

CRL Use Only

Subject #:

Panel #: P144

CRL #: CRLNJ2020-0493

INFORMED CONSENT TO PARTICIPATE IN A REPEATED INSULT PATCH TEST (RIPT)

Name of Testing Facility / Study Title: Eurofins CRL Cosmetics, Inc. / “Evaluation of Bemotrizinol in Human Repeated Insult Patch Test (HRIPT) and Cumulative Irritation Test”

Protocol Number: DSM RIPT 2020 / 2020-0493

Principal Investigator: Samantha Poweski

Telephone: 732-562-1010 (24 Hours)

Address: Eurofins Clinical Research Laboratories
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 study in which you are asked to participate is a research study to determine if test materials will produce an irritation or sensitization (allergic reaction) following repeated applications to the skin.

WHAT WILL HAPPEN DURING THE STUDY

Approximately 190 subjects will be enrolled in this patch study.

You will be required to make fifteen (15) visits (approximately 15 minutes each) to the clinic for the two study phases (Induction Phase and Challenge Phase) over a six (6) week period. During the Induction Phase, on the first day your back will be wiped with alcohol, then the test materials, the investigational product, vehicle controls, saline control, and undosed negative control will be applied to your upper back under adhesive patches every Monday, Wednesday, and Friday for three (3) weeks (9 visits). 6 (six) occlusive (non-breathable adhesive) adhesive patches (with fabric areas measuring $\frac{3}{4}$ " x $\frac{3}{4}$ ", similar to adhesive bandages) will be applied to your back at each visit.

You must make a 10th visit for a final Induction Phase scoring. The patches applied to your back must be kept dry and intact and must remain in place for 24 hours. You will be instructed to remove the patches after 24 hours (on Tuesdays, Thursdays and Saturdays). Patch sites on your back will be marked with a surgical marker. (This marker and test products may stain your clothing). You may get the patch sites wet **only** when the patches have been removed; however, you may not scrub the area or remove the marks.

If you have a strong reaction (usually a 2+ redness or greater, but sometimes less) to one of the test products, that product may be moved to a different site on your back for the rest of the Induction Phase. If you have greater than a 2+ reaction to the new site, patching of the product will be discontinued for the Induction Phase and you may or may not be patched with the product during the Challenge Phase.

Following the last Induction visit (visit 10) you will have an approximate 14 (fourteen) day rest period after which you will return to the clinic on Monday for the Challenge Phase. All test materials will be applied to new sites on your lower back (approximately 6 patches) after the test sites are wiped with alcohol. Patches will remain in place for 24 hours and sites will be evaluated at 24, 48, 72 and 96 hours. You must return to the lab at the same time on Monday and Tuesday for patch application and removal of 24 hour patches and on Wednesday, Thursday and Friday for scoring of all sites.

If for any reason you are unable to report to the clinic on an assigned date, you must notify Eurofins CRL, Inc., to schedule a make-up day. Only one missed visit/make-up day is permitted during the Induction Phase (first 3 weeks). No missed visits are permitted during the last week of the study (Challenge Phase).

If reactions are observed during the Challenge Phase, you may be asked to return for a re-challenge of that test material(s) (a repeat of the Challenge Phase conducted on your arm or back) at a future date, usually 21-28 days after the challenge application. You will receive additional compensation for the re-challenge.

POTENTIAL BENEFITS

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.

ALTERNATIVES TO PARTICIPATING IN THE STUDY

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

POTENTIAL SIDE EFFECTS AND RISKS

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

The reactions may consist of:

- Redness
- Dryness
- Swelling
- Scaling
- Itching
- Oozing
- Crusting
- Papules, bumps
- Pustules, bumps filled with pus
- Superficial erosions, skin rubbed off (like a peeling sunburn or an opened blister)
- Scabbing of the test site

These side effects rarely may extend beyond the test site.

A score of 2+ or greater reaction will result in a site change and repeat patching and/or stoppage.

