



CK 98/49428/23

PO Box 2693, Beacon Bay, East London, South Africa
Jua Kali, C-10, Holm Hill, Beacon Bay, East London, South Africa
Tel: +27 43 730 7374 Fax: +27 86 537 5587
Email: info@repello.com Web: www.repello.com

Summary Repello Geraniol Mosquito Repellent Spray Toxicity Reports

Investigation for:

ACUTE ORAL TOXICITY

ACCORDING TO OECD, SECTION 4, SUBSECTION 401

Result: Test applying 20 g/kg bodyweight animals for 14 days. As all tested animals survived the 14 days observation period under normal increase of body weight and the histology for bacteria remained without result. No substance related mortality according to the OECD, S.4, SS 401, a further check of the product for acute oral toxicity could be omitted. The tested substance is, as expected, to be classified as acute non toxic substance.

Investigation for:

ACUTE DERMAL TOXICITY

ACCORDING OECD, SECTION 4, SUBSECTION 402

Result: The tested Geraniol product did not show any system related mortality being tested for acute dermal toxicity for the rabbits of the species New Zealand, which are known for being extremely sensitive. All tested animals survived the observation period of 14 days and did not show any toxic reactions against the tested substance, to be classified as acute dermal non toxic.

Investigation for:

ACUTE TOXICITY AFTER INHALATION

ACCORDING OECD, SECTION 4, SUBSECTION 403

Result: All tested animals survived the inhalation application of the tested Geraniol spray product without any sign of toxicity symptoms and have survived the observation period with normal increase of body weight. The dissection with subsequently following macro- and microscopic investigation of the interior organs confirmed observed results. The tested will be classified as non acute toxicity after inhalation.

Investigation for:

LOCAL COMPATIBILITY PATCH TEST ON RABBIT

ACCORDING OECD, SECTION 4, SUBSECTION 404

Result: The tested Geraniol spray formulation did not result in any primary irritations on shaved skin of the the tested animals, New Zealand albino rabbits. To be classified therefore as local very good compatible. The second growth of the pelt (fur) on the treated areas did not show any abnormalities in comparison to the second growth of untreated control shavings.

Investigation for:

LOCAL COMPATIBILITY PATCH TEST ON HUMAN SUBJECT

ACCORDING TO FEDERAL REGISTER VOL.38, No. 187, § 1500.41 dated 27.9.1973

Result: Similar to rabbit patch test, the geraniol spray formulation patch test series for local compatibility on human subjects, with 60 volunteers, resulted in no noticeable effects on human skin. The test confirmed the results of good local compatibility.

Investigation for:

MUCOUS MEMBRANE COMPATIBILITY ON THE RABBIT EYE

ACCORDING TO J.H. DRAIZE, APPRAISAL OF THE SAFETY IN FOOD, DRUGS AND COSMETICS, ASS. OF FOOD AND DRUG OFFICIALS OF THE U.S.p.p. 49- 52 (1959)

Result: The conjunctival reaction against the applied tested substance Geraniol Mosquito Spray, which was injected into the right eye (conjunctive membrane pouch) of the tested animals was expressed in hardly perceptible reddish colour of the mucous membrane which disappeared after 24 hours observation period completely. The rigid evaluation according to DRAIZE justifies however for the tested substance a classification as mucous membrane irritating on the rabbit eye.

Investigation for:

a) CHRONIC ORAL TOXICITY WITH REPEATED DOSAGE FOR 150 DAYS

b) CHRONIC INHALATIVE TOXICITY WITH REPEATED DOSAGE FOR 72 DAYS

ACCORDING OECD, SECTION 4, SUBSECTION 452

Result for Geraniol Mosquito Spray, Test A: a) All tested animals have survived the daily dosage of 3 ml/kg body weight of the testing substance for a trial period of 150 days using a esophagus probang (probe) without interference in the increase of the body weight in comparison to untreated control groups and did not show after dissection which was performed 14 days after the end of the trial period any macroscopic abnormalities of the interior organs, stomach – colon tract and liver. Also the checks for Toxicity symptoms without lethal process (bristling of fur, sedation) remained without result. Geraniol Mosquito Spray to be classified as chronic oral non toxic for a dosage period of 150 days.

Result Test B) Trial guidelines OECD S.4, SS.452, In addition the evaluations have been performed according to the Good Laboratory Practice guidelines following the methods of the MELLON INSTITUTE OF INDUSTRIAL RESEARCH, PITTSBURGH, PENNSYLVANIA, USA, for Range – Finding Toxicity. For this purpose the tested animals in the investigation program of the tested substance Geraniol Mosquito Spray have been exposed over a period of 72 days to a saturated flowing air stream. All animals have survived this exposure and did not show after dissection 14 days after the respective end of the trial any histologic changes and abnormalities with esophagus and lungs. The total amount of exposition of tested substance was 697 g/kg body weight for 72 days, that as a consequence the chronic lethal dose for rats has to be adjusted much higher as the border line of 4g/kg body weight which has to be survived as stated in the regulations in order to classify a product as chronic inhalative Non Toxic.

Investigation for:

OEOTOXICITY WITH GOLDORFENTEST

ACCORDING OECD GUIDE LINE 203, DIN 38412, PART 15

Result: The LC 50 = Concentration where 50 % of the applied fish have been killed during the trial period was obtained as follows: 583,6 mg/litre The tested substance have therefore to be classified as Not fish toxic. STUDY: Skin Penetration Test of Geraniol Spray Mosquito repellent in accordance with OECD Guidelines in Vitro Skin Absorption draft new guideline 428 University of Vienna, Department of Pharmaceutical Chemistry , Althanstrasse 14, 1090 Vienna, Austria. Austrian Research Centres Seibersdorf (ARCS), 2444 Seibersdorf, Austria Results: Due to this product safety it is to be expected, that even a skin exposure 10-fold higher than a typical one will not cause any ill effects to health, because even in this very unlikely case the uptake of active components will be 149-fold to 1.456-fold lower than the corresponding No Observed Effect Level (NOEL). If the product is used as intended, this enormous safety factor of minimum 149-fold (in term of figures that translates to a human with 70 kg bodyweight must apply 23,840 litres product daily to reach the NOEL). No harmful effects even when applied to infants or babies.