ORIGINAL

# TSCA NON-CONFIDENTIAL BUSINESS INFORMATION

| DOCUMENT DESCRIPTION | DOCUMENT CONTROL NUMBER | DATE RECEIVED |
|---|---|---|
| 8EHQ - 91-1708 | 89110000233 | 4/6/11 |

COMMENTS: COMMUN S (DECLASS)

**DOES NOT CONTAIN CBI**

334514

RECEIVED
OPPT

11 APR -6 AM 11:24

Rhodia
Chemistry is our world, Responsibility is our way

April 5, 2011

By Facsimile (202- 564-8955) & U.S. Mail
Attention. TSCA Declassification Coordinator
U.S. EPA
Office of Pollution Prevention and Toxics
Document Control Office (7407M)
1200 Pennsylvania Ave., NW
Washington, DC 20460

**CONTAINS NO CBI**

Re: TSCA Section 8(e) Supplement;
EPA Document Control Number 8EHQ 1191 1708 88920000354

Dear Sir/Madam·

Rhodia Inc. is the successor in interest to the former Rhône-Poulenc Inc. ALIPAL CO-436 product and related manufacturing and business assets that are the subject of the referenced TSCA 8(e) submission, dated November 26, 1991. The former Rhône-Poulenc (now known as Bayer CropScience Inc.) contributed these assets to Rhodia Inc. by way of an Asset Contribution Agreement between the companies, dated January 1, 1998. As such, Rhodia Inc. is the proper party to provide EPA with an updated confidentiality determination for the information contained therein.

After reconsidering the substance of the referenced TSCA 8(e) submission, Rhodia Inc. hereby agrees to declassify from confidential business information to public information all of the bracketed information identified in and redacted from the Public Notice Copy of this filing.

More specifically, Rhodia Inc. agrees that the chemical names and Chemical Abstract Service (CAS) Registry Numbers of the chemical substances associated with the referenced product that are associated with the following CAS Registry Numbers may be declassified and made public from EPA's TSCA 8(e) file

- CAS Registry No. 9051-57-4
- CAS Registry No. 7732-18-5
- CAS Registry No 64-17-5

Should you have any questions, or require any further information, please let me know. Thank you.

Very truly yours,

8911000023 3

Judith L. Kranetz
Manager, Regulatory Compliance & Product Stewardship
Rhodia Novecare

Cc: Scott M. Sherlock, Attorney Advisor
Environmental Assistance Division
Office of Pollution Prevention and Toxics

JLK/
Ref. 11-0009.doc

*CN 7500 Cranbury, New Jersey 08512*
*Direct Telephone 215-369-9734, Direct Fax. 609-860-5927*
*E-mail. Judith.Kranetz@us.rhodia.com*

## CODING FORM FOR SRC INDEXING

REVISED 10/15/86

| | |
|---|---|
| Microfiche No. | OTS0534805 |
| New Doc I.D. | 88-920000354S |
| Old Doc I.D. | 8EHQ-1191-1708S |
| Date Produced | 11/02/84 |
| Date Recieved | 11/27/91 |
| TSCA section | 8ECP |
| Submitting Organization | RHONE-POULENC INC |
| Contractor | FOOD & DRUG RES LABS |
| Document Title | INITIAL SUBMISSION: PRIMARY EYE IRRITATION STUDY OF ALIPAL CO-436 IN NEW ZEALAND WHITE RABBITS (FINAL REPORT) WITH ATTACHMENTS AND COVER LETTER DATED 112691 (SANITIZED) |
| Chemical Category | ALIPAL CO-436 |

COMPANY SANITIZED

RHÔNE-POULENC

RHÔNE-POULENC INC.
CN 5266, PRINCETON, NJ 08543-5266
TELEPHONE: (609) 297-0100 TELEX: 211066

8EHQ-1191 1708 S INIT

27pp

PUBLIC NOTICE COPY

8892 0000354 S

November 26, 1991

FEDERAL EXPRESS 8904096902

Document Processing Center (TS-790)
Attn: Section 8(e) Coordinator (CAP Agreement)
Office of Toxic Substances
Environmental Protection Agency
401 M Street, S.W.
Washington, DC 20460

RE: Report Submitted Pursuant to the TSCA Section 8(e) Compliance Audit Program

CAP ID NO.: 8ECAP - 0004
RP CAP REPORT NO.: RPS - 0029

Dear Sir/Maiam:

On behalf of Rhône-Poulenc Inc (RPI, CN5266, Princeton, NJ 08543-5266) and its subsidiaries, the attached report is being submitted to the Environmental Protection Agency (EPA) pursuant to the Toxic Substances Control Act (TSCA) Section 8(e) Compliance Audit Program and the Agreement for a TSCA Section 8(e) Compliance Audit Program (CAP Agreement) executed by RPI and EPA (8ECAP - 0004).

The enclosed report provides information on the following chemical mixture;
Product Name: ALIPAL CO-436

CAS Registry No.: 9051-57-4 [ ]

CAS Registry Name: MIXTURE OF POLY(OXY-1,2-ETHANEDIYL), ALPHA-SULFO-OMEGA-(NONYLPHENOXY)-,AMMONIUMSALT, [ ]

Synonym: AMMONIUM SALT OF SULFATED NONYLPHENOXYPOLY(ETHYLENEOXY) ETHANOL



0 0 0 3

**PUBLIC NOTICE COPY**

The title of the enclosed report is;

"Primary Eye Irritation Study of Alipal CO-436 in New Zealand White Rabbits"

The following is a summary of the adverse effects/exposures observed in this report.

This material is a severe ocular irritant without rinse, with blistering of eyelid, and moderately irritating with rinse.

The pH of a 10% aqueous solution is 6.5 - 7.5.

RPI has not previously submitted any TSCA Section 8(e) notices or premanufacture notifications on the subject chemical mixture.

In total, RPI is submitting six copies of the enclosed report and this cover letter: an original and two copies, plus a sanitized original and two copies.

Further questions regarding this submission may be directed to Dr. Glenn S. Simon, Director of Toxicology at (919) 549-2222 (Rhône-Poulenc, P.O. Box 12014, 2 T.W. Alexander Drive, Research Triangle Park, NC 27709).

Sincerely,

Charles E. Moyer, Jr., Ph.D.
Director, Product Safety
(908) 821-3635

CEMjr/rc
Enclosures
017.EPA



0 0 0 4

FOOD & DRUG RESEARCH LABORATORIES, INC.
ROUTE 17C, P. O. BOX 107, WAVERLY, NY 14892-0107 607 565-8131

# PRIMARY EYE IRRITATION STUDY
# OF
# ALIPAL CO-436
# IN
# NEW ZEALAND WHITE RABBITS

As sold.

Submitted to: GAF Corporation
1361 Alps Road
Wayne, New Jersey 07470

FDRL Study No. $8289_B$

Date: November 2, 1984

Elizabeth L. Reagan, A.A.S.
Associate Toxicologist/
Study Director

Peter J. Secci, Ph. D.,
President

This report is submitted for the exclusive use of the person, partnership, or corporation to whom it is addressed, and neither the report nor the name of these Laboratories nor of any members of its staff, may be used in connection with the advertising or sale of any product or process without written authorization.

