, glycerine, hormones or known skin irritants.</p> <p>Manufactured for Biotech Lubricants Ltd, Petersfield, GU31 4AT, UK www.yesyesyes.com Yes and the Yes Purity Mark are trademarks of the Yes Group.</p> <div style="display: flex; justify-content: space-between; align-items: center;"> <div style="text-align: center;">    </div> <div style="text-align: center;">   </div> </div> |  <p style="text-align: center;">99.8% ORGANIC</p> <div style="display: flex; justify-content: space-around; align-items: center;">  <div style="text-align: center;">  40ml 1.4fl oz e </div> </div> |
|--|--|

YES[®] oil-based 40 ml / 1.4 fluid ounce tube label.



YES® Vaginal Moisturizer 100 ml / 3.4 fluid ounce tube carton label (Zoom View of Principal Display Panel).

YES VM WATER BASED NATURAL, LONG-LASTING VAGINAL MOISTURISING GEL

- relieves vaginal atrophy and dryness
- alleviates irritation, itching and burning
- moisturises and soothes dry and sensitive vaginal tissues
- pH balanced iso-tonic gel for the vagina
- no fragrances, colour, taste or residue
- gynaecologist recommended (see website)
- hypoallergenic formulated to minimise the risk of allergies

YES products are not made with parabens, glycerine, hormones or known skin irritants.

Ingredients: Aqua (water), Linum usitatissimum (Flax) Extract*, Aloe barbadensis leaf juice powder (Aloe vera)*, Ceratonia siliqua (Locust bean gum)*, Cyamopsis tetragonolobus (Guar gum)*, Sodium chloride, Xanthan gum, Citric acid, Potassium sorbate, Phenoxylethanol.

*Organically grown ingredients
 Certified 95% organic by The Soil Association, Bristol, UK

Indications for use: A personal lubricant, for vaginal and penile application, intended to moisturise and lubricate, to enhance the ease and comfort of intimate sexual activity and supplement the body's natural lubrication. YES VM water based Vaginal Moisturiser is compatible with natural rubber latex, polyurethane or polyisoprene condoms.

Caution: This device is not a contraceptive or a spermicide.

Warning: If irritation or discomfort occurs, discontinue use and see a doctor.

Please read full details & directions for use inside.






MOISTURISING GEL





YES® is proud to be planet friendly. All our packaging is recyclable, sustainably sourced where available and all our products are certified organic.

Protected by International Patents

Manufactured for Biotech Lubricants LTD Ltd, Petersfield, GU31 4AT, UK

24/7 care line +44 (0)8456 448 813
 Email hello@yesyesyes.org

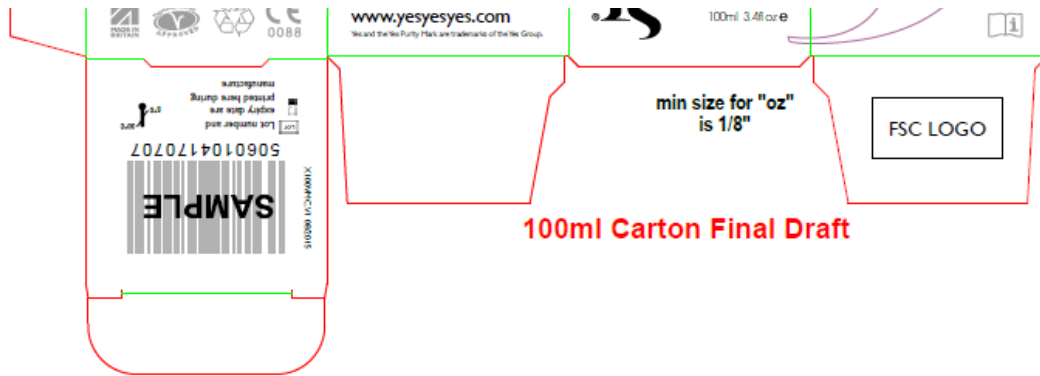
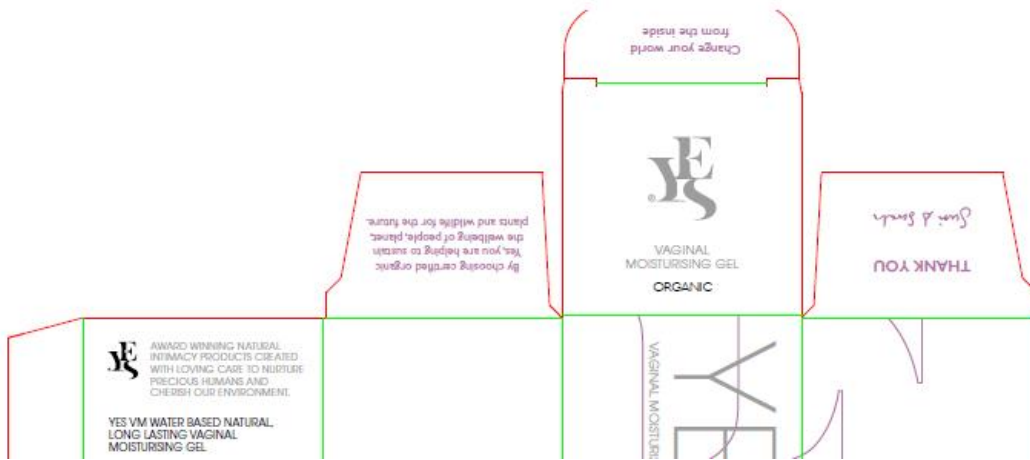
www.yesyesyes.com

Yes and the Yes Purity Mark are trademarks of the Yes Group.



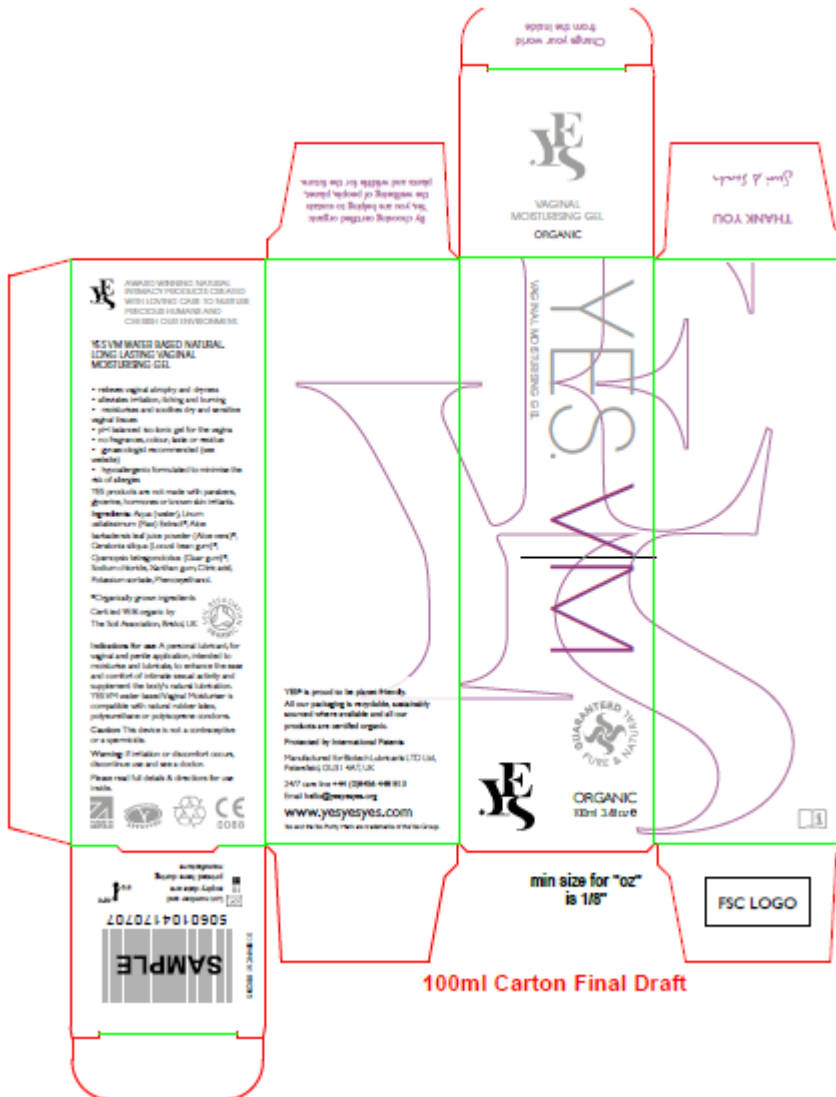
ORGANIC
100ml 3.4 fl oz e

YES® Vaginal Moisturizer 100 ml / 3.4 fluid ounce tube carton label. (View of top and bottom of carton).



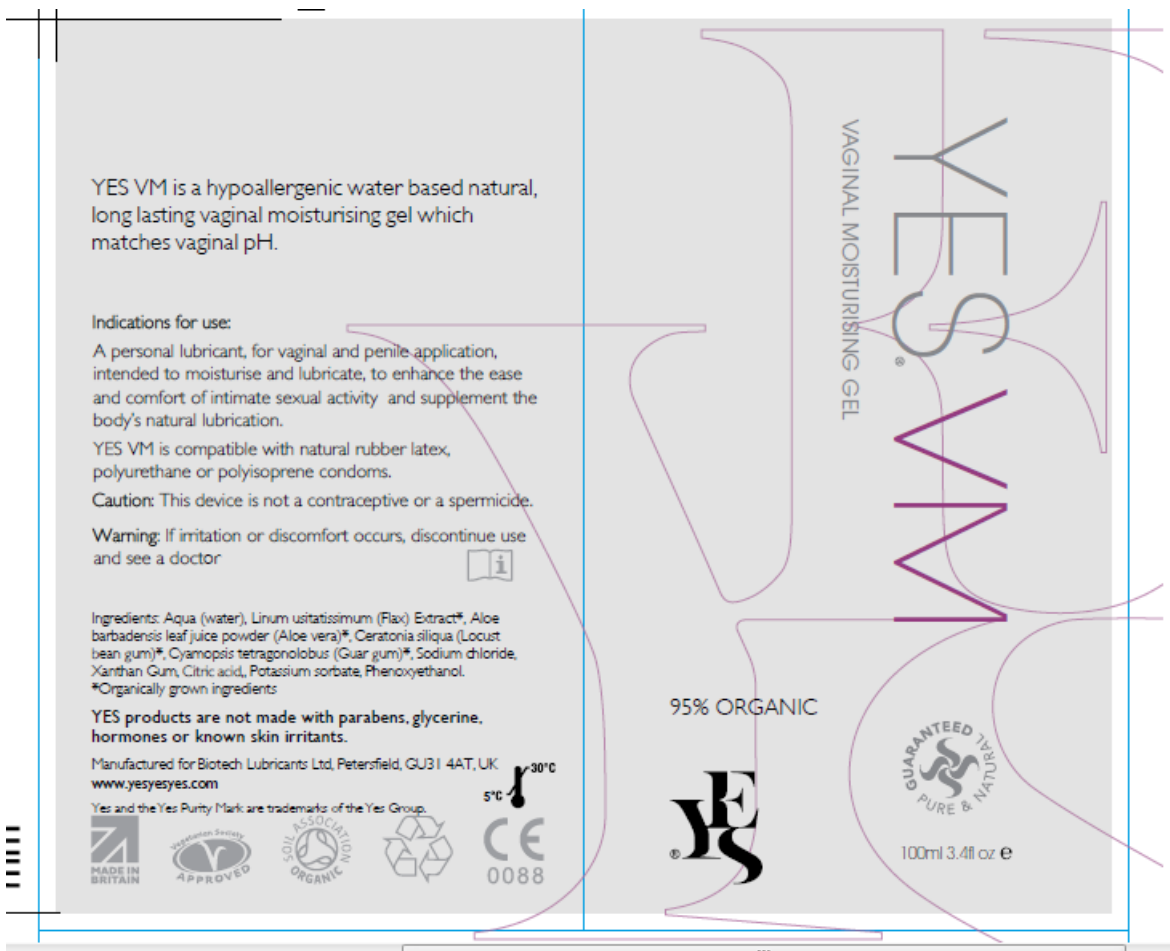
100ml Carton Final Draft

YES® Vaginal Moisturizer 100 ml / 3.4 fluid ounce tube carton label.

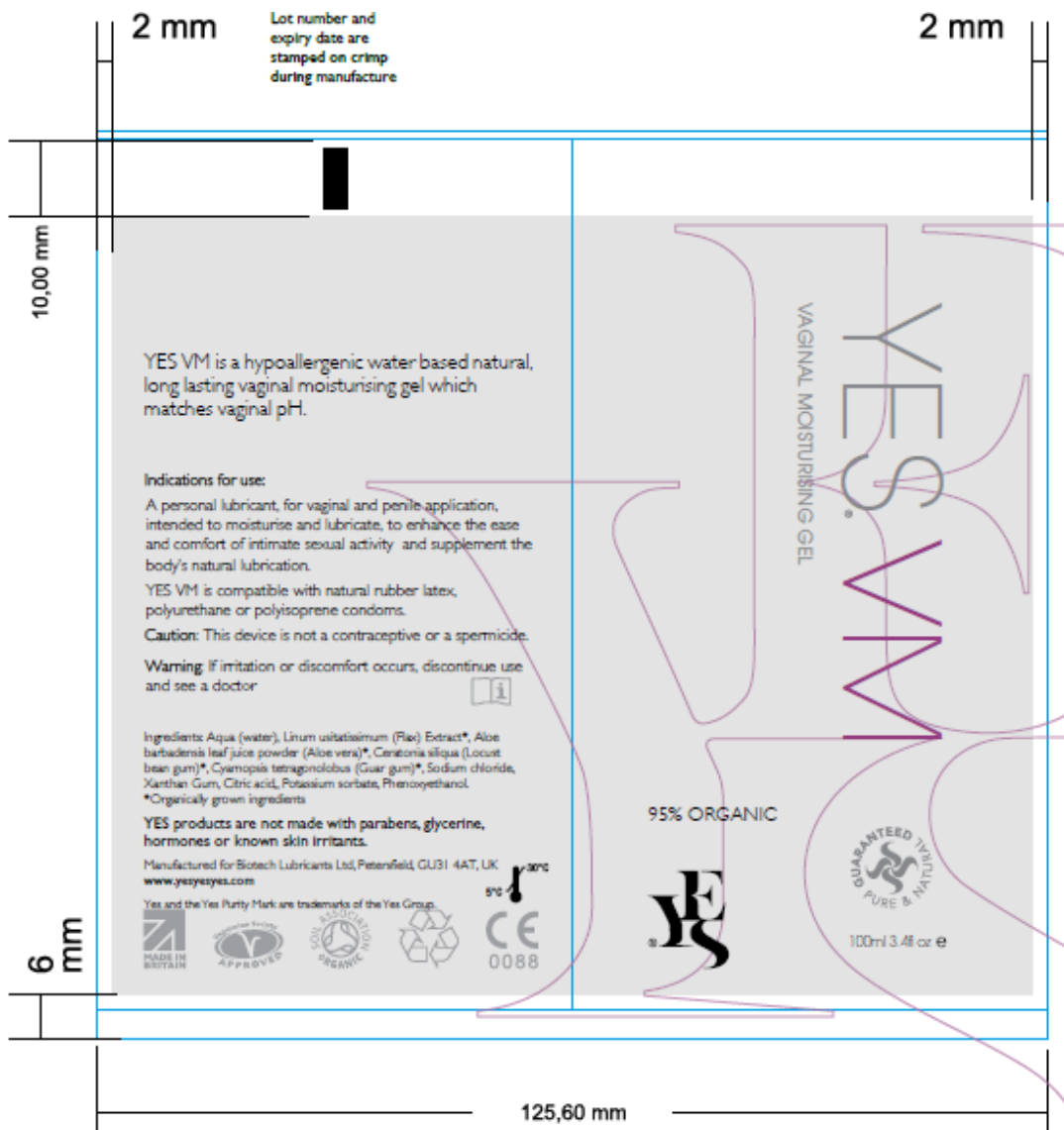


100ml Carton Final Draft

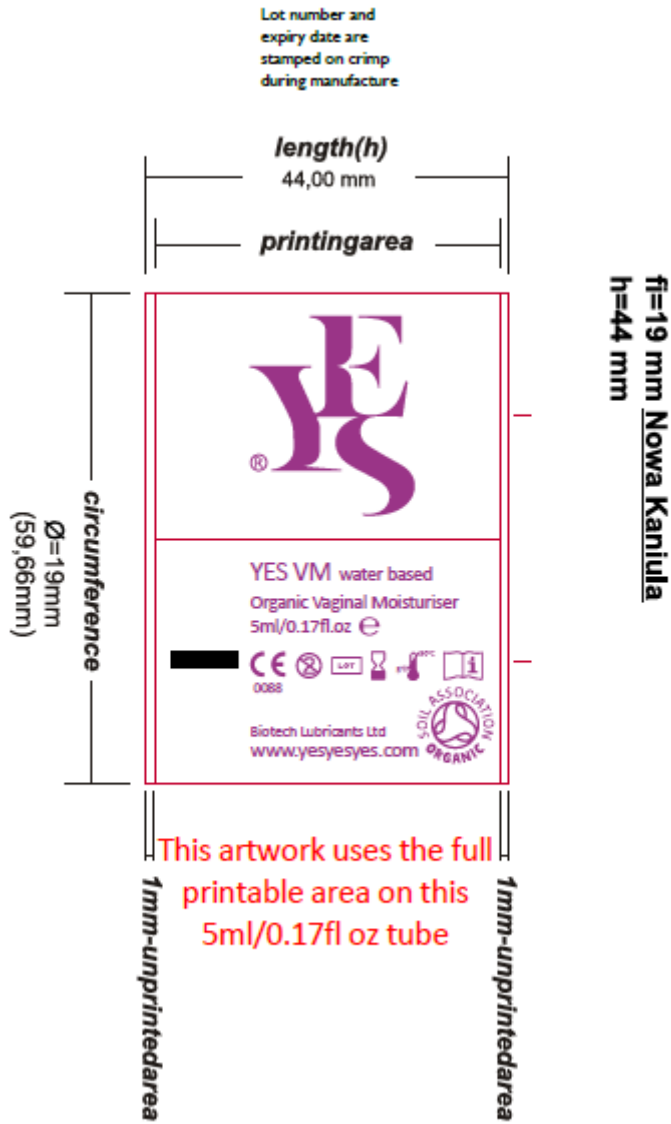
YES® Vaginal Moisturizer 100 ml / 3.4 fluid ounce tube label (Zoom View of Principle Display Panel).



YES® Vaginal Moisturizer 100 ml / 3.4 fluid ounce tube label.



YES® Vaginal Moisturizer 5 ml / 0.17 fluid ounce applicator tube label.



YES® Vaginal Moisturizer 5 ml / 0.17 fluid ounce applicator tube carton label (Zoom View of Principal Display Panel).



 WITH LOVING CARE TO NURTURE
PRECIOUS HUMANS AND
CHERISH OUR ENVIRONMENT.

YES VM WATER BASED IS A NATURAL, LONG-LASTING VAGINAL MOISTURISING GEL IN SIX CONVENIENT PRE-FILLED SINGLE USE APPLICATORS

- enables discreet and hygienic delivery of the right amount of moisturising gel inside the vagina
- relieves vaginal atrophy and dryness
- alleviates irritation, itching and burning
- moisturises and soothes dry and sensitive vaginal tissues
- pH balanced iso-tonic gel for the vagina
- no fragrances, colour, taste or residue
- recommended by gynaecologists (see website)
- hypoallergenic: formulated to minimise the risk of allergies

YES products are not made with parabens, glycerine, hormones or known skin irritants.

Ingredients: Aqua (water), Linum usitatissimum (Flax) Extract*, Aloe barbadensis leaf juice powder (Aloe vera)*, Ceratonia siliqua (Locust bean gum)*, Cyamopsis tetragonolobus (Guar gum)*, Sodium chloride, Xanthan gum, Citric acid, Potassium sorbate, Phenoxyethanol.

*Organically grown ingredients

Certified 95% organic by The Soil Association, Bristol, UK

Indications for use: A personal lubricant, for vaginal and penile application, intended to moisturise and lubricate, to enhance the ease and comfort of intimate sexual activity and supplement the body's natural lubrication. YES VM water based Vaginal Moisturiser is compatible with natural rubber latex, polyurethane or polyisoprene condoms.

Caution: This device is not a contraceptive or a spermicide.

Warning: If irritation or discomfort occurs, discontinue use and see a doctor.

Please read full details & directions for use inside.



A 5ml applicator used every 2-3 days, is typically sufficient to maintain a moist, comfortable vagina



GUARANTEED 100% PURE & NATURAL

YES® is proud to be planet friendly. All our packaging is recyclable, sustainably sourced where available and all our products are certified organic.

Protected by International Patents

Manufactured for Biotech Lubricants Ltd, Petersfield, GU31 4AT, UK

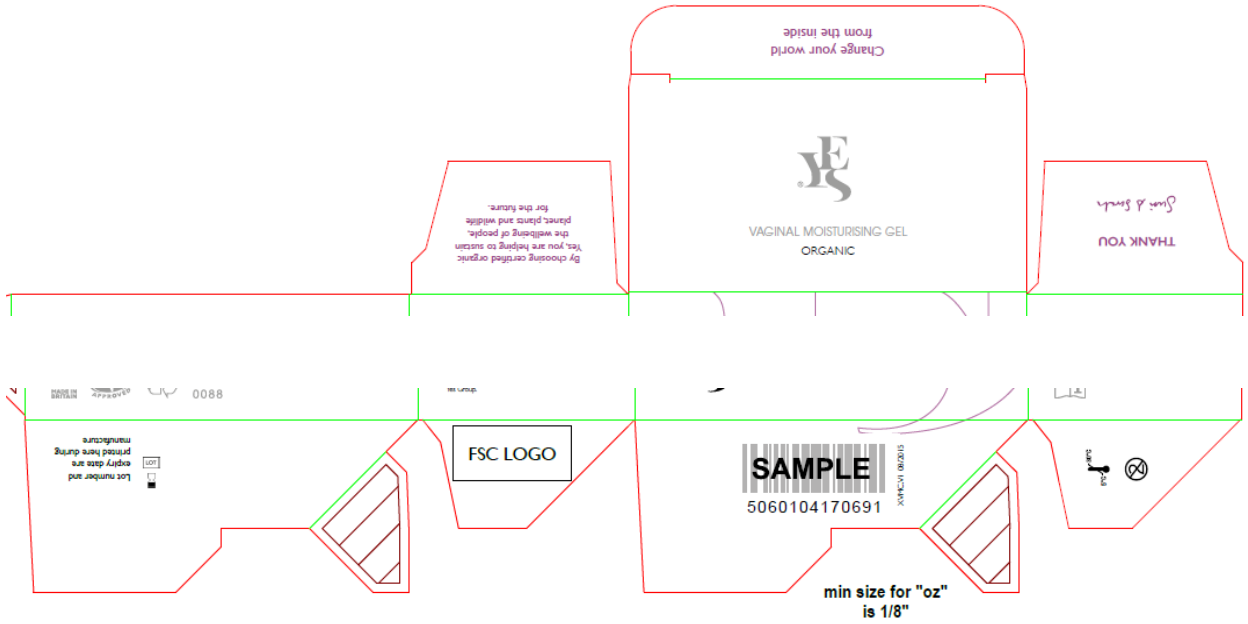
24/7 care line +44 (0)8456 448 813
Email hello@yesyesyes.org

www.yesyesyes.com

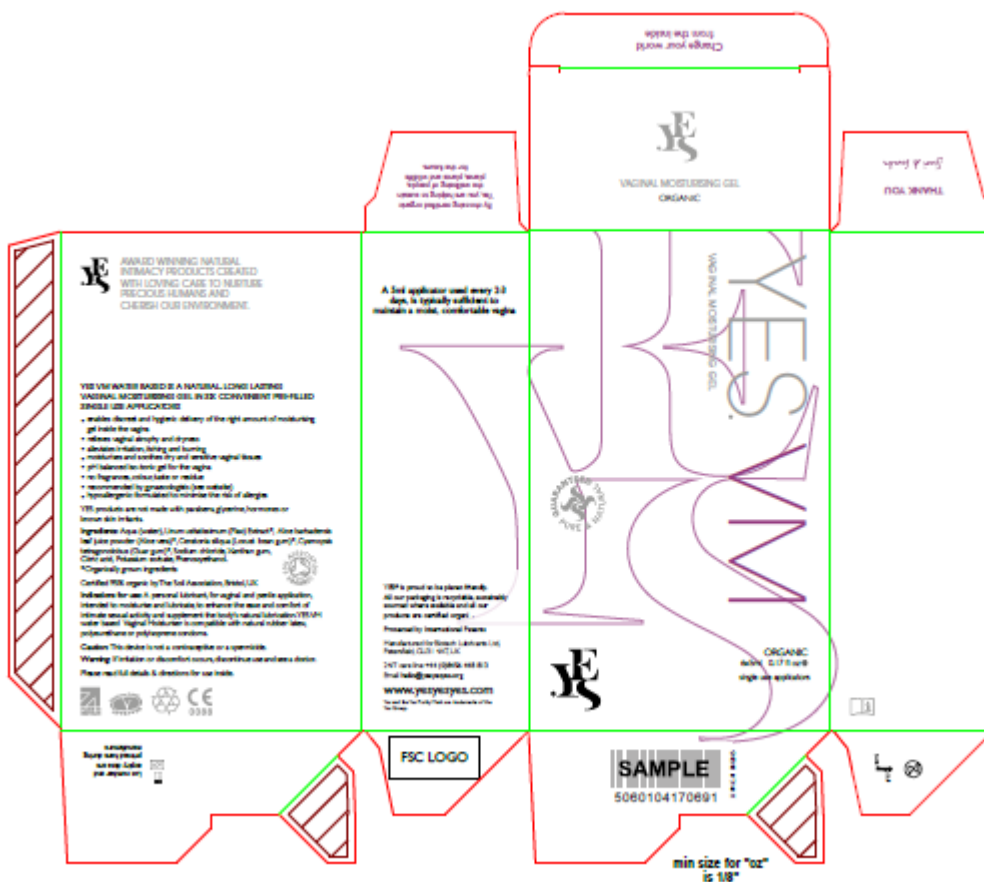
Yes and the Yes Purity Mark are trademarks of the Yes Group.



YES[®] Vaginal Moisturizer 5 ml / 0.17 fluid ounce applicator tube carton label (Top and bottom of carton).



YES[®] Vaginal Moisturizer 5 ml / 0.17 fluid ounce applicator tube carton label.



Always use

Instructions For Use - YES® Oil-based Personal Lubricant. (Page 1).

Final Draft YES OB IFU - OB_IFU_EN V1.pdf

YES® OB plant-oil based personal lubricant

1

Lubricant Description

- Alleviates vaginal dryness
- Natural plant-based intimate lubricant
- For lasting lubricity and glide
- Dual function: outstanding lubrication and body massage
- With a velvety sensuous feel
- The natural plant-based alternative to silicone lubricants
- No known side effects
- NOT compatible with condoms
- YES OB is not made with glycerin or petrochemicals or parabens
- Safe for use with silicone toys but not latex compatible
- Plant oils and butters condition skin, no need to wash off
- Can be applied freely and generously, according to the body's needs

Ingredients

YES® OB: Helianthus annuus (Sunflower) seed oil*, Butyrospermum parkii (Shea butter)*, Prunus dulcis (Sweet almond) oil*, Cera alba (Bees wax)*, Theobroma cacao (Cocoa) seed butter*, Tocopherol (Vitamin E).

* Organically grown ingredients

Directions for use

YES® OB assists your lovemaking by enabling penetration, increasing pleasurable glide and sensation. Warm YES® OB in your hands to ensure a smooth velvety quality. Apply where desired, externally and internally, to self and partner.

Apply a layer of YES® OB with YES® WB on top for a new dimension in lasting lubrication.

Replace cap when not in use. Store in a cool dry place, not in direct sunlight.

Every care has been taken to ensure the safety of this product.

Caution: This device is not a contraceptive or a spermicide.

Warning: If irritation or discomfort occurs, discontinue use and see a doctor.

Pleasure Tip: Double Glide apply a layer of YES® OB with YES® WB on top for a new dimension in lasting lubrication

Indications for use:

A personal lubricant, for vaginal and perile application, intended to moisturise and lubricate, to enhance the ease and comfort of intimate sexual activity and supplement the body's natural lubrication.

YES OB is NOT compatible with condoms

Why Certified Organic?

When you buy something that is certified organic, not only are you making the best choice for your own well being, your purchase is also supporting a system that respects human health, animals, wildlife and the environment.

Certified organic products meet stringent standards and organic certification is your assurance that our ingredients and products have been grown and processed according to strict procedures. Production, processing, distribution and sales are monitored to maintain the finest organic and ecological integrity.

Packaging and Recycling

YES® aims to minimise the environmental impacts of all our packaging. So please do your part. All our bottles are MDPE. Polyethylene (MDPE) is the most often accepted plastic by recycling centres. The cartons, boxes and package inserts can all be recycled.



OB_IFU_EN V1

© Yes Synergy 2016

Instructions For Use - YES[®] Oil-based Personal Lubricant. (Page 2).

2

100% Guarantee: YES[®] products are 100% satisfaction guaranteed. Please contact us by phone or email if you have any concerns or questions.

Certified Organic by: The Soil Association, Bristol, UK.
Approved by: The Vegetarian Society

Manufactured in Great Britain for
Biotech Lubricants Ltd.
Trademark House, Ramshill
Petersfield, Hampshire. GU31 4AT, UK

Contact us
USA/Canada Toll Free: 1-888-777-0125
UK Free Phone: 0-800-978-8525
All other countries: +44 845 094 1141
Website: www.yesyesyes.org
Email: hello@yesyesyes.org



06_IFU_DN V3

© Yes Synergy 2016

Instructions For Use - YES[®] Oil-based Personal Lubricant. (Zoom View of Directions for Use).

Ingredients

YES[®] OB: Helianthus annuus (Sunflower) seed oil*, Butyrospermum parkii (Shea butter)*, Prunus dulcis (Sweet almond) oil*, Cera alba (Bees wax)*, Theobroma cacao (Cocoa) seed butter*, Tocopherol (Vitamin E).

* Organically grown ingredients

Directions for use

YES[®] OB assists your lovemaking by enabling penetration, increasing pleasurable glide and sensation. Warm YES[®] OB in your hands to ensure a smooth velvety quality. Apply where desired, externally and internally, to self and partner.

Apply a layer of YES[®] OB with YES[®] WB on top for a new dimension in lasting lubrication.

Replace cap when not in use. Store in a cool dry place, not in direct sunlight.

Every care has been taken to ensure the safety of this product.

Caution: This device is not a contraceptive or a spermicide.

Warning: If irritation or discomfort occurs, discontinue use and see a doctor.

Pleasure Tip: Double Glide apply a layer of YES[®] OB with YES[®] WB on top for a new dimension in lasting lubrication

Indications for use:

A personal lubricant, for vaginal and penile application, intended to moisturise and lubricate, to enhance the ease and comfort of intimate sexual activity and supplement the body's natural lubrication.

YES OB is NOT compatible with latex, polyisoprene or polyurethane condoms

Instructions For Use - YES[®] Water-based Personal Lubricant. (Page 1).

Final Draft Yes WB IFU - (English YWB72C) Yes
WB72C_IFU_EN V1 Final Draft.pdf

1

YES[®] WB water based personal

Lubricant Description

- Alleviates vaginal dryness
- Natural plant-based intimate moisturiser and lubricant
- A soft, clear bio-adhesive gel which adheres to the vaginal walls to lubricate and protect the tissues
- Lubricates vaginal and penile tissues
- Compatible with latex, polyurethane and polyisoprene condoms
- pH balanced to match the typical vaginal environment
- Guaranteed purity through its certified organic status
- Reassuringly realistic feel
- YES WB is not made with glycerin or petrochemicals or parabens
- Can be used freely and frequently
- No known side effects
- Neither a spermicide nor a contraceptive
- Certified Organic by the Soil Association (UK)

Description: YES[®] WB in applicators

- The discreet & convenient way to deliver lubrication & hydration in the right amount to the right place
- YES[®] WB in applicators is designed to be used before love making or at any time to easily allow the moisture to be distributed throughout the vagina
- Pre-filled for single use

Ingredients

Aqua (Water), Aloe barbadensis (Aloe vera) leaf juice powder*, Unum usitissimum (Flax) seed extract*, Cyamopsis tetragonolobus (Guar Gum)*, Ceratonia siliqua (Locust Bean Gum)*, Xanthan gum, Sodium chloride, Potassium sorbate, Citric acid, Phenoxethanol.

* Organically grown ingredients
Internationally Patented

Directions for use

YES[®] WB assists your love-making by: enabling penetration, easing vaginal and penile dryness, increasing pleasurable glide and sensation, and promoting the day-to-day comfort of intimate tissues. May be applied externally and internally, to self and partner. For discreet use, may be applied in advance of intercourse. Use generously as required (make sure you use enough). Do re-apply, as YES[®] can be used freely and frequently according to the body's own needs.

Replace cap when not in use. Store in a cool dry place, not in direct sunlight.

Every care has been taken to ensure the safety of this product. Stop use if any irritation occurs.

Directions for use: YES[®] WB in applicators

Hold the applicator at the wide end, shake the contents down to the narrow end, before insertion.

Remove the cap, by twisting and pulling it off.

To apply, insert the narrow end of the applicator only into the vagina. You can lie down, stand or sit to insert the applicator - whichever position is most comfortable.

Once inserted squeeze the wide end, several times, to ensure the contents are released.



WB72C_IFU_EN V1

© Yes Synergy 2016

Instructions For Use - YES[®] Water-based Personal Lubricant. (Page 2).

2

Continue to squeeze the applicator, to extract it and discard. Both cap and applicator are made from recyclable materials, please recycle where possible.

Dosage, to enhance pleasure and ease in love-making: A 5ml applicator is typically sufficient, but more may be used if required.

Dosage, for the alleviation of discomfort: A 5ml applicator, used every 2-3 days, is typically sufficient to maintain comfort.

Indications for use:

A personal lubricant, for vaginal and penile application, intended to moisturise and lubricate, to enhance the ease and comfort of intimate sexual activity and supplement the body's natural lubrication.

YES WB is compatible with natural rubber latex, polyurethane or polyisoprene condoms.

Caution: This device is not a contraceptive or a spermicide.

Warning: If irritation or discomfort occurs, discontinue use and see a doctor.

Why Certified Organic?

When you buy something that is certified organic, not only are you making the best choice for your own well being, your purchase is also supporting a system that respects human health, animals, wildlife and the environment.

Certified organic products meet stringent standards and organic certification is your assurance that our ingredients and products have been grown and processed according to strict procedures. Production, processing, distribution and sales are monitored to maintain the finest organic and ecological integrity.

Packaging and Recycling

YES[®] aims to minimise the environmental impacts of all our packaging. So please do your part. All our bottles are MDPE. Polyethylene (MDPE) is the most often accepted plastic by recycling centres. The cartons, boxes and package inserts can all be recycled.

100% Guarantee: YES[®] products are 100% satisfaction guaranteed. Please contact us by phone or email if you have any concerns or questions.

Certified Organic by: The Soil Association, Bristol, UK.
Approved by: The Vegetarian Society

100% Guarantee: YES[®] products are 100% satisfaction guaranteed. Please contact us by phone or email if you have any concerns or questions.

Certified Organic by: The Soil Association, Bristol, UK.
Approved by: The Vegetarian Society

Manufactured in Great Britain for

Biotech Lubricants Ltd.
Trademark House, Ramshill
Petersfield, Hampshire, GU31 4AT, UK

Contact us

USA/Canada Toll Free: 1-888-777-0125
UK Free Phone: 0-800-978-8525
All other countries: +44 845 094 1141
Website: www.yesyesyes.org
Email: hello@yesyesyes.org



WB72C_IU_EN V1

© Yes Synergy 2016

Instructions For Use - YES® Water-based Personal Lubricant (Zoom View of Directions for Use).

Directions for use

YES® WB assists your love-making by: enabling penetration, easing vaginal and penile dryness, increasing pleasurable glide and sensation, and promoting the day-to-day comfort of intimate tissues. May be applied externally and internally, to self and partner. For discreet use, may be applied in advance of intercourse. Use generously as required (make sure you use enough). Do re-apply, as YES® can be used freely and frequently according to the body's own needs.

Replace cap when not in use. Store in a cool dry place, not in direct sunlight.

Every care has been taken to ensure the safety of this product. Stop use if any irritation occurs.

Directions for use: YES® WB in applicators

Hold the applicator at the wide end, shake the contents down to the narrow end, before insertion.

Remove the cap, by twisting and pulling it off.

To apply, insert the narrow end of the applicator only into the vagina. You can lie down, stand or sit to insert the applicator - whichever position is most comfortable.

Once inserted squeeze the wide end, several times, to ensure the contents are released.



WB72C_IFU_EN V1

© Yes Syzygy 2016

2

Continue to squeeze the applicator, to extract it and discard. Both cap and applicator are made from recyclable materials, please recycle where possible.

Dosage, to enhance pleasure and ease in love-making: A 5ml applicator is typically sufficient, but more may be used if required.

Dosage, for the alleviation of discomfort: A 5ml applicator, used every 2–3 days, is typically sufficient to maintain comfort.

Indications for use:

A personal lubricant, for vaginal and penile application, intended to moisturise and lubricate, to enhance the ease and comfort of intimate sexual activity and supplement the body's natural lubrication.

YES WB is compatible with natural rubber latex, polyurethane or polyisoprene condoms.

Caution: This device is not a contraceptive or a spermicide.

Warning: If irritation or discomfort occurs, discontinue use and see a doctor.

Instructions For Use - YES[®] Vaginal Moisturizer (Page 1).

Please read this leaflet carefully before use

YES. VM

YES VM water based organic Vaginal Moisturising gel uses a patented technology to provide natural, long-lasting moisture to dry vaginal mucosa

YES VM is available in 100ml tubes and packs of 6 pre-filled applicators

- When menopausal oestrogen depletion causes itching, burning and irritation of the dry vaginal tissues, YES VM gives effective, fast and long-lasting relief, and restores intimate comfort
- YES VM uses bio-adhesive plant polymers which adhere to the vaginal walls, and provide prolonged hydration for up to 3 days
- Case studies show that YES VM is fast-acting and long-lasting while replenishing intimate moisture safely and naturally

www.yesyesyes.com

YES VM IFU Final Draft

Provides symptomatic relief from:

- Vaginal dryness
- Vaginal Atrophy
- Itching
- Irritation, burning and soreness
- Dyspareunia

Temporary vaginal dryness can have various origins: after childbirth, when breastfeeding, and when taking oral contraceptives. Certain anti-depressants and anti-histamines can cause intimate dryness, as can extreme stress.

Caution: This device is not a contraceptive or a spermicide.

Warning: If irritation or discomfort occurs, discontinue use and see a doctor.

Ingredients

Water, Flax extract*, Aloe vera*, Locust Bean Gum*, Guar Gum*, Sodium Chloride, Xanthan Gum, Potassium sorbate, Citric Acid, Phenoxyethanol.

* Organically grown ingredients

95% organic

Protected by International Patents

- A soft, clear bio-adhesive gel
- **Discreet** no smell, taste, colour, stickiness or fallout. Close to the texture and feel of a woman's own lubrication
- **pH matched** to restore and stabilise the protective acidity of the intimate environment, supporting vaginal health
- **Hormone-free**
- **Free From.** YES Products are not made with known mucosal irritants such as glycerine, or petroleum products, parabens (hormone mimics) and other concerning chemicals

- **Gentle and natural**, for even the most sensitive conditions
- Guaranteed purity through its certified organic status
- Compatible with latex, polyurethane & polyisoprene condoms
- **Trusted** by Health Care Professionals and women to bring soothing, safe and welcome relief to the debilitating symptoms of menopausal dryness
- A non-hormonal natural alternative to chemical intimate moisturisers



Manufactured in Great Britain for

Biotech Lubricants Ltd, Trademark House, Ramshill, Petersfield, Hampshire. GU31 4AT, UK

YES VM is the registered trademark of The Yes Yes Company Ltd

24/7 telephone order lines

UK Free Phone: 0-800-978-8525

USA/Canada Toll Free: 1-888-777-0125

All other countries: +44 8456 44 88 13

Certified Organic by: The Soil Association, Bristol, UK

Approved by: The Vegetarian Society

100% Guarantee: Yes products are 100% satisfaction guaranteed, please contact us by phone or email if you have any concerns or questions.

For more info, call or visit:

Careline: 08456 44 88 13

Email: hello@yesyesyes.com

www.yesyesyes.com



Instructions For Use - YES[®] Vaginal Moisturizer (Page 2).

YES VM in Applicators

The discreet and convenient way to deliver lubrication and moisture in the right amount to the source of discomfort

Directions for use

1 Shake down the applicator



2 Twist off the top



The applicator can be inserted from three different positions, according to personal ease and preference:

How to insert the applicator when sitting



How to insert the applicator when standing



How to insert the applicator when lying



When inserted, squeeze the end of the applicator several times to release product high into the vagina



When emptied, squeeze the end of the applicator to withdraw it safely



Please dispose of the applicator tube and top by recycling



Frequency of use

A 5ml applicator used every 2-3 days, is typically sufficient to maintain a moist, comfortable vagina.

Provides intimate moisture for up to three days in typical cases of vaginal atrophy

Cases of severe dryness will benefit from more frequent use (1 applicator every 1-2 days) initially until improvement is gained.

If using to alleviate painful sex, apply as required before intercourse and to ensure comfort afterwards.

Iso-tonic: the iso-tonic nature of YES VM has been carefully matched to human tissues.

Why is this balance important? Products which are hyper-tonic (often containing chemicals such as glycerine & glycols) can cause irritation to intimate tissues. By being iso-tonic*, YES VM protects against such irritation.

*for more information, see our website.

When cancer treatment (surgery or chemotherapy) has resulted in vaginal dryness, YES VM is safe for hormone sensitive conditions, and successfully moisturises delicate or traumatised intimate tissues.

© Yes Syzygy 2016

YES VM_JRU_V1

YES VM is also suitable for use with dilators, whether or not these are part of a cancer recovery programme.

Indications for use:



A personal lubricant, for vaginal and penile application, intended to moisturise and lubricate, to enhance the ease and comfort of intimate sexual activity and supplement the body's natural lubrication.

YES VM is compatible with natural rubber latex, polyurethane or polyisoprene condoms.












Award-winning YES provides scientifically advanced, certified organic, lubricants and moisturisers for intimate use and the promotion of sexual health. Pioneering the use of natural, pure ingredients for intimate use, YES products are deceptively discreet in presentation yet based on complex science and provide essential lubrication and moisturisation to meet a variety of usage needs. Discover all the products in our range at yesyesyes.com

Instructions For Use - YES® Water-based Personal Lubricant in Applicators (Page 1).

| | | | |
|---|--|--|--|
| <p>Please read this leaflet carefully before use</p>  <p>Yes® water-based organic intimate lubricant and moisturiser in applicators uses a patented technology to provide natural, long-lasting moisture to dry vaginal mucosa</p> | <p>Available on prescription in the UK from 1st March 2014</p> <p>Provides symptomatic relief from:</p> <ul style="list-style-type: none"> • Vaginal Atrophy • Intimate dryness • Itching • Irritation, burning and soreness • Dyspareunia <p>A 5ml applicator used every 2-3 days, is typically sufficient to maintain a moist, comfortable vagina</p> | <ul style="list-style-type: none"> • A soft, clear bio-adhesive gel • Discreet no smell, taste, colour, stickiness or fallout. Close to the texture and feel of a woman's own lubrication • pH matched to the protective acidity of the intimate environment, supporting vaginal health • Hormone-free • Free From. YES Products are not made with known mucosal irritants such as glycerine, or petroleum products, parabens (hormone mimics) and other concerning chemicals | <p>Manufactured In Great Britain for Biotech Lubricants Ltd., Trademark House, Ramshill, Petersfield, Hampshire. GU31 4AT, UK</p> <p>Yes® is the registered trademark of The Yes Yes Company Ltd</p> <p>Protected by International Patents</p> <p>24/7 telephone order lines</p> <p>UK Free Phone: 0-800-978-8525 USA/Canada Toll Free: 1-888-777-0125 All other countries: +44 845 094 1141</p> |
| <ul style="list-style-type: none"> • The discreet and convenient way to deliver lubrication and moisture in the right amount to the source of discomfort • Yes® uses bio-adhesive plant polymers which adhere to the vaginal walls, and provide prolonged hydration for up to 3 days • Case studies show that Yes® water-based is fast-acting and long-lasting while replenishing intimate moisture safely and naturally <p>www.yesyesyes.org</p> | <p>When menopausal oestrogen depletion causes itching, burning and irritation of the dry vaginal tissues, Yes® water-based in applicators gives effective, fast and long-lasting relief, and restores intimate comfort</p> <p>Temporary vaginal dryness can have various origins: after childbirth, when breastfeeding, and when taking oral contraceptives. Certain anti-depressants and anti-histamines can cause intimate dryness, as can extreme stress.</p> | <ul style="list-style-type: none"> • Gentle and natural, for even the most sensitive conditions • Guaranteed purity through its certified organic status • Yes water-based is compatible with latex, polyurethane and polyisoprene condoms • Trusted by Health Care Professionals and women to bring soothing, safe and welcome relief to the debilitating symptoms of menopausal dryness • Pre-filled for single use • A non-hormonal natural alternative to chemical intimate moisturisers | <p>Certified Organic by: The Soil Association, Bristol, UK</p> <p>Approved by: The Vegetarian Society</p> <p>100% Guarantee: Yes products are 100% satisfaction guaranteed, please contact us by phone or email if you have any concerns or questions.</p> <p>For more info, call or visit: Careline: 08456 44 88 13 Email: hello@yesyesyes.org</p> <p>www.yesyesyes.org</p>  |

Instructions For Use - YES® Water-based Personal Lubricant in Applicators (Page 2).

| | | | |
|--|---|---|---|
| <p>Directions for use</p> | | | |
| <p>1</p> <p>Shake down the applicator</p>  | <p>2</p> <p>Twist off the top</p>  | <p>3</p> <p>The applicator can be inserted from three different positions, according to personal ease and preference:</p> <p>How to insert the applicator when sitting</p>  <p>How to insert the applicator when standing</p>  | <p>4</p> <p>When inserted, squeeze the end of the applicator several times to release product high into the vagina</p>  |
| <p>5</p> <p>When emptied, squeeze the end of the applicator to withdraw it safely</p>  | <p>6</p> <p>Please dispose of the applicator tube and top by recycling</p>  | <p>Frequency of use</p> <p>One 5ml applicator dose intravaginally every 2-3 days.</p> <p>Provides intimate moisture for up to three days in typical cases of vaginal atrophy</p> <p>Cases of severe dryness will benefit from more frequent use (1 applicator every 1-2 days) initially until improvement is gained.</p> <p>If using to alleviate painful sex, apply as required before intercourse and to ensure comfort afterwards.</p>  <p>© 1995 Syngene 2016 W872C_N4L_APPF_RL14</p> | <p>Ingredients 96% organic</p> <p>Water; Aloe vera*, Flax extract*, Guar Gum*, Locust Bean Gum*, Xanthan Gum, Citric acid, Potassium sorbate, Sodium chloride, Phenoxyethanol.</p> <p>* Organically grown ingredients</p> <p>Indications for use:</p> <p>A personal lubricant, for vaginal and penile application, intended to moisturise and lubricate, to enhance the ease and comfort of intimate sexual activity and supplement the body's natural lubrication.</p> <p>YES WB is compatible with natural rubber latex, polyurethane or polyisoprene condoms.</p>  <p>When cancer treatment (surgery or chemotherapy) has resulted in vaginal dryness, Yes® water-based is safe for hormone sensitive conditions, and successfully moisturises delicate or traumatised intimate tissues. Yes® is also suitable for use with dilators, whether or not these are part of a cancer recovery programme.</p> <div style="border: 1px solid black; padding: 5px;"> <p>Caution</p> <p>Do not use if applicator tab is damaged or broken</p> <p>This device is not a contraceptive or a spermicide.</p> <p>Warning: If irritation or discomfort occurs, discontinue use and see a doctor.</p> <p>Observe the best before date</p> </div> <p>Award-winning Yes® provides scientifically advanced, certified organic, lubricants and moisturisers for intimate use and the promotion of sexual health.</p> <p>Pioneering the use of natural, pure ingredients for intimate use, Yes products are deceptively discreet in presentation yet based on complex science and provide essential lubrication and moisturisation to meet a variety of usage needs. Discover all the products in our range at:</p> <p>www.yesyesyes.org</p> |

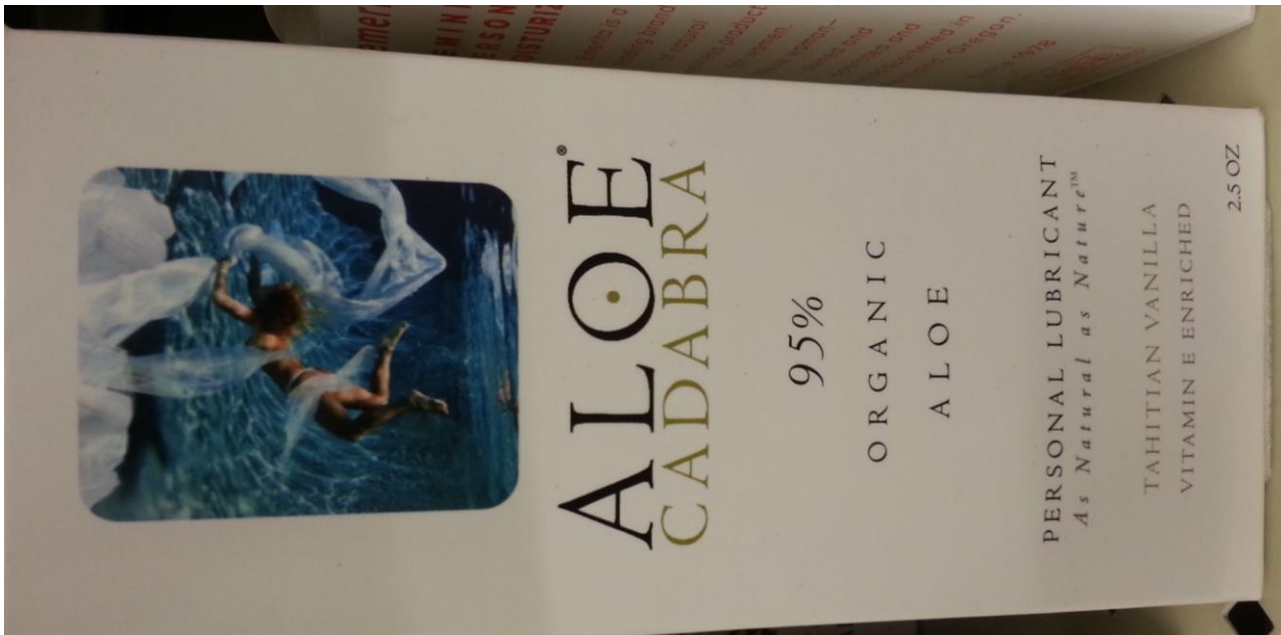
Section 13: Proposed Labeling / Predicate Device(s) Labels**Aloe Cadabra Personal Lubricants**

| Description | Size | Container Type | Model No. |
|--|-------------|-----------------------|------------------|
| Aloe Cadabra Personal Lubricant – Tahitian Vanilla | 2.5 oz. | Carton | Unknown |
| Aloe Cadabra Personal Lubricant – Tahitian Vanilla | 2.5 oz. | Bottle | Unknown |
| Aloe Cadabra Personal Lubricants | n/a | Website | n/a |

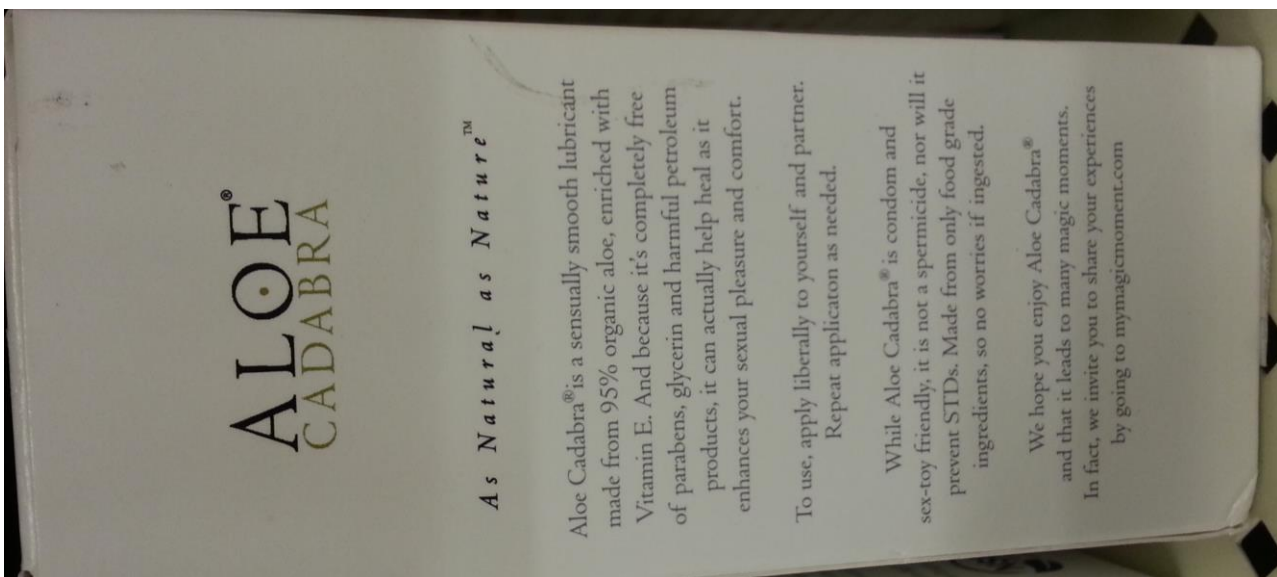
LifeStyles Luxe Personal Lubricants

| Description | Size | Container Type | Model No. |
|--|-------------|-----------------------|------------------|
| LifeStyles Luxe Premium Personal Lubricant | 3.5 oz. | Carton | Unknown |
| LifeStyles Luxe Premium Personal Lubricant | 3.5 oz. | Bottle | Unknown |
| LifeStyles Personal Lubricants | n/a | Website | n/a |

Aloe Cadabra Carton (front)



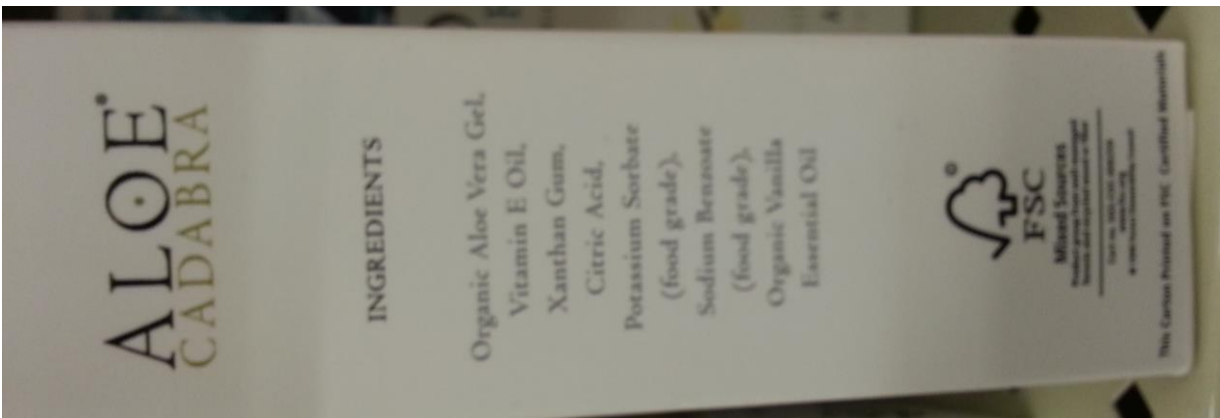
Aloe Cadabra Carton (back)



Aloe Cadabra Carton (side 1)



Aloe Cadabra Carton (side 2)



Aloe Cadabra Carton (top)



Aloe Cadabra Carton (bottom)



Aloe Cadabra Bottle (front)



Aloe Cadabra Bottle (back)



Aloe Cadabra Bottle (top)



Aloe Cadabra Website



 The first premium personal lubricant certified to organic standards


[what](#) [why](#) [who](#) [FAQ's](#) [my magic moments](#) [shop](#) [connect](#)

[Store Locator](#)  [Ordering from Canada?](#)  [View Cart](#)

The only personal lubricant made from 95% certified organic Aloe Vera and enriched with a special blend of natural ingredients. Nourishes while it moisturizes for a smooth, pleasurable glide. No parabens or harsh chemicals • pH balanced • edible • absorbs cleanly with no sticky mess. Please select desired quantities of each product then click, "Add To Cart" button below.

