# *Primary Cutaneous Tolerance on Healthy Participants by Single 48-hr Patch Test*

## *Final Report*
## *Study Nº20H-0224-34*

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***This final report was prepared by a clinical testing laboratory with quality management system registered to ISO 9001.***

***This report is composed of 10 pages including appendices (2 pages).***

## *February 28th, 2020*

# Table of Contents

**STUDY OBJECTIVE** ..... **4**
**PROTOCOL** ..... **4**
1. Ethics Committee ..... 4
2. Duration ..... 4
3. Investigation Site ..... 4
4. Personnel ..... 4
5. Test Product ..... 4
6. Material ..... 4
7. Quality Assurance ..... 4
8. Adverse Events or Severe Adverse Events ..... 5
9. Data Analysis ..... 5
10. Amendments to Protocol ..... 5
11. Primary Cutaneous Tolerance Test ..... 6
- Type of Study ..... 6
- Participants ..... 6
- Design of the Study ..... 7

**RESULTS** ..... **8**
**CONCLUSION** ..... **8**
**APPENDICES** ..... **9**

# SUMMARY

## Single 48-hr Patch Test
## Study 20H-0224-34

**Sponsor Code:** LG

**Test:** Study of a cream for Primary Cutaneous Tolerance (irritation potential) tested on 25 healthy participants with a single 48-hr patch application.

**Product:** Lice Shredder
**Customer Lot#:** LS123019
**Evalulab Lot#:** 200116.LG.01

**Date:** February 27th, 2020

**Results:** Under the conditions of the test procedure referenced herein, and based on the results presented in this report, the test product referenced above has produced no signs of primary cutaneous irritation or intolerance.
Hence, the test product may be considered as non-irritant.
Also, given the control provided by a dermatologist, the test product may bear the claim "Tested under the control of a dermatologist".

**Signatures:**

Doctor Michel Journet, M.D.
Dermatologist F.R.C.P (C)

Elisabeth Fiquet, M. Sc.
Investigator, Evalulab Inc.

Marilou Nadeau, B. Sc.
Quality Assurance Director, Evalulab Inc.

## STUDY OBJECTIVE

To determine the primary cutaneous tolerance to a cream and to determine the existence of an allergic pre-disposition on 25 healthy participants with a single 48-hour patch application.

## PROTOCOL

### 1. Ethics Committee

This standard procedure and associated documents were reviewed and approved prior to the commencement of the study, by an Ethics Committee (an independent organization whose responsibility is to ensure the protection of the rights, safety and well-being of the subjects participating in the study).

### 2. Duration

The study took place from February 24th to February 26th, 2020.

### 3. Investigation Site

Evalulab Inc. located at 5475 rue Paré, Suite 206, Mont-Royal, Quebec, H4P 1P7, Canada.

### 4. Personnel

This study was conducted by Evalulab Inc., represented by Rébecca Padey, M.A. – Laboratory Assistant, under the supervision of Elisabeth Fiquet, M. Sc. – Investigator and under the control of Doctor Michel Journet, MD Dermatologist.

### 5. Test Product

Upon reception, the test product was registered in the "Receptions Book" and assigned a code, followed by its storage at ambient humidity and temperature in its original container (as received) in an area allocated for this purpose.

Two (2) units of 100g were received.

Description of the test product:

| | |
|---|---|
| Product name: | Lice Shredder |
| Category: | Cream |
| Customer Lot#: | LS123019 |
| Evalulab Lot#: | 200116.LG.01 |
| Description of control: | Pure Vaseline USP. |
| Application: | The product was diluted at 10% and was generously applied on the entire surface of the patch. The total area of application is about 2.25 $cm^2$. |

### 6. Material

The patches used in this study were TruMed® semi-occlusive, cotton "BBA149-129 Absorbent" with "3M 1530 Tape" adhesive backing.

### 7. Quality Assurance

Good Clinical Practice (GCP) is defined by the totality of the pronouncements put in place for ensuring the quality and authenticity of the trials and the obtained data on one hand and the respect for the ethics on the other.

The data obtained for each participant is recorded in individual Case Report Forms. The data entry is made in black ink. In case of errors or omissions, the initial entry is crossed out and initialed by the investigator.

All recorded data is validated by the investigator, who assumes responsibility for the quality of the work presented and verifies that all gathered data is in agreement with the protocol.

The records obtained during the study will be kept by Evalulab Inc. for a period of 2 years.

## 8. Adverse Events or Severe Adverse Events

An "Adverse Event" is defined as any noxious and unintended response observed in a participant testing a product that does not necessarily have a causal relation with the test product in question.

The risks for adverse events associated with this test may vary amongst the participants. Participants may be subject to rash (intense redness), stinging and burning sensations, cracking, exfoliation effect, dryness or even pain if the test product is strongly irritant or if the participant is particularly sensitive to the product. Participants may also develop an allergic sensitization to the test product or to its components.

The term "Serious Adverse Event" refers to any untoward medical occurrence, related or not to the test product that may lead to death, persistent or significant disability, that requires hospitalization or prolongation of a hospitalization period or that provokes invalidity, significant or permanent incapacity, or that translates to congenital anomaly or malformation.

