II. 510(k) Summary

JUN 2 8 2013

Submitter Name:	Church & Dwight Co., Inc.
Submitter Address:	469 North Harrison Street Princeton, NJ 08543
Contact Person:	Emily Perez Senior Regulatory Affairs Specialist Church & Dwight Co., Inc. 469 North Harrison Street Princeton, NJ 08543 Tel: (609) 806-1430 Fax: (609) 403-7415
Date Prepared:	May 28, 2013
510(k) Number:	K123427
Device Trade Name:	Nirvana D Personal Lubricant
Device Common Name:	Personal Lubricant
Product Code:	NUC – Condom (21 C.F.R. § 884.5300)
Classification:	Class II
Predicate Device:	K-Y® Brand Intrigue™ Intense Warming Sensation (K072360)
Intended Use:	Nirvana D is a personal lubricant for penile and/or vaginal application, intended to lubricate and moisturize, 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. Not compatible with polyurethane or other condoms.
Device Description:	The Nirvana D Personal Lubricant is an anhydrous, non-sterile, clear silicone-based personal lubricant composed of dimethicone, dimethiconol, vanillyl butyl ether ("VBE") and hexyl nicotinate. Nirvana D Personal Lubricant is compatible with natural rubber latex and polyisoprene condoms. This product is not a spermicide or a contraceptive. The product is packaged in a polyethylene terephthalate (PET) bottle with a screw-on, flip top polypropylene (PP) closure constituting the device's primary packaging. One bottle is packaged into a cardboard carton, which constitutes the device outer packaging.

Technological Characteristics:

There is no difference in the fundamental technological characteristic of the Nirvana D Personal Lubricant and the predicate K-Y® Brand Intrigue™ Intense Warming Sensation Personal Lubricant. Nirvana D Personal Lubricant is composed of dimethicone, dimethiconol, vanilly butyl ether, and hexyl nicotinate. The proposed device is substantially equivalent to the predicate K-Y® Brand Intrigue™ Intense Warming Sensation Personal Lubricant cleared under 510(k) # K072360. Three of the four ingredients, dimethicone, dimethiconol, and vanillyl butyl ether, in Nirvana D Personal Lubricant are identical to those in the predicate device. The additional ingredient, hexyl nicotinate, does not raise new questions of safety or effectiveness.

Biocompatibility:

Biocompatibility testing was performed in accordance with ISO 10993, Biological Evaluation of Medical Devices, 2009.

Testing Performed:

Testing Performed	Results
Cytotoxicity	Non-cytotoxic
Rabbit Vaginal Irritation	Non-irritating
Rabbit Penile Irritation	Non-irritating
Acute Systemic Toxicity	Non-systemically toxic
Guinea Pig Maximization	Non-sensitizing
Primary Rabbit Skin Irritation	Non-irritating

Condom Compatibility:

Condom Compatibility Testing was performed with Nirvana D Personal Lubricant and ASTM D7761-10 "Standard Testing Method for Determining Compatibility of Personal Lubricants with Natural Rubber Latex Condoms" which was modified to include pre-lubricated and un-lubricated dry condoms. Three marketed brands of pre-lubricated and un-lubricated dry natural rubber latex condoms and one brand of polyisoprene condoms were tested.

Condom compatibility testing results demonstrate that Nirvana D Personal Lubricant is compatible with commercially available natural rubber latex condoms and polyisoprene condoms.

Shelf-life:

In order to establish the stability of the proposed device for its intended shelf-life, an accelerated aging stability test was conducted. Evaluation of viscosity, odor, color and appearance was conducted. Microbial evaluation was conducted via USP testing for Total Microbial Count, Total Yeast and Mold count and Absence of Microbial Pathogens. Satisfactory results were obtained for all parameters evaluated.

Based on the results of the accelerated aging study and microbial testing, Nirvana D Personal Lubricant has a proposed shelf-life of two-years.

A Real-Time aging study is being performed in order to verify results of the accelerated aging study.

Substantially Equivalence:

Based on non-clinical performance data, biocompatibility review and testing and safety data, the proposed device is substantially equivalent to K-Y® Brand Intrigue™ Intense Warming Sensation in technology, intended use, safety and effectiveness.

Conclusion:

The results from laboratory testing and non-clinical evaluation of human use testing show that the proposed device performs equivalently to the predicate device and is safe for use as a personal lubricant.

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 28, 2013

Church & Dwight Co., Inc.
% Ms. Emily Perez
Senior Regulatory Affairs Specialist
469 North Harrison Street
PRINCETON NJ 08543

Re: K123427
Trade/Device Name: Nirvana D Personal Lubricant
Regulation Number: 21 CFR§ 884.5300
Regulation Name: Condom
Regulatory Class: II
Product Code: NUC
Dated: May 28, 2013
Received: May 30, 2013

Dear Ms. Perez:

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.

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 go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 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 Small Manufacturers, International and Consumer Assistance 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 yours,

Herbert P. Lerner -S

for
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

I. Indications For Use

510(k) Number (if known): K123427

Device Name: Nirvana D Personal Lubricant

INDICATIONS FOR USE:

Nirvana D is a personal lubricant for penile and/or vaginal application, intended to lubricate and moisturize, 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. Not compatible with polyurethane or other condoms.

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ____ OR Over-The-Counter Use __X_
(Part 21 C.F.R. 801 Subpart D) (21 C.F.R. 801 Subpart C)

Herbert P. Lerner -S

K123427

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 28, 2013

Church & Dwight Co., Inc.
% Ms. Emily Perez
Senior Regulatory Affairs Specialist
469 North Harrison Street
PRINCETON NJ 08543

Re: K123427
Trade/Device Name: Nirvana D Personal Lubricant
Regulation Number: 21 CFR§ 884.5300
Regulation Name: Condom
Regulatory Class: II
Product Code: NUC
Dated: May 28, 2013
Received: May 30, 2013

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Sincerely yours,

Herbert P. Lerner -S

for
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

Concurrence & Template History Page
[THIS PAGE IS INCLUDED IN IMAGE COPY ONLY]

Full Submission Number: **K123427/S001 – Church & Dwight Co., Inc.**

For Office of Compliance Contact Information:

http://insideportlets.fda.gov:9010/portal/page?_pageid=197,415881&_dad=portal&_schema=PORTAL&org=318

For Office of Surveillance and Biometrics Contact Information:

http://insideportlets.fda.gov:9010/portal/page?_pageid=197,415881&_dad=portal&_schema=PORTAL&org=423

Digital Signature Concurrence Table	
Reviewer Sign-Off	Haijing Hu-PhD 2013.06.28 10:10:40 -04'00'
Branch Chief Sign-Off *Acting BC for EHB*	Becky Robinson-PhD 2013.06.28 10:22:39 -04'00'
Division Sign-Off	Herbert P. Lerner -S 2013.06.28 10:45:59 -04'00'

Template Name: K1(A) – SE after 1996

Template History:

Date of Update	By	Description of Update
7/27/09	Brandi Stuart	Added Updates to Boiler Table
8/7/09	Brandi Stuart	Updated HFZ Table
1/11/10	Diane Garcia	Liability/Warranty sentence added at bottom of 1st page
10/4/11	M. McCabe Janicki	Removed IFU sheet and placed in Forms
9/25/12	Edwena Jones	Added digital signature format

cc: DCC – sign-off & original
ODE/DRGUD/OGDB – (Haijing Hu)

Final: KAS:kas:clr:6/28/2013

I. Indications For Use

510(k) Number (if known): K123427

Device Name: Nirvana D Personal Lubricant

INDICATIONS FOR USE:

Nirvana D is a personal lubricant for penile and/or vaginal application, intended to lubricate and moisturize, 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. Not compatible with polyurethane or other condoms.

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ____ OR Over-The-Counter Use __X__
(Part 21 C.F.R. 801 Subpart D) (21 C.F.R. 801 Subpart C)

Herbert P. Lerner -S

K123427

K123427 vol. 1

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

January 4, 2013

Ms. Emily Perez
Senior Regulatory Affairs Specialist
Church & Dwight Co., Inc.
469 North Harrison Street
PRINCETON NJ 08543

Re: K123427
Trade Name: Nirvana D Personal Lubricant
Dated: November 6, 2012
Received: November 7, 2012

Dear Ms. Perez:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above. We cannot determine if the device is substantially equivalent to a legally marketed predicate based solely on the information you provided. To complete the review of your submission, we require the following additional information:

(b)(4) Trade Secret Process

[redacted]

(b)(4) Trade Secret Process

[redacted]

(b)(4) Trade Secret Process

[redacted]

(b)(4) Trade Secret Process

[redacted]

You may not market this device until you have provided adequate information described above and required by 21 CFR 807.87(l), and you have received a letter from FDA allowing you to do so. If you market the device without conforming to these requirements, you will be in violation of the Act. You may, however, distribute this device for investigational purposes to obtain clinical data if needed to establish substantial equivalence. Clinical investigations of this device must be conducted in accordance with the investigational device exemption (IDE) regulations (21 CFR 812).

In accordance with 21 CFR 807.87(l), FDA may consider a 510(k) to be withdrawn if the submitter fails to provide additional information within 30 days of an Additional Information (AI) request. FDA generally permits submitters additional time to respond to such requests. FDA intends to automatically grant a maximum of 180 calendar days from the date of the AI

request, even if the submitter has not requested an extension. Therefore, submitters are no longer required to submit written requests for extension. However, you should be aware that FDA intends to issue a notice of withdrawal under 21 CFR 807.87(l) if FDA does not receive, in a submission to the appropriate Document Control Center, a complete response to all of the deficiencies in this AI request within 180 calendar days of the date of this request. If you then

wish to resubmit this 510(k) notification, a new number will be assigned and your submission will be considered a new premarket notification submission.

For further information regarding how various FDA and industry actions that may be taken on 510(k)s should affect the review clock for purposes of meeting the Medical Device User Fee Amendments of 2012 (MDUFA III), to the Federal Food, Drug, and Cosmetic Act, you may refer to our guidance document entitled "Guidance for Industry and Food and Drug Administration Staff FDA and Industry Actions on Premarket Notification (510(k)) Submissions: Effect on FDA Review Clock and Goals". You may review this document at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm089735.htm.
The requested information should reference your above 510(k) number and should be submitted in duplicate to:

U.S. Food and Drug Administration
Center for Devices and Radiological Health
Document Control Center – WO66-G609
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

If you have any questions concerning the contents of the letter and would like to set up a teleconference, please contact Michelle Luo, Ph.D. at (301) 796-5314. If you need information or assistance concerning the IDE regulations, please contact the Division of Small Manufacturers, International and Consumer Assistance 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 yours,

Sharon M. Andrews

Acting Branch Chief for:
Elaine H. Blyskun
Chief, Obstetrics and Gynecology
Devices Branch
Division of Reproductive, Gastro-Renal,
and Urological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Jones, Ashlee *

From: Microsoft Outlook
To: 'emily.perez@churchdwight.com'
Sent: Friday, January 04, 2013 2:26 PM
Subject: Relayed: K123427 Hold Letter

Delivery to these recipients or groups is complete, but no delivery notification was sent by the destination server:

'emily.perez@churchdwight.com' (emily.perez@churchdwight.com) <mailto:emily.perez@churchdwight.com>

Subject: K123427 Hold Letter

Food and Drug Administration
Office of Device Evaluation &
Office of In Vitro Diagnostics

COVER SHEET MEMORANDUM

From: Reviewer Name __Michelle Luo_____

Subject: 510(k) Number __K123427_____

To: The Record

Please list CTS decision code __AI_____

☐ Refused to accept (Note: this is considered the first review cycle, See Screening Checklist http://eroom.fda.gov/eRoomReg/Files/CDRH3/CDRHPremarketNotification510kProgram/0_5631/Screening%20Checklist%207%202%2007.doc)

x Hold (Additional Information or Telephone Hold).

☐ Final Decision (SE, SE with Limitations, NSE (select code below), Withdrawn, etc.).

Not Substantially Equivalent (NSE) Codes

☐	NO	NSE for lack of predicate
☐	NI	NSE for new intended use
☐	NQ	NSE for new technology that raises new questions of safety and effectiveness
☐	NU	NSE for new intended use AND new technology raising new questions of safety and effectiveness
☐	NP	NSE for lack of performance data
☐	NS	NSE no response
☐	NL	NSE for lack of performance data AND no response
☐	NM	NSE pre-amendment device call for PMAs (515i)
☐	NC	NSE post-amendment device requires PMAs
☐	NH	NSE for new molecular entity requires PMA
☐	TR	NSE for transitional device

Please complete the following for a final clearance decision (i.e., SE, SE with Limitations, etc.):		YES	NO
Indications for Use Page	*Attach IFU*	✓	
510(k) Summary /510(k) Statement	*Attach Summary*	✓	
Truthful and Accurate Statement.	*Must be present for a Final Decision*	✓	
Is the device Class III?			✓
If yes, does firm include Class III Summary?	*Must be present for a Final Decision*		
Does firm reference standards? (If yes, please attach form from http://www.fda.gov/opacom/morechoices/fdaforms/FDA-3654.pdf)		✓	
Is this a combination product? (Please specify category _____, see http://eroom.fda.gov/eRoomReg/Files/CDRH3/CDRHPremarketNotification510kProgram/0_413b/COMBINATION%20PRODUCT%20ALGORITHM%20(REVISED%203-12-03).DOC			✓
Is this a reprocessed single use device? (Guidance for Industry and FDA Staff – MDUFMA - Validation Data in 510(k)s for Reprocessed Single-Use Medical Devices, http://www.fda.gov/cdrh/ode/guidance/1216.html)			✓
Is this device intended for pediatric use only?			✓
Is this a prescription device? (If both prescription & OTC, check both boxes.)			✓
Did the application include a completed FORM FDA 3674, Certification with Requirements of ClinicalTrials.gov Data Bank?			✓
Is clinical data necessary to support the review of this 510(k)?			✓

For United States-based clinical studies **only**: Did the application include a completed FORM FDA 3674, *Certification with Requirements of ClinicalTrials.gov Data Bank*? (If study was conducted in the United States, and FORM FDA 3674 was not included or incomplete, then applicant must be contacted to obtain completed form.)			
Does this device include an Animal Tissue Source?			✓
All Pediatric Patients age<=21			✓
Neonate/Newborn (Birth to 28 days)			✓
Infant (29 days -< 2 years old)			✓
Child (2 years -< 12 years old)			✓
Adolescent (12 years -< 18 years old)			✓
Transitional Adolescent A (18 - <21 years old) Special considerations are being given to this group, different from adults age ≥ 21 (different device design or testing, different protocol procedures, etc.)			✓
Transitional Adolescent B (18 -<= 21; No special considerations compared to adults => 21 years old)			✓
Nanotechnology			✓
Is this device subject to the Tracking Regulation? (Medical Device Tracking Guidance, http://www.fda.gov/cdrh/comp/guidance/169.html)	*Contact OC.*		✓

Regulation Number	**Class***	**Product Code**
884.5300	II	NUC

(*If unclassified, see 510(k) Staff)

Additional Product Codes:_____

Digital Signature Concurrence Table	
Reviewer Sign-Off	Michelle Luo 2013.01.03 16:47:36 -05'00'
Branch Chief Sign-Off (for Elaine Blyskun)	Sharon M. Andrews 2013.01.03 17:09:12 -05'00'

DEPARTMENT OF HEALTH AND HUMAN SERVICES **MEMORANDUM**

Food and Drug Administration
Office of Device Evaluation
10903 New Hampshire Avenue
Silver Spring, MD 20993

Premarket Notification [510(k)] Review
Traditional

K123427

Date:	January 02, 2012	**Office:**	ODE
To:	The Record	**Division:**	DRGUD
From:	Michelle Luo, Ph.D Biologist	**Branch:**	OGDB

510(k) Holder:	Church & Dwight Co., Inc.
Device Name:	Nirvana D Personal Lubricant
Contact:	Karen Vescovi, Regulatory Affairs
Address:	469 North Harrison Street, Princeton, NJ 08543
Phone:	(609) 688-5347
Fax:	(609) 497-7179
Email:	Karen.Vescovi@churchdwight.com

I. Purpose and Submission Summary

The purpose of this 510(k) submission is to introduce Nirvana D personal lubricant into interstate commerce.

(b)(4) Trade Secret Process

[redacted]

II. Administrative Requirements

	Yes	No	N/A
Indications for Use Form – OTC	X		
Truthful and Accuracy Statement	X		
510(k) Summary	X		

	Yes	No	N/A
Standards Data Report for 510(k) Form (Form 3654)	X		
ClinicalTrials.gov Data Bank Form (Form 3674)	x		

Indications for Use Form - The sponsor provided Indications for Use form that is in line with FDA recommended format.

510(k) Statement/Summary - The sponsor provided a 510(k) Summary. We will recommend the sponsor revise the 510(k) Summary based on their responses to the deficiencies identified in AI letter (details see Attachment 1).

Standards Data Report for 510(k) Form (Form 3654) - The sponsor provided a complete, most recent FDA-recognized Standards Data Report form (Form 3654) for following standards referenced in this submission. I used all of the standards referenced in this submission to make my decision.

(b)(4) Trade Secret Process [redacted]

Truthful and Accuracy Statement – Acceptable.

ClinicalTrials.gov Data Bank Form (Form 3674): (b)(4) Trade Secret Process [redacted]

III. Device Description

	Yes	No	N/A
Is the device life-supporting or life sustaining?		X	
Is the device an implant (implanted longer than 30 days)?		X	
Does the device design use software?		X	
Is the device sterile?		X	
Is the device reusable (not reprocessed single use)?		X	
Are "cleaning" instructions included for the end user?			X

(b)(4) Trade Secret Process

[redacted]

Table 1. Lubricant Formulation

Ingredient	Function	CAS Number	% w/w	Supplier
Dimethylpolysiloxane	Lubricant, (b)(4) Trade Secret	63148-62-9	(b)(4) Trade Secret Process [redacted]	
Dimethylpolysiloxane, Hydroxyl-terminated	Lubricant, (b)(4) Trade Secret	70131-67-8		
Vanillyl Butyl Ether	(b)(4) Trade	82654-98-6		
Hexyl Nicotinate	(b)(4) Trade Secret	23597-82-2		
Total				

(b)(4) Trade Secret Process

[redacted]

IV. Indications for Use

The sponsor proposed the following *Indications for Use*:

(b)(4) Trade Secret Process

[redacted]

V. Predicate Device Comparison

Predicate Device Description

The manufacturer's proposed predicate device is the K-Y® Brand Intrigue™ Intense Warming Sensation cleared under 510(k) K072360. The proposed predicate device is also a silicone-based personal lubricant classified under same regulation 21 CFR §884.5300 and product code NUC as the subject device. The following table provides a matrix comparison of subject and predicate device.

Table 2. Substantial Equivalence Comparison

	Nirvana D Personal Lubricant K123427	**K-Y® Brand Intrigue™ K072360**
Indications for Use	Nirvana D 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 and polyisoprene condoms. Not compatible with polyurethane and other condoms.	K-Y® Brand Intrigue™ Intense Warming Sensation is intended as a personal lubricant for penile and vaginal application compatible with latex condom[s]
Lubricant, skin-conditioning agent	Dimethicone	Dimethicone
	Dimethiconol	Dimethiconol
Warming agent	Vanillyl butyl ether	Vanillyl butyl ether
Warming/Tingling agent	Hexyl nicotinate	--
Performance Data	Compatible with natural latex, and polyisoprene condoms	Compatible with natural latex condoms
Biocompatibility	The pre-clinical evaluation and testing, and human use data show that the proposed device is safe for use as a personal lubricant	The pre-clinical evaluations and testing, and human use data show that the proposed device is safe for use as a personal lubricant
Sterility	non-sterile	non-sterile

Substantial Equivalence Discussion

Indications for Use

The current subject lubricant's Instructions for Use is in line with FDA recommended format. Although it is different from the predicate, the revision does not represent a new intended use.

Technological Characteristics

As shown in the Table 2, both subject and predicate lubricant are silicone-based. Both lubricants contain dimethicone, dimethiconol and vanillyl butyl ether. The subject lubricant has hexyl nicotinate, which is not

present in the predicate. Neither has flavoring. (b)(4) Trade Secret Process [redacted] However, because different formulations between personal lubricant 510(k) submissions is very common, these changes do not constitute the new technological characteristics. Therefore, the subject and predicate devices have the same technological characteristics.

Descriptive characteristics are not precise enough to ensure equivalence because they are not sufficient to assess biocompatibility, condom compatibility, and shelf life. There are not sufficient performance data at this time to ensure equivalence, particularly to evaluate condom compatibility. The sponsor needs to address concerns related to the performance data provided to demonstrate substantial equivalence of the subject device. See Sections VII, VIII and XI for a detailed review of the performance testing provided.

VI. Labeling

(b)(4) Trade Secret Process [redacted]

VII. Packaging & Sterilization/Shelf Life/Reuse

Packaging

The subject lubricant will be packaged (b)(4) Trade Secret Process [redacted]

Sterilization

The subject lubricant is provided non-sterile.

Shelf-Life

(b)(4) Trade Secret Process [redacted]

(b)(4) Trade Secret Process

[redacted]

VIII. Biocompatibility

(b)(4) Trade Secret Process

[redacted]

(b)(4) Trade Secret Process

[redacted]

(b)(4) Trade Secret Process

[redacted]

IX. Software

This section does not apply to this submission.

X. Electromagnetic Compatibility and Electrical, Mechanical and Thermal Safety

This section does not apply to this submission.

XI. Performance Testing – Bench

(b)(4) Trade Secret Process

[redacted]

(b)(4) Trade Secret Process

[redacted]

XII. Performance Testing – Animal

This section does not apply to this submission.

XIII. Performance Testing – Clinical

(b)(4) Trade Secret Process

[redacted]

(b)(4) Trade Secret Process

[redacted]

XIV. Deficiencies

Please see Attachment 1

XV. Contact History

An RTA checklist was sent on 12/3/2012 requesting the missing information in the submission. The sponsor responded in 12/4/2012.

XVI. Recommendation

Additional Information Required

Regulation Number: **21 CFR 884.5300**
Regulation Name: **Condom**
Regulatory Class: **Class II**
Product Code: **NUC**

Digital Signature Concurrence Table	
Reviewer Sign-Off	Michelle Luo 2013.01.03 16:48:51 -05'00'
Branch Chief Sign-Off (for Elaine Blyskun)	Sharon M. Andrews 2013.01.03 17:11:30 -05'00'

(b)(4) Trade Secret Process = Product Specs

[redacted]

Device Specifications

(b)(4) Trade Secret Process = Product Specs

[redacted]

Shelf life

(b)(4) Trade Secret Process = Product Specs

[redacted]

(b)(4) Trade Secret Process = Product Specs

[redacted]

Clinical Evaluation

(b)(4) Trade Secret Process = Product Specs

[redacted]

Labeling

(b)(4) Trade Secret Process = Product Specs

[redacted]

Administrative

(b)(4) Trade Secret Process = Product Specs

[redacted]

(b)(4) Trade Secret Process = Product Specs

[redacted]

Luo, Michelle T

From: Cochran, Chrissy
Sent: Wednesday, December 12, 2012 4:45 PM
To: Luo, Michelle T
Subject: K123427 consult
Attachments: K123427_ChurchandDwight_NirvanaDPersonalLubricant_ConsultMemo.doc

Hi Michelle,

Attached is the consult in Word. Please let me know if anything is unclear or if there is anything else you would like for me to address before I sign it.

Thanks,
-Chrissy

Office of Device Evaluation
Center for Devices and Radiological Health
Food and Drug Administration

DEPARTMENT OF HEALTH & HUMAN SERVICES

Memorandum

Date: December 12, 2012

From: Chrissy J. Cochran, Regulatory Advisor (Toxicologist), DRGUD/OGDB

Subject: **K123427** – Nirvana D Personal Lubricant
Biological Safety Assessment Consult Review

To: Michelle Luo, Biologist, DRGUD/OGDB

Applicant: Church & Dwight Co., Inc.

I. Scope of Review

(b)(4) Trade Secret Process = Product Specs

[redacted]

II. Device Description

Nirvana D Personal Lubricant is an anhydrous, non-sterile, clear silicone-based personal lubricant composed of dimethicone, dimethiconol, vanillyl butyl ether, and hexyl nicotinate.

III. Indications for Use

Church & Dwight states the intended use of the device is *"a personal lubricant for penile and/or vaginal application, intended to lubricate and moisturize, 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. Not compatible with polyurethane or other condoms."*

IV. Background

Hexyl nicotinate is a lipophilic ester of nicotinic acid (i.e., Vitamin B3, Niacin). Nicotinic acid is the major metabolite of hexyl nicotinate and is used as a nutritional supplement. Prescription-strength nicotinic acid is used as a treatment for high total cholesterol, high blood lipids, and niacin deficiency. Overdoses of nicotinic acid have been associated with severe skin flushing with dizziness, rapid heartbeat, itching, nausea and vomiting, abdominal pain, diarrhea, and hepatotoxicity.

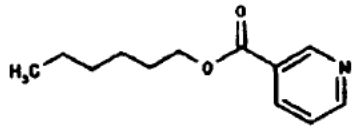


Figure 1. Hexyl nicotinate

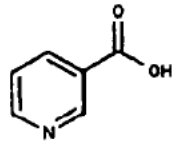


Figure 2. Nicotinic Acid

(b)(4) Trade Secret Process -Testing

[redacted]

V. Hexyl Nicotinate Assessment

(b)(4) Trade Secret Process -Testing

[redacted]

(b)(4) Trade Secret Process -Testing

[redacted]

VI. Conclusion

(b)(4) Trade Secret Process -Testing

[redacted]

VII. Recommendation

(b)(4) Trade Secret Process -Testing

[redacted]

Chrissy J. Cochran, Ph.D., Regulatory Advisor (Toxicologist)
ODE/DRGUD/OGDB

K123427
Nirvana D Clinical Review

From: Catherine Sewell, Medical Officer, CDRH/DRGUD/OGDB

To: Michelle Luo, Lead Reviewer, CDRH/DRGUD/OGDB

CC: Elaine Blyskun, Branch Chief, CDRH/DRGUD/OGDB

Re: K123427

Nirvana D personal lubricant

Church & Dwight Co., Inc.

Date: December 4, 2012

Summary

(b)(4) Trade Secret Process -Product Specs

[redacted]

Device Description

(b)(4) Trade Secret Process -Product Specs

[redacted]

Predicate Device

The sponsor has identified K-Y Intrigue (K072360) as a predicate device, with the formulation below
Table II. Formulation of K-Y Intrigue (predicate)

Ingredient	Function	(%w/w)
DC Q7-9120 (20cSt and 1000cSt)—silicone fluid	Lubricant	99.98%
DC blend 20 (dimethiconol/silicone blend)	Lubricant	
Vanillyl butyl ether	Warming agent	0.02%

(b)(4) Trade Secret Process -Product Specs

[redacted]

Proposed Indication for Use

(b)(4) Trade Secret Process -Product Specs

[redacted]

Clinical Performance Data

(b)(4) Trade Secret Process -Product Specs

[redacted]

(b)(4) Trade Secret Process -Product Specs

[redacted]

Study Results

(b)(4) Trade Secret Process -Product Specs

[redacted]

Results--Comfort

(b)(4) Trade Secret Process -Product Specs

[redacted]

(b)(4) Trade Secret Process -Product Specs

[redacted]

Results(b)(4) Trade [redacted]

(b)(4) Trade Secret Process -Product Specs

[redacted]

Results—Safety

(b)(4) Trade Secret Process -Product Specs

[redacted]

Consumer Preference

(b)(4) Trade Secret Process -Product Specs

[redacted]

(b)(4) Trade Secret Process -Product Specs

[redacted]

Clinical Review Issues

(b)(4) Trade Secret Process -Product Specs

[redacted]

(b)(4) Trade Secret Process -Product Specs

[redacted]

Catherine A. Sewell -S
2013.01.03 15:05:27 -05'00'

Catherine A. Sewell, MD, MPH, Medical Officer, CDRH/DRGUD/OGDB, Date

(b)(4) Trade Secret Process -Testing Report

(b)(4) Trade Secret Process -Testing Report

(b)(4) Trade Secret Process -Testing Report

(b)(4) Trade Secret Process -Testing Report

(b)(4) Trade Secret Process -Testing Report

(b)(4) Trade Secret Process -Testing Report

(b)(4) Trade Secret Process -Testing Report

(b)(4) Trade Secret Process -Testing Report

(b)(4) Trade Secret Process -Testing Report

(b)(4) Trade Secret Process -Testing Report

(b)(4) Trade Secret Process -Testing Report

(b)(4) Trade Secret Process -Testing Report

Luo, Michelle T

From: Perez, Emily <Emily.Perez@churchdwight.com>
Sent: Tuesday, December 04, 2012 11:39 AM
To: Luo, Michelle T
Subject: FW: K123427_ Nirvana D personal lubricant
Attachments: K123427 RTA Traditional Cklist Personal Lubricant .pdf

Importance: High

Hi Michelle,

We received the RTA checklist you submitted to Karen Vescovi and wanted to inform you that I will be serving as the contact person for this 510(k). All of the elements identified as missing or inconsistent in the attached checklist, is reiterated below, each followed by our response to the requested information.

(b)(4) Trade Secret Process -Product Specs

[redacted]

(b)(4) Trade Secret Process -Product Specs

[redacted]

Thank you,
Emily

Emily Perez
Regulatory Affairs

Church & Dwight Co., Inc.
469 North Harrison St.
Princeton, NJ 08543
Tel: (609) 688-5347

From: Vescovi, Karen
Sent: Monday, December 03, 2012 5:24 PM
To: Perez, Emily
Subject: FW: K123427_ Nirvana D personal lubricant
Importance: High

From: Luo, Michelle T [Michelle.Luo@fda.hhs.gov]
Sent: Monday, December 03, 2012 4:57 PM
To: Vescovi, Karen
Subject: K123427_ Nirvana D personal lubricant

Hi Ms. Vescovi,

(b)(4) Trade Secret Process -Product Specs

[redacted]

(b)(4) Trade Secret Process -Product Specs

[redacted]

Sincerely,

Michelle T. Luo, Ph.D
Regulatory Scientist
FDA/CDRH/ODE/DRGUD
10903 New Hampshire Avenue
Silver Spring, MD 20993
Phone: 301-796-5314
Fax: 301-847-8111

Food and Drug Administration
Office of Device Evaluation &
Office of In Vitro Diagnostics

COVER SHEET MEMORANDUM

From: Reviewer Name Michelle

Subject: 510(k) Number K123427

To: The Record

Please list CTS decision code AT

☐ Refused to accept (Note: this is considered the first review cycle, See Screening Checklist http://eroom.fda.gov/eRoomReq/Files/CDRH3/CDRHPremarketNotification510kProgram/0_5631/Screening%20Checklist%207202%2007.doc)

☐ Hold (Additional Information or Telephone Hold).

☐ Final Decision (SE, SE with Limitations, NSE (select code below), Withdrawn, etc.).