NEW

Peppermint Tingle Flavor. Mild Sensation!



Price: \$12.95 Qty 0

Natural Aloe Unscented



Price: \$9.95 Qty 0

YOUR PERFECT MATCH

pH balanced, low osmolality and certified organic for your health and well being

Feel the Difference

 The first personal lubricant made to new organic standards.

FREE SHIPPING
on orders of 3 bottles or more

Tahitian Vanilla Flavor



Price: \$9.95 Qty 0

Piña Colada Flavor



Price: \$9.95 Qty 0

French Lavender Scent

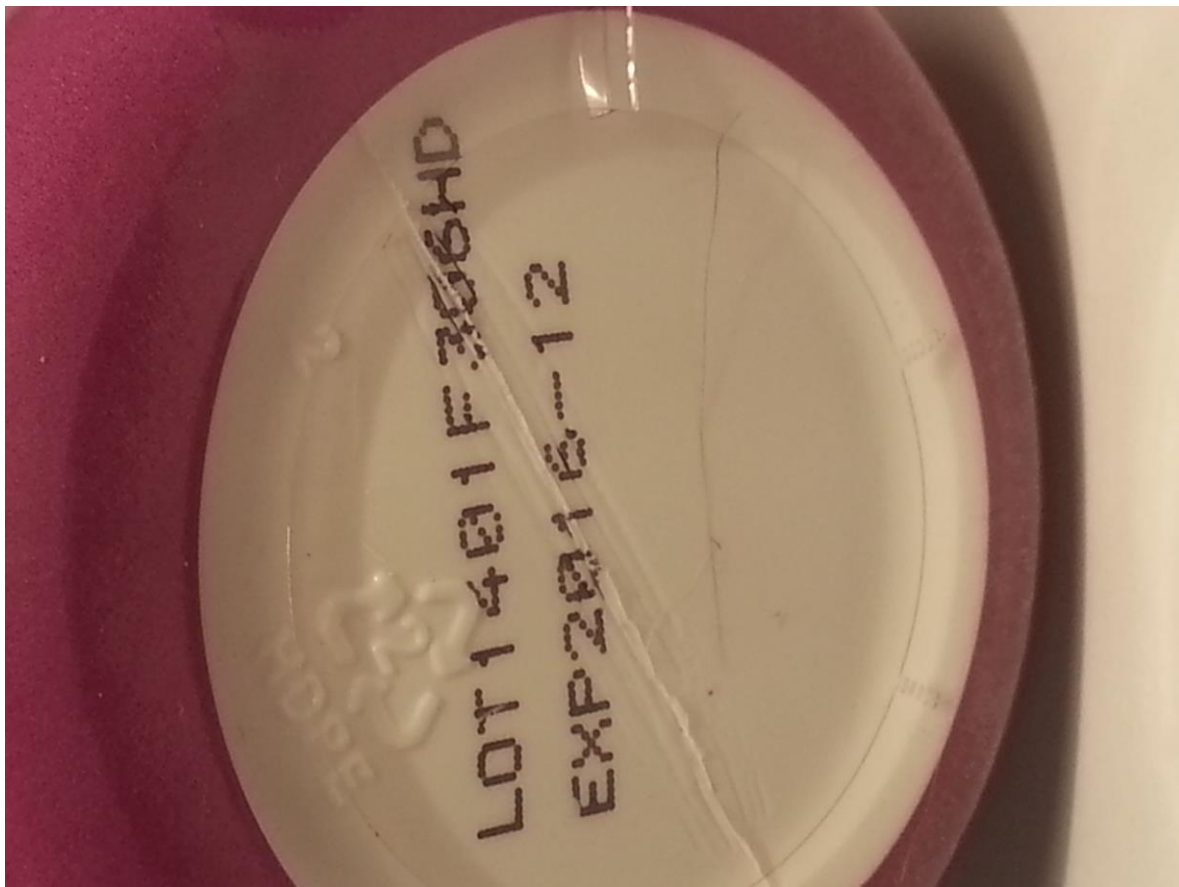


Price: \$9.95 Qty 0

LifeStyles Luxe Bottle (front)



LifeStyles Luxe Bottle (bottom)




Lifestyles Luxe Bottle (back)



Lifestyle Luxe – Carton/box



(Lifestyles Luxe is not sold in a carton/box/outer container.)





Lifestyles® Luxe Premium Personal Lubricant – Website




Home // Products // LifeStyles Lubricants // LifeStyles Luxe™ Premium Personal Lubricant

PRODUCTS • CHANGE THE SCORE • COME PLAY • HEALTH AND WELLNESS • FOR HEALTH EDUCATORS • ABOUT



LifeStyles Luxe™ Premium Personal Lubricant

f Recommend < 21

Long-lasting silicone-based formula provides superior comfort

- Proven to last at least 3 times longer than regular water-based lubricants*
- Enhances your opportunity for adventurous intimacy as it works in the bath, hot tub, shower or pool
- Non-sticky and fragrance free
- Doesn't dry out
- Easy to wash off with regular soap after use

* According to *In Vitro* study, April 2010

OUR PRODUCTS

- LifeStyles® Condoms
- LifeStyles Lubricants
- LifeStyles Personal Massager & Vibrating Devices
- Quality Pledge
- Where to Buy

SEXTOID

Both sexes prefer the Cowgirl position over Reverse Cowgirl... by a wide margin.

HEALTH & WELLNESS

Section 14: Sterilization and Shelf Life

Common Name: Personal Lubricant
Product Code: NUC
Device Class: II
Regulation Number: 884.5300

YES[®] Oil-based personal lubricant, YES[®] Water-based personal lubricant, and YES[®] Vaginal Moisturizer are non-sterile devices with a shelf-life of two (2) years.

Objective:

To evaluate real-time product samples to demonstrate the devices are able to sustain a 2-year shelf life.

Current Stability Testing

Shelf-life testing has been conducted on YES[®] Oil-based Personal Lubricant, YES[®] Water-based Personal Lubricant and YES[®] Vaginal Moisturizer in order to evaluate real-time product samples to demonstrate the device conforms to a 2-year shelf life. This testing was conducted (b)(4) [REDACTED] [REDACTED] The legal manufacturer however, intends to market the device under the brand name YES[®]. This is only a brand-name change and there are no other differences on the test protocol and reports unless stated within Section 14 of this submission.

(b)(4) [REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]

[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]
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[REDACTED]
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[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]

[REDACTED]
[REDACTED]

(b)(4)



Section 16: Software

This section does not apply. There is no software associated with any of these proposed medical devices.

End of Section 16

Section 17: Electromagnetic Compatibility and Electrical Safety

This section does not apply. These devices do not include any electrical components and have no integral power source.

End of Section 17

Section 19: Performance Testing - Animal

21 CFR Part 807.92(b)(1)

Animal performance testing for this device is not required.

{

End of Section 19

Section 20: Performance Testing - Clinical

21 CFR Part 807.92(b) (2)

Clinical studies are not required for this device; this device is a Class II, non-significant risk device.

End of Section 20

Section 21: Kit Certification

This section does not apply. This 510(k) application does not contain kits comprised of two or more separate types of devices packaged together for the convenience of the user per <http://www.fda.gov/medicaldevices/deviceregulationandguidance/howtomarketyourdevice/premarket submissions/premarketnotification510k/ucm134578.htm#kits>

End of Section 21

Section 1: MDUFA User Fee Sheet.

Content unchanged from original submission.

End of Section 1

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Windows is either a registered trademark or a trademark of Microsoft Corporation in the United States and/or other countries. Mac is a trademark of Apple Inc., registered in the United States and other countries. Linux is the registered trademark of Linus Torvalds in the U.S. and other countries.

If you have any questions, I can be contacted at either +44 115 704 3364, or by email at kcornelius@maetrics.com.

Kind regards,

K. Cornelius . May 9, 2017 .

Karen Cornelius.

Senior Associate,
Maetrics,
BioCity Nottingham,
Pennyfoot Street,
Nottingham.
NG1 1GF.
United Kingdom.

End of Cover letter

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

Indications for Use

510(k) Number (if known)
K162569

Device Name

YES® oil-based Personal Lubricant, YES® water-based Personal Lubricant, YES® Vaginal Moisturizer

Indications for Use (Describe)

Device Name: YES® oil-based Personal Lubricant

Indications for Use:

A personal lubricant, for vaginal and penile application, intended to moisturize and lubricate, to enhance the ease and comfort of intimate sexual activity and supplement the body's natural lubrication. YES® oil-based Personal Lubricant is not compatible with natural rubber latex, polyurethane or polyisoprene condoms.

Device Name: YES® water-based Personal Lubricant

Indications for Use:

A personal lubricant, for vaginal and penile application, intended to moisturize and lubricate, to enhance the ease and comfort of intimate sexual activity and supplement the body's natural lubrication. YES® water-based Personal Lubricant is compatible with natural rubber latex and polyisoprene condoms. This product is not compatible with polyurethane condoms.

Device Name: YES® Vaginal Moisturizer

Indications for Use:

A personal lubricant, for vaginal and penile application, intended to moisturize and lubricate, to enhance the ease and comfort of intimate sexual activity and supplement the body's natural lubrication. YES® Vaginal Moisturizer is compatible with natural rubber latex and polyisoprene condoms. This product is not compatible with polyurethane condoms.

Type of Use (Select one or both, as applicable)

Prescription Use (Part 21 CFR 801 Subpart D)

Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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Section 5: 510(k) Summary

In accordance with 21 CFR 807.87(h) and 21 CFR 807.92 the 510(k) Summary for YES[®] oil-based Personal Lubricant, YES[®] water-based Personal Lubricant, and YES[®] Vaginal Moisturizer is provided below:

Device Common Name: Personal Lubricant
Device Proprietary Names: YES[®] oil-based Personal Lubricant
YES[®] water-based Personal Lubricant
YES[®] Vaginal Moisturizer
Sponsor: Biotech Lubricants Limited,
Ramshill,
Petersfield,
GU31 4AT,
United Kingdom
Official Correspondent: Karen Cornelius, Maetrics
BioCity Nottingham.
Pennyfoot Street,
Nottingham.
NG1 1GF.
United Kingdom.
Phone: +44 115 921 6200
Email: kcornelius@maetrics.com
Date Prepared: May 8, 2016
Classification Regulation: 884.5300
Classification Name: Condom
Panel: Obstetrics/Gynecology
Product Code: NUC
Predicate Device: K124044 Aloe Cadabra Personal Lubricant (Seven Oaks Ranch Inc)
K122477 Lifestyles Luxe Premium Personal Lubricant (Ansell Healthcare Product LLC)

Indications for Use:

YES[®] oil-based Personal Lubricant: A personal lubricant, for vaginal and penile application, intended to moisturize and lubricate, to enhance the ease and comfort of intimate sexual activity and supplement the body's natural lubrication. YES[®] oil-based Personal Lubricant is not compatible with natural rubber latex, polyurethane or polyisoprene condoms.

YES[®] water-based Personal Lubricant: A personal lubricant, for vaginal and penile application, intended to moisturize and lubricate, to enhance the ease and comfort of intimate sexual activity and supplement the body's natural lubrication. YES[®] water-based Personal Lubricant is compatible with natural rubber latex and polyisoprene condoms. This product is not compatible with polyurethane condoms.

YES[®] Vaginal Moisturizer: A personal lubricant, for vaginal and penile application, intended to moisturize and lubricate, to enhance the ease and comfort of intimate sexual activity and supplement the body's natural lubrication. YES[®] water-based Personal Lubricant is compatible with natural rubber latex, and polyisoprene condoms. This product is not compatible with polyurethane condoms.

YES® oil-based Personal Lubricant, YES® water-based Personal Lubricant and YES® Vaginal Moisturizer and the predicate devices have the same Indications For Use Statements.

Substantial Equivalence

Device Comparison Tables

| YES® water-based Personal Lubricant | | |
|--|--|--|
| 510(k) # | | K124044 |
| Device name | YES® water-based Personal Lubricant | Aloe Cadabra Personal lubricant |
| Manufacturer | Bio-tech Lubricants Ltd | Seven Oaks Ranch, Inc. |
| Classification | 884.5300 | 884.5300 |
| Product code | NUC | NUC |
| Description | Personal Lubricant | Personal Lubricant |
| Indications for use | YES® water-based Personal Lubricant is a personal lubricant, for vaginal and penile application, intended to moisturize and lubricate, to enhance the ease and comfort of intimate sexual activity and supplement the body's natural lubrication. YES® water-based Personal Lubricant is compatible with NRL and Polyisoprene condoms. This product is not compatible with polyurethane condoms. | Aloe Cadabra lubricants, are personal lubricants for penile and/or vaginal application, intended to moisturize and lubricate, to enhance the ease and comfort of intimate sexual activity and supplement the body's natural lubrication. This product is compatible with NRL and Polyisoprene condoms. This product is not compatible with polyurethane condoms. |
| Over-the-counter use | YES | YES |
| Biocompatible | YES | YES |
| Non-sterile | YES | YES |
| Packaging Materials | Plastic / PE | Plastic / PE |
| Contains plant extracts | YES | YES |
| Contains preservatives | YES | YES |

| YES[®] oil-based Personal Lubricant | | |
|---|--|---|
| 510(k) # | | K122477 |
| | YES [®] oil-based personal lubricant | LifeStyles Luxe Premium Personal Lubricant |
| Manufacturer | Bio-tech Lubricants Ltd | Ansell Healthcare Products, LLC |
| Classification | 884.5300 | 884.5300 |
| Product code | NUC | NUC |
| Description | Personal Lubricant | Personal Lubricant |
| Indications for use | YES [®] oil-based personal lubricant is a personal lubricant, for vaginal and penile application, intended to moisturize and lubricate, to enhance the ease and comfort of intimate sexual activity and supplement the body's natural lubrication. This product is not compatible with NRL, polyurethane or Polyisoprene condoms. | LifeStyles Luxe Premium Personal Lubricant Is a personal lubricant, for penile and/or vaginal application, intended to moisturize and lubricate, to enhance the ease and comfort of intimate sexual activity and supplement the body's natural lubrication. This product is compatible with natural rubber latex, polyurethane, and Polyisoprene condoms. |
| Over-the-counter use | YES | YES |
| Biocompatible | YES | YES |
| Non-sterile | YES | YES |
| Packaging Materials | Plastic / PE | Plastic / PE |
| Contains plant extracts | YES | No |
| Contains preservatives | No - Product cannot support microbial growth | No - Product cannot support microbial growth |

| YES® Vaginal Moisturizer | | |
|---------------------------------|--|--|
| 510(k) # | | K124044 |
| | YES® VM (Vaginal Moisturizer) | Aloe Cadabra Personal lubricant |
| Manufacturer | Bio-tech Lubricants Ltd | Seven Oaks Ranch, Inc. |
| Classification | 884.5300 | 884.5300 |
| Product code | NUC | NUC |
| Description | Personal Lubricant | Personal Lubricant |
| Indications for use | YES® VM (Vaginal Moisturizer) is a personal lubricant, for vaginal and penile application, intended to moisturize and lubricate, to enhance the ease and comfort of intimate sexual activity and supplement the body's natural lubrication. YES® VM is compatible with NRL and Polyisoprene condoms. This product is not compatible with polyurethane condoms. | Aloe cadabra lubricants, are personal lubricants for penile and/or vaginal application, intended to moisturize and lubricate, to enhance the ease and comfort of intimate sexual activity and supplement the body's natural lubrication. This product is compatible with NRL and Polyisoprene condoms. This product is not compatible with polyurethane condoms. |
| Over-the-counter use | YES | YES |
| Biocompatible | YES | YES |
| Non-sterile | YES | YES |
| Packaging Materials | Plastic / PE, pre-filled applicators | Plastic / PE |
| Contains preservatives | YES | YES |

Device Descriptions:

YES® oil-based Personal Lubricant: A non-sterile, non-condom compatible oil-based personal lubricant formulated to supplement the body's natural lubricating fluids when vaginal dryness causes discomfort. It is neither a contraceptive nor a spermicide. The formulation is a cream coloured non-staining, thick paste that melts at body temperature.

YES® water-based Personal Lubricant: A non-sterile condom compatible high viscosity water-based personal lubricant formulated to supplement the body's natural lubricating fluids when vaginal dryness causes discomfort. It is neither a contraceptive nor a spermicide. The formulation is a lightly opaque, non-staining, non-greasy natural liquid gel.

YES® Vaginal Moisturizer: A non-sterile condom compatible personal lubricant formulated to supplement the body's own natural lubricating fluids to provide personal moisturization when vaginal dryness causes discomfort. It is neither a contraceptive nor a spermicide. The formulation is a lightly opaque, non-staining, non-greasy natural liquid gel.

Technological Characteristics - Formulation:

YES® oil-based Personal Lubricant formula is proprietary. The product however, is an oil-based or oil containing lubricant comprised of naturally occurring ingredients. The plant based oils and butters in the proposed device are all GRAS (Generally Recognized as Safe by FDA). It has no exceptional technological characteristics and is similar to other lubricants containing natural ingredients which are currently on the U.S. market. It is also substantially equivalent to the predicate device which is formulated from natural ingredients which are all GRAS.

YES® water-based Personal Lubricant formula is proprietary. The product however, is a water-based gel consisting mainly of water and water-soluble ingredients. It has no exceptional technological characteristics and is similar to other lubricants currently on the U.S. market. It is substantially equivalent to the predicate device.

YES® Vaginal Moisturizer formula is proprietary. The product however, is a water-based gel consisting mainly of water and water-soluble ingredients. It has no exceptional technological characteristics and is similar to other lubricants currently on the U.S. market. It is substantially equivalent to the predicate device.

Technological Characteristics - Biocompatibility Testing:

Biocompatibility Testing was conducted on YES® oil-based Personal Lubricant, YES® water-based Personal Lubricant and YES® Vaginal Moisturizer for Cytotoxicity, Vaginal Irritation, Sensitization, and Acute Systemic Toxicity in accordance with the ISO 10993-5, 10993-10 and 10993-11 standards.

The results for all three devices show that all meet the acceptance requirements of each test and are all non-cytotoxic, non-irritating, non-sensitizing and non-systemically toxic. The predicate device also meets the requirements for biocompatibility testing.

Technological Characteristics - Condom Compatibility Testing:

YES® oil-based Personal Lubricant: Condom compatibility testing was performed on natural rubber latex and polyisoprene condoms as per ASTM D7661-10. Test results indicate that the device affects the mechanical or physical integrity of the natural rubber latex and polyisoprene condoms. Therefore, the device is not compatible with natural rubber latex or polyisoprene condoms. Additionally, the device is labeled “not compatible with natural rubber latex or polyisoprene condoms”. The predicate device has also been tested in an identical manner and is compatible with rubber latex and polyisoprene condoms. The difference is due to the characteristics of non-silicone oils used in YES® oil-based Personal Lubricant. The device has not been tested with polyurethane condoms and is labeled “not compatible with natural rubber latex, polyisoprene or polyurethane condoms”.

YES® Vaginal Moisturizer and YES® water-based Personal Lubricant: Condom compatibility testing was performed on natural rubber latex and polyisoprene condoms as per ASTM D7661-10, Results indicated that the devices are compatible with natural rubber latex and polyisoprene condoms. The devices are labeled “compatible with natural rubber latex or polyisoprene condoms” in an identical manner to the predicate device. Both devices are not tested with polyurethane condoms and are labeled “not compatible with polyurethane condoms”

Technological Characteristics - Shelf Life and Microbial Limits:

YES® oil-based Personal Lubricant, YES® water-based Personal Lubricant, and YES® Vaginal Moisturizer have a 9-month shelf life based on the results of a real time aging study in accordance with the International Council For Harmonisation (ICH) Guidelines – Q1A(R2) – Stability Testing of Drug

Substances and Products. For each device, the predicate shelf-life has also been determined by real and accelerated aging studies.

Microbial limits testing has been conducted on YES[®] oil-based Personal Lubricant, YES[®] water-based Personal Lubricant, and YES[®] Vaginal Moisturizer in accordance with the requirements of USP <61> and USP <62> and microbial quality has been indicated. Both predicate devices have acceptable microbial quality determined by microbial limits testing.

Clinical Testing:

No clinical testing was required to demonstrate substantial equivalence to the predicate devices.

Conclusion:

YES[®] oil-based Personal Lubricant, YES[®] water-based Personal Lubricant, and YES[®] Vaginal Moisturizer have the same intended use and similar technological characteristics as the predicate devices. Biocompatibility, Non-Clinical condom compatibility or shelf life testing has demonstrated that these devices raise no new issues of safety or effectiveness. Therefore, these lubricants are substantially equivalent to the predicate devices.

End of Section 5

Section 6: Truthful and Accurate Statement

[As Required by 21 CFR 807.87(k)]

I certify that, in my capacity as Managing Director of Bio-Tech Lubricants Ltd, I believe to the best of my knowledge, that all data and information submitted in the premarket notification are truthful and accurate and that no material fact has been omitted.



(Signature)

Sarah Brooks

(Typed Name)

May 08 2017

(Date)

Section 7: Class III Summary and Certification.

Content unchanged from original submission.

End of Section 7

Section 8: Financial Certification or Disclosure Statement.

Content unchanged from original submission.

End of Section 8

Section 9: Declarations of Conformity and Summary Reports.

Content unchanged from original submission.

End of Section 9

Section 10: Executive Summary

This is a Traditional, Bundled, 510(k) Submission of three (3) Proposed Devices.

Common Name: Personal Lubricant

Product Code: NUC

Device Class: II

Regulation Number: 884.5300

Proposed Devices:

| Proprietary Names | Description | Intended Use | Technology |
|---|---|--|---|
| YES [®] Water-based Personal Lubricant | A non-sterile, water-based personal lubricant, compatible with natural rubber latex and polyisoprene condoms. | Personal lubricants, for vaginal or penile application, intended to moisturize and lubricate, to enhance the ease and comfort of intimate sexual activity and supplement the body's natural lubrication. | Water-based, natural, plant thickeners not glycerin based. Slightly hypo-to iso osmotic |
| YES [®] oil-based Personal Lubricant | A non-sterile, non-condom compatible, oil-based personal lubricant. | | Oil-based, natural plant oils, butters & bees wax. |
| YES [®] Vaginal Moisturizer | A non-sterile, water-based personal lubricant, compatible with natural rubber latex and polyisoprene condoms. | | Water-based, natural, plant thickeners not glycerin based. Iso osmotic |

Technological Characteristics:

The three proposed devices are proprietary formulations; however, the products have no exceptional technological characteristics. YES[®] water-based Personal Lubricant and YES[®] Vaginal Moisturizer consist of water-soluble natural plant based ingredients and YES[®] oil-based Personal Lubricant consists of natural plant based oils, butters and bees wax. All ingredients in all three proposed devices are NF, USP, or GRAS food ingredients.

Indications for Use:

All three proposed devices have the same intended use; Personal lubricants, for vaginal and penile application, intended to moisturize and lubricate, to enhance the ease and comfort of intimate sexual activity and supplement the body's natural lubrication as their predicates.

Device Comparison Tables

| YES[®] water-based Personal Lubricant | | |
|---|--|--|
| 510(k) # | | K124044 |
| Device name | YES [®] water-based Personal Lubricant | Aloe Cadabra Personal lubricant |
| Manufacturer | Bio-tech Lubricants Ltd | Seven Oaks Ranch, Inc. |
| Classification | 884.5300 | 884.5300 |
| Product code | NUC | NUC |
| Description | Personal Lubricant | Personal Lubricant |
| Indications for use | YES [®] water-based Personal Lubricant is a personal lubricant, for vaginal and penile application, intended to moisturize and lubricate, to enhance the ease and comfort of intimate sexual activity and supplement the body's natural lubrication. YES [®] water-based Personal Lubricant is compatible with NRL and Polyisoprene condoms. This product is not compatible with polyurethane condoms. | Aloe Cadabra lubricants, are personal lubricants for penile and/or vaginal application, intended to moisturize and lubricate, to enhance the ease and comfort of intimate sexual activity and supplement the body's natural lubrication. This product is compatible with NRL and Polyisoprene condoms. This product is not compatible with polyurethane condoms. |
| Over-the-counter use | YES | YES |
| Biocompatible | YES | YES |
| Non-sterile | YES | YES |
| Packaging Materials | Plastic / PE | Plastic / PE |
| Contains plant extracts | YES | YES |
| Contains preservatives | YES | YES |

| YES[®] oil-based Personal Lubricant | | |
|---|--|---|
| 510(k) # | | K122477 |
| | YES [®] oil-based personal lubricant | LifeStyles Luxe Premium Personal Lubricant |
| Manufacturer | Bio-tech Lubricants Ltd | Ansell Healthcare Products, LLC |
| Classification | 884.5300 | 884.5300 |
| Product code | NUC | NUC |
| Description | Personal Lubricant | Personal Lubricant |
| Indications for use | YES [®] oil-based personal lubricant is a personal lubricant, for vaginal and penile application, intended to moisturize and lubricate, to enhance the ease and comfort of intimate sexual activity and supplement the body's natural lubrication. This product is not compatible with NRL, polyurethane or Polyisoprene condoms. | LifeStyles Luxe Premium Personal Lubricant Is a personal lubricant, for penile and/or vaginal application, intended to moisturize and lubricate, to enhance the ease and comfort of intimate sexual activity and supplement the body's natural lubrication. This product is compatible with natural rubber latex, polyurethane, and Polyisoprene condoms. |
| Over-the-counter use | YES | YES |
| Biocompatible | YES | YES |
| Non-sterile | YES | YES |
| Packaging Materials | Plastic / PE | Plastic / PE |
| Contains plant extracts | YES | No |
| Contains preservatives | No - Product cannot support microbial growth | No - Product cannot support microbial growth |

| YES® Vaginal Moisturizer | | |
|---------------------------------|--|--|
| 510(k) # | | K124044 |
| | YES® Vaginal Moisturizer (VM) | Aloe Cadabra Personal lubricant |
| Manufacturer | Bio-tech Lubricants Ltd | Seven Oaks Ranch, Inc. |
| Classification | 884.5300 | 884.5300 |
| Product code | NUC | NUC |
| Description | Personal Lubricant | Personal Lubricant |
| Indications for use | YES® Vaginal Moisturizer (VM) is a personal lubricant, for vaginal and penile application, intended to moisturize and lubricate, to enhance the ease and comfort of intimate sexual activity and supplement the body's natural lubrication. YES® VM is compatible with NRL and Polyisoprene condoms. This product is not compatible with polyurethane condoms. | Aloe cadabra lubricants, are personal lubricants for penile and/or vaginal application, intended to moisturize and lubricate, to enhance the ease and comfort of intimate sexual activity and supplement the body's natural lubrication. This product is compatible with NRL and Polyisoprene condoms. This product is not compatible with polyurethane condoms. |
| Over-the-counter use | YES | YES |
| Biocompatible | YES | YES |
| Non-sterile | YES | YES |
| Packaging Materials | Plastic / PE, pre-filled applicators | Plastic / PE |
| Contains preservatives | YES | YES |

Non-Clinical Performance Data

This table summarizes the results of the non-clinical performance data. Detailed results are included in Sections 14, 15, and 18 of this 510(k) submission.

The legal manufacturer originally intended to market all 3 devices (YES® water-based Personal Lubricant, YES® oil-based Personal Lubricant and YES® Vaginal Moisturizer) (b)(4) [redacted]. Detailed results included in Sections 14, 15 and 18 show the results of testing for (b)(4) [redacted] as submitted in (b)(4) [redacted] (b)(4) [redacted]

[redacted]
[redacted]
[redacted]
[redacted]

- YES® water-based Personal Lubricant is comparable to [redacted] (water-based Personal Lubricant).
- YES® oil-based Personal Lubricant is comparable to [redacted] (oil-based Personal Lubricant).
- YES® Vaginal Moisturizer is comparable to A [redacted] (Vaginal Moisturizer).

| | |
|-------------------------------------|---|
| Proposed Devices | Condom compatible (ASTM D7661, ASTM D3492, and ASTM D6324) |
| YES® water-based Personal Lubricant | YES with NRL and Polyisoprene condoms |
| YES® oil-based Personal Lubricant | No |
| YES® Vaginal Moisturizer | YES with NRL and Polyisoprene condoms |
| Proposed Devices | Stability & Packaging Testing |
| YES® water-based Personal Lubricant | 9 months |
| YES® oil-based Personal Lubricant | |
| YES® Vaginal Moisturizer | |
| Proposed Devices | Osmolality Testing |
| YES® water-based Personal Lubricant | Slightly Hypo to Iso-osmotic, non irritant |
| YES® oil-based Personal Lubricant | No water, N/A |
| YES® Vaginal Moisturizer | Iso-osmotic, non irritant |
| Proposed Devices | Preservative Efficacy |
| YES® water-based Personal Lubricant | Pass |
| YES® oil-based Personal Lubricant | Water assay level does not support microbial growth. |
| YES® Vaginal Moisturizer | Pass |
| Proposed Devices | Toxicology Assessment (ISO 10993-10) |
| All three Devices | No safety concerns |
| Proposed Devices | Cytotoxicity Testing (ISO 10993-5) |
| All three Devices | Biocompatible |

Biocompatibility Testing:

Biocompatibility testing was completed according to USP 34<87> (ISO 10993-5), ISO 10993-10, and ISO 10993-11 for YES[®] Vaginal Moisturizer and YES[®] oil-based Personal Lubricants. [REDACTED] b [REDACTED] The test results indicated that devices are non-toxic and non-irritating for their intended use.

Performance Testing – Bench:

YES[®] Vaginal Moisturizer was tested according to ASTM D7661, ASTM D3492, and ASTM D6324. [REDACTED] b [REDACTED]. Testing demonstrated that YES[®] Vaginal Moisturizer and YES[®] water-based Personal Lubricant are compatible with Natural Rubber Latex (NRL) and Polyisoprene condoms. These products are not compatible with Polyurethane condoms.

YES[®] oil-based Personal Lubricant was tested on polyurethane condoms according to ASTM D7661, ASTM D3492 and ASTM D6324 at the request of FDA. Condom compatibility testing on NRL or Polyisoprene condoms was not required because it is known that most oil-based lubricants are not condom compatible. Test results indicated that YES[®] oil-based Personal Lubricant is not compatible with polyurethane condoms.

Performance Testing – Animal:

Performance testing on animals is not required for this device.

Performance Testing – Clinical:

Clinical performance testing is not required for this device.

Conclusion:

The avoidance of ingredients known to irritate the mucosal tissues such as glycerin and glycols; and their replacement with plant derived gums, oils and butters of known beneficial properties to the mucosa mean that rather than just saying “this difference does not negatively affect the safety, efficacy or intended use of the proposed devices,” we expect “these differences to positively affect the safety and the efficacy of these three proposed devices” when compared to the predicate devices.

1. The Intended Use of the proposed devices are identical to predicate devices.
2. The Technological Characteristics are similar to predicate devices.
3. The Non-Clinical condom compatibility testing to ASTM D7661, ASTM D3492, and ASTM D6324 indicates the proposed devices exhibit the same properties as predicate devices.
4. Biocompatibility testing according to USP 34<87> (ISO 10993-5), ISO 10993-10 and ISO 10993-11 have demonstrated that the proposed devices do not present any new issues regarding biocompatibility.

Substantial Equivalence Determination:

We conclude that the three proposed devices are substantially equivalent to their predicate devices in intended use and technological characteristics. Biocompatibility and performance testing raised no new concerns regarding safety, and efficacy.

End of Section 10

Section 11: Device Description

Proprietary Name: YES®

Common Name: Personal Lubricant

Product Code: NUC

Device Class: II

Regulation Number: 884.5300

Narrative Description

YES® personal lubricants are non-sterile personal lubricants and are available in three variations; YES® Oil-based Personal Lubricant, YES® Water-based Personal Lubricant, and YES® Vaginal Moisturizer.

YES® Oil-based Personal Lubricant (YES® OB)

- is a non-sterile, oil-based, slightly opaque, non-staining personal lubricant formulated to supplement the body's own natural lubricating fluids to provide personal lubrication when vaginal dryness causes discomfort.
- is packed in three different sizes of tube (1.4 fluid ounce, 2.7 fluid ounce and 4.7 fluid ounce).
- is not compatible with condoms. YES® oil-based has been tested on polyurethane condoms (See Section 18) and proven to be not compatible.

YES® Water-based Personal Lubricants (YES® WB)

- is a non-sterile, water-based, thixotropic soft gel, slightly cloudy (not water white) in appearance. It is formulated to supplement the body's own natural lubricating fluids to provide personal moisturization when vaginal dryness causes discomfort.
- is packed in four different sizes of tube (1.7 fluid ounce, 2.6 fluid ounce, 3.4 fluid ounce, and 5.1 fluid ounce, and one size of prefilled single-use applicators (.17 fluid ounce). The prefilled applicators provide added convenience and are sufficient for a single use only.
- is compatible with latex and polyisoprene condoms and not compatible with polyurethane condoms as demonstrated in the Condom Compatibility Testing in Section 18.

YES® Vaginal Moisturizer (YES® VM)

- is a non-sterile, water-based, slightly opaque, non-greasy, non-staining vaginal gel formulated to act as a long-lasting moisturizer for vaginal dryness. The prefilled applicators provide added convenience in application and are sufficient for a single use only. YES® VM is formulated to supplement the body's own natural lubricating fluids to provide personal moisturization when vaginal dryness causes discomfort.
- are packed in one size of tube (3.4 fluid ounce) and one size of prefilled single-use applicators (0.17 fluid ounce).
- (b)(4) [REDACTED]
- is compatible with latex and polyisoprene condoms and not compatible with polyurethane condoms as demonstrated in Section 18.

Indications for Use

YES® oil-based Personal Lubricant: A personal lubricant, for vaginal and penile application, intended to moisturize and lubricate, to enhance the ease and comfort of intimate sexual activity and supplement the body's natural lubrication. YES® oil-based Personal Lubricant is not compatible with natural rubber latex, polyurethane or polyisoprene condoms.

YES® water-based Personal Lubricant: A personal lubricant, for vaginal and penile application, intended to moisturize and lubricate, to enhance the ease and comfort of intimate sexual activity and supplement the body's natural lubrication. YES® water-based Personal Lubricant is compatible with natural rubber latex and polyisoprene condoms. This product is not compatible with polyurethane condoms.

YES® Vaginal Moisturizer: A personal lubricant, for vaginal and penile application, intended to moisturize and lubricate, to enhance the ease and comfort of intimate sexual activity and supplement the body's natural lubrication. YES® Vaginal Moisturizer is compatible with natural rubber latex and polyisoprene condoms. This product is not compatible with polyurethane condoms.

Principals of Operation

The YES® product line is a gel-like, formulary product, which provides supplemental lubrication to male and female genitalia.

Composition:

(b)(4) [Redacted]

| [Redacted] | | | | | |
|------------|------------|------------|------------|------------|------------|
| [Redacted] | [Redacted] | [Redacted] | [Redacted] | [Redacted] | [Redacted] |
| [Redacted] | [Redacted] | [Redacted] | [Redacted] | [Redacted] | [Redacted] |
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| [REDACTED] | [REDACTED] |
| [REDACTED] | [REDACTED] |
| [REDACTED] | [REDACTED] |

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| [REDACTED] | | | | | |
| [REDACTED] | [REDACTED] | [REDACTED] | [REDACTED] | [REDACTED] | [REDACTED] |
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| [REDACTED] | [REDACTED] | [REDACTED] | [REDACTED] | [REDACTED] | [REDACTED] |
| [REDACTED] | [REDACTED] | [REDACTED] | [REDACTED] | [REDACTED] | [REDACTED] |
| [REDACTED] | [REDACTED] | [REDACTED] | [REDACTED] | [REDACTED] | [REDACTED] |
| [REDACTED] | [REDACTED] | [REDACTED] | [REDACTED] | [REDACTED] | [REDACTED] |
| [REDACTED] | [REDACTED] | [REDACTED] | [REDACTED] | [REDACTED] | [REDACTED] |
| [REDACTED] | [REDACTED] | [REDACTED] | [REDACTED] | [REDACTED] | [REDACTED] |
| [REDACTED] | [REDACTED] | [REDACTED] | [REDACTED] | [REDACTED] | [REDACTED] |
| [REDACTED] | [REDACTED] | [REDACTED] | [REDACTED] | [REDACTED] | [REDACTED] |
| [REDACTED] | [REDACTED] | [REDACTED] | [REDACTED] | [REDACTED] | [REDACTED] |

| (b)(4) | |
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| [Redacted] | [Redacted] |
| [Redacted] | [Redacted] |

| (b)(4) | |
|--|--|
| [REDACTED] | [REDACTED] |
| [REDACTED] [REDACTED] [REDACTED] | [REDACTED] [REDACTED] [REDACTED] [REDACTED] [REDACTED] |
| [REDACTED] [REDACTED] | [REDACTED] [REDACTED] [REDACTED] [REDACTED] |

Physical Description:YES® Oil-based Personal Lubricant Packaging

YES® oil-based personal lubricants are available in three (3) HDPE flip-top tubes. The individual tubes are packaged into cartons.

| Model # | Container Size | Container Type | Material | Units per Case |
|---------|--------------------|----------------|----------|----------------|
| OB40C | 40ml / 1.4 fl. oz. | Tube | HDPE | 12 |
| OB80C | 80ml / 2.7 fl. oz. | Tube | HDPE | 12 |
| OB140C | 140ml/ 4.7 fl.oz. | Tube | HDPE | 12 |

YES® Water-based Personal Lubricant Packaging

YES® Water-based personal lubricants are available in four (4) HDPE flip-top tube sizes and one (1) HDPE single-use applicator. The individual bottles are packaged into cartons, and the single-use applicators are packaged six (6) to a carton. An “Instructions for Use” leaflet is also included in the carton with the single-use applicators.

| Model # | Container Size | Container Type | Material | Units per Case |
|---------|-----------------------------|-----------------|----------|----------------|
| WB50C | 50ml/ 1.7 fl.oz. | Tube | HDPE | 12 |
| W75C | 75ml/ 2.6 fl. oz. | Tube | HDPE | 12 |
| WB100C | 100ml / 3.4 fl. oz. | Tube | HDPE | 12 |
| WB150C | 150ml / 5.1 fl. oz. | Tube | HDPE | 12 |
| WB5AC6 | 5ml / 0.17 fl. oz. (6/pack) | Single use tube | HDPE | 6 |

YES® Vaginal Moisturizer Packaging

YES® Vaginal Moisturizer is available in one (1) HDPE flip-top tube size and one (1) HDPE single-use applicator. The individual tubes are packaged into cartons, and the single-use applicators are packaged six (6) to a carton and an “Instructions for Use” leaflet is included in the carton.

| Model # | Container Size | Container Type | Material | Units per Case |
|---------|--------------------------|---------------------------------------|----------|----------------|
| VM100C | 100ml / 3.4 fl. oz. | Tube | HDPE | 12 |
| VM5AC6 | 5ml / 0.17fl oz (6/pack) | Single use tube/pre-filled applicator | HDPE | 6 |

YES® water-based personal lubricants Carton for 75ml (2.6 fl. oz) HDPE flip-top tubes. Code W75C.

- Product Carton Dimensions in mm/inches.
 - Height = 160 mm/ 6.30 inches.
 - Width = 45 mm/ 1.97 inches.
 - Depth = 40 mm/ 1.57 inches.

YES® water-based personal lubricants Carton for 100ml (3.4 fl. oz) HDPE flip-top tubes. Code WB100C.

- Product Carton Dimensions in mm/inches.
 - Height = 150 mm/ 5.91 inches.
 - Width = 50 mm/ 1.97 inches.
 - Depth = 50 mm/ 1.97 inches.

YES® water-based personal lubricants Carton for 150ml (5.1 fl. oz) HDPE flip-top tubes. Code WB150C.

- Product Carton Dimensions in mm/inches.
 - Height = 190 mm/ 7.48 inches.
 - Width = 50 mm/ 1.97 inches.
 - Depth = 50 mm/ 1.97 inches.

YES® water-based personal lubricants Carton for 5 ml Single-use tubes. Code WB5AC6.

- Product Carton Dimensions in mm/inches.
 - Height = 145 mm/ 5.71 inches.
 - Width = 90 mm/ 3.54 inches.
 - Depth = 50 mm/ 1.97 inches.

YES® Vaginal Moisturizer Carton for 100ml (3.4 fl. oz) HDPE flip-top tubes. Code VM100C.

- Product Carton Dimensions in mm/inches.
 - Height = 150 mm/ 5.91 inches.
 - Width = 50 mm/ 1.97 inches.
 - Depth = 50 mm/ 1.97 inches.

YES® Vaginal Moisturizer Carton for 5ml (0.17 fl. oz) Single-use tubes. Code VM5AC6.

- Product Carton Dimensions in mm/inches.
 - Height = 150 mm/ 5.71 inches.
 - Width = 50 mm/ 3.54 inches.
 - Depth = 50 mm/ 1.97 inches.

Section 12: Substantial Equivalence – Update to address K162569 AINN Letter dated November 14, 2016.

This is a Traditional, Bundled, 510(k) Submission of three (3) Proposed Devices.

Common Name: Personal Lubricant

Product Code: NUC

Device Class: II

Regulation Number: 884.5300

| Proposed Device: | Predicate Device: |
|-------------------------------------|--|
| YES® oil-based Personal Lubricant | LifeStyles Luxe Premium Personal Lubricant (K122477) |
| YES® Water-based Personal Lubricant | Aloe Cadabra Personal Lubricant (K124044) |
| YES® Vaginal Moisturizer | Aloe Cadabra Personal Lubricant (K124044) |

Device Comparison Tables

| YES® water-based Personal Lubricant | | |
|--|---|--|
| 510(k) # | | K124044 |
| Device name | YES® water-based Personal Lubricant | Aloe Cadabra Personal lubricant |
| Manufacturer | Bio-tech Lubricants Ltd | Seven Oaks Ranch, Inc. |
| Classification | 884.5300 | 884.5300 |
| Product code | NUC | NUC |
| Description | Personal Lubricant | Personal Lubricant |
| Indications for use | YES® water-based Personal Lubricant is a personal lubricant, for vaginal and penile application, intended to moisturize and lubricate, to enhance the ease and comfort of intimate sexual activity and supplement the body's natural lubrication. This product is compatible with NRL and Polyisoprene condoms. This product is not compatible with polyurethane condoms. | Aloe Cadabra lubricants, are personal lubricants for penile and/or vaginal application, intended to moisturize and lubricate, to enhance the ease and comfort of intimate sexual activity and supplement the body's natural lubrication. This product is compatible with NRL and Polyisoprene condoms. This product is not compatible with polyurethane condoms. |
| Over-the-counter use | YES | YES |
| Biocompatible | YES | YES |
| Condom Compatible | Natural Rubber Latex (NRL), Polyisoprene, and NOT compatible with Polyurethane condoms. | Natural Rubber Latex (NRL), Polyisoprene and NOT compatible with Polyurethane condoms |
| Non-sterile | YES | YES |
| Packaging Materials | Plastic / PE | Plastic / PE |
| Contains plant extracts | YES | YES |
| Contains preservatives | YES | YES |

| YES® oil-based Personal Lubricant | | |
|--|--|---|
| 510(k) # | | K122477 |
| | YES® oil-based personal lubricant | LifeStyles Luxe Premium Personal Lubricant |
| Manufacturer | Bio-tech Lubricants Ltd | Ansell Healthcare Products, LLC |
| Classification | 884.5300 | 884.5300 |
| Product code | NUC | NUC |
| Description | Personal Lubricant | Personal Lubricant |
| Indications for use | YES® oil-based personal lubricant is a personal lubricant, for vaginal and penile application, intended to moisturize and lubricate, to enhance the ease and comfort of intimate sexual activity and supplement the body's natural lubrication. This product is not compatible with NRL, polyurethane or Polyisoprene condoms. | LifeStyles Luxe Premium Personal Lubricant Is a personal lubricant, for penile and/or vaginal application, intended to moisturize and lubricate, to enhance the ease and comfort of intimate sexual activity and supplement the body's natural lubrication. This product is compatible with natural rubber latex, polyurethane, and Polyisoprene condoms. |
| Over-the-counter use | YES | YES |
| Biocompatible | YES | YES |
| Condom Compatible | NO (non-silicone oil-based products are known to be NOT compatible with NRL, polyisoprene or polyurethane condoms) | YES |
| Non-sterile | YES | YES |
| Packaging Materials | Plastic / PE | Plastic / PE |
| Contains plant extracts | YES | YES |
| Contains preservatives | No - Product cannot support microbial growth | No - Product cannot support microbial growth |

| YES® Vaginal Moisturizer | | |
|---------------------------------|--|--|
| 510(k) # | | K124044 |
| | YES® VM (Vaginal Moisturizer) | Aloe Cadabra Personal lubricant |
| Manufacturer | Bio-tech Lubricants Ltd | Seven Oaks Ranch, Inc. |
| Classification | 884.5300 | 884.5300 |
| Product code | NUC | NUC |
| Description | Personal Lubricant | Personal Lubricant |
| Indications for use | YES® VM (Vaginal Moisturizer) is a personal lubricant, for vaginal application, intended to moisturize and lubricate, to enhance the ease and comfort of intimate sexual activity and supplement the body's natural lubrication. This product is compatible with NRL and Polyisoprene condoms. This product is not compatible with polyurethane condoms. | Aloe cadabra lubricants, are personal lubricants for penile and/or vaginal application, intended to moisturize and lubricate, to enhance the ease and comfort of intimate sexual activity and supplement the body's natural lubrication. This product is compatible with NRL and Polyisoprene condoms. This product is not compatible with polyurethane condoms. |
| Over-the-counter use | YES | YES |
| Biocompatible | YES | YES |
| Condom Compatible | Natural Rubber Latex (NRL), Polyisoprene, and NOT compatible with Polyurethane condoms | Natural Rubber Latex (NRL), Polyisoprene, and NOT compatible with Polyurethane condoms |
| Non-sterile | YES | YES |
| Packaging Materials | Plastic / PE | Plastic / PE |
| Contains preservatives | YES | YES |

Conclusion:

The avoidance of ingredients known to irritate the mucosal tissues such as glycerin and glycols; and their replacement with plant derived gums, oils and butters of known beneficial properties to the mucosa mean that rather than just saying “this difference does not negatively affect the safety, efficacy or intended use of the proposed devices,” we expect “these differences to positively affect the safety and the efficacy of these three proposed devices” when compared to the predicate devices.

1. The Intended Use of the proposed devices are identical to predicate devices.
2. The Technological Characteristics are similar to predicate devices.
3. The Non-Clinical condom compatibility testing to ASTM D7661 indicates the proposed devices exhibit the same properties as predicate devices for NRL and polyisoprene condoms. Although the oil-based product is not condom compatible unlike the silicone predicate; it is commonly known and accepted that natural oil-based products will break down NRL condoms. All 3 products are not compatible with polyurethane condoms and are labelled as ‘not compatible with polyurethane condoms’.
4. Biocompatibility testing according to USP 34<87< (ISO 10993-5), ISO 10993-10 and ISO 10993-11 have demonstrated that the proposed devices do not present any new issues regarding biocompatibility.
5. The avoidance of Sodium benzoate as a preservative reduces the risk of mucosal irritation.

Substantial Equivalence Determination:

We conclude that the three proposed devices are substantially equivalent to their predicate devices in intended use and technological characteristics. Biocompatibility and performance testing raised no new concerns regarding safety, and efficacy.

