

Subject:

November 14, 1974

irc: H. A. Birnbaum - 220-2E
E. J. Deviny - 236-2B
C. G. Klaus - 236-3A
J. D. LaZerte - 236-1
J. A. Pendergrass - 220-2E
F. A. Ubel - 220-2E

TO: D. R. RICKER - COMMERCIAL CHEMICALS - 236-2B

FM: J. E. LONG - MEDICAL DEPT. - TOXICOLOGY SERVICES - 220-2E

Attached please find copies of the reports on the primary skin irritation and eye irritation assessments conducted with your FC-95 (T-1117) by WARF Institute.

FC-95 was found to be non-irritating to the skin of albino rabbits under the study conditions utilized. No signs of dermal irritation were observed in any of the test animals at any time during the study period.

This product was found to be minimally to mildly irritating to the eyes of albino rabbits under the study conditions utilized. The ocular irritation was limited to that of the conjunctivae in the six test animals at one, twenty-four, and forty-eight hours post-instillation. No conjunctival irritation was observed at the 72 hour examination. No signs of corneal opacity or iridal irritation were observed in any of the test animals at any time during the study period.

Flushing the eyes with plenty of water immediately upon contact should arrest/reverse the irritation process.

Precautionary label text should indicate that this product may be irritating to eyes.

(JEL:mn)
JEL:mn

bcc: H. A. Birnbaum - 220-2E
E. J. Deviny - 236-2B
C. G. Klaus - 236-3A
J. D. LaZerte - 236-1
J. A. Pendergrass - 220-2E
F. A. Ubel - 220-2E

NOTE FOR 3M COPIES:

T-1117 = FC-95, CC#7410-16

October 24, 1974

Dr. Donald L. Harris
WARF Institute
Biological Department
P.O. Box 2599
Madison, WI 53701

Dear Dr. Harris:

Under separate cover, I am forwarding one 3M sample labeled T-1117 to your laboratory. Please consider this to be a request/authorization for WARF Institute to conduct eye irritation and primary skin irritation assessments with this sample.

In order to assess the eye irritation potential, please instill one-tenth of one gram of test sample into the conjunctival sac of six albino rabbits. Hold the eyelid shut for one second and then examine the test eyes at one, 24, 48, and 72 hours post-instillation and score for ocular irritation according to the procedure of Draize.

For the purpose of assessing the primary skin irritation potential, apply five-tenths of one gram of test sample to intact (dry and wet) and abraded (dry and wet) skin test sites. At 24 and 72 hours post-application, examine the skin test sites and score for dermal irritation according to the procedure of Draize.

Our purchase order for \$200 will be forwarded to you in the near future.

We thank you for your assistance and cooperation in this matter.

Sincerely yours,

J. E. Long, Sc.D.
Medical Department
Manager, Toxicology
Services

JEL:mn

Interoffice Correspondence



T-1117

Subject: Toxicity Testing of
FC-95, CC 7410-16

c. c. E. J. Deviny 236-2A
 C. G. Klaus 236-3A
 J. D. LaZerte 236-1

October 16, 1974

TO: J. E. Long - Toxicology - 220-2E

FROM: D. Ricker - Comm. Chems. - 236-2B

As per your suggestion, please arrange to have the following studies conducted on FC-95:

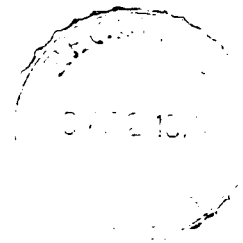
- 1) Primary Skin Irritation Assessment
- 2) Eye Irritation Assessment.

I will send you a sample of FC-95 to be used for this testing. Please let me know under what T No. this testing will be done.

Thank you

D. Ricker

DR:dl



WARF INSTITUTE, INC.

MADISON, WISCONSIN

Reports are submitted to clients on a confidential basis. No reference to the work, the results or to the Institute in any form of advertising, news release or other public announcement may be made without written authorization from the Institute.

REPORT

Sample: T-1117

WARF No. 4102871

Date Received: 10-31-74

Submitted by:

J. E. Long
3M Company
St. Paul, Minnesota 55101

Testing requested:

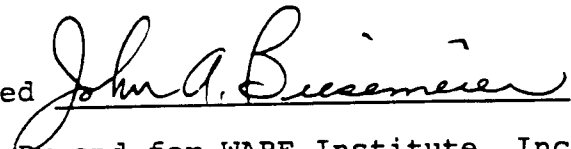
Skin Irritation
Eye Irritation

Conclusion:

Under the conditions specified the product has a primary skin irritation index of zero and zero for both dry and wet applications and eye irritation scores of 8.00, 9.33, 3.33 and zero at 1, 24, 48 and 72 hours respectively.

The product is not irritating to the skin and is irritating to the eye.

