



RHÔNE-POULENC INC.

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October 16, 1992

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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, D.C. 20460

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

CAP ID NO.: 8ECAP - 0004

RP CAP REPORT NO.: RPS - 0366

Dear Sir/Madam:

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 (CAP Agreement) executed by RPI and EPA (8ECAP - 0004).

The title of the enclosed report is: Toxicology Laboratory Report T-4037.

This report is being submitted under Section 8(e) CAP because the following products were found to be corrosive to intact skin:

Product Name: Bottlex - Mixture of the following:

Chemical Identity:	Caustic soda, powdered, spec. 2060	72.63%
CAS Registry No:	✓1310-73-2	
CAS Registry Name:	Sodium hydroxide	
Chemical Identity:	Sodium tripolyphosphate, granular	25.00%
CAS Registry No.:	✓7758-29-4	
CAS Registry Name:	Triphosphoric acid, pentasodium salt	
Chemical Identity:	Tergitol 15-S-9	1.25%
CAS Registry No.:	✓68131-40-8	
CAS Registry Name:	Alcohols, C ₁₁₋₁₅ secondary, ethoxylated	
Chemical Identity:	Biosoft S-100	1.12%
CAS Registry No.:	Unknown	

0/17/95

Product Name: Cipex
Chemical Identity: Unknown
CAS Registry No: Unknown

Product Name: Complete
Chemical Identity: Unknown
CAS Registry No: Unknown

Product Name: Crown detergent
Chemical Identity: Unknown
CAS Registry No: Unknown

Product Name: Crystamet 2040
Chemical Identity: Sodium metasilicate
CAS Registry No: 10213-79-3
CAS Registry Name: Silicic acid, disodium salt, pentahydrate
pH: 12.4 of 1% solution

Product Name: Drymet DD
Chemical Identity: Sodium metasilicate, anhydrous
CAS Registry No: 6834-92-0
CAS Registry Name: Silicic acid, disodium salt
pH: 12.6 of 1% solution

Product Name: Dryorth
Chemical Identity: Unknown
CAS Registry No: Unknown

Product Name: Dryorth LD
Chemical Identity: Unknown
CAS Registry No: Unknown

Product Name: Econodet
Chemical Identity: Unknown
CAS Registry No: Unknown

Product Name: Mildupruf
Chemical Identity: Unknown
CAS Registry No: Unknown

Product Name: Moov
Chemical Identity: Unknown
CAS Registry No: Unknown

Product Name: One shot cleaner
Chemical Identity: Unknown
CAS Registry No: Unknown

Product Name: Round
Chemical Identity: Unknown
CAS Registry No: Unknown

Product Name: Sanitizer
Chemical Identity: Unknown
CAS Registry No: Unknown

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Chemical Identity: Sodium metasilicate anhydrous
CAS Registry No: ✓6834-92-0
CAS Registry Name: Silicic acid, disodium salt
pH: 12.6 of a 1% solution

Product Name: SOL-ESCO
Chemical Identity: Unknown
CAS Registry No: Unknown

Product Name: Super Desoil
Chemical Identity: Unknown
CAS Registry No: Unknown

Product Name: Twin-Det
Chemical Identity: Unknown
CAS Registry No: Unknown

Chemical Identity: Sodium hydroxide
CAS Registry No: ✓1310-73-2
CAS Registry Name: Sodium hydroxide

Chemical Identity: Benzene phosphorus thiodichloride
CAS Registry No: ✓3497-00-5
CAS Registry Name: Phosphonothioic dichloride, phenyl

Chemical Identity: Di-2-ethylhexyl phosphorodithioic acid
CAS Registry No: Unknown

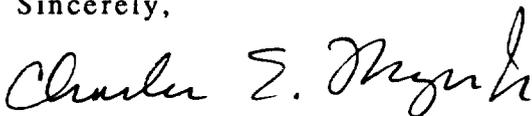
Chemical Identity: Thiophosphoryl chloride
CAS Registry No: ✓3982-91-0
CAS Registry Name: Thiophosphoryl chloride

Chemical Identity: Benzene phosphorus dichloride
CAS Registry No: ✓644-97-3
CAS Registry Name: Phosphonous dichloride, phenyl-

RPI does not claim any portion of the information in this submission to be TSCA confidential business information (TSCA CBI). No previous TSCA Section 8(e) notices or premanufacturing notices have been submitted on any of the subject chemical substances. In total, RPI is submitting three copies of the enclosed report and this cover letter: an 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
(609)860-3589

BEGIN REPORT

T-44037

REVIEWED FOR THE SECTION 8(e) COMPLIANCE

AUDIT PROGRAM, ON 3-2-92 BY

ROF/SZV CAD ID NO. B-CB-ROF-1033

TOXICOLOGY REQUEST FORM

T-No. 4037

CONFIDENTIAL

Project No. 70 0110

Compound 21 INDUSTRIALS

Date 8-8-72

Identification (lot, batch, etc.) U

Use (insect., herbicide, etc.) CLEANING

Purity (%) _____

by (IR, m.p., etc) _____

Known Impurities _____

STRUCTURE	8- DRYLITE CLEAR	16- Round
1- BLEND FT	9- DRYNET DD	17- SANITIZER
2- BUTLEX	10- DRYBATH	18- sodium met ALLICATE
3- CIPAX	11- DRYURTH LD	19- SOL ESCO
4- CLEAN CHANGE	12- ECONODOT	20- SUPER DRYSOIL
5- COMPLETE	13- MILDURAVE	21- TWIN DOT
6- CROWN DETERGENT	14- MOOV	
7- CRYSTAMET	15- CHEF SMT CLEANER	

22- Crystamet 1% vs. NaOH 1% + 10%

Complete for formulations:

Per cent technical _____
 solvent _____
 per cent _____

Check and Complete:

- Acute oral toxicity - species _____
- Acute dermal toxicity - rabbits
- Primary skin irritation (Industrials) - rabbits
- Acute eye irritation - rabbits
- Other (specify) _____

Report Distribution _____

Remarks _____

B. SKIN IRRITATION INDEX

COMPOUND BLEND

CONFIDENTIAL

Rabbit No.	Skin	Erythema-eschar Observation			Edema Observation			Sum Total	Score*
		4 hr.	24 hr.	48 hr.	4 hr.	24 hr.	24 hr.		
1	Intact	2	2	1	0	0	0	24	4.00
	Abraded	4	4	4	2	2	3		
2	Intact	1	1	1	0	0	0	19	3.16
	Abraded	4	4	4	1	1	2		
3	Intact	1	0	0	0	0	0	15	2.50
	Abraded	3	4	4	1	1	1		
4	Intact	2	2	1	1	1	0	26	4.33
	Abraded	4	4	4	2	2	3		
5	Intact	2	2	1	1	1	0	24	4.00
	Abraded	3	4	4	2	2	2		
6	Intact	2	1	1	1	1	0	22	3.66
	Abraded	3	4	4	1	2	2		

Primary Irritant Score ----- 3.6

*Score = sum of individual values for each rabbit divided by six.

Observations: Eschar formation was observed on the abraded test sites of all test animals at the 4, 24 and 72 hour observation periods

Skin Irritant Score and Irritant Classification: 3.62, Moderate irritant

Test site	Evaluation of skin reaction	Ratio regarding six rabbits; Observation time		
		4 hr.	24 hr.	48 hr.
Intact	Corrosive	0/6	0/6	0/6
Abraded	Corrosive	3/6	6/6	6/6

FDA PROPOSED REVISION OF TEST FOR PRIMARY SKIN IRRITANTS

CONFIDENTIAL

The proposed method of testing irritant substances is described in the Code of Federal Regulations under the Federal Hazardous Substances Labeling Act, Part 191.11, Chapter 1, Title 21 as follows:

Primary irritation to the skin is measured by a patch-test technique on abraded and intact skin of healthy albino rabbits. At least six rabbits must be used. The back of each animal is clipped free of hair 24 hours before application of the test material. The shaved area is divided into four quadrants, each being no less than 4 square inches in area. Two of the test sites are abraded and two are left intact.

The abraded areas are prepared 24 hours after shaving by making four epidermal incisions through the stratum corneum, two incisions perpendicular to the other two in a manner resembling a "tic-tac-toe" pattern. These incisions should not be so deep that they disturb the derma or produce bleeding.

Liquid test materials (0.5 milliliter) and/or solid or semi-solid test materials (0.5 gram) are introduced under a 1.5 x 1.5 inch 12-ply gauze patch which is secured in place by two narrow strips of adhesive tape. The substance tested (liquid, solid, or semisolid) represents a homogeneous aliquot of the substance under investigation. This factor is most important when testing formulated products containing several ingredients, such as emulsions or suspensions, which can separate due to standing, shipping, or temperature changes. Dry blended powders can segregate due to standing and shipping. Solid substances such as powders should be moistened with sufficient solvent to make a paste (and the quantity of solvent specified) or should be made into a 50-percent weight-to-volume solution. If the bulk density of a powder sample is such that it is physically impossible to place 0.5-gram samples under the patches, the largest practical amount is applied and reported.

The animals are then immobilized in stocks and the trunk of each animal is loosely wrapped with an impervious material, such as a rubberized cloth, for an exposure period of 4 hours. After 4 hours of exposure, the patches are removed and the resulting reactions are evaluated as described in Table 1.

Table 1

Skin Reaction	Value
Erythema and eschar formation:	
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
Edema formation:	
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 millimeter)	3
Severe edema (raised more than 1 millimeter and extending beyond the area of exposure)	4

Following this initial reading, all test sites are washed with appropriate solvent to prevent further exposure. Readings are again made at 24 and 48 hours after the initial application. The primary irritation index is calculated by adding the values for erythema or eschar formation, and edema at 4, 24, and 48 hours on intact and abraded skin (12 values) and dividing by six to obtain an individual score on each rabbit. The combined average of the six individual scores is the primary irritation index.

A material is considered to be corrosive when tissue destruction is observed on any of the six intact skin sites with or without similar destruction on the abraded areas. The ratio of tissue destruction observed on both intact and abraded skin sites is recorded.

STAUFFER CHEMICAL COMPANY

WESTERN RESEARCH CENTER

CONFIDENTIAL
COMPANY CONFIDENTIAL

TOXICOLOGY LAB REPORT -- T-4037-2

August 18, 1972

BOTTLEX

I. OBJECTIVE

To evaluate the skin irritation properties of BOTTLEX according to the proposed DOT 4-hour exposure procedure.

II. MATERIALS

BOTTLEX, a white granular material, received from the Specialty Division on August 8, 1972.

III. SUMMARY

Skin irritation index	8.0
and classification:	corrosive

IV. PROCEDURE

Skin Irritation Index, Draize Dermal

The Draize Dermal procedure was followed as outlined in the Code of Federal Regulations (Part 191.11, Chap. 1, Title 21) for evaluating hazardous substances. The test procedure is designed to determine whether a chemical is a primary skin irritant, ie., capable of initiating an extreme tissue reaction or skin inflammation to an insult or injury. The inflammatory process may vary from a barely perceptible hyperemia, to edema formation and vesiculation, and finally to an intense suppurative process. Irritation itself is not directly measured, but the result or consequence of irritation, that is, the injury reaction following irritation.

The Draize Dermal test is further discussed in Appendix A.

V. RESULTS

Primary Skin Irritation (Draize) Dermal

See chart on page 2.

Submitted by C. H. Bullock
C. H. Bullock

Approved by F. X. Kamienski
F. X. Kamienski

B. SKIN IRRITATION INDEX

COMPOUND: BOTTLEX

Rabbit No.	Skin	Erythema-eschar Observation			Edema Observation			Sum Total	Score*
		4 hr.	24 hr.	48 hr.	4 hr.	24 hr.	24 hr.		
1	Intact	4	4	4	4	4	4	48	8.0
	Abraded	4	4	4	4	4	4		
2	Intact	4	4	4	4	4	4	48	8.0
	Abraded	4	4	4	4	4	4		
3	Intact	4	4	4	4	4	4	48	8.0
	Abraded	4	4	4	4	4	4		
4	Intact	4	4	4	4	4	4	48	8.0
	Abraded	4	4	4	4	4	4		
5	Intact	4	4	4	4	4	4	48	8.0
	Abraded	4	4	4	4	4	4		
6	Intact	4	4	4	4	4	4	48	8.0
	Abraded	4	4	4	4	4	4		

Primary Irritant Score ----- 8.0

*Score = sum of individual values for each rabbit divided by six.

Observations: Eschar formation was observed on both intact and abraded test sites of all test animals.

Skin Irritant Score and Irritant Classification: 8.0, corrosive

Test site	Evaluation of skin reaction	Ratio regarding six rabbits; Observation time		
		4 hr.	24 hr.	48 hr.
Intact	Corrosive	6/6	6/6	6/6
Abraded	Corrosive	6/6	6/6	6/6

APPENDIX A

FDA PROPOSED REVISION OF TEST FOR PRIMARY SKIN IRRITANTS

The proposed method of testing irritant substances is described in the Code of Federal Regulations under the Federal Hazardous Substances Labeling Act, Part 191.11, Chapter 1, Title 21 as follows:

Primary irritation to the skin is measured by a patch-test technique on abraded and intact skin of healthy albino rabbits. At least six rabbits must be used. The back of each animal is clipped free of hair 24 hours before application of the test material. The shaved area is divided into four quadrants, each being no less than 4 square inches in area. Two of the test sites are abraded and two are left intact.

The abraded areas are prepared 24 hours after shaving by making four epidermal incisions through the stratum corneum, two incisions perpendicular to the other two in a manner resembling a "tic-tac-toe" pattern. These incisions should not be so deep that they disturb the derma or produce bleeding.

Liquid test materials (0.5 milliliter) and/or solid or semi-solid test materials (0.5 gram) are introduced under a 1.5 x 1.5 inch 12-ply gauze patch which is secured in place by two narrow strips of adhesive tape. The substance tested (liquid, solid, or semisolid) represents a homogeneous aliquot of the substance under investigation. This factor is most important when testing formulated products containing several ingredients, such as emulsions or suspensions, which can separate due to standing, shipping, or temperature changes. Dry blended powders can segregate due to standing and shipping. Solid substances such as powders should be moistened with sufficient solvent to make a paste (and the quantity of solvent specified) or should be made into a 50-percent weight-to-volume solution. If the bulk density of a powder sample is such that it is physically impossible to place 0.5-gram samples under the patches, the largest practical amount is applied and reported.

The animals are then immobilized in stocks and the trunk of each animal is loosely wrapped with an impervious material, such as a rubberized cloth, for an exposure period of 4 hours. After 4 hours of exposure, the patches are removed and the resulting reactions are evaluated as described in Table 1.

Table 1

Skin Reaction	Value
Erythema and eschar formation:	
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
Edema formation:	
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 millimeter)	3
Severe edema (raised more than 1 millimeter and extending beyond the area of exposure)	4

Following this initial reading, all test sites are washed with appropriate solvent to prevent further exposure. Readings are again made at 24 and 48 hours after the initial application. The primary irritation index is calculated by adding the values for erythema or eschar formation, and edema at 4, 24, and 48 hours on intact and abraded skin (12 values) and dividing by six to obtain an individual score on each rabbit. The combined average of the six individual scores is the primary irritation index.

A material is considered to be corrosive when tissue destruction is observed on any of the six intact skin sites with or without similar destruction on the abraded areas. The ratio of tissue destruction observed on both intact and abraded skin sites is recorded.

STAUFFER CHEMICAL COMPANY

WESTERN RESEARCH CENTER

COMPANY CONFIDENTIAL

TOXICOLOGY LAB REPORT -- T-4037-3

August 18, 1972

CIPEX

I. OBJECTIVE

To evaluate the skin irritation properties of CIPEX according to the proposed DOT 4-hour exposure procedure.

II. MATERIALS

CIPEX, a white granular material, was received from the Specialty Division on August 8, 1972.

III. SUMMARY

Skin irritation index	8.0
and classification:	corrosive

IV. PROCEDURE

Skin Irritation Index, Draize Dermal

The Draize Dermal procedure was followed as outlined in the Code of Federal Regulations (Part 191.11, Chap. 1, Title 21) for evaluating hazardous substances. The test procedure is designed to determine whether a chemical is a primary skin irritant, i.e., capable of initiating an extreme tissue reaction or skin inflammation to an insult or injury. The inflammatory process may vary from a barely perceptible hyperemia, to edema formation and vesiculation, and finally to an intense suppurative process. Irritation itself is not directly measured, but the result or consequence of irritation, that is, the injury reaction following irritation.

The Draize Dermal test is further discussed in Appendix A.

V. RESULTS

Primary skin Irritation (Draize) Dermal

See chart on page 2.

Submitted by C. H. Bullock
C. H. Bullock

Approved by F. X. Kamienski
F. X. Kamienski

APPENDIX A

FDA PROPOSED REVISION OF TEST FOR PRIMARY SKIN IRRITANTS

The proposed method of testing irritant substances is described in the Code of Federal Regulations under the Federal Hazardous Substances Labeling Act, Part 191.11, Chapter 1, Title 21 as follows:

Primary irritation to the skin is measured by a patch-test technique on abraded and intact skin of healthy albino rabbits. At least six rabbits must be used. The back of each animal is clipped free of hair 24 hours before application of the test material. The shaved area is divided into four quadrants, each being no less than 4 square inches in area. Two of the test sites are abraded and two are left intact.

The abraded areas are prepared 24 hours after shaving by making four epidermal incisions through the stratum corneum, two incisions perpendicular to the other two in a manner resembling a "tic-tac-toe" pattern. These incisions should not be so deep that they disturb the derma or produce bleeding.

Liquid test materials (0.5 milliliter) and/or solid or semi-solid test materials (0.5 gram) are introduced under a 1.5 x 1.5 inch 12-ply gauze patch which is secured in place by two narrow strips of adhesive tape. The substance tested (liquid, solid, or semisolid) represents a homogeneous aliquot of the substance under investigation. This factor is most important when testing formulated products containing several ingredients, such as emulsions or suspensions, which can separate due to standing, shipping, or temperature changes. Dry blended powders can segregate due to standing and shipping. Solid substances such as powders should be moistened with sufficient solvent to make a paste (and the quantity of solvent specified) or should be made into a 50-percent weight-to-volume solution. If the bulk density of a powder sample is such that it is physically impossible to place 0.5-gram samples under the patches, the largest practical amount is applied and reported.

The animals are then immobilized in stocks and the trunk of each animal is loosely wrapped with an impervious material, such as a rubberized cloth, for an exposure period of 4 hours. After 4 hours of exposure, the patches are removed and the resulting reactions are evaluated as described in Table 1.

Table 1

Skin Reaction	Value
Erythema and eschar formation:	
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
Edema formation:	
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 millimeter)	3
Severe edema (raised more than 1 millimeter and extending beyond the area of exposure)	4

Following this initial reading, all test sites are washed with appropriate solvent to prevent further exposure. Readings are again made at 24 and 48 hours after the initial application. The primary irritation index is calculated by adding the values for erythema or eschar formation, and edema at 4, 24, and 48 hours on intact and abraded skin (12 values) and dividing by six to obtain an individual score on each rabbit. The combined average of the six individual scores is the primary irritation index.

A material is considered to be corrosive when tissue destruction is observed on any of the six intact skin sites with or without similar destruction on the abraded areas. The ratio of tissue destruction observed on both intact and abraded skin sites is recorded.

STAUFFER CHEMICAL COMPANY

WESTERN RESEARCH CENTER

COMPANY CONFIDENTIAL

TOXICOLOGY LAB REPORT - T-4037-4

August 18, 1972

CLEAN CHARGE

I. OBJECTIVE

To evaluate the skin irritation properties of CLEAN CHARGE according to the proposed DOT 4-hour exposure procedure.

II. MATERIALS

CLEAN CHARGE, a clear liquid, was received from the Industrial Division on August 8, 1972.

III. SUMMARY

Skin irritation index	3.26
and classification:	moderate irritant

IV. PROCEDURE

Skin Irritation Index, Draize Dermal

The Draize Dermal procedure was followed as outlined in the Code of Federal Regulations (Part 191.11, Chap. 1, Title 21) for evaluating hazardous substances. The test procedure is designed to determine whether a chemical is a primary skin irritant, i.e., capable of initiating an extreme tissue reaction or skin inflammation to an insult or injury. The inflammatory process may vary from a barely perceptible hyperemia, to edema formation and vesiculation, and finally to an intense suppurative process. Irritation itself is not directly measured, but the result or consequence of irritation, that is, the injury reaction following irritation.

The Draize Dermal test is further discussed in Appendix A.

V. RESULTS

Primary Skin Irritation (Draize) Dermal

See chart on page 2.

Submitted by Michael F. McGowan
M. F. McGowan

Approved by F. X. Kamienski
F. X. Kamienski

B. SKIN IRRITATION INDEX

COMPOUND CLEAN CHARGE

Rabbit No.	Skin	Erythema-eschar Observation			Edema Observation			Sum Total	Score*
		4 hr.	24 hr.	48 hr.	4 hr.	24 hr.	24 hr.		
1	Intact	2	2	2	2	2	2	24	4.00
	Abraded	2	2	2	2	2	2		
2	Intact	0	2	2	0	2	2	17	2.83
	Abraded	1	2	2	0	2	2		
3	Intact	0	1	1	0	0	1	4	0.67
	Abraded	0	0	0	0	0	1		
4	Intact	3	3	3	2	2	2	30	5.00
	Abraded	3	3	3	2	2	2		
5	Intact	3	3	3	2	2	2	33	5.50
	Abraded	4*	4	4	2	2	2		
6	Intact	0	2	1	0	1	1	10	1.67
	Abraded	0	2	1	0	1	1		

Primary Irritant Score ----- 3.26

*Score = sum of individual values for each rabbit divided by six.

Observations: *Eschar formation was observed in one animal on the abraded site.

Skin Irritant Score and Irritant Classification: 3.26, Moderate irritant

Test site	Evaluation of skin reaction	Ratio regarding six rabbits; Observation time		
		4 hr.	24 hr.	48 hr.
Intact	Corrosive	0/6	0/6	0/6
Abraded	Corrosive	1/6	0/6	0/6

APPENDIX A

FDA PROPOSED REVISION OF TEST FOR PRIMARY SKIN IRRITANTS

The proposed method of testing irritant substances is described in the Code of Federal Regulations under the Federal Hazardous Substances Labeling Act, Part 191.11, Chapter 1, Title 21 as follows:

Primary irritation to the skin is measured by a patch-test technique on abraded and intact skin of healthy albino rabbits. At least six rabbits must be used. The back of each animal is clipped free of hair 24 hours before application of the test material. The shaved area is divided into four quadrants, each being no less than 4 square inches in area. Two of the test sites are abraded and two are left intact.

