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Chemical:	**1-Octadecanaminium, N,N-dimethyl-N-(3-(t**
PC Code:	**107401**
HED File Code	**13000 Tox Reviews**
Memo Date:	**10/13/94**
File ID:	**TX011292**
Accession Number:	**412-02-0281**

HED Records Reference Center
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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

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OPP OFFICIAL RECORD
HEALTH EFFECTS DIVISION
SCIENTIFIC DATA REVIEWS
EPA SERIES 361

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

MEMORANDUM

SUBJECT: EPA ID No. 107401-034292, Reregistration Case # 3148; Dow Corning 5772 Antimicrobial Agent; Containing 3-(Trimethoxysilyl) propyldimethyloctadecyl Ammonium Chloride as the Active Ingredient; Review of Acute Dermal Toxicity Study on Rabbits and Comment on Developmental Toxicity Study on Rats

DP Barcode D203155
Case 816088
Submission S465158

Tox. Chem. No. 892B
P.C. Code No. 107401
MRID No. 432199-01

FROM: Edwin R. Budd, Toxicologist
Review Section III
Toxicology Branch I
Health Effects Division (7509C)

Budd 10/5/94

TO: Dona Canales/Virginia Dietrich
Product Manager Team 51
Special Review and Reregistration Division (7508W)

THRU: Karen Hamernik, Ph.D., Section Head
Review Section III
Toxicology Branch I
Health Effects Division (7509C)

10/5/94 10/14/94

I. ACTION REQUESTED

A. Review acute dermal toxicity study on rabbits (Guideline 81-2, MRID # 432199-01) using Dow Corning 5772 Antimicrobial Agent as the test material contained in submission from Dow Corning Corporation, dated April 15, 1994.

B. Comment on acceptability of developmental toxicity study on rats (Guideline 83-3(a), MRID # 414380-03) referred to in same submission of April 15, 1994.

II. CONCLUSIONS/RECOMMENDATIONS

A. The subject acute dermal toxicity study on rabbits (MRID # 432199-01) has been reviewed. The acute dermal LD50 of the test material is > 2,000 mg/kg (Toxicity Category III). The

study is classified as "Acceptable", and satisfies the requirement for an acute dermal toxicity study (Guideline 81-2). An Executive Summary for this study is presented below and a DER is attached.

EXECUTIVE SUMMARY: In an acute dermal toxicity study on albino rabbits (Guideline 81-2), a single dose of 2,000 mg/kg of undiluted Dow Corning 5772 Antimicrobial Agent was uniformly applied to the clipped dorsal surface area of the trunk of each of 10 (5/sex) New Zealand strain rabbits. The application was to intact skin only and covered approximately 10% of the total body surface area of each rabbit. Following a 24 hour exposure period, the wrappings were removed and the treated skins were washed with tap water. The rabbits were then observed twice daily for signs of toxicity and behavioral abnormalities during a 14 day observation period. No mortalities, signs of toxicity or behavioral changes were observed during the 14 day observation period. No effects on body weight gains or food consumption were noted. Necropsies did not reveal any treatment related effects due to the test material. **The acute dermal LD50 in rabbits for Dow Corning 5772 Antimicrobial Agent is > 2,000 mg/kg (Toxicity Category III).**

This study is classified as "Acceptable" and satisfies the requirement for an acute dermal toxicity study (Guideline 81-2).

B. The developmental toxicity study on rats (Guideline 83-3(a), MRID # 414380-03) referred to in the Dow Corning Corporation submission of April 15, 1994 has previously been reviewed in Toxicology Branch I. See memorandum from John Redden to Jim Wilson/John Lee (PM Team # 31, RD), dated July 10, 1991 and memorandum from John Redden to Valdis Goncarovs (Antimicrobial Branch, RD), dated April 1, 1993. This study is currently classified as Core Minimum and satisfies the requirement for a developmental toxicity study in one species (Guideline 83-3(a)). It should be noted that the test material in this study was Dow Corning 5700 Hydrolysate, 3-(hydroxysilyl) propyldimethyloctadecyl ammonium chloride.

