Panel #: **P144**
CRL #: **CRLNJ2020-0493**

CRL Use Only
Subject #:

INFORMED CONSENT TO PARTICIPATE IN A CUMULATIVE SKIN IRRITATION STUDY

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 study 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 objective of the cumulative irritation patch is to determine the cumulative irritation potential of test products topically applied to the skin of human subjects over a 21-day period.

WHAT WILL HAPPEN DURING THE STUDY

Approximately 35 subjects will be enrolled in this patch study.

Subjects will be consented and screened to determine eligibility and qualified subjects will be enrolled. Subjects will participate in a 21-day cumulative irritation patch study on the back. Test products, along with a positive and negative control, will be tested during the study.

You will be required to make twenty-one (**21**) visits (approximately 15 minutes each) to the clinic. **No** missed visits will be allowed. At the Day 1 Visit, the upper back of each subject (between the shoulder blades to either side of the spine) will be wiped with 70% isopropyl alcohol and allowed to dry. Controls and test products will be applied to the back daily, for approximately 21 days. Patches will remain in place for a period of approximately 24 hours. Test sites will be graded following each patch removal. The patches applied to your back must be kept dry and intact patch sites on your back will be marked with a surgical marker. You must return to the lab at the same time throughout the length of the study for patch applications, removal and grading of the back area.

Approximately 14 days after your final Induction phase, you will return to the clinic for a 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.

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.

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 oversite 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 IRB, and by the U.S. Food and Drug Administration (FDA) or governing agencies from other countries, if requested.

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 $400.00 for completing the study. The payment will be within 7 to 10 business days on your Clincard. If you are required to participate, all visits must be completed as scheduled. If you do not finish the study, you will be paid $15.38 for each completed study visit.

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 procedure 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 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 & 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.