

CRL Use Only**CRLNJ: 2020-0494****Panel: 145-20****Subject #: _____****INFORMED CONSENT TO PARTICIPATE IN A RESEARCH STUDY****Name of Testing Facility / Study Title:** Eurofins CRL Cosmetics, Inc. / “Evaluation of Topically Applied Bemotrizinol for Human Phototoxic Potential”**Protocol Number:** DSM PT 2020 / CRLNJ2020-0494**Principal Investigator:** Gladys Osis**Telephone:** (732)562-1010 Ext 310
(732)562-1010**Address:** Eurofins CRL , Inc
371 Hoes Lane Suite 100
Piscataway, NJ 08854**INTRODUCTION**

You are deciding if you would like to volunteer for a research study. You must read, sign and date this form before you agree to take part in this study. This form will give you more information about this study. Please ask as many questions as you need to before you decide if you want to be in the study. This document may contain words you do not understand. Do not sign and date this form if you have any questions that have not been answered. Please ask the investigator or study staff to explain any words that you do not understand.

The investigator is being paid by the sponsor (the company paying for this study) to conduct this research study.

You must be honest with the investigator about your health history, or you may harm yourself by participating in this study.

PURPOSE OF THE STUDY

The purpose of this study is to determine if the test product and/or its vehicle (way to administer the test product) have potential to cause skin reactions when exposed to ultraviolet (UV) radiation (the kind you are exposed to when you are out in the sun). The reaction is referred to as a phototoxic reaction and typically looks like a bad sunburn.

DO NOT PARTICIPATE IN THIS STUDY IF:

You are female AND are pregnant, planning to become pregnant during this study or are breastfeeding.
You have a history of pre-existing sensitivity or other types of allergies to sunscreens, cosmetics, toiletries, or personal care products

TEST PROCEDURE

Up to 35 male and female subjects, ages 18-75, will be enrolled in this patch study. You will be required to make up to five (5) visits to the clinic over a one (1) week period. The products or ingredients being tested may include raw materials, cosmetics, toiletries, latex products, sunscreens, and personal care products.

Visit 1: This visit will take approximately 30 minutes and will involve the following:

You will:

- Be asked to read, sign and date this informed consent form. A photocopy will be given to you to keep; the original copy will be kept in the study file.
- Be asked about the history of your health, and any over-the counter or prescription medications you may take.
- Have your skin visually evaluated by the investigator or an expert grader.

After signing and dating this informed consent, and your eligibility is verified, one test site on your back will be isolated from the actual test sites and will be tested for minimal erythema dose (MED). MED is the smallest amount of ultraviolet irradiation from a solar simulator, to unprotected skin site, to determine how much light exposure it takes to produce minimum sunburn. To do this, you will be seated comfortably, and your shirt will be lifted and held up with a clip to expose your back. You will be required not to move during the exposure period. Total exposure time may be up to fifteen (10) minutes.

Duplicate test sites on the lower back between the beltline and below the shoulder blade, lateral to the midline will be identified. Test product will be applied directly to the patch and then applied to your back.

The patch is an occlusive strip (manufactured by Strukmyer LLC, Mesquite, TX or equivalent) consisting of a breathable tape with non-breathable adhesive and center portion of 3/4" x 3/4" fabric.

One test site will be designated as treated irradiated and the other will be used as a treated, non-irradiated control. Two additional patches with no test product will be applied, adjacent to the test sites. One will be irradiated and the other will not be irradiated. The patches must be kept dry and intact, and you must not wash off the skin marker. You will keep the patches on your back for approximately 24 hours

Visit 2 - This visit will take up to 40 minutes.

You will return to the clinic for MED evaluation, removal of the patches, evaluation of the test sites, and irradiation of designated test sites with a standard dose of UVA light and 0.5 of your MED. From this visit forward you will be asked about any medication you have taken if any.

Visits 3 & 4 - These visits will take approximately 15 minutes.

You will return to the clinic approximately twenty-four (24) and forty-eight hours (48) after irradiation to have the test sites evaluated.

You will be asked to return for a 72-hour post-irradiation (Visit 5) evaluation if a reaction was observed at the twenty-four (24) or forty-eight hours (48) evaluation.

