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Document Title	INITIAL SUBMISSION: GENETIC TOXICOLOGY SALMONELLA/MICROSOMAL ASSAY OF SAYTEX 115 (PENTABROMODIPHENYLOXIDE)		
Chemical Category	PENTABROMODIPHENYLOXIDE		

741-0794-000974



84940000074

E T H Y L   C O R P O R A T I O N

QUALITY ASSURANCE UNIT STATEMENT

This study was performed in accordance with the Good Laboratory Practices Regulations for nonclinical laboratory studies developed by the U. S. Food and Drug Administration and Environmental Protection Agency.



FYI-94-000974  
INIT 07/26/94

Study No. Ames 091 - #091

The following inspections were performed:

Interval	Date
<u>Reporting Phase</u>	<u>11/25/85</u>
_____	_____
_____	_____
_____	_____
_____	_____

Contains No-CBI

9th JUL 26 PM 3:59

RECEIVED

Results of the above inspections were submitted to the Study Director and Management during the course of the study.

11/25/85  
(Date)

Beverly Pancano  
Quality Assurance Unit

**ETHYL CORPORATION**

TOXICOLOGY AND INDUSTRIAL HYGIENE DEPARTMENT

ETHYL TECHNICAL CENTER  
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BATON ROUGE, LOUISIANA 70820  
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December 12, 1985

Genetic Toxicology  
Salmonella/Microsomal Assay

Ames 091 - #091

Saytex 115

  
\_\_\_\_\_  
D. E. Johnson, Study Director  
Associate Director  
Toxicology and Industrial  
Hygiene Department

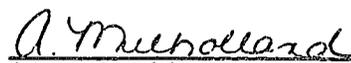
  
\_\_\_\_\_  
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## STUDY DESCRIPTION

Compound Name: Pentabromodiphenyl Oxide (Lot #5315-61)  
[Saytex 115]

G.T. #: 091

Date Received: 7/12/85

Received From: M. Templeton

Solvent: DMSO

Doses Tested: 30, 6, 3, 0.6 and 0.3 ug/plate

Assay Performed by: R. O. Johannessen

Study Initiated: 7/30/85

Study Completed: 9/17/85

PROTOCOL - ETTOX-027

AMES ASSAY  
Salmonella typhimurium

Sponsor:

Ethyl Corporation  
8000 GSRI Avenue  
Baton Rouge, Louisiana 70808

Testing Facility:

Genetic Toxicology Laboratory  
Ethyl Technical Center  
P.O. Box 14799  
Baton Rouge, Louisiana 70898

Test Facility

S.O.P. Number

ETTOX-027

Test Substance:

Saytex 115 (6T 091)

Study-Number:

091

Purpose of the Study:

To evaluate the test substance over a wide range of concentrations for genetic activity using Salmonella typhimurium with and without the addition of a mammalian metabolic activation system.

Study Director:

D. E. Johnson

Q.A.U.

Responsible  
Personnel:

Beverly Pancamo

Rationale for  
Test System:

Chemicals capable of inducing mutations have been shown to increase the reversion frequency at the histidine locus in selected tester strains of Salmonella typhimurium with and without the addition of a metabolic activation systems. (Ames, Bruce N., et al. Mutation Research 31: [1975] 347-364.)

Date of Performance:

The proposed date of study initiation is one month from the receipt of the test substance and signed protocol.

Good Laboratory  
Practices Statement:

The study will be conducted in compliance with the Good Laboratory Practices Regulations as stated in the Federal Register, Vol. 43, No. 247 Friday, December 22, 1978. The study meets all EPA and OECD requirements.

Protocol  
Ames Assay  
Page 2

Tentative Date of  
Submission of Final  
Report:

Approximate date for submission of the final report to the sponsor is one month after study initiation.

Records Maintained:

All correspondence pertinent to the study, protocol, amendments to the protocol, raw data, test substance weight or volume, dispensation reports, quality assurance reports and the final report will be maintained in the Genetic Toxicology Laboratory - Ethyl Technical Center.

Raw Data:

Genetic Toxicology Laboratory Notebook

Archive Retention:

All raw data.

#### EXPERIMENTAL PROCEDURE

Plate Incorporation Ames Assay  
Salmonella typhimurium

Objective:

To evaluate the test substance over a wide range of concentrations for genetic activity using Salmonella typhimurium with and without the addition of a mammalian metabolic activation system.

Organism:

Salmonella typhimurium

Tester Strain:

TA1535, TA1537, TA98 and TA100

Source:

Dr. Bruce N. Ames, University of California, Biochemistry Dept., Berkeley, California 94720

Storage:

The tester strains as prepared in S.O.P. ETTOX-021 are maintained at a minimum of -60°C, and serve as master and stock culture.

Aseptic Technique:

All aseptic techniques, where possible, are carried out in the Baker NCB-4 Hood.

Working Cultures:

Fresh cultures are prepared for each test according to S.O.P. ETTOX-020.

Ames Assay:

The plate incorporation Ames Assay is carried out according to S.O.P. ETTOX-016, 017, 018, 019 and 022.

Sponsor:

Ethyl Corp.

Study Director:

D. E. Johnson

Date:

7/30/85

Date:

7/31/85

## RESULTS AND DISCUSSION

Test article, Saytex 115, was received as an extremely viscous golden-brown liquid.

Salmonella typhimurium strains TA1535, TA1537, TA98 and TA100 were treated in the presence and absence of metabolic activation (Aroclor 1254 induced rat liver S-9 fraction) with Saytex 115 in DMSO. Dose levels tested were 30, 6, 3, 0.6, and 0.3 ug/plate. Saytex 115 was soluble at all dose levels tested. Each dose was treated in triplicate. An untreated control, solvent control and positive control were treated concurrently.

Saytex 115 did not demonstrate toxicity in any strain with and without metabolic activation at the top dose level tested. Saytex 115 did not cause a dose related increase in mutant colonies in any strain in the absence and presence of metabolic activation.

Color and appearance of the test article did not change from the time of receipt to the time of use.

Data are given on next page.

## CONCLUSION

Saytex 115 was not genetically active in the Salmonella/ Microsome Assay conducting according to Protocol - Etox 027.

Saytex 115

DATA

Strain	Activation	Solvent Control	Positive Control	30 ug/plate	6 ug/plate	3 ug/plate	0.6 ug/plate	0.3 ug/plate
TA1535	-	22	333*	11	12	19	17	10
	+	28	260*	28	27	32	38	21
TA1537	-	13	207*	10	12	10	15	13
	+	10	1140*	7	19	16	13	12
TA98	-	37	277*	57	64	65	55	48
	+	47	4747*	56	58	55	65	61
TA100	-	81	1212*	65	47	50	32	47
	+	72	1000*	56	88	54	57	53

\* 3 times solvent control  
\*\* Precipitation - not counted