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IIT RESEARCH INST

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INITIAL SUBMISSION: ACUTE INHALATION TOXICITY STUDY OF AMQCOOL HD SOLUBLE OIL IN RATS (FINAL REPORT) WITH COVER LETTER DATED 022592 (SANITIZED)

**Chemical Category**

AMQCOOL HB SOLUBLE OIL

COMPANY SANITIZED

92 FEB 26 PM 2:29

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February 25, 1992

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CONTAINS CONFIDENTIAL BUSINESS  
INFORMATION

Dear Sir or Madam:

CAP Identification Number : 8ECAP-0112  
Category: Unit: II.B.2.b.

This notice is being submitted in accordance with the TSCA Section 8(e) Compliance Audit Program (CAP) and the CAP Agreement (56 FR 4128, 56 FR 19514 and 56 FR 2). Information in this notice was obtained from a designed, controlled study on Amocool HD Soluble Oil. The components of this material are as follows:

- Solvent refined paraffinic petroleum oil
- 2-Butoxy ethanol
- Petroleum sulfonate

(CASRN-111-76-2)  
SM5H0N10CY

The study entitled "Acute Inhalation Toxicity Study of Amocool HD Soluble Oil in Rats" was conducted as part of our research and development work in toxicology and our product stewardship efforts.

The material was administered as a vapor/aerosol by nose-only inhalation to a single group of five male and five female rats. The rats were exposed to a respirable liquid aerosol concentration (i.e.  $\leq$  10 microns) of 1.78 mg/l.

Sanitized Version

Five rats died during the study. Therefore, the 4-hour acute inhalation median lethal concentration (LC<sub>50</sub>) of Amocool HS Soluble Oil in male and female rats was estimated to be 1.78 mg/l.

All deaths occurred within one or two days subsequent to exposure. Dark red and/or mottled lungs which remained inflated when removed were observed in the dead rats at necropsy. Findings in the five surviving rats were within normal limits.

Confidentiality Statement

This letter and the attachments contain confidential business information. These claims are asserted pursuant to §14 of TSCA and to 40 CFR Part 2. All information claimed as confidential is boxed. A sanitized version of this letter and the attachments are provided. No public disclosure may be made of information in this letter or attachment that has been claimed as confidential absent prior notification to Amoco, pursuant to 40 CFR Part 2.

Support Information for Confidentiality Claims

Response to the questions in the document provided with the Compliance Audit Agreement (CAP) entitled "Substantiating Claims of Confidentiality" are given below:

1.

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3.

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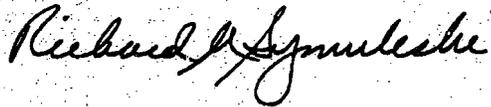
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7.

If you have any questions concerning this data, please contact Dr. Susan L. Schmitt  
at (312) 856-5792.

Sincerely,

A handwritten signature in cursive script, appearing to read "Richard J. Smyulski".

Enclosure

Sanitized Version

**COMPANY SANITIZED**

Category:

Unit II.B.2.b.

**ACUTE INHALATION TOXICITY STUDY OF  
AMOCOOL HD SOLUBLE OIL ( ) IN RATS**

**FINAL REPORT**

**IITRI Project No. L8100  
Study No. 1297  
Test Article No. 514**

**Contractor:**

**IIT Research Institute  
Life Sciences Research  
10 West 35th Street  
Chicago, IL 60616**

**Sponsor:**

**Amoco Corporation  
200 E. Randolph Drive  
Chicago, IL 60601**

**March 10, 1988**

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**TOXICOLOGY**

**IIT RESEARCH INSTITUTE**

**IITRI**

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ACUTE INHALATION TOXICITY STUDY OF  
AMOCOOL HD SOLUBLE OIL ( ) IN RATS

Study No. 1297  
Test Article No. 514

Study Initiation: November 18, 1987  
Study Termination: December 2, 1987  
Amoco ID Number: LF-8853

SUMMARY

Amocool HD Soluble Oil ( ) was administered as a vapor/aerosol by nose-only inhalation to a single group of five male and five female Sprague-Dawley rats. The rats were exposed to an uncorrected liquid aerosol concentration of 1.98 mg/L. The average particle size of the chamber atmosphere was 4.71 microns with 89.9% of the particles measuring less than 10 microns. Thus, the rats were exposed to a respirable liquid aerosol concentration (i.e.  $\leq 10$  microns) of 1.78 mg/L.

Five rats died during the study. Therefore, the 4-hour acute inhalation median lethal concentration ( $LC_{50}$ ) of Amocool HD Soluble Oil ( ) in male and female rats was estimated to be 1.78 mg/L.