End of Section 12

Section 13: Proposed Labeling / YES[®] Labels

21 CFR Part 807.87(e)

YES[®] Water-based Personal Lubricant

| Description | Size | Container Type | Model No. |
|---|--------------------|-----------------------|------------------|
| YES [®] Water-based Personal Lubricant | 0.17 fl.oz (5 ml). | Carton /Applicator | WB5AC6 |
| YES [®] Water-based Personal Lubricant | 1.7 fl.oz (50ml). | Carton/ Tube | WB50C |
| YES [®] Water-based Personal Lubricant | 2.6 fl.oz (75ml). | Carton/ Tube | W75C |
| YES [®] Water-based Personal Lubricant | 3.4 fl.oz (100ml). | Carton/ Tube | WB100C |
| YES [®] Water-based Personal Lubricant | 5.1 fl.oz (150ml). | Carton/ Tube | WB150C |
| YES [®] Water-based Personal Lubricant | n/a | Instructions For Use | n/a |

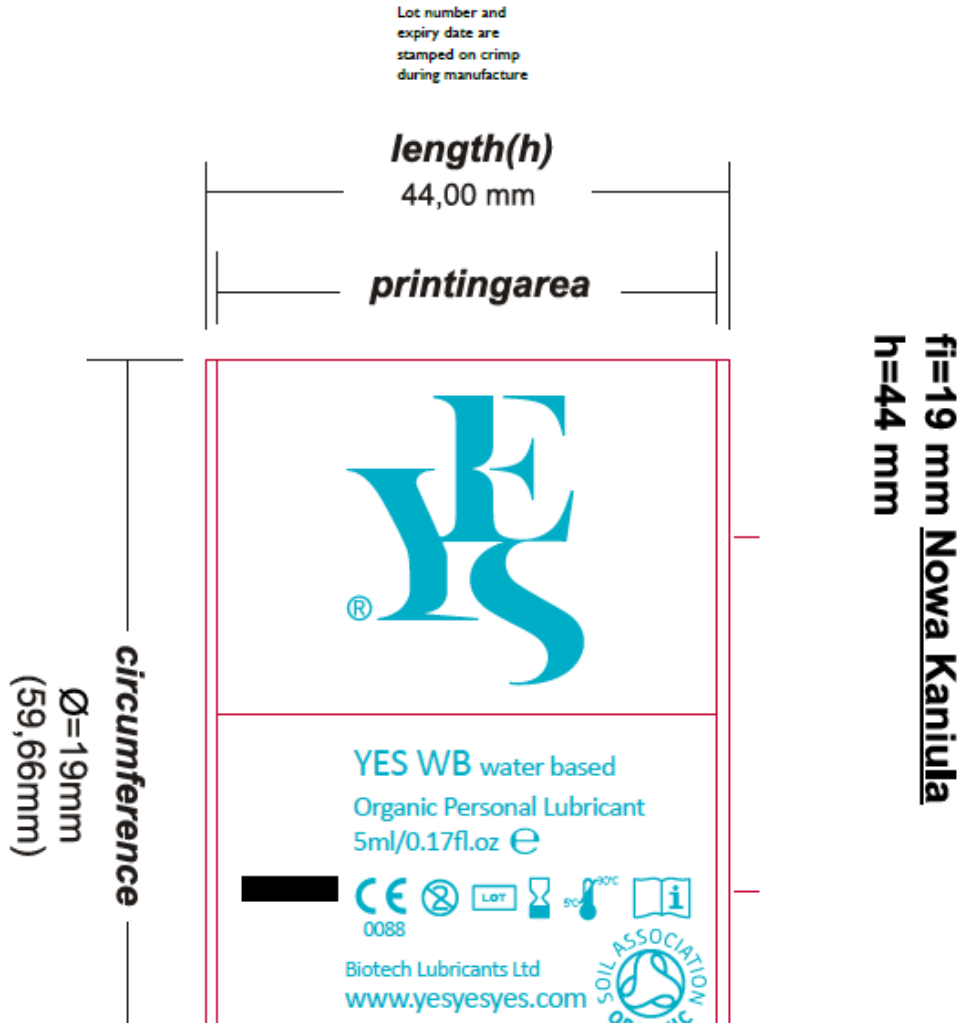
YES[®] Oil-based Personal Lubricant

| Description | Size | Container Type | Model No. |
|---|--------------------|-----------------------|------------------|
| YES [®] Oil-based Personal Lubricant | 1.4 fl.oz (40 ml) | Carton/ Tube | OB40C |
| YES [®] Oil-based Personal Lubricant | 2.7 fl.oz (80 ml) | Carton/ Tube | OB80C |
| YES [®] Oil-based Personal Lubricant | 4.7 fl.oz (140 ml) | Carton/ Tube | OB140C |
| YES [®] Oil-based Personal Lubricant | n/a | Instructions For Use | n/a |

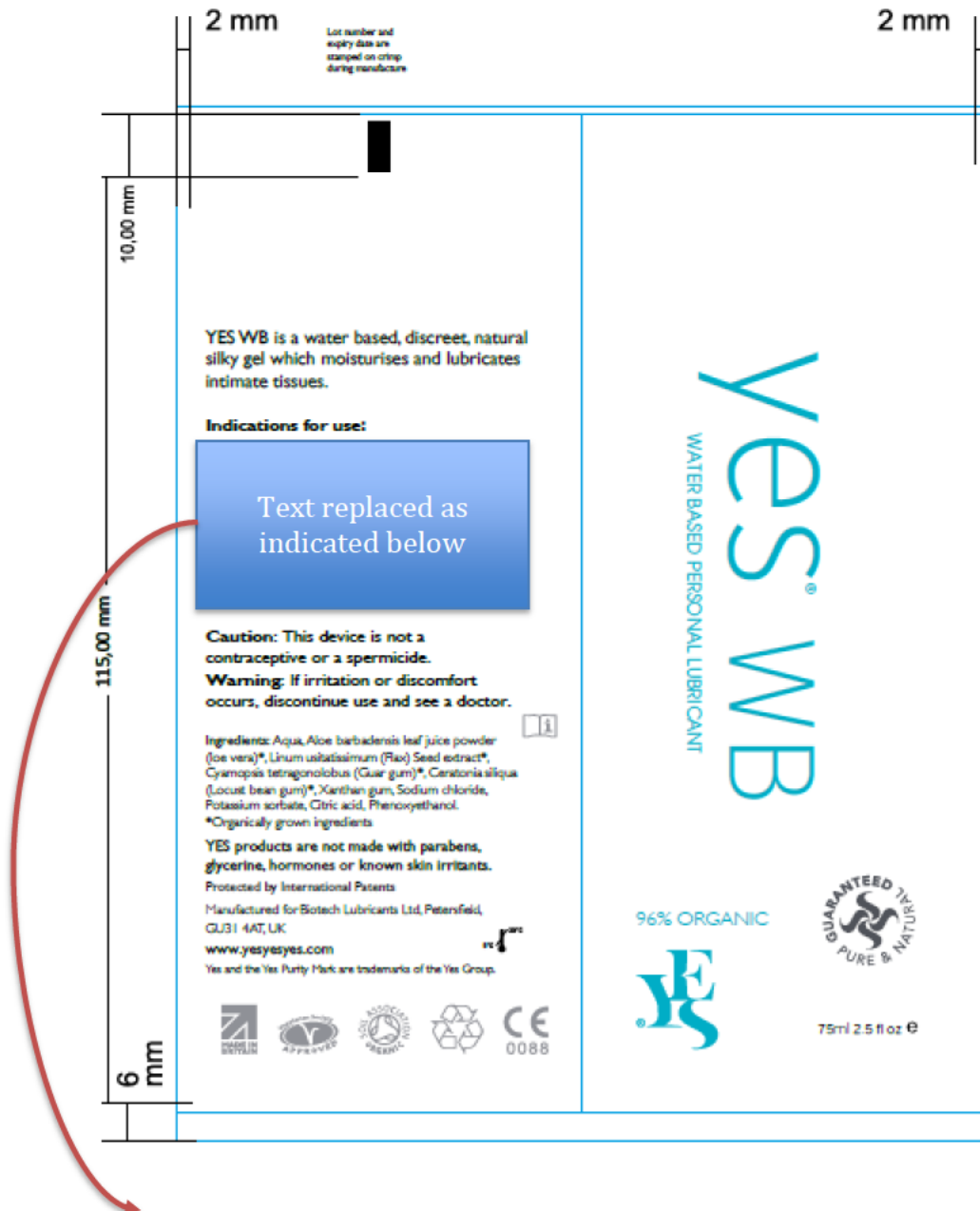
YES[®] Vaginal Moisturizer

| Description | Size | Container Type | Model No. |
|--------------------------------------|--------------------|-----------------------|------------------|
| YES [®] Vaginal Moisturizer | 0.17 fl.oz (5 ml) | Carton /Applicator | VM5AC6 |
| YES [®] Vaginal Moisturizer | 3.4 fl.oz (100 ml) | Carton/ Tube | VM100C |
| YES [®] Vaginal Moisturizer | n/a | Instructions For Use | n/a |

YES® water-based 5ml / .17 fluid ounce applicator label.

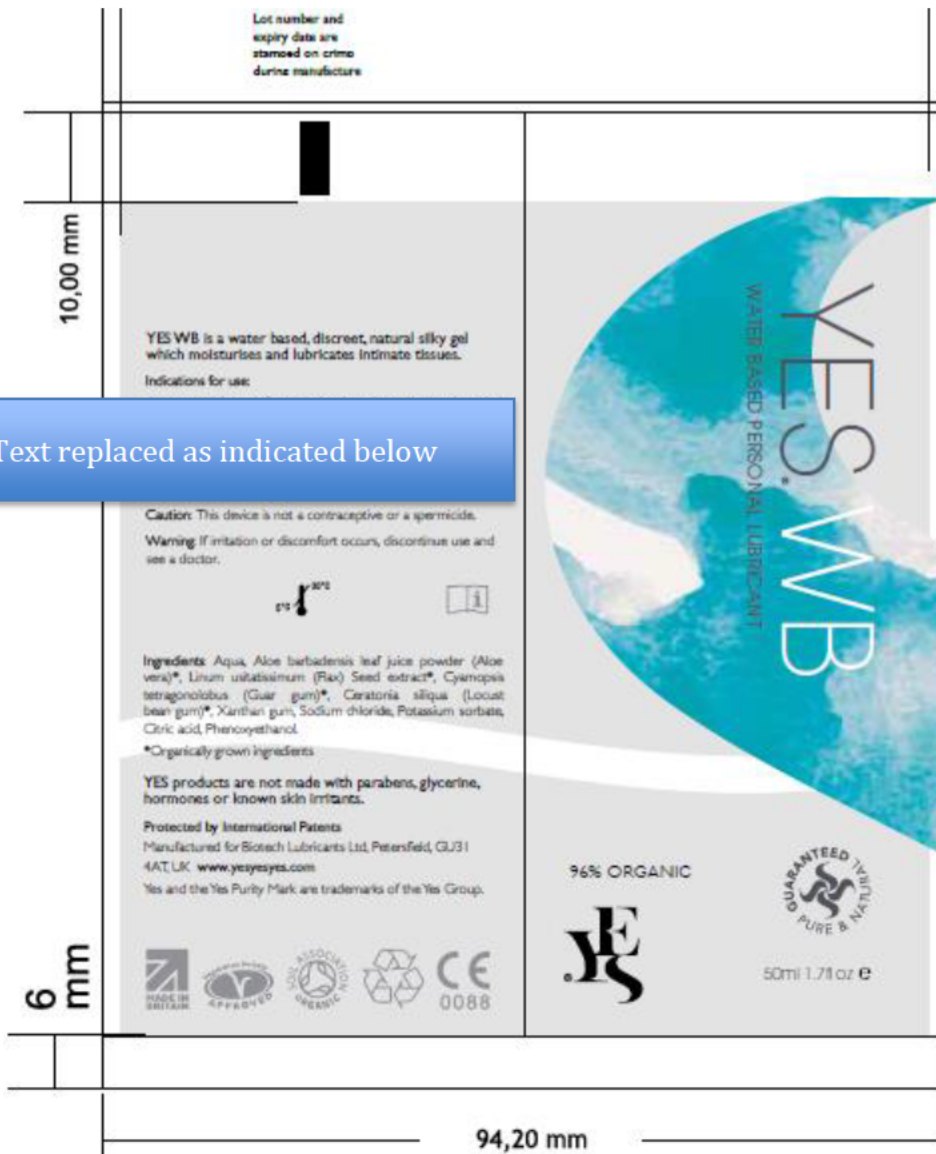


YES® water-based 75ml / 2.6 fluid ounce tube label.



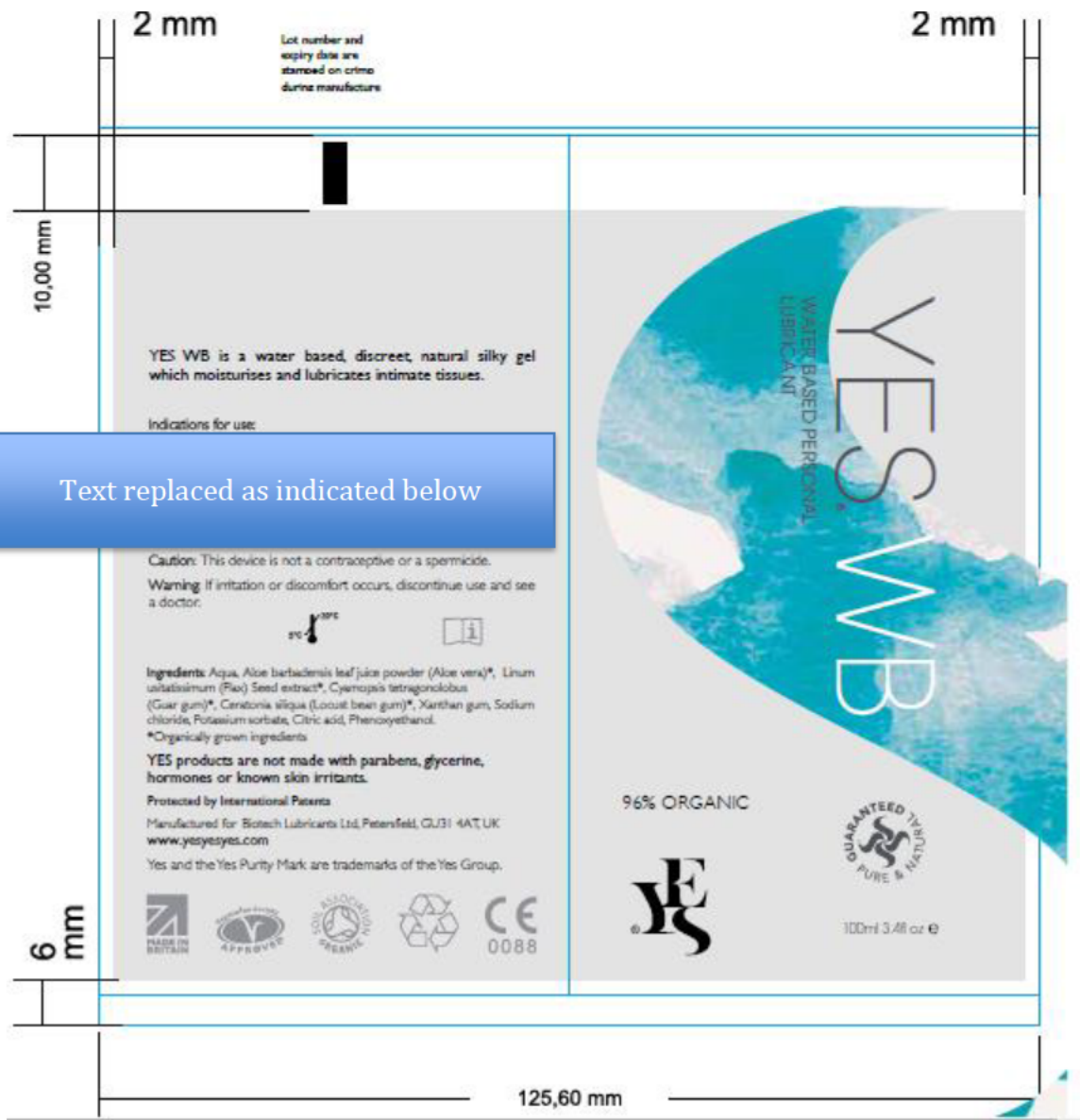
Indications for Use: YES® water-based Personal Lubricant is a personal lubricant, for vaginal and penile application, intended to moisturize and lubricate, to enhance the ease and comfort of intimate sexual activity and supplement the body's natural lubrication. YES® water-based Personal Lubricant is compatible with natural rubber latex and polyisoprene condoms. This product is not compatible with polyurethane condoms

YES® water-based 50ml / 1.7 fluid ounce tube label.



Indications for Use: YES® water-based Personal Lubricant is a personal lubricant, for vaginal and penile application, intended to moisturize and lubricate, to enhance the ease and comfort of intimate sexual activity and supplement the body's natural lubrication. YES® water-based Personal Lubricant is compatible with natural rubber latex and polyisoprene condoms. This product is not compatible with polyurethane condoms

YES® water-based 100ml / 3.4 fluid ounce tube label.



Text replaced as indicated below

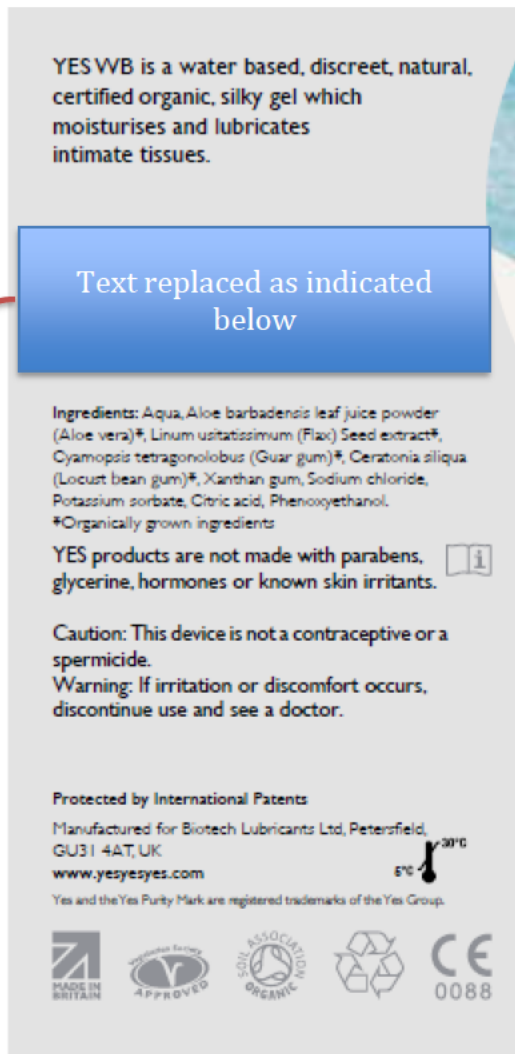
Indications for Use: YES® water-based Personal Lubricant is a personal lubricant, for vaginal and penile application, intended to moisturize and lubricate, to enhance the ease and comfort of intimate sexual activity and supplement the body's natural lubrication. YES® water-based Personal Lubricant is compatible with natural rubber latex and polyisoprene condoms. This product is not compatible with polyurethane condoms

YES® water-based 150ml / 5.1 fluid ounce tube label.



Indications for Use: YES® water-based Personal Lubricant is a personal lubricant, for vaginal and penile application, intended to moisturize and lubricate, to enhance the ease and comfort of intimate sexual activity and supplement the body's natural lubrication. YES® water-based Personal Lubricant is compatible with natural rubber latex and polyisoprene condoms. This product is not compatible with polyurethane condoms

YES® water-based 150ml / 5.1 fluid ounce tube label (Zoom-View of Principal Display Panel).



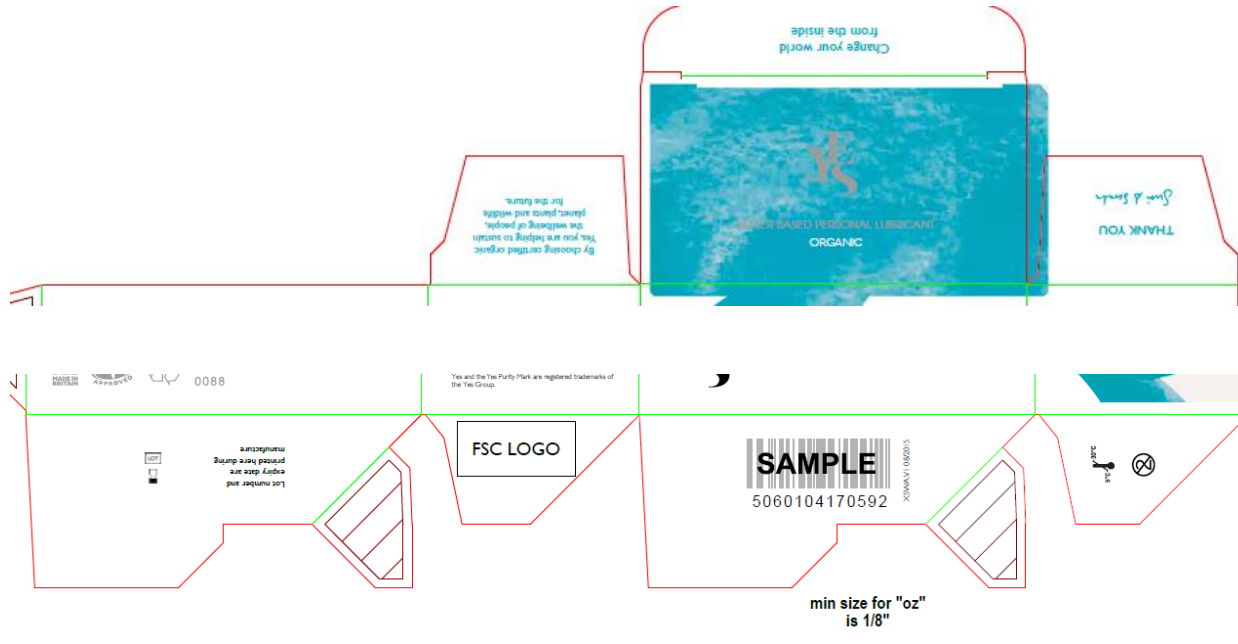
Indications for Use: YES® water-based Personal Lubricant is a personal lubricant, for vaginal and penile application, intended to moisturize and lubricate, to enhance the ease and comfort of intimate sexual activity and supplement the body's natural lubrication. YES® water-based Personal Lubricant is compatible with natural rubber latex and polyisoprene condoms. This product is not compatible with polyurethane condoms

YES® water-based 5 ml / 0.17 fluid ounce applicator carton label (Zoom view of Principal Display Panel).



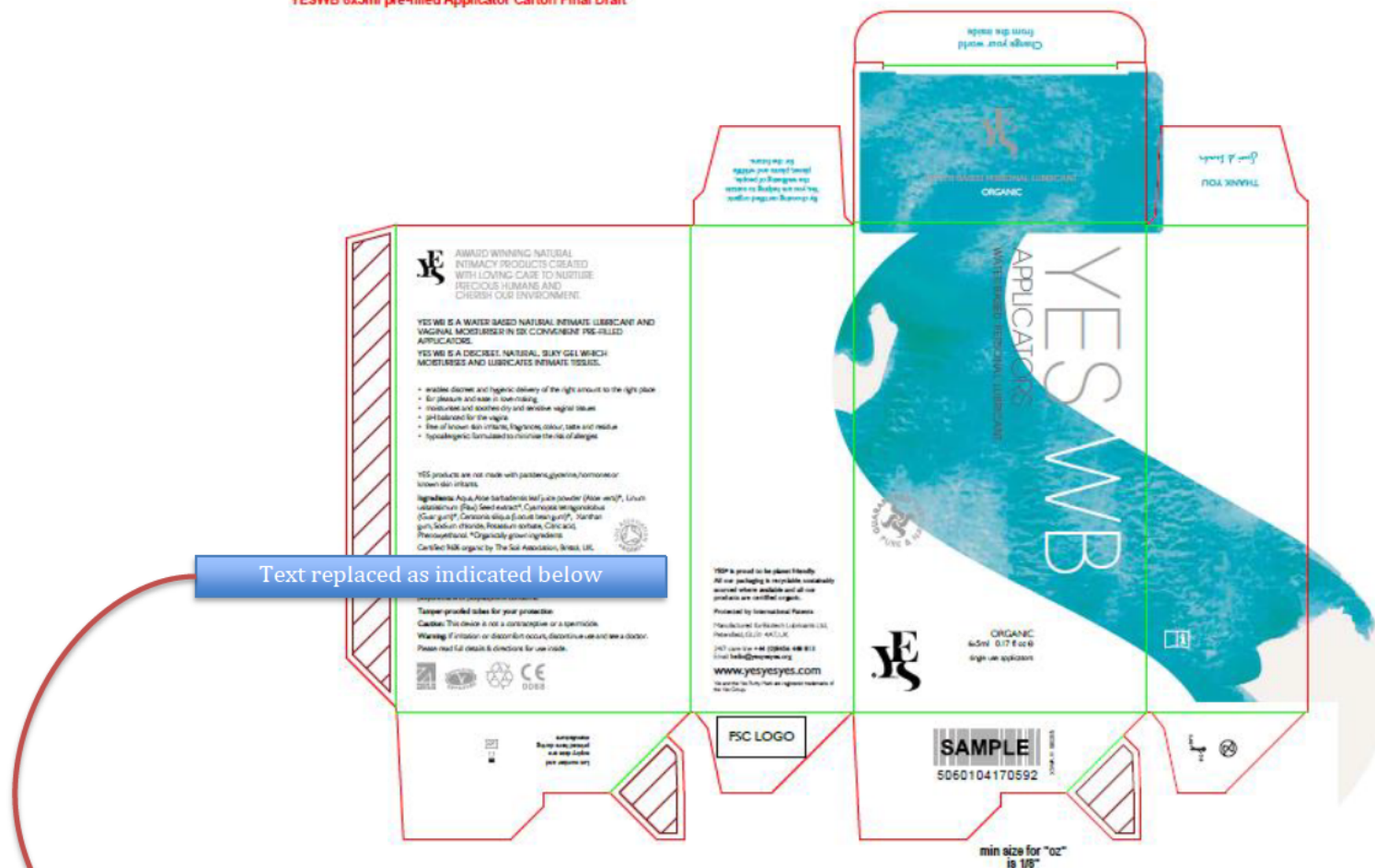
Indications for Use: YES® water-based Personal Lubricant is a personal lubricant, for vaginal and penile application, intended to moisturize and lubricate, to enhance the ease and comfort of intimate sexual activity and supplement the body's natural lubrication. YES® water-based Personal Lubricant is compatible with natural rubber latex and polyisoprene condoms. This product is not compatible with polyurethane condoms.

YES[®] water-based 5 ml / 0.17 fluid ounce applicator carton label (Zoom view of Ends).



YES® water-based 5 ml / 0.17 fluid ounce applicator carton label.

YESWB 6x5ml pre-filled Applicator Carton Final Draft

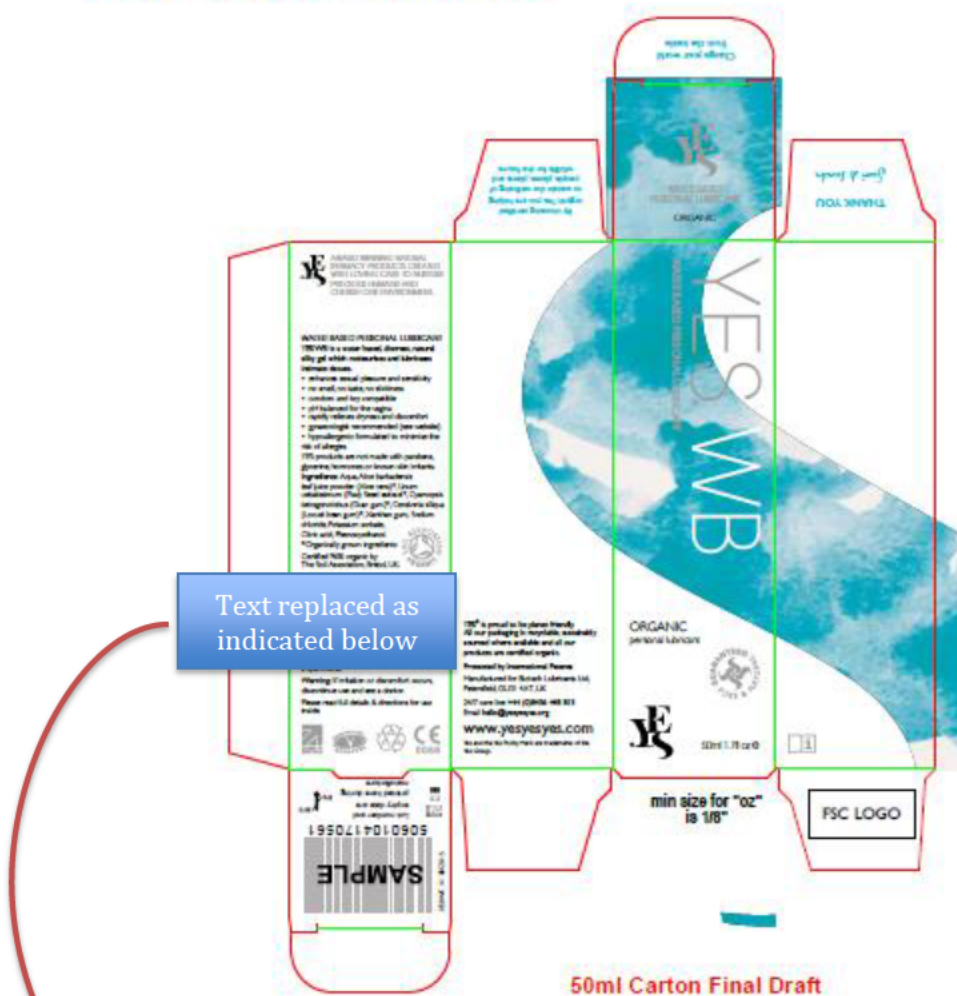


Text replaced as indicated below

Indications for Use: YES® water-based Personal Lubricant is a personal lubricant, for vaginal and penile application, intended to moisturize and lubricate, to enhance the ease and comfort of intimate sexual activity and supplement the body's natural lubrication. YES® water-based Personal Lubricant is compatible with natural rubber latex and polyisoprene condoms. This product is not compatible with polyurethane condoms

YES® water-based 50 ml / 1.7 fluid ounce tube carton label.

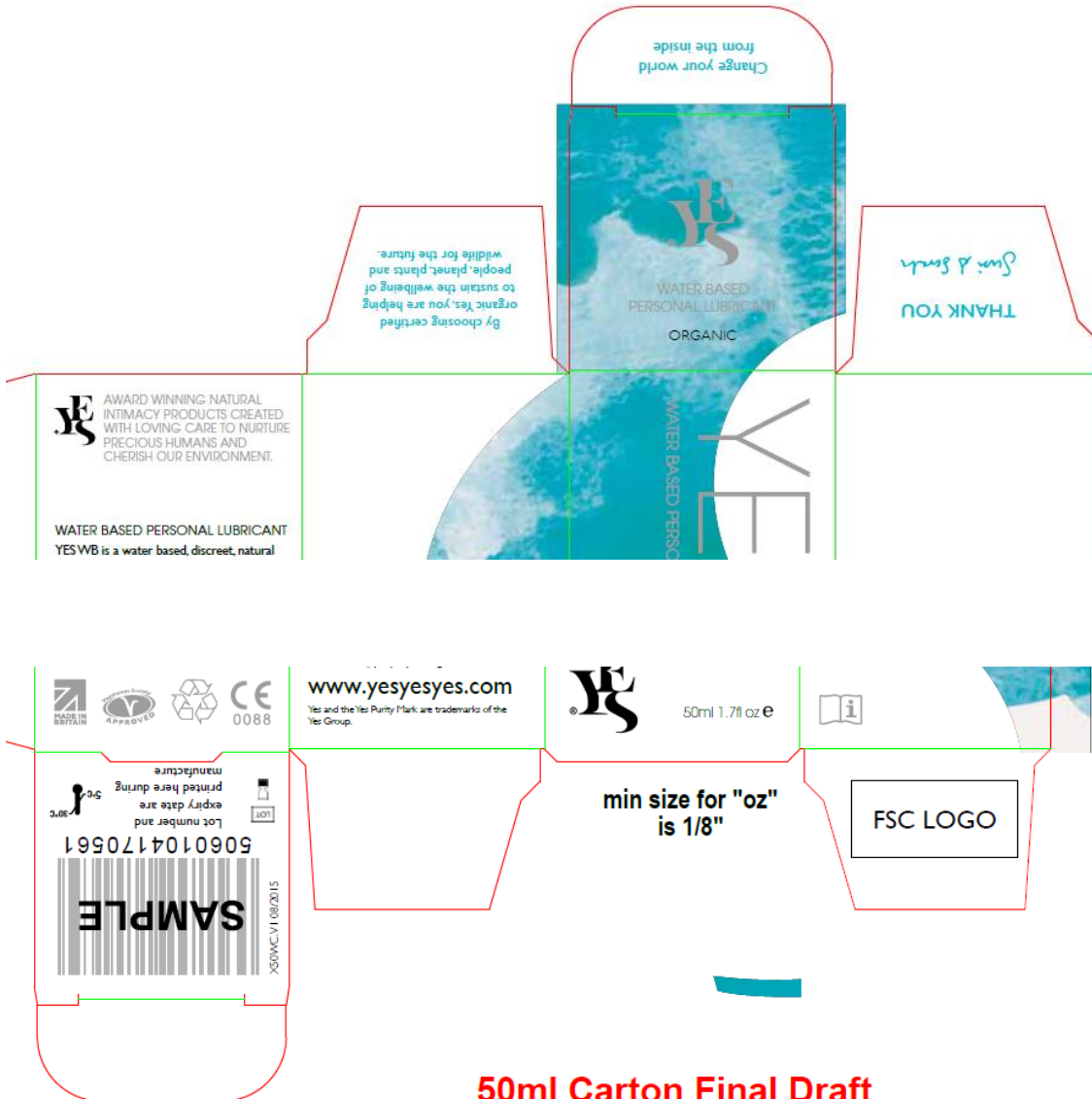
YesWB_50ml Carton and Tube Labels Final Draft



Text replaced as indicated below

Indications for Use: YES® water-based Personal Lubricant is a personal lubricant, for vaginal and penile application, intended to moisturize and lubricate, to enhance the ease and comfort of intimate sexual activity and supplement the body's natural lubrication. YES® water-based Personal Lubricant is compatible with natural rubber latex and polyisoprene condoms. This product is not compatible with polyurethane condoms

**YES® water-based 50 ml / 1.7 fluid ounce tube carton label (Top and bottom sections).
Identical information is displayed on other sized tube cartons.**



50ml Carton Final Draft

YES® water-based 50 ml / 1.7 fluid ounce tube carton label (Zoom View of Principal Display Panel).



Text replaced as indicated below

Indications for Use: YES® water-based Personal Lubricant is a personal lubricant, for vaginal and penile application, intended to moisturize and lubricate, to enhance the ease and comfort of intimate sexual activity and supplement the body's natural lubrication. YES® water-based Personal Lubricant is compatible with natural rubber latex and polyisoprene condoms. This product is not compatible with polyurethane condoms

YES® water-based 100 ml / 3.4 fluid ounce tube carton label.

YesWB_100ml Carton and Tube Labels Final Draft



Text replaced as indicated below

Indications for Use: YES® water-based Personal Lubricant is a personal lubricant, for vaginal and penile application, intended to moisturize and lubricate, to enhance the ease and comfort of intimate sexual activity and supplement the body's natural lubrication. YES® water-based Personal Lubricant is compatible with natural rubber latex and polyisoprene condoms. This product is not compatible with polyurethane condoms

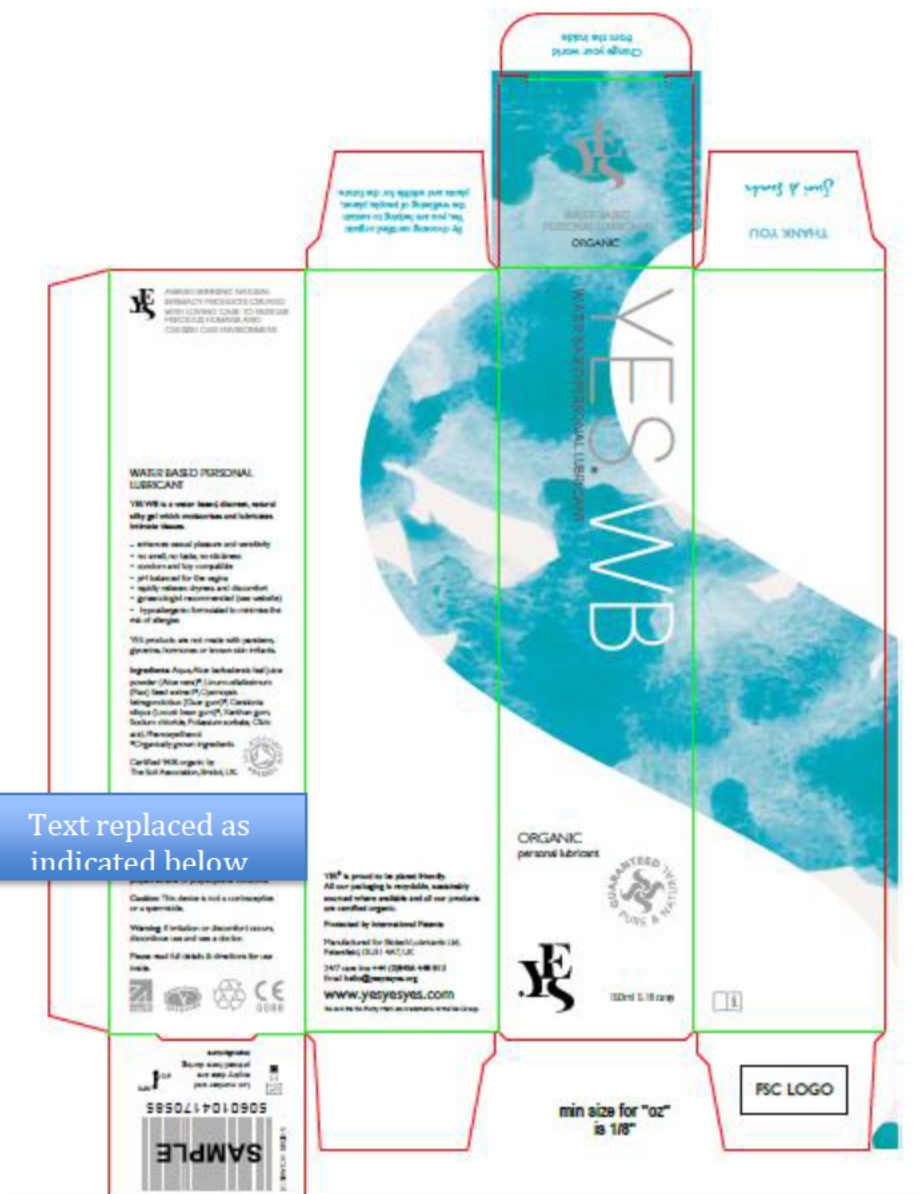
YES® water-based 100 ml / 3.4 fluid ounce tube carton label (Zoom View of Principal Display Panel).



Text replaced as indicated below

Indications for Use: YES® water-based Personal Lubricant is a personal lubricant, for vaginal and penile application, intended to moisturize and lubricate, to enhance the ease and comfort of intimate sexual activity and supplement the body's natural lubrication. YES® water-based Personal Lubricant is compatible with natural rubber latex and polyisoprene condoms. This product is not compatible with polyurethane condoms

YES® water-based 150 ml / 5.1 fluid ounce tube carton label.



Text replaced as indicated below

Indications for Use: YES® water-based Personal Lubricant is a personal lubricant, for vaginal and penile application, intended to moisturize and lubricate, to enhance the ease and comfort of intimate sexual activity and supplement the body's natural lubrication. YES® water-based Personal Lubricant is compatible with natural rubber latex and polyisoprene condoms. This product is not compatible with polyurethane condoms

YES® water-based 150 ml / 5.1 fluid ounce tube carton label (Zoom View of Principal Display Panel).

WATER BASED PERSONAL LUBRICANT

YES WB is a water based, discreet, natural silky gel which moisturises and lubricates intimate tissues.

- enhances sexual pleasure and sensitivity
- no smell, no taste, no stickiness
- condom and toy compatible
- pH balanced for the vagina
- rapidly relieves dryness and discomfort
- gynaecologist recommended (see website)
- hypoallergenic formulated to minimise the risk of allergies

YES products are not made with parabens, glycerine, hormones or known skin irritants.

Ingredients: Aqua, Aloe barbadensis leaf juice powder (Aloe vera)®, Linum usitatissimum (Flax) Seed extract®, Cymopsis tetragonolobus (Guar gum)®, Ceratonia siliqua (Locust bean gum)®, Xanthan gum, Sodium chloride, Potassium sorbate, Citric acid, Phenoxethanol.

*Organically grown ingredients

Certified 96% organic by The Soil Association, Bristol, UK.

Indications for use: A personal lubricant, for

Text replaced as indicated below

Caution: This device is not a contraceptive or a spermicide.

Warning: If irritation or discomfort occurs, discontinue use and see a doctor.

Please read full details & directions for use inside.

MADE IN BRITAIN APPROVED RECYCLED 0088

YES® is proud to be planet friendly. All our packaging is recyclable, sustainably sourced where available and all our products are certified organic.

Protected by International Patents

Manufactured for Biotech Lubricants Ltd, Petersfield, GU31 4AT, UK

24/7 care line +44 (0)8456 448 813
Email hello@yesyesyes.org

www.yesyesyes.com

Yes and the Yes Purify Mark are trademarks of the Yes Group.

ORGANIC personal lubricant

GUARANTEED TRIPLE PURITY & NATURAL

YES

150ml 5.1 fl oz e

Indications for Use: YES® water-based Personal Lubricant is a personal lubricant, for vaginal and penile application, intended to moisturize and lubricate, to enhance the ease and comfort of intimate sexual activity and supplement the body's natural lubrication. YES® water-based Personal Lubricant is compatible with natural rubber latex and polyisoprene condoms. This product is not compatible with polyurethane condoms

YES® oil-based 140 ml / 4.7 fluid ounce tube carton label (Zoom View of Principal Display Panel).

**PLANT-OIL BASED
PERSONAL LUBRICANT**

YES OB is a luxurious plant-oil based natural lubricant, whose rich oils and butters nourish and condition skin, giving lasting lubricity and comfort.

- dual purpose intimate lubricant and massage oil
- perfect for prolonged love-making
- natural plant-oil based alternative to silicone lubricants
- safe for use with silicone toys
- hypoallergenic formulated to minimise the risk of allergies
- richly nourishing, providing soothing relief
- gynaecologist recommended (see website)
- YES OB is NOT condom compatible

YES products are not made with parabens, glycerine, hormones or known skin irritants.

Ingredients: Helianthus annuus (Sunflower) seed oil*, Butyrospermum parkii (Shea) butter*, Prunus dulcis (Sweet almond) oil*, Cera alba (Bees wax)*, Theobroma cacao (Cocoa) seed butter*, Tocopherol (Vitamin E).

*Organically grown ingredients

Certified 99.8% organic by The Soil Association, Bristol, UK



Indications for use: A personal lubricant, for vaginal and penile application, intended to moisturise and lubricate, to enhance the ease and comfort of intimate sexual activity and supplement the body's natural lubrication. YES OB plant-oil based Personal Lubricant is not compatible with natural rubber latex, polyurethane or polyisoprene condoms.

Caution: This device is not a contraceptive or a spermicide.

Warning: If irritation or discomfort occurs, discontinue use and see a doctor.

Please read full details & directions for use inside.



ORGANIC
personal lubricant



YES® is proud to be planet friendly. All our packaging is recyclable, sustainably sourced where available and all our products are certified organic.

Manufactured for Biotech Lubricants Ltd, Petersfield, GU31 4AT, UK

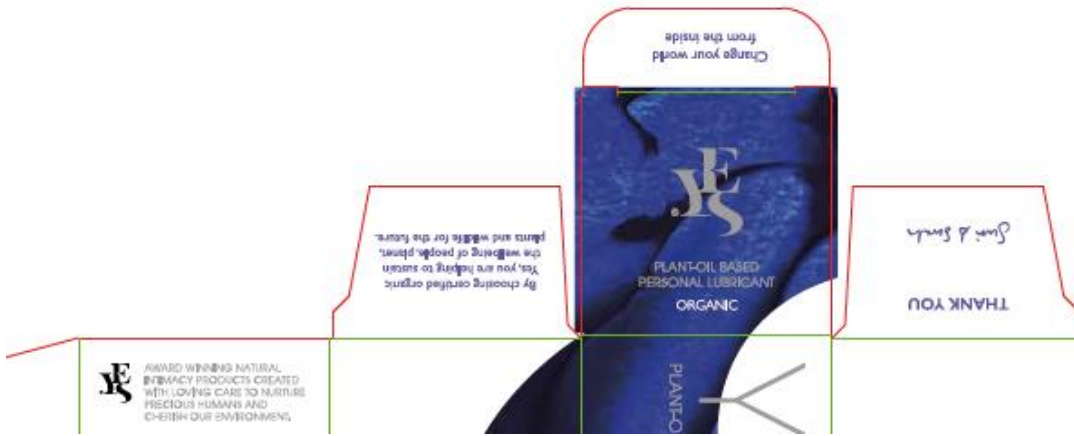
24/7 care line +44 (0)8456 448 813
Email hello@yesyesyes.org

www.yesyesyes.com



140ml 4.7fl oz e

**YES® oil-based 140 ml / 4.7 fluid ounce tube carton label (Top and bottom of Carton).
All YES® oil-based tube carton labels for all sizes contain identical information on the
top and bottom sections.**



YES[®] oil-based 140 ml / 4.7 fluid ounce tube carton label.

YesOB_80ml Carton and Tube Labels Final Draft



YES® oil-based 140 ml / 4.7 fluid ounce tube label.



YES® oil-based 140 ml / 4.7 fluid ounce tube label (Zoom View of Principal Display Panel).

YES OB is a luxurious plant-oil based natural lubricant, whose rich oils and butters nourish and condition skin, giving lasting lubricity and comfort. This device is not a contraceptive or a spermicide. YES OB is NOT condom compatible.

Indications for use:
A personal lubricant, for vaginal and penile application, intended to moisturise and lubricate, to enhance the ease and comfort of intimate sexual activity and supplement the body's natural lubrication.

YES OB is NOT compatible with natural rubber latex, polyurethane or polyisoprene condoms.

Caution: This device is not a contraceptive or a spermicide.







Warning: If irritation or discomfort occurs, discontinue use and see a doctor.

Ingredients: Helianthus annuus (Sunflower) seed oil*, Butyrospermum parkii (Shea) butter*, Prunus dulcis (Sweet almond) oil*, Cera alba (Bees wax)*, Theobroma cacao (Cocoa) seed butter*, Tocopherol (Vitamin E).
*Organically grown ingredients

YES products are not made with parabens, glycerine, hormones or known skin irritants.

Manufactured for Biotech Lubricants Ltd, Petersfield, GU31 4AT, UK
www.yesyesyes.com

Yes and the Yes Purity Mark are trademarks of the Yes Group.



YES® oil-based 80 ml / 2.7 fluid ounce tube carton label (Zoom View of Principal Display Panel).

| | | |
|--|--|---|
| <p>YES INTIMACY PRODUCTS CREATED WITH LOVING CARE TO NURTURE PRECIOUS HUMANS AND CHERISH OUR ENVIRONMENT.</p> <p>PLANT-OIL BASED PERSONAL LUBRICANT</p> <p>YES OB is a luxurious plant-oil based natural lubricant, whose rich oils and butters nourish and condition skin, giving lasting lubricity and comfort.</p> <ul style="list-style-type: none"> • dual purpose intimate lubricant and massage oil • perfect for prolonged lovemaking • natural plant-oil based alternative to silicone lubricants • safe for use with silicone toys • hypoallergenic: formulated to minimise the risk of allergies • richly nourishing providing soothing relief • gynaecologist recommended (see website) • YES OB is NOT condom compatible <p>YES products are not made with parabens, glycerine, hormones or known skin irritants.</p> <p>Ingredients: Helianthus annuus (Sunflower) seed oil*, Butyrospermum parkii (Shea) butter*, Prunus dulcis (Sweet almond) oil*, Cera alba (Bees wax)*, Theobroma cacao (Cocoa) seed butter*, Tocopherol (Vitamin E). *Organically grown ingredients</p> <p>Certified 99.8% organic by The Soil Association, Bristol, UK</p> <p>Indications for use: A personal lubricant, for vaginal and penile application, intended to moisturise and lubricate, to enhance the ease and comfort of intimate sexual activity and supplement the body's natural lubrication. YES OB plant-oil based Personal Lubricant is not compatible with natural rubber latex, polyurethane or polyisoprene condoms.</p> <p>Caution: This device is not a contraceptive or a spermicide.</p> <p>Warning: If irritation or discomfort occurs, discontinue use and see a doctor.</p> <p>Please read full details & directions for use inside.</p>  |  <p>ORGANIC personal lubricant</p> <p>YES® is proud to be planet friendly. All our packaging is recyclable, sustainably sourced where available and all our products are certified organic.</p> <p>Manufactured for Biotech Lubricants Ltd, Petersfield, GU31 4AT, UK</p> <p>24/7 care line +44 (0)8456 448 813 Email hello@yesyesyes.org</p> <p>www.yesyesyes.com</p>  | <p>PLANT-OIL BASED PERSONAL LUBRICANT</p> <p>YES OB</p>  <p>GUARANTEED 100% PURE & NATURAL</p> <p>80ml 2.7fl oz e</p> |
|--|--|---|

YES® oil-based 80 ml / 2.7 fluid ounce tube carton label.



YES® oil-based 80 ml / 2.7 fluid ounce tube label (Zoom View of Principal Display Panel).



YES OB is a luxurious plant-oil based natural lubricant, whose rich oils and butters nourish and condition skin, giving lasting lubricity and comfort. This device is not a contraceptive or a spermicide. YES OB is NOT condom compatible.

Indications for use:
A personal lubricant, for vaginal and penile, application intended to moisturise and lubricate, to enhance the ease and comfort of intimate sexual activity and supplement the body's natural lubrication.

YES OB is NOT compatible with natural rubber latex, polyurethane or polyisoprene condoms.

Caution: This device is not a contraceptive or a spermicide.






Warning: If irritation or discomfort occurs, discontinue use and see a doctor.

Ingredients: Helianthus annuus (Sunflower) seed oil*, Butyrospermum parkii (Shea) butter*, Prunus dulcis (Sweet almond) oil*, Cera alba (Bees wax)*, Theobroma cacao (Cocoa) seed butter*, Tocopherol (Vitamin E).
*Organically grown ingredients

YES products are not made with parabens, glycerine, hormones or known skin irritants.



Manufactured for Biotech Lubricants Ltd, Petersfield, GU31 4AT, UK
www.yesyesyes.com
Yes and the Yes Purity Mark are trademarks of the Yes Group.

PLANT-OIL BASED PERSONAL LUBRICANT

YES
OB

99.8% ORGANIC

80ml 2.7fl oz e

mm

YES® oil-based 80 ml / 2.7 fluid ounce tube label.



YES® oil-based 40 ml / 1.4 fluid ounce tube carton label (Zoom View of Principal Display Panel).










| | | |
|--|---|---|
| <p>PLANT-OIL BASED PERSONAL LUBRICANT YES OB is a luxurious plant-oil based natural lubricant, whose rich oils and butters nourish and condition skin, giving lasting lubricity and comfort.</p> <ul style="list-style-type: none"> • dual purpose intimate lubricant and massage oil • perfect for prolonged love-making • natural plant-oil based alternative to silicone lubricants • safe for use with silicone toys • hypoallergenic: formulated to minimise the risk of allergies • richly nourishing, providing soothing relief • gynaecologist recommended (see website) • YES OB is NOT condom compatible <p>YES products are not made with parabens, glycerine, hormones or known skin irritants. Ingredients: Helianthus annuus (Sunflower) seed oil*, Butyrospermum parkii (Shea) butter*, Prunus dulcis (Sweet almond) oil*, Cera alba (Bees wax)*, Theobroma cacao (Cocoa) seed butter*, Tocopherol (Vitamin E). *Organically grown ingredients Certified 99.8% organic by The Soil Association, Bristol, UK</p> <p>Indications for use: A personal lubricant, for vaginal and penile application, intended to moisturise and lubricate, to enhance the ease and comfort of intimate sexual activity and supplement the body's natural lubrication. YES OB plant-oil based Personal Lubricant is not compatible with natural rubber latex, polyurethane or polyisoprene condoms.</p> <p>Caution: This device is not a contraceptive or a spermicide.</p> <p>Warning: If irritation or discomfort occurs, discontinue use and see a doctor.</p> <p>Please read full details & directions for use inside.</p> <p>MADE IN BRITAIN APPROVED CE 0088</p> | <p>PLANT-OIL BASED PERSONAL LUBRICANT</p> <p>YES OB</p> <p>ORGANIC personal lubricant</p> <p>GUARANTEED 100% PURE & NATURAL</p> <p>Manufactured for Biotech Lubricants Ltd, Petersfield, GU31 4AT, UK</p> <p>24/7 care line +44 (0)8456 448 813 Email hello@yesyesyes.org</p> <p>www.yesyesyes.com</p> <p>Yes and the Yes Purity Mark are trademarks of the Yes Group.</p> | <p>YES OB</p> <p>ORGANIC personal lubricant</p> <p>GUARANTEED 100% PURE & NATURAL</p> <p>YES</p> <p>40ml 1.4fl oz e</p> <p></p> |
|--|---|---|

YES[®] oil-based 40 ml / 1.4 fluid ounce tube carton label.