Your responsibilities during the study include:

- To avoid exposure of the test sites to the sun and to refrain from visits to tanning salons during the study.
- Refrain from getting patches wet during the study.
- If you are a woman able to get pregnant, then you must agree to use adequate form of birth control. If you become pregnant during the study, you must report this to the investigator or study staff.
- You must report any medications taken during the study.
- You must refrain from using new topical products during the study.
- Agree to the study procedures.

POTENTIAL BENEFITS AND ALTERNATIVES

There is no direct benefit to you in participating in this study however the test results may permit new or improved products to be marketed. The results of the study will be used commercially, for example, for the further development and commercialization of the investigational product but will not generate any ownership rights or financial rights for you.

There are no alternatives for obtaining the information provided by this test procedure. Your alternative is not to participate in this study.

COVID-19 SAFETY PROCEDURES

Please read the following as part of Eurofins CRL, Inc. new guidelines to participate in clinical studies at our facility.

Only subjects with scheduled appointment times are permitted to enter the building. Subjects may only be in the laboratory during their scheduled appointment time; if subjects arrive early, they must wait in their vehicles until their scheduled appointment time. A face mask must be always worn. Upon entering the building, leaving the assigned laboratory area, and when exiting the building. All subjects will be reminded that if they begin to exhibit any signs or symptoms of illness, they should not come to Eurofins CRL, Inc. Subjects exhibiting signs or symptoms of illness must call and inform Eurofins CRL, Inc. of their illness and the last date and time they were present at the facility.

Six feet of distance is required between subjects to allow for social distancing. Subject waiting areas are limited in capacity and spaced out to allow for social distancing. Cleaning and disinfection are performed after each subject visit and at the end of each workday in all clinical areas

COVID-19 safety procedures are outside of the scope of Quality Assurance study audits. These procedures will be routinely monitored by Eurofins CRL, Inc. management and will not be audited on an individual study basis as part of the clinical study audit.

POTENTIAL RISKS

If you do not understand what any of these side effects mean, please ask the investigator or study staff to explain these terms to you.

You must tell the investigator or study staff about all side effects or new symptoms that you may have whether or not you think they are caused by investigational product. If you are not honest about your side effects, you may harm yourself by staying in this study.

As with any consumer product applied to the skin, there is the possibility that a test product may produce an irritant or allergic reaction. The potential for reactions during this study is not anticipated to be other than the reactions usually associated with applying cosmetics or toiletries. The reactions may consist of:

- Mild to heavy erythema (redness)
- Pruritus (itching)
- Dryness
- Cracking
- Peeling
- Burning/stinging sensation
- Skin discoloration
- Swelling

In rare cases, blistering or an allergic reaction may also occur. Reaction to the tape adhesive may also be observed.

During the study, because of the irradiation with the sun lamp, varying degrees of redness will develop on the skin. Since the areas involved are one centimeter in diameter, about the size of a dime, there should be little or no discomfort. In some cases, these reddened areas will “tan”. The pigmentation may persist for months or years.

In addition to the known risks described above, there may be unknown risks that are unforeseeable.

IN CASE OF STUDY RELATED INJURY

If you become ill or are injured while you are in the study, get the medical care that you need right away. You should inform the healthcare professional treating you that you are participating in this study. If you tell the study staff that you think you have been injured then they will help you get the care you need. The sponsor will not pay for those medical expenses necessary to treat your injury, you/your insurance will be responsible for these expenses.

LEGAL RIGHTS

You will not lose any of your legal rights by signing and dating this consent form.

WHOM TO CONTACT ABOUT THIS STUDY

During the study, if you experience any medical problems, suffer a research-related injury, or have questions, concerns or complaints about the study such as:

- Whom to contact in the case of a research-related injury or illness;
- Payment or compensation for being in the study, if any;
- Your responsibilities as a research subject;
- Eligibility to participate in the study;
- The investigator's or study site's decision to exclude you from participation;
- Results of tests and/or procedures;

Please contact the investigator at the telephone number listed on the first page of this consent document.

If you seek emergency care, or hospitalization is required, alert the treating physician that you are participating in this research study.

