

Miljøstyrelsen
Pesticider og Genteknologi
Strandgade 29
1401 København K

Efficacy evaluation of data concerning Care Plus Anti-Insect Spray 20% (790-2, MST-671-04051).

Dept. of Agroecology
Aarhus University
Forsøgsvej 1
DK-4200 Slagelse

Conclusion:

It is recommended that Care Plus Anti-Insect Spray 20% is approved as an repellent against mosquitoes with a protection time of 4 hours and against ticks with a protection time of 2 hours.

Michael Kristensen

Associate Professor

Date: 25 May 2016

Company: Tropenzorg B.V., Almere, The Netherlands.

Active ingredient: 20% N,N-diethyl-m-toluamide (DEET)

Pest: Mosquitoes, ticks.

Dosage recommended on label: Apply sparingly. Use only once a day.

Documentation presented:

SPC

Product Assessment Report Care Plus Anti-Insect DEET Spray 20% (12-2014)

Efficacy studies:

- 1) Repellent efficacy of a product on human arms against mosquitoes. Care Plus Anti-Insect DEET Spray 20%.
- 2) Evaluation of Care Plus Anti-Insect DEET Spray 20% against the European sheep tick, *Ixodes ricinus*, on human volunteers.

Direct Tel.: +45 8715 8116
Mobile Tel.: +45 29645725
E-mail: mikr@agro.au.dk

Journal no.: 145662
Reference: MK

Page 1/2

Evaluation: According to the “Product Assessment Report” the target organisms are Mosquitoes (Culicidae): i) house mosquitoes – *Culex* spp., ii) malaria mosquitoes - *Anopheles* spp., iii) yellow fever mosquitoes – *Aedes* spp., iv) ticks (Ixodoidea) (not tested against tropical species).

Section 2.5 of the “Product Assessment Report” summarise efficacy data performed with Care Plus Anti-Insect DEET Spray 20%. The data are from the two abovementioned efficacy studies.

Arm-in-cage tests with Care Plus Anti-Insect DEET Spray 20% with 5 volunteers show protection time of at least 4 hours for *Culex quinquefasciatus*, *Anophles gambiae* and *Aedes aegypti*.

The repellent efficacy of Care Plus Anti-Insect DEET Spray 20% against ticks was tested by 10 human volunteers. The forearm of a person was treated from elbow to wrist. A tick was placed on the vertically held arm 1 cm below the treated area. Ticks entering the treated skin and walking >3 cm in direction of the elbow were considered not repelled. The protection time against *Ixodes ricinus* was at least 2 hours.

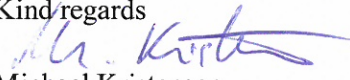
The complete protection time approved and given on a label is decided on the basis of the study with the lowest complete protection time. Arm-in-cage experiments are performed under optimum conditions and you will expect the complete protection time during normal use will be a bit lower. The complete protection time value is rounded down to the nearest full hour.

It is noted that the NL CA has accepted the lack of field a field study even though the TNsG (CA-Dec12-Doc.6.2.a – Final) requirement of a mosquito repellent for Europe is “Products intended for use as repellent on skin or clothes: - a simulated-use test (arm-in-cage) showing repellence and - a field study showing repellence in the field.” The applicant states that the guidance was not available during the process of data collection and competent authorities should therefore accept data based on the latest available guidance published, where details of repellents were not available. It must be emphasized that the material supplied by the applicant is insufficient for approval, but as laboratory and field studies are available from similar products and have been published in publically available research journal. We are confident that Care Plus Anti-Insect Spray 20% will be an efficient repellent.


The label should include information about intended use(s) and protection time. The dosage recommended on the label “Apply sparingly” is not acceptable. How sparingly should the product be applied to protect against mosquitoes for 4 hours?

Conclusion: It is recommended that Care Plus Anti-Insect Spray 20% is approved as an repellent against mosquitoes with a protection time of 4 hours and against ticks with a protection time of 2 hours.

Kind regards



Michael Kristensen
Associate professor



Karl-Martin Vagn Jensen
Senior scientist