The abraded areas are prepared 24 hours after shaving by making four epidermal incisions through the stratum corneum, two incisions perpendicular to the other two in a manner resembling a "tic-tac-toe" pattern. These incisions should not be so deep that they disturb the derma or produce bleeding.

Liquid test materials (0.5 milliliter) and/or solid or semi-solid test materials (0.5 gram) are introduced under a 1.5 x 1.5 inch 12-ply gauze patch which is secured in place by two narrow strips of adhesive tape. The substance tested (liquid, solid, or semisolid) represents a homogeneous aliquot of the substance under investigation. This factor is most important when testing formulated products containing several ingredients, such as emulsions or suspensions, which can separate due to standing, shipping, or temperature changes. Dry blended powders can segregate due to standing and shipping. Solid substances such as powders should be moistened with sufficient solvent to make a paste (and the quantity of solvent specified) or should be made into a 50-percent weight-to-volume solution. If the bulk density of a powder sample is such that it is physically impossible to place 0.5-gram samples under the patches, the largest practical amount is applied and reported.

The animals are then immobilized in stocks and the trunk of each animal is loosely wrapped with an impervious material, such as a rubberized cloth, for an exposure period of 4 hours. After 4 hours of exposure, the patches are removed and the resulting reactions are evaluated as described in Table 1.

Table 1

Skin Reaction	Value
Erythema and eschar formation:	
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
Edema formation:	
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 millimeter)	3
Severe edema (raised more than 1 millimeter and extending beyond the area of exposure)	4

Following this initial reading, all test sites are washed with appropriate solvent to prevent further exposure. Readings are again made at 24 and 48 hours after the initial application. The primary irritation index is calculated by adding the values for erythema or eschar formation, and edema at 4, 24, and 48 hours on intact and abraded skin (12 values) and dividing by six to obtain an individual score on each rabbit. The combined average of the six individual scores is the primary irritation index.

A material is considered to be corrosive when tissue destruction is observed on any of the six intact skin sites with or without similar destruction on the abraded areas. The ratio of tissue destruction observed on both intact and abraded skin sites is recorded.

STAUFFER CHEMICAL COMPANY
WESTERN RESEARCH CENTER

COMPANY CONFIDENTIAL

TOXICOLOGY LAB REPORT -- T-4037-5

August 18, 1972

COMPLETE

I. OBJECTIVE

To evaluate the skin irritation properties of COMPLETE according to the proposed DOT 4-hour exposure procedure.

II. MATERIALS

COMPLETE, a yellow granular material, was received from the Industrial Division August 8, 1972.

III. SUMMARY

Skin irritation index	8.0
and classification:	corrosive

IV. PROCEDURE

Skin Irritation Index, Draize Dermal

The Draize Dermal procedure was followed as outlined in the Code of Federal Regulations (Part 191.11, Chap. 1, Title 21) for evaluating hazardous substances. The test procedure is designed to determine whether a chemical is a primary skin irritant, i.e., capable of initiating an extreme tissue reaction or skin inflammation to an insult or injury. The inflammatory process may vary from a barely perceptible hyperemia, to edema formation and vesiculation, and finally to an intense suppurative process. Irritation itself is not directly measured, but the result or consequence of irritation, that is, the injury reaction following irritation.

The Draize Dermal test is further discussed in Appendix A.

V. RESULTS

Primary Skin Irritation (Draize) Dermal

See chart on page 2.

Submitted by Michael F. McGowan
M. F. McGowan

Approved by F. X. Kamienski
F. X. Kamienski

FXK:ea

B. SKIN IRRITATION INDEX

COMPOUND COMPLETE

Rabbit No.	Skin	Erythema-eschar Observation			Edema Observation			Sum Total	Score*
		4 hr.	24 hr.	48 hr.	4 hr.	24 hr.	24 hr.		
1	Intact	4	4	4	4	4	4	48	8.0
	Abraded	4	4	4	4	4	4		
2	Intact	4	4	4	4	4	4	48	8.0
	Abraded	4	4	4	4	4	4		
3	Intact	4	4	4	4	4	4	48	8.0
	Abraded	4	4	4	4	4	4		
4	Intact	4	4	4	4	4	4	48	8.0
	Abraded	4	4	4	4	4	4		
5	Intact	4	4	4	4	4	4	48	8.0
	Abraded	4	4	4	4	4	4		
6	Intact	4	4	4	4	4	4	48	8.0
	Abraded	4	4	4	4	4	4		

Primary Irritant Score ----- 8.0

*Score = sum of individual values for each rabbit divided by six.

Observations: Eschar formation was observed on both intact and abraded test sites of all test animals.

Skin Irritant Score and Irritant Classification: 8.0, corrosive

Test site	Evaluation of skin reaction	Ratio regarding six rabbits; Observation time		
		4 hr.	24 hr.	48 hr.
Intact	Corrosive	6/6	6/6	6/6
Abraded	Corrosive	6/6	6/6	6/6

APPENDIX A

FDA PROPOSED REVISION OF TEST FOR PRIMARY SKIN IRRITANTS

The proposed method of testing irritant substances is described in the Code of Federal Regulations under the Federal Hazardous Substances Labeling Act, Part 191.11, Chapter 1, Title 21 as follows:

Primary irritation to the skin is measured by a patch-test technique on abraded and intact skin of healthy albino rabbits. At least six rabbits must be used. The back of each animal is clipped free of hair 24 hours before application of the test material. The shaved area is divided into four quadrants, each being no less than 4 square inches in area. Two of the test sites are abraded and two are left intact.

The abraded areas are prepared 24 hours after shaving by making four epidermal incisions through the stratum corneum, two incisions perpendicular to the other two in a manner resembling a "tic-tac-toe" pattern. These incisions should not be so deep that they disturb the derma or produce bleeding.

Liquid test materials (0.5 milliliter) and/or solid or semi-solid test materials (0.5 gram) are introduced under a 1.5 x 1.5 inch 12-ply gauze patch which is secured in place by two narrow strips of adhesive tape. The substance tested (liquid, solid, or semisolid) represents a homogeneous aliquot of the substance under investigation. This factor is most important when testing formulated products containing several ingredients, such as emulsions or suspensions, which can separate due to standing, shipping, or temperature changes. Dry blended powders can segregate due to standing and shipping. Solid substances such as powders should be moistened with sufficient solvent to make a paste (and the quantity of solvent specified) or should be made into a 50-percent weight-to-volume solution. If the bulk density of a powder sample is such that it is physically impossible to place 0.5-gram samples under the patches, the largest practical amount is applied and reported.

The animals are then immobilized in stocks and the trunk of each animal is loosely wrapped with an impervious material, such as a rubberized cloth, for an exposure period of 4 hours. After 4 hours of exposure, the patches are removed and the resulting reactions are evaluated as described in Table 1.

Table 1

Skin Reaction	Value
Erythema and eschar formation:	
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
Edema formation:	
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 millimeter)	3
Severe edema (raised more than 1 millimeter and extending beyond the area of exposure)	4

Following this initial reading, all test sites are washed with appropriate solvent to prevent further exposure. Readings are again made at 24 and 48 hours after the initial application. The primary irritation index is calculated by adding the values for erythema or eschar formation, and edema at 4, 24, and 48 hours on intact and abraded skin (12 values) and dividing by six to obtain an individual score on each rabbit. The combined average of the six individual scores is the primary irritation index.

A material is considered to be corrosive when tissue destruction is observed on any of the six intact skin sites with or without similar destruction on the abraded areas. The ratio of tissue destruction observed on both intact and abraded skin sites is recorded.

STAUFFER CHEMICAL COMPANY

WESTERN RESEARCH CENTER

COMPANY CONFIDENTIAL

TOXICOLOGY LAB REPORT -- T-4037-6

August 18, 1972

CROWN DETERGENT

I. OBJECTIVE

To evaluate the skin irritation properties of CROWN DETERGENT according to the proposed DOT 4-hour exposure procedure.

II. MATERIAL

CROWN DETERGENT, a green granular, was received from the Industrial Division August 8, 1972.

III. SUMMARY

Skin irritation index and classification:	8.0 corrosive
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IV. PROCEDURE

Skin Irritation Index (Draize) Dermal

The Draize Dermal procedure was followed as outlined in the Code of Federal Regulations (Part 191.11, Chap. 1, Title 21) for evaluating hazardous substances. The test procedure is designed to determine whether a chemical is a primary skin irritant, i.e., capable of initiating an extreme tissue reaction or skin inflammation to an insult or injury. The inflammatory process may vary from a barely perceptible hyperemia, to edema formation and vesiculation, and finally to an intense suppurative process. Irritation itself is not directly measured, but the result or consequence of irritation, that is, the injury reaction following irritation.

The Draize Dermal test is further discussed in Appendix A.

V. RESULTS

Primary Skin Irritation (Draize) Dermal

See chart on page 2.

Submitted by Michael F. McGowan
M. F. McGowan

Approved by F. X. Kamienski
F. X. Kamienski

B. SKIN IRRITATION INDEX

COMPOUND CROWN DETERGENT

Rabbit No.	Skin	Erythema-eschar Observation			Edema Observation			Sum Total	Score*
		4 hr.	24 hr.	48 hr.	4 hr.	24 hr.	24 hr.		
1	Intact	4	4	4	4	4	4	48	8.0
	Abraded	4	4	4	4	4	4		
2	Intact	4	4	4	4	4	4	48	8.0
	Abraded	4	4	4	4	4	4		
3	Intact	4	4	4	4	4	4	48	8.0
	Abraded	4	4	4	4	4	4		
4	Intact	4	4	4	4	4	4	48	8.0
	Abraded	4	4	4	4	4	4		
5	Intact	4	4	4	4	4	4	48	8.0
	Abraded	4	4	4	4	4	4		
6	Intact	4	4	4	4	4	4	48	8.0
	Abraded	4	4	4	4	4	4		

Primary Irritant Score ----- 8.0

*Score = sum of individual values for each rabbit divided by six.

Observations: Eschar formation was observed on both intact and abraded test sites of all test animals.

Skin Irritant Score and Irritant Classification: 8.0, corrosive

Test site	Evaluation of skin reaction	Ratio regarding six rabbits; Observation time		
		4 hr.	24 hr.	48 hr.
Intact	Corrosive	6/6	6/6	6/6
Abraded	Corrosive	6/6	6/6	6/6

APPENDIX A

FDA PROPOSED REVISION OF TEST FOR PRIMARY SKIN IRRITANTS

The proposed method of testing irritant substances is described in the Code of Federal Regulations under the Federal Hazardous Substances Labeling Act, Part 191.11, Chapter 1, Title 21 as follows:

Primary irritation to the skin is measured by a patch-test technique on abraded and intact skin of healthy albino rabbits. At least six rabbits must be used. The back of each animal is clipped free of hair 24 hours before application of the test material. The shaved area is divided into four quadrants, each being no less than 4 square inches in area. Two of the test sites are abraded and two are left intact.

The abraded areas are prepared 24 hours after shaving by making four epidermal incisions through the stratum corneum, two incisions perpendicular to the other two in a manner resembling a "tic-tac-toe" pattern. These incisions should not be so deep that they disturb the derma or produce bleeding.

Liquid test materials (0.5 milliliter) and/or solid or semi-solid test materials (0.5 gram) are introduced under a 1.5 x 1.5 inch 12-ply gauze patch which is secured in place by two narrow strips of adhesive tape. The substance tested (liquid, solid, or semisolid) represents a homogeneous aliquot of the substance under investigation. This factor is most important when testing formulated products containing several ingredients, such as emulsions or suspensions, which can separate due to standing, shipping, or temperature changes. Dry blended powders can segregate due to standing and shipping. Solid substances such as powders should be moistened with sufficient solvent to make a paste (and the quantity of solvent specified) or should be made into a 50-percent weight-to-volume solution. If the bulk density of a powder sample is such that it is physically impossible to place 0.5-gram samples under the patches, the largest practical amount is applied and reported.

The animals are then immobilized in stocks and the trunk of each animal is loosely wrapped with an impervious material, such as a rubberized cloth, for an exposure period of 4 hours. After 4 hours of exposure, the patches are removed and the resulting reactions are evaluated as described in Table 1.

Table 1

Skin Reaction	Value
Erythema and eschar formation:	
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
Edema formation:	
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 millimeter)	3
Severe edema (raised more than 1 millimeter and extending beyond the area of exposure)	4

Following this initial reading, all test sites are washed with appropriate solvent to prevent further exposure. Readings are again made at 24 and 48 hours after the initial application. The primary irritation index is calculated by adding the values for erythema or eschar formation, and edema at 4, 24, and 48 hours on intact and abraded skin (12 values) and dividing by six to obtain an individual score on each rabbit. The combined average of the six individual scores is the primary irritation index.

A material is considered to be corrosive when tissue destruction is observed on any of the six intact skin sites with or without similar destruction on the abraded areas. The ratio of tissue destruction observed on both intact and abraded skin sites is recorded.

STAUFFER CHEMICAL COMPANY

WESTERN RESEARCH CENTER

COMPANY CONFIDENTIAL

TOXICOLOGY LAB REPORT -- T-4037-7

August 18, 1972

CRYSTAMET 2040

I. OBJECTIVE

To evaluate the skin irritation properties of CRYSTAMET 2040 according to the proposed DOT 4-hour exposure procedure.

II. MATERIALS

CRYSTAMET 2040, a white granular material, was received from the Industrial Division August 8, 1972.

III. SUMMARY

Skin irritation index and classification:	8.0 corrosive
--	------------------

IV. PROCEDURE

Skin Irritation Index, Draize Dermal

The Draize Dermal procedure was followed as outlined in the Code of Federal Regulations (Part 191.11, Chap. 1, Title 21) for evaluating hazardous substances. The test procedure is designed to determine whether a chemical is a primary skin irritant, i.e., capable of initiating an extreme tissue reaction or skin inflammation to an insult or injury. The inflammatory process may vary from a barely perceptible hyperemia, to edema formation and vesiculation, and finally to an intense suppurative process. Irritation itself is not directly measured, but the result or consequence of irritation, that is, the injury reaction following irritation.

The Draize Dermal test is further discussed in Appendix A.

V. RESULTS

See chart on page 2.

Submitted by Michael F. McGowan
M. F. McGowan

Approved by F. X. Kamienski
F. X. Kamienski

FXK:ea

B. SKIN IRRITATION INDEX

COMPOUND CRYSTAMET 2040

Rabbit No.	Skin	Erythema-eschar Observation			Edema Observation			Sum Total	Score*
		4 hr.	24 hr.	48 hr.	4 hr.	24 hr.	24 hr.		
1	Intact	4	4	4	4	4	4	48	8.0
	Abraded	4	4	4	4	4	4		
2	Intact	4	4	4	4	4	4	48	8.0
	Abraded	4	4	4	4	4	4		
3	Intact	4	4	4	4	4	4	48	8.0
	Abraded	4	4	4	4	4	4		
4	Intact	4	4	4	4	4	4	48	8.0
	Abraded	4	4	4	4	4	4		
5	Intact	4	4	4	4	4	4	48	8.0
	Abraded	4	4	4	4	4	4		
6	Intact	4	4	4	4	4	4	48	8.0
	Abraded	4	4	4	4	4	4		

Primary Irritant Score ----- 8.0

*Score = sum of individual values for each rabbit divided by six.

Observations: Eschar formation was observed on both intact and abraded test sites of all test animals.

Skin Irritant Score and Irritant Classification: 8.0, corrosive

Test site	Evaluation of skin reaction	Ratio regarding six rabbits; Observation time		
		4 hr.	24 hr.	48 hr.
Intact	Corrosive	6/6	6/6	6/6
Abraded	Corrosive	6/6	6/6	6/6

APPENDIX A

FDA PROPOSED REVISION OF TEST FOR PRIMARY SKIN IRRITANTS

The proposed method of testing irritant substances is described in the Code of Federal Regulations under the Federal Hazardous Substances Labeling Act, Part 191.11, Chapter 1, Title 21 as follows:

Primary irritation to the skin is measured by a patch-test technique on abraded and intact skin of healthy albino rabbits. At least six rabbits must be used. The back of each animal is clipped free of hair 24 hours before application of the test material. The shaved area is divided into four quadrants, each being no less than 4 square inches in area. Two of the test sites are abraded and two are left intact.

The abraded areas are prepared 24 hours after shaving by making four epidermal incisions through the stratum corneum, two incisions perpendicular to the other two in a manner resembling a "tic-tac-toe" pattern. These incisions should not be so deep that they disturb the derma or produce bleeding.

Liquid test materials (0.5 milliliter) and/or solid or semi-solid test materials (0.5 gram) are introduced under a 1.5 x 1.5 inch 12-ply gauze patch which is secured in place by two narrow strips of adhesive tape. The substance tested (liquid, solid, or semisolid) represents a homogeneous aliquot of the substance under investigation. This factor is most important when testing formulated products containing several ingredients, such as emulsions or suspensions, which can separate due to standing, shipping, or temperature changes. Dry blended powders can segregate due to standing and shipping. Solid substances such as powders should be moistened with sufficient solvent to make a paste (and the quantity of solvent specified) or should be made into a 50-percent weight-to-volume solution. If the bulk density of a powder sample is such that it is physically impossible to place 0.5-gram samples under the patches, the largest practical amount is applied and reported.

The animals are then immobilized in stocks and the trunk of each animal is loosely wrapped with an impervious material, such as a rubberized cloth, for an exposure period of 4 hours. After 4 hours of exposure, the patches are removed and the resulting reactions are evaluated as described in Table 1.

Table 1

Skin Reaction	Value
Erythema and eschar formation:	
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
Edema formation:	
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 millimeter)	3
Severe edema (raised more than 1 millimeter and extending beyond the area of exposure)	4

Following this initial reading, all test sites are washed with appropriate solvent to prevent further exposure. Readings are again made at 24 and 48 hours after the initial application. The primary irritation index is calculated by adding the values for erythema or eschar formation, and edema at 4, 24, and 48 hours on intact and abraded skin (12 values) and dividing by six to obtain an individual score on each rabbit. The combined average of the six individual scores is the primary irritation index.

A material is considered to be corrosive when tissue destruction is observed on any of the six intact skin sites with or without similar destruction on the abraded areas. The ratio of tissue destruction observed on both intact and abraded skin sites is recorded.

B. SKIN IRRITATION INDEX

COMPOUND DRYLITE CLEAR

Rabbit No.	Skin	Erythema-eschar Observation			Edema Observation			Sum Total	Score*
		4 hr.	24 hr.	48 hr.	4 hr.	24 hr.	24 hr.		
1	Intact	1	1	1	1	1	1	12	2.00
	Abraded	1	1	1	1	1	1		
2	Intact	0	1	1	1	1	1	10	1.67
	Abraded	0	1	1	1	1	1		
3	Intact	1	1	1	1	1	1	12	2.00
	Abraded	1	1	1	1	1	1		
4	Intact	0	1	1	0	2	1	11	1.83
	Abraded	1	1	1	0	2	1		
5	Intact	0	0	0	0	0	0	3	0.50
	Abraded	0	1	1	0	0	1		
6	Intact	0	1	1	0	2	1	10	1.67
	Abraded	0	1	1	0	2	1		

Primary Irritant Score ----- 1.61

*Score = sum of individual values for each rabbit divided by six.

Observations: Slight erythema and edema were observed in five of six animals on the intact areas, and in all animals on the abraded areas.

Skin Irritant Score and Irritant Classification: 1.61, mild irritant

Test site	Evaluation of skin reaction	Ratio regarding six rabbits; Observation time		
		4 hr.	24 hr.	48 hr.
Intact	Corrosive	0/6	0/6	0/6
Abraded	Corrosive	0/6	0/6	0/6

APPENDIX A

FDA PROPOSED REVISION OF TEST FOR PRIMARY SKIN IRRITANTS

The proposed method of testing irritant substances is described in the Code of Federal Regulations under the Federal Hazardous Substances Labeling Act, Part 191.11, Chapter 1, Title 21 as follows:

Primary irritation to the skin is measured by a patch-test technique on abraded and intact skin of healthy albino rabbits. At least six rabbits must be used. The back of each animal is clipped free of hair 24 hours before application of the test material. The shaved area is divided into four quadrants, each being no less than 4 square inches in area. Two of the test sites are abraded and two are left intact.

The abraded areas are prepared 24 hours after shaving by making four epidermal incisions through the stratum corneum, two incisions perpendicular to the other two in a manner resembling a "tic-tac-toe" pattern. These incisions should not be so deep that they disturb the derma or produce bleeding.

Liquid test materials (0.5 milliliter) and/or solid or semi-solid test materials (0.5 gram) are introduced under a 1.5 x 1.5 inch 12-ply gauze patch which is secured in place by two narrow strips of adhesive tape. The substance tested (liquid, solid, or semisolid) represents a homogeneous aliquot of the substance under investigation. This factor is most important when testing formulated products containing several ingredients, such as emulsions or suspensions, which can separate due to standing, shipping, or temperature changes. Dry blended powders can segregate due to standing and shipping. Solid substances such as powders should be moistened with sufficient solvent to make a paste (and the quantity of solvent specified) or should be made into a 50-percent weight-to-volume solution. If the bulk density of a powder sample is such that it is physically impossible to place 0.5-gram samples under the patches, the largest practical amount is applied and reported.

The animals are then immobilized in stocks and the trunk of each animal is loosely wrapped with an impervious material, such as a rubberized cloth, for an exposure period of 4 hours. After 4 hours of exposure, the patches are removed and the resulting reactions are evaluated as described in Table 1.

Table 1

Skin Reaction	Value
Erythema and eschar formation:	
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
Edema formation:	
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 millimeter)	3
Severe edema (raised more than 1 millimeter and extending beyond the area of exposure)	4

Following this initial reading, all test sites are washed with appropriate solvent to prevent further exposure. Readings are again made at 24 and 48 hours after the initial application. The primary irritation index is calculated by adding the values for erythema or eschar formation, and edema at 4, 24, and 48 hours on intact and abraded skin (12 values) and dividing by six to obtain an individual score on each rabbit. The combined average of the six individual scores is the primary irritation index.

A material is considered to be corrosive when tissue destruction is observed on any of the six intact skin sites with or without similar destruction on the abraded areas. The ratio of tissue destruction observed on both intact and abraded skin sites is recorded.

STAUFFER CHEMICAL COMPANY
WESTERN RESEARCH CENTER

COMPANY CONFIDENTIAL

TOXICOLOGY LAB REPORT -- T-4037-9

August 18, 1972

DRYMET DD

I. OBJECTIVE

To evaluate the skin irritation properties of DRYMET DD according to the proposed DOT 4-hour exposure procedure.

II. MATERIALS

DRYMET DD, a white colored granular material, was received from the Industrial Division August 8, 1972.

