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Chemical Category		SILVER TRIFLUOROMETHANE SULFONATE	

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8EHQ-97-14053

Subject: TSCA Section 8(e) Submission 8EHQ-1197-14053

Dear Sir/Madam:

Elf Atochem North America, Inc. (Elf Atochem) is submitting a primary eye irritation study and a skin irritation study to the Environmental Protection Agency (EPA) pursuant to Toxic Substances Control Act (TSCA) Section 8(e). Preliminary results from these studies were submitted to the Agency by Elf Atochem on October 31, 1997. These studies provide information on silver trifluoromethane sulfonate (CAS Registry Number 2923-28-6) and do not involve effects in humans.

Nothing in this letter or the enclosed study reports is considered confidential business information of Elf Atochem.

Further questions regarding this submission may be directed to me at (215) 419-5890.

Best Regards,

Debra Randall, DABT
Product Safety Manager

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**A PRIMARY EYE IRRITATION STUDY IN RABBITS WITH
SILVER TRIFLUOROMETHANE SULFONATE**

FINAL REPORT

Author

Deborah A. Douds, M.S.

Study Completed on

November 3, 1997

Performing Laboratory

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SLI Study No.

3255.132

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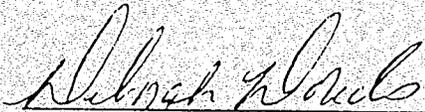
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SLI Study No. 3255.132

(2)

COMPLIANCE STATEMENT

This study was conducted in compliance with the Good Laboratory Practice Standards as described by the EPA (40 CFR Part 792) and the OECD [Annex 2 C(81)30].



Deborah A. Douds, M.S.
Study Director/Author
Springborn Laboratories, Inc.

Date 11/3/97

QUALITY ASSURANCE STATEMENT

This study was inspected by the Quality Assurance Unit and reports were submitted to management and the Study Director in accordance with SLI's Standard Operating Procedures as follows:

<u>Phase</u>	<u>Date</u>
Animal Receipt	09/02/97
Dermal Observations	09/09/97
Data Audit	10/14/97
Draft Report Review	10/14/97
Final Report Review	11/03/97
Reports to Study Director and Management	09/02/97, 10/22/97, 11/03/97

This study was conducted in compliance with the Good Laboratory Practice Standards as described by the EPA (40 CFR Part 792).

Richard J. Clarke
Richard J. Clarke, B.S.
Senior Quality Assurance Auditor

Date 11-3-97

Anita M. Bosau
Anita M. Bosau
Director of Compliance Assurance

Date 11/3/97

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SUMMARY

The potential irritant and/or corrosive effects of Silver Trifluoromethane Sulfonate were evaluated on the skin of New Zealand White rabbits. Each of six rabbits received three 0.50 g doses of the test article as a single dermal application. Each test site was moistened with deionized water to enhance test article contact with the skin. The doses were held in contact with the skin under a semi-occlusive binder for exposure periods of 3 minutes, 1 hour and 4 hours, respectively. Following the 3-minute exposure period, an approximate 2" x 2" section of the overlying elastic wrap was cut and the patch was removed. Any residual test article was removed by wiping the test site with gauze moistened with deionized water. Following the 1-hour exposure period, an approximate 2" x 2" section of the overlying elastic wrap was cut and the patch was removed. Any residual test article was removed by wiping the test site with gauze moistened with deionized water. Following the 4-hour exposure, the binder was removed and the remaining test article was wiped from the skin using gauze moistened with deionized water. Test sites were subsequently examined and scored for potential in-depth injury or dermal irritation for up to 10 days following patch removal.

Exposure to the test article for a three-minute exposure period produced no potential in-depth injury on 2/6 test sites and grade 1 blanching on 1/6 test sites immediately after patch removal and at 1 hour following patch removal.

Exposure to the test article for a one-hour exposure period produced very slight erythema on 5/6 test sites (two of which had focal/pinpoint blanching), slight edema on 6/6 test sites and grade 2 blanching on 1/6 test sites immediately after patch removal. The test sites turned dark purple/black within a few minutes of patch removal. Due to this color, the test sites could not be scored for erythema at the 1, 24 and 48 hour scoring intervals. However, the dermal irritation progressed to eschar on all test sites by the 72 hour scoring interval. The dermal irritation (eschar and very slight to moderate edema) persisted on all test sites through study day 10. Additional dermal findings of desquamation and eschar exfoliation were noted on 1/6 and 6/6 test sites, respectively. After consultation with the Sponsor, it was determined that exposure to light was causing the test article to change color. Therefore, the animals were placed under yellow lighting prior to removal of the four-hour patch.

