

Exponent®

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May 15, 2008

TSCA Confidential Business Information Center (7407M)
EPA East – Room 6428 Attn: TSCA Section 8(e) Coordinator
U.S. Environmental Protection Agency
1201 Constitution Avenue, NW
Washington, DC 20004-3302

RECEIVED
OFFICE
2008 MAY 15 PM 12:51

Re: Alkyl Ammonium Chloride Salts
CAS # 70750-47-9



TSCA Section 8(e) Coordinator:

On behalf of our client the Joint Inerts Task Force (JITF) Cluster Support Team 7 (JITF CST 7) (1156 15th St. N.W., Suite 400, Washington, D.C. 20005, EPA Company Number 84881), Exponent, Inc. is submitting information pursuant to the provisions of Section 8(e) of the Toxic Substance Control Act (TSCA). The JITF CST 7 includes the following member companies: Akzo Nobel Surface Chemistry LLC, Bayer Crop Science, Monsanto, and Syngenta.

The following information is a summary of available preliminary data (not subject to laboratory quality assurance at this time) that is being reported under TSCA Section 8(e):

The JITF CST 7 is conducting a Combined Repeated Dose Toxicity Study with a Reproduction/Developmental Toxicity Screening Test (OECD 422 – OPPTS 870.3650) using Alkyl Ammonium Chloride Salts (CAS # 70750-47-9). Dose levels were based on a range-find study. Definitive study dose levels are 0, 25, 50, 100 mg/kg bw/day.

Mortality

At 100 mg/kg bw/day one male and two females were found dead after four doses. Four additional males were in moribund conditions. The clinical signs noted were piloerection, diarrhea, reduced activity, and general bad condition. Body weights were markedly decreased. Based on these adverse effects, it was decided to terminate the treatment at a dose of 100 mg/kg bw/day.

At 50 mg/kg bw/day one female showed body weight reduction and piloerection. This animal was found dead the following day. Four additional females were sacrificed in moribund conditions two days later.

Contains No CBI

CONTAINS NO CBI

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Food consumption and body weight data

At 50 mg/kg bw/day food consumption was statistically reduced in males during the first week of the pre-pairing period. Body weight was also reduced, attaining statistical significance on days 8 and 9 of the pre-pairing period. Body weight remained slightly lower than control mean value for the rest of the study, with terminal body weight 4.1% lower than controls at termination.

A similar statistically significant reduction in food consumption was noted in females of this group during the first week of the pre-pairing period. However, body weight was only slightly reduced though the study, and terminal body weight was only 2.9% lower than control animals at termination, on day 5 of lactation.

At 25 mg/kg bw/day body weight and food consumption values were comparable to controls.

FOBs (data incomplete)

In the open standard arena observations of all 5 males and 5 females at 50 mg/kg bw/day were noted to have ruffled fur.

For 2 males treated at 25 mg/kg bw/day the number of rearing was decreased (<3); the same observation was recorded in one male treated at 50 mg/kg bw/day while for another one reduced activity was reported.

Reproduction data

All available females mated successfully (10 in the control and 25 mg/kg bw/day groups, 5 in the 50 mg/kg bw/day group). Duration of gestation was comparable among groups (the value for the control was calculated on 9 animals as for rat No. 45 mating was not detected).

The number of implantations was higher in the treated groups compared to the control (but data for control rats No. 43, 49, and 50 need to be further elaborated).

Postnatal loss (days 0 to 4) was low, with a total 5, 1, and 0 pups dying, respectively, in order of ascending dosage.

Mean body weight of pups at days 1 and 4 post partum were slightly lower than historical control values at 25 mg/kg bw/day, but completely within historical control values and comparable to concurrent controls at 50 mg/kg bw/day (no dose-response).

Macroscopic findings and organ weights

Nodule(s) in the stomach of one male and 3 female rats treated at 25 mg/kg bw/day were noted at necropsy, stomach thickened was also noted in another female. Absolute and relative (to body weight and to brain weight) spleen weights were statistically reduced compared to control values in males treated at 25 mg/kg bw/day (and slightly reduced, without attaining statistical significance, in males treated at 50 mg/kg bw/day).

Histopathology

Is ongoing for 5 rats/sex of the control and high dose groups (50 mg/kg/day).

If a target organ will be identified the examination will be extended also to the low dose animals.

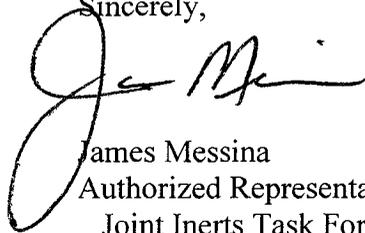
Gross abnormalities (as the above-mentioned nodule(s) in the stomach of four animals at 25 mg/kg/day) will be examined microscopically.

A previous TSCA 8(e) submission was made on January 3, 2008 for the range-find study.

JITF CST 7 asserts that none of the information contained within this notice constitutes confidential business information.

If you have any questions, please contact me by phone at (202) 772-4932.

Sincerely,



James Messina
Authorized Representative of
Joint Inerts Task Force CST 7

cc: FIFRA 6(a)(2)
JITF CST 7
Angelina Duggan, Exponent
Michela Dall'Osto, Exponent