III. SUMMARY

Skin irritation index	8.0
and classification:	corrosive

IV. PROCEDURE

Skin Irritation Index, Draize Dermal

The Draize Dermal procedure was followed as outlined in the Code of Federal Regulations (Part 191.11, Chap. 1, Title 21) for evaluating hazardous substances. The test procedure is designed to determine whether a chemical is a primary skin irritant, i.e., capable of initiating an extreme tissue reaction or skin inflammation to an insult or injury. The inflammatory process may vary from a barely perceptible hyperemia, to edema formation and vesiculation, and finally to an intense suppurative process. Irritation itself is not directly measured, but the result or consequence of irritation, that is, the injury reaction following irritation.

The Draize Dermal test is further discussed in Appendix A.

V. RESULTS

Primary Skin Irritation (Draize) Dermal

See chart on page 2.

Submitted by Michael F. McGowan
M. F. McGowan

Approved by F. X. Kamienski
F. X. Kamienski

FXK:ea

B. SKIN IRRITATION INDEX

COMPOUND DRYMET DD

Rabbit No.	Skin	Erythema-eschar Observation			Edema Observation			Sum Total	Score*
		4 hr.	24 hr.	48 hr.	4 hr.	24 hr.	24 hr.		
1	Intact	4	4	4	4	4	4	48	8.0
	Abraded	4	4	4	4	4	4		
2	Intact	4	4	4	4	4	4	48	8.0
	Abraded	4	4	4	4	4	4		
3	Intact	4	4	4	4	4	4	48	8.0
	Abraded	4	4	4	4	4	4		
4	Intact	4	4	4	4	4	4	48	8.0
	Abraded	4	4	4	4	4	4		
5	Intact	4	4	4	4	4	4	48	8.0
	Abraded	4	4	4	4	4	4		
6	Intact	4	4	4	4	4	4	48	8.0
	Abraded	4	4	4	4	4	4		

Primary Irritant Score ----- 8.0

*Score = sum of individual values for each rabbit divided by six.

Observations: Eschar formation was observed on both intact and abraded test sites of all test animals.

Skin Irritant Score and Irritant Classification: 8.0, corrosive

Test site	Evaluation of skin reaction	Ratio regarding six rabbits; Observation time		
		4 hr.	24 hr.	48 hr.
Intact	Corrosive	6/6	6/6	6/6
Abraded	Corrosive	6/6	6/6	6/6

APPENDIX A

FDA PROPOSED REVISION OF TEST FOR PRIMARY SKIN IRRITANTS

The proposed method of testing irritant substances is described in the Code of Federal Regulations under the Federal Hazardous Substances Labeling Act, Part 191.11, Chapter 1, Title 21 as follows:

Primary irritation to the skin is measured by a patch-test technique on abraded and intact skin of healthy albino rabbits. At least six rabbits must be used. The back of each animal is clipped free of hair 24 hours before application of the test material. The shaved area is divided into four quadrants, each being no less than 4 square inches in area. Two of the test sites are abraded and two are left intact.

The abraded areas are prepared 24 hours after shaving by making four epidermal incisions through the stratum corneum, two incisions perpendicular to the other two in a manner resembling a "tic-tac-toe" pattern. These incisions should not be so deep that they disturb the derma or produce bleeding.

Liquid test materials (0.5 milliliter) and/or solid or semi-solid test materials (0.5 gram) are introduced under a 1.5 x 1.5 inch 12-ply gauze patch which is secured in place by two narrow strips of adhesive tape. The substance tested (liquid, solid, or semisolid) represents a homogeneous aliquot of the substance under investigation. This factor is most important when testing formulated products containing several ingredients, such as emulsions or suspensions, which can separate due to standing, shipping, or temperature changes. Dry blended powders can segregate due to standing and shipping. Solid substances such as powders should be moistened with sufficient solvent to make a paste (and the quantity of solvent specified) or should be made into a 50-percent weight-to-volume solution. If the bulk density of a powder sample is such that it is physically impossible to place 0.5-gram samples under the patches, the largest practical amount is applied and reported.

The animals are then immobilized in stocks and the trunk of each animal is loosely wrapped with an impervious material, such as a rubberized cloth, for an exposure period of 4 hours. After 4 hours of exposure, the patches are removed and the resulting reactions are evaluated as described in Table 1.

Table 1

Skin Reaction	Value
Erythema and eschar formation:	
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
Edema formation:	
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 millimeter)	3
Severe edema (raised more than 1 millimeter and extending beyond the area of exposure)	4

Following this initial reading, all test sites are washed with appropriate solvent to prevent further exposure. Readings are again made at 24 and 48 hours after the initial application. The primary irritation index is calculated by adding the values for erythema or eschar formation, and edema at 4, 24, and 48 hours on intact and abraded skin (12 values) and dividing by six to obtain an individual score on each rabbit. The combined average of the six individual scores is the primary irritation index.

A material is considered to be corrosive when tissue destruction is observed on any of the six intact skin sites with or without similar destruction on the abraded areas. The ratio of tissue destruction observed on both intact and abraded skin sites is recorded.

B. SKIN IRRITATION INDEX

COMPOUND DRYORTH

Rabbit No.	Skin	Erythema-eschar Observation			Edema Observation			Sum Total	Score*
		4 hr.	24 hr.	48 hr.	4 hr.	24 hr.	48 hr.		
1	Intact	4	4	4	4	4	4	48	8.0
	Abraded	4	4	4	4	4	4		
2	Intact	4	4	4	4	4	4	48	8.0
	Abraded	4	4	4	4	4	4		
3	Intact	4	4	4	4	4	4	48	8.0
	Abraded	4	4	4	4	4	4		
4	Intact	4	4	4	4	4	4	48	8.0
	Abraded	4	4	4	4	4	4		
5	Intact	4	4	4	4	4	4	48	8.0
	Abraded	4	4	4	4	4	4		
6	Intact	4	4	4	4	4	4	48	8.0
	Abraded	4	4	4	4	4	4		

Primary Irritant Score ----- 8.0

*Score = sum of individual values for each rabbit divided by six.

Observations: Eschar was observed on both the intact and abraded test sites 4-hours after treatment.

Skin Irritant Score and Irritant Classification: 8.0 corrosive

Test site	Evaluation of skin reaction	Ratio regarding six rabbits; Observation time		
		4 hr.	24 hr.	48 hr.
Intact	Corrosive	6/6	6/6	6/6
Abraded	Corrosive	6/6	6/6	6/6

APPENDIX A

FDA PROPOSED REVISION OF TEST FOR PRIMARY SKIN IRRITANTS

The proposed method of testing irritant substances is described in the Code of Federal Regulations under the Federal Hazardous Substances Labeling Act, Part 191.11, Chapter 1, Title 21 as follows:

Primary irritation to the skin is measured by a patch-test technique on abraded and intact skin of healthy albino rabbits. At least six rabbits must be used. The back of each animal is clipped free of hair 24 hours before application of the test material. The shaved area is divided into four quadrants, each being no less than 4 square inches in area. Two of the test sites are abraded and two are left intact.

The abraded areas are prepared 24 hours after shaving by making four epidermal incisions through the stratum corneum, two incisions perpendicular to the other two in a manner resembling a "tic-tac-toe" pattern. These incisions should not be so deep that they disturb the derma or produce bleeding.

Liquid test materials (0.5 milliliter) and/or solid or semi-solid test materials (0.5 gram) are introduced under a 1.5 x 1.5 inch 12-ply gauze patch which is secured in place by two narrow strips of adhesive tape. The substance tested (liquid, solid, or semisolid) represents a homogeneous aliquot of the substance under investigation. This factor is most important when testing formulated products containing several ingredients, such as emulsions or suspensions, which can separate due to standing, shipping, or temperature changes. Dry blended powders can segregate due to standing and shipping. Solid substances such as powders should be moistened with sufficient solvent to make a paste (and the quantity of solvent specified) or should be made into a 50-percent weight-to-volume solution. If the bulk density of a powder sample is such that it is physically impossible to place 0.5-gram samples under the patches, the largest practical amount is applied and reported.

The animals are then immobilized in stocks and the trunk of each animal is loosely wrapped with an impervious material, such as a rubberized cloth, for an exposure period of 4 hours. After 4 hours of exposure, the patches are removed and the resulting reactions are evaluated as described in Table 1.

Table 1

Skin Reaction	Value
Erythema and eschar formation:	
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
Edema formation:	
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 millimeter)	3
Severe edema (raised more than 1 millimeter and extending beyond the area of exposure)	4

Following this initial reading, all test sites are washed with appropriate solvent to prevent further exposure. Readings are again made at 24 and 48 hours after the initial application. The primary irritation index is calculated by adding the values for erythema or eschar formation, and edema at 4, 24, and 48 hours on intact and abraded skin (1.2 values) and dividing by six to obtain an individual score on each rabbit. The combined average of the six individual scores is the primary irritation index.

A material is considered to be corrosive when tissue destruction is observed on any of the six intact skin sites with or without similar destruction on the abraded areas. The ratio of tissue destruction observed on both intact and abraded skin sites is recorded.

STAUFFER CHEMICAL COMPANY

WESTERN RESEARCH CENTER

COMPANY CONFIDENTIAL

TOXICOLOGY LABORATORY REPORT T-4037-11

August 24, 1972

DRYORTH LD

I. OBJECTIVE

To evaluate the skin irritation properties of DRYORTH LD according to the proposed DOT 4-hour exposure procedure.

II. MATERIALS

DRYORTH LD, a white granular compound, was received from the Industrial Chemical Division on August 8, 1972.

III. SUMMARY

Skin irritation index and classification:	8.0 corrosive
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IV. PROCEDURE

B. Skin Irritation Index, Draize Dermal

The Draize Dermal procedure was followed as outlined in the Code of Federal Regulations (Part 191.11, Chap. 1, Title 21) for evaluating hazardous substances. The test procedure is designed to determine whether a chemical is a primary skin irritant, ie., capable of initiating an extreme tissue reaction or skin inflammation to an insult or injury. The inflammatory process may vary from a barely perceptible hyperemia, to edema formation and vesiculation, and finally to an intense suppurative process. Irritation itself is not directly measured, but the result or consequence of irritation, that is, the injury reaction following irritation.

The Draize Dermal test is further discussed in Appendix A.

V. RESULTS

Primary Skin Irritation (Draize) Dermal -- see chart on page 2.

Submitted by M. Mc Gowan
M. Mc Gowan

Approved by F. X. Kamienski
F. X. Kamienski

B. SKIN IRRITATION INDEX

COMPOUND DRYORTH LD

Rabbit No.	Skin	Erythema-eschar Observation			Edema Observation			Sum Total	Score*
		4 hr.	24 hr.	48 hr.	4 hr.	24 hr.	48 hr.		
1	Intact	4	4	4	4	4	4	48	8.0
	Abraded	4	4	4	4	4	4		
2	Intact	4	4	4	4	4	4	48	8.0
	Abraded	4	4	4	4	4	4		
3	Intact	4	4	4	4	4	4	48	8.0
	Abraded	4	4	4	4	4	4		
4	Intact	4	4	4	4	4	4	48	8.0
	Abraded	4	4	4	4	4	4		
5	Intact	4	4	4	4	4	4	48	8.0
	Abraded	4	4	4	4	4	4		
6	Intact	4	4	4	4	4	4	48	8.0
	Abraded	4	4	4	4	4	4		

Primary Irritant Score ----- 8.0

*Score = sum of individual values for each rabbit divided by six.

Observations: Eschar was observed on both the intact and abraded test sites 4-hours after treatment.

Skin Irritant Score and Irritant Classification: 8.0 corrosive

Test site	Evaluation of skin reaction	Ratio regarding six rabbits; Observation time		
		4 hr.	24 hr.	48 hr.
Intact	Corrosive	6/6	6/6	6/6
Abraded	Corrosive	6/6	6/6	6/6

APPENDIX A

FDA PROPOSED REVISION OF TEST FOR PRIMARY SKIN IRRITANTS

The proposed method of testing irritant substances is described in the Code of Federal Regulations under the Federal Hazardous Substances Labeling Act, Part 191.11, Chapter 1, Title 21 as follows:

Primary irritation to the skin is measured by a patch-test technique on abraded and intact skin of healthy albino rabbits. At least six rabbits must be used. The back of each animal is clipped free of hair 24 hours before application of the test material. The shaved area is divided into four quadrants, each being no less than 4 square inches in area. Two of the test sites are abraded and two are left intact.

The abraded areas are prepared 24 hours after shaving by making four epidermal incisions through the stratum corneum, two incisions perpendicular to the other two in a manner resembling a "tic-tac-toe" pattern. These incisions should not be so deep that they disturb the derma or produce bleeding.

Liquid test materials (0.5 milliliter) and/or solid or semi-solid test materials (0.5 gram) are introduced under a 1.5 x 1.5 inch 12-ply gauze patch which is secured in place by two narrow strips of adhesive tape. The substance tested (liquid, solid, or semisolid) represents a homogeneous aliquot of the substance under investigation. This factor is most important when testing formulated products containing several ingredients, such as emulsions or suspensions, which can separate due to standing, shipping, or temperature changes. Dry blended powders can segregate due to standing and shipping. Solid substances such as powders should be moistened with sufficient solvent to make a paste (and the quantity of solvent specified) or should be made into a 50-percent weight-to-volume solution. If the bulk density of a powder sample is such that it is physically impossible to place 0.5-gram samples under the patches, the largest practical amount is applied and reported.

The animals are then immobilized in stocks and the trunk of each animal is loosely wrapped with an impervious material, such as a rubberized cloth, for an exposure period of 4 hours. After 4 hours of exposure, the patches are removed and the resulting reactions are evaluated as described in Table 1.

Table 1

Skin Reaction	Value
Erythema and eschar formation:	
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
Edema formation:	
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 millimeter)	3
Severe edema (raised more than 1 millimeter and extending beyond the area of exposure)	4

Following this initial reading, all test sites are washed with appropriate solvent to prevent further exposure. Readings are again made at 24 and 48 hours after the initial application. The primary irritation index is calculated by adding the values for erythema or eschar formation, and edema at 4, 24, and 48 hours on intact and abraded skin (12 values) and dividing by six to obtain an individual score on each rabbit. The combined average of the six individual scores is the primary irritation index.

A material is considered to be corrosive when tissue destruction is observed on any of the six intact skin sites with or without similar destruction on the abraded areas. The ratio of tissue destruction observed on both intact and abraded skin sites is recorded.

STAUFFER CHEMICAL COMPANY

WESTERN RESEARCH CENTER

COMPANY CONFIDENTIAL

TOXICOLOGY LABORATORY REPORT T-4037-12

August 24, 1972

ECONODET

I. OBJECTIVE

To evaluate the skin irritation properties of ECONODET according to the proposed DOT 4-hour exposure procedure.

II. MATERIALS

ECONODET, a green granular compound, was received from the Industrial Chemical Division on August 8, 1972.

III. SUMMARY

Skin irritation index	8.0
and classification:	corrosive

IV. PROCEDURE

Skin Irritation Index, Draize Dermal

The Draize Dermal procedure was followed as outlined in the Code of Federal Regulations (Part 191.11, Chap. 1, Title 21) for evaluating hazardous substances. The test procedure is designed to determine whether a chemical is a primary skin irritant, ie., capable of initiating an extreme tissue reaction or skin inflammation to an insult or injury. The inflammatory process may vary from a barely perceptible hyperemia, to edema formation and vesiculation, and finally to an intense suppurative process. Irritation itself is not directly measured, but the result or consequence of irritation, that is, the injury reaction following irritation.

The Draize Dermal test is further discussed in Appendix A.

V. RESULTS

Primary Skin Irritation (Draize) Dermal -- See chart on page 2.

Submitted by C. H. Bullock
C. H. Bullock

Approved by F. X. Kamienski
F. X. Kamienski

COMPOUND ECONODET

Rabbit No.	Skin	Erythema-eschar Observation			Edema Observation			Sum Total	Score*
		4 hr.	24 hr.	48 hr.	4 hr.	24 hr.	48 hr.		
1	Intact	4	4	4	4	4	4	48	8.0
	Abraded	4	4	4	4	4	4		
2	Intact	4	4	4	4	4	4	48	8.0
	Abraded	4	4	4	4	4	4		
3	Intact	4	4	4	4	4	4	48	8.0
	Abraded	4	4	4	4	4	4		
4	Intact	4	4	4	4	4	4	48	8.0
	Abraded	4	4	4	4	4	4		
5	Intact	4	4	4	4	4	4	48	8.0
	Abraded	4	4	4	4	4	4		
6	Intact	4	4	4	4	4	4	48	8.0
	Abraded	4	4	4	4	4	4		

Primary Irritant Score ----- 8.0

*Score = sum of individual values for each rabbit divided by six.

Observations: All animals exhibited eschar formation and severe edema on both the intact and the abraded skin areas.

Skin Irritant Score
and Irritant Classification: 8.0 corrosive

Test site	Evaluation of skin reaction	Ratio regarding six rabbits; Observation time		
		4 hr.	24 hr.	48 hr.
Intact	Corrosive	6/6	6/6	6/6
Abraded	Corrosive	6/6	6/6	6/6

APPENDIX A

FDA PROPOSED REVISION OF TEST FOR PRIMARY SKIN IRRITANTS

The proposed method of testing irritant substances is described in the Code of Federal Regulations under the Federal Hazardous Substances Labeling Act, Part 191.11, Chapter 1, Title 21 as follows:

Primary irritation to the skin is measured by a patch-test technique on abraded and intact skin of healthy albino rabbits. At least six rabbits must be used. The back of each animal is clipped free of hair 24 hours before application of the test material. The shaved area is divided into four quadrants, each being no less than 4 square inches in area. Two of the test sites are abraded and two are left intact.

The abraded areas are prepared 24 hours after shaving by making four epidermal incisions through the stratum corneum, two incisions perpendicular to the other two in a manner resembling a "tic-tac-toe" pattern. These incisions should not be so deep that they disturb the derma or produce bleeding.

Liquid test materials (0.5 milliliter) and/or solid or semi-solid test materials (0.5 gram) are introduced under a 1.5 x 1.5 inch 12-ply gauze patch which is secured in place by two narrow strips of adhesive tape. The substance tested (liquid, solid, or semisolid) represents a homogeneous aliquot of the substance under investigation. This factor is most important when testing formulated products containing several ingredients, such as emulsions or suspensions, which can separate due to standing, shipping, or temperature changes. Dry blended powders can segregate due to standing and shipping. Solid substances such as powders should be moistened with sufficient solvent to make a paste (and the quantity of solvent specified) or should be made into a 50-percent weight-to-volume solution. If the bulk density of a powder sample is such that it is physically impossible to place 0.5-gram samples under the patches, the largest practical amount is applied and reported.

The animals are then immobilized in stocks and the trunk of each animal is loosely wrapped with an impervious material, such as a rubberized cloth, for an exposure period of 4 hours. After 4 hours of exposure, the patches are removed and the resulting reactions are evaluated as described in Table 1.

Table 1

Skin Reaction	Value
Erythema and eschar formation:	
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
Edema formation:	
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 millimeter)	3
Severe edema (raised more than 1 millimeter and extending beyond the area of exposure)	4

Following this initial reading, all test sites are washed with appropriate solvent to prevent further exposure. Readings are again made at 24 and 48 hours after the initial application. The primary irritation index is calculated by adding the values for erythema or eschar formation, and edema at 4, 24, and 48 hours on intact and abraded skin (1.2 values) and dividing by six to obtain an individual score on each rabbit. The combined average of the six individual scores is the primary irritation index.

A material is considered to be corrosive when tissue destruction is observed on any of the six intact skin sites with or without similar destruction on the abraded areas. The ratio of tissue destruction observed on both intact and abraded skin sites is recorded.

STAUFFER CHEMICAL COMPANY

WESTERN RESEARCH CENTER

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TOXICOLOGY LABORATORY REPORT T- 4037-13

August 25, 1972

MILDUPRUF

I. OBJECTIVE

To evaluate the skin irritation properties of MILDUPRUF according to the proposed DOT 4-hour exposure procedure.

II. MATERIALS

MILDUPRUF, a clear colorless liquid, was received from the Industrial Chemical Division on August 8, 1972.

III. SUMMARY

Skin irritation index
and classification: 8.0
corrosive

IV. PROCEDURE

Skin Irritation Index, Draize Dermal

The Draize Dermal procedure was followed as outlined in the Code of Federal Regulations (Part 191.11, Chap. 1, Title 21) for evaluating hazardous substances. The test procedure is designed to determine whether a chemical is a primary skin irritant, ie., capable of initiating an extreme tissue reaction or skin inflammation to an insult or injury. The inflammatory process may vary from a barely perceptible hyperemia, to edema formation and vesiculation, and finally to an intense suppurative process. Irritation itself is not directly measured, but the result or consequence of irritation, that is, the injury reaction following irritation.

The Draize Dermal test is further discussed in Appendix A.

V. RESULTS

Primary Skin Irritation (Draize) Dermal

see chart on page 2

Submitted by C. H. Bullock
C. H. Bullock.

Approved by F. X. Kamienski
F. X. Kamienski

B. SKIN IRRITATION INDEX

COMPOUND MILDUPRUF

Rabbit No.	Skin	Erythema-eschar Observation			Edema Observation			Sum Total	Score*
		4 hr.	24 hr.	48 hr.	4 hr.	24 hr.	48 hr.		
1	Intact	4	4	4	4	4	4	48	8.0
	Abraded	4	4	4	4	4	4		
2	Intact	4	4	4	4	4	4	48	8.0
	Abraded	4	4	4	4	4	4		
3	Intact	4	4	4	4	4	4	48	8.0
	Abraded	4	4	4	4	4	4		
4	Intact	4	4	4	4	4	4	48	8.0
	Abraded	4	4	4	4	4	4		
5	Intact	4	4	4	4	4	4	48	8.0
	Abraded	4	4	4	4	4	4		
6	Intact	4	4	4	4	4	4	48	8.0
	Abraded	4	4	4	4	4	4		

Primary Irritant Score ----- 8.0

*Score = sum of individual values for each rabbit divided by six.

Observations: Eschar was observed on both the intact and abraded test sites 4-hours after treatment.

Skin Irritant Score and Irritant Classification: 8.0 corrosive

Test site	Evaluation of skin reaction	Ratio regarding six rabbits; Observation time		
		4 hr.	24 hr.	48 hr.
Intact	Corrosive	6/6	6/6	6/6
Abraded	Corrosive	6/6	6/6	6/6

STAUFFER CHEMICAL COMPANY
WESTERN RESEARCH CENTER

COMPANY CONFIDENTIAL

TOXICOLOGY LABORATORY REPORT T-4037-14

August 25, 1972

MOOV

I. OBJECTIVE

To evaluate the skin irritation properties of MOOV, according to the proposed DOT 4-hour exposure procedure.