In some darker skin tones, although rare, there is the possibility of post-inflammatory hyperpigmentation (brownish discoloration of the skin). The hyperpigmentation usually fades with time but may last for an indefinite period. You may also experience hypopigmentation (a loss of natural skin color) which is usually temporary in nature.

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

If you experience a skin reaction resulting from this study, you must contact the investigator or study staff at the number listed on the first page of this form and make an immediate appointment for evaluation. In case of a severe reaction, this number may be called after working hours and on weekends and you should follow the prompt for reporting an emergency. Medical treatment will be provided at no cost to you for side effects as deemed necessary by the Investigator. All side effects will be monitored, examined, and treated until resolution. No other compensation will be offered.

COVID-19 FACE MASK REQUIREMENT

Subjects will be required to wear face masks during their laboratory visits. Study staff are not permitted to remove their face masks at any time during the study visit. Face masks should fit snugly but comfortably against the sides of the face. The masks should be secured with ties or ear loops and should completely cover the mouth and the nose, making sure that it extends from the top of the nose, as close as possible to the eyes without obstructing sight, to under the chin. The masks should cover the face side-to-side, well past the opening of the mouth.

In the context of the Coronavirus (COVID-19) pandemic, the clinical site will follow all FDA, Centers for Disease Control and Prevention (CDC), and institutional review board (IRB) recommendations in its oversight and conduct of the study. This may include changing the schedule of follow-up visits if it is considered necessary after a full risk/benefit analysis.

CONFIDENTIALITY

Eurofins CRL, Inc. will keep confidential information concerning you that is obtained in connection with this study. Your records of being in this study will be kept private except when ordered by law. This information, however, may be examined by the investigator, the Sponsor of the study, Sponsor's representatives, members of the Advarra Institutional Review Board, and by the U.S. Food and Drug Administration (FDA) or governing agencies from other countries, if requested.

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.

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: Pro00061064.

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 of the information you gave us before you left the study will still be used.

PAYMENT FOR BEING IN THE STUDY

You may receive up to \$300.00 (\$20.00 per completed visit) for completing the study. The payment will be within 7 to 10 business days on your Clincard. If you do not finish the study, you will be paid for each completed study visit.

If you are required to participate in the re-challenge portion of the study, you may receive up to an additional \$45.00 for up to 3 products tested. Additional compensation will be received if 4 or more products are tested.

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.

INFORMED CONSENT

I have freely and without reservation volunteered to participate in the clinical study described above. I understand that the products I am testing are proprietary and highly confidential. I agree that I will not disclose or describe the products to anyone who is not an employee of Eurofins CRL, Inc. I also agree that if, as part of the testing procedure, I am required to take the products out of the building for use, I will not give or show them to any friend, family member or acquaintance. I will not use the products or any information I received about them for any purpose other than my participation in the current testing process.

I have been informed of the test procedures and understand the potential risks, including possible skin reactions. All of my questions have been answered and I understand that I may ask additional questions at any time by calling the number listed on the first page of this form. For questions regarding my rights as a research subject, I may contact Advarra IRB.

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 understand I must avoid sun exposure or tanning beds and may be disqualified if I get sunburn on the test sites, scrub the test area or remove purple marks and may forfeit payment.

I also hereby swear to the following: Since I last filled out a Eurofins CRL, Inc., Panelist Profile Form, I have not developed any new medical condition(s), nor am I now taking any new medication(s). I have no known history of acute or chronic dermatologic, medical and/or physical conditions. If female able to become pregnant, to my knowledge, I am not now pregnant nor am I a breastfeeding mother, and I agree to use a reliable method of birth control, such as condoms plus spermicide, IUD, oral, injectable, or implanted hormonal methods, or tubal ligation. I have not taken any antihistamines, non-steroidal anti-inflammatory agents, and/or corticosteroids within one (1) week before initiation of the test.

Adult Study Subject's Name (Print Clearly)

Adult Study Subject's Signature

Date

Name of Person Obtaining Consent

Signature of Person Obtaining Consent

Date

You will receive a signed and dated copy of this consent form to keep.