Not Substantially Equivalent (NSE) Codes

☐	NO	NSE for lack of predicate
☐	NI	NSE for new intended use
☐	NQ	NSE for new technology that raises new questions of safety and effectiveness
☐	NU	NSE for new intended use AND new technology raising new questions of safety and effectiveness
☐	NP	NSE for lack of performance data
☐	NS	NSE no response
☐	NL	NSE for lack of performance data AND no response
☐	NM	NSE pre-amendment device call for PMAs (515i)
☐	NC	NSE post-amendment device requires PMAs
☐	NH	NSE for new molecular entity requires PMA
☐	TR	NSE for transitional device

Please complete the following for a final clearance decision (i.e., SE, SE with Limitations, etc.):		YES	NO
Indications for Use Page	*Attach IFU*		
510(k) Summary /510(k) Statement	*Attach Summary*		
Truthful and Accurate Statement.	*Must be present for a Final Decision*		
Is the device Class III?			
If yes, does firm include Class III Summary?	*Must be present for a Final Decision*		
Does firm reference standards? (If yes, please attach form from http://www.fda.gov/opacom/morechoices/fdaforms/FDA-3654.pdf)			
Is this a combination product? (Please specify category _____, see http://eroom.fda.gov/eRoomReq/Files/CDRH3/CDRHPremarketNotification510kProgram/0_413b/COMBINATION%20PRODUCT%20ALGORITHM%20(REVISED%203-12-03).DOC			
Is this a reprocessed single use device? (Guidance for Industry and FDA Staff – MDUFMA - Validation Data in 510(k)s for Reprocessed Single-Use Medical Devices, http://www.fda.gov/cdrh/ode/guidance/1216.html)			
Is this device intended for pediatric use only?			
Is this a prescription device? (If both prescription & OTC, check both boxes.)			
Did the application include a completed FORM FDA 3674, Certification with Requirements of ClinicalTrials.gov Data Bank?			
Is clinical data necessary to support the review of this 510(k)?			
For United States-based clinical studies **only**: Did the application include a completed FORM FDA 3674, *Certification with Requirements of ClinicalTrials.gov Data Bank?* (If study was			

conducted in the United States, and FORM FDA 3674 was not included or incomplete, then applicant must be contacted to obtain completed form.)

Does this device include an Animal Tissue Source?

All Pediatric Patients age<=21

Neonate/Newborn (Birth to 28 days)

Infant (29 days -< 2 years old)

Child (2 years -< 12 years old)

Adolescent (12 years -< 18 years old)

Transitional Adolescent A (18 - <21 years old) Special considerations are being given to this group, different from adults age ≥ 21 (different device design or testing, different protocol procedures, etc.)

Transitional Adolescent B (18 -<= 21; No special considerations compared to adults => 21 years old)

Nanotechnology

Is this device subject to the Tracking Regulation? (Medical Device Tracking Guidance, http://www.fda.gov/cdrh/comp/guidance/169.html) *Contact OC.*

Regulation Number **Class*** **Product Code**

(*If unclassified, see 510(k) Staff)

Additional Product Codes:

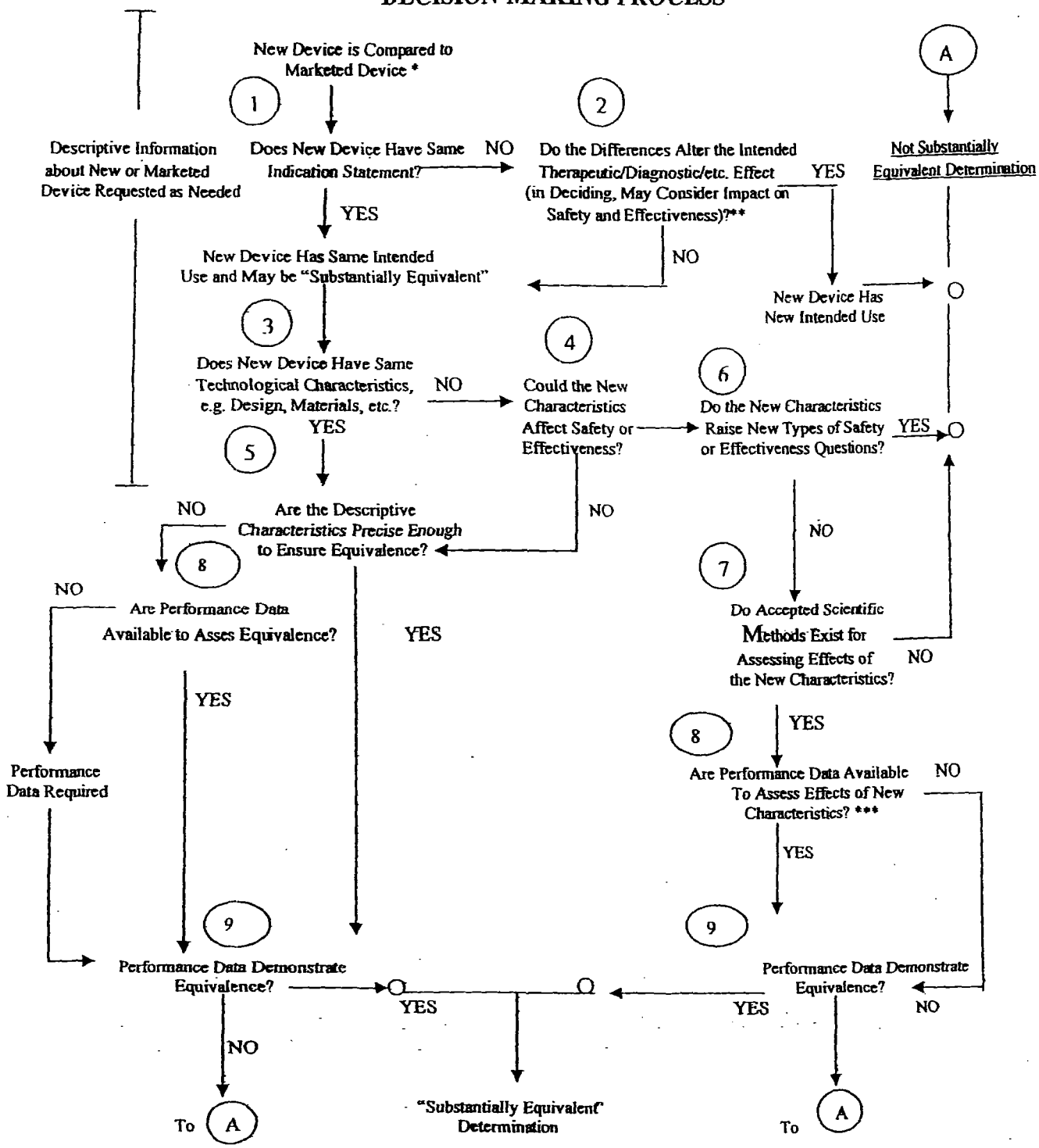
Review:

(Branch Chief) (Branch Code) (Date)

Final Review:

(Division Director) (Date)

510(k) "SUBSTANTIAL EQUIVALENCE" DECISION-MAKING PROCESS



* 510(k) Submissions compare new devices to marketed devices. FDA requests additional information if the relationship between marketed and "predicate" (pre-Amendments or reclassified post-Amendments) devices is unclear.

** This decision is normally based on descriptive information alone, but limited testing information is sometimes required.

*** Data maybe in the 510(k), other 510(k)s, the Center's classification files, or the literature.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

U.S. Food and Drug Administration
Center for Devices and Radiological Health
Document Control Center WO66-G609
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

November 07, 2012

CHURCH & DWIGHT CO., INC.
469 NORTH HARRISON STREET
PRINCETON, NEW JERSEY 08543
ATTN: EMILY PEREZ

510k Number: K123427

Received: 11/7/2012

Product: NIRVANA D PERSONAL LUBRICANT (

The Food and Drug Administration (FDA), Center for Devices and Radiological Health (CDRH), has received the Premarket Notification, (510(k)), you submitted in accordance with Section 510(k) of the Federal Food, Drug, and Cosmetic Act(Act) for the above referenced product and for the above referenced 510(k) submitter. Please note, if the 510(k) submitter is incorrect, please notify the 510(k) Staff immediately. We have assigned your submission a unique 510(k) number that is cited above. Please refer prominently to this 510(k) number in all future correspondence that relates to this submission. We will notify you when the processing of your 510(k) has been completed or if any additional information is required. YOU MAY NOT PLACE THIS DEVICE INTO COMMERCIAL DISTRIBUTION UNTIL YOU RECEIVE A LETTER FROM FDA ALLOWING YOU TO DO SO.

Please remember that all correspondence concerning your submission MUST be sent to the Document Mail Center (DMC) at the above letterhead address. Correspondence sent to any address other than the one above will not be considered as part of your official 510(k) submission.

On September 27, 2007, the President signed an act reauthorizing medical device user fees for fiscal years 2008 - 2012. The legislation - the Medical Device User Fee Amendments of 2007 is part of a larger bill, the Food and Drug Amendments Act of 2007. Please visit our website at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Overview/MedicalDeviceUserFeeandModernizationActMDUFMA/default.htm for more information regarding fees and FDA review goals. In addition, effective January 2, 2008, any firm that chooses to use a standard in the review of ANY new 510(k) needs to fill out the new standards form (Form 3654) and submit it with their 510(k). The form may be found at http://www.fda.gov/AboutFDA/ReportsManualsForms/Forms/default.htm.

We remind you that Title VIII of the Food and Drug Administration Amendments Act of 2007 (FDAAA) amended the PHS Act by adding new section 402(j) (42 U.S.C. § 282(j)), which expanded the current database known as ClinicalTrials.gov to include mandatory registration and reporting of results for applicable clinical trials of human drugs (including biological products) and devices. Section 402(j) requires that a certification form http://www.fda.gov/AboutFDA/ReportsManualsForms/Forms/default.htm accompany 510(k)/HDE/PMA submissions. The agency has issued a draft guidance titled: "Certifications To Accompany Drug, Biological

Product, and Device Applications/Submissions: Compliance with Section 402(j) of The Public Health Service Act, Added By Title VIII of The Food and Drug Administration Amendments Act of 2007" http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/PremarketSubmissions/PremarketNotification510k/ucm134034.htm. According to the draft guidance, 510(k) submissions that do not contain clinical data do not need the certification form.

Please note the following documents as they relate to 510(k) review: 1) Guidance for Industry and FDA Staff entitled, "Interactive Review for Medical Device Submissions: 510(k)s, Original PMAs, PMA Supplements, Original BLAs and BLA Supplements". This guidance can be found at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm089402.htm. Please refer to this guidance for information on a formalized interactive review process. 2) Guidance for Industry and FDA Staff entitled, "Format for Traditional and Abbreviated 510(k)s". This guidance can be found at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm084365.htm. Please refer to this guidance for assistance on how to format an original submission for a Traditional or Abbreviated 510(k).

In all future premarket submissions, we encourage you to provide an electronic copy of your submission. By doing so, you will save FDA resources and may help reviewers navigate through longer documents more easily. Under CDRH's e-Copy Program, you may replace one paper copy of any premarket submission (e.g., 510(k), IDE, PMA, HDE) with an electronic copy. For more information about the program, including the formatting requirements, please visit our web site at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/PremarketSubmissions/ucm134508.html. In addition, the 510(k) Program Video is now available for viewing on line at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/PremarketSubmissions/PremarketNotification510k/ucm070201.htm .

Please ensure that whether you submit a 510(k) Summary as per 21 CFR 807.92, or a 510(k) Statement as per 21 CFR 807.93, it meets the content and format regulatory requirements.

Lastly, you should be familiar with the regulatory requirements for medical devices available at Device Advice http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/default.htm. If you have questions on the status of your submission, please contact DSMICA at (301)796-7100 or the toll-free number (800)638-2041 , or at their internet address http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/default.htm. If you have procedural questions, please contact the 510(k) Staff at (301)796-5640.

Sincerely,

510(k) Staff

Pugh, Dominique *

From: Microsoft Outlook
To: emily.perez@churchdwight.com
Sent: Wednesday, November 07, 2012 12:58 PM
Subject: Relayed: K123427 ACK Letter

Delivery to these recipients or groups is complete, but no delivery notification was sent by the destination server:

emily.perez@churchdwight.com (emily.perez@churchdwight.com)

Subject: K123427 ACK Letter

K-24

K123427

CHURCH & DWIGHT CO., INC.
469 North Harrison Street, Law Department - Building 100, Princeton, NJ 08543

November 6, 2012

Food and Drug Administration
Center for Devices and Radiological Health
Document Mail Center
10903 New Hampshire Ave., Bldg. 66, Rm. G609
Silver Spring, Maryland 20993-0002

RE: 510(k) Premarket Notification (Traditional)
Trade Name: Nirvana D Personal Lubricant (TBD)
Device Common Name: Personal Lubricant
Classification: Condom [21 C.F.R. § 884.5300]
Class: II
Panel: Obstetrics/Gynecology
Product Code: NUC

Dear Sir or Madam:

Church & Dwight Co., Inc. (the "Company") is notifying the United States Food and Drug Administration ("FDA") of its intent to market Nirvana D Personal Lubricant a new medical device, and requests appropriate clearance via the 510(k) process. The Nirvana D Personal Lubricant is a silicone-based, clear, colorless liquid that is intended for use as a personal lubricant compatible with natural rubber latex and polyisoprene condoms. Please note that the name "Nirvana D" is a place holder and will not be the brand name under which the product is actually marketed.

Nirvana D Personal Lubricant is substantially equivalent to the legally marketed predicate device, K-Y Brand Intrigue™ Intense Warming Sensation. The Company submits the attached documentation to demonstrate substantial equivalence to the predicate device and to demonstrate that the device is as safe and effective as the predicate device. Note that no special controls exist for this device. However, an ASTM standard (D7661-10, "Standard Test Method for Determining Compatibility of Personal Lubricants with Natural Rubber Latex Condoms") does apply for determining compatibility of personal lubricants with natural rubber latex condoms. Testing has been completed using a modification of the ASTM standard. Biocompatibility testing was also completed in accordance with ISO 10993.

The principal factors concerning the design and use of Nirvana D Personal Lubricant are as follows:

Question	YES	NO
Is the device intended for prescription use (21 CFR 801 Subpart D)?		X
Is the device intended for over-the-counter use (21 CFR 807 Subpart C)?	X	
Does the device contain components derived from a tissue or other biologic source?		X
Is the device provided sterile?		X
Is the device intended for single use?		X
Is the device a reprocessed single use device?		X
If yes, does this device type require reprocessed validation data?		X
Does the device contain a drug?		X
Does the device contain a biologic?		X
Does the device use software?		X
Does the submission include clinical information?		X
Is the device implanted?		X

This 510(k) submission may contain trade secret or confidential commercial information that is exempt from disclosure pursuant to 21 C.F.R. § 20.61, 21 U.S.C. § 331(j), and the Freedom of Information Act, 5 U.S.C. § 552(b)(4). We ask that you consult with Church & Dwight as provided in 21 C.F.R. § 20.47 before making any part of this submission publicly available.

If you have any questions or require additional information, please feel free to contact Ms. Emily Perez by phone at (609) 688-5347, by facsimile at (609) 497-7179, or by e-mail at emily.perez@churchdwight.com.

We look forward to the earliest possible review of this premarket notification.

Respectfully submitted,

Jeffrey Shaul
Director, Regulatory Affairs
Church & Dwight Co., Inc

MEDICAL DEVICE USER FEE

DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION
MEDICAL DEVICE USER FEE COVER SHEET

PAYMENT IDENTIFICATION NUMBER: (b)(4) Trade Secret
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/coversheet.html

1. COMPANY NAME AND ADDRESS (include name, street address, city state, country, and post office code)

CHURCH AND DWIGHT CO INC
469 NORTH HARRISON STREET
PRINCETON NJ 08543
US

1.1 EMPLOYER IDENTIFICATION NUMBER (EIN)
(b)(4)

2 CONTACT NAME
Karen Vescovi - Karen Vescovi

2.1 E-MAIL ADDRESS
karen vescovi@churchdwight.com

2.2 TELEPHONE NUMBER (include Area code)
609-279-7715

2.3 FACSIMILE (FAX) NUMBER (Include Area code)
609-497-7179

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/oc/mdufma

Select an application type:
[X] Premarket notification(510(k)); except for third party
[ ] 513(g) Request for Information
[ ] Biologics License Application (BLA)
[ ] Premarket Approval Application (PMA)
[ ] Modular PMA
[ ] Product Development Protocol (PDP)
[ ] Premarket Report (PMR)
[ ] Annual Fee for Periodic Reporting (APR)
[ ] 30-Day Notice

3.1 Select a center
[X] CDRH
[ ] CBER

3.2 Select one of the types below
[X] Original Application

Supplement Types:
[ ] Efficacy (BLA)
[ ] Panel Track (PMA, PMR, PDP)
[ ] Real-Time (PMA, PMR, PDP)
[ ] 180-day (PMA, PMR, PDP)

4. ARE YOU A SMALL BUSINESS? (See the instructions for more information on determining this status)
[ ] YES, I meet the small business criteria and have submitted the required qualifying documents to FDA
[X] NO, I am not a small business
4.1 If Yes, please enter your Small Business Decision Number:

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?
[ ] YES (All of our establishments have registered and paid the fee, or this is our first device, and we will register and pay the fee within 30 days of FDA's approval/clearance of this device)
[ ] NO (If "NO," FDA will not accept your submission until you have paid all fees due to FDA. This submission will not be processed; see http://www.fda.gov/cdrh/mdufma for additional information)

6. IS THIS PREMARKET APPLICATION COVERED BY ANY OF THE FOLLOWING USER FEE EXCEPTIONS? IF SO, CHECK THE APPLICABLE EXCEPTION
[ ] This application is the first PMA submitted by a qualified small business, including any affiliates
[ ] This biologics application is submitted under section 351 of the Public Health Service Act for a product licensed for further manufacturing use only
[ ] The sole purpose of the application is to support conditions of use for a pediatric population
[ ] 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 [X] 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, 1350 Piccard Drive, 4th Floor Rockville, MD 20850
[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)
24-Sep-2012

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Medical Device User Fee

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I. Indications For Use

510(k) Number (if known): N/A

Device Name: Nirvana D Personal Lubricant (TBD)

INDICATIONS FOR USE:

Nirvana D is a personal lubricant for penile and/or vaginal application, intended to lubricate and moisturize, 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. Not compatible with polyurethane or other condoms.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ____	OR	Over-The-Counter Use __X__
(Part 21 C.F.R. 801 Subpart D)		(21 C.F.R. 801 Subpart C)

II. 510(k) Summary

Submitter Name:	Church & Dwight Co., Inc.
Submitter Address:	469 North Harrison Street Princeton, NJ 08543
Contact Person:	Emily Perez Senior Regulatory Affairs Specialist Church & Dwight Co., Inc. 469 North Harrison Street Princeton, NJ 08543 Tel: (609) 688-5347 Fax: (609) 497-7179
Date Prepared:	November 6, 2012
Device Trade Name:	Nirvana D Personal Lubricant (TBD)
Device Common Name:	Personal Lubricant
Product Code:	NUC – Condom (21 C.F.R. § 884.5300)
Classification:	Class II
Predicate Device:	K-Y® Brand Intrigue™ Intense Warming Sensation (K072360)
Intended Use:	Nirvana D is a personal lubricant for penile and/or vaginal application, intended to lubricate and moisturize, 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. Not compatible with polyurethane or other condoms.
Device Description:	The Nirvana D Personal Lubricant is an anhydrous, non-sterile, clear silicone-based personal lubricant composed of dimethicone, dimethiconol, vanillyl butyl ether ("VBE") and hexyl nicotinate. Nirvana D Personal Lubricant is compatible with natural rubber latex and polyisoprene condoms. This product is not a spermicide or a contraceptive. The product is packaged in a polyethylene terephthalate (PET) bottle with a screw-on, flip top polypropylene (PP) closure constituting the device's primary packaging. One bottle is packaged into a cardboard carton, which constitutes the device outer packaging.

Technological Characteristics:

There is no difference in the fundamental technological characteristic of the Nirvana D Personal Lubricant and the predicate K-Y® Brand Intrigue™ Intense Warming Sensation Personal Lubricant. Nirvana D Personal Lubricant is composed of dimethicone, dimethiconol, vanilly butyl ether, and hexyl nicotinate. The proposed device is substantially equivalent to the predicate K-Y® Brand Intrigue™ Intense Warming Sensation Personal Lubricant cleared under 510(k) # K072360. Three of the four ingredients, dimethicone, dimethiconol, and vanillyl butyl ether, in Nirvana D Personal Lubricant are identical to those in the predicate device. The additional ingredient, hexyl nicotinate, does not raise new questions of safety or effectiveness.

Biocompatibility:

Biocompatibility testing was performed in accordance with ISO 10993, Biological Evaluation of Medical Devices, 2009.

Testing Performed:

Testing Performed	Results
Cytotoxicity	Non-cytotoxic
Rabbit Vaginal Irritation	Non-irritating
Rabbit Penile Irritation	Non-irritating
Acute Systemic Toxicity	Non-systemically toxic
Guinea Pig Maximization	Non-sensitizing
Primary Rabbit Skin Irritation	Non-irritating

Condom Compatibility:

Condom Compatibility Testing was performed with Nirvana D Personal Lubricant and ASTM D7761-10 "Standard Testing Method for Determining Compatibility of Personal Lubricants with Natural Rubber Latex Condoms" which was modified to include pre-lubricated and un-lubricated dry condoms. Three marketed brands of pre-lubricated and un-lubricated dry natural rubber latex condoms and one brand of polyisoprene condoms were tested.

Condom compatibility testing results demonstrate that Nirvana D Personal Lubricant is compatible with commercially available natural rubber latex condoms and polyisoprene condoms.

Shelf-life:

Nirvana D Personal Lubricant has a two-year shelf-life based on the results of an accelerated aging study.

A Real-Time aging study is being performed in order to verify results of the accelerated aging study.

Substantially Equivalence:

Based on non-clinical performance data, biocompatibility review and testing and safety data, the proposed device is substantially equivalent to K-Y® Brand Intrigue™ Intense Warming Sensation in technology, intended use, safety and effectiveness.

Conclusion:

The results from laboratory testing and non-clinical evaluation of human use testing show that the proposed device performs equivalently to the predicate device and is safe for use as a personal lubricant.

III. Truthful and Accurate Statement

I certify that, in my capacity as Director of Research & Development, Global Sexual and Reproductive Health of Church & Dwight Co., Inc., I believe to the best of my knowledge, that all data and information submitted in the premarket notification is truthful and accurate and that no material fact has been omitted.

Alfred J. Smetana

Alfred J. Smetana, Ph.D
Director
Research & Development
Global Sexual and Reproductive Health
Church & Dwight Co., Inc

06 NOV '12

Date

IV. Class III Summary and Certification

Not applicable.

V. Financial Certification/Disclosure

Not applicable.

VI. Declarations of Conformity and Summary Reports

Not applicable.

VII. Device Description

1. General Information Required by 21 C.F.R. § 807.87

The following information is provided as required by 21 C.F.R. § 807.87 for the Nirvana D Personal Lubricant 510(k) premarket notification:

A. Name of Device

Trade Name:	Nirvana D Personal Lubricant
Common Names:	Personal Lubricant
Classification Name:	Condom (21 C.F.R. § 884.5300)
Product Code:	NUC

B. Establishment Registration Information

Manufacturer:	(b)(4) Trade Secret Process [redacted]
Manufacturer Registration Number:	
Distributor:	Church & Dwight Co., Inc.

C. Device Classification

The Nirvana D Personal Lubricant is classified as "Condom" as a Class II device pursuant to 21 C.F.R. § 884.5300.

2. Device Description

The Nirvana D Personal Lubricant is an anhydrous, non-sterile, clear silicone-based personal lubricant compatible with natural rubber latex and polyisoprene condoms. The silicone base is a blend of dimethylpolysiloxane (also called "dimethicone") and dimethylpolysiloxane, hydroxyl-terminated (also called "dimethiconol"). Vanillyl butyl ether ("VBE") and hexyl nicotinate are blended into the silicone base. The lubricant is packaged in a polyethylene terephthalate (PET) bottle.

Intended Use of the Device

The intended use of this device is as a personal lubricant for penile and/or vaginal application, intended to lubricate and moisturize, 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. Not compatible with polyurethane or other condoms.

Technological Characteristics

The Nirvana D Personal Lubricant is an anhydrous, non-sterile, clear silicone-based personal lubricant compatible with natural rubber latex and polyisoprene condoms. The silicone base is a blend of dimethicone and dimethiconol. Vanillyl butyl ether ("VBE") and hexyl nicotinate are blended into the silicone base. The silicone-based lubricant formula is similar to those typically found in other personal lubricants, cosmetic products, and over-the-counter dermatological products.

Three of the four ingredients, dimethicone, dimethiconol and vanillyl butyl ether ("VBE"), in Nirvana D Personal Lubricant are identical to those in the predicate device. The Nirvana D Personal Lubricant also contains hexyl nicotinate. Hexyl nicotinate and its major metabolite, nicotinic acid, have been reported to be used in a variety of personal care preparations (See Exhibit A – Safety Assessment, Exhibit 2, pp 6-7). Its inclusion does not raise new questions of safety or effectiveness.

The Nirvana D Personal Lubricant is packaged in a polyethylene terephthalate (PET) bottle with a screw-on, flip top polypropylene (PP) closure. An induction seal will be placed over the bottle for tamper resistance and preservation. One bottle is then packaged into a cardboard carton, which constitutes the device outer package.

Lubricant Formulation – **CONFIDENTIAL**

Item	Ingredient	CAS No.	(% w/w) Formula D	Supplier Name
1	Dimethylpolysiloxane (and) Dimethylpolysiloxane, Hydroxyl terminated	63148-62-9 70131-67-8	(b)(4) Trade Secret Process [redacted]	
2	Vanillyl Butyl Ether	82654-98-6		
3	Hexyl Nicotinate	23597-82-2		
	Total			

Safety

The Nirvana D Personal Lubricant is substantially equivalent to K-Y® Brand Intrigue™ Intense Warming Sensation and does not raise different questions of safety. Each of the ingredients alone is safe at the levels present.
Three of the four ingredients in Nirvana D Personal Lubricant are present in the predicate device. These three ingredients include dimethicone, dimethiconol, and vanillyl butyl ether ("VBE").

The additional ingredient, hexyl nicotinate and its major metabolite, nicotinic acid, have been reported to be used in a variety of personal care preparations (See Exhibit A – Safety Assessment, Attachment 2, pp 6-7). Final product testing via ISO 10993 and consumer use testing further support the safety of Nirvana D Personal Lubricant. *See* Exhibit A – Safety Assessment.

The safety of each ingredient is presented in Exhibit A and summarized below:

- ***Dimethicone*** is used in the K-Y® Brand Intrigue™ Intense Warming Sensation predicate and its associated compounds are extensively used in cosmetics, household products, and personal lubricants. Dimethicone is approved as a food additive in the United States and Europe. *See e.g.* 21 C.F.R. §§ 145.180, 146.185, 173.340. The attached Safety Assessment, Exhibit A, which included a literature search, and the fact that dimethylpolysiloxane is present in the predicate device, supports the safe use of the material in a personal lubricant product.

- ***Dimethiconol*** is also used in the K-Y® Brand Intrigue™ Intense Warming Sensation predicate. It has the same structure as dimethicone, but with hydroxyl (R-OH) groups on its ends rather than methyl (R-CH_3) groups. Most of the data generated on this group of compounds has been generated on dimethicone, and applied to the entire group of compounds due to structural similarity. (*See* Exhibit A, Reference 4). Therefore, minor modifications are not expected to impact the overall safety. Accordingly, dimethiconol is safe for use in a personal lubricant product.

- ***Vanillyl butyl ether*** ("VBE") serves as a warming agent and is used in the K-Y® Brand Intrigue™ Intense Warming Sensation predicate. It is also used in foods, a variety of beverages, and candy. *See* Exhibit A, Reference 6 and 7

- ***Hexyl nicotinate*** serves as a warming and tingling agent and has been reported to be used in body and hand (personal care) products (Exhibit A, Attachment 2, Section 3, p. 6). Attachment 2 of Exhibit A provides a safety assessment for (b)(4) hexyl nicotinate in the context of Nirvana D Personal Lubricant. It includes chemistry, metabolism, uses, biological effects, conservative human exposure assessment, and safety factor calculations which supports the safe use of hexyl nicotinate in the proposed device.

  The major metabolite of hexyl nicotinate, nicotinic acid, is used in topical cosmetics and a marketed clitoral arousal gel (KY Brand Intense) and is classified as GRAS 21 C.F.R § 184.1530. The levels of nicotinic acid from (b)(4) hexyl nicotinate falls within the rages of nicotinic acid levels found in personal care products (See Exhibit A, Attachment 2, pp. 7). Nicotinic acid is used in food as a nutrient supplement as defined in 21 C.F. R

170.3(o)(20) and in infant formula in accordance with section 412(g) of the Federal Food, Drug, and Cosmetic Act (the Act.).

The final formulation has been tested and was determined to be safe. Biocompatibility tests according to ISO 10993, Biological evaluation of medical devices, were completed and passed. *See* Exhibit A – Safety Assessment. Additionally, a consumer preference test compared the proposed device to currently marketed benchmarks (KY Yours and Mine and KY Intense) and no serious adverse events or adverse events related to the proposed device or any of the benchmark lubricants were reported. *See* Exhibit A – Safety Assessment, Attachment 9.

Condom Compatibility

Latex condoms were evaluated using Nirvana D Personal Lubricant and a modified ASTM D7661-10 test method. In the U.S. market, the three main brands are Trojan™, Lifestyles, and Durex. Since most condoms are sold pre-lubricated, it was decided to evaluate pre-lubricated condoms in addition to dry, un-lubricated condoms. This is also in accordance with FDA's note on the Recognized Consensus Standards results for the ASTM D7661-10 standard.

Condoms selected from the Trojan™ brand were Trojan™ ENZ (dry and lubricated), manufactured by Church & Dwight Co., Inc. Brand also sells latex condoms under the Trojan™ name which are manufactured by Okamoto; therefore, Trojan™ Ultra Thin, Lubricated made by Okamoto was included. For the other two brands, it was decided to select top selling Lifestyles (dry and lubricated) and Durex (dry and lubricated) condoms in the United States. Based on marketing data, Lifestyles Ultra Sensitive, Lubricated, Lifestyles Ultra Sensitive Non-Lubricated, Durex Extra Sensitive, Lubricated, and Durex Natural Feeling Non-Lubricated were selected. It was also decided to include the top selling synthetic latex (polyisoprene) U.S. condom because the general public may mistake this condom as being natural latex. Using marketing data, Durex Avanti Bare, Lubricated was selected for the synthetic latex product.

During a Special Meeting on March 10, 2010, ASTM International, Task Group D11.40.01 on Condoms convened with FDA at BWI to discuss the D7661-10 Standard. The discussion noted that "historically FDA has variably accepted whatever the sponsor submitted as

evidence of compatibility, typically accepting a <10% difference between treated and untreated (Control or Baseline) as noise, 10% to 20% or 25% as maybe a mild effect and generally acceptable if only occurring with one of several metrics, but >25% difference or more than one metric was a cause for concern – although, it was unknown what >25% difference meant clinically." Summary of statement by Mr. Pollard, former Branch Chief, ODE, ObGyn Devices (March 11, 2010). Additionally, "Dr. Harrison said his experience in research and development was similar with about a 25% difference considered significant." Summary of statement by Dr. Harrison, Senior Principal Scientist New Technology, Church & Dwight Co., Inc. (March 11, 2010).

