

74I-0794-000947

ETHYL CORPORATION

Health and Environment Department

ETHYL TOWER, 451 FLORIDA
BATON ROUGE, LOUISIANA 70801



84940000047

May 23, 1988

(A)



FYI-94-000947
INIT 07/26/94

Mr. Robert Brink
Executive Secretary
TSCA Interagency Testing
Committee (TS-792)
U. S. Environmental Protection Agency
401 M Street, S.W.
Washington, DC 20460

RECEIVED
54 JUL 26 PM 3:55

Dear Mr. Brink:

RE: Decabromodiphenyl oxide, Octabromodiphenyl oxide, Hexabromocyclododecane, Pentabromodiphenyl oxide

Ethyl Corporation is submitting the enclosed information in response to ITC's request for comments and data on brominated flame retardants.

Ethyl is a manufacturer of decabromodiphenyl oxide (1163-19-5), octabromodiphenyl oxide (32536-52-0), pentabromodiphenyl oxide (32534-81-9), and hexabromocyclododecane (3194-55-6). For your information, we have enclosed the following technical and toxicity data:

1. Saytex® Flame Retardants Product List (Ethyl Chemicals Group).
2. Technical Bulletins for decabromodiphenyl oxide, octabromodiphenyl oxide, and hexabromocyclododecane.
3. Material Safety Data Sheets for decabromodiphenyl oxide, octabromodiphenyl oxide, pentabromodiphenyl oxide, and hexabromocyclododecane.
4. Toxicology tests on:

Decabromodiphenyl oxide:

- Determination of DBDPO in rat livers (5/2/80)
- 90-day subchronic study in rats [Tracor-Jetco]
- Comedogenicity (9/21/81)
- Eye irritation (3/24/86)
- Human repeat insult patch test (6/4/75)
- 13-week feeding study in mice (7/27/79) [Tracor-Jetco]

RECEIVED
9/9/95

Octabromodiphenyl oxide:

- 1-hour dust inhalation (1/31/84)
- Two year dietary study in rates (?) paper/Dow
- Acute oral toxicity (12/5/83)
- Dermal irritation (11/29/83)
- Eye irritation (12/5/83)
- Ames test (7/1/85)
- Dose Range Finding Study (12/7/84)
- Embryo/fetal toxicity (4/15/85) & Review

Hexabromocyclododecane:

- Ames test (11/17/78)
- Inhalation LC₅₀/Dermal LC₅₀ (11/7/78)
- Primary dermal irritation/dermal corrosion/ocular irritation/oral LD₅₀ (10/17/78)

Pentabromodiphenyl oxide:

- Acute inhalation in rates (11/77)
- Acute oral toxicity in rates (11/84)
- Ames test (12/85)
- Bromacnegenic (9/77)
- Acute toxicity (9/77)
- Acute oral and percutaneous toxicity (9/77)
- Delayed hypersensitivity (10/77)
- Embryo/fetal toxicity (4/15/85)

In addition, under separate cover as attachment, Ethyl is submitting proprietary information which we are requesting the ITC to hold as "TSCA Confidential Business Information".

If you have any questions, please call me at (504) 388-7650.

Sincerely,



Louise L. Wen
Regulatory Affairs Associate

LLW/ccj
2600r



GULF SOUTH RESEARCH INSTITUTE

Post Office Box 26518

New Orleans, Louisiana 70186

Telephone 504 283-4223

HEXABROMOCYCLODODECANE

Ethyl Corp (1988)

MUTAGENICITY TEST OF GLS-S6-41A

November 17, 1978

Test performed by Asya Shoichet, Technician

Certified by Kenneth Ehrlich, Project Supervisor,
Department of Cytology and Applied Biochemistry

The sample, GLS-S6-41A, was dissolved in dimethyl sulfoxide (10 mg/ml) and tested by the Ames Salmonella/microsome test procedure [Ames, B.N., J. McCann, and E. Yamasaki (1975) Mutation Res. 3 347]. The test was performed at levels of 2 to 1000 µg per plate and results are given in the table. The number of Salmonella revertants obtained per plate can be compared to the control values. With Salmonella strains TA1535, TA100, and TA1537 the number of revertants in sample-treated plates was equal to the number found for the untreated DMSO control plates. With TA98 tested in the presence of sample and liver homogenate, there was an increase of 20 colonies above DMSO control for plates treated with 40, 200, and 1000 µg of sample. The activity of the liver homogenate was confirmed by its ability to convert benzo(a)pyrene and 9-aminoacridine to mutagenic products.

