

CODING FORMS FOR SRC INDEXING

Microfiche No.		OTS0001098	
New Doc ID	FYI-OTS-0794-1098	Old Doc ID	
Date Produced	12/05/83	Date Received	07/26/94
		TSCA Section	FYI
Submitting Organization		PHARMAKON RESEARCH INTL INC	
Contractor			
Document Title		INITIAL SUBMISSION: ACUTE EYE IRRITATION TEST IN RABBITS WITH SAYTEX 111; AND ATTACHED SAYTEX 111 TECHNICAL BULLETIN	
Chemical Category		SAYTEX 111	

741-0794-001098

PHARMAKON RESEARCH INTERNATIONAL, INC.

WAVERLY, PENNSYLVANIA 18471



PHONE
(717) 586-2411

Contains No CBI



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INIT 07/26/94

Acute Eye Irritation Test in Rabbits

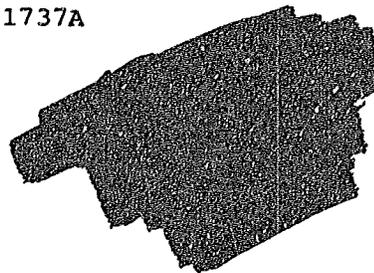
PH 421-ET-009-83

Saytex 111

Lot #20-1737A



84940000102



Submitted to

Ethyl Corporation
Baton Rouge, Louisiana

Victor T. Mallory
Victor T. Mallory, B.S.
Study Director

Robert W. Naismith
Robert W. Naismith, Ph.D.
Director of Toxicology

Richard J. Matthews
Richard J. Matthews, Ph.D.
President

December 5, 1983

Acute Eye Irritation Test in Rabbits

PH 421-ET-009-83

SUMMARY

Test article, Saytex 111, Lot #20-1737A, was instilled in the right eye of six rabbits. Observations were recorded at 1, 24, 48 and 72 hours and on Day 7 following treatment. One positive ocular response was observed at the 1 hour observation period. No other positive responses were observed and the study was terminated on Day 7.

Based upon the results of the Acute Eye Irritation Test in Rabbits, Saytex 111, Lot #20-1737A, was not considered to be an eye irritant.

Acute Eye Irritation Test in Rabbits

PH 421-ET-009-83

or: Ethyl Corporation
Ethyl Tower, 451 Florida
Baton Rouge, Louisiana 70801

ng Facility: Pharmakon Research International, Inc.
Waverly, Pennsylvania 18471

ng Facility
. No.: PH-421

No.: PH 421-ET-009-83

se of
tudy: To evaluate the eye irritation produced by the test
substance in rabbits.

ship of
tudy: The sponsor owns the study. All raw data, analysis,
and reports are the property of the sponsor.

Monitor: Mrs. Beverly Pancamo, Ethyl Corporation

Director: Victor T. Mallory, B.S., Pharmakon Research
International, Inc.

ical
rmance: Rosemary Lynott, Dennis Margitich and Stanley Zuczek

nsible
nnel: Leslie Maas, B.S.

of
rmance: November 22, 1983 through November 29, 1983

Laboratory
ices
ment: This study was conducted in compliance with the Good
Laboratory Practice Regulations except if noted.
There were no significant deviations from the GLP
Regulations which affected the quality or integrity
of the study. Q.A.U. findings derived from the

inspection(s) during the conduct of this study and from the audit of the final report are documented and have been provided to the director and the test facility management.

Records Maintained:

All raw data, final reports, documentation and protocol will be maintained in the central files of Pharmakon Research International, Inc.

Recordings:

Standard Pharmakon Notebook

Notebook Reference:

Notebook #415, pages 31-33

Raw Data:

Copies of notebook recordings attached.

TEST ARTICLE

Compound Description:

Saytex 111 -- yellow powder

Lot No.:

20-1737A

Base Factor:

Not applicable

Amount Submitted:

136 grams (material and container)

Date Submitted:

November 21, 1983

Special Handling Instructions:

Standard precautions

Analysis of Purity:

The purity of the test article is the responsibility of the sponsor.