0 0 0 5

CAP ID No. S-CR-BKH-0005
Reviewed for Sec. 8 (e)
Compliance Program
On 9/5/91 By [illegible]

# Primary Eye Irritation Study in Rabbits
(Wolcott Design)

**FDRL Test Article ID: 84-0755**

**Sponsor Test Article ID: ALIPAL CO-436**

**RESULTS:**

| No. of Animals | Condition | Mean Irritation Scores | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| | | Hours | | | Days | | | | | |
| | | 24 | 48 | 72 | 7 | 10 | 13 | 16 | 19 | 21 |
| 6 | No Washout | 39.3 ±2.3 | 35.5 ±4.0 | 31.2 ±6.2 | 17.7 ±10.7 | 17.3 ±20.8 | 20.8 ±38.7 | 18.2 ±39.8 | 16.5 ±40.4 | 16.5 ±40.4 |
| 3 | 30-Second Washout | 27.0 ±15.1 | 19.7 ±21.7 | 13.3 ±15.9 | 9.3 ±14.5 | 8.7 ±13.3 | 8.7 ±13.3 | 6.0 ±10.4 | 4.0 ±6.9 | 4.0 ±6.9 |

**CONCLUSION:**

Based on the scoring and classification systems presented in Appendix I, the test article is considered to be severely irritating to the rabbit eyes without a washout and moderately irritating with a washout 30-seconds after instillation.

# Primary Eye Irritation Study in Rabbits
(Wolcott Design)

## Purpose:

To determine the ocular irritation potential of the test article when administered to albino rabbits by the method described below.

## Compliance with Government Regulations:

This study was conducted in accordance with the regulations for Good Laboratory Practice as described by the FDA (21 CFR Part 58) and FDRL Standard Operating Procedures. All data and pertinent records have been retained by FDRL and are available upon request.

## Experimental Design:

### Animals and Animal Care

Nine young adult New Zealand White rabbits were obtained from LaCrosse Industries, Inc., Schenectady, New York for use in this study.

All housing and care conformed to the standards established in "Guide for the Care and Use of Laboratory Animals" DHEW Publication No. (NIH) 78-23. Animals were individually housed in wire mesh bottom cages in an environment controlled room. The rabbits were provided NIH Animal Feed A (certified) and water ad libitum. Animals were identified with ear tags and color coded cage cards and acclimated for a minimum of 5 days. During this period, the rabbits were examined daily with respect to their general health to assure their suitability as test animals.

### Procedure

Prior to the test initiation, the eyes of each rabbit were examined with sodium fluorescein and an ultraviolet lamp. Only those rabbits whose eyes were free of irritation and corneal lesions were used.



0 0 0 8

A volume of 0.1 ml of the test article was instilled into one eye of each rabbit. The test article was instilled into the eye by gently pulling the lower lid away from the eyeball to form a cup into which the test article was deposited.

The treated eyes of six animals remained unwashed and three rabbits' eyes were irrigated with physiological saline 30-seconds after instillation of the test article.

The other eye served as the untreated control. The treated and control eyes were examined with sodium fluorescein and an ultraviolet lamp at 24, 48 and 72 hours and on days 7, 10, 13, 16, 19 and 21 using the Draize Scale for Scoring Ocular Lesions (Appendix I).

Test Article Classification

The mean eye irritation score and the standard deviation of the mean were determined for each observation period. The greatest mean score observed was used to assign the test article an ocular irritation rating in accordance with the classification system presented in Appendix I.



0 0 0 4

# Appendix I

## Raw Data

## Raw Data

### INDIVIDUAL RABBIT EYE IRRITATION SCORES

(FDRL)

FDRL Study No.: 8289B

FDRL Material ID No.: 84-0755

Dosage (per eye): 0.1 ml

Date: 9/24/84

Time Dosed: 10:31

Dosed by: MAC CC

| Rabbit Number | Item | Tissue | Reading: Hours 24 | Hours 48 | Hours 72 | Day 7 | Day 10 |
|---|---|---|---|---|---|---|---|
| 84-3289 No Rinse | A | Cornea Opacity | 1 | 1 | 1 | 1 | 1 |
| | B | Cornea Area | 4 | 2 | 3 | 1 | 1 |
| | | (1) Cornea Total=(AxB) x 5 | 20 | 2 | 15 | 5 | 5 |
| | C | Iris | 1 | 1 | 1 | 1 | 1 |
| | | (2) Iris Total=(C) x 5 | 5 | 5 | 5 | 5 | 5 |
| | D | Conjunctiva Redness | 2 | 2 | 2 | 1 | 1 |
| | E | Conjunctiva Chemosis | 2 | 2 | 2 | 1 | 0 |
| | F | Conjunctiva Discharge | 1 | 1 | 1 | 0 | 0 |
| | | (3) Conjunctiva Total (D+E+F) x 2 | 10 | 10 | 10 | 4 | 2 |
| | | Totals Added = (1+2+3) | 35 | 35 | 30 | 14 | 12 |
| 84-3295 No Rinse | A | Cornea Opacity | 1 | 1 | 1 | 1 | 2 |
| | B | Cornea Area | 4 | 4 | 4 | 4 | 4 |
| | | (1) Cornea Total=(AxB) x 5 | 20 | 20 | 20 | 20 | 40 |
| | C | Iris | 1 | 1 | 1 | 1 | 1 |
| | | (2) Iris Total=(C) x 5 | 5 | 5 | 5 | 5 | 5 |
| | D | Conjunctiva Redness | 2 | 2 | 2 | 2 | 2 |
| | E | Conjunctiva Chemosis | 3A | 3A | 4A | 3A | 3A |
| | F | Conjunctiva Discharge | 3 | 2 | 2 | 2 | 2 |
| | | (3) Conjunctiva Total (D+E+F) x 2 | 16 | 14 | 16 | 14 | 14 |
| | | Totals Added = (1+2+3) | 41 | 39 | 41 | 39 | 59 |
| 84-3297 No Rinse | A | Cornea Opacity | 1 | 1 | 1 | 0 | 0 |
| | B | Cornea Area | 4 | 3 | 1 | 0 | 0 |
| | | (1) Cornea Total (AxB) x 5 | 20 | 15 | 5 | 0 | 0 |
| | C | Iris | 1 | 1 | 1 | 1 | 1 |
| | | (2) Iris Total=(C) x 5 | 5 | [illegible] | 5 | 5 | 5 |
| | D | Conjunctiva Redness | 2 | 2 | 2 | 1 | 1 |
| | E | Conjunctiva Chemosis | 3A | 2 | 2 | | |
| | F | Conjunctiva Discharge | 2 | 1 | 2 | 0 | [illegible] |
| | | (3) Conjunctiva Total (D+E+F) x 2 | 14 | | 12 | 4 | [illegible] |
| | | Totals Added = (1+2+3) | [illegible] | [illegible] | [illegible] | 9 | [illegible] |
| | | Tech. Initials and Date 10/15/84 | MAC 9/25/84 | [illegible] | MAC 9/27/84 | [illegible] 10/1/84 | [illegible] |

A- see comment sheet

Raw Data

INDIVIDUAL RABBIT EYE IRRITATION SCORES
(FDRL)