II. MATERIALS

MOOV, a clear yellow colored liquid, was received from the Industrial Chemical Division on August 8, 1972.

III. SUMMARY

Skin irritation index	8.0
and classification:	corrosive

IV. PROCEDURE

Skin Irritation Index, Draize Dermal

The Draize Dermal procedure was followed as outlined in the Code of Federal Regulations (Part 191.11, Chap. 1, Title 21) for evaluating hazardous substances. The test procedure is designed to determine whether a chemical is a primary skin irritant, i.e., capable of initiating an extreme tissue reaction or skin inflammation to an insult or injury. The inflammatory process may vary from a barely perceptible hyperemia, to edema formation and vesiculation, and finally to an intense suppurative process. Irritation itself is not directly measured, but the result or consequence of irritation, that is, the injury reaction following irritation.

The Draize Dermal test is further discussed in Appendix A.

V. RESULTS

Primary Skin Irritation (Draize) Dermal -- See chart on page 2.

Submitted by C. H. Bullock
C. H. Bullock

Approved by F. X. Kamienski
F. X. Kamienski

B. SKIN IRRITATION INDEX

COMPOUND MOOV

Rabbit No.	Skin	Erythema-eschar Observation			Edema Observation			Sum Total	Score*
		4 hr.	24 hr.	48 hr.	4 hr.	24 hr.	48 hr.		
1	Intact	4	4	4	4	4	4	48	8.0
	Abraded	4	4	4	4	4	4		
2	Intact	4	4	4	4	4	4	48	8.0
	Abraded	4	4	4	4	4	4		
3	Intact	4	4	4	4	4	4	48	8.0
	Abraded	4	4	4	4	4	4		
4	Intact	4	4	4	4	4	4	48	8.0
	Abraded	4	4	4	4	4	4		
5	Intact	4	4	4	4	4	4	48	8.0
	Abraded	4	4	4	4	4	4		
6	Intact	4	4	4	4	4	4	48	8.0
	Abraded	4	4	4	4	4	4		

Primary Irritant Score ----- 8.0

*Score = sum of individual values for each rabbit divided by six.

Observations: Eschar was observed on both the intact and abraded test sites 4-hours after treatment.

Skin Irritant Score and Irritant Classification: 8.0 corrosive

Test site	Evaluation of skin reaction	Ratio regarding six rabbits; Observation time		
		4 hr.	24 hr.	48 hr.
Intact	Corrosive	6/6	6/6	6/6
Abraded	Corrosive	6/6	6/6	6/6

APPENDIX A

FDA PROPOSED REVISION OF TEST FOR PRIMARY SKIN IRRITANTS

The proposed method of testing irritant substances is described in the Code of Federal Regulations under the Federal Hazardous Substances Labeling Act, Part 191.11, Chapter 1, Title 21 as follows:

Primary irritation to the skin is measured by a patch-test technique on abraded and intact skin of healthy albino rabbits. At least six rabbits must be used. The back of each animal is clipped free of hair 24 hours before application of the test material. The shaved area is divided into four quadrants, each being no less than 4 square inches in area. Two of the test sites are abraded and two are left intact.

The abraded areas are prepared 24 hours after shaving by making four epidermal incisions through the stratum corneum, two incisions perpendicular to the other two in a manner resembling a "tic-tac-toe" pattern. These incisions should not be so deep that they disturb the derma or produce bleeding.

Liquid test materials (0.5 milliliter) and/or solid or semi-solid test materials (0.5 gram) are introduced under a 1.5 x 1.5 inch 12-ply gauze patch which is secured in place by two narrow strips of adhesive tape. The substance tested (liquid, solid, or semisolid) represents a homogeneous aliquot of the substance under investigation. This factor is most important when testing formulated products containing several ingredients, such as emulsions or suspensions, which can separate due to standing, shipping, or temperature changes. Dry blended powders can segregate due to standing and shipping. Solid substances such as powders should be moistened with sufficient solvent to make a paste (and the quantity of solvent specified) or should be made into a 50-percent weight-to-volume solution. If the bulk density of a powder sample is such that it is physically impossible to place 0.5-gram samples under the patches, the largest practical amount is applied and reported.

The animals are then immobilized in stocks and the trunk of each animal is loosely wrapped with an impervious material, such as a rubberized cloth, for an exposure period of 4 hours. After 4 hours of exposure, the patches are removed and the resulting reactions are evaluated as described in Table 1.

Table 1

Skin Reaction	Value
Erythema and eschar formation:	
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
Edema formation:	
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 millimeter)	3
Severe edema (raised more than 1 millimeter and extending beyond the area of exposure)	4

Following this initial reading, all test sites are washed with appropriate solvent to prevent further exposure. Readings are again made at 24 and 48 hours after the initial application. The primary irritation index is calculated by adding the values for erythema or eschar formation, and edema at 4, 24, and 48 hours on intact and abraded skin (12 values) and dividing by six to obtain an individual score on each rabbit. The combined average of the six individual scores is the primary irritation index.

A material is considered to be corrosive when tissue destruction is observed on any of the six intact skin sites with or without similar destruction on the abraded areas. The ratio of tissue destruction observed on both intact and abraded skin sites is recorded.

STAUFFER CHEMICAL COMPANY

WESTERN RESEARCH CENTER

COMPANY CONFIDENTIAL

TOXICOLOGY LABORATORY REPORT T-4037-15

August 25, 1972

ONE SHOT CLEANER

I. OBJECTIVE

To evaluate the skin irritation properties of ONE SHOT CLEANER, according to the proposed DOT 4-hour exposure procedure.

II. MATERIALS

ONE SHOT CLEANER, a yellow granular material, was received from the Industrial Chemical Division on August 8, 1972.

III. SUMMARY

Skin irritation index	8.0
and classification:	corrosive

IV. PROCEDURE

The Draize Dermal procedure was followed as outlined in the Code of Federal Regulations (Part 191.11, Chap. 1, Title 21) for evaluating hazardous substances. The test procedure is designed to determine whether a chemical is a primary skin irritant, ie., capable of initiating an extreme tissue reaction or skin inflammation to an insult or injury. The inflammatory process may vary from a barely perceptible hyperemia, to edema formation and vesiculation, and finally to an intense suppurative process. Irritation itself is not directly measured, but the result or consequence of irritation, that is, the injury reaction following irritation.

The Draize Dermal test is further discussed in Appendix A.

V. RESULTS

Primary Skin Irritation (Draize) Dermal -- See chart on page 2.

Submitted by C. H. Bullock
C. H. Bullock

Approved by F. X. Kamienski
F. X. Kamienski

B. SKIN IRRITATION INDEX

COMPOUND ONE SHOT CLEANER

Rabbit No.	Skin	Erythema-eschar Observation			Edema Observation			Sum Total	Score*
		4 hr.	24 hr.	48 hr.	4 hr.	24 hr.	48 hr.		
1	Intact	4	4	4	4	4	4	48	8.0
	Abraded	4	4	4	4	4	4		
2	Intact	4	4	4	4	4	4	48	8.0
	Abraded	4	4	4	4	4	4		
3	Intact	4	4	4	4	4	4	48	8.0
	Abraded	4	4	4	4	4	4		
4	Intact	4	4	4	4	4	4	48	8.0
	Abraded	4	4	4	4	4	4		
5	Intact	4	4	4	4	4	4	48	8.0
	Abraded	4	4	4	4	4	4		
6	Intact	4	4	4	4	4	4	48	8.0
	Abraded	4	4	4	4	4	4		

Primary Irritant Score ----- 8.0

*Score = sum of individual values for each rabbit divided by six.

Observations: Eschar was observed on both the intact and abraded test sites 4-hours after treatment.

Skin Irritant Score and Irritant Classification: 8.0 corrosive

Test site	Evaluation of skin reaction	Ratio regarding six rabbits; Observation time		
		4 hr.	24 hr.	48 hr.
Intact	Corrosive	6/6	6/6	6/6
Abraded	Corrosive	6/6	6/6	6/6

APPENDIX A

FDA PROPOSED REVISION OF TEST FOR PRIMARY SKIN IRRITANTS

The proposed method of testing irritant substances is described in the Code of Federal Regulations under the Federal Hazardous Substances Labeling Act, Part 191.11, Chapter 1, Title 21 as follows:

Primary irritation to the skin is measured by a patch-test technique on abraded and intact skin of healthy albino rabbits. At least six rabbits must be used. The back of each animal is clipped free of hair 24 hours before application of the test material. The shaved area is divided into four quadrants, each being no less than 4 square inches in area. Two of the test sites are abraded and two are left intact.

The abraded areas are prepared 24 hours after shaving by making four epidermal incisions through the stratum corneum, two incisions perpendicular to the other two in a manner resembling a "tic-tac-toe" pattern. These incisions should not be so deep that they disturb the derma or produce bleeding.

Liquid test materials (0.5 milliliter) and/or solid or semi-solid test materials (0.5 gram) are introduced under a 1.5 x 1.5 inch 12-ply gauze patch which is secured in place by two narrow strips of adhesive tape. The substance tested (liquid, solid, or semisolid) represents a homogeneous aliquot of the substance under investigation. This factor is most important when testing formulated products containing several ingredients, such as emulsions or suspensions, which can separate due to standing, shipping, or temperature changes. Dry blended powders can segregate due to standing and shipping. Solid substances such as powders should be moistened with sufficient solvent to make a paste (and the quantity of solvent specified) or should be made into a 50-percent weight-to-volume solution. If the bulk density of a powder sample is such that it is physically impossible to place 0.5-gram samples under the patches, the largest practical amount is applied and reported.

The animals are then immobilized in stocks and the trunk of each animal is loosely wrapped with an impervious material, such as a rubberized cloth, for an exposure period of 4 hours. After 4 hours of exposure, the patches are removed and the resulting reactions are evaluated as described in Table 1.

Table 1

Skin Reaction	Value
Erythema and eschar formation:	
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
Edema formation:	
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 millimeter)	3
Severe edema (raised more than 1 millimeter and extending beyond the area of exposure)	4

Following this initial reading, all test sites are washed with appropriate solvent to prevent further exposure. Readings are again made at 24 and 48 hours after the initial application. The primary irritation index is calculated by adding the values for erythema or eschar formation, and edema at 4, 24, and 48 hours on intact and abraded skin (12 values) and dividing by six to obtain an individual score on each rabbit. The combined average of the six individual scores is the primary irritation index.

A material is considered to be corrosive when tissue destruction is observed on any of the six intact skin sites with or without similar destruction on the abraded areas. The ratio of tissue destruction observed on both intact and abraded skin sites is recorded.

STAUFFER CHEMICAL COMPANY

WESTERN RESEARCH CENTER

COMPANY CONFIDENTIAL

TOXICOLOGY LABORATORY REPORT T-4037-16

August 25, 1972

ROUND

I. OBJECTIVE

To evaluate the skin irritation properties of ROUND, according to the proposed DOT 4-hour exposure procedure.

II. MATERIALS

ROUND, a white granular material, was received from the Industrial Chemical Division on August 8, 1972.

III. SUMMARY

Skin irritation index and classification:	8.0 corrosive
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IV. PROCEDURE

B. Skin Irritation Index, Draize Dermal

The Draize Dermal procedure was followed as outlined in the Code of Federal Regulations (Part 191.11, Chap. 1, Title 21) for evaluating hazardous substances. The test procedure is designed to determine whether a chemical is a primary skin irritant, i.e., capable of initiating an extreme tissue reaction or skin inflammation to an insult or injury. The inflammatory process may vary from a barely perceptible hyperemia, to edema formation and vesiculation, and finally to an intense suppurative process. Irritation itself is not directly measured, but the result or consequence of irritation, that is, the injury reaction following irritation.

The Draize Dermal test is further discussed in Appendix A.

V. RESULTS

Primary Skin Irritation (Draize) Dermal

See chart on page 3.

Submitted by C. H. Bullock
C. H. Bullock

Approved by F. X. Kamienski
F. X. Kamienski

FXK:ea

B. SKIN IRRITATION INDEX

COMPOUND _____ ROUND _____

Rabbit No.	Skin	Erythema-eschar Observation			Edema Observation			Sum Total	Score*
		4 hr.	24 hr.	48 hr.	4 hr.	24 hr.	48 hr.		
1	Intact	4	4	4	4	4	4	48	8.0
	Abraded	4	4	4	4	4	4		
2	Intact	4	4	4	4	4	4	48	8.0
	Abraded	4	4	4	4	4	4		
3	Intact	4	4	4	4	4	4	48	8.0
	Abraded	4	4	4	4	4	4		
4	Intact	4	4	4	4	4	4	48	8.0
	Abraded	4	4	4	4	4	4		
5	Intact	4	4	4	4	4	4	48	8.0
	Abraded	4	4	4	4	4	4		
6	Intact	4	4	4	4	4	4	48	8.0
	Abraded	4	4	4	4	4	4		

Primary Irritant Score ----- 8.0

*Score = sum of individual values for each rabbit divided by six.

Observations: Eschar was observed on both the intact and abraded test sites 4-hours after treatment.

Skin Irritant Score and Irritant Classification: 8.0 corrosive

Test site	Evaluation of skin reaction	Ratio regarding six rabbits; Observation time		
		4 hr.	24 hr.	48 hr.
Intact	Corrosive	6/6	6/6	6/6
Abraded	Corrosive	6/6	6/6	6/6

APPENDIX A

FDA PROPOSED REVISION OF TEST FOR PRIMARY SKIN IRRITANTS

The proposed method of testing irritant substances is described in the Code of Federal Regulations under the Federal Hazardous Substances Labeling Act, Part 191.11, Chapter 1, Title 21 as follows:

Primary irritation to the skin is measured by a patch-test technique on abraded and intact skin of healthy albino rabbits. At least six rabbits must be used. The back of each animal is clipped free of hair 24 hours before application of the test material. The shaved area is divided into four quadrants, each being no less than 4 square inches in area. Two of the test sites are abraded and two are left intact.

The abraded areas are prepared 24 hours after shaving by making four epidermal incisions through the stratum corneum, two incisions perpendicular to the other two in a manner resembling a "tic-tac-toe" pattern. These incisions should not be so deep that they disturb the derma or produce bleeding.

Liquid test materials (0.5 milliliter) and/or solid or semi-solid test materials (0.5 gram) are introduced under a 1.5 x 1.5 inch 12-ply gauze patch which is secured in place by two narrow strips of adhesive tape. The substance tested (liquid, solid, or semisolid) represents a homogeneous aliquot of the substance under investigation. This factor is most important when testing formulated products containing several ingredients, such as emulsions or suspensions, which can separate due to standing, shipping, or temperature changes. Dry blended powders can segregate due to standing and shipping. Solid substances such as powders should be moistened with sufficient solvent to make a paste (and the quantity of solvent specified) or should be made into a 50-percent weight-to-volume solution. If the bulk density of a powder sample is such that it is physically impossible to place 0.5-gram samples under the patches, the largest practical amount is applied and reported.

The animals are then immobilized in stocks and the trunk of each animal is loosely wrapped with an impervious material, such as a rubberized cloth, for an exposure period of 4 hours. After 4 hours of exposure, the patches are removed and the resulting reactions are evaluated as described in Table 1.

Table 1

Skin Reaction	Value
Erythema and eschar formation:	
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
Edema formation:	
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 millimeter)	3
Severe edema (raised more than 1 millimeter and extending beyond the area of exposure)	4

Following this initial reading, all test sites are washed with appropriate solvent to prevent further exposure. Readings are again made at 24 and 48 hours after the initial application. The primary irritation index is calculated by adding the values for erythema or eschar formation, and edema at 4, 24, and 48 hours on intact and abraded skin (12 values) and dividing by six to obtain an individual score on each rabbit. The combined average of the six individual scores is the primary irritation index.

A material is considered to be corrosive when tissue destruction is observed on any of the six intact skin sites with or without similar destruction on the abraded areas. The ratio of tissue destruction observed on both intact and abraded skin sites is recorded.

STAUFFER CHEMICAL COMPANY

WESTERN RESEARCH CENTER

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TOXICOLOGY LABORATORY REPORT T-4037-17

August 25, 1972

SANITIZER

I. OBJECTIVE

To evaluate the skin irritation properties of SANITIZER.

II. MATERIALS

SANITIZER, a white powder, was received from the Industrial Chemical Division on August 8, 1972.

III. SUMMARY

Skin irritation index and classification: 4.9
corrosive

IV. PROCEDURE

Skin Irritation Index, Draize Dermal

The Draize Dermal procedure was followed as outlined in the Code of Federal Regulations (Part 191.11, Chap. 1, Title 21) for evaluating hazardous substances. The test procedure is designed to determine whether a chemical is a primary skin irritant, i.e., capable of initiating an extreme tissue reaction or skin inflammation to an insult or injury. The inflammatory process may vary from a barely perceptible hyperemia, to edema formation and vesiculation, and finally to an intense suppurative process. Irritation itself is not directly measured, but the result or consequence of irritation, that is, the injury reaction following irritation.

The Draize Dermal test is further discussed in Appendix A.

V. RESULTS

Primary Skin Irritation (Draize) Dermal -- see chart on page 2.

Submitted by C. H. Bullock (F. X. K.)
C. H. Bullock

Approved by F. X. Kamienski
F. X. Kamienski

Rabbit No.	Skin	Erythema-eschar Observation			Edema Observation			Sum Total	Score*
		4 hr.	24 hr.	48 hr.	4 hr.	24 hr.	48 hr.		
1	Intact	4	4	4	1	2	2	34	5.66
	Abraded	4	4	4	1	2	2		
2	Intact	4	4	4	1	1	1	30	5.00
	Abraded	4	4	4	1	1	1		
3	Intact	4	4	4	1	1	1	30	5.00
	Abraded	4	4	4	1	1	1		
4	Intact	4	4	4	1	1	1	30	5.00
	Abraded	4	4	4	1	1	1		
5	Intact	4	4	4	1	0	0	26	4.33
	Abraded	4	4	4	1	0	0		
6	Intact	4	4	4	1	0	0	26	4.33
	Abraded	4	4	4	1	0	0		

Primary Irritant Score ----- 4.9

*Score = sum of individual values for each rabbit divided by six.

Observations: Eschar was observed on both the intact and abraded test sites

Skin Irritant Score and Irritant Classification: 4.9 corrosive

Test site	Evaluation of skin reaction	Ratio regarding six rabbits; Observation time		
		4 hr.	24 hr.	48 hr.
Intact	Corrosive	6/6	6/6	6/6
Abraded	Corrosive	6/6	6/6	6/6

FDA PROPOSED REVISION OF TEST FOR PRIMARY SKIN IRRITANTS

The proposed method of testing irritant substances is described in the Code of Federal Regulations under the Federal Hazardous Substances Labeling Act, Part 191.11, Chapter 1, Title 21 as follows:

Primary irritation to the skin is measured by a patch-test technique on abraded and intact skin of healthy albino rabbits. At least six rabbits must be used. The back of each animal is clipped free of hair 24 hours before application of the test material. The shaved area is divided into four quadrants, each being no less than 4 square inches in area. Two of the test sites are abraded and two are left intact.

The abraded areas are prepared 24 hours after shaving by making four epidermal incisions through the stratum corneum, two incisions perpendicular to the other two in a manner resembling a "tic-tac-toe" pattern. These incisions should not be so deep that they disturb the derma or produce bleeding.

Liquid test materials (0.5 milliliter) and/or solid or semi-solid test materials (0.5 gram) are introduced under a 1.5 x 1.5 inch 12-ply gauze patch which is secured in place by two narrow strips of adhesive tape. The substance tested (liquid, solid, or semisolid) represents a homogeneous aliquot of the substance under investigation. This factor is most important when testing formulated products containing several ingredients, such as emulsions or suspensions, which can separate due to standing, shipping, or temperature changes. Dry blended powders can segregate due to standing and shipping. Solid substances such as powders should be moistened with sufficient solvent to make a paste (and the quantity of solvent specified) or should be made into a 50-percent weight-to-volume solution. If the bulk density of a powder sample is such that it is physically impossible to place 0.5-gram samples under the patches, the largest practical amount is applied and reported.

The animals are then immobilized in stocks and the trunk of each animal is loosely wrapped with an impervious material, such as a rubberized cloth, for an exposure period of 4 hours. After 4 hours of exposure, the patches are removed and the resulting reactions are evaluated as described in Table 1.

Table 1

Skin Reaction	Value
Erythema and eschar formation:	
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
Edema formation:	
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 millimeter)	3
Severe edema (raised more than 1 millimeter and extending beyond the area of exposure)	4

Following this initial reading, all test sites are washed with appropriate solvent to prevent further exposure. Readings are again made at 24 and 48 hours after the initial application. The primary irritation index is calculated by adding the values for erythema or eschar formation, and edema at 4, 24, and 48 hours on intact and abraded skin (12 values) and dividing by six to obtain an individual score on each rabbit. The combined average of the six individual scores is the primary irritation index.

A material is considered to be corrosive when tissue destruction is observed on any of the six intact skin sites with or without similar destruction on the abraded areas. The ratio of tissue destruction observed on both intact and abraded skin sites is recorded.

STAUFFER CHEMICAL COMPANY

WESTERN RESEARCH CENTER

COMPANY CONFIDENTIAL

TOXICOLOGY LABORATORY REPORT T-4037-18

August 25, 1972

SODIUM METASILICATE, ANHYDROUS

I. OBJECTIVE

To evaluate the skin irritation properties of SODIUM METASILICATE, ANHYDROUS.

II. MATERIALS

SODIUM METASILICATE, ANHYDROUS, a white granular material, was received from the Industrial Chemical Division on August 8, 1972.

III. SUMMARY

Skin irritation index
and classification:

7.9
corrosive

IV. PROCEDURE

Skin Irritation Index, Draize Dermal

The Draize Dermal procedure was followed as outlined in the Code of Federal Regulations (Part 191.11, Chap. 1, Title 21) for evaluating hazardous substances. The test procedure is designed to determine whether a chemical is a primary skin irritant, ie., capable of initiating an extreme tissue reaction or skin inflammation to an insult or injury. The inflammatory process may vary from a barely perceptible hyperemia, to edema formation and vesiculation, and finally to an intense suppurative process. Irritation itself is not directly measured, but the result or consequence of irritation, that is, the injury reaction following irritation.

The Draize Dermal test is further discussed in Appendix A.

V. RESULTS

Primary Skin Irritation (Draize) Dermal -- see chart on page 2.