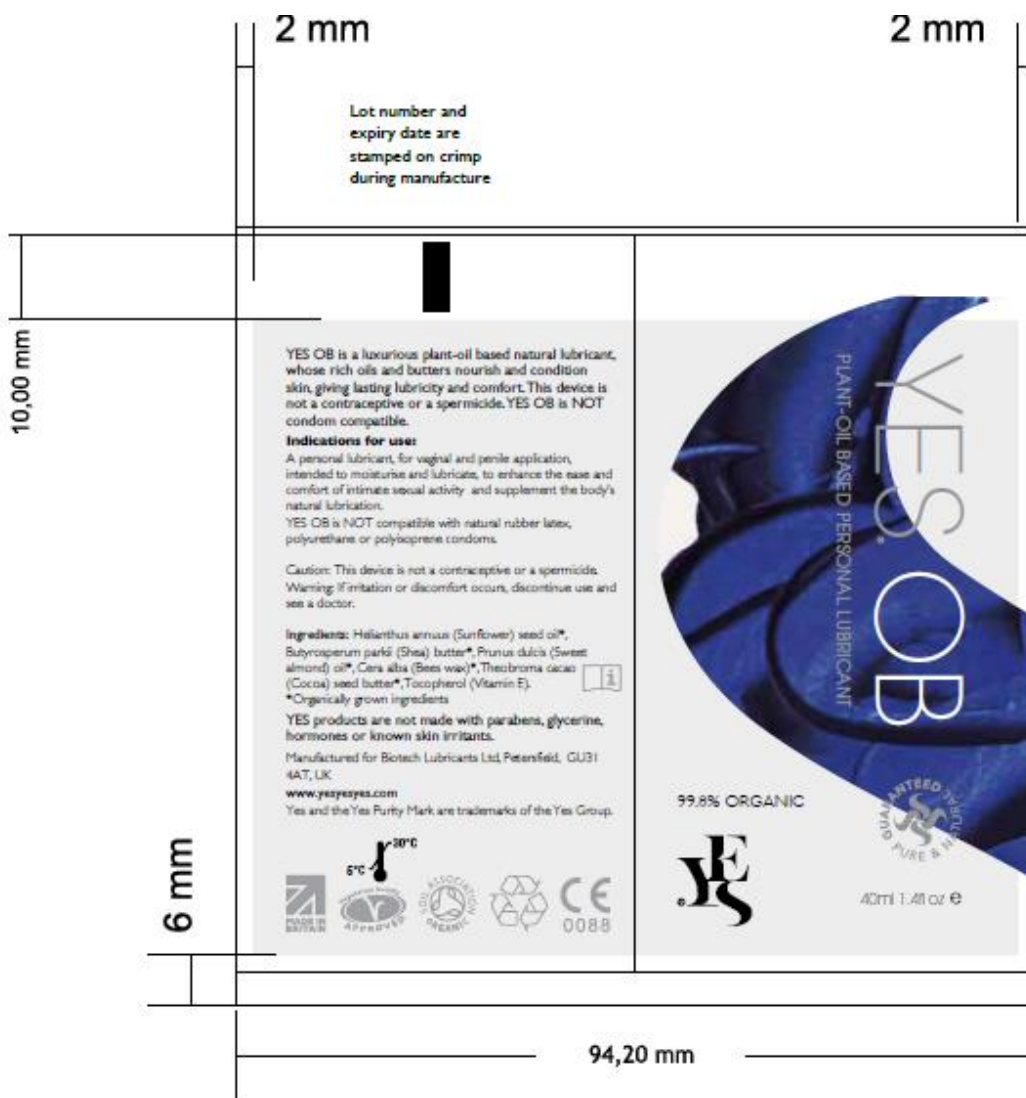


40ml Carton Final Draft

YES® oil-based 40 ml / 1.4 fluid ounce tube label (Zoom View of Principal Display Panel).

| | |
|---|---|
| <p>YES OB is a luxurious plant-oil based natural lubricant, whose rich oils and butters nourish and condition skin, giving lasting lubricity and comfort. This device is not a contraceptive or a spermicide. YES OB is NOT condom compatible.</p> <p>Indications for use: A personal lubricant, for vaginal and penile application, intended to moisturise and lubricate, to enhance the ease and comfort of intimate sexual activity and supplement the body's natural lubrication. YES OB is NOT compatible with natural rubber latex, polyurethane or polyisoprene condoms.</p> <p>Caution: This device is not a contraceptive or a spermicide. Warning: If irritation or discomfort occurs, discontinue use and see a doctor.</p> <p>Ingredients: Helianthus annuus (Sunflower) seed oil*, Butyrosperum parkii (Shea) butter*, Prunus dulcis (Sweet almond) oil*, Cera alba (Bees wax)*, Theobroma cacao (Cocoa) seed butter*, Tocopherol (Vitamin E). </p> <p>*Organically grown ingredients</p> <p>YES products are not made with parabens, glycerine, hormones or known skin irritants.</p> <p>Manufactured for Biotech Lubricants Ltd, Petersfield, GU31 4AT, UK www.yesyesyes.com Yes and the Yes Purity Mark are trademarks of the Yes Group.</p> <p>    </p> |  <p>PLANT-OIL BASED PERSONAL LUBRICANT</p> <p>YES OB</p> <p>99.8% ORGANIC</p> <p></p> <p></p> <p>40ml 1.4fl oz e</p> |
|---|---|

YES® oil-based 40 ml / 1.4 fluid ounce tube label.



YES® Vaginal Moisturizer 100 ml / 3.4 fluid ounce tube carton label (Zoom View of Principal Display Panel).

YES VM WATER BASED NATURAL, LONG-LASTING VAGINAL MOISTURISING GEL

- relieves vaginal atrophy and dryness
- alleviates irritation, itching and burning
- moisturises and soothes dry and sensitive vaginal tissues
- pH balanced iso-tonic gel for the vagina
- no fragrances, colour, taste or residue
- gynaecologist recommended (see website)
- hypoallergenic formulated to minimise the risk of allergies

YES products are not made with parabens, glycerine, hormones or known skin irritants.

Ingredients: Aqua (water), Linum usitatissimum (Flax) Extract*, Aloe barbadensis leaf juice powder (Aloe vera)*, Ceratonia siliqua (Locust bean gum)*, Cyamopsis tetragonolobus (Guar gum)*, Sodium chloride, Xanthan gum, Citric acid, Potassium sorbate, Phenoxethanol.

*Organically grown ingredients
 Certified 95% organic by The Soil Association, Bristol, UK





MOISTURISING GEL

YES®

GUARANTEED NATURAL PURE & NATURAL

ORGANIC
100ml 3.4 fl oz e



polyurethane or polyisoprene condoms.

Caution: This device is not a contraceptive or a spermicide.

Warning: If irritation or discomfort occurs, discontinue use and see a doctor.

Please read full details & directions for use inside.






YES® is proud to be planet friendly. All our packaging is recyclable, sustainably sourced where available and all our products are certified organic.

Protected by International Patents

Manufactured for Biotech Lubricants LTD Ltd, Petersfield, GU31 4AT, UK

24/7 care line +44 (0)8456 448 813
 Email hello@yesyesyes.org

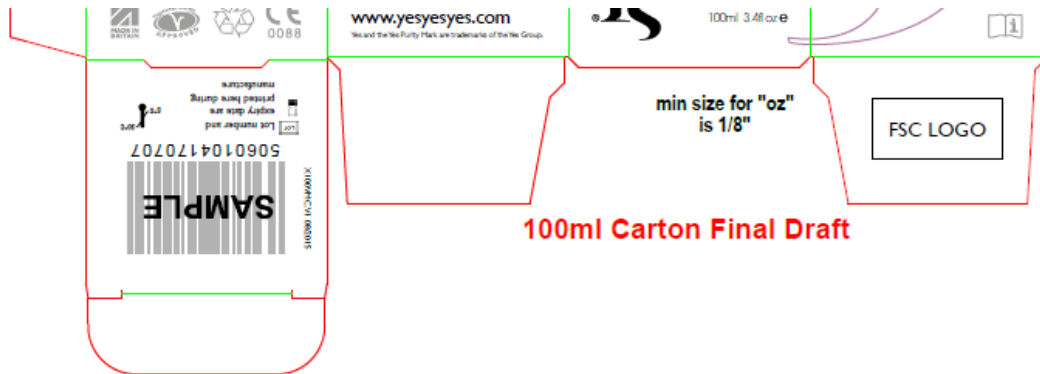
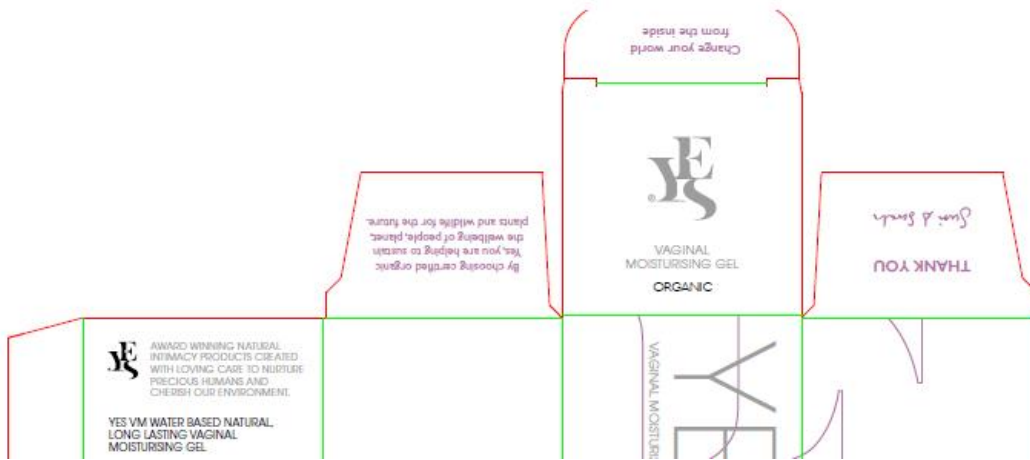
www.yesyesyes.com

Yes and the Yes Purity Mark are trademarks of the Yes Group.

Text replaced as indicated below

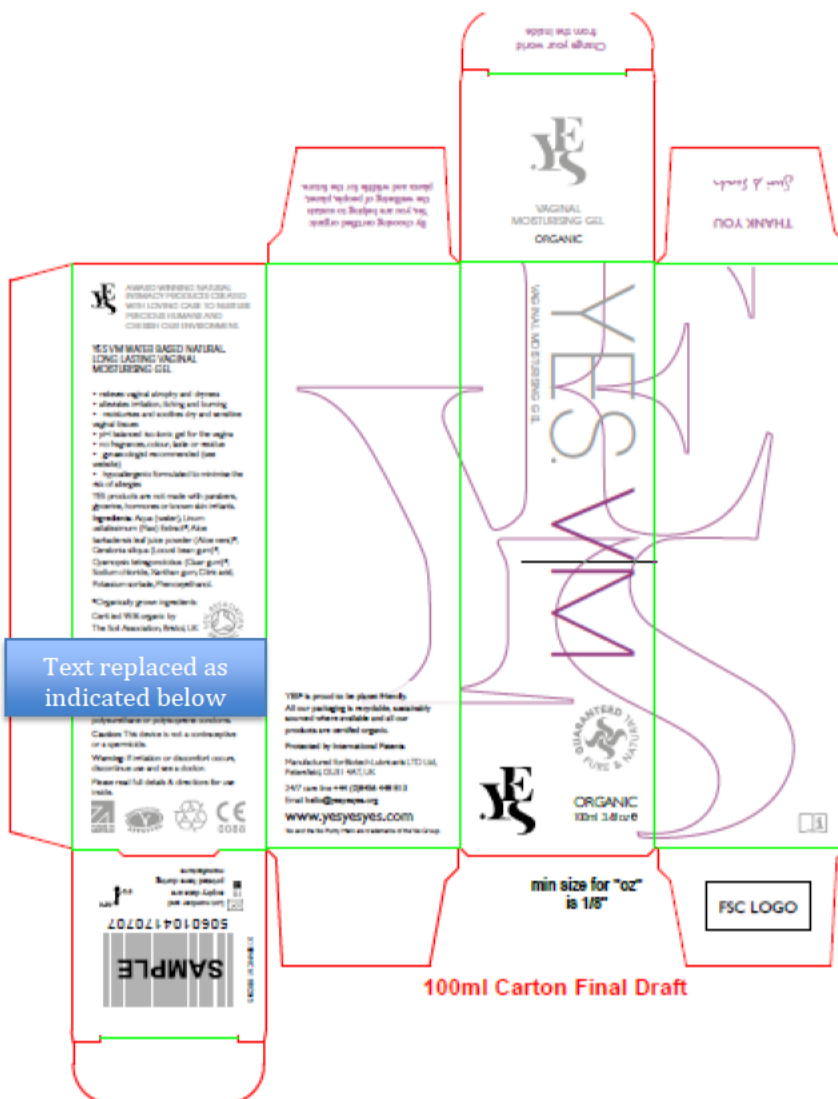
Indications for Use: YES® Vaginal Moisturizer is a personal lubricant, for vaginal and penile application, intended to moisturize and lubricate, to enhance the ease and comfort of intimate sexual activity and supplement the body's natural lubrication. YES® Vaginal Moisturizer is compatible with natural rubber latex and polyisoprene condoms. This product is not compatible with polyurethane condoms

YES® Vaginal Moisturizer 100 ml / 3.4 fluid ounce tube carton label. (View of top and bottom of carton).



100ml Carton Final Draft

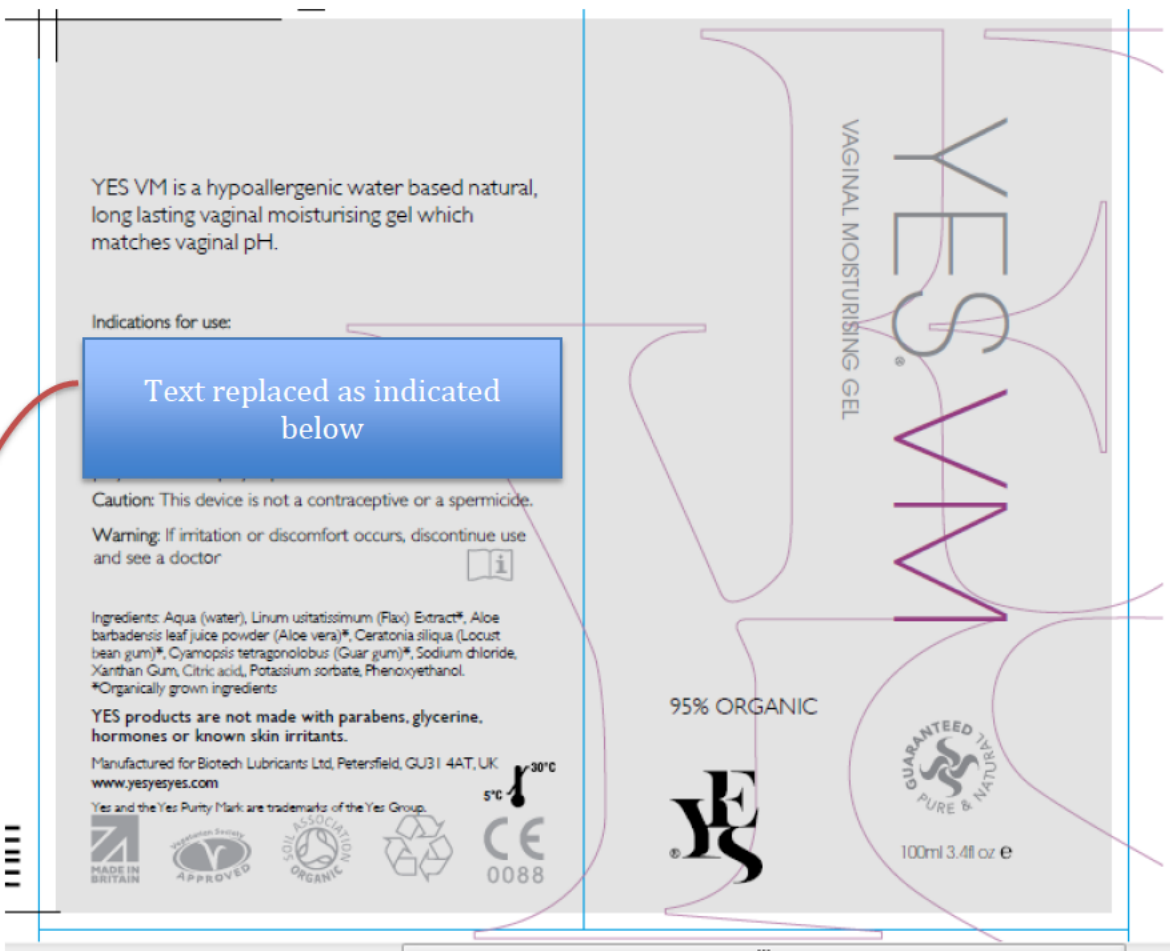
YES® Vaginal Moisturizer 100 ml / 3.4 fluid ounce tube carton label.



Text replaced as indicated below

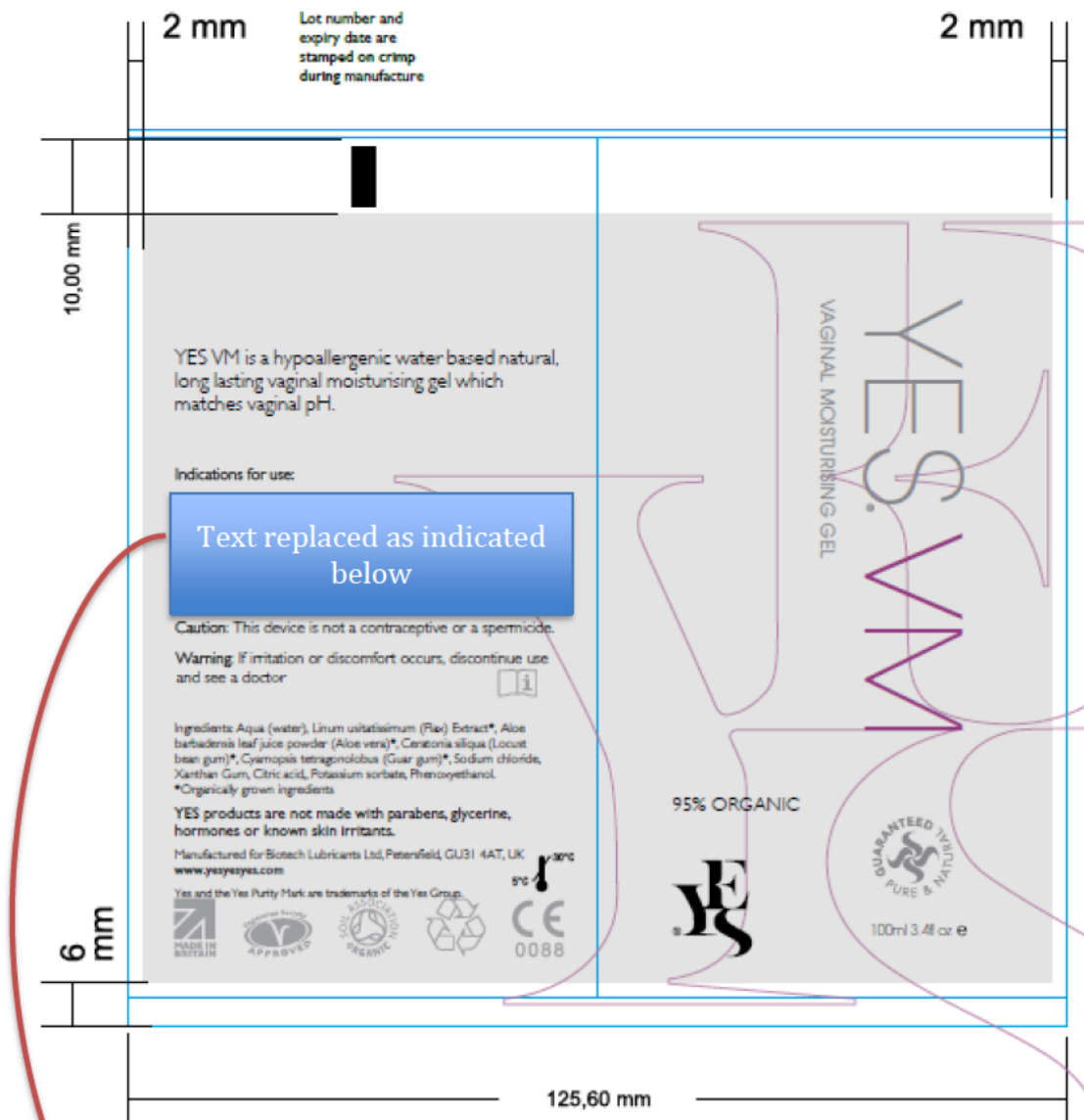
Indications for Use: YES® Vaginal Moisturizer is a personal lubricant, for vaginal and penile application, intended to moisturize and lubricate, to enhance the ease and comfort of intimate sexual activity and supplement the body's natural lubrication. YES® Vaginal Moisturizer is compatible with natural rubber latex and polyisoprene condoms. This product is not compatible with polyurethane condoms

YES® Vaginal Moisturizer 100 ml / 3.4 fluid ounce tube label (Zoom View of Principle Display Panel).



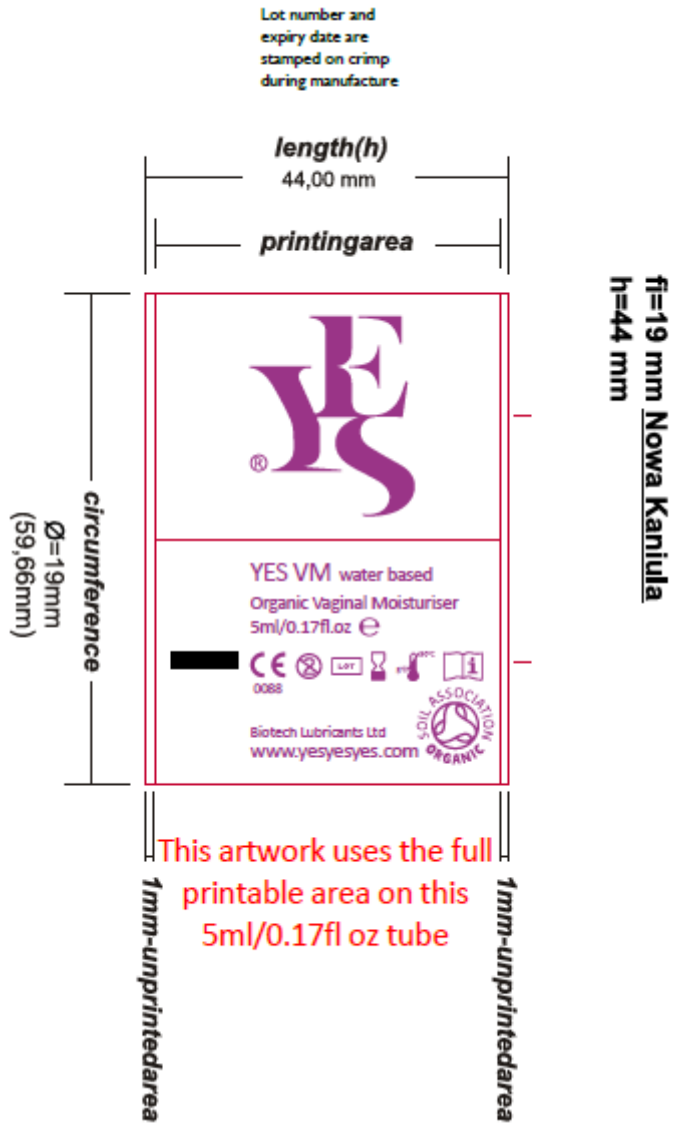
Indications for Use: YES® Vaginal Moisturizer is a personal lubricant, for vaginal and penile application, intended to moisturize and lubricate, to enhance the ease and comfort of intimate sexual activity and supplement the body's natural lubrication. YES® Vaginal Moisturizer is compatible with natural rubber latex and polyisoprene condoms. This product is not compatible with polyurethane condoms

YES® Vaginal Moisturizer 100 ml / 3.4 fluid ounce tube label.



Indications for Use: YES® Vaginal Moisturizer is a personal lubricant, for vaginal and penile application, intended to moisturize and lubricate, to enhance the ease and comfort of intimate sexual activity and supplement the body's natural lubrication. YES® Vaginal Moisturizer is compatible with natural rubber latex and polyisoprene condoms. This product is not compatible with polyurethane condoms

YES® Vaginal Moisturizer 5 ml / 0.17 fluid ounce applicator tube label.



YES® Vaginal Moisturizer 5 ml / 0.17 fluid ounce applicator tube carton label (Zoom View of Principal Display Panel).

WITH LOVING CARE TO NURTURE
PRECIOUS HUMANS AND
CHERISH OUR ENVIRONMENT.

YES VM WATER BASED IS A NATURAL, LONG LASTING
VAGINAL MOISTURISING GEL IN SIX CONVENIENT PRE-FILLED
SINGLE USE APPLICATORS

- enables discreet and hygienic delivery of the right amount of moisturising gel inside the vagina
- relieves vaginal atrophy and dryness
- alleviates irritation, itching and burning
- moisturises and soothes dry and sensitive vaginal tissues
- pH balanced iso-tonic gel for the vagina
- no fragrances, colour, taste or residue
- recommended by gynaecologists (see website)
- hypoallergenic: formulated to minimise the risk of allergies

YES products are not made with parabens, glycerine, hormones or known skin irritants.

Ingredients: Aqua (water), Linum usitatissimum (Flax) Extract*, Aloe barbadensis leaf juice powder (Aloe vera)*, Ceratonia siliqua (Locust bean gum)*, Cyamopsis tetragonolobus (Guar gum)*, Sodium chloride, Xanthan gum, Citric acid, Potassium sorbate, Phenoxyethanol.
*Organically grown ingredients

Certified 95% organic by The Soil Association, Bristol, UK.

SOIL ASSOCIATION
ORGANIC

A 5ml applicator used every 2-3 days, is typically sufficient to maintain a moist, comfortable vagina

GUARANTEED PURE & NATURAL

YES® is proud to be planet friendly. All our packaging is recyclable, sustainably sourced where available and all our products are certified organic.

Protected by International Patents

Manufactured for Biotech Lubricants Ltd, Petersfield, GU31 4AT, UK

24/7 care line +44 (0)8456 448 813
Email hello@yesyesyes.org
www.yesyesyes.com

Yes and the Yes Purity Mark are trademarks of the Yes Group.

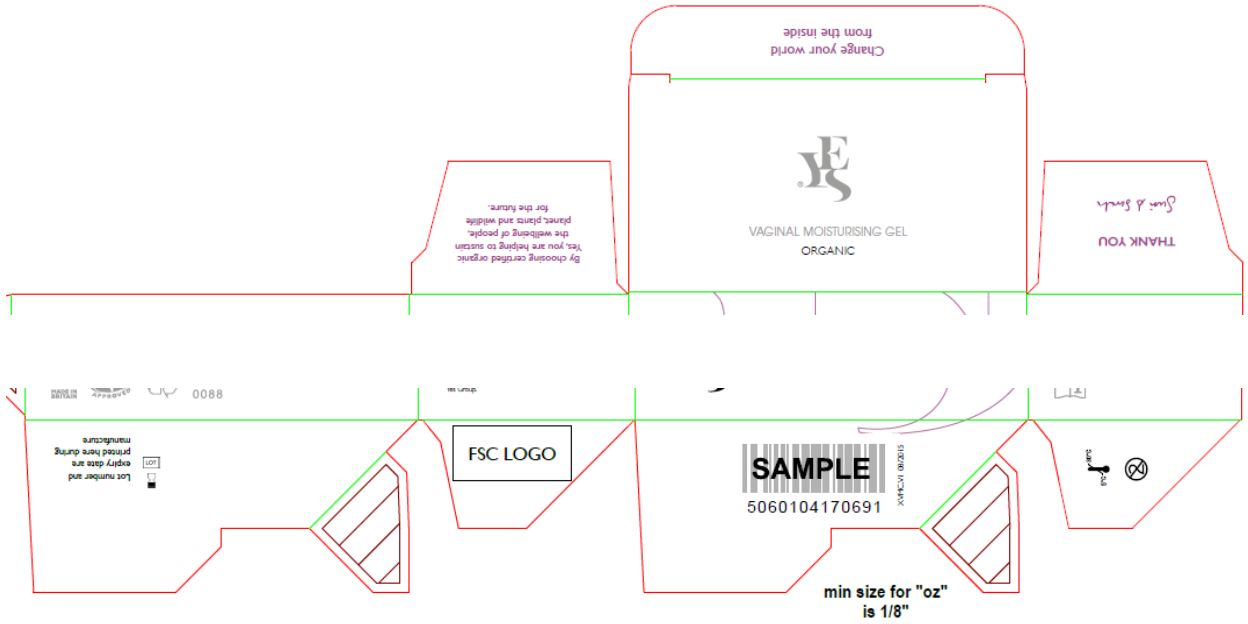
MADE IN BRITAIN APPROVED CE 0088

YES

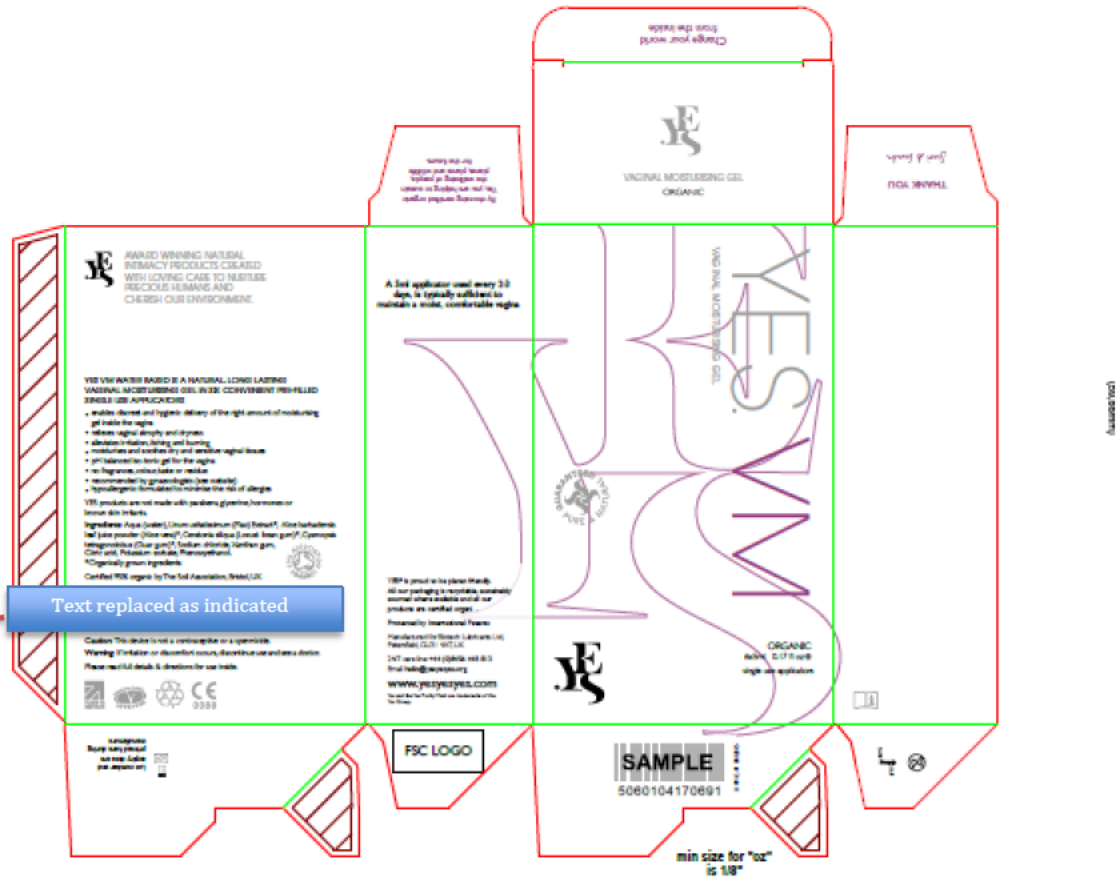
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Indications for Use: YES® Vaginal Moisturizer is a personal lubricant, for vaginal and penile application, intended to moisturize and lubricate, to enhance the ease and comfort of intimate sexual activity and supplement the body's natural lubrication. YES® Vaginal Moisturizer is compatible with natural rubber latex and polyisoprene condoms. This product is not compatible with polyurethane condoms

YES® Vaginal Moisturizer 5 ml / 0.17 fluid ounce applicator tube carton label (Top and bottom of carton).



YES® Vaginal Moisturizer 5 ml / 0.17 fluid ounce applicator tube carton label.



Indications for Use: YES® Vaginal Moisturizer is a personal lubricant, for vaginal and penile application, intended to moisturize and lubricate, to enhance the ease and comfort of intimate sexual activity and supplement the body's natural lubrication. YES® Vaginal Moisturizer is compatible with natural rubber latex and polyisoprene condoms. This product is not compatible with polyurethane condoms

Instructions For Use - YES® Oil-based Personal Lubricant. (Page 1).

Final Draft YES OB IFU - OB_IFU_EN V1.pdf

YES® OB plant-oil based personal lubricant

Description

- Alleviates vaginal dryness
- Natural plant-based intimate lubricant
- For lasting lubricity and glide
- Dual function: outstanding lubrication and body massage
- With a velvety sensuous feel
- The natural plant-based alternative to silicone lubricants
- No known side effects
- NOT compatible with condoms
- YES OB is not made with glycerin or petrochemicals or parabens
- Safe for use with silicone toys but not latex compatible
- Plant oils and butters condition skin, no need to wash off
- Can be applied freely and generously, according to the body's needs

Ingredients

YES® OB: Helianthus annuus (Sunflower) seed oil*, Butyrospermum parkii (Shea butter)*, Prunus dulcis (Sweet almond) oil*, Cera alba (Bees wax)*, Theobroma cacao (Cocoa) seed butter*, Tocopherol (Vitamin E).

* Organically grown ingredients

Directions for use

YES® OB assists your lovemaking by enabling penetration, increasing pleasurable glide and sensation. Warm YES® OB in your hands to ensure a smooth velvety quality. Apply where desired, externally and internally, to self and partner.

Apply a layer of YES® OB with YES® WB on top for a new dimension in lasting lubrication.

Replace cap when not in use. Store in a cool dry place, not in direct sunlight.

Every care has been taken to ensure the safety of this product.

Caution: This device is not a contraceptive or a spermicide.

Warning: If irritation or discomfort occurs, discontinue use and see a doctor.

Indications for Use: YES® OB is a personal lubricant, for vaginal and penile application, intended to moisturize and lubricate, to enhance the ease and comfort of intimate sexual activity and supplement the body's natural lubrication.

YES® OB is NOT compatible with condoms.



OB_IFU_EN V1

© Yes Syzygy 2016

Instructions For Use - YES® Oil-based Personal Lubricant. (Page 2).

Pleasure Tip: Double Glide apply a layer of YES® OB with YES® WB on top for a new dimension in lasting lubrication

My YOB feels gritty: Some separation can be expected as these natural oils and butters are temperature sensitive, it is easily reversed. If YES OB feels gritty, warm the tube until it is all liquid (upside down in mug of warm water), shake to mix and cool it quickly, popping it in the fridge for 30 minutes works well.

Why Certified Organic?

When you buy something that is certified organic, not only are you making the best choice for your own well being, your purchase is also supporting a system that respects human health, animals, wildlife and the environment.

Certified organic products meet stringent standards and organic certification is your assurance that our ingredients and products have been grown and processed according to strict procedures. Production, processing, distribution and sales are monitored to maintain the finest organic and ecological integrity.

Packaging and Recycling

YES® aims to minimise the environmental impacts of all our packaging. So please do your part. All our bottles are MDPE. Polyethylene (MDPE) is the most often accepted plastic by recycling centres. The cartons, boxes and package inserts can all be recycled.

100% Guarantee: YES® products are 100% satisfaction guaranteed. Please contact us by phone or email if you have any concerns or questions.

Certified Organic by: The Soil Association, Bristol, UK.

Approved by: The Vegetarian Society

Manufactured in Great Britain for

BioTech Lubricants Ltd.

Trademark House, Ramshill

Petersfield, Hampshire. GU31 4AT, UK

Contact us

USA/Canada Toll Free: 1-888-777-0125

UK Free Phone: 0-800-978-8525

All other countries: +44 845 094 1141

Website: www.yesyesyes.org

Email: hello@yesyesyes.org



OB_IFU_EN V1

© Yes Syzygy 2016

Instructions For Use - YES[®] Oil-based Personal Lubricant. (Zoom View of Directions for Use).

Ingredients

YES[®] OB: Helianthus annuus (Sunflower) seed oil*, Butyrospermum parkii (Shea butter)*, Prunus dulcis (Sweet almond) oil*, Cera alba (Bees wax)*, Theobroma cacao (Cocoa) seed butter*, Tocopherol (Vitamin E).

* Organically grown ingredients

Directions for use

YES[®] OB assists your lovemaking by enabling penetration, increasing pleasurable glide and sensation. Warm YES[®] OB in your hands to ensure a smooth velvety quality. Apply where desired, externally and internally, to self and partner.

Apply a layer of YES[®] OB with YES[®] WB on top for a new dimension in lasting lubrication.

Replace cap when not in use. Store in a cool dry place, not in direct sunlight.

Every care has been taken to ensure the safety of this product.

Caution: This device is not a contraceptive or a spermicide.

Warning: If irritation or discomfort occurs, discontinue use and see a doctor.

Pleasure Tip: Double Glide apply a layer of YES[®] OB with YES[®] WB on top for a new dimension in lasting lubrication

Indications for use:

A personal lubricant, for vaginal and penile application, intended to moisturise and lubricate, to enhance the ease and comfort of intimate sexual activity and supplement the body's natural lubrication.

YES OB is NOT compatible with condoms

Instructions For Use - YES® Water-based Personal Lubricant. (Page 1).

Final Draft YES WB IFU - (English YWB72C) YES
WB72C_IFU_EN V3 Final Draft.pdf

1

YES® WB water based personal Lubricant

Description

- Alleviates vaginal dryness
- Natural plant-based intimate moisturiser and lubricant
- Lubricates vaginal and penile tissues
- Compatible with latex and polyisoprene condoms. Not compatible with polyurethane condoms
- pH balanced to match the typical vaginal environment
- Guaranteed purity through its certified organic status
- Reassuringly realistic feel
- YES WB is not made with glycerin or petrochemicals or parabens
- Can be used freely and frequently
- No known side effects
- Neither a spermicide nor a contraceptive
- Certified Organic by the Soil Association (UK)

Description: YES® WB in applicators

- The discreet & convenient way to deliver lubrication & hydration in the right amount to the right place
- YES® WB in applicators is designed to be used before love making or at any time to easily allow the moisture to be distributed throughout the vagina
- Pre-filled for single use

Ingredients

Aqua (Water), Aloe barbadensis (Aloe vera) leaf juice powder*, Linum usitatissimum (Flax) seed extract*, Cyamopsis tetragonolobus (Guar Gum)*, Ceratonia siliqua (Locust Bean Gum)*, Xanthan gum, Sodium chloride, Potassium sorbate, Citric acid, Phenoxyethanol.

* Organically grown ingredients

Internationally Patented

Directions for use

YES® WB assists your love-making by: enabling penetration, easing vaginal and penile dryness, increasing pleasurable glide and sensation, and promoting the day-to-day comfort of intimate tissues. May be applied externally and internally, to self and partner. For discreet use, may be applied in advance of intercourse. Use generously as required (make sure you use enough). Do re-apply, as YES® can be used freely and frequently according to the body's own needs.

Replace cap when not in use. Store in a cool dry place, not in direct sunlight.

Every care has been taken to ensure the safety of this product. Stop use if any irritation occurs.

Directions for use: YES® WB in applicators

Hold the applicator at the wide end, shake the contents down to the narrow end, before insertion.

Remove the cap, by twisting and pulling it off.

To apply, insert the narrow end of the applicator only into the vagina. You can lie down, stand or sit to insert the applicator - whichever position is most comfortable.

Once inserted squeeze the wide end, several times, to ensure the contents are released.



WB72C_IFU_EN V3

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Instructions For Use - YES® Water-based Personal Lubricant. (Page 2).

2

Continue to squeeze the applicator, to extract it and discard. Both cap and applicator are made from recyclable materials, please recycle where possible.

Dosage, to enhance pleasure and ease in love-making: A 5ml applicator is typically sufficient, but more may be used if required.

Dosage, for the alleviation of discomfort: A 5ml applicator, used every 2–3 days, is typically sufficient to maintain comfort.

Caution: This device is not a contraceptive or a spermicide.

Warning: If irritation or discomfort occurs, discontinue use and see a doctor.

Indications for Use: YES® WB is a personal lubricant, for vaginal and penile application, intended to moisturize and lubricate, to enhance the ease and comfort of intimate sexual activity and supplement the body's natural lubrication. YES® WB is compatible with natural rubber latex and polyisoprene condoms. This product is not compatible with polyurethane condoms

Why Certified Organic?

When you buy something that is certified organic, not only are you making the best choice for your own well being, your purchase is also supporting a system that respects human health, animals, wildlife and the environment.

Certified organic products meet stringent standards and organic certification is your assurance that our ingredients and products have been grown and processed according to strict procedures. Production, processing, distribution and sales are monitored to maintain the finest organic and ecological integrity.

Packaging and Recycling

YES® aims to minimise the environmental impacts of all our packaging. So please do your part. All our bottles are MDPE. Polyethylene (MDPE) is the most often accepted plastic by recycling centres. The cartons, boxes and package inserts can all be recycled.

100% Guarantee: YES® products are 100% satisfaction guaranteed. Please contact us by phone or email if you have any concerns or questions.

Certified Organic by: The Soil Association, Bristol, UK.

Approved by: The Vegetarian Society

Manufactured in Great Britain for

BioTech Lubricants Ltd.
Petersfield, Hampshire. GU31 4AT, UK

Contact us

USA/Canada Toll Free: 1-888-777-0125

UK Free Phone: 0-800-978-8525

All other countries: +44 845 094 1141

Website: www.yesyesyes.org

Email: hello@yesyesyes.org



WB72C_IFU_EN V3

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Instructions For Use - YES[®] Vaginal Moisturizer (Page 1).

Please read this leaflet carefully before use

YES. VM

YES VM water based organic Vaginal Moisturising gel uses a patented technology to provide natural, long-lasting moisture to dry vaginal mucosa

YES VM is available in 100ml tubes and packs of 6 pre-filled applicators

- Case studies show that YES VM is fast-acting and long-lasting while replenishing intimate moisture safely and naturally
- **Indications for Use:** YES VM Vaginal Moisturizer is a personal lubricant, for vaginal and penile application, intended to moisturize and lubricate, to enhance the ease and comfort of intimate sexual activity and supplement the body's natural lubrication. YES VM Vaginal Moisturizer is compatible with natural rubber latex and polyisoprene condoms. This product is not compatible with polyurethane condoms

YES VM IFU V4 Final Draft

Provides symptomatic relief from:

- Vaginal dryness
- Vaginal Atrophy
- Itching
- Irritation, burning and soreness
- Dyspareunia

Temporary vaginal dryness can have various origins: after childbirth, when breastfeeding, and when taking oral contraceptives. Certain anti-depressants and anti-histamines can cause intimate dryness, as can extreme stress.

Ingredients

Water, Flax extract*, Aloe vera*, Locust bean gum*, Guar gum*, Sodium chloride, Xanthan gum, Potassium sorbate, Citric acid, Phenoxyethanol.

* Organically grown ingredients

95% organic

Protected by International Patents



- A soft, clear bio-adhesive gel
- **Discreet** no smell, taste, colour, stickiness or fallout. Close to the texture and feel of a woman's own lubrication
- **pH matched** to restore and stabilise the protective acidity of the intimate environment, supporting vaginal health
- **Hormone-free**
- **Free from** known mucosal irritants, and ingredients such as glycerine, petroleum products, parabens (hormone mimics) which can disrupt or compromise intimate health

- **Gentle and natural**, for even the most sensitive conditions
- Guaranteed purity through its certified organic status
- Safe for use with latex and polyisoprene condoms
- **Trusted** by Health Care Professionals and women to bring soothing, safe and welcome relief to the debilitating symptoms of menopausal dryness
- A non-hormonal natural alternative to synthetic chemical intimate moisturisers

www.yesyesyes.org

Manufactured in Great Britain for

Biotech Lubricants Ltd
Petersfield
UK

YES VM is the registered trademark of The YES YES Company Ltd

24/7 telephone order lines

USA/Canada Toll Free:
1-888-777-0125

UK Free Phone:
0-800-978-8525

All other countries:
+ 44 (0) 3450 941 141

Certified Organic by: The Soil Association, Bristol, UK

Approved by: The Vegetarian Society

100% Guarantee: YES products are 100% satisfaction guaranteed, please contact us by phone or email if you have any concerns or questions.

For more info, call or visit:

Careline: + 44 (0) 3450 941 141

Email: hello@yesyesyes.org

www.yesyesyes.org



Instructions For Use - YES[®] Vaginal Moisturizer (Page 2).

Directions for use — YES VM in Pre-filled Applicators

When you want to reach higher in the vagina, this product offers you a discreet and convenient way to deliver lubrication and moisture in the right amount to the source of discomfort.

Directions for use — YES VM in 100ml tube

This product is a soft clear gel, easy to dispense and distribute, and is designed for finger application, which allows you to decide how much you want to put where. Simply squeeze the soft gel on to your hand and use your finger tips to apply the desired amount to the vaginal tissues. YESVM may also be used to moisturise the labia. (No applicator included)

1 Shake down the applicator



2 Twist off the top



The applicator can be inserted from three different positions, according to personal ease and preference:

How to insert the applicator when sitting



How to insert the applicator when standing



How to insert the applicator when lying



When inserted, squeeze the end of the applicator several times to release product high into the vagina



When emptied, squeeze the end of the applicator to withdraw it safely



Please dispose of the applicator tube and top by recycling



YES VM Frequency of use

A 5ml application used every 2–3 days, is typically sufficient to maintain a moist, comfortable vagina.

Cases of severe dryness will benefit from more frequent use (1 application every 1–2 days) initially until improvement is gained.

If using to alleviate painful sex, apply as required before intercourse and to ensure comfort afterwards.

Iso-tonic*: the iso-tonic / iso-osmotic nature of YES VM is carefully matched to human tissues.

Why is this balance important? Products which are hyper-tonic (often containing chemicals such as glycerine and glycols) can cause irritation to intimate tissues.

By being iso-tonic / iso-osmotic*, YES VM protects against such irritation.

*for more information, see website

Storage: Keep out of direct sunlight. Store between 5–30°C. Use before expiry date.

Caution: This device is not a contraceptive or a spermicide

Warning: If irritation or discomfort occurs, discontinue use and see a doctor.

The award-winning YES range includes scientifically advanced, certified organic lubricants, washes and moisturisers for intimate use and the promotion of sexual health.

Pioneering the use of natural, pure ingredients for intimate use, YES products are deceptively discreet in presentation yet are based on complex science and provide essential lubrication and moisturisation to meet a variety of usage needs.


