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CHEMICAL MANUFACTURERS ASSOCIATION

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VIA CERTIFIED MAIL

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Document Processing Center (TS-790)
Office of Pollution Prevention and Toxics
Attention: Section 8(e) Coordinator
U.S. Environmental Protection Agency
401 M Street, SW
Washington, DC 20460

Re: TSCA Section 8(e) Reporting/Notification for Methyl Bromide

Dear Sir or Madam:

The Chemical Manufacturers Association (CMA) hereby submits for your office's information notice of information regarding methyl bromide (CAS No. 74-83-9) that has been submitted to EPA pursuant to Section 6(a)(2) of the Federal, Insecticide, Fungicide and Rodenticide Act (FIFRA). This notification is made on behalf of the members the Methyl Bromide Industry Panel. The Panel consists of TriCal, Inc., Ameribrom, Inc., Ethyl Corp., and Great Lakes Chemical Corp.

The reported information stems from a 90-Day Inhalation Neurotoxicity study being conducted pursuant to EPA's Methyl Bromide Data Call-In issued under Section 3 of the Federal, Insecticide, Fungicide and Rodenticide Act (FIFRA). The study is required for the continued registration of methyl bromide as a pesticide.

Based upon the explicit exemption for pesticides contained in Section 3 of the Toxic Substances Control Act (TSCA), and EPA's TSCA 8(e) Statement of Interpretation and Enforcement Policy, the Panel believes that the study is not subject to TSCA Section 8(e) reporting requirements.

The Panel has sought confirmation of this understanding from EPA officials in both the Office of Pesticide Programs and the Office of Pollution Prevention and Toxics, but received conflicting opinions regarding the application of TSCA to chemicals also regulated under FIFRA. In light of the lack of a consistent policy on the applicability of TSCA to chemicals regulated under FIFRA, the Panel is notifying the TSCA 8(e) Coordinator of the attached submission to the Office of Pesticide Programs as a precaution.

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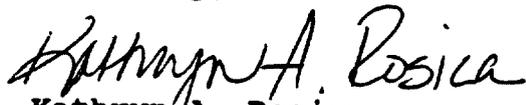
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The filing of this notice does not authorize any use of the information by any person outside the EPA Office of Pesticide Programs or any other release of the reported information to the public. The information is the property of the Methyl Bromide Industry Panel and its members and, as such, must be protected by the Agency from public disclosure.

If you have any questions regarding this notice, please call me at 202/887-1293.

Sincerely,



Kathryn A. Rosica
Manager
Methyl Bromide Industry Panel

Attachment

cc: Methyl Bromide Industry Panel

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CHEMICAL MANUFACTURERS ASSOCIATION

September 17, 1993

VIA CERTIFIED MAIL

FIFRA Section 6(a)(2)

Document Processing Desk
Office of Pesticide Programs - H7504c
U.S. Environmental Protection Agency
401 M Street, S.W.
Washington, D.C. 20460-0001
Attention: Ruth R. Douglas, Product Manager, PM-32

Re: FIFRA Section 6(a)(2) Report

Dear Ms. Douglas:

On behalf of the Methyl Bromide Industry Panel (MBIP), the Chemical Manufacturers Association submits the attached information pursuant to Section 6(a)(2) of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) and the EPA guidance on Section 6(a)(2) reporting requirements published in the Federal Register on July 12, 1979 (1979 Guidance).^{1/} The MBIP consists of three manufacturers of technical product -- Ameribrom, Inc., Ethyl Corporation, and Great Lakes Chemical Corporation -- and one major formulator, TriCal, Inc.

Pursuant to the 1991 Methyl Bromide Data Call-In (DCI), the MBIP is jointly conducting a 90-day Vapor Inhalation Neurotoxicity Study (Guideline No. 82-5(b)). According to the 1979 Guidance, the Agency does not require the routine submission of information regarding preliminary or inconclusive testing results. Rather, registrants have 90 days or more after testing has been done to complete the final analysis of study results.^{2/} Nonetheless, some of the specific, preliminary results of the above-referenced Study may not be known by the Agency. Thus, as a precaution, the MBIP is advising EPA of the following information regarding the preliminary results of the Study:

Fifteen CD® rats/sex/group were exposed to methyl bromide vapor, CAS No. 74-83-9, by inhalation six hours/day, five days/week, for at least 13 weeks at target concentration of . . . Clinical signs of toxicity, body weight, food

1/ 44 Fed. Reg. 40716 (July 12, 1979).

2/ See 44 Fed. Reg. 40716, 40718.

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consumption, functional observations, motor activity, perfused brain weights, gross pathology, and histologic neuropathology were assessed. Rats scheduled for pathologic examination (10/sex/group) were sacrificed during the 14th week of exposure.

_____ was statistically significant in the ppm exposure group during Weeks 4-13 for the females and during Weeks 5-13 for the males. _____ decrease was statistically significant in the _____ ppm group during Weeks 9 and 11-13. _____ was statistically significant during weeks 1-13 in the _____ ppm group and only during Week 1 in the _____ group, whereas the decrease in _____ was statistically significant during Weeks 1-13 in the _____ ppm group and during Weeks 5-13 in the _____ ppm group.

During Weeks 4, 8, and 13, males in the _____ ppm group had a statistically significant correlation between concentration and level of arousal for Weeks 8 and 13. There was a

The _____ analysis of the female data revealed statistically significant decreases in the _____ and _____ ppm groups at Week 13. Although not statistically significant, the results of Week 8 revealed a similar pattern. The _____ in the number of _____ for the females at _____ ppm was statistically significant at Weeks 4, 8, and 13. There was not significant effects on _____ for males throughout the study. Histopathological observations included _____ and _____.

A detailed assessment and final analysis of these, and other results of the Study is in progress. In accordance with the DCI, the audited final study report will be submitted to EPA on October 1, 1993.

If you have any questions concerning this report, please call me at (202) 887-1293.

Sincerely,


Kathryn A. Rosica
Manager
Methyl Bromide Industry Panel

cc: Methyl Bromide Industry Panel