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

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OFFICE OF
PESTICIDES AND TOXIC
SUBSTANCES

MEMORANDUM

Subject: EPA ID # 10182-293: Captan Technical - Response to ICI's comments to Agency questions on 1 year chronic dog study (MRID No. 408936-04)
Tox. Chem. Number: 159
Project Number: 1-1239
Submission Number: S395961

From: Paul Chin, PhD
Section 2
Toxicology Branch I
Health Effects Division (H7509C)

Paul Chin 12/12/91

To: Carol Peterson, PM 71
Reregistration Branch
Special Review and Reregistration Division (H7508W)

Thru: Joycelyn Stewart, Ph.D.
Acting Section Head
Section 2, Toxicology Branch I
Health Effects Division (H7509C)

12/17/91 KB 12/30/91

Registrant: ICI Americas, Inc.

CONCLUSIONS:

The Toxicology Branch I concludes that the above 1-year oral toxicity study in dogs with Captan technical has been adequately conducted. Thus, Toxicology Branch I is upgrading the study (MRID No. 408936-04, Study No. IRDC 151-198) from core-supplementary to core-minimum. This study satisfy the guideline requirement No. 83-1 for a chronic (oral) non-rodent. This memorandum will serve as a supplement to the DER (HED Document No. 006978, dated Dec. 21, 1988).

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TOXICOLOGY BRANCH EVALUATION OF ICI'S COMMENTS:

Questions raised by the Toxicology Branch and ICI's comments are listed below; Toxicology Branch comments follow each item.

Toxicology Branch Request

There are several reporting deficiencies including:
- no reported purity or percent a.i. for the technical,
- no stability data for captan technical and
- no information on the concentration of the 5 gm samples of captan taken during the study.

ICI's Comments

The initial assay of Captan Technical Lot No. WRC 4921-26-15 determined that this sample contained 90.4 wt.% captan. {Captan samples (5 gm each) were collected at 6 months and at study termination}. Analyses of these samples 35-months after the initial analysis found 89.0 and 88.8 wt.% captan. These results are well within the analytical variability of the gas chromatographic methodology used in the analyses. These data confirm the stability of the test material substantially beyond the 12-month oral dosing regimen used in the dog chronic toxicity study.

Toxicology Branch Response

ICI's comments adequately satisfied Toxicology Branch request. Thus, we are upgrading the study (MRID No. 408936-04, Study No. IRDC 151-198) from core-supplementary to core-minimum. This study satisfy the guideline requirement No. 83-1 for a chronic (oral) non-rodent. This memorandum will serve as a supplement to the DER (HED Document No. 006978, dated Dec. 21, 1988).

REQUESTED ACTION:

The Reregistration Branch requested that the Toxicology Branch determine the adequacy of the ICI's comments (dated April 27, 1990) to Agency questions posed in our review of the one year chronic dog study with captan referred to above (MRID No. 408936-04).

DATA GAP:

The following 2 studies which have been identified as data gaps in the previous memorandum by the Toxicology Branch (Marion Copley to Richard Mountford, Registration Division, dated Dec. 21, 1988, HED Doc. 006978) have satisfactorily completed data requirements.

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1. Chronic (oral) non-rodent-- MRID No. 408936-04 (see this memorandum)
2. Subchronic inhalation (rat)--MRID No. 412344-02 (see HED Doc. 007938)
3. Metabolism (THPI moiety)-- 4 studies (MRID Nos. 415054-01 to 415054-04) have been submitted to EPA and they are being reviewed by the Toxicology Branch I.

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