Over 80% of the samples examined with Formula D (Nirvana D) using ASTM D7661-10 showed a change of less than 10% from Control. Out of 32 tests, 5 showed a drop in physical characteristics between 10% and 22%. Only 1 sample showed a drop greater than 25%. These 6 tests were varied among the Break Force, Burst Pressure and Burst Volume measurements. As discussed in the report, (Exhibit B) noise is a significant factor when analyzing these reductions in values. Comparing the data from ASTM D7661-10's interlaboratory tests in 2009, Nirvana D Personal Lubricant is much more like the Water-Based & Silicone Lubricant standards than the negative control, Mineral Oil. Thus, the body of the data demonstrates overall acceptability for purposes of clearance of the Nirvana D Personal Lubricant for use with natural rubber latex and polyisoprene condoms. *See* Exhibit B – Latex Condom Compatibility Testing Results.

VIII. Substantial Equivalence

Nirvana D Personal Lubricant has the same intended use as the previously cleared K-Y® Brand Intrigue™ Intense Warming Sensation (K072360). In addition, the Nirvana D Personal Lubricant shares three of its four ingredients with the predicate device and has similar technological characteristics. The presence of hexyl nicotinate in Nirvana D Personal Lubricant does not raise different questions of safety or effectiveness. Table 1, below, provides a comparison of the ***characteristics*** of the new device and the legally marketed predicate device. Table 2, below, provides a comparison of the ***ingredients*** of the new device and the legally marketed predicate device. Thus, the Nirvana D Personal Lubricant is substantially equivalent to legally marketed devices. This claim is further substantiated by comparison of the Nirvana D Personal Lubricant labeling (*see* XII. Draft Labeling), to K-Y® Brand Intrigue™ Intense Warming Sensation (*see* Exhibit C – Predicate Device Labeling). **CONFIDENTIAL:**

Table 1. Substantial Equivalence Comparison Matrix

Feature Being Compared	NEW DEVICE TROJAN™ LUBRICANTS Nirvana D Personal Lubricant	PREDICATE DEVICE K-Y® Brand Intrigue™ Intense Warming Sensation
Intended Use	The intended use of this device is as a personal lubricant compatible with natural rubber latex and polyisoprene condoms.	The intended use of this device is as a personal lubricant compatible with latex condom.
Indications for Use	Nirvana D is as personal lubricant for penile and/or vaginal application, intended to lubricate and moisturize, 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. Not compatible with polyurethane or other condoms.	This device is intended as a personal lubricant for penile and vaginal application compatible with latex condom.
Device Composition	(See Table 2)	(See Table 2)
Performance Data	Compatible with natural rubber latex and polyisoprene condoms.	Compatible with latex condoms.
Biocompatibility	The pre-clinical evaluation and testing, and human use data show that the proposed device is safe for use as a personal lubricant.	The pre-clinical evaluations and testing, and human use data show that the proposed device is safe for use as a personal lubricant.
Sterility	N/A (non-sterile)	N/A (non-sterile)

Table 2. Comparison of Ingredients

Ingredient Function	NEW DEVICE Nirvana D Personal Lubricant	PREDICATE DEVICE K-Y® Brand Intrigue™ Intense Warming Sensation
Lubricant, skin-conditioning agent	Dimethicone	Dimethicone
	Dimethiconol	Dimethiconol
Warming agent	Vanillyl butyl ether	Vanillyl butyl ether
Warming/ Tingling agent	Hexyl Nicotinate	--

IX. Draft Labeling

1. Directions for Use

The Directions for Use (DFU) are printed on the outer carton and bottle in accordance with the applicable requirements of 21 C.F.R. parts 801 and 820. The draft DFU for the Nirvana D Personal Lubricant are provided below as part of Package Labeling. The DFUs for the predicate device and the K-Y® Brand Intrigue™ Intense Warming Sensation labeling is presented in Exhibit C.

2. Package Labeling

The package labeling for Nirvana D Personal Lubricant was designed in accordance with the applicable requirements of 21 C.F.R. parts 801 and 820. Draft labeling for both the Nirvana D Personal Lubricant bottle label and the carton label are provided below.

a) Primary Packaging — BOTTLE

Bottle Front Face Panel:

TROJAN™

LUBRICANTS

Nirvana D

Personal Lubricant

3.0 FL OZ

Bottle Back Panel:

DIRECTIONS: Apply to intimate areas. Compatible with natural rubber latex and polyisoprene condoms. Not compatible with polyurethane or other condoms.

WARNINGS: If irritation occurs, immediately rinse with water and discontinue use. If irritation persists, consult a physician. In case of eye contact, flush with water. This product is not a spermicide or a contraceptive. Keep out of reach of children.

CAUTION: Extremely slippery – clean spill immediately.

INGREDIENTS: Dimethicone, Dimethiconol, Hexyl Nicotinate, Vanillyl Butyl Ether.

Manufactured For: Church & Dwight Co., Inc. Princeton, NJ 08543

Bottle Bottom Panel:

Date/Lot code information is applied during manufacturing.

b) Outer Packaging — CARTON

Carton Front Face Panel – Principal Display Panel:

TROJAN™

LUBRICANTS

Nirvana D

3.0 FL OZ

Carton Back Panel:

TROJAN™

LUBRICANTS

Nirvana D

INDICATION FOR USE: Nirvana D is a personal lubricant for penile and/or vaginal application, intended to lubricate and moisturize, 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. Not compatible with polyurethane or other condoms.

DIRECTIONS: Apply to intimate areas and reapply as desired. When ready for intercourse, reapply as desired. You may experience sensations such as warming, heat, cooling and/or tingling. Close cap lid immediately after use. Do not use if quality seal under cap is broken or missing. To avoid leaks, tightly twist cap onto bottle once quality seal is removed.

WARNINGS: If irritation occurs, immediately rinse with water and discontinue use. If irritation persists, consult a physician. In case of eye contact, flush with water. This product is not a spermicide or a contraceptive. Keep out of reach of children.

CAUTION: Extremely slippery – clean spill immediately.

Avoid exposure to direct sunlight or storage for prolonged periods at temperatures above 100°F.

INGREDIENTS: Dimethicone, Dimethiconol, Hexyl Nicotinate, Vanillyl Butyl Ether

Carton Bottom Panel:

Manufactured for: Church & Dwight Co., Inc.,
Princeton, NJ 08543
Exp. Date & Lot Code

X. Sterilization and Shelf Life

STERILIZATION

(b)(4) Trade Secret Process [redacted]

SHELF LIFE

The Nirvana D Personal Lubricant will have a 2-year shelf life.

a) Purpose

(b)(4) Trade Secret Process [redacted]

b) Method

(b)(4) Trade Secret Process [redacted]

c) Results

(b)(4) Trade Secret Process

[redacted]

d) Discussion

(b)(4) Trade Secret Process

[redacted]

XI. Non-Clinical Performance

Nirvana D Personal Lubricant was tested for compatibility with latex condoms using a modification of ASTM D7661-10. See VII. Device Description (above) and Exhibit B – Latex Condom Compatibility Testing Results.

XII. Biocompatibility Studies

(b)(4) Trade Secret Process - Testing

[redacted]

(b)(4) Trade Secret Process - Testing

[redacted]

Additional information

Additional information is attached, as Exhibit A – Safety Assessment.

XIII. Software Information

Not applicable.

XIV. Electromagnetic Compatibility and Electrical Safety

Not applicable.

Exhibit A

CONFIDENTIAL
Tracking No. 2012-028-MI
Issue Date: 07/20/2012

CHURCH & DWIGHT CO., INC.

Safety Assessment for Nirvana-D (Arouses and Intensifies) Personal Lubricant

CONCLUSION

Based upon an assessment of the ingredients, and the finished product safety testing presented below, the Nirvana-D Personal Lubricant (Arouses and Intensifies) is considered safe for consumers under normal use and reasonably foreseeable misuse conditions.

BACKGROUND

The Nirvana-D Personal Lubricant, (Attachment 1) contains (b)(4) Trade Secret Process [redacted] (Dimethylpolysiloxane), (b)(4) [redacted] Hexyl Nicotinate and (b)(4) [redacted] Vanillyl Butyl Ether (VBE).

INGREDIENT SAFETY ASSESSMENT

(b)(4) Trade Secret Process - Testing

[redacted]

CONFIDENTIAL
Tracking No. 2012-028-MI
Issue Date: 07/20/2012

(b)(4) Trade Secret Process - Testing

[redacted]

CONFIDENTIAL
Tracking No. 2012-028-MI
Issue Date: 07/20/2012

(b)(4) Trade Secret Process - Testing

[redacted]

CONFIDENTIAL
Tracking No. 2012-028-MI
Issue Date: 07/20/2012

(b)(4) Trade Secret Process - Testing

[redacted]

CONFIDENTIAL
Tracking No. 2012-028-MI
Issue Date: 07/20/2012

(b)(4) Trade Secret Process - Testing

[redacted]

CONFIDENTIAL
Tracking No. 2012-028-MI
Issue Date: 07/20/2012

(b)(4) Trade Secret Process - Testing

[redacted]

CONFIDENTIAL
Tracking No. 2012-028-MI
Issue Date: 07/20/2012

(b)(4) Trade Secret Process - Testing

[redacted]

CONFIDENTIAL
Tracking No. 2012-028-MI
Issue Date: 07/20/2012

(b)(4) Trade Secret Process - Testing

[redacted]

CONFIDENTIAL
Tracking No. 2012-028-MI
Issue Date: 07/20/2012

PACKAGE SAFETY LABELING

Nirvana-D contains sensory ingredients, hexyl nicotinate and VBE. In addition to safety related statements as mandated by the FDA, it is recommended that the product package for Nirvana-D carry cautionary statement to advise consumers to: (1) Discontinue product use immediately if they experience any irritation or intense sensory effects; (2) Flush eyes with water in case of accidental eye contact; and (3) See a physician if the effect persists.

Prepared By: 7/20/2012
Wafaa Ayad, PhD Date
Senior Toxicologist
R&D – Toxicology & Clinical Research
Church & Dwight Co., Inc

Concurred By: 7/20/12
Annahita Ghassemi, PhD, DABT Date
Senior Toxicology and Clinical Manager
R&D – Toxicology & Clinical Research
Church & Dwight Co., Inc

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2. US FDA Food additive database. EAFUS: A Food Additive Database, under CAS number 9016-00-6 (Accessed 8 December 2011) http://vm.cfsan.fda.gov/~dms/eafus.html
3. E Number Index http://www.ukfoodguide.net/enumeric.htm (Accessed 8 December 2011).
4. Nair, B; Cosmetic Ingredients Review Expert Panel (2003). "Final Report on the Safety Assessment of Stearoxy Dimethicone, Dimethicone, Methicone, Amino Bispropyl Dimethicone, Aminopropyl Dimethicone, Amodimethicone, Amodimethicone Hydroxystearate, Behenoxy Dimethicone, C24-28 Alkyl Methicone, C30-45 Alkyl Methicone, C30-45 Alkyl Dimethicone, Cetearyl Methicone, Cetyl Dimethicone, Dimethoxysilyl Ethylenediaminopropyl Dimethicone, Hexyl Methicone, Hydroxypropyldimethicone, Stearamidopropyl Dimethicone, Stearyl Dimethicone, Stearyl Methicone, and Vinyldimethicone". *International Journal of Toxicology* **22** (2 Suppl): 11–35.
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ATTACHMENT 1

Nirvana-D Lubricant Formulation

Attachment 1. Nirvana-D Lubricant Formulation

Ingredient	CAS No.	% Level
(b)(4) Trade Secret		(b)
(b)(4) Dimethylpolysiloxane	63148-62-9	
(b)(4) Dimethylpolysiloxane, Hydroxyl-terminated	70131-67-8	
Hexyl Nicotinate	23597-82-2	(b)
Vanillyl butyl ether (VBE)	82654-98-6	(b)
Total		**100.00**

ATTACHMENT 2

Safety Assessment of Hexyl Nicotinate in a Personal Lubricant

Attachment 2. Safety Assessment of Hexyl Nicotinate in a Personal Lubricant

SAFETY ASSESSMENT OF HEXYL NICOTINATE IN A PERSONAL LUBRICANT

Attachment 2. Safety Assessment of Hexyl Nicotinate in a Personal Lubricant

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Attachment 2. Safety Assessment of Hexyl Nicotinate in a Personal Lubricant

SAFETY ASSESSMENT OF HEXYL NICOTINATE IN A PERSONAL LUBRICANT

1. INTRODUCTION

The objective of this document is to provide safety assessment of hexyl nicotinate (CAS No. 23597-82-2) in a personal/condom lubricant with emphasis on its potential cardiovascular risk, particularly in individuals with cardiovascular disease. The data presented in this assessment were based search of the scientific literature. Assumptions used in this review are that consumers will use 5 g/day of a product containing hexyl nicotinate (b)(4) and that 100% of the applied hexyl nicotinate will be absorbed. Such use and absorption will result in daily absorption of 2.5 mg hexyl nicotinate.

The specified use of the product indicates the major routes of exposure to hexyl nicotinate will be *via* genital mucosal membranes (i.e., vaginal mucosa), penile skin, oral ingestion, and buccal absorption. Hexyl nicotinate is used in a number of cosmetics, but no information could be located concerning potential adverse effects when applied to mucosal tissues or genital areas.

Although very limited toxicity data exist for hexyl nicotinate, a relatively large number of studies have been conducted on absorption kinetics, and topical application of hexyl nicotinate resulting in a well-defined and measurable response. Extensive studies have been conducted on nicotinic acid (niacin), major metabolite of hexyl nicotinate. Therefore, this safety assessment provides data summary on hexyl nicotinate and nicotinic acid

Attachment 2. Safety Assessment of Hexyl Nicotinate in a Personal Lubricant

2. GENERAL DESCRIPTION

Hexyl nicotinate is the ester of hexyl alcohol and nicotinic acid. Hexyl nicotinate is colorless or straw yellow transparent liquid oil. The molecular weight of hexyl nicotinate is 207.3 (ChemIDplus Advance, 2008). Synonyms for hexyl nicotinate are listed in Table 1. Hexyl nicotinate is the most lipophilic of the nicotinic esters (Pyka and Klimczok, 2005).[1] The chemical structure is indicated in Figure 1. The European inventory of existing commercial chemical substances (EINECS) gives the EC# as 245-767-4 (ECB, 2006).

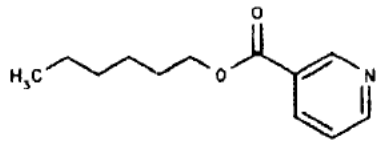

Figure 1. Hexyl nicotinate chemical structure

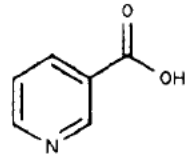

Figure 2. Nicotinic Acid

Because hexyl nicotinate is metabolized (de-esterified) to nicotinic acid (CAS No. 59-67-6), this safety review will include nicotinic acid. Nicotinic acid is incorporated into nicotinate ribonucleotide and amidated to form nicotinamide-adenine dinucleotide (NAD), which can be phosphorylated to nicotinamide-adenine dinucleotide phosphate (NADP) (Combs, 1998). Nicotinamide is not a direct metabolite of hexyl nicotinate or nicotinic acid; in fact nicotinamide is converted to nicotinic acid first before incorporation into NAD. Therefore, nicotinamide has been excluded from this safety review.

Esters of nicotinic acid have long been recognized for their ability to induce vasodilation when applied dermally (Huber, 1947). This document describes hexyl nicotinate and nicotinic acid in terms of their physical properties, uses, biological and pharmacological properties, and known health effects to support decision-making regarding the cardiovascular safety and labeling of formulations of a personal lubricant that contains hexyl nicotinate at a concentration of [redacted]

[1] The nicotinic acid esters evaluated are methyl nicotinate, ethyl nicotinate, isopropyl nicotinate, butyl nicotinate, hexyl nicotinate, benzyl nicotinate, nicotinamide, *N*-methylnicotinamide, and nicotinic acid.

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Table 1. Synonyms of Nicotinates

Hexyl Nicotinate (23597-82-2)	Nicotinic acid hexyl ester	AI3-15769
	Hexyl niconinoate	EINECS 245-767-4
	Nicotherm	NSC 72758
	3-pyridinecarboxylic acid, hexyl ester	Nicotinsaeure-n-hexylester
	Hexyl 3-pyridinecarboxylate	UNII-BN07PB44IV
Nicotinic Acid (59-67-6)	Niacin	Nicocidin
	3-Pyridinecarboxylic acid	Nicocrisina
	3-Carboxylpyridine	Nicodan
	AI3-18994	Nicodelmine
	Acide nicotinique [INN-French]	Nicodon
	Acido nicotinico [INN-Spanish]	Nicolar
	Acidum nicotinicum [INN-Latin]	Niconacid
	Akotin	Niconat
	Apelagrin	Niconazid
	BRN 0109591	Nicorol
	Bionic	Nicosan 3
	CCRIS 1902	Nicoside
	Caswell No. 598	Nicosyl
	Daskil	Nicotamin
	Davitamon PP	Nicotene
	Diacin	Nicotil
	Direktan	Nicotine acid
	EINECS 200-441-0	Nicotinic acid
	EPA Pesticide Chemical Code	Nicotinipca
	056701	Nicotinsaure [German]
	Efacin	Nicovasan
	Enduracin	Nicovasen
	HSDB 3134	Nicyl
	Kyselina nikotinova [Czech]	Nipellen
	Linic nicotinic acidH	Nyclin
	NICO	Pellagramin
	NSC 169454	Pellagrin
	Naotin	Pelonin Peviton
	Niac	Pyridine-3-carboxylic acid
	Niacor	Pyridine-beta-carboxylic acid
	Niaspan	Pyridine-carboxylique-3 [French]
	Niaspan Titration Starter Pack	S115 SK-Niacin
	Nicacid	SR 4390
	Nicagin	Slo-niacin
	Nicamin	Tega-Span
	Nicangin	Tinic
	Nico-400	UNII-2679MF687A
	Nico-span	Vitaplex N
	Nicobid	Wampocap
	Nicocap	3-Pyridinecarboxylic acid

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Table 2. Physical Properties of Nicotinates[a]

Property	Hexyl Nicotinate (2216-51-5)	Nicotinic Acid (89-78-1)
Molecular Weight	207.3	123.11
Density g/cm^3 at 25° C	1.02[b]	1.473
Boiling Point °C	140[b]	Sublimes
Melting Point °C	na[c]	236.6
Log P (octanol/water)	3.51	0.36
Henry's Law Constant[2] atm-m^3/mole	1.87×10^{-07}	5.11×10^{-11}
Vapor Pressure mm Hg	9.95×10^{-04}	5.70×10^{-06}
Water Solubility mg/L	460	$1.80 \times 10^{+04}$

[a] Source: ChemIDplus (http://toxnet.nlm.nih.gov/cgi-bin/sis/htmlgen?CHEM)
[b] http://www.chemicalbook.com/ProductChemicalPropertiesCB8391416_EN.htm
[c] na. Not available.

3. USES

Nicotinate esters have been included in rubefacient creams and lotions to increase blood flow and reduce pain, possibly by acting as counter irritants (Moore, 2002). Hexyl nicotinate has been used in a topical cream (2% cream applied three times daily) applied mainly to the hands and feet of people with perniosis[2] (Jordaan, 2007). Hexyl nicotinate has been reported to be used in a variety of body and hand preparations (excluding shaving preparations) as a skin-conditioning agent (Gottschalck and McEwen Jr., 2009). Generally, these products contain hexyl nicotinate at a 2% concentration, but exact formulations were not located (Marrakchi and Maibach, 2009).

Nicotinate esters (methyl, hexyl, benzyl, and ethyl) have been used in creams and lotions to increase blood flow and to warm the skin. "Hot Tingle Tanning Lotions" are marketed for indoor tanning salons; these lotions contain different concentrations of proprietary blends of nicotinate esters (i.e., ethyl, benzyl, methyl, and hexyl esters). As explained on one of the web sites that market or review indoor tanning lotion products: "Because it does increase the blood flow it speeds up the repair process of the skin. The tanning process comes from damage being done to your skin by sun or [ultraviolet] rays and melanin rising to repair the skin."[3]

[2] A condition in which cutaneous lesions occur after exposure to cold and high humidity during cold months of the year, and may be due to arteriolar and venular constriction (Jordaan, 2007); also known as chilblains.
[3] How to Know If Tingle Tanning Lotion Is for You | eHow.com http://www.ehow.com/how_4785791_tingle-tanning-lotion.html#ixzz1LzMcKNGp

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The major metabolite of hexyl nicotinate is nicotinic acid, which is used in cosmetics at concentrations from 0.01% (body and hand creams, lotions, powders, and sprays) to 0.1% (mud packs) (Cosmetic Ingredient Review [CIR], 2009). One clitoral stimulant (K-Y® Brand Intense) was found on the internet that contained nicotinic acid. This product includes the following warning: If irritation or discomfort occurs, discontinue use and consult your healthcare provider.

3.1 Regulatory history

Although hexyl nicotinate has not been approved for use in food by FDA, FEMA, JECFA, IOFI, or CoE. Nicotinic acid has been affirmed GRAS for use in food with no limitation other than current good manufacturing practice.[4] Nicotinic acid is used as a nutritional supplement and may also be used in infant formula in accordance with section 412(g) of the Federal Food, Drug, and Cosmetic Act. The current recommended dietary intake (RDI) for nicotinic acid is 20 mg/day. The Dietary Reference Intakes (DRIs; National Academies) for non-pregnant/non-lactating females 19–70 years of age are as follows:

Estimated average requirement	11 mg/day
Recommended dietary allowance and adequate intake	14 mg/day
Tolerable upper intake level	35 mg/day

3.2 Pharmaceutical history

No Rx or OTC uses of hexyl nicotinate were located in the literature. However, immediate release and extended release of nicotinic acid is used to treat elevated total cholesterol, low density lipoprotein-cholesterol, apolipoprotien-B, and triglycerides and to increase high density lipoprotein-cholesterol levels (Niaspan®; niacin extended-release tablets). Instructions from the Niaspan® full prescribing information literature indicate that doses of 500 mg/day are used to initiate treatment and increased to a maintenance dose of between 1000–2000 mg/day are achieved (Abbott, 2010).

4. HUMAN EXPOSURE ASESSMENT

The main route of exposure to hexyl nicotinate in personal lubricant will be mucosal (vaginal and urethral) and dermal (penile, perineal, or other skin). Exposure to the oral or anal mucosa

[4] Title 21 of the US Code of Federal Regulations (CFR), section 184.1530, 2008.

may also occur, and oral ingestion may be anticipated. Due to the route of contact, it is assumed that the majority of hexyl nicotinate utilized in the product will be directly absorbed into the bloodstream through dermal or mucosal contact. The rate of percutaneous absorption is important for determining the effectiveness and/or potential toxicity of substances that are administered *via* the skin (Levin and Maibach, 2005). Variations in the rate of absorption may arise from the physical chemical properties of the topical substance, the time of application, or the method of measurement. In addition, there is inter-individual variation (*e.g.*, skin condition, age of the individual, ethnicity, and blood flow) and intra-individual variations (*e.g.*, differences between anatomic sites of an individual). Due to the rich blood supply of the penis and body orifices with which hexyl nicotinate may be in contact during use of the personal lubricant, complete absorption of hexyl nicotinate will be assumed when estimating exposure.

The human exposure assessment assumes that 5.0 g of lubricant containing (b)(4) hexyl nicotinate will be applied daily. According to Piccino and Mosher (1998) and cited in a report by The Kinsey Institute (2009), 18-29 years olds have sex more often than any other group studied, with an average of 112 times *per* year (approximately twice *per* week). Therefore, the assumption of daily use of lubricant greatly overestimates exposure.

Daily use 5.0 g/d * (b)(4) hexyl nicotinate * 1000 mg/g = 2.5 mg hexyl nicotinate/d

(0.042 mg/kg bw[5]/day for a 60 kg individual, if the individual used the lubricant every day)

Because nicotinic acid represents about 59% of the weight of hexyl nicotinate (Table 2), metabolism of the entire hexyl nicotinate dose to nicotinic acid would result in absorption after use of the lubricant of just under 1.5 mg nicotinic acid (25 µg/kg bw/day for a 60-kg individual). This amount is 7.3% of the estimated daily nutritional requirement for nicotinic acid and 4.3% of the tolerable upper intake level.

5. BIOLOGICAL DATA

5.1 Absorption, Metabolism and Excretion

In general, esters of nicotinic acid diffuse through the stratum corneum, reaching the junction between the dermal vasculature and the viable epidermis at a concentration that is adequate to

[5] bw = Body weight

initiate vasodilation within minutes (Bunker and Dowd, 1987). Hexyl nicotinate induces a clear erythema response, and therefore has been extensively used as a prototype chemical to analyze the basic concepts of chemical absorption through the skin, including analysis of basic diffusion kinetics. Alterations in the rate and ability of absorption through the skin may affect the safety of hexyl nicotinate when topically applied. Albery and Hadgraft (1979) analyzed the percutaneous absorption of esters of nicotinic acid, including hexyl nicotinate, and found that when hexyl nicotinate (0.92 mM in 40% glycerol:water, approximately 0.01% hexyl nicotinate) was applied *via* a skin patch to human skin for three minutes, hexyl nicotinate induced erythema 9.4 minutes after the patch was removed from the skin. Albery *et al.* (1983) reported that continued transport of hexyl nicotinate and the concurrent spread of erythema both outwards from the site of exposure and deeper through the skin layers is caused by direct uptake of the substance in the dermal capillaries. The release of hexyl nicotinate from a simple aqueous and oily cream (hexyl nicotinate was incorporated into the lipid phase) was found to be directly dependent on the function of the square root of the length of time of exposure, directly following diffusion coefficient calculations, when analyzed both *in vitro* (synthetic membrane studies) and *in vivo* (application of the hexyl nicotinate to the flexor aspect of the forearm in 20 subjects) (Beastall *et al.*, 1986). The time of onset of erythema for hexyl nicotinate when prepared in an aqueous cream is presented in Table 3. Urea has been analyzed as a penetration enhancer for hexyl nicotinate, in which increasing concentrations of urea added to an oily cream containing 1% hexyl nicotinate decreased the mean time of onset of erythema (Table 4). However, Duval *et al.* (2003) reported that the addition of urea actually increased the lag time between application and initial hexyl nicotinate response, while a lipid-dense cream decreased the lag time to a maximal erythema response.

Table 3. Time of erythema onset for hexyl nicotinate in aqueous cream (Beastall *et al.*, 1986)

Hexyl nicotinate (%)	Time of Erythema Onset [min ± SE)]
0.05	18.5 (0.48)
0.1	12.9 (0.49)
0.2	11.08 (0.35)
0.5	8.7 (0.43)
1.0	7.1 (0.3)

Number of subjects = 20; SE = Standard error

Table 4. Time of erythema onset for hexyl nicotinate (1%) in oily cream containing urea (Beastall *et al.*, 1986)

Urea (%)	Mean Time of Erythema Onset [min ±SE)]
0.0	11.6 (0.8)
0.5	10.4 (0.7)
1.0	8.6 (0.5)
2.0	8.6 (0.6)
5.0	6.7 (0.4)
10.0	6.5 (0.4)

Number of subjects = 20; SE = Standard error

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In a study analyzing the potential of various chemicals to enhance skin permeability, the application of a mixture of propylene glycol and hexyl nicotinate enhanced the flux of hexyl nicotinate in human subjects ($n = 35$), but a mixture of fatty acids and hexyl nicotinate did not modulate hexyl nicotinate permeation (Boelsma *et al.*, 1997; 1998). The vehicle used to apply hexyl nicotinate may also affect the amount of vasodilation, as the use of a hydrogel containing hydroxyethylcellulose, glycerol, and water significantly increased the penetration of hexyl nicotinate through the skin and resulted in faster absorption kinetics and increased the vasodilation by up to 2-fold compared to a gel containing mostly polyethylene glycol or a lipid-based gel (Realdon *et al.*, 1995). Depending on the type of application (*e.g.*, under occlusive dressing[6] or with various topical adjuvants), the onset of vasodilation can vary from a mean of 12.5 minutes (no topical adjuvant, no occlusive dressing), to less than a minute when applied under occlusion with laurocapram.[7] Depending on the type of application or use of a penetration enhancer, the time to peak vasodilation response may also decrease from 35 minutes (control) to approximately 17 minutes (Ryatt *et al.*, 1986). However, in general, occlusion increases the rate and amount of absorption of topically applied substances (Zhai and Maibach, 2001). The lag time between the application of hexyl nicotinate to the skin (in a 5% ethanol solution) and the beginning of forearm dermal vessel dilation (as assessed by a laser Doppler method)[8] was 218 seconds (approximately 3.5 minutes), but lag time may vary up to 20% dependent on circadian rhythms (Reinberg *et al.*, 1995).

Variations in the hydration of the skin can also alter hexyl nicotinate absorption rates. A significant increase in transepidermal water loss (TEWL) will significantly decrease lag time between application of hexyl nicotinate (a 10-μL volume of a 5% hexyl nicotinate solution in 95:5 (v/v)[9] ethanol:propylene glycol solution) and the resulting vasodilation response when applied to forearm skin (Kompaore *et al.*, 1991). Zhai *et al.* (2002) found that wet occlusion

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[6] Occlusion is the covering of the skin by tape, gloves, impermeable dressings, or transdermal devices. Topical vehicles that contain fats or some polymer oils may also reduce water loss to the atmosphere and be viewed as occlusive dressings (Zhai and Maibach, 2001)

[7] A penetration enhancer used in cosmetic preparations and personal-care products. http://chemicalland21.com/lifeschience/foco/laurocapram.htm; site visited May 11, 2009.

[8] The laser Doppler velocimeter is a noninvasive method of measuring microvascular flow velocity in skin utilizing light that penetrates the skin to a depth of approximately 1-1.5 mm that is reflected by stationary and moving components of the skin. Light reflected from moving objects is phase-shifted, while light from the stationary components are not, and therefore the increase in blood flow velocity can be quantified (Marks, 1985).

[9] v/v = volume/volume

patches on the forearm increased the skin hydration level compared to control unpatched skin and also increased the initial permeation rate of hexyl nicotinate. Overhydration of the skin did not increase permeation rates past the initial ten-minute period of hexyl nicotinate treatment. Therefore, the hydration of the skin changes absorption kinetics of hexyl nicotinate up to a point then has no additional effect. Variations in skin properties will also affect TEWL values, thereby affecting rates of absorption, as patients with keratinization disorders ($n = 39$) had altered penetration values for hexyl nicotinate applied to the skin (Lavrijsen *et al.*, 1993; Oestmann *et al.*, 1993). Compared to healthy controls, patients with ichthyosis[10] had significantly increased TEWL values, which resulted in a shorter lag time between hexyl nicotinate application and the initial vascular response, suggesting that the absorption of hexyl nicotinate does not occur through the intercellular lipids but could be a transcellular pathway or a pathway along the cornified cell envelope (Lavrijsen *et al.*, 1993).

Uchimura *et al.* (2008) found that hexyl nicotinate quickly binds to rat serum protein *in vitro*, with 98.5% protein binding. Even with this high level of protein binding, hexyl nicotinate is quickly metabolized in serum, with a serum half-life ($t_{1/2}$) of 3.94 minutes in rat serum. Evaluation of the permeation of hexyl nicotinate and other nicotinates such as methyl nicotinate by Uchimura *et al.* (2008) found that hexyl nicotinate is readily metabolized *via* enzymatic hydrolysis to nicotinic acid during permeation through the cutaneous tissue, as indicated in Table 5. For hexyl nicotinate, complete metabolism was obtained during permeation through full thickness skin, as well as through isolated dermis and was more pronounced than for methyl nicotinate (Müller *et al.*, 2003).