Submitted by C. H. Bullock (F.X.K.)
C. H. Bullock

Approved by F. X. Kamienski
F. X. Kamienski

Rabbit No.	Skin	Erythema-eschar Observation			Edema Observation			Sum Total	Score*
		4 hr.	24 hr.	48 hr.	4 hr.	24 hr.	48 hr.		
1	Intact	4	4	4	3	4	4	47	7.85
	Abraded	4	4	4	3	4	4		
2	Intact	4	4	4	3	4	4	47	7.85
	Abraded	4	4	4	3	4	4		
3	Intact	4	4	4	3	4	4	47	7.85
	Abraded	4	4	4	3	4	4		
4	Intact	4	4	4	3	4	4	47	7.85
	Abraded	4	4	4	3	4	4		
5	Intact	4	4	4	3	4	4	47	7.85
	Abraded	4	4	4	3	4	4		
6	Intact	4	4	4	3	4	4	47	7.85
	Abraded	4	4	4	3	4	4		

Primary Irritant Score ----- 7.9

*Score = sum of individual values for each rabbit divided by six.

Observations: Eschar was observed on both the intact and abraded test sites

Skin Irritant Score and Irritant Classification: 7.9 corrosive

Test site	Evaluation of skin reaction	Ratio regarding six rabbits; Observation time		
		4 hr.	24 hr.	48 hr.
Intact	Corrosive	6/6	6/6	6/6
Abraded	Corrosive	6/6	6/6	6/6

FDA PROPOSED REVISION OF TEST FOR PRIMARY SKIN IRRITANTS

The proposed method of testing irritant substances is described in the Code of Federal Regulations under the Federal Hazardous Substances Labeling Act, Part 191.11, Chapter 1, Title 21 as follows:

Primary irritation to the skin is measured by a patch-test technique on abraded and intact skin of healthy albino rabbits. At least six rabbits must be used. The back of each animal is clipped free of hair 24 hours before application of the test material. The shaved area is divided into four quadrants, each being no less than 4 square inches in area. Two of the test sites are abraded and two are left intact.

The abraded areas are prepared 24 hours after shaving by making four epidermal incisions through the stratum corneum, two incisions perpendicular to the other two in a manner resembling a "tic-tac-toe" pattern. These incisions should not be so deep that they disturb the derma or produce bleeding.

Liquid test materials (0.5 milliliter) and/or solid or semi-solid test materials (0.5 gram) are introduced under a 1.5 x 1.5 inch 12-ply gauze patch which is secured in place by two narrow strips of adhesive tape. The substance tested (liquid, solid, or semisolid) represents a homogeneous aliquot of the substance under investigation. This factor is most important when testing formulated products containing several ingredients, such as emulsions or suspensions, which can separate due to standing, shipping, or temperature changes. Dry blended powders can segregate due to standing and shipping. Solid substances such as powders should be moistened with sufficient solvent to make a paste (and the quantity of solvent specified) or should be made into a 50-percent weight-to-volume solution. If the bulk density of a powder sample is such that it is physically impossible to place 0.5-gram samples under the patches, the largest practical amount is applied and reported.

The animals are then immobilized in stocks and the trunk of each animal is loosely wrapped with an impervious material, such as a rubberized cloth, for an exposure period of 4 hours. After 4 hours of exposure, the patches are removed and the resulting reactions are evaluated as described in Table 1.

Table 1

Skin Reaction	Value
Erythema and eschar formation:	
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
Edema formation:	
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 millimeter)	3
Severe edema (raised more than 1 millimeter and extending beyond the area of exposure)	4

Following this initial reading, all test sites are washed with appropriate solvent to prevent further exposure. Readings are again made at 24 and 48 hours after the initial application. The primary irritation index is calculated by adding the values for erythema or eschar formation, and edema at 4, 24, and 48 hours on intact and abraded skin (12 values) and dividing by six to obtain an individual score on each rabbit. The combined average of the six individual scores is the primary irritation index.

A material is considered to be corrosive when tissue destruction is observed on any of the six intact skin sites with or without similar destruction on the abraded areas. The ratio of tissue destruction observed on both intact and abraded skin sites is recorded.

STAUFFER CHEMICAL COMPANY

WESTERN RESEARCH CENTER

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TOXICOLOGY LABORATORY REPORT T- 4037-19

September 5, 1972

SOL-ESCO

I. OBJECTIVE

To evaluate the skin irritation properties of SOL ESCO according to the proposed DOT 4-hour exposure procedure.

II. MATERIALS

SOL-ESCO, a green colored granular material, was received from the Industrial Chemical Division on August 8, 1972.

III. SUMMARY

Skin irritation index	8.0
and classification:	corrosive

IV. PROCEDURE

The Draize Dermal procedure was followed as outlined in the Code of Federal Regulations (Part 191.11, Chap. 1, Title 21) for evaluating hazardous substances. The test procedure is designed to determine whether a chemical is a primary skin irritant, ie., capable of initiating an extreme tissue reaction or skin inflammation to an insult or injury. The inflammatory process may vary from a barely perceptible hyperemia, to edema formation and vesiculation, and finally to an intense suppurative process. Irritation itself is not directly measured, but the result or consequence of irritation, that is, the injury reaction following irritation.

The Draize Dermal test is further discussed in Appendix A.

V. RESULTS

Primary Skin Irritation (Draize) Dermal -- See chart on page 2.

Submitted by C. H. Bullock
C. H. Bullock

Approved by F. X. Kamienski
F. X. Kamienski

B. SKIN IRRITATION INDEX

COMPOUND SOL-ESCO

Rabbit No.	Skin	Erythema-eschar Observation			Edema Observation			Sum Total	Score*
		4 hr.	24 hr.	48 hr.	4 hr.	24 hr.	48 hr.		
1	Intact	4	4	4	4	4	4	48	8.0
	Abraded	4	4	4	4	4	4		
2	Intact	4	4	4	4	4	4	48	8.0
	Abraded	4	4	4	4	4	4		
3	Intact	4	4	4	4	4	4	48	8.0
	Abraded	4	4	4	4	4	4		
4	Intact	4	4	4	4	4	4	48	8.0
	Abraded	4	4	4	4	4	4		
5	Intact	4	4	4	4	4	4	48	8.0
	Abraded	4	4	4	4	4	4		
6	Intact	4	4	4	4	4	4	48	8.0
	Abraded	4	4	4	4	4	4		

Primary Irritant Score ----- 8.0

*Score = sum of individual values for each rabbit divided by six.

Observations: Eschar was observed on both the intact and abraded test sites 4-hours after treatment.

Skin Irritant Score and Irritant Classification: 8.0 corrosive

Test site	Evaluation of skin reaction	Ratio regarding six rabbits; Observation time		
		4 hr.	24 hr.	48 hr.
Intact	Corrosive	6/6	6/6	6/6
Abraded	Corrosive	6/6	6/6	6/6

APPENDIX A

FDA PROPOSED REVISION OF TEST FOR PRIMARY SKIN IRRITANTS

The proposed method of testing irritant substances is described in the Code of Federal Regulations under the Federal Hazardous Substances Labeling Act, Part 191.11, Chapter 1, Title 21 as follows:

Primary irritation to the skin is measured by a patch-test technique on abraded and intact skin of healthy albino rabbits. At least six rabbits must be used. The back of each animal is clipped free of hair 24 hours before application of the test material. The shaved area is divided into four quadrants, each being no less than 4 square inches in area. Two of the test sites are abraded and two are left intact.

The abraded areas are prepared 24 hours after shaving by making four epidermal incisions through the stratum corneum, two incisions perpendicular to the other two in a manner resembling a "tic-tac-toe" pattern. These incisions should not be so deep that they disturb the derma or produce bleeding.

Liquid test materials (0.5 milliliter) and/or solid or semi-solid test materials (0.5 gram) are introduced under a 1.5 x 1.5 inch 12-ply gauze patch which is secured in place by two narrow strips of adhesive tape. The substance tested (liquid, solid, or semisolid) represents a homogeneous aliquot of the substance under investigation. This factor is most important when testing formulated products containing several ingredients, such as emulsions or suspensions, which can separate due to standing, shipping, or temperature changes. Dry blended powders can segregate due to standing and shipping. Solid substances such as powders should be moistened with sufficient solvent to make a paste (and the quantity of solvent specified) or should be made into a 50-percent weight-to-volume solution. If the bulk density of a powder sample is such that it is physically impossible to place 0.5-gram samples under the patches, the largest practical amount is applied and reported.

The animals are then immobilized in stocks and the trunk of each animal is loosely wrapped with an impervious material, such as a rubberized cloth, for an exposure period of 4 hours. After 4 hours of exposure, the patches are removed and the resulting reactions are evaluated as described in Table 1.

Table 1

Skin Reaction	Value
Erythema and eschar formation:	
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
Edema formation:	
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 millimeter)	3
Severe edema (raised more than 1 millimeter and extending beyond the area of exposure)	4

Following this initial reading, all test sites are washed with appropriate solvent to prevent further exposure. Readings are again made at 24 and 48 hours after the initial application. The primary irritation index is calculated by adding the values for erythema or eschar formation, and edema at 4, 24, and 48 hours on intact and abraded skin (12 values) and dividing by six to obtain an individual score on each rabbit. The combined average of the six individual scores is the primary irritation index.

A material is considered to be corrosive when tissue destruction is observed on any of the six intact skin sites with or without similar destruction on the abraded areas. The ratio of tissue destruction observed on both intact and abraded skin sites is recorded.

STAUFFER CHEMICAL COMPANY

WESTERN RESEARCH CENTER

COMPANY CONFIDENTIAL

TOXICOLOGY LABORATORY REPORT T-4037-20

September 5, 1972

SUPER DESOIL

I. OBJECTIVE

To evaluate the skin irritation properties of SUPER DESOIL, according to the proposed DOT 4-hour exposure procedure.

II. MATERIALS

SUPER DESOIL, a white colored granular material, was received from the Industrial Chemical Division on August 8, 1972.

III. SUMMARY

Skin irritation index	8.0
and classification:	corrosive

IV. PROCEDURE

The Draize Dermal procedure was followed as outlined in the Code of Federal Regulations (Part 191.11, Chap. 1, Title 21) for evaluating hazardous substances. The test procedure is designed to determine whether a chemical is a primary skin irritant, ie., capable of initiating an extreme tissue reaction or skin inflammation to an insult or injury. The inflammatory process may vary from a barely perceptible hyperemia, to edema formation and vesiculation, and finally to an intense suppurative process. Irritation itself is not directly measured, but the result or consequence of irritation, that is, the injury reaction following irritation.

The Draize Dermal test is further discussed in Appendix A.

V. RESULTS

Primary Skin Irritation (Draize) Dermal

See chart on page 2.

Submitted by C. H. Bullock
C. H. Bullock

Approved by F. X. Kamienski
F. X. Kamienski

B. SKIN IRRITATION INDEX

COMPOUND. SUPER DESOIL

Rabbit No.	Skin	Erythema-eschar Observation			Edema Observation			Sum Total	Score*
		4 hr.	24 hr.	48 hr.	4 hr.	24 hr.	48 hr.		
1	Intact	4	4	4	4	4	4	48	8.0
	Abraded	4	4	4	4	4	4		
2	Intact	4	4	4	4	4	4	48	8.0
	Abraded	4	4	4	4	4	4		
3	Intact	4	4	4	4	4	4	48	8.0
	Abraded	4	4	4	4	4	4		
4	Intact	4	4	4	4	4	4	48	8.0
	Abraded	4	4	4	4	4	4		
5	Intact	4	4	4	4	4	4	48	8.0
	Abraded	4	4	4	4	4	4		
6	Intact	4	4	4	4	4	4	48	8.0
	Abraded	4	4	4	4	4	4		

Primary Irritant Score ----- 8.0

*Score = sum of individual values for each rabbit divided by six.

Observations: Eschar was observed on both the intact and abraded test sites 4-hours after treatment.

Skin Irritant Score and Irritant Classification: 8.0 corrosive

Test site	Evaluation of skin reaction	Ratio regarding six rabbits; Observation time		
		4 hr.	24 hr.	48 hr.
Intact	Corrosive	6/6	6/6	6/6
Abraded	Corrosive	6/6	6/6	6/6

APPENDIX A

FDA PROPOSED REVISION OF TEST FOR PRIMARY SKIN IRRITANTS

The proposed method of testing irritant substances is described in the Code of Federal Regulations under the Federal Hazardous Substances Labeling Act, Part 191.11, Chapter 1, Title 21 as follows:

Primary irritation to the skin is measured by a patch-test technique on abraded and intact skin of healthy albino rabbits. At least six rabbits must be used. The back of each animal is clipped free of hair 24 hours before application of the test material. The shaved area is divided into four quadrants, each being no less than 4 square inches in area. Two of the test sites are abraded and two are left intact.

The abraded areas are prepared 24 hours after shaving by making four epidermal incisions through the stratum corneum, two incisions perpendicular to the other two in a manner resembling a "tic-tac-toe" pattern. These incisions should not be so deep that they disturb the derma or produce bleeding.

Liquid test materials (0.5 milliliter) and/or solid or semi-solid test materials (0.5 gram) are introduced under a 1.5 x 1.5 inch 12-ply gauze patch which is secured in place by two narrow strips of adhesive tape. The substance tested (liquid, solid, or semisolid) represents a homogeneous aliquot of the substance under investigation. This factor is most important when testing formulated products containing several ingredients, such as emulsions or suspensions, which can separate due to standing, shipping, or temperature changes. Dry blended powders can segregate due to standing and shipping. Solid substances such as powders should be moistened with sufficient solvent to make a paste (and the quantity of solvent specified) or should be made into a 50-percent weight-to-volume solution. If the bulk density of a powder sample is such that it is physically impossible to place 0.5-gram samples under the patches, the largest practical amount is applied and reported.

The animals are then immobilized in stocks and the trunk of each animal is loosely wrapped with an impervious material, such as a rubberized cloth, for an exposure period of 4 hours. After 4 hours of exposure, the patches are removed and the resulting reactions are evaluated as described in Table 1.

Table 1

Skin Reaction	Value
Erythema and eschar formation:	
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
Edema formation:	
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 millimeter)	3
Severe edema (raised more than 1 millimeter and extending beyond the area of exposure)	4

Following this initial reading, all test sites are washed with appropriate solvent to prevent further exposure. Readings are again made at 24 and 48 hours after the initial application. The primary irritation index is calculated by adding the values for erythema or eschar formation, and edema at 4, 24, and 48 hours on intact and abraded skin (12 values) and dividing by six to obtain an individual score on each rabbit. The combined average of the six individual scores is the primary irritation index.

A material is considered to be corrosive when tissue destruction is observed on any of the six intact skin sites with or without similar destruction on the abraded areas. The ratio of tissue destruction observed on both intact and abraded skin sites is recorded.

STAUFFER CHEMICAL COMPANY

WESTERN RESEARCH CENTER

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TOXICOLOGY LABORATORY REPORT T-4037-21

September 5, 1972

TWIN-DET

I. OBJECTIVE

To evaluate the skin irritation properties of TWIN-DET, according to the proposed DOT 4-hour exposure procedure.

II. MATERIALS

TWIN-DET, a white colored granular material, was received from the Industrial Chemical Division on August 8, 1972.

III. SUMMARY

Skin irritation index	8.0
and classification:	corrosive

IV. PROCEDURE

Skin Irritation Index, Draize Dermal

The Draize Dermal procedure was followed as outlined in the Code of Federal Regulations (Part 191.11, Chap. 1, Title 21) for evaluating hazardous substances. The test procedure is designed to determine whether a chemical is a primary skin irritant, i.e., capable of initiating an extreme tissue reaction or skin inflammation to an insult or injury. The inflammatory process may vary from a barely perceptible hyperemia, to edema formation and vesiculation, and finally to an intense suppurative process. Irritation itself is not directly measured, but the result or consequence of irritation, that is, the injury reaction following irritation.

The Draize Dermal test is further discussed in Appendix A.

V. RESULTS

See chart on page 2.

Submitted by C. H. Bullock
C. H. Bullock

Approved by F. X. Kamienski
F. X. Kamienski

FXK:ea

Rabbit No.	Skin	Erythema-eschar Observation			Edema Observation			Sum Total	Score*
		4 hr.	24 hr.	48 hr.	4 hr.	24 hr.	48 hr.		
1	Intact	4	4	4	4	4	4	48	8.0
	Abraded	4	4	4	4	4	4		
2	Intact	4	4	4	4	4	4	48	8.0
	Abraded	4	4	4	4	4	4		
3	Intact	4	4	4	4	4	4	48	8.0
	Abraded	4	4	4	4	4	4		
4	Intact	4	4	4	4	4	4	48	8.0
	Abraded	4	4	4	4	4	4		
5	Intact	4	4	4	4	4	4	48	8.0
	Abraded	4	4	4	4	4	4		
6	Intact	4	4	4	4	4	4	48	8.0
	Abraded	4	4	4	4	4	4		

Primary Irritant Score ----- 8.0

*Score = sum of individual values for each rabbit divided by six.

Observations: Eschar was observed on both the intact and abraded test sites 4-hours after treatment.

Skin Irritant Score and Irritant Classification: 8.0 corrosive

Test site	Evaluation of skin reaction	Ratio regarding six rabbits; Observation time		
		4 hr.	24 hr.	48 hr.
Intact	Corrosive	6/6	6/6	6/6
Abraded	Corrosive	6/6	6/6	6/6

FDA PROPOSED REVISION OF TEST FOR PRIMARY SKIN IRRITANTS

The proposed method of testing irritant substances is described in the Code of Federal Regulations under the Federal Hazardous Substances Labeling Act, Part 191.11, Chapter 1, Title 21 as follows:

Primary irritation to the skin is measured by a patch-test technique on abraded and intact skin of healthy albino rabbits. At least six rabbits must be used. The back of each animal is clipped free of hair 24 hours before application of the test material. The shaved area is divided into four quadrants, each being no less than 4 square inches in area. Two of the test sites are abraded and two are left intact.

The abraded areas are prepared 24 hours after shaving by making four epidermal incisions through the stratum corneum, two incisions perpendicular to the other two in a manner resembling a "tic-tac-toe" pattern. These incisions should not be so deep that they disturb the derma or produce bleeding.

Liquid test materials (0.5 milliliter) and/or solid or semi-solid test materials (0.5 gram) are introduced under a 1.5 x 1.5 inch 12-ply gauze patch which is secured in place by two narrow strips of adhesive tape. The substance tested (liquid, solid, or semisolid) represents a homogeneous aliquot of the substance under investigation. This factor is most important when testing formulated products containing several ingredients, such as emulsions or suspensions, which can separate due to standing, shipping, or temperature changes. Dry blended powders can segregate due to standing and shipping. Solid substances such as powders should be moistened with sufficient solvent to make a paste (and the quantity of solvent specified) or should be made into a 50-percent weight-to-volume solution. If the bulk density of a powder sample is such that it is physically impossible to place 0.5-gram samples under the patches, the largest practical amount is applied and reported.

The animals are then immobilized in stocks and the trunk of each animal is loosely wrapped with an impervious material, such as a rubberized cloth, for an exposure period of 4 hours. After 4 hours of exposure, the patches are removed and the resulting reactions are evaluated as described in Table 1.

Table 1

Skin Reaction	Value
Erythema and eschar formation:	
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
Edema formation:	
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 millimeter)	3
Severe edema (raised more than 1 millimeter and extending beyond the area of exposure)	4

Following this initial reading, all test sites are washed with appropriate solvent to prevent further exposure. Readings are again made at 24 and 48 hours after the initial application. The primary irritation index is calculated by adding the values for erythema or eschar formation, and edema at 4, 24, and 48 hours on intact and abraded skin (12 values) and dividing by six to obtain an individual score on each rabbit. The combined average of the six individual scores is the primary irritation index.

A material is considered to be corrosive when tissue destruction is observed on any of the six intact skin sites with or without similar destruction on the abraded areas. The ratio of tissue destruction observed on both intact and abraded skin sites is recorded.

CONFIDENTIAL
STAUFFER CHEMICAL COMPANY

WESTERN RESEARCH CENTER

COMPANY CONFIDENTIAL

TOXICOLOGY LAB REPORT -- T-4037-22

Date 10/31/72

CRYSTAMET 2040 WATER SOLUTIONS

I. OBJECTIVE

To evaluate the skin irritation properties of 1% and 10% CRYSTAMET 2040 solutions according to the FDA proposed 4-hour exposure test for primary skin irritants. The skin irritation of a 1% NaOH solution was also evaluated for comparison.

II. MATERIALS

A. CRYSTAMET 2040, received from the Industrial Chemical Division on August 8, 1972.

B. NaOH pellets, analytical reagent grade.

The test solutions were made up with deionized water immediately prior to testing.

III. SUMMARY

<u>Test Solution</u>	<u>Skin Irritant Classification</u>
CRYSTAMET 1%	Non-irritant
CRYSTAMET 10%	Corrosive
NaOH 1%	Corrosive

IV. PROCEDURES

Skin Irritation Index, Draize Dermal

The Draize Dermal procedure was followed as outlined in the Code of Federal Regulations (Part 191.11, Chap. 1, Title 21) with one modification. The test solutions were administered on intact skin areas only, not on abraded areas. Since a material is considered to be corrosive when tissue destruction is observed on any one of six intact skin sites with or without similar destruction on abraded areas, the test as modified retains its validity for comparative purposes.

The Draize Dermal test is discussed further in Appendix A.

V. RESULTS

CONFIDENTIAL

See charts on pages 2-4.

Submitted by M. F. McGowan (FXX)
M. F. McGowan

Approved by F. X. Kamienski
F. X. Kamienski

FXX:js

COMPOUND CRYSTAMET 2040 (1% Solution)**CONFIDENTIAL**

Rabbit No.	Skin	Erythema-eschar Observation			Edema Observation			Sum Total	Score*
		4 hr.	24 hr.	48 hr.	4 hr.	24 hr.	48 hr.		
1	Intact	0	0	0	0	0	0	0	0
	Abraded								
2	Intact	0	0	0	0	0	0	0	0
	Abraded								
3	Intact	0	0	0	0	0	0	0	0
	Abraded								
4	Intact	0	0	0	0	0	0	0	0
	Abraded								
5	Intact	0	0	0	0	0	0	0	0
	Abraded								
6	Intact	0	0	0	0	0	0	0	0
	Abraded								

Primary Irritant Score ----- 0

*Score = sum of individual values for each rabbit divided by six.

Observations: No skin irritation was observed in any of the test animals.Skin Irritant Score
and Irritant Classification: 0; Non-irritant

Test site	Evaluation of skin reaction	Ratio regarding six rabbits; Observation time		
		4 hr.	24 hr.	48 hr.
Intact	Corrosive	0/6	0/6	0/6
Abraded	Corrosive			

B. SKIN IRRITATION INDEX

COMPOUND CRYSTAMET 2040 (10% Solution)

CONFIDENTIAL

Rabbit No.	Skin	Erythema-eschar Observation			Edema Observation			Sum Total	Score*
		4 hr.	24 hr.	48 hr.	4 hr.	24 hr.	48 hr.		
1	Intact	4	4	4	3	3	3	21	7.00
	Abraded								
2	Intact	4	4	4	2	2	2	18	6.00
	Abraded								
3	Intact	4	4	4	2	2	2	18	6.00
	Abraded								
4	Intact	2	4	4	1	1	2	14	4.67
	Abraded								
5	Intact	0	3	4	0	1	2	10	3.33
	Abraded								
6	Intact	4	4	4	0	1	2	15	5.00
	Abraded								

Primary Irritant Score ----- 5.33

*Score = sum of individual values for each rabbit divided by six.