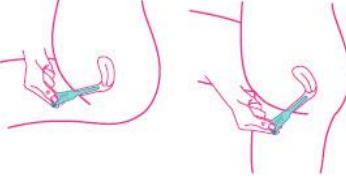
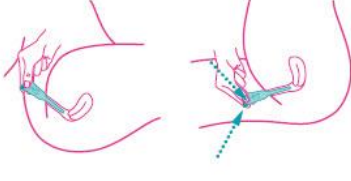



Discover all the products in our range at:

www.yesyesyes.org

Instructions For Use - YES® Water-based Personal Lubricant in Applicators (Page 1).

| | | | |
|---|---|--|--|
| <p>Please read this leaflet carefully before use</p>  <p>Yes® water-based organic Intimate lubricant and moisturiser in applicators uses a patented technology to provide natural, long-lasting moisture to dry vaginal mucosa</p> | <div style="border: 1px solid black; padding: 5px; text-align: center;"> <p>Available on prescription in the UK from 1st March 2014</p> </div> <p>Provides symptomatic relief from:</p> <ul style="list-style-type: none"> ◆ Vaginal Atrophy ◆ Intimate dryness ◆ Itching ◆ Irritation, burning and soreness ◆ Dyspareunia <div style="border: 1px solid black; padding: 5px; text-align: center;"> <p>A 5ml applicator used every 2-3 days, is typically sufficient to maintain a moist, comfortable vagina</p> </div> | <ul style="list-style-type: none"> ◆ A soft, clear gel ◆ Discreet no smell, taste, colour, stickiness or fallout. Close to the texture and feel of a woman's own lubrication ◆ pH matched to the protective acidity of the intimate environment, supporting vaginal health ◆ Hormone-free ◆ Free From. YES Products are not made with known mucosal irritants such as glycerine, or petroleum products, parabens (hormone mimics) and other concerning chemicals | <p>Manufactured in Great Britain for</p> <p>TBioTech Lubricants Ltd., Petersfield, Hampshire. GU31 4AT, UK</p> <p>Yes® is the registered trademark of The Yes Yes Company Ltd</p> <p>24/7 telephone order lines</p> <p>UK Free Phone: 0-800-978-8525</p> <p>USA/Canada Toll Free: 1-888-777-0125</p> <p>All other countries: +44 845 094 1141</p> |
| <ul style="list-style-type: none"> ◆ The discreet and convenient way to deliver lubrication and moisture in the right amount to the source of discomfort ◆ Case studies show that Yes water-based is fast-acting and long-lasting while replenishing intimate moisture safely and naturally ◆ Temporary vaginal dryness can have various origins: after childbirth, when breastfeeding, and when taking oral contraceptives. Certain anti-depressants and anti-histamines can cause intimate dryness, as can extreme stress. | <p>Indications for Use:</p> <p>YES® water-based Personal Lubricant is a personal lubricant, for vaginal and penile application, intended to moisturize and lubricate, to enhance the ease and comfort of intimate sexual activity and supplement the body's natural lubrication. YES® water-based Personal Lubricant is compatible with natural rubber latex and polyisoprene condoms.</p> <p>This product is not compatible with polyurethane condoms</p> | <ul style="list-style-type: none"> ◆ Gentle and natural, for even the most sensitive conditions ◆ Guaranteed purity through its certified organic status ◆ Yes water-based is compatible with latex and polyisoprene condoms. Not compatible with polyurethane condoms. ◆ Trusted by Health Care Professionals and women to bring soothing, safe and welcome relief to the debilitating symptoms of menopausal dryness ◆ Pre-filled for single use ◆ A non-hormonal natural alternative to chemical intimate moisturisers | <p>Certified Organic by: The Soil Association, Bristol, UK</p> <p>Approved by: The Vegetarian Society</p> <p>100% Guarantee: Yes products are 100% satisfaction guaranteed, please contact us by phone or email if you have any concerns or questions.</p> <p>For more info, call or visit:</p> <p>Careline: 08456 44 88 13</p> <p>Email: hello@yesyesyes.org</p> <p>www.yesyesyes.org</p>  |

Instructions For Use - YES® Water-based Personal Lubricant in Applicators (Page 2).

| | | | |
|---|---|---|--|
| <p>Directions for use</p> <p>1 Shake down the applicator</p> <p>2 Twist off the top</p>  | <p>The applicator can be inserted from three different positions, according to personal ease and preference:</p> <p>How to insert the applicator when sitting</p> <p>How to insert the applicator when standing</p>  | <p>How to insert the applicator when lying</p> <p>When inserted, squeeze the end of the applicator several times to release product high into the vagina</p>  | <p>When emptied, squeeze the end of the applicator to withdraw it safely</p> <p>Please dispose of the applicator tube and top by recycling</p>  |
| <p>Frequency of use</p> <p>One 5ml applicator dose intravaginally every 2-3 days.</p> <p>Cases of severe dryness will benefit from more frequent use (1 applicator every 1-2 days) initially until improvement is gained.</p> <p>If using to alleviate painful sex, apply as required before intercourse and to ensure comfort afterwards.</p> <p>© Yes Syzygy 2017</p> <p>WB72C_NHS_APPS_IFU_V3</p> | <p>Ingredients</p> <p>Water, Aloe vera*, Flax extract*, Guar Gum*, Locust Bean Gum*, Xanthan Gum, Citric acid, Potassium sorbate, Sodium chloride, Phenoxyethanol.</p> <p>* Organically grown ingredients</p> <p>96% organic</p> <p>Protected by International Patents</p>  | <p>Caution</p> <p><i>Do not use if applicator tab is damaged or broken</i></p> <p><i>This device is not a contraceptive or a spermicide.</i></p> <p><i>Warning: If irritation or discomfort occurs, discontinue use and see a doctor.</i></p> <p><i>Observe the best before date</i></p> |  <p>Award-winning Yes® provides scientifically advanced, certified organic, lubricants and moisturisers for intimate use and the promotion of sexual health.</p> <p>Pioneering the use of natural, pure ingredients for intimate use, Yes products are deceptively discreet in presentation yet based on complex science and provide essential lubrication and moisturisation to meet a variety of usage needs. Discover all the products in our range at:</p> <p>www.yesyesyes.org</p> |

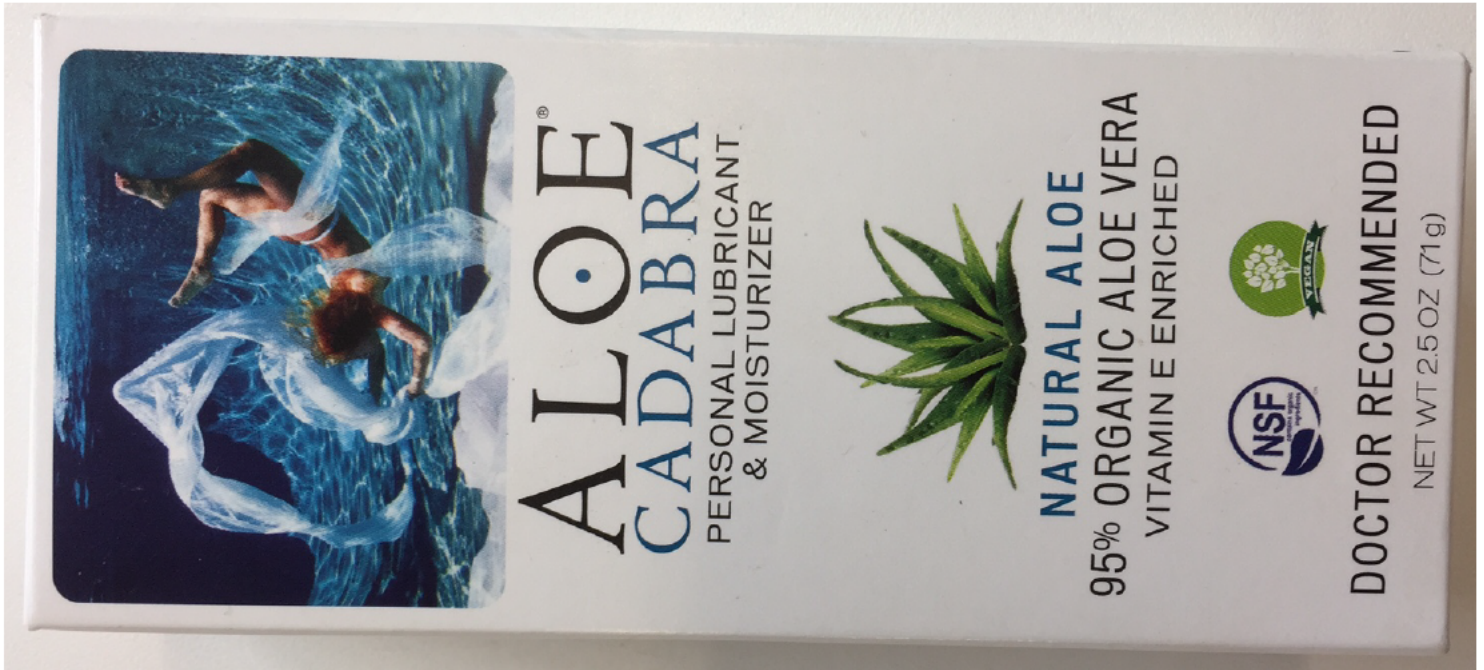
Section 13: Proposed Labeling / Predicate Device(s) Labels**Aloe Cadabra Personal Lubricants**

| Description | Size | Container Type | Model No. |
|--|-------------|-----------------------|------------------|
| Aloe Cadabra Personal Lubricant – Tahitian Vanilla | 2.5 oz. | Carton | Unknown |
| Aloe Cadabra Personal Lubricant – Tahitian Vanilla | 2.5 oz. | Bottle | Unknown |
| Aloe Cadabra Personal Lubricants | n/a | Website | n/a |

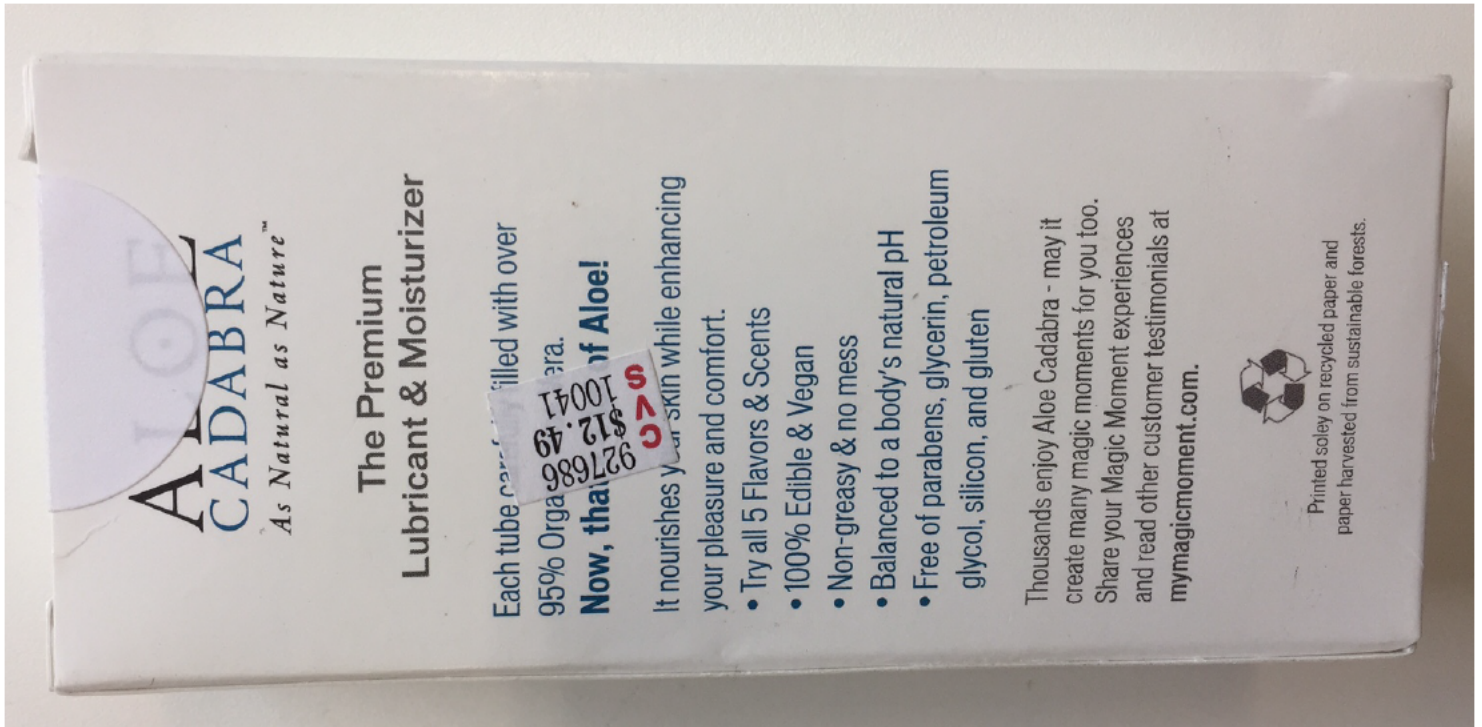
LifeStyles Luxe Personal Lubricants

| Description | Size | Container Type | Model No. |
|--|-------------|-----------------------|------------------|
| LifeStyles Luxe Premium Personal Lubricant | 3.5 oz. | Carton | Unknown |
| LifeStyles Luxe Premium Personal Lubricant | 3.5 oz. | Bottle | Unknown |
| LifeStyles Personal Lubricants | n/a | Website | n/a |

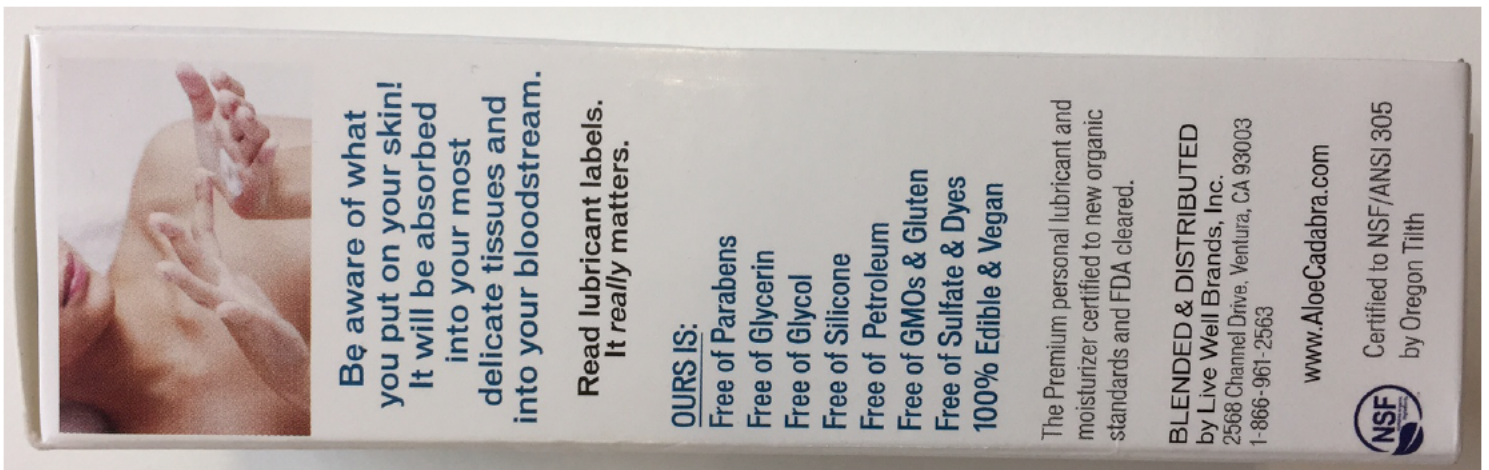
Aloe Cadabra Carton (front)



Aloe Cadabra Carton (back)



Aloe Cadabra Carton (side 1)



Aloe Cadabra Carton (side 2)



Aloe Cadabra Carton (top)



Aloe Cadabra Carton (bottom)



Aloe Cadabra Bottle (front)



Aloe Cadabra Bottle (back)



Aloe Cadabra Bottle (top)



Aloe Cadabra Website









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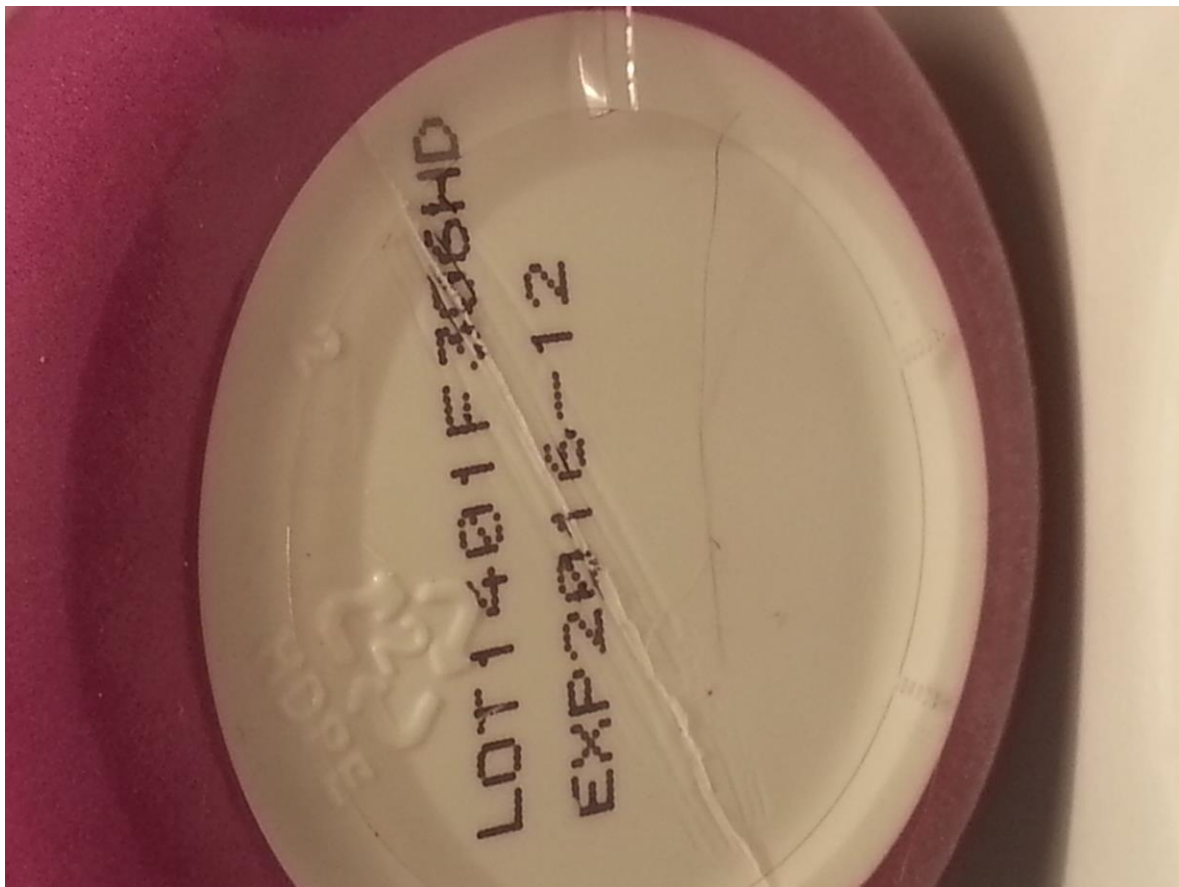
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LifeStyles Luxe Bottle (front)



Lifestyles Luxe Bottle (bottom)




Lifestyles Luxe Bottle (back)



Lifestyle Luxe – Carton/box



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Commentary

Condoms and condiments: compatibility and safety of personal lubricants and their use in Africa

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Abstract

Previous research on the use of personal lubricants for sexual intercourse is limited and has primarily focused on condom compatibility and breakage, with only recent limited assessment of lubricant safety and possible epidemiologic implications. This article discusses the global evidence of lubricant compatibility with latex condoms and biological safety of lubricants, as well as documentation of lubricant use and current guidelines for HIV prevention programming in Africa. Data on lubricant compatibility with condoms are less available than commonly realized, and many lubricant products may not have been thoroughly tested for safety due to flexible regulatory environments. Recent laboratory and study findings from microbicides research also suggest that some water-based lubricants may have safety issues. Some African populations are using several types of lubricants, especially oil-based petroleum jellies, and receive little evidence-based guidance. More research is needed from the medical community to guide prevention programming.

Keywords: lubricants; condoms; HIV prevention; Africa.

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Introduction

Among the vast catalogue of African condom legends, this author's favourite is a mythological experiment heard in Malawi 15 years ago. A young student reported that pouring *piri-piri* sauce – a popular spicy food sauce in Malawi – on a condom-sheathed penis would induce a burning sensation; hence proof that condoms have holes in them and cannot be trusted. This is symptomatic of most condom myths in Africa, which hypothesize inherent physical flaws in condoms themselves. But there is another hypothesis to the *piri-piri* experiment the student did not consider: Did the hot sauce itself weaken or damage the condom, therefore facilitating penetration of the latex barrier? Could it be possible that some myths in Africa result not of the *condom*, but of the *condiments* that are applied?

Table condiments aside, substances used during sexual intercourse can be applied for the purpose of lubricating the penis and the vagina or rectum in which it is inserted. This eases discomfort that may arise from dry friction during sex, and can increase pleasure or enjoyment. In Africa, however, most HIV prevention programmes focus little, if at all, on lubrication issues. Additionally, some marketing and packaging of government-distributed or socially marketed condoms do not strongly emphasize public advice on compatible lubricants.

Recent increased awareness of same-sex and anal sex practice in Africa has highlighted the lack of provision of personal lubricants [1,2]. Prevention programmes that provide lubricant supplies usually follow near-universally accepted recommendations that oil-based lubricants are to be avoided, and

only water-based products should be used with condoms [3,4]. But has the potential epidemiologic impact of lubricant use in Africa – condom or no condom – been adequately assessed? Towards answering this question, it is worthwhile to review the global evidence regarding the effect of lubricants on condom structural integrity and the biological safety of lubricant use, as well as the prevalence of lubricant use and current guidance for prevention programming in Africa.

Discussion

Effect of lubricants on latex condoms: global evidence

Two ways to measure the effect of lubricants on latex condoms have been documented in the medical literature. One method is to apply lubricants in a laboratory setting and conduct precisely measured mechanical strength or burst tests. The other is to recruit actual condom users and measure lubrication use and condom breakages, either within a prospective cohort or retrospectively among a cross-sectional sample. Strength or burst testing is perhaps the easiest to measure and observe, as it is done in a controlled laboratory setting. Associating lubricant use with condom breakage in study populations is more challenging, since this relies on self-reported data and can be confounded by other factors such as incorrect use or slippage.

Condoms are usually tested according to standardized guidelines, such as ISO 4074:2002 "Natural latex rubber condoms – Requirements and test methods," [5] and ASTM D3492 – 08 "Standard specification for rubber contraceptives (male condoms)" [6]. In 2011, the United States Food

and Drug Administration (FDA) added ASTM D7661 – 10 “Standard test method for determining compatibility of personal lubricants with natural rubber latex condoms” to its list of recognized standards for use in pre-market product reviews [7,8]. It is not clear, though, to what extent previously marketed lubricant products, including those *not* marketed for sexual use, meet any of these standards.

The most-cited laboratory evidence describing condom breakage and oil-based substances is a 1989 paper published in *Contraception*, where the authors conducted burst testing with various substances, and concluded that mineral oil-based lubrications such as baby oil or body lotion had a significant degrading effect on latex [9]. A careful reading, however, reveals that Voeller *et al.* did not test petroleum jellies in this analysis, as is sometimes implied when this article is referenced. From the same year, an abstract from the 5th International AIDS Conference claimed that similar mechanical testing found petroleum jelly to have a significant weakening effect on latex condoms [10]. A 1999 study reported similar testing with vaginal application products, and found that products containing vegetable oil to weaken latex condoms [11]. A 2011 study reported that two commercial lubricants tested (one oil-based and one silicone-based) and mineral oil were found to decrease condom puncture strength, while all water-based products tested had a significant strengthening effect. A search of the indexed medical literature reveals limited laboratory-based evidence to test condom compatibility of petroleum jelly and silicone-based lubricants.

Numerous studies have examined condom breakage and slippage during vaginal intercourse among study populations. Breakage rates of less than 4% in the United States [12,13], 4% in Kenya and Mali and 13.3% in Ghana have been documented [14]. Another study also found breakage rates of 12.9% in Barbados, 10.1% in St. Lucia and 6.7% in the United States to be uncorrelated with breakage rates of same-lot condoms in the laboratory tests, and concluded the breakages were more likely due to incorrect use or other factors [15]. A study of men in Mexico, the Philippines and the Dominican Republic also concluded that reasons for breakage were complex and usually associated with historical breakage among individuals [16].

A 1993 assessment of men who have sex with men (MSM) in the Netherlands documented much lower condom failure rates among users of water-based lubricants (1.7%), than those who used oil-based lubricants (10.3%) or saliva/no lubricant (5.7%) [17]. Other results in the literature have been mixed. In 1999, a study of MSM in the United States also found lubricant use to have a protective effect against condom breakage, but the types of lubricant used by respondents were not described [18]. A 1996 study also reported that users of water-based lubricants reported significantly lower condom failure rates, yet at the same time showed no significant association between breakage and use of oil-based lubricants [19]. Some other studies have also failed to demonstrate significantly lower breakage rates due to oil-based lubricants [20,21]. One study of female sex workers (FSW) in Europe reported an association between use of oil-based lubricants and HIV positivity, but the authors

did not relate this finding to possible breakage [22]. More recent studies, however, have reported users of oil-based lubricants were significantly more likely to have experienced condom breakage, including among African-American men in the United States [23] and male sex workers in Mombasa, Kenya [24].

Safety of lubricant products: regulation and emerging global evidence

There is a lack of documentation of the human safety of personal lubricants, which may have resulted from a flexible regulatory environment. Many developing countries lack the capacity to monitor and review the safety of pharmaceutical products, and often rely on guidance from more stringent regulatory bodies such as the FDA or the European Medicines Agency [25]. This influence also extends to international HIV programming, where the President’s Emergency Plan for AIDS Relief’s (PEPFAR) and other US-based initiatives purchase and/or distribute these products. For example, the FDA approves the PEPFAR purchase of specific anti-retroviral drugs for use in cooperating countries [26].

The FDA has usually classified some personal lubricants as “medical devices” since 1976, depending on marketing or claim of the product itself. Under the 1976 FDA regulation 21 CFR 880.6375, a lubricant is considered a “medical device” when “intended for medical purposes that is used to lubricate a body orifice to facilitate entry of a diagnostic or therapeutic device.” Personal lubricant products that claim to “moisturize” or “cleanse” have often been considered as a “cosmetic.” In 2003, the FDA announced a safety and efficacy review, and clarified how moisturizer/lubricant product claims to decrease pain, enhance sexual pleasure or contain spermicide would be categorized. Such product statements would be considered to be “drug” claims since they are related to easing discomfort or alleviating a condition (“mitigation or treatment of disease”). Furthermore, the FDA announcement stated they would *not* consider lubricants/moisturizers to be “cosmetic claims because they do not relate to ‘cleansing, beautifying, promoting attractiveness, or altering the appearance’” [27].

In response to the FDA review, some lubricant manufacturers and their representatives have opposed the FDA’s assertions, arguing that the “intended use” of lubricants is “cosmetic claims,” as their products aim to “cleanse” and not “treat disease.” Arguments included that the purpose of the lubricant products is not to alter body structure, and that the enhancement of sexual pleasure can broadly be interpreted as “beautifying” [28–30]. While this is not a comprehensive review of responses to the FDA, the arguments for “cosmetic” classification may, or may not, be influenced by a possibility that having lubricants classified as “drugs” by the FDA could add further regulatory burden upon lubricant manufacturers to test for safety. In 2008, the FDA stated that further guidance on lubricants and vaginal moisturizers is forthcoming [31], but this guidance does not yet appear to be final or readily accessible.

In the meantime, the regulatory environment does not appear to always require lubricant manufacturers to rigorously confirm the vaginal and rectal safety of these products,

especially if the product does not claim to be intended for sexual use. However, thanks to an emerging interest in the development of vaginal and rectal microbicides, new information is emerging.

Preliminary data suggest that some water-based lubricants – depending on their formulation – may be less safe than previously believed. One clinical study reported greater rectal epithelial damage when exposed to hyperosmolar water-based gels [32]. Recent studies have also evaluated *in vitro* and *ex vivo* impacts of some water- and silicone-based lubricants, and found that some caused greater epithelial damage or irritation to cervical or rectal tissue than others [33–36]. Among these results, one study found that some hyperosmolar lubricants exposed to an *in vitro* epithelial model caused reduction of epithelial integrity, and four lubricants showed increased HIV replication *in vitro* [35]. Another recent study of some water-based lubricants found similar associations with epithelial damage *in vitro*, but with no increase in HIV replication [36]. These studies provide preliminary insights, but have not yet demonstrated definitive epidemiologic impacts on human populations.

Evidence from behavioural data remains limited, as lubricant use has not often been assessed as HIV or STI risk factors in previous studies. One recent study, however, has found that rectal STI prevalence among lubricant-using men and women were significantly higher than non-lubricant users [37]. Combined with the recent laboratory evidence, this may be the cause for concern and more data are needed.

Use of lubricants in Africa

Both practices of dry sex and use of lubricants for the increase of pleasure, decrease of pain or replacement/removal of vaginal secretions have been documented in Africa; as has vaginal hygiene or washing practices – especially among sex workers [38]. General personal lubricant use, however, is rarely investigated in population-based surveys. It is only more recently that some studies have assessed lubricant usage, albeit among more key populations at risk such as MSM and FSW.

A 2004 study of MSM in Nairobi reported that Vaseline® or petroleum jelly was used by 84% of respondents, baby oil or body lotion by 26% and water-based products by 41% [39]. Other MSM studies in Africa have also reported high levels of petroleum jelly use and sometimes other “condiments,” such as butter/margarine, yoghurt, shea butter, and cooking oils [40–42].

Information on lubricant use for heterosexual vaginal intercourse in Africa is less available, though limited evidence suggests that oil-based lubricants may often be used in heterosexual encounters. Separate studies of FSW in Nairobi, Kenya, have documented petroleum jelly use by 20–40% of participants [43,44]. Additionally, male sex workers in Mombasa reported using such lubricants as petroleum jelly, baby oil, lotions, vegetable oil, and coconut oil with both male *and* female sexual partners for both anal and vaginal sex (Population Council, unpublished data).

Petroleum jellies may be a lubricant used for sex in many African countries, regardless of types of sexual intercourse or sexualities. These products, such as Vaseline®, are widely

available and can be purchased everywhere from a city supermarket to remote rural kiosks. They are also relatively inexpensive compared to water-based pharmaceutical products such as KY Jelly®, which are usually only accessible in supermarkets and pharmacies. These factors may make petroleum jellies more attractive options in developing or poorer areas in Africa [45].

Current guidance for lubricant procurement and prevention programming in Africa

Confidence in the condom-compatibility of water-based lubrication appears to be universal, and past guidance has strongly recommended their use [3,4]. However, the emerging evidence of possible correlations between use of water-based lubricants and HIV/STI transmission (especially rectal) has influenced some updated guidance. The PEPFAR guidance for combination prevention for MSM [46] recommends only procuring lubricants deemed safer by evidence presented at the Microbicides 2010 conference [36,37]. The PEPFAR guidance, however, does not specifically summarize which lubricant products are preferable.

In 2011, the World Health Organization (WHO), in collaboration with United Nations Population Fund and Family Health International, published an advisory document which reconfirms that oil-based lubricants should be avoided, and provides more clarity on the procurement of safer water-based lubricants. A list of household products are listed as damaging to latex including: baby oil, burn ointment, dairy butter, palm or coconut oil, cooking oil, fish oil, mineral oil, suntan oil, haemorrhoid cream, petroleum jelly and body/hand lotions [47]. This WHO list, however, references a behavioural study in Jamaica [48] which actually does not specifically mention, or scientifically test the condom compatibility of most of these “condiments,” as is implied.

Based on the evidence documenting epithelial or mucosal damage and/or irritation [32,34,35], the WHO advisory recommends a systematic review of lubricant safety, and provides interim recommendations for procurement agencies to avoid products with high osmolality and products containing polyquaternary compounds. Additional pH specifications for lubricants intended for vaginal or anal sex are provided [47]. The WHO document relists some commercial lubricants with their osmolality and pH from one of the recent studies [35], but – as with the PEPFAR guidance – stops short of declaring specific products as “safe” for procurement.

Based on this guidance, it seems that programmers are currently expected to independently research the formulation or ingredients of lubricant products before procurement. Additionally, in Africa water-based lubricants remain costly, and prevention programmes also remain unable to advise on the safety and condom compatibility of some inexpensive “condiments” reportedly used by MSM and FSW in Africa – including butter, yoghurt and coconut oil. In response, some organizations, most notably the International Rectal Microbicides Advocates (IRMA), are monitoring these research developments, distributing summaries and fact sheets of lubricant safety, and advocating for greater research resources on lubricant safety and use both in Africa and worldwide [49].

Conclusions

The literature and evidence of lubricant condom compatibility and safety is not as thoroughly assessed and/or documented as commonly believed, and our knowledge is currently evolving and improving. This includes emerging awareness that Africans are using lubricants that may or may not be compatible with condoms, and that some Africans are engaging in anal sex, which requires more access to water-based lubricants. Additionally, further confirmation is needed on the safety and procurement criteria for some water- and silicone-based lubricants. Thus, the potential epidemiologic impact of lubricant use is under-assessed, and more attention must be given.

First, the current global regulatory environment for lubricants may not always require rigorous safety testing and assessment, especially if a product is not marketed for sexual use. Whether lubricants or vaginal moisturizers should be classified as “drugs” or “cosmetics” and tested for safety accordingly is currently under debate, while Africans continue to use lubricants based on intuition, availability and affordability – sometimes with no knowledge of the current public health guidance. While the recent information on vaginal and rectal safety testing from microbicides research has been helpful, further guidance from the FDA and more research is needed to resolve outstanding safety concerns. This will help assure HIV prevention programmers and lubricant users that they are distributing or using lubricants which are safe, and do not put Africans at increased risk of HIV or STIs.

Second, a thorough and modern review of lubricants and their impact on latex condom integrity is needed, including assessment of some Africa-specific substances. Confirmation of latex-degrading effects from the laboratory and breakage rates from behavioural data may be modelled with the existing data on the probabilities of HIV transmission via vaginal and anal sex [50,51] to determine if breakage is a problem of epidemiologic concern.

Third, broader population surveys in Africa – not just among MSM and FSW – should assess lubricant use and accessibility, and whether African populations are actually using lubricants which are “condom compatible.” Further analysis of condom failure in Africa may test for correlations between breakage and non-compatible lubricant use.

Condom acceptance has come a long way since the Malawian student worried about *piri-piri* hot sauce seeping through holes in condoms. It is now time to shift focus to the *piri-piri* sauce itself – or actually the other “condiments” used for sexual lubrication – so we can better understand how these substances affect the African HIV epidemic.

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Competing interests

The author has no competing interests to declare.

Author's contribution

SG was the sole author of this article.

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ORIGINAL ARTICLE

The impact of lubricants on latex condoms during vaginal intercourse

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Summary: The objective was to evaluate the impact of additional lubricant on condom breakage and slippage. Two hundred and sixty-eight couples used 6 new and 6 aged condoms during vaginal intercourse and were instructed to use 2 of each type with either water-based lubricant, oil-based lubricant or no additional lubricant.

The use of either oil-based or water-based lubricant increased slippage rates of new and aged condoms, although only one pairwise comparison (oil-based lubricant vs. no additional lubricant) was statistically significant (8.5% vs. 3.8%, $P=0.004$). The use of oil-based lubricant increased breakage, although not statistically significantly, in both new and aged condoms. Water-based lubricant did not impact the breakage rate of the new condoms and decreased the breakage rate of the aged condoms (no additional lubricant 4.5% vs. water-based lubricant 2.1%, $P=0.029$).

From a functional perspective, this study suggests that condom users should be told not to use oil-based lubricants. The negative impact of water-based lubricant on slippage may be outweighed by the protective influence on breakage, especially for aged condoms.

Over three-quarters of the couples (76%) had at least some incorrect knowledge, according to current condom instructions, of the type of lubricant that should be used with condoms.

Keywords: Condom, breakage, lubricant, contraceptive devices—male, coitus, contraception behaviour, sexually transmitted diseases, prevention

INTRODUCTION

More than 10 years after the first case of acquired immunodeficiency syndrome (AIDS) was diagnosed in the United States, current research is addressing condom breakage in greater detail and results suggest that breakage may be a more serious problem than had previously been thought. As recently as 1990, the scientific literature and the popular press were asserting that condoms break less than 1% of the time^{1,2}. At that time, the main emphasis of the public health community was to provide sexually active people access to condoms. Instructions on proper condom use to lower the risk of breakage were often neglected.

More recent data suggest that the range of condom breakage during vaginal intercourse is

between less than 1% to 12%³⁻¹⁴ with many US-based studies falling in the 2-5% range. With these new findings, there is growing interest in better understanding what causes condom breakage and adopting strategies to reduce such breakage.

In the December 1991 issue of *Network*, factors that may cause condoms to break were grouped into 3 general categories; quality at manufacture, storage conditions and user behaviour. Recent studies suggest that of these 3 categories, user behaviour has the largest impact on determining condom breakage rates^{11,12,15,16}. Preliminary qualitative research has identified 4 types of user behaviour that may cause condoms to break; incorrect methods of putting on condoms, use of oil-based lubricants, re-use of condoms, and duration or intensity of coitus^{17,18}.

Laboratory studies have shown that oil-based lubricants are detrimental to latex condoms¹⁹⁻²¹. Voeller *et al.* assert that 60 sec of exposure to mineral oil caused approximately 90% decrease in strength as measured by the International Standards Organization (ISO) air burst test¹⁹.

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To our knowledge, no study to date has been specifically designed to assess the impact of lubricant on condom breakage and slippage during intercourse. Three recent studies explored the impact of lubricants on condom breakage during vaginal intercourse during secondary analysis^{13,14,16}. None of these studies found statistically significant differences in condom breakage due to lubricant use. However, this may have been due to the lack of statistical power because of the small number of lubricant users in these 3 studies.

Although there is a lack of data linking the use of oil-based lubricants with condom breakage during intercourse, results from laboratory studies have been so convincing that most condom instructions caution against their use. The problem with these condom instructions are 2-fold. First, many condom users cannot distinguish between oil-based and water-based lubricants²². Second, even if condom users can successfully avoid oil-based lubricants, they may not have access to water-based lubricants, especially in the developing world.

To complicate matters further, there is a debate on the effect of water-based lubricants on condom slippage and breakage. Some researchers speculate that condom breakage may be reduced if water-based lubricants are used because mechanical friction between the condom and the vaginal lining may be lessened²³. To date, no study provides data to support this assertion. Interestingly, Trussell *et al.* found slippage to be significantly related to the use of any type of lubricant¹⁴.

Considering the problems associated with correctly identifying the different types of lubricants, it is of paramount importance that there actually is an appropriate lubricant to be used with condoms before we spend resources on education. The purpose of the present study was to quantify breakage and slippage rates of condoms during vaginal intercourse when used with an oil-based lubricant, a water-based lubricant or no additional lubricant.

METHODS

Study subjects

Three-hundred couples were recruited from professional organizations and institutions in the Research Triangle Park area of North Carolina (Raleigh, Durham and Chapel Hill) via fliers and word of mouth. Interested couples were sent a fact sheet outlining the purpose of the study and a list of selection criteria for participation in the study.

Participants were at least 18 years of age; in exclusive, heterosexual relationships during the course of the study; protected against pregnancy by recognized, reliable non-barrier methods of contraception; not at risk of sexually transmitted diseases, including HIV; and had no known sensitivities to latex, baby oil or water-based lubricants.

If they qualified for the study, they were requested to return the signed informed consent form. Family Health International's (FHI) Protection of Human Subjects Committee approved the study protocol and informed consent form prior to study initiation.

Study products

Two lots of 52 mm latex condoms obtained from the Commodities Procurement and Support Division of the US Agency for International Development were studied. Both lots of condoms were pre-lubricated with silicone. One lot of condoms consisted of recently manufactured (new) condoms that passed both the American Society for Testing Materials (ASTM) and the International Standards Organization (ISO) standards.

Since the breakage rate for the new condoms was expected to be low, we were concerned that it would be difficult to detect statistically a clinically significant effect of the different types of lubricants on these new condoms without evaluating a very large number of condoms. Therefore, one lot of older condoms was also evaluated in the hopes of amplifying the impact of the different lubricants. This second lot of (aged) condoms consisted of condoms retrieved from Jamaica after one year of storage in a hot and humid climate. The aged condoms passed the ASTM standards, but failed the ISO standard for airburst volume.

Two types of lubricants were used in this study. The first is an oil-based lubricant marketed under the brandname of Johnson's Baby Oil by Johnson & Johnson, Skillman, NJ. It contains mineral oil and fragrance. The second lubricant used in the study is a water-based lubricant marketed by Astro-Lube Inc., North Hollywood, CA under the brandname Astroglide®. This lubricant contains purified water, glycerin, propylene glycol, polyquaterium #5, methyl paraben and propylparaban.

General procedures

Enrolled couples were mailed the study condoms along with corresponding sections of a self-administered questionnaire and asked to use the study condoms during vaginal intercourse. The 12 study condoms were divided into 3 study packets with 2 new and 2 aged condoms per packet. Two of the 3 study packets also included additional lubricant (Johnson's Baby Oil or Astroglide®). If the study packet contained a lubricant, the participants were instructed to don the condoms and then lubricate them well with the lubricant found in that packet before using the condoms during vaginal intercourse.

Participants were sent the 3 study packets and were asked to choose the order in which they used the study packets and the condoms within each study packet. Upon receipt of the completed questionnaires, couples were remunerated for each condom used.

Table 1. Wording of breakage and slippage questions

| |
|--|
| Did the condom slip off completely? |
| 0=no |
| 1=yes |
| →if yes, when did the condom slip off? |
| 1=during sex |
| 2=during withdrawal |
| 3=don't know |
| Did the condom break? |
| 0=no→end of section |
| 1=yes |
| When did condom break? |
| 1=opening package |
| 2=unrolling onto penis |
| 3=during sex |
| 4=withdrawing penis |
| 5=taking condom off |
| 6=do not know |

Definition of breakage, slippage and total failure

The self-administered questionnaire asked couples a series of specific questions about each condom used (Table 1). To avoid double counting and to calculate accurate rates for breakage, slippage and total failure, a hierarchical convention similar to one developed by Trussell *et al.*¹⁴ was used in the analysis. If a condom broke while opening the package or putting on the condom, the condom was counted as a break and was subtracted from the denominator used to calculate the slippage, clinical breakage and clinical failure rates. Hence, only condoms which were used during intercourse were used to calculate these 3 rates. Condom slippage was defined as condoms that were reported to have slipped off completely.

Condoms that both broke and slipped off were counted only as breaks. This convention is based on the assumption that in most of these cases, condom breakage led to condom slippage. Total failure is calculated by adding all the broken condoms to the number of condoms that slipped off during intercourse and dividing by the total number of condoms used by the participants.

When calculating condom breakage rates, some researchers only employ a subset of the total breaks (clinical breaks). They argue that condom breaks occurring before intercourse (non-clinical breaks) do not put the couple at risk of pregnancy and STD transmission. Although we believe in the importance of both clinical and non-clinical breaks¹², in this paper our statistical analysis is based only on clinical failure (clinical breaks and slippage). The rationale for this decision is that the exposure of latex to lubricant prior to intercourse is minimal and would not impact non-clinical breakage rates.

Statistical tests

The test of marginal homogeneity for ordered data (an extension of McNemar's test) was used to test

pairwise comparisons of clinical breakage, slippage and clinical failure rates of the three lubricant groups (oil-based, water-based and no additional lubricant)²⁴. Differences in preference ratings of the 3 lubricant groups on a 5-point scale (1=liked very much to 5=strongly disliked) were assessed with a 2-tailed Wilcoxon matched pairs signed rank test.

Alpha of 0.05 was used for the tests of statistical significance. To adjust for any potential effect of multiple testing on the P-values, alpha was set at ≤ 0.05 for a family of 3 paired comparisons of functionality. Each paired comparison (water vs. oil, water vs. none and oil vs. none) within a family of tests (clinical breakage, slippage and clinical failure) was assessed at 0.017. For the tests of differences in preference ratings, alpha was also set at ≤ 0.05 for the family of 3 paired comparisons. Each paired comparison was assessed at 0.017.

Approximate 95% confidence intervals for condom failure rates were calculated using the normal approximation to the binomial distribution (with an added continuity correction factor).

RESULTS

Background characteristics

Of the original 300 couples recruited, 293 couples used at least one study condom and completed the

Table 2. Socio-demographic characteristics (n=268 couples)

| | Female | | Male | |
|-------------------------|--------|------------------|------|------------------|
| | n | (%) ^a | n | (%) ^a |
| Age (in years) | | | | |
| 18 to 25 | 58 | (22) | 38 | (14) |
| 26 to 30 | 70 | (26) | 75 | (28) |
| 31 to 35 | 60 | (22) | 50 | (19) |
| 36 to 40 | 43 | (16) | 54 | (20) |
| 41 to 45 | 36 | (13) | 50 | (19) |
| Not specified | 1 | (<1) | 1 | (<1) |
| Median | 31 | | 32 | |
| Education | | | | |
| Less than 12 years | 5 | (2) | 10 | (4) |
| 12 years | 57 | (21) | 66 | (25) |
| 13 to 16 years | 161 | (60) | 132 | (49) |
| More than 16 years | 43 | (16) | 59 | (22) |
| Not specified | 2 | (1) | 1 | (<1) |
| Median | 14.5 | | 15 | |
| Ethnic background | | | | |
| Asian | 3 | (1) | 3 | (1) |
| Black | 34 | (13) | 33 | (12) |
| Caucasian | 228 | (85) | 224 | (84) |
| Hispanic | 1 | (<1) | 1 | (<1) |
| Other | 1 | (<1) | 1 | (<1) |
| Not specified | 1 | (<1) | 6 | (2) |
| Marital status | | | | |
| Living with partner | 236 | | (88) | |
| Not living with partner | 30 | | (11) | |
| Not specified | 2 | | (1) | |

^aOn this and all subsequent tables, percentages may not add up to 100 due to rounding

Table 3. Condom experience in past (n = 268 couples)

| Number of condoms | Female | | Male | |
|-----------------------------|--------|------|------|------|
| | n | (%) | n | (%) |
| Used during lifetime | | | | |
| None | 9 | (3) | 1 | (<1) |
| 1 to 9 | 18 | (7) | 13 | (5) |
| 10 to 25 | 63 | (24) | 51 | (19) |
| 26 to 100 | 131 | (49) | 143 | (53) |
| More than 100 | 45 | (17) | 55 | (20) |
| Not specified | 2 | (1) | 5 | (2) |
| Used in past year | | | | |
| None | 21 | (8) | 18 | (7) |
| 1 to 9 | 40 | (15) | 42 | (16) |
| 10 to 25 | 131 | (49) | 129 | (48) |
| 26 to 100 | 66 | (25) | 69 | (26) |
| More than 100 | 7 | (3) | 7 | (3) |
| Not specified | 3 | (1) | 3 | (1) |

data collection forms. However, this analysis is based on the 268 couples who used all 12 of their study condoms (Table 2). Participants reported a median age slightly over 30 years (females=31 years, males=32 years) with a high level of formal education (median: females=14.5 years, males=15 years). Eighty-eight per cent of the participants reported living together and they were predominantly Caucasian (female=85%, males=84%).

Past condom use

Most of the study participants had experience using condoms, with well over half reporting having used more than 25 condoms during their lifetime (females=66%, males=74%) (Table 3). Of the participants with condom experience in the past year, about 40% of both females and males reported using lubricants at least some of the time (Table 4).

Table 4. Past experience with lubricants (n = 268 couples)

| | Female | | Male | |
|---|--------|------|------|------|
| | n | (%) | n | (%) |
| Did you use condoms in the past year? | | | | |
| No | 23 | (8) | 20 | (7) |
| Yes | 245 | (91) | 248 | (92) |
| If yes, how often did you use additional lubricant with the condoms? | | | | |
| Never | 147 | (60) | 151 | (61) |
| Less than half the time | 65 | (26) | 65 | (26) |
| More than half the time | 25 | (10) | 23 | (9) |
| Always | 7 | (3) | 6 | (2) |
| Not specified | 1 | (<1) | 3 | (1) |
| Type of lubricant used most often in past year^a | | | | |
| Oil-based | 29 | (30) | 27 | (29) |
| Water-based | 57 | (59) | 57 | (61) |
| Combination of the two | 3 | (3) | 2 | (2) |
| Not specified | 8 | (8) | 8 | (9) |

^aExcludes subjects who did not report using a lubricant during the past year

Table 5. Incorrect knowledge of lubricant use (n = 268 couples)

| | Couples who said they agreed with statement | |
|--|---|------|
| | n | (%) |
| Oil-based lubricants can be used^a | | |
| Baby oil | 169 | (63) |
| Massage oil | 107 | (40) |
| Vaseline | 94 | (35) |
| Subtotal with at least one incorrect response | 196 | (73) |
| Water-based lubricants cannot be used¹ | | |
| Astroglide | 10 | (4) |
| KY Jelly | 11 | (4) |
| Contraceptive Foam | 34 | (13) |
| Subtotal with at least one incorrect response | 51 | (19) |
| Total with at least one incorrect response | 203 | (76) |

^aMultiple responses allowed

However, less than 5% said they always used lubricants with their condoms in the past year. Almost one-third of both female and male participants reported using oil-based lubricants in the past year (females=30%, males=29%).

Knowledge about lubricant type

When couples were asked what type of lubricant should not be used with condoms, 76% gave at least one incorrect answer according to information in current condom instructions (Table 5). Over half the couples (63%) believed it was correct to use baby oil (massage oil 40% and vaseline 35%).

Condom breakage, slippage and total failure rates

The 268 couples used 2 condoms from each of the 6 groups presented in Table 6. To help decide whether to pool the data from both types of lots (new and aged), clinical breakage, slippage and clinical rates were calculated separately for each type. The ratio of slippage rates of condoms lubricated with water-based and oil-based lubricant compared with slippage rates of condoms with no additional lubricant were similar in both new and aged lots. However, the ratio of breakage rates, when compared in the same manner, were not similar. This interaction was contrary to what was expected. Thus we chose to perform the analyses separately by new and aged condom lots.

Total breakage rates for the new condoms ranged from 3.2% for the condoms used with the water-based lubricant to 4.5% for the condoms used with the oil-based lubricant. For the aged condoms, total breakage rates ranged from 3.5% for the condoms used with water-based lubricant to 6.0% for the condoms used with oil-based lubricant.

Table 6. Condom failure rates (breakage and slippage) by age of condom lot and type of lubricant used (n = 268 couples)

| | New condoms | | | Aged condoms | | |
|---|-------------------------|---------------------|-----------------------|-------------------------|---------------------|-----------------------|
| | No additional lubricant | Oil-based lubricant | Water-based lubricant | No additional lubricant | Oil-based lubricant | Water-based lubricant |
| Breakage | | | | | | |
| Number of condoms used | 536 | 536 | 536 | 536 | 536 | 536 |
| Non-clinical breakage rate ^a | 0.9% | 0.9% | 0.7% | 0.9% | 0.9% | 1.5% |
| (Confidence interval 95%) | (0.3, 2.3) | (0.3, 2.3) | (0.2, 2.0) | (0.3, 2.3) | (0.3, 2.3) | (0.7, 3.0) |
| Clinical breakage rate ^b | 2.4% | 3.6% | 2.4% | 4.5% | 5.1% | 2.1% |
| (Confidence interval 95%) | (1.4, 4.3) | (2.2, 5.6) | (1.4, 4.3) | (3.0, 6.7) | (3.4, 7.4) | (1.1, 3.8) |
| Total breakage rate ^a | 3.4% | 4.5% | 3.2% | 5.4% | 6.0% | 3.5% |
| (Confidence interval 95%) | (2.1, 5.4) | (3.0, 6.7) | (1.9, 5.1) | (3.7, 7.8) | (4.2, 8.4) | (2.2, 5.6) |
| Slippage | | | | | | |
| Slippage rate ^b | 3.8% | 8.5% | 7.0% | 5.6% | 9.4% | 6.4% |
| (Confidence interval 95%) | (2.4, 5.9) | (6.3, 11.3) | (5.0, 9.5) | (3.9, 8.1) | (7.1, 12.3) | (4.6, 9.0) |
| Total failure | | | | | | |
| Clinical failure rate | 6.2% | 12.1% | 9.4% | 10.2% | 14.5% | 8.5% |
| (Confidence interval 95%) | (4.4, 8.7) | (9.5, 15.2) | (7.1, 12.3) | (7.8, 13.1) | (11.7, 17.9) | (6.3, 11.3) |
| Total failure rate ^a | 7.1% | 12.9% | 10.1% | 11.0% | 15.3% | 9.9% |
| (Confidence interval 95%) | (5.1, 9.7) | (10.2, 16.1) | (7.7, 13.0) | (8.5, 14.0) | (12.4, 18.7) | (7.6, 12.8) |

^aIncludes all condoms used^bIncludes all condoms not broken before intercourseTable 7. P-values for pairwise comparisons^a of condom failure rates by age of condom lot and type of lubricant used (n = 268 couples)

| Rates compared | New condoms | P-value | Aged condoms | P-value |
|---------------------------|-------------|---------|--------------|---------|
| | Rates | | Rates | |
| Clinical breakage | | | | |
| None added vs oil-based | 2.4 vs 3.6 | 0.379 | 4.5 vs 5.1 | 0.789 |
| None added vs water-based | 2.4 vs 2.4 | 1.000 | 4.5 vs 2.1 | 0.029 |
| Oil-based vs water-based | 3.6 vs 2.4 | 0.379 | 5.1 vs 2.1 | 0.018 |
| Slippage | | | | |
| None added vs oil-based | 3.8 vs 8.5 | 0.004 | 5.6 vs 9.4 | 0.037 |
| None added vs water-based | 3.8 vs 7.0 | 0.026 | 5.6 vs 6.4 | 0.701 |
| Oil-based vs water-based | 8.5 vs 7.0 | 0.442 | 9.4 vs 6.4 | 0.056 |
| Clinical failure | | | | |
| None added vs oil-based | 6.2 vs 12.1 | 0.001 | 10.2 vs 14.5 | 0.056 |
| None added vs water-based | 6.2 vs 9.4 | 0.067 | 10.2 vs 8.5 | 0.376 |
| Oil-based vs water-based | 12.1 vs 9.4 | 0.198 | 14.5 vs 8.5 | 0.001 |

^aTest of marginal homogeneity for ordered data with exact P-values for 2-tailed test

The slippage rates ranged from 3.8% for the new condoms used with no additional lubricant to 8.5% for the new condoms used with the oil-based lubricant. For the aged condoms, slippage rates ranged from 5.6% for the ones used with no additional lubricant to 9.4% for the aged condoms used with oil-based lubricant.

Table 7 presents the P-values for the pairwise comparisons of clinical breakage, slippage and clinical failure rates of the 3 lubricant groups (oil-based, water-based and no additional lubricant). For the new condoms, the oil-based lubricant had a small, though non-significant, negative impact on the clinical breakage rate when compared to new condoms used with no additional lubricant (3.6% vs 2.4%, $P=0.379$). Water-based lubricant had no impact on the clinical breakage rate when compared to the clinical breakage rate of the new condoms

used with no additional lubricant (both 2.4%). For the new condoms, slippage rates increased with both lubricants (oil-based 8.5%, water-based 7.0%) when compared to no additional lubricant (3.8%). The pairwise comparison of the slippage rate of new condoms used with no additional lubricant vs. new condoms used with oil-based lubricant was significant ($P=0.004$) and the pairwise comparison of no additional lubricant vs. water-based lubricant approached significance ($P=0.026$) at the study's alpha level, which was set at 0.017 to control for multiple testing.

The pairwise comparison of clinical failure rates was statistically significant for new condoms used with no additional lubricant vs. new condoms used with the oil-based lubricant (6.2% vs 12.1%, $P=0.001$). New condoms used with water-based lubricant had a higher clinical failure rate than their

counterparts used with no additional lubricant (9.4% vs 6.2%); however, this difference was not statistically significant ($P=0.067$).

For aged condoms, the oil-based lubricant had a small, though non-significant, negative impact on the clinical breakage rate when compared to the clinical breakage rate of the aged condoms used with no additional lubricant (5.1% vs 4.5%, $P=0.789$). Interestingly, the water-based lubricant reduced the clinical breakage rate of aged condoms when compared to the clinical breakage rate of aged condoms used with no additional lubricant (2.1 vs 4.5%); however, this difference was not statistically significant ($P=0.029$) at the study's alpha level of 0.017. The pairwise comparison of the clinical breakage rate of aged condoms used with the water-based lubricant vs the clinical breakage rate of aged condoms used with the oil-based lubricant approached significance (2.1% vs 5.1%, $P=0.018$).

The slippage rates of aged condoms used with either lubricant (oil-based 9.4% and water-based 6.4%), was higher than the slippage rate of the aged condoms used with no additional lubricant (5.6%), though neither of the pairwise comparisons was statistically significant.

Adding clinical breakage and slippage, the clinical failure rate of the aged condoms used with the oil-based lubricant was higher than the clinical failure rate of aged condoms used with no additional lubricant (14.5% vs 10.2%, $P=0.056$). The water-based lubricant's negative effect on the slippage rate is outweighed by the water-based lubricant's positive effect on clinical breakage of aged condoms. As a result, the clinical failure rate of the aged condoms used with water-based lubricant is lower than the clinical failure rate of the aged condoms used with no additional lubricant (8.5% vs 10.2%,

$P=0.376$). Finally, the pairwise comparison of the clinical failure rate of aged condoms used with oil-based lubricant (14.5%) vs the clinical failure rate of aged condoms used with water-based lubricant (8.5%) was statistically significant ($P=0.001$).

Preference for lubricants

Couples were asked to rate how well they liked the condom lubricant when oil-based, water-based or no additional lubricant were added to the condoms (Table 8). When no additional lubricant was compared to the oil-based lubricant, couples preferred no additional lubricant ($P<0.001$). When the comparison was between no additional lubricant and the water-based lubricant, they preferred the water-based lubricant ($P<0.001$). As expected, couples preferred the water-based lubricant over the oil-based lubricant ($P<0.001$).