Exposure to the test article for a four-hour exposure period produced slight to moderate edema on 6/6 test sites immediate after patch removal. Erythema scores were unobtainable due to white test article residue covering the test sites. The dermal irritation progressed to eschar on all test sites by the 48 hour scoring interval. The dermal irritation (eschar and very slight to moderate edema) persisted on all test sites through study day 10. An additional dermal finding of eschar exfoliation was noted on 6/6 test sites.

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Under the conditions of this test, Silver Trifluoromethane Sulfonate is not considered to be corrosive to the skin of the rabbit following a 3-minute exposure, but is considered to be corrosive at the 1-hour and 4-hour exposure periods due to the apparent irreversibility of the injury.

I. INTRODUCTION

This study was performed to assess the potential irritant and/or corrosive effects of Silver Trifluoromethane Sulfonate in New Zealand White rabbits when administered by a single dermal dose. This study is intended to provide information on the potential health hazards of the test article with respect to dermal exposure. Data from this study may serve as a basis for classification and/or labeling of the test article. This study was performed at Springham Laboratories, Inc., 553 North Broadway, Spencerville, Ohio. The protocol was signed by the Study Director on September 5, 1997 (GLP initiation date). The in-life phase of the study was initiated with test article administration on September 9, 1997 and concluded with final scoring on September 19, 1997.

II. MATERIALS AND METHODS

A. Experimental Protocol

The protocol is included in Appendix A.

B. Test Article

The test article was received from the Sponsor and identified as follows:

Sponsor's ID	Assigned SLI ID	Physical Description	Receipt Date	Expiration Date
Silver Trifluoromethane Sulfonate Lot No.: JB-1-196	S97.011.3255	Off-white powder	August 13, 1997	November 4, 1997

The test article was stored at room temperature. The Sponsor is responsible for any necessary evaluations related to chemical composition, purity, strength, stability and other data required by 40 CFR Part 792.105. A Certificate of Analysis for the test article was provided by the Sponsor and is presented in Appendix B.

C. Retention Sample

The Sponsor was responsible for maintaining a retention sample of the test article.

D. Test Article Disposition

The remaining test article was returned to the Sponsor following completion of all studies with the test article.

E. Method of Test Article Preparation

The test article was administered as received from the Sponsor.

F. Animals and Animal Husbandry

1. Description, Identification and Housing

Adult, New Zealand White rabbits were received at SLI from Myrtle's Rabbitry, Thompson Station, TN. Upon receipt, plastic ear tags displaying unique identification numbers were used to individually identify the animals. Cage cards displaying at least the study number, animal number and sex were affixed to each cage. The animals were housed individually in suspended stainless steel cages. All housing and care were based on the standards recommended by the Guide for the Care and Use of Laboratory Animals [1].

2. Environment

The animal room temperature and relative humidity ranges were 68-73°F and 39-49%, respectively. Environmental control equipment was monitored and adjusted as necessary to minimize fluctuations in the animal room environment. Light timers were set to maintain a 12-hour light/12-hour dark cycle and room ventilation was set to produce 10-15 air changes/hour. The animal room temperature and relative humidity were recorded a minimum of once daily.

3. Food

PMI Certified Rabbit Chow #5322 (Purina Mills, Inc.) was provided ad libitum to the animals throughout the study. The lot number and expiration date of each batch of diet used during the study were recorded. The feed was analyzed and certified by the supplier for nutritional components and environmental contaminants. Dietary limitations for various environmental contaminants, including heavy metals, pesticides, polychlorinated biphenyls and total aflatoxin are set by the manufacturer. Within these limits, contaminants which may have been present were not expected to compromise the purpose of this study. Results of the dietary analyses (Certificates of Analysis) are provided by the manufacturer for each lot of diet. These are maintained by SLI.

4. Water

Municipal tap water treated by reverse osmosis was available ad libitum throughout the study. The purified water was supplied by an automatic watering system. Monitoring of the drinking water for contaminants is conducted annually by SLI and the records are available for inspection. Within generally accepted limits, contaminants which may have been present were not expected to compromise the purpose of this study. The water meets the standards specified under the EPA National Drinking Water Regulations (40 CFR, Part 141).

