NELSON
LABORATORIES

20 NOV 2001

Joseph Zdrok
Joseph Zdrok & Associates
24 Tower Street
Webster, MA 01570

Dear Joseph:

Enclosed is the final report for the testing we coordinated for you. The information is retained by the testing laboratory.

NELSON NUMBER: 195232

TESTING LAB: NAMSA, Inc.

TYPE OF TEST: IRRITATION: PRIMARY SKIN FHSA

SAMPLE IDENTIFICATION:
Makrite inside facemask

If you have any questions, please feel free to call any of our Customer Service personnel at 801-963-2600 or 800-826-2088. Thank you for testing with Nelson Laboratories.

Sincerely,

Jared A. Forsyth

Jared A. Forsyth
Customer Service Representative

SOP/QAU/046G.1-4/062001[LIMS:SC_PPW.RDL]

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STUDY TITLE:

PRIMARY SKIN IRRITATION STUDY IN THE RABBIT

(FHSA Method)

TEST ARTICLE:

Makrite Inside Facemask

IDENTIFICATION NO.:

Nelson Lab Number: 195232

TEST FACILITY:

NAMSA
9 Morgan
Irvine, CA 92618-2078

SPONSOR:

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TABLE OF CONTENTS

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SUMMARY

The test article, Makrite Inside Facemask, Nelson Lab Number: 195232, was evaluated for primary skin irritation in accordance with the guidelines of the Federal Hazardous Substances Act (FHSA) Regulations, 16 CFR 1500. An approximate 1 inch x 1 inch section of the test article was topically applied to the intact and abraded skin of six rabbits and left in place for 24 hours. Test sites were graded for erythema and edema at 24 and 72 hours after the single sample application.

Under the conditions of this study, irritation was not observed on the skin of the rabbits. The primary irritation index was calculated to be 0.0. The test article would not be considered a primary irritant to the skin since the empirical score was less than 5.00.

Study and Supervisory Personnel: Brenda Gonzales, A.S., LVT
David Vergil
Carlos Ramos

Approved by: Jackie Nichols, B.S.
Study Director, Toxicology

11-15-01
Date Completed

/nee

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INTRODUCTION

The test article identified below was evaluated for primary skin irritation in accordance with the guidelines of the Federal Hazardous Substances Act (FHSA) Regulations, 16 CFR 1500. The purpose of this study was to determine the potential for a single topical application of the test article to irritate intact and abraded skin of the rabbit. The test article was received on October 31, 2001. Patches were applied on November 8, 2001, and the observations were concluded on November 11, 2001.

MATERIALS

The sample provided by the sponsor was identified and handled as follows:

Test Article:	Makrite Inside Facemask
Identification No.:	Nelson Lab Number: 195232
Storage Conditions:	Room temperature
Preparation:	An approximate 1" x 1" portion of the test article was moistened with 0.5 ml of saline, applied to 2-ply gauze and backed with plastic for direct application to the animals' skin. The inside of the test article was tested.

METHODS

Test System:

Species:	Rabbit (*Oryctolagus cuniculus*)
Breed:	New Zealand White
Source:	Myrtle's Rabbitry, Inc.
Sex:	Male
Body Weight Range:	No particular body weight range was prescribed for this test
Age:	No particular age was prescribed for this test
Acclimation Period:	Minimum 5 days
Number of Animals:	Six
Identification Method:	Ear tag

Justification of Test System:

The albino rabbit is specified in the Federal Hazardous Substance Act (FHSA) as an appropriate animal model for evaluating potential skin irritants. The rabbit is widely used for this purpose and relative ranking of irritant scores can be determined.

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10030

Animal Management:

Husbandry:	Conditions conformed to Standard Operating Procedures which are based on the "Guide for the Care and Use of Laboratory Animals."
Food:	PROLAB® High Fiber Rabbit Diet was provided daily.
Water:	Freely available, municipal (Irvine, CA) water was delivered through an automatic watering system.
Contaminants:	Reasonably expected contaminants in feed or water supplies did not have the potential to influence the outcome of this test.
Housing:	Animals were individually housed in stainless steel suspended cages identified by a card indicating the lab number, animal number, test code, sex, and date dosed.
Environmental:	The room temperature was monitored daily. The temperature range for the room was within a range of 61-72°F. The room humidity was monitored daily. The humidity range for the room was 30-70%. The light cycle was controlled using an automatic timer (12 hours light, 12 hours dark).
Facility:	NAMSA is an AAALAC International accredited facility and is registered with the United States Department of Agriculture. Additionally, NAMSA maintains an approved Animal Welfare Assurance on file with the National Institutes of Health, Office for Laboratory Animal Welfare
Personnel:	Associates involved were appropriately qualified and trained.
Selection:	Only healthy, previously unused animals free from irritation or other dermatological lesions that could interfere with the test were selected.