DISCUSSION

Laboratory studies clearly show that even short exposure of latex condoms to oil-based lubricants adversely affects the results of various laboratory tests used by the International Standard Organization (ISO) and the American Society for Testing Materials (ASTM)¹⁹⁻²¹. How well these laboratory tests predict condom performance in human use is still not well understood. In a recent study correlating 9 laboratory tests with condom breakage during vaginal intercourse, the age of the condom was the best predictor of breakage²⁵. The objective of the present study was to assess whether an oil-based lubricant impacts condom integrity during vaginal intercourse as adversely as suggested by laboratory tests.

For new condoms that passed both the ISO and ASTM standards, the use of either an oil-based, a water-based or no additional lubricant did not significantly impact clinical breakage rates. However, the clinical breakage rate for the new condoms used with oil-based lubricant was higher (3.6%) than the clinical breakage rate for the new condoms used with either no additional lubricant or water-based lubricant (both 2.4%).

For the aged condoms, the use of oil-based lubricant again led to a small increase in clinical breakage when compared to the aged condoms used with no additional lubricant. Interestingly, for the aged condoms, our data supports the theory that a water-based lubricant reduces clinical breakage. The clinical breakage rate was reduced from 4.5% (no additional lubricant) to 2.1% (water-based lubricant), although this difference was not statistically significant ($\alpha=0.017$). These findings suggest that the protective influence of water-based lubricants may become more pronounced as the material integrity of the latex deteriorates over time.

Although many researchers have focused solely on condom breakage, condoms that slip off completely during intercourse also contribute to a decrease in barrier protection. In this study, the use of either lubricant increased the slippage rates for both

Table 8. Lubricant preference (n = 268 couples)

| Lubricant preference | No additional lubricant | | Oil-based lubricant | | Water-based lubricant | |
|--|--|-------|---------------------|-------|-----------------------|-------|
| | n | (%) | n | (%) | n | (%) |
| Liked very much | 27 | (10) | 23 | (9) | 98 | (37) |
| Liked fairly well | 68 | (25) | 55 | (20) | 65 | (24) |
| Neutral | 83 | (31) | 42 | (16) | 30 | (11) |
| Somewhat disliked | 35 | (13) | 72 | (27) | 30 | (11) |
| Strongly disliked | 16 | (6) | 51 | (19) | 14 | (5) |
| Not specified | 39 | (15) | 25 | (9) | 31 | (12) |
| Total | 268 | (100) | 268 | (100) | 268 | (100) |
| Mean score ^a | 2.8 | | 3.3 | | 2.1 | |
| Two-tailed Wilcoxon matched pairs signed rank test | No additional lubricant vs oil-based lubricant | | | | $P<0.001$ | |
| | No additional lubricant vs water-based lubricant | | | | $P<0.001$ | |
| | Oil-based lubricant vs water-based lubricant | | | | $P<0.001$ | |

^aOn a scale from 1 to 5, where 1=liked very much and 5=strongly disliked

new and aged condoms, although only the pairwise comparison of the slippage rate of new condoms used with the oil-based lubricant vs new condoms used with no additional lubricant was statistically significant ($\alpha=0.017$). How much this increase in slippage is due in part to the excessive use of lubricants by some study participants is not known.

For the new condoms, the clinical failure rate (clinical breakage and slippage) was highest for the condoms used with the oil-based lubricant (12.1%) and lowest for the condoms used with no additional lubricant (6.2%). For the aged condoms, again the condoms used with the oil-based lubricant had the highest clinical failure rate (14.5%). However, the water-based lubricant's protective influence on clinical breakage outweighed its negative impact on slippage. As a result, the aged condoms used with the water-based lubricant had the lowest clinical failure rate (8.5%).

From a functional perspective, this study suggests that condom users should be told not to use oil-based lubricants. The impact of using a water-based lubricant is less clear. The negative impact of water-based lubricant on slippage may be outweighed by the protective influence on clinical breakage, especially for aged condoms.

Study participants showed a statistically significant preference for the use of an additional water-based lubricant. Couples were asked on a 5-point scale how they liked the water-based, the oil-based and no additional lubricant. They reported the highest preference for the water-based lubricant and the lowest preference for the oil-based lubricant.

Condom users are often instructed to use additional water-based lubricant for increased sensitivity²⁶. Caution should be used when providing these types of instructions because many condom users cannot distinguish water-based from oil-based lubricants²². In our study, 76% of the couples had at least some incorrect knowledge, according to current condom instructions, of the type of lubricant that should be used. Condom instructions need to make certain that users can correctly identify water-based lubricants. In developed countries where there is ready access to lubricants that contain spermicidal agents such as nonoxynol-9 (N-9), we would advise condom users who desire additional lubricant to choose lubricants containing N-9 for the additional protection against pregnancy and STDs the spermicide may offer²⁷.

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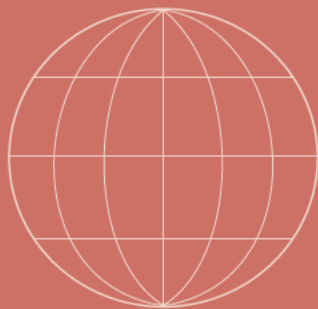
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Use and procurement of additional lubricants for male and female condoms: WHO/UNFPA/FHI360 Advisory note

Use and procurement of additional lubricants for male and female condoms: WHO/UNFPA/FHI360 Advisory note

Introduction

The World Health Organization, Department of Reproductive Health and Research, in collaboration with United Nations Population Fund (UNFPA) and Family Health International (FHI360) convened the WHO/UNFPA/FHI Female Condom Technical Review Committee Meeting at World Health Organization, Geneva, Switzerland from 11 to 15 April 2011. Among the issues technical experts were asked to address was the question raised by Member States as to whether or not WHO could review the evidence and recommend to UNFPA the linked provision of lubricants for bulk procurement with male and female condoms.

Following discussion of the issues at the meeting, a draft position paper was circulated for review. At this stage additional experts with specialist knowledge of personal lubricants were invited to contribute to the review process. The conclusions of the review are detailed in this document.

Background

Additional lubricants, supplied separately and applied to the condom, vagina, penis or rectum at the time of intercourse, are sometimes used to improve lubrication, moistening and comfort during intercourse. These lubricants are usually referred to as personal lubricants.

Moreover, additional lubricants are also frequently used by men who have sex with men (MSM) and sex workers. In a survey of Latino MSM in New York City, 93% used additional lubricants (59% always and 74% in at least 80% of sexual encounters) regardless of condom use (1). In a survey of MSM in San Francisco 89% reported always using a lubricant (2). Female sex workers also report high rates of additional lubricant use with condoms. Sex workers in brothels in the American state of Nevada used additional water-based lubricant with condoms 89% of the time (3). These women most frequently apply the additional lubricant to the outside of the condom or the surfaces of the vagina.

Impact of additional lubricants on condom failure rates

Anal intercourse: research suggests that the use of additional water-based lubricants is particularly important for anal intercourse. In a prospective study (4), condom breakage was found to be associated with the type of additional lubricant used ($\chi^2 = 44.34$, $p < 0.0001$). When the water-based lubricant that was supplied with the study condoms was used, the breakage rate was 3% whereas it was 21.4% when no additional lubricant was used.



Vaginal intercourse: evidence for the impact of additional water-based lubricant use on condom breakage and slippage rates in vaginal intercourse is equivocal. In a retrospective study (5), the use of additional water-based lubrication was associated with lower condom failure rates (odds ratio 8.88, 95% confidence interval 3.78–20.8). A further study (6) found an association between additional water-based lubricant use and reduced breakage rates for aged condoms but not for new condoms. With aged condoms¹ the breakage rate reduced from 4.5% to 2.1% ($p=0.029$). With new condoms, the breakage rate was 2.4% irrespective of additional lubricant use.

Other studies have failed to show any improvement in condom failure rates resulting from additional water-based lubricant use. For example, Smith et al. (7) in a prospective study found that additional lubricants had no effect on slippage and breakage during vaginal intercourse. However, when the additional lubricant was inserted directly into the vagina, the odds ratio for breakage reduced to 0.34 but the authors did not state whether this result was statistically significant. Sparrow and Lavill (8) also found no association between the use of additional lubricants and breakage or slippage rates, although they reported that “not enough lubrication or dryness” was cited as the second most frequent explanation for condom breakage.

What type of lubricant should be procured?

Any additional lubricant that is used must not have a deleterious effect on the properties of the condoms, such that the risk of breakage is increased.

Therefore the most important issue to consider is the type of lubricant that is used as latex condoms rapidly lose strength if exposed to oil-based lubricants. Evidence suggests that using incorrect lubricants contributes significantly to increased rates of breakage and slippage (9).

Silicone oils (polydimethylsiloxane), also known as silicone fluids, are the most commonly used lubricants that are applied to male and female condoms during manufacture. A very wide range of different silicone fluids is available but condom manufacturers generally use polydimethylsiloxanes with viscosities in the range 200–350 centistokes. Silicone fluids are inert, safe and have minimal effect on the properties of the latex film (10). They are not, however, widely available as personal lubricants in many markets. They also tend to be relatively expensive. Although silicone fluids are expected to be safe and effective when used as personal lubricants, there are currently no published clinical studies supporting their use in this role, particularly when used with latex condoms for anal intercourse.

Most widely available personal lubricants are water based, and these are commonly used as additional lubricants with condoms. Examples include K-Y Jelly, Astroglide, ID Glide and many others (see Annex 1). Many condom manufacturers also supply a range of water-based, condom-compatible lubricants.

Water-based lubricants normally contain one or more water soluble polymers to control their viscosity, together with humectants, viscosity modifiers, moisturizers and other components to modify their texture, rate of water evaporation and lubricating properties. Some lubricants are claimed to be long lasting and are marketed as vaginal moisturizers. The hydrophilic polymers used in those products are claimed to be bio-adhesive and to provide long term moisturizing effects.

Water-based lubricants must contain preservatives to prevent microbial growth. These preservatives can cause irritation and sensitization in some individuals. The most commonly used preservatives are esters of p-hydroxybenzoic acid (parabens). Other preservatives that are used include sorbic acid and sorbates, phenoxyethanol, benzoic acid, and less commonly chlorhexidine gluconate and domiphen bromide.

Other lubricants that are suitable for use with condoms are glycol based. Glycols, such as glycerol and propylene glycol, are commonly added to water-based lubricants as humectants but propylene glycol is also used as the primary component in some lubricant formulations. Warming lubricants often contain high levels of propylene glycol.

Household products are also sometimes used as personal lubricants. Some have a highly damaging effect on latex and should not be used with natural rubber latex condoms (see Table 1) (11).

Table 1

Household products that should not be used with latex condoms

| |
|----------------------------|
| Baby oil |
| Burn ointment |
| Dairy butter |
| Palm or coconut oil |
| Cooking oil |
| Fish oil |
| Mineral oil |
| Suntan oil |
| Haemorrhoid cream |
| Petroleum jelly (Vaseline) |
| Body/hand lotions |

¹ The aged condoms were stored for one year.

Condom compatibility

Natural rubber latex condoms

Methods of testing additional lubricants for compatibility with condoms are being developed by technical working group 15 of the International Organization for Standardization (ISO) Technical Committee for Non-Systemic Contraceptives and STI Barrier Prophylactics (ISO/TC 157 WG 15). At present this working group has not completed its assignment because poor inter-laboratory reproducibility has delayed the development of a widely acceptable test procedure.

Water and glycol based personal lubricants, as described above, are generally accepted as being compatible with natural rubber latex and are therefore safe to use with latex condoms. Silicone oil-based lubricants are also compatible with natural rubber latex but are more expensive than water and glycol based lubricants.

Condoms made from polyurethanes and synthetic materials

Almost any lubricant with proven levels of safety for human use can be used with polyurethane condoms (12) and some other types of synthetic condoms. However, other synthetic materials now used for making condoms, such as polyisoprene, are just as sensitive to oil-based lubricants as are latex condoms. It is therefore necessary to check very carefully the material used to make the condom before using an oil-based lubricant.

Safety issues

Personal lubricants are generally regarded as low-risk products and are subjected to only limited regulatory controls. Depending upon product claims and intended duration of action, they are classified as class 1 or class 2 medical devices in the United States and subject to 510(k) premarket approval. In Europe they are classified as class I or class IIa medical devices, again depending on product claims including duration of action.

Depending on classification they can be marketed based on the manufacturer's declaration of conformity (class I) or following Notified Body review (class IIa). Safety testing is often restricted to vaginal and penile irritation/sensitization studies in the rabbit.

Recent studies have identified a number of potential safety issues with personal lubricants. Much of this new information is based on laboratory (in vitro) testing. Several papers (13–16) suggest that lubricants with high osmolality might cause vaginal and anal epithelial damage. Confirmation that lubricants with high osmolality can cause epithelium damage when applied rectally to humans has been demonstrated in a group of 10 volunteers (15).

Epithelial damage could in turn increase the risk of infection, for example by HIV and other sexually transmitted infections (STIs), particularly when condom use is inconsistent. The effect of high osmolality might be more important when these lubricants are used rectally (15).

Most commercial personal lubricants have high osmolalities (2000–6000 mOsm/kg). Table 1 summarizes data on a wide range of current commercial products (16). By comparison, the normal osmolality of female vaginal secretions is 260–290 mOsm/kg and in human semen it is 250–380 mOsm/kg (17, 18). Ideally, the osmolality of a personal lubricant should not exceed 380 mOsm/Kg to minimize any risk of epithelial damage. Given that most commercial lubricants significantly exceed this value, imposing such a limit at this time could severely limit the options for sourcing personal lubricants for sector procurement. It is therefore recommended on an interim basis that procurement agencies should source lubricants with osmolalities of not greater than 1200 mOsm/kg.

The primary factor determining the osmolality of the majority of lubricants is the concentration of glycol. Glycols are added as humectants/moisturizers. Glycerol and propylene glycol are most commonly used. To maintain osmolalities below 1200 mOsm/kg the concentration of glycerol in the formulation should not exceed 9.9% mass fraction (w/w) and the concentration of propylene glycol should not exceed 8.3% mass fraction. If a mixture of glycols is used then the total glycol content should be kept below approximately 8.3% mass fraction although the exact limit will depend upon the ratio of the glycols.

Procurement agencies might therefore want to consider requesting information about the osmolality of lubricants from the manufacturers when selecting products for bulk purchase, especially if the products could be used rectally and/or by high-risk populations. If manufacturers are unable to supply information about the osmolality of their lubricants then information about the glycol content should be requested.

In a study undertaken by Population Council (16), four lubricants (Astroglide Liquid, Astroglide Warming Liquid, Astroglide Glycerin & Paraben-Free Liquid, and Astroglide Silken Secret) significantly enhanced HIV-1 replication in vitro compared with other lubricants in the study ($p < 0.0001$). A common ingredient in all of these preparations is polyquaternium (polyquaternium-15 is specified in three of them). A related polyquaternium compound, MADQUAT, was also found to increase HIV-1 replication, suggesting that this class of compound might increase HIV infection risk.

Other researchers found that polyquaternium-32 disrupted infected leukocytes in vitro within 5 minutes, which resulted in

inhibition of infectious HIV production by infected leukocytes (19). It is not clear whether the different effects seen in these studies are due to the test methods used or differences between specific polyquaternium compounds. Until the role of polyquaternium compounds is clarified they are best avoided in personal lubricants, particularly in products intended for use by high-risk populations.

The pH of the healthy vagina is normally in the range 3.8–4.5. The pH of the rectum is closer to neutral (pH 7). High vaginal pH can lead to an increase in the risk of bacterial vaginosis. High pH is also more supportive of HIV survival. Ideally therefore a vaginal lubricant should have a pH of about 4.5 and a rectal lubricant of about 5.5 to 7. It is unfortunate that these optimum requirements cannot be bridged in a single lubricant. The preservation of water-based lubricants is easier if the pH is maintained below 7. For these reasons it is recommended that procurement agencies purchase lubricants that have a pH of 7 or less. Also, agencies should consider the primary intended target population when specifying personal lubricant requirements, and also consider the likelihood of cross over use, e.g. a lubricant designated for rectal use being used vaginally and vice versa.

In the process of developing the recommendations in this paper a review of the literature was undertaken but this was not done on a formal, systematic basis. To provide a definitive recommendation on lubricants, it is proposed that a systematic review of the literature on the safety of personal lubricants be undertaken to define both the knowledge and research gaps.

In the interim, it would seem prudent for procurement agencies purchasing personal lubricants for public sector distribution to:

- Try and limit osmolality to less than 1200 mOsm/kg (total glycol content below ca 8.3% mass fraction (w/w)).
- Avoid lubricant formulations containing polyquaternium 15 specifically, and perhaps polyquaternary compounds in general.

In addition:

- If the primary intended target population use is vaginal use then a pH of 4.5 is preferable.
- If the primary intended users are MSM or cannot be determined, then a pH in the range 5.5–7 would be more appropriate.

Careful consideration should be given to the potential risk factors particularly when procuring lubricants for HIV/STI prevention programmes and for MSM.

Adopting an upper limit of 1200 mOsm/kg will have a significant impact on the number of available commercial lubricants that can be currently procured. Most current commercial lubricants, as reported above, have osmolalities in the 2000–6000 mOsm/kg range. The formulation of low osmolal lubricants does not, however, present any significant technical challenges. There are a number of products available that meet or only just exceed the recommended limit of 1200 mOsm/kg.

Spermicidal additives

Spermicidal additives to the lubricant have been used in some commercial products. Recent summaries of research findings suggest that these spermicides (predominantly nonoxynol-9) have significant irritant effects, and, overall, **their use is not recommended** (12).

Addition of medicinal and other active substances to condom lubricants

In the commercial sector there is increasing availability of condoms containing medicinal substances such as local anaesthetics. A common example is benzocaine, which is added to delay ejaculation. Lubricants containing medicinal substances are subject to local regulatory requirements for medicines. It may not be legal to distribute them in many countries without specific local regulatory approvals. **The inclusion of such products in bulk procurement programmes is therefore not recommended.**

Personal lubricants are also available with herbal and other substances that are claimed to have specific benefits, such as stimulating, warming, tingling and other effects. Since these lubricants do not contain medicinal substances, they are not regulated as medicines. Nevertheless, the safety of such lubricants in high-risk populations such as MSM and sex workers may not have been adequately assessed to date. Again, their inclusion in bulk procurement programmes is not recommended.

Conclusion and recommendations

Based on discussions at the meeting and an extended review with additional technical experts following the meeting, the technical experts recommended that:

1. There is a significant demand for additional lubricants to be used with condoms, particularly for MSM, female sex workers and women in menopause, and post-menopause.
2. The correct type of additional lubricant for male latex and female condoms can be bulk procured with either male or female condoms, if justified by programmatic requirements.
3. When procuring water-based lubricants, the osmolality should preferably be 1200 mOsm/kg or less. This can be achieved by limiting the glycerol content of the lubricant to 9.9% mass fraction or less, the propylene content to 8.3% mass fraction or less, or if a mixture of glycols is used a total limit of ca 8.3% mass balance.
4. Lubricants containing polyquaternary compounds should be avoided until there is further evidence on the effect of polyquaternium compounds on HIV replication rates.
5. When procuring water-based lubricants, a pH of around 4.5 is recommended if the primary intended target population will use the product for vaginal intercourse. For lubricants intended primarily for MSM or where the nature of the intended use cannot be ascertained, a pH in the range 5.5 to 7 is recommended. Lubricants with pH exceeding 7 are not recommended.
6. The bulk procurement and distribution of lubricants containing spermicides, medicinal and other active substances is not recommended.
7. A formal, systematic review of the literature should be undertaken by WHO to determine the sum of evidence on which recommendations can be made for the bulk procurement and distribution of personal lubricants that can be safely used as additional lubricant with male and female condoms.

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Annex 1. Properties of some commercial lubricants

| Lubricant | Manufacturer | Osmolality (mOsm/kg) | pH |
|---|---|----------------------|-----------|
| KY Jelly | Johnson & Johnson, Langhorne, PA, USA | 2007 | 4.55 |
| KY Warming Jelly | Johnson & Johnson, Langhorne, PA, USA | ND | 4.50–6.50 |
| KY Tingling Jelly | Johnson & Johnson, Langhorne, PA, USA | 5047 | 3.61 |
| KY Sensual Silk | Johnson & Johnson, Langhorne, PA, USA | 5467 | 3.39 |
| KY Sensual Silk Warming | Johnson & Johnson, Langhorne, PA, USA | ND | 5.00–7.00 |
| KY Sensual Silk Tingling Ultragel | Johnson & Johnson, Langhorne, PA, USA | 5381 | 3.36 |
| KY Natural Feeling Liquid | Johnson & Johnson, Langhorne, PA, USA | 4523 | 3.86 |
| Wet Original Gel Lubricant | Trigg Laboratories, Valencia, PA, USA | 3679 | 5.9 |
| Wet Light | Trigg Laboratories, Valencia, PA, USA | 3946 | 6.02 |
| Wet Warming | Trigg Laboratories, Valencia, PA, USA | ND | 6.0–7.5 |
| Durex Play Soothing | Ssl international, London, United Kingdom | 1373 | 4.2 |
| Durex Play Warmer | Ssl international, London, United Kingdom | ND | 4 |
| Durex Play Piña Colada | Ssl international, London, United Kingdom | ND | 4.29 |
| Durex Play More | Ssl international, London, United Kingdom | 1332 | 4.49 |
| ID Glide | Westridge Laboratories Inc, Santa Ana, CA, USA | 2901 | 5.2 |
| ID Juicy Lube Cherry | Westridge Laboratories Inc, Santa Ana, CA, USA | 3030 | 5.35 |
| ID Pleasure | Westridge Laboratories Inc, Santa Ana, CA, USA | 2898 | 5.26 |
| ID Sensation | Westridge Laboratories Inc, Santa Ana, CA, USA | ND | 5.95–6.5 |
| Astroglide Liquid | BioFilm Inc, Vista, CA, USA | 8064 | 4.44 |
| Astroglide Gel | BioFilm Inc, Vista, CA, USA | 2299 | 4.3 |
| Astroglide Warming Liquid | BioFilm Inc, Vista, CA, USA | ND | 6.45–6.73 |
| Astroglide Glyceryn & Paraben-Free Liquid | BioFilm Inc, Vista, CA, USA | 4806 | 4.54 |
| Astroglide Strawberry | BioFilm Inc, Vista, CA, USA | ND | 5.35 |
| Astroglide Silken Secret | BioFilm Inc, Vista, CA, USA | 6121 | 4.73 |
| Lifestyles Liquid (with Aloe & Vit. E) | Ansell Limited, Richmond, Victoria, Australia | 4229 | 6.3 |
| Lifestyles Excite Sensual Gel | Ansell Limited, Richmond, Victoria, Australia | 3728 | 7.2 |
| Lifestyles Warm Lovin' | Ansell Limited, Richmond, Victoria, Australia | ND | 5.24 |
| Maximus | Bodywise Limited, Isle of Wight, United Kingdom | 6415 | 6.05 |
| Babelube | Babeland, Seattle, WA, USA | 19 | 6.78 |
| Elbow Grease Thin Gel | B. Cumming Company Inc, Sun Valley, CA, USA | 2977 | 5.77 |
| Slippery Stuff Gel | Wallace O'Farrell Inc, Puyallup, WA, USA | 13 | 6.89 |
| O'My Natural Lubricant | O'My Products Inc, Vancouver, BC, Canada | 4348 | 5.46 |
| Liquid Silk | Bodywise Limited, Isle of Wight, United Kingdom | 3167 | 5.26 |
| Probe Personal Lubricant | Darvryan Laboratories Inc, Portland, OR, USA | 341 | 7.67 |
| Anal Lube Original Formula | California Exotic Novelties Inc, Chino, CA, USA | 3456 | 5.77 |
| ForPlay Gel-Plus | Trimensa Pharmaceuticals, Newbury Park, CA, USA | 9177 | 6.58 |
| Gun Oil H ₂ O | Empowered Products Inc, Las Vegas, NV, USA | 3955 | 5.61 |
| Duane Reade Lubricating Jelly | Duane Reade Inc, New York, NY, USA | 737 | 4.79 |
| Moist Again Vaginal Moisturizing Gel | Lake Consumer Products Inc, Jackson, WI, USA | 187 | 5.68 |
| Replens | Lil' Drug Store Products Inc, Cedar Rapids, IA, USA | 1491 | 2.98 |
| FemGlide | Cooper Surgical Inc, Puyallup, WA, USA | 15 | 6.13 |

Source: (16).

For more information, please contact:

Department of Reproductive Health and Research
World Health Organization
Avenue Appia 20, CH-1211 Geneva 27 Switzerland
Fax: +41 22 791 4171
E-mail: reproductivehealth@who.int
www.who.int/reproductivehealth

WHO/RHR/12.33

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End of Section 18.

Section 19: Performance Testing - Animal.

Content unchanged from original submission.

End of Section 19

Section 20: Performance Testing - Clinical.

Content unchanged from original submission.

End of Section 20

Section 21: Kit Certification.

Content unchanged from original submission.

End of Section 21

Section 22: Previous Submission Statement.

Content unchanged from original submission.

End of Section 22

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Section 5: 510(k) Summary

In accordance with 21 CFR 807.87(h) and 21 CFR 807.92 the 510(k) Summary for YES[®] oil-based Personal Lubricant, YES[®] water-based Personal Lubricant, and YES[®] Vaginal Moisturizer is provided below:

Device Common Name: Personal Lubricant

Device Proprietary Names: YES[®] oil-based Personal Lubricant
YES[®] water-based Personal Lubricant
YES[®] Vaginal Moisturizer

Sponsor: Biotech Lubricants Limited,
Ramshill,
Petersfield,
GU31 4AT,
United Kingdom

Official Correspondent: Karen Cornelius, Maetrics
BioCity Nottingham.
Pennyfoot Street,
Nottingham.
NG1 1GF.
United Kingdom.
Phone: +44 115 921 6200
Email: kcornelius@maetrics.com

Date Prepared: May 8, 2016

Classification Regulation: 884.5300

Classification Name: Condom

Panel: Obstetrics/Gynecology

Product Code: NUC

Predicate Device: K124044 Aloe Cadabra Personal Lubricant (Seven Oaks Ranch Inc)
K122477 Lifestyles Luxe Premium Personal Lubricant (Ansell Healthcare Product LLC)

Indications for Use:

YES[®] oil-based Personal Lubricant: A personal lubricant, for vaginal and penile application, intended to moisturize and lubricate, to enhance the ease and comfort of intimate sexual activity and supplement the body's natural lubrication. YES[®] oil-based Personal Lubricant is not compatible with natural rubber latex, polyurethane or polyisoprene condoms.

YES[®] water-based Personal Lubricant: A personal lubricant, for vaginal and penile application, intended to moisturize and lubricate, to enhance the ease and comfort of intimate sexual activity and supplement the body's natural lubrication. YES[®] water-based Personal Lubricant is compatible with natural rubber latex and polyisoprene condoms. This product is not compatible with polyurethane condoms.

YES[®] Vaginal Moisturizer: A personal lubricant, for vaginal and penile application, intended to moisturize and lubricate, to enhance the ease and comfort of intimate sexual activity and supplement the body's natural lubrication. YES[®] water-based Personal Lubricant is compatible with natural rubber latex, and polyisoprene condoms. This product is not compatible with polyurethane condoms.

YES[®] oil-based Personal Lubricant, YES[®] water-based Personal Lubricant and YES[®] Vaginal Moisturizer and the predicate devices have the same Indications For Use Statements.

Substantial Equivalence

Device Comparison Tables

| YES[®] water-based Personal Lubricant | | |
|---|--|--|
| 510(k) # | | K124044 |
| Device name | YES [®] water-based Personal Lubricant | Aloe Cadabra Personal lubricant |
| Manufacturer | Bio-tech Lubricants Ltd | Seven Oaks Ranch, Inc. |
| Classification | 884.5300 | 884.5300 |
| Product code | NUC | NUC |
| Description | Personal Lubricant | Personal Lubricant |
| Indications for use | YES [®] water-based Personal Lubricant is a personal lubricant, for vaginal and penile application, intended to moisturize and lubricate, to enhance the ease and comfort of intimate sexual activity and supplement the body's natural lubrication. YES [®] water-based Personal Lubricant is compatible with NRL and Polyisoprene condoms. This product is not compatible with polyurethane condoms. | Aloe Cadabra lubricants, are personal lubricants for penile and/or vaginal application, intended to moisturize and lubricate, to enhance the ease and comfort of intimate sexual activity and supplement the body's natural lubrication. This product is compatible with NRL and Polyisoprene condoms. This product is not compatible with polyurethane condoms. |
| Over-the-counter use | YES | YES |
| Biocompatible | YES | YES |
| Non-sterile | YES | YES |
| Packaging Materials | Plastic / PE | Plastic / PE |
| Contains plant extracts | YES | YES |
| Contains preservatives | YES | YES |

| YES[®] oil-based Personal Lubricant | | |
|---|--|---|
| 510(k) # | | K122477 |
| | YES [®] oil-based personal lubricant | LifeStyles Luxe Premium Personal Lubricant |
| Manufacturer | Bio-tech Lubricants Ltd | Ansell Healthcare Products, LLC |
| Classification | 884.5300 | 884.5300 |
| Product code | NUC | NUC |
| Description | Personal Lubricant | Personal Lubricant |
| Indications for use | YES [®] oil-based personal lubricant is a personal lubricant, for vaginal and penile application, intended to moisturize and lubricate, to enhance the ease and comfort of intimate sexual activity and supplement the body's natural lubrication. This product is not compatible with NRL, polyurethane or Polyisoprene condoms. | LifeStyles Luxe Premium Personal Lubricant Is a personal lubricant, for penile and/or vaginal application, intended to moisturize and lubricate, to enhance the ease and comfort of intimate sexual activity and supplement the body's natural lubrication. This product is compatible with natural rubber latex, polyurethane, and Polyisoprene condoms. |
| Over-the-counter use | YES | YES |
| Biocompatible | YES | YES |
| Non-sterile | YES | YES |
| Packaging Materials | Plastic / PE | Plastic / PE |
| Contains plant extracts | YES | No |
| Contains preservatives | No - Product cannot support microbial growth | No - Product cannot support microbial growth |

| YES[®] Vaginal Moisturizer | | |
|--|--|--|
| 510(k) # | | K124044 |
| | YES [®] VM (Vaginal Moisturizer) | Aloe Cadabra Personal lubricant |
| Manufacturer | Bio-tech Lubricants Ltd | Seven Oaks Ranch, Inc. |
| Classification | 884.5300 | 884.5300 |
| Product code | NUC | NUC |
| Description | Personal Lubricant | Personal Lubricant |
| Indications for use | YES [®] VM (Vaginal Moisturizer) is a personal lubricant, for vaginal and penile application, intended to moisturize and lubricate, to enhance the ease and comfort of intimate sexual activity and supplement the body's natural lubrication. YES [®] VM is compatible with NRL and Polyisoprene condoms. This product is not compatible with polyurethane condoms. | Aloe cadabra lubricants, are personal lubricants for penile and/or vaginal application, intended to moisturize and lubricate, to enhance the ease and comfort of intimate sexual activity and supplement the body's natural lubrication. This product is compatible with NRL and Polyisoprene condoms. This product is not compatible with polyurethane condoms. |
| Over-the-counter use | YES | YES |
| Biocompatible | YES | YES |
| Non-sterile | YES | YES |
| Packaging Materials | Plastic / PE, pre-filled applicators | Plastic / PE |
| Contains preservatives | YES | YES |

Device Descriptions:

YES[®] oil-based Personal Lubricant: A non-sterile, non-condom compatible oil-based personal lubricant formulated to supplement the body's natural lubricating fluids when vaginal dryness causes discomfort. It is neither a contraceptive nor a spermicide. The formulation is a cream coloured non-staining, thick paste that melts at body temperature.

YES[®] water-based Personal Lubricant: A non-sterile condom compatible high viscosity water-based personal lubricant formulated to supplement the body's natural lubricating fluids when vaginal dryness causes discomfort. It is neither a contraceptive nor a spermicide. The formulation is a lightly opaque, non-staining, non-greasy natural liquid gel.

YES[®] Vaginal Moisturizer: A non-sterile condom compatible personal lubricant formulated to supplement the body's own natural lubricating fluids to provide personal moisturization when vaginal dryness causes discomfort. It is neither a contraceptive nor a spermicide. The formulation is a lightly opaque, non-staining, non-greasy natural liquid gel.

Technological Characteristics - Formulation:

YES[®] oil-based Personal Lubricant formula is proprietary. The product however, is an oil-based or oil containing lubricant comprised of naturally occurring ingredients. The plant based oils and butters in the proposed device are all GRAS (Generally Recognized as Safe by FDA). It has no exceptional technological characteristics and is similar to other lubricants containing natural ingredients which are currently on the U.S. market. It is also substantially equivalent to the predicate device which is formulated from natural ingredients which are all GRAS.

YES[®] water-based Personal Lubricant formula is proprietary. The product however, is a water-based gel consisting mainly of water and water-soluble ingredients. It has no exceptional technological characteristics and is similar to other lubricants currently on the U.S. market. It is substantially equivalent to the predicate device.

YES[®] Vaginal Moisturizer formula is proprietary. The product however, is a water-based gel consisting mainly of water and water-soluble ingredients. It has no exceptional technological characteristics and is similar to other lubricants currently on the U.S. market. It is substantially equivalent to the predicate device.

Technological Characteristics - Biocompatibility Testing:

Biocompatibility Testing was conducted on YES[®] oil-based Personal Lubricant, YES[®] water-based Personal Lubricant and YES[®] Vaginal Moisturizer for Cytotoxicity, Vaginal Irritation, Sensitization, and Acute Systemic Toxicity in accordance with the ISO 10993-5, 10993-10 and 10993-11 standards.

The results for all three devices show that all meet the acceptance requirements of each test and are all non-cytotoxic, non-irritating, non-sensitizing and non-systemically toxic. The predicate device also meets the requirements for biocompatibility testing.

Technological Characteristics - Condom Compatibility Testing:

YES[®] oil-based Personal Lubricant: Condom compatibility testing was performed on natural rubber latex and polyisoprene condoms as per ASTM D7661-10. Test results indicate that the device affects the mechanical or physical integrity of the natural rubber latex and polyisoprene condoms. Therefore, the device is not compatible with natural rubber latex or polyisoprene condoms. Additionally, the device is labeled “not compatible with natural rubber latex or polyisoprene condoms”. The predicate device has also been tested in an identical manner and is compatible with rubber latex and polyisoprene condoms. The difference is due to the characteristics of non-silicone oils used in YES[®] oil-based Personal Lubricant. The device has not been tested with polyurethane condoms and is labeled “not compatible with natural rubber latex, polyisoprene or polyurethane condoms”.

YES[®] Vaginal Moisturizer and YES[®] water-based Personal Lubricant: Condom compatibility testing was performed on natural rubber latex and polyisoprene condoms as per ASTM D7661-10, Results indicated that the devices are compatible with natural rubber latex and polyisoprene condoms. The devices are labeled “compatible with natural rubber latex or polyisoprene condoms” in an identical manner to the predicate device. Both devices are not tested with polyurethane condoms and are labeled “not compatible with polyurethane condoms”

Technological Characteristics - Shelf Life and Microbial Limits:

YES[®] oil-based Personal Lubricant, YES[®] water-based Personal Lubricant, and YES[®] Vaginal Moisturizer have a 9-month shelf life based on the results of a real time aging study in accordance with the International Council For Harmonisation (ICH) Guidelines – Q1A(R2) – Stability Testing of Drug

Substances and Products. For each device, the predicate shelf-life has also been determined by real and accelerated aging studies.

Microbial limits testing has been conducted on YES[®] oil-based Personal Lubricant, YES[®] water-based Personal Lubricant, and YES[®] Vaginal Moisturizer in accordance with the requirements of USP <61> and USP <62> and microbial quality has been indicated. Both predicate devices have acceptable microbial quality determined by microbial limits testing.

Clinical Testing:

No clinical testing was required to demonstrate substantial equivalence to the predicate devices.

Conclusion:

YES[®] oil-based Personal Lubricant, YES[®] water-based Personal Lubricant, and YES[®] Vaginal Moisturizer have the same intended use and similar technological characteristics as the predicate devices. Biocompatibility, Non-Clinical condom compatibility or shelf life testing has demonstrated that these devices raise no new issues of safety or effectiveness. Therefore, these lubricants are substantially equivalent to the predicate devices.

End of Section 5

From: Cornelius, Karen [mailto:kcornelius@maetrics.com]
Sent: Friday, June 02, 2017 11:40 AM
To: Gallagher, Patrick
Subject: RE: K162569-S001 Biotech lubricant, Edits for 510(k) Summary

Hello Patrick,

Thank you for your email and the updated 510K summary.

I have made the changes requested below and attached a clean version of the updated summary.

Let me know if you need any additional information or if there are any further changes that I need to make.

With best wishes

Karen

Karen Cornelius
Senior Associate



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From: Gallagher, Patrick [mailto:Patrick.Gallagher@fda.hhs.gov]
Sent: 01 June 2017 22:11
To: Cornelius, Karen
Subject: RE: K162569-S001 Biotech lubricant, Edits for 510(k) Summary

Hello Karen,

I have a few comments for the 510(k) summary for the above file. After making these changes, please provide an updated summary (DOC format) by COB 6/5/17. In addition to the changes I've made to the attached summary, please make the following changes:

- a. Please include contact information (e.g., phone, email) for the submitter.
- b. In the device comparison tables, please include a comparison of physical parameters of the device (e.g., key specifications). In addition, The Technological Characteristics- Formulation section may not be necessary if this information is included in the tables.
- c. Please add a column to the comparison table which compares each category for the predicate and subject devices, and

lists whether they are the same, different, or similar. (Please see the 510(k) summary for K163395 as a rough guide for these changes)

- d. Beneath each table, please provide a summary which includes 1) a comparison of indications for use, and why any differences do not represent a new intended use, and 2) a discussion of differences between the subject and predicate devices, and why differences do not raise different questions of safety or effectiveness. The addition of the comparison column, described above, will help to simplify this summary.
- e. For the Shelf Life and Microbial Limits, please include the endpoints (i.e., device specifications and microbial limits) assessed in the studies. You may wish to include these in the device comparison tables or device specification tables, and simply reference them in this section

Thank you,
Patrick

Patrick Gallagher / Biomedical Engineer
Obstetrics and Gynecology Devices Branch
Office of Device Evaluation / Center for Devices and Radiological Health
Phone: 301-796-6486 | Patrick.Gallagher@fda.hhs.gov
10903 New Hampshire Avenue, WO66, Room G217, Silver Spring, MD 20993

[cid:image001.png@01D1C57E.DFA022A0](#)



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From: Cornelius, Karen [<mailto:kcornelius@maetrics.com>]
Sent: Tuesday, May 23, 2017 6:45 AM
To: Gallagher, Patrick
Subject: K162569-S001 Biotech lubricant, Edits for 510(k) Summary

Dear Patrick,

Further to your email to John Shepperson regarding K162569-S001, please find attached the requested 510(k) summary in word format.

I would like to take this opportunity to let you know that John has recently left the company and to ask that all future correspondence regarding this 510(k) be directed to myself if possible.

Please don't hesitate to let me know if you have any queries.

With best wishes

Karen

Karen Cornelius
Senior Associate



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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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From: Cornelius, Karen [mailto:kcornelius@maetrics.com]
Sent: Friday, June 09, 2017 4:30 AM
To: Gallagher, Patrick
Subject: RE: K162569-S001 Biotech lubricant, Edits for 510(k) Summary

Hello Patrick,

Many thanks for the final updated summary.

We have reviewed and can confirm that we are happy to accept all the changes in the attached document.

Please do let me know if you require any additional information from me.

With best wishes

Karen

Karen Cornelius
Senior Associate



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From: Gallagher, Patrick [mailto:Patrick.Gallagher@fda.hhs.gov]
Sent: 08 June 2017 22:49
To: Cornelius, Karen
Subject: RE: K162569-S001 Biotech lubricant, Edits for 510(k) Summary

Hi Karen

We had a few final changes during administrative review of the 510(k) summary. Could you please review these changes and provide your concurrence? Please note the deadline for this submission is tomorrow (6/8). I have one meeting from 12-1:30pm (UTC-5), but otherwise I will be available to answer any questions.

Thank you,
Patrick

Patrick Gallagher | Biomedical Engineer

Obstetrics and Gynecology Devices Branch
Office of Device Evaluation / Center for Devices and Radiological Health
Phone: 301-796-6486 | Patrick.Gallagher@fda.hhs.gov
10903 New Hampshire Avenue, WO66, Room G217, Silver Spring, MD 20993

[cid:image001.png@01D1C57E.DFA022A0](#)



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From: Cornelius, Karen [<mailto:kcornelius@maetrics.com>]
Sent: Thursday, June 08, 2017 11:29 AM
To: Gallagher, Patrick
Subject: RE: K162569-S001 Biotech lubricant, Edits for 510(k) Summary

Hello Patrick,

Many thanks for the amended 510(k) summary.

As discussed on the phone I have reviewed and accepted all the changes in the attached version of the summary apart from those relating to viscosity.

Let me know if the attached is acceptable or if you need any additional information.

With best wishes

Karen

Karen Cornelius
Senior Associate



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From: Gallagher, Patrick [<mailto:Patrick.Gallagher@fda.hhs.gov>]
Sent: 07 June 2017 19:46
To: Cornelius, Karen
Subject: RE: K162569-S001 Biotech lubricant, Edits for 510(k) Summary

Hello Karen,

During the administrative review, another round of changes were made to the 510(k) summary. Please provide your concurrence with these changes by COB tomorrow (6/8).

Thank you,
Patrick

Patrick Gallagher / Biomedical Engineer
Obstetrics and Gynecology Devices Branch
Office of Device Evaluation / Center for Devices and Radiological Health
Phone: 301-796-6486 | Patrick.Gallagher@fda.hhs.gov
10903 New Hampshire Avenue, WO66, Room G217, Silver Spring, MD 20993

cid:image001.png@01D1C57E.DFA022A0



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From: Cornelius, Karen [<mailto:kcornelius@maetrics.com>]
Sent: Friday, June 02, 2017 11:40 AM
To: Gallagher, Patrick
Subject: RE: K162569-S001 Biotech lubricant, Edits for 510(k) Summary

Hello Patrick,

Thank you for your email and the updated 510K summary.
I have made the changes requested below and attached a clean version of the updated summary.
Let me know if you need any additional information or if there are any further changes that I need to make.

With best wishes

Karen

Karen Cornelius
Senior Associate



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From: Gallagher, Patrick [<mailto:Patrick.Gallagher@fda.hhs.gov>]
Sent: 01 June 2017 22:11
To: Cornelius, Karen
Subject: RE: K162569-S001 Biotech lubricant, Edits for 510(k) Summary

Hello Karen,

I have a few comments for the 510(k) summary for the above file. After making these changes, please provide an updated summary (DOC format) by COB 6/5/17. In addition to the changes I've made to the attached summary, please make the following changes:

- a. Please include contact information (e.g., phone, email) for the submitter.
- b. In the device comparison tables, please include a comparison of physical parameters of the device (e.g., key specifications). In addition, The Technological Characteristics- Formulation section may not be necessary if this information is included in the tables.
- c. Please add a column to the comparison table which compares each category for the predicate and subject devices, and lists whether they are the same, different, or similar. (Please see the 510(k) summary for K163395 as a rough guide for these changes)
- d. Beneath each table, please provide a summary which includes 1) a comparison of indications for use, and why any differences do not represent a new intended use, and 2) a discussion of differences between the subject and predicate devices, and why differences do not raise different questions of safety or effectiveness. The addition of the comparison column, described above, will help to simplify this summary.
- e. For the Shelf Life and Microbial Limits, please include the endpoints (i.e., device specifications and microbial limits) assessed in the studies. You may wish to include these in the device comparison tables or device specification tables, and simply reference them in this section

Thank you,
Patrick

Patrick Gallagher / Biomedical Engineer
Obstetrics and Gynecology Devices Branch
Office of Device Evaluation / Center for Devices and Radiological Health
Phone: 301-796-6486 | Patrick.Gallagher@fda.hhs.gov
10903 New Hampshire Avenue, WO66, Room G217, Silver Spring, MD 20993

[cid:image001.png@01D1C57E.DFA022A0](#)



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From: Cornelius, Karen [<mailto:kcornelius@maetrics.com>]
Sent: Tuesday, May 23, 2017 6:45 AM
To: Gallagher, Patrick
Subject: K162569-S001 Biotech lubricant, Edits for 510(k) Summary

Dear Patrick,

Further to your email to John Shepperson regarding K162569-S001, please find attached the requested 510(k) summary in word format.

I would like to take this opportunity to let you know that John has recently left the company and to ask that all future correspondence regarding this 510(k) be directed to myself if possible.

Please don't hesitate to let me know if you have any queries.

With best wishes

Karen

Karen Cornelius
Senior Associate



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From: Cornelius, Karen [mailto:kcornelius@maetrics.com]
Sent: Tuesday, May 23, 2017 6:45 AM
To: Gallagher, Patrick
Subject: K162569-S001 Biotech lubricant, Edits for 510(k) Summary

Dear Patrick,

Further to your email to John Shepperson regarding K162569-S001, please find attached the requested 510(k) summary in word format.

I would like to take this opportunity to let you know that John has recently left the company and to ask that all future correspondence regarding this 510(k) be directed to myself if possible.

Please don't hesitate to let me know if you have any queries.

With best wishes

Karen

Karen Cornelius
Senior Associate



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510(k) Summary

Submitter: Biotech Lubricants Limited
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Phone: +44 (0) 3450 94 11 41
Email: sarah@biotechlubricants.com

Official Correspondent: Karen Cornelius,
Maetrics,
BioCity Nottingham, Pennyfoot Street,
Nottingham, NG1 1GF.
United Kingdom.
Phone: +44 (115) 921 6200
Email: kcornelius@maetrics.com

Date Prepared: December 6, 2018

Device Proprietary Names: YES[®] oil-based Personal Lubricant
YES[®] water-based Personal Lubricant
YES[®] Vaginal Moisturizer

Device Common Name: Personal Lubricant

Classification: Condom (CFR 884.5300)

Regulatory Class: II

Product Code: NUC (lubricant, personal)

Predicate Device: K124044 Aloe Cadabra Personal Lubricant (Seven Oaks Ranch Inc)
K122477 Lifestyles Luxe Premium Personal Lubricant (Ansell Healthcare Product LLC)

The predicate devices have never been subject to a design-related recall.

Device Description:

YES[®] oil-based Personal Lubricant: A non-sterile, non-condom compatible oil-based personal lubricant formulated to supplement the body's natural lubricating fluids when vaginal dryness causes discomfort. It is neither a contraceptive nor a spermicide. The formulation is a cream colored non-staining, thick paste that melts at body temperature.

| Parameter | Specification |
|---|----------------------------------|
| Color | Opaque paste |
| Odor | Slight beeswax and/or cocoa odor |
| Total yeast/mold count | <10 cfu/g (USP<61>) |
| Total aerobic mesophilic count | <100 cfu/g (USP<61>) |
| <i>Staphylococcus aureus</i> , <i>gram negative bacteria and candida albicans</i> | Absent in 1g (USP<62>) |

YES[®] water-based Personal Lubricant: A non-sterile condom compatible high viscosity water-based personal lubricant formulated to supplement the body's natural lubricating fluids when vaginal dryness causes discomfort. It is neither a contraceptive nor a spermicide. The formulation is a lightly opaque, non-staining, non-greasy natural liquid gel.

| Parameter | Specification |
|---|--|
| Color | Opaque gel |
| Odor | Slight-mild, delicate linseed / leather note |
| Viscosity | 2,000 – 20,000 cP |
| Total yeast/mold count | <10 cfu/g (USP<61>) |
| Total aerobic mesophilic count | <100 cfu/g (USP<61>) |
| <i>Staphylococcus aureus</i> , gram negative bacteria and <i>candida albicans</i> | Absent in 1g (USP<62>) |

YES[®] Vaginal Moisturizer: A non-sterile condom compatible personal lubricant formulated to supplement the body's own natural lubricating fluids to provide personal moisturization when vaginal dryness causes discomfort. It is neither a contraceptive nor a spermicide. The formulation is a lightly opaque, non-staining, non-greasy natural liquid gel.

| Parameter | Specification |
|---|---|
| Color | Opaque gel |
| Odor | Slight-mild, delicate linseed / leather |
| Viscosity | 2,000 – 20,000 cP |
| Total yeast/mold count | <10 cfu/g (USP<61>) |
| Total aerobic mesophilic count | <100 cfu/g (USP<61>) |
| <i>Staphylococcus aureus</i> , gram negative bacteria and <i>candida albicans</i> | Absent in 1g (USP<62>) |

Indications for Use:

YES[®] oil-based Personal Lubricant: A personal lubricant, for vaginal and penile application, intended to moisturize and lubricate, to enhance the ease and comfort of intimate sexual activity and supplement the body's natural lubrication. YES[®] oil-based Personal Lubricant is not compatible with natural rubber latex, polyurethane or polyisoprene condoms.

YES[®] water-based Personal Lubricant: A personal lubricant, for vaginal and penile application, intended to moisturize and lubricate, to enhance the ease and comfort of intimate sexual activity and supplement the body's natural lubrication. YES[®] water-based Personal Lubricant is compatible with natural rubber latex and polyisoprene condoms. This product is not compatible with polyurethane condoms.

YES[®] Vaginal Moisturizer: A personal lubricant, for vaginal and penile application, intended to moisturize and lubricate, to enhance the ease and comfort of intimate sexual activity and supplement the body's natural lubrication. YES[®] Vaginal Moisturizer is compatible with natural rubber latex, and polyisoprene condoms. This product is not compatible with polyurethane condoms.