The participants were instructed to immediately communicate any reactions to Evalulab.

No "Severe Adverse Event" occurred during the entire length of the study.

## 9. Data Analysis

The tolerance to the product was evaluated by a laboratory technician (trained by a dermatologist) - considering the scores, observed reactions, the level of intensity and the reproducibility from one participant to another.
The individual results are presented in the Appendices – Table II.

## 10. Amendments to Protocol

There were no amendments to the protocol.

## 11. Primary Cutaneous Tolerance Test

- **Type of Study**

Monocentric and open-ended, meaning the evaluator, participants, and sponsors alike, were aware of the nature of the test material.

- **Participants**

Recruitment of participants

A total of 27 participants were recruited based on the inclusion and exclusion criteria. The profile of each participant is presented in Table I in the Appendices.

Subject Demographics

| Sex | Number | Age | Average Age |
|---|---|---|---|
| Male | 7 | 18 to 63 | 43.43 |
| Female | 20 | 19 to 79 | 49.40 |
| **Total** | **27** | **18 to 79** | **47.85** |

Informed Consent Form

All participants had to sign and date the Informed Consent Forms explaining the conditions of the test, the risks involved and briefly describing the product to be tested. Each participant was informed verbally and in writing about the nature of the test and of the potential risks involved.

Confidentiality

Participation of the subjects in this study is confidential. The information gathered in the course of the study was recorded in individual case report forms, that are numerically coded and do not contain the names of the participants. Only the employees of Evalulab, auditors of the sponsor, and regulatory bodies (FDA, Health Canada and the Ethics Committee) may have access to the confidential information.

Inclusion Criteria

1. Participants of the feminine or masculine sex, aged 18 years or older,
2. With phototype I to IV according to Fitzpatrick's classification (very clear to mat) and with a skin type that does not interfere with the assessment of cutaneous reactions,
3. Healthy and without any dermal anomalies on the areas to be tested,
4. With no excessive body hair, especially on the test area,
5. Who will cooperate and be present for a follow-up at every visit, informed and sensitized about the duration and the importance of controls allowing for a complete compliance with the study protocol,
6. Who have read, signed and dated the Informed Consent Forms upon full knowledge of the risks involved with the study,
7. Women who use a method of contraception (oral contraceptive, condoms, spermicidal creams, an intra-uterine device (IUD), abstinence…) or are in a menopausal status.

Exclusion Criteria

1. Participants with a history of skin irritation or allergies to the type of product to be tested or in general, to glues (sticking plaster), with allergies to certain foods, to certain chemical products, to jewellery…,
2. With a serious illness, health problem or chronic or progressive disease (asthma, diabetes, cancer, immunological deficiency, ablated organ…),
3. With a history of eczema, dermatitis, psoriasis or significant dermal anomalies on the test area,
4. On medication or having taken medication in the last 7 days prior to the study that could affect skin characteristics or could bias the study (antibiotics, anti-inflammatory drugs, steroids, antihistamines…),
5. Who frequent tanning salons or foresee exposure to the sun,
6. Who abuse alcohol, drugs or/and tobacco,
7. Women who are pregnant, breastfeeding or expecting to become pregnant during the study.

- **Design of the Study**

Procedure

Prior to application of the patches, the test area (upper back, between the two shoulder blades) was carefully examined and wiped with alcohol if necessary (oily skin only). A patch containing the test product and another containing the negative control were applied to the test area, and were left in contact with the skin for 48 hours. Care was taken when positioning the patches to minimize the possibility of displacement or rubbing. The participants were not to remove or wet the patches and were to keep them covered with clothing and to avoid exposure to sun or other sources of tanning.

The use of any other topical pharmaceutical or cosmetic products was not permitted during the study.

Observation and Data collection

Forty-eight (48) hours after application, the patches were removed and all observations (types described below) were recorded.

In addition to the observations made and recorded by Evalulab, the participants were encouraged to observe and report to Evalulab any immediate or delayed reactions such as redness, irritation, itching, or other sensations on the application sites for up to 72 hours after application.

The test area and its surrounding area were observed for erythema, oedema, vesicles, blisters, ulcerations, dryness and acne (papules). These parameters were evaluated and graded as follows:

Reaction Scale:

0 = No visible reaction,
+ = Erythema barely noticeable,
1 = Mild / slight erythema in the patch zone,
2 = Moderate but well defined erythema and presence of slight or barely visible oedema,
3 = Marked erythema, presence of oedema and vesicles,
4 = Severe erythema, presence of vesicles, blisters, and ulcerations.

All observations and comments provided by the participants were recorded in their respective Case Report Form. The obtained scores were then entered in a tabular form showing the number of reactions after treatment.

## RESULTS

Twenty-seven (27) participants, men & women from 18 to 79 years of age (Average Age = 47.85), were recruited and completed this study.

The data obtained during the study is presented in Table II in the Appendices.

No pertinent reaction to the test product was observed during the study.

Similarly, no reaction with the control (Vaseline USP) was observed.

