MINISTRY OF HEALTH AND PUBLIC ASSISTANCE
NATIONAL INSTITUTE OF HYGIENE
"RAFAEL RANGEL"

Caracas, 25 Jan 1999

Citizen:
Mr. José Fernando Gomez
Manager East Zone of the Country
Santafé de Bogotá - Colombia
Present.-

ATTENTION: MESSRS SALDER LTD.
NOPIKEX SOAP

In accordance with your request for an analysis on the product **NOPIKEX REPELLENT SOAP**, I annex the toxicity studies report conducted by the Department of Pharmacology - Division of Pharmacodynamics of this Institution.

Yours faithfully,

Signed: **DR. FRANCISCO ARAOZ ROCHA**
PRESIDENT

MPV/MdeL/IM/ia.-

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REPORT

TOXICITY ASSAY OF THE PRODUCT "SOAP REPELLENT NOPIKEX"

In accordance with the request for a Toxicity study of the Product Soap Repellent NOPIKEX, identified as FAX No. 6624797, dated 26 of October, 1 998; from JGB BOGOTA, Santafé de Bogotá, Colombia; the received literature was perused and the requested study for the sent samples began.

I DETAILS OF THE SAMPLE:

Memorandum: DCMC 6777
Date: 29-10-98
Name of Product: Repellent Soap NOPIKEX

Type of Product: Insect repellent soap in foam form for human use.

Method of application printed in the package: "1 Moisten exposed parts to bites, 2 Rub with Nopikex and evenly apply the lather, 3 Allow the lather to dry on the skin (do not rinse off), Apply every 8 hours. If there is contact with the eyes, wash with clean water:

Declared ingredients on the package: "Saponified vegetable oils, Diethyltoluamide 20.45%, Permethrin 0.56%".

Manufacturer: Salder Limited. Distributor: JGB S.A., carrera 2 Norte, No. 21-103, Cali, Colombia. Telephones: 8892153, 6534055, 6678445, 8836906, Fax: 6678445.

Package: Printed cardboard box contained in a display with 12 units; the name of the product, "NOPIKEX Foam Repellent" is printed on all packages

Appearance of the Contents: Homogeneous, compact, white solid mass, of rectangular form with a 48 g weight and characteristic perceptible odor.

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II STUDIES CONDUCTED:

1 ACUTE DERMAL TOXICITY TESTS:

The Acute Dermal Toxicity Study was conducted following the Organization for Economic Cooperation and Development (OECD, L'OCDE) method in undamaged skin of adult albino rats, Wistar strain, of both sexes, with 200 to 300 g of body weight. The dorsal hair was removed with an electric shaver 24 hours prior to the test.
Only one application of an aqueous solution of the sample was applied to the scapular area of the animal and was left without occlusion and cleansing. Observations were made during the first 24 hours after application and daily for 14 days. Experimental outline completely at random.

Applied Doses:

53.7 g of the sample/Kg b.w., (body weight), equivalent to 0.3 g of Permethrin/Kg b.w., and 10.7 g of Diethy-Toluamide/Kg p.c., applied in 8 g of foam per animal.

71.7 g of the sample/Kg b.w., equivalent to 0.4 g of Permethrin/Kg b.w., and 14.8 of Diethyl-Toluamide/Kg b.w., applied in 10.7 g of foam per animal.

Number of treated animals: 10: (5 males and 5 females) for each dose.
Number of animal controls: 10: (5 males and 5 females) to which distilled water was applied.

Results obtained: At the doses used, under the conditions and time frame of the observation no deaths nor intoxication symptoms were seen in the animals treated with the sample, with regards to the animal controls.

2 DERMAL INNOCUOUSNESS TESTS:

The Local Dermal Innocuousness Test was performed in rabbit skin following the Modified Draize Method.
To that effect an aqueous solution of the product at a concentration of 30% p.v., in distilled water was prepared daily and a volume of 0,5 ml was used per application. Adult, albino rabbits of both sexes, New Zealand strain, of from 2.5 to 3.5 Kg of corporeal weight were used; their dorsal hair was removed with an electric shaver 24 hours prior to the assay.

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1- Consecutive application of the product to abraded and unabraded skin was performed during three days. Observations were made at 24, 48 and 72 hours after the first application. The irritant effect of the erythema and the edema were evaluated according to the Draize scale.

Dosage: 0.15 g of the product in 0.5 ml per application.

Number of animals used: 3 rabbits.

Results obtained: the highest median value for the erythema was 2.0, it was observed at the 48th hour and it remained to the 72nd hour.

2- Occluded Patch Test through only one application of the product to abraded and unabraded skin with a 24 hour timeframe. Observations were made at the 24th and 72nd. hours after application. The irritant effect of the erythema and the edema were evaluated according to the Draize scale.

Dosage: 0.15 g of the product in 0.5 ml per application.

Number of animals used: 3 rabbits.

Results obtained: Median value of the erythema irritation: 1.5
Median value of the edema irritation: 1.4

For tests 1 and 2 the product is considered irritant if the median value for the erythema and edema is equal to or greater than 2.5.

3 TEST FOR ACUTE TOXICITY BY INHALATION:

The Acute Toxicity Test by Inhalation was performed according to the OECD (Organization for Economic Cooperation and Development) method in albino, adult rats, of both sexes, Wistar strain, of from 230 to 250 g of corporal weight. The animals under study were exposed for four hours to an aerosol atmosphere of the product in a dynamic inhalation system powered by a humidity disperser. Observations were made 24 hours after exposure and afterwards daily for 14 days.

Concentration of the Product: 197 mg/liter of air.

Results Obtained: At the concentration used, in the conditions of the assay and during the timeframe of the observation, no signs of intoxication were present, nor the occurrence deaths of treated animals, with respect to the control animals.

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4 TEST FOR IRRITATION OF OCULAR MUCOUS MEMBRANE:

The Test for Ocular Mucous Membrane Irritation in Rabbit was performed following the Draize Modified Method.

0.1 ml of a newly prepared 30% aqueous solution of the product was instilled in the eye's conjunctival sac of albino, adult rabbits, of both sexes, New Zealand strain, of from 2.5 to 3.5 Kg of corporal weight, with immediate washing with 300 ml of tap water.. The untreated eye was used as control. Observations were performed at the 24th., 48th., 72nd., and 96th hours after application. The irritant effect in cornea, iris and conjunctiva according to the Draize scale.

Number of Animals Used: 3 rabbits.

Results Obtained: a lesion in the cornea and conjunctiva was observed which reverted 72 hours after application of the product. No lesion was observed in the iris. The obtained values, according to Draize's scale, indicate that the product is moderately irritant to the ocular mucous membrane with an effect which lasts for a moderate period of time.

III CONCLUSIONS:

According to the results obtained in the assays conducted, in the experimental conditions of the tests; the product is considered nontoxic to the animal rat spp. through the dermis and by inhalation at the dosage used in these tests. Also, it is not considered irritant to rabbit skin, but it is considered moderately irritant in degree and duration to the ocular mucous membrane of the rabbit.

IV BIBLIOGRAPHY:

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