FDRL Study No.: 3289B

Date: 9/24/84

FDRL Material ID No.: N/A

Time Dosed: N/A

Dosage (per eye): N/A

Dosed by: N/A

Untreated Contralateral Eye

| Rabbit Number | Item | Tissue | Reading Hours 24 | 48 | 72 | Day 7 | 10 |
|---|---|---|---|---|---|---|---|
| 84-3289 | A | Cornea Opacity | 0 | 0 | 0 | 0 | 0 |
| | B | Cornea Area | 0 | 0 | 0 | 0 | 0 |
| | | (1) Cornea Total=(AxB) x 5 | 0 | 0 | 0 | 0 | 0 |
| | C | Iris | 0 | 0 | 0 | 0 | 0 |
| | | (2) Iris Total=(C) x 5 | 0 | 0 | 0 | 0 | 0 |
| | D | Conjunctiva Redness | 0 | 0 | 0 | 0 | 0 |
| | E | Conjunctiva Chemosis | 0 | 0 | 0 | 0 | 0 |
| | F | Conjunctiva Discharge | 0 | 0 | 0 | 0 | 0 |
| | | (3) Conjunctiva Total (D+E+F) x 2 | 0 | 0 | 0 | 0 | 0 |
| | | Totals Added = (1+2+3) | 0 | 0 | 0 | 0 | 0 |
| 84-3295 | A | Cornea Opacity | 0 | 0 | 0 | 0 | 0 |
| | B | Cornea Area | 0 | 0 | 0 | 0 | 0 |
| | | (1) Cornea Total=(AxB) x 5 | 0 | 0 | 0 | 0 | 0 |
| | C | Iris | 0 | 0 | 0 | 0 | 0 |
| | | (2) Iris Total=(C) x 5 | 0 | 0 | 0 | 0 | 0 |
| | D | Conjunctiva Redness | 0 | 0 | 0 | 0 | 0 |
| | E | Conjunctiva Chemosis | 0 | 0 | 0 | 0 | 0 |
| | F | Conjunctiva Discharge | 0 | 0 | 0 | 0 | 0 |
| | | (3) Conjunctiva Total (D+E+F) x 2 | 0 | 0 | 0 | 0 | 0 |
| | | Totals Added = (1+2+3) | 0 | 0 | 0 | 0 | 0 |
| 84-3297 | A | Cornea Opacity | 0 | 0 | 0 | 0 | 0 |
| | B | Cornea Area | 0 | 0 | 0 | 0 | 0 |
| | | (1) Cornea Total (AxB) x 5 | 0 | 0 | 0 | 0 | 0 |
| | C | Iris | 0 | 0 | 0 | 0 | 0 |
| | | (2) Iris Total=(C) x 5 | 0 | 0 | 0 | 0 | 0 |
| | D | Conjunctiva Redness | 0 | 0 | 0 | 0 | 0 |
| | E | Conjunctiva Chemosis | 0 | 0 | 0 | 0 | 0 |
| | F | Conjunctiva Discharge | 0 | 0 | 0 | 0 | 0 |
| | | (3) Conjunctiva Total (D+E+F) x 2 | 0 | 0 | 0 | 0 | 0 |
| | | Totals Added = (1+2+3) | 0 | 0 | 0 | 0 | 0 |
| | | Tech. Initials and Date | mac 9/25/84 | KP 9/26/84 | mac 9/27/84 | [illegible] 10/1/84 | [illegible] 10/8/84 |

## INDIVIDUAL RABBIT EYE IRRITATION SCORES
(FDRL)

FDRL Study No.: 328913 Date: 9/24/84

FDRL Material ID No.: 34-0755 Time Dosed: 10:31

Dosage (per eye): 0.1 ml Dosed by: [illegible]

| Rabbit Number | Item | Tissue | Reading Days 13 | 16 | | 19 | | 21 | |
|---|---|---|---|---|---|---|---|---|---|
| 84-3234 No Rinse | A | Cornea Opacity | 1 | 1 | | 0 | | | |
| | B | Cornea Area | 1 | 1 | | 0 | | | |
| | | (1) Cornea Total=(AxB) x 5 | 5 | 5 | | 0 | | | |
| | C | Iris | 1 | 1 | | 0 | | | |
| | | (2) Iris Total=(C) x 5 | 5 | 5 | | 0 | | | |
| | D | Conjunctiva Redness | 1 | 0 | | 0 | | | |
| | E | Conjunctiva Chemosis | 0 | 0 | | 0 | | | |
| | F | Conjunctiva Discharge | 0 | 0 | | 0 | | | |
| | | (3) Conjunctiva Total (D+E+F) x 2 | 2 | 0 | | 0 | | | |
| | | Totals Added = (1+2+3) | 12 | 10 | | 0 | | | |
| 84-3245 No Rinse | A | Cornea Opacity | 4 | 4 | | 4 | | 4 | |
| | B | Cornea Area | 4 | 4 | | 4 | | 4 | |
| | | (1) Cornea Total=(AxB) x 5 | 80 | 80 | | 80 | | 80 | |
| | C | Iris | 1 | 1 | | 1 | | 1 | |
| | | (2) Iris Total=(C) x 5 | 5 | 5 | | 5 | | 5 | |
| | D | Conjunctiva Redness | 2 | 2 | | 2 | | 2 | |
| | E | Conjunctiva Chemosis | 3 | 3 | | 3 | | 3 | |
| | F | Conjunctiva Discharge | 2 | 2 | | 2 | | 2 | |
| | | (3) Conjunctiva Total (D+E+F) x 2 | 14 | 14 | | 14 | | 14 | |
| | | Totals Added = (1+2+3) | 99 | 99 | | 99 | | 99 | |
| 84-3247 No Rinse | A | Cornea Opacity | 0 | | | | | | |
| | B | Cornea Area | 0 | | | | | | |
| | | (1) Cornea Total (AxB) x 5 | 0 | | | | | | |
| | C | Iris | 0 | | | | | | |
| | | (2) Iris Total=(C) x 5 | 0 | | | | | | |
| | D | Conjunctiva Redness | 0 | | | | | | |
| | E | Conjunctiva Chemosis | | | | | | | |
| | F | Conjunctiva Discharge | | | | | | | |
| | | (3) Conjunctiva Total (D+E+F) x 2 | | | | | | | |
| | | Totals Added = (1+2+3) | | | | | | | |
| | | Tech. Initials and Date SE 10/15/84 | [illegible] | [illegible] | | [illegible] 10/15/84 | | [illegible] 10/15/84 | |