All deaths occurred within one or two days subsequent to exposure. Significant clinical signs observed within 24 hours following exposure consisted of rapid respiration and a single incident of rales. Dyspnea was also observed later in the study. Surviving rats appeared normal within a few days and gained weight during the study. Dark red and/or mottled lungs which remained inflated when removed (i.e. edematous) were observed in the dead rats at necropsy. Findings in the five surviving rats were within normal limits.

STUDY PARTICIPANTS:

Allen Ledbetter and Marion Calow-Kasch, B.S., Test Data Collection  
J. Fred Krueger, M.S., assisted in the preparation of this report.

*Allen Ledbetter* 3/10/88  
Allen Ledbetter Date  
Study Director  
Life Sciences Research

*Nabil Hatoum* 3/10/88  
Nabil Hatoum, Ph.D., D.A.B.T. Date  
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*Larry G. Derrick* 3/10/88  
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ACUTE INHALATION TOXICITY STUDY OF  
AMOCOL HD SOLUBLE OIL ( ) IN RATSI. INTRODUCTION

The purpose of this study was to determine the acute inhalation toxicity of Amocool HD Soluble Oil ( ) when administered to rats by a single nose-only exposure.

II. MATERIALS AND METHODS

a. Test Article: Amocool HD Soluble Oil ( ), identification no. LF-8853, was received March 18, 1987. The test article was a dark red/brown liquid and was stored in its original container at room temperature (approximately 22°C).

b. Test Atmosphere Generation: The generating system used to produce a vapor/aerosol mixture of the test article is described in Appendix 1.

c. Animals: Male and female Sprague-Dawley rats weighing 100-125 g were purchased from Charles River Breeding Laboratories, Inc., Portage, MI, for use in this study. Upon arrival (11/11/87), the rats were held in quarantine for approximately one week and examined carefully to ensure their health and suitability as test subjects. Rats selected for the study were identified by a uniquely numbered metal tag inserted through the pinna of the right ear and by a cage card.

d. Food and Water: Purina Rodent Chow 5001 (Ralston Purina Company, St. Louis, MO) and water supplied from a reverse-osmosis purifier by an automatic watering system were available *ad libitum*, except during the exposure period.

e. Environment: During the quarantine and post-exposure observation periods, the rats were housed individually in suspended stainless steel cages measuring 15.8 x 15.5 x 17.0 cm. Deotized animal cage boards (Shepherd Specialty Papers, Kalamazoo, MI) were provided beneath the suspended cages, except during the exposure. The rats were confined in nose-only exposure tubes during the exposure. Air conditioned animal rooms were maintained at approximately 22°C and 40% relative humidity. Fluorescent lighting was provided automatically for 12 hours followed by 12 hours of darkness.

f. Methods:

1. Assignment to Groups: Rats were randomly selected for testing and assigned to a single group consisting of five males and five females. There was no control group.

2. Exposure: The rats were exposed for 4 hours (11/18/87) to a vapor/aerosol generated from a single batch of the test article. The target exposure concentration was 2 mg/L. The rats were placed in exposure tubes and inserted into a glass and stainless steel exposure chamber (Unifab Corp., Kalamazoo, MI), the door of which was adapted to hold nose-only exposure tubes.
3. Test Atmosphere Monitoring: The aerosol concentration was determined gravimetrically by drawing a known volume of the test atmosphere across an open-face filter and dividing the weight of test article collected by the sample volume. The particle size of the aerosol was determined twice during the exposure using an Andersen cascade impactor (Andersen Samplers, Atlanta, GA).
4. Daily Observations: The test rats were observed approximately 1/2 and 1-3/4 hours after the exposure, and at least once per day for the balance of the 14-day observation period.
5. Body Weights: All test rats were weighed prior to the exposure, one week later, and immediately prior to necropsy.
6. Necropsy: All rats which died during the study and/or survived to the end of the observation period (12/2/87) were necropsied.

### III. RESULTS:

a. Mortality: Five rats (three males and two females) died during the study. No rats died during the exposure, but all five deaths occurred within 48 hours following the exposure.

b. Chamber Concentration: The test article was generated as a vapor/aerosol. The nominal concentration based on the total amount of test article consumed was 17.7 mg/L. The gravimetric time weighted average (TWA) concentration obtained was 1.98 mg/l with 89.9% of the particles measuring less than 10 microns, thus resulting in an actual respirable concentration of 1.78 mg/L. The average particle size was 4.71 microns with a geometric standard deviation of 1.81.

c. Chamber Conditions: The average chamber temperature was 22°C during the exposure. Relative humidity averaged 42%.

d. Daily Observations: The inguinal fur of all rats was soiled with excreta after the exposure due to confinement in the exposure tubes. Clinical signs observed

within 24 hours following exposure included rapid respiration, discolored inguinal fur, test article around the nose, discolored facial fur, discolored paws, redness around the nose/eyes and a single incident of rales. Dyspnea and single incidents of hypothermia and ptosis were also observed during the study. Surviving rats appeared normal within a few days. A summary of clinical observations is presented in Table 1.

e. Body Weight: The mean initial body weights of the male and female rats were 180 g and 155 g, respectively. The five rats which survived gained weight during the study. Individual and mean body weights, and cumulative body weight changes are summarized in Table 2.

f. Gross Pathology: The lungs of the five rats which died were dark red, mottled and/or remained inflated upon removal (i.e. edematous). Red fluid-filled small intestines and a white pancreas were also observed (Table 3). Findings in the five rats which survived were within normal limits.

