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SPONSOR:ALCOHOLES MONTPLET, S.A.

TITLE: Verification of skin compatibility in man of an insect repellent after making a unique application on patch (Patch-test).

Study code:13-16002-M

Date: 30/10/2013

FINAL REPORT

Sponsor

ALCOHOLES MONTPLET, S.A.
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Sponsor's Representative: Ana Mª López

Test Centre / Laboratory

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Laboratory manager: Sergio Grané Pereda

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Autorizado como Laboratorio de Control de Productos Sanitarios y Cosméticos. por el Ministerio de Sanidad, Política Social e Igualdad. Agencia Española de Medicamentos y Productos Sanitarios (nº8933LC). Inscrito y Autorizado por la *Generalitat de Catalunya* como Laboratorio Agroalimentario (nº157) y de Salud Ambiental y Alimentaria (R5-196-04). Autorizado por la *Generalitat Valenciana* (LA-0212), Castilla-La Mancha (LA/AL/CS/045) y Andalucía (A.455/III). Reconocido como Establecimiento Técnico Auxiliar de l' *Agència Catalana de l' Aigua*.





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Final Report Approval

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1. DATA FROM THE STUDY

Study code: 13-16002-M

Title: Verification of skin compatibility in man of an insect repellent after making a unique application on patch (Patch-test).

Name of the test product:

Child insect repellent

Name and Surname of Study Director: Eva Soriano Tárraga

Identification of specimens (if applicable): Not applicable

2. INTRODUCTION

This study aims to verify skin compatibility of the product KIDS INSECT REPELLENT after performing a single application to the skin in exaggerated experimental conditions and with a volunteer with sensitive skin.

The product was applied once on the skin under patch (patch). The compatibility of the product was verified after removing the patches and a visual examination of the experimental area was done by the responsible.

The compatibility of the product tested with skin, after use in normal conditions product, has been appreciated by extrapolation of results obtained under these particular experimental conditions.

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3. PURPOSE OF THE STUDY

The objective of this test is to verify the skin compatibility with the product after performing a single application under patch, on volunteer with sensitive skin.

4. TYPE OF STUDY

This study was performed as an open assay.

Each participant volunteer has been his own control.

The study was performed according to the general conditions established for the realization of a study project in human volunteers.

The study project was submitted to the opinion of the Internal Committee, which approved the realization of the study (opinion nºCEIC-1310, 2th October 2013).

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5. IDENTIFICATION OF THE TEST SUBSTANCE

The study was carried out with the test product, whose analysis certificate was not provided by the sponsor. The information found in the table below has been provided by the sponsor

Denomination	Child insect repellent
Reference	-
Batch	M17913
Number and type of packaging	Two containers of 50 ml with diffuser
Contents of packages	50 ml
Composition	See section 13

The handling administered to remaining product at the end of the study: According to advices in the form 186 "Descriptive sheet of the product" filled by the sponsor. The remaining test product at study endpoint will be eliminated according to internal procedures Research ETYCA, being applicable the SOP GL007 "Destruction of Samples and Waste"

Information related to the product.

Documents relating to the tested product, that must accompany the samples, were the qualitative formula and the letter of commitment of the sponsor, in particular that one that refers to the conformity of the formula with the current regulations and its safety.

6. STAFF INVOLVED IN THE STUDY

Organization/Charge	Name and surname	E-mail
ETYCA RESEARCH Laboratory Manager	Sergio Grané Pereda	sergigrane@etyca.net
ETYCA RESEARCH Study Director	Eva Soriano Tárraga	evasoriano@etyca.net
ETYCA RESEARCH QAU Manager	Laura Sánchez Jiménez	laurasanchez@etyca.net

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The address and telephone number to get in touch for notifications to Etyca Research staff are the same that the test institutions ones.

The appointment of a substitute for the Study Director has not been needed, in accordance with the internal procedure OR001: Organization and Identification Sraff.

7. STANDARD OPERATION PROCEDURES

The study has been developed according to the internal SOP's Etyca Research. The Standard Operating Procedures (SOP) used, have been the following:

<i>Test</i>	<i>Internal procedure</i>	<i>Methodology</i>
<i>Skin compatibility test (Patch Test); Clinical Trials</i>	<i>CO024</i>	<i>Response evaluation</i>

8. VOLUNTAREERS

Number of volunteers:

10 volunteers were included in the study.

No dropout was recorded and no exclusion was decided by the researcher.

The product compatibility was therefore verified in 10 volunteers.