Discussion

Reversion of the Salmonella histidine auxotrophs is caused by mutagenesis. The different Salmonella strains have differing sensitivities to base-pair substitution mutations and to frameshift mutation. Strains TA100 and TA98 are particularly sensitive to most mutagenic substances but due to their intrinsically high spontaneous mutation frequency, small increases in number of revertants compared to background levels must be interpreted cautiously. The fact that no dose-response reversion of TA98 was found, although there was a slight increase compared to solvent control, may be considered evidence that this increase is not due to mutagenesis. Furthermore, since the increased mutation frequency is less than 70 revertants more than control at the highest dose tested, the agent would be, at best, only an extremely weak mutagen. For these reasons we interpret the results to suggest that GLS-S6-41A is a nonmutagenic substance.

MUTAGENICITY TEST OF GLS-S6-41A

µg/plate	S9	Revertants per plate			
		TA98	TA100	TA1535	TA1537
1000	-	35	247	25	7
	+	63	290	22	7
200	-	30	240	26	7
	+	61	257	21	7
40	-	25	234	22	6
	+	56	260	19	8
2	-	22	218	20	6
	+	47	242	17	8

Controls

DMSO 0.1 ml,	+	42	234	21	10
Benzo(a)pyrene, (5µg)	+	114	543	NT	NT
N-methyl-N-nitroso N-nitroguanidine, - (5µg)	-	NT	NT	220	NT
9-aminoacridine (5µg)	+	NT	NT	NT	350

NT = Not tested.

Tested 7/25/78 K. Shih



Consumer Product Testing

Company Incorporated

Bldg. No. 2-15B
1275 Bloomfield Avenue
Fairfield, New Jersey 07006

(201) 575-7688
(201) 575-7689

F I N A L R E P O R T

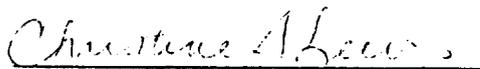
CLIENT: Saytech Inc.
880 Main Street
Sayreville, New Jersey 08872

ATTENTION: LaVerne J. Makfinsky
Manager, Technical Compliance

TESTS: Inhalation LC₅₀ (Rat)
Dermal LD₅₀ (Rabbit)

TEST MATERIAL: GLS-S6-41A

EXPERIMENT REFERENCE NO.: 78385-2


Christine A. Lewis, B.S.
Laboratory Supervisor
Project Director


Allen L. Palanker
President

Date November 7, 1978
ALP/CAL/nlm

This report is submitted for the exclusive use of the person, partnership, or corporation to whom it is addressed, and neither the report nor the name of these Laboratories nor of any member of its staff, may be used in connection with the advertising or sale of any product or process without written authorization.

This report details :

a dermal LD₅₀ study in albino rabbits and
an inhalation LC₅₀ study in albino rats

performed at the behest of :

Saytech Inc.
880 Main Street
Sayreville, New Jersey 08872

The test material, supplied by :

Saytech Inc.

was received on :

September 15, 1978

and identified as :

GLS-S6-41A

and was used as indicated in the Final Report Summaries.

Study Interval : September 28, 1978 to November 2, 1978

All animals are fed and watered ad libitum; with Wayne animal feeds used exclusively. Animals are received from Summit View Farm, Belvidere, New Jersey and are conditioned prior to use. Samples, raw data and final report copies are retained at these laboratories unless otherwise indicated.

Project Director and study supervisor are signatory to this report. Date of submission is recorded on title page. Names of persons performing these tests are recorded on raw data sheets and laboratory log books and are available upon request.

Final Report Summary

DATE: November 7, 1978
CLIENT: Saytech Inc.
STUDY NO.: 78385-2
REFERENCE NO.: P. O. #00323
MATERIAL: GLS-S6-41A

Acute Dermal Toxicity (LD₅₀)

Method: Following 14-day range finding, albino rabbits in groups of six (3M:3F), ½ abraded, 1.88 - 2.07 kg, highest dose level mechanically possible, single application dermally under occluded patch, observed fourteen days. Material used as received, LD₅₀ and 95% confidence limits according to the method of Litchfield and Wilcoxin, when possible. Upper limit possible due to mechanical and physical limitations is 8 g/kg.

