

**NATIONAL UNIVERSITY OF COLOMBIA
SCHOOL OF SCIENCES
DEPARTMENT OF PHARMACOLOGY**

Santafé de Bogotá, D.C., Noviembre 10 de 1 998
AFARI-097-98

ANALYSIS REPORT

SENDER:	Laboratorios J.G.B. S. A.
PRODUCT GENERIC NAME:	Insect Repellent
COMMERCIAL NAME:	NOPIKEX® Repellent Foam
ACTIVE INGREDIENTS:	Diethyltoluamide and Permethrin
PHARMACEUTICAL FORM:	Bar for topical application
CONCENTRATION:	20.45% of Diethyltoluamide 0.56% of Permethrin
DATE REQUESTED:	September 98
DATE SAMPLE RECEIVED:	IX-98
DATE OF ANALYSIS:	X and XI-98
SUPPLIED BY:	Laboratorios J.G.B. S.A.
MANUFACTURED BY:	Salder Limitada, Cali-Colombia
LOT NUMBER:	Not specified. Bar Code 773644001039 Health Registration: V-001585
EXPIRY DATE:	Not specified.
RECORD OF SAMPLE TAKING:	Was not received.
RESPONSIBLE PARTY OF SAMPLE TAKING	Laboratorios J.G.B. S. A.
SAMPLES RECEIVED:	10 boxes with 1 bar in each box.
ASSAYS REQUESTED:	Biological assays of: 1. Determination of oral Lethal dose 50 2. Acute dermal toxicity in rabbits 3. Ocular irritation in rabbits.

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AFARI-097-98

RESULTS

1. Description of the sample

The sample corresponds to a creamy white bar of rectangular shape with the appearance and texture as that of soap, with a characteristic non-objectionable odor, homogeneous aspect.

The sample is packed in a white and shiny black cardboard box, with a logotype in red and white and letters in white and black. The information on the box does not specify the Lot No.

2. Determination of the oral Lethal Dose 50 (LD-50)

Method: According to the method of the OECD by orogastric probe

Animals under Experimentation: Female mice STRAIN ICR colony OF1, of 30g corporal weight, sourced from the Bioterium of the Department of Pharmacology National University of Colombia.

Administered by: Oral orogastric intubation.

Control Group: Administered the same way with a 0.9% saline sterile solution.

Results:

It was found that the oral Lethal Dose 50 (LD-50) in female mice, is 8.70 grams of the finished product per kilogram of corporal weight, which corresponds to 1,773 mg of Diethyl Toluamide and to 48.55 mg of Permethrin. This indicates that the insect repellent NOPIKEX is cataloged in Toxicological Category IV or practically NONTOXIC.

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AFARI-097-98

EDEMA

Rabbit Observation	1		2		3	
	Target	Sample	Target	Sample	Target	Sample
24 hr.	0	1	0	1	0	1
48 hr.	0	0	0	0	0	0
72 hr.	0	0	0	0	0	0

Total Response: Erythema + Edema: The difference between the sample and the target should be less than 1.

Target Mean = 0
Sample Mean = 0.66

It was found that 24 hours after exposure to the product NOPIKEX a WELL DEFINED ERYTHEMA was present (value of 2), which resolved by itself at the 72nd hour; also a slight edema was observed and a barely perceptible reaction (value of 1). At the assayed dosages there was not a significant difference between the dermal response of the three doses.

There were no deaths in the treated animals, therefore, the Dermal Lethal Dose 50 (LD-50) is much greater than 10g/Kg in rabbits.

NOTE: The dosages used in this assay are far higher than those recommended by the manufacturer for normal use.

CONCEPT

According to the results obtained, the Dermal Lethal dose 50 (LD-50) is greater than 10g/Kg of corporal weight, which is higher than the dose recommended by the manufacturer for normal use.

4. Ocular Irritation Assay:

Method : According to OECD Standards.
Animals Used : Albino rabbits, New Zealand strain
Weight : 3 Kg.
Solutions Used : 0.5%, 1%, 2%
P. H. of the solutions : 8.5

**NATIONAL UNIVERSITY OF COLOMBIA
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AFARI-097-98

Time of Observation : 72 hours
Reactions Observed : In cornea, Iris and Conjunctiva
Control Group : Instillment in the eye of a 0.9% saline sterile solution

Results

Observations in the cornea, iris and conjunctiva were made, conjunctival and palpebral hyperemia was found in a value of 1 (values between 0 and 3), this effect was resolved favorably at 24 hours. No inflammation or swelling of any kind was observed (0). There was no significant difference between ocular reactions at the three doses assayed.

CONCLUSION

The sample of the product Foam Repellent NOPIKEX®, Lot Number unspecified, identified by Bar Code number 7703644001039, manufactured by Salder Limited - Cali, for J.G.B. S. A. was tested for the Biological assays requested and their results allow us to conclude:

1. According to the results of the Oral LD50 assay [8.67g of the finished product per kilogram of corporal weight] the product is cataloged in Toxicological Category IV "Practically NONTOXIC". According to Ministry of Health Bill 1843 of 1 991.
2. According to the results of the Acute Dermal Toxicity Assay there were no deaths among the treated animals at the dosages tested. This indicates that Dermal LD-50 is greater than 10g/Kg, also the dermal response is in accordance with the parameters established in the USP XIII for this assay.
3. The assay for ocular irritation showed an initial ocular irritation, which receded 1 hour later and disappears completely at 24 hours, the latter permits that avoid contact with the eye area be recommended.

NOTE: The following results correspond only to the samples received and assayed.

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DEPARTMENT OF PHARMACOLOGY**

AFARI-097-98

BIBLIOGRAPHY

THE UNITED STATES PHARMACOPOEIA USP XXIII. The National Formulary NF XVII United States Pharmacopeial Convention, Inc. Rockville, Md., 1 995.

WHO: Publication. Environmental Health Criteria. 6, Principles and Methods for Evaluating the Toxicity of Chemicals. Part II.

Bill 1843 of 1 991. Emanated from The Ministry of Health. Republic of Colombia.

Responsibility of the analysis Professor **DIEGO ARIAS Q.F. MSc.**

Sincerely,

ROBERTO PINZÓN SERRANO
Director Department of Pharmacology

JAIME H. ROJAS B.
Head Unit of Consulting
Services and Extension

Clara I.