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FINAL

DATA EVALUATION REPORT

CAPTAN

Study Type: Mutagenicity: Microbial Gene Mutation Assays (without S9-Activation)

Prepared for:

Health Effects Division
Office of Pesticide Programs
Environmental Protection Agency
1921 Jefferson Davis Highway
Arlington, VA 22202

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Contract Number: 68D10075
Work Assignment Number: 1-05
Clement Number: 91-52
Project Officer: James Scott

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GUIDELINE SERIES 84: MUTAGENICITY
MICROBIAL GENE MUTATION

MUTAGENICITY STUDIES

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DATA EVALUATION REPORT

STUDY TYPE: Mutagenicity: Microbial gene mutation assays (without S9-activation)

EPA IDENTIFICATION Numbers:

Tox Chem. Number: 159

MRID Number: 00138762

TEST MATERIAL: Captan

SYNONYMS: cis-N-trichloromethylthio-4-cyclohexene, 1,2-dicarboximide

SPONSOR: ICI Americas Inc., Wilmington, DE

STUDY NUMBER: TX 74007

TESTING FACILITY: Boots Company, Ltd. (location not provided)

TITLE OF REPORT: In Vitro Screening for Mutagenic Activity Using Genetically-Defined Strains of Escherichia coli and Salmonella typhimurium

AUTHOR: R.P. Everest

REPORT ISSUED: February 8, 1974

CONCLUSIONS--EXECUTIVE SUMMARY: Captan was one of 18 known mutagens used to evaluate qualitative (spot tests) and semi-quantitative (plate incorporation assay) procedures used in microbial gene mutation assays. Captan was dissolved in dimethyl sulfoxide and applied to the various test systems as follows:

1. Salmonella typhimurium strains TA1535, TA1536, TA1537, and TA1538--spot tests with 1% captan.

2. S. typhimurium strain TA1535--plate incorporation assay with 10^{-5} captan (unit not specified).

3. Escherichia coli strains WP2, WP2 uvrA$^-$ CM561(exrA$^-$) and CM611 (uvrA$^-$ exrA$^-$)--spot test only with 10 mg/mL captan.

No information on captan purity, stability, storage conditions, or other information that defined the test material were reported. A quality assurance statement was not provided. With the exception of a 12.6-fold increase in mutant colonies of S. typhimurium 1535 exposed to 10^{-5} captan (unit not specified), no quantitative data were presented. Results for the remaining studies indicated that captan (10 mg/mL) was mutagenic in E. coli strains WP2, WP2 uvrA$^-$, and CM611 and negative in E. coli strain CM561. In the S. typhimurium spot test, 1% captan induced a minimal mutagenic response in strain TA1535 and no response in strains TA1536, TA1537, and TA1538.

The findings from this battery of tests are in general agreement with other microbial mutagenicity assays conducted with captan (see Data Evaluation Records 91-49, 91-51, and 91-53); however, the lack of procedural information and quantitative data precludes the use of the study results as an individual data source. The study, therefore, does not satisfy Guideline requirements for genetic effects, Category I, Gene Mutations.

STUDY CLASSIFICATION: The study is unacceptable for regulatory purposes but can be used to support the findings of other microbial mutation assays with captan.

A. ... APPENDIX: Appendix A, Materials and Methods, pp. 49-53.

APPENDIX A

MATERIALS AND METHODS
pp. 49-53

_____Captan review_____

Page _____ is not included in this copy.

Pages __5__ through __9__ are not included in this copy.

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