Comparison of Intended Use and Technological Characteristics of Subject and Predicate Devices:**Device Comparison Tables**

| YES® water-based Personal Lubricant | | | Comparison |
|--|--|--|---|
| 510(k) # | K162569 | K124044 | |
| Device name | YES® water-based Personal Lubricant | Aloe Cadabra Personal lubricant | |
| Manufacturer | Bio-tech Lubricants Ltd | Seven Oaks Ranch, Inc. | |
| Classification | 884.5300 | 884.5300 | |
| Product code | NUC | NUC | |
| Description | Personal Lubricant | Personal Lubricant | Same |
| Indications for use | A personal lubricant, for vaginal and penile application, intended to moisturize and lubricate, to enhance the ease and comfort of intimate sexual activity and supplement the body's natural lubrication. YES® water-based Personal Lubricant is compatible with natural rubber latex and polyisoprene condoms. This product is not compatible with polyurethane condoms. | Aloe Cadabra Lubricant and Aloe Cadabra Flavored/Scented Lubricants are personal lubricants for penile and/or vaginal application, intended to moisturize and lubricate, to enhance the ease and comfort of intimate sexual activity and supplement the body's natural lubrication. This product is compatible with natural rubber latex and polyisoprene condoms. This product is not compatible with polyurethane condoms. | Same: The subject and predicate devices have the same indication for use, and therefore have the same intended use. |
| Water-based lubricant | YES | YES | Same |
| Over-the-counter use | YES | YES | Same |
| Biocompatible | YES | YES | Same |
| Non-sterile | YES | YES | Same |
| Packaging Materials | Plastic / PE | Plastic / PE | Same |
| Contains plant extracts | YES | YES | Same |
| Contains preservatives | YES | YES | Same |
| Microbial limits | See product specifications table (USP <61> & <62>) | Not known | Different: the microbial limits of the predicate are not known; however this does not raise different questions of S & E (e.g. microbial specifications within the accepted range for these types of devices) |
| Viscosity | 2,000 – 20,000 cP | Not Known | Different: the viscosity of the predicate is not known; however this does not raise different questions of S & E (e.g. viscosity specification within the |

| YES [®] water-based Personal Lubricant | | | Comparison |
|---|--|--|---|
| | | | accepted range for these types of devices |

As noted in the table above the subject and predicate devices are similar in that they have the same indications for use, are both non-sterile personal lubricants that are compatible with natural rubber latex and polyisoprene condoms and not compatible with polyurethane condoms. Differences do exist in the product formulations and specifications for microbial limits and viscosity. The differences do not raise different questions of safety and effectiveness as discussed in the table above.

| YES [®] oil-based Personal Lubricant | | | Comparison |
|---|--|---|--|
| 510(k) # | K162569 | K122477 | |
| Device Name | YES [®] oil-based personal lubricant | LifeStyles Luxe Premium Personal Lubricant | |
| Manufacturer | Bio-tech Lubricants Ltd | Ansell Healthcare Products, LLC | |
| Classification | 884.5300 | 884.5300 | |
| Product code | NUC | NUC | |
| Description | Personal Lubricant | Personal Lubricant | Same |
| Indications for use | A personal lubricant, for vaginal and penile application, intended to moisturize and lubricate, to enhance the ease and comfort of intimate sexual activity and supplement the body's natural lubrication. This product is not compatible with natural rubber latex, polyurethane or polyisoprene condoms. | LifeStyles Luxe Premium Personal Lubricant Is a personal lubricant, for penile and/or vaginal application, intended to moisturize and lubricate, to enhance the ease and comfort of intimate sexual activity and supplement the body's natural lubrication. This product is compatible with natural rubber latex, polyurethane, and polyisoprene condoms. | Same: The subject and predicate devices have the same indication for use, and therefore have the same intended use. |
| Oil-based lubricant | YES | YES | Same: the subject and predicate devices are based on different oils; however this does not raise different questions of S & E (e.g. biocompatibility). Condom compatibility is different and is addressed within labelling |
| Over-the-counter use | YES | YES | Same |
| Biocompatible | YES | YES | Same |
| Non-sterile | YES | YES | Same |
| Packaging Materials | Plastic / PE | Plastic / PE | Same |
| Contains plant extracts | YES | NO | Different: the predicate device does not contain plant extracts however this does not raise different questions of S & E (e.g. biocompatibility) |
| Contains preservatives | No - Product cannot support microbial growth | No - Product cannot support microbial growth | Same |

| YES [®] oil-based Personal Lubricant | | | Comparison |
|---|--|---|---|
| Microbial limits | See product specifications table (USP <61> & <62>) | Meets the requirements of USP <61> & <62> | Different: Microbial limits of predicate not known, however this does not raise different questions of S & E (e.g. microbial specifications within the accepted range for these types of devices) |

As noted in the table above the subject and predicate devices are similar in that they have the same indications for use and are both non-sterile personal lubricants. Differences do exist in the product formulations, condom compatibility and specifications for microbial limits. The differences do not raise different questions of safety and effectiveness as discussed in the table above.

| YES [®] Vaginal Moisturizer | | | Comparison |
|--------------------------------------|---|--|--|
| 510(k) # | K162569 | K124044 | |
| Device Name | YES [®] VM (Vaginal Moisturizer) | Aloe Cadabra Personal lubricant | |
| Manufacturer | Bio-tech Lubricants Ltd | Seven Oaks Ranch, Inc. | |
| Classification | 884.5300 | 884.5300 | |
| Product code | NUC | NUC | |
| Description | Personal Lubricant | Personal Lubricant | Same |
| Indications for use | A personal lubricant, for vaginal and penile application, intended to moisturize and lubricate, to enhance the ease and comfort of intimate sexual activity and supplement the body's natural lubrication. YES [®] Vaginal Moisturizer is compatible with natural rubber latex and polyisoprene condoms. This product is not compatible with polyurethane condoms. | Aloe Cadabra Lubricant and Aloe Cadabra Flavored/Scented Lubricants are personal lubricants for penile and/or vaginal application, intended to moisturize and lubricate, to enhance the ease and comfort of intimate sexual activity and supplement the body's natural lubrication. This product is compatible with natural rubber latex and polyisoprene condoms. This product is not compatible with polyurethane condoms. | Same: The subject and predicate devices have the same indication for use, and therefore have the same intended use. |
| Water-based lubricant | YES | YES | Same |
| Over-the-counter use | YES | YES | Same |
| Biocompatible | YES | YES | Same |
| Non-sterile | YES | YES | Same |
| Packaging Materials | Plastic / PE, pre-filled applicators | Plastic / PE | Same |
| Contains preservatives | YES | YES | Same |
| Microbial Limits | See product specifications table (USP <61> & <62>) | Not known | Different: the microbial limits of the predicate are not known; however this does not raise different questions of S & E (e.g. |

| YES [®] Vaginal Moisturizer | | | Comparison |
|--------------------------------------|-------------------|-----------|---|
| | | | microbial specifications within the accepted range for these types of devices) |
| Viscosity | 2,000 – 20,000 cP | Not known | Different: the viscosity of the predicate is not known; however this does not raise different questions of S & E (e.g. viscosity specification within the accepted range for these types of devices |

As noted in the table above the subject and predicate devices are similar in that they have the same indication for use, are both non-sterile personal lubricants that are compatible with natural rubber latex and polyisoprene condoms and not compatible with polyurethane condoms. Differences do exist in the specifications for microbial limits and viscosity. The differences do not raise different questions of safety and effectiveness as discussed in the table above.

Performance Testing:

Biocompatibility:

Testing was conducted to assess the biocompatibility of the YES[®] oil-based Personal Lubricant, YES[®] water-based Personal Lubricant and YES[®] Vaginal Moisturizer. Testing included assessments for Cytotoxicity (ISO 10993-5:2009(R)2014), Vaginal Irritation (ISO 10993-10:2010(R)2014), Sensitization (ISO 10993-10:2010(R)2014), and Acute Systemic Toxicity (ISO 10993-11:2006).

The results for all three devices show that all meet the acceptance requirements of each test and are all non-cytotoxic, non-irritating, non-sensitizing and non-systemically toxic. The predicate device also meets the requirements for biocompatibility testing.

Condom Compatibility:

YES[®] oil-based Personal Lubricant: Condom compatibility testing was performed for polyurethane condoms per ASTM D7661-10. The results indicate that the device is not compatible with polyurethane condoms. Additionally, compatibility testing was not performed for natural rubber latex or polyisoprene condoms; therefore, the device is not compatible with natural rubber latex or polyisoprene condoms. The device is labeled “not compatible with natural rubber latex, polyurethane or polyisoprene condoms.”

YES[®] Vaginal Moisturizer and YES[®] water-based Personal Lubricant: Condom compatibility testing was performed per ASTM D7661-10. The results indicated that the devices are compatible with natural rubber latex and polyisoprene condoms, but are not compatible with polyurethane condoms. The devices are labeled “compatible with natural rubber latex or polyisoprene condoms” in an identical manner to the predicate device. Both devices are labeled “not compatible with polyurethane condoms.”

Shelf Life and Microbial Limits:

YES[®] oil-based Personal Lubricant, YES[®] water-based Personal Lubricant, and YES[®] Vaginal Moisturizer have a 9-month shelf life based on the results of an accelerated aging study in accordance with the International Council For Harmonization (ICH) Guidelines – Q1A (R2) – Stability Testing of Drug Substances and Products. The results demonstrated that the subject lubricants met all device specifications for the duration of the accelerated aging study.

Microbial limits testing has been conducted on YES[®] oil-based Personal Lubricant, YES[®] water-based Personal Lubricant, and YES[®] Vaginal Moisturizer in accordance with the requirements of USP <61> and USP <62> and microbial quality has been indicated (see product specification tables). Both predicate devices have acceptable microbial quality determined by microbial limits testing.

Conclusion:

YES[®] oil-based Personal Lubricant, YES[®] water-based Personal Lubricant, and YES[®] Vaginal Moisturizer have the same intended use and similar technological characteristics as the predicate devices. The results of the performance testing conducted on the subject devices demonstrate that they are as safe and effective as the predicate devices and support substantial equivalence.

510(k) Summary

Submitter: Biotech Lubricants Limited
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GU31 4AT
United Kingdom
Phone: +44 (0) 3450 94 11 41
Email: sarah@biotechlubricants.com

Official Correspondent: Karen Cornelius
Maetrics
BioCity Nottingham, Pennyfoot Street
Nottingham, NG1 1GF
United Kingdom
Phone: +44 (115) 921 6200
Email: kcornelius@maetrics.com

Date Prepared: December 6, 2018

Device Proprietary Names: YES[®] oil-based Personal Lubricant
YES[®] water-based Personal Lubricant
YES[®] Vaginal Moisturizer

Device Common Name: Personal Lubricant

Classification: Condom (21 CFR 884.5300)

Regulatory Class: II

Product Code: NUC (lubricant, personal)

Predicate Device: K124044 Aloe Cadabra Personal Lubricant (Seven Oaks Ranch, Inc.)
K122477 Lifestyles Luxe Premium Personal Lubricant (Ansell Healthcare Products LLC)

The predicate devices have not been subject to a design-related recall.

Device Description:

YES[®] oil-based Personal Lubricant: This non-sterile and oil-based personal lubricant consists primarily of Sunflower oil and Shea butter, and is not compatible with condoms. It is neither a contraceptive nor a spermicide. The formulation is a cream-colored thick paste that melts at body temperature. The product is packaged in a high density polyethylene (HDPE) tube with a flip-top cap. The specifications for the YES[®] oil-based Personal Lubricant are shown below:

| Parameter | Specification |
|--|---|
| Color | Opaque paste |
| Odor | Slight beeswax and/or cocoa odor |
| Viscosity | N/A: measuring viscosity is not feasible, since changes in phase during measurement lead to differences in viscosity readings |
| Total yeast/mold count | <10 cfu/g (USP<61>) |
| Total aerobic mesophilic count | <100 cfu/g (USP<61>) |
| Absence of Pathogenic bacteria: <i>Staphylococcus aureus, Candida</i> | Absent in 1g (USP<62>) |

| | |
|--|--|
| <i>albicans, and gram negative bacteria (e.g., Pseudomonas aeruginosa)</i> | |
|--|--|

YES® water-based Personal Lubricant: This non-sterile and water-based personal lubricant ~~consists of primarily of~~ contains Aloe vera and other components, and is compatible with natural rubber latex and polyisoprene condoms. This product is not compatible with polyurethane condoms. It is neither a contraceptive nor a spermicide. The formulation is a lightly opaque, non-greasy liquid gel. The product is packaged in a HDPE tube with a flip-top cap, and a HDPE single-use applicator. The specifications for the YES® water-based Personal Lubricant are shown below:

| Parameter | Specification |
|---|---|
| Color | Opaque gel |
| Odor | Slight-mild, delicate linseed / leather note |
| Viscosity | 2,000 – 20,000 cP |
| pH | 3.70 - 4.50 |
| Osmolality | 100 - 400 mOsm/kg |
| Antimicrobial Effectiveness | <u>At least 2.0 log reduction from the initial count at 14 days; no increase from the 14 days count at 28 days; no increase from the initial calculated count at 14 and 28 days Category 2 (USP <51>)</u> |
| Total yeast/mold count | <10 cfu/g (USP<61>) |
| Total aerobic mesophilic count | <100 cfu/g (USP<61>) |
| <i>Absence of Pathogenic bacteria: Staphylococcus aureus, Candida albicans, and gram negative bacteria (e.g., Pseudomonas aeruginosa)</i> | Absent in 1g (USP<62>) |

YES® Vaginal Moisturizer: This non-sterile and water-based personal lubricant ~~consists of primarily of~~ contains Aloe vera and other components, and is compatible with natural rubber latex, and polyisoprene condoms. This product is not compatible with polyurethane condoms. It is neither a contraceptive nor a spermicide. The formulation is a lightly opaque, non-greasy liquid gel. The product is packaged in a HDPE tube with a flip-top cap, and a HDPE single-use applicator. The specifications for the YES® Vaginal Moisturizer are shown below:

| Parameter | Specification |
|--|---|
| Color | Opaque gel |
| Odor | Slight-mild, delicate linseed / leather |
| Viscosity | 2,000 – 20,000 cP |
| pH | 3.50-4.50 |
| Osmolality | 250-400 mOsm/kg |
| Antimicrobial Effectiveness | <u>At least 2.0 log reduction from the initial count at 14 days; no increase from the 14 days count at 28 days; no increase from the initial calculated count at 14 and 28 days Category 2 (USP <51>)</u> |
| Total yeast/mold count | <10 cfu/g (USP<61>) |
| Total aerobic mesophilic count | <100 cfu/g (USP<61>) |
| <i>Absence of Pathogenic bacteria:</i> | Absent in 1g (USP<62>) |

| | |
|---|--|
| <i>Staphylococcus aureus, Candida albicans, and gram negative bacteria (e.g., Pseudomonas aeruginosa)</i> | |
|---|--|

Indications for Use:

YES[®] oil-based Personal Lubricant: A personal lubricant, for vaginal and penile application, intended to moisturize and lubricate, to enhance the ease and comfort of intimate sexual activity and supplement the body's natural lubrication. YES[®] oil-based Personal Lubricant is not compatible with natural rubber latex, polyurethane or polyisoprene condoms.

YES[®] water-based Personal Lubricant: A personal lubricant, for vaginal and penile application, intended to moisturize and lubricate, to enhance the ease and comfort of intimate sexual activity and supplement the body's natural lubrication. YES[®] water-based Personal Lubricant is compatible with natural rubber latex and polyisoprene condoms. This product is not compatible with polyurethane condoms.

YES[®] Vaginal Moisturizer: A personal lubricant, for vaginal and penile application, intended to moisturize and lubricate, to enhance the ease and comfort of intimate sexual activity and supplement the body's natural lubrication. YES[®] Vaginal Moisturizer is compatible with natural rubber latex, and polyisoprene condoms. This product is not compatible with polyurethane condoms.

Comparison of Intended Use and Technological Characteristics of Subject and Predicate Devices:

| YES [®] oil-based Personal Lubricant | | | Comparison |
|---|--|---|--|
| 510(k) # | K162569 | K122477 | |
| Device Name | YES [®] oil-based personal lubricant | LifeStyles Luxe Premium Personal Lubricant | |
| Manufacturer | Bio-tech Lubricants Ltd | Ansell Healthcare Products, LLC | |
| Classification | 884.5300 | 884.5300 | |
| Product code | NUC | NUC | |
| Description | Personal Lubricant | Personal Lubricant | Same |
| Indications for use | A personal lubricant, for vaginal and penile application, intended to moisturize and lubricate, to enhance the ease and comfort of intimate sexual activity and supplement the body's natural lubrication. This product is not compatible with natural rubber latex, polyurethane or polyisoprene condoms. | LifeStyles Luxe Premium Personal Lubricant Is a personal lubricant, for penile and/or vaginal application, intended to moisturize and lubricate, to enhance the ease and comfort of intimate sexual activity and supplement the body's natural lubrication. This product is compatible with natural rubber latex, polyurethane, and polyisoprene condoms. | Same <u>Different</u> : The subject and predicate devices <u>indication for use statements differ in regards to compatibility with condoms. Differences noted do not represent a new intended use have the same indication for use, and therefore have the same intended use.</u> |
| Oil-based lubricant | YES | YES | Same: the subject and predicate devices are both oil-based lubricants; however, the specific oils in the formulation are |

| YES [®] oil-based Personal Lubricant | | | Comparison |
|---|---|---|--|
| | | | different. This does not raise different questions of S & E (e.g. biocompatibility). |
| Primary ingredients | Sunflower seed oil , and Shea butter, Sweet almond oil , Bees wax , Cocoa seed butter , Vitamin E | Not known | Different: The difference in ingredients do not raise different questions of S & E. |
| Biocompatible | YES | YES | Same |
| Non-sterile | YES | YES | Same |
| Contains preservatives | NO | NO | Same |
| Microbial limits (TAMC, TYMC, and absence of pathogenic bacteria) | See product specifications table (USP <61> & <62>) | Meets the requirements of USP <61> & <62> | Different: the microbial limits of the predicate are not known; however this does not raise different questions of S & E as the microbial limits specifications are within the accepted ranges for these types of devices. |
| Condom Compatibility | Not compatible with natural rubber latex, polyurethane, or polyisoprene condoms. | Compatible with natural rubber latex, polyurethane, and polyisoprene condoms. | Different: The condom compatibility for the subject and predicate devices are different; However, this difference does not represent a new intended use. |

As noted in the table above the subject and predicate devices [indications are similar in that they are both used to moisturize and lubricate, to enhance the ease and comfort of intimate sexual activity and supplement the body's natural lubrication](#). However, they do differ in regards to condom compatibility as [the subject device is not compatible with condoms, while the predicate is condom compatible](#). [Differences in condom compatibility between the subject and predicate devices do not represent a new intended use](#). [In regards to technology, have the same indication for use and intended use](#). ~~In addition,~~ the subject and predicate devices are similar in that they are both non-sterile and are oil-based. Differences do exist as described in the table above (e.g., product formulations, specifications for microbial limits, [viscosity](#), condom compatibility, etc.). The differences identified do not raise different questions of safety and effectiveness as discussed in the table above

| YES [®] water-based Personal Lubricant | | | Comparison |
|---|---|---|---|
| 510(k) # | K162569 | K124044 | |
| Device name | YES [®] water-based Personal Lubricant | Aloe Cadabra Personal lubricant | |
| Manufacturer | Bio-tech Lubricants Ltd | Seven Oaks Ranch, Inc. | |
| Classification | 884.5300 | 884.5300 | |
| Product code | NUC | NUC | |
| Description | Personal Lubricant | Personal Lubricant | Same |
| Indications for use | A personal lubricant, for vaginal and penile application, intended to | Aloe Cadabra Lubricant and Aloe Cadabra Flavored/Scented Lubricants | Same: The subject and predicate devices have the same indication for use, |

| YES® water-based Personal Lubricant | | | Comparison |
|---|---|--|--|
| | moisturize and lubricate, to enhance the ease and comfort of intimate sexual activity and supplement the body's natural lubrication. YES® water-based Personal Lubricant is compatible with natural rubber latex and polyisoprene condoms. This product is not compatible with polyurethane condoms. | are personal lubricants for penile and/or vaginal application, intended to moisturize and lubricate, to enhance the ease and comfort of intimate sexual activity and supplement the body's natural lubrication. This product is compatible with natural rubber latex and polyisoprene condoms. This product is not compatible with polyurethane condoms. | and therefore have the same intended use. |
| Water-based lubricant | YES | YES | Same |
| Primary Ingredients | Water , Aloe vera , Flax seed extract , Guar gum , Locust bean gum , Xanthan gum , Sodium chloride , Potassium sorbate , Citric acid , Phenoxyethanol | Aloe vera | Same |
| Biocompatible | YES | YES | Same |
| Non-sterile | YES | YES | Same |
| Contains preservatives | YES | YES | Same |
| Microbial limits (TAMC, TYMC, and absence of pathogenic bacteria) | See product specifications table (USP <61> & <62>) | Not known | Different: the microbial limits of the predicate are not known; however this does not raise different questions of S & E as these specifications are within the accepted range for these types of devices. |
| Viscosity | 2,000 – 20,000 cP | Not known | Different: the viscosity of the predicate is not known. This does not raise different questions of S & E as the viscosity specification is within the accepted range for these types of devices. |
| pH | 3.70 - 4.50 | Not known | Different: the pH of the predicate is not known. This does not raise different questions of S & E as the pH specification is within the accepted range for these types of devices. |
| Osmolality | 100 - 400 mOsm/kg | Not known | Different: the osmolality of the predicate is not known. This does not raise different questions of S & E as the osmolality specification is within the accepted range for these types of devices. |

| YES [®] water-based Personal Lubricant | | | Comparison |
|---|--|--|------------|
| Condom Compatibility | Compatible with natural rubber latex and polyisoprene condoms. Not compatible with polyurethane condoms. | Compatible with natural rubber latex and polyisoprene condoms. Not compatible with polyurethane condoms. | Same |

As noted in the table above the subject and predicate devices have the same indication for use and intended use. In addition, the subject and predicate devices are similar in that they are both non-sterile, compatible with the same types of condoms, ~~and contain are~~ Aloe vera, ~~and are water~~-based. Differences do exist as described in the table above (e.g., product formulations, specifications for microbial limits, viscosity, etc.). The differences identified do not raise different questions of safety and effectiveness as discussed in the table above.

| YES [®] Vaginal Moisturizer | | | Comparison |
|--------------------------------------|---|--|---|
| 510(k) # | K162569 | K124044 | |
| Device Name | YES [®] VM (Vaginal Moisturizer) | Aloe Cadabra Personal lubricant | |
| Manufacturer | Bio-tech Lubricants Ltd | Seven Oaks Ranch, Inc. | |
| Classification | 884.5300 | 884.5300 | |
| Product code | NUC | NUC | |
| Description | Personal Lubricant | Personal Lubricant | Same |
| Indications for use | A personal lubricant, for vaginal and penile application, intended to moisturize and lubricate, to enhance the ease and comfort of intimate sexual activity and supplement the body's natural lubrication. YES [®] Vaginal Moisturizer is compatible with natural rubber latex and polyisoprene condoms. This product is not compatible with polyurethane condoms. | Aloe Cadabra Lubricant and Aloe Cadabra Flavored/Scented Lubricants are personal lubricants for penile and/or vaginal application, intended to moisturize and lubricate, to enhance the ease and comfort of intimate sexual activity and supplement the body's natural lubrication. This product is compatible with natural rubber latex and polyisoprene condoms. This product is not compatible with polyurethane condoms. | Same: The subject and predicate devices have the same indication for use, and therefore have the same intended use. |
| Water-based lubricant | YES | YES | Same |
| Primary Ingredients | Water , Aloe vera , Flax seed extract , Guar gum , Locust bean gum , Xanthan gum , Sodium chloride , Potassium sorbate , Citric acid , Phenoxyethanol | Aloe vera | Same |
| Biocompatible | YES | YES | Same |
| Non-sterile | YES | YES | Same |
| Contains preservatives | YES | YES | Same |
| Microbial Limits | See product specifications | Not known | Different: the microbial |

| YES [®] Vaginal Moisturizer | | | Comparison |
|--|--|--|--|
| (TAMC, TYMC, and absence of pathogenic bacteria) | table (USP <61> & <62>) | | limits of the predicate are not known; however this does not raise different questions of S & E as these specifications are within the accepted range for these types of devices. |
| Viscosity | 2,000 – 20,000 cP | Not known | Different: the viscosity of the predicate is not known. This does not raise different questions of S & E as the viscosity specification is within the accepted range for these types of devices |
| pH | 3.50-4.50 | Not known | Different: the pH of the predicate is not known. This does not raise different questions of S & E as the pH specification is within the accepted range for these types of devices. |
| Osmolality | 250-400 mOsm/kg | Not known | Different: the osmolality of the predicate is not known. This does not raise different questions of S & E as the osmolality specification is within the accepted range for these types of devices. |
| Condom Compatibility | Compatible with natural rubber latex and polyisoprene condoms. Not compatible with polyurethane condoms. | Compatible with natural rubber latex and polyisoprene condoms. Not compatible with polyurethane condoms. | Same |

As noted in the table above the subject and predicate devices have the same indication for use and intended use. In addition, the subject and predicate devices are similar in that they are both non-sterile, compatible with the same types of condoms, ~~and are contain~~ Aloe vera, ~~and are water~~-based. Differences do exist as described in the table above (e.g., product formulations, specifications for microbial limits, viscosity, etc.). The differences identified do not raise different questions of safety and effectiveness as discussed in the table above.

Performance Testing:

Biocompatibility:

Testing was conducted to assess the biocompatibility of the YES[®] oil-based Personal Lubricant, YES[®] water-based Personal Lubricant and YES[®] Vaginal Moisturizer. Testing included assessments for Cytotoxicity (ISO 10993-5:2009(R)2014), Vaginal Irritation (ISO 10993-10:2010(R)2014), Sensitization (ISO 10993-10:2010(R)2014), and Acute Systemic Toxicity (ISO 10993-11:2006).

The results of testing demonstrated that they are non-cytotoxic, non-irritating, non-sensitizing and non-systemically toxic.

Condom Compatibility:

YES[®] oil-based Personal Lubricant: Condom compatibility testing was performed for polyurethane condoms per ASTM D7661-10. The results indicate that the device is not compatible with polyurethane condoms. Additionally, compatibility testing was not performed for natural rubber latex or polyisoprene condoms; therefore, the device is not compatible with natural rubber latex or polyisoprene condoms.

YES[®] Vaginal Moisturizer and YES[®] water-based Personal Lubricant: Condom compatibility testing was performed per ASTM D7661-10. The results indicated that the devices are compatible with natural rubber latex and polyisoprene condoms, but are not compatible with polyurethane condoms.

Shelf Life and Microbial Limits:

YES[®] oil-based Personal Lubricant, YES[®] water-based Personal Lubricant, and YES[®] Vaginal Moisturizer have a 9-month shelf life. The results [of shelf-life testing](#) demonstrated that the subject lubricants met all device specifications as shown in the Device Description section for the duration of the [9-month shelf-life study](#).

Conclusion:

YES[®] oil-based Personal Lubricant, YES[®] water-based Personal Lubricant, and YES[®] Vaginal Moisturizer have the same intended use and similar technological characteristics as the predicate devices. The results of the performance testing conducted on the subject devices demonstrate that they are as safe and effective as the predicate devices and support substantial equivalence.

510(k) Summary

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Date Prepared: June 9, 2017

Device Proprietary Names: YES[®] oil-based Personal Lubricant
YES[®] water-based Personal Lubricant
YES[®] Vaginal Moisturizer

Device Common Name: Personal Lubricant

Classification: Condom (21 CFR 884.5300)

Regulatory Class: II

Product Code: NUC (lubricant, personal)

Predicate Device: K124044 Aloe Cadabra Personal Lubricant (Seven Oaks Ranch, Inc.)
K122477 Lifestyles Luxe Premium Personal Lubricant (Ansell Healthcare Products LLC)

The predicate devices have not been subject to a design-related recall.

Device Description:

YES[®] oil-based Personal Lubricant: This non-sterile and oil-based personal lubricant consists primarily of Sunflower oil and Shea butter, and is not compatible with condoms. It is neither a contraceptive nor a spermicide. The formulation is a cream-colored thick paste that melts at body temperature. The product is packaged in a high density polyethylene (HDPE) tube with a flip-top cap. The specifications for the YES[®] oil-based Personal Lubricant are shown below:

| Parameter | Specification |
|--|---|
| Color | Opaque paste |
| Odor | Slight beeswax and/or cocoa odor |
| Viscosity | N/A: measuring viscosity is not feasible, since changes in phase during measurement lead to differences in viscosity readings |
| Total yeast/mold count | <10 cfu/g (USP<61>) |
| Total aerobic mesophilic count | <100 cfu/g (USP<61>) |
| Absence of Pathogenic bacteria: <i>Staphylococcus aureus</i> , <i>Candida</i> | Absent in 1g (USP<62>) |

| | |
|--|--|
| <i>albicans, and gram negative bacteria (e.g., Pseudomonas aeruginosa)</i> | |
|--|--|

YES® water-based Personal Lubricant: This non-sterile and water-based personal lubricant contains Aloe vera and other components, and is compatible with natural rubber latex and polyisoprene condoms. This product is not compatible with polyurethane condoms. It is neither a contraceptive nor a spermicide. The formulation is a lightly opaque, non-greasy liquid gel. The product is packaged in a HDPE tube with a flip-top cap, and a HDPE single-use applicator. The specifications for the YES® water-based Personal Lubricant are shown below:

| Parameter | Specification |
|---|---|
| Color | Opaque gel |
| Odor | Slight-mild, delicate linseed / leather note |
| Viscosity | 2,000 – 20,000 cP |
| pH | 3.70 - 4.50 |
| Osmolality | 100 - 400 mOsm/kg |
| Antimicrobial Effectiveness | At least 2.0 log reduction from the initial count at 14 days; no increase from the 14 days count at 28 days; no increase from the initial calculated count at 14 and 28 days (USP <51>) |
| Total yeast/mold count | <10 cfu/g (USP<61>) |
| Total aerobic mesophilic count | <100 cfu/g (USP<61>) |
| <i>Absence of Pathogenic bacteria: Staphylococcus aureus, Candida albicans, and gram negative bacteria (e.g., Pseudomonas aeruginosa)</i> | Absent in 1g (USP<62>) |

YES® Vaginal Moisturizer: This non-sterile and water-based personal lubricant contains Aloe vera and other components, and is compatible with natural rubber latex, and polyisoprene condoms. This product is not compatible with polyurethane condoms. It is neither a contraceptive nor a spermicide. The formulation is a lightly opaque, non-greasy liquid gel. The product is packaged in a HDPE tube with a flip-top cap, and a HDPE single-use applicator. The specifications for the YES® Vaginal Moisturizer are shown below:

| Parameter | Specification |
|--|---|
| Color | Opaque gel |
| Odor | Slight-mild, delicate linseed / leather |
| Viscosity | 2,000 – 20,000 cP |
| pH | 3.50-4.50 |
| Osmolality | 250-400 mOsm/kg |
| Antimicrobial Effectiveness | At least 2.0 log reduction from the initial count at 14 days; no increase from the 14 days count at 28 days; no increase from the initial calculated count at 14 and 28 days (USP <51>) |
| Total yeast/mold count | <10 cfu/g (USP<61>) |
| Total aerobic mesophilic count | <100 cfu/g (USP<61>) |
| <i>Absence of Pathogenic bacteria:</i> | Absent in 1g (USP<62>) |

| |
|---|
| <i>Staphylococcus aureus, Candida albicans, and gram negative bacteria (e.g., Pseudomonas aeruginosa)</i> |
|---|

Indications for Use:

YES[®] oil-based Personal Lubricant: A personal lubricant, for vaginal and penile application, intended to moisturize and lubricate, to enhance the ease and comfort of intimate sexual activity and supplement the body's natural lubrication. YES[®] oil-based Personal Lubricant is not compatible with natural rubber latex, polyurethane or polyisoprene condoms.

YES[®] water-based Personal Lubricant: A personal lubricant, for vaginal and penile application, intended to moisturize and lubricate, to enhance the ease and comfort of intimate sexual activity and supplement the body's natural lubrication. YES[®] water-based Personal Lubricant is compatible with natural rubber latex and polyisoprene condoms. This product is not compatible with polyurethane condoms.

YES[®] Vaginal Moisturizer: A personal lubricant, for vaginal and penile application, intended to moisturize and lubricate, to enhance the ease and comfort of intimate sexual activity and supplement the body's natural lubrication. YES[®] Vaginal Moisturizer is compatible with natural rubber latex, and polyisoprene condoms. This product is not compatible with polyurethane condoms.

Comparison of Intended Use and Technological Characteristics of Subject and Predicate Devices:

| YES [®] oil-based Personal Lubricant | | | Comparison |
|---|--|---|--|
| 510(k) # | K162569 | K122477 | |
| Device Name | YES [®] oil-based personal lubricant | LifeStyles Luxe Premium Personal Lubricant | |
| Manufacturer | Bio-tech Lubricants Ltd | Ansell Healthcare Products, LLC | |
| Classification | 884.5300 | 884.5300 | |
| Product code | NUC | NUC | |
| Description | Personal Lubricant | Personal Lubricant | Same |
| Indications for use | A personal lubricant, for vaginal and penile application, intended to moisturize and lubricate, to enhance the ease and comfort of intimate sexual activity and supplement the body's natural lubrication. This product is not compatible with natural rubber latex, polyurethane or polyisoprene condoms. | LifeStyles Luxe Premium Personal Lubricant Is a personal lubricant, for penile and/or vaginal application, intended to moisturize and lubricate, to enhance the ease and comfort of intimate sexual activity and supplement the body's natural lubrication. This product is compatible with natural rubber latex, polyurethane, and polyisoprene condoms. | Different: The subject and predicate devices indication for use statements differ in regards to compatibility with condoms. Differences noted do not represent a new intended use. |
| Oil-based lubricant | YES | YES | Same: the subject and predicate devices are both oil-based lubricants; however, the specific oils in the formulation are |

| YES [®] oil-based Personal Lubricant | | | Comparison |
|---|---|---|--|
| | | | different. This does not raise different questions of S & E (e.g. biocompatibility). |
| Ingredients | Sunflower seed oil, Shea butter, Sweet almond oil, Bees wax, Cocoa seed butter, Vitamin E | Not known | Different: The difference in ingredients do not raise different questions of S & E. |
| Biocompatible | YES | YES | Same |
| Non-sterile | YES | YES | Same |
| Contains preservatives | NO | NO | Same |
| Microbial limits (TAMC, TYMC, and absence of pathogenic bacteria) | See product specifications table (USP <61> & <62>) | Meets the requirements of USP <61> & <62> | Different: the microbial limits of the predicate are not known; however this does not raise different questions of S & E as the microbial limits specifications are within the accepted ranges for these types of devices. |
| Condom Compatibility | Not compatible with natural rubber latex, polyurethane, or polyisoprene condoms. | Compatible with natural rubber latex, polyurethane, and polyisoprene condoms. | Different: The condom compatibility for the subject and predicate devices are different; However, this difference does not represent a new intended use. |

As noted in the table above the subject and predicate devices indications are similar in that they are both used to moisturize and lubricate, to enhance the ease and comfort of intimate sexual activity and supplement the body's natural lubrication. However, they do differ in regards to condom compatibility as the subject device is not compatible with condoms, while the predicate is condom compatible. Differences in condom compatibility between the subject and predicate devices do not represent a new intended use. In regards to technology, the subject and predicate devices are similar in that they are both non-sterile and are oil-based. Differences do exist as described in the table above (e.g., product formulations, specifications for microbial limits, condom compatibility, etc.). The differences identified do not raise different questions of safety and effectiveness as discussed in the table above

| YES [®] water-based Personal Lubricant | | | Comparison |
|---|--|---|--|
| 510(k) # | K162569 | K124044 | |
| Device name | YES [®] water-based Personal Lubricant | Aloe Cadabra Personal lubricant | |
| Manufacturer | Bio-tech Lubricants Ltd | Seven Oaks Ranch, Inc. | |
| Classification | 884.5300 | 884.5300 | |
| Product code | NUC | NUC | |
| Description | Personal Lubricant | Personal Lubricant | Same |
| Indications for use | A personal lubricant, for vaginal and penile application, intended to moisturize and lubricate, to | Aloe Cadabra Lubricant and Aloe Cadabra Flavored/Scented Lubricants are personal lubricants for | Same: The subject and predicate devices have the same indication for use, and therefore have the |

| YES® water-based Personal Lubricant | | | Comparison |
|---|---|--|--|
| | enhance the ease and comfort of intimate sexual activity and supplement the body's natural lubrication. YES® water-based Personal Lubricant is compatible with natural rubber latex and polyisoprene condoms. This product is not compatible with polyurethane condoms. | penile and/or vaginal application, intended to moisturize and lubricate, to enhance the ease and comfort of intimate sexual activity and supplement the body's natural lubrication. This product is compatible with natural rubber latex and polyisoprene condoms. This product is not compatible with polyurethane condoms. | same intended use. |
| Water-based lubricant | YES | YES | Same |
| Ingredients | Water, Aloe vera, Flax seed extract, Guar gum, Locust bean gum, Xanthan gum, Sodium chloride, Potassium sorbate, Citric acid, Phenoxylethanol | Aloe vera | Different: The difference in ingredients do not raise different questions of S & E. |
| Biocompatible | YES | YES | Same |
| Non-sterile | YES | YES | Same |
| Contains preservatives | YES | YES | Same |
| Microbial limits (TAMC, TYMC, and absence of pathogenic bacteria) | See product specifications table (USP <61> & <62>) | Not known | Different: the microbial limits of the predicate are not known; however this does not raise different questions of S & E as these specifications are within the accepted range for these types of devices. |
| Viscosity | 2,000 – 20,000 cP | Not known | Different: the viscosity of the predicate is not known. This does not raise different questions of S & E as the viscosity specification is within the accepted range for these types of devices. |
| pH | 3.70 - 4.50 | Not known | Different: the pH of the predicate is not known. This does not raise different questions of S & E as the pH specification is within the accepted range for these types of devices. |
| Osmolality | 100 - 400 mOsm/kg | Not known | Different: the osmolality of the predicate is not known. This does not raise different questions of S & E as the osmolality specification is within the accepted range for these types of devices. |

| YES [®] water-based Personal Lubricant | | | Comparison |
|---|--|--|------------|
| Condom Compatibility | Compatible with natural rubber latex and polyisoprene condoms. Not compatible with polyurethane condoms. | Compatible with natural rubber latex and polyisoprene condoms. Not compatible with polyurethane condoms. | Same |

As noted in the table above the subject and predicate devices have the same indication for use and intended use. In addition, the subject and predicate devices are similar in that they are both non-sterile, compatible with the same types of condoms, contain Aloe vera, and are water-based. Differences do exist as described in the table above (e.g., product formulations, specifications for microbial limits, viscosity, etc.). The differences identified do not raise different questions of safety and effectiveness as discussed in the table above.

| YES [®] Vaginal Moisturizer | | | Comparison |
|--------------------------------------|---|--|---|
| 510(k) # | K162569 | K124044 | |
| Device Name | YES [®] VM (Vaginal Moisturizer) | Aloe Cadabra Personal lubricant | |
| Manufacturer | Bio-tech Lubricants Ltd | Seven Oaks Ranch, Inc. | |
| Classification | 884.5300 | 884.5300 | |
| Product code | NUC | NUC | |
| Description | Personal Lubricant | Personal Lubricant | Same |
| Indications for use | A personal lubricant, for vaginal and penile application, intended to moisturize and lubricate, to enhance the ease and comfort of intimate sexual activity and supplement the body's natural lubrication. YES [®] Vaginal Moisturizer is compatible with natural rubber latex and polyisoprene condoms. This product is not compatible with polyurethane condoms. | Aloe Cadabra Lubricant and Aloe Cadabra Flavored/Scented Lubricants are personal lubricants for penile and/or vaginal application, intended to moisturize and lubricate, to enhance the ease and comfort of intimate sexual activity and supplement the body's natural lubrication. This product is compatible with natural rubber latex and polyisoprene condoms. This product is not compatible with polyurethane condoms. | Same: The subject and predicate devices have the same indication for use, and therefore have the same intended use. |
| Water-based lubricant | YES | YES | Same |
| Ingredients | Water, Aloe vera, Flax seed extract, Guar gum, Locust bean gum, Xanthan gum, Sodium chloride, Potassium sorbate, Citric acid, Phenoxyethanol | Aloe vera | Different: The difference in ingredients do not raise different questions of S & E. |
| Biocompatible | YES | YES | Same |
| Non-sterile | YES | YES | Same |
| Contains preservatives | YES | YES | Same |
| Microbial Limits | See product specifications | Not known | Different: the microbial |

| YES® Vaginal Moisturizer | | Comparison | |
|--|--|--|--|
| (TAMC, TYMC, and absence of pathogenic bacteria) | table (USP <61> & <62>) | | limits of the predicate are not known; however this does not raise different questions of S & E as these specifications are within the accepted range for these types of devices. |
| Viscosity | 2,000 – 20,000 cP | Not known | Different: the viscosity of the predicate is not known. This does not raise different questions of S & E as the viscosity specification is within the accepted range for these types of devices |
| pH | 3.50-4.50 | Not known | Different: the pH of the predicate is not known. This does not raise different questions of S & E as the pH specification is within the accepted range for these types of devices. |
| Osmolality | 250-400 mOsm/kg | Not known | Different: the osmolality of the predicate is not known. This does not raise different questions of S & E as the osmolality specification is within the accepted range for these types of devices. |
| Condom Compatibility | Compatible with natural rubber latex and polyisoprene condoms. Not compatible with polyurethane condoms. | Compatible with natural rubber latex and polyisoprene condoms. Not compatible with polyurethane condoms. | Same |

As noted in the table above the subject and predicate devices have the same indication for use and intended use. In addition, the subject and predicate devices are similar in that they are both non-sterile, compatible with the same types of condoms, contain Aloe vera, and are water-based. Differences do exist as described in the table above (e.g., product formulations, specifications for microbial limits, viscosity, etc.). The differences identified do not raise different questions of safety and effectiveness as discussed in the table above.

Performance Testing:

Biocompatibility:

Testing was conducted to assess the biocompatibility of the YES® oil-based Personal Lubricant, YES® water-based Personal Lubricant and YES® Vaginal Moisturizer. Testing included assessments for Cytotoxicity (ISO 10993-5:2009(R)2014), Vaginal Irritation (ISO 10993-10:2010(R)2014), Sensitization (ISO 10993-10:2010(R)2014), and Acute Systemic Toxicity (ISO 10993-11:2006).

The results of testing demonstrated that they are non-cytotoxic, non-irritating, non-sensitizing and non-systemically toxic.

Condom Compatibility:

YES[®] oil-based Personal Lubricant: Condom compatibility testing was performed for polyurethane condoms per ASTM D7661-10. The results indicate that the device is not compatible with polyurethane condoms. Additionally, compatibility testing was not performed for natural rubber latex or polyisoprene condoms; therefore, the device is not compatible with natural rubber latex or polyisoprene condoms.

YES[®] Vaginal Moisturizer and YES[®] water-based Personal Lubricant: Condom compatibility testing was performed per ASTM D7661-10. The results indicated that the devices are compatible with natural rubber latex and polyisoprene condoms, but are not compatible with polyurethane condoms.

Shelf Life and Microbial Limits:

YES[®] oil-based Personal Lubricant, YES[®] water-based Personal Lubricant, and YES[®] Vaginal Moisturizer have a 9-month shelf life. The results of shelf-life testing demonstrated that the subject lubricants met all device specifications as shown in the Device Description section for the duration of the 9-month shelf-life.

Conclusion:

YES[®] oil-based Personal Lubricant, YES[®] water-based Personal Lubricant, and YES[®] Vaginal Moisturizer have the same intended use and similar technological characteristics as the predicate devices. The results of the performance testing conducted on the subject devices demonstrate that they are as safe and effective as the predicate devices and support substantial equivalence.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

K162569

Biotech Lubricants Ltd

Device Trade Name: Yes Oil-based Personal Lubricant, Yes Water-based Personal Lubricant,
Yes Vaginal Moisturizer

Contact Name: John Shepperson

This document is being communicated via e-mail as an attachment. The date on which FDA sent this e-mail is the official date of this correspondence.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

Indications for Use

510(k) Number (if known)
K162569

Device Name

YES® oil-based Personal Lubricant, YES® water-based Personal Lubricant, YES® Vaginal Moisturizer

Indications for Use (Describe)

Device Name: YES® oil-based Personal Lubricant

Indications for Use:

A personal lubricant, for vaginal and penile application, intended to moisturize and lubricate, to enhance the ease and comfort of intimate sexual activity and supplement the body's natural lubrication. YES® oil-based Personal Lubricant is not compatible with natural rubber latex, polyurethane or polyisoprene condoms.

Device Name: YES® water-based Personal Lubricant

Indications for Use:

A personal lubricant, for vaginal and penile application, intended to moisturize and lubricate, to enhance the ease and comfort of intimate sexual activity and supplement the body's natural lubrication. YES® water-based Personal Lubricant is compatible with natural rubber latex and polyisoprene condoms. This product is not compatible with polyurethane condoms.

Device Name: YES® Vaginal Moisturizer

Indications for Use:

A personal lubricant, for vaginal and penile application, intended to moisturize and lubricate, to enhance the ease and comfort of intimate sexual activity and supplement the body's natural lubrication. YES® Vaginal Moisturizer is compatible with natural rubber latex and polyisoprene condoms. This product is not compatible with polyurethane condoms.

Type of Use (Select one or both, as applicable)

Prescription Use (Part 21 CFR 801 Subpart D)

Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRASStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

June 9, 2017

Biotech Lubricants Ltd
% Karen Cornelius
Senior Associate
Maetrics
BioCity Nottingham, Pennyfoot Street
Nottingham, NG1 1GF
United Kingdom

Re: K162569
Trade/Device Name: YES® oil-based Personal Lubricant, YES® water-based Personal Lubricant, YES® Vaginal Moisturizer
Regulation Number: 21 CFR 884.5300
Regulation Name: Condom
Regulatory Class: II
Product Code: NUC
Dated: May 9, 2017
Received: May 11, 2017

Dear Karen Cornelius:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Page 2 - Karen Cornelius

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely,

Benjamin R. Fisher, Ph.D.
Director
Division of Reproductive, Gastro-Renal,
and Urological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure



Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center WO66 G609
Silver Spring, MD 20993 0002

June 9, 2017

Biotech Lubricants Ltd
% Karen Cornelius
Senior Associate
Maetrics
BioCity Nottingham, Pennyfoot Street
Nottingham, NG1 1GF
United Kingdom

Re: K162569
Trade/Device Name: YES® oil-based Personal Lubricant, YES® water-based Personal Lubricant, YES® Vaginal Moisturizer
Regulation Number: 21 CFR 884.5300
Regulation Name: Condom
Regulatory Class: II
Product Code: NUC
Dated: May 9, 2017
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Dear Karen Cornelius:

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Page 2 - Karen Cornelius

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<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely,


Benjamin R. Fisher -S

Benjamin R. Fisher, Ph.D.
Director
Division of Reproductive, Gastro-Renal,
and Urological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Form Approved: OMB No. 0910 0120
Expiration Date: January 31, 2017
See PRA Statement below.

Indications for Use

510(k) Number (if known)
K162569

Device Name

YES® oil based Personal Lubricant, YES® water based Personal Lubricant, YES® Vaginal Moisturizer

Indications for Use (Describe)

Device Name: YES® oil-based Personal Lubricant

Indications for Use:

A personal lubricant, for vaginal and penile application, intended to moisturize and lubricate, to enhance the ease and comfort of intimate sexual activity and supplement the body's natural lubrication. YES® oil-based Personal Lubricant is not compatible with natural rubber latex, polyurethane or polyisoprene condoms.

Device Name: YES® water-based Personal Lubricant

Indications for Use:

A personal lubricant, for vaginal and penile application, intended to moisturize and lubricate, to enhance the ease and comfort of intimate sexual activity and supplement the body's natural lubrication. YES® water-based Personal Lubricant is compatible with natural rubber latex and polyisoprene condoms. This product is not compatible with polyurethane condoms.

Device Name: YES® Vaginal Moisturizer

Indications for Use:

A personal lubricant, for vaginal and penile application, intended to moisturize and lubricate, to enhance the ease and comfort of intimate sexual activity and supplement the body's natural lubrication. YES® Vaginal Moisturizer is compatible with natural rubber latex and polyisoprene condoms. This product is not compatible with polyurethane condoms.

Type of Use (Select one or both, as applicable)

Prescription Use (Part 21 CFR 801 Subpart D)

Over The Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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PRASStaff@fda.hhs.gov

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510(k) Summary

Submitter: Biotech Lubricants Limited
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Phone: +44 (0) 3450 94 11 41
Email: sarah@biotechlubricants.com

Official Correspondent: Karen Cornelius
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United Kingdom
Phone: +44 (115) 921 6200
Email: kcornelius@maetrics.com

Date Prepared: June 9, 2017

Device Proprietary Names: YES[®] oil-based Personal Lubricant
YES[®] water-based Personal Lubricant
YES[®] Vaginal Moisturizer

Device Common Name: Personal Lubricant

Classification: Condom (21 CFR 884.5300)

Regulatory Class: II

Product Code: NUC (lubricant, personal)

Predicate Device: K124044 Aloe Cadabra Personal Lubricant (Seven Oaks Ranch, Inc.)
K122477 Lifestyles Luxe Premium Personal Lubricant (Ansell Healthcare Products LLC)

The predicate devices have not been subject to a design-related recall.

Device Description:

YES[®] oil-based Personal Lubricant: This non-sterile and oil-based personal lubricant consists primarily of Sunflower oil and Shea butter, and is not compatible with condoms. It is neither a contraceptive nor a spermicide. The formulation is a cream-colored thick paste that melts at body temperature. The product is packaged in a high density polyethylene (HDPE) tube with a flip-top cap. The specifications for the YES[®] oil-based Personal Lubricant are shown below:

| Parameter | Specification |
|--|---|
| Color | Opaque paste |
| Odor | Slight beeswax and/or cocoa odor |
| Viscosity | N/A: measuring viscosity is not feasible, since changes in phase during measurement lead to differences in viscosity readings |
| Total yeast/mold count | <10 cfu/g (USP<61>) |
| Total aerobic mesophilic count | <100 cfu/g (USP<61>) |
| Absence of Pathogenic bacteria: <i>Staphylococcus aureus, Candida</i> | Absent in 1g (USP<62>) |

| | |
|--|--|
| <i>albicans, and gram negative bacteria (e.g., Pseudomonas aeruginosa)</i> | |
|--|--|

YES® water-based Personal Lubricant: This non-sterile and water-based personal lubricant contains Aloe vera and other components, and is compatible with natural rubber latex and polyisoprene condoms. This product is not compatible with polyurethane condoms. It is neither a contraceptive nor a spermicide. The formulation is a lightly opaque, non-greasy liquid gel. The product is packaged in a HDPE tube with a flip-top cap, and a HDPE single-use applicator. The specifications for the YES® water-based Personal Lubricant are shown below:

| Parameter | Specification |
|---|---|
| Color | Opaque gel |
| Odor | Slight-mild, delicate linseed / leather note |
| Viscosity | 2,000 – 20,000 cP |
| pH | 3.70 - 4.50 |
| Osmolality | 100 - 400 mOsm/kg |
| Antimicrobial Effectiveness | At least 2.0 log reduction from the initial count at 14 days; no increase from the 14 days count at 28 days; no increase from the initial calculated count at 14 and 28 days (USP <51>) |
| Total yeast/mold count | <10 cfu/g (USP<61>) |
| Total aerobic mesophilic count | <100 cfu/g (USP<61>) |
| <i>Absence of Pathogenic bacteria: Staphylococcus aureus, Candida albicans, and gram negative bacteria (e.g., Pseudomonas aeruginosa)</i> | Absent in 1g (USP<62>) |

YES® Vaginal Moisturizer: This non-sterile and water-based personal lubricant contains Aloe vera and other components, and is compatible with natural rubber latex, and polyisoprene condoms. This product is not compatible with polyurethane condoms. It is neither a contraceptive nor a spermicide. The formulation is a lightly opaque, non-greasy liquid gel. The product is packaged in a HDPE tube with a flip-top cap, and a HDPE single-use applicator. The specifications for the YES® Vaginal Moisturizer are shown below:

| Parameter | Specification |
|--|---|
| Color | Opaque gel |
| Odor | Slight-mild, delicate linseed / leather |
| Viscosity | 2,000 – 20,000 cP |
| pH | 3.50-4.50 |
| Osmolality | 250-400 mOsm/kg |
| Antimicrobial Effectiveness | At least 2.0 log reduction from the initial count at 14 days; no increase from the 14 days count at 28 days; no increase from the initial calculated count at 14 and 28 days (USP <51>) |
| Total yeast/mold count | <10 cfu/g (USP<61>) |
| Total aerobic mesophilic count | <100 cfu/g (USP<61>) |
| <i>Absence of Pathogenic bacteria:</i> | Absent in 1g (USP<62>) |

| | |
|---|--|
| <i>Staphylococcus aureus, Candida albicans, and gram negative bacteria (e.g., Pseudomonas aeruginosa)</i> | |
|---|--|

Indications for Use:

YES[®] oil-based Personal Lubricant: A personal lubricant, for vaginal and penile application, intended to moisturize and lubricate, to enhance the ease and comfort of intimate sexual activity and supplement the body's natural lubrication. YES[®] oil-based Personal Lubricant is not compatible with natural rubber latex, polyurethane or polyisoprene condoms.

YES[®] water-based Personal Lubricant: A personal lubricant, for vaginal and penile application, intended to moisturize and lubricate, to enhance the ease and comfort of intimate sexual activity and supplement the body's natural lubrication. YES[®] water-based Personal Lubricant is compatible with natural rubber latex and polyisoprene condoms. This product is not compatible with polyurethane condoms.

YES[®] Vaginal Moisturizer: A personal lubricant, for vaginal and penile application, intended to moisturize and lubricate, to enhance the ease and comfort of intimate sexual activity and supplement the body's natural lubrication. YES[®] Vaginal Moisturizer is compatible with natural rubber latex, and polyisoprene condoms. This product is not compatible with polyurethane condoms.

