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BUCKMAN LABORATORIES INTERNATIONAL, INC.

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Via Federal Express

PDCN-460700000006

November 13, 2006

CONTAIN NO CBI

OPPT Document Control Office  
U.S. Environmental Protection Agency  
EPA East Building, Room 6428  
1201 Constitution Avenue, NW  
Washington DC 20004

ATTN: 8(d) Health and Safety Reporting Rule (Notification/Reporting)

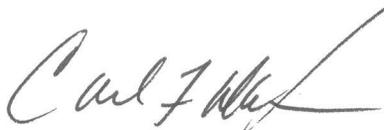
RE: HPV Orphan Chemical:  
CAS #111-44-4, Ethane, 1,1'-oxybis[2-chloro-  
Docket ID No. EPA-HQ-OPPT-2005-0055

To Whom It May Concern:

Pursuant to the TSCA 8(d) rule issued August 16, 2006, Buckman Laboratories earlier submitted copies of unpublished health and safety studies for above the listed chemical. Enclosed are hard copies of the robust summaries and an electronic copy for those studies.

Please don't hesitate to call me at (901) 272-6228 should you have any questions or require additional information.

Sincerely,  
BUCKMAN LABORATORIES INTERNATIONAL, INC.



Carl F. Watson, Ph.D.  
Senior Regulatory Toxicologist



300127

# EPA High Production Volume (HPV) Track

Toxicity End Point:  
Toxicity in Vivo (Chromosomal Aberrations)

Sponsor ID	1100104	Buckman Laboratories, Inc.	Create Date	10/17/2006
CAS Number	111444	Ether, bis(2-chloroethyl)	Study Number	1
Consortia ID			Completed:	N

## Test Substance

Revision Date:

11/2/2006

Remarks

## Chemical Category

## Method

>> Method/Guideline followed

>> Test Type

Micronucleus assay

>> GLP Yes

>> Year study performed 1989

>> Species

mouse

>> Strain Mammal strain ICR

>> Sex Both

>> Number of males per dose

5

>> Number of females per dose

5

>> Route of Administration

Oral

>> Doses 18, 60 & 180 mg/kg

>> Exposure period

24, 48, 72 Hr.

>> Statistical Method

ANOVA w/ Tukey's Studentized range test

Remarks for Metho

# EPA High Production Volume (HPV) Track

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Toxicity in Vivo (Chromosomal Aberrations)

Sponsor ID	1100104	Buckman Laboratories, Inc.	Create Date	10/17/2006
CAS Number	111444	Ether, bis(2-chloroethyl)	Study Number	1
Consortia ID			Completed:	N

- \* Age at study initiation: Adult, ~8 1/2 wks.
- \* No. of animals per dose: 5
- \* Vehicle: Corn oil
- \* Duration of test: 72 Hr.
- \* Frequency of treatment: Single
- \* Sampling times and number of samples: 24, 48, 72 hrs; 5(M)/5(F) per time point per dose.
- \* Control groups and treatment: Negative Control - corn oil; Positive Control - cyclophosphamide.
- \* Clinical observations performed (clinical pathology, functional observations, etc.):  
Functional observations.
- \* Organs examined at necropsy (macroscopic and microscopic): NA
- \* Criteria for evaluating results (for example, cell types examined, number of cells counted in a mouse micronucleus test): Bone marrow polychromatic erythrocytes; 1000 PCE's per animal were scored.
- \* Criteria for selection of maximum tolerated dose. 3-day Range-finder study, mortality was:
 

100 mg/kg	0/3(M)	0/3(F)
250 mg/kg	0/3(M)	2/3(F)
500 mg/kg	3/3(M)	3/3(F)
750 mg/kg	3/3(M)	3/3(F)
1000 mg/kg	3/3(M)	3/3(F)

## Results

### >> Effects on Mitosi

see below.

### >> Genotoxic Effect

Negative

### >> Statistical result

No significant difference than corresponding negative control,  $p < 0.05$ .

### Results Remark

\* Mortality at each dose level by sex: None

\* Mutant/aberration/mPCE/polyploidy frequency, as appropriate:

Treatment	T(Hr)	% PCEs, Mean of 1000/animal (+/- SE)		Ratio PCE:NCE	
		Total		Males	Females
-----					
Control					
Vehicle	24	0.03 (0.02)		0.58(0.06)	0.73(0.08)
Positive	24	0.82 (0.17)*		0.58(0.06)	0.73(0.08)
Test Substance					
18 mg/kg	24	0.07 (0.03)		0.58(0.04)	0.71(0.04)

# EPA High Production Volume (HPV) Track

Toxicity End Point:  
Toxicity in Vivo (Chromosomal Aberrations)

Sponsor ID	1100104	Buckman Laboratories, Inc.	Create Date	10/17/2006
CAS Number	111444	Ether, bis(2-chloroethyl)	Study Number	1
Consortia ID			Completed:	N

	48	0.12 (0.08)	0.48(0.04)	0.86(0.09)
	72	0.03 (0.02)	0.77(0.07)	0.68(0.12)
60.0 mg/kg	24	0.04 (0.03)	0.56(0.07)	0.78(0.13)
	48	0.09 (0.04)	0.50(0.03)	0.70(0.13)
	72	0.06 (0.02)	0.51(0.04)	0.95(0.09)
180 mg/kg	24	0.08 (0.03)	0.56(0.14)	0.82(0.15)
	48	0.09 (0.03)	0.51(0.06)	0.76(0.12)
	72	0.07 (0.03)	0.51(0.08)	0.75(0.08)

\*significantly greater than the corresponding negative control, p<0.05

\* Description, severity, time of onset and duration of clinical signs at each dose level and sex:  
All animals appeared normal after dosing and remained healthy until sacrifice.

\* Body weight changes by dose and sex

\* Food/water consumption changes by dose and sex

## Conclusions

The test material, DCEE, did not induce a significant increase in micronuclei in bone marrow polychromatic erythrocytes under the conditions of this assay and is considered negative in the mouse bone marrow micronucleus test.

## Data Quality

Reliability 2(c)

## Data Reliability Remarks

Comparable to guideline study with acceptable restrictions.

