

SIMULATED-USE TRIAL OF A SKIN MOSQUITO REPELLENT PRODUCT

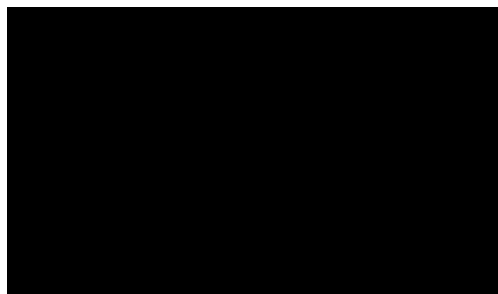
Trial against *Aedes albopictus*, *Culex pipiens* and *Anopheles gambiae*

MONTPLET Insect Repellent 10% IR3535 RD-M-21-338

DECEMBER 2021
Report 2742d/1121

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SPONSOR:

LABORATORIOS MONTPLET S.L.U.

Via Trajana 53-59
08020 Barcelona
SPAIN

GOOD PRACTICE

STUDY TEC N°: 2742d/1121
NUMBER OF PAGES: 10
SPONSOR: Laboratorios Montplet (Barcelona - Spain)
TEST PRODUCT: MONTPLET Insect Repellent 10% IR3535 RD-M-21-338
sample received the 21th December 2021

FACILITIES:

DATE OF TESTING: 27th to 28th December 2021

REPLICATES: 10 volunteers

STUDY DIRECTOR:

STUDY ENGINEER:

QUALITY INSURANCE RESPONSIBLE:

METHODOLOGY:

The test system was adapted from the guideline WHO/HTM/NTD/WHOPES/2009.4; GUIDELINES FOR EFFICACY TESTING OF MOSQUITO REPELLENTS FOR HUMAN SKIN. This method is part of the Appendix of proposed methodologies for PT19 Biocides registration, in the document "Guidance on the Biocidal Products Regulation - Volume II Efficacy – Assessment and Evaluation (Parts B+C) – Version 4.0 – December 2021 - ECHA".

ARCHIVING: 10 years, hard and electronic copies

There were no circumstances which can have affected the reliability of the data presented in this report.

Date: 28th December 2021

SIMULATED-USE TRIAL OF A SKIN MOSQUITO REPELLENT PRODUCT

Trial against *Aedes albopictus*, *Culex pipiens* and *Anopheles gambiae*

1. PURPOSE

The purpose of the study was to measure the duration of efficacy of a product towards three mosquito species.

The trial was an "arm in cage test" and was carried out on human volunteers, against mosquitoes *Aedes albopictus*, *Culex pipiens* and *Anopheles gambiae*.

2. DEFINITIONS

Efficacy duration: it is defined as the time between the application of the repellent and the last assessment time without bites. The trial was stopped when one bite was observed and confirmed by a second one in succession.

3. EXPERIMENTAL DESIGN

The study was conducted in the laboratory on 10 persons and 3 species, in operating conditions previously defined according to the standard method:

Guidelines for efficacy testing of mosquito repellents for human skin
(WHO/HTM/NTD/WHOPES/2009.4), World Health Organization, 2009,

3.1. Human volunteers

The study was conducted on 10 subjects, 5 women and 5 men. The test area was the forearm from wrist to elbow, i.e. an average area of 600 cm²

They were all informed about the purpose of the study and the corresponding risks (bites) and they all consented to this in a complete knowledge and understanding of the trial.

The volunteers did not apply on their forearms perfumes or repellents in the 12 hours before the test. They were non-smoking and have not smoked for a period of 12 hours before the start of the study and throughout the duration of the test.

3.2. Species

The study was conducted on the following species, females only because they bite:

Aedes albopictus

Culex pipiens

Anopheles gambiae

6. RESULTS

The raw data are presented in Appendix.

Testing on the untreated control has proved the natural will of the females to sting.

Table 1: Duration of protection without bites in hours:

The details of the calculation is in Appendix.

PRODUCT	TARGET	COMPLETE PROTECTION TIME
Montplet Insect Repellent 10% IR3535	<i>Aedes albopictus</i>	6.0 hours
	<i>Culex pipiens</i>	6.1 hours
	<i>Anopheles gambiae</i>	6.2 hours

7. CONCLUSION

Under the conditions of this test, the samples provided, the strains of insects and the method used, the product

MONTPLET Insect Repellent 10% IR3535 RD-M-21-338

applied at a rate of 0.69 g / 600 cm² (average area of a forearm), i.e. 1.15 mg/cm², has proved a complete protection between of 6 hours

against mosquitoes *Aedes albopictus*, *Culex pipiens* and *Anopheles gambiae*.