Table 5. Mean degradation rates during permeation for different skin layers to form nicotinic acid (Müller *et al.*, 2003)

	Epidermis	Dermis	Full thickness skin
Hexyl nicotinate	3.4%	100%	100%
Methyl nicotinate	0.4%[a,b] 1.7%[c]	5.2%[b]	32.8%[b]

[a]Amount within chemical degradation range; [b]Donor concentration, 365 mM; [c]Donor concentration, 1 mM

[10]Any of a group of skin disorders characterized by increased or aberrant keratinization, resulting in dryness, roughness, and scaliness of the skin. Merck Source (2007), http://www.mercksource.com/pp/us/cns/cns_hl_dorlands_split.jsp?pg=/ppdocs/us/common/dorlands/dorland/four/000052124.htm; site visited May 11, 2009.

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Nicotinic acid is used in the production of the pyridine nucleotide coenzymes NAD(H) and NADP(H) or metabolized through a series of steps ultimately to acetyl-CoA. NAD(H), NADP(H), and acetyl-CoA are essential in the production of adenosine triphosphate (ATP). Excess nicotinic acid is metabolized to several metabolites, including 1-methylnicotinamide and its oxidation product 1-methyl-6-pyridone-3-carboxamide, which are excreted in the urine. High doses of nicotinic acid (approximately 2000–3000 mg/day, 1333–2000 times the amount of free nictotinic acid available from 5 g of personal lubricant containing (b)(4) hexyl nicotinate) taken orally may lead to flushing, itching, heartburn, nausea, vomiting, altered glucose tolerance, hyperuricemia, and elevations in plasma liver enzyme activity (Combs Jr., 1998). Additional information on possible cardiovascular effects is discussed below in section 5.3 (Observations in Humans). Topical or oral nicotinic acid exposure is readily metabolized or excreted *via* the urine (Cosmetic Ingredient Review (CIR), 2009).

The ability of topically applied, radioactively labeled, methyl-, ethyl-, hexyl-, and benzyl-nicotinates to penetrate the skin *in vivo* in humans was determined by evaluating the urinary excretion of total radioactivity in four human subjects (Guy *et al.*, 1986a). The substances were individually administered topically to the forearm at a dose of 4 $\mu g/cm^2$ in acetone. The amount of radioactivity was 2–5 μCi. Urine was collected for five days after test substance application.[11] The percent "dose" (as total radioactivity) excreted was determined for each time interval. The octanol:water partition coefficient for hexyl nicotinate was experimentally determined at 3910,[12] and is consistent with the log octanol:water partition coefficient (log P) of hexyl nicotinate of 3.51 (Houk and Guy, 1988). The *in vivo* skin absorption and distribution of ^{14}C-labeled nicotinates was determined by the rate of excretion *via* the urine in hours (Table 6) (Guy *et al.*, 1986a).

[11] Urine was collected according to the following schedule: 0–4 h, 4–8 h, 8–12 h, 12–24 h, 24–36 h, 36–48 h, day 3, day 4, and day 5.

[12] As a reference, the octanol:water partition coefficients for methyl-, ethyl-, and benzyl-nicotinates are 11, 30, and 254, respectively (Guy *et al.*, 1986b). A higher octanol:water partition coefficient indicates greater lipophilicity.

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Table 6. *In vivo* skin absorption of ^{14}C-labeled nicotinates (Guy *et al.*, 1986a)[a]

Time at mid-point of urine collection (h)	Rate of excretion, % dose/h			
	Methyl nicotinate	Ethyl nicotinate	Hexyl nicotinate	Benzyl nicotinate
2	0.104	0.100	0.117	0.123
6	0.462	0.181	0.132	0.181
10	0.308	0.142	0.166	0.434
18	0.145	0.094	0.258	0.293
30	0.127	0.106	0.325	0.286
42	0.101	0.061	0.209	0.256
60	0.097	0.058	0.179	0.257
84	0.076	0.056	0.126	0.137
108	0.094	0.044	0.116	0.214

[a]Mean ($n = 6$) urinary excretion of ^{14}C-labeled nicotinates as a function of time post-administration. The data have been corrected for incomplete urinary excretion.

A significant increase in the rate of ^{14}C-labeled hexyl nicotinate excretion (% dose/hour) occurred over 18 hours post-administration (0.166 at 10 hours *vs.* 0.258 % dose/h at 18 hours post dose, respectively). The hexyl and benzyl esters were found to be freely soluble in the outermost layer of skin, while the acetone solvent did not affect this absorption. In contrast, the rate of movement out of the stratum corneum into the more aqueous viable tissue was dependent on the hydrophobic nature of hexyl and benzyl nicotinates. For more hydrophilic nicotinic acids, acetone sped up the ability of methyl and ethyl nicotinate to bypass the stratum corneum barrier and quickly enter the more aqueous dermal layer. These data indicate that the lipid solubility of hexyl nicotinate is a factor in the rate at which the substance will initiate vasodilation and that hexyl nicotinate has a higher affinity for the stratum corneum than for viable tissue (Guy *et al.*, 1986a).

5.2 Toxicological studies

Hexyl nicotinate has vasodilating properties when applied to the skin (Dowd *et al.*, 1987; Moore and Cunningham, 1992). Nicotinic acid, the major metabolite of hexyl nicotinate, has been evaluated for toxicity in conjunction with the structurally similar nicotinamide by the Cosmetic Ingredient Review (Cosmetic Ingredient Review (CIR), 2005). In brief, it was concluded that nicotinic acid and nicotinamide had a low level of toxicity when used in cosmetic ingredients. Nicotinic acid was not mutagenic in the Ames test, with or without metabolic activation, did not induce chromosomal aberrations or sister chromatid exchanges at 2 mg/mL in Chinese hamster ovary cells but produced structural chromosome aberrations at 3 mg/mL. Repeat-dose oral,

parenteral, and dermal toxicity studies did not indicate irreversible toxicity from exposure to nicotinic acid or nicotinamide (CIR, 2005). No toxicological studies on hexyl nicotinate were located in the literature. Nicotinic acid is not teratogenic in rats at up to 1000 mg/kg (40,000 times the weight adjusted dose of nicotinic acid available from 5 g of a personal lubricant containing (b)(4) hexyl nicotinate). Nicotinic acid induced maternal toxicity at a dose of 200 mg/kg (8000 times the amount of nicotinic acid available from 5 g of the personal lubricant) (OECD/SIDS, 2011).

Administration of nicotinic acid 130 mg/kg to rats caused a small transient decrease in blood pressure (Kjekshus, 1975). No studies were located in which nicotinic acid caused cardiovascular impairment in experimental animals. Three studies were located in which nicotinic acid ameliorated the cardiotoxicity of other treatments: (1) Nicotinic acid 130 mg/kg prevented some of the myocardial necrosis associated with subsequent isoproterenol infusion in rats (Kjekshus, 1975). (2) Administration of nicotinic acid 500 mg/kg to mice prevented the myocardial injury associated with adriamycin treatment (Schmitt-Gräff and Scheulen, 1986). (3) Treatment of dogs with a nicotinic acid infusion at 0.3 mg/kg bw/min for 30 minutes before coronary artery occlusion resulted in less reperfusion injury to the myocardium, attributed to a decrease in fatty acid uptake by the damaged tissue (Gross *et al.*, 1987).

5.3 Observations in humans

Dowd *et al.* (1987) applied a topical lotion containing 0, 0.025, 0.05, or 0.1% hexyl nicotinate to ten subjects (4 male and 6 female, ages ranged from 19 to 51) and evaluated erythema formation by a noninvasive laser Doppler flowmeter technique. A standard 0.01 mL volume of the lotion was applied to separate 4 cm^2 areas of the skin of the ventral surface of the forearm and of the buttock. One female subject did not respond to any of the hexyl nicotinate concentrations (*i.e.*, no erythema formation), while one male and one female subject had barely detectable erythematous responses. The other subjects had quantitative levels of erythema formation. The mean erythematous responses indicated a dose-related mean increase in blood cell flux (BCF). The authors stated that no subject experienced pain or irritation at the hexyl nicotinate sites.

In a separate study, Bunker *et al.* (1988) evaluated the ability of topically applied hexyl nicotinate (in lotion) to affect skin blood flow in healthy subjects (n = 5) or patients with

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Raynaud's phenomenon[13] (75 sites assessed in 23 patients evaluated with 0.1% hexyl nicotinate; 1.0% hexyl nicotinate was evaluated at 13 sites[14] in seven patients). The age and sex of the patients were not stated in the publication. Hexyl nicotinate (0.1% and 1.0%, approximately equivalent to1.0 and 10 mg/60 kg person) was added to a lotion formulation that also contained zinc stearate (1%), stearic acid (5%), cetosterol alcohol (4%), cetrimide (1%), dimethicone 350 (7.5%), isopropyl myristate (7.5%), glycerol (25%), chlorocresol (0.1%), and water (to 100%) with 0.025 mL of the lotion applied to 2 cm^2 diameter symmetrical test sites on the skin of the ventral surface of the forearm, the dorsal surface of the hand, or the dorsal surface of the middle phalanx of the fingers of both hands. Vehicle was applied to some subjects (number not stated) as a control. Cutaneous blood flow velocity was assessed using laser Doppler velocimetry, with a positive response defined as a greater than 1.5-fold increase in blood flow velocity from baseline. At 0.1% hexyl nicotinate, there was a 100% response (as noted by an increase in blood flow velocity) at the forearm accompanied by erythema in both controls and patients with Raynaud's phenomenon. However, in both the controls and Raynaud patients, there was a reduced response with application to the hands (33 and 42% of the sites assessed, respectively). At 1.0% hexyl nicotinate, five out of the seven Raynaud patients responded at seven of the 13 sites evaluated (54% response), a significant increase over 0.1% hexyl nicotinate application ($P<0.01$). The authors stated that "there were no side-effects from application of the lotion apart from a feeling of warmth at the site of application in two patients, which was not considered unpleasant," but "it was noticed that the act of rubbing the lotion into the skin produced an immediate increase in blood flow in some patients," which could indicate a placebo effect (Bunker *et al.*, 1988).

The application of hexyl and methyl nicotinate was utilized by Berardesca and Maibach (1988; 1990) to evaluate racial differences in pharmacodynamic erythematous responses in the skin to nicotinates. The transcutaneous penetration of hexyl and methyl nicotinate (evaluated separately) did not differ between Caucasian (n=9) and Hispanic-American (n=7) male volunteers (Berardesca and Maibach, 1988). The exact amount of hexyl nicotinate was not stated, only that 10 mM hexyl nicotinate in 60:40 water:isopropyl alcohol vehicle was administered (calculated at approximately a 0.21% hexyl nicotinate solution, approximately 2.0 mg hexyl nicotinate/60 kg

[13] Raynaud's phenomenon is a condition in which an abnormal spasm of the blood vessels causes a diminished blood supply to the local tissues. http://www.medicinenet.com/; site visited April 30, 2009.
[14] The upper limb sites evaluated were the ventral surface of the forearm, the dorsal surface of the hand, or the dorsal surface of the middle phalanx of the fingers.

person), and that "administration of nicotinates was achieved *via* a filter paper disk saturated with the solution." Hexyl nicotinate was applied to the skin for five minutes, and blood flow responses were measured every 15 minutes. In a separate study, hexyl nicotinate was applied to both control and delipidized skin (*via* application of ethyl acetate) in male subjects (nine Caucasian and ten African-American) (Berardesca and Maibach, 1988). Hexyl and methyl nicotinate were evaluated separately. Berardesca and Maibach (1990) concluded that African Americans had decreased levels of hexyl nicotinate penetration based on lower levels of skin blood flow velocity increases induced by hexyl nicotinate. In a later study, Kompaore and Tsuruta (1993) reported that the stratum corneum barrier function in Asian skin was more sensitive to stripping[15] compared to Caucasian or black skin (Africans living in France), but that decreasing the stratum corneum barrier function increased absorption of both methyl and hexyl nicotinate. This finding suggests that disruption to the outer layers of the skin may increase the rate of absorption of hexyl nicotinate and may vary by ethnicity.

Hexyl nicotinate was used by Marrakchi and Maibach (2006) to analyze the effect of the age of the person or the location on the body that is exposed to an agent in the induction of nonimmunologic contact urticaria.[16] To determine if the age of the subject or the area of placement on the body affected the level of response to hexyl nicotinate (a 5 mM solution in ethanol, which corresponds to approximately a 0.1% hexyl nicotinate solution, 2 times greater concentration of (b)(4) hexylnicotinate in the lubricant) was applied to eight different regions on the skin (forehead, nose, cheek, nasolabial and perioral areas, chin, neck, and volar forearm) for 15 seconds to elicit erythema, after which blood flow velocity measurements were taken every 10 minutes for one hour with a laser Doppler flowmeter to determine the maximum vascular response of the skin to hexyl nicotinate. The subjects were composed of two age groups: Group A was comprised of ten subjects ranging from 24 to 34 years of age (average age was 29.8±3.9 years), and Group B contained ten subjects with an average age of 73.6±17.4 years, with the ages ranging from 66 to 83 years. Hexyl nicotinate induced measureable increases in erythema at the

[15] Stripping is a technique to remove the horny layer, in which a piece of adhesive tape is applied to the skin for 15 seconds under constant 500 g weight, followed by quick removal. This stripping procedure was repeated 12 times on each site of 5 cm^2.

[16] Urticaria is commonly referred to as hives, a vascular reaction of the upper dermis marked by transient appearance of slightly elevated patches (wheals) that are redder or paler than the surrounding skin and often attended by severe itching; the cause may be certain foods or drugs, infection, or emotional stress. http://medical-dictionary.thefreedictionary.com/urticaria; site visited April 30, 2009

different skin sites, with the perioral and nasolabial areas, the nose, forehead, and the neck more sensitive to hexyl nicotinate than the forearm. The formation of erythema was significantly different between the two populations, with the older Group B showing greater peak erythema values at the forehead, cheek, and nasolabial area.

Overall, clinical studies indicate that hexyl nicotinate dose-dependently increases vasodilation when applied topically, and the amount of vasodilation varies according to age, ethnicity, vehicle matrix, and the site of application. The integrity of the skin will also have a marked effect on the penetration of hexyl nicotinate, with abrasions or skin disorders significantly increasing hexyl nicotinate absorption.

No studies of genital mucus membrane absorption of hexyl nicotinate or nicotinic acid were identified. However, the vaginal epithelium lacks a stratum corneum and is, in general, more permeable than keratinized skin. The vagina has more loosely packed cell layers providing less resistance to absorption and a less structured lipid barrier offering lower resistance to diffusion. Parts of the vaginal epithelium are thinner than normal keratinized skin (reviewed by Farage and Scheffler, 2011). Nonkeratinized epithelia of the buccal mucosa and the floor of the mouth are 10- and 20-times more permeable, respectively, to water than keratinized skin (Lesch *et al.* 1989). It is reasonable to assume that the entire amount of hexyl nicotinate applied to the vagina will be absorbed and rapidly metabolized to nicotinic acid.

The flushing response from topical application is the same response obtained from oral ingestion of nicotinic acid for treating hyperlipidemia (Abbott, 2010). The flushing response or erythema arises from nicotinic acid-induced cutaneous vasodilatation. Several studies (Kamanna *et al.* 2009; Sood and Arora, 2008; Dunbar and Gelfand, 2010 [review]) demonstrated that nicotinic acid-induced flushing is mediated by the G protein-coupled receptor 109A (GPR109A), expressed in neutrophils, adipocytes, Langerhans cells, keratinocytes, and monocytes. Stimulation of GPR109A in immune cells promotes activation of phospholipase A_2, production of arachidonic acid, and production through cyclooxygenases of prostaglandins D_2 and E_2. These prostaglandins cause relaxation of vascular smooth muscle.

Treatment with aspirin (a prostaglandin synthesis inhibitor) prior to nicotinic acid treatment can inhibit the flushing response (Sood and Arora, 2008 and references therein). Non-specific

esterase activity is present in many murine tissues including vagina (Markert and Hunter, 1959). Because Langerhans cells can mediate the flushing effects of nicotinic acid, and Langerhans cells populate normal human vaginal epithelium (Patton *et al.* 2000), vasodilation effects would be expected to occur with adequate doses of hexyl nicotinate applied to the vaginal epithelium.

Nicotinic acid has been reported in case series to have beneficial effects in the treatment of headache, presumably due to vasoactive effects (Prousky and Seely, 2005). Although oral nicotinic acid has been associated with liver failure, gastrointestinal distress, glucose intolerance, and elevations of uric acid serum concentration, reports of hypotension with typical clinical use of nicotinic acid are unusual. Blood pressure response to infused nicotinic acid 1400 mg given over 500 minutes was studied in 11 normotensive and 10 hypotensive subjects (Gadegbeku *et al.*, 2003). The hypertensive subjects had been off anti-hypertensive medication for a week. Nicotinic acid increased heart rate 11–13% and decreased systemic vascular resistance by 6% in both normotensive and hypertensive individuals. Blood pressure was not altered in the normotensive subjects. In hypertensive patients, there was a decrease in systolic, diastolic, and mean arterial blood pressure. Systolic blood pressure went from 136 to 130 mm, diastolic blood pressure went from 89 to 84 mm Hg, and mean arterial blood pressure went from 105 to 99 mm Hg. There was a decrease in arterial compliance in the normotensive group that may have served to maintain blood pressure, while no changes in arterial compliance occurred in hypertensive subjects.

There is a case report of a 41-year-old man who took nicotinic acid 3000 mg/day (1,200 fold higher than the dose from lubricant) and developed lactic acidosis and hypoglycemia (Earthman *et al.*, 1991). Hypotension (blood pressure 80/40) was part of his presentation, but the low blood pressure was associated with dehydration and responded to the infusion of an intravenous glucose solution.

There have been three case reports of nicotinic acid overdosage in which hypotension was noted. In one case, a 20-year-old man self-medicated with nicotinic acid 6000 mg/day (4,000 fold higher than the dose from lubricant) for 7 days. He developed hepatic injury and vomited blood.

He was described as having orthostatic blood pressure (Ferenchik and Rovner, 1989).[17] In another case, a 56-year-old schizophrenic man took nicotinic acid 11,000 mg in 12 hours, because he had read that this treatment was beneficial for schizophrenia (Mularski *et al.*, 2006). He was also taking zinc and vitamins B_6 and B_{12}. The patient presented with abdominal and chest pain and his blood pressure fell to 59/40. He was supported with dopamine and recovered. There was no laboratory evidence or liver or cardiac injury. In the third case, a 23-year-old man took nicotinic acid 22,500 mg over two days, because he believed it would obscure his abuse of 3,4-methylenedioxymethamphetamine (MDMA) on urine drug screening (Daul and Meuhler, 2011). He developed hepatic failure, hemolysis, coagulopathy, hyperglycemia, and renal failure, but no circulatory problem. Initial blood pressure was 104/62, but 90 minutes later, it decreased to 81/45. The hypotension responded to intravenous fluids. After supportive care for multi-organ failure, the patient made a full recovery.

Nicotinic acid therapy produces some impairment of glucose tolerance (Guyton and Bays, 2007). In 11 of 17 heart transplant patients, nicotinic acid therapy was discontinued due to hyperglycemia (Henkin *et al.*, 1991, cited by CIR, 2005). In diabetic patients, nicotinic acid therapy worsened fasting blood glucose measurements, but only when the nicotinic acid dose was 1500 mg/day, without an effect at 1000 mg/day (Grundy *et al.*, 2002). The no effect dose of 1,000 mg/day is 667 fold greater than 2.5 mg/day exposure to hexyl nicotinate (1.5 mg/day nicotinic acid) if an individual uses the lubricant every day.

There is clinical evidence that nicotinic acid therapy does not produce adverse cardiovascular effects in individuals with pre-existing atherosclerotic cardiovascular disease. Niacin therapy is used regularly in lowering serum lipids in patients with documented coronary artery disease (Spósoto *et al.*, 1999). The Coronary Drug Project, sponsored by the National Heart, Lung, and Blood Institute, tested the effectiveness of lipid lowering therapy in the prevention of cardiovascular adverse outcomes in men with a history of a previous myocardial infarction (Berge and Conner, 1991). In this randomized, placebo-controlled trial, 1119 men between 30 and 65 years of age received nicotinic acid 3000 mg/day. There was a decrease in nonfatal myocardial infarction and all-cause mortality in the nicotinic acid group, suggesting that

[17] Orthostatic blood pressure refers to blood pressure that decreases more than normal when a patient sits or stands. It implies autonomic dysregulation or a decrease in blood volume, resulting in symptoms or signs when blood pools in the legs with position change.

nicotinic acid did not have important adverse health effects in these subjects with documented pre-existing cardiovascular disease.

There have been occasional clinical reports of cardiac arrhythmias or palpitations occurring on nicotinic acid therapy (Gibbons *et al.*, 1995; Mills *et al.*, 2003). An increase in atrial fibrillation from 2.9% in placebo-treated patients to 4.7% in nicotinic acid-treated patients has been described (Guyton and Bays, 2007). Nicotinic acid is not considered contraindicated in patients with atrial fibrillation, because therapy does not affect the ventricular response (Guyton and Bays, 2007).

6. SAFETY FACTOR CALCULATION

Assuming absorption of the entire amount of hexyl nicotinate in a 5-g application of personal lubricant containing (b)(4) hexyl nicotinate, and assuming complete metabolism to nicotinic acid, a nicotinic acid dose of 1.5 mg can be anticipated. This exposure is 667 times lower than the low end maintenance dose of Niaspan® of 1000 mg/day and 1333 times lower than the high end maintenance doses of Niaspan® of 2000 mg/day. This estimated 1.5-mg dose of nicotinic acid from exposure to the lubricant is 23 times lower than the tolerable upper intake level (35 mg/day) for niacin and 9 times lower than the recommended dietary intake (14 mg/day). Human reports suggest that there may be decrements in glucose control in diabetic patients and decreases in blood pressure in hypertensive patients at nicotinic acid dose levels above 1000 mg/day. The dose of nicotinic acid that is theoretically available from a 5-g application of lubricant is 667 times lower than this 1000 mg/day dose.

7. CONCLUSIONS AND RECOMMENDATIONS

A relatively large number of studies have been conducted on absorption kinetics, because topical application of hexyl nicotinate resulting in a well-defined and measurable response. Extensive studies have been conducted on the major metabolite nicotinic acid, but these studies do not address the irritation or sensitization potential of the parent hexyl nicotinate. Hexyl nicotinate is currently being used in a number of cosmetics, but no information could be located concerning potential adverse effects when applied to mucosal tissues or genital areas of the body. Topical use of this ingredient may result in sensory effects.

Attachment 2. Safety Assessment of Hexyl Nicotinate in a Personal Lubricant

No systemic toxic effects from nicotinic acid would be expected to occur at the 1.5-mg exposure to nicotinic acid that would be expected following application of 5 g of a personal lubricant containing (b)(4) hexyl nicotinate. Nicotinic acid therapy is regularly prescribed in patients with pre-existing atherosclerotic cardiovascular disease and no adverse cardiovascular outcomes have been reported except for a possible increase in atrial fibrillation. Experiments in laboratory animals and clinical studies suggest that nicotinic acid therapy has beneficial effects on the heart, perhaps mediated by a reduction in fatty acid uptake by the myocardium. Although dilatation of cutaneous blood vessels could in theory lead to hypotension, this complication does not appear to occur after typical clinical doses of nicotinic acid. Evaluation of hypertensive subjects showed a small decrease in blood pressure after infusion of nicotinic acid 1400 mg over 500 minutes. This effect may be beneficial, but even assuming that the decrease in blood pressure is an adverse effect, it occurred at a high exposure level compared to the maximum exposure that would be anticipated from use of 5 g of a lubricant containing (b)(4) hexyl nicotinate.

Based upon the above safety assessment,

1. The presence of (b)(4) hexyl nicotinate in personal lubricant is not expected to pose a safety issue.

2. ISO 10993 standard finished product testing battery should address safety of hexyl nicotinate in the context of the personal lubricant.

Attachment 2. Safety Assessment of Hexyl Nicotinate in a Personal Lubricant

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ATTACHMENT 3

ISO 10993-5 Cytotoxicity with Agarose Overlay (ST-7433.5)

(b)(4) Trade Secret Process - Testing

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CHURCH & DWIGHT CO., INC.

CONSUMER PRODUCTS • SPECIALTY PRODUCTS

MATERIAL SAFETY DATA SHEET

4. FIRST AID MEASURES

SKIN: Wash skin with plenty of water.
EYES: Flush eyes thoroughly with water for several minutes. Check for and remove contacts. Rinse eyes with clean flowing water for another 10 minutes. Seek medical attention if irritation develops.
INGESTION: No emergency medical treatment is necessary.
INHALATION: Remove to fresh air. Seek medical attention if symptoms persist.

5. FIRE FIGHTING MEASURES

FLAMMABLE PROPERTIES	FLAMMABLE LIMITS
FLASHPOINT: Not combustible	LFL: Not applicable
METHOD USED: Not applicable	UFL: Not applicable

EXTINGUISHING MEDIA: This material is non-combustible. Use extinguishing media appropriate for surrounding fire.
FIRE-FIGHTING INSTRUCTIONS: Carbon monoxide and carbon dioxide.
UNUSUAL FIRE AND EXPLOSION HAZARDS: None known.

6. ACCIDENTAL RELEASE MEASURES

Contain the spill, and depending on the consistency of the material, either pick up with absorbent material or scoop directly into a clean, dry container for later disposal. Wash away residue with plenty of water.

7. HANDLING AND STORAGE

Store in cool, dry areas and away from incompatible substances (see Section 10).

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

EXPOSURE LIMITS: Not established.
RESPIRATORY PROTECTION: Not required under normal handling conditions.
PROTECTIVE GLOVES: Impervious gloves recommended where prolonged or frequent contact could occur.
EYE PROTECTION: Safety glasses when handling bulk material.
OTHER PROTECTIVE CLOTHING OR EQUIPMENT: Impervious apron where splashing may occur.
PROTECTIVE WORK/HYGIENIC PRACTICES: No special requirements with respect to chemical exposure beyond those provided above. Requirements with respect to specific equipment and applications are the responsibility of the user.

9. PHYSICAL AND CHEMICAL PROPERTIES

APPEARANCE: Clear, colorless to slightly hazy liquid
ODOR: Characteristic.

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CONSUMER PRODUCTS • SPECIALTY PRODUCTS

MATERIAL SAFETY DATA SHEET

PHYSICAL STATE:Gel
pH (1% SOLN. w/v): Not applicable
VAPOR PRESSURE: Not applicable
VAPOR DENSITY: Not applicable
BOILING POINT: Not applicable
FREEZING/MELTING POINT: Not applicable
SOLUBILITY IN WATER: Complete
DENSITY (g/cc): Approximately 1.12
VISCOSITY: 600-1500 cps
VOLATILE ORGANIC COMPOUNDS: Not applicable

10. STABILITY AND REACTIVITY

CHEMICAL STABILITY: Stable at ambient-room temperature range conditions.
CONDITIONS TO AVOID: Temperatures above 40°C (104°F).
INCOMPATIBILITY WITH OTHER MATERIALS: Incompatibilities include strong oxidizing agents.
HAZARDOUS DECOMPOSITION PRODUCTS: Decomposition may result in the release of carbon monoxide and carbon dioxide.
HAZARDOUS POLYMERIZATION: Not likely to occur.

11. TOXICOLOGICAL INFORMATION

Occupational exposure is not expected to produce adverse human health effects following normal workplace practices. Product has very low acute toxicity. No known chronic health effects. Direct eye contact may cause temporary discomfort with mild redness.

12. ECOLOGICAL INFORMATION

TOXICITY: This material is expected not to be toxic to aquatic life.
PERSISTENCE: This material is not expected to be persistent.
BIOACCUMULATION: This material is not expected to significantly bioaccumulate.

13. DISPOSAL CONSIDERATIONS

Bury in a secured landfill in accordance with all local, state and federal environmental regulations.

14. TRANSPORTATION INFORMATION

Not regulated

15. REGULATORY INFORMATION

CLEAN AIR ACT SECTION 611: Product neither contains nor is it manufactured with ozone depleting substances (ODS).

CHURCH & DWIGHT CO., INC.

CONSUMER PRODUCTS • SPECIALTY PRODUCTS

MATERIAL SAFETY DATA SHEET

CERCLA REPORTABLE QUANTITY: Contains no ingredients at levels that would be subject to reporting requirements.
RCRA: Not a hazardous material or a hazardous waste by listing or characteristic.

SARA TITLE III:
Section 302, Extremely Hazardous Substances: None
Section 311/312, Hazardous Categories: Immediate/Acute
Section 313, Toxic Chemicals: None
The ingredients in this product are reported in the EPA TSCA Inventory List and the Canadian DSL.

16. OTHER INFORMATION

SUPERSEDES DATE: New REASON FOR REVISION: New
For additional non-emergency health, safety and environmental information telephone 609.279.7705 or write to:

Church & Dwight Co., Inc.
Product Stewardship
469 North Harrison Street
Princeton, New Jersey 08543

ATTACHMENT 4

ISO 10993-10 Rabbit Vaginal Irritation Study (ST-7433.1)

(b)(4) Trade Secret Process - Testing

(b)(4) Trade Secret Process - Testing

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Appendix 5- Test Article MSDS Sheet

CHURCH & DWIGHT CO., INC.

CONSUMER PRODUCTS • SPECIALTY PRODUCTS

MATERIAL SAFETY DATA SHEET

MSDS NUMBER: MSDS-1130 **ISSUE DATE: 12/02/11** **PAGE 1 OF 4**

1. PRODUCT AND COMPANY IDENTIFICATION

Product Name

Nirvana Arouses & Intensifies 1 A [EXP]

PRODUCT USE: Personal Lubricating Liquid
CHEMICAL NAME: Mixture
CHEMICAL FORMULA: Proprietary Mixture
SYNONYMS/COMMON NAMES: N/A

Church & Dwight Co., Inc.
469 N. Harrison Street
Princeton, NJ 08543

Information Phone:
1-888-367-6022

Medical Emergency Phone:
1-888-234-1828

Emergency Phone:
1-800-424-9300

2. HAZARDS IDENTIFICATION

EMERGENCY OVERVIEW

A clear to slightly hazy liquid. May cause eye irritation.
Not a fire hazard.
No significant health or environmental effects associated with this material.

HMIS Rating	
Health	0
Fire	0
Reactivity	0

Potential Health Effects

EYE: May cause irritation to eyes.
SKIN CONTACT: None.
INGESTION: None.
INHALATION: None.
SUBCHRONIC EFFECTS/CARCINOGENICITY: The ingredients in this product are not listed as carcinogens or potential carcinogens by NTP, IARC, OSHA, NIOSH, or ACGIH.

3. COMPOSITION/INFORMATION ON INGREDIENTS

Chemical Ingredient	(% by W)	CAS Number	OSHA PEL (8-hr TWA)	ACGIH LIMITS (8-hr TWA)
Cosmetic Fluid	90-99%	63148-62-9; 70131-67-8		None
Hexyl Nicotinate	<1%	23597-82-2	None	None
Vanillyl Butyl Ether	<1%	82654-98-6	None	

CORPORATE HEADQUARTERS 469 North Harrison street • Princeton, New Jersey 08543-5297 • Phone (609) 683-5900

Appendix 5 Continued – Test Article MSDS Sheet

CHURCH & DWIGHT CO., INC.

