

Thomas G. Grumbles

VISTA
IGG: JCL: ~~MMG~~: AJO: RF
XF: none

To CHRIS Pierson

Date

4/25

Here is the study

that Steve was asking
about. Feel free to
send him a copy.

Based on the descriptions
I don't believe this is near
our stuff.

TGG

VVV 000010397



EPA-OTS
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CONTAINS NO CBI

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Amoco Oil Company

200 East Randolph Drive
Post Office Box 87707
Chicago, Illinois 60680-0707
Product Safety Division of
Environmental Affairs & Safety Department

December 16, 1988

BEHQ-1288-0775 INIT
POCN 88-890000021

Document Control Officer (TS-790)
(Attn: Section 8(e) Coordinator)
Information Management Division
Office of Toxic Substances
U.S. Environmental Protection Agency
401 M Street, S.W.
Washington, D.C. 20460

Dear Sir or Madam:

This notice is being submitted in accordance with Section 8(e) of the Toxic Substances Control Act. Information in this notice has been obtained from a designed, controlled study on a hydrotreated middle distillate (CAS #64742-46-7). The results reported here are based on preliminary reports from laboratory personnel. A copy of the final report of the study will be forwarded to you as soon as it is available.

This study was conducted as part of our research and development work in toxicology and was designed to provide information on the tumorigenic potential of the test material.

The experimental design was as follows:

Two groups of 50 male mice were used in the study. One group was treated dermally twice weekly for 104 weeks with 50 microliters of undiluted test article. The second group of 50 mice served as sham controls, and were treated the same as the test-article group except that no material was applied to the skin. All mice underwent gross necropsy, and the application site skin and other organs were collected, fixed, stained, and examined microscopically.

Preliminary histopathological examination indicates that five mice in the test-article treated group had histologically confirmed tumors. Four of those mice had squamous cell carcinomas, one mouse had a squamous cell papilloma, and one of the mice with a carcinoma also had a keratoacanthoma. The mean latency period was 97.7 weeks. Tissues from the sham control group have not yet been processed histologically, so tumor information on this group is incomplete. This study indicates that the test material possessed weak tumorigenic potential.

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Previous studies have shown that the test material is not a tumor initiator, but that it does possess weak tumor promoting activity.

We interpret these results to indicate that this hydrotreated distillate has the potential to induce skin tumors following lifetime exposure. This material has been sold as a highly purified mineral seal oil under the name Amoco NT-45 Process Oil. The Material Safety Data Sheets provided with this product already contains a warning of possible tumorigenic effects. The information from this new study will be incorporated into Material Safety Data Sheets.

Please call Dr. John Bennington as 312/856-5792 if you have any questions regarding this notice.

Sincerely,


J. C. Klasing
Manager, Product Safety
& Toxicology
Mail Code 4901

VVV 000010399

DATE: JAN 23 1989

SUBJECT: Status Report* 8EHQ-1288-0775

FROM: James F. Darr, Section Head *James F. Darr*
Chemical Risk Identification Section/CSB

TO: Frank D. Kover, Branch Chief
Chemical Screening Branch/ECAD/OTS/OPTS

Approved: *OK 1/27/89*Submission Description

The Amoco Oil Company provided the following summary information regarding the conduct and preliminary results of a chronic mouse skin application study of Amoco NT-45 Process Oil, a hydrotreated middle distillate (CAS No. 64742-46-7):

"Two groups of 50 male mice were used in the study. One group was treated dermally twice weekly for 104 weeks with 50 microliters of undiluted test material. The second group of 50 mice served as sham controls, and were treated the same as the test-article group except that no material was applied to the skin. All mice underwent gross necropsy, and the application site skin and other organs were collected, fixed, stained, and examined microscopically.

"Preliminary histopathological examination indicates that five mice in the test-article treated group had histologically confirmed tumors. Four of those mice had squamous cell carcinomas, one mouse had a squamous cell papilloma, and one of the mice with a carcinoma also had a keratoacanthoma. The mean latency period was 97.7 weeks. Tissues from the sham control group have not yet been processed histologically, so tumor information on this group is incomplete. This study indicates that the test material possessed weak tumorigenic potential. . . .

". . . [Amoco interprets] these results to indicate that this hydrotreated distillate has the potential to induce skin tumors following lifetime exposure."

In its submission, Amoco also reported that "previous studies have shown that the test material is not a tumor initiator, but that it does possess weak tumor promoting activity."

