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		TSCA Section	8E
Submitting Organization	ARIZONA CHEM CO		
Contractor	BIODYNAMICS INC		
Document Title	INITIAL SUBMISSION: LETTER FROM ARIZONA CHEM CO TO USEPA REPORTING RESULTS OF 3 ACUTE ORAL TOXICITY STUDIES AND 24 ECOTOXICITY STUDIES ON VAR PRODUCTS, W/ATTCHMTS & DATED 4/14/00		
Chemical Category	GLYCEROL ESTER OF ROSIN; *		

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ARNOLD & PORTER

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NEW YORK  
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April 14, 2000

VIA HAND DELIVERY



BEHQ-00-14700

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Attention: TSCA Section 8(e) Coordinator  
Office of Pollution Prevention and Toxics  
U.S. Environmental Protection Agency  
401 M Street, S.W.  
Washington, D.C. 20460

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Re: TSCA § 8(e) Submittal

Dear Sir/Madam:

Enclosed are 27 studies (or summaries of studies) that are being submitted pursuant to Section 8(e) of the Toxic Substances Control Act (TSCA). These studies are being submitted pursuant to the TSCA Compliance Audit Agreement between EPA and the Arizona Chemical Company (Arizona). Arizona Chemical Company has its headquarters at 4600 Touchton Road, Suite 500, Jacksonville, Florida 32246.

Following is a summary of the relevant results of each study, including the chemical identity of the substance tested, the adverse effects being reported, and a discussion of exposure and other considerations.

**1. Three Acute Oral Toxicity Studies on Two Arizona Products.**

- a. Two acute oral toxicity studies in rats were conducted on the commercial Arizona product glycerol ester of rosin (Chemical Abstract Services Registry Number [CASRN] 8050-31-5; Chemical Abstract Service (CAS) preferred name "resin acids and rosin acids, esters with glycerol"). Both tests were by conducted by Bio/dynamics, Inc (project #5787-79 and #5788-79). No animals died in the studies and the LD<sub>50</sub> was determined to be > 5000 mg/kg in both studies. However, in study # 5787-79, the test laboratory reported observations of "motor activity decrease . . . during the first week of the study, most notably during the 48 hours following intubations" and "all signs of effect diminished during the second week with the exception of piloerection (4 animals)." In study # 5788-79, the test laboratory

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reported observations of "piloerection and motor activity decrease in many of the animals during the first week of the observation period, most notably in the first 24 hours following intubation", and "motor activity decrease and piloerection were the only signs noted during the second week of the observation period in two and one animals, respectively."

- b. An acute oral toxicity study in rats was conducted on a now discontinued Arizona product tall oil fatty acids, 2-ethylhexyl esters (CASRN 68334-13-4, CAS preferred name "fatty acids, tall-oil, 2-ethylhexyl esters"). The test was conducted by Pharmakon Research International, Inc. (project #PH 402-AC-003-84). No animals died in the study and the LD<sub>50</sub> was determined to be > 5000 mg/kg. However, the test laboratory reported observations of "decreased activity, decreased muscle tone, poor grooming, piloerection and abnormal gait."

The above three studies are being submitted pursuant to Section 8(e) out of an abundance of caution based upon published EPA guidance that lethargy, excess salivation, ataxia, piloerection, gait abnormalities, and behavioral changes in test animals potentially are indicative of neurotoxicological effects of the test substance.

**2. 24 Ecotoxicity studies on 8 Arizona products: rosin, tall oil heads, distilled tall oil, pentaerythritol ester of rosin, glycerol ester of rosin, pine oil, Ca/Mg resinate, and Zn resinate.**

EPA has provided guidance to industry regarding the reportability of acute ecotoxicity studies under TSCA Section 8(e). Based upon this guidance, test materials with LC<sub>50</sub> or EC<sub>50</sub> values of less than 1 mg/L are considered by the Agency to be of "high" concern; test materials with LC<sub>50</sub> or EC<sub>50</sub> values between 1 and 100 mg/L are considered to be of "moderate" concern; and test materials with LC<sub>50</sub> or EC<sub>50</sub> values of greater than 100 mg/L are considered to be of "low" concern. EPA guidance further states that acute ecotoxicity studies indicating a high concern should be submitted under Section 8(e) if there also is evidence that the test material has bioaccumulated to a pronounced degree or that it is or could be (based upon use patterns) widespread in environmental media. Agency guidance states that test results showing moderate concerns should be reported if usage patterns and/or monitoring data for the test material suggest that the material is present in environmental media at or near concentrations where the effects in question reasonably could be expected to be manifested. According to EPA, results of acute ecotoxicity studies indicating a low concern need not be submitted.