An institutional review board (IRB) is an independent committee established to help protect the rights of research subjects. If you have any questions about your rights as a research subject, contact:

- By **mail**:
Study Subject Adviser
Advarra IRB
6100 Merriweather Dr., Suite 600
Columbia, MD 21044
- or call **toll free**: 877-992-4724
- or by **email**: adviser@advarra.com

Please reference the following number when contacting the Study Subject Adviser: Pro00060762.

CONFIDENTIALITY

Eurofins CRL, Inc. will keep confidential information concerning you that is obtained during this study, except when ordered by law. However, upon request, this information may be examined by the investigator, the Sponsor of the study, their representatives, Advarra IRB, and by the U.S. Food and Drug Administration (FDA) or governing agencies from other countries. The products you will test are proprietary and highly confidential. You must agree that you will not disclose or describe these test products to anyone who is not an employee of Eurofins CRL, Inc.

The Institutional Review Board (IRB), Advarra, and accrediting agencies may inspect and copy your records, which may have your name on them. Therefore, total confidentiality cannot be guaranteed. If the study results are presented at meetings or printed in publications, your name will not be used.

VOLUNTEERING TO BE IN THE STUDY

It is your choice if you want to be in the study. No one can force you to be in the study. You may not want to be in this study, or you may leave the study at any time without penalty or loss of benefits to which you are otherwise entitled.

The investigator, the sponsor company, or Advarra, may take you out of the study without your permission, at any time, for the following reasons:

- If you do not follow the investigator’s instructions
- If we find out, you should not be in the study
- If the study is stopped
- If it becomes harmful to your health

If information generated from this study is published or presented, your identity will not be revealed. If you leave the study, no more information about you will be collected for this study. However, all the information you gave us before you left the study will still be used.

PAYMENT FOR BEING IN THE STUDY

I will be paid as follow for my study participation:

For completing 4 study visits	\$100.00
For completing 5 study visits	\$125.00
If I discontinue the study	\$25.00 per completed visit.

You will receive payment via Clincard 7 to 10 days after the last day of the study.

COSTS

There will be no charge to you for your participation in this study. The test product, study-related procedures, and study visits will be provided at no charge to you.

NEW FINDINGS

If there is new information or any significant new findings that could relate to your willingness to continue participation, we will tell you. You can then decide if you still want to be in the study.

AGREEMENT TO BE IN THE STUDY

I have freely and without reservation volunteered to participate in the clinical study described above. I understand that by signing and dating this informed consent form I am not waiving my legal rights. I also understand that I may refuse to participate or withdraw from the study without loss of any benefits I would have otherwise been entitled to receive. I have been informed of the test procedure and understand the potential risks, including possible skin reactions. All my questions have been answered and I understand that I may ask additional questions at any time by calling the number listed above. For questions regarding my rights as a research subject, I may contact Advarra Institutional Review Board.

I understand that the product I am testing is proprietary and highly confidential. I agree that I will not disclose or describe this test product to anyone who is not an employee of the testing facility. I also agree that if, as part of the testing procedure, I am required to take the test product out of the building for use, I will not give it or show it to any friend, family member, or acquaintance. I will not use the test product, or any information I received about the test product, for any purpose other than my participation in the current testing process.

I have been informed that my participation is only possible once the separately completed and signed and dated Health Insurance Portability and Accountability Act (HIPAA) declaration is on file at Eurofins CRL, Inc.

I am free to withdraw my consent and discontinue participation at any time without prejudice or penalty. I agree to comply with all instructions regarding the study.

I also hereby swear to the following: To my knowledge I am not pregnant, breastfeeding, or planning to become pregnant. I do not have a history of sun hypersensitivity/photosensitivity or photosensitive dermatoses. I do not have allergies or sensitivities to sunscreen, cosmetics, toiletries, dermatological products, or any of the test products. I am not currently using any systemic or topical drugs that can cause photoreactions.

I understand that I will be given a signed and dated copy of this form to keep.

Subject's Name (Print Clearly)

Subject's Signature

Date

Printed Name of Person Obtaining Consent

Signature of Person Obtaining Consent

Date