

8EHQ-0399-14346

**BROMINATED SOLVENTS COMMITTEE**

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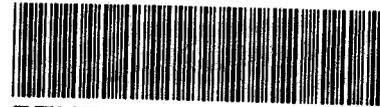
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March 9, 1999

VIA CERTIFIED MAIL

Document Control Office (7407)  
U.S. Environmental Protection Agency  
ATTN: TSCA Section 8(e) Coordinator  
Office of Pollution Prevention and Toxics  
401 M Street, SW  
Washington, DC 20460

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8EHQ-98-14346

RE: Followup Submission to an Earlier TSCA Section 8(e)  
Notification for 1-Bromopropane (CAS No. 106-94-5)  
TSCA Section 8(e) Document Control No. 8EHQ-98-14346

Dear TSCA 8(e) Coordinator:

The Brominated Solvents Committee (BSOC) is submitting this notification as a followup to a previous TSCA Section 8(e) substantial risk notification dated December 23, 1998, (TSCA Section 8(e) Document Control No. 8EHQ-98-14346). The information that was submitted involved preliminary data associated with unaudited draft summary tables for a range-finding developmental/reproduction toxicity study in rats with 1-bromopropane (CAS No. 106-94-5). Members of BSOC are: Albemarle Corporation, AmeriBrom Inc., and Great Lakes Chemical Corporation.

This followup submission is in regards to an unaudited draft report for the definitive developmental study in rats via whole-body inhalation exposure with 1-bromopropane, which was scheduled to follow the completion of the range-finder study (HLS Study No.: 98-4140). The developmental study is being performed at Huntingdon Life Sciences, East Millstone, New Jersey under their project study number 98-4141.

Time-mated female rats were exposed to 1-bromopropane via inhalation at concentrations of either 100, 498 or 996 ppm for six hours per day during gestation

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days 6 through 19. Female body weights and food consumption were recorded on days 0, 4 and 6 through 20 of gestation. Females were sacrificed on gestation day 20 and macroscopically examined. One female from the high exposure group was sacrificed on gestation day 13 due to non-treatment related reasons. During the female postmortem evaluation, gravid uterine weights, corpora lutea and uterine implantation data were recorded. Fetuses were examined externally, weighed and sacrificed. Approximately one-half of the fetuses from each litter were processed and examined for either visceral or skeletal malformations and/or variations.

Pregnant rats in the 100 and 498 ppm groups had limited clinical signs during exposure and post-exposure that were not considered treatment-related. Rats in the 996 ppm group had limited signs of salivation during exposure. Lacrimation and excessive salivation were noted occasionally during post-exposure observations in seven animals in the 996 ppm group. No effects on body weight, body weight gain, food consumption, gravid uterine weight or uterine data were noted in the 100 ppm group. When compared with the control group, mean body weights of both the 498 and 996 ppm groups were statistically decreased 4.0 to 4.2% and 5.8 to 7.3% during gestation days 18 through 20 and 8 through 20, respectively. In addition, overall mean body weight gains (gestation days 6 through 20) of both the 498 and 996 ppm groups were statistically decreased 14.3% and 24.4%, respectively. In the case of overall mean food consumption (gestation days 6 through 20), the 996 ppm group was statistically decreased 8.3% (gm/animal/day) and 6.3% (gm/Kg/day), when compared with the control group. The mean net body weight change minus uterine weight of both the 498 and 996 ppm groups were statistically decreased 32.5% and 62.5%, respectively, when compared to the control group.

Limited, but statistically significant, decreases in mean fetal weights were observed at all dose levels. The values for males, females and combined means were affected except for the 100 ppm males. Fetal examinations did not reveal any skeletal malformations. One control visceral malformation and four unrelated malformations in the high dose group were observed, however, there was no indication that these affects were treatment-related. Fetal skeletal variations of reduced ossification(s) of the skull at 498 and 996 ppm, and bent rib(s) at 996 ppm, were statistically noted as a litter incident. Although not statistically different, unossification of the hyoid body/arch(es) at 498 and 996 ppm, and reduced ossification of the rib(s) at 996 ppm, were at a higher litter incident than the control group. These results are preliminary/unaudited and require additional

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TSCA 8(e) Coordinator

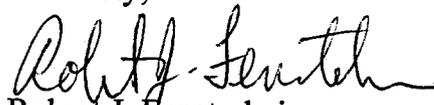
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analysis with historical control data before the biological significance, if any, of these findings can be determined.

If you have any questions, please contact me at (202) 637-9040.

Sincerely,



Robert J. Fensterheim

Executive Director

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