Result: LD₅₀: > 8 g/kg

	<u>Dose Level</u> (g/kg)	<u>Sex</u>	<u>#dead/#dosed</u>	<u>% Mortality</u>
Range	0.5	1F	0/1	0
Finding:	2.0	1F	0/1	0
	5.0	1F	0/1	0
	8.0	1F	0/1	0
Test Dosage:	8.0	3M:3F	0/3:0/3	0

Not a toxic material dermally to rabbits under conditions of this test.

Consumer Product Testing Company, Inc.

Final Report Summary

DATE: November 7, 1978
CLIENT: Saytech Inc.
STUDY NO.: 78385-2
REFERENCE NO.: P. O. #00323
MATERIAL: GLS-S6-41A

Inhalation LC₅₀

Method: Albino rats in groups to ten (5M:5F), 233-292 g, exposed to concentrations of 200 mg/liter (highest possible chamber concentration) for one hour, observed two weeks. Material used as received.

Result: LC₅₀ : > 200 mg/l

<u>Dose Level</u> <u>(mg/l)</u>	<u>Sex</u>	<u>#dead/#dosed</u>	<u>%</u>
200	5M:5F	0/5:0/5	0

Gross
Pathology: No gross changes observed.

Not a toxic material by inhalation to rats under conditions of this test.

Consumer Product Testing Company, Inc.

METHOD:

Acute Dermal Toxicity in Rabbits (LD₅₀)

Acute dermal toxicity in rabbits was determined according to the procedures suggested by Hagan.¹ New Zealand white rabbits, as indicated in the summary, were maintained under standard laboratory conditions prior to administration of the test material.

Prior to determination of LD₅₀ single animals, skin un-abraded, were dosed at various levels to determine a range within which the LD₅₀ could be determined. Animals were observed fourteen full days following application to determine mortality during this period.

Following the range finding the rabbits were dosed individually by dermal application under occluded patch at a dose level according to the results of the 14-day range finding previously performed. Applications were made to the clipped backs of six (3M:3F) animals, 1/2 abraded, under 1" x 1" gauze patches over 10% of the body surface. The dosed area was then covered with an impermeable plastic wrapping for 24 hours, after which it was removed and the skin gently cleansed. Animals were returned to quarters where food and water were available ad libitum following the dose application.

Animals were observed for signs of pharmacologic activity and drug toxicity at 1, 3, 6, and 24 hours post-dosage. Observations were made daily thereafter to a total of fourteen days.

Non-survivors and animals sacrificed at the end of the 14-day observation period were subjected to complete gross necropsy. LD₅₀ together with 95% confidence limits was determined, where possible, by the method of Litchfield and Wilcoxin.²

The highest dose mechanically feasible to use is considered to be 8 g(ml)/kg bodyweight. Doses as high as 20 g/kg are used when instructed under EPA regulations; however, the data derived at, at these extraordinary high levels cannot be deemed as accurate as that derived at, at the lower dose levels.

¹Hagan, E.C. (1959) Acute Toxicity; Appraisal of the Safety of Chemicals in Foods, Drugs, and Cosmetics, pp. 17 - 25.

²Litchfield, J.T. and Wilcoxin, F. (1949) Acute Toxicity; J. Pharm. & Ex. Ther., pp. 96, 99.

Inhalation LC₅₀ in Rats

A group of adult Wistar-derived albino rats as indicated in the summary, was housed in a three-cubic-foot plastic chamber for the single one (1) hour dynamic exposure period. The chamber was initially charged with test material at a concentration of 200 mg/l. Preconditioned supportive air was supplied at five (5) liters per minute, and the test material was presented from a dust generator to continue a nominal chamber concentration of 200 mg/liter air, over the one hour period.

At the end of the one-hour period, the animals were returned to individual quarters and observed daily for two weeks after which time they were sacrificed and autopsied.

RESULTS:

Acute Dermal Toxicity in Rabbits

Individual results are presented in Tables 1 & 2.

Acute Inhalation Toxicity

Individual results are presented in Table 3.

Summaries of all results are found preceding the text.

Table 1
Acute Dermal Toxicity in Rabbits

Range Finding		GLS-S6-41A												
Dose g/kg	Animal Number and Sex	Bodyweight (kg)	Hours:				Days:							Bodyweight (kg)
			1	3	6	24	2	3	4	5	6	7--14		
0.5	1F	1.95	N	N	N	N	N	N	N	N	N	N	N	2.11
2.0	2F	2.03	N											2.36
5.0	3F	1.94	N				NO CHANGES OBSERVED						2.28	
8.0	4F	2.25	N											2.51

a = abraded skin

N = Normal

D = Depression

SD = Slight Depression

XD = Severe Depression

+ = Animal Death

Comments: Animal #1 - #4: Skin pliable and non-irritated. No gross changes observed.