Specific inclusion criteria:

The specific inclusion criteria ,defined in the protocol, were the following:

- Age: 18-70 years.
- Sex: both.
- Sensitive skin.

All volunteers responded to these specific inclusion criteria.

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Specific no inclusion criteria:

The specific no inclusion criteria were the following:

- Cutaneous mark in the experimental area that could interfere with the evaluation of the skin reaction (pigmentation disorders, scars, hair too much developed, freckles and nevus in excessive amount, sunburns etc.).
- Eczematous reaction that does not have totally disappeared, consequences of scars or pigmentation of previous studies in the experimental area.
- Rosin allergy.
- Allergy or reactivity to a cosmetic product of the same category of the tested product.
- Cutaneous hyperreactivity.
- Atopy.
- Reactivity to the medical tape.
- Intense sun exposure during the month prior to the study.
- Prevision of intense sun exposure (directly to the sun or in UV ray booths) during the study period.
- Intention of having a bath in a bathtub, sea or swimming pool, or having a sauna or turkish bath during the study period.
- Practice one or more sports intensively or regularly, whose momentary interruption could provide a problem.
- Realization of a treatment that contains acid vitamin A or its derivatives during the three months prior to the study.
- Realization of a treatment that contains topical corticoids in the experimental area during the 8 days prior to the start of the study.
- Realization of a treatment of PUVA or UVB during the month prior to the start of the study.
- Prevision of being vaccinated during the study period, being the last vaccine during the 3 weeks prior to the study.

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All the volunteers responded to this specific no inclusion criteria.

9. METHODOLOGY

The experimental conditions were the following:

Aplication zone	Patch material	Experimental conditions of use	Applied quantity	Contact time	Control time after patch removal
Back	occlusive patch * Finn Chamber Std*	Application of the product as it was supplied by the sponsor	1 pulv.	24h +/- 5h	15 mín. 24h +/- 2h

10. RESULTS

Time control	Number of volunteers reactive	Types of reaction	Daily Average Irritation Score	% of reactive volunteers
15 minuts	0	-/-	0	0%
24 hours	0	-/-	0	0%
Maximum Average Irritation Score				0
% of reactive volunteers				0%

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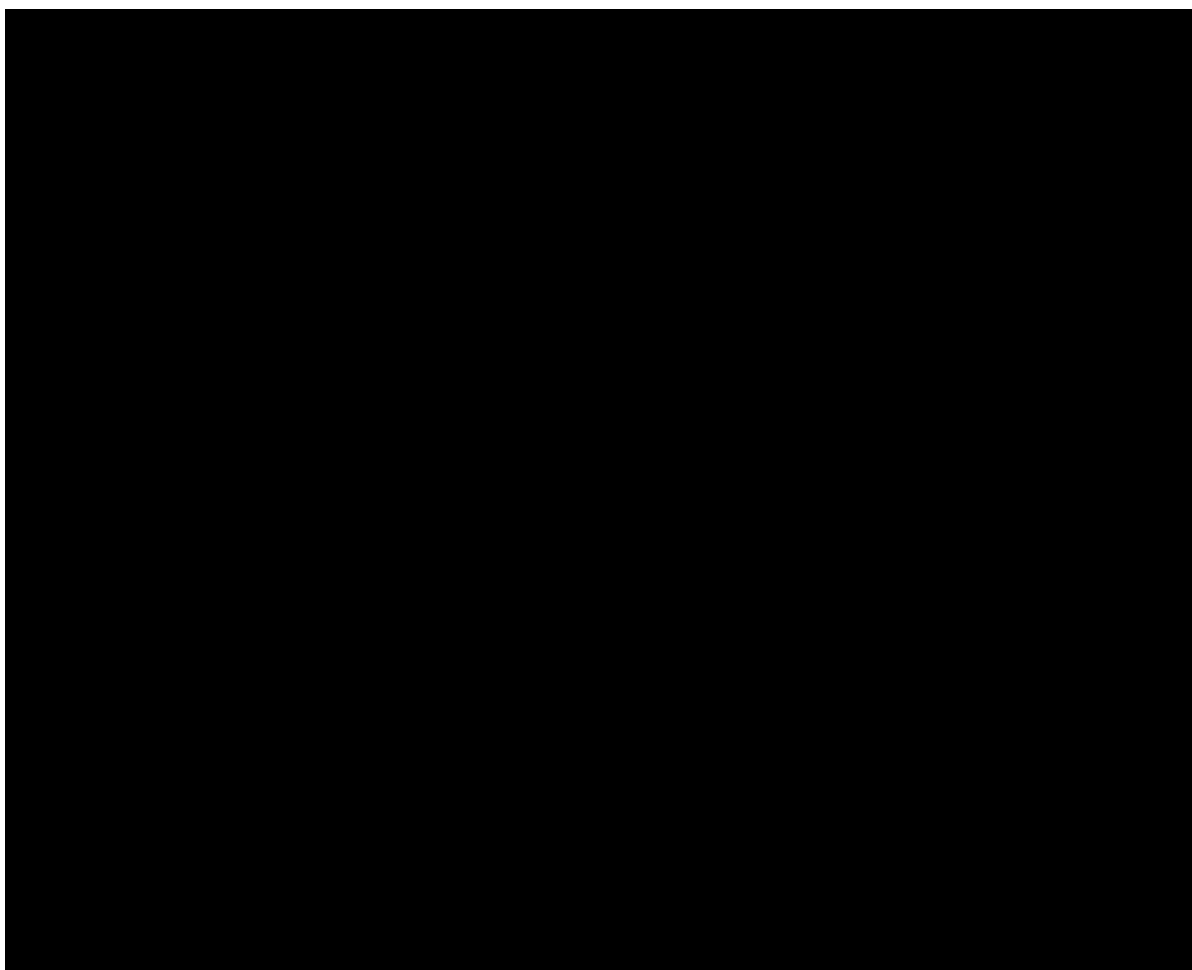
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11. CONCLUSIONS