## Reference

### >> Remarks

Ivett, J.L. 1989. Mutagenicity Test on DCEE In Vitro Mouse Micronucleus Assay. HLA Study No. 10924-0-0305. Hazleton Laboratories Americal, Inc., Kensington, MD.

# EPA High Production Volume (HPV) Track

Toxicity End Point:  
Toxicity in Vivo (Chromosomal Aberrations)

Sponsor ID	<input type="text" value="1100104"/>	Buckman Laboratories, Inc.	Create Date	<input type="text" value="10/17/2006"/>
CAS Number	<input type="text" value="111444"/>	Ether, bis(2-chloroethyl)	Study Number	<input type="text" value="1"/>
Consortia ID	<input type="text"/>		Completed:	<input type="text" value="N"/>

## General

# EPA High Production Volume (HPV) Track

Toxicity End point:  
Toxicity in Vitro (Gene Mutations)

Sponsor ID

Buckman Laboratories, Inc.

Create Date

CAS Number

Ether, bis(2-chloroethyl)

Study Number

Consortia ID

Completed:

Revision Date:

## Test Substance

Remarks

## Chemical Category

## Method

### >> Method/Guideline followed

### >> Test Type

### >> System of Testing

### >> GLP

### >> Year study performed

### >> Species

### >> Metabolic Activation

### >> Concentration

### >> Statistical Method

### Remarks for Metho

#### \* Test Design

- Number of replicates: Triplicate cover slips (150 total cells)
- Frequency of Dosing
- Positive and negative control groups and treatment: 2-AAF, 0.1 ug/ml; DMSO, 1%; DCEE (see concentrations above).
- Number of metaphases analyzed for chromosomal studies

# EPA High Production Volume (HPV) Track

Toxicity End point:  
Toxicity in Vitro (Gene Mutations)

Sponsor ID	1100104	Buckman Laboratories, Inc.	Create Date	10/17/2006
CAS Number	111444	Ether, bis(2-chloroethyl)	Study Number	1
Consortia ID			Completed:	N

\* Solvent/vehicle, if used, and concentration: DMSO, 1%  
\* If follow-up study, describe how different from original  
\* Criteria for evaluating results (e.g. cell evaluated per dose group): UDS was measured by counting nuclear grains and subtracting the average number of grains in three nuclear-sized areas adjacent to each nucleus (background count). Only nuclei with normal morphologies were scored. Acceptance criterial (8) specified in report.

## Results

>> Result Negative

>> Cytotoxic Concentration

Moderately toxic at test conc of 2010 ug/ml and 1000 ug/ml (70.3% and 86.4% survival respectively).

>> Genotoxic Effect Unconfirmed

>> Statistical result

## Results Remark

\* Note test-specific confounding factors such as pH, osmolarity, whether substance is volatile, water soluble, precipitated, etc., particularly if they effect the selection of test concentrations or interpretation of the results: The test materials was insoluble in media tat concentrations above 714 ug/ml.

\* Provide at a minimum qualitative descriptions of elements where dose effect related observations were seen.  
In Trial 1, fifteen treatments from 2010 ug/ml to 0.050 ug/ml were initiated. Six treatments from 2010 ug/ml to 50.1 ug/ml covered a good range of toxicity (70.3% to 107/1% survival) and were selected for analysis of nuclear labeling. A slight elevation in nuclear labeling was observed at a concentration of 2010 ug/ml but only one of the 2 criteria for a positive response was met (the percent of cells containing 5 or more net nuclear grains). None of the criterial used to indicate UDS were approached by the remaining chemical treatments in Trial 1 and no dose-response was observed.  
Based upon the cytotoxicity information obtained in Trial 1, ten dose levels from 2860 ug/ml to 59.5 ug/ml were initiated in Trial 2. Treatment at 2860 ug/ml was not analyzed due to high toxicity. Six treatments from 2380 ug/ml to 476 ug/ml covered a good range of toxicity (59.8% to 94.85 survival) and were selected for analysis of nuclear labeling. None of the test material treatments induced a significant increase in UDS. The increase observed in Trial 1 was there fore considered spurious.

\* Frequency of reversions/mutations/aberrations, polyploidy as appropriate  
\* Mitotic index

## Conclusions

# EPA High Production Volume (HPV) Track

Toxicity End point:  
Toxicity in Vitro (Gene Mutations)

Sponsor ID	1100104	Buckman Laboratories, Inc.	Create Date	10/17/2006
CAS Number	111444	Ether, bis(2-chloroethyl)	Study Number	1
Consortia ID			Completed:	N

The test material, DCEE (Dichloroethylene), did not induce significant changes in the nuclear labeling of rat primary hepatocytes in two independent trials for an applied concentration range of 2389 ug/ml to 50.1 ug/ml. DCEE was therefore evaluated as inactive in the Rat Primary Hepatocyte UDS Assay.

## Data Quality

Reliability

1(b)

## Data Reliability Remarks

Comparable to study guideline study.

## Reference

### >> Remarks

Cifone, M.A. 1990. Mutagenicity Test on DCEE (Dichloroethylene) in the In Vitro Rat Primary Hepatocyte Unshcheduled DNA Synthesis Assay. HLA Study No. 10924-0-447. Hazleton Laboratories America, Inc. Kensington, MD.

## General

# EPA High Production Volume (HPV) Track

Toxicity End point:  
Toxicity in Vitro (Gene Mutations)

Sponsor ID	1100104	Buckman Laboratories, Inc.	Create Date	10/17/2006
CAS Number	111444	Ether, bis(2-chloroethyl)	Study Number	2
Consortia ID			Completed:	N

Revision Date:

10/31/2006

## Test Substance

Remarks

Purity: 97.3%

## Chemical Category

## Method

### >> Method/Guideline followed

Ames Test

### >> Test Type

Ames test

### >> System of Testing

Bacterial

### >> GLP

Yes

### >> Year study performed

1991

### >> Species

Salmonella typhimurium

### >> Metabolic Activation

SD rats, liver microsomal enzymes induced with Aroclor 1254

### >> Concentration

5,10, 25, 50, 100, 150 ul

### >> Statistical Method

### Remarks for Metho

#### \* Test Design

Two designs used: 1) Standard Taped-Plate Method; and 2) Reservoir Modification Method.

