

US EPA ARCHIVE DOCUMENT



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CASWELL FILE

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

JAN 9 1990
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007676

MEMORANDUM

OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

SUBJECT: ARSENIC ACID - ACUTE ORAL TOXICITY STUDY

TO: E. FERIS
PRODUCT MANAGER (74)
REGISTRATION DIVISION (H7505C)

FROM: LINDA L. TAYLOR, PH.D. *Linda Lee Taylor 1/4/90*
TOXICOLOGY BRANCH II, SECTION II
HEALTH EFFECTS DIVISION (H7509C)

THRU: K. CLARK SWENTZEL *K. Clark Swentzel 1/5/90*
SECTION II HEAD, TOXICOLOGY BRANCH II
HEALTH EFFECTS DIVISION (H7509C)

AND

MARCIA VAN GEMERT, PH.D. *Marcia van Gemert 1/5/90*
CHIEF, TOXICOLOGY BRANCH/HFAS/HED (H7509C)

REGISTRANT: PENNWALT CORPORATION
CHEMICAL: ARSENIC ACID
SYNONYM: NONE
PROJECT: 0-0233
CASWELL No.: 56
RECORD No.: 255118
IDENTIFYING No.: 4581-231
MRID No.: 404090-01
ACTION REQUESTED: PLEASE REVIEW DATA.

COMMENT: IN RESPONSE TO THE EPA REGISTRATION STANDARD FOR NON-WOOD PRESERVING USES OF ARSENIC ACID (DATED SEPTEMBER 10, 1986), AN ACUTE ORAL STUDY WAS SUBMITTED. THIS WAS RECEIVED IN TB II ON NOVEMBER 29, 1989.

THE STUDY HAS BEEN REVIEWED AND THE DER IS ATTACHED.

UNDER THE CONDITIONS OF THIS STUDY, THE LD50 FOR ARSENIC ACID (75% W/W) WAS DETERMINED TO BE 141 MG/KG FOR MALE MICE, 160 MG/KG FOR FEMALE MICE, AND 150 MG/KG FOR THE COMBINED SEXES.

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REVIEWED BY: LINDA L. TAYLOR, PH.D.
TOX. BRANCH II, SECTION II (H7509C)
SECONDARY REVIEWER: K. CLARK SWENTZEL
HEAD SECTION II, TOX. BRANCH II (H7509C)

Linda L. Taylor 1/4/90
K. Clark Swentzel 1/5/90

DATA EVALUATION REPORT

STUDY TYPE: ACUTE ORAL LD₅₀ - MICE

TOX CHEM NO: 56

ACCESSION NO.: 404090-01

TEST MATERIAL: ARSENIC ACID

SYNONYMS: NONE

STUDY NUMBER: HLA 70602444

SPONSOR: PENNWALT CORPORATION, PUYALLUP, WASHINGTON

TESTING FACILITY: HAZLETON LABORATORIES AMERICA, INC.

TITLE OF REPORT: ACUTE ORAL TOXICITY STUDY OF ARSENIC ACID: 75% w/w IN MICE

AUTHORS: STEVEN M. GLAZA

REPORT ISSUED: OCTOBER 16, 1987

QUALITY ASSURANCE: A QUALITY ASSURANCE STATEMENT WAS PROVIDED.

CONCLUSIONS: UNDER THE CONDITIONS OF THIS STUDY, THE LD₅₀ FOR ARSENIC ACID (75% w/w) WAS DETERMINED TO BE 141 MG/KG FOR MALE MICE, 160 MG/KG FOR FEMALE MICE, AND 150 MG/KG FOR THE COMBINED SEXES.

CLASSIFICATION: CORE: GUIDELINE. THIS STUDY SATISFIES THE GUIDELINE REQUIREMENTS (81.1) FOR AN ACUTE ORAL STUDY.

TOXICITY CATEGORY: II

A. MATERIALS:

1. TEST COMPOUND: ARSENIC ACID

DESCRIPTION: CLEAR, GREEN LIQUID

PURITY: STATED TO BE THE SPONSOR'S RESPONSIBILITY (ALSO THE STABILITY)

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2. TEST ANIMALS:

SPECIES: MOUSE
STRAIN: ALBINO CRL: CD-1 (ICR)BR
AGE: NOT PROVIDED
WEIGHT: 18-25 GRAMS
SOURCE: CHARLES RIVER LABORATORIES, INC., PORTAGE, MI

STUDY DESIGN: FIVE MALE AND 5 FEMALE MICE PER DOSE GROUP WERE ADMINISTERED (GAVAGE) THE TEST MATERIAL IN SINGLE DOSES OF 75, 100, OR 200 MG/KG (DOSE VOLUME 10 ML/KG). NO CONTROLS WERE UTILIZED. ALL ANIMALS WERE OBSERVED FOR CLINICAL SIGNS AND MORTALITY AT 1, 2.5, AND 4 HOURS FOLLOWING DOSING AND DAILY THEREAFTER (CLINICAL SIGNS) UP TO DAY OF SACRIFICE (DAY 14) AND TWICE DAILY FOR MORTALITY. ALL ANIMALS WERE WEIGHED PRIOR TO DOSING AND AT 7 AND 14 DAYS (OR AT DEATH). ALL ANIMALS WERE SUBJECTED TO NECROPSY.

RESULTS: WITH THE EXCEPTION OF ONE DEATH (HIGH-DOSE FEMALE) ON DAY 3, ALL DEATHS OCCURRED ON DAY ONE (ONE/SEX AT THE MID DOSE AND 4 MALES, 2 FEMALES AT THE HIGH DOSE). CLINICAL SIGNS OBSERVED IN THE MID- AND HIGH-DOSE ANIMALS ONLY INCLUDED HYPOACTIVITY, ATAXIA, AND TREMORS. ALL CLINICAL SIGNS HAD DISAPPEARED BY DAY 4. ALL GROUPS GAINED WEIGHT OVER THE COURSE OF THE STUDY; THE GAINS FOR EACH GROUP ARE LISTED BELOW

GROUP	BODY-WEIGHT GAIN (GRAMS)	
	MALES	FEMALES
LOW	7.6	3.8
MID	8.4	1.4
HIGH	8.4	2.0

AT NECROPSY, MACROSCOPIC FINDINGS INCLUDED THE FOLLOWING.

MACROSCOPIC FINDING

STOMACH - CONTAINS DARK BROWN SEMIFLUID MATERIAL: ONE LOW-DOSE MALE
UTERUS - LUMEN FILLED WITH CLEAR FLUID: ONE LOW-DOSE FEMALE
PERINEUM - STAINED BROWN: ONE MID-DOSE/4 HIGH-DOSE MALES
ONE MID-DOSE/3 HIGH-DOSE FEMALES

UNDER THE CONDITIONS OF THIS STUDY, THE LD₅₀ FOR ARSENIC ACID (75% W/W) WAS DETERMINED TO BE 141 MG/KG FOR MALES, 160 MG/KG FOR FEMALES, AND 150 MG/KG FOR THE COMBINED SEXES.

CONCLUSION: LD₅₀ FOR ARSENIC ACID IN MICE WAS FOUND TO BE 141 MG/KG FOR MALES AND 160 MG/KG FOR FEMALES. THIS STUDY IS CLASSIFIED AS CORE GUIDELINE.

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