CONSUMER PRODUCTS • SPECIALTY PRODUCTS

MATERIAL SAFETY DATA SHEET

4. FIRST AID MEASURES

SKIN: Wash skin with plenty of water.
EYES: Flush eyes thoroughly with water for several minutes. Check for and remove contacts. Rinse eyes with clean flowing water for another 10 minutes. Seek medical attention if irritation develops.
INGESTION: No emergency medical treatment is necessary.
INHALATION: Remove to fresh air. Seek medical attention if symptoms persist.

5. FIRE FIGHTING MEASURES

FLAMMABLE PROPERTIES	FLAMMABLE LIMITS
FLASHPOINT: Not combustible	LFL: Not applicable
METHOD USED: Not applicable	UFL: Not applicable

EXTINGUISHING MEDIA: This material is non-combustible. Use extinguishing media appropriate for surrounding fire.
FIRE-FIGHTING INSTRUCTIONS: Carbon monoxide and carbon dioxide.
UNUSUAL FIRE AND EXPLOSION HAZARDS: None known.

6. ACCIDENTAL RELEASE MEASURES

Contain the spill, and depending on the consistency of the material, either pick up with absorbent material or scoop directly into a clean, dry container for later disposal. Wash away residue with plenty of water.

7. HANDLING AND STORAGE

Store in cool, dry areas and away from incompatible substances (see Section 10).

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

EXPOSURE LIMITS: Not established.
RESPIRATORY PROTECTION: Not required under normal handling conditions.
PROTECTIVE GLOVES: Impervious gloves recommended where prolonged or frequent contact could occur.
EYE PROTECTION: Safety glasses when handling bulk material.
OTHER PROTECTIVE CLOTHING OR EQUIPMENT: Impervious apron where splashing may occur.
PROTECTIVE WORK/HYGIENIC PRACTICES: No special requirements with respect to chemical exposure beyond those provided above. Requirements with respect to specific equipment and applications are the responsibility of the user.

9. PHYSICAL AND CHEMICAL PROPERTIES

APPEARANCE: Clear, colorless to slightly hazy liquid
ODOR: Characteristic.

CORPORATE HEADQUARTERS: 469 North Harrison street • Princeton, New Jersey 08543-5297 • Phone (609) 683-5900

Appendix 5 Continued – Test Article MSDS Sheet

CHURCH & DWIGHT CO., INC.

CONSUMER PRODUCTS • SPECIALTY PRODUCTS

MATERIAL SAFETY DATA SHEET

MSDS NUMBER: MSDS-1130 **ISSUE DATE: 12/02/11** **PAGE 3 OF 4**

PHYSICAL STATE:Gel
pH (1% SOLN. w/v): Not applicable
VAPOR PRESSURE: Not applicable
VAPOR DENSITY: Not applicable
BOILING POINT: Not applicable
FREEZING/MELTING POINT: Not applicable
SOLUBILITY IN WATER: Complete
DENSITY (g/cc): Approximately 1.12
VISCOSITY: 600-1500 cps
VOLATILE ORGANIC COMPOUNDS: Not applicable

10. STABILITY AND REACTIVITY

CHEMICAL STABILITY: Stable at ambient-room temperature range conditions.
CONDITIONS TO AVOID: Temperatures above 40°C (104°F).
INCOMPATIBILITY WITH OTHER MATERIALS: Incompatibilities include strong oxidizing agents.
HAZARDOUS DECOMPOSITION PRODUCTS: Decomposition may result in the release of carbon monoxide and carbon dioxide.
HAZARDOUS POLYMERIZATION: Not likely to occur.

11. TOXICOLOGICAL INFORMATION

Occupational exposure is not expected to produce adverse human health effects following normal workplace practices. Product has very low acute toxicity. No known chronic health effects. Direct eye contact may cause temporary discomfort with mild redness.

12. ECOLOGICAL INFORMATION

TOXICITY: This material is expected not to be toxic to aquatic life.
PERSISTENCE: This material is not expected to be persistent.
BIOACCUMULATION: This material is not expected to significantly bioaccumulate.

13. DISPOSAL CONSIDERATIONS

Bury in a secured landfill in accordance with all local, state and federal environmental regulations.

14. TRANSPORTATION INFORMATION

Not regulated

15. REGULATORY INFORMATION

CLEAN AIR ACT SECTION 611: Product neither contains nor is it manufactured with ozone depleting substances (ODS).

CORPORATE HEADQUARTERS 469 North Harrison street • Princeton, New Jersey 08543-5297 • Phone (609) 683-5900

Appendix 5 Continued – Test Article Composition

CHURCH & DWIGHT CO., INC.

CONSUMER PRODUCTS • SPECIALTY PRODUCTS

MATERIAL SAFETY DATA SHEET

MSDS NUMBER: MSDS-1130 **ISSUE DATE: 12/02/11** **PAGE 4 OF 4**

CERCLA REPORTABLE QUANTITY: Contains no ingredients at levels that would be subject to reporting requirements.
RCRA: Not a hazardous material or a hazardous waste by listing or characteristic.

SARA TITLE III:
Section 302, Extremely Hazardous Substances: None
Section 311/312, Hazardous Categories: Immediate/Acute
Section 313, Toxic Chemicals: None
The ingredients in this product are reported in the EPA TSCA Inventory List and the Canadian DSL.

16. OTHER INFORMATION

SUPERSEDES DATE: New REASON FOR REVISION: New
For additional non-emergency health, safety and environmental information telephone 609.279.7705 or write to:
Church & Dwight Co., Inc.
Product Stewardship
469 North Harrison Street
Princeton, New Jersey 08543

(b)(4) Trade Secret Process - Testing

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(b)(4) Trade Secret Process - Testing

ATTACHMENT 5

ISO 10993-10 Rabbit Penile Irritation Study (ST-7433.2)

(b)(4) Trade Secret Process - Testing

(b)(4) Trade Secret Process - Testing

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Appendix 6- Test Article MSDS Sheet

CHURCH & DWIGHT CO., INC.

CONSUMER PRODUCTS • SPECIALTY PRODUCTS

MATERIAL SAFETY DATA SHEET

MSDS NUMBER: MSDS-1130 **ISSUE DATE: 12/02/11** **PAGE 1 OF 4**

1. PRODUCT AND COMPANY IDENTIFICATION

Product Name

Nirvana Arouses & Intensifies 1 A [EXP]

PRODUCT USE: Personal Lubricating Liquid
CHEMICAL NAME: Mixture
CHEMICAL FORMULA: Proprietary Mixture
SYNONYMS/COMMON NAMES: N/A

Church & Dwight Co., Inc.
469 N. Harrison Street
Princeton, NJ 08543

Information Phone:
1-888-367-5722

Medical Emergency Phone
1-888-234-1828

Emergency Phone:
1-800-424-9300

2. HAZARDS IDENTIFICATION

EMERGENCY OVERVIEW

A clear to slightly hazy liquid. May cause eye irritation.
Not a fire hazard.
No significant health or environmental effects associated with this material.

HMIS Rating

Health	1
Fire	0
Reactivity	0

Potential Health Effects

EYE: May cause irritation to eyes.
SKIN CONTACT: None.
INGESTION: None.
INHALATION: None.
SUBCHRONIC EFFECTS/CARCINOGENICITY: The ingredients in this product are not listed as carcinogens or potential carcinogens by NTP, IARC, OSHA, NIOSH, or ACGIH

3. COMPOSITION/INFORMATION ON INGREDIENTS

Chemical Ingredient	(% by W)	CAS Number	OSHA PEL (8-hr TWA)	ACGIH LIMITS (8-hr TWA)
Cosmetic Fluid	90-99%	63148-62-9; 70131-67-8		None
Hexyl Nicotinate	<1%	23597-82-2	None	None
Vanillyl Butyl Ether	<1%	82654-98-6	None	

Appendix 5 Continued – Test Article MSDS Sheet

CHURCH & DWIGHT CO., INC.

CONSUMER PRODUCTS • SPECIALTY PRODUCTS

MATERIAL SAFETY DATA SHEET

MSDS NUMBER: MSDS-1130 **ISSUE DATE: 12/02/11** **PAGE 2 OF 4**

4. **FIRST AID MEASURES**
SKIN: Wash skin with plenty of water.
EYES: Flush eyes thoroughly with water for several minutes. Check for and remove contacts. Rinse eyes with clean flowing water for another 10 minutes. Seek medical attention if irritation develops.
INGESTION: No emergency medical treatment is necessary.
INHALATION: Remove to fresh air. Seek medical attention if symptoms persist.

5. **FIRE FIGHTING MEASURES**
FLAMMABLE PROPERTIES — FLAMMABLE LIMITS
FLASHPOINT: Not combustible — LFL: Not applicable
METHOD USED: Not applicable — UFL: Not applicable
EXTINGUISHING MEDIA: This material is non-combustible. Use extinguishing media appropriate for surrounding fire.
FIRE-FIGHTING INSTRUCTIONS: Carbon monoxide and carbon dioxide.
UNUSUAL FIRE AND EXPLOSION HAZARDS: None known.

6. **ACCIDENTAL RELEASE MEASURES**
Contain the spill, and depending on the consistency of the material, either pick up with absorbent material or scoop directly into a clean, dry container for later disposal. Wash away residue with plenty **of water.**

7. **HANDLING AND STORAGE**
Store in cool, dry areas and away from incompatible substances (see Section 10)

8. **EXPOSURE CONTROLS/PERSONAL PROTECTION**
EXPOSURE LIMITS: Not established
RESPIRATORY PROTECTION: Not required under normal handling conditions.
PROTECTIVE GLOVES Impervious gloves recommended where prolonged or frequent contact could occur.
EYE PROTECTION Safety glasses when handling bulk material
OTHER PROTECTIVE CLOTHING OR EQUIPMENT: Impervious apron where splashing may occur.
PROTECTIVE WORK/HYGIENIC PRACTICES: No special requirements with respect to chemical **exposure beyond those provided above. Requirements** with respect to specific equipment and **applications are the responsibility of the user.**

9. **PHYSICAL AND CHEMICAL PROPERTIES**
APPEARANCE: Clear, colorless to slightly hazy liquid
ODOR: Characteristic.

Appendix 5 Continued – Test Article MSDS Sheet

CHURCH & DWIGHT CO., INC.

CONSUMER PRODUCTS • SPECIALTY PRODUCTS

MATERIAL SAFETY DATA SHEET

PHYSICAL STATE: Gel
pH (1% SOLN. w/v): Not applicable
VAPOR PRESSURE: Not applicable
VAPOR DENSITY: Not applicable
BOILING POINT: Not applicable
FREEZING/MELTING POINT: Not applicable
SOLUBILITY IN WATER: Complete
DENSITY (g/cc): Approximately 1.12
VISCOSITY: 600-1500 cps
VOLATILE ORGANIC COMPOUNDS. Not applicable

10. STABILITY AND REACTIVITY

CHEMICAL STABILITY: Stable at ambient-room temperature range conditions.
CONDITIONS TO AVOID: Temperatures above 40°C (104°F).
INCOMPATIBILITY WITH OTHER MATERIALS: Incompatibilities include strong oxidizing agents
HAZARDOUS DECOMPOSITION PRODUCTS: Decomposition may result in the release of carbon monoxide and carbon dioxide.
HAZARDOUS POLYMERIZATION: Not likely to occur.

11. TOXICOLOGICAL INFORMATION

Occupational exposure is not expected to produce adverse human health effects following normal workplace practices. Product has very low acute toxicity. No known chronic health effects. Direct eye contact may cause temporary discomfort with mild redness

12. ECOLOGICAL INFORMATION

TOXICITY: This material is expected not to be toxic to aquatic life
PERSISTENCE: This material is not expected to be persistent.
BIOACCUMULATION: This material is not expected to significantly bioaccumulate

13. DISPOSAL CONSIDERATIONS

Bury in a secured landfill in accordance with all local, state and federal environmental regulations.

14. TRANSPORTATION INFORMATION

Not regulated

15. REGULATORY INFORMATION

CLEAN AIR ACT SECTION 611: Product neither contains nor is it manufactured with ozone depleting substances (ODS)

CORPORATE HEADQUARTERS: 469 North Harrison street • Princeton, New Jersey 08543-5297 • Phone (609) 683-5900

CHURCH & DWIGHT CO., INC.

CONSUMER PRODUCTS • SPECIALTY PRODUCTS

MATERIAL SAFETY DATA SHEET

CERCLA REPORTABLE QUANTITY: Contains no ingredients at levels that would be subject to reporting requirements
RCRA: Not a hazardous material or a hazardous waste by listing or characteristic.

SARA TITLE III:
Section 302, Extremely Hazardous Substances: None
Section 311/312, Hazardous Categories: Immediate/Acute
Section 313, Toxic Chemicals: None
The ingredients in this product are reported in the EPA TSCA Inventory List and the Canadian DSL.

16. OTHER INFORMATION

SUPERSEDES DATE: New REASON FOR REVISION: New
For additional non-emergency health, safety and environmental information telephone 609.279.7705 or write to
Church & Dwight Co., Inc.
Product Stewardship
469 North Harrison Street
Princeton, New Jersey 08543

(b)(4) Trade Secret Process - Testing

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ATTACHMENT 6

ISO 10993-11 Acute Systemic Toxicity Study (ST-7469)

(b)(4) Trade Secret Process - Testing

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Appendix 3 – Test Article MSDS Sheet

CHURCH & DWIGHT CO., INC.

CONSUMER PRODUCTS • SPECIALTY PRODUCTS

MATERIAL SAFETY DATA SHEET

MSDS NUMBER: MSDS-1130 **ISSUE DATE: 12/02/11** **PAGE 1 OF 4**

1. PRODUCT AND COMPANY IDENTIFICATION

Product Name

Nirvana Arouses & Intensifies 1 A [EXP]

PRODUCT USE: Personal Lubricating Liquid
CHEMICAL NAME: Mixture
CHEMICAL FORMULA: Proprietary Mixture
SYNONYMS/COMMON NAMES: N/A

Church & Dwight Co., Inc.
469 N. Harrison Street
Princeton, NJ 08543

Information Phone:
1-888-367-6022

Medical Emergency Phone:
1-888-234-1828

Emergency Phone:
1-800-424-9300

2. HAZARDS IDENTIFICATION

EMERGENCY OVERVIEW

A clear to slightly hazy liquid. May cause eye irritation.
Not a fire hazard.
No significant health or environmental effects associated with this material.

HMIS Rating	
Health	0
Fire	0
Reactivity	0

Potential Health Effects

EYE: May cause irritation to eyes.
SKIN CONTACT: None.
INGESTION: None.
INHALATION: None.
SUBCHRONIC EFFECTS/CARCINOGENICITY: The ingredients in this product are not listed as carcinogens or potential carcinogens by NTP, IARC, OSHA, NIOSH, or ACGIH.

3. COMPOSITION/INFORMATION ON INGREDIENTS

Chemical Ingredient	(% by W)	CAS Number	OSHA PEL (8-hr TWA)	ACGIH LIMITS (8-hr TWA)
Cosmetic Fluid	90-99%	63148-62-9; 70131-67-8		None
Hexyl Nicotinate	<1%	23597-82-2	None	None
Vanillyl Butyl Ether	<1%	82654-98-6	None	

CORPORATE HEADQUARTERS: 469 North Harrison street • Princeton, New Jersey 08543-5297 • Phone (609) 683-5900

Appendix 3 Continued – Test Article MSDS Sheet

CHURCH & DWIGHT CO., INC.

CONSUMER PRODUCTS • SPECIALTY PRODUCTS

MATERIAL SAFETY DATA SHEET

MSDS NUMBER: MSDS-1130 **ISSUE DATE: 12/02/11** **PAGE 2 OF 4**

4. FIRST AID MEASURES

SKIN: Wash skin with plenty of water.
EYES: Flush eyes thoroughly with water for several minutes. Check for and remove contacts. Rinse eyes with clean flowing water for another 10 minutes. Seek medical attention if irritation develops.
INGESTION: No emergency medical treatment is necessary.
INHALATION: Remove to fresh air. Seek medical attention if symptoms persist.

5. FIRE FIGHTING MEASURES

FLAMMABLE PROPERTIES	FLAMMABLE LIMITS
FLASHPOINT: Not combustible	LFL: Not applicable
METHOD USED: Not applicable	UFL: Not applicable

EXTINGUISHING MEDIA: This material is non-combustible. Use extinguishing media appropriate for surrounding fire.
FIRE-FIGHTING INSTRUCTIONS: Carbon monoxide and carbon dioxide.
UNUSUAL FIRE AND EXPLOSION HAZARDS: None known.

6. ACCIDENTAL RELEASE MEASURES

Contain the spill, and depending on the consistency of the material, either pick up with absorbent material or scoop directly into a clean, dry container for later disposal. Wash away residue with plenty of water.

7. HANDLING AND STORAGE

Store in cool, dry areas and away from incompatible substances (see Section 10).

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

EXPOSURE LIMITS: Not established.
RESPIRATORY PROTECTION: Not required under normal handling conditions.
PROTECTIVE GLOVES: Impervious gloves recommended where prolonged or frequent contact could occur.
EYE PROTECTION: Safety glasses when handling bulk material.
OTHER PROTECTIVE CLOTHING OR EQUIPMENT: Impervious apron where splashing may occur.
PROTECTIVE WORK/HYGIENIC PRACTICES: No special requirements with respect to chemical exposure beyond those provided above. Requirements with respect to specific equipment and applications are the responsibility of the user.

9. PHYSICAL AND CHEMICAL PROPERTIES

APPEARANCE: Clear, colorless to slightly hazy liquid
ODOR: Characteristic.

CORPORATE HEADQUARTERS: 469 North Harrison street • Princeton, New Jersey 08543-5297 • Phone (609) 683-5900

Appendix 3 Continued – Test Article MSDS Sheet

CHURCH & DWIGHT CO., INC.

CONSUMER PRODUCTS • SPECIALTY PRODUCTS

MATERIAL SAFETY DATA SHEET

MSDS NUMBER: MSDS-1130 **ISSUE DATE: 12/02/11** **PAGE 3 OF 4**

PHYSICAL STATE:Gel
pH (1% SOLN. w/v): Not applicable
VAPOR PRESSURE: Not applicable
VAPOR DENSITY: Not applicable
BOILING POINT: Not applicable
FREEZING/MELTING POINT: Not applicable
SOLUBILITY IN WATER: Complete
DENSITY (g/cc): Approximately 1.12
VISCOSITY: 600-1500 cps
VOLATILE ORGANIC COMPOUNDS: Not applicable

10. STABILITY AND REACTIVITY

CHEMICAL STABILITY: Stable at ambient-room temperature range conditions.
CONDITIONS TO AVOID: Temperatures above 40°C (104°F).
INCOMPATIBILITY WITH OTHER MATERIALS: Incompatibilities include strong oxidizing agents.
HAZARDOUS DECOMPOSITION PRODUCTS: Decomposition may result in the release of carbon monoxide and carbon dioxide.
HAZARDOUS POLYMERIZATION: Not likely to occur.

11. TOXICOLOGICAL INFORMATION

Occupational exposure is not expected to produce adverse human health effects following normal workplace practices. Product has very low acute toxicity. No known chronic health effects. Direct eye contact may cause temporary discomfort with mild redness.

12. ECOLOGICAL INFORMATION

TOXICITY: This material is expected not to be toxic to aquatic life.
PERSISTENCE: This material is not expected to be persistent.
BIOACCUMULATION: This material is not expected to significantly bioaccumulate.

13. DISPOSAL CONSIDERATIONS

Bury in a secured landfill in accordance with all local, state and federal environmental regulations.

14. TRANSPORTATION INFORMATION

Not regulated

15. REGULATORY INFORMATION

CLEAN AIR ACT SECTION 611: Product neither contains nor is it manufactured with ozone depleting substances (ODS).

CORPORATE HEADQUARTERS: 469 North Harrison street • Princeton, New Jersey 08543-5297 • Phone (609) 683-5900

Appendix 3 Continued – Test Article MSDS Sheet

CHURCH & DWIGHT CO., INC.

CONSUMER PRODUCTS • SPECIALTY PRODUCTS

MATERIAL SAFETY DATA SHEET

MSDS NUMBER: MSDS-1130 **ISSUE DATE: 12/02/11** **PAGE 4 OF 4**

CERCLA REPORTABLE QUANTITY: Contains no ingredients at levels that would be subject to reporting requirements.
RCRA: Not a hazardous material or a hazardous waste by listing or characteristic.

SARA TITLE III:
Section 302, Extremely Hazardous Substances: None
Section 311/312, Hazardous Categories: Immediate/Acute
Section 313, Toxic Chemicals: None
The ingredients in this product are reported in the EPA TSCA Inventory List and the Canadian DSL.

16. OTHER INFORMATION

SUPERSEDES DATE: New **REASON FOR REVISION: New**
For additional non-emergency health, safety and environmental information telephone 609.279.7705 or write to:

Church & Dwight Co., Inc.
Product Stewardship
469 North Harrison Street
Princeton, New Jersey 08543

(b)(4) Trade Secret Process - Testing

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(b)(4) Trade Secret Process - Testing

ATTACHMENT 7

ISO 10993-10 Guinea Pig Maximization Sensitization Study (ST-7433.3)

(b)(4) Trade Secret Process - Testing

(b)(4) Trade Secret Process - Testing

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Appendix 5- Test Article MSDS Sheet

CHURCH & DWIGHT CO., INC.

CONSUMER PRODUCTS • SPECIALTY PRODUCTS

MATERIAL SAFETY DATA SHEET

MSDS NUMBER: MSDS-1130 **ISSUE DATE: 12/02/11** **PAGE 1 OF 4**

1. PRODUCT AND COMPANY IDENTIFICATION

Product Name

Nirvana Arouses & Intensifies 1 A [EXP]

PRODUCT USE: Personal Lubricating Liquid
CHEMICAL NAME: Mixture
CHEMICAL FORMULA: Proprietary Mixture
SYNONYMS/COMMON NAMES: N/A

Church & Dwight Co., Inc.
469 N. Harrison Street
Princeton, NJ 08543

Information Phone:
1-888-367-5022

Medical Emergency Phone:
1-888-234-1828

Emergency Phone:
1-800-424-9300

2. HAZARDS IDENTIFICATION

EMERGENCY OVERVIEW

A clear to slightly hazy liquid. May cause eye irritation.
Not a fire hazard.
No significant health or environmental effects associated with this material.

HMIS Rating

Health	**0**
Fire	0
Reactivity	**0**

Potential Health Effects

EYE: **May cause irritation to eyes.**
SKIN CONTACT: None.
INGESTION: None.
INHALATION: None.
SUBCHRONIC EFFECTS/CARCINOGENICITY: The ingredients in this product are not listed as carcinogens or potential carcinogens by NTP, IARC, OSHA, NIOSH, or ACGIH.

3. COMPOSITION/INFORMATION ON INGREDIENTS

Chemical Ingredient	(% by W)	CAS Number	OSHA PEL (8-hr TWA)	ACGIH LIMITS (8-hr TWA)
Cosmetic Fluid	**90-99%**	**63148-62-9; 70131-67-8**		None
Hexyl Nicotinate	**<1%**	**23597-82-2**	**None**	None
Vanillyl Butyl Ether	**<1%**	82654-98-6	None	

Appendix 5 Continued – Test Article MSDS Sheet

CHURCH & DWIGHT CO., INC.

CONSUMER PRODUCTS • SPECIALTY PRODUCTS

MATERIAL SAFETY DATA SHEET

MSDS NUMBER: MSDS-1130 **ISSUE DATE: 12/02/11** **PAGE 2 OF 4**

4. **FIRST AID MEASURES**
SKIN: Wash skin with plenty of water.
EYES: Flush eyes thoroughly with water for several minutes. Check for and remove contacts. Rinse eyes with clean flowing water for another 10 minutes. Seek medical attention if irritation develops.
INGESTION: No emergency medical treatment is necessary.
INHALATION: Remove to fresh air. Seek medical attention if symptoms persist.

5. **FIRE FIGHTING MEASURES**
FLAMMABLE PROPERTIES
FLASHPOINT: Not combustible
METHOD USED: Not applicable
FLAMMABLE LIMITS
LFL: Not applicable
UFL: Not applicable
EXTINGUISHING MEDIA: This material is non-combustible. Use extinguishing media appropriate for surrounding fire.
FIRE-FIGHTING INSTRUCTIONS: Carbon monoxide and carbon dioxide.
UNUSUAL FIRE AND EXPLOSION HAZARDS: None known.

6. **ACCIDENTAL RELEASE MEASURES**
Contain the spill and depending on the consistency of the material, either pick up with absorbent material or scoop directly into a clean, dry container for later disposal. Wash away residue with plenty of water.

7. **HANDLING AND STORAGE**
Store in cool, dry areas and away from incompatible substances (see Section 10).

8. **EXPOSURE CONTROLS/PERSONAL PROTECTION**
EXPOSURE LIMITS: Not established.
RESPIRATORY PROTECTION: Not required under normal handling conditions.
PROTECTIVE GLOVES: Impervious gloves recommended where prolonged or frequent contact could occur.
EYE PROTECTION: Safety glasses when handling bulk material.
OTHER PROTECTIVE CLOTHING OR EQUIPMENT: Impervious apron where splashing may occur.
PROTECTIVE WORK/HYGIENIC PRACTICES: No special requirements with respect to chemical exposure beyond those provided above. Requirements with respect to specific equipment and applications are the responsibility of the user.

9. **PHYSICAL AND CHEMICAL PROPERTIES**
APPEARANCE: Clear, colorless to slightly hazy liquid
ODOR: Characteristic.

CORPORATE HEADQUARTERS: 469 North Harrison street • Princeton, New Jersey 08543-5297 • Phone (609) 683-5900

Appendix 5 Continued – Test Article MSDS Sheet

CHURCH & DWIGHT CO., INC.

CONSUMER PRODUCTS • SPECIALTY PRODUCTS

MATERIAL SAFETY DATA SHEET

MSDS NUMBER: MSDS-1130 | **ISSUE DATE: 12/02/11** | PAGE 3 OF 4

PHYSICAL STATE:Gel
pH (1% SOLN. w/v): Not applicable
VAPOR PRESSURE: Not applicable
VAPOR DENSITY: Not applicable
BOILING POINT: Not applicable
FREEZING/MELTING POINT: Not applicable
SOLUBILITY IN WATER: Complete
DENSITY (g/cc): Approximately 1.12
VISCOSITY: 600-1500 cps
VOLATILE ORGANIC COMPOUNDS: Not applicable

10. STABILITY AND REACTIVITY
CHEMICAL STABILITY: Stable at ambient-room temperature range conditions.
CONDITIONS TO AVOID: Temperatures above 40°C (104°F).
INCOMPATIBILITY WITH OTHER MATERIALS: Incompatibilities include strong oxidizing agents.
HAZARDOUS DECOMPOSITION PRODUCTS: Decomposition may result in the release of carbon monoxide and carbon dioxide.
HAZARDOUS POLYMERIZATION: Not likely to occur.

11. TOXICOLOGICAL INFORMATION
Occupational exposure is not expected to produce adverse human health effects following normal workplace practices. Product has very low acute toxicity. No known chronic health effects. Direct eye contact may cause temporary discomfort with mild redness.

12. ECOLOGICAL INFORMATION
TOXICITY: This material is expected not to be toxic to aquatic life
PERSISTENCE: This material is not expected to be persistent.
BIOACCUMULATION: This material is not expected to significantly bioaccumulate.

13. DISPOSAL CONSIDERATIONS
Bury in a secured landfill in accordance with all local, state and federal environmental regulations.

14. TRANSPORTATION INFORMATION
Not regulated

15. REGULATORY INFORMATION
CLEAN AIR ACT SECTION 611: Product neither contains nor is it manufactured with ozone depleting substances (ODS).

CORPORATE HEADQUARTERS: 469 North Harrison street • Princeton, New Jersey 08543-5297 • Phone (609) 683-5900

Appendix 5 Continued – Test Article Composition

CHURCH & DWIGHT CO., INC.

CONSUMER PRODUCTS • SPECIALTY PRODUCTS

MATERIAL SAFETY DATA SHEET

MSDS NUMBER: MSDS-1130 **ISSUE DATE: 12/02/11** **PAGE 4 OF 4**

CERCLA REPORTABLE QUANTITY: Contains no ingredients at levels that would be subject to reporting requirements.
RCRA: Not a hazardous material or a hazardous waste by listing or characteristic.

SARA TITLE III:
Section 302, Extremely Hazardous Substances: None
Section 311/312, Hazardous Categories: Immediate/Acute
Section 313, Toxic Chemicals: None
The ingredients in this product are reported in the EPA TSCA Inventory List and the Canadian DSL.

16. OTHER INFORMATION

SUPERSEDES DATE: New REASON FOR REVISION: New
For additional non-emergency health, safety and environmental information telephone 609.279.7705 or write to.

Church & Dwight Co., Inc.
Product Stewardship
469 North Harrison Street
Princeton, New Jersey 08543

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ATTACHMENT 9

MRD# 11-174

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ATTACHMENT 8

ISO 10993-10 Primary Rabbit Skin Irritation Study (ST-7433.4)

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Appendix 4- Test Article MSDS Sheet

CHURCH & DWIGHT CO., INC.

CONSUMER PRODUCTS • SPECIALTY PRODUCTS

MATERIAL SAFETY DATA SHEET

MSDS NUMBER: MSDS-1130 **ISSUE DATE: 12/02/11** **PAGE 1 OF 4**

1. PRODUCT AND COMPANY IDENTIFICATION

Product Name

Nirvana Arouses & Intensifies 1 A [EXP]

PRODUCT USE: Personal Lubricating Liquid
CHEMICAL NAME: Mixture
CHEMICAL FORMULA: Proprietary Mixture
SYNONYMS/COMMON NAMES: N/A

Church & Dwight Co., Inc.
469 N. Harrison Street
Princeton, NJ 08543

Information Phone:
1-888-367-6022

Medical Emergency Phone:
1-888-234-1828

Emergency Phone:
1-800-424-9300

2. HAZARDS IDENTIFICATION

EMERGENCY OVERVIEW

A clear to slightly hazy liquid. May cause eye irritation.
Not a fire hazard.
No significant health or environmental effects associated with this material.

HMIS Rating	
Health	0
Fire	0
Reactivity	0

Potential Health Effects

EYE: May cause irritation to eyes.
SKIN CONTACT: None.
INGESTION: None.
INHALATION: None.
SUBCHRONIC EFFECTS/CARCINOGENICITY: The ingredients in this product are not listed as carcinogens or potential carcinogens by NTP, IARC, OSHA, NIOSH, or ACGIH.

3. COMPOSITION/INFORMATION ON INGREDIENTS

Chemical Ingredient	(% by W)	CAS Number	OSHA PEL (8-hr TWA)	ACGIH LIMITS (8-hr TWA)
Cosmetic Fluid	90-99%	63148-62-9; 70131-67-8		None
Hexyl Nicotinate	<1%	23597-82-2	None	None
Vanillyl Butyl Ether	<1%	82654-98-6	None	

CORPORATE HEADQUARTERS: 469 North Harrison street • Princeton, New Jersey 08543-5297 • Phone (609) 683-5900

Appendix 4 Continued – Test Article MSDS Sheet

CHURCH & DWIGHT CO., INC.