Experimental Procedure:

The back of each animal was clipped free of fur with an electric clipper at least 4 hours but no more than 24 hours before testing. Just prior to test article application, each rabbit received four parallel epidermal abrasions with a sterile needle at one test site while the skin at the opposite site remained intact.

An approximate 1 inch x 1 inch section of the test article was moistened with 0.5 ml of saline, and applied to each cranial site (two sites per rabbit) by introduction under a double gauze layer to an area of skin approximately 1 inch x 1 inch square. The patches were backed with plastic and covered with a non-reactive tape. The trunk of each animal was wrapped with an elastic binder to maintain the test patches in position. Animals were returned to their cages after treatment.

After the 24 hour exposure, the binders, tape, and patches were removed. At least 30 minutes was allowed to elapse before sites were scored. An evaluation was also conducted at 72 hours after application.

Each test site was examined for dermal reactions in accordance with the FHS Are recommended Draize scoring criteria (Appendix 1). The primary irritation index of the test article was calculated following test completion. As defined in 16 CFR 1500, a substance with an empirical score of less than 5.00 is not a primary irritant to the skin.

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RESULTS

Individual results of dermal scoring appear in Table I. The primary irritation index of the test article was calculated to be 0.0. No irritation was observed on the skin of the rabbits.

Results and conclusions apply only to the test article tested. No further evaluation of these results is made by NAMSA. Any extrapolation of these data to other samples is the responsibility of the sponsor. All procedures were conducted in conformance with good laboratory practice and ISO 17025.

CONCLUSION

Under the conditions of this study, the test article would not be considered a primary skin irritant since the primary irritation index was less than 5.00.

RECORD STORAGE

All raw data pertaining to this study and a copy of the final report are to be retained in designated NAMSA archive files.

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TABLE I

DERMAL OBSERVATIONS

Rabbit Number/ Gender	Reaction	24 Hours		72 Hours	
		Intact	Abraded	Intact	Abraded
64090	Erythema	0	0	0	0
Male	Edema	0	0	0	0
64091	Erythema	0	0	0	0
Male	Edema	0	0	0	0
64092	Erythema	0	0	0	0
Male	Edema	0	0	0	0
64093	Erythema	0	0	0	0
Male	Edema	0	0	0	0
64094	Erythema	0	0	0	0
Male	Edema	0	0	0	0
64095	Erythema	0	0	0	0
Male	Edema	0	0	0	0

Primary Irritation Index (PII): $\frac{0.0}{24} = 0.0$

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APPENDIX I

DRAIZE* EVALUATION OF TOPICAL REACTIONS

	SCORE
Erythema and Eschar Formation (Most predominant condition):	
No erythema	0
Very slight erythema (barely perceptible)	1
Well-defined erythema	2
Moderate to severe erythema	3
Severe erythema (beet redness) to slight eschar formation (injuries in depth)	4

NOTE: Test sites assigned a "4" score for erythema require further description as to the extent of tissue injury.

Edema Formation (Most predominant condition):	
No edema	0
Very slight edema (barely perceptible)	1
Slight edema (edges of area well defined by definite raising)	2
Moderate edema (raised approximately 1 mm)	3
Severe edema (raised more than 1 mm and extending beyond the area of exposure)	4

*Draize, J.H. 1959. Dermal Toxicity. Pages 46-59 in Appraisal of the Safety of Chemicals in Foods, Drugs and Cosmetics. The Association of Food and Drug Officials of the United States, Bureau of Food and Drugs, Austin, TX.

EVALUATION OF PRIMARY IRRITATION INDEX (PII)**

INDEX	EVALUATION
0.00	No irritation
0.04 to 0.99	Irritation barely perceptible
1.00 to 1.99	Slight irritation
2.00 to 2.99	Mild irritation
3.00 to 5.99	Moderate irritation
6.00 to 8.00	Severe irritation

**The sum of the scored reactions is divided by a factor representing the number of scoring intervals multiplied by the number of test parameters multiplied by the number of rabbits.

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