Comparison of Intended Use and Technological Characteristics of Subject and Predicate Devices:

| YES [®] oil-based Personal Lubricant | | | Comparison |
|---|--|---|--|
| 510(k) # | K162569 | K122477 | |
| Device Name | YES [®] oil-based personal lubricant | LifeStyles Luxe Premium Personal Lubricant | |
| Manufacturer | Bio-tech Lubricants Ltd | Ansell Healthcare Products, LLC | |
| Classification | 884.5300 | 884.5300 | |
| Product code | NUC | NUC | |
| Description | Personal Lubricant | Personal Lubricant | Same |
| Indications for use | A personal lubricant, for vaginal and penile application, intended to moisturize and lubricate, to enhance the ease and comfort of intimate sexual activity and supplement the body's natural lubrication. This product is not compatible with natural rubber latex, polyurethane or polyisoprene condoms. | LifeStyles Luxe Premium Personal Lubricant Is a personal lubricant, for penile and/or vaginal application, intended to moisturize and lubricate, to enhance the ease and comfort of intimate sexual activity and supplement the body's natural lubrication. This product is compatible with natural rubber latex, polyurethane, and polyisoprene condoms. | Different: The subject and predicate devices indication for use statements differ in regards to compatibility with condoms. Differences noted do not represent a new intended use. |
| Oil-based lubricant | YES | YES | Same: the subject and predicate devices are both oil-based lubricants; however, the specific oils in the formulation are |

| YES [®] oil-based Personal Lubricant | | | Comparison |
|---|---|---|--|
| | | | different. This does not raise different questions of S & E (e.g. biocompatibility). |
| Ingredients | Sunflower seed oil, Shea butter, Sweet almond oil, Bees wax, Cocoa seed butter, Vitamin E | Not known | Different: The difference in ingredients do not raise different questions of S & E. |
| Biocompatible | YES | YES | Same |
| Non-sterile | YES | YES | Same |
| Contains preservatives | NO | NO | Same |
| Microbial limits (TAMC, TYMC, and absence of pathogenic bacteria) | See product specifications table (USP <61> & <62>) | Meets the requirements of USP <61> & <62> | Different: the microbial limits of the predicate are not known; however this does not raise different questions of S & E as the microbial limits specifications are within the accepted ranges for these types of devices. |
| Condom Compatibility | Not compatible with natural rubber latex, polyurethane, or polyisoprene condoms. | Compatible with natural rubber latex, polyurethane, and polyisoprene condoms. | Different: The condom compatibility for the subject and predicate devices are different; However, this difference does not represent a new intended use. |

As noted in the table above the subject and predicate devices indications are similar in that they are both used to moisturize and lubricate, to enhance the ease and comfort of intimate sexual activity and supplement the body's natural lubrication. However, they do differ in regards to condom compatibility as the subject device is not compatible with condoms, while the predicate is condom compatible. Differences in condom compatibility between the subject and predicate devices do not represent a new intended use. In regards to technology, the subject and predicate devices are similar in that they are both non-sterile and are oil-based. Differences do exist as described in the table above (e.g., product formulations, specifications for microbial limits, condom compatibility, etc.). The differences identified do not raise different questions of safety and effectiveness as discussed in the table above

| YES [®] water-based Personal Lubricant | | | Comparison |
|---|--|---|--|
| 510(k) # | K162569 | K124044 | |
| Device name | YES [®] water-based Personal Lubricant | Aloe Cadabra Personal lubricant | |
| Manufacturer | Bio-tech Lubricants Ltd | Seven Oaks Ranch, Inc. | |
| Classification | 884.5300 | 884.5300 | |
| Product code | NUC | NUC | |
| Description | Personal Lubricant | Personal Lubricant | Same |
| Indications for use | A personal lubricant, for vaginal and penile application, intended to moisturize and lubricate, to | Aloe Cadabra Lubricant and Aloe Cadabra Flavored/Scented Lubricants are personal lubricants for | Same: The subject and predicate devices have the same indication for use, and therefore have the |

| YES® water-based Personal Lubricant | | | Comparison |
|---|---|--|--|
| | enhance the ease and comfort of intimate sexual activity and supplement the body's natural lubrication. YES® water-based Personal Lubricant is compatible with natural rubber latex and polyisoprene condoms. This product is not compatible with polyurethane condoms. | penile and/or vaginal application, intended to moisturize and lubricate, to enhance the ease and comfort of intimate sexual activity and supplement the body's natural lubrication. This product is compatible with natural rubber latex and polyisoprene condoms. This product is not compatible with polyurethane condoms. | same intended use. |
| Water-based lubricant | YES | YES | Same |
| Ingredients | Water, Aloe vera, Flax seed extract, Guar gum, Locust bean gum, Xanthan gum, Sodium chloride, Potassium sorbate, Citric acid, Phenoxylethanol | Aloe vera | Different: The difference in ingredients do not raise different questions of S & E. |
| Biocompatible | YES | YES | Same |
| Non-sterile | YES | YES | Same |
| Contains preservatives | YES | YES | Same |
| Microbial limits (TAMC, TYMC, and absence of pathogenic bacteria) | See product specifications table (USP <61> & <62>) | Not known | Different: the microbial limits of the predicate are not known; however this does not raise different questions of S & E as these specifications are within the accepted range for these types of devices. |
| Viscosity | 2,000 – 20,000 cP | Not known | Different: the viscosity of the predicate is not known. This does not raise different questions of S & E as the viscosity specification is within the accepted range for these types of devices. |
| pH | 3.70 - 4.50 | Not known | Different: the pH of the predicate is not known. This does not raise different questions of S & E as the pH specification is within the accepted range for these types of devices. |
| Osmolality | 100 - 400 mOsm/kg | Not known | Different: the osmolality of the predicate is not known. This does not raise different questions of S & E as the osmolality specification is within the accepted range for these types of devices. |

| YES [®] water-based Personal Lubricant | | | Comparison |
|---|--|--|------------|
| Condom Compatibility | Compatible with natural rubber latex and polyisoprene condoms. Not compatible with polyurethane condoms. | Compatible with natural rubber latex and polyisoprene condoms. Not compatible with polyurethane condoms. | Same |

As noted in the table above the subject and predicate devices have the same indication for use and intended use. In addition, the subject and predicate devices are similar in that they are both non-sterile, compatible with the same types of condoms, contain Aloe vera, and are water-based. Differences do exist as described in the table above (e.g., product formulations, specifications for microbial limits, viscosity, etc.). The differences identified do not raise different questions of safety and effectiveness as discussed in the table above.

| YES [®] Vaginal Moisturizer | | | Comparison |
|--------------------------------------|---|--|---|
| 510(k) # | K162569 | K124044 | |
| Device Name | YES [®] VM (Vaginal Moisturizer) | Aloe Cadabra Personal lubricant | |
| Manufacturer | Bio-tech Lubricants Ltd | Seven Oaks Ranch, Inc. | |
| Classification | 884.5300 | 884.5300 | |
| Product code | NUC | NUC | |
| Description | Personal Lubricant | Personal Lubricant | Same |
| Indications for use | A personal lubricant, for vaginal and penile application, intended to moisturize and lubricate, to enhance the ease and comfort of intimate sexual activity and supplement the body's natural lubrication. YES [®] Vaginal Moisturizer is compatible with natural rubber latex and polyisoprene condoms. This product is not compatible with polyurethane condoms. | Aloe Cadabra Lubricant and Aloe Cadabra Flavored/Scented Lubricants are personal lubricants for penile and/or vaginal application, intended to moisturize and lubricate, to enhance the ease and comfort of intimate sexual activity and supplement the body's natural lubrication. This product is compatible with natural rubber latex and polyisoprene condoms. This product is not compatible with polyurethane condoms. | Same: The subject and predicate devices have the same indication for use, and therefore have the same intended use. |
| Water-based lubricant | YES | YES | Same |
| Ingredients | Water, Aloe vera, Flax seed extract, Guar gum, Locust bean gum, Xanthan gum, Sodium chloride, Potassium sorbate, Citric acid, Phenoxyethanol | Aloe vera | Different: The difference in ingredients do not raise different questions of S & E. |
| Biocompatible | YES | YES | Same |
| Non-sterile | YES | YES | Same |
| Contains preservatives | YES | YES | Same |
| Microbial Limits | See product specifications | Not known | Different: the microbial |

| YES® Vaginal Moisturizer | | | Comparison |
|--|--|--|--|
| (TAMC, TYMC, and absence of pathogenic bacteria) | table (USP <61> & <62>) | | limits of the predicate are not known; however this does not raise different questions of S & E as these specifications are within the accepted range for these types of devices. |
| Viscosity | 2,000 – 20,000 cP | Not known | Different: the viscosity of the predicate is not known. This does not raise different questions of S & E as the viscosity specification is within the accepted range for these types of devices |
| pH | 3.50-4.50 | Not known | Different: the pH of the predicate is not known. This does not raise different questions of S & E as the pH specification is within the accepted range for these types of devices. |
| Osmolality | 250-400 mOsm/kg | Not known | Different: the osmolality of the predicate is not known. This does not raise different questions of S & E as the osmolality specification is within the accepted range for these types of devices. |
| Condom Compatibility | Compatible with natural rubber latex and polyisoprene condoms. Not compatible with polyurethane condoms. | Compatible with natural rubber latex and polyisoprene condoms. Not compatible with polyurethane condoms. | Same |

As noted in the table above the subject and predicate devices have the same indication for use and intended use. In addition, the subject and predicate devices are similar in that they are both non-sterile, compatible with the same types of condoms, contain Aloe vera, and are water-based. Differences do exist as described in the table above (e.g., product formulations, specifications for microbial limits, viscosity, etc.). The differences identified do not raise different questions of safety and effectiveness as discussed in the table above.

Performance Testing:

Biocompatibility:

Testing was conducted to assess the biocompatibility of the YES® oil-based Personal Lubricant, YES® water-based Personal Lubricant and YES® Vaginal Moisturizer. Testing included assessments for Cytotoxicity (ISO 10993-5:2009(R)2014), Vaginal Irritation (ISO 10993-10:2010(R)2014), Sensitization (ISO 10993-10:2010(R)2014), and Acute Systemic Toxicity (ISO 10993-11:2006).

The results of testing demonstrated that they are non-cytotoxic, non-irritating, non-sensitizing and non-systemically toxic.

Condom Compatibility:

YES[®] oil-based Personal Lubricant: Condom compatibility testing was performed for polyurethane condoms per ASTM D7661-10. The results indicate that the device is not compatible with polyurethane condoms. Additionally, compatibility testing was not performed for natural rubber latex or polyisoprene condoms; therefore, the device is not compatible with natural rubber latex or polyisoprene condoms.

YES[®] Vaginal Moisturizer and YES[®] water-based Personal Lubricant: Condom compatibility testing was performed per ASTM D7661-10. The results indicated that the devices are compatible with natural rubber latex and polyisoprene condoms, but are not compatible with polyurethane condoms.

Shelf Life and Microbial Limits:

YES[®] oil-based Personal Lubricant, YES[®] water-based Personal Lubricant, and YES[®] Vaginal Moisturizer have a 9-month shelf life. The results of shelf-life testing demonstrated that the subject lubricants met all device specifications as shown in the Device Description section for the duration of the 9-month shelf-life.

Conclusion:

YES[®] oil-based Personal Lubricant, YES[®] water-based Personal Lubricant, and YES[®] Vaginal Moisturizer have the same intended use and similar technological characteristics as the predicate devices. The results of the performance testing conducted on the subject devices demonstrate that they are as safe and effective as the predicate devices and support substantial equivalence.



Contains Nonbinding Recommendations

Print Form

Acceptance Checklist for Traditional 510(k)s

(Should be completed within 15 days of DCC receipt)

The following information is not intended to serve as a comprehensive review.
FDA recommends that the submitter include this completed checklist as part of the submission.

510(k) #: K162207 Date Received by DCC: Aug 12, 2016
Lead Reviewer: Patrick Gallagher
Branch: OGDB Division: DRGUD Center/Office: CDRH/ODE

Note: If an element is left blank on the checklist, it does not mean the checklist is incomplete; it means the reviewer did not assess the element during the RTA review and that the element will be assessed during substantive review.

IMPORTANT - Many checklist elements include additional details regarding information to address the element that can be seen by hovering over the element (Example - Element 4 in Section A of the checklist).

| Preliminary Questions | | | |
|--|-----|----|-----|
| Answers in the shaded blocks indicate consultation with a Center advisor is needed. (Boxes checked in this section represent FDA's preliminary assessment of these questions at the time of administrative review.) | Yes | No | N/A |
| <p>1) Is the product a device (per section 201(h) of the FD&C Act) or a combination product (per 21 CFR 3.2(e)) with a device constituent part subject to review in a 510(k)?</p> <p>If it appears not to be a device (per section 201(h) of the FD&C Act) or such a combination product, or you are unsure, consult with the CDRH Jurisdictional Officer or the CBER Product Jurisdiction Liaison to determine the appropriate action, and inform division management. <i>Provide a summary of the Jurisdictional Officer's/Liaison's determination.</i> If the product does not appear to be a device or such a combination product, mark "No."</p> | X | | |
| Comments: | | | |
| <p>2. Is the submission with the appropriate Center?</p> <p>If the product is a device or a combination product with a device constituent part, is it subject to review by the Center in which the submission was received? If you believe the submission is not with the appropriate Center or you are unsure, consult with the CDRH Jurisdictional Officer or CBER Product Jurisdiction Liaison to determine the appropriate action and inform your division management. <i>Provide a summary of the Jurisdictional Officer's/Liaison's determination.</i> If submission should not be reviewed by your Center mark "No."</p> | X | | |
| Comments: | | | |
| <p>3) If a Request for Designation (RFD) was submitted for the device or combination product with a device constituent part and assigned to your center, identify the RFD # and confirm the following:</p> <p>a) Is the device or combination product the same (e.g., design, formulation) as that presented in the RFD submission?</p> <p>b) Are the indications for use for the device or combination product identified in the 510(k) the same as those identified in the RFD submission?</p> <p>If you believe the product or the indications presented in the 510(k) have changed from the RFD, or you are unsure, consult with the CDRH Jurisdictional Officer or the CBER Product Jurisdiction Liaison to determine the appropriate action and inform your division management. <i>Provide summary of Jurisdictional Officer's/Liaison's determination.</i></p> <p>If the answer to either question above is no, mark "No." If there was no RFD, mark "N/A."</p> | | | X |
| Comments: | | | |

| | | | |
|---|---|---|---|
| <p>4) Is this device type eligible for a 510(k) submission?</p> <p>If a 510(k) does not appear to be appropriate (e.g., Class III type and PMA required, or Class I or II type and 510(k)-exempt), you should consult with the CDRH 510(k) Program Director or appropriate CBER staff during the acceptance review. If 510(k) is not the appropriate regulatory submission, mark "No."</p> | × | | |
| <p>Comments:</p> | | | |
| <p>5) Is there a pending PMA for the same device with the same indications for use?</p> <p>If yes, consult division management and the CDRH 510(k) Program Director or appropriate CBER staff to determine the appropriate action.</p> | | × | |
| <p>Comments:</p> | | | |
| <p>6) If clinical studies have been submitted, is the submitter the subject of an Application Integrity Policy (AIP)?</p> <p>If yes, consult with the CDRH Office of Compliance/Division of Bioresearch Monitoring (OC/DBM) or CBER Office of Compliance and Biologics Quality/Division of Inspections and Surveillance/Bioresearch Monitoring Branch (OCBQ/DIS/BMB) to determine the appropriate action. Check on web at http://www.fda.gov/ICECI/EnforcementActions/ApplicationIntegrityPolicy/ucm134453.htm</p> <p>If no clinical studies have been submitted, mark "N/A."</p> | | | × |
| <p>Comments:</p> | | | |

- If the answer to 1 or 2 appears to be "No," then stop review of the 510(k) and issue the "Original Jurisdictional Product" letter.
- If the answer to 3a or 3b appears to be "No," then stop the review and contact the CDRH Jurisdictional Officer or CBER Office of Jurisdiction Liaison.
- If the answer to 4 is "No," the lead reviewer should consult division management and other Center resources to determine the appropriate action.
- If the answer to 5 is "Yes," then stop review of the 510(k), contact the CDRH 510(k) Staff and PMA Staff, or appropriate CBER staff.
- If the answer to 6 is "Yes," then contact CDRH/OC/DBM or CBER/OCBQ/DIS/BMB, provide a summary of the discussion with DBM or BMB Staff, and indicate their recommendation/action.

Organizational Elements

Failure to include these items should not result in an RTA designation.

| *Submitters including the checklist with their submission should identify the page numbers where requested information located. Use the comments section for an element if additional space is needed to identify the location of supporting information. | Yes | No | *Page # |
|---|-----|----|---------|
| 1) Submission contains a Table of Contents | X | | |
| 2) Each section is labeled (e.g., headings or tabs designating Device Description section, Labeling section, etc.) | X | | |
| 3) All pages of the submission are numbered. | X | | |
| 4) Type of 510(k) is identified (i.e., Traditional, Abbreviated, or Special). | X | | |

Comments:

Elements of a Complete Submission (RTA Items)

(21 CFR 807.87 unless otherwise indicated)

Submission should be designated RTA if not addressed.

- Any "No" answer will result in a "Refuse to Accept" decision; however, FDA staff has discretion to determine whether missing items are needed to ensure that the submission is administratively complete to allow the submission to be accepted or to request missing checklist items interactively from submitters during RTA review.
- Each element on the checklist should be addressed within the submission. The submitter may provide a rationale for omission for any criteria that are deemed not applicable. If a rationale is provided, the criterion is considered present (Yes). An assessment of the rationale will be considered during the review of the submission.

| | | | | | |
|--|------------|-----------|------------|----------------|----------------|
| Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed. | | | | | |
| *Submitters including the checklist with their submission should identify the page numbers where requested information is located. Use the comments section for an element if additional space is needed to identify the location of supporting information. | Yes | No | N/A | Comment | *Page # |

A. Administrative

| | | | | | |
|---|---|---|---|---|--|
| 1) All content used to support the submission is written in English (including translations of test reports, literature articles, etc.) | × | | | | |
| 2) Submission identifies the following (FDA recommends use of the CDRH Premarket Review Submission Cover Sheet form [Form 3514]): | | | | | |
| a) Device trade/proprietary name | × | | | | |
| b) Device class and panel or Classification regulation or Statement that device has not been classified with rationale for that conclusion | × | | | | |
| 3) Submission contains an Indication for Use Statement with Rx and/or OTC designated (see also 21 CFR 801.109, and FDA's guidance " Alternative to Certain Prescription Devices Labeling Requirements. ") See <i>recommended format.</i> (http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM360431.pdf). | × | | | | |
| 4) Submission contains a 510(k) Summary or 510(k) Statement. | × | | | | |
| 5) Submission contains a Truthful and Accuracy Statement per 21 CFR 807.87(k) See <i>recommended format.</i> (http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/PremarketSubmissions/PremarketNotification510k/ucm142707.htm). | × | | | | |
| 6) Submission is a Class III 510(k) device. | | | × | | |
| 7) Submission contains clinical data | | | × | | |
| 8) The submission identifies prior submissions for the same device included in the current submission (e.g., submission numbers for a prior not substantially equivalent [NSE] determination, prior deleted or withdrawn 510(k), Pre-Submission, IDE, PMA, etc.). OR States that there were no prior submissions for the subject device. | | × | | × | |
| a) If there were prior submissions, the submitter has identified where in the current submission any issues related to a determination of substantial equivalence from prior submissions for this device are addressed. | | | × | | |
| Comments: The sponsor did not state if there was a prior submission, however, per ODE policy we do not "reject" for this reason. | | | | | |

B. Device Description

| | | | | | |
|--|---|--|---|--|--|
| 9) The device has a device-specific guidance document, special controls document, and/or requirements in a device-specific regulation regarding device description that is applicable to the subject device. | | | × | | |
| 10) Descriptive information is present and consistent within the submission (e.g., the device description section is consistent with the device description in the labeling). | × | | | | |
| 11) The submission includes descriptive information for the device, including the following: | | | | | |
| a) A description of the principle of operation or mechanism of action for achieving the intended effect. | × | | | | |

| Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed. *Submitters including the checklist with their submission should identify the page numbers where requested information is located. Use the comments section for an element if additional space is needed to identify the location of supporting information. | Yes | No | N/A | Comment | *Page # |
|--|-----|----|-----|---------|---------|
| b) A description of proposed conditions of use, such as surgical technique for implants; anatomical location of use; user interface; how the device interacts with other devices; and/or how the device interacts with the patient. | X | | | | |
| c) A list and description of each device for which clearance is requested. | X | | | | |
| d) Submission contains representative engineering drawing(s), schematics, illustrations, photos and/or figures of the device. OR Submission includes a statement that engineering drawings, schematics, etc. are not applicable to the device (e.g., device is a reagent and figures are not pertinent to describe the device). | X | | | | |
| 12) Device is intended to be marketed with multiple components, accessories, and/or as part of a system. | X | | | X | |
| a) Submission includes a list of all components and accessories to be marketed with the subject device. | X | | | | |
| b) Submission includes a description (as detailed in item 11(a), 11(b) and 11(d) above) of each component or accessory. | X | | | | |
| c) A 510(k) number is provided for each component or accessory that received a prior 510(k) clearance AND A statement is provided that identifies components or accessories that have not received prior 510(k) clearance. | X | | | | |

Comments: The subject device is intended to be marketed with a vaginal applicator manufactured by SRC Medical Inc. The sponsor has not identified a 510(k) number for this device, nor provided a statement that identifies components or accessories that have not received prior clearance. However, per 21 CFR 884.4520, a vaginal applicator is a Class I exempt device, and does not require 510(k) clearance prior to marketing.

C. Substantial Equivalence Discussion

| | | | | | |
|---|---|--|--|--|--|
| 13) Submitter has identified a predicate device(s), including the following information: | | | | | |
| a) Predicate device identifier provided (e.g., 510(k) number, de novo number, reclassified PMA number, regulation number if exempt or statement that the predicate is a preamendment device). For predicates that are preamendments devices, information is provided to document preamendments status. <i>Information regarding documenting preamendment status is available online. (http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/MedicalDeviceQualityandCompliance/ucm379552.htm).</i> | X | | | | |
| b) The identified predicate(s) is consistent throughout the submission (e.g., the predicate(s) identified in the Substantial Equivalence section is the same as that listed in the 510(k) Summary (if applicable) and that used in comparative performance testing). | X | | | | |
| 14) Submission includes a comparison of the following for the predicate(s) and subject device and a discussion why any differences between the subject and predicate(s) do not impact safety and effectiveness [see section 513(i)(1)(A) of the FD&C Act and 21 CFR 807.87(f)] <i>See "The 510(k) Program: Evaluating Substantial Equivalence in Premarket Notifications [510(k)]" guidance document for more information on comparing intended use and technological characteristics.</i> | | | | | |

| Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed. *Submitters including the checklist with their submission should identify the page numbers where requested information is located. Use the comments section for an element if additional space is needed to identify the location of supporting information. | Yes | No | N/A | Comment | *Page # |
|--|-----|----|-----|---------|---------|
| a) Indications for Use | X | | | | |
| b) Technology, including features, materials, and principles of operation | X | | | | |

D. Proposed Labeling (see also 21 CFR part 801 and 809 as applicable)

| | | | | | |
|---|---|--|--|---|--|
| 15) Submission includes proposed package labels and labeling (e.g., instructions for use, package insert, operator's manual). | X | | | X | |
| a) Indications for use are stated in labeling and are identical to Indications for Use form and 510(k) Summary (if 510(k) Summary provided). | X | | | | |
| b) Labeling includes: - Statements of conditions, purposes or uses for which the device is intended (e.g., hazards, warnings, precautions, contraindications) (21 CFR 801.5) AND - Includes adequate directions for use (see 21 CFR 801.5) OR - Submission states that device qualifies for exemption per 21 CFR 801 Subpart D | X | | | | |

Comments: The indications for use as stated in the labeling is not identical to the Indications for Use statement. However, since this device is designated as OTC, the indications for use can be stated in the directions for use. The application will not be "rejected", per reviewer discretion.

| | | | | | |
|--|---|--|---|--|--|
| 16) Labeling includes name and place of business of the manufacturer, packer, or distributor (21 CFR 801.1). | X | | | | |
| 17) Labeling includes the prescription statement [see 21 CFR 801.109(b)(1)] or Rx Only symbol (see also Section 502(a) of the FD&C Act and FDA's guidance "Alternative to Certain Prescription Device Labeling Requirements"). | | | X | | |
| 18) The device has a device-specific guidance document, special controls document, and/or requirements in a device-specific regulation regarding labeling that is applicable to the subject device. | | | X | | |
| 19) If the device is an in vitro diagnostic device, provided labeling includes all applicable information required per 21 CFR 809.10 . | | | X | | |

E. Sterilization

| | | | | | |
|--|--|--|--|--|--|
| If an <i>in vitro</i> diagnostic (IVD) device and sterilization is not applicable, select "N/A." The criteria in this section will be omitted from the checklist if "N/A" is selected. | | | | | |
| Submission states that the device, and/or accessories, and/or components are: (one of the below must be checked) | | | | | |
| Provided sterile, intended to be single-use | | | | | |
| Requires processing during its use-life | | | | | |
| X Non-sterile when used (and no processing required) | | | | | |
| Information regarding the sterility status of the device is not provided. (If this box is checked, please also check one of the two boxes below.) | | | | | |
| Sterility status not needed for this device (e.g., software-only device) | | | | | |
| Sterility status needed or need unclear | | | | | |

| | | | | | |
|--|------------|-----------|------------|----------------|----------------|
| Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed. *Submitters including the checklist with their submission should identify the page numbers where requested information is located. Use the comments section for an element if additional space is needed to identify the location of supporting information. | Yes | No | N/A | Comment | *Page # |
| | | | | | |

This information will determine whether and what type of additional information may be necessary for a substantial equivalence determination.
 Please refer to the guidance document titled "[Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling](#)" for additional information.

F. Shelf Life

| | | | | | |
|--|---|--|---|--|--|
| 24) Proposed shelf life/expiration date stated OR Statement that shelf-life is not applicable because of low likelihood of time-dependent product degradation | ✗ | | | | |
| 25) For a sterile device, submission includes summary of methods used to establish that device packaging will maintain a sterile barrier for the entirety of the proposed shelf life. | | | ✗ | | |
| 26) Submission includes summary of methods used to establish that device performance is maintained for the entirety of the proposed shelf-life (e.g., mechanical properties, coating integrity, pH, osmolality, etc.). OR Statement why performance data is not needed to establish maintenance of device performance characteristics over the shelf-life period. | ✗ | | | | |

G. Biocompatibility

| | | | | | |
|--|---|--|--|--|--|
| If an <i>in vitro</i> diagnostic (IVD) device, select "N/A." The criteria in this section will be omitted from the checklist if "N/A" is selected. | | | | | |
| Submission states that there: (one of the below must be checked) | | | | | |
| ✗ | Are direct or indirect patient-contacting components. | | | | |
| | Are no direct or indirect patient-contacting components. | | | | |
| Information regarding patient contact status of the device is not provided (if this box checked, please also check one of the two boxes below). | | | | | |
| | Patient contact information not needed for this device (e.g., software-only device) | | | | |
| | Patient contact information needed or need unclear | | | | |

This information will determine whether and what type of additional information may be necessary for a substantial equivalence determination.

| | | | | | |
|---|---|---|--|---|--|
| 27) Submission includes a list identifying each of patient-contacting device component (e.g., implant, delivery catheter) and associated materials of construction for each component, including identification of color additives, if present. | ✗ | | | | |
| 28) Submission identifies contact classification (e.g., surface-contacting, less than 24 hour duration) for each patient-contacting device component (e.g., implant, delivery catheter) | | ✗ | | ✗ | |

Comments: The sponsor did not identify the contact classification for the subject device. However, a personal lubricant is a surface device that contacts both the skin and mucosal membranes for a limited (<24 hour) contact duration. Per reviewer discretion, the application will not be "rejected" for omitting this information.

| Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed. *Submitters including the checklist with their submission should identify the page numbers where requested information is located. Use the comments section for an element if additional space is needed to identify the location of supporting information. | Yes | No | N/A | Comment | *Page # |
|--|-----|----|-----|---------|---------|
| 29) Biocompatibility assessment of patient-contacting components Submission includes: Test protocol (including identification and description of test article), methods, pass/fail criteria, and results provided for each completed test. OR A statement that biocompatibility testing is not needed with a rationale (e.g., materials and manufacturing/processing are identical to the predicate). | X | | | | |

H. Software

| | | | | | |
|---|--|--|--|--|--|
| Submission states that the device: (one of the below must be checked) | | | | | |
| Does contain software/firmware | | | | | |
| X Does not contain software/firmware | | | | | |
| Information on whether device contains software/firmware is not provided. (If this box is checked, please also check one of the two boxes below.) | | | | | |
| | Software/firmware information not needed for this device (e.g., surgical suture, condom) | | | | |
| | Software/firmware information is needed or need unclear | | | | |
| This information will determine whether and what type of additional information may be necessary for a substantial equivalence determination. | | | | | |

I. Electrical Safety and EMC

| | | | | | |
|--|--|--|--|--|--|
| Electrical Safety Submission states that the device: (one of the below must be checked) | | | | | |
| Does require electrical safety evaluation | | | | | |
| X Does not require electrical safety evaluation | | | | | |
| Information on whether device requires electrical safety evaluation is not provided. (If this box is checked, please also check one of the two boxes below.) | | | | | |
| | Electrical safety information not needed for this device (e.g., surgical suture, condom) | | | | |
| | Electrical safety information is needed or need unclear | | | | |
| This information will determine whether and what type of additional information may be necessary for a substantial equivalence determination. | | | | | |

| | | | | | |
|--|--|--|--|--|--|
| EMC Submission states that the device: (one of the below must be checked) | | | | | |
| Does require EMC evaluation | | | | | |
| X Does not require EMC evaluation | | | | | |
| Information on whether device requires EMC evaluation is not provided. (If this box is checked, please also check one of the two boxes below.) | | | | | |
| | EMC information not needed for this device (e.g., surgical suture, condom) | | | | |
| | EMC information is needed or need unclear | | | | |

| | | | | | |
|--|------------|-----------|------------|----------------|----------------|
| Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed. *Submitters including the checklist with their submission should identify the page numbers where requested information is located. Use the comments section for an element if additional space is needed to identify the location of supporting information. | Yes | No | N/A | Comment | *Page # |
|--|------------|-----------|------------|----------------|----------------|

This information will determine whether and what type of additional information may be necessary for a substantial equivalence determination.

J. Performance Data - General

| | | | |
|--|--|---|--|
| If an in vitro diagnostic (IVD) device, select "N/A." The criteria in this section will be omitted from checklist if "N/A" is selected. Performance data criteria relating to IVD devices is addressed in Section K. | | X | |
|--|--|---|--|

K. Performance Characteristics - In Vitro Diagnostic Devices Only
 (Also see [21 CFR 809.10\(b\)\(12\)](#))

| | | |
|---|--|--|
| Submission states that the device: (one of the below must be checked) | | |
| <input type="checkbox"/> is an in vitro diagnostic device. | | |
| <input checked="" type="checkbox"/> is not an in vitro diagnostic device. | | |

If "is not" is selected, the performance data-related criteria below are omitted from the checklist.

Decision: Accept Refuse to Accept

If Accept, notify applicant.

If Refuse to Accept, notify applicant electronically and include a copy of this checklist.

Digital Signature Concurrence Table

| | |
|--|---|
| Reviewer Sign-Off | Patrick Gallagher -S 2016.08.22 08:29:57 -04'00' |
| Branch Chief Sign-Off (digital signature optional)* | Sharon M. Andrews -S 2016.08.22 09:06:12 -04'00' |
| Division Sign-Off (digital signature optional)* | |

* Branch and Division review of checklist and concurrence with decision required.
Branch and Division digital signature optional.

510(k) Summary

Submitter: Biotech Lubricants Limited
Ramshill
Petersfield
GU31 4AT
United Kingdom
Phone: +44 (0) 3450 94 11 41
Email: sarah@biotechlubricants.com

Official Correspondent: Karen Cornelius
Maetrics
BioCity Nottingham, Pennyfoot Street
Nottingham, NG1 1GF
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Phone: +44 (115) 921 6200
Email: kcornelius@maetrics.com

Date Prepared: June 9, 2017

Device Proprietary Names: YES[®] oil-based Personal Lubricant
YES[®] water-based Personal Lubricant
YES[®] Vaginal Moisturizer

Device Common Name: Personal Lubricant

Classification: Condom (21 CFR 884.5300)

Regulatory Class: II

Product Code: NUC (lubricant, personal)

Predicate Device: K124044 Aloe Cadabra Personal Lubricant (Seven Oaks Ranch, Inc.)
K122477 Lifestyles Luxe Premium Personal Lubricant (Ansell Healthcare Products LLC)

The predicate devices have not been subject to a design-related recall.

Device Description:

YES[®] oil-based Personal Lubricant: This non-sterile and oil-based personal lubricant consists primarily of Sunflower oil and Shea butter, and is not compatible with condoms. It is neither a contraceptive nor a spermicide. The formulation is a cream-colored thick paste that melts at body temperature. The product is packaged in a high density polyethylene (HDPE) tube with a flip-top cap. The specifications for the YES[®] oil-based Personal Lubricant are shown below:

| Parameter | Specification |
|--|---|
| Color | Opaque paste |
| Odor | Slight beeswax and/or cocoa odor |
| Viscosity | N/A: measuring viscosity is not feasible, since changes in phase during measurement lead to differences in viscosity readings |
| Total yeast/mold count | <10 cfu/g (USP<61>) |
| Total aerobic mesophilic count | <100 cfu/g (USP<61>) |
| Absence of Pathogenic bacteria: <i>Staphylococcus aureus, Candida</i> | Absent in 1g (USP<62>) |

| | |
|--|--|
| <i>albicans, and gram negative bacteria (e.g., Pseudomonas aeruginosa)</i> | |
|--|--|

YES® water-based Personal Lubricant: This non-sterile and water-based personal lubricant contains Aloe vera and other components, and is compatible with natural rubber latex and polyisoprene condoms. This product is not compatible with polyurethane condoms. It is neither a contraceptive nor a spermicide. The formulation is a lightly opaque, non-greasy liquid gel. The product is packaged in a HDPE tube with a flip-top cap, and a HDPE single-use applicator. The specifications for the YES® water-based Personal Lubricant are shown below:

| Parameter | Specification |
|---|---|
| Color | Opaque gel |
| Odor | Slight-mild, delicate linseed / leather note |
| Viscosity | 2,000 – 20,000 cP |
| pH | 3.70 - 4.50 |
| Osmolality | 100 - 400 mOsm/kg |
| Antimicrobial Effectiveness | At least 2.0 log reduction from the initial count at 14 days; no increase from the 14 days count at 28 days; no increase from the initial calculated count at 14 and 28 days (USP <51>) |
| Total yeast/mold count | <10 cfu/g (USP<61>) |
| Total aerobic mesophilic count | <100 cfu/g (USP<61>) |
| <i>Absence of Pathogenic bacteria: Staphylococcus aureus, Candida albicans, and gram negative bacteria (e.g., Pseudomonas aeruginosa)</i> | Absent in 1g (USP<62>) |

YES® Vaginal Moisturizer: This non-sterile and water-based personal lubricant contains Aloe vera and other components, and is compatible with natural rubber latex, and polyisoprene condoms. This product is not compatible with polyurethane condoms. It is neither a contraceptive nor a spermicide. The formulation is a lightly opaque, non-greasy liquid gel. The product is packaged in a HDPE tube with a flip-top cap, and a HDPE single-use applicator. The specifications for the YES® Vaginal Moisturizer are shown below:

| Parameter | Specification |
|--|---|
| Color | Opaque gel |
| Odor | Slight-mild, delicate linseed / leather |
| Viscosity | 2,000 – 20,000 cP |
| pH | 3.50-4.50 |
| Osmolality | 250-400 mOsm/kg |
| Antimicrobial Effectiveness | At least 2.0 log reduction from the initial count at 14 days; no increase from the 14 days count at 28 days; no increase from the initial calculated count at 14 and 28 days (USP <51>) |
| Total yeast/mold count | <10 cfu/g (USP<61>) |
| Total aerobic mesophilic count | <100 cfu/g (USP<61>) |
| <i>Absence of Pathogenic bacteria:</i> | Absent in 1g (USP<62>) |

| |
|---|
| <i>Staphylococcus aureus, Candida albicans, and gram negative bacteria (e.g., Pseudomonas aeruginosa)</i> |
|---|

Indications for Use:

YES[®] oil-based Personal Lubricant: A personal lubricant, for vaginal and penile application, intended to moisturize and lubricate, to enhance the ease and comfort of intimate sexual activity and supplement the body's natural lubrication. YES[®] oil-based Personal Lubricant is not compatible with natural rubber latex, polyurethane or polyisoprene condoms.

YES[®] water-based Personal Lubricant: A personal lubricant, for vaginal and penile application, intended to moisturize and lubricate, to enhance the ease and comfort of intimate sexual activity and supplement the body's natural lubrication. YES[®] water-based Personal Lubricant is compatible with natural rubber latex and polyisoprene condoms. This product is not compatible with polyurethane condoms.

YES[®] Vaginal Moisturizer: A personal lubricant, for vaginal and penile application, intended to moisturize and lubricate, to enhance the ease and comfort of intimate sexual activity and supplement the body's natural lubrication. YES[®] Vaginal Moisturizer is compatible with natural rubber latex, and polyisoprene condoms. This product is not compatible with polyurethane condoms.

Comparison of Intended Use and Technological Characteristics of Subject and Predicate Devices:

| YES [®] oil-based Personal Lubricant | | | Comparison |
|---|--|---|--|
| 510(k) # | K162569 | K122477 | |
| Device Name | YES [®] oil-based personal lubricant | LifeStyles Luxe Premium Personal Lubricant | |
| Manufacturer | Bio-tech Lubricants Ltd | Ansell Healthcare Products, LLC | |
| Classification | 884.5300 | 884.5300 | |
| Product code | NUC | NUC | |
| Description | Personal Lubricant | Personal Lubricant | Same |
| Indications for use | A personal lubricant, for vaginal and penile application, intended to moisturize and lubricate, to enhance the ease and comfort of intimate sexual activity and supplement the body's natural lubrication. This product is not compatible with natural rubber latex, polyurethane or polyisoprene condoms. | LifeStyles Luxe Premium Personal Lubricant Is a personal lubricant, for penile and/or vaginal application, intended to moisturize and lubricate, to enhance the ease and comfort of intimate sexual activity and supplement the body's natural lubrication. This product is compatible with natural rubber latex, polyurethane, and polyisoprene condoms. | Different: The subject and predicate devices indication for use statements differ in regards to compatibility with condoms. Differences noted do not represent a new intended use. |
| Oil-based lubricant | YES | YES | Same: the subject and predicate devices are both oil-based lubricants; however, the specific oils in the formulation are |

| YES [®] oil-based Personal Lubricant | | | Comparison |
|---|---|---|--|
| | | | different. This does not raise different questions of S & E (e.g. biocompatibility). |
| Ingredients | Sunflower seed oil, Shea butter, Sweet almond oil, Bees wax, Cocoa seed butter, Vitamin E | Not known | Different: The difference in ingredients do not raise different questions of S & E. |
| Biocompatible | YES | YES | Same |
| Non-sterile | YES | YES | Same |
| Contains preservatives | NO | NO | Same |
| Microbial limits (TAMC, TYMC, and absence of pathogenic bacteria) | See product specifications table (USP <61> & <62>) | Meets the requirements of USP <61> & <62> | Different: the microbial limits of the predicate are not known; however this does not raise different questions of S & E as the microbial limits specifications are within the accepted ranges for these types of devices. |
| Condom Compatibility | Not compatible with natural rubber latex, polyurethane, or polyisoprene condoms. | Compatible with natural rubber latex, polyurethane, and polyisoprene condoms. | Different: The condom compatibility for the subject and predicate devices are different; However, this difference does not represent a new intended use. |

As noted in the table above the subject and predicate devices indications are similar in that they are both used to moisturize and lubricate, to enhance the ease and comfort of intimate sexual activity and supplement the body's natural lubrication. However, they do differ in regards to condom compatibility as the subject device is not compatible with condoms, while the predicate is condom compatible. Differences in condom compatibility between the subject and predicate devices do not represent a new intended use. In regards to technology, the subject and predicate devices are similar in that they are both non-sterile and are oil-based. Differences do exist as described in the table above (e.g., product formulations, specifications for microbial limits, condom compatibility, etc.). The differences identified do not raise different questions of safety and effectiveness as discussed in the table above

| YES [®] water-based Personal Lubricant | | | Comparison |
|---|--|---|--|
| 510(k) # | K162569 | K124044 | |
| Device name | YES [®] water-based Personal Lubricant | Aloe Cadabra Personal lubricant | |
| Manufacturer | Bio-tech Lubricants Ltd | Seven Oaks Ranch, Inc. | |
| Classification | 884.5300 | 884.5300 | |
| Product code | NUC | NUC | |
| Description | Personal Lubricant | Personal Lubricant | Same |
| Indications for use | A personal lubricant, for vaginal and penile application, intended to moisturize and lubricate, to | Aloe Cadabra Lubricant and Aloe Cadabra Flavored/Scented Lubricants are personal lubricants for | Same: The subject and predicate devices have the same indication for use, and therefore have the |

| YES® water-based Personal Lubricant | | | Comparison |
|---|---|--|--|
| | enhance the ease and comfort of intimate sexual activity and supplement the body's natural lubrication. YES® water-based Personal Lubricant is compatible with natural rubber latex and polyisoprene condoms. This product is not compatible with polyurethane condoms. | penile and/or vaginal application, intended to moisturize and lubricate, to enhance the ease and comfort of intimate sexual activity and supplement the body's natural lubrication. This product is compatible with natural rubber latex and polyisoprene condoms. This product is not compatible with polyurethane condoms. | same intended use. |
| Water-based lubricant | YES | YES | Same |
| Ingredients | Water, Aloe vera, Flax seed extract, Guar gum, Locust bean gum, Xanthan gum, Sodium chloride, Potassium sorbate, Citric acid, Phenoxylethanol | Aloe vera | Different: The difference in ingredients do not raise different questions of S & E. |
| Biocompatible | YES | YES | Same |
| Non-sterile | YES | YES | Same |
| Contains preservatives | YES | YES | Same |
| Microbial limits (TAMC, TYMC, and absence of pathogenic bacteria) | See product specifications table (USP <61> & <62>) | Not known | Different: the microbial limits of the predicate are not known; however this does not raise different questions of S & E as these specifications are within the accepted range for these types of devices. |
| Viscosity | 2,000 – 20,000 cP | Not known | Different: the viscosity of the predicate is not known. This does not raise different questions of S & E as the viscosity specification is within the accepted range for these types of devices. |
| pH | 3.70 - 4.50 | Not known | Different: the pH of the predicate is not known. This does not raise different questions of S & E as the pH specification is within the accepted range for these types of devices. |
| Osmolality | 100 - 400 mOsm/kg | Not known | Different: the osmolality of the predicate is not known. This does not raise different questions of S & E as the osmolality specification is within the accepted range for these types of devices. |

| YES [®] water-based Personal Lubricant | | | Comparison |
|---|--|--|------------|
| Condom Compatibility | Compatible with natural rubber latex and polyisoprene condoms. Not compatible with polyurethane condoms. | Compatible with natural rubber latex and polyisoprene condoms. Not compatible with polyurethane condoms. | Same |

As noted in the table above the subject and predicate devices have the same indication for use and intended use. In addition, the subject and predicate devices are similar in that they are both non-sterile, compatible with the same types of condoms, contain Aloe vera, and are water-based. Differences do exist as described in the table above (e.g., product formulations, specifications for microbial limits, viscosity, etc.). The differences identified do not raise different questions of safety and effectiveness as discussed in the table above.

| YES [®] Vaginal Moisturizer | | | Comparison |
|--------------------------------------|---|--|---|
| 510(k) # | K162569 | K124044 | |
| Device Name | YES [®] VM (Vaginal Moisturizer) | Aloe Cadabra Personal lubricant | |
| Manufacturer | Bio-tech Lubricants Ltd | Seven Oaks Ranch, Inc. | |
| Classification | 884.5300 | 884.5300 | |
| Product code | NUC | NUC | |
| Description | Personal Lubricant | Personal Lubricant | Same |
| Indications for use | A personal lubricant, for vaginal and penile application, intended to moisturize and lubricate, to enhance the ease and comfort of intimate sexual activity and supplement the body's natural lubrication. YES [®] Vaginal Moisturizer is compatible with natural rubber latex and polyisoprene condoms. This product is not compatible with polyurethane condoms. | Aloe Cadabra Lubricant and Aloe Cadabra Flavored/Scented Lubricants are personal lubricants for penile and/or vaginal application, intended to moisturize and lubricate, to enhance the ease and comfort of intimate sexual activity and supplement the body's natural lubrication. This product is compatible with natural rubber latex and polyisoprene condoms. This product is not compatible with polyurethane condoms. | Same: The subject and predicate devices have the same indication for use, and therefore have the same intended use. |
| Water-based lubricant | YES | YES | Same |
| Ingredients | Water, Aloe vera, Flax seed extract, Guar gum, Locust bean gum, Xanthan gum, Sodium chloride, Potassium sorbate, Citric acid, Phenoxyethanol | Aloe vera | Different: The difference in ingredients do not raise different questions of S & E. |
| Biocompatible | YES | YES | Same |
| Non-sterile | YES | YES | Same |
| Contains preservatives | YES | YES | Same |
| Microbial Limits | See product specifications | Not known | Different: the microbial |

| YES® Vaginal Moisturizer | | Comparison | |
|--|--|--|--|
| (TAMC, TYMC, and absence of pathogenic bacteria) | table (USP <61> & <62>) | | limits of the predicate are not known; however this does not raise different questions of S & E as these specifications are within the accepted range for these types of devices. |
| Viscosity | 2,000 – 20,000 cP | Not known | Different: the viscosity of the predicate is not known. This does not raise different questions of S & E as the viscosity specification is within the accepted range for these types of devices |
| pH | 3.50-4.50 | Not known | Different: the pH of the predicate is not known. This does not raise different questions of S & E as the pH specification is within the accepted range for these types of devices. |
| Osmolality | 250-400 mOsm/kg | Not known | Different: the osmolality of the predicate is not known. This does not raise different questions of S & E as the osmolality specification is within the accepted range for these types of devices. |
| Condom Compatibility | Compatible with natural rubber latex and polyisoprene condoms. Not compatible with polyurethane condoms. | Compatible with natural rubber latex and polyisoprene condoms. Not compatible with polyurethane condoms. | Same |

As noted in the table above the subject and predicate devices have the same indication for use and intended use. In addition, the subject and predicate devices are similar in that they are both non-sterile, compatible with the same types of condoms, contain Aloe vera, and are water-based. Differences do exist as described in the table above (e.g., product formulations, specifications for microbial limits, viscosity, etc.). The differences identified do not raise different questions of safety and effectiveness as discussed in the table above.

Performance Testing:

Biocompatibility:

Testing was conducted to assess the biocompatibility of the YES® oil-based Personal Lubricant, YES® water-based Personal Lubricant and YES® Vaginal Moisturizer. Testing included assessments for Cytotoxicity (ISO 10993-5:2009(R)2014), Vaginal Irritation (ISO 10993-10:2010(R)2014), Sensitization (ISO 10993-10:2010(R)2014), and Acute Systemic Toxicity (ISO 10993-11:2006).

The results of testing demonstrated that they are non-cytotoxic, non-irritating, non-sensitizing and non-systemically toxic.

Condom Compatibility:

YES[®] oil-based Personal Lubricant: Condom compatibility testing was performed for polyurethane condoms per ASTM D7661-10. The results indicate that the device is not compatible with polyurethane condoms. Additionally, compatibility testing was not performed for natural rubber latex or polyisoprene condoms; therefore, the device is not compatible with natural rubber latex or polyisoprene condoms.

YES[®] Vaginal Moisturizer and YES[®] water-based Personal Lubricant: Condom compatibility testing was performed per ASTM D7661-10. The results indicated that the devices are compatible with natural rubber latex and polyisoprene condoms, but are not compatible with polyurethane condoms.

Shelf Life and Microbial Limits:

YES[®] oil-based Personal Lubricant, YES[®] water-based Personal Lubricant, and YES[®] Vaginal Moisturizer have a 9-month shelf life. The results of shelf-life testing demonstrated that the subject lubricants met all device specifications as shown in the Device Description section for the duration of the 9-month shelf-life.

Conclusion:

YES[®] oil-based Personal Lubricant, YES[®] water-based Personal Lubricant, and YES[®] Vaginal Moisturizer have the same intended use and similar technological characteristics as the predicate devices. The results of the performance testing conducted on the subject devices demonstrate that they are as safe and effective as the predicate devices and support substantial equivalence.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

K162569

Biotech Lubricants Ltd

Device Trade Name: Yes Oil-based Personal Lubricant, Yes Water-based Personal Lubricant,
Yes Vaginal Moisturizer

Contact Name: John Shepperson

This document is being communicated via e-mail as an attachment. The date on which FDA sent this e-mail is the official date of this correspondence.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug AdministrationForm Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.**Indications for Use**510(k) Number (if known)
K162569

Device Name

YES® oil-based Personal Lubricant, YES® water-based Personal Lubricant, YES® Vaginal Moisturizer

Indications for Use (Describe)

Device Name: YES® oil-based Personal Lubricant

Indications for Use:

A personal lubricant, for vaginal and penile application, intended to moisturize and lubricate, to enhance the ease and comfort of intimate sexual activity and supplement the body's natural lubrication. YES® oil-based Personal Lubricant is not compatible with natural rubber latex, polyurethane or polyisoprene condoms.

Device Name: YES® water-based Personal Lubricant

Indications for Use:

A personal lubricant, for vaginal and penile application, intended to moisturize and lubricate, to enhance the ease and comfort of intimate sexual activity and supplement the body's natural lubrication. YES® water-based Personal Lubricant is compatible with natural rubber latex and polyisoprene condoms. This product is not compatible with polyurethane condoms.

Device Name: YES® Vaginal Moisturizer

Indications for Use:

A personal lubricant, for vaginal and penile application, intended to moisturize and lubricate, to enhance the ease and comfort of intimate sexual activity and supplement the body's natural lubrication. YES® Vaginal Moisturizer is compatible with natural rubber latex and polyisoprene condoms. This product is not compatible with polyurethane condoms.

Type of Use (Select one or both, as applicable)

 Prescription Use (Part 21 CFR 801 Subpart D) Over-The-Counter Use (21 CFR 801 Subpart C)**CONTINUE ON A SEPARATE PAGE IF NEEDED.**

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

June 9, 2017

Biotech Lubricants Ltd
% Karen Cornelius
Senior Associate
Maetrics
BioCity Nottingham, Pennyfoot Street
Nottingham, NG1 1GF
United Kingdom

Re: K162569
Trade/Device Name: YES® oil-based Personal Lubricant, YES® water-based Personal Lubricant, YES® Vaginal Moisturizer
Regulation Number: 21 CFR 884.5300
Regulation Name: Condom
Regulatory Class: II
Product Code: NUC
Dated: May 9, 2017
Received: May 11, 2017

Dear Karen Cornelius:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Page 2 - Karen Cornelius

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely,

Benjamin R. Fisher, Ph.D.
Director
Division of Reproductive, Gastro-Renal,
and Urological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
 CDRH/ODE/DRGUD/OGDB
 WO66 RMG201C
 10903 New Hampshire Ave
 Silver Spring, MD 20993-0002
 301-796-6486

Premarket Notification 510(k) Review

| | | | |
|--|---|--|--------------------------------|
| Date: November 14, 2016 | | | |
| Reviewer: Patrick Gallagher | | | |
| Subject: Traditional 510(k)# K162569 | | | |
| Applicant: Biotech Lubricants Ltd | Device Trade Name: Yes Oil-based Personal Lubricant, Yes Water-based Personal Lubricant, Yes Vaginal Moisturizer | | |
| Contact Name: John Shepperson | Contact Title: Senior Associate | | |
| Correspondent Firm: Maetrics | Phone: 44 (115) 921-6200 Email: jshepperson@maetrics.com | | |
| Received Date: September 15, 2016 | Due Date: December 14, 2016 | | |
| Pro Code(s): NUC Class: II Reg #: 884.5300 | Reg Name: Condom | | |
| Predicate Devices: | | | |
| Submission # | Pro Code | Device Trade Name | Owner |
| K124044 | NUC | Aloe Cadabra Lubricant, Aloe Cadabra Flavored/scented Lubricants | Seven Oaks Ranch, Inc. |
| K122477 | NUC | Lifestyles Luxe Premium Personal Lubricant | Ansell Healthcare Products LLC |
| Review Summary | | | |
| The subject device is a personal lubricant with the following Indications for Use: | | | |
| “YES® oil-based Personal Lubricant is a personal lubricant, for vaginal and penile application, intended to moisturize and lubricate, to enhance the ease and comfort of intimate sexual activity and supplement the body's natural lubrication. YES® oil-based Personal Lubricant is not compatible with natural rubber latex, polyurethane or polyisoprene condoms.” | | | |
| “YES® water-based Personal Lubricant or YES® Vaginal Moisturizer is a personal lubricant, for vaginal and penile application, intended to moisturize and lubricate, to enhance the ease and comfort of intimate sexual activity and supplement the body's natural lubrication. YES® water-based Personal Lubricant/YES® Vaginal Moisturizer is compatible with natural rubber latex, polyurethane and polyisoprene condoms.” | | | |
| All three lubricants are for OTC use. This is the first round of substantive review for this submission. During the RTA review, I identified the submission to be administratively complete and “accepted” the submission (RTAA). The decision was communicated to the sponsor in an email dated September 21, 2016. | | | |
| During the first round of review, I identified deficiencies in the performance testing, labeling, and 510(k) summary. Therefore, I recommend that we place the file on hold to request the necessary information. | | | |
| Recommendation | | | |
| I recommend that the Yes Oil-based Personal Lubricant, Yes Water-based Personal Lubricant, Yes Vaginal Moisturizer is/are in need of Additional Information (AINN) | | | |

Review Team