Stability:

There was no apparent change in the physical state of the test article during administration.

TEST SYSTEM

Species:

Rabbit

Strain:

Albino New Zealand White

Acute Eye Irritation Test in Rabbits
PH 421-ET-009-83

Supplier

Source:

Sgarlat's Rabbitry, Harvey's Lake, Pennsylvania

Sex:

Male and female

Weight at
Initiation:

2 - 3 kilograms

No. on Study:

Six (6) (three males and three females)

Method and
Justification for
Randomization:

Selection of study animals was based upon sex, body weight and apparent good health.

Acclimation
Period:

Five (5) days

System of
Identification:

Cages were marked with a study number, dose level, starting date, animal number and sex. Each animal was identified by a metal numbered ear tag.

HUSBANDRY

Research Facility
Registration:

U.S.D.A. Registration No. 23-107 under the Animal Welfare Act 74: SC 2131 et seq.

Animal Rooms:

Separate isolation by test system

Light cycle - 12 hours light, 12 hours dark

Temperature/Humidity - maintained at a temperature of 20°C ± 3°C, and a humidity of 30 to 70%.

Housing:

Rabbits were housed individually in cages sized in accordance with the "Guide for the Care and Use of Laboratory Animals" of the Institute of Laboratory Resources, National Research Council.

Sanitization:

Waste material removed daily. Cages and feeders were sanitized every two weeks.

Acute Eye Irritation Test in Rabbits
PH 421-ET-009-83

Food: Wayne Rabbit Ration^R, ad libitum, checked daily and added or replaced as needed. Feeders are designed to reduce soiling, bridging and scattering.

Food Analysis: There were no contaminants that were reasonably expected to be present in the dietary material known to be capable of interfering with the purpose or conduct of the study.

Water: Availability - fresh tap water, fit for human consumption, ad libitum, using 16 ounce glass bottles with rubber stopper and stainless steel sipper tube or an automatic watering system supplied by Edstrom Industries, Inc., Waterford, Wisconsin.

Water Analysis: Conducted by the Pennsylvania Gas and Water Company and the results provided to Pharmakon Research International, Inc.

METHODS

Rationale for Test System: As required by the regulatory agencies

Compound Preparation: As received

Dose Administration: 100 mg/eye

Rationale for Dose Selection: As required by the regulatory agencies

Vehicle: As received

Route of Administration: Test material was administered directly into the eye.

Rationale for Route of Administration: The study was designed specifically to evaluate the irritant potential of the test article on the eye.

Acute Eye Irritation Test in Rabbits
PH 421-ET-009-83

Frequency and
Duration of
Administration:

Once (1)

No. of Animals
Per Dose Group:

Six (6) (three male and three female)

No. and Code of
Dose Group:

Rabbit No.
491-4922

Dose
100 mg

Length of Study:

Seven (7) days

Method of
Performance:

Twenty-four hours prior to the application of the test material, the eyes of the rabbits were examined using 2% sodium fluorescein stain. Animals showing preexisting corneal injury were eliminated from the study. The test substance was placed in the right eye of each animal by gently pulling the lower lid away from the eyeball (conjunctival cul-de-sac) to form a cup. The upper and lower lids were then gently held together for one second to prevent loss of material. The other eye remained untreated and served as a control.

Type and
Frequency of
Test, Analysis,
and Measurements
to be Made:

The eyes were examined at 1, 24, 48 and 72 hours and on Day 7 following treatment. The grades of ocular reaction (Table I) were recorded at each examination.

Scoring:

An animal exhibited a positive reaction when the test substance produced one or more of the following signs: ulceration of the cornea (other than a fine stippling), opacity of the cornea (other than a slight dulling of the normal luster), inflammation of the iris (other than a slight deepening of the rugae or a

light hyperemia of the circumcorneal blood vessels), or an obvious swelling in the conjunctivae (excluding the cornea and iris) with partial eversion of the eyelids and a diffuse crimson color with individual vessels not easily discernible.

