

Labex.

Laboratoire d'Expertise Clinique Espagne S.A.U.

Study report

for : LABORATORIOS MONTPLET S.L.U.



Safety

Date : 25/07/2019

N° : E190244

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CONFIDENTIAL

REPORT : ACCEPTABILITY STUDY**IN-USE TEST UNDER DERMATOLOGICAL CONTROL****CLINICAL STUDY FOR THE APPRAISAL OF THE CUTANEOUS ACCEPTABILITY OF
A COSMETIC INVESTIGATIONAL PRODUCT, APPLIED UNDER NORMAL
CONDITIONS OF USE, FOR 3 WEEKS, IN BOTH SEX ADULT SUBJECTS**

INVESTIGATIONAL PRODUCT : **EMULSIÓN CALMANTE CON MENTOL (ref.:CILMTI003)**

LABEX PRODUCT CODE : E190244 376005

EXPERIMENTAL PROTOCOL N° : PE190010G, of 11 January 2019

REPORT N° : E190244RD version 1, of 25 July 2019

START OF OBSERVATIONS : 20 June 2019

END OF OBSERVATIONS : 11 July 2019

STUDY MONITOR	RESPONSIBLE FOR THE STUDY	CLINICAL INVESTIGATOR
A. MULA LABORATORIOS MONTPLET S.L.U. Vía Trajana, 53-55 08020 BARCELONA BARCELONA CIF B6713034	M. PÉREZ Technical Responsible LABEX. Passeig Sant Joan, 76 08009 BARCELONA	Dr. J. GALVE (Study Director) Dermatologist LABEX. Passeig Sant Joan, 76 08009 BARCELONA

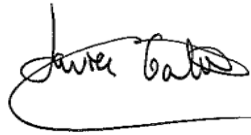
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A U T H E N T I C A T I O N

The study subject of the present report was conducted under my responsibility, in compliance with the experimental protocol, according to the Labex. Standard Operating Procedures and in the spirit of the general principles of the Good Clinical Practices.

All observations and numerical data obtained during this study are reported in the present document.



Dr. Javier GALVE
Dermatologist, M. D.
Study Director

All observations and numerical data collected during this study are reflected in this document. After reading, I certify that these data are accurate reflection of the results obtained and I agree with its content.



Martín PÉREZ
Responsible for the Study

Q U A L I T Y C O N T R O L

This study was performed in conformity with the Standard Operating Procedures of the Laboratoire d'Expertise Clinique Espagne, the protocol signed with the sponsor and "in the spirit" of the general principles of the Good Clinical Practices published by I.C.H. (Topic E6 : CPMP/ICH/135/95).

Audits of clinical studies are conducted every 6 months for each type of study. They are intended to check the correct application of the procedures during the study. The results of these audits are subject to reporting to the Investigator, the Technical Responsible and the Responsible for the Study.

Labex. Quality Unit confirms the compliance of this report with the data generated during the study.

