

BB-407
TXR-2337



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

002337

MEMORANDUM

OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

TO: W. H. Miller, Product Manager, Team #16
Registration Division (TS-767)

THRU: Edwin R. Budd, Section Head
Section II, Toxicology Branch
Hazard Evaluation Division (TS-769)

THRU: O. E. Paynter, Chief
Toxicology Branch
Hazard Evaluation Division (TS-769)

SUBJECT: MONITOR: Mutagenic Study (Ames Test).
EPA Accession No. None
EPA Record No. 64423--

TOX Chem. No. 378 A

The above-mentioned study has been evaluated and found acceptable. Monitor Technical was not mutagenic under the conditions of this test.

Krystyna K. Locke
Krystyna K. Locke, Ph.D.

Toxicology Branch
Hazard Evaluation Division (TS-769)

OPP:HED:TOX: K.LOCKE:sh 12/14/82 X71511 Rm 824

#m20

1084

002337

Salmonella/Mammalian Microsome Mutagenicity Test (Ames Test)
with MONITOR Technical by M. L. Machado, Standard Oil Company
of California (SOCAL); Stud. No. SOCAL 1711, 2/3/82

EPA Accession No. None
EPA Record No. 64423
TOX Chem No. 378A

Summary:

MONITOR Technical (0.1, 0.5, 1.0, 5.0 and 10.0 mg/plate) was tested for mutagenicity using the following histidine-deficient strains of Salmonella typhimurium: TA 1538, TA 1537, TA 1535, TA 100 and TA 98, with and without metabolic activation. MONITOR Technical was not mutagenic under the conditions of this test.

Mutagenicity was observed with the following positive controls (ug/plate): 2-Nitrofluorene (10), 2-aminoanthracene (2), sodium azide (1) and 9-aminoacridine (50).

Classification of this study: Acceptable.

Materials and Methods:

This test was conducted by the procedure of Ames, B. N., J. McCann and E. Yamasaki (Methods for detecting carcinogens and mutagens with the Salmonella/mammalian-microsome mutagenicity test. Mut. Res., 31 (1975), 347-363).

The bacterial strains used were histidine auxotrophs derived originally from Salmonella typhimurium LT₂ and supplied by B. N. Ames, Univ. of California, Berkeley. The following strains were used: TA 1335 and TA 100 (which detect base-pair substitution) and TA 1537, TA 1538 and TA 98 (which detect frame-shift mutations). The levels of MONITOR used were 0.1, 0.5, 1, 5 and 10 mg/plate. The histidine-deficient strains of Salmonella typhimurium were grown on media that contained only minimal amounts of histidine and biotin. Only bacteria that reverted and were able to synthesize histidine grew into a colony after 2-3 days of incubation at 37°C. The number of colonies per plate was an index of the mutation rate. Metabolic activation was effected by growing the Salmonella typhimurium strains used in the presence of a liver microsomal fraction S-9 (purchased from EG & G Mason Research Institute, Rockville, Maryland).

2

002337

Positive controls (known mutagens) were used as follows:

<u>Salmonella</u> <u>typhimurium</u> Strain	Positive Controls -			
	2-Nitrofluorene, 10 ug/plate	2-Aminoanthracene, 2 ug/plate	sodium azide lug/plate	9-Aminoacridine, 50 ug/plate
TA 98 + S-9		x		
Without S-9	x			
TA 100 + S-9		x		
Without S-9			x	
TA 1535 + S-9		x		
Without S-9			x	
TA 1537 + S-9		x		
Without S-9				x
TA 1538 + S-9		x		
Without S-9	x			

Distilled water (0.1 ml) was used as a negative control. Each assay was performed in triplicate.

Results:

MONITOR Technical (0.1-10.0 mg/plate) was not mutagenic in any strain of Salmonella typhimurium tested, with or without metabolic activation. The numbers of revertant colonies/plate were small and were similar for the control plates and the MONITOR-containing plates. There was also no difference in the number of revertant colonies/plate between the different levels of MONITOR tested. In the case of the positive controls used, there were about 6-133 times more revertant colonies/plate, when compared with the MONITOR-containing and the negative control plates. These data are summarized below.

002337

Test Material	Number of Revertant Colonies Per Plate				
	TA 98	TA 100	TA 1535	TA 1537	TA 1538
None + S-9	34-60	120-130	11-26	13-20	25-35
Without S-9	27-31	94-128	31-35	12-14	14-20
MONITOR (0.1-10.0 mg/plate) + S-9	26-49	103-144	10-40	14-24	18-40
Without S-9	19-36	101-132	27-52	7-22	15-28
2-Nitrofluorine* (10 ug/plate) + S-9					
Without S-9	1198-1557				3469-3721
2-Aminoanthracene* (2 ug/plate) + S-9	2831-3505	1143-1268	300-305	269-383	2770-3211
Without S-9					
Sodium azide* (1 ug/plate + S-9					
Without S-9		684-744	520-591		
9-Aminoacridine* (50 ug/plate) + S-9					
Without S-9				194-319	

* Positive controls. Blank space means that the control was not used.

Classification of study: Acceptable

Reviewed By: Krystyna K. Locke
 Krystyna K. Locke, Ph.D.
 Section II
 Toxicology Branch 12/10/82
 HED/TS-769

Approved By: Edwin R. Budd
 Edwin R. Budd,
 Section Head 12/15/82
 Section II
 Toxicology Branch
 HED/TS-769