CONSUMER PRODUCTS • SPECIALTY PRODUCTS

MATERIAL SAFETY DATA SHEET

MSDS NUMBER: MSDS-1130 **ISSUE DATE: 12/02/11** **PAGE 2 OF 4**

4. FIRST AID MEASURES

SKIN: Wash skin with plenty of water.
EYES: Flush eyes thoroughly with water for several minutes. Check for and remove contacts. Rinse eyes with clean flowing water for another 10 minutes. Seek medical attention if irritation develops.
INGESTION: No emergency medical treatment is necessary.
INHALATION: Remove to fresh air. Seek medical attention if symptoms persist.

5. FIRE FIGHTING MEASURES

FLAMMABLE PROPERTIES	FLAMMABLE LIMITS
FLASHPOINT: Not combustible	LFL: Not applicable
METHOD USED: Not applicable	UFL: Not applicable

EXTINGUISHING MEDIA: This material is non-combustible. Use extinguishing media appropriate for surrounding fire.
FIRE-FIGHTING INSTRUCTIONS: Carbon monoxide and carbon dioxide.
UNUSUAL FIRE AND EXPLOSION HAZARDS: None known.

6. ACCIDENTAL RELEASE MEASURES

Contain the spill, and depending on the consistency of the material, either pick up with absorbent material or scoop directly into a clean, dry container for later disposal. Wash away residue with plenty of water.

7. HANDLING AND STORAGE

Store in cool, dry areas and away from incompatible substances (see Section 10).

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

EXPOSURE LIMITS: Not established.
RESPIRATORY PROTECTION: Not required under normal handling conditions.
PROTECTIVE GLOVES: Impervious gloves recommended where prolonged or frequent contact could occur.
EYE PROTECTION: Safety glasses when handling bulk material.
OTHER PROTECTIVE CLOTHING OR EQUIPMENT: Impervious apron where splashing may occur.
PROTECTIVE WORK/HYGIENIC PRACTICES: No special requirements with respect to chemical exposure beyond those provided above. Requirements with respect to specific equipment and applications are the responsibility of the user.

9. PHYSICAL AND CHEMICAL PROPERTIES

APPEARANCE: Clear, colorless to slightly hazy liquid
ODOR: Characteristic.

CORPORATE HEADQUARTERS: 469 North Harrison street • Princeton, New Jersey 08543-5297 • Phone (609) 683-5900

Appendix 4 Continued – Test Article MSDS Sheet

CHURCH & DWIGHT CO., INC.

CONSUMER PRODUCTS • SPECIALTY PRODUCTS

MATERIAL SAFETY DATA SHEET

MSDS NUMBER: MSDS-1130 **ISSUE DATE: 12/02/11** **PAGE 3 OF 4**

PHYSICAL STATE:Gel
pH (1% SOLN. w/v): Not applicable
VAPOR PRESSURE: Not applicable
VAPOR DENSITY: Not applicable
BOILING POINT: Not applicable
FREEZING/MELTING POINT: Not applicable
SOLUBILITY IN WATER: Complete
DENSITY (g/cc): Approximately 1.12
VISCOSITY: 600-1500 cps
VOLATILE ORGANIC COMPOUNDS: Not applicable

10. STABILITY AND REACTIVITY

CHEMICAL STABILITY: Stable at ambient-room temperature range conditions.
CONDITIONS TO AVOID: Temperatures above 40°C (104°F).
INCOMPATIBILITY WITH OTHER MATERIALS: Incompatibilities include strong oxidizing agents.
HAZARDOUS DECOMPOSITION PRODUCTS: Decomposition may result in the release of carbon monoxide and carbon dioxide.
HAZARDOUS POLYMERIZATION: Not likely to occur.

11. TOXICOLOGICAL INFORMATION

Occupational exposure is not expected to produce adverse human health effects following normal workplace practices. Product has very low acute toxicity. No known chronic health effects. Direct eye contact may cause temporary discomfort with mild redness.

12. ECOLOGICAL INFORMATION

TOXICITY: This material is expected not to be toxic to aquatic life.
PERSISTENCE: This material is not expected to be persistent.
BIOACCUMULATION: This material is not expected to significantly bioaccumulate.

13. DISPOSAL CONSIDERATIONS

Bury in a secured landfill in accordance with all local, state and federal environmental regulations.

14. TRANSPORTATION INFORMATION

Not regulated

15. REGULATORY INFORMATION

CLEAN AIR ACT SECTION 611: Product neither contains nor is it manufactured with ozone depleting substances (ODS).

CORPORATE HEADQUARTERS: 469 North Harrison street • Princeton, New Jersey 08543-5297 • Phone (609) 683-5900

Appendix 4 Continued – Test Article Composition

CHURCH & DWIGHT CO., INC.

CONSUMER PRODUCTS • SPECIALTY PRODUCTS

MATERIAL SAFETY DATA SHEET

MSDS NUMBER: MSDS-1130 **ISSUE DATE: 12/02/11** **PAGE 4 OF 4**

CERCLA REPORTABLE QUANTITY: Contains no ingredients at levels that would be subject to reporting requirements.
RCRA: Not a hazardous material or a hazardous waste by listing or characteristic.

SARA TITLE III:
Section 302, Extremely Hazardous Substances: None
Section 311/312, Hazardous Categories: Immediate/Acute
Section 313, Toxic Chemicals: None
The ingredients in this product are reported in the EPA TSCA Inventory List and the Canadian DSL.

16. OTHER INFORMATION

SUPERSEDES DATE: New **REASON FOR REVISION: New**
For additional non-emergency health, safety and environmental information telephone 609.279.7705 or write to:

Church & Dwight Co., Inc.
Product Stewardship
469 North Harrison Street
Princeton, New Jersey 08543

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Exhibit B

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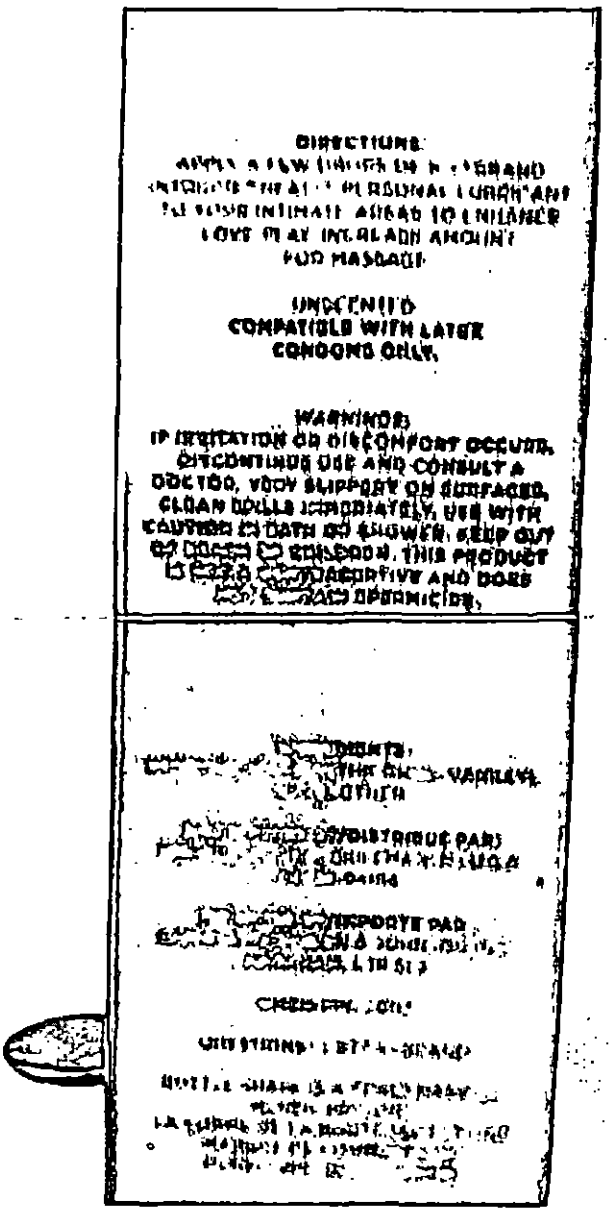
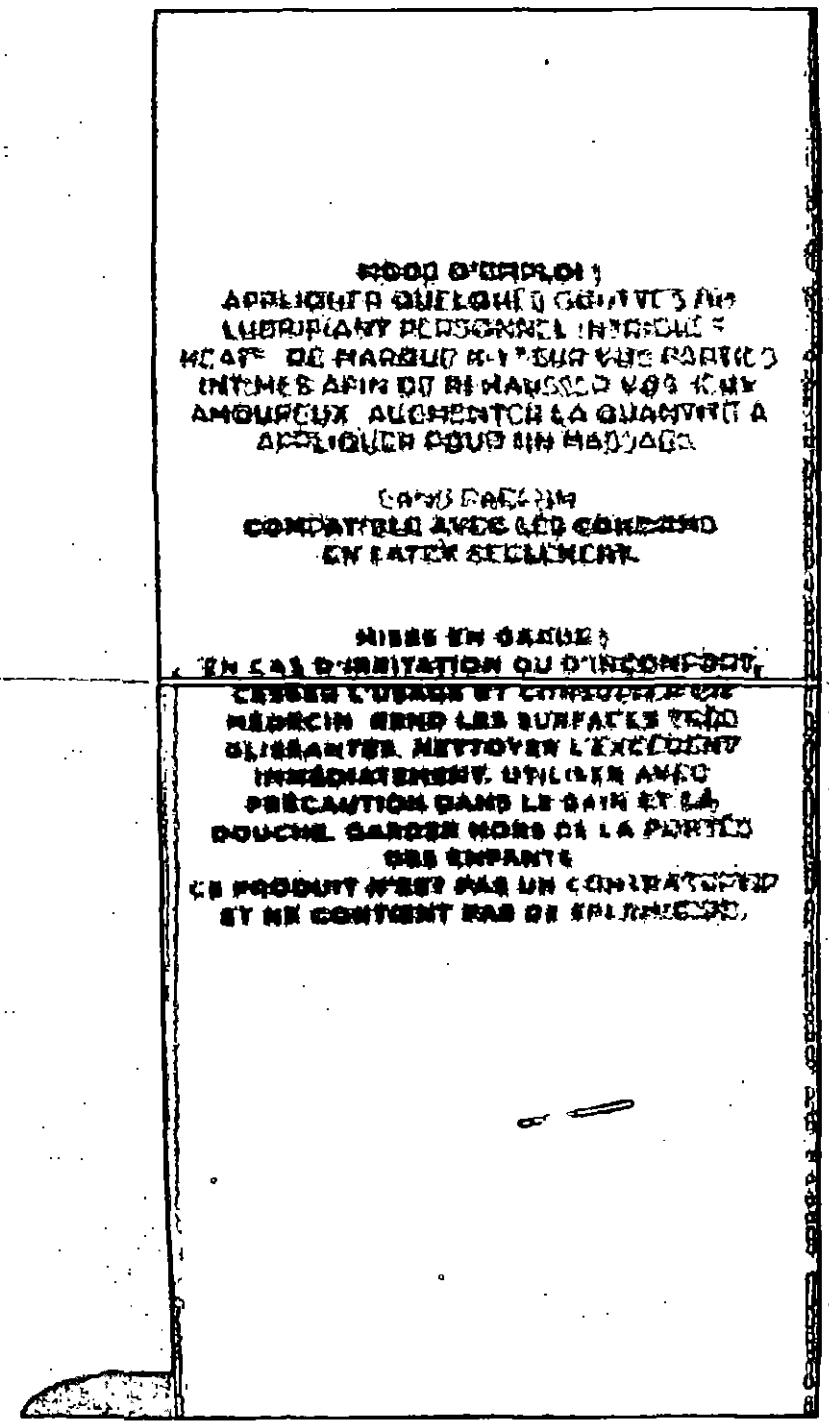
Exhibit C

K-Y® Brand Intrigue™ Intense Warming Sensation
(Marketed as "K-Y Brand Intrigue™ Heat™")
Carton Principal Display Panel

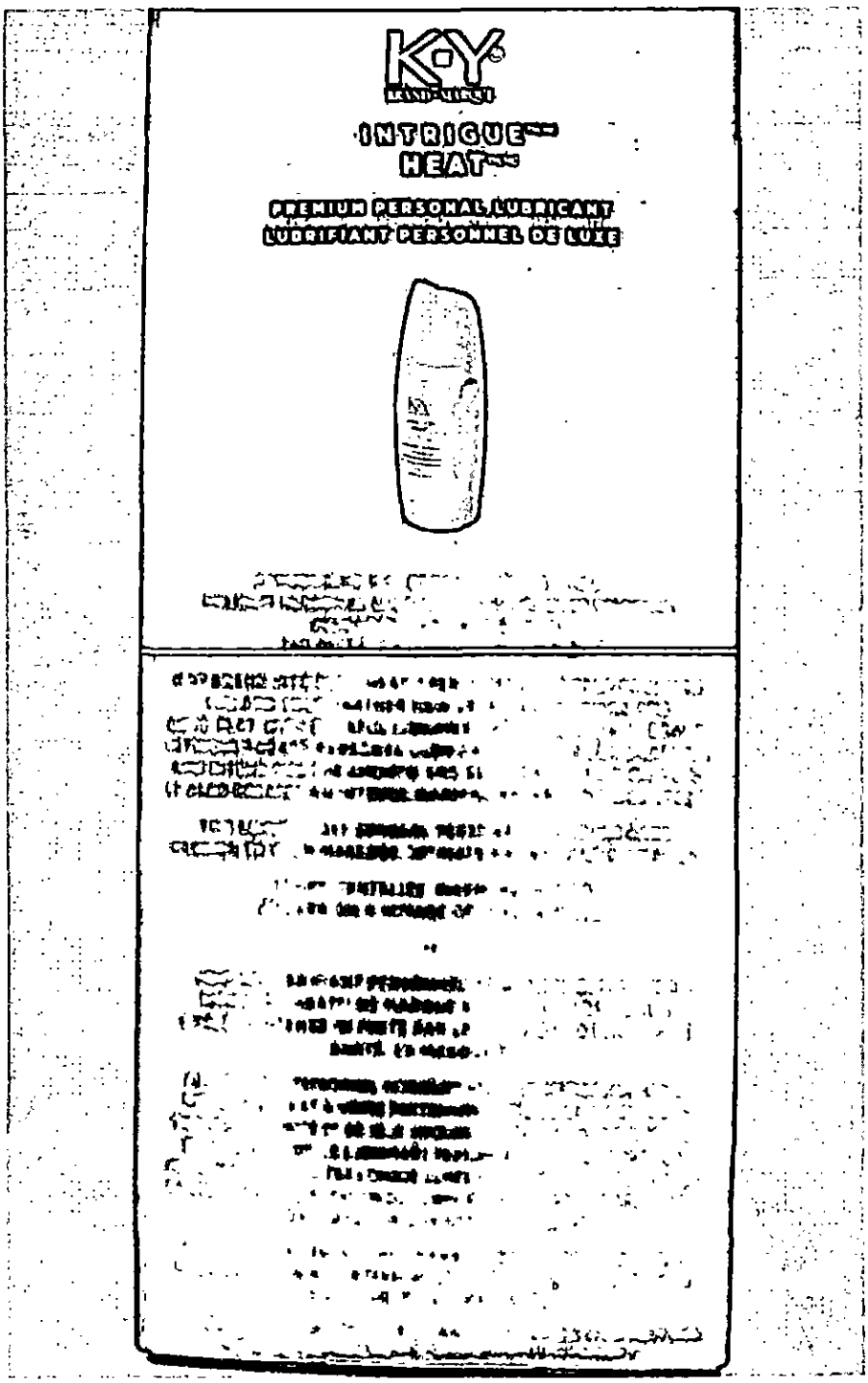
K-Y® Brand Intrigue™ Intense Warming Sensation – Carton Side Panel A



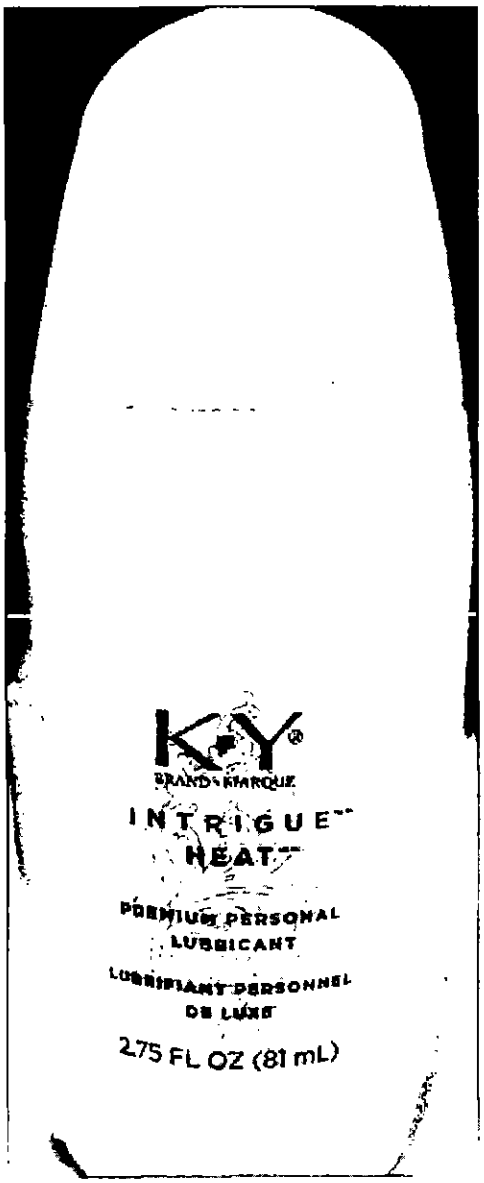
K-Y® Brand Intrigue™ Intense Warming Sensation – Carton Side Panel B



K-Y® Brand Intrigue™ Intense Warming Sensation – Carton Back Panel



K-Y® Brand Intrigue™ Intense Warming Sensation – Bottle Front Panel



K-Y® Brand Intrigue™ Intense Warming Sensation – Bottle Back Panel

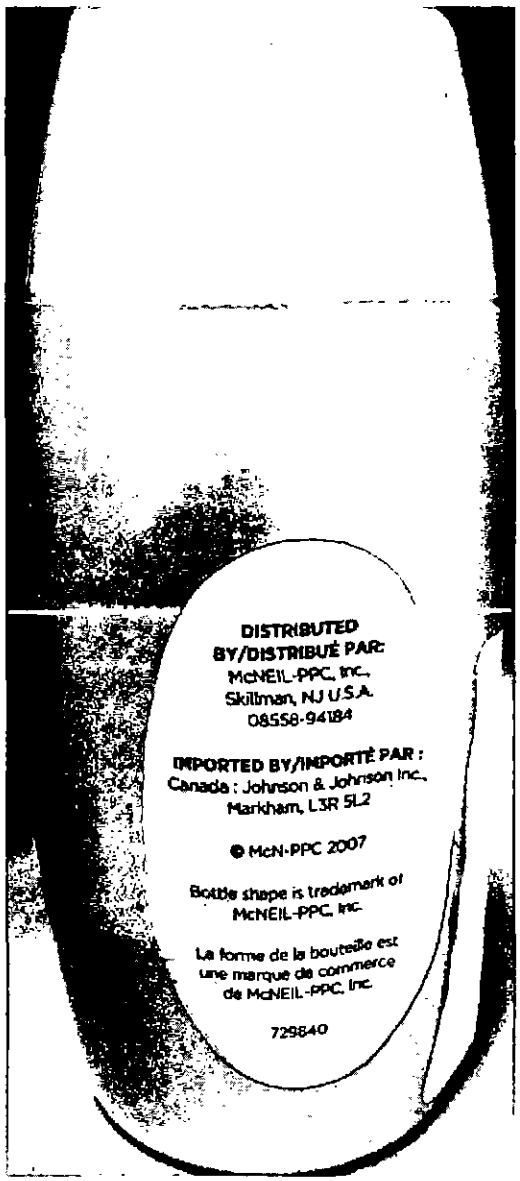


Exhibit D

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Exhibit E

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Exhibit G

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Exhibit H

See OMB Statement on Reverse. Form Approved: OMB No. 0910-0616; Expiration Date: 2-28-2015

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Certification of Compliance, under 42 U.S.C. § 282(j)(5)(B), with Requirements of ClinicalTrials.gov Data Bank (42 U.S.C. § 282(j))

(For submission with an application/submission, including amendments, supplements, and resubmissions, under §§ 505, 515, 520(m), or 510(k) of the Federal Food, Drug, and Cosmetic Act or § 351 of the Public Health Service Act.)

SPONSOR / APPLICANT / SUBMITTER INFORMATION

1. NAME OF SPONSOR/APPLICANT/SUBMITTER
Church & Dwight Co., Inc.

2. DATE OF THE APPLICATION/SUBMISSION WHICH THIS CERTIFICATION ACCOMPANIES
Nov 6, 2012

3. ADDRESS *(Number, Street, State, and ZIP Code)*
469 North Harrison Street
Princeton, NJ 08543

4. TELEPHONE AND FAX NUMBERS *(Include Area Code)*
(Tel.) (609) 497-7448
(Fax) (609) 497-7179

PRODUCT INFORMATION

5. **FOR DRUGS/BIOLOGICS:** Include Any/All Available Established, Proprietary and/or Chemical/Biochemical/Blood/Cellular/Gene Therapy Product Name(s)
FOR DEVICES: Include Any/All Common or Usual Name(s), Classification, Trade or Proprietary or Model Name(s) and/or Model Number(s)
(Attach extra pages as necessary)

TROJAN™ Personal Lubricant

Nirvana- D Personal Lubricant

APPLICATION / SUBMISSION INFORMATION

6. TYPE OF APPLICATION/SUBMISSION WHICH THIS CERTIFICATION ACCOMPANIES

☐ IND ☐ NDA ☐ ANDA ☐ BLA ☐ PMA ☐ HDE ☒ 510(k) ☐ PDP ☐ Other

7. INCLUDE IND/NDA/ANDA/BLA/PMA/HDE/510(k)/PDP/OTHER NUMBER *(If number previously assigned)*

8. SERIAL NUMBER ASSIGNED TO APPLICATION/SUBMISSION WHICH THIS CERTIFICATION ACCOMPANIES

CERTIFICATION STATEMENT / INFORMATION

9. CHECK ONLY ONE OF THE FOLLOWING BOXES *(See instructions for additional information and explanation)*

☒ A. I certify that the requirements of 42 U.S.C. § 282(j), Section 402(j) of the Public Health Service Act, enacted by 121 Stat. 823, Public Law 110-85, do not apply because the application/submission which this certification accompanies does not reference any clinical trial.

☐ B. I certify that the requirements of 42 U.S.C. § 282(j), Section 402(j) of the Public Health Service Act, enacted by 121 Stat. 823, Public Law 110-85, do not apply to any clinical trial referenced in the application/submission which this certification accompanies.

☐ C. I certify that the requirements of 42 U.S.C. § 282(j), Section 402(j) of the Public Health Service Act, enacted by 121 Stat. 823, Public Law 110-85, apply to one or more of the clinical trials referenced in the application/submission which this certification accompanies and that those requirements have been met.

10. IF YOU CHECKED BOX C, IN NUMBER 9, PROVIDE THE NATIONAL CLINICAL TRIAL (NCT) NUMBER(S) FOR ANY "APPLICABLE CLINICAL TRIAL(S)," UNDER 42 U.S.C. § 282(j)(1)(A)(i), SECTION 402(j)(1)(A)(i) OF THE PUBLIC HEALTH SERVICE ACT, REFERENCED IN THE APPLICATION/ SUBMISSION WHICH THIS CERTIFICATION ACCOMPANIES *(Attach extra pages as necessary)*

NCT Number(s):

The undersigned declares, to the best of her/his knowledge, that this is an accurate, true, and complete submission of information. I understand that the failure to submit the certification required by 42 U.S.C. § 282(j)(5)(B), section 402(j)(5)(B) of the Public Health Service Act, and the knowing submission of a false certification under such section are prohibited acts under 21 U.S.C. § 331, section 301 of the Federal Food, Drug, and Cosmetic Act. Warning: A willfully and knowingly false statement is a criminal offense, U.S. Code, title 18, section 1001.

11. SIGNATURE OF SPONSOR/APPLICANT/SUBMITTER OR AN AUTHORIZED REPRESENTATIVE (Sign)

12. NAME AND TITLE OF THE PERSON WHO SIGNED IN NO. 11
(Name) Jeffrey Shaul
(Title) Director, Regulatory Affairs

13. ADDRESS *(Number, Street, State, and ZIP Code) (of person identified in Nos. 11 and 12)*
469 North Harrison Street
Princeton, NJ 08543

14. TELEPHONE AND FAX NUMBERS *(Include Area Code)*
(Tel.) (609) 497-7448
(Fax) (609) 497-7179

15. DATE OF CERTIFICATION
6-Nov-2012

PSC Publishing Services (301) 443-6740 EF

Exhibit I

Form Approved: OMB No. 0910-0120; Expiration Date: 12/31/13

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]

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

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)?	☐	☒
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
D7661-10 Standard Test Method for Determining Compatibility of Personal Lubricants with natural Rubber Latex Condoms

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
7	Sampling Overview, Sample Groups, Sample Size	☐ Yes ☐ No ☒ N/A

TYPE OF DEVIATION OR OPTION SELECTED *
Inclusion of lubricated latex and lubricated synthetic polyisopren condoms into the test sampling plan.

DESCRIPTION
D7661-10 Section 7 specifies using non-lubricated natural latex condoms only

JUSTIFICATION
Adding lubricated latex and lubricated synthetic polyisoprene condoms to the testing plan was conducted to better reflect actual use conditions with the consumer

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
12	Report	☐ Yes ☒ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED *
Exclusion of Relative humidity

DESCRIPTION
The laboratory relative humidity was not recorded during testing.

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		☐ Yes ☐ No ☐ 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.

Form Approved: OMB No. 0910-0120; Expiration Date: 12/31/13

Department of Health and Human Services
Food and Drug Administration

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]

ASTM D3492:2008, Standard Specification for Rubber Contraceptives (Male Condom), 9/8/2009

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? 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

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EXTENT OF STANDARD CONFORMANCE
SUMMARY REPORT TABLE

STANDARD TITLE
D3492:2008 Standard Specification for Rubber Contraceptives (Male Condoms)

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
X1.4.1	Method-Condom Preparation	[ ] Yes [X] No [ ] N/A

TYPE OF DEVIATION OR OPTION SELECTED ◆
Pre-lubricated condoms did not receive the lubricant removal process treatment before preparing ring specimens for tensile measurements as required in D7661-10

DESCRIPTION
The deviation was made to better simulate actual use conditions between lubricated latex condoms and personal lubricants

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
X1.4.8	Method- Test Report	[ ] Yes [X] No [ ] N/A

TYPE OF DEVIATION OR OPTION SELECTED ◆
Per D7661-10, ring tensile specimens are evaluated for Break Force and % Elongation at Break

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
4	Requirements	[ ] Yes [ ] No [X] N/A

TYPE OF DEVIATION OR OPTION SELECTED ◆
Exclusion of Dimensions and Leakage testing

DESCRIPTION
Specific tests in D3492 are used to support D7661-10. Dimensions and leakage testing are not required and were excluded from the study

JUSTIFICATION
Per D7661-10, dimensions and leakage testing are not part of latex condoms- personal lubricant compatibility evaluation.

* 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.

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Paperwork Reduction Act Statement

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TYPE OF 510(K) SUBMISSION

☒ Traditional ☐ Special ☐ Abbreviated

STANDARD TITLE [1]

ISO 10993-5:2009, Biological evaluation of medical devices -- Part 5: Tests for In Vitro cytotoxicity, 05/05/2010

Please answer the following questions	Yes	No
Is this standard recognized by FDA [2]?	☒	☐
FDA Recognition number [3]	#2-153	
Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?	☒	☐
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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: ISO 10993-12:2007: Biological Evaluation of Medical Devices -- Part 12: Sample preparation and referenc

[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

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
	See Exhibit A, Attachment 3, page 9 of 10	☐ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ♦

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		☐ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ♦

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
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TYPE OF DEVIATION OR OPTION SELECTED ♦

DESCRIPTION

JUSTIFICATION

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TYPE OF 510(K) SUBMISSION

☒ Traditional ☐ Special ☐ Abbreviated

STANDARD TITLE [1]

ISO 10993-10:2010, Biological evaluation of medical devices - Part 10: Tests for irritation and skin sensitization.;3/16/2012

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)?	☒	☐
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.	☐	☒
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Title of guidance: ISO 10993-12:2007 Biological evaluation of Medical Devices - Part 12: Sample preparation and reference

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[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

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
	See Exhibit A, Attachment 4, page 13 of 18	☐ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ◆

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		☐ Yes ☐ No ☐ 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]

ISO 10993-10:2010, Biological evaluation of medical devices - Part 10: Tests for irritation and skin sensitization.;3/16/2012

Please answer the following questions	Yes	No
Is this standard recognized by FDA [2]?	☒	☐
FDA Recognition number [3]	#2-173	
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Title of guidance: ISO 10993-12:2007 Biological evaluation of Medical Devices - Part 12: Sample preparation and reference

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EXTENT OF STANDARD CONFORMANCE SUMMARY REPORT TABLE

STANDARD TITLE

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
	See Exhibit A, Attachment 5, page 13 of 18	☐ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ◆

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		☐ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ◆

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
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TYPE OF 510(K) SUBMISSION

☒ Traditional ☐ Special ☐ Abbreviated

STANDARD TITLE [1]

ISO 10993-11 Biological evaluation of medical devices-- Part 11: Test for systemic toxicity; 3/16/2012

Please answer the following questions	Yes	No
Is this standard recognized by FDA [2]?	☒	☐
FDA Recognition number [3]	#2-118	
Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?	☒	☐
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Title of guidance: ISO 10993-12:2007: Biological Evaluation of Medical Devices-- Part 12: Sample preparation and ref.

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EXTENT OF STANDARD CONFORMANCE SUMMARY REPORT TABLE

STANDARD TITLE

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
	See Exhibit A, Attachment 6, page 11 of 16	☐ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED •

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		☐ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED •

DESCRIPTION

JUSTIFICATION

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STANDARD TITLE [1]

ISO 10993-10:2010, Biological evaluation of medical devices - Part 10: Tests for irritation and skin sensitization.;3/16/2012

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Is this standard recognized by FDA [2]?	☒	☐
FDA Recognition number [3]	#2-173	
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Title of guidance: ISO 10993-12:2007 Biological evaluation of Medical Devices - Part 12: Sample preparation and reference

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EXTENT OF STANDARD CONFORMANCE SUMMARY REPORT TABLE

STANDARD TITLE

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
	See Exhibit A, Attachment 7, page 15 of 20	☐ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ♦

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		☐ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ♦

DESCRIPTION

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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.

Paperwork Reduction Act Statement

Public reporting burden for this collection of information is estimated to average 1 hour 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:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
1350 Piccard Drive, Room 400
Rockville, MD 20850

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.

Form Approved: OMB No. 0910-0120; Expiration Date: 12/31/13

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 10993-10:2010, Biological evaluation of medical devices - Part 10: Tests for irritation and skin sensitization.;3/16/2012

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)?	☒	☐
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: ISO 10993-12:2007 Biological evaluation of Medical Devices - Part 12: Sample preparation and reference

[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

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
	See Exhibit A, Attachment 8, page 11 of 16	☐ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ♦

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		☐ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ♦

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		☐ Yes ☐ No ☐ 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.

