TXR 002487

Coberly 10

89013

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

10740/

SUBJECT: File Symbol 34292-R
X9-5700 Bacteriostat, Fungistat and Algistat
Dow Corning Corp.

DATE: June 11, 1975

FROM: TB

TO: PRODUCT MANAGER 31

Action Requested: Registration of New Chemical

Recommendation : No Adverse Comment

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 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

[redacted] Manufacturing process information not included.

42% $(MeO)_3Si(CH_2)_3\overset{\oplus}{N}(Me)_2$

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

EPA Form 1320-6 (Rev. 4-72)

28 Day Rabbit Dermal With Treated Fabrics - fabrics containing one or ten times the use concentration produced no adverse local or systemic toxicity

BACKGROUND INFORMATION

As of the results of the TB review of December 3, 1974 the following toxicity data were requested by TB in order to fully evaluate the proposed formulation.

1) Acute rat inhalation LC_{50} (X-2-5700).
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.

As a direct result of these data requirements, Dow Corning representatives met with us on January 21, 1975. It was explained to us that without the solvent methanol, the 3(trimethoxysilyl) propyldimethyloctadecyl ammonium chloride is an ionic moiety which is not volitile and a polymer. In other words, the 50% product is really the technical material on which toxicity data had already been provided. Based on this explanation, we omitted items 2, 3 and 4 of the data requirements. They agreed to provide item number 1.

The 21 day inhalation study was to be held in abeyance until an air sampling study determined if there was air contamination resulting from use of the product. If a reading of greater than zero was found, then the study would be necessary.

PRESENT ACTION

Dow Corning submitted the following data:

Acute Rat Inhalation (X9-5700) LC_{50} => 81.9 mg/L

Air Sampling Study May 27, 1975

METHOD

A. Methanol Vapor Determination

In a 6 x 8 x 8 ft. enclosed room, a 600 ml beaker containing 300 ml of distilled water was mechanically stirred and heated to 70°C. Dow Corning Q9-5700, lot #3 (25.0 g) and an additional 175 ml of distilled water were added in order to obtain a final concentration of five weight percent Dow Corning Q9-5700 in water. This concentration is five times the maximum usage rate recommended in proposed accompanying product labeling. An air sample (five liters over five minutes) was collected immediately at a point six inches above and one inch to the side of the bath and contained within a five liter Saran® gas bag. A second air sample was collected utilizing the same method after three hours. These samples were analyzed for methanol by Dow Corning's Toxicology and Industrial Hygiene Department using a Perkin-Elmer Infrared Spectrometer with a 20 meter gas cell.

B. Airborne Amine Determination

An air sample from this same batch of Dow Corning Q9-5700 was sampled at the same point and collected for amine analysis. The sample was continuously collected for a period of 75 minutes employing a portable pump which pulled 1.35 liters of air per minute through a smalled canister of Saran charcoal. The charcoal was exposed to a total of 100 liters of collected air. Immediately following this first sampling/collecting period, a second canister of Saran charcoal was exposed for the next 2-1/2 hours until an additional volume of 200 liters of air was collected. The charcoal canisters were submitted to the Dow Corning Analytical Department along with appropriate controls for individual amine analysis.

Results

A) Methanol Conc. - The initial five minute air sample contained 13 ppm of methanol. The second sample contained [illegible].

B) The 75 minute collection of 100 liters of air contained 16.8 mg of amine or 0.168 mg/L. The 2.25 hour collection of 200 liters of air contained [illegible].

Manufacturing process information not included.

DISCUSSION - According to Dow Corning, the method of analysis used (CTM-0094) will determine the presence of both the silicone quaternary amine and the unreacted amine starting material [redacted] This starting material has been shown by chemical analysis of lot #3 of Q9-5700, to be present at the maximum of [redacted] No rodent inhalation data are available on the starting material. However, the manufacturers conclude it to be free from any known adverse inhalation hazard due to extended industrial experience.

CONCLUSION: This reviewer believes that the proposed user of this product will result in air contamination. This theory is supported by the air sampling study provided by Dow. Since humans will be exposed to this air contamination over extended periods of time, only chronic or subacute inhalation studies can reveal the possible health hazards. However, since the Act does not charge us with determining the safety of pesticides used in industrial manufacturing sites, we cannot require this type of toxicity data.

The toxicity data submitted satisfies the requirements for registration.

Robert D. Coberly, Biologist
Toxicology Branch
Registration Division

CC: Branch Reading File
RCoberly:jem: 6/11/75
Initial O. E. Paynter

TXR 002487 R046786

Page _____ is not included in this copy.

Pages 5 through 8 are not included in this copy.

The material not included contains the following type of information:

_____ Identity of product inert ingredients.

_____ Identity of product impurities.

_____ Description of the product manufacturing process.

_____ Description of quality control procedures.

_____ Identity of the source of product ingredients.

_____ Sales or other commercial/financial information.

_____ A draft product label.

_____ The product confidential statement of formula.

_____ Information about a pending registration action.

X_____ FIFRA registration data.

_____ The document is a duplicate of page(s) _____.

_____ The document is not responsive to the request.

The information not included is generally considered confidential by product registrants. If you have any questions, please contact the individual who prepared the response to your request.

13544

046786

Chemical:	**1-Octadecanaminium, N,N-dimethyl-N-(3-(t**
PC Code:	**107401**
HED File Code	**13100 Other Tox Documents**
Memo Date:	**06/11/75**
File ID:	**00000000**
Accession Number:	**412-03-0116**

HED Records Reference Center
06/30/2003