TXR 002486

12/5/74

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

DATE: December 3, 1974

SUBJECT: 002486

FROM:

TO: Mr. Jesse E. Mayes, Acting Chief
Coordination Branch
Registration Division (WH-567)

Registration No.: 34292-R

Product Name: X9-5700 Bacteriostat, Fungistat and Algistat

Registrant: Dow Corning Corp

Action Requested: Registration of new chemical

Formulation: X9-5700

50% - 3(trimethoxysilyl) propyldimethyloctadecyl ammonium chloride

Inert

50% - methanol

Use: On textiles

Application Rate: 0.1 - 1.0 weight percent of active ingredients depending on the textile

Application Method: Submersion

Toxicity Data

Acute Rat Oral LD_{50} (50% formulation)*

The test material was identified as Dow Corning X-9-5700, Lot AD-0003.

[redacted] Manufacturing process information not included.

42% $(MeO)_3Si(CH_2)_3N^{\oplus}(Me)_2$

$C_{18}H_{37}Cl^{\ominus}$

50% MeOH

EPA Form 1320-6 (Rev. 6-72)

Five Sprague-Dawley rats of each sex were tested per level of 3.98, 7.95, 15.8 and 31.6 gms/kg. The material was administered undiluted.

Results

LD_{50} = 12.27 gms/kg ± 0.16 gms/kg

Acute Rabbit Dermal LD_{50} (50% formulation)*

The test material was identified as Dow Corning X-9-5700, Lot AD-0003.

Four New Zealand albino rabbits were tested per level of 2.00, 3.98 and 7.95 gms/kg. The test material was administered undiluted to the clipped and unabraded test sites. Exposure was for 24 hours.

Results

No deaths occurred. LD_{50} is greater than 7.95 gms/kg.

Acute Rabbit Eye Irritation (50% formulation)*

The test material was identified as Dow Corning X-9-5700, Lot AD-0003.

Two drops of the test material were placed into each eye of six rabbits. The left eye was washed within 30 seconds for two minutes. Observations were made at 1, 24, 48 hrs. and 7 days and 14 days.

Results

Severe irritation and tissue destruction was present at 7 and 14 days. Category I labeling is indicated.

Primary Rabbit Dermal Irritation (50% formulation)*

The test material was identified as Dow Corning X-9-5700, Lot AD-0003.

Approximately 0.5 ml was applied to three test sites--the ear, the intact abdomen and the abraded abdomen. Three consecutive daily applications were made.

Results

Slight to moderate irritation was observed during the first twelve days on all animals. Irritation was noted 3/6 for the ear, 1/6 intact skin and 1/6 abraded skin at termination of the study.

[redacted]

42% $(MeO)_3Si(CH_2)_3N^{\oplus}(Me)_2C_{18}H_{37}Cl^{\ominus}$

50% MeOH

Manufacturing process information not included.

Rabbit Eye Irritation

The test materials were a 10% and a 2% solution of the Corning X-9-5700 which is a 50% formulation. Both washed and unwashed eyes were tested.

Results

10% w/v - produced moderate irritation and slight corneal injury in washed eyes. Normal by day seven. Unwashed eyes exhibited severe conjunctivitis and corneal injury. Corneal injury persisted thru day 7 but was normal by day 10.

2% w/v - Produced moderate conjunctivitis and slight corneal injury in washed and unwashed eyes. Normal at 48 hours.

Comment - These eye irritation data were presented by the registrant in a summarized form. Based on this somewhat restricted data the signal "Danger" must be required on the 10% w/v labels to reflect the ocular hazards.

Subacute Rabbit Dermal

Material	Site of Application	Condition of skin	No. of Applications	Response
10% w/v Dow Corning X-9-5700 (5% solids)	Ear	Intact	10	None
	Belly	Intact	10	Slight exfoliation after 5 applications
	Belly	Abraded	3	None
2% w/v Dow Corning X-9-5700 (1% solids)	Ear	Intact	10	None
	Belly	Intact	10	Slight exfoliation after 5 applications
	Belly	Abraded	3	None

Human Repeated Insult Patch Test

The material tested was identified as TX-793 (Dow Corning X-9-5700).