- Number of replicates: Triplicate
- Frequency of Dosing: Single, 4-hr exposure.
- Positive and negative control groups and treatment:  
Postivie Controls - 2-Aminoantracene, Methylene chloride, & sodium azide;

# EPA High Production Volume (HPV) Track

Toxicity End point:  
Toxicity in Vitro (Gene Mutations)

Sponsor ID	1100104	Buckman Laboratories, Inc.	Create Date	10/17/2006
CAS Number	111444	Ether, bis(2-chloroethyl)	Study Number	2
Consortia ID			Completed:	N

Negative control - no test material.  
- Number of metaphases analyzed for chromosomal studies

- \* Solvent/vehicle, if used, and concentration
- \* If follow-up study, describe how different from original
- \* Criteria for evaluating results (e.g. cell evaluated per dose group):  
Tester strain integrity - rfa Wall mutation: sensitivity to crystal violet; pKM101 plasmid R-Factor - resistance to ampicillin; Characteristic No. of Spontaneous Revertants - 60-240 revertants/plate; Tester Strain Titers -  $\geq 5 \times 10^8$ ; Positive Control Values - 3-fold increase in mean # revertants/plate over vehicle control.  
Cytotoxicity - minimum of 3 non-toxic dose levels.

## Results

>> Result Positive

>> Cytotoxic Concentration

50 & 100 ul, growth inhibitory effect.

>> Genotoxic Effect Dose-response

>> Statistical result

## Results Remark

\* Note test-specific confounding factors such as pH, osmolarity, whether substance is volatile, water soluble, precipitated, etc., particularly if they effect the selection of test concentrations or interpretation of the results

\* Provide at a minimum qualitative descriptions of elements where dose effect related observations were seen. Single tester TA100. After 72 hrs of total incubation, increases of 2-fold or greater in the number of revertants per plate over the corresponding negative controls were observed for the vapor-treated plates in both the presence and absence of S9 using both exposure methodologies. In addition, these increases were observed to be dose-responsive to increasing volumes of the test article.

- \* Frequency of reversions/mutations/aberrations, polyploidy as appropriate
- \* Mitotic index

## Conclusions

# EPA High Production Volume (HPV) Track

Toxicity End point:  
Toxicity in Vitro (Gene Mutations)

Sponsor ID	1100104	Buckman Laboratories, Inc.	Create Date	10/17/2006
CAS Number	111444	Ether, bis(2-chloroethyl)	Study Number	2
Consortia ID			Completed:	N

The results of the Salmonella/Mammalian-Microsome Reverse Mutation Assay (Ames Test) Modified for Vapor Phase Exposure indicate that under the conditions of this study, DCEE (Dichloroethylether), did cause a positive increase in the number of TA100 revertants per plate in both the presence and absence of microsomal enzymes from Aroclor-induced rat liver.

## Data Quality

Reliability

2(c)

## Data Reliability Remarks

Comparable to guideline study with acceptable restrictions.

## Reference

### >> Remarks

Lawlor, T.E. 1991. Mutagenicity Test on DCEE (Dichloroethylether) in the Salmonella/Mammalian-Microsome Reverse Mutation Assay (Ames Test) Modified for Vapor Phase Exposure. HLA Study No. 10924-0-401. Hazleton Laboratories America, Inc. Kensington, MD.

## General

# EPA High Production Volume (HPV) Track

Toxicity End point:  
Toxicity in Vitro (Gene Mutations)

Sponsor ID	1100104	Buckman Laboratories, Inc.	Create Date	10/17/2006
CAS Number	111444	Ether, bis(2-chloroethyl)	Study Number	3
Consortia ID			Completed:	N

## Test Substance

Revision Date:

10/31/2006

Remarks

Purity: 97.3%

## Chemical Category

## Method

>> Method/Guideline followed

Ames Test

>> Test Type

Ames test

>> System of Testing Bacterial

>> GLP Yes

>> Year study performed 1989

>> Species

Salmonella typhimurium

>> Metabolic Activation

SD rats, liver microsomal enzymes induced with Aroclor 1254

>> Concentration

100, 333, 667, 1000, 3330 & 6670 ug

>> Statistical Method

Remarks for Metho

\* Test Design

- Number of replicates: 3 plates per dose level.
- Frequency of Dosing: Single
- Positive and negative control groups and treatment: Positive Control - 2-aminoanthracene, 2-nitrofluorene, ICR-191 and sodium azide; Negative Control - DMSO.
- Number of metaphases analyzed for chromosomal studies

11/9/2006

# EPA High Production Volume (HPV) Track

Toxicity End point:  
Toxicity in Vitro (Gene Mutations)

Sponsor ID	1100104	Buckman Laboratories, Inc.	Create Date	10/17/2006
CAS Number	111444	Ether, bis(2-chloroethyl)	Study Number	3
Consortia ID			Completed:	N

\* Solvent/vehicle, if used, and concentration: DMSO, 50 ul  
\* If follow-up study, describe how different from original  
\* Criteria for evaluating results (e.g. cell evaluated per dose group)  
Tester strain integrity - rfa Wall mutation: sensitivity to crystal violet; pKM101 plasmid R-Factor - resistance to ampicillin; Characteristic No. of Spontaneous Revertants - all tester strain cultures must exhibit a characteristic # of spontaneous revertants/plate in the vehicle controls; Tester Strain Titters - > or = 5 X 10E8; Positive Control Values - 3-fold increase in mean # revertants/plate over vehicle control.  
Cytotoxicity - minimum of 3 non-toxic dose levels.

## Results

>> Result Negative

>> Cytotoxic Concentration

> or = 3330 ug per plate in the presence or absence of metabolic activation.

>> Genotoxic Effect Unconfirmed

>> Statistical result

## Results Remark

\* Note test-specific confounding factors such as pH, osmolarity, whether substance is volatile, water soluble, precipitated, etc., particularly if they effect the selection of test concentrations or interpretation of the results

\* Provide at a minimum qualitative descriptions of elements where dose effect related observations were seen. A dose rangefinding study, using ten dose levels of the test article was conducted using 10000 to 10 ug per plate. Cytotoxicity was observed at 3330 ug per plate and above in both the presence and absence of S9 as evidenced by the thinning or disappearance of the bacterial background lawn and the reduced number of revertants per plate. In the definitive test, concentrations used were 6670 to 100 ug per plate. Tester strains were TA98, TA100, TA1535, TA1537 and TA 1538. A non-dose-responsive 2.8-fold increase in the mean revertants per plate was observed with tester strain TA1535 in the presence of S9 at one dose only (3330 ug per plate). In addition, a non-dose-responsive 1.6-fold increase was observed at 3330 ug per plate dose level in the absence of S9 with tester strain 1535. Non-dose-responsive increases less than 3-fold in magnitude are not evaluated as positive with tester strain TA1535. All criteria for a valid study were met.