Grading:

Grading of irritation is according to the method of Draize, J.H., (1965) Appraisal of the Safety of Chemicals in Foods, Drugs, and Cosmetics - Dermal Toxicity pp. 49-52. Association of Food and Drug Officials of the U.S., Topeka, Kansas.

Classification
of Test Substance:

Non-irritant	0 or 1 rabbit with positive scores
Indeterminate	2 or 3 rabbits with positive scores
Irritant	4 to 6 rabbits with positive scores

Results:

Individual rabbit data on body weights and scoring of irritation may be found in the attached copies of notebook recordings. One positive ocular response was observed at the 1 hour observation period. No other positive responses were observed and the study was terminated on Day 7.

Conclusion:

Based upon the results of the Acute Eye Irritation Test in Rabbits, Saytex 111, Lot #20-1737A was not considered to be an eye irritant.

TABLE I

Scale for Scoring Ocular Lesions*

(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
Score equals 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 reactions is positive)	1**
No reaction to light, hemorrhage, gross destruction (any or all of these)	2
Score equals 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 equals (A + B + C) x 2	Total maximum = 20

The maximum total score is the sum of all scores obtained for the cornea, iris, and conjunctivae. Total maximum score possible = 110

* Draize, J. H., et al., J. Pharm, Exp. Ther. 82:377-390, 1944.
 **Figures indicate lowest grades considered positive under the Federal Hazardous Substances Act Regulations at 16 CFR 1500.42.

PHARMAKON RESEARCH INTERNATIONAL, INC.

WAVERLY, PENNSYLVANIA 15471

PHONE
(717) 586-2411

QUALITY ASSURANCE UNIT STATEMENT

This study was performed in accordance with the Good Laboratory Practices Regulation for non-clinical laboratory studies as developed by the U. S. Food and Drug Administration, as indicated in the Federal Register, Part I of December 22, 1978; Part 58, Title 21.

Study No. PH 421-ET-009-83

The following inspections were performed:

Interval	Date
<u>Predosing Phase</u>	<u>11/21/83</u>
<u>Dosing Phase</u>	<u>11/22/83</u>
<u>Reporting Phase</u>	<u>12/6/83</u>
<u> </u>	<u> </u>

Results of the above inspections were submitted to the Study Director and Management during the course of the study.

12/6/83
Date

Leslie Maas
Quality Assurance Unit

RAW DATA
APPENDIX

Eye Irritation Test

No. _____
 Sponsor: Eckyl Corporation
 Purpose: To evaluate the eye irritation produced by the test substance in rabbits.
 Method: Protocol 421 from sponsor
 Date of Initiation: 11/22/83 Study Performed: Top I
 Date of Termination: 11/29/83
 Length of Study: Seven (7) days
 Test Article: Saytep 111 Lot #: 20-1737 A
 Test Article Description: fine yellow powder
 Test Article Receipt: 11/21/83
 Amount Submitted: 136 grams (material + container)
 Dose Level: 100 mg./right eye
 Vehicle: as received
 Species: Rabbit Strain: Albino New Zealand White
 Animal PO #: 111583 A Top (S)
 Food Lot #: 2968.1383
 Weight: 2-3 kilograms
 No. of animals on study: Six (3♂ and 3♀)
 Animals Fluorescined: 11/21/83
 Scale #: 10, calibrated 11/21/83 and weekly.
 Animal Identification: Ear tag, study number, sex & date.
 Animal Randomization: By weight, sex and healthy eyes.
 Route of Administration: The test article is administered directly into the eye.