Observations: Eschar and edema were observed in all the test animals.

Skin Irritant Score and Irritant Classification: 5.33; corrosive

Test site	Evaluation of skin reaction	Ratio regarding six rabbits; Observation time		
		4 hr.	24 hr.	48 hr.
Intact	Corrosive	4/6	5/6	6/6
Abraded	Corrosive			

B. SKIN IRRITATION INDEX

COMPOUND NaOH (1% Solution)

CONFIDENTIAL

Rabbit No.	Skin	Erythema-eschar Observation			Edema Observation			Sum Total	Score*
		4 hr.	24 hr.	48 hr.	4 hr.	24 hr.	48 hr.		
1	Intact	4	4	4	3	3	2	20	6.67
	Abraded								
2	Intact	0	0	1	0	1	1	3	1.00
	Abraded								
3	Intact	2	1	1	1	1	2	8	2.67
	Abraded								
4	Intact	1	1	1	1	1	1	6	2.00
	Abraded								
5	Intact	1	4	4	1	1	2	13	4.33
	Abraded								
6	Intact	0	4	4	0	1	2	11	3.66
	Abraded								

Primary Irritant Score ----- 3.38

*Score = sum of individual values for each rabbit divided by six.

Observations: Erthema and edema were observed in all the test animals.

Skin Irritant Score and Irritant Classification: 3.38; corrosive

Test site	Evaluation of skin reaction	Ratio regarding six rabbits; Observation time		
		4 hr.	24 hr.	48 hr.
Intact	Corrosive	1/6	3/6	3/6
Abraded	Corrosive			

APPENDIX A

FDA PROPOSED REVISION OF TEST FOR PRIMARY SKIN IRRITANTS

CONFIDENTIAL

Primary irritation to the skin is measured by a patch-test technique on abraded and intact skin of healthy albino rabbits. At least six rabbits must be used. The back of each animal is clipped free of hair 24 hours before application of the test material. The shaved area is divided into four quadrants, each being no less than 4 square inches in area. Two of the test sites are abraded and two are left intact.

The abraded areas are prepared 24 hours after shaving by making four epidermal incisions through the stratum corneum, two incisions perpendicular to the other two in a manner resembling a "tic-tac-toe" pattern. These incisions should not be so deep that they disturb the derma or produce bleeding.

Liquid test materials (0.5 milliliter) and/or solid or semi-solid test materials (0.5 gram) are introduced under a 1.5 x 1.5 inch 12-ply gauze patch which is secured in place by two narrow strips of adhesive tape. The substance tested (liquid, solid, or semisolid) represents a homogeneous aliquot of the substance under investigation. This factor is most important when testing formulated products containing several ingredients, such as emulsions or suspensions, which can separate due to standing, shipping, or temperature changes. Dry blended powders can segregate due to standing and shipping. Solid substances such as powders should be moistened with sufficient solvent to make a paste (and the quantity of solvent specified) or should be made into a 50-percent weight-to-volume solution. If the bulk density of a powder sample is such that it is physically impossible to place 0.5-gram samples under the patches, the largest practical amount is applied and reported.

The animals are then immobilized in stocks and the trunk of each animal is loosely wrapped with an impervious material, such as a rubberized cloth, for an exposure period of 4 hours. After 4 hours of exposure, the patches are removed and the resulting reactions are evaluated as described in Table 1.

Table 1

Skin Reaction	Value
Erythema and eschar formation:	
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
Edema formation:	
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 millimeter)	3
Severe edema (raised more than 1 millimeter and extending beyond the area of exposure)	4

Following this initial reading, all test sites are washed with appropriate solvent to prevent further exposure. Readings are again made at 24 and 48 hours after the initial application. The primary irritation index is calculated by adding the values for erythema or eschar formation, and edema at 4, 24, and 48 hours on intact and abraded skin (12 values) and dividing by six to obtain an individual score on each rabbit. The combined average of the six individual scores is the primary irritation index.

A material is considered to be corrosive when tissue destruction is observed on any of the six intact skin sites with or without similar destruction on the abraded areas. The ratio of tissue destruction observed on both intact and abraded skin sites is recorded.

STAUFFER CHEMICAL COMPANY

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TOXICOLOGY LABORATORY REPORT T- 4037-23

September 21, 1972

BENZENE PHOSPHORUS THIODICHLORIDE

I. OBJECTIVE

To evaluate the skin irritation properties of BENZENE PHOSPHORUS THIODICHLORIDE.

II. MATERIALS

BENZENE PHOSPHORUS THIODICHLORIDE, a light yellow liquid, was received from New York on September 15, 1972.

III. SUMMARY

Skin irritation index and classification:	4.2 corrosive
--	------------------

IV. PROCEDURE

Skin Irritation Index, Draize Dermal

The Draize Dermal procedure was followed as outlined in the Code of Federal Regulations (Part 191.11, Chap. 1, Title 21) for evaluating hazardous substances. The test procedure is designed to determine whether a chemical is a primary skin irritant, ie., capable of initiating an extreme tissue reaction or skin inflammation to an insult or injury. The inflammatory process may vary from a barely perceptible hyperemia, to edema formation and vesiculation, and finally to an intense suppurative process. Irritation itself is not directly measured, but the result or consequence of irritation, that is, the injury reaction following irritation.

The Draize Dermal test is further discussed in Appendix A.

V. RESULTS

Primary Skin Irritation (Draize) Dermal

See chart on page 3.

Submitted by C. H. Bullock (F.X.K.)
C. H. Bullock

Approved by F. X. Kamienski
F. X. Kamienski

FXX:ea

COMPOUND

BENZENE PHOSPHORUS THIODICHLORIDE

Rabbit	Skin	Erythema-eschar Observation			Edema Observation			Sum Total	Score*
		4 hr.	24 hr.	48 hr.	4 hr.	24 hr.	48 hr.		
1	Intact	1	0	4	2	0	2	27	4.50
	Abraded	3	4	4	4	1	2		
2	Intact	1	1	2	2	0	2	25	4.17
	Abraded	3	2	4	4	1	3		
3	Intact	2	1	2	2	0	2	30	5.00
	Abraded	4	4	4	4	2	3		
4	Intact	1	1	1	2	0	2	21	3.50
	Abraded	3	2	3	3	0	3		
5	Intact	2	1	4	1	0	2	27	4.50
	Abraded	4	4	4	3	0	2		
6	Intact	1	1	2	2	0	2	19	3.17
	Abraded	0	1	2	3	0	2		

Primary Irritant Score ----- 4.2

*Score = sum of individual values for each rabbit divided by six.

Observations: Eschar was observed on two intact test sites, thereby classifying this compound as a corrosive.

Skin Irritant Score
and Irritant Classification: 4.2 corrosive

Test site	Evaluation of skin reaction	Ratio regarding six rabbits; Observation time		
		4 hr.	24 hr.	48 hr.
Intact	Corrosive	0/6	0/6	2/6
Abraded	Corrosive	2/6	3/6	4/6

FDA PROPOSED REVISION OF TEST FOR PRIMARY SKIN IRRITANTS

The proposed method of testing irritant substances is described in the Code of Federal Regulations under the Federal Hazardous Substances Labeling Act, Part 191.11, Chapter 1, Title 21 as follows:

Primary irritation to the skin is measured by a patch-test technique on abraded and intact skin of healthy albino rabbits. At least six rabbits must be used. The back of each animal is clipped free of hair 24 hours before application of the test material. The shaved area is divided into four quadrants, each being no less than 4 square inches in area. Two of the test sites are abraded and two are left intact.

The abraded areas are prepared 24 hours after shaving by making four epidermal incisions through the stratum corneum, two incisions perpendicular to the other two in a manner resembling a "tic-tac-toe" pattern. These incisions should not be so deep that they disturb the derma or produce bleeding.

Liquid test materials (0.5 milliliter) and/or solid or semi-solid test materials (0.5 gram) are introduced under a 1.5 x 1.5 inch 12-ply gauze patch which is secured in place by two narrow strips of adhesive tape. The substance tested (liquid, solid, or semisolid) represents a homogeneous aliquot of the substance under investigation. This factor is most important when testing formulated products containing several ingredients, such as emulsions or suspensions, which can separate due to standing, shipping, or temperature changes. Dry blended powders can segregate due to standing and shipping. Solid substances such as powders should be moistened with sufficient solvent to make a paste (and the quantity of solvent specified) or should be made into a 50-percent weight-to-volume solution. If the bulk density of a powder sample is such that it is physically impossible to place 0.5-gram samples under the patches, the largest practical amount is applied and reported.

The animals are then immobilized in stocks and the trunk of each animal is loosely wrapped with an impervious material, such as a rubberized cloth, for an exposure period of 4 hours. After 4 hours of exposure, the patches are removed and the resulting reactions are evaluated as described in Table 1.

Table 1

Skin Reaction	Value
Erythema and eschar formation:	
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
Edema formation:	
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 millimeter)	3
Severe edema (raised more than 1 millimeter and extending beyond the area of exposure)	4

Following this initial reading, all test sites are washed with appropriate solvent to prevent further exposure. Readings are again made at 24 and 48 hours after the initial application. The primary irritation index is calculated by adding the values for erythema or eschar formation, and edema at 4, 24, and 48 hours on intact and abraded skin (12 values) and dividing by six to obtain an individual score on each rabbit. The combined average of the six individual scores is the primary irritation index.

A material is considered to be corrosive when tissue destruction is observed on any of the six intact skin sites with or without similar destruction on the abraded areas. The ratio of tissue destruction observed on both intact and abraded skin sites is recorded.

STAUFFER CHEMICAL COMPANY

WESTERN RESEARCH CENTER

COMPANY CONFIDENTIAL

TOXICOLOGY LABORATORY REPORT T-4037-24

September 21, 1972

DI-2-ETHYLHEXYL PHOSPHORODITHIOIC ACID

I. OBJECTIVE

To evaluate the skin irritation properties of DI-2-ETHYLHEXYL-PHOSPHORODITHIOIC ACID.

II. MATERIALS

DI-2-ETHYL HEXYL PHOSPHORODITHIOIC ACID, a dark liquid, was received from New York on September 15, 1972.

III. SUMMARY

Skin irritation index and classification:	4.8 corrosive
--	------------------

IV. PROCEDURE

Skin Irritation Index, Draize Dermal

The Draize Dermal procedure was followed as outlined in the Code of Federal Regulations (Part 191.11, Chap. 1, Title 21) for evaluating hazardous substances. The test procedure is designed to determine whether a chemical is a primary skin irritant, i.e., capable of initiating an extreme tissue reaction or skin inflammation to an insult or injury. The inflammatory process may vary from a barely perceptible hyperemia, to edema formation and vesiculation, and finally to an intense suppurative process. Irritation itself is not directly measured, but the result or consequence of irritation, that is, the injury reaction following irritation.

The Draize Dermal test is further discussed in Appendix A.

V. RESULTS

Primary Skin Irritation (Draize) Dermal

See chart on page 3.

Submitted by C. H. Bullock (F.X.K.)
C. H. Bullock

Approved by F. X. Kamienski
F. X. Kamienski

FXK:ea

COMPOUND DI-2-ETHYLHEXYL PHOSPHORODITHIOIC ACID

Rabbit No.	Skin	Erythema-eschar Observation			Edema Observation			Sum Total	Score*
		4 hr.	24 hr.	48 hr.	4 hr.	24 hr.	48 hr.		
1	Intact	1	4	4	1	2	2	31	5.17
	Abraded	3	4	4	2	2	2		
2	Intact	2	2	4	1	2	1	29	4.83
	Abraded	3	3	4	2	0	2		
3	Intact	1	2	4	1	2	1	27	4.50
	Abraded	2	4	4	2	2	2		
4	Intact	2	3	4	0	1	1	27	4.50
	Abraded	3	4	4	1	2	2		
5	Intact	1	2	4	0	1	1	25	4.17
	Abraded	3	4	4	1	2	2		
6	Intact	2	4	4	1	2	1	32	5.33
	Abraded	3	4	4	2	3	2		

Primary Irritant Score ----- 4.8

*Score = sum of individual values for each rabbit divided by six.

Observations: Eschar was observed on all test sites.

Skin Irritant Score and Irritant Classification: 4.8 corrosive

Test site	Evaluation of skin reaction	Ratio regarding six rabbits; Observation time		
		4 hr.	24 hr.	48 hr.
Intact	Corrosive	0/6	2/6	6/6
Abraded	Corrosive	0/6	5/6	6/6

FDA PROPOSED REVISION OF TEST FOR PRIMARY SKIN IRRITANTS

The proposed method of testing irritant substances is described in the Code of Federal Regulations under the Federal Hazardous Substances Labeling Act, Part 191.11, Chapter 1, Title 21 as follows:

Primary irritation to the skin is measured by a patch-test technique on abraded and intact skin of healthy albino rabbits. At least six rabbits must be used. The back of each animal is clipped free of hair 24 hours before application of the test material. The shaved area is divided into four quadrants, each being no less than 4 square inches in area. Two of the test sites are abraded and two are left intact.

The abraded areas are prepared 24 hours after shaving by making four epidermal incisions through the stratum corneum, two incisions perpendicular to the other two in a manner resembling a "tic-tac-toe" pattern. These incisions should not be so deep that they disturb the derma or produce bleeding.

Liquid test materials (0.5 milliliter) and/or solid or semi-solid test materials (0.5 gram) are introduced under a 1.5 x 1.5 inch 12-ply gauze patch which is secured in place by two narrow strips of adhesive tape. The substance tested (liquid, solid, or semisolid) represents a homogeneous aliquot of the substance under investigation. This factor is most important when testing formulated products containing several ingredients, such as emulsions or suspensions, which can separate due to standing, shipping, or temperature changes. Dry blended powders can segregate due to standing and shipping. Solid substances such as powders should be moistened with sufficient solvent to make a paste (and the quantity of solvent specified) or should be made into a 50-percent weight-to-volume solution. If the bulk density of a powder sample is such that it is physically impossible to place 0.5-gram samples under the patches, the largest practical amount is applied and reported.

The animals are then immobilized in stocks and the trunk of each animal is loosely wrapped with an impervious material, such as a rubberized cloth, for an exposure period of 4 hours. After 4 hours of exposure, the patches are removed and the resulting reactions are evaluated as described in Table 1.

Table 1

Skin Reaction	Value
Erythema and eschar formation:	
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
Edema formation:	
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 millimeter)	3
Severe edema (raised more than 1 millimeter and extending beyond the area of exposure)	4

Following this initial reading, all test sites are washed with appropriate solvent to prevent further exposure. Readings are again made at 24 and 48 hours after the initial application. The primary irritation index is calculated by adding the values for erythema or eschar formation, and edema at 4, 24, and 48 hours on intact and abraded skin (12 values) and dividing by six to obtain an individual score on each rabbit. The combined average of the six individual scores is the primary irritation index.

A material is considered to be corrosive when tissue destruction is observed on any of the six intact skin sites with or without similar destruction on the abraded areas. The ratio of tissue destruction observed on both intact and abraded skin sites is recorded.

STAUFFER CHEMICAL COMPANY

WESTERN RESEARCH CENTER

COMPANY CONFIDENTIAL

TOXICOLOGY LABORATORY REPORT T- 4037-25

September 21, 1972

THIOPHOSPHORYL CHLORIDE

I. OBJECTIVE

To evaluate the skin irritation properties of THIOPHOSPHORYL CHLORIDE according to the proposed DOT 4-hour exposure procedure.

II. MATERIALS

THIOPHOSPHORYL CHLORIDE, a clear colorless liquid, was received from New York on September 15, 1972.

III. SUMMARY

Skin irritation index	8.0
and classification:	corrosive

IV. PROCEDURE

B. Skin Irritation Index, Draize Dermal

The Draize Dermal procedure was followed as outlined in the Code of Federal Regulations (Part 191.11, Chap. 1, Title 21) for evaluating hazardous substances. The test procedure is designed to determine whether a chemical is a primary skin irritant, i.e., capable of initiating an extreme tissue reaction or skin inflammation to an insult or injury. The inflammatory process may vary from a barely perceptible hyperemia, to edema formation and vesiculation, and finally to an intense suppurative process. Irritation itself is not directly measured, but the result or consequence of irritation, that is, the injury reaction following irritation.

The Draize Dermal test is further discussed in Appendix A.

V. RESULTS

Primary Skin Irritation (Draize) Dermal -- See page 2 (chart)

Submitted by C. H. Bullock
C. H. Bullock

Approved by F. X. Kamienski
F. X. Kamienski

B. SKIN IRRITATION INDEX

COMPOUND. THIOPHOSPHORYL CHLORIDE

Rabbit No.	Skin	Erythema-eschar Observation			Edema Observation			Sum Total	Score*
		4 hr.	24 hr.	48 hr.	4 hr.	24 hr.	48 hr.		
1	Intact	4	4	4	4	4	4	48	8.0
	Abraded	4	4	4	4	4	4		
2	Intact	4	4	4	4	4	4	48	8.0
	Abraded	4	4	4	4	4	4		
3	Intact	4	4	4	4	4	4	48	8.0
	Abraded	4	4	4	4	4	4		
4	Intact	4	4	4	4	4	4	48	8.0
	Abraded	4	4	4	4	4	4		
5	Intact	4	4	4	4	4	4	48	8.0
	Abraded	4	4	4	4	4	4		
6	Intact	4	4	4	4	4	4	48	8.0
	Abraded	4	4	4	4	4	4		

Primary Irritant Score ----- 8.0

*Score = sum of individual values for each rabbit divided by six.

Observations: Eschar was observed on both the intact and abraded test sites 4-hours after treatment.

Skin Irritant Score and Irritant Classification: 8.0 corrosive

Test site	Evaluation of skin reaction	Ratio regarding six rabbits; Observation time		
		4 hr.	24 hr.	48 hr.
Intact	Corrosive	6/6	6/6	6/6
Abraded	Corrosive	6/6	6/6	6/6

APPENDIX A

FDA PROPOSED REVISION OF TEST FOR PRIMARY SKIN IRRITANTS

The proposed method of testing irritant substances is described in the Code of Federal Regulations under the Federal Hazardous Substances Labeling Act, Part 191.11, Chapter 1, Title 21 as follows:

Primary irritation to the skin is measured by a patch-test technique on abraded and intact skin of healthy albino rabbits. At least six rabbits must be used. The back of each animal is clipped free of hair 24 hours before application of the test material. The shaved area is divided into four quadrants, each being no less than 4 square inches in area. Two of the test sites are abraded and two are left intact.

The abraded areas are prepared 24 hours after shaving by making four epidermal incisions through the stratum corneum, two incisions perpendicular to the other two in a manner resembling a "tic-tac-toe" pattern. These incisions should not be so deep that they disturb the derma or produce bleeding.

Liquid test materials (0.5 milliliter) and/or solid or semi-solid test materials (0.5 gram) are introduced under a 1.5 x 1.5 inch 12-ply gauze patch which is secured in place by two narrow strips of adhesive tape. The substance tested (liquid, solid, or semisolid) represents a homogeneous aliquot of the substance under investigation. This factor is most important when testing formulated products containing several ingredients, such as emulsions or suspensions, which can separate due to standing, shipping, or temperature changes. Dry blended powders can segregate due to standing and shipping. Solid substances such as powders should be moistened with sufficient solvent to make a paste (and the quantity of solvent specified) or should be made into a 50-percent weight-to-volume solution. If the bulk density of a powder sample is such that it is physically impossible to place 0.5-gram samples under the patches, the largest practical amount is applied and reported.

The animals are then immobilized in stocks and the trunk of each animal is loosely wrapped with an impervious material, such as a rubberized cloth, for an exposure period of 4 hours. After 4 hours of exposure, the patches are removed and the resulting reactions are evaluated as described in Table 1.

Table 1

Skin Reaction	Value
Erythema and eschar formation:	
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
Edema formation:	
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 millimeter)	3
Severe edema (raised more than 1 millimeter and extending beyond the area of exposure)	4

Following this initial reading, all test sites are washed with appropriate solvent to prevent further exposure. Readings are again made at 24 and 48 hours after the initial application. The primary irritation index is calculated by adding the values for erythema or eschar formation, and edema at 4, 24, and 48 hours on intact and abraded skin (12 values) and dividing by six to obtain an individual score on each rabbit. The combined average of the six individual scores is the primary irritation index.

A material is considered to be corrosive when tissue destruction is observed on any of the six intact skin sites with or without similar destruction on the abraded areas. The ratio of tissue destruction observed on both intact and abraded skin sites is recorded.

B. SKIN IRRITATION INDEX

CONFIDENTIAL

COMPOUND Crystenet 2040 (1% Solution)

Date 9/1/72

PRODUCT DESCRIPTION White Granules dissolved in H₂O

Operator Att, MM

Rabbit No.	Skin	Erythema-eschar Observation						Sum Total	Score*
		4 hr.	24 hr.	48 hr.	4 hr.	24 hr.	24 hr.		
7	front 11 ³⁰ Intact	0	0	0	0	0	0		
	Abraded	0			0				
3	Intact	0	0	0	0	0	0		
	Abraded								
1	Intact	0	0	0	0	0	0		
	Abraded								
0	Intact	0	0	0	0	0	0		
	Abraded								
11	Intact	0	0	0	0	0	0		
	Abraded								
12	455 Intact	0	0	0	0	0	0		
	Abraded								0

Primary Irritant Score -----

*Score = sum of individual values for each rabbit divided by six.

Observations:

Skin Irritant Score and Irritant Classification: non-irritant

Test site	Evaluation of skin reaction	Ratio regarding six rabbits; Observation time		
		4 hr.	24 hr.	48 hr.
Intact	Corrosive	0/6	0/6	0/6
Abraded	Corrosive			

B. SKIN IRRITATION INDEX

COMPOUND Crystenet 2040 (10% solution) **CONFIDENTIAL** Date 9/1/72
PRODUCT DESCRIPTION White granules dissolved in H₂O Operator AA, MM

Rabbit No.	Skin	Erythema-eschar Observation			Edema Observation			Sum Total	Score*
		4 hr.	24 hr.	48 hr.	4 hr.	24 hr.	48 hr.		
7	Intact	4	4	4	3	3	3	21	7.00
	Abraded	4			2				
8	Intact	4	4	4	2	2	2	18	6.00
	Abraded								
9	Intact	4	4	4	2	2	2	18	6.00
	Abraded								
10	Intact	2	4	4	1	1	2	14	4.67
	Abraded								
11	Intact	0	3	4	0	1	2	10	3.33
	Abraded								
12	Intact	4	4	4	0	1	2	15	5.00
	Abraded								32.00/6

Primary Irritant Score ----- 5.33

*Score = sum of individual values for each rabbit divided by six.