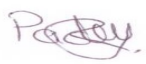
## CONCLUSION

**Under the conditions of the study described herein, and based on the results obtained, the test product "Lice Shredder" has produced no signs of cutaneous irritation, it is therefore considered as non-irritant.**

**However, this test procedure does not allow for evaluation of the sensitization potential of the test product.**

**Finally, given the control provided by a dermatologist, the test product may bear the claim "Tested under the control of a dermatologist".**

I the undersigned, Rébecca Padey – Laboratory Assistant, declare that the study was conducted in accordance with the principles of *"Good Clinical Practice"*. The recorded results show exactly and completely the raw data of the study.



Signature Date: Mont-Royal – February 28th, 2020
Rébecca Padey, M.A.
Laboratory Assistant

I the undersigned, Elisabeth Fiquet, declare that the information provided in this report reflects in a complete and exact manner the results obtained during the study.

Signature Date: Mont-Royal – February 28th, 2020
Elisabeth Fiquet, M. Sc
Investigator

I the undersigned, Marilou Nadeau, declare having validated the information provided in this report.

Signature Date: Mont-Royal – February 28th, 2020
Marilou Nadeau, B. Sc.
Quality Assurance Director

## APPENDICES

**Table I: Participants' Profile 20H-0224-34**

| Participant # | | | Initials | Age | Sex |
|---|---|---|---|---|---|
| 01 | -0224- | 001 | HZ | 47 | F |
| 02 | -0224- | 002 | DT | 63 | M |
| 01 | -0224- | 003 | AM | 49 | F |
| 01 | -0224- | 004 | MP | 46 | F |
| 01 | -0224- | 005 | AA | 43 | F |
| 01 | -0224- | 006 | GS | 46 | F |
| 01 | -0224- | 007 | JP | 37 | F |
| 01 | -0224- | 008 | LC | 42 | F |
| 01 | -0224- | 009 | MA | 77 | F |
| 01 | -0224- | 010 | CP | 74 | F |
| 01 | -0224- | 011 | JB | 79 | F |
| 01 | -0224- | 012 | CL | 60 | F |
| 02 | -0224- | 013 | JJ | 36 | M |
| 01 | -0224- | 014 | MM | 19 | F |
| 01 | -0224- | 015 | JG | 33 | F |
| 02 | -0224- | 016 | CS | 40 | M |
| 02 | -0224- | 017 | LA | 42 | M |
| 01 | -0224- | 018 | CM | 50 | F |
| 02 | -0224- | 019 | PL | 58 | M |
| 01 | -0224- | 020 | CT | 37 | F |
| 01 | -0224- | 021 | ST | 40 | F |
| 01 | -0224- | 022 | SB | 62 | F |
| 01 | -0224- | 023 | NR | 38 | F |
| 02 | -0224- | 024 | CM | 47 | M |
| 01 | -0224- | 025 | RC | 47 | F |
| 02 | -0224- | 026 | CM | 18 | M |
| 01 | -0224- | 027 | SY | 62 | F |

**Table II:** **Individual results of 48-Hour Patch-Test 20H-0224-34**

| Participant Identification | | | | | Challenge Period Observations | |
|---|---|---|---|---|---|---|
| No. | | | Initials | Sex | 48h | 72h* |
| 01 | -0224- | 001 | HZ | F | 0 | - |
| 02 | -0224- | 002 | DT | M | 0 | - |
| 01 | -0224- | 003 | AM | F | 0 | - |
| 01 | -0224- | 004 | MP | F | 0 | - |
| 01 | -0224- | 005 | AA | F | 0 | |
| 01 | -0224- | 006 | GS | F | 0 | - |
| 01 | -0224- | 007 | JP | F | 0 | - |
| 01 | -0224- | 008 | LC | F | 0 | - |
| 01 | -0224- | 009 | MA | F | 0 | - |
| 01 | -0224- | 010 | CP | F | 0 | - |
| 01 | -0224- | 011 | JB | F | 0 | - |
| 01 | -0224- | 012 | CL | F | 0 | - |
| 02 | -0224- | 013 | JJ | M | 0 | - |
| 01 | -0224- | 014 | MM | F | 0 | - |
| 01 | -0224- | 015 | JG | F | 0 | - |
| 02 | -0224- | 016 | CS | M | 0 | - |
| 02 | -0224- | 017 | LA | M | 0 | - |
| 01 | -0224- | 018 | CM | F | 0 | - |
| 02 | -0224- | 019 | PL | M | 0 | - |
| 01 | -0224- | 020 | CT | F | 0 | - |
| 01 | -0224- | 021 | ST | F | 0 | - |
| 01 | -0224- | 022 | SB | F | 0 | - |
| 01 | -0224- | 023 | NR | F | 0 | - |
| 02 | -0224- | 024 | CM | M | 0 | - |
| 01 | -0224- | 025 | RC | F | 0 | - |
| 02 | -0224- | 026 | CM | M | 0 | - |
| 01 | -0224- | 027 | SY | F | 0 | - |

* :Optional

0 :No visible reaction