Route Eye Irritation Test

No. 31

Animal #	Sex	Compound	Initial wt. (gms.)	Time of Dose	Final wt. (gms.)
4917	♂	Sagtef	2.014	9:40	2.088
4918	♂	III	2.144	↓	2.206
4919	♂	Lot. No.:	2.022		2.124
4920	♀	20-1737-A	2.009		2.255
4921	♀		2.275		2.204
4922	♀		2.206		9:45

11/22/83 L&L 11/29/83 L&L

One Hour

Animal #	Sex	Cornea		Iris	Conjunctivae		
		opacity	area		Redness	Chemosis	Discharge
4917	♂	0	0	0	1	0	0
4918	♂	0	0	0	1	0	1
4919	♂	0	0	0	1	0	0
4920	♀	0	0	0	1	0	0
4921	♀	0	0	0	1	0	0
4922	♀	0	0	0	1	0	0

11/22/83 L&L

Twenty-four Hours

Animal #	Sex	Cornea		Iris	Conjunctivae		
		opacity	area		Redness	Chemosis	Discharge
4917	♂	0	0	0	0	0	0
4918	♂	0	0	0	0	0	0
4919	♂	0	0	0	0	0	0
4920	♀	0	0	0	0	0	0
4921	♀	0	0	0	0	0	0
4922	♀	0	0	0	0	0	0

11/23/83 L&L

PHARMAKON RESEARCH INTERNATIONAL, INC.

WAVERLY, PENNSYLVANIA 18471

PHONE
(717) 586-2411

Protocol - 421

Acute Eye Irritation Test

Sponsor: Ethyl Corporation
Ethyl Tower, 451 Florida
Baton Rouge, Louisiana 70801

Testing Facility: Pharmakon Research International, Inc.
Waverly, Pennsylvania 18471

Test Facility
S.O.P. No.: PH-421

Study No.: To be assigned at study initiation. PH 421-ET-00983

Purpose of the Study: To evaluate the eye irritation produced by the test substance in rabbits.

Ownership of the Study: The sponsor owns the study. All raw data, analysis, and reports are the property of the sponsor.

Study Monitor:

Study Director: Mr. Victor Mallory, Pharmakon Research International, Inc.

Q.A.U. Responsible Personnel: Leslie Maas

Dates of Performance: The study will begin within one month of the receipt of the test article and authorized protocol.

Good Laboratory Practices Statement: This study will be conducted in compliance with the Good Laboratory Practices Regulations as stated in the Federal Register, Vol. 43, No. 247, Friday, December 22, 1978.

Tentative Date of Submission of Final Report: Within one month following the completion of the study.

Records Maintained: All raw data, final reports, documentation and protocol will be maintained in the Pharmakon Central Files.
Amendments to protocol
Feed Lot Number
Body weights, initial and final
Compound preparation
Grading and scoring of irritation according to the method of Draize
Description of lesions

Raw Data: Maintained in a Standard Pharmacokinetic Notebook

Record Retention: All raw data and completed notebooks.

TEST SYSTEM

Species: Rabbit

Strain: Albino New Zealand White

Supplier: Perfection Breeders, Inc., Douglasville, Pennsylvania
(Source): or from any U.S.D.A. acceptable source.

Sex: Male and female

Weight at Initiation: 2 - 3 kilograms

No. on Study: Six (6) per test article

Method and Justification for Randomization: Stratification by body weight.

Acclimation Period: Five (5) days

System of Identification: Cage number and ear tattoo or tag.

HUSBANDRY

Research Facility Registration: U.S.D.A. Registration No. 23-107 under the Animal Welfare Act 74: SC 2131 et seq.

Animal Rooms: Separate isolation by test system
Light cycle - 12 hours light, 12 hours dark
Temperature/Humidity - every attempt will be made to maintain a temperature of 20°C ± 3°C, and a humidity of 30 to 70%.

Housing: Rabbits are housed individually in cages sized in accordance with the "Guide for the Care and Use of Laboratory Animals" of the Institute of Laboratory Resources, National Research Council.