\* Frequency of reversions/mutations/aberrations, polyploidy as appropriate  
\* Mitotic index

## Conclusions

# EPA High Production Volume (HPV) Track

Toxicity End point:  
Toxicity in Vitro (Gene Mutations)

Sponsor ID	1100104	Buckman Laboratories, Inc.	Create Date	10/17/2006
CAS Number	111444	Ether, bis(2-chloroethyl)	Study Number	3
Consortia ID			Completed:	N

The results of the Salmonella/Reverse Mutation Assay (Ames Test) Preincubation Method indicate that under the conditions of this study, DCEE (Dichloroethylether), did not cause a positive increase in the number of histidine revertants per plate in any of the tester strains either in the presence or absence of microsomal enzymes prepared from Aroclor-induced rat liver.

## Data Quality

Reliability

2(c)

## Data Reliability Remarks

Comparable to guideline study with acceptable restrictions.

## Reference

### >> Remarks

Lawlor, T.E. & Valentine, D.C. 1989. Mutagenicity Test on DCEE (Dichloroethylether) in the Salmonella/Reverse Mutation Assay (Ames Test) Preincubation Method. HLA Study No. 10924-0-420. Hazleton Laboratories America, Inc. Kensington, MD.

## General

# EPA High Production Volume (HPV) Track

Toxicity End point:  
Toxicity in Vitro (Gene Mutations)

Sponsor ID	1100104	Buckman Laboratories, Inc.	Create Date	10/17/2006
CAS Number	111444	Ether, bis(2-chloroethyl)	Study Number	4
Consortia ID			Completed:	N

Revision Date:

10/31/2006

## Test Substance

Remarks Purity: 97.3%

## Chemical Category

## Method

>> Method/Guideline followed

>> Test Type

Cytogenetic assay

>> System of Testing Non-bacterial

>> GLP Yes

>> Year study performed 1989

>> Species

Chinese Hamster Ovary cells

>> Metabolic Activation

SD rats, liver microsomal enzymes induced with Aroclor 1254

>> Concentration

w/o activation - 1520, 2030, 2540 & 3050 ug/ml; w/ activation - 17.6, 25, 32.6 & 39.9 ug/ml

>> Statistical Method Fisher's Exact Test w/ multiple comparisons

## Remarks for Metho

\* Test Design

- Number of replicates: 2
- Frequency of Dosing: Single
- Positive and negative control groups and treatment: Positive Controls - Mitomycin C & Cyclophosphamide; Negative Control - DMSO.
- Number of metaphases analyzed for chromosomal studies

# EPA High Production Volume (HPV) Track

Toxicity End point:  
Toxicity in Vitro (Gene Mutations)

Sponsor ID	1100104	Buckman Laboratories, Inc.	Create Date	10/17/2006
CAS Number	111444	Ether, bis(2-chloroethyl)	Study Number	4
Consortia ID			Completed:	N

- \* Solvent/vehicle, if used, and concentration: DMSO, 10 ul
- \* If follow-up study, describe how different from original
- \* Criteria for evaluating results (e.g. cell evaluated per dose group)

## Results

>> Result Positive

>> Cytotoxic Concentration

2960 ug/ml w/o metabolic activation ; 40 ug/ml with metabolic activation

>> Genotoxic Effect With metabolic activation

>> Statistical result

At 20 hrs - up to 3050 ug/ml w/o activation, no significant difference,  $p < 0.01$ . At 20 hrs - 32.7 and 40 ug/ml and at 30 hrs - 25 to 39.9 ug/ml w/activation significant differences,  $p < 0.01$ , observed.

### Results Remark

\* Note test-specific confounding factors such as pH, osmolarity, whether substance is volatile, water soluble, precipitated, etc., particularly if they effect the selection of test concentrations or interpretation of the results.: Oily percipitate was observed after dosing and prior to harvest at 2540 and 3050 ug/ml. Slightly oily percipitate was observed after dosing at 2030 ug/ml.

\* Provide at a minimum qualitative descriptions of elements where dose effect related observations were seen.

Without Activation: Slightly unhealthy cell monolayer, ~40% reductions in the cell monolayer confluence, floating dead cells and debris, and slight reductions in visible mitotic cells were observed at 2540 and 3050 ug/ml. A slight reduction in visible mitotic cells was observed at 2030 ug/ml. Results were analyzed at 1520, 2030, 2540 and 3050 ug/ml. No significant increase in cells with chromosomal aberrations was observed at the concentrations analyzed. The sensitivity of the cell culture for induction of chromosomal aberrations in the cells exposed to the posiitive control agent.

With Activation - In the first 20-hr assay, slightly unhealthy cell monolayers, slight reductions in visible mitotic cells and ~25% reduction in cell monolayer confluence were observed at 33.0 and 40.6 ug/ml. Since the slides from this assay could not be analyzed due to poor quality, this test was repeated testing the same concentrations. In the second 20-hr assay, slightly unhealthy cell monolayer, slight reduction in visible mitotic cells, and ~15% reduction in the cell monolayer confluence were observed at 40 ug/ml No toxicity was observed at subsequent dose levels. Results were analyzed at 17.7, 25, 32.7 and 40 ug/ml. A significant increase in cells with chromosomal aberrations was observed at 32.7 and 40 ug/ml. The aberrations observed included several complex rearrangements. In the 30-hr assay, a slightly unhealthy cell monolayer and ~15% reduction in the cell monolayer confluence were observed at 39.9 ug/ml. Reduction of ~15% in the cell monolayer confluence was observed at 32.6 ug/ml. Results were analyzed at 17.6, 25, 32.7 and 39.9 ug/ml. A weakly significant increase in cells with chromosomal aberrations was observed at 39.9 ug/ml. A dose dependent increase in polyploid cells was also observed at the dose levels analyzed.

