

Interoffice Communication

To Distribution
 From J. J. Hall
 Date October 21, 1980
 Subject CARCINOGENESIS BIOASSAY OF DOP

The National Cancer Institute has released a long-awaited prepublication draft of their now famous carcinogenesis bioassay on di(2-ethylhexyl) phthalate. This draft has been made available for the purpose of scientific peer-review. The final report is scheduled to be published in three to six months.

Attached is a copy of the summary. I will keep you advised as to the significance of this study as information develops. If you have questions please call.



James J. Hall

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Attachment

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CARCINOGENESIS BIOASSAY

Of

DI(2-ETHYLHEXYL)PHTHALATE

DRAFT

(CAS No. 117-81-7)

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NOTICE

This is not a final report. Until this DRAFT is reviewed and approved by the Technical Reports Review Subcommittee of the NTP Board of Scientific Counselors, this DRAFT does not represent the official position of the National Toxicology Program.

Public Health Service
Department of Health and Human Services

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BIOASSAY OF
DI(2-ETHYLHEXYL)PHTHALATE
FOR POSSIBLE CARCINOGENICITY

Carcinogenesis Testing Program
National Cancer Institute/National Toxicology Program

FOREWORD

This report presents the results of the bioassay of di(2-ethylhexyl)-phthalate conducted for the Carcinogenesis Testing Program, National Cancer Institute (NCI)/National Toxicology Program (NTP). This is one of a series of experiments designed to determine whether selected chemicals have the capacity to produce cancer in animals. A negative result, in which the test animals do not have a greater incidence of cancer than control animals, does not necessarily mean that a test chemical is not a carcinogen, inasmuch as the experiments are conducted under a limited set of circumstances. A positive result demonstrates that a test chemical is carcinogenic for animals under the conditions of the test and indicates that exposure to the chemical is a potential risk to man. The actual determination of the risk to man from chemicals found to be carcinogenic in animals requires a wider analysis which extends beyond the purview of this study.

SUMMARY

A bioassay of di(2-ethylhexyl)phthalate, the most commonly used plasticizer for polyvinylchloride polymers, for possible carcinogenicity was conducted by feeding diets containing 6,000 or 12,000 ppm of the test chemical to groups of 50 male or female F344 rats and 3,000 or 6,000 ppm to groups of 50 male or female B6C3F1 mice for 103 weeks. Matched controls consisted of 50 untreated rats and 50 untreated mice of either sex.

Mean body weights of dosed rats and mice were lower than those of the corresponding controls throughout the study. Hepatocellular carcinomas or neoplastic nodules in high-dose rats of either sex and in low-dose females and hepatocellular carcinomas or adenomas in low- and high-dose mice of either sex occurred at incidences significantly higher than those in the matched controls. Degeneration of the seminiferous tubules and atrophy of the testes and hypertrophy of cells in the anterior pituitary were also found at increased incidences in high-dose male rats.

Under the conditions of this bioassay, di(2-ethylhexyl)phthalate was carcinogenic for F344 rats and B6C3F1 mice of either sex, causing increased incidences of hepatocellular carcinomas or neoplastic nodules in rats and hepatocellular carcinomas or adenomas in mice.

To VIRGINIA MOORE

Date

This may explain why I don't hold John Bransford in high regard. This is an example of an individual's report with Bransford's explanation of why each part is "required" by regulation.

I think you'll find it of interest.

JH

SES

THYROID MEDICATION
VITAMINS

IN THE LAST TWO YEARS PATIENT STATES THAT HE HAS HAD
A COMPLETE PHYSICAL
A BLOOD PRESSURE CHECK
A CHEST X-RAY

Employee General Medical History and Industrial History

- General Medical History enables the examining physician to determine the employee's present state of health, as well as to discover any past health problems.
- Industrial History (See page Three)

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