Draize Scores at 24 Hours: Animal #1 0/0
Animal #2 0/0
Animal #3 0/0
Animal #4 0/0

Table 2
Acute Dermal Toxicity in Rabbits

GLS-S6-41A

Dose g/kg	Animal Number and Sex	Bodyweight (kg)	Hours:				Days:							Bodyweight (kg)
			1	3	6	24	2	3	4	5	6	7--14		
8.0	1 M	1.98	N	N	N	N	N	N	N	N	N	N	N	2.52
	2 M a	1.88	N											2.38
	3 M a	1.98	N	NO CHANGES OBSERVED								2.42		
	4 F	2.00	N											2.06
	5 F a	2.07	N											2.19
	6 F	2.06	N											2.69

a = abraded skin

N = Normal

D = Depression

SD = Slight Depression

XD = Severe Depression

+ = Animal Death

Comments: Animal #1 - #6: No gross changes observed.

Draize Scores at 24 Hours:

Animal #1	0/0
Animal #2	0/0
Animal #3	0/0
Animal #4	0/0
Animal #5	0/0
Animal #6	0/0

Table 3
Acute Inhalation Toxicity

GLS-S6-41A

Dose mg/l	Animal Number and Sex	Bodyweight (grams)	Hours:				Days:							Bodyweight (grams)
			1	3	6	24	2	3	4	5	6	7--14		
200	1 M	284	N	N	N	N	N	N	N	N	N	N	N	366
	2 M	292	N											344
	3 M	274	N											330
	4 M	264	N											320
	5 M	270	N	NO CHANGES OBSERVED									284	
	6 F	282	N											370
	7 F	242	N											278
	8 F	233	N											268
	9 F	244	N											276
	10 F	242	N											268

N = Normal
D = Depression
SD = Slight Depression
XD = Severe Depression
+ = Animal Death

Comments; Animal #1 - #10: No gross changes observed.



Consumer Product Testing

Company Incorporated

Bldg. No. 2-15B
1275 Bloomfield Avenue
Fairfield, New Jersey 07006

(201) 575-7688
(201) 575-7689

FINAL REPORT

CLIENT: Saytech Inc.
880 Main Street
Sayreville, New Jersey 08872

ATTENTION: LaVerne J. Makfinsky
Manager, Technical Compliance

TESTS: Primary Dermal Irritation (Rabbit)
Dermal Corrosion (Rabbit)
Ocular Irritation (Rabbit)
Oral LD₅₀ (Rat)

TEST MATERIAL: GLS-S6-41A

EXPERIMENT REFERENCE NO.: 78385-1

Christine A. Lewis, B.S.
Laboratory Supervisor
Project Director

Allen L. Palanker
President

Date October 17, 1978
CAL/nlm

This report details :

a primary dermal irritation study,
a dermal corrosion study, and
an ocular irritation study in albino rabbits and
an oral LD₅₀ study in albino rats

performed at the behest of :

Saytech Inc.
880 Main Street
Sayreville, New Jersey 08872

The test material, supplied by :

Saytech Inc.

was received on :

September 15, 1978

and identified as :

GLS-S6-41A

and was used as indicated in the Final Report Summaries.

Study Interval : September 25, 1978 to October 13, 1978

All animals are fed and watered ad libitum; with Wayne animal feeds used exclusively. Animals are received from Summit View Farm, Belvidere, New Jersey and are conditioned prior to use. Samples, raw data and final report copies are retained at these laboratories unless otherwise indicated.

Project Director and study supervisor are signatory to this report. Date of submission is recorded on title page. Names of persons performing these tests are recorded on raw data sheets and laboratory log books and are available upon request.

Final Report Summary

DATE: October 17, 1978
CLIENT: Saytech Inc.
STUDY NO.: 78385-1
REFERENCE NO.: P. O. #00323
MATERIAL: GLS-S6-41A

Primary Dermal Irritation

Method: Six rabbits, mixed sex, each abraded and non-abraded, 0.5 ml single application under occluded patch, 24 and 72 hour observation. Material used as received.

Result: Primary Irritation Index:*

0.0

Not a primary dermal irritant to rabbits under the conditions of this test.

* See Table 1A for evaluation.