# EPA High Production Volume (HPV) Track

Toxicity End point:  
Toxicity in Vitro (Gene Mutations)

Sponsor ID	1100104	Buckman Laboratories, Inc.	Create Date	10/17/2006
CAS Number	111444	Ether, bis(2-chloroethyl)	Study Number	4
Consortia ID			Completed:	<b>N</b>

\* Frequency of reversions/mutations/aberrations, polyploidy as appropriate

Test Material (ug/ml)	No. of Aberr./cell	% Cells w/ Abber.	% Cells w/ >1 Aberr.	% poly ploidy
20-HR				
17.7	0.00	0.0	0.0	----
25.0	0.04	3.0	0.5	----
32.7	0.10	8.0	1.0	----
40.0	0.35	25.1*	5.7*	----
30-HR				
17.6	0.01	1.0	0.0	10.5
25.0	0.00	0.0	0.0	15.0*
32.6	0.05	3.5	0.5	20.5*
39.9	0.08	6.5*	0.5	44.0*

\*significantly greater than the pooled negative and solvent controls, p<0.01.

\*Mitotic index

## Conclusions

The test article, DCEE (Dichloroethylether), was considered negative for inducing chromosomal aberrations in Chinese hamster ovary cells under the nonactivation conditions of this assay. The test article is consider positive under conditions of metabolic activation at high dose levels in the 20-hr assay (32.6 and 40 ug/ml) and weakly positive at a single dose (39.9 ug/ml) in the 30-hr assay.

## Data Quality

Reliability 2(c)

## Data Reliability Remarks

Comparable to guideline study with acceptable restrictions.

## Reference

# EPA High Production Volume (HPV) Track

Toxicity End point:  
Toxicity in Vitro (Gene Mutations)

Sponsor ID	1100104	Buckman Laboratories, Inc.	Create Date	10/17/2006
CAS Number	111444	Ether, bis(2-chloroethyl)	Study Number	4
Consortia ID			Completed:	N

## >> Remarks

Murli, H. 1989. Mutagenicity Test on DCEE (Dichloroethylether) in an In Vitro Cytogenetic Assay Measuring Chromosomal Aberration Frequencies in Chinese Hamster Ovary (CHO) Cells. HLA Study No. 10924-0-437. Hazleton Laboratories America, Inc. Kensington, MD.

## General

# EPA High Production Volume (HPV) Track

Toxicity End Point:  
Acute Toxicity

Sponsor ID	1100104	Buckman Laboratories, Inc.	Create Date	10/17/2006
CAS Number	111444	Ether, bis(2-chloroethyl)	Study Number	1
Consortia ID			Completed:	Y

Revision Date:  
10/26/2006

## Test Substance

Remarks

Purity: 97.3%

## Chemical Category

## Method

>> Method/Guideline followed

Other - Acute Oral Toxicity

>> GLP Yes

>> Year study performed 1990

>> Species

mouse

>> Strain CD-1

>> Sex Both

>> Number of males per dose

5

>> Number of females per dose

5

>> Vehicle Cottonseed oil

>> Route of Administration

Oral

Remarks for Metho

# EPA High Production Volume (HPV) Track

Toxicity End Point:  
Acute Toxicity

Sponsor ID	1100104	Buckman Laboratories, Inc.	Create Date	10/17/2006
CAS Number	111444	Ether, bis(2-chloroethyl)	Study Number	1
Consortia ID			Completed:	Y

\* Age of animals used: Young adult, 6-7 wks.  
\* Doses (OECD guidelines 420, 423, and 425 do not provide dose levels, so these must be described in detail): 140, 200, 240, 290 mg/kg  
\* Doses per time period: Single  
\* Volume administered or concentration: 10 ml/kg  
\* Post dose observation period: 14 days  
\* Exposure duration (for inhalation studies).

## Results

>> Precision =

>>Acute Lethal Value 211

>> Unit mg/kg-bw

>> Deaths per Dose

140 mg/kg - 0(M), 0(F); 200 mg/kg - 3/5(M); 2/5(F), 240 mg/kg - 4/5(M&F); 290 mg/kg - 3/5(M), 5/5(F)

## Results Remark

\* Time of death (provide individual animal time if less than 24 hours after dosing)  
\* Description, severity, time of onset and duration of clinical signs at each dose level: At the 140 mg/kg dose level symptoms included low carriage, decreased activity and anogenital staining at 2 1/2 hrs or 4 hrs post-dose and persisted to day 2. Three animals in this group exhibited these findings, all others exhibited no visible abnormalities. Findings observed at 2 1/2 and 4 hrs post-dose in moribund animals from the 200 mg/kg group included low carriage, decreased activity, ataxia and anogenital staining. Findings delayed to days 2, 3, and/or 4 prior to death included decreased defecation or no stool, tremors, ataxia and decreased activity. Findings observed prior to death in 6 of the 8 moribund animals in the 240 mg/kg groups included ataxia, prostration, ptosis and cold to touch. No other abnormalities were observed. In the 290 mg/kg group, findings prior to death on day 2 included prostration, ataxia, decreased activity and tremors. One female additionally exhibited loss of righting reflex at 4 hr post-dose. No other symptoms were observed in surviving animals.  
\* Necropsy findings, included doses affected, severity and number of animals affected: At the postmortem examination, one female from each of the 200 and 290 mg/kg dose groups which died during the study exhibited congestion of the gastric glandular mucosa. Two females from the 240 mg/kg that died had black foci of the gastric glandular mucosa. One male from this group which had died had mild lung congestion. Yellow staining or material along the ventral surface of deceased animals was noted in one male and one female from the 200 mg/kg dose group, however, these findings were considered incidental and not test article related. No visible abnormalities were observed in mice surviving to study termination

# EPA High Production Volume (HPV) Track

Toxicity End Point:  
Acute Toxicity

Sponsor ID	1100104	Buckman Laboratories, Inc.	Create Date	10/17/2006
CAS Number	111444	Ether, bis(2-chloroethyl)	Study Number	1
Consortia ID			Completed:	<input checked="" type="checkbox"/>

from any group.  
\* Potential target organs (if identified in the report)  
\* If both sexes tested, results should be compared

## Conclusions

## Data Quality

Reliability

## Data Reliability Remarks

Meets generally accepted scientific standards and is described in sufficient detail.