Under the experimental conditions adopted, the product has a **good cutaneous compatibility**.

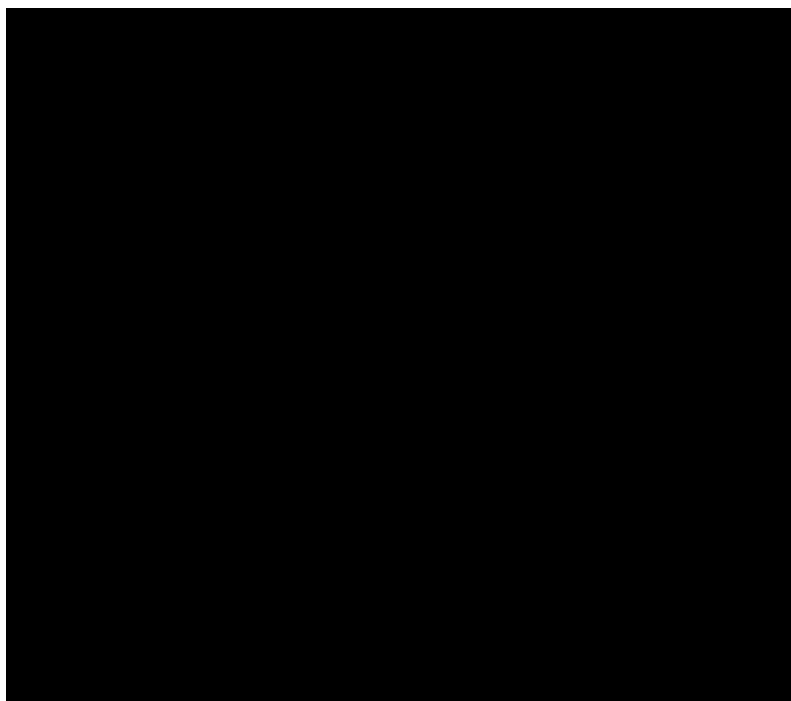
12. DATA STORAGE

All the spawned data and the attendant documentation with the study are stored in the archive GLP of Etyca Research.

The remaining test product at study endpoint will be eliminated according to internal procedures Research ETYCA, being applicable the SOP GL007 "Destruction of Samples and Waste", as indications of sponsor.

13. BIBLIOGRAPHY

- *ICH E6 (R1): Guideline for Good Clinical Practice. June 10th 1996.*
- *OECD 1998: OECD Series on principles of good laboratory practice and compliance monitoring Number 1.*



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Final Report Approval

Study Director

Eva Soriano Tárraga

I declare that the study was conducted following the essence of the principles of Good Clinical Practice (ICH Topic E6 international recommendations, CPM / ICH / 135/95 of 01/05/96, Directive of the European Parliament and Council 2001/20 / EC - OJ of 01.05.2001).

Date:

Quality Assurance Unit

Laura Sánchez Jiménez

Date:

Test Facility / Laboratory

ETYCA RESEARCH (Estudio Técnico y Control Analítico, S.L.)

Laboratory Manager: Sergio Grané Pereda

Date:

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