Final Report Summary

DATE: October 17, 1978
CLIENT: Saytech Inc.
STUDY NO.: 78385-1
REFERENCE NO.: P. O. #00323
MATERIAL: GLS-S6-41A

Dermal Corrosion

Method: Six rabbits, mixed sex, each non-abraded, 0.5 ml single application under occluded patch, 4 and 48 hour observation.
Material used as received.

Result: Primary Irritation Index: 0.0

Corrosive:
49 CFR 173.240 (a)(1):

IS
IS NOT X

Final Report Summary

DATE: October 17, 1978
CLIENT: Saytech Inc.
STUDY NO.: 78385-1
REFERENCE NO.: P. O. #00323
MATERIAL: GLS-S6-41A

Ocular Irritation

Method: Six rabbits, mixed sex, 1.8 - 2.4 kg, 0.1 ml single administration, all with no wash for 24 hours and up to seven day observation. Material used as received.

Result:

Group	Draize Score			
	-----Day-----			
	1	2	3	4-----7
No Wash	6.2	2.8	0.3	0

Mild, transient ocular irritant in rabbits under the conditions of this test.

Final Report Summary

DATE: October 17, 1978
CLIENT: Saytech Inc.
STUDY NO.: 78385-1
REFERENCE NO.: P. O. #00323
MATERIAL: GLS-S6-41A

Oral LD₅₀

Method: Albino rats in groups of ten (5M:5F), 192 - 260 g, single dosed orally, (40 ml/kg top dose mechanically feasible) observed fourteen days. Material used as a 25% gravimetric suspension in corn oil.

Result: LD₅₀: > 10 g/kg

	<u>Dose Level</u> <u>(g/kg)</u>	<u>Sex</u>	<u>#dead/#dosed</u>	<u>%</u>
Range	1.0	1M	0/1	0
Finding:	3.0	1M	0/1	0
	5.0	1M	0/1	0
	10.0	1M	0/1	0
Test Dosage:	10.0	5M:5F	1/5:0/5	10

Not a toxic material orally to rats under the conditions of this test.

Consumer Product Testing Company, Inc.

METHOD:

Primary Dermal Irritation in Rabbits

A group of albino New Zealand rabbits as indicated in the summary were used in this study. The test method was essentially that of Draize et.al.

Briefly paraphrased, it consisted of application of 0.5 ml (0.5 g) of the test material to clipped areas of intact and abraded skin. The abrasions were longitudinal epidermal incisions sufficiently deep to penetrate the stratum corneum, but not so deep as to destroy the integrity of the derma. Applications were made under occlusive patches (2" x 2" gauze, covered by adhesive tape). Following application of the test material the entire trunk of each animal was covered with an impermeable occlusive wrapping. The availability of the test site to the animal is restricted by use of everted Elizabethan collars. The wrapping and test material were removed 24 hours following application. The sites were individually examined and scored separately for erythema and edema at 24 and 72 hours. The mean scores for 24 and 72 hour gradings were averaged to determine final irritation indices.

¹Draize, John H., Woodward, Geoffrey, and Calvery, Herbert O., "Methods for the Study of Irritation and Toxicity of Substances Applied Topically to the Skin and Mucous Membranes", J. Pharm. & Ex. Ther. 82, 377, (1944).

Dermal Corrosion in Rabbits
49 CFR 173.240 (a)(1):

A group of six (6) albino New Zealand rabbits in a weight range of 1.8 - 2.4 kg, were used in this study. The test method was essentially that of Draize et.al.

Briefly paraphrased, it consisted of application of 0.5 ml (0.5 g) of the test material to clipped areas of intact skin. Applications were made under occlusive patches (2" x 2" gauze, covered by adhesive tape). Following application of the test material the entire trunk of each animal was covered with an impermeable occlusive wrapping. The animals were then immobilized. The wrapping and test material were removed 4 hours following application. The sites were individually examined and scored separately for erythema and edema at 4 and 48 hours. The mean scores for 4 and 48 hour gradings were averaged to determine final irritation indices. Corrosiveness seen at four and/or 48 hours alone indicates a corrosive material. Tissue destruction (corrosiveness) does not include merely sloughing of the epidermis, or erythema, edema or fissuring.

¹Draize, John H., Woodard, Geoffrey, and Calvery, Herbert O., "Methods for the Study of Irritation and Toxicity of Substances Applied Topically to the Skin and Mucous Membranes", J. Pharm. & Ex. Ther. pp. 82, 377 (1944).