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Arizona has in its possession ecotoxicity studies on rosin, tall oil heads, distilled tall oil, pentaerythritol ester of rosin, glycerol ester of rosin, pine oil, Ca/Mg resinate, and Zn resinate. The results of the studies are summarized below. Arizona does not have any information to support a conclusion that these substances are widespread in environmental media or that they are present in environmental media at or near concentrations where the effects in question reasonably could be expected to be manifested. Further, Arizona has questions regarding the interpretation of these data because of the manner in which the test materials were introduced into the test medium. Nevertheless, Arizona is submitting these data pursuant to Section 8(e) out of an abundance of caution, because six of these substances (rosin, tall oil heads, distilled tall oil, pentaerythritol ester of rosin, glycerol ester of rosin and pine oil) are commercial products currently manufactured by Arizona. The other two substances (Ca/Mg resinate and Zn resinate) are discontinued products that Arizona may make again some time in the future.

- a. Of seven ecotoxicity studies conducted on rosin (CASRN 8050-09-7), four studies indicated moderate concern and three indicated low concern. An algal growth inhibition study conducted on a composite sample of rosin from several European rosin manufacturers showed an  $EC_{50}$ (biomass) value of 200 mg/L (test report #WQI-308061/471). An immobilization test with *Daphnia Magna* conducted on a composite sample showed a 48 hour  $EC_{50}$  value of 327 mg/L (test report #WQI-308069/471). An acute toxicity test on zebrafish conducted on a composite sample of rosin showed a 96 hour  $LC_{50}$  of 100 - 200 mg/L (test report #WQI-308065/471). Two summaries of studies of gum rosin with *Daphnia Magna* showed 48 hour  $EC_{50}$  values of 10 - 100 mg/L (test report #RGL F98086 T 98006 ODA and #RGL F98088 T 98007 ODA). A summary of a study of gum rosin on zebrafish reported a 96 hour  $LC_{50}$  of 1 - 10 mg/L (test report #RGL F98083 T 98006 OFB). A summary of a study of gum rosin on zebrafish reported a 96 hour  $LC_{50}$  of 1 - 10 mg/L (test report #RGL F98084 T 98007 OFB). Nominal concentrations of the test substance were used to determine the  $EC_{50}$  and  $LC_{50}$  values in these studies. It is likely that the actual water solubility of the test substance is less than 10 mg/L; thus, it also is likely that  $EC_{50}$  and  $LC_{50}$  values for the soluble portion of the test substance are less than 10 mg/L.
- b. Three ecotoxicity studies conducted on a composite sample of tall oil heads (CASRN 65997-03-7) indicated moderate concern. An algal growth inhibition study showed an  $EC_{50}$ (biomass) value of 2.07 mg/L (test report #WQI-308061/474). An immobilization test with *Daphnia Mag.ia* showed a 48 hour  $EC_{50}$  value of 67.3 mg/L (test report #WQI-308069/474). An acute toxicity test on zebrafish showed a 96 hour

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LC<sub>50</sub> of 50 - 100 mg/L (test report #WQI-308065/474). Nominal concentrations of the test substance were used to determine the EC<sub>50</sub> and LC<sub>50</sub> values in these studies. It is likely that the actual water solubility of the test substance is less than 10 mg/L; thus, it also is likely that EC<sub>50</sub> and LC<sub>50</sub> values for the soluble portion of the test substance are less than 10 mg/L.