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Rockville, MD 20850

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

Mawii, Lal Pek *

From:	Microsoft Outlook
To:	Emily.Perez@churchdwight.com
Sent:	Monday, July 01, 2013 9:15 AM
Subject:	Relayed: K123427 - SE Close Out Letter

Delivery to these recipients or groups is complete, but no delivery notification was sent by the destination server:

Emily.Perez@churchdwight.com (Emily.Perez@churchdwight.com)

Subject: K123427 - SE Close Out Letter

5

Mawii, Lal Pek *

From: Microsoft Outlook
To: DCCLetters
Sent: Monday, July 01, 2013 9:15 AM
Subject: Delivered: K123427 - SE Close Out Letter

Your message has been delivered to the following recipients:

DCCLetters (DCCLetters@fda.hhs.gov)

Subject: K123427 - SE Close Out Letter

6

DEPARTMENT OF HEALTH AND HUMAN SERVICES **MEMORANDUM**

Food and Drug Administration
Office of Device Evaluation
10903 New Hampshire Avenue
Silver Spring, MD 20993

Premarket Notification [510(k)] Review
Traditional

K123427/S1

Date: June 24, 2013
To: The Record
From: Haijing Hu

Office: ODE
Division: DRGUD
Branch: OGDB

510(k) Holder:	Church & Dwight Co., Inc.
Device Name:	Nirvana D Personal Lubricant
Contact:	Emily Perez, Regulatory Affairs
Address:	469 North Harrison Street, Princeton, NJ 08543
Phone:	(609) 688-5347
Fax:	(609) 497-7179
Email:	Emily.Perez@churchdwight.com

I. Purpose and Submission Summary

The purpose of this 510(k) submission is to introduce Nirvana D personal lubricant into interstate commerce. Personal lubricants are regulated as Class II devices under the condom regulation (21 CFR § 884.5300) with the product code NUC. When reviewing a 510(k) for a personal lubricant, we analyze device description, indications for use, predicate device comparison, labeling, shelf-life, biocompatibility, and condom compatibility. OGDB has a review checklist for personal lubricants.

(b)(4) Trade Secret Process - Product Specs

[redacted]

II. Administrative Requirements

	Yes	No	N/A
Indications for Use Form – OTC	X		
Truthful and Accuracy Statement	X		
510(k) Summary	X		
Standards Data Report for 510(k) Form (Form 3654)	X		
ClinicalTrials.gov Data Bank Form (Form 3674)	X		

Indications for Use Form – Acceptable

510(k) Summary – Acceptable
The 510(k) summary in S1 listed the device name as "Nirvana D (TBD)". Per FDA request, the sponsor removed TBD.

Standards Data Report for 510(k) Form (Form 3654) - The sponsor provided complete Standards Data Report forms (Form 3654) for the following standards referenced in this submission. The standards the sponsor referenced are the most recent, FDA recognized versions of the standard.

- ASTM D3492:2008 Standard Specification for Rubber Contraceptives (Male Condom)
- ASTM D7661-10 Standard Test Method for Determining Compatibility of Personal Lubricants with Natural Rubber Latex Condoms
- ISO 10993-1:2010 Biological Evaluation of Medical Devices, Part 1
- ISO 10993-5:2009 Biological Evaluation of Medical Devices, Part 5 – Tests for In Vitro Cytotoxicity
- ISO 10993-10:2010 Biological Evaluation of Medical Devices, Part 10 – Tests for Irritation and Delayed-Type Hypersensitivity
- ISO 10993-11:2006 Biological Evaluation of Medical Devices, Part 11 – Tests for Systemic Toxicity

After the first round of the review, Dr. Luo asked the sponsor to include the most updated standards to perform the shelf life and stability testing. The sponsor added forms for USP <61> and USP <62>. This is acceptable. I did not use these forms to complete my review.

Truthful and Accuracy Statement – Acceptable

ClinicalTrials.gov Data Bank Form (Form 3674) – Acceptable
The sponsor submitted in the original submission a ClinicalTrials.gov Data Bank Form (Form 3674) in which they stated that the 510(k) submission did not reference a clinical trial. However, the submission includes a consumer preference test which evaluated human subjects. Per FDA request, the sponsor provided in S1 a revised ClinicalTrials.gov Data Bank Form stating that the submission referenced a clinical study that did not need to be registered on clincialtrials.gov (option B).

III. Device Description

	Yes	No	N/A
Is the device life-supporting or life sustaining?		X	

10

	Yes	No	N/A
Is the device an implant (implanted longer than 30 days)?		X	
Does the device design use software?		X	
Is the device sterile?		X	
Is the device reusable (not reprocessed single use)?		X	
Are "cleaning" instructions included for the end user?			X

The sponsor stated that Nirvana D Personal Lubricant is an anhydrous, non-sterile, silicone-based personal lubricant compatible with natural rubber latex and polyisoprene condoms. The lubricant is packaged in a 3.5 oz bottle (primary packaging) and a carton box (secondary packaging).

In the original submission, the sponsor used "Trojan Aroused & Intensifies" as the device name in some places. In S1, the sponsor decided to use Nirvana D. Per FDA request, the sponsor revised the 510(k) summary and only used Nirvana D as device name.

The sponsor provided the formulation information which I summarized in the table below.

Ingredient	Function	CAS Number	% w/w	Supplier
Dimethylpolysiloxane	Lubricant, (b)(4) Trade Secret	63148-62-9	(b)(4) Trade Secret	(b)(4) (b)(4) Trade
Dimethylpolysiloxane, Hydroxyl-terminated	Lubricant, (b)(4) Trade S t P	70131-67-8		
Vanillyl Butyl Ether	(b)(4) Trade	82654-98-6	(b)	(b)(4) Trade
Hexyl Nicotinate	(b)(4) Trade Secret	23597-82-2	(b)	(b)
Total			100.00	

The sponsor did not provide the specifications for the subject lubricant in the original submission, although they evaluated viscosity, odor, color, appearance and microbial limits as part of shelf life testing. In S1, they stated that the specifications for the subject lubricant are same as the parameters in shelf life testing. The specifications are listed on page 283 of the original submission.

Because this device is a non-water based formulation, osmolality, pH and antimicrobial effectiveness are not applicable. Information on microbial counts was not provided in the original submission. Per FDA request, the information was provided in S1. The microbial limit meets the FDA expectation and is acceptable.

All the specifications are summarized in the table below.

Characteristic	Specification
Appearance	Viscous liquid
Odor	Mild odor of hexyl nicotinate

C1

Viscosity	400 - 800 cpm
Microbial count	Total aerobic microbial count (TAMC) < 100 cfu/g Total yeast and mold count (TYMC) < 10 cfu/g Negative for Candida albicans, Pseudomonas aeruginosa, Staphylococcus aureus, and gram negative bacteria.

The device description is acceptable.

IV. Indications for Use

The sponsor proposed the following *Indications for Use*:

Nirvana D 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 and polyisoprene condoms. Not compatible with polyurethane and other condoms.

The Indications for Use is in line with FDA recommended format. This is acceptable.

V. Predicate Device Comparison

Predicate Device Description

The manufacturer's proposed predicate device is the K-Y® Brand Intrigue™ Intense Warming Sensation (K072360). The predicate device is also a silicone-based personal lubricant. I summarized the similarities and differences between the two devices in the table below.

	Nirvana D Personal Lubricant K123427	**K-Y® Brand Intrigue™ K072360**
Indications for Use	Nirvana D 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 and polyisoprene condoms. Not compatible with polyurethane and other condoms.	K-Y Brand Intrigue Intense Warming Sensation is intended as a personal lubricant for penile and vaginal application compatible with latex condom[s]
Formulation	Dimethicone/Dimethiconol (b)(4) Vanillyl butyl ether (b)(4) Hexyl nicotinate (Warming/Tingling agent) (b)(4)	Dimethicone/Dimethiconol 99.98% Vanillyl butyl ether 0.02%
Specifications	Appearance: viscous liquid	Appearance: viscous liquid

Biocompatibility testing was conducted at (b)(4) [redacted]. The sponsor submitted the following biocompatibility test reports for the subject lubricant:

- Rabbit Vaginal Irritation Study (in accordance with ISO 10993-10, 2010)
- Rabbit Penile Irritation Study (in accordance with ISO 10993-10 and 10993-2, 2002)
- Guinea Pig Maximization Sensitization Test (in accordance with ISO 10993-10,2010)
- In Vitro Cytotoxicity (in accordance with ISO 10993-5, 2009)
- Acute Systemic Toxicity (in accordance with ISO 10993-11, 2006).
- Rabbit Skin irritation study (in accordance with ISO 10993-10, 2010).

The previous lead reviewer reviewed the biocompatibility tests with the (b)(4) biocompatibility checklists. (b)(4) Trade Secret Process - Product Specs [redacted]. Dr. Cochran reviewed the test report and stated the test report was acceptable.

Biocompatibility information is complete.

IX. Software

This section does not apply to this submission.

X. Electromagnetic Compatibility and Electrical, Mechanical and Thermal Safety

This section does not apply to this submission.

XI. Performance Testing – Bench

Condom Compatibility

Condoms compatibility was evaluated using the subject device per ASTM D7661-10 test methods. The sponsor evaluated three different brands of lubricated and unlubricated NRL condoms (Trojan ENZ, Lifestyle Ultrasensitive, Durex Natural Feeling and Durex Extra Sensitive), as well as one brand of polyisoprene condoms (Durex Avanti Bare).

The sponsor calculated the percentage difference between the test articles and the control condoms and provided the test results in the table below.

Condom Compatibility Test Results (Percent Change from Control)

		Natural Latex- Non-lubricated			Natural Latex-lubricated				Synthetic Latex
		Trojan ENZ	Lifestyles Ultra Sensitive	Durex Natural Feeling	Trojan ENZ	Trojan Ultra Thin	Lifestyles Ultra Sensitive	Durex Extra Sensitive	Durex Avanti Bare
Break Force	% Difference	*2.83*	*-5.71*	*-0.38*	*-13.67*	*1.83*	*-11.57*	*-4.98*	*-7.99*
Elongation	%	*1.21*	*0.60*	*0.37*	*-2.35*	*-1.97*	*-2.41*	*-2.13*	*-0.21*

	Difference								
Burst Pressure	% Difference	*-5.33*	*0.51*	*7.65*	*-8.06*	*-21.60*	*-1.79*	*20.42*	*25.58*
Burst Volume	% Difference	*5.55*	*-30.16*	*-20.25*	*0.23*	*-17.82*	*-7.30*	*-1.41*	*9.19*

(b)(4) Trade Secret Process - Product Specs

[redacted]

Information on condom compatibility testing is complete.

XII. Performance Testing – Animal

This section does not apply to this submission.

XIII. Performance Testing – Clinical

(b)(4) Trade Secret Process - Product Specs

[redacted]

The clinical performance testing is acceptable.

XIV. Substantially Equivalent Discussions.

1. Same Indication Statement?	Yes		If **YES** = Go To 3
2. Do Differences Alter The Effect Or Raise New Issues of Safety Or Effectiveness?			If **YES** = Stop **NSE**
3. Same Technological Characteristics?	Yes		If **YES** = Go To 5
4. Could The New Characteristics Affect Safety Or Effectiveness?			If **YES** = Go To 6
5. Descriptive Characteristics Precise Enough?		No	If **NO** = Go To 8 If **YES** = Stop **SE**
6. New Types Of Safety Or Effectiveness Questions? 7. Accepted Scientific Methods Exist?			If **YES** = Stop **NSE** If **NO** = Stop **NSE**
8. Performance Data Available?	Yes		If **NO** = Request Data
9. Data Demonstrate Equivalence?	Yes		Final Decision: SE

1. Explain how the new indication differs from the predicate device's indication:
N/A
2. Explain why there is or is not a new effect or safety or effectiveness issue:
N/A
3. Describe the new technological characteristics:
N/A
4. Explain how new characteristics could or could not affect safety or effectiveness:
N/A
5. Explain how descriptive characteristics are not precise enough:
Performance data are needed to assess SE, particularly to evaluate shelf life, biocompatibility, and condom compatibility.
6. Explain new types of safety or effectiveness question(s) raised or why the question(s) are not new:
N/A
7. Explain why existing scientific methods cannot be used:
N/A
8. Explain what performance data is needed:
N/A
9. Explain how the performance data demonstrates that the device is or is not substantially equivalent:
The performance data demonstrated that the subject device maintains its specification over its proposed shelf-life, is biocompatible, and is compatible to natural rubber latex and polyisoprene condoms. The data demonstrate the device was SE to the predicate device.

XV. Contact History

June 19, 2013	Emailed sponsor for additional information
June 21, 2013	Sponsor emailed response

	Odor: mild odor of hexyl nicotinate Viscosity: 400-800 cps Microbial limits: TAMC < 100 cfu/g TYMC < 10 cfu/g Negative for relevant pathogens	Odor: odorless Viscosity: 30-270 cps Microbial limits: information not found in IMAGE 2000
Condom compatibility	Compatible with natural rubber latex and polyisoprene condoms	Compatible with natural rubber latex condoms
Shelf life	Two years	Two years
Sterility	non-sterile	non-sterile

Substantial Equivalence Discussion

Indications for Use

(b)(4) Trade Secret Process - Product Specs [redacted]

Technological Characteristics

As shown in the comparison table, both subject and predicate lubricants are silicone-based: They both contain dimethicone, dimethiconol and vanillyl butyl ether with variation in concentrations. The subject lubricant has hexyl nicotinate, which is not present in the predicate. However, because the subject and predicate devices have predominately the same ingredients, I believe they have the same technological characteristics.

Performance data

Descriptive characteristics are not precise enough to ensure equivalence because they are not sufficient to assess biocompatibility, condom compatibility, and shelf life. The sponsor provided sufficient performance data to address these concerns and demonstrate substantial equivalence of the subject device.

VI. Labeling

The sponsor provided the draft labeling for the primary packaging (bottle) and the secondary packaging (carton box).

During the first round of review, the previous lead reviewer asked the sponsor to make the following revisions:

- Include the Indications for Use on the bottle, the primary packaging.
- Add the following information to both primary and secondary packaging.
  - Storage conditions.
  - Final trade name in place of "Nirvana D" in the labeling.

- State "the lubricant causes a warming/tingling sensation".
- Add statement "May cause burning and irritation"

The sponsor provided a revised labeling in Attachment 5 of S1. They made the above requested changes. They stated that they would include date information, but it is not clear if they meant manufacturing date or expiration date. During interactive review, the sponsor confirmed that the expiration date would be provided on the bottle bottom panel.

I summarized the labeling information on the primary packaging in the table below.

Required labeling information on the primary packaging (bottle)	**Presented and acceptable (Y/N)**
Sponsor name & contact information	Y
Product name	Y
Product description	Y
Indication for use statement	Y
Direction for use	Y
Volume of product	Y
Storage conditions	Y
Lot number	Y
Expiration date	Y
List of ingredients	Y
Statement regarding condom compatibility	Y
Appropriate warning statements, • If irritation or discomfort occurs, discontinue use and see a doctor • This is not a contraceptive or spermicide	Y
Any inappropriate labeling claim	N

The information on labeling is complete.

VII. Packaging & Sterilization/Shelf Life/Reuse

Packaging

The subject lubricant will be packaged in a 3.5 oz bottle as primary packaging and a carton box as secondary packaging.

Sterilization

The subject lubricant is provided non-sterile.

Shelf-Life

(b)(4) Trade Secret Process - Product Specs [redacted]

[redacted]

(b)(4) Trade Secret Process - Product Specs

[redacted]

Shelf life information is complete.

VIII. Biocompatibility

(b)(4) Trade Secret Process - Product Specs

[redacted]

XVI. Recommendation

The sponsor addressed all the deficiencies identified in the AI letter dated Jan. 4, 2013. I recommend that the device is determined as SE to the predicate device.

Regulation Number:	**21 CFR 884.5300**
Regulation Name:	**Condom**
Regulatory Class:	**Class II**
Product Code:	**NUC**

Digital Signature Concurrence Table	
Reviewer Sign-Off	Haijing Hu, PhD 2013.06.28 10:00:07 -04'00'

(b)(4) Trade Secret Process - Product Specs

[redacted]

(b)(4) Trade Secret Process - Product Specs

[redacted]

(b)(4) Trade Secret Process - Product Specs

[redacted]

(b)(4) Trade Secret Process - Product Specs

[redacted]

(b)(4) Trade Secret Process - Product Specs

[redacted]

(b)(4) Trade Secret Process - Product Specs

[redacted]

Hu, Haijing

From: Perez, Emily <Emily.Perez@churchdwight.com>
Sent: Friday, June 21, 2013 1:14 PM
To: Hu, Haijing
Subject: K123427S1 Nirvana D personal lubricant
Attachments: IFU_Revised 6.21.13.pdf; Revised 510(k) Summary_6.21.13.pdf; Amendment to vaginal irritation final report ST-7484.pdf; Updated Nirvana D stability data 6.20.13.pdf; Nirvana_D_microbial limits-candida albicans.pdf

Haijing,

Enclosed please find our response to your request for additional information. The requests for additional information are reiterated below, each followed by our response to the requested information.

(b)(4) Trade Secret Process - Product Specs

[redacted]

(b)(4) Trade Secret Process - Product Specs

[redacted]

Thanks,
Emily

Emily Perez
Regulatory Affairs

Church & Dwight Co., Inc.
469 North Harrison St.
Princeton, NJ 08543
Tel: (609) 806-1430

From: Hu, Haijing [mailto:Haijing.Hu@fda.hhs.gov]
Sent: Wednesday, June 19, 2013 2:33 PM
To: Perez, Emily
Subject: K123427S1 Nirvana D personal lubricant

Emily,

We are reviewing your 510(k) submission and have the following questions.

(b)(4) Trade Secret Process - Product Specs

[redacted]

Thank you.

Haijing

I. Indications For Use

510(k) Number (if known): K123427

Device Name: Nirvana D Personal Lubricant

INDICATIONS FOR USE:

Nirvana D is a personal lubricant for penile and/or vaginal application, intended to lubricate and moisturize, 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. Not compatible with polyurethane or other condoms.

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ____ OR Over-The-Counter Use __X__
(Part 21 C.F.R. 801 Subpart D) (21 C.F.R. 801 Subpart C)

II. 510(k) Summary

Submitter Name:	Church & Dwight Co., Inc.
Submitter Address:	469 North Harrison Street Princeton, NJ 08543
Contact Person:	Emily Perez Senior Regulatory Affairs Specialist Church & Dwight Co., Inc. 469 North Harrison Street Princeton, NJ 08543 Tel: (609) 806-1430 Fax: (609) 403-7415
Date Prepared:	May 28, 2013
510(k) Number:	K123427
Device Trade Name:	Nirvana D Personal Lubricant
Device Common Name:	Personal Lubricant
Product Code:	NUC – Condom (21 C.F.R. § 884.5300)
Classification:	Class II
Predicate Device:	K-Y® Brand Intrigue™ Intense Warming Sensation (K072360)
Intended Use:	Nirvana D is a personal lubricant for penile and/or vaginal application, intended to lubricate and moisturize, 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. Not compatible with polyurethane or other condoms.
Device Description:	The Nirvana D Personal Lubricant is an anhydrous, non-sterile, clear silicone-based personal lubricant composed of dimethicone, dimethiconol, vanillyl butyl ether ("VBE") and hexyl nicotinate. Nirvana D Personal Lubricant is compatible with natural rubber latex and polyisoprene condoms. This product is not a spermicide or a contraceptive. The product is packaged in a polyethylene terephthalate (PET) bottle with a screw-on, flip top polypropylene (PP) closure constituting the device's primary packaging. One bottle is packaged into a cardboard carton, which constitutes the device outer packaging.

Technological Characteristics:

There is no difference in the fundamental technological characteristic of the Nirvana D Personal Lubricant and the predicate K-Y® Brand Intrigue™ Intense Warming Sensation Personal Lubricant. Nirvana D Personal Lubricant is composed of dimethicone, dimethiconol, vanilly butyl ether, and hexyl nicotinate. The proposed device is substantially equivalent to the predicate K-Y® Brand Intrigue™ Intense Warming Sensation Personal Lubricant cleared under 510(k) # K072360. Three of the four ingredients, dimethicone, dimethiconol, and vanillyl butyl ether, in Nirvana D Personal Lubricant are identical to those in the predicate device. The additional ingredient, hexyl nicotinate, does not raise new questions of safety or effectiveness.

Biocompatibility:

Biocompatibility testing was performed in accordance with ISO 10993, Biological Evaluation of Medical Devices, 2009.

Testing Performed:

Testing Performed	Results
Cytotoxicity	Non-cytotoxic
Rabbit Vaginal Irritation	Non-irritating
Rabbit Penile Irritation	Non-irritating
Acute Systemic Toxicity	Non-systemically toxic
Guinea Pig Maximization	Non-sensitizing
Primary Rabbit Skin Irritation	Non-irritating

Condom Compatibility:

Condom Compatibility Testing was performed with Nirvana D Personal Lubricant and ASTM D7761-10 "Standard Testing Method for Determining Compatibility of Personal Lubricants with Natural Rubber Latex Condoms" which was modified to include pre-lubricated and un-lubricated dry condoms. Three marketed brands of pre-lubricated and un-lubricated dry natural rubber latex condoms and one brand of polyisoprene condoms were tested.

Condom compatibility testing results demonstrate that Nirvana D Personal Lubricant is compatible with commercially available natural rubber latex condoms and polyisoprene condoms.

Shelf-life:

In order to establish the stability of the proposed device for its intended shelf-life, an accelerated aging stability test was conducted. Evaluation of viscosity, odor, color and appearance was conducted. Microbial evaluation was conducted via USP testing for Total Microbial Count, Total Yeast and Mold count and Absence of Microbial Pathogens. Satisfactory results were obtained for all parameters evaluated.

Based on the results of the accelerated aging study and microbial testing, Nirvana D Personal Lubricant has a proposed shelf-life of two-years.

A Real-Time aging study is being performed in order to verify results of the accelerated aging study.

Substantially Equivalence:

Based on non-clinical performance data, biocompatibility review and testing and safety data, the proposed device is substantially equivalent to K-Y® Brand Intrigue™ Intense Warming Sensation in technology, intended use, safety and effectiveness.

Conclusion:

The results from laboratory testing and non-clinical evaluation of human use testing show that the proposed device performs equivalently to the predicate device and is safe for use as a personal lubricant.

(b)(4) Trade Secret Process - Testing

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(b)(4) Trade Secret Process - Testing

Church & Dwight Co., Inc.
469 N. Harrison Street
Princeton, NJ

To: Emily Perez

From: Mitchell Berman

Date: 6/21/2013
Subject: Response to Nirvana D 510(k) submission question 5

Emily,
In response to question #5 on the 510(k) submission form for Nirvana D-

(b)(4) Trade Secret Process - Product Specs

[redacted]

Mitchell H. Berman **Ph.D.**
Corporate Microbiologist
Church & Dwight Co., Inc.
469 N. Harrison St.
Princeton, NJ 08543
Tel: (609) 806-1934

Hu, Haijing

ɔm: Cochran, Chrissy
ɹnt: Tuesday, June 11, 2013 4:33 PM
To: Hu, Haijing
Subject: K123427/S001 consult

Hi Haijing,

(b)(4) Trade Secret Process - Product Specs

[redacted]

Kind Regards,
-Chrissy

issy J. Cochran, PhD
Regulatory Advisor (Toxicologist)
Office of Compliance, CDRH
WO 66, Rm 3450
Phone: 301-796-5633
Chrissy.Cochran@fda.hhs.gov

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COVER SHEET MEMORANDUM

Food and Drug Administration
Office of Device Evaluation &
Office of In Vitro Diagnostics and
Radiological Health

From: Reviewer Name Haijing Hu

Subject: 510(k) Number K123427S1

To: The Record

Please list CTS decision code: SE

☐ Refused to Accept (Note: this is considered the first review cycle. See screening checklist.)

☐ Hold (Additional Information or Telephone Hold)

☒ Final Decision (SE, SE with Limitations, NSE (select code below), Withdrawn, etc.)

Please complete the following for a final clearance decision (i.e, SE, SE with Limitations, etc.)	YES	NO
Indications for Use Page *(Attach IFU)*	X	
510(k) Summary or 510(k) Statement *(Attach Summary or Statement)*	X	
Truthful and Accurate Statement *(Must be present for a Final Decision)*	X	
Is the device Class III?		X
Does firm reference standards? (If yes, please attach Form 3654.)	X	
Is this a combination product?		X
Is this a reprocessed single use device? (See Guidance for Industry and FDA Staff - MDUFMA - Validation Data in 510(k)s for Reprocessed Single-Use Medical Devices.)		X
Is this device intended for pediatric use only?		X
Is this a prescription device? (If both prescription & OTC, check both boxes.)		X
Is clinical data necessary to support the review of this 510(k)?		X
For United States based clinical studies only, did the application include a completed Form FDA 3674, Certification with Requirements of ClinicalTrials.gov Data Bank? (If study was conducted in the United States and Form FDA 3674 was not included or was incomplete, then applicant must be contacted to obtain completed form.)	X	
Does this device include an Animal Tissue Source?		X
All Pediatric Patients age <= 21		X
Neonate/Newborn (Birth to 28 days)		X
Infant (29 days to < 2 years)		X
Child (2 years to <12 years)		X
Adolescent (12 years to <18 years)		X
Transitional Adolescent A (18 years to <21 years); Special considerations are being given to this group, different from adults age >= 21 (different device design or tesating, different protocol procedures, etc.)		X
Transitional Adolescent B (18 years to <21 years); No special considerations compared to adults >= 21 years)		X

Nanotechnology		X
Is this device subject to the Tracking Regulation? (Medical Device Tracking Guidance)		X

Regulation Number:	884.5300
Class:	II
Product Code:	NUC
Additional Product Codes:	

Digital Signature Concurrence Table
(Not all signatures may be required)

Branch Chief Sign-Off	Becky Robinson, PhD 2013.06.28 10:23:51 -04'00'
Division Sign-Off	Herbert P. Lerner -S 2013.06.28 10:47:32 -04'00'

K123427/S001

CHURCH & DWIGHT CO., INC.

Corporate Headquarters:
469 North Harrison Street
Princeton, New Jersey 08543-5297
Main Phone: (609) 806-1200

May 29, 2013

U.S Food and Drug Administration
Center for Devices and Radiological Health
Document Mail Center- W066-G609
1903 New Hampshire Avenue
Silver Spring, MD 20993-0002

FDA CDRH DMC
MAY 30 2013
Received

Re: K123427/S001
510(k) notification K123427
Additional Information Response
Nirvana D Personal Lubricant
Submitted in Duplicate

THIS SUBMISSION CONTAINS CONFIDENTIAL COMMERCIAL INFORMATION AS DEFINED IN 21 CFR§20.61 WHICH IS TO BE HELD CONFIDENTIAL PURSUANT TO 21 CFR §201.619(c) AND §807.95

Dear Haijing Hu,

This submission is being made in response to FDA's letter dated January 4, 2013, requesting additional information relating to the above referenced 510(k) and subject device.

Enclosed please find the Replacement eCopy for K123427/S001. This eCopy is the exact duplicate of the paper copy.

If you have any questions regarding this submission, please contact me via telephone at 609-806-1430 or email at emily.perez@churchdwight.com

Sincerely,

Emily Perez
Senior Regulatory Affairs Specialist

51

K123427/S001

CHURCH & DWIGHT CO., INC.

Corporate Headquarters:
469 North Harrison Street
Princeton, New Jersey 08543-5297
Main Phone: (609) 806-1200

May 28, 2013

U.S Food and Drug Administration
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Document Mail Center- W066-G609
1903 New Hampshire Avenue
Silver Spring, MD 20993-0002

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Sincerely,

Emily Perez
Senior Regulatory Affairs Specialist

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Re: 510(k) notification K123427
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(b)(4) Trade Secret Process - Product Specs

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(b)(4) Trade Secret Process - Product Specs

[redacted]

Device Specifications

(b)(4) Trade Secret Process - Product Specs

[redacted]

Shelf life

(b)(4) Trade Secret Process - Product Specs

[redacted]

(Continue…)

(b)(4) Trade Secret Process - Product Specs

[redacted]

(Continue…)

(b)(4) Trade Secret Process - Product Specs

[redacted]

Clinical Evaluation

(b)(4) Trade Secret Process - Product Specs

[redacted]

Labeling

(b)(4) Trade Secret Process - Product Specs

[redacted]

(Continue…)

(b)(4) Trade Secret Process - Product Specs

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Appendix 4 – Test Article MSDS Sheet

CHURCH & DWIGHT CO., INC.

CONSUMER PRODUCTS • SPECIALTY PRODUCTS

MATERIAL SAFETY DATA SHEET

MSDS NUMBER: MSDS-1130 ISSUE DATE: 12/02/11 PAGE 1 OF 4

1. PRODUCT AND COMPANY IDENTIFICATION

Product Name

Nirvana Arouses & Intensifies 1 A [EXP]

PRODUCT USE: Personal Lubricating Liquid
CHEMICAL NAME: Mixture
CHEMICAL FORMULA: Proprietary Mixture
SYNONYMS/COMMON NAMES: N/A

Church & Dwight Co., Inc.
469 N. Harrison Street
Princeton, NJ 08543

Information Phone:
1-888-367-6022

Medical Emergency Phone:
1-888-234-1828

Emergency Phone:
1-800-424-9300

2. HAZARDS IDENTIFICATION

EMERGENCY OVERVIEW

A clear to slightly hazy liquid. May cause eye irritation.
Not a fire hazard.
No significant health or environmental effects associated with this material.

HMIS Rating	
Health	0
Fire	0
Reactivity	0

Potential Health Effects

EYE: May cause irritation to eyes.
SKIN CONTACT: None.
INGESTION: None.
INHALATION: None.
SUBCHRONIC EFFECTS/CARCINOGENICITY: The ingredients in this product are not listed as carcinogens or potential carcinogens by NTP, IARC, OSHA, NIOSH, or ACGIH.

3. COMPOSITION/INFORMATION ON INGREDIENTS

Chemical Ingredient	(% by W)	CAS Number	OSHA PEL (8-hr TWA)	ACGIH LIMITS (8-hr TWA)
Cosmetic Fluid	90-99%	63148-62-9; 70131-67-8		None
Hexyl Nicotinate	<1%	23597-82-2	None	None
Vanillyl Butyl Ether	<1%	82654-98-6	None	

CORPORATE HEADQUARTERS: 469 North Harrison street • Princeton, New Jersey 08543-5297 • Phone (609) 683-5900

Appendix 4 Continued – Test Article MSDS Sheet

CHURCH & DWIGHT CO., INC.

CONSUMER PRODUCTS • SPECIALTY PRODUCTS

MATERIAL SAFETY DATA SHEET

MSDS NUMBER: MSDS-1130 ISSUE DATE: 12/02/11 PAGE 2 OF 4

4. FIRST AID MEASURES

SKIN: Wash skin with plenty of water.
EYES: Flush eyes thoroughly with water for several minutes. Check for and remove contacts. Rinse eyes with clean flowing water for another 10 minutes. Seek medical attention if irritation develops.
INGESTION: No emergency medical treatment is necessary.
INHALATION: Remove to fresh air. Seek medical attention if symptoms persist.