Primary Eye Irritation in Rabbits (FHSA)

New Zealand rabbits as indicated in the summary without ocular defects were used. The procedure followed was a modification of that used by Dr. J.H. Draize in Appraisal of The Safety of Chemicals in Foods, Drugs and Cosmetics, compiled by the staff of the Division of Pharmacology, Food and Drug Administration - Department of Health, Education and Welfare.

In the technique of determining toxicity of substances to eye mucosa, observations of injuries were made on the cornea, iris and the bulbar and palpebral conjunctivae. Numerical scores were assigned to lesions observed according to the Draize standard scoring system. In this system of scoring, the injuries to the cornea and iris account for approximately eighty (80%) percent of the total score; these structures are purposely weighted because of their vital role in vision. Healthy New Zealand rabbits were used for this test. One-tenth of a milliliter of each test substance was instilled in the right eye; the left eye, remaining untreated, served as a control. The treated eyes of all rabbits remained unwashed for 24 hours.

Readings facilitated by hand-held lenses were made 1, 2, and 3 days after treatment, and up to seven (7) days when necessary.

¹Draize, John H., Woodard, Geoffrey, and Calvery, Herbert O., "Methods for the Study of Irritation and Toxicity of Substances Applied Topically to the Skin and Mucous Membranes", J. Pharm. & Ex. Ther. 82, 377, (1944).

Acute Oral Toxicity in Rats (LD₅₀)

Acute oral toxicity in rats was determined according to the procedure suggested by Hagan.¹ Wistar-derived albino rats, as indicated in the summary were assigned to groups, and maintained under standard laboratory conditions for a minimum of seven days, and fasted overnight prior to administration of the test material.

The rats were dosed individually by gavage, at graded dose levels (following range finding) after which they were returned to quarters where food and water were available ad libitum.

Animals were observed for signs of pharmacologic activity and drug toxicity at 1, 3, 6 and 24 hours post-dosage. Observations were made daily thereafter to a total of fourteen days.

Animals sacrificed at the end of the 14-day observation period were subjected to complete gross necropsy.

LD₅₀ was calculated, (including the 95% confidence limits) where possible, using the method of Litchfield and Wilcoxin² except when the highest maximum dose mechanically possible (40 ml/kg) is used.

¹Hagan, E.C. (1959) Acute Toxicity; Appraisal of the Safety of Chemicals in Foods, Drugs and Cosmetics, pp. 17 - 25.

²Litchfield, J.T. and Wilcoxin, F. (1949) J. Pharmacol. Exptl. Therap. pp. 96, 99.

RESULTS:

Primary Dermal Irritation and Dermal Corrosion
in Rabbits

The scoring scale used is presented in Table 1. The individual results are presented in Tables 2 and 3.

Primary Eye Irritation in Rabbits

Table 4 details scoring criteria. The individual results are presented in Table 5.

Oral LD₅₀ in Rats

Individual results are presented in Tables 6 and 7.

Summaries of all results are found preceding the text.

Table 1
Scoring Criteria for Skin Reactions

Erythema and Edema Formation

Very slight erythema (barely perceptible)	1
Well-defined erythema	2
Moderate to severe erythema	3
Severe erythema (beet redness) to slight eschar formation (injuries in depth)	4

Total possible erythema score = 4

Edema Formation

Very slight edema (barely perceptible)	1
Slight edema (edges of area well-defined by definite raising)	2
Moderate edema (area raised approximately 1 mm)	3
Severe edema (raised more than 1 mm and extending beyond area of exposure)	4

Total possible edema score = 4

Total possible primary irritation score = 8

Table 1A
Scale of Interpreting
Primary Dermal Irritation Scores
(Draize - Rabbit)

Score	Interpretation
C	Corrosive - highly dangerous, warning labels must be used
5.0 and above	Primary Dermal Irritant - highly dangerous, warning label must be used
3.0 - 4.9	Potential for severe irritation - warning label would be advised
2.0 - 2.9	Potential for moderate irritation - may be irritating to humans under conditions similar to test (may consider warning label)
1.0 - 1.9	Potential for mild irritation - possibly irritating to some people under occlusive wrap conditions - usually no warning required
0.1 - 0.9	Potential for slight irritation - rarely irritating to people - no warning required
0.0	No irritation potential - no warning required

Table 2

Primary Skin Irritation - Rabbits
SUMMARY OF SCORES FOR SKIN IRRITATION

GLS-S6-41A

Rabbit Number	Skin	Hours:					
		E ¹	24 /	Ed	E	72 /	Ed
1	NA ²	0		0	0		0
	A ³	0		0	0		0
2	NA	0		0	0		0
	A	0		0	0		0
3	NA	0		0	0		0
	A	0		0	0		0
4	NA	0		0	0		0
	A	0		0	0		0
5	NA	0		0	0		0
	A	0		0	0		0
6	NA	0		0	0		0
	A	0		0	0		0
Average	NA	0.0		0.0	0.0		0.0
	A	0.0		0.0	0.0		0.0