## Reference

### >> Remarks

Myers, J.R. 1990. Acute Oral Toxicity Study in Mice. IRDC Study No. 631-002. International Research and Development Corporation, Mattawan, MI.

## General

# EPA High Production Volume (HPV) Track

Toxicity End Point:  
Acute Toxicity

Sponsor ID	1100104	Buckman Laboratories, Inc.	Create Date	10/17/2006
CAS Number	111444	Ether, bis(2-chloroethyl)	Study Number	2
Consortia ID			Completed:	<input checked="" type="checkbox"/> Y

Revision Date:

10/30/2006

## Test Substance

Remarks

Purity: 97.3%

## Chemical Category

## Method

>> Method/Guideline followed

Other - Acute Oral Toxicity

>> GLP  Yes

>> Year study performed  1990

>> Species

rat

>> Strain  Charles Rivers

>> Sex  Both

>> Number of males per dose  5

>> Number of females per dose

5

>> Vehicle  Cottonseed oil

>> Route of Administration

Oral

Remarks for Metho

# EPA High Production Volume (HPV) Track

Toxicity End Point:  
Acute Toxicity

Sponsor ID	1100104	Buckman Laboratories, Inc.	Create Date	10/17/2006
CAS Number	111444	Ether, bis(2-chloroethyl)	Study Number	2
Consortia ID			Completed:	<input checked="" type="checkbox"/>

\* Age of animals used: Young adult, 8-9 wks  
\* Doses (OECD guidelines 420, 423, and 425 do not provide dose levels, so these must be described in detail): 70, 100, 150, 210 mg/kg.  
\* Doses per time period: Single  
\* Volume administered or concentration: 10 ml/kg  
\* Post dose observation period: 14 days  
\* Exposure duration (for inhalation studies).

## Results

>> Precision =

>>Acute Lethal Value

>> Unit

>> Deaths per Dose

70 mg/kg - 0/5(M&F); 100 mg/kg - 1/5 (M&F); 150 mg/kg - 2/5(M), 4/5(F); 210 mg/kg - 3/5(M), 5/5(F).

## Results Remark

\* Time of death (provide individual animal time if less than 24 hours after dosing):  
\* Description, severity, time of onset and duration of clinical signs at each dose level:  
Symptoms observed frequently during the 4 hr post-dose observation period in rats that died on study and in those that survived included ptosis, increased salivation, yellow anogenital staining, mucoid diarrhea, soft stool, and decreased activity. The anogenital staining affected several rats from each of the 70 and 100 mg/kg dose groups, increased salivation was observed in several 100 mg/kg rats and in most of the 210 mg/kg treatment group, and ptosis was exhibited in most 150 mg/kg animals and in all 210 mg/kg animals. All rats from each dosage level exhibited decreased activity, and most exhibited mucoid diarrhea and/or soft stool. Most of these findings cleared in surviving rats by study day 2. All survivors appeared normal by study day 5.  
\* Necropsy findings, included doses affected, severity and number of animals affected: At the postmortem examination, congestion of the lung and/or thymus was exhibited by most 100 mg/kg and 150 mg/kg rats dying on study and in three of eight 210 mg/kg rats dying on study. One additional rat each dying on study from the 150 and 210 mg/kg levels exhibited black foci of the stomach glandular mucosa or pelvic dilation of the kidney, respectively. There were no visible abnormalities observed in any rat sacrificed at study termination.  
\* Potential target organs (if identified in the report)  
\* If both sexes tested, results should be compared

## Conclusions

# EPA High Production Volume (HPV) Track

Toxicity End Point:  
Acute Toxicity

Sponsor ID	1100104	Buckman Laboratories, Inc.	Create Date	10/17/2006
CAS Number	111444	Ether, bis(2-chloroethyl)	Study Number	2
Consortia ID			Completed:	Y

## Data Quality

Reliability 1(d)

## Data Reliability Remarks

Meets generally accepted scientific standards and is described in sufficient detail.

## Reference

### >> Remarks

Myers, J.R. 1990. Acute Oral Toxicity Study in Rats. IRDC Study No. 631-001. International Research and Development Corporation, Mattawan, MI.

## General

# EPA High Production Volume (HPV) Track

Toxicity End Point:  
Acute Toxicity

Sponsor ID

Buckman Laboratories, Inc.

Create Date

CAS Number

Ether, bis(2-chloroethyl)

Study Number

Consortia ID

Completed:

Revision Date:

## Test Substance

Remarks

## Chemical Category

## Method

>> Method/Guideline followed

>> GLP

>> Year study performed

>> Species

>> Strain

>> Sex

>> Number of males per dose

>> Number of females per dose

>> Vehicle

>> Route of Administration

Remarks for Metho

# EPA High Production Volume (HPV) Track

Toxicity End Point:  
Acute Toxicity

Sponsor ID	1100104	Buckman Laboratories, Inc.	Create Date	10/17/2006
CAS Number	111444	Ether, bis(2-chloroethyl)	Study Number	3
Consortia ID			Completed:	<input checked="" type="checkbox"/>

\* Age of animals used: Young adult, approximately 7 wks  
\* Doses (OECD guidelines 420, 423, and 425 do not provide dose levels, so these must be described in detail): 500 mg/kg  
\* Doses per time period Single  
\* Volume administered or concentration: 10 ml/kg  
\* Post dose observation period: 24 hrs  
\* Exposure duration (for inhalation studies).

## Results

>> Precision >

>> Acute Lethal Value 50

>> Unit mg/kg-bw

>> Deaths per Dose

0/5 (M); 0/5 (F)

## Results Remark

\* Time of death (provide individual animal time if less than 24 hours after dosing)  
\* Description, severity, time of onset and duration of clinical signs at each dose level: Onset of diarrhea occurred all 5 males and 2 females within 1 hr following dosing. It had cleared in all males and 4 of the 5 female by the following day. No other symptoms reported.  
\* Necropsy findings, included doses affected, severity and number of animals affected Not performed.  
\* Potential target organs (if identified in the report)  
\* If both sexes tested, results should be compared

## Conclusions

In accordance with CFR, Title 49 (Dept. of Transportation), 173.343, this compound is not considered a Class B poison by the oral route of administration.