5. Acclimation

Upon receipt, the animals were removed randomly from the shipping cartons, examined by qualified personnel, identified with plastic ear tags and then acclimated to the laboratory conditions for a minimum of five days. The animals were observed daily for overt physical or behavioral abnormalities, general health/moribundity and mortality.

6. Animal Selection

The animals chosen for study use were arbitrarily selected from healthy stock animals to avoid potential bias. All animals received a detailed pretest observation prior to dosing. Only healthy animals were chosen for study use. Females were nulliparous and nonpregnant.

III. EXPERIMENTAL DESIGN AND PROCEDURES

A. Study Group Design

A 3-minute, 1-hour and 4-hour exposure were performed [2].

B. Preliminary Procedures

On day -1, the animals chosen for use on the dermal corrosivity study had the fur removed from the dorsal area of the trunk using an animal clipper. Care was taken to avoid abrading the skin during the clipping procedure.

C. Dosing

On the following day (day 0), the test article was applied to a small area of intact skin on each test animal (approximately 1 inch x 1 inch) for each exposure period (one site per exposure interval) as indicated below:

Exposure Period	Concentration (%)	Amount Applied	Patch Design	No. of Animals	
				Males	Females
3-Minute	100	0.5 g	-1" x 1" square 4-ply gauze patch	2	4
1-Hour	100	0.5 g	-1" x 1" square 4-ply gauze patch		
4-Hour	100	0.5 g	-1" x 1" square 4-ply gauze patch		

For the 3-minute, 1- and 4-hour dosing procedures, the test article was applied to the gauze patch. The test article was then moistened with 0.5 mL of deionized water and the gauze patch applied to the test site. The gauze patch was held in contact with the skin at the cut edges with a nonirritating tape. Removal and ingestion of the test article was prevented by placing an elastic wrap over the trunk and test area (semi-occlusive binding). The elastic wrap was then further secured with adhesive tape around the trunk at the cranial and caudal ends. Using an indelible marker, a dot was placed on the elastic wrap over the area where each test site was located in order to facilitate removal of each patch at the appropriate exposure time interval. After dosing, collars were placed on each animal and remained in place until removal on day 3.

Following completion of the 3-minute exposure period, an approximate 2" x 2" window was cut into the elastic wrap over the first test site and the gauze patch and tape were removed. The corners of the test site were delineated using a marker and the residual test article was removed using gauze moistened with deionized water. Following patch removal for the exposure, the elastic wrap was taped down with nonirritating tape around the cut window in order to insure that the test site remained nonoccluded during the remainder of the study. Following completion of the 1-hour exposure period, an approximate 2" x 2" window was cut into the elastic wrap over the second test site and the gauze patch and tape were removed. The corners of the test site were delineated using a marker and the residual test article was removed using gauze moistened with deionized water. Following patch removal for the exposure, the elastic wrap was taped down with nonirritating tape around the cut window in order to insure that the test site remained nonoccluded during the remainder of the study. Following completion of the 4-hour exposure period, the gauze patch and tape on the third test site and the entire elastic wrap were removed and the corners of the test site delineated using a marker. Residual test article was removed using gauze moistened with deionized water.

Note: Following removal of the 1-hour exposure patch, it was noted that the test sites were turning a dark purple/black color within minutes. It was determined that the test article was reacting with the light. Therefore, prior to removal of the 4-hour exposure patches, the animals were placed under yellow lighting. The animals were subsequently housed and scored under yellow lighting until day 10 when they were scored under normal lighting conditions.

D. Dermal Observations

1. The 3-minute test sites were evaluated for the presence of corrosion immediately after patch removal, 1 hour after patch removal according to the Dermal Grading System for Potential In-depth Injury presented in Protocol Appendix A.
2. The 1-hour test sites were examined for signs of erythema and edema and the responses scored immediately after patch removal and 1 hour after patch removal according to the Macroscopic Dermal Grading System presented in Protocol Appendix B which is based on Draize [3]. The 1-hour sites were further examined for signs of erythema and edema and the responses scores at approximately 24, 48 and 72 hours and up to 10 days after patch application.
3. The 4-hour test sites were examined for signs of erythema and edema and the responses scored immediately after patch removal and 1 hour after patch removal according to the Macroscopic Dermal Grading System presented in Protocol Appendix B which is based on Draize [3]. The 4-hour sites were further examined for signs of erythema and edema and the responses scores at approximately 24, 48 and 72 hours and up to 10 days after patch application.