Combined Averages: 0.0
 Primary Irritation Index: 0.0

¹E/Ed= Erythema and Edema

²NA = Non-abraded skin

³A = Abraded Skin

Table 3
 Primary Skin Irritation - Rabbits
 SUMMARY OF SCORES FOR SKIN IRRITATION
 GLS-S6-41A

Rabbit Number	Skin	Hours:		Ed	48	
		E ¹	/		E	/
1	NA ²	0		0		0
2	NA	0		0		0
3	NA	0		0		0
4	NA	0		0		0
5	NA	0		0		0
6	NA	0		0		0
Average	NA	0.0		0.0		0.0

Combined Averages: 0.0
 Primary Irritation Index: 0.0

¹E/Ed = Erythema and Edema

²NA = Non-abraded skin

Table 4
Eye Irritation Test
Scale of Weighted Scores for
Grading the Severity of Ocular Lesions

Ocular Tissues	Description	Grading
Cornea	<u>Opacity (A)</u>	
	Opacity - degree of density (area which is dense is taken for reading)	
	Scattered or diffuse area, details of iris clearly visible.	1
	Easily discernible translucent areas, details of iris slightly obscured.	2
	Opalescent areas, no details of iris visible, size of pupil barely discernible.	3
	Opaque, iris invisible.	4
	<u>Area of Cornea Involved (B)</u>	
	One-quarter (or less), but not zero.	1
	Greater than one-quarter, but less than one-half.	2
	Greater than one-half, but less than three-quarters.	3
Greater than three-quarters, up to whole area.	4	
	Score equals A x B x 5	Total maximum = 80
Iris	<u>Values (A)</u>	
	Folds above normal, congestion, swelling, circumcorneal injection (any or all of these or combinations of any thereof), iris still reacting to light.	
	Sluggish reaction is positive.	1
	No reaction to light hemorrhage, gross destruction, (any or all of these).	2
		Score equals A x 5

Table 4 (cont'd.)
Eye Irritation Test
Scale of Weighted Scores for
Grading the Severity of Ocular Lesions

Ocular Tissues	Description	Grading
Conjunctivae	<u>Redness (A)</u>	
	Redness (refers to palpebral conjunctivae only). Vessels definitely injected above normal.	1
	More diffuse, crimson red, individual vessels not easily discernible.	2
	Diffuse beefy red.	3
	<u>Chemosis (B)</u>	
	Any swelling above normal (includes nictitating membrane).	1
	Obvious swelling with partial eversion of the lids.	2
	Swelling with lids about half-closed.	3
	Swelling with lids about half-closed to completely closed.	4
	<u>Discharge (C)</u>	
	Any amount different from normal (does not include small amount observed in inner canthus of normal animals).	1
	Discharge with moistening of the lids and hairs just adjacent to the lids.	2
Discharge with moistening of the lids and hairs and considerable area around eye.	3	

Score equals (A + B + C) x 2

Total maximum = 20

Note: The maximum total score is the sum of all scores obtained for the cornea, iris and conjunctivae.

Table 5
Primary Eye Irritation - Rabbits
SUMMARY OF EYE IRRITATION

GLS-S6-41A

Rabbit Number	Day	Cornea: A x B x 5 +		Iris: A x 5 +	Conjunctivae: (A + B + C) x 2 =			Total Scores*	
-----No Wash Group-----									
1	1	0	0	0	(B)	1	0	0	2
	2	0	0	0		1	0	0	2
	3	0	0	0		0	0	0	0
	4	-	-	-		-	-	-	-
	7	-	-	-		-	-	-	-
2	1	0	0	0		0	0	0	0
	2	0	0	0		0	0	0	0
	3	0	0	0		0	0	0	0
	4	-	-	-		-	-	-	-
	7	-	-	-		-	-	-	-
3	1	0	0	0	(B)	1	1	0	4
	2	0	0	0		0	0	0	0
	3	0	0	0		0	0	0	0
	4	-	-	-		-	-	-	-
	7	-	-	-		-	-	-	-
4	1	0	0	1	(B)	1	1	1	11
	2	0	0	0		1	1	0	4
	3	0	0	0		0	0	0	0
	4	-	-	-		-	-	-	-
	7	-	-	-		-	-	-	-
5	1	1	1	1	(B)	2	2	1	20
	2	1	1	0		1	1	1	11
	3	0	0	0		0	1	0	2
	4	0	0	0		0	0	0	0
	7	-	-	-		-	-	-	-
6	1	0	0	0		0	0	0	0
	2	0	0	0		0	0	0	0
	3	0	0	0		0	0	0	0
	4	-	-	-		-	-	-	-
	7	-	-	-		-	-	-	-
Average	1								6.2
	2								2.8
	3								0.3
	4								0
	7								0

