

8E HQ - 0394 - 12934

Confidential No. 02

Amoco Corporation

200 East Randolph Drive
Post Office Box 87703
Chicago, Illinois 60680-0703
Environment, Health & Safety Department
312-856-3993
Facsimile: 312-856-7584

Lawrence C. Heidemann
General Manager, Environment, Health & Product Stewardship

March 14, 1994

(A)



INIT 03/16/94



88940000176

RECEIVED
OFFICE OF POLLUTION
PREVENTION AND TOXICS
16 MAR 16 PM 2:36

Document Processing Center (TS-790)
ATTN: Section 8(e) Coordinator
Information Management Division
Office of Toxic Substances
Environmental Protection Agency
401 M Street, S.W.
Washington, DC 20460

Dear Sir or Madam:

This notice is being submitted in accordance with TSCA Section 8(e). Information in this notice was obtained from a designed, controlled study on Indopol L-14 (CAS# 9003-29-6), which is a butene-isobutene copolymer.

This study, entitled "Acute Inhalation Toxicity Study of Indopol L-14 Polybutene Polymer in Rats," was conducted as part of our research and development work in toxicology and our product stewardship efforts and was designed to provide information on the acute inhalation toxicity of butene-isobutene copolymers.

The material was administered as an aerosol via nose-only inhalation exposure to a group of five male and five female Sprague-Dawley rats. The rats were exposed to the aerosol for 4 hours at a target concentration of 5000 mg/m³ followed by a 3-day post-exposure observation period. A copy of the study protocol is enclosed. Preliminary results, obtained verbally from the contract toxicity testing laboratory retained to conduct this study, indicate a total of five animals (three males and two females) died during the post-exposure observation period. Further discussions with the testing facility have revealed the actual exposure concentration was 4.82 mg/l (4,820 mg/m³). Moreover, this aerosol concentration resulted in formation of a dense aerosol cloud within the exposure chamber, which completely obstructed visual observation of the test animals during exposure. The final report has not been issued by the testing facility, therefore, additional details regarding clinical observations and gross findings upon necropsy are not available at present. A copy of the report will be forwarded upon receipt. The limited data available to-date suggests the acute median lethal concentration of Indopol L-14 Polybutene Polymer in rats is approximately 4.82 mg/l (4,829 mg/m³).

The absence of adverse effects following skin (LD₅₀ > 10,250 mg/kg) and oral (LD₅₀ > 34,600 mg/kg) administration of chemically similar materials of higher viscosity indicate the deaths observed in the inhalation study were not due to a systemic toxic effect, but rather due to a local effect on the lungs. The air concentration at which this study was conducted is extremely high and not

RECEIVED
5-9-94

7 pas-

7

Document Processing Center (TS-790)

Page 2

typically encountered under normal use conditions. The material safety data sheet (MSDS) is being modified to reflect this new data.

If you have any questions concerning this data, please contact Dr. Jim Jernigan at (312) 856-3509.

Sincerely,

Lawrence C. Heidemann

LCH/laz

Enclosure

file: TSCA Section 8(e) Submission Indopol L-14

REC'D
OFFICE OF POLLUTION
PREVENTION AND TOXICS
04 MAR 15 PM 2:35

PROTOCOL

REC'D
OFFICE OF POLLUTION
PREVENTION AND TOXICS
31 MAR 16 PM '94

1. **Title:** Acute Inhalation Toxicity Study of Indopol L-14 Polybutene Polymer Rats.
2. **Sponsor:** Amoco Corporation
200 East Randolph Drive
Chicago, IL 60601
ATTN: James Jernigan, Ph.D.
MC: 4901
3. **Testing Facility:** IIT Research Institute
10 West 35th Street
Chicago, IL 60616
4. **Objective:** The objective of the study is to determine the toxicity of the test article when administered by a single nose-only inhalation exposure.
5. **Duration:** The duration of the study will be 3 days.
6. **Proposed Study Dates:**
 - a. Animal Receipt: February 9, 1994
 - b. Treatment Initiation: February 21, 1994
 - c. Biophase Termination: February 24, 1994
 - d. Draft Report Completion: April 22, 1994
7. **Protocol Approval:**
 - a. Study Director: Scott Mathewite Date: 2-18-94
 - b. Section Head: Catherine Beames Date: 2/18/94
 - c. Sponsor Representative: James Jernigan Date: 2/22/94