# INDIVIDUAL RABBIT EYE IRRITATION SCORES

FDRL Study No.: 32398 | Date: 9/20/91

FDRL Material ID No.: N/A | Time Dosed: N/A

Dosage (per eye): N/A | Dosed by: N/A

Untreated Contralateral Eye

| Rabbit Number | Item | Tissue | Reading Days 13 | 16 | 19 | 21 |
|---|---|---|---|---|---|---|
| 34-32351 | A | Cornea Opacity | 0 | 0 | 0 | |
| | B | Cornea Area | 0 | 0 | 0 | |
| | | (1) Cornea Total=(AxB) x 5 | 0 | 0 | 0 | |
| | C | Iris | 0 | 0 | 0 | |
| | | (2) Iris Total=(C) x 5 | 0 | 0 | 0 | |
| | D | Conjunctiva Redness | 0 | 0 | 0 | |
| | E | Conjunctiva Chemosis | 0 | 0 | 0 | |
| | F | Conjunctiva Discharge | 0 | 0 | 0 | |
| | | (3) Conjunctiva Total (D+E+F) x 2 | 0 | 0 | 0 | |
| | | Totals Added = (1+2+3) | 0 | 0 | 0 | |
| 34-32395 | A | Cornea Opacity | 0 | 0 | 0 | 0 |
| | B | Cornea Area | 0 | 0 | 0 | 0 |
| | | (1) Cornea Total=(AxB) x 5 | 0 | 0 | 0 | 0 |
| | C | Iris | 0 | 0 | 0 | 0 |
| | | (2) Iris Total=(C) x 5 | 0 | 0 | 0 | 0 |
| | D | Conjunctiva Redness | 0 | 0 | 0 | 0 |
| | E | Conjunctiva Chemosis | 0 | 0 | 0 | 0 |
| | F | Conjunctiva Discharge | 0 | 0 | 0 | 0 |
| | | (3) Conjunctiva Total (D+E+F) x 2 | 0 | 0 | 0 | 0 |
| | | Totals Added = (1+2+3) | 0 | 0 | 0 | 0 |
| 34-32397 | A | Cornea Opacity | 0 | | | |
| | B | Cornea Area | 0 | | | |
| | | (1) Cornea Total (AxB) x 5 | 0 | | | |
| | C | Iris | 0 | | | |
| | | (2) Iris Total=(C) x 5 | 0 | | | |
| | D | Conjunctiva Redness | 0 | | | |
| | E | Conjunctiva Chemosis | | | | |
| | F | Conjunctiva Discharge | 0 | | | |
| | | (3) Conjunctiva Total (D+E+F) x 2 | 0 | | | |
| | | Totals Added = (1+2+3) | 0 | | | |
| | | Initials and Date | BF 11/5/91 | MMC 10/8/91 | MMC 10/11/91 | H 10/14/91 |

0 0 1 4

Raw Data

# INDIVIDUAL RABBIT EYE IRRITATION SCORES

(FDRL)

FDRL Study No.: 8289B

FDRL Material ID No.: 84-0755

Dosage (per eye): 0.1 ml

Date: 9/24/84

Time Dosed: 10:31

Dosed by: MAC CC

| Rabbit Number | Item | Tissue | Reading: Hours 24 | Hours 48 | Hours 72 | Day 7 | Day 10 |
|---|---|---|---|---|---|---|---|
| 84-3299 No Rinse | A | Cornea Opacity | 1 | 1 | 1 | 1 | 1 |
| | B | Cornea Area | 4 | 4 | 3 | 1 | 1 |
| | | (1) Cornea Total=(AxB) x 5 | 20 | [illegible] | 15 | 5 | 5 |
| | C | Iris | 1 | 1 | 1 | 1 | 1 |
| | | (2) Iris Total=(C) x 5 | 5 | 5 | 5 | 5 | 5 |
| | D | Conjunctiva Redness | 2 | 2 | 2 | 1 | 1 |
| | E | Conjunctiva Chemosis | 3A | 3A | 3 | 1 | 0 |
| | F | Conjunctiva Discharge | 3 | 3 | 2 | 1 | 0 |
| | | (3) Conjunctiva Total (D+E+F) x 2 | 16 | 16 | 14 | 6 | 2 |
| | | Totals Added = (1+2+3) | 41 | 41 | 34 | 16 | 12 |
| 84-3301 No Rinse | A | Cornea Opacity | 1 | 1 | 1 | 1 | 0 |
| | B | Cornea Area | 4 | 4 | 3 | 1 | 0 |
| | | (1) Cornea Total=(AxB) x 5 | 20 | [illegible] | 15 | 5 | 0 |
| | C | Iris | 1 | 1 | 1 | 1 | 0 |
| | | (2) Iris Total=(C) x 5 | 5 | 5 | 5 | 5 | 0 |
| | D | Conjunctiva Redness | 2 | 2 | 2 | 1 | 1 |
| | E | Conjunctiva Chemosis | 3A | 2 | 2 | 1 | 0 |
| | F | Conjunctiva Discharge | 2 | 0 | 1 | 0 | 0 |
| | | (3) Conjunctiva Total (D+E+F) x 2 | 14 | 8 | 10 | 4 | 2 |
| | | Totals Added = (1+2+3) | 39 | 33 | [illegible] | 14 | 2 |
| 84 3302 No Rinse | A | Cornea Opacity | 1 | 1 | 1 | 1 | 1 |
| | B | Cornea Area | 4 | 4 | 3 | 1 | 1 |
| | | (1) Cornea Total (AxB) x 5 | [illegible] | [illegible] | 15 | 5 | 5 |
| | C | Iris | 1 | 1 | 1 | 1 | 1 |
| | | (2) Iris Total=(C) x 5 | 5 | 5 | 5 | 5 | 5 |
| | D | Conjunctiva Redness | 2 | 2 | 2 | [illegible] | [illegible] |
| | E | Conjunctiva Chemosis | 3A | 2 | 2 | [illegible] | [illegible] |
| | F | Conjunctiva Discharge | 3 | 1 | 1 | 0 | [illegible] |
| | | (3) Conjunctiva Total (D+E+F) x 2 | [illegible] | [illegible] | 10 | 4 | 2 |
| | | Totals Added = (1+2+3) | 41 | [illegible] | [illegible] | 14 | 12 |
| | | Tech. Initials and Date | MAC 9/24/84 | M [illegible] | MAC 9/24/84 | [illegible] 10/1/84 | CC [illegible] |

[illegible] comment sheet

Raw Data

INDIVIDUAL RABBIT EYE IRRITATION SCORES
(FDRL)