*Total score possible/animal/observation interval = 110
(B) = Blanched

Table 6
Acute Oral Toxicity

GLS-S6-41A

Range Finding	Dose g/kg	Animal Number and Sex	Bodyweight (grams)	Hours:				Days:							Bodyweight (grams)	
				1	3	6	24	2	3	4	5	6	7--14			
	1.0	1 M	234	N	N	N	N	N	N	N	N	N	N	N	348	;
	3.0	2 M	240	N				N	N	N	N	N	N	N	316	.
	5.0	3 M	250	N				NO CHANGES OBSERVED							340	.
	10.0	4 M	260	N											-340	.

N = Normal
D = Depression
SD = Slight Depression
XD = Severe Depression
+ = Animal Death

Comments: Animal #1 - #4: No gross changes observed.

Table 7
Acute Oral Toxicity

GLS-S6-41A

Dose g/kg	Animal Number and Sex	Bodyweight (grams)	Hours:				Days:							Bodyweight (grams)
			1	3	6	24	2*	3	4	5	6	7--14		
10.0	1 M	200	N	N	N	N	N	N	N	N	N	N	N	310
	2 M	202	N	N	N	N	N	N	N	N	N	N	N	334
	3 M	212	N	N	N	N	N	N	N	N	+	-	-	180
	4 M	254	N	N	N	N	N	N	N	N	N	N	N	352
	5 M	250	N	N	N	N	N	N	N	N	N	N	N	402
	6 F	194	N	N	N	N	N	N	N	N	N	N	N	268
	7 F	192	N	N	N	N	N	N	N	N	N	N	N	252
	8 F	200	N	N	N	N	N	N	N	N	N	N	N	286
	9 F	194	N	N	N	N	N	N	N	N	N	N	N	264
	10 F	200	N	N	N	N	N	N	N	N	N	N	N	258

N = Normal
D = Depression
SD = Slight Depression
XD = Severe Depression
+ = Animal Death
* = Hair moist, matted at 2 days

Comments: Animal #1, #2, #4 - #10: No gross changes observed.
Animal #3: Fibrous tissue encasing heart and lungs.

ETHYL FLAME RETARDANT APPLICATION MATRIX



APPLICATION	RB-49	RB-79	FR-1138	RB-100	HBCD	BCL-462	S-111	S-102	S-102E	S-120	BT-93	BN-451	S-115	S-125	VBR
SOLID THERMOPLASTICS															
ABS			●			●	●	●	●	●			●		
POLYSTYRENE (HIPS)				●	●		●	●	●	●					
NYLON						●	●	●	●	●		●			
POLYESTER (PBT/PET)							●	●	●	●					
POLYCARBONATE			○				●	●	●	●					
POLYPROPYLENE				●			●	●	●	●		●			
POLYETHYLENE							●	●	●	●					
THERMOPLASTIC ELASTOMER							●	●	●	●					
THERMOPLASTIC POLYURETHANE					●		●	●	●	●					
FOAMS															
EXPANDED POLYSTYRENE				●	●										
RIGID POLYURETHANE	○	○													
FLEXIBLE POLYURETHANE		○											●	●	
WIRE AND CABLE															
SILICONE							●	●	●	●					
PVC				●	●		●	●				●	●		
EPDM							●	●	●	●					
SYNTHETIC RUBBER							●	●	●	●					
HIGH PERFORMANCE JACKETS								●	●	●					
THERMOSETS															
EPOXY	○		○												
PHENOLIC			●				●	●				●	●		
UNSATURATED POLYESTER	○	○	○												
MOD. ACRYLIC FIBERS															○
ADHESIVES AND COATINGS															
TEXTILES	○			●	●		●	●	●		●				
PAINTS			○					●	●	●					
HOT MELT ADHESIVES				●			●	●	●	●		●	●		

○ = Reactive
● = Additive