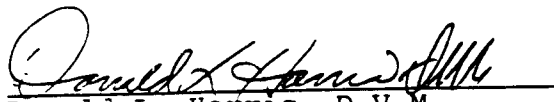
Signed



By and for WARF Institute, Inc.

Report approved by:

Date: November 7, 1974



Donald L. Harris, D.V.M.
Chief Pathologist/Toxicologist

WARF INSTITUTE, INC.

MADISON, WISCONSIN

Sample: T-1117

WARF No. 4102871

Primary Skin Irritation:

Method: Albino rabbits were used for this work. They were housed in individual screen bottom cages and fed water and rabbit chow ad libitum. The hair was clipped from the back and flanks of the animal. Five tenths of one gram of test material was placed in intimate contact with the skin on prepared test sites (intact-wet; abraded-wet), and covered with gauze patch and tape to maintain contact with the skin. After a 24 hour contact period, the coverings were removed and the degree of erythema and edema was recorded according to the scale below. Readings were taken again at 72 hours and the 24 and 72 hour readings used to determine the primary skin irritation score.

Results:

<u>Animal</u> <u>Number</u>	<u>24 Hours</u>		<u>72 Hours</u>		<u>Average</u>
	<u>Abraded</u>	<u>Unabraded</u>	<u>Abraded</u>	<u>Unabraded</u>	
1					
2					
3					
4					
5					
6					

no noted irritation
all sites read negative

Primary skin irritation score: 0

Scale for Evaluation of Skin Reaction

<u>Erythema and Eschar Formation</u>	<u>Score</u>	<u>Edema Formation</u>	<u>Score</u>
Slight erythema	1	Slight edema (barely perceptible)	1
Defined erythema	2		
Moderate to severe erythema	3	Defined edema (edges definite rising)	2
Severe erythema to slight eschar formation	4	Moderate edema (area raised 1 mm)	3
		Severe edema (raised more than 1 mm)	4

Score equals sum of erythema and edema readings.

Skin irritation index equals average of 24 and 72 hour scores.

WARF INSTITUTE, INC.

MADISON, WISCONSIN

Sample: T-1117

WARF No. 4102871

Primary Skin Irritation:

Method: Albino rabbits were used for this work. They were housed in individual screen bottom cages and fed water and rabbit chow ad libitum. The hair was clipped from the back and flanks of the animal. Five tenths of one gram of test material was placed in intimate contact with the skin on prepared test sites (intact-dry; abraded-dry), and covered with gauze patch and tape to maintain contact with the skin. After a 24 hour contact period, the coverings were removed and the degree of erythema and edema was recorded according to the scale below. Readings were taken again at 72 hours and the 24 and 72 hour readings used to determine the primary skin irritation score.

Results:

Animal Number	24 Hours		72 Hours		Average
	<u>Abraded</u>	<u>Unabraded</u>	<u>Abraded</u>	<u>Unabraded</u>	
1					
2					
3					
4					
5					
6					

no noted irritation
all sites read negative

Primary skin irritation score: 0

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Severe erythema to slight eschar formation	4	Moderate edema (area raised 1 mm)	3
		Severe edema (raised more than 1 mm)	4

Score equals sum of erythema and edema readings.
Skin irritation index equals average of 24 and 72 hour scores.

WARF INSTITUTE, INC.

MADISON, WISCONSIN

Sample: T-1117

WARF No. 4102871

Eye Irritation:

Method: Adult albino rabbits of the New Zealand White variety were placed in a collar such that the animals could not rub their eyes. One-tenth of a milliliter (0.1 gm for solids) of test substance was instilled in one eye, the other untreated eye served as a control. A series of six albino rabbits was used for each substance. The reaction to the test material was read according to the scale of scoring for damage to the cornea, iris and the bulbar and palpebral conjunctivae at 1, 24, 48 and 72 hours after eye instillation. Any residue of the test material and accumulated discharge are flushed from the eye each time they are scored.

Administration:

Concentration of test sample: as submitted

Diluent or solvent: none

Special washing: none

Results:

Rabbit Number	Cornea		Iris	Conjunctivae		
	Opacity	Area		Redness	Chemosis	Discharge
1 hour	1	0	0	0	2	1
	2	0	0	0	2	1
	3	0	0	0	2	1
	4	0	0	0	2	1
	5	0	0	0	2	1
	6	0	0	0	2	1

1 hour eye irritation score: 8.00

24 hours	1	0	0	0	2	1
	2	0	0	0	2	1
	3	0	0	0	2	1
	4	0	0	0	2	1
	5	0	0	0	2	1
	6	0	0	0	2	2

24 hour eye irritation score: 9.33

48 hours	1	0	0	0	1	0
	2	0	0	0	1	0
	3	0	0	0	1	0
	4	0	0	0	1	0
	5	0	0	0	1	0
	6	0	0	0	1	1

48 hour eye irritation score: 3.33

72 hour eye irritation score was zero. All readings were negative.