5. FIRE FIGHTING MEASURES

FLAMMABLE PROPERTIES	FLAMMABLE LIMITS
FLASHPOINT: Not combustible	LFL: Not applicable
METHOD USED: Not applicable	UFL: Not applicable

EXTINGUISHING MEDIA: This material is non-combustible. Use extinguishing media appropriate for surrounding fire.
FIRE-FIGHTING INSTRUCTIONS: Carbon monoxide and carbon dioxide.
UNUSUAL FIRE AND EXPLOSION HAZARDS: None known.

6. ACCIDENTAL RELEASE MEASURES

Contain the spill, and depending on the consistency of the material, either pick up with absorbent material or scoop directly into a clean, dry container for later disposal. Wash away residue with plenty of water.

7. HANDLING AND STORAGE

Store in cool, dry areas and away from incompatible substances (see Section 10).

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

EXPOSURE LIMITS: Not established.
RESPIRATORY PROTECTION: Not required under normal handling conditions.
PROTECTIVE GLOVES: Impervious gloves recommended where prolonged or frequent contact could occur.
EYE PROTECTION: Safety glasses when handling bulk material.
OTHER PROTECTIVE CLOTHING OR EQUIPMENT: Impervious apron where splashing may occur.
PROTECTIVE WORK/HYGIENIC PRACTICES: No special requirements with respect to chemical exposure beyond those provided above. Requirements with respect to specific equipment and applications are the responsibility of the user.

9. PHYSICAL AND CHEMICAL PROPERTIES

APPEARANCE: Clear, colorless to slightly hazy liquid
ODOR: Characteristic.

CORPORATE HEADQUARTERS: 469 North Harrison street • Princeton, New Jersey 08543-5297 • Phone (609) 683-5900

Appendix 4 Continued – Test Article MSDS Sheet

CHURCH & DWIGHT CO., INC.

CONSUMER PRODUCTS • SPECIALTY PRODUCTS

MATERIAL SAFETY DATA SHEET

PHYSICAL STATE:Gel
pH (1% SOLN. w/v): Not applicable
VAPOR PRESSURE: Not applicable
VAPOR DENSITY: Not applicable
BOILING POINT: Not applicable
FREEZING/MELTING POINT: Not applicable
SOLUBILITY IN WATER: Complete
DENSITY (g/cc): Approximately 1.12
VISCOSITY: 600-1500 cps
VOLATILE ORGANIC COMPOUNDS: Not applicable

10. STABILITY AND REACTIVITY

CHEMICAL STABILITY: Stable at ambient-room temperature range conditions.
CONDITIONS TO AVOID: Temperatures above 40°C (104°F).
INCOMPATIBILITY WITH OTHER MATERIALS: Incompatibilities include strong oxidizing agents.
HAZARDOUS DECOMPOSITION PRODUCTS: Decomposition may result in the release of carbon monoxide and carbon dioxide.
HAZARDOUS POLYMERIZATION: Not likely to occur.

11. TOXICOLOGICAL INFORMATION

Occupational exposure is not expected to produce adverse human health effects following normal workplace practices. Product has very low acute toxicity. No known chronic health effects. Direct eye contact may cause temporary discomfort with mild redness.

12. ECOLOGICAL INFORMATION

TOXICITY: This material is expected not to be toxic to aquatic life.
PERSISTENCE: This material is not expected to be persistent.
BIOACCUMULATION: This material is not expected to significantly bioaccumulate.

13. DISPOSAL CONSIDERATIONS

Bury in a secured landfill in accordance with all local, state and federal environmental regulations.

14. TRANSPORTATION INFORMATION

Not regulated

15. REGULATORY INFORMATION

CLEAN AIR ACT SECTION 611: Product neither contains nor is it manufactured with ozone depleting substances (ODS).

CORPORATE HEADQUARTERS: 469 North Harrison street • Princeton, New Jersey 08543-5297 • Phone (609) 683-5900

Appendix 4 Continued – Test Article MSDS Sheet

CHURCH & DWIGHT CO., INC.

CONSUMER PRODUCTS • SPECIALTY PRODUCTS

MATERIAL SAFETY DATA SHEET

CERCLA REPORTABLE QUANTITY: Contains no ingredients at levels that would be subject to reporting requirements.
RCRA: Not a hazardous material or a hazardous waste by listing or characteristic.

SARA TITLE III:

Section 302, Extremely Hazardous Substances: None
Section 311/312, Hazardous Categories: Immediate/Acute
Section 313, Toxic Chemicals: None

The ingredients in this product are reported in the EPA TSCA Inventory List and the Canadian DSL.

16. OTHER INFORMATION

SUPERSEDES DATE: New REASON FOR REVISION: New

For additional non-emergency health, safety and environmental information telephone 609.279.7705 or write to:

Church & Dwight Co., Inc.
Product Stewardship
469 North Harrison Street
Princeton, New Jersey 08543

(b)(4) Trade Secret Process - Testing

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(b)(4) Trade Secret Process

Attachment 2

- § 211.166 Stability Testing
- Stability Testing (21 CFR 211.116) – refer to page 2 of 5

(b)(4) Trade Secret Process - Testing

U.S. Department of Health & Human Services

U.S. Food and Drug Administration

Inspections, Compliance, Enforcement, and Criminal Investigations

Expiration Dating and Stability Testing for Human Drug Products

[Previous Chapter [1]] [Table of Contents [2]] [Next Chapter [3]]

DEPT. OF HEALTH, EDUCATION, AND WELFARE PUBLIC HEALTH SERVICE FOOD AND DRUG ADMINISTRATION *ORA/ORO/DEIO/IB*

Date: 10/18/85 Number: 41
Related Program Areas: Drugs

ITG SUBJECT: EXPIRATION DATING AND STABILITY TESTING FOR HUMAN DRUG PRODUCTS

BACKGROUND

Publishing of 21 CFR Part 211 - Current Good Manufacturing Practice for Finished Pharmaceuticals established requirements concerning the expiration date on a drug product and stability testing to assure the appropriateness of that date. Each drug product may be a unique article because of, for instance, differences in (1) chemical and physical properties of the active ingredients or the excipients, (2) manufacturing procedures, (3) formulations, (4) containers and closures, (5) proposed storage conditions, and (6) the stability of the article to maintain its quality or purity through the use of antioxidants or preservatives. Because of the uniqueness of each drug product, it is virtually impossible to provide one set of rules that can apply to all situations. The CGMPs were purposely written broadly to allow for such unique differences.

EXPIRATION DATING (21 CFR 211.137)

A. Absence of an Expiration Date

The absence of an expiration date on any drug product packaged after September 29, 1979, except for those drugs specifically exempt by 211.137 (e), (f), and (g), is cause to initiate regulatory action against the product and/or the responsible firm.

B. Exemptions

OTC drug products meeting the exemption of 211.137 (g) may utilize accelerated testing programs to support the requirement that they are stable for at least three years. Information obtained from old stock, not previously the subject of stability studies, may also be utilized.

C. Products Intended for Reconstitution

Any drug product intended for reconstitution and not bearing an expiration date for the unreconstituted product and another expiration date for the product after reconstitution is considered to be out of compliance with 211.137 (c).

There must be separate stability studies to support each expiration date.

STABILITY TESTING (21 CFR 211.166)

A. Written Stability Testing Program

The absence of a written protocol for stability testing is cause to initiate regulatory action against the product and/or the responsible firm.

B. Supportive Stability Data

1. Number and Size of Batches

   Initial stability testing by accelerated testing may be performed on a batch smaller than the normal production size as long as the batch is produced by similar equipment as would be used for regular production.

   Generally, the placing of three initial batches into the long term stability program is considered minimal to assure batch uniformity for establishing an expiration date. Since a dosage form is a complex unit and there are continued variables in the production process, such as change in personnel, raw material lots and suppliers, and equipment, it is imperative that stability studies are not limited only to initial production batches but a portion of annual production batches be the subject of an ongoing stability program.

2. Accelerated Studies

   When accelerated stability studies are performed, one batch may be adequate in order to establish a tentative expiration date. This is acceptable since it is not the purpose of an accelerated test to determine batch uniformity but rather to test for kinetic degradation.

   The use of accelerated testing data to establish a tentative expiration dating period of greater than three years is discouraged when it is based solely on accelerated data. Combining data compiled at room temperature and at accelerated temperature is possible to justify an expiration dating period of over two years. This can be done, as an example, by taking a sample product that has been at room temperature for one year and subjecting that sample to accelerated temperature conditions. The expiration dating period used would then be the sum of that justified individually at each storage condition.

   We do not believe it is reasonable to perform accelerated testing at very high temperatures for a very short time and expect to extrapolate results to a very long expiration dating period since the actual mechanism of degradation at high temperature may be different than at room temperature.

3. Test Intervals

   It is commonly recommended that stability testing be performed initially, than every three months for the first year, then every six months for the second year, and then annually thereafter. However, more frequent testing near the end of the anticipated expiration date is often likely to give better information about the actual stability of the finished product. Nonetheless, testing at least annually is considered minimal for compliance with CGMPs. Some firms have chosen, for economical purposes, random dates to test all stability samples of a given product. As long as there is at least one test performed annually, this approach can be quite satisfactory.

4. Storage Conditions

   If a product was stored under controlled conditions, those actual conditions (temperature and humidity) should be recorded. Merely stating that a product was stored at room temperature is not sufficient for purposes of determining stability. The USP defines controlled room temperature as being between 15 and 30 C (59 and 86 F). A product stored for stability at or near 15 C may have quite a different quality profile at its expiration date than a product stored at or near 30 C. Based on published information, it appears that 24-25 C is a reasonable reference for thermal exposure at room temperature.

Stability studies should be conducted on product stored under normal storage conditions or, preferably, under exaggerated conditions. Products liable to degradation by light or moisture should be stored either in a lighted area or under conditions of high humidity unless it can be demonstrated that the packaging will prevent deterioration by that condition of interest. For example, a product liable to degrade by light need not be stored in a lit area if it is normally packaged and stored for use in an opaque container.

5. Test Methods

While 211.166 (a) (3) merely requires that test methods be reliable, meaningful, and specific, section 211.165 (e) gives more guidance by stating that the accuracy, sensitivity, specificity, and reproducibility of test methods employed by the firm shall be established and documented. Section 211.194 (a) (2) further requires that all testing methods used shall be verified under actual conditions of use. Testing procedures must include a stability indicating test which will distinguish the active ingredient from any degradation products and be able to make a reliable estimate of the quantity of any degradate. The stability indicating test does not have to be the assay method used to determine product strength.

Manufacturers, who contract with analytical laboratories to perform either end product testing or stability studies, or who produce product under contract for other firms are ultimately responsible for the quality of the product and must have copies of all analytical procedures employed and the appropriate documentation to assure their validity on file. Likewise, repackers who rely on stability studies performed by the manufacturer must have copies of all analytical data necessary to support the expiration dating period.

Although specific methods are critical to determine product stability, they do not have to employ any specific technique. The use of quantitative analysis, where limits are known, such as thin layer chromatography, may be satisfactory. While many USP tests are specific for the drug or its degradates and may be used for stability testing, some USP monographs do not incorporate stability indicating tests. Additionally, it may be unreasonable to expect a manufacturer to develop specific methodology for each component of some multi-component drugs containing ingredients of botanical origin such as benzoin, Peruvian balsam or tolu balsam.

6. Container-Closure Systems

The requirement that stability testing be performed in the same container-closure system as that in which the drug product is marketed has been subject to interpretation. The courts ruled in U.S. vs. Kaybel that when a "new drug" was repackaged, the repacker did not have to obtain pre-market approval of the repackaged product or the firm's repacking procedures. However, the repacker is subject to applicable current good manufacturing practices.

Although stability studies were performed on the dosage unit in the original manufacturer's container, the event of placing the dosage unit into a different storage unit may and often does affect the product's shelf life. It is the policy of the Center for Drugs and Biologics to allow repacking into container-closure systems that can be demonstrated to be at least as protective or more protective than the original system without performing new stability studies prior to marketing.

Satisfactory comparison of container-closure systems may be done by several methods, i.e., literature reference to permeation properties of different container materials; performance of moisture permeation testing; or comparing the properties of the original container-closure system to a new system by stress testing. (Stress testing refers to testing the product after storage under exaggerated conditions. This will usually involve high temperature and high humidity.)

It is also current policy to allow firms to repackage solid dosage units from plastic containers into glass containers because glass has been shown to be a superior moisture and gas barrier. This policy does not apply to liquid drugs because of pH problems resulting from the alkaline nature of glass. Policies relating to the expiration dating of unit dose repackaged drugs may be found in Compliance Policy Guide 7132b.11. This also does not apply to repacking from bulk containers.

7. Container Sizes to be Tested

When the same product is marketed in more than one size, e.g., bottles containing 100 tablets and bottles

containing 1,000 tablets, or bottles containing 4 oz of syrup and bottles containing 16 oz of syrup, it can be demonstrated, by comparing the ratio of the surface area of the container to the internal volume, that smaller containers have a higher ratio than larger containers. This indicates that the smallest marketed container is the most critical in terms of the container properties contributing to product degradation. Thus, moisture or oxygen permeation through a 4 oz bottle is more critical than through a 16 oz bottle of similar construction. For this reason, when studying stability of the product marketed in several sizes of similar containers, testing of the smallest container size is imperative to be in compliance with CGMPs. While we recommend that all other container sizes be subjected to stability testing, the fact that some may not is not necessarily a violation of CGMPs.

8. Preservatives

   Products formulated to contain preservatives to inhibit microbial growth should be monitored throughout their shelf life to assure the effectiveness of the preservative system. Once a minimally effective level of preservative is established, chemical testing for the preservative(s) may be performed. The preservative system should be monitored at the same stability testing times as other ingredients are monitored.

9. Bulk Drug Substances (Bulk Pharmaceutical Chemicals)

   While expiration dating is not required specifically for bulk drugs in the CGMP regulations, it is feasible and valuable to expect the manufacturer of bulk drug substances to assure that their product is stable for the intended period of use.

   A stability testing program for bulk drug substances should contain, at the minimum, the following features:

   a. The program shall be in writing.
   b. The program should include samples from at least one commercial-size batch; thereafter, one batch each year should be entered into the program.
   c. Samples should be stored in containers that approximate the market containers; if it is not practical to do so, samples may be stored in other similar containers, provided that data show that such containers will yield results comparable to those obtained with market containers.
   d. Samples should be stored at room temperature; an additional sample stored at elevated temperatures or under other stress conditions may be used if it is appropriate to do so.

10. Sterility Testing

    Products manufactured as sterile must maintain that quality throughout the labeled expiration dating period as long as the product is unopened and stored according to labeled instructions. The ability of the product to retain its sterile condition is a function of the container-closure system. When qualifying the container-closure system, sterility testing should be performed initially and at the end of the expiration dating period. Once any particular container-closure system can be demonstrated to maintain sterility throughout the expiration dating period, it is unnecessary to revalidate its ability to maintain sterility for other ingredients that may be placed into the same container-closure system.

    Products sterilized in glass ampuls need not be subjected to sterility testing as part of the stability testing program.

[Previous Chapter [4]] [Table of Contents [5]] [Next Chapter [6]]

Links on this page:

1. http://www.fda.govssLINK/UCM072918.htm
2. http://wcms.fda.gov/FDAgov/ICECI/Inspections/InspectionGuides/InspectionTechnicalGuides/default.htm
3. http://www.fda.govssLINK/UCM072921.htm

4. http://www.fda.govssLINK/UCM072918.htm
5. http://wcms.fda.gov/FDAgov/ICECI/Inspections/InspectionGuides/InspectionTechnicalGuides/default.htm
6. http://www.fda.govssLINK/UCM072921.htm

CHURCH & DWIGHT CO., INC.

Corporate Headquarters:
469 North Harrison Street
Princeton, NJ 08543-5297
Main Phone: (609) 683-5900

To: File

From: M. Carsky-Wilson

Date: January 16, 2013

RE: Nirvana D (Trojan Arouses & Intensifies) Personal Lubricant (Follow-up Questions)

(b)(4) Trade Secret Process - Product Specs

[redacted]

Sincerely,

Meg Carsky-Wilson

Meg Carsky-Wilson
Senior Manager Marketing Research
Church & Dwight Co., Inc.
469 No. Harrison St.
Princeton, NJ 08543-5297
(609)497-7241 office
Margaret.Carsky-Wilson@churchdwight.com

(b)(4) Trade Secret Process - Testing

(b)(4) Trade Secret Process - Testing

IX. Draft Labeling

1. Directions for Use

The Directions for Use (DFU) are printed on the outer carton and bottle in accordance with the applicable requirements of 21 C.F.R. parts 801 and 820. The draft DFU for the Nirvana D Personal Lubricant are provided below as part of Package Labeling. The DFUs for the predicate device and the K-Y® Brand Intrigue™ Intense Warming Sensation labeling is presented in Exhibit C.

2. Package Labeling

The package labeling for Nirvana D Personal Lubricant was designed in accordance with the applicable requirements of 21 C.F.R. parts 801 and 820. Draft labeling for both the Nirvana D Personal Lubricant bottle label and the carton label are provided below.

a) Primary Packaging — BOTTLE

Bottle Front Face Panel:

TROJAN™

LUBRICANTS

Nirvana D

Personal Lubricant

3.0 FL OZ

Bottle Back Panel:

DIRECTIONS: Apply to intimate areas (penis/vagina) to lubricate & moisturize during intercourse. Compatible with natural rubber latex & polyisoprene condoms. Not compatible with polyurethane or other condoms.

WARNINGS: May cause burning or irritation. If irritation occurs, immediately rinse with water & discontinue use. If irritation persists, consult a physician. In case of eye contact, flush with water. This product is not a spermicide or a contraceptive. KEEP OUT OF REACH OF CHILDREN.

CAUTION: Extremely slippery – clean spill immediately.

INGREDIENTS: Dimethicone, Dimethiconol, Hexyl Nicotinate, Vanillyl Butyl Ether.

Bottle Side Panel:

Avoid exposure to direct sunlight or storage for prolonged periods above 100˚F.

Manufactured For: Church & Dwight Co., Inc. Ewing, NJ 08628

Bottle Bottom Panel:

Date/Lot code information is applied during manufacturing.

b) Outer Packaging — CARTON

Carton Front Face Panel – Principal Display Panel:

TROJAN™

LUBRICANTS

Nirvana D

3.0 FL OZ

Carton Back Panel:

TROJAN™

LUBRICANTS

Nirvana D

INDICATION FOR USE: Nirvana D is a personal lubricant for penile and/or vaginal application, intended to lubricate and moisturize, 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. Not compatible with polyurethane or other condoms.

DIRECTIONS: Apply to intimate areas and reapply as desired. When ready for intercourse, reapply as desired. You may experience sensations such as warming, heat, cooling and/or tingling. Close cap lid immediately after use. Do not use if quality seal under cap is broken or missing. To avoid leaks, tightly twist cap onto bottle once quality seal is removed.

WARNINGS: May cause burning or irritation. If irritation occurs, immediately rinse with water and discontinue use. If irritation persists, consult a physician. In case of eye contact, flush with water. This product is not a spermicide or a contraceptive. Keep out of reach of children.

CAUTION: May cause burning and irritation. Extremely slippery – clean spill immediately.

Avoid exposure to direct sunlight or storage for prolonged periods above 100˚F.

INGREDIENTS: Dimethicone, Dimethiconol, Hexyl Nicotinate, Vanillyl Butyl Ether

Carton Bottom Panel:

Manufactured for: Church & Dwight Co., Inc.,
Ewing, NJ 08628
Exp. Date & Lot Code

Form Approved: OMB No. 0910-0120; Expiration Date: 12/31/13

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]

<61> Microbiological Examination of Nonsterile Products: Microbial Enumeration Tets.(Sterility); 2012

Please answer the following questions	Yes	No
Is this standard recognized by FDA [2]?	☒	☐
FDA Recognition number [3]	#14-366	
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: USP <61> Microbiological Examination of Nonsterile Products: Microbial Enumeration Tests

[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

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE? ☐ Yes ☐ No ☐ N/A
TYPE OF DEVIATION OR OPTION SELECTED ◆		
DESCRIPTION		
JUSTIFICATION		

SECTION NUMBER	SECTION TITLE	CONFORMANCE? ☐ Yes ☐ No ☐ N/A
TYPE OF DEVIATION OR OPTION SELECTED ◆		
DESCRIPTION		
JUSTIFICATION		

SECTION NUMBER	SECTION TITLE	CONFORMANCE? ☐ Yes ☐ No ☐ 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.

Paperwork Reduction Act Statement

Public reporting burden for this collection of information is estimated to average 1 hour 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:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
1350 Piccard Drive, Room 400
Rockville, MD 20850

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.

Form Approved: OMB No. 0910-0120; Expiration Date: 12/31/13

Department of Health and Human Services
Food and Drug Administration

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]

<62> Microbiological Examination of Nonsterile Products: Tests for Specified Microorganisms(Sterility); 2012

Please answer the following questions	Yes	No
Is this standard recognized by FDA [2]?	☒	☐
FDA Recognition number [3]	#14-375	
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: USP <62> Microbiological Examination of Nonsterile Products: Tests for Specified Microorganisms

[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

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE? ☐ Yes ☐ No ☐ N/A
TYPE OF DEVIATION OR OPTION SELECTED ◆		
DESCRIPTION		
JUSTIFICATION		
SECTION NUMBER	SECTION TITLE	CONFORMANCE? ☐ Yes ☐ No ☐ N/A
TYPE OF DEVIATION OR OPTION SELECTED ◆		
DESCRIPTION		
JUSTIFICATION		
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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.

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Paperwork Reduction Act Statement

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Department of Health and Human Services
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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.

Form Approved: OMB No. 0910-0120; Expiration Date: 12/31/13

Department of Health and Human Services
Food and Drug Administration

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]

ISO 10993-10:2010, Biological evaluation of medical devices- Part 10: Tests for irritation and skin sensitization; 3/16/2012

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)?	☒	☐
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: ISO 10993-12:2007 Biological evaluation of Medical Devices- Part 12: Sample preparation and reference

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

[2] Authority [21 U.S.C. 360d], www.fda.gov/cdrh/stdsprog.html

[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 www.fda.gov/cdrh/guidance.html

EXTENT OF STANDARD CONFORMANCE SUMMARY REPORT TABLE

STANDARD TITLE

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
	See Attachment A, Appendix 5, page 17 of 26	☐ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ◆

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		☐ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ◆

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		☐ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ◆

DESCRIPTION

JUSTIFICATION

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See OMB Statement on Reverse. Form Approved: OMB No. 0910-0616, Expiration Date: 2-28-2015

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Certification of Compliance, under 42 U.S.C. § 282(j)(5)(B), with Requirements of ClinicalTrials.gov Data Bank (42 U.S.C. § 282(j))

(For submission with an application/submission, including amendments, supplements, and resubmissions, under §§ 505, 515, 520(m), or 510(k) of the Federal Food, Drug, and Cosmetic Act or § 351 of the Public Health Service Act.)

SPONSOR / APPLICANT / SUBMITTER INFORMATION

1. NAME OF SPONSOR/APPLICANT/SUBMITTER
Church & Dwight Co., Inc.

2. DATE OF THE APPLICATION/SUBMISSION WHICH THIS CERTIFICATION ACCOMPANIES
11/06/2012

3. ADDRESS *(Number, Street, State, and ZIP Code)*
500 Charles Ewing Boulevard
Ewing, New Jersey 08628

4. TELEPHONE AND FAX NUMBERS *(Include Area Code)*
(Tel.) (609) 806-1992
(Fax) (609) 403-7415

PRODUCT INFORMATION

5. **FOR DRUGS/BIOLOGICS:** Include Any/All Available Established, Proprietary and/or Chemical/Biochemical/Blood/Cellular/Gene Therapy Product Name(s)
FOR DEVICES: Include Any/All Common or Usual Name(s), Classification, Trade or Proprietary or Model Name(s) and/or Model Number(s)
(Attach extra pages as necessary)

Trojan™ Personal Lubricant

Nirvana D Personal Lubricant

APPLICATION / SUBMISSION INFORMATION

6. TYPE OF APPLICATION/SUBMISSION WHICH THIS CERTIFICATION ACCOMPANIES

☐ IND ☐ NDA ☐ ANDA ☐ BLA ☐ PMA ☐ HDE ☒ 510(k) ☐ PDP ☐ Other

7. INCLUDE IND/NDA/ANDA/BLA/PMA/HDE/510(k)/PDP/OTHER NUMBER *(If number previously assigned)*

8. SERIAL NUMBER ASSIGNED TO APPLICATION/SUBMISSION WHICH THIS CERTIFICATION ACCOMPANIES

CERTIFICATION STATEMENT / INFORMATION

9. CHECK ONLY ONE OF THE FOLLOWING BOXES *(See instructions for additional information and explanation)*

☐ A. I certify that the requirements of 42 U.S.C. § 282(j), Section 402(j) of the Public Health Service Act, enacted by 121 Stat. 823, Public Law 110-85, do not apply because the application/submission which this certification accompanies does not reference any clinical trial.

☒ B. I certify that the requirements of 42 U.S.C. § 282(j), Section 402(j) of the Public Health Service Act, enacted by 121 Stat. 823, Public Law 110-85, do not apply to any clinical trial referenced in the application/submission which this certification accompanies.

☐ C. I certify that the requirements of 42 U.S.C. § 282(j), Section 402(j) of the Public Health Service Act, enacted by 121 Stat. 823, Public Law 110-85, apply to one or more of the clinical trials referenced in the application/submission which this certification accompanies and that those requirements have been met.

10. IF YOU CHECKED BOX C, IN NUMBER 9, PROVIDE THE NATIONAL CLINICAL TRIAL (NCT) NUMBER(S) FOR ANY "APPLICABLE CLINICAL TRIAL(S)," UNDER 42 U.S.C. § 282(j)(1)(A)(i), SECTION 402(j)(1)(A)(i) OF THE PUBLIC HEALTH SERVICE ACT, REFERENCED IN THE APPLICATION/ SUBMISSION WHICH THIS CERTIFICATION ACCOMPANIES *(Attach extra pages as necessary)*

NCT Number(s):

The undersigned declares, to the best of her/his knowledge, that this is an accurate, true, and complete submission of information. I understand that the failure to submit the certification required by 42 U.S.C. § 282(j)(5)(B), section 402(j)(5)(B) of the Public Health Service Act, and the knowing submission of a false certification under such section are prohibited acts under 21 U.S.C. § 331, section 301 of the Federal Food, Drug, and Cosmetic Act.
Warning: A willfully and knowingly false statement is a criminal offense, U.S. Code, title 18, section 1001.

11. SIGNATURE OF SPONSOR/APPLICANT/SUBMITTER OR AN AUTHORIZED REPRESENTATIVE (Sign)
Sign

12. NAME AND TITLE OF THE PERSON WHO SIGNED IN NO. 11
(Name) Jeffrey Shaul
(Title) Director, Regulatory Affairs

13. ADDRESS *(Number, Street, State, and ZIP Code) (of person identified in Nos. 11 and 12)*
469 North Harrison Street
Princeton, New Jersey 08543

14. TELEPHONE AND FAX NUMBERS *(Include Area Code)*
(Tel.) (609) 806-1992
(Fax) (609) 403-7415

15. DATE OF CERTIFICATION
24-May-2013

PSC Publishing Services (301) 443-6740 EF

II. 510(k) Summary

Submitter Name:	Church & Dwight Co., Inc.
Submitter Address:	469 North Harrison Street Princeton, NJ 08543
Contact Person:	Emily Perez Senior Regulatory Affairs Specialist Church & Dwight Co., Inc. 469 North Harrison Street Princeton, NJ 08543 Tel: (609) 806-1430 Fax: (609) 403-7415
Date Prepared:	May 28, 2013
Device Trade Name:	Nirvana D Personal Lubricant (TBD)
Device Common Name:	Personal Lubricant
Product Code:	NUC – Condom (21 C.F.R. § 884.5300)
Classification:	Class II
Predicate Device:	K-Y® Brand Intrigue™ Intense Warming Sensation (K072360)
Intended Use:	Nirvana D is a personal lubricant for penile and/or vaginal application, intended to lubricate and moisturize, 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. Not compatible with polyurethane or other condoms.
Device Description:	The Nirvana D Personal Lubricant is an anhydrous, non-sterile, clear silicone-based personal lubricant composed of dimethicone, dimethiconol, vanillyl butyl ether ("VBE") and hexyl nicotinate. Nirvana D Personal Lubricant is compatible with natural rubber latex and polyisoprene condoms. This product is not a spermicide or a contraceptive. The product is packaged in a polyethylene terephthalate (PET) bottle with a screw-on, flip top polypropylene (PP) closure constituting the device's primary packaging. One bottle is packaged into a cardboard carton, which constitutes the device outer packaging.

Technological Characteristics:

There is no difference in the fundamental technological characteristic of the Nirvana D Personal Lubricant and the predicate K-Y® Brand Intrigue™ Intense Warming Sensation Personal Lubricant. Nirvana D Personal Lubricant is composed of dimethicone, dimethiconol, vanilly butyl ether, and hexyl nicotinate. The proposed device is substantially equivalent to the predicate K-Y® Brand Intrigue™ Intense Warming Sensation Personal Lubricant cleared under 510(k) # K072360. Three of the four ingredients, dimethicone, dimethiconol, and vanillyl butyl ether, in Nirvana D Personal Lubricant are identical to those in the predicate device. The additional ingredient, hexyl nicotinate, does not raise new questions of safety or effectiveness.

Biocompatibility:

Biocompatibility testing was performed in accordance with ISO 10993, Biological Evaluation of Medical Devices, 2009.

Testing Performed:

Testing Performed	Results
Cytotoxicity	Non-cytotoxic
Rabbit Vaginal Irritation	Non-irritating
Rabbit Penile Irritation	Non-irritating
Acute Systemic Toxicity	Non-systemically toxic
Guinea Pig Maximization	Non-sensitizing
Primary Rabbit Skin Irritation	Non-irritating

Condom Compatibility:

Condom Compatibility Testing was performed with Nirvana D Personal Lubricant and ASTM D7761-10 “Standard Testing Method for Determining Compatibility of Personal Lubricants with Natural Rubber Latex Condoms” which was modified to include pre-lubricated and un-lubricated dry condoms. Three marketed brands of pre-lubricated and un-lubricated dry natural rubber latex condoms and one brand of polyisoprene condoms were tested.

Condom compatibility testing results demonstrate that Nirvana D Personal Lubricant is compatible with commercially available natural rubber latex condoms and polyisoprene condoms.

Shelf-life:

In order to establish the stability of the proposed device for its intended shelf-life, an accelerated aging stability test was conducted. Evaluation of viscosity, odor, color and appearance was conducted. Microbial evaluation was conducted via USP testing for Total Microbial Count, Total Yeast and Mold count and Absence of Microbial Pathogens. Satisfactory results were obtained for all parameters evaluated.

Based on the results of the accelerated aging study and microbial testing, Nirvana D Personal Lubricant has a proposed shelf-life of two-years.

A Real-Time aging study is being performed in order to verify results of the accelerated aging study.

Substantially Equivalence:

Based on non-clinical performance data, biocompatibility review and testing and safety data, the proposed device is substantially equivalent to K-Y® Brand Intrigue™ Intense Warming Sensation in technology, intended use, safety and effectiveness.

Conclusion:

The results from laboratory testing and non-clinical evaluation of human use testing show that the proposed device performs equivalently to the predicate device and is safe for use as a personal lubricant.