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Section III, Toxicology Branch (TS-769c)

DATA EVALUATION REPORT (DER)

STUDY TYPE: Mutagenicity: Salmonella typhimurium assay

CHEMICAL: Oxamyl; IND 1410

EPA ACCESSION NO.: 406065-09 CASWELL NO.: 561A

EPA RECORD NO.: 222981/222982 EPA PROJECT NO.: 8-0881

SPONSOR: E. I. du Pont de Nemours & Co., Inc.

TESTING LABORATORY: Haskell Laboratory for Toxicology and Industrial Medicine, E. I. du Pont de Nemours & Co., Inc.

CITATION: Arce, G. T. (1981). Mutagenicity evaluation of IND 1410-196 in Salmonella typhimurium. Haskell Laboratory; Report No.: 614-81. Oct 5, 1981. Submitted by E. I. du Pont de Nemours & Co., Inc.; April 29, 1988.

SUMMARY: Under the testing conditions, IND 1410-196 did not cause gene mutation in Salmonella typhimurium TA1535, TA1537, TA98 and TA100 in the presence or absence of the metabolic activation system. This study is classified as Unacceptable for reasons presented in the Discussion section of this DER.

METHODS AND MATERIALS:

Test Compound: IND1410-196; Oxamyl (toxicological sample which is different from the technical) 97.1% purity. White crystalline solid.

Bacteria: Salmonella typhimurium strains TA1535, TA1537, TA98 and TA100

Postive control agents: 2-aminoanthracene (2AA)
9-aminoacridine (9AAc)
N-methyl-N'-nitro-N-nitrosoguanidine (MNNG)
2-nitrofluorene (2NF)

Solvent for test agent: dimethylsulfoxide (DMSO) for positive control agents
water for test article

EXPERIMENTAL PROCEDURES:

The experimental procedures used in these assays were reported to be similar to those described by Ames et al. (Mutation Res. 31:347-364, 1975). The submitted report further summarized some

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of the methods which were excerpted from the report and presented in the Appendix. The statistical analyses used in this study are also presented in the Appendix.

RESULTS:

For the cytotoxicity study, strain TA1535 was used. Concentrations up to 10,000 ug/ml were tested; no cytotoxicity was seen in treated bacteria in the presence or absence of metabolic acti-activation system (Table 1).

Salmonella typhimurium strains TA1535, TA1537, TA98, and TA100 were treated with IND 1410-196 at concentrations of 50, 100, 500, 1000, 5000, and 10000 ug/ml in Salmonella assays with or without metabolic activation system; the results indicated no increase in the frequencies of revertants in all IND 1410-196 treated bacteria relative to the controls in the presence or absence of the metabolic activation system (Tables II, III, IV, V, VI, VII, VIII, and IX).

DISCUSSION:

Under the testing conditons, IND 1410-196 did not cause gene mutation in Salmonella typhimurium TA1535, TA1537, TA98 and TA100 in the presence or absence of the metabolic activation system.

There is a question concerning the test article, IND 1410-196. The registrant informed the Agency during a meeting held on July 12, 1988 that IND 1410-196 is synthesized in the laboratory for toxicological testing, and it does not contain three contaminants as does the technical grade. The registrant has been requested by the Agency to provide a logical explanation for this difference. Under the presence circumstances, this study is classified as Unacceptable. After receipt and satisfactory evaluation of the explanation concerning the test article, this study may be upgraded to acceptable.

OXAMYL

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