FDRL Study No.: 8289 B

Date: 9/24/84

FDRL Material ID No.: N/A

Time Dosed: N/A

Dosage (per eye): N/A

Dosed by: N/A

Untreated Contralateral Eye

| Rabbit Number | Item | Tissue | Reading: Hours 24 | Hours 48 | Hours 72 | Day 7 | Day 10 |
|---|---|---|---|---|---|---|---|
| 84-3299 | A | Cornea Opacity | 0 | 0 | 0 | 0 | 0 |
| | B | Cornea Area | 0 | 0 | 0 | 0 | 0 |
| | | (1) Cornea Total=(AxB) x 5 | 0 | 0 | 0 | 0 | 0 |
| | C | Iris | 0 | 0 | 0 | 0 | 0 |
| | | (2) Iris Total=(C) x 5 | 0 | 0 | 0 | 0 | 0 |
| | D | Conjunctiva Redness | 0 | 0 | 0 | 0 | 0 |
| | E | Conjunctiva Chemosis | 0 | 0 | 0 | 0 | 0 |
| | F | Conjunctiva Discharge | 0 | 0 | 0 | 0 | 0 |
| | | (3) Conjunctiva Total (D+E+F) x 2 | 0 | 0 | 0 | 0 | 0 |
| | | Totals Added = (1+2+3) | 0 | 0 | 0 | 0 | 0 |
| 84-3301 | A | Cornea Opacity | 0 | 0 | 0 | 0 | 0 |
| | B | Cornea Area | 0 | 0 | 0 | 0 | 0 |
| | | (1) Cornea Total=(AxB) x 5 | 0 | 0 | 0 | 0 | 0 |
| | C | Iris | 0 | 0 | 0 | 0 | 0 |
| | | (2) Iris Total=(C) x 5 | 0 | 0 | 0 | 0 | 0 |
| | D | Conjunctiva Redness | 0 | 0 | 0 | 0 | 0 |
| | E | Conjunctiva Chemosis | 0 | 0 | 0 | 0 | 0 |
| | F | Conjunctiva Discharge | 0 | 0 | 0 | 0 | 0 |
| | | (3) Conjunctiva Total (D+E+F) x 2 | 0 | 0 | 0 | 0 | 0 |
| | | Totals Added = (1+2+3) | 0 | 0 | 0 | 0 | 0 |
| 84-3302 | A | Cornea Opacity | 0 | 0 | 0 | 0 | 0 |
| | B | Cornea Area | 0 | 0 | 0 | 0 | 0 |
| | | (1) Cornea Total (AxB) x 5 | 0 | 0 | 0 | 0 | 0 |
| | C | Iris | 0 | 0 | 0 | 0 | 0 |
| | | (2) Iris Total=(C) x 5 | 0 | 0 | 0 | 0 | 0 |
| | D | Conjunctiva Redness | 0 | 0 | 0 | 0 | 0 |
| | E | Conjunctiva Chemosis | 0 | 0 | 0 | 0 | 0 |
| | F | Conjunctiva Discharge | 0 | 0 | 0 | 0 | 0 |
| | | (3) Conjunctiva Total (D+E+F) x 2 | 0 | 0 | 0 | | 0 |
| | | Totals Added = (1+2+3) | 0 | 0 | 0 | 0 | 0 |
| | | Tech. Initials and Date BL 10/15/84 | mac 9/25/84 | KP 9/26/84 | mac 9/27/84 | cc [illegible] | cc 10/4/84 |

# INDIVIDUAL RABBIT EYE IRRITATION SCORES

FDRL Study No.: [illegible] Date: [illegible]

FDRL Material ID No.: [illegible] Time Dosed: [illegible]

Dosage (per eye): [illegible] Dosed by: [illegible]

| Rabbit Number | Item | Tissue | Reading Days 13 | 16 | | 19 | | 21 | |
|---|---|---|---|---|---|---|---|---|---|
| [illegible] No Rinse | A | Cornea Opacity | 0 | 0 | | | | | |
| | B | Cornea Area | 0 | 0 | | | | | |
| | | (1) Cornea Total=(AxB) x 5 | 0 | 0 | | | | | |
| | C | Iris | 0 | 0 | | | | | |
| | | (2) Iris Total=(C) x 5 | 0 | 0 | | | | | |
| | D | Conjunctiva Redness | 1 | 0 | | | | | |
| | E | Conjunctiva Chemosis | 0 | 0 | | | | | |
| | F | Conjunctiva Discharge | 0 | 0 | | | | | |
| | | (3) Conjunctiva Total (D+E+F) x 2 | 2 | 0 | | | | | |
| | | Totals Added = (1+2+3) | 2 | 0 | | | | | |
| [illegible] No Rinse | A | Cornea Opacity | 0 | | | | | | |
| | B | Cornea Area | 0 | | | | | | |
| | | (1) Cornea Total=(AxB) x 5 | 0 | | | | | | |
| | C | Iris | 0 | | | | | | |
| | | (2) Iris Total=(C) x 5 | 0 | | | | | | |
| | D | Conjunctiva Redness | 0 | | | | | | |
| | E | Conjunctiva Chemosis | 0 | | | | | | |
| | F | Conjunctiva Discharge | 0 | | | | | | |
| | | (3) Conjunctiva Total (D+E+F) x 2 | 0 | | | | | | |
| | | Totals Added = (1+2+3) | 0 | | | | | | |
| [illegible] No Rinse | A | Cornea Opacity | 1 | 0 | | | | | |
| | B | Cornea Area | 1 | 0 | | | | | |
| | | (1) Cornea Total (AxB) x 5 | 5 | | | | | | |
| | C | Iris | 1 | 0 | | | | | |
| | | (2) Iris Total=(C) x 5 | 5 | 0 | | | | | |
| | D | Conjunctiva Redness | 1 | 0 | | | | | |
| | E | Conjunctiva Chemosis | 1 | 0 | | | | | |
| | F | Conjunctiva Discharge | | 0 | | | | | |
| | | (3) Conjunctiva Total (D+E+F) x 2 | | | | | | | |
| | | Totals Added = (1+2+3) | [illegible] | | | | | | |
| | | Tech. Initials and Date | [illegible] | [illegible] | | | | | |

# INDIVIDUAL RABBIT EYE IRRITATION SCORES

FDRL Study No.: 8289B

Date: 9/24/84

FDRL Material ID No.: N/A

Time Dosed: N/A

Dosage (per eye): N/A

Dosed by: N/A

Untreated Contralateral Eye

| Rabbit Number | Item | Tissue | Reading Days 13 | 16 | | 19 | | 21 | |
|---|---|---|---|---|---|---|---|---|---|
| 84-3299 | A | Cornea Opacity | 0 | 0 | | | | | |
| | B | Cornea Area | 0 | 0 | | | | | |
| | | (1) Cornea Total=(AxB) x 5 | 0 | 0 | | | | | |
| | C | Iris | 0 | 0 | | | | | |
| | | (2) Iris Total=(C) x 5 | 0 | 0 | | | | | |
| | D | Conjunctiva Redness | 0 | 0 | | | | | |
| | E | Conjunctiva Chemosis | 0 | 0 | | | | | |
| | F | Conjunctiva Discharge | 0 | 0 | | | | | |
| | | (3) Conjunctiva Total (D+E+F) x 2 | 0 | 0 | | | | | |
| | | Totals Added = (1+2+3) | 0 | 0 | | | | | |
| 84-3301 | A | Cornea Opacity | 0 | | | | | | |
| | B | Cornea Area | 0 | | | | | | |
| | | (1) Cornea Total=(AxB) x 5 | 0 | | | | | | |
| | C | Iris | 0 | | | | | | |
| | | (2) Iris Total=(C) x 5 | 0 | | | | | | |
| | D | Conjunctiva Redness | 0 | | | | | | |
| | E | Conjunctiva Chemosis | 0 | | | | | | |
| | F | Conjunctiva Discharge | 0 | | | | | | |
| | | (3) Conjunctiva Total (D+E+F) x 2 | 0 | | | | | | |
| | | Totals Added = (1+2+3) | 0 | | | | | | |
| 84-3302 | A | Cornea Opacity | 0 | 0 | | | | | |
| | B | Cornea Area | 0 | 0 | | | | | |
| | | (1) Cornea Total (AxB) x 5 | 0 | 0 | | | | | |
| | C | Iris | 0 | 0 | | | | | |
| | | (2) Iris Total=(C) x 5 | 0 | 0 | | | | | |
| | D | Conjunctiva Redness | 0 | 0 | | | | | |
| | E | Conjunctiva Chemosis | 0 | 0 | | | | | |
| | F | Conjunctiva Discharge | 0 | 0 | | | | | |
| | | (3) Conjunctiva Total (D+E+F) x 2 | 0 | 0 | | | | | |
| | | Totals Added = (1+2+3) | 0 | 0 | | | | | |
| | | Tech. Initials and Date | SC 10/15/84 | MAC 10/16/84 | | | | | |