Observations:

Skin Irritant Score and Irritant Classification: 5.33; Corrosive

Test site	Evaluation of skin reaction	Ratio regarding six rabbits; Observation time		
		4 hr.	24 hr.	48 hr.
Intact	Corrosive	4/6	5/6	6/6
Abraded	Corrosive			

B. SKIN IRRITATION INDEX

COMPOUND Blendol

CONFIDENTIAL

Date 8-14-72

PRODUCT DESCRIPTION Granular powder

Operator W. B. Smith

Rabbit No.	Skin	Erythema-eschar Observation			Edema Observation			Sum Total	Score*
		4 hr.	24 hr.	48 hr.	4 hr.	24 hr.	24 hr.		
027 6	Intact	2	2	1	0	0	0	24	4.00
	Abraded	4	4	4	2	2	3		
1034 13	Intact	1	1	1	0	0	0	19	3.16
	Abraded	4	4	4	1	1	2		
1035 14	Intact	1	0	0	0	0	0	15	2.50
	Abraded	3	4	4	1	1	1		
1044 21	Intact	2	2	1	1	1	0	26	4.33
	Abraded	4	4	4	2	2	3		
1055 29	Intact	2	2	1	1	1	0	24	4.00
	Abraded	3	4	4	2	2	2		
1057 30	Intact	2	1	1	1	1	0	22	3.66
	Abraded	3	4	4	1	2	2		

Primary Irritant Score ----- 3.62

*Score = sum of individual values for each rabbit divided by six.

Observations: ESCHAR ~~at~~ abraded side

Skin Irritant Score and Irritant Classification:

Test site	Evaluation of skin reaction	Ratio regarding six rabbits; Observation time		
		4 hr.	24 hr.	48 hr.
Intact	Corrosive	0/6	0/6	0/6
Abraded	Corrosive	3/6	6/6	6/6

B. SKIN IRRITATION INDEX

COMPOUND Bottlex 'CONFIDENTIAL' Date 8-14-72
 PRODUCT DESCRIPTION Granular powder Operator W. B. Miller

Rabbit No.	Skin	Erythema-eschar Observation			Edema Observation			Sum Total	Score*
		4 hr.	24 hr.	48 hr.	4 hr.	24 hr.	24 hr.		
15	1103 Intact	4	4	4	4	4	4	8	
	Abraded	4	4	4	4	4	4		
16	1109 Intact	4	4	4	4	4	4	8	
	Abraded	4	4	4	4	4	4		
17	1114 Intact	4	4	4	4	4	4	8	
	Abraded	4	4	4	4	4	4		
31	1130 Intact	4	4	4	4	4	4	8	
	1130 Abraded	4	4	4	4	4	4		
32	1128 Intact	4	4	4	4	4	4	8	
	Abraded	4	4	4	4	4	4		
33	1128 Intact	4	4	4	4	4	4	8	
	Abraded	4	4	4	4	4	4		

Primary Irritant Score -----

*Score = sum of individual values for each rabbit divided by six.

Observations: TOTAL ERYTHEMA - ESCRAR. BLEEDING TO

Skin Irritant Score and Irritant Classification:

Test site	Evaluation of skin reaction	Ratio regarding six rabbits; Observation time		
		4 hr.	24 hr.	48 hr.
Intact	Corrosive	6/6	6/6	6/6
Abraded	Corrosive	6/6	6/6	6/6

B. SKIN IRRITATION INDEX

(WORK PAPER)

COMPOUND Cipes

Date 8

PRODUCT DESCRIPTION

CONFIDENTIAL

Operator W.B.M

Rabbit No.	Skin	Erythema-eschar Observation			Edema Observation			Sum Total	Score*
		4 hr.	24 hr.	48 hr.	4 hr.	24 hr.	24 hr.		
1	Intact	4	4	4	4	4	4	8	
	Abraded	4	4	4	4	4	4		
2	Intact	4	4	4	4	4	4	8	
	Abraded	4	4	4	4	4	4		
3	Intact	4	4	4	4	4	4	8	
	Abraded	4	4	4	4	4	4		
4	Intact	4	4	4	4	4	4	8	
	Abraded	4	4	4	4	4	4		
5	Intact	4	4	4	4	4	4	8	
	Abraded	4	4	4	4	4	4		
6	Intact	4	4	4	4	4	4	8	
	Abraded	4	4	4	4	4	4		

Primary Irritant Score -----

*Score = sum of individual values for each rabbit divided by six.

Observations: . TOTAL ESCAR TO

Skin Irritant Score and Irritant Classification:

Test site	Evaluation of skin reaction	Ratio regarding six rabbits; Observation time		
		4 hr.	24 hr.	48 hr.
Intact	Corrosive	6/6	6/6	6/6
Abraded	Corrosive	6/6	6/6	6/6

B. SKIN IRRITATION INDEX

COMPOUND CLEAN CHARGE CONFIDENTIAL Date 8-15-72

PRODUCT DESCRIPTION CLEAR, COLORLESS LIQUID Operator MM, CB

Rabbit No.	Skin	Erythema-eschar Observation			Edema Observation			Sum Total	Score*
		4 hr.	24 hr.	48 hr.	4 hr.	24 hr.	48 hr.		
Right 1 30♀	Intact	2	2	2	2	2	2	24	2.4
	Abraded	2	2	2	2	2	2	24	2.4
40♀	Intact	0	2	2	0	2	2	17	2.8
	Abraded	1	2	2	0	2	2	15	2.5
50♀	Intact	0	1	1	0	0	1	4	.67
	Abraded	0	0	0	0	0	1	1	.17
19♀	Intact	3	3	3	2	2	2	30	5.0
	Abraded	3	3	3	2	2	2	30	5.0
20♀	Intact	3	3	3	2	2	2	33	5.5
	Abraded	4 eschar	4	4	2	2	2	38	6.3
21♀	Intact	0	2	1	0	1	1	10	1.6
	Abraded	0	2	1	0	1	1	8	1.3

Primary Irritant Score ----- 3.26

*Score = sum of individual values for each rabbit divided by six.

Observations: Eschar formation on abraded patch in 1/6

Skin Irritant Score and Irritant Classification:

Test site	Evaluation of skin reaction	Ratio regarding six rabbits; Observation time		
		4 hr.	24 hr.	48 hr.
Intact	Corrosive	0/6	0/6	0/6
Abraded	Corrosive	1/6	1/6	1/6

B. SKIN IRRITATION INDEX

COMPOUND COMPLETE Date 8-15-72

CONFIDENTIAL

PRODUCT DESCRIPTION YELLOW COLORED GRANULE Operator MM, CB

Rabbit No.	Skin	Erythema-eschar Observation			Edema Observation			Sum Total	Score*				
		4 hr.	24 hr.	48 hr.	4 hr.	24 hr.	48 hr.						
1 <i>9²³</i> <i>60⁹</i>	Intact	4	4	4	4	4	4	24	4 8				
	Abraded	4	4	4	4	4	4						
2 <i>70⁹</i>	Intact	4	4	4	4	4	4			24	4 8		
	Abraded	4	4	4	4	4	4						
3 <i>80⁹</i>	Intact	4	4	4	4	4	4					24	4 8
	Abraded	4	4	4	4	4	4						
4 <i>22⁹</i>	Intact	4	4	4	4	4	4	24	4 8				
	Abraded	4	4	4	4	4	4						
5 <i>23⁹</i>	Intact	4	4	4	4	4	4			24	4 8		
	Abraded	4	4	4	4	4	4						
6 <i>24⁹</i>	Intact	4	4	4	4	4	4					24	4 8
	Abraded	4	4	4	4	4	4						

Primary Irritant Score ----- 8

*Score = sum of individual values for each rabbit divided by six.

Observations: eschar in all

Skin Irritant Score and Irritant Classification: Corrosive

Test site	Evaluation of skin reaction	Ratio regarding six rabbits; Observation time		
		4 hr.	24 hr.	48 hr.
Intact	Corrosive	6/6	_____	_____
Abraded	Corrosive	6/6	_____	_____

B. SKIN IRRITATION INDEX

COMPOUND CROWN DETERGENT **CONFIDENTIAL** Date 8-15-72

PRODUCT DESCRIPTION GREEN COLORED, GRANULE Operator MM, CB

Rabbit No.	Skin	Erythema-eschar Observation			Edema Observation			Sum Total	Score*
		4 hr.	24 hr.	48 hr.	4 hr.	24 hr.	24 hr.		
1 90♀	Intact	4*	4	4	4	4	4	24	8
	Abraded	4†	4	4	4	4			
2 108♀	Intact	4*	4	4	4	4			
	Abraded	4†	4	4	4	4			
3 110♀	Intact	4*	4	4	4	4			
	Abraded	4*	4	4	4	4			
4 25♀	Intact	4*	4		4	4			
	Abraded	4*	4		4	4			
5 26♀	Intact	4*	4		4	4			
	Abraded	4*†	4		4	4			
6 27♀	Intact	4†	4		4	4		24	8
	Abraded 10's	4*	4	4	4	4	4		

Primary Irritant Score ----- 8

*Score = sum of individual values for each rabbit divided by six.

Observations: * open sore surrounded by eschar
† eschar

Skin Irritant Score and Irritant Classification: Corrosive

Test site	Evaluation of skin reaction	Ratio regarding six rabbits; Observation time		
		4 hr.	24 hr.	48 hr.
Intact	Corrosive	6/6	_____	_____
Abraded	Corrosive	6/6	_____	_____

B. SKIN IRRITATION INDEX

COMPOUND CRYSTAMET 2040 **CONFIDENTIAL** Date 8-16-72

PRODUCT DESCRIPTION WHITE GRANULE Operator MM-CB

Rabbit No.	Skin	Erythema-eschar Observation			Edema Observation			Sum Total	Score*
		4 hr.	24 hr.	48 hr.	4 hr.	24 hr.	24 hr.		
1 120♂	Intact	4	4		4	4	4	24	8
	Abraded	4	4		4	4	4		
2 130♂	Intact	4	4		4	4	4		4
	Abraded	4	4		4	4	4	24	
3 140♂	Intact	4	4		4	4	4	24	4
	Abraded	4	4		4	4	4	24	
4 28♀	Intact	4	4	4	4	4	4	24	4
	Abraded	4	4	4	4	4	4	24	
5 29♀	Intact	4	4	4	4	4	4	24	4
	Abraded	4	4	4	4	4	4	24	
6 30♀	Intact	4	4	4	4	4	4	24	4
	Abraded	4	4	4	4	4	4	24	

Primary Irritant Score ----- 8

*Score = sum of individual values for each rabbit divided by six.

Observations: eschar in all

Skin Irritant Score and Irritant Classification: Corrosive

Test site	Evaluation of skin reaction	Ratio regarding six rabbits; Observation time		
		4 hr.	24 hr.	48 hr.
Intact	Corrosive	6/4	_____	_____
Abraded	Corrosive	6/6	_____	_____

B. SKIN IRRITATION INDEX

COMPOUND DRYLIFE CLEAR ~~DRYLIFE CLEAR~~ **CONFIDENTIAL** Date 8-16-72

PRODUCT DESCRIPTION CLEAR Amber colored liquid Operator MM-CB

Rabbit No.	Skin	Erythema-eschar Observation			Edema Observation			Sum Total	Score*
		4 hr.	24 hr.	48 hr.	4 hr.	24 hr.	24 hr.		
1 1507	Intact	1	1	1	1	1	1	12	2
	Abraded	1	1	1	1	1	1		
2 1607	Intact	0	1	1	1	1	1	10	1.67
	Abraded	0	1	1	1	1	1		
3 1787	Intact	1	1	1	1	1	1	12	2.00
	Abraded	1	1	1	1	1	1		
4 319	Intact	0	1	1	0	2	1	11	1.83
	Abraded	1	1	1	0	2	1		
5 329	Intact	0	0	0	0	0	0	3	.50
	Abraded	0	1	1	0	0	1		
6 339	Intact	0	1	1	0	2	1	10	1.67
	Abraded	0	1	1	0	2	1		

Primary Irritant Score ----- 1.61

*Score = sum of individual values for each rabbit divided by six.

Observations:

Skin Irritant Score and Irritant Classification:

Test site	Evaluation of skin reaction	Ratio regarding six rabbits; Observation time		
		4 hr.	24 hr.	48 hr.
Intact	Corrosive	0/6	_____	
Abraded	Corrosive	0/6	_____	

COMPOUND DRYMET OO

Date 8-16-72

PRODUCT DESCRIPTION WHITE GRANULE

Operator MM-CB

Rabbit No.	Skin	Erythema-eschar Observation			Edema Observation			Sum Total	Score*
		4 hr.	24 hr.	48 hr.	4 hr.	24 hr.	24 hr.		
1	Intact	4	4	4	4	4	4	48	8
	Abraded	4	4	4	4	4	4		
2	Intact	4	4	4	4	4	4		
	Abraded	4	4	4	4	4	4		
3	Intact	4	4	4	4	4			
	Abraded	4	4	4	4	4	4		
4	Intact	4	4	4	4	4	4		
	Abraded	4	4	4	4	4	4		
5	Intact	4	4	4	4	4	4		
	Abraded	4	4	4	4	4	4		
6	Intact	4	4	4	4	4	4		
	Abraded	4	4	4	4	4	4		

Primary Irritant Score ----- 8

*Score = sum of individual values for each rabbit divided by six.

Observations:

Skin Irritant Score and Irritant Classification: Corrosive

Test site	Evaluation of skin reaction	Ratio regarding six rabbits; Observation time		
		4 hr.	24 hr.	48 hr.
Intact	Corrosive	6/6	_____	_____
Abraded	Corrosive	6/6	_____	_____

B. SKIN IRRITATION INDEX

T-4037-10

COMPOUND DRYORTH

Done
CONFIDENTIAL

Date 8-21-72

PRODUCT DESCRIPTION WHITE GRANULE

Operator MM / CB

Rabbit No.	Skin	Erythema-eschar Observation			Edema Observation			Sum Total	Score*
		4 hr.	24 hr.	48 hr.	4 hr.	24 hr.	24 hr.		
1	Intact	4*	4	4	4*	4	4		
10♂	Abraded	4*			4*				
2	Intact	4			4				
20♀	Abraded	4			4				
3	Intact	4			4				
30♂	Abraded	4			4				
4	Intact	4			4				
19♀	Abraded	4			4				
5	Intact	4			4				
20♀	Abraded	4			4				
6	Intact	4			4				
21♀	Abraded	4			4				

Primary Irritant Score ----- 8

*Score = sum of individual values for each rabbit divided by six.

Observations: + bleeding + ulceration + eschar
eschar in 211

Skin Irritant Score and Irritant Classification:

Test site	Evaluation of skin reaction	Ratio regarding six rabbits; Observation time		
		4 hr.	24 hr.	48 hr.
Intact	Corrosive			
Abraded	Corrosive			

B. SKIN IRRITATION INDEX

T-4007-11

COMPOUND

DRYORTH LD

CONFIDENTIAL

Date

8-21-72

PRODUCT DESCRIPTION

WHITE GRANULE.

Operator

mm/cs

Rabbit No.	Skin	Erythema-eschar Observation			Edema Observation			Sum Total	Score*
		4 hr.	24 hr.	48 hr.	4 hr.	24 hr.	48 hr.		
1	Intact	4	4	4	4	4	4	48	8
40♂	Abraded	4			4				
2	Intact	4			4				
50♂	Abraded	4			4				
3	Intact	4			4				
60♂	Abraded	4			4				
4	Intact	4			4				
22♀	Abraded	4			4				
5	Intact	4*			4*				
23♀	Abraded	4*			4*				
6	Intact	4			4				
24♀	Abraded	4			4				

Primary Irritant Score -----

*Score = sum of individual values for each rabbit divided by six.

Observations: * ulceration

eschar in all

Skin Irritant Score and Irritant Classification: _____

Test site	Evaluation of skin reaction	Ratio regarding six rabbits; Observation time		
		4 hr.	24 hr.	48 hr.
Intact	Corrosive			
Abraded	Corrosive			

B. SKIN IRRITATION INDEX

T-4037-12

COMPOUND

ECONOJET

CONFIDENTIAL

Date

8-21-72

PRODUCT DESCRIPTION

GREEN GRANULE

Operator

MM/CB

Rabbit No.	Skin	Erythema-eschar Observation			Edema Observation			Sum Total	Score*
		4 hr.	24 hr.	48 hr.	4 hr.	24 hr.	24 hr.		
right 1	Intact	4	4	4	4	4	4	48	8
209	Abraded	4	4	4	4	4	4		
2	Intact	4	4	4	4	4	4	48	8
80	Abraded	4	4	4	4	4	4		
3	Intact	4	4	4	4	4	4		
90	Abraded	4	4	4	4	4	4		
4	Intact	4	4	4	4	4	4		
259	Abraded	4	4	4	4	4	4		
5	Intact	4	4	4	4	4	4		
269	Abraded	4	4	4	4	4	4		
6	Intact	4	4	4	4	4	4		
279	Abraded	4	4	4	4	4	4		

Primary Irritant Score -----

*Score = sum of individual values for each rabbit divided by six.

Observations: eschar in all

Skin Irritant Score and Irritant Classification:

Test site	Evaluation of skin reaction	Ratio regarding six rabbits; Observation time		
		4 hr.	24 hr.	48 hr.
Intact	Corrosive			
Abraded	Corrosive			

B. SKIN IRRITATION INDEX

(WORK PAPER)
T-4037-13

COMPOUND MILOUPRUF

CONFIDENTIAL

Date 8-22-72

PRODUCT DESCRIPTION CLEAR COLOURED LIQUID

Operator MM/CS

Rabbit No.	Skin	Erythema-eschar Observation			Edema Observation			Sum Total	Score*
		4 hr.	24 hr.	48 hr.	4 hr.	24 hr.	48 hr.		
1 ^{right} 10♂	Intact	4	4	4	4	4	4		
	Abraded	4	4	4	4	4	4		
2 11♂	Intact	4	4	4	4	4	4		
	Abraded	4	4	4	4	4	4		
3 12♂	Intact	4*	4	4	4	4	4		
	Abraded	4	4	4	4	4	4		
4 28♀	Intact	4*	4	4	4	4	4		
	Abraded	4	4	4	4	4	4		
5 29♀	Intact	4	4	4	4	4	4		
	Abraded	4	4	4	4	4	4		
6 30♀	Intact	4	4	4	4	4	4		
	Abraded	4	4	4	4	4	4		

Primary Irritant Score -----

*Score = sum of individual values for each rabbit divided by six.

Observations: eschar

* Very light burns

Handwritten signature/initials

Skin Irritant Score and Irritant Classification:

Test site	Evaluation of skin reaction	Ratio regarding six rabbits; Observation time		
		4 hr.	24 hr.	48 hr.
Intact	Corrosive			
Abraded	Corrosive			

B. SKIN IRRITATION INDEX

T-4037-14

COMPOUND

MOOV

CONFIDENTIAL

Date

8-22-72

PRODUCT DESCRIPTION

CLEAR, yellow colored liquid Operator mm/cs

Rabbit No.	Skin	Erythema-eschar Observation			Edema Observation			Sum Total	Score*
		4 hr.	24 hr.	48 hr.	4 hr.	24 hr.	24 hr.		
130♂	Intact	4							
	Abraded	4							
140♂	Intact	4			4				
	Abraded	4			4				
150♂	Intact	4	4	4	4	4	4		
	Abraded	4	4	4	4	4	4		
31♀	Intact	4	4	4	4	4	4		
	Abraded	4	4	4	4	4	4		
22♀	Intact	4			3				
	Abraded	4			3				
33♀	Intact	4			4				
	Abraded	4			4				

Primary Irritant Score -----

*Score = sum of individual values for each rabbit divided by six.

Observations:

Skin Irritant Score and Irritant Classification:

Test site	Evaluation of skin reaction	Ratio regarding six rabbits; Observation time		
		4 hr.	24 hr.	48 hr.
Intact	Corrosive			
Abraded	Corrosive			

B. SKIN IRRITATION INDEX

T-4037-15

COMPOUND ONE SHOT CLEANER

CONFIDENTIAL

Date 8-22-72

PRODUCT DESCRIPTION YELLOW GRANULE

Operator MM/CS

Rabbit No.	Skin	Erythema-eschar Observation			Edema Observation			Sum Total	Score*
		4 hr.	24 hr.	48 hr.	4 hr.	24 hr.	24 hr.		
1 160	Intact	4	4	4	4	4	4		
	Abraded	4	4	4	4	4	4		
2 170	Intact	4*	4	4	4	4	4		
	Abraded	4	4	4	4	4	4		
3 180	Intact	4*	4	4	4	4	4		
	Abraded	4	4	4	4	4	4		
4 349	Intact	4	4	4	4	4	4		
	Abraded	4	1	4	4	1	4		
5 359	Intact	4	1	4	4	1	4		
	Abraded	4	1	4	4	1	4		
6 369	Intact	4	1	4	4	1	4		
	Abraded	4	1	4	4	1	4		

Primary Irritant Score -----

*Score = sum of individual values for each rabbit divided by six.

Observations: ulcerations through the entire skin perforating the skin

Skin Irritant Score and Irritant Classification:

Test site	Evaluation of skin reaction	Ratio regarding six rabbits; Observation time		
		4 hr.	24 hr.	48 hr.
Intact	Corrosive			
Abraded	Corrosive			

COMPOUND Round CONFIDENTIAL Date P-23-72

PRODUCT DESCRIPTION WHITE GRANULE Operator mm/cb

Rabbit No.	Skin	Erythema-eschar Observation			Edema Observation			Sum Total	Score*
		4 hr.	24 hr.	48 hr.	4 hr.	24 hr.	48 hr.		
1 ♂ <i>Right</i>	Intact	4	4	4	4	4	4		
	Abraded	4	4	4	4	4	4		
2 ♂	Intact	4	4	4	4	4	4		
	Abraded	4	4	4	4	4	4		
3 ♂ <i>(left)</i>	Intact	4	4	4	4	4	4		
	Abraded	4	4	4	4	4	4		
4 ♂	Intact	4	4	4	4	4	4		
	Abraded	4	4	4	4	4	4		
5 ♂	Intact	4	4	4	4	4	4		
	Abraded	4	4	4	4	4	4		
6 ♂	Intact	4	4	4	4	4	4		
	Abraded	4	4	4	4	4	4		

Primary Irritant Score -----

*Score = sum of individual values for each rabbit divided by six.