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- NOTE: This status report is the result of a preliminary evaluation of information submitted to EPA pursuant to Section 8(e), the substantial risk information reporting provision of the Toxic Substances Control Act (TSCA). The statements made in this report should not be regarded as expressing final EPA policy or intent with respect to the subject chemical(s). Any review of this status report should take into account the fact that the report may be based on incomplete information.

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It should be noted that in a previously received supplemental TSCA Section 8(e) submission (8EHQ-1087-0604 Supplement), the Amoco Corporation provided a full copy of the final report from a CD-1 mouse tumor initiation study of a number of Amoco products including Amoco NT-45 Process Oil. The "SUMMARY" section of that final report presents the following information with regard to the conduct and results of the initiation study:

"Dermal tumorigenicity bioassays were conducted to assess the initiation potential of Amoco NT-45 Process Oil . . . Groups of 30 male [CD-1] mice were topically dosed once a day for 5 days with 50 ul of the undiluted test article. The initiated mice, along with 60 sham control mice, were rested for 2 weeks and then dosed twice weekly for 25 weeks with 50 ul (0.1 mg/ml) of phorbol-12-myristate-13-acetate (PMA) in acetone as a promoter. . . .

"No significant differences in tumor incidence were detected between [the] groups treated with Amoco NT-45 Process Oil . . . and the sham controls."

The reader's attention is directed also to the status report that was prepared by EPA in response to another previously received TSCA Section 8(e) submission (8EHQ-0280-0333). In this previous Section 8(e) submission, the Kerr-McGee Corporation reported that Kermac 600W (also CAS No. 64742-46-7) was found to be mutagenic in an Ames Salmonella typhimurium (bacteria) assay.

Submission Evaluation

An EPA evaluation of the overall significance of the reported oncogenicity findings should be possible upon EPA's receipt of full copies of the final reports from the chronic mouse skin application study and the previously conducted tumor promotion study cited in the present Amoco submission; EPA's evaluation will also include the Amoco NT-45 Process Oil tumor initiation study and Kermac 600W Ames test submitted previously to EPA.

Current Production and Use

Appendix A of the printed 1985 Edition of EPA's initial TSCA Chemical Substance Inventory reports that CAS No. 64742-46-7 refers to "hydrotreated middle distillates (petroleum)" and identifies this material as follows:

"A complex combination of hydrocarbons obtained by treating a petroleum fraction with hydrogen in the presence of a catalyst. It consists of hydrocarbons having carbon numbers predominantly in the range of C₁₁ through C₂₅ and boiling in the range of approximately 205°C to 400°C (401°F to 752°F)."

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A review of the production range (includes importation volumes) statistics for CAS No. 64742-46-7, which is listed in the initial TSCA Chemical Substance Inventory, has shown that over 1 billion pounds were reported as manufactured and/or imported in 1977. This production range information does not include any information claimed as TSCA Confidential Business Information (TSCA CBI) by the person(s) reporting for the initial TSCA Inventory, nor does it include any information that would compromise TSCA CBI. All data reported for the initial TSCA Inventory, including the production range data, are subject to the limitations contained in the initial TSCA Inventory Reporting Regulations (40 CFR 710).

In the present TSCA Section 8(e) submission, Amoco reported that Amoco NT-45 Process Oil is "sold as a highly purified mineral seal oil." It should be noted also that in a previous TSCA Section 8(e) notice (8EHQ-0280-0333), the Kerr-McGee Corporation reported that one of its customers may have used Kerr-McGee's mineral seal oil product (Kermac 600W; CAS No. 64742-46-7) in the formulation of printing inks. Kerr-McGee also stated, however, that the company no longer produced or sold Kermac 600W and had replaced the Kermac 600W with Kermac 600 (CAS No. 64741-44-2). According to Kerr-McGee, Kermac 600 is similar to Kermac 600W in composition, constituents and physical characteristics and is the petroleum feed-stock from which the Kermac 600W was produced via hydrotreating.

Comments/Recommendations

In the present Section 8(e) notice, Amoco stated that although the current Amoco NT-45 Process Oil Material Safety Data Sheet (MSDS) already contains a warning about possible tumorigenic effects, Amoco is revising that MSDS to reflect the findings from the company's new chronic mouse skin application study.