Barcelona, 26 July 2019



Amina RADI
Auditor Quality

P R O T O C O L									
<u>STUDY OBJECTIVE</u>	<p>To appraise the cutaneous acceptability of a cosmetic investigational product, applied under the normal conditions of use, during 3 weeks, in both sex adult subjects.</p> <p>Claims to justify: "Tolerance tested under Dermatological control" and "Sensitive Skins"</p>								
<u>TYPE OF STUDY</u>	Acceptability study ("in-use test"), under Dermatologist control, in "open".								
<u>STUDY RELEVANCE</u>	<p>Cutaneous irritation can be defined as an attack on the integrity of the skin by lesions in the epidermis and the appearance of an inflammatory reaction in the dermis, resulting in macroscopically visible phenomena, which manifests from a redness (erythema) to edema.</p> <p>In man, the "use test" ("acceptability" test) performed under Dermatological control (subjects individually examined by a Dermatologist Investigator) allow to verify the absence of discomfort reactions or cumulative irritation (functional and physical signs) associated to the application of the investigational product for 3 weeks in normal conditions of use, under subjects who met specific inclusion criteria.</p> <p>Overall, the clinical evaluation performed by the Dermatologist Investigator and the assessment made by the subjects, based on a specific and adapted questionnaire, allows to appreciate the effectiveness of the investigational product and cosmetic acceptability.</p>								
<u>INCLUSION CRITERIA</u> <i>(in addition to the standard criteria of Labex.)</i>	<ul style="list-style-type: none"> . Number of subjects : 20 . Sex : both . Age : 18 to 70 years old . Origin : caucasian . Body skin type : indifferent . Sensitivity of the skin : 100%, being considered sensitive the subjects that have a recent history and repeated functional symptomatology of skin discomfort (ex. tingling, stiffness, warmth, stinging, burning, redness ...) . Healthy subjects with atopy background: 40 % 								
<u>METHODOLOGY</u>	<p>Modalities application of the investigational product</p> <table border="1" style="width: 100%; border-collapse: collapse;"> <tr> <td style="width: 30%;">Area</td> <td>Forearm</td> </tr> <tr> <td>Frequency and duration</td> <td>Once a day, during 3 weeks</td> </tr> <tr> <td>Application conditions</td> <td>By the subject himself, at home (starting on D1 and ending on D21), under the normal conditions of use, following the Sponsor's instructions</td> </tr> <tr> <td>Concomitant application of other products</td> <td>Usual hygiene products</td> </tr> </table> <p>Modalities of evaluations</p> <ul style="list-style-type: none"> . <i>Cutaneous acceptability by:</i> <ul style="list-style-type: none"> → clinical examinations by the Dermatologist Investigator on D1 and D22 days. → questionnaire to be filled in by the subject. . Cosmetic qualities and efficacy: by a questionnaire prepared in collaboration with the Study Monitor, to be filled in by the subject, at home, before the last visit to Labex., and completed with the global appraisal in the presence of the Dermatologist Investigator on D22. 	Area	Forearm	Frequency and duration	Once a day, during 3 weeks	Application conditions	By the subject himself, at home (starting on D1 and ending on D21), under the normal conditions of use, following the Sponsor's instructions	Concomitant application of other products	Usual hygiene products
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Concomitant application of other products	Usual hygiene products								

<u>DATA ANALYSIS</u>	Cutaneous acceptability: <u>Calculation of the appearance frequency for the following reactions:</u> <ul style="list-style-type: none">. all reactions observed in the whole study,. reactions noted by the subjects themselves (discomfort, irritation),. reactions observed by the Clinical Investigator,. reactions requiring modification in the pace of application, or its interruption,. reactions considered as "pertinent",. adverse reactions. <u>Interpretation of the results obtained under the adopted experimental conditions of use, based on:</u> <ul style="list-style-type: none">. the expected effects, according to the Study Monitor,. the type of investigational product,. analysis of the nature, location, intensity, frequency, duration and appearance period of the reactions.
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CONCLUSION

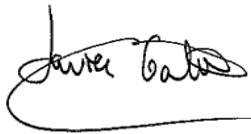
The CUTANEOUS ACCEPTABILITY of the investigational product designated as:

“EMULSIÓN CALMANTE CON MENTOL (ref.: CILMTI0003)

can be judged, on the whole, as **GOOD**, after repeated applications under normal conditions of use, once a day, during 3 consecutive weeks, on the forearm skin, by 20 healthy adult subjects of both sexes, with sensitive body skin, of whom 50% have atopy background.

The claims such as **“TOLERANCE TESTED UNDER DERMATOLOGICAL CONTROL”** and **“FOR SENSITIVE SKIN”** can thus be justified.

Barcelona, 25 July 2019



Dr. J. GALVE
Dermatologist M. D.
Study Director



M. PÉREZ
Responsible for the Study

This study was conducted by LABORATOIRE D'EXPERTISE CLINIQUE ESPAGNE, managed by Mr. B. RAÏS, PhD Biological and Medical Sciences, European Registered Toxicologist - EUROTOX.