Observations:

Skin Irritant Score and Irritant Classification: _____

Test site	Evaluation of skin reaction	Ratio regarding six rabbits; Observation time		
		4 hr.	24 hr.	48 hr.
Intact	Corrosive			
Abraded	Corrosive			

B. SKIN IRRITATION INDEX

T-4037-17

COMPOUND

SANITIZER

CONFIDENTIAL

Date

P-23-72

PRODUCT DESCRIPTION

WHITE POWDER

Operator

MM/CS

Rabbit No.	Skin	Erythema-eschar Observation			Edema Observation			Sum Total	Score*
		4 hr.	24 hr.	48 hr.	4 hr.	24 hr.	48 hr.		
1 right 70	Intact	4	4	4	1	2	2		
	Abraded	4	4	4	1	2	2		
2 80	Intact	4	4	4	1	1	1		
	Abraded	4	4	4	1	1	1		
3 90	Intact	4	4	4	1	1	1		
	Abraded	4	4	4	1	1	1		
4 100	Intact	4	4	4	1	1	1		
	Abraded	4	4	4	1	1	1		
5 110	Intact	4	4	4	1	0	0		
	Abraded	4	4	4	1	0	0		
6 120	Intact	4	4	4	1	0	0		
	Abraded	4	4	4	1	0	0		

Primary Irritant Score -----

*Score = sum of individual values for each rabbit divided by six.

Observations:

eschar in all

41

Handwritten calculations:

$$\begin{array}{r} 32 \\ 144 \\ \hline 176 \\ 2 \\ \hline 178 \end{array}$$

$$\begin{array}{r} 36 \\ 176 \\ \hline 212 \\ 2 \\ \hline 214 \end{array}$$

$$\begin{array}{r} 547 \\ 176 \\ \hline 723 \\ 2 \\ \hline 725 \end{array}$$

Skin Irritant Score and Irritant Classification:

Test site	Evaluation of skin reaction	Ratio regarding six rabbits; Observation time		
		4 hr.	24 hr.	48 hr.
Intact	Corrosive			
Abraded	Corrosive			

B. SKIN IRRITATION INDEX

CONFIDENTIAL

T-4037-18

COMPOUND Sodium METASILICATE ANHYDROUS Date 8-23-72

PRODUCT DESCRIPTION WHITE GRANULE Operator MM/CS

Rabbit No.	Skin	Erythema-eschar Observation			Edema Observation			Sum Total	Score*
		4 hr.	24 hr.	48 hr.	4 hr.	24 hr.	24 hr.		
1	right 10 ³⁰ Intact								
	Abraded								
2	Intact								
	Abraded								
3	Intact	4	4	4	3	4	4		
	Abraded	4	4	4	3	4	4		
4	Intact	4	4	4	3	4	4		
	Abraded	4	4	4	3	4	4		
5	Intact	4	4	4	3	4	4		
	Abraded	4	4	4	3	4	4		
6	Intact	4	4	4	3	4	4		
	Abraded	4	4	4	3	4	4		

130
 140
 150
 160
 170
 180

dozed with
 T-4039-19
 52:11:11

Primary Irritant Score -----

*Score = sum of individual values for each rabbit divided by six.

Observations: eschar in all

Skin Irritant Score and Irritant Classification:

Test site	Evaluation of skin reaction	Ratio regarding six rabbits; Observation time		
		4 hr.	24 hr.	48 hr.
Intact	Corrosive			
Abraded	Corrosive			

B. SKIN IRRITATION INDEX

1-4037-19 (WORK PAPER)

COMPOUND Sol - Esc

Date 8-28-72

PRODUCT DESCRIPTION Greenish granular powder

Operator Paul R. Smith

CONFIDENTIAL

Rabbit No.	Skin	Erythema-eschar Observation			Edema Observation			Sum Total	Score*
		4 hr.	24 hr.	48 hr.	4 hr.	24 hr.	24 hr.		
1	Intact	4	4	4	4	4	4		
1907	Abraded	4			4				
2	Intact	4			4				
200	Abraded	4			4				
3	Intact	4			4				
210	Abraded	4			4				
4	Intact	4			4				
220	Abraded	4			4				
5	Intact	4			4				
230	Abraded	4			4				
6	Intact	4			4				
240	Abraded	4			4				

Primary Irritant Score -----

*Score = sum of individual values for each rabbit divided by six.

Observations: eschar in all

Skin Irritant Score and Irritant Classification:

Test site	Evaluation of skin reaction	Ratio regarding six rabbits; Observation time		
		4 hr.	24 hr.	48 hr.
Intact	Corrosive			
Abraded	Corrosive			

B. SKIN IRRITATION INDEX

T-4031-20

(WORK PAPER)

COMPOUND Super Resoil

CONFIDENTIAL

Date 8-28-72

PRODUCT DESCRIPTION Off-white granular powder

Operator W. B. Smith

Rabbit No.	Skin	Erythema-eschar Observation			Edema Observation			Sum Total	Score*
		4 hr.	24 hr.	48 hr.	4 hr.	24 hr.	48 hr.		
1	Intact	4	4	4	4	4	4		
250	Abraded	4			4				
2	Intact	4			4				
260	Abraded	4			4				
3	Intact	4			4				
270	Abraded	4			4				
4	Intact	4			4				
280	Abraded	4			4				
5	Intact	4			4				
290	Abraded	4			4				
6	Intact	4			4				
300	Abraded	4			4				

Primary Irritant Score -----

*Score = sum of individual values for each rabbit divided by six.

Observations: eschar in all

Skin Irritant Score and Irritant Classification: _____

Test site	Evaluation of skin reaction	Ratio regarding six rabbits; Observation time		
		4 hr.	24 hr.	48 hr.
Intact	Corrosive			
Abraded	Corrosive			

B. SKIN IRRITATION INDEX

T-4037-21 (WORK PAPER)

COMPOUND Tween-D₁₂ **CONFIDENTIAL** Date 8-28-72
 PRODUCT DESCRIPTION White granular powder Operator W. B. [Signature]

Rabbit No.	Skin	Erythema-eschar Observation			Edema Observation			Sum Total	Score*
		4 hr.	24 hr.	48 hr.	4 hr.	24 hr.	24 hr.		
310	Intact	4	4	4	4	4	4		
	Abraded	4			4				
320	Intact	4			4				
	Abraded	4			4				
330	Intact	4			4				
	Abraded	4			4				
340	Intact	4			4				
	Abraded	4			4				
350	Intact	4			4				
	Abraded	4			4				
360	Intact	4			4				
	Abraded	4			4				

Primary Irritant Score -----

*Score = sum of individual values for each rabbit divided by six.

Observations:

Skin Irritant Score and Irritant Classification:

Test site	Evaluation of skin reaction	Ratio regarding six rabbits; Observation time		
		4 hr.	24 hr.	48 hr.
Intact	Corrosive			
Abraded	Corrosive			

B. SKIN IRRITATION INDEX

COMPOUND BENZENE PHOSPHORUS TRIOXIDE Date 9-19-72

PRODUCT DESCRIPTION LT yellow liquid Operator _____

Rabbit No.	Skin	Erythema-eschar Observation			Edema Observation			Sum Total	Score*
		4 hr.	24 hr.	48 hr.	4 hr.	24 hr.	24 hr.		
1	Intact	1	0	4	2	0	2	27	4.50
55	Abraded	3	4*	4	4	1	2		
2	Intact	1	1	2	2	0	2	25	4.17
56	Abraded	3	2	4	4	1	3		
3	Intact	2	1	2	2	0	2	30	5.00
57	Abraded	4*	4*	4	4	2	3		
4	Intact	1	0	1	2	0	2	21	3.50
58	Abraded	3	2	3	3	0	3		
5	Intact	2	1	4	1	0	2	27	4.50
59	Abraded	4*	4*	4	3	0	2		
6	Intact	1	0	2	2	0	2	19	3.17
60	Abraded	3	1	2	3	0	2		

Primary Irritant Score ----- 4.2

*Score = sum of individual values for each rabbit divided by six.

Observations:

* on Abrasions

ESCHAR WAS OBSERVED ON TWO INTACT TEST SITES, THEREBY CLASSIFYING THIS COMPOUND AS A CORROSIVE.

Skin Irritant Score and Irritant Classification: 4.2 CORROSIVE

Test site	Evaluation of skin reaction	Ratio regarding six rabbits; Observation time		
		4 hr.	24 hr.	48 hr.
Intact	Corrosive	0/6	0/6	2/6
Abraded	Corrosive	2/6	3/6	4/6

B. SKIN IRRITATION INDEX

T-4037-24

COMPOUND Di-2-ETHYLHEXYL DITHIOPHOSPHORODITHIOIC

Acid Date 9-19-72

PRODUCT DESCRIPTION ~~Ferrous dactyl~~ TRANSLUCENT LIQUID

Operator mm/cb

Rabbit No.	Skin	Erythema-eschar Observation			CONFIDENTIAL Erythema-observation			Sum Total	Score*
		4 hr.	24 hr.	48 hr.	4 hr.	24 hr.	24 hr.		
1	Intact	1	4	4	1	2	2	37	5.17
	Abraded	3	4	4	2	2	2		
2	Intact	2	2	4	1	2	1	29	4.83
	Abraded	3	3	4	2	0	2		
3	Intact	1	2	4	1	2	1	27	4.50
	Abraded	2	4	4	2	2	2		
4	Intact	2	3	4	0	1	1	27	4.50
	Abraded	3	4	4	1	2	2		
5	Intact	1	2	4	0	1	1	25	4.17
	Abraded	3	4	4	1	2	2		
6	Intact	2	4	4	1	2	1	32	5.33
	Abraded	3	4	4	2	3	2		

Primary Irritant Score ----- 4.8

*Score = sum of individual values for each rabbit divided by six.

Observations: (C) (U) (A) (P) TOTAL

Skin Irritant Score and Irritant Classification: 4.8 - CORROSIVE

Test site	Evaluation of skin reaction	Ratio regarding six rabbits; Observation time		
		4 hr.	24 hr.	48 hr.
Intact	Corrosive	0/6	2/6	6/6
Abraded	Corrosive	0/6	5/6	6/6

B. SKIN IRRITATION INDEX

(WORK PAPER)

T-4037-25

COMPOUND THIOPHOS DITHARYL CHLORIDE Date 9-19-72

PRODUCT DESCRIPTION CLEAR COLORLESS LIQUID Operator MM/CS

Rabbit No.	Skin	Erythema-eschar Observation			CONFIDENTIAL Edema Observation			Sum Total	Score*
		4 hr.	24 hr.	48 hr.	4 hr.	24 hr.	24 hr.		
1	Intact	4	4	4	4	4	4		
	Abraded	4	4	4	4	4	4		
2	Intact	4	4	4	4	4	4		
	Abraded	4	4	4	4	4	4		
3	Intact	4	4	4	4	4	4		
	Abraded	4	4	4	4	4	4		
4	Intact	4	4	4	4	4	4		
	Abraded	4	4	4	4	4	4		
5	Intact	4	4	4	4	4	4		
	Abraded	4	4	4	4	4	4		
6	Intact	4	4	4	4	4	4		
	Abraded	4	4	4	4	4	4		

Primary Irritant Score -----

*Score = sum of individual values for each rabbit divided by six.

Observations:

Skin Irritant Score and Irritant Classification:

Test site	Evaluation of skin reaction	Ratio regarding six rabbits; Observation time		
		4 hr.	24 hr.	48 hr.
Intact	Corrosive			
Abraded	Corrosive			

1470 ()

T-4037-22

ACUTE ORAL SHEET

Date 9-21-72

CONFIDENTIAL

Material Benzene Phosphorus Dichloride

Batch #

Dose 464 mg/kg

Concentration 200 mg/ml

20% Oil

Factor 2.32

Rat No.	Body Weight (g)	Total Dose (ml)
1	200 av	0.46
2		
3		
4		
5		

Observations:

9-21 2¹⁵ P 0/5 dead. Moderately depressed

4²⁵ P " " " "

9-23 8⁰⁰ A " " - Normal

9-25 " " " "

120 P

125 P

T-4037-22

ACUTE ORAL SHEET

91

Date 9-22-72

CONFIDENTIAL

Material Benzene Phosphorus Dichloride

Batch # _____

Dose 1000 mg/kg

Concentration 200 mg/ml

20% BA
Out

Factor 5

<u>Rat No.</u>	<u>Body Weight (g)</u>	<u>Total Dose (ml)</u>
1	<u>200g</u>	<u>1.0</u>
2		
3		
4		
5		

9/20
A

9/25
A

Observations:

9-22 10⁰⁰A 0/5 dead, all moderately depressed
3:00 P " " " " "
9/25 8:00 A " " Normal

T-4037-22

ACUTE ORAL SHEET

Date 9-22-72

CONFIDENTIAL

Material Benzene Phosphorus Dichloride Batch # _____

Dose 2150 mg/kg

Concentration 200 mg/ml _____ 20% *Oil*

Factor 10.8

Rat No. 2100 Body Weight (g)

Total Dose (ml)

- 1
- 2
- 3
- 4
- 5

200gr

2.2

9 3/4
9 3/4

Observations:

9-21 10⁰⁰ 0/5 dead. All very depressed.

10⁴⁰ 4/5 " " "

Autopsy shows hemorrhage of entire
G.I. tract

2³⁰ P 5/5 dead

~~_____~~
~~_____~~

1-4057-22

ACUTE ORAL SHEET

Date 9-21-72

CONFIDENTIAL

Material Benzene Phosphorus Trichloride Batch # _____

Dose 4640mg/kg

Concentration 200mg/ml _____ 20% (Cm) (Al)

Factor 23:2

Rat No.	Body Weight (g)	Total Dose (ml)
1	200 g	4.6
2		
3		
4		
5		

Observations:

9-21 11³⁰ A 0/5 dead, all obviously in pain

12⁰⁰ P 5/5 dead

B. SKIN IRRITATION INDEX

36000 0000 (WORK PAPER)

T-4037-22

COMPOUND BENZENE PHOSPHORUS DICHLORIDE Date 9-19-77

PRODUCT DESCRIPTION CLEAR-COLORED Liquid Operator ma/cd

Rabbit No.	Skin	Erythema-eschar Observation			Edema Observation			Sum Total	Score*
		4 hr.	24 hr.	48 hr.	4 hr.	24 hr.	24 hr.		
		CONFIDENTIAL							
1	Intact	4	4	4	4	4	4		
55	Abraded	4	4	4	4	4	4		
2	Intact	4	4	4	4	4	4		
56	Abraded	4	4	4	4	4	4		
3	Intact	4	4	4	4	4	4		
57	Abraded	4	4	4	4	4	4		
4	Intact	4	4	4	4	4	4		
58	Abraded	4	4	4	4	4	4		
5	Intact	4	4	4	4	4	4		
59	Abraded	4	4	4	4	4	4		
6	Intact	4	4	4	4	4	4		
60	Abraded	4	4	4	4	4	4		

Primary Irritant Score -----

*Score = sum of individual values for each rabbit divided by six.

Observations: Rabbits alternate ~~with~~ and instantaneous burnings taken place.

Skin Irritant Score and Irritant Classification:

Test site	Evaluation of skin reaction	Ratio regarding six rabbits; Observation time		
		4 hr.	24 hr.	48 hr.
Intact	Corrosive			
Abraded	Corrosive			

W F W

IN: 4
OF: 4
8

WT ON 78.5 ?
OFF 77.5
USED 1.0
8 x 60 = 480 + 98 =

1,000
576 TF

INH
10-16-72

1.74 mg/L / HR

T₉₅ = ~12'

START: 2:25

CONFIDENTIAL

T₉₅ ~~2370~~

3:00 - 0/10 - NASAL DISCHARGE, DYSPNOEA, ACUTE DEPRESSION

3:15 - 0/10. SEVERE

10-17 9:20 0/10 - SLIGHT DEP - Pilo ERECTION.

BENZENE PHOSPHORUS DICHLORIDE

T-4037-22

IU 2
D-6
TF 8

WT ON - 79.0g
OFF - 78.5
u - 0.5

INHALATION
10-16-72

$8 \times 60 = 480 + 96^{T^2}$ 576 TF / 500mg = 0.87 mg/L / HR

CONFIDENTIAL

T²⁵ - 12°

START: 1¹⁵/_P

T²⁵ PASSED 1³⁰/_P 0/10 - S-dypr - GASPING

2⁰⁰/_P 0/10 - EYE IRRIT, GASPING, DYSPNOEA, DEPRESSION.

2¹⁰/_P 0/10 - ACUTE DEPRESSION

2¹⁵/_P 0/10 - CHAMBER BLOWN. } ANIMALS REMOVED

2²⁵/_P 0/10

10-17- 9³⁰/_A 0/10 - NORMAL.

IN-6
DF-2
8

W T ON 78.8 ?
OFF 77.2
used 1.6

T-4037-22
INH
10-17-72

F-576 L

= 2.77 ~ 1/2 HR

T 90 ~ 12'

CONFIDENTIAL

START: 9⁴⁰A

10⁰⁰A - 0/10 - blow out!
10⁰⁷A - 0/10 - depressed

Triage of 8(e) Submissions

Date sent to triage: _____

NON-CAP

CAP

Submission number: 12458A

TSCA Inventory:

Y

N

D

Study type (circle appropriate):

Group 1 - Dick Clements (1 copy total)

ECO AQUATO

Group 2 - Ernie Falke (1 copy total)

ATOX SBTOX SEN w/NEUR

Group 3 - Elizabeth Margosches (1 copy each)

STOX CTOX EPI RTOX GTOX
STOX/ONCO CTOX/ONCO IMMUNO CYTO NEUR

Other (FATE, EXPO, MET, etc.): _____

Notes:

THIS IS THE ORIGINAL 8(e) SUBMISSION; PLEASE REFILE AFTER TRIAGE DATABASE ENTRY

For Contractor Use Only	
entire document: <u>0</u> 1 2 pages <u>1-3</u>	pages _____
Notes:	
Contractor reviewer: <u>JW</u>	Date: <u>1/17/96</u>

CECATS TRIAGE TRACKING DBASE ENTRY FORM

CECATS DATA: Submission # BEHO-1092-12458 SEQ. A

TYPE: INT. SUPP FLWP SUBMITTER NAME: Rhone - Paulenc Inc.

SUB. DATE: 10/16/92 OTS DATE: 10/23/92 CSRAD DATE: 02/17/95

CHEMICAL NAME: Blendet
see attached
Bofflex

CASE: none
none

3 Clean Charge none
4 Drylite clear '1'

INFORMATION REQUESTED: FLWP DATE:
 0501 NO INFO REQUESTED
 0502 INFO REQUESTED (TECH)
 0503 INFO REQUESTED (VOL. ACTIONS)
 0504 INFO REQUESTED (REPORTING RATIONAL/F)

DISPOSITION:
667 REFER TO CHEMICAL SCREENING
669 CAP NOTICE

ADDITIONAL ACTIONS:
 0401 ACTION IN PROGRESS
 0402 STUDIES PLANNED WITHIN 90 DAY
 0403 NOTIFICATION IN WORK PROGRESS
 0404 LABELS/DSDS (TIAMCIS)
 0405 PROFESSIONAL INQUIRY (TIAMCIS)
 0406 APPRAISE DISCONTINUED
 0407 PRODUCTION DISCONTINUED
 0408 CONFIDENTIAL

INFORMATION TYPE:	P.F.C.	INFORMATION TYPE:	P.F.C.
0201 ONCO (HUMAN)	01 02 04	EPICLIN	01 02 04
0202 ONCO (ANIMAL)	01 02 04	HUMAN EXPOS (PROD CONTAM)	01 02 04
0203 CELL TRANS (IN VITRO)	01 02 04	HUMAN EXPOS (ACCIDENTAL)	01 02 04
0204 MUTA (IN VITRO)	01 02 04	HUMAN EXPOS (MONITORING)	01 02 04
0205 MUTA (IN VIVO)	01 02 04	ECOVAQUA TOX	01 02 04
0206 REPRO/TERATO (HUMAN)	01 02 04	ENV. OCCURREL/FATE	01 02 04
0207 REPRO/TERATO (ANIMAL)	01 02 04	EMER INCI OF ENV CONTAM	01 02 04
0208 NEURO (HUMAN)	01 02 04	RESPONSE REOBST DELAY	01 02 04
0209 NEURO (ANIMAL)	01 02 04	PROD/COMP/CHEM ID	01 02 04
0210 ACUTE TOX. (HUMAN)	01 02 04	REPORTING RATIONALE	01 02 04
0211 CHR. TOX. (HUMAN)	01 02 04	CONFIDENTIAL	01 02 04
0212 ACUTE TOX. (ANIMAL)	01 02 04	ALLERG (HUMAN)	01 02 04
0213 SUB ACUTE TOX (ANIMAL)	01 02 04	ALLERG (ANIMAL)	01 02 04
0214 SUB CHRONIC TOX (ANIMAL)	01 02 04	METAB/PHARMACO (ANIMAL)	01 02 04
0215 CHRONIC TOX (ANIMAL)	01 02 04	METAB/PHARMACO (HUMAN)	01 02 04

TRIAGE DATA: NON-CEI INVENTORY YES (DROP/REFER) NO (CONTINUE) REFR

CAS SR: YES NO IN PROGRESS

TOXICOLOGICAL CONCERN: LOW Dermal Irritation MED Dermal Irritation HIGH Dermal Irritation

USE: Industrial cleaners

PRODUCTION:

12458
changed
12548A

BOTTLEX, CIPEX, COMPLETE, CROWN DETERGENT, CRYSTAMET 2040, DRYMET DD, DRYORTH, DRYORTH LD, ECONODET, MILDUPRUF, MOOV, ONE SHOT CLEANER, ROUND, SANITIZER, ANHYDROU SODIUM METASILICATE, SOL ESCO, SUPER DESOIL, TWIN-DET, CRYSTAMET 2040 (10%), NaOH (1%) DI-2-ETHYLHEXYL PHOSPHORODITHIOIC ACID, THIOPHOSPHORYL CHLORIDE

H

Dermal irritation is of high concern based on corrosive effects in 6/6 rabbits.

BENZENE PHOSPHORUS THIODICHLORIDE

H

Dermal irritation is of high concern based on corrosive effects in 2/6 rabbits.

BLENDET

M

Dermal irritation is of medium concern based on well-defined erythema and very slight edema in 6 rabbits, which lessened in severity over 48 hours.

CLEAR CHARGE

M

Dermal irritation is of medium concern based on moderate to severe erythema and slight edema in 6 rabbits, which persisted over 48 hours.

DRYLITE CLEAR

L

Dermal irritation is of low concern based on very slight erythema and very slight to slight edema in 6 rabbits.

CRYSTAMET 2040 (1%)

L

Dermal irritation is of low concern based on no irritation in 6/6 rabbits.