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OFFICE OF POLLUTION  
PREVENTION AND TOXICS  
94 MAR 25 PM 2:16

March 25, 1994

(A)

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Office of Pollution Prevention and Toxics  
Attention: Section 8(e) Coordinator  
U.S. Environmental Protection Agency  
401 M Street, S.W.  
Washington, D.C. 20460

COMPANY SANITIZED

8EH 6034-129415

88940000183

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

INIT

Dear Sir or Madam:

The Chemical Manufacturers Association (CMA) hereby submits for your office's information, notice of a report 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 of the Methyl Bromide Industry Panel. The Panel consists of Ameribrom, Inc., Ethyl Corporation, Great Lakes Chemical Corp. and TriCal, Inc.

The reported information stems from preliminary range-finding toxicity testing in dogs being conducted pursuant to California's Birth Defect Prevention Act of 1984 (SB950). Specifically, the 4-day study is being conducted to establish dose levels for a dog chronic inhalation study which is required for the continued registration of methyl bromide as a pesticide in California.

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 this study is not subject to TSCA Section 8(e) reporting requirements.

The Panel 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 regulated under FIFRA. In light of the lack of a consistent policy on the applicability of TSCA to chemicals also 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.

RECEIVED  
5-9-94



5 Pgs.

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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 studies are 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 Rosica  
Manager  
Methyl Bromide Industry Panel

Attachment

cc: Methyl Bromide Industry Panel



CHEMICAL MANUFACTURERS ASSOCIATION

REC'D  
OFFICE OF POLLUTION  
PREVENTION AND TOXICS  
94 MAR 25 PM 2:16

March 25, 1994

FIFRA Section 6(a)(2)  
Document Processing Desk  
Office of Pesticide Programs - H7504C  
U.S. Environmental Protection Agency  
401 M Street, NW  
Washington, DC 20460-0001

COMPANY SANITIZED

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)<sup>1</sup>. 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 data requirements of California's Birth Defects Prevention Act of 1984 (SB950), the MBIP is jointly conducting a Chronic 1-Year Dog Inhalation Study. As part of the preliminary work being done to conduct the definitive study, a 4-day range-finding study was designed to determine appropriate dose levels. As more fully explained in the attached summary, an initial 4-day range-finding study was terminated after two days of exposure. However, an additional 4-day study at lower dose levels has now been completed.

According to the 1979 Guidance, the Agency does not require the routine submission of information regarding preliminary and incomplete testing results. Rather, registrants have time after testing has been done to complete the final analysis of study results<sup>2</sup>. Nonetheless, some of the specific effects shown in the aborted 4-day study and the completed 4-day study may not be known by the Agency. Thus, as a precaution, the MBIP is advising EPA of the attached information.

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

<sup>2</sup> See 44 Fed. Reg. 40716, 40718.

FIFRA Section 6(a)(2) Document  
Processing Desk  
March 24, 1994  
Page 2

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

Sincerely,



Kathryn A. Rosica  
Manager  
Methyl Bromide Industry Panel

Attachment

cc: Methyl Bromide Industry Panel

Summary of Effects Shown

A 4-day repeated exposure inhalation toxicity study in beagle dogs with methyl bromide was initiated at Pharmaco:LSR on February 28, 1994. This study was a dose range-finding study to select test concentrations for a 28-day exposure study. Two groups of three dogs were scheduled to be exposed to test concentrations of ppm and ppm for 7 hours each day. These concentrations were selected based on the results from single 7-hour exposures to individual dogs at concentrations ranging from to 300 ppm. The 4-day study was terminated due to extreme toxic effects noted after 2 days of exposure.

At ppm, all dogs vomited after the 7-hour exposure on study day one but appeared normal prior to exposure on day 2. Approximately 3 to 4 hours into the exposure on Day 2, vomiting and diarrhea were noted for the dogs and exposure was terminated. The dogs were sacrificed on March 2, 1994.

At ppm, no clinical signs of toxicity were seen during or after the 7-hour exposures on Day 1 nor through exposure on Day 2. Approximately 1 hour after exposure on Day 2, the dogs showed signs of hyperactivity characterized by rapid circling in the cages. During brief intervals, the dogs would stop circling and appear catatonic. The staff veterinarian observed these animals and the dogs were sacrificed.