Sanitization: Waste material is removed daily. Cages and feeders are sanitized every two weeks.

Food: Wayne Rabbit Ration^R, ad libitum, checked daily and added or replaced as needed. Feeders are designed to reduce soiling, bridging and scattering.

Food Analysis:

Acute doses minimize the effect of contaminants. There are no contaminants that are reasonably expected to be present in the dietary material known to be capable of interfering with the purpose or conduct of the study.

Water:

Availability - fresh tap water, fit for human consumption, ad libitum, using 16 ounce glass bottles with rubber stopper and stainless steel sipper tube or an automatic watering system supplied by Edstrom Industries, Inc., Waterford, Wisconsin.

Water Analysis:

Conducted by the Pennsylvania Gas and Water Company and the results provided to Pharmakon Research International, Inc. annually.

METHODS

Rationale for Test System:

Required by the regulatory agencies.

Rationale for Dose Selection:

Established by the regulatory agencies.

Dose Administration:

0.1 ml of liquid test articles
100 mg of solid test articles

Compound Preparation:

The test article is administered as received.

Vehicle:

As received

Volume Administration:

Not applicable

Route of Administration:

The test article is administered directly into the eye.

Rationale for Route of Administration:

To evaluate the irritant potential of the test article on the eye.

Frequency and Duration of Administration:

Once (1)

No. and Description of Rabbits per Dose Groups:

Six (6) (three males and three females)

Length of Study:

One week, or at least twenty-one (21) days if injury persists.

Method of Study
Performance:

At least 24 hours prior to the application of the test material, the eyes of the rabbits are examined using 2% sodium fluorescein stain; animals showing preexisting corneal injury are eliminated from the study. The test substance is placed in one eye of each animal by gently pulling the lower lid away from the eyeball (conjunctival cul-de-sac) to form a cup. The upper and lower lids are then gently held together for one second to prevent loss of material. The other eye remains untreated and serves as a control.

Type and Frequency
of Test, Analysis
and Measurement
to be Made:

The eyes will be examined at 1, 24, 48 and 72 hours and 7 days after treatment. In addition to the required observations of the cornea, iris, conjunctivae, serious lesions such as pannus, phlyctena (blistering of the conjunctivae) and rupture of the globe will be reported. The grades of ocular reaction (Table I) will be recorded at each examination. If the cornea, iris or conjunctivae has not healed completely by the seventh day, the unhealed animals will be retained and re-examined on the 14th day and again at the 21st day, if injury persists.

Scoring:

An animal has exhibited a positive reaction if the test substance has produced at any observation one or more of the following signs: ulceration of the cornea (other than a fine stippling), opacity of the cornea (other than a slight dulling of the normal luster), inflammation of the iris (other than a slight deepening of the rugae or a light hypermià of the circumcorneal blood vessels) or an obvious swelling in the conjunctivae (excluding the cornea and iris) with partial eversion of the eyelids and a diffuse crimson color with individual vessels not easily discernible.

Grading:

Grading of irritation is according to the method of Draize, J. H. (1965), Appraisal of the Safety of Chemicals in Foods, Drugs and Cosmetics - Dermal Toxicity, pg. 49-52. Association of Food and Drug Officials of the U.S., Topeka, Kansas, and Draize, J. H. (1959), Appraisal of Chemicals in Foods, Drugs and Cosmetics, pg. 36-45. Association of Food and Drugs Officials of the U.S., Austin, Texas, and Draize, J. H., et. al., J. Pharm. Exp. Ther. 82: 377-390, 1944 (see Table I). Serious effects, such as pannus or blistering of the conjunctivae and other effects indicative of corrosive action shall be reported separately.