Reviewed by: Edwin R. Budd, M.A. Budd 10/5/94
Review Section III, Toxicology Branch I, HED (7509C)
Secondary Reviewer: Karen Hamernik, Ph.D., Section Head
Review Section III, Toxicology Branch I, HED (7509C)

DATA EVALUATION REPORT

Study Type: Acute Dermal Toxicity, Rabbits
EPA Subdivision F Guideline 81-2

Test Material: Dow Corning 5772 Antimicrobial Agent
(Dow Corning X9-6346)

Tox. Chem. No.: 892B

P.C. Code No.: 107401

MRID No.: 432199-01

Study Title: Acute Dermal Toxicity Study of DOW CORNING X9-6346
(DOW CORNING 5772 Antimicrobial Agent)

Testing Laboratory: Toxicology Department
Health & Environmental Sciences
Dow Corning Corporation (Midland, MI)

Laboratory Project I.D.: 4211-3

Authors: C. R. DeVries, W. H. Siddiqui

Report Date: February 17, 1983

Sponsor: Dow Corning Corporation
(Midland, MI)

EXECUTIVE SUMMARY: In an acute dermal toxicity study on albino rabbits (Guideline 81-2), a single dose of 2,000 mg/kg of undiluted Dow Corning 5772 Antimicrobial Agent was uniformly applied to the clipped dorsal surface area of the trunk of each of 10 (5/sex) New Zealand strain rabbits. The application was to intact skin only and covered approximately 10% of the total body surface area of each rabbit. Following a 24 hour exposure period, the wrappings were removed and the treated skins were washed with tap water. The rabbits were then observed twice daily for signs of toxicity and behavioral abnormalities during a 14 day observation period. No mortalities, signs of toxicity or behavioral changes were observed during the 14 day observation period. No effects on body weight gains or food consumption were noted. Necropsies did not reveal any treatment related effects

due to the test material. **The acute dermal LD50 in rabbits for Dow Corning 5772 Antimicrobial Agent is > 2,000 mg/kg (Toxicity Category III).**

This study is classified as "Acceptable" and satisfies the requirement for an acute dermal toxicity study (Guideline 81-2).

I. DETAILED REVIEW:

A. Test Material: Dow Corning 5772 Antimicrobial Agent; Dow Corning X9-6346; identified as TX-83-9010-02; containing 3-(trimethoxysilyl) propyldimethyloctadecyl ammonium chloride; as the active ingredient, purity = 72%

Description: tan colored viscous liquid

B. Test Animals: Albino rabbits, New Zealand white strain, males and females

Description: from Langshaw Farms, Augusta, Michigan; quarantined for 7 days prior to treatment; approximately 2.5 kg

Environment: Housed individually in stainless steel cages; standard environmental conditions (temperature, humidity and light controlled room); Purina Rabbit Chow and fresh water ad libitum

C. Study Design: A single dose of 2,000 mg/kg of undiluted Dow Corning 5772 Antimicrobial Agent was uniformly applied to the clipped dorsal surface area of the trunk of each of 10 (5/sex) young rabbits. The application was to intact skin only and covered approximately 10% of the total body surface area of each rabbit. The test material was held in contact with the skin with gauze dressings and bandages. Following a 24 hour exposure period, the wrappings were removed and the treated skins were washed with tap water. The rabbits were then observed twice daily for signs of toxicity and behavioral abnormalities during a 14 day observation period. The animals were weighed weekly and a complete gross pathological examination was conducted on all animals at 14 days post application.

D. Quality Assurance and GLP Compliance: Signed quality assurance and GLP compliance statements were present.

E. Observations and Results: No mortalities, signs of toxicity or behavioral changes were observed during the 14 day observation period. No effects on body weight gains or food consumption were noted. Necropsies did not reveal any treatment related effects due to the test material. The acute dermal LD50 of the test material was > 2,000 mg/kg (Toxicity Category III).

F. Reviewer Comments: This study is classified as "Acceptable", and satisfies the requirement for an acute dermal toxicity study (Guideline 81-2).