#### IV. EVALUATION

Based on the results of this study, the 4-hour acute inhalation median lethal concentration ( $LC_{50}$ ) of Amocool HD Soluble Oil ( ) in male and female rats in a nose-only exposure was estimated to be 1.78 mg/L.

#### V. QUALITY ASSURANCE

Laboratory operations were inspected on December 2, 1987 by Larry Derrick. The final draft report was audited on January 15, 1988 by Julie McPhillips. All operations were found to be in compliance with IIT Research Institute Quality Assurance criteria. Raw data generated during the study are retained in the IITRI Life Sciences Archives as specified by standard operating procedures.

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VI. TABLES

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TABLE 1  
Summary Of Mortality and Clinical Observations  
(5 Rats/Sex)

<u>Observation</u>	<u>Incidence</u>	
	<u>Males</u>	<u>Females</u>
Death	3	2
Rales	0	1
Dyspnea	4	3
Rapid respiration	5	5
Hypothermia	0	1
Test article around nose	5	5
Redness around nose	5	5
Redness around eyes	0	3
Ptosis	1	0
Soiled inguinal area	5	5
Discolored inguinal fur	1	5
Discolored facial fur	5	5
Discolored paws	2	3

**TABLE 2**  
**Summary of Body Weights**  
**(5 Rats/Sex)**

MALES				
Animal Number	Body Weights (g)			Cumulative Body Weight Change (g) (Week 2 - Week 0)
	Week 0	Week 1	Week 2	
531	184	- <sup>a</sup>	-	-
532	172	202	258	86
533	180	-	-	-
534	185	-	-	-
535	181	217	279	98
Mean	180	210	269	92
S.D. <sup>b</sup>	5.1	10.6	14.8	8.5

FEMALES				
Animal Number	Body Weights (g)			Cumulative Body Weight Change (g) (Week 2 - Week 0)
	Week 0	Week 1	Week 2	
536	160	-	-	-
537	151	172	189	38
538	158	-	-	-
539	158	176	189	31
540	150	168	185	35
Mean	155	172	188	35
S.D.	4.6	4.0	2.3	3.5

<sup>a</sup>- = rat died following exposure.  
<sup>b</sup>S.D. = standard deviation

**TABLE 3**  
**Summary of Gross Necropsy Findings**  
**(5 Rats/Sex)**

<u>Observation</u>	<u>Incidence</u>	
	<u>Males</u>	<u>Females</u>
No gross lesions	2	3
Lungs		
dark red	(2) <sup>a</sup>	(2)
mottled	(1)	-
remained inflated upon removal (i.e. edematous)	(2)	-
Small intestine		
red	(1)	(1)
fluid-filled	(1)	-
Pancreas		
white	(1)	-

<sup>a</sup> (N) = incidence observed in rats which died during the study.

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VII. APPENDIX

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## APPENDIX 1

## GENERATING AND EXPOSURE SYSTEM

The generating system consisted of a model 1/4 J-SS air atomizing nozzle assembly equipped with a 1650 fluid cap and a 1342055 air cap (Spraying System Co., Arlington Heights, Illinois). The test article was siphoned by air pressure from a metal reservoir, through the spray nozzle (operated at 40-60 psi), and into the exposure chamber.

The exposure was conducted in a stainless steel and glass chamber measuring 68.6 x 68.6 x 68.6 cm (0.5 m<sup>3</sup>), the door of which was adapted to hold nose-only exposure tubes. Chamber airflow was 37-100 liters per minute and the chamber was operated under a slight negative pressure (i.e. 0.18-0.4 in. H<sub>2</sub>O).

The test article vapor/aerosol entered the exposure chamber through a hole in the rear of the chamber and passed immediately through an atomization plenum. This plenum was used to improve the distribution of the test article vapor/aerosol within the chamber, and to reduce the size disparity of the aerosol. The atomization plenum was constructed from a 6 inch diameter steel ducting and was positioned at the top of the cubical portion of the chamber. The test article which was entrained within the plenum was pumped into a waste container using an FMI pump (Fluid Metering Inc., Oyster Bay, N.Y.). The test article vapor/aerosol exited the exposure chamber through an exhaust line located at the bottom of the chamber. The chamber air was exhausted through a filtering system before being discharged to the outside environment.

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