0018

Raw Data

INDIVIDUAL RABBIT EYE IRRITATION SCORES

(FDRL)

FDRL Study No.: 5259 B

FDRL Material ID No.: 84-0755

Dosage (per eye): 0.1 ml

Date: 9/24/84

Time Dosed: 10:31

Dosed by: MAC CC

| Rabbit Number | Item | Tissue | Reading Hours 24 | 48 | 72 | Day 7 | 10 |
|---|---|---|---|---|---|---|---|
| 84-3234 Rinse 30 sec. after installation | A | Cornea Opacity | 0 | 0 | 0 | 0 | 0 |
| | B | Cornea Area | 0 | 0 | 0 | 0 | 0 |
| | | (1) Cornea Total=(AxB) x 5 | 0 | 0 | 0 | 0 | 0 |
| | C | Iris | 1 | 0 | 0 | 0 | 0 |
| | | (2) Iris Total=(C) x 5 | 5 | 0 | 0 | 0 | 0 |
| | D | Conjunctiva Redness | 1 | 0 | 0 | 0 | 0 |
| | E | Conjunctiva Chemosis | 1 | 0 | 0 | 0 | 0 |
| | F | Conjunctiva Discharge | 1 | 0 | 0 | 0 | 0 |
| | | (3) Conjunctiva Total (D+E+F) x 2 | 6 | 0 | 0 | 0 | 0 |
| | | Totals Added = (1+2+3) | 11 | 0 | 0 | 0 | 0 |
| 84-3240 Rinse 30 sec. after instillation | A | Cornea Opacity | 1 | 1 | 1 | 1 | 1 |
| | B | Cornea Area | 4 | 2 | 2 | 1 | 1 |
| | | (1) Cornea Total=(AxB) x 5 | 20 | 10 | 10 | 5 | 5 |
| | C | Iris | 1 | 1 | 1 | 1 | 1 |
| | | (2) Iris Total=(C) x 5 | 5 | 5 | 5 | 5 | 5 |
| | D | Conjunctiva Redness | 2 | 2 | 2 | 2 | 2 |
| | E | Conjunctiva Chemosis | 3A | 2A | 4A | 3A | 3A |
| | F | Conjunctiva Discharge | 3 | 3 | 2 | 3 | 3 |
| | | (3) Conjunctiva Total (D+E+F) x 2 | 16 | 18 | 16 | 16 | 14 |
| | | Totals Added = (1+2+3) | 41 | 43 | 31 | 26 | 24 |
| 84-3252 Rinse 30 sec. after instillation | A | Cornea Opacity | 1 | 1 | 0 | 0 | 0 |
| | B | Cornea Area | 2 | 1 | 0 | 0 | 0 |
| | | (1) Cornea Total (AxB) x 5 | 10 | 5 | 0 | 0 | 0 |
| | C | Iris | 1 | 1 | 1 | 0 | 0 |
| | | (2) Iris Total=(C) x 5 | 5 | 5 | 5 | 0 | 0 |
| | D | Conjunctiva Redness | 2 | 2 | 1 | 1 | 1 |
| | E | Conjunctiva Chemosis | 3A | 1 | 1 | 0 | 0 |
| | F | Conjunctiva Discharge | 2 | 0 | 0 | 0 | 0 |
| | | (3) Conjunctiva Total (D+E+F) x 2 | 14 | 2 | 4 | 2 | 2 |
| | | Totals Added = (1+2+3) | 29 | 10 | 7 | 2 | 2 |
| See comment sheet | | Tech. Initials and Date RF 10/15/84 | MAC 9/25/84 | MC 9/26/84 | MAC 9/27/84 | CC 10/1/84 | CC 10/2/84 |



0019

Raw Data

INDIVIDUAL RABBIT EYE IRRITATION SCORES
(FDRL)

FDRL Study No.: 8289 B  Date: 9/24/84

FDRL Material ID No.: N/A  Time Dosed: N/A

Dosage (per eye): N/A  Dosed by: N/A

Untreated Contralateral Eye

| Rabbit Number | Item | Tissue | Reading: Hours 24 | Hours 48 | Hours 72 | Day 7 | Day 10 |
|---|---|---|---|---|---|---|---|
| 84-3234 | A | Cornea Opacity | 0 | 0 | 0 | 0 | 0 |
| | B | Cornea Area | 0 | 0 | 0 | 0 | 0 |
| | | (1) Cornea Total=(AxB) x 5 | 0 | | 0 | 0 | 0 |
| | C | Iris | 0 | 0 | 0 | 0 | 0 |
| | | (2) Iris Total=(C) x 5 | 0 | 0 | 0 | 0 | 0 |
| | D | Conjunctiva Redness | 0 | 0 | 0 | 0 | 0 |
| | E | Conjunctiva Chemosis | 0 | 0 | 0 | 0 | 0 |
| | F | Conjunctiva Discharge | 0 | 0 | 0 | 0 | 0 |
| | | (3) Conjunctiva Total (D+E+F) x 2 | 0 | 0 | 0 | 0 | 0 |
| | | Totals Added = (1+2+3) | 0 | 0 | 0 | 0 | 0 |
| 84-3240 | A | Cornea Opacity | 0 | 0 | 0 | 0 | 0 |
| | B | Cornea Area | 0 | 0 | 0 | 0 | 0 |
| | | (1) Cornea Total=(AxB) x 5 | 0 | 0 | 0 | 0 | 0 |
| | C | Iris | 0 | 0 | 0 | 0 | 0 |
| | | (2) Iris Total=(C) x 5 | 0 | 0 | 0 | 0 | 0 |
| | D | Conjunctiva Redness | 0 | 0 | 0 | 0 | 0 |
| | E | Conjunctiva Chemosis | 0 | 0 | 0 | 0 | 0 |
| | F | Conjunctiva Discharge | 0 | 0 | 0 | 0 | 0 |
| | | (3) Conjunctiva Total (D+E+F) x 2 | 0 | 0 | 0 | 0 | 0 |
| | | Totals Added = (1+2+3) | 0 | 0 | 0 | 0 | 0 |
| 84-3252 | A | Cornea Opacity | 0 | 0 | 0 | 0 | 0 |
| | B | Cornea Area | 0 | 0 | 0 | 0 | 0 |
| | | (1) Cornea Total (AxB) x 5 | 0 | 0 | 0 | 0 | 0 |
| | C | Iris | 0 | 0 | 0 | 0 | 0 |
| | | (2) Iris Total=(C) x 5 | 0 | 0 | 0 | 0 | 0 |
| | D | Conjunctiva Redness | 0 | 0 | 0 | 0 | 0 |
| | E | Conjunctiva Chemosis | 0 | 0 | 0 | 0 | 0 |
| | F | Conjunctiva Discharge | 0 | 0 | 0 | 0 | 0 |
| | | (3) Conjunctiva Total (D+E+F) x 2 | 0 | 0 | 0 | 0 | 0 |
| | | Totals Added = (1+2+3) | 0 | 0 | 0 | 0 | 0 |
| | | Tech. Initials and Date BR 10/15/84 | MAC 9/25/84 | H 9/26/84 | MAC 9/27/84 | CC [illegible] | CC [illegible] |



