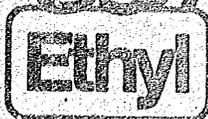


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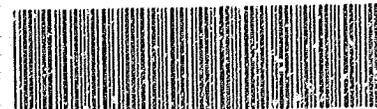
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TOXICOLOGY AND INDUSTRIAL HYGIENE

July 1, 1985



FYI-94-001100
INIT 07/26/94



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Genetic Toxicology
Salmonella/Microsomal Assay

Ames 089 - #082

Saytex 111

D. E. Johnson

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SUMMARY

Test article, Saytex 111, was received as a light orange-pink powder.

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 111 in acetone. Dose levels tested were 5.0, 2.5, 0.5, 0.25 and 0.05 mg/plate. Saytex 111 was soluble in DMSO at all dose levels tested. Each dose was treated in triplicate. An untreated control, solvent control and positive control were treated concurrently.

Saytex 111 did not cause a dose related increase in mutant colonies over the background in the presence or absence of metabolic activation.

STUDY DESCRIPTION

Compound Name: Saytex 111
G.T. #: 082
Date Received: 3/12/85
Received From: R. Zussman
Solvent: DMSO
Doses Tested: 5.0, 2.5, 0.5, 0.25 and 0.05 mg/plate
Assay Performed by: R. O. Johannessen
Study Initiated: 3/18/85
Study Completed: 5/31/85

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: Sayer III

Study-Number: 082

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.

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:

3/12/85

Date:

3/19/85

RESULTS AND DISCUSSION

Color and appearance of the test article did not change from the time of receipt to the time of use. Although Saytex 111 was soluble in DMSO at all dose levels tested, the 50 mg/mL dose level precipitated into the agar and was not counted. Saytex 111 was tested at the time of its solubility.

Saytex 111 did not induce a dose related increase of mutant colonies over the background in any strain in the absence or presence of metabolic activation.

Data are given on next page.

CONCLUSION

Saytex 111 was not genetically active in the Salmonella/Microsome Assay conducting according to Protocol - Ettox 027.

Saytex 111

DATA

Run	Activation	Solvent Control	Positive Control	5.0 mg/plate	2.5 mg/plate	0.5 mg/plate	0.25 mg/plate	0.05 mg/plate
535	-	16	771*	**	7	9	11	8
	+	5	205*	**	7	9	7	7
537	-	14	204*	**	18	15	19	20
	+	14	894*	**	26	23	26	29
8	-	24	588*	**	39	13	33	35
	+	24	3236*	**	10	15	17	20
00	-	317	1610*	**	313	359	336	327
	+	377	4690*	**	367	363	387	383

3 times solvent control
Precipitation - not counted