Classification of
Test Substance:

Non-irritant	0 or 1 rabbit with positive scores
Indeterminate	2 or 3 rabbits with positive scores
Irritant	4 to 6 rabbits with positive scores

Conclusions:

The test will be considered positive if four or more of the animals in the test group exhibit a positive reaction. If only one animal exhibits a positive reaction, the test shall be regarded as negative. If two or three animals exhibit a positive reaction, the study director in charge of the test may designate the substance to be an irritant unless the sponsor suggests repeating the test using a different group of six animals. The second test shall be considered positive if three or more of the animals exhibit a positive reaction.

TABLE I

Scale for Scoring Ocular Lesions*

(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
Score equals 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 reactions is positive)	1
No reaction to light, hemorrhage, gross destruction (any or all of these)	2
Score equals 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 equals (A + B + C) x 2	Total maximum = 20

The maximum total score is the sum of all scores obtained for the cornea, iris, and conjunctivae. Total maximum score possible = 110

* Draize, J. H., et al., J. Pharm, Exp. Ther. 82:377-390, 1944.

TEST ARTICLE

Compound:

Lot No.:

Description:

Amount Submitted:

Date Submitted:

How Supplied:

Special Handling
Instructions:

Test Article/
Carrier Mixtures: Analysis for stability, uniformity and correctness of concentration is the responsibility of the sponsor.

Return Test Article/Carrier Mixtures to the Sponsor

Dispose of Test Article/Carrier Mixtures

Analysis of
Purity/Stability: Analysis of the purity and stability of the test article is the responsibility of the sponsor.

Test Article
Disposition:

Test article will be disposed of 3 months following the submission of the final report.

Test article to be returned upon completion of the study.

APPROVAL OF PROTOCOL

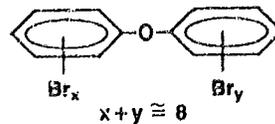
Date 11/10/83 Study Monitor Beverly Fancams
Date 8/15/83 Study Director Victor J. Malloy

AMENDMENTS _____

Saytex®

FLAME RETARDANTS

SAYTEX 111



SAYTEX 111, octabromodiphenyl oxide, is an aromatic bromine-containing additive flame retardant with 79% bromine. It offers these key performance features:

- low addition rate
- excellent heat stability
- low cost

SUGGESTED USES:

ABS • high impact polystyrene • polyamides • elastomers • adhesives and coatings

TYPICAL PROPERTIES:

Appearance	light tan granular powder
Bromine Content	79%
5% weight loss by TGA	305°C
Specific Gravity	2.75
Solubility	Insoluble in water, somewhat soluble in chlorinated and aromatic solvents

SPECIFICATIONS:

Melting Point Range °C	70 - 150°C
Volatiles % @100°C	0.25 maximum
Iron ppm	20 maximum

SUGGESTED FORMULATIONS:

The following are practical formulations to obtain the UL-94 test ratings as shown:

	Saytex 111 (wt. %)	Saytex 111/Sb ₂ O ₃ Ratio	UL-94* Rating
ABS	14 - 16	5/1	V-0
High Impact polystyrene	12 - 14	3/1	V-0
Polyamides	12 - 15	3/1	V-0

SAFETY AND HANDLING:

Although Saytex 111 is not considered hazardous within the Federal Hazardous Substances Act, basic handling precautions are recommended. Avoid prolonged or repeated skin contact. Avoid inhalation of dust or contact with eyes. Protective gloves, chemical safety goggles and approved dust respirators should be worn where there is a chance of exposure. Smoking and eating should be avoided when handling the product.

Complete material safety data and a summary of toxicological evaluations are available upon request.

* The data reported above is based upon laboratory flammability tests and should not be used to predict performance under actual fire conditions.

The facts stated and the recommendations made in this publication are based on our own research and the research of others, and are believed to be accurate. However, no guarantee of their accuracy is made because we cannot cover every possible contingency in manufacturing equipment and methods. For the same reason, the products discussed are sold without warranty, express or implied, and on the condition that purchasers shall make their own tests to determine the suitability of such products for their particular purposes. Statements concerning the possible use of our products are not intended as recommendations to use our products in the infringement of any patent.