0020

TABLE 1 - Raw Data

INDIVIDUAL RABBIT EYE IRRITATION SCORES

[illegible] No.: [illegible]

[illegible] Material ID No.: 34-0755

[illegible] (per eye): [illegible]

Date: 9/24/84

Time Dosed: [illegible]

Dosed by: MAC [illegible]

| [illegible] | Item | Tissue | Reading Days 13 | 16 | | 19 | | 21 | |
|---|---|---|---|---|---|---|---|---|---|
| Rinse [illegible] sec. after instillation | A | Cornea Opacity | | | | | | | |
| | B | Cornea Area | | | | | | | |
| | | (1) Cornea Total=(AxB) x 5 | | | | | | | |
| | C | Iris | | | | | | | |
| | | (2) Iris Total=(C) x 5 | | | | | | | |
| | D | Conjunctiva Redness | | | | | | | |
| | E | Conjunctiva Chemosis | | | | | | | |
| | F | Conjunctiva Discharge | | | | | | | |
| | | (3) Conjunctiva Total (D+E+F) x 2 | | | | | | | |
| | | Totals Added = (1+2+3) | | | | | | | |
| 34-3249 Rinse 30 sec. after instillation | A | Cornea Opacity | 1 | 1 | | 1 | | 1 | |
| | B | Cornea Area | 1 | 1 | | 1 | | 1 | |
| | | (1) Cornea Total=(AxB) x 5 | 5 | 5 | | 5 | | 5 | |
| | C | Iris | 1 | 1 | | 1 | | 1 | |
| | | (2) Iris Total=(C) x 5 | 5 | 5 | | 5 | | 5 | |
| | D | Conjunctiva Redness | 2 | 1 | | 0 | | 0 | |
| | E | Conjunctiva Chemosis | 3 | 2 | | 1 | | 1 | |
| | F | Conjunctiva Discharge | 2 | 1 | | 0 | | 0 | |
| | | (3) Conjunctiva Total (D+E+F) x 2 | 14 | 8 | | 2 | | 2 | |
| | | Totals Added = (1+2+3) | 24 | 18 | | 12 | | 12 | |
| 34-3252 Rinse 30 sec. after instillation | A | Cornea Opacity | 0 | 0 | | | | | |
| | B | Cornea Area | 0 | 0 | | | | | |
| | | (1) Cornea Total (AxB) x 5 | 0 | 0 | | | | | |
| | C | Iris | 0 | 0 | | | | | |
| | | (2) Iris Total=(C) x 5 | 0 | 0 | | | | | |
| | D | Conjunctiva Redness | 1 | 0 | | | | | |
| | E | Conjunctiva Chemosis | 0 | 0 | | | | | |
| | F | Conjunctiva Discharge | 1 | 0 | | | | | |
| | | (3) Conjunctiva Total (D+E+F) x 2 | 2 | 0 | | | | | |
| | | Totals Added = (1+2+3) | 2 | 0 | | | | | |
| | | Tech. Initials and Date BR 10/15/84 | [illegible] | MAC 10/10/84 | | MAC 10/15/84 | | [illegible] | |



0021

# INDIVIDUAL RABBIT EYE IRRITATION SCORES

FDRL Study No.: 32[illegible]13 Date: [illegible]

FDRL Material ID No.: N/A Time Dosed: N/A

Dosage (per eye): N/A Dosed by: N/A

Untreated Contralateral Eye

| Rabbit Number | Item | Tissue | Reading Days 13 | 16 | | 19 | | 21 | |
|---|---|---|---|---|---|---|---|---|---|
| | A | Cornea Opacity | | | | | | | |
| | B | Cornea Area | | | | | | | |
| | | (1) Cornea Total=(AxB) x 5 | | | | | | | |
| | C | Iris | | | | | | | |
| | | (2) Iris Total=(C) x 5 | | | | | | | |
| | D | Conjunctiva Redness | | | | | | | |
| | E | Conjunctiva Chemosis | | | | | | | |
| | F | Conjunctiva Discharge | | | | | | | |
| | | (3) Conjunctiva Total (D+E+F) x 2 | | | | | | | |
| | | Totals Added = (1+2+3) | | | | | | | |
| 84-3240 | A | Cornea Opacity | 0 | 0 | | 0 | | 0 | |
| | B | Cornea Area | 0 | 0 | | 0 | | 0 | |
| | | (1) Cornea Total=(AxB) x 5 | 0 | 0 | | 0 | | 0 | |
| | C | Iris | 0 | 0 | | 0 | | 0 | |
| | | (2) Iris Total=(C) x 5 | 0 | 0 | | 0 | | 0 | |
| | D | Conjunctiva Redness | 0 | 0 | | 0 | | 0 | |
| | E | Conjunctiva Chemosis | 0 | 0 | | 0 | | 0 | |
| | F | Conjunctiva Discharge | 0 | 0 | | 0 | | 0 | |
| | | (3) Conjunctiva Total (D+E+F) x 2 | 0 | 0 | | 0 | | 0 | |
| | | Totals Added = (1+2+3) | 0 | 0 | | 0 | | 0 | |
| 84-3252 | A | Cornea Opacity | 0 | 0 | | | | | |
| | B | Cornea Area | 0 | 0 | | | | | |
| | | (1) Cornea Total (AxB) x 5 | 0 | 0 | | | | | |
| | C | Iris | 0 | 0 | | | | | |
| | | (2) Iris Total=(C) x 5 | 0 | 0 | | | | | |
| | D | Conjunctiva Redness | 0 | 0 | | | | | |
| | E | Conjunctiva Chemosis | | 0 | | | | | |
| | F | Conjunctiva Discharge | 0 | 0 | | | | | |
| | | (3) Conjunctiva Total (D+E+F) x 2 | 0 | 0 | | | | | |
| | | Totals Added = (1+2+3) | 0 | 0 | | | | | |
| | | Tech. Initials and Date BR 10/15/84 | [illegible] 10/13/84 | MAC 10/16/84 | | MAC 10/13/84 | | [illegible] 10/15/84 | |

## TEST ARTICLE PREPARATION DATA

[illegible] Wolfers Eye — FDRL Study No.: 8289 B

[illegible] Rabbit — FDRL Test Article I.D.: 84-0755

Concentration Prepared: undil

[illegible] Density: N/A gm/ml — Diluent: NONE

[illegible] Dispensed: 10 ml — Prepared Physical State: as is.