A second 4-day exposure study was initiated on March 8, 1994 with 2 groups of 2 dogs at concentrations of an ppm. At ppm, both dogs vomited during exposure on Day 3 and appeared depressed. They also showed signs of low activity during exposure on Day 4. Dogs exposed to ppm showed no clinical signs of toxicity during the 4-day study.



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
WASHINGTON, D.C. 20460

Kathryn A. Rosica  
Manager, Methyl Bromide Panel  
Chemical Manufacturers Association  
2501 M Street, N.W.  
Washington, D.C. 20037

OFFICE OF  
PREVENTION, PESTICIDES AND  
TOXIC SUBSTANCES

DEC 27 1994

EPA acknowledges the receipt of information submitted by your organization under Section 8(e) of the Toxic Substances Control Act (TSCA). For your reference, copies of the first page(s) of your submission(s) are enclosed and display the TSCA §8(e) Document Control Number (e.g., 8EHQ-00-0000) assigned by EPA to your submission(s). Please cite the assigned 8(e) number when submitting follow-up or supplemental information and refer to the reverse side of this page for "EPA Information Requests".

All TSCA 8(e) submissions are placed in the public files unless confidentiality is claimed according to the procedures outlined in Part X of EPA's TSCA §8(e) policy statement (43 FR 11110, March 16, 1978). Confidential submissions received pursuant to the TSCA §8(e) Compliance Audit Program (CAP) should already contain information supporting confidentiality claims. This information is required and should be submitted if not done so previously. To substantiate claims, submit responses to the questions in the enclosure "Support Information for Confidentiality Claims". This same enclosure is used to support confidentiality claims for non-CAP submissions.

Please address any further correspondence with the Agency related to this TSCA 8(e) submission to:

Document Processing Center (7407)  
Attn: TSCA Section 8(e) Coordinator  
Office of Pollution Prevention and Toxics  
U.S. Environmental Protection Agency  
Washington, D.C. 20460-0001

EPA looks forward to continued cooperation with your organization in its ongoing efforts to evaluate and manage potential risks posed by chemicals to health and the environment.

Sincerely,

*Terry R. O'Bryan*  
Terry R. O'Bryan  
Risk Analysis Branch

Enclosure

12941 A



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**Triage of 8(e) Submissions**

Date sent to triage: JAN 11 1995

**NON-CAP**

CAP

Submission number: 12941A

TSCA Inventory: **Y** N D

Study type (circle appropriate):

Group 1 - Dick Clements (1 copy total)

**E00** **AQUATO**

Group 2 - Ernie Falke (1 copy total)

ATOX **SBTOX** SEN w/NEUR

Group 3 - Elizabeth Margosches (1 copy each)

STOX CTOX EPI RTOX GTOX  
STOX/ONCO CTOX/ONCO IMMUNO CYTO NEUR

Other (FATE, EXPO, MET, etc.): \_\_\_\_\_

Notes:

**THIS IS THE ORIGINAL 8(e) SUBMISSION; PLEASE REFILE AFTER TRIAGE DATA USE ENTRY**

For Contractor Use Only	
entire document: <u>6</u> 1 2 pages <u>1, 2</u>	pages <u>1, 2, TAB</u>
Notes:	
Contractor reviewer: <u>POW</u>	Date: <u>11/7/94</u>

CECATS/TRIAGE TRACKING DBASE ENTRY FORM

CECATS DATA: Submission # BEHQ: 0394-12941 (S) SEQ: A

TYPE: (INT) SUPP FLWP  
 SUBMITTER NAME: Chemical Manufacturers Association

INFORMATION REQUESTED: ELY P DATE:  
 0501 NO INFO REQUESTED  
 0502 INFO REQUESTED (TECH)  
 0503 INFO REQUESTED (VOL. ACTIONS)  
 0504 INFO REQUESTED (REPORTING RATIONAL.F.)  
 DISPOSITION:  
 (S) REFER TO CHEMICAL SCREENING  
 0578 CAP NOTICE

