

Labex.

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

Study report

for : **LABORATORIOS MONTPLET S.L.U.**



Safety

Date :16/12/2022.....

N° :E220503.....

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CONFIDENTIAL

REPORT : ACCEPTABILITY STUDY

IN-USE TEST UNDER PEDIATRIC 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 CHILDREN AND BABIES SUBJECTS

INVESTIGATIONAL PRODUCT : **SPRAY SOLAR SPF 50 2022 CON CITRONELA ORGÁNICA (ref.: RELMIB016 - Batch: RD-M22- 205)**

LABEX PRODUCT CODE : E220503 376009

EXPERIMENTAL PROTOCOL N° : PE220027G, of 03 February 2022

REPORT N° : E220503RD version 1, of 16 December 2022

START OF OBSERVATIONS : 03 November 2022

END OF OBSERVATIONS : 24 November 2022

STUDY MONITOR	RESPONSIBLE FOR THE STUDY	CLINICAL INVESTIGATOR
M. AGUILERA LABORATORIOS MONTPLET S.L.U. Vía Trajana, 53-55 08020 BARCELONA	M. JIMÉNEZ Degree in Biotechnology Master in Biomedical Research LABEX. Passeig Sant Joan, 76, 08009 BARCELONA	Dr. C. SORRIBES (Study Director) Pediatrician LABEX. Passeig Sant Joan, 76 08009 BARCELONA

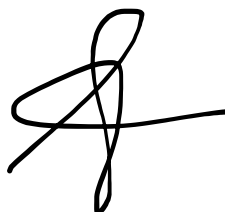
Document of 13 pages

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. Quality system management certified by AENOR, register n° ER-0352/2006.

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. Clara SORRIBES
Pediatrician, 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.



Marina JIMÉNEZ
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, on 16 December 2022



Amina RADI
Auditor Quality

CONCLUSION

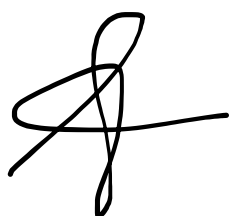
The CUTANEOUS ACCEPTABILITY of the investigational product designated as:

“SPRAY SOLAR SPF 50 2022 CON CITRONELA ORGÁNICA (ref.: RELMIB016 - Batch: RD-M22-205)”

can be judged, on the whole, as **VERY GOOD**, after repeated applications under normal conditions of use, once a day, during 3 consecutive weeks, on the body and face skin, by 18 healthy both sex children or babies' subjects, of whom 50 % were aged between 3 and 36 months and 50 % were aged between 3 and 12 years.

The claim such as **“TOLERANCE TESTED UNDER PEDIATRIC CONTROL”** can thus be justified.

Barcelona, 16 December 2022



Dr. C. SORRIBES
Pediatrician, M. D.
Study Director



M. JIMÉNEZ
Responsible for Clinical
Studies

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