## Data Quality

Reliability 2

## Data Reliability Remarks

# EPA High Production Volume (HPV) Track

Toxicity End Point:  
Acute Toxicity

Sponsor ID	<input type="text" value="1100104"/>	Buckman Laboratories, Inc.	Create Date	<input type="text" value="10/17/2006"/>
CAS Number	<input type="text" value="111444"/>	Ether, bis(2-chloroethyl)	Study Number	<input type="text" value="3"/>
Consortia ID	<input type="text"/>		Completed:	<input checked="" type="checkbox"/>

Meets generally accepted scientific standards.

## Reference

### >> Remarks

Thompson, G.W. 1981. D.O.T. Oral Toxicity. RT Lab No. 824147. Raltech Scientific Services, Madison, WI.

## General

# EPA High Production Volume (HPV) Track

Toxicity End Point:  
Acute Toxicity

Sponsor ID	1100104	Buckman Laboratories, Inc.	Create Date	10/17/2006
CAS Number	111444	Ether, bis(2-chloroethyl)	Study Number	4
Consortia ID			Completed:	N

Revision Date:

10/30/2006

## Test Substance

Remarks

## Chemical Category

## Method

>> Method/Guideline followed

DOT Skin Corrosivity

>> GLP No

>> Year study performed 1981

>> Species

rabbit

>> Strain New Zealand white

>> Sex Both

>> Number of males per dose

3

>> Number of females per dose

3

>> Vehicle Undiluted

>> Route of Administration

Dermal

Remarks for Metho

# EPA High Production Volume (HPV) Track

Toxicity End Point:  
Acute Toxicity

Sponsor ID	<input type="text" value="1100104"/>	Buckman Laboratories, Inc.	Create Date	<input type="text" value="10/17/2006"/>
CAS Number	<input type="text" value="111444"/>	Ether, bis(2-chloroethyl)	Study Number	<input type="text" value="4"/>
Consortia ID	<input type="text"/>		Completed:	<input type="text" value="N"/>

- \* Age of animals used: Young adults, approximately 14 wks.
- \* Doses (OECD guidelines 420, 423, and 425 do not provide dose levels, so these must be described in detail)
- \* Doses per time period: Single (4-hr exposure)
- \* Volume administered or concentration: 0.5 ml
- \* Post dose observation period: 4, 24 & 48 hr.
- \* Exposure duration (for inhalation studies).

## Results

>> Precision

>> Acute Lethal Value

>> Unit

>> Deaths per Dose

0/3 (M); 0/3(F)

## Results Remark

- \* Time of death (provide individual animal time if less than 24 hours after dosing)
- \* Description, severity, time of onset and duration of clinical signs at each dose level: No edema or erythema observed.
- \* Necropsy findings, included doses affected, severity and number of animals affected: NA
- \* Potential target organs (if identified in the report)
- \* If both sexes tested, results should be compared

## Conclusions

In accordance with CFR, Title 49, 173.1200, Appendix A, this compound is not considered to be corrosive.

## Data Quality

Reliability

## Data Reliability Remarks

# EPA High Production Volume (HPV) Track

Toxicity End Point:  
Acute Toxicity

Sponsor ID

Buckman Laboratories, Inc.

Create Date

CAS Number

Ether, bis(2-chloroethyl)

Study Number

Consortia ID

Completed:

Meets generally accepted scientific standards.

## Reference

>> Remarks

Thompson, G.W. 1981. D.O.T. Skin Corrosivity..RT Lab No. 824147. Raltech Scientific Services, Madison, WI.

## General

# EPA High Production Volume (HPV) Track

Toxicity End Point:  
Acute Toxicity

Sponsor ID	1100104	Buckman Laboratories, Inc.	Create Date	10/17/2006
CAS Number	111444	Ether, bis(2-chloroethyl)	Study Number	5
Consortia ID			Completed:	N

Revision Date:

10/30/2006

## Test Substance

Remarks

## Chemical Category

## Method

>> Method/Guideline followed

DOT Acute Dermal Toxicity

>> GLP No

>> Year study performed 1981

>> Species

rabbit

>> Strain New Zealand white

>> Sex Both

>> Number of males per dose

5

>> Number of females per dose

5

>> Vehicle Undiluted

>> Route of Administration

Dermal

Remarks for Metho

# EPA High Production Volume (HPV) Track

Toxicity End Point:  
Acute Toxicity

Sponsor ID

Buckman Laboratories, Inc.

Create Date

CAS Number

Ether, bis(2-chloroethyl)

Study Number

Consortia ID

Completed:

- \* Age of animals used: Young adults, approximately 14 wks.
- \* Doses (OECD guidelines 420, 423, and 425 do not provide dose levels, so these must be described in detail)
- \* Doses per time period: Single
- \* Volume administered or concentration: 200 mg/kg
- \* Post dose observation period: 48-hrs.
- \* Exposure duration (for inhalation studies).

## Results

>> Precision

>> Acute Lethal Value

>> Unit

>> Deaths per Dose

0/5 (M); 0/5 (F)

### Results Remark

- \* Time of death (provide individual animal time if less than 24 hours after dosing)
- \* Description, severity, time of onset and duration of clinical signs at each dose level: All animals appeared normal, no mortality.
- \* Necropsy findings, included doses affected, severity and number of animals affected: NA
- \* Potential target organs (if identified in the report)
- \* If both sexes tested, results should be compared

## Conclusions

In accordance with CFR, Title 49 (Dept. of Transportation), 173.343, this compound is not considered a Class B poison by the dermal route of administration.

## Data Quality

Reliability

### Data Reliability Remarks

# EPA High Production Volume (HPV) Track

Toxicity End Point:  
Acute Toxicity

Sponsor ID	1100104	Buckman Laboratories, Inc.	Create Date	10/17/2006
CAS Number	111444	Ether, bis(2-chloroethyl)	Study Number	5
Consortia ID			Completed:	<input checked="" type="checkbox"/> N

Meets generally accepted scientific standards.

## Reference

### >> Remarks

Thompson, G.W. 1981. Acute Dermal Toxicity (D.O.T. Procedure). RT Lab No. 836554. Raltech Scientific Services, Madison, WI.