Approximately 0.03 ml of a 2.0% w/v aqueous solution of the test material was applied under a gauge patch to fifty test subjects three times a week for three weeks. Each exposure was for 24 hours. After the ninth sensitizing application, the subjects had a rest period of two weeks before receiving the challenge patch. The site chosen for the 24 hour challenge patch was adjacent to a sensitizing site. The

fifty test subjects were selected as outlined below.

Number	Sex	Race	Number of Subjects	Age Range (years)
1-22	Male	Caucasian	22	17-36
23-24	Male	Negro	2	23-39
25	Male	Oriental	1	33
		Subtotal	25	
26-49	Female	Caucasian	24	16-42
50	Female	Oriental	1	38
		Subtotal	25	
		Total	50	16-42

Results

Two of the fifty subjects each reacted once to the application of the test material. The reactions consisted of very slight edema and erythema. No sensitization was reported.

28 Day Rabbit Dermal With Treated Fabrics - 12/31/73

The two fabrics treated with the test material were identified as TX991-A (0.5% treatment) and TX991-B (50% treatment).

Five rabbits of each sex were used per treatment level of 1X (0.5%) and 10X (5.0%) where 1X is the use concentration.

Approximately sixty square inches of fabric were allowed to contact the shaved skin for six hours per day, for five days a week for four weeks. Two animals in each level were tested with abraded skin. All test sites were premoistened with normal saline.

Observations and tests for effects included mortality, abnormal behavioral reactions, local skin reactions, weekly body weights, RBC, hemoglobin conc., hematocrit value, total leukocyte count, differential leukocyte count, fasting blood glucose conc., BUN, SAP, SGPT, SGOT, glucose, albumin, pH of urine, and microscopic examination of the following tissues:

Adrenal Glands
Aorta
Brain
Peripheral Nerve (sciatic)
Pituitary Gland
Prostate Gland

Caecum	Salivary Glands
Colon	Seminal Vesicle
Esophagus	Skeletal Muscle (thigh)
Gall Bladder	Skin from the Control and Application Sites
Gonads	Small Intestine (duodenum, jejunum, and ileum)
Kidneys	Spleen
Liver	Sternum
Lungs	Stomach
Lymph Nodes (mediastinal and mesenteric)	Thyroid Gland
Pancreas	Trachea
Parathyroid Glands	Urinary Bladder
	Uterus

Results

The treated fabrics were non-irritating to the skin. All others parameters were unremarkable.

Summary

Acute Rat Oral LD_{50} (50% formulation) - 12.27 gms/kg
Acute Rabbit Dermal LD_{50} (50% formulation) - > 7.95 gms/kg
Acute Rabbit Eye Irritation (50% formulation) - severe irritation and tissue destruction
Acute Rabbit Eye Irritation (50% formulation) - 10% w/v produced corneal damage
2% w/v normal at 48 hours
Acute Rabbit Dermal Irritation (50% formulation) - slight to moderate irritation
Subacute Rabbit Dermal (50% formulation) - 10% w/v and 2% w/v dilutions produced from none to slight irritation
Human Repeated Patch Test (50% formulation) - very slight irritation noted in 2 of 50 subject once only- no sensitization noted
28 Day Rabbit Dermal With Treated Fabrics - fabrics containing one or ten times the use concentration produced no adverse local or systemic toxicity.

Conclusion

These toxicity data clearly show this formulation to exhibit a low degree of acute oral and acute dermal lethal toxicity. The acute and subacute effects of local dermal contact do not indicate an undue human health

hazard. The eye irritation studies with both the undiluted X-9-5700 product and the 10% w/v dilution, clearly show adverse ocular alterations. These findings are severe enough to require Category I labeling for the X-9-5700 product if it is registered.

According to our guidelines, the following data are required in addition to that submitted before this product can be considered for registration.

1) Acute Rat Inhalation LC_{50} (X-9-5700)
2) 21 day rat inhalation at one and 5 times the expected air concentration in the treatment area of the factory.
3) Acute rat oral LD_{50} on the active ingredient
4) Acute rabbit dermal LD_{50} on the active ingredient
5) Acute rat inhalation LC_{50} on the active ingredient

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cc: Branch File
Division File

RDCoberly/km 12-04-74