E. Clinical Observations

Any unusual observations and/or mortality were recorded. General health/mortality checks were performed twice daily (in the morning and in the afternoon).

F. Body Weights

Individual body weights were obtained for each animal prior to dosing on day 0.

G. Scheduled Euthanasia

Each animal was euthanized by an intravenous injection of sodium pentobarbital following its final scoring interval. Gross necropsy examinations were not required for these animals.

H. Protocol Deviations

The lot number of food fed on 9/19/97 was not recorded. Body weights were not obtained from any of the animals prior to scheduled euthanasia. These occurrences were considered to have had no adverse effect on the outcome of this study.

IV. ANALYSIS OF DATA

Each exposure period was evaluated independently. Corrosion was considered to have resulted in any test site that exhibited disintegration or irreversible alteration at the site of contact. Eschar may be defined as corrosion provided that the integrity of the dermis is altered. Corrosion is generally manifested by ulceration and necrosis with subsequent scar tissue formation. Erythema, edema, subcutaneous hemorrhage, fissuring and atonia are not considered evidence of corrosion. For each exposure period, the test article was considered corrosive if corrosion was present in two or more test sites.

V. MAINTENANCE OF RAW DATA AND RECORDS

All original paper data, the final report and magnetically encoded records were transferred to the SLI archives for a period of 10 years. The Sponsor will be contacted prior to final disposition of these items.

VI. RESULTS

A. Dermal Observations:

Individual Data: Tables 1-3

Exposure to the test article for a three-minute exposure period produced no potential in-depth injury on 2/6 test sites and grade 1 blanching on 4/6 test sites immediately after patch removal and at 1 hour following patch removal.

Exposure to the test article for a one-hour exposure period produced very slight erythema on 5/6 test sites (two of which had focal/pinpoint blanching), slight edema on 6/6 test sites and grade 2 blanching on 1/6 test sites immediately after patch removal. The test sites turned dark purple/black within a few minutes of patch removal. Due to this color, the test sites could not be scored for erythema at the 1, 24 and 48 hour scoring intervals. However, the dermal irritation progressed to eschar on all test sites by the 72 hour scoring interval. The dermal irritation (eschar and very slight to moderate edema) persisted on all test sites through study day 10. Additional dermal findings of desquamation and eschar exfoliation were noted on 1/6 and 6/6 test sites, respectively. After consultation with the Sponsor, it was determined that exposure to light was causing the test article to change color. Therefore, the animals were placed under yellow lighting prior to removal of the four-hour patch.

Exposure to the test article for a four-hour exposure period produced slight to moderate edema on 6/6 test sites immediate after patch removal. Erythema scores were unobtainable due to white test article residue covering the test sites. The dermal irritation progressed to eschar on all test sites by the 48 hour scoring interval. The dermal irritation (eschar and very slight to moderate edema) persisted on all test sites through study day 10. An additional dermal finding of eschar exfoliation was noted on 6/6 test sites.

VII. CONCLUSION

Under the conditions of this test, Silver Trifluoromethane Sulfonate is not considered to be corrosive to the skin of the rabbit following a 3-minute exposure, but is considered to be corrosive at the 1-hour and 4-hour exposure periods due to the apparent irreversibility of the injury.



Deborah A. Douds, M.S.
Study Director

Date

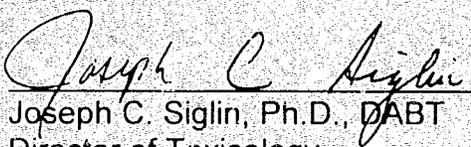
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VIII. REPORT REVIEW



Kimberly L. Bonnette, M.S., LATG
Manager of Acute Toxicology

Date 11/3/97



Joseph C. Siglin, Ph.D., DABT
Director of Toxicology

Date 11/3/97

IX. REFERENCES

1. Guide for the Care and Use of Laboratory Animals, DHHS Publication No. (NIH) 96-03, 1996.
2. U.S. Department of Transportation, 49 CFR, Part 173, Sections 173.136, 173.137 and Appendix A, October 1, 1993.
3. Draize, J.H., Appraisal of the Safety of Chemicals in Foods, Drugs and Cosmetics, The Association of Food and Drug Officials of the United States, 49-51, 1959.