UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

007667

JAN - 5 1990

OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

MEMORANDUM

SUBJECT: Review of 3 Studies Submitted: (a) Eye, (b) Skin Irritation and (c) Inhalation on Dow Corning X-9-5700 to Fulfill Reregistration Requirements
ID# 34292-1

Tox Chem. No.: 892B
Project No.: 9-2248
Record No.: 253085

TO: Jim Wilson, P.M. #31
Registration Branch
Review Reregistration Division (H7508C)

FROM: Henry Spencer, Ph.D. 12/4/89
Review Section II
Toxicology Branch I - Insecticide, Rodenticide Support
Health Effects Division (H7509C)

THRU: Marion Copley, D.V.M., Section Head 12/28/89
Review Section II
Toxicology Branch I - Insecticide, Rodenticide Support
Health Effects Division (H7509C)

Conclusions:

1. The data submitted for eye and dermal irritation evaluations are a conglomerate of old summary data and are incomplete (MRID# 411578-01, MRID# 411578-02) and therefore are useless. These are data gaps.

2. Only a more recent study (acute inhalation toxicity - MRID# 411578-03) by Dow Corning was reviewed and classified as core supplementary.

1

Comments:

Skin and Eye Irritation Studies (MRID# 411578-01 and 411578-02)

1. Individual data are missing, and importantly the skimpy information is incorrectly referred to as "Q9-5700 in MRID# 4115788-99. In either case these two pieces of "data" will not be reviewed as studies in their present condition: i.e., no inclusion of the number of animals used, and individual data and scores and source, age, etc. for the findings. These several toxicity areas remain data gaps.

2. Review of Acute Inhalation study with Dow Corning 5772 Compound in rats indicates that Dow Corning 5772 compound is of rather low inhalation toxicity. This remains a data gap and needs to be upgraded.

Primary Review By: Henry Spencer 12/4/89
Section II, Toxicology Branch I/HED

Secondary Review by: Marion Copley, DVM, Section Head 12/28/89
Section II, Toxicology Branch I/HED

DATA EVALUATION REPORT

Study Type: Acute Inhalation Toxicity
Tox Chem. No. 892B
MRID No.: 411578-03
Project No.: 9-2248

Test Material: Dow Corning 5772
Lots 2,3,4 from New Ventures TS&D purity not stated
Mixed 20% by weight in distilled water
pH adjusted to 55 with glacial acetic acid

Study No.: 1312

Sponsor: Dow Corning Corporation

Testing Facility: Dow Corning Corp., Department of Toxicology, Midland, MI 48640

Title of Report: An Acute Aerosol Inhalation Toxicity Study with Dow Corning 5772 Compound in Rats

Author: C. B. Kolesar, W. H. Siddique and E. Stanton

Report Issued: February 15, 1985

Conclusions:

In a 4 hr. exposure to 0.35 and 0.45 mg/L of Dow Corning 5772 test material as an aerosol toxicity noted was minimal and the LC50 was greater than 0.45 mg/L (HDT). Tox. Cat. II.

Core: Supplementary - requested rational for such low test doses used. Purity of test compound not provided. The study may be upgraded.

Methods

Male and female rats of the Sprague-Dawley strain weighing 175-200 gm. were purchased from Charles River and acclimated for 7 days prior to experimentation.

Animals were offered Purina Rodent chow and water libiturn excepting at exposure.

Temperature in observation rooms was 22+2 C and relative humidity was kept at 30-50%.

The animals were exposed in 450 liter chambers under dynamic conditions with 9-17 air changes per hour.

Spraying Systems Inc., Chicago, IL provided the aerosoling equipment.

Mass concentrations of the aerosol in the chamber was sampled each 30 minutes.

Particle size and ranges were determined using a cascade impactor.

Two control groups were used int he study. One control group of 5 per/sex was matched and studied concurrently with the 0.35 mg/L test group and the second was used concurrently the following day with the 0.45 mg/L test group.

After the 4 hr exposure, the animals were held for 14 days with observations only on the week days.

Body wts were determined prior to exposure and on days 1,2,4,7 and 14 post exposure.

Lungs were weighted when test animals were sacrificed. A signed QA statement was present.

Result

Relative humidity was elevated in the Test Dose II group over controls. Controls were in approximately 50% RH and the test group II (0.45 mg/L) was in an (TWA) average of 75% RH for the 4 hr. period.

Particle Size:

The particle size (geometric mean particle size (Micrometer) was 1.3+0.1 for the 0.35 mg/L test group and 2.3+0.1 for the 0.45 mg/L group.

Toxicity:

There were no deaths. Body weights were reduced significantly in males on days 1 and 2 post exposure in the Test 1 group and in both males and females at 1, 2 and 4 post exposure days in Test 2 animals.

Lung Weights:

Absolute and relative lung weights were increased (though not significantly) in the test group males and females.

Females in group 2 test animals produced slight (not statistically significant) decreases in absolute and relative lung weights. Lung weights in males were not consistent.

Conclusion:

The dose of 0.35 mg/L produced minimal toxicity as reduction in net gain for a short post exposure period.

Toxicity was more evident (weight loss) at 0.45 mg/L exposure. No deaths occurred at either dose throughout the exposure and observation period.

The LC_{50} is greater than 0.45 mg/L following a 4 hour exposure.

The study does not allow for a toxicity of less than Tox. Cat.II.

Purity of the D.C. 5772 compound must be provided.