8. This protocol complies with specific requirements of the Sponsor.

9. Test Article:

- a. Identification: The test article is Indopol L-14 Polybutene Polymer, identification number N93C93P3. It is a clear, bright liquid.
- b. Handling Precautions: When working with the test article, study personnel must wear an organic vapor respirator, eye protection and two pairs of gloves (latex over polyethylene).
- c. Assay: The Sponsor will perform all necessary analyses on the test article and will retain the attendant documentation.
- d. Storage: The test article will be stored at room temperature (approximately 22 °C).
- e. Dispensation: Reserve samples of the test article will be retained by the Sponsor. All quantities of the test article which are dispensed will be documented. At the time of the acceptance of the report by the Sponsor, arrangements will be made to return any residual material to the Sponsor. IITRI will not be required to retain any samples.

10. Test System:

- a. Model: Male and female Sprague-Dawley rats (CrI:CD[®]BR; Charles River Laboratories, Inc., Portage, MI) will be used in this study. The animals will be approximately 6 weeks of age and will weigh approximately 125-150 grams on arrival.
- b. Selection of Test System: The Sprague-Dawley rat is a model widely used in acute toxicity testing. A significant body of experience with this animal exists against which its reaction to the test article can be evaluated.
- c. Housing: Animals will be housed individually in stainless steel wire cages suspended over excrement pans, except during the inhalation exposure. The rats will be held in nose-only tubes during the exposure.
- d. Cleaning and Sanitation: Animal rooms and cages will be cleaned and sanitized prior to placing animals in them, and periodically thereafter in accordance with accepted animal care practices and relevant standard operating procedures.
- e. Food: Purina Rodent Chow 5001 or 5002 (Ralston Purina Company, St. Louis, MO) will be provided *ad libitum* except during the inhalation exposure. To the best of our knowledge, no known contaminants are expected to be present in the basal diet that would interfere with the test article or test system and would confound the interpretation of the study.
- f. Water: Water from a reverse osmosis purifier will be provided *ad libitum* by

means of an automatic watering system, except during the inhalation exposure. Supply water is periodically monitored for bacterial contamination and chemical composition (i.e., electrolytes, metals, etc.).

- g. **Animal Identification:** Animals selected for the study will receive a unique permanent identification number tag which will be inserted through the pinna of the right ear. Individual cage cards will also be provided.
- h. **Environmental Control:** Animal rooms will be lighted automatically with fluorescent lights and maintained on a 12-hour light/12-hour dark cycle. Room temperature and humidity will be regulated to avoid extreme fluctuations.

11. **Methods:**

- a. **Quarantine:** The animals will be held in quarantine for approximately one week prior to study initiation. During the quarantine period the animals will be observed at least daily, and at the end of the period they will receive a thorough physical examination to ensure their suitability for use as test animals. Also, the animals will be acclimatized to the nose-only exposure tubes prior to treatment initiation.
- b. **Assignment to Groups:** Animals will be assigned randomly by weight to groups using a computer program. The body weight variation of each rat will not exceed $\pm 20\%$ of the mean for each sex.
- c. **Exposure Levels:** Study animals will be exposed to the test article for 4 hours at a target concentrations of 5 mg/L, or the maximum obtainable concentration if less than 5 mg/L. An additional group will be used as a control and will be exposed to filtered air only.
- d. **Test Atmosphere Generation:**
 - 1. Details of test atmosphere generation will be documented in the raw data.
 - 2. The nominal concentration of test article in the exposure atmosphere will be determined by recording the amount of material consumed in the generation of a measured volume of atmosphere.
 - 3. The actual concentration of the test article in the exposure atmosphere will be measured using standard gravimetric methods. At least 2 measurements will be taken during the exposure.
 - 4. Exposures will be such that the time required for equilibration of the chamber to 99% of the intended concentration (T-99) will be less than 10% of the total exposure duration. The animals will remain in the chamber after the shut down of the generator for a period of time equal to the T-99.
 - 5. The particle size distribution will be determined at least once during the exposure using an Andersen Cascade Impactor. Only that portion of the test article in air, which is in a respirable form (i.e., having an equivalent

