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AmeriBrom, Inc.

MEMBER OF THE DEAD SEA BROMINE GROUP



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8EHQ - 1298 - 14345

December 23, 1998

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

Contains No CBI

Re: TSCA Section 8(e) Notification on Ammonium Bromide (CAS No. 12124-97-9)

Dear TSCA Section 8(e) Coordinator:

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Ameribrom, Inc. is hereby submitting a TSCA Section 8(e) substantial risk notification on initial results from a Preliminary Developmental Toxicity Study in Rats performed with ammonium bromide. This study is being performed at Inveresk Research, Tranent, Scotland under project number 492371.

Time-mated female rats (six/group) were exposed to ammonium bromide via gavage at dose levels of 125, 250, 500, and 1000 mg/kg/day during gestational days 6-16. 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.

Preliminary word received from the laboratory indicates some developmental findings. One fetus of the 1000 mg/kg group was observed with spina bifida: on gross observation the spinal column was visible in the lower dorsal lumbar/sacral region. This fetus also was observed with a flattened cranium, downward flexure of the forelimbs, malrotated hindlimbs, and slightly short tail (kinked at the end). One fetus in the 250 mg/kg dose group was small in size with umbilical hernia and small portion of the liver exposed. One animal in the 125 mg/kg dose group had an apparently large placenta.

While the incidence of spina bifida and umbilical hernia are infrequent, they are known to occur spontaneously. Currently, without the draft report and/or additional studies we are unable to conclude whether the findings were test material induced. Certain facts point to the possibility that the findings were spontaneous: some effects were only seen at the lower dose levels, occurred in only one fetus, and developmental parameters were similar to the controls (fetal weight, pre-implantation loss, and implants - total, live, dead and early or late embryonic dead).

A full developmental study is scheduled to start in late January 1999. When the definitive study is completed, the exact nature of these preliminary findings should be clarified.

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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