PD-606
TXR-2901

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

002901

DATE: March 29, 1978

SUBJECT: Hyamine 3500-50% - Review of Additional Data EPA Reg.No. 707-63
Caswell#16E Shaughnessy#069105

FROM: William Greear W. Greear
Toxicology Branch

TO: Joseph Tavano
Product Manager #31

Recommendations

The teratogenic study (Hazleton, #417-364) is inadequate as submitted; however, at that time when individual animal data are submitted, verifying the conclusions reached in the summary, the adequacy of the teratologic evaluation will be reassessed. The repeated insult patch test (FDRL, I.B.L.#11465 and 11466) is adequate.

*No RPAR criteria have been exceeded.

Review

The review consists only of those newly submitted studies which are not currently on file.

1. Teratogenic Evaluation of Hyamine 3500 in Rabbits - (Hazleton Laboratories America, Inc., Project #417-364, 1/6/78, Acc.#232857)

(The submitted report consists of a summary of the design and results of a teratology study).

Hyamine 3500 was administered orally by gavage from Day 7 through 19 of gestation to 3 groups of 15 rabbits at levels of 10, 30 and 100 mg/kg/day. A 4th group received distilled water and served as the control group. The following maternal and fetal data were evaluated for compound effects: pregnancy rates; ovaries, uterine and litter data; fetal development; maternal body weights, appearance, behavior and survival.

Results

Maternal toxicity was noted in the low-, mid-and high dose groups and was manifested as anorexia, nasal discharge, depression, wheezing and/or labored breathing, body weight loss and death (high-and mid dose groups). In those dams that died, gross alterations of the trachea, lungs, gall bladder, liver, stomach, and/or kidneys were frequently observed.

Signs of embryotoxicity were observed in the low-and mid-dose fetuses. The incidence of fetal viability and the mean fetal weights and lengths were comparable among the control, low-and mid-dose groups. The results of the visceral examinations were unremarkable, except for pale kidneys and an umbilical hernia in 2 fetuses of the low dose group.

1 of 3 (1)

EPA FORM 1320-6 (REV. 3-76)

No differences attributed to treatment were found among the skeletal development of the low-and mid dose fetuses and the control fetuses.

Classification: Supplementary Data (Provisional)

(1) until individual animal data are submitted to verify the conclusions reached in the teratologic evaluation the study can not be raised to Core status. (The summary was 2½ pages in length.)

2. Repeated Insult Patch Test of Hyamine 3500 Treated Leather in Humans - (Food and Drug Research Laboratories, Inc., I.B.L. No. 11465 and 11466, 7/2/72, Acc.#232857)

Both of the original external surfaces of Hyamine 3500 treated leather and untreated leather were applied as a 1 sq. inch patch, to a predesignated site on the upper arm of each of 50 subjects and covered with lintine gauze. The lintine, in turn, was covered with polypropylene. At the end of 24 hours, the patches were removed. The contact sites were examined and the observations were assigned scores of 0-4, depending on the severity of the reaction. The applications were made 3 times per week for a total of 15 exposures. After removal of the last application preceding the challenge, the sites were examined immediately and once daily for at least 2 days. The challenge was applied to the original contact site, 14 days after the last of the series of 15 applications. The challenge was terminated after 24 hours. The sites were examined for immediate reactions and were re-examined 24 and 48 hours later for delayed reactions.

Results

Under completely occluded conditions, Hyamine 3500 treated leather did not elicit visible skin changes consistent with the criteria deemed characteristic of a primary irritant, fatiguing agent, or sensitizer in any of the subjects.

Classification: Core Data

Note: Hyamine 3500-50 and 80% differ only with respect to the amount of active ingredient [redacted]

inert ingredient information

Typists: TH

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HYAMINE 3500 (50%)

ACCEPTED
8-7-73
UNDER THE FEDERAL INSECTICIDE
FUNGICIDE AND RODENTICIDE ACT
FOR FORMULATION USE ONLY
AS A GERMICIDE
EPA REG. NO. 707-63

GERMICIDE CONCENTRATE

ACTIVE INGREDIENT:	
n-Alkyl (50% C_{12}, 40% C_{14}, 10% C_{16}) dimethyl benzyl ammonium chloride	50%
INERT INGREDIENTS:	
Water and Ethanol	50%
Total	100%

EPA Reg. No. 707-63-AA

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NET CONTENTS

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