aerodynamic diameter of less than 10 microns) will be included in the determination of the exposure atmosphere concentration.

- e. **Justification for Route of Exposure:** This inhalation test was chosen by the Sponsor due to the possibility of human exposure via this route.
 - f. **Exposure Chambers:** All exposures will be conducted in stainless steel and glass nose-only chambers. Temperature, humidity, and dynamic flow conditions will be recorded at approximate half hour intervals. Total air flow will be adjusted as a means of controlling the concentration of the exposure atmosphere, but will provide enough air changes to maintain a safe oxygen level for the animals.
 - g. **Chamber Loading:** The test animals will comprise no more than 5% of the total chamber volume (one kilogram equals approximately one liter).
 - h. **Final Disposition of Animals:** All animals surviving to the end of the 3-day observation period will be euthanized and subjected to a necropsy with limited tissue collection.
12. **Experimental Design:** A group of 5 male and 5 female rats will be exposed to the test article via inhalation for 4 hours at a target concentration of 5 mg/L, or the maximum obtainable concentration if less than 5 mg/L. An additional group of 5 male and 5 female rats will be used as a control and will be exposed to filtered air only.
13. **Observations:**
- a. **Mortality and Reactions:** All animals in the study will be observed closely during the exposure and periodically throughout the remainder of the first day. They will be observed at least once daily during the subsequent 3-day observation period. Animals found dead will be removed for necropsy and the deaths recorded. All signs of altered behavior, changes in coat condition, unusual discharge of body fluids, lesions, or other relevant observations will be recorded.
 - b. **Body Weight:** All animals in the study will be weighed prior to exposure and at the termination of the study.
 - c. **Necropsy:** All animals which die during the study or are euthanized at the termination of the study will be subjected to a necropsy with limited tissue collection. The necropsy will consist of examination of all body surfaces and openings, as well as the appearance of the lungs and the external appearance of the brain, heart, spleen, liver, kidneys, gastrointestinal tract, urinary bladder and gonads. The gastrointestinal tract and the urinary bladder will be opened and examined if external lesions are present on them. The entire respiratory tract will be fixed and saved for possible future histopathology.
14. **Results:**
- a. Mortality, clinical observations, body weights, necropsy results, and other appropriate data will be tabulated and presented in a formal written report.

15. Data Notebooks:

- a. **Contents:** All original data will be maintained in notebooks and will include, but not necessarily be limited to, the following:
1. the original signed protocol and all amendments
 2. test article characterization
 3. animals purchase and receiving records
 4. randomization procedures
 5. exposure calculations
 6. description of generation systems
 7. chamber environment
 8. body weights
 9. daily observations
 10. necropsy results
- b. **Storage:** All original data and a copy of the final report will be kept in the IITRI archives for a period of one year after the submission of the signed final report. At that time, the Sponsor will be contacted in order to determine the final disposition of the raw data and will be responsible for all costs associated with continued storage of the raw data in the IITRI Archives or for the shipment of these materials to a new storage facility.

16. Personnel:

Curriculum vitae for all personnel involved in the execution of the study are on file at IITRI.

