Reviewed by : Whang Phang, Ph.D. Whang Phang 9/29/87
Section III, Toxicology Branch (TS-769c)
Secondary Reviewer: Marcia van Gemert, Ph.D.
Section III, Toxicology Branch (TS-769c) Marcia van Gemert 9/30/87

DATA EVALUATION REPORT

STUDY TYPE: Gene Mutation Assay: Ames Assay

MRID NO.: 116486 TOX. CHEM. No.: 320

TEST MATERIAL: 2, 4-DP (purity not specified) "Technical"

SPONSOR: Amchem Products, Inc., Ambler, PA

TESTING FACILITY: Pharmakon Laboratories, Scranton, PA

CITATION:

Naismith, R.; Matthews, R.; Godek, E. (1979) Summary Data: Ames Salmonella Microsome Plate Test. (Unpublished study received Mar 26, 1979 under 264-231; prepared by Pharmakon Laboratories, submitted by Union Carbide agricultural Products Co., Inc., Research Triangle Park, NC; CDL: 237875-N).

CONCLUSION: This study had been reviewed (Holder; Tox. Doc. No. 001995); the conclusion derived by the previous reviewer was accurate based upon the limited data presented (Attachment). However, the report has many deficiencies.

1). No data were reported on the preliminary toxicity test.

2). The number of bacteria/plate was not indicated.

3). Data on duplicate plate were not reported.

4). Another independent study was not carried out to confirm the results seen in this study.

Therefore, this study is re-classified as unacceptable, and a new DER is not prepared for this study.

§2.0 Ames Salmonella Point Mutation Test (Section M of 264-231; EPA 237875)

Duplicate plates were run on Salmonella to select for His^- to His^+ revertants. Two base altered mutants TA 1535 and TA 100 were challenged with 2,4 DP acid as well as three frame shift mutants TA 1537, TA 1538, and TA 98. Each strain was challenged at each dose level with and without S-9 rat liver supernate metabolic activation mix (induced by Aroclor 1254).

Dose selection came from preliminary tests wherein the highest level showed some degree of toxicity in at least one of the Salmonella tester strains. Doses were 0.1, 0.5, 2, 8, 40, 200, and 1000 ug/plate. Positive controls NMNG (base change causing transitions or transversions), 9-aminoacridine (intercalation causing frame shift mutations) or 2-aminofluorene (frameshifer with S-9 activation) were employed at unspecified doses to check the tester strains for the proper mutational responses. Negative vehicle control DMSO was also tested.

Results are given in Table II. The negative controls are well within spontaneous mutation levels previously reported for these Salmonella strains (de Serres and Shelby, Environmental Mutagenesis 1(1) 1979, 87-92).

The positive controls show typical mutagenic activities showing the strains were responsive.

2.1 Conclusions: 2,4 DP acid was not chemically identified other than a "beige powder". The experiment was performed under GLP and was adequately controled. The results show that with doses up to 1000 ug of 2,4 DP acid per plate, no revertants were scored in excess of negative controls. Thus, 2,4,DP did not exhibit mutagenic activity in the Ames test.

2.2 Classification of Study: Valid

---

* Classification of "valid" and "invalid" are used in the reviews here, indicating meeting (or surpassing) minimum 1982 Gene-Tox Program Standards or the failure to meet these standards, respectively.

TABLE II

Compound	S-9	TA 1535	TA 1537	TA 1538	TA 98	TA 100
DMSO (vehicle)	-	8	12	29	26	131
	+	14	2/18	44	56	140
Positive Controls						
N-methyl-N-nitro-N-nitrosoguanidine NMNG	-	>1000				941
	+					
9-aminoacridine	-		936			
2-aminofluorene	-					
	+			957	798	

ug 2,3 DP/plate		Revertant Colonies/Plate ($\bar{x}$)				
1000	-	11	6	13	24	127
	+	10	13	34	33	103
2000	-	10	14	15	19	182
	+	11	16	45	52	131
40	-	13	9	25	31	163
	+	12	16	39	50	160
8	-	14	15	14	30	168
	+	11	17	46	41	146
2	-	9	9	24	42	176
	+	14	18	43	46	167
0.5	-	16	9	21	29	198
	+	9	16	47	52	136
0.1	-	14	9	14	31	166
	+	14	18	51	45	149