- c. Of three ecotoxicity studies conducted on a composite sample of distilled tall oil (CASRN 61790-12-3) one study indicated high concern and two indicated moderate concern. An algal growth inhibition study showed an EC<sub>50</sub>(biomass) value of 0.87 mg/L (test report #WQI-308061/475). An immobilization test with *Daphnia Magna* showed a 48 hour EC<sub>50</sub> value of 39.7 mg/L (test report #WQI-308069/475). An acute toxicity test on zebrafish showed a 96 hour LC<sub>50</sub> of 5 - 10 mg/L (test report #WQI-308065/475). Nominal concentrations of the test substance were used to determine the EC<sub>50</sub> and LC<sub>50</sub> values in these studies.
- d. Four ecotoxicity studies were conducted on a product known as fatty acid dipentaester or pentaerythritol ester of rosin (CASRN 68424-56-6; CAS preferred name "fatty acids, tall oil, polymers with pentaerythritol"). These studies indicated moderate to low concern. An algal growth inhibition study showed an EC<sub>50</sub>(biomass) value of 39 mg/L (test report #WQI-308061/489). An immobilization test with *Daphnia Magna* showed a 48 hour EC<sub>50</sub> value of > 2000 mg/L (test report #WQI-308069/489). An acute toxicity test on zebrafish showed a 96 hour LC<sub>50</sub> of 200 - 500 mg/L (test report #WQI-308065/489). An immobilization test with *Daphnia Magna* conducted on a composite sample of the pentaerythritol ester of rosin showed a 48 hour EC<sub>50</sub> value of 166 mg/L (test report #WQI-308069/477). Nominal concentrations of the test substance were used to determine the EC<sub>50</sub> value in these studies. It is likely that the actual water solubility of the test substance is less than 10 mg/L; thus, it also is likely that EC<sub>50</sub> values for the soluble portion of the test substance are less than 10 mg/L.
- e. An immobilization test with *Daphnia Magna* conducted on a composite sample of glycerol ester of rosin (CASRN 8050-31-5; CAS preferred name "resin acids and rosin acids, esters with glycerol") showed a 48 hour EC<sub>50</sub> value of 259 mg/L (test report #WQI-308069/478) and indicated low concern. Nominal concentrations of the test substance were used to determine the EC<sub>50</sub> value in this study. It is likely that the actual water solubility of the test substance is less than 10 mg/L; thus, it also is likely that EC<sub>50</sub> value for the soluble portion of the test substance is less than 10 mg/L.

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April 14, 2000

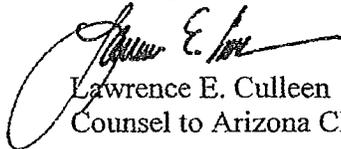
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Page 5

- f. An acute toxicity study on Mysid Shrimp conducted on the commercial Arizona product pine oil (CASRN 8002-09-3) showed a 96 hour LC<sub>50</sub> value of 65 mg/L (test report #ESE-89320-0210-2130) and indicated moderate concern. Nominal concentration of the test substance was used to determine the LC<sub>50</sub> value in this study.
- g. Three ecotoxicity studies were conducted on a discontinued Arizona product Ca/Mg resinate (Mixture of CASRN 9007-13-0 and 68440-56-2; CAS preferred names, "resin acids and rosin acids, calcium salts" and "resin acids and rosin acids, magnesium salts"). These studies indicated low concern. An algal growth inhibition study showed an EC<sub>50</sub>(biomass) value of 500 - 1000 mg/L (test report #WQI-308061/482). An immobilization test with *Daphnia Magna* showed a 48 hour EC<sub>50</sub> value of 726 mg/L (test report #WQI-308069/482). An acute toxicity test on zebrafish showed a 96 hour LC<sub>50</sub> of 100 -200 mg/L (test report #WQI-308065/482). Nominal concentrations of the test substance were used to determine the EC<sub>50</sub> and LC<sub>50</sub> values in these studies. It is likely that the actual water solubility of the test substance is less than 10 mg/L; thus, it also is likely that EC<sub>50</sub> and LC<sub>50</sub> values for the soluble portion of the test substance are less than 10 mg/L.
- h. Two ecotoxicity studies were conducted on a discontinued Arizona product Zn resinate (CASRN 9010-69-9; CAS preferred name "resin acids and rosin acids, zinc salts"). These studies indicated low and moderate concern. An algal growth inhibition study showed an EC<sub>50</sub>(biomass) value of 20 - 50 mg/L (test report #WQI-308061/490). An immobilization test with *Daphnia Magna* showed a 48 hour EC<sub>50</sub> value of > 2000 mg/L (test report #WQI-308069/490). Nominal concentrations of the test substance were used to determine the EC<sub>50</sub> values in these studies. It is likely that the actual water solubility of the test substance is less than 10 mg/L; thus, it also is likely that EC<sub>50</sub> values for the soluble portion of the test substance are less than 10 mg/L.

Please contact me (at 202/942-5477) with any comments or questions that you have concerning these matters. Thank you.

Sincerely,



Lawrence E. Culleen

Counsel to Arizona Chemical Company

Enclosures

cc (w/out enclosures): Tony Ellis, EPA

TITLE PAGE

TITLE OF REPORT: Acute Oral Toxicity Study in Rats

TEST SUBSTANCE: ZONESTER<sup>®</sup> 85 DB-3012

TEST SPECIES: Sprague-Dawley male albino rats

ROUTE OF ADMINISTRATION: Oral

DURATION OF STUDY: Fourteen days

TESTING FACILITY: Bio/dynamics Inc.  
Mettlers Road  
East Millstone, New Jersey 07873