17. Compliance with Government Regulations:

This study will be conducted in compliance with the EPA Good Laboratory Practice Standards set forth in Part 160 (FIFRA) of Title 40 of the Code of Federal Regulations.

This protocol will be the controlling document for the conduct of this study. Any changes or discrepancies from the Protocol will be documented in Protocol Amendments, or Deviation, through which the Sponsor will be notified immediately.



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

Lawrence C. Heidemann
General Manager, Environmental & Product Stewardship
Amoco Corporation
200 East Randolph Drive
P.O. Box 87703
Chicago, Illinois 60680-0703

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

DEC 08 1994

EPA acknowledges the receipt of information submitted by your organization under Section 8(e) of the Toxic Substances Control Act (TSCA). For your reference, copies of the first page(s) of your submission(s) are enclosed and display the TSCA §8(e) Document Control Number (e.g., 8EHQ-00-0000) assigned by EPA to your submission(s). Please cite the assigned 8(e) number when submitting follow-up or supplemental information and refer to the reverse side of this page for "EPA Information Requests".

All TSCA 8(e) submissions are placed in the public files unless confidentiality is claimed according to the procedures outlined in Part X of EPA's TSCA §8(e) policy statement (43 FR 11110, March 16, 1978). Confidential submissions received pursuant to the TSCA §8(e) Compliance Audit Program (CAP) should already contain information supporting confidentiality claims. This information is required and should be submitted if not done so previously. To substantiate claims, submit responses to the questions in the enclosure "Support Information for Confidentiality Claims". This same enclosure is used to support confidentiality claims for non-CAP submissions.

Please address any further correspondence with the Agency related to this TSCA 8(e) submission to:

Document Processing Center (7407)
Attn: TSCA Section 8(e) Coordinator
Office of Pollution Prevention and Toxics
U.S. Environmental Protection Agency
Washington, D.C. 20460-0001

EPA looks forward to continued cooperation with your organization in its ongoing efforts to evaluate and manage potential risks posed by chemicals to health and the environment.

Sincerely,

Terry R. O'Bryan
Terry R. O'Bryan
Risk Analysis Branch

Enclosure

12934 A



Recycled/Recyclable
Printed with SoyCanna ink or paper that
contains at least 50% recycled fiber

Triage of 8(e) Submissions

Date sent to triage: DEC 14 1994

NON-CAP

CAP

Submission number: 12934A

TSCA Inventory: Y N D

Study type (circle appropriate)

Group 1 - Dick Clements (1 copy total)

ECO

AQUATO

Group 2 - Ernie Falke (1 copy total)

ATOX

SBTOX

SEN

w/NEUR

Group 3 - Elizabeth Margosches (1 copy each)

STOX

CTOX

EPI

RTOX

GTOX

STOX/ONCO

CTOX/ONCO

IMMUNO

CYTO

NEUR

Other (FATE, EXPO, MET, etc.): _____

Notes:

THIS IS THE ORIGINAL 8(e) SUBMISSION; PLEASE REFILE AFTER TRIAGE DATABASE ENTRY

For Contractor Use Only

entire document: 0 1 2 pages 42 pages 1,2

Notes:

Contractor reviewer: FOR Date: 11/1/94

CECATS/TRIAGE TRACKING DRASE ENTRY FORM

CECATS DATA: Submission # BEHQ: 0394 - 12934 SEQ. A

TYPE: IND SUPP FLWP
 SUBMITTER NAME: Amose Corporation

INFORMATION REQUESTED: FLY P DATE
 0501 NO INFO REQUESTED
 0502 INFO REQUESTED (TECH)
 0503 INFO REQUESTED (VOL ACTIONS)
 0504 INFO REQUESTED (REPORTING RATIONAL F)