**[illegible] PROCEDURES**

____ Test article dispensed undiluted.

____ Weighed ____ gm ml test article, Q.S. to ____ ml with ____.

____ Test article ground with mortar and pestle.

____ Test article blended at ____ speed for ____.

**[illegible] INFORMATION**

| [illegible] | Coefficient[a] | Level | Coefficient[a] |
|---|---|---|---|
| | | | |
| | | | |
| | | | |

[illegible] Instructions:

Comments:

Calculations: L.W. 9-24-84 Initials/Date — Preparation: L.W. 9-24-84 Initials/Date

Review: [illegible] 7/24/84 BL 10/15/84 Initials/Date

[a] Coefficient x kg body weight = dose  N/A = Not Applicable



0023

Study No.: 8289B

Date: 9/24/84

**COMMENTS**

A- mucous membrane of eyelid appears blistered

Tech. Init.: MAC

Date: 9/25/84 BE10/15/84



0 0 2 4

## Raw Data

### Body Weight Sheet

Type of Test: WOLCOTT EYE FDRL Study No.: 8289B

Initiation Date: 9/24/84

| Animal Number and Sex | Initial Body Weight (kg) |
|---|---|
| 84-3289F | 2.58 |
| 84-3295F | 1.91 |
| 84-3297F | 2.73 |
| 84-3299F | 2.50 |
| 84-3301F | 2.45 |
| 84-3302F | 2.98 |
| 84-3234M | 2.31 |
| 84-3240M | 2.62 |
| 84-3252M | 2.38 |
| | |
| | |
| | |
| | |
| | |
| | |
| | |
| | |
| | |
| | |
| | |
| Tech. Init.: | MAC |
| Date: | 9/24/84 RE 10/15/84 |

Comments: Received from LaCrosse ~~Laboratory~~ Industries, Inc. Animals on 9/4/84

[a] Incorrect name of rabbit supplier [illegible] 9/25/84



0025

## Scale for Scoring Ocular Lesions
### Codes[a]

(1) CORNEA

(A) Opacity-degree of density (area most dense taken for reading)

| | |
|---|---|
| No Opacity | 0 |
| Scattered or diffuse area, details of iris clearly visible | 1 |
| Easily discernible translucent areas, details of iris slightly obscured | 2 |
| Opalescent areas, no details of iris visible, size of pupil barely discernible | 3 |
| Opaque, iris invisible | 4 |

(B) Area of cornea involved

| | |
|---|---|
| One quarter (or less) but not zero | 1 |
| Greater than one quarter, but less than half | 2 |
| Greater than half, but less than three quarters | 3 |
| Greater than three quarters, up to whole area | 4 |

A X B X 5 Total Maximum = 80

(2) IRIS

(A) Values

| | |
|---|---|
| Normal | 0 |
| Folds above normal, congestion, swelling, circumcorneal injection (any or all of these or combination of any thereof) iris still reacting to light (sluggish reaction is positive) | 1 |
| No reaction to light, hemorrhage, gross destruction (any or all of these) | 2 |

A X 5 Total Maximum = 10

(3) CONJUNCTIVAE

(A) Redness (refers to palpebral and bulbar conjunctivae ~~excluding cornea and iris~~)

| | |
|---|---|
| Vessels normal | 0 |
| Vessels definitely injected above normal | 1 |
| More diffuse, deeper crimson red, individual vessels not easily discernible | 2 |
| Diffuse beefy red | 3 |

(B) Chemosis

| | |
|---|---|
| No swelling | 0 |
| Any swelling above normal (includes nictitating membrane) | 1 |
| Obvious swelling with partial eversion of lids | 2 |
| Swelling with lids about half closed | 3 |
| Swelling with lids about half closed to completely closed | 4 |

(C) Discharge

| | |
|---|---|
| No discharge | 0 |
| Any amount different from normal (does not include small amounts observed in inner canthus of normal animals) | 1 |
| Discharge with moistening of the lids and hairs just adjacent to lids | 2 |
| Discharge with moistening of the lids and hairs, and considerable area around the eye | 3 |

Score (A + B + C) X 2 Total Maximum = 20

a) Draize, J. H., Woodard, G. and Calvery, H. O., Methods for the Study of Irritation and Toxicity of Substances Applied Topically to the skin and Mucous Membranes, J. Pharmacol. Exp. Ther., 377-390, 1944.

## Classification of Test Article Based on Eye Irritation Properties[a]

| Rating | Range of Mean Score[b] | Definition[c] |
|---|---|---|
| Non-Irritating | 0.0 - 0.5 | To maintain this rating, all scores at the 48-hour reading must be zero; otherwise, increase rating one level. |
| Practically Non-Irritating | Greater than 0.5 - 2.5 | To maintain this rating, all scores at the 48-hour reading must be zero; otherwise, increase rating one level. |
| Minimally Irritating | Greater than 2.5 - 15.0 | To maintain this rating, all scores at the 72-hour reading must be zero; otherwise, increase rating one level. |
| Mildly Irritating | Greater than 15.0 - 25.0 | To maintain this rating, all scores at the 7-day reading must be zero; otherwise, increase rating one level. |
| Moderately Irritating | Greater than 25.0 - 50.0 | To maintain this rating, scores at 7 days must be less than or equal to 10 for 60% or more of the animals. Also, mean 7-day score must be less than or equal to 20. If 7-day mean score is less than or equal to 20 and more than 60% of animals show scores less than 10, then no animal among those showing scores greater than 10 can exceed a score of 30 if rating is to be maintained; otherwise, increase rating one level. |
| Severely Irritating | Greater than 50.0 - 80.0 | To maintain this rating, scores at 7 days must be less than or equal to 30 for 60% or more of the animals. Also, mean 7-day score must be less than or equal to 40. If 7-day mean score is less than or equal to 40 and more than 60% of the animals show scores less than or equal to 30, then no animal among those showing scores greater than 30 can exceed a score of 60 if rating is to be maintained, otherwise, increase rating one level. |
| Extremely Irritating | Greater than 80.0 - 110.0 | |

a) Modification of Kay, J. H. and Colandra, J. C., "Interpretation of Eye Irritation Tests," Journal of Society of Cosmetic Chemists 13, 281-289 (1962)

b) Mean score for rating is taken from the observation time which has the highest mean score.

c) Where responses are persistent, rating will be increased by only one level.



0 0 2 7

# Appendix II

## Quality Assurance Unit Statement



0028

This final report was reviewed as required by Good Laboratory Practice Regulations for non-clinical laboratory studies, 21 CFR Part 58 and the study protocol. Inspections were accomplished as noted, and reported to the study director and management immediately following their completion. Based on these inspections and the review of the report, this study was conducted and reported in conformance with the Good Laboratory Practice regulations.

STUDY NO. 8289..... QAU INSPECTION SCHEDULE (ACUTES)

| Type Test | Inspection Dates | | | | |
|---|---|---|---|---|---|
| A oral LD50 | 9/12/84 JAP | 9/20/84 SEA | 9/28/84 SEA | Final report | |
| | reviewed | 12/20/84 SEA | | | |
| A PST | 9/20/84 SEA | Final | report | reviewed | 10/11/84 SEA |
| | | | | | |
| A Eye | 9/20/84 SEA | 9/28/84 SEA | Final | report | reviewed |
| | 10/11/84 SEA | | | | |
| B Eye | 9/28/84 SEA | 10/9/84 SEA | Final | report | reviewed |
| | 10/11/84 SEA | | | | |
| | | | | | |
| | | | | | |
| | | | | | |
| | | | | | |
| | *wrong date | 10/11/84 SEA | | | |

Susan E. Albert
Quality Assurance Unit



0029

## CERTIFICATE OF AUTHENTICITY

THIS IS TO CERTIFY that the microimages appearing on this microfiche are accurate and complete reproductions of the records of U.S. Environmental Protection Agency documents as delivered in the regular course of business for microfilming.

Date produced 4 30 92 Theresa Tubolino
(Month) (Day) (Year) Camera Operator

Place Syracuse New York
(City) (State)

AMTEK corp

END