## General

# EPA High Production Volume (HPV) Track

Toxicity End Point:  
Acute Toxicity

Sponsor ID	1100104	Buckman Laboratories, Inc.	Create Date	10/17/2006
CAS Number	111444	Ether, bis(2-chloroethyl)	Study Number	6
Consortia ID			Completed:	<input checked="" type="checkbox"/> Y

Revision Date:

10/30/2006

## Test Substance

Remarks

## Chemical Category

## Method

>> Method/Guideline followed

DOT Inhalation Toxicity

>> GLP  No

>> Year study performed

>> Species

rat

>> Strain

>> Sex

>> Number of males per dose  >> Number of females per dose

>> Vehicle

>> Route of Administration

Inhalation

Remarks for Metho

# EPA High Production Volume (HPV) Track

Toxicity End Point:  
Acute Toxicity

Sponsor ID	1100104	Buckman Laboratories, Inc.	Create Date	10/17/2006
CAS Number	111444	Ether, bis(2-chloroethyl)	Study Number	6
Consortia ID			Completed:	<input checked="" type="checkbox"/> Y

- \* Age of animals used: Young adults, approximately 8 wks.
- \* Doses (OECD guidelines 420, 423, and 425 do not provide dose levels, so these must be described in detail): 2.0, 5.0 & 6.4 mg/L (nominal). The protocol procedure was to conduct the initial conc. at 2 mg/L per L of air for 1 Hr. However, the rats of each exposure group were divided into 2 subgroups of 5 animals and each subgroup was exposed at a different but consecutive time, due to the volume of the chamber used.
- \* Doses per time period:
- \* Volume administered or concentration:
  - Group 1a: 6.4 mg/L of air
  - Group 1b: 5.0 mg/L of air
  - Group 2a: 2.0 mg/L of air
  - Group 2b: 2.0 mg/L of air
- \* Post dose observation period: 48hrs.
- \* Exposure duration (for inhalation studies). 1-hr.

## Results

>> Precision >

>> Acute Lethal Value 2

>> Unit mg/L(air)

>> Deaths per Dose

2.0 mg/L - 0/5, 0/5; 5.0 mg/L - 3/5; 6.4 mg/L - 3/5.

## Results Remark

- \* Time of death (provide individual animal time if less than 24 hours after dosing)
- \* Description, severity, time of onset and duration of clinical signs at each dose level: At the high dose exposure, all animals immediately became inactive and had eyes closed. Over the next hour of observation, the animals exhibited labored breathing, gasping, clear nasal and ocular discharge, and remained lethargic. The animals eyes and skin became dark and eyes became swollen. Similar effects were noted within 1-hr observation of animals exposed to 5.0 mg/L of air. Three of the five 6.4 mg/L dose group and two of five in the 5.0 mg/L group died within 24 hr. One moribund animal in the 5.0 mg/L group exhibited a reddish-brown discharge around the nose and mouth. It had died by the following day. All surviving animals in these groups were lethargic and had a reddish ocular discharge. Observations within the first hour of exposure to 2.0 mg/L in air included hypoactivity, eye irritation, labored breathing and darkening of eye and skin color. Animals remained hypoactive through the 48 hrs observation period, but the labored breathing appeared to abate to normal.
- \* Necropsy findings, included doses affected, severity and number of animals affected
- \* Potential target organs (if identified in the report)

# EPA High Production Volume (HPV) Track

Toxicity End Point:  
Acute Toxicity

Sponsor ID	1100104	Buckman Laboratories, Inc.	Create Date	10/17/2006
CAS Number	111444	Ether, bis(2-chloroethyl)	Study Number	6
Consortia ID			Completed:	<input checked="" type="checkbox"/> Y

\* If both sexes tested, results should be compared

## Conclusions

Ten male rats of the first test group were exposed to dichloroethylether via the route of inhalation at nominal concentrations of 5.0 to 6.4 mg/L of air. Because the mortality was greater than 50%, a second test group was exposed using the same method in which the nominal concentration was 2.0 mg/L of air. All 10 rats exposed to the nominal concentration of 2.0 mg/L of air survived the 1-hr exposure and 2-day post exposure periods. Therefore, the compound by definition\* is not a Class B poison.

\*Supported by the Regulations of MTB, CFR, Vol. 49, Part 173.343(2), 1976.

## Data Quality

Reliability 2

## Data Reliability Remarks

Meets generally accepted scientific standards.

## Reference

### >> Remarks

Biesemeier, J.A. 1980. D.O.T. Inhalation Toxicity. RT Lab No. 824147. Raltech Scientific Services, Madison, WI.

## General

# EPA High Production Volume (HPV) Track

Physical-Chemical End Point:  
Vapor Pressure

Sponsor ID  Buckman Laboratories, Inc.

Create Date

CAS Number  Ether, bis(2-chloroethyl)

Study Number

Consortia ID

Completed:  Y

Revision Date:

## Test Substance

Remarks

## Chemical Category

## Method

>> Method/Guideline followed

>> GLP

>> Year study performed

Remarks for Metho

## Results

>> Precision =

>> Vapor Pressure Value

>> Upper Value

# EPA High Production Volume (HPV) Track

Physical-Chemical End Point:  
Vapor Pressure

Sponsor ID	1100104	Buckman Laboratories, Inc.	Create Date	10/17/2006
CAS Number	111444	Ether, bis(2-chloroethyl)	Study Number	1
Consortia ID			Completed:	Y

>> Unit mm Hg

>> Temperature 25

>> Decomposition No

## Results Remark

## Conclusions

## Data Quality

Reliability 2(e)

## Data Reliability Remarks

Meets generally accepted scientific standards, well documented and acceptable for assessment

## Reference

# EPA High Production Volume (HPV) Track

Physical-Chemical End Point:  
Vapor Pressure

Sponsor ID

Buckman Laboratories, Inc.

Create Date

CAS Number

Ether, bis(2-chloroethyl)

Study Number

Consortia ID

Completed:

## >> Remarks

Gibson, J. And Flynn, T. 1992. Vapour Pressure Determination of DCEE. Unisearch Ltd, School of Chemistry, Univ. of New South Wales.

## General