DISPOSITION:
 REFER TO CHEMICAL SCREENING
 0578 CAP NOTICE

VOLUNTARY ACTIONS:
 0401 NO ACTION REQUESTED
 0402 STUDIES PLANNED (TIMING ONLY)
 0403 NOTIFICATION (H. WINKEL REVISIONS)
 0404 LABELS/MSDS (TIAMINIS)
 0405 PROFESSIONAL ING. (TIAMINIS)
 0406 APPROUSE DISCONTINUED
 0407 PRODUCTION DISCONTINUED
 0408 CONFIDENTIAL

SUB. DATE: 03/14/94 OTS DATE: 03/16/94 CSRAD DATE: 05/09/94

CHEMICAL NAME: _____
 CASE: 9003-29-6

INFORMATION TYPE:	P.F.C.	INFORMATION TYPE:	P.F.C.	INFORMATION TYPE:	P.F.C.
0201 ONCO (HUMAN)	01 02 04	0216 EPICLIN	01 02 04	0241 IMBUNO (ANIMAL)	01 02 04
0202 ONCO (ANIMAL)	01 02 04	0217 HUMAN EXPOS (PROD CONTAM)	01 02 04	0242 IMBUNO (HUMAN)	01 02 04
0203 CELL. TRANS (IN VITRO)	01 02 04	0218 HUMAN EXPOS (ACCIDENTAL)	01 02 04	0243 CHEMPHY'S PROP	01 02 04
0204 MUTA (IN VITRO)	01 02 04	0219 HUMAN EXPOS (MONITORING)	01 02 04	0244 CLASTO (IN VITRO)	01 02 04
0205 MUTA (IN VIVO)	01 02 04	0220 ECO/AQUA TOX	01 02 04	0245 CLASTO (ANIMAL)	01 02 04
0206 REPRO/TERATO (HUMAN)	01 02 04	0221 ENV. OCCUREL/FATE	01 02 04	0246 CLASTO (HUMAN)	01 02 04
0207 REPRO/TERATO (ANIMAL)	01 02 04	0222 EMER INCI OF ENV CONTAM	01 02 04	0247 DNA DAM/REPAIR	01 02 04
0208 NEURO (HUMAN)	01 02 04	0223 RESPONSE REQEST DELAY	01 02 04	0248 PRODUSE/PROC	01 02 04
0209 NEURO (ANIMAL)	01 02 04	0224 PRODCOMP/CHEM ID	01 02 04	MSDS	01 02 04
0210 ACUTE TOX. (HUMAN)	01 02 04	0225 REPORTING RATIONALE	01 02 04	OTHER	01 02 04
0211 CHR. TOX. (HUMAN)	01 02 04	CONFIDENTIAL	01 02 04		
0212 ACUTE TOX. (ANIMAL)	01 02 04	ALLERG (HUMAN)	01 02 04		
0213 SUB ACUTE TOX (ANIMAL)	01 02 04	ALLERG (ANIMAL)	01 02 04		
0214 SUB CHRONIC TOX (ANIMAL)	01 02 04	METAB/PHARMACO (ANIMAL)	01 02 04		
0215 CHRONIC TOX (ANIMAL)	01 02 04	METAB/PHARMACO (HUMAN)	01 02 04		

USE: R: D

TOXICOLOGICAL CONCERNS:

SPECIES: RAT

ONGOING REVIEW: YES (DROPPREF) NO (CONTINUE) REF:R

TRIAGE DATA: NON-CHL INVENTORY: YES NO IN IN MMIM

LOW MED HIGH

USE: Non-Cap

0 0 0 >

<ID NUMBER>

8(e)-12934A >

<TOX CONCERN>

L >

<COMMENT>

ACUTE INHALATION TOXICITY IN RATS IS OF LOW CONCERN, BASED ON
PRELIMINARY RESULTS. FOLLOWING 4-HOUR EXPOSURE TO A CONCENTRATION
OF 4.82 MG/L, MORTALITY OCCURRED IN 3/5 MALES AND 2/5 FEMALES.
\$\$\$\$ -CPSS- 0406951403