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

DEC - 6 1984

MEMORANDUM

OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

SUBJECT: Micro-Emulsion Concentrate Type A (Didecyl dimethyl ammonium chloride and 3-iodo-2-propynyl-butyl carbamate)-EPA File Symbol 453-EOT; CASWELL Nos.: 331A and 501A.

TO: Henry Jacoby, PM #21
Fungicide-Herbicide Branch
Registration Division (TS-767C)

FROM: Carlos A. Rodriguez CAR 11/30/84
Review Section IV
Toxicology Branch/HED(TS_769)

THRU: Jane E. Harris, Ph.D. JEH 11/30/84
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Toxicology Branch/HED (TS-769)

Applicant: Koppers Company, Inc.
1201 Koppers Building
Pittsburgh, Pa. 15217

Action Request: Review miscellaneous mutagenicity study to be added to the file for this product.

Recommendation(s):

The study as submitted follows the recommendations of the Pesticide Assessment Guidelines; however, the study is classified unacceptable until registrant submit the requested information concerning the composition of the test material as cited under Evaluation.

Testing should also be performed with the technical grade of each active ingredient in the product addressing the following category:

a) Gene mutation in mammalian cell.

Safety Data Review:

Salmonella/Mammalian-Microsome Plate Incorporation Mutagenicity Assay of Micro-Emulsion Concentrate Type A, (Microbiological Associates, Study No. T2389-501, March 30, 1984).

Procedure:

The test method used is the one described by Ames B.N. (Ames et al., Mutation Research 31:347-364, 1975). Five his- strains of Salmonella typhimurium (TA1538, TA1537, TA1535, TA98, TA100) were treated with the test compound by the standard Ames plate incorporation procedure at dose levels ranging from 0.01 ug to 2.0 ug per plate (based upon toxicity and precipitation tests at the highest dose tested). The assays were performed both in the absence and presence of metabolic activation provided by the microsomal fraction prepared from Sprague-Dawley rat livers induced by Aroclor 1254 (induced S-9) five days prior to kill. Paralell cultures were exposed to the mutagen (positive controls) appropriate for each strain: 2-NF, Sod. azide, 9 AmAc for non activated tests; and 2AA for all activated tests. All positive controls, solvent controls, and test article doses were plated in triplicate.

In addition to the L-histidine and D-biotin mutations each strain possesses two additional mutations which enhance their sensitivity to some mutagenic compounds. These are the rfa wall mutation and the uvr B gene mutation, of which the latter results in a deficient DNA excision-repair system. Strains TA98 and TA100 also contain the pKM101 plasmid (carrying the R-factor) which increases the sensitivity to some mutagens.

Results:

The test article Micro-Emulsion Concentrate did not cause any dose related revertant increases over solvent (water) controls in any of the tester strains at concentrations of 0.01 to 2.0 ug/plate with or without the metabolic activation. Positive results were obtained with positive control substances with the tester strains in the presence or absence of metabolic activation.

The authors concluded that Micro-Emulsion Concentrate was not mutagenic in the Salmonella/microsome (Ames) assay by the procedures employed in five indicator strains TA1535, TA1537, TA1535, TA98 and TA100 either with or without rat liver S-9 activation.

Evaluation:

The study would be classifed "acceptable" with registrants submission of the nature of the active ingredients, e.g., technical grade, the characteristics of the test subtance and per cent of active ingredients.

The performance of only a bacterial test for this compound is insufficient to determine the full mutagenic potential of this product. Therefore, testing should be performed addressing the "Gene Mutation in Mammalian Cell Assay"

Classification: Nonacceptable.

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