

8EHQ-0899-14345



DSBG
Dead Sea Bromine Group

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August 19, 1999

Document Processing Center (TS-790)
ATTN: TSCA Section 8(e) Coordinator
Office of Pollution Prevention and Toxics
U.S. Environmental Protection Agency
401 M Street, S.W.
Washington, D.C. 20460



8EHQ-98-14345



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Re: Follow-up to 12/23/98 TSCA Section 8(e) Notification on Ammonium Bromide (CASN 12124-97-9)

Dear TSCA Section 8(e) Coordinator:

Ameribrom, Inc. is hereby submitting a follow-up to the TSCA Section 8(e) substantial risk notification mailed December 23, 1998 that pertained to initial results from a Preliminary Developmental Toxicity Study in Rats performed with ammonium bromide (Inveresk Research, Tranent, Scotland; project number 492371). The follow-up data are from the definitive Developmental Toxicity Study in Rats performed with ammonium bromide (Inveresk Project No. 492387).

Time-mated female rats (24/group) were exposed to ammonium bromide via gavage at dose levels of 100, 300, and 1000 mg/kg/day during gestational days 6-19. The study was terminated on day 20 of gestation. Study observations included body weight, food consumption, viability, externally visible abnormalities, and clinical and developmental parameters.

We have received preliminary tabulated data from the definitive Developmental Toxicity Study. No statistical analysis is available. Currently no historical data are available and the laboratory has not interpreted the biological significance of the findings. Notwithstanding, there was noted a high incidence of the following observations in at least the high dose group fetuses: curved scapula, kinked rib(s), kidney absent/small/displaced with/without absent adrenal and absent ureter, spleen flattened and/or reduced in size, narrow uterine horn with flattened ovarian end and displaced from ovary, short tail with/without thickening, and minor abnormalities/variants or affects in ossification parameters. The biological significance of this data will be evaluated once the full results are available.

If you have any questions on this submission, please feel free to call me at 212-692-6633

Sincerely,

Francis J. Koschier, Ph.D., DABT
Vice-President, HSE & Regulatory Affairs

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