TESTING FACILITY'S REPORT NO.: 5787-79

SPONSOR: Arizona Chemical Company  
Wayne, New Jersey 07470

SPONSOR'S REPORT NO.: 79-37 A

DATE OF REPORT: August 28, 1979

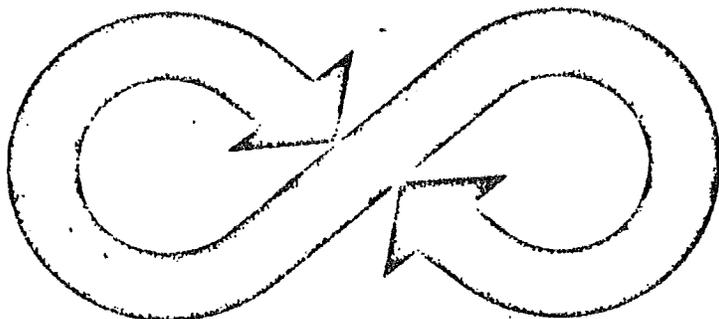
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**Bio/dynamics Inc.**

Division of Biology and Safety Evaluation

PROJECT NO. 5787-79

ACUTE ORAL TOXICITY STUDY IN RATS

TEST MATERIAL: Zonester® 85 DB-3012

Submitted to: The American Cyanamid Company  
Wayne, N.J.

Date: August 28, 1979

## I. INTRODUCTION

This study was conducted for The American Cyanamid Company in order to evaluate the acute oral toxicity of Zonester® 85, DB-3012. The study was performed at Bio/dynamics, Inc., East Millstone, New Jersey, and was designed to determine the oral LD50 of the test material or to establish a non-lethal dose level of 5.0 grams of test material per kilogram of body weight, which represents the maximum dose which can be administered.

## II. MATERIALS AND METHODS

This study was performed as described in the study protocol submitted June 5, 1979, which is presented as Appendix A of this report.

Information which applies specifically to this study is as follows:

Bio/dynamics Project No.: 5787-79

Dates of Study:

Initiation of Study: July 5, 1979.

Termination of Study: July 19, 1979.

Test Material:

Label Information: Zonester® 85, Gum Grade, LO-5-14; DB-3012

Description: Amber crystalline solid.

Date of Receipt: May 29, 1979.

Storage: Room temperature

Test Material Preparation:

Concentration: 10% w/v suspension.

Vehicle: Corn oil.

Temperature of dosing mixture: Ambient.

### III. RESULTS

#### A. Mortality

A single dose of 5.0 g/kg of Zonester® 85 DB-3012 was administered to ten rats. No deaths occurred, therefore the oral LD<sub>50</sub> of Zonester® 85, DB-3012 can be considered to be greater than 5.0 g/kg.

#### B. Body Weights (Table I)

Body weight gain during the first week of the two-week post-dose observation period was minimal. During the second week of the observation period considerable weight gain was exhibited by all animals, the result being a net weight gain in all animals on the study.

#### C. Physical Observations (Table II)

Urinary and fecal staining of the abdomen, soft stool, red nasal discharge and motor activity decrease were noted during the first week of the study, most notably during the 48 hours following intubation. All signs of effect diminished during the second week with the exception of piloerection (4 animals). Other signs occurred sporadically in one or two animals as outlined in Table II.

#### D. Necropsy Observations (Table III)

Observations of the terminal gross necropsy performed on each animal are presented in Table III.

IV. SUMMARY

All ten animals administered a single dose of 5.0 g/kg of Zonester® 85, DB-3012, survived the two week observation period. Therefore, the LD50 for Zonester® 85, DB-3012, can be considered to be greater than 5.0 g/kg.

Physical signs, including urinary and fecal staining of the abdomen, soft stool and motor activity decrease were evident most notably within the 48 hours following intubation. With the exception of piloerection, all signs of effect diminished during the second week of the two-week post-dose observation period.

Carol S. Auletta

Carol S. Auletta, B.A.  
Study Director

William E. Rinehart

William E. Rinehart, Sc.D.  
Vice-President

Prepared with the technical assistance of:

Donna L. Blaszak, B.S. Laboratory Supervisor  
Rita Peek, B.A. Report Preparation

TABLE 1  
ACUTE ORAL TOXICITY STUDY IN RATS  
TEST MATERIAL: Zonester® 85, DB-3012  
Individual Body Weights (grams)

<u>Dose Level</u> g/kg	<u>Animal No. &amp; Sex</u>	<u>Pre-fast</u>	<u>Body Weight - g</u>			
			<u>Day 7</u>	<u>Δ<sup>a</sup></u>	<u>Day 14</u>	<u>Δ<sup