VOLUNTARY ACTIONS:  
 0401 NO ACTION REPORTED  
 0402 STUDIES PLANNED (WITHIN 6 MONTHS)  
 0403 NOTIFICATION OF WORKING CONDITIONS  
 0404 LABELS/MSDS (TIANCHIS)  
 0405 PROCESS/ANAL. ING. (TIANCHIS)  
 0406 APP USE DISCONTINUED  
 0407 PRODUCTION DISCONTINUED  
 0408 CONFIDENTIAL

SUB. DATE: 03/25/94 OTS DATE: 03/25/94 CSRAD DATE: 05/09/94

CHEMICAL NAME: \_\_\_\_\_  
 CASE: 74-83-9

INFORMATION TYPE:	P F C	INFORMATION TYPE:	P F C
0201 (NC) (HUMAN)	01 02 04	0216 EPICLJN	01 02 04
0202 (NC) (ANIMAL)	01 02 04	0217 HUMAN EXPOS (PROD CONTAM)	01 02 04
0203 (T-L TRANS (IN VITRO))	01 02 04	0218 HUMAN EXPOS (ACCIDENTAL)	01 02 04
0204 MUTA (IN VITRO)	01 02 04	0219 HUMAN EXPOS (MONITORING)	01 02 04
0205 MUTA (IN VIVO)	01 02 04	0220 ECO/AQUA TOX	01 02 04
0206 REPRO/TERATO (HUMAN)	01 02 04	0221 ENV. OCCUR/REL.FATE	01 02 04
0207 REPRO/TERATO (ANIMAL)	01 02 04	0222 EMER INCI OF ENV CONTAM	01 02 04
0208 NEURO (HUMAN)	01 02 04	0223 RESPONSE REQEST DELAY	01 02 04
0209 NEURO (ANIMAL)	01 02 04	0224 PROD/COMP/CHEM ID	01 02 04
0210 ACUTE TOX. (HUMAN)	01 02 04	0225 REPORTING RATIONALE	01 02 04
0211 CHR. TOX. (HUMAN)	01 02 04	0226 CONFIDENTIAL	01 02 04
0212 ACUTE TOX. (ANIMAL)	01 02 04	0227 ALLERG (HUMAN)	01 02 04
0213 SUB ACUTE TOX (ANIMAL)	01 02 04	0228 ALLERG (ANIMAL)	01 02 04
0214 SUB CHRONIC TOX (ANIMAL)	01 02 04	0229 METAB/PHARMACO (ANIMAL)	01 02 04
0215 CHRONIC TOX (ANIMAL)	01 02 04	0230 METAB/PHARMACO (HUMAN)	01 02 04
		0241 IMMUNO (ANIMAL)	01 02 04
		0242 IMMUNO (HUMAN)	01 02 04
		0243 CHEMPHYS PROP	01 02 04
		0244 CLASTO (IN VITRO)	01 02 04
		0245 CLASTO (ANIMAL)	01 02 04
		0246 CLASTO (HUMAN)	01 02 04
		0247 DNA DAM/REPAIR	01 02 04
		0248 PROD/USE/PROC	01 02 04
		0251 MSDS	01 02 04
		0259 OTHER	01 02 04

USE: Pesticide

TOXICOLOGICAL CONCERNS:

SPECIES: DOG  
 YES (DROP/PREFER): NO  
 NO (CONTINUE): NO  
 HIGH: NO

TRIAJE DATA: NON-CBI INVENTORY

(YES) NO

12-25-94 Non-Cap

-CPSS- 0609951336

0 0 0 0 0 0 0 0 0 0 0

> <ID NUMBER>

8(E)-12941A

> <TOX CONCERN>

ND

> <COMMENT>

SUBACUTE INHALATION TOXICITY IN DOGS COULD NOT BE DETERMINED DUE TO LACK OF DOSE INFORMATION PROVIDED IN THE STUDY SUMMARY SUBMITTED. DOGS WERE EXPOSED TO VAPORS OF THE TEST MATERIAL FOR 7 HOURS AT VARIOUS CONCENTRATIONS FOR 2-4 DAYS. CLINICAL SIGNS INCLUDED VOMITING, DIARRHEA, HYPERACTIVITY (RAPID CIRCLING), CATATONIC STATE, DEPRESSION, AND LOW ACTIVITY.

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