EPA's Office of Toxic Substances has received and evaluated a number of TSCA Section 8(e) and "For Your Information" (FYI) submissions containing toxicologic and/or exposure information on coal-, shale- and petroleum-derived oil products, process streams and/or waste materials.

- a) The Chemical Screening Branch will ask Amoco to ensure that EPA receives complete copies of the final reports (including the actual experimental protocols, results of gross and histopathological examinations, results of any statistical analyses, etc.) from the chronic mouse skin application study and the previously conducted tumor promotion study cited in the submission.

In view of EPA's general interest in corporate actions taken on a voluntary basis in response to new chemical toxicity or exposure information, Amoco will be asked to describe the nature and results, if available, of all studies (other than those reported already to EPA

or those cited in the open scientific literature) about which Amoco is aware or that Amoco has conducted, is conducting or plans to conduct that are designed to determine the toxicity of or the exposure to hydro-treated middle distillate.

- b) The Chemical Screening Branch will review the reported information in order to determine the need for further OTS assessment of hydrotreated middle distillate.
- c) The Chemical Screening Branch will transmit copies of this status report to NIOSH, OSHA, CPSC, FDA, NTP, OSWER/EPA, OW/EPA, OAR/EPA, ORD/EPA and OPP/OTS/EPA. In addition, copies of this status report will be sent to the TSCA Assistance Office (TAO/OTS/OTS/EPA) for further distribution.

VVV 000010403



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

JAN 31 1989

OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

CERTIFIED MAIL

Dr. J. C. Klasing
Manager, Product Safety &
Toxicology (MC 4901)
Amoco Oil Company
200 East Randolph Drive
Chicago, IL 60680-0707

Dear Dr. Klasing:

With regard to:

TSCA Section 8(e) submission on: Amoco NT-45 Process Oil

Submitted by: Amoco Oil Company

Date submitted: December 16, 1988

EPA Document Control Number: 8EHQ-1288-0775

The Office of Toxic Substances (OTS) has completed a preliminary evaluation of the above referenced submission under Section 8(e), the "substantial risk" information reporting provision of the Toxic Substances Control Act (TSCA). The enclosed status report is the result of that preliminary OTS evaluation but does not necessarily represent EPA's conclusion on the subject material.

With regard to the above referenced TSCA Section 8(e) submission, please ensure that the Agency receives full copies of the final reports (including the actual experimental protocols, results of gross and histopathologic examinations, results of statistical analyses, etc.) from the chronic mouse skin application and tumor promotion studies cited in the submission.

In view of EPA's general interest in corporate actions that are taken on a voluntary basis in response to chemical toxicity or exposure information, please describe the nature and results, if available, of all studies (other than those submitted already to the Agency or those published in the open scientific literature) about which Amoco is aware or that the company has conducted, is conducting, or plans to conduct that are designed to determine the toxicity of or the exposure to the subject material.

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In responding to this request for information, or in otherwise communicating with EPA regarding this submission under Section 8(e), please refer to the EPA Document Control Number that has been assigned to the submission. As in the case of initial 8(e) submissions, all responses/correspondence will be placed in the public files unless confidentiality is claimed according to the procedures outlined in Part X of EPA's TSCA Section 8(e) policy statement ("Statement of Interpretation and Enforcement Policy; Notification of Substantial Risk" 43 FR 11110; March 16, 1978). Any confidentiality claims should be supported by submission of information as described in the enclosed item entitled "Support Information for Confidentiality Claims."

All available information requested by this letter should be transmitted to the EPA Document Processing Center at the address provided below within 20 working days of your receipt of this letter; any requested information or supplemental information that becomes available following your response to this EPA letter should be sent to EPA immediately upon your company's receipt of such information.

Document Processing Center (TS-790)
(Attn: Section 8(e) Coordinator)
Office of Toxic Substances
U.S. Environmental Protection Agency
401 "M" Street, S.W.
Washington, D.C. 20460

Should you have any questions or comments prior to responding to the Agency's request for additional information, please contact Mr. David R. Williams of the Chemical Screening Branch/ECAD at (202)-382-3468.

The Environmental Protection Agency looks forward to continued cooperation with the Amoco Oil Company in its ongoing efforts to evaluate and minimize the potential risks posed by chemicals to health or the environment.

Sincerely,



Frank D. Kover, Chief
Chemical Screening Branch
CSB/ECAD/OTS/OPTS (TS-778)

Enclosures

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