

**CRL Use Only****CRLNJ: 2020-0495****Panel: 146 - 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 Photoallergic Potential”**Protocol Number:** DSM PA 2020 / CRLNJ2020-0495**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 and 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 evaluate the potential of a test product to produce a photoallergic response. Photoallergy is a skin reaction produced by the combination of ultraviolet radiation (the kind you get when exposed to the sun) and a chemical agent through an immunological mechanism. This reaction is only seen in individuals who have been sensitized by exposure to the chemical agent together with ultraviolet radiation.

**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 50 male and female subjects, ages 18-75, will be enrolled in this patch study. You will be required to make up to twenty (20) visits to the clinic over a six (6) week period. The products or ingredients being tested may include raw materials, cosmetics, toiletries, fabrics, latex products, sunscreens, and personal care products.

**Induction Phase:**

Visit 1: This visit will take approximately 40 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 to give a 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 once your eligibility is verified, one 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 the untreated, unprotected skin site to determine how much light exposure it takes to produce 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 (15) minutes.

A duplicate test site on the lower back between the beltline and below the shoulder blade, lateral to the midline will be identified. Test product will be applied to the patch and the patch will be 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 ¾" x ¾" fabric.

One site will be designated as treated irradiated and the other will be used as a treated, non-irradiated control. The patches must be kept dry and intact, and you must not wash off the skin marker.

Visit 2 - This visit will take up to 30 minutes.

You will return approximately 24 hours later to the clinic for MED evaluation, removal of the patches, evaluation of the test sites, and UV irradiation of designated sites with 2 times your determined MED.

Visits 3 - This visit will take approximately 15 minutes.

You will return to the clinic for evaluation of the sites and the application of the patches.

The patching, irradiation and evaluation procedures will be performed for total of six sequences, as in Visits 1, 2 and 3, within 3 weeks for a total of 15 visits, during the induction phase, followed by 10 to 21 days of rest period.

### **Challenge Phase**

When you return to the clinic after the rest period (10 to 21 days) a new area on your back will be selected, and a duplicate set of patches with the test product will be applied on your back. Two additional patches with no test product will be applied, adjacent to the test sites.

The patches must be kept dry and intact. You will keep the patches on your back for approximately 24 hours.

You will return to the clinic for removal of the patches and evaluation of the test sites. One set of the sites will be irradiated with a standard dose of UVA light and other set will not be irradiated.

### **Re-Challenge Phase (if required)**

At the discretion of the investigator, and with the sponsor's approval, a subject may be re-challenged with the test product if reactions suggestive of sensitization or photo sensitization are observed during the Challenge Phase. You will be asked to return to the clinic no sooner than two weeks after you completed the study and the Challenge procedures will be repeated. A patch with the test product will be applied to your back and allowed to remain in direct contact with the skin for 24 hours. You will return after 24 hours for removal of the patch and grading of the site, without irradiation if an allergy to the test product is suspected or with irradiation of an additional treated site (24 hour exposure) if photoallergy is suspected based on the reactions during the challenge phase. You will return for a 48 hour and 72 hour post-patch application grading and additional 96 hour evaluation if a reaction persists.

If the sites are irradiated after patch removal, you will return for evaluation at 24, 48 and 72 hours post UV exposure.

Additional products (usually a breakdown of components of the original test product) may be challenged simultaneously or following the re-challenge of the original test product by agreement between the sponsor and investigator. You will be compensated for participating in a Rechallenge.

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 course of the study.
- Avoid getting the patches wet during the course of 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 then you must report this to the investigator or study staff.
- You must report any medications taken during the study.

### **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 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 CRL 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 course of the study, as a result of 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.

## **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](mailto:adviser@advarra.com)

Please reference the following number when contacting the Study Subject Adviser: Pro00061070.

### **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, members of the 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 or the sponsor company 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**

You will be paid as follows for your study participation:

For completing all 20 study visits	\$350.00
For completing the Induction Phase visits \$15.00 per visit (15 visits)	\$225.00
For completing the Challenge phase visits \$25.00 per visit (5 visits)	\$125.00
For completing a rechallenge (if required) \$20.00 per visit	\$100.00

You will receive payment via Clinocard 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 on the first page of this form. For questions regarding my rights as a research subject, I may contact Advarra IRB.

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 completed and signed 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.

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Subject's Name (Print Clearly)

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Subject's Signature

Date

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Printed Name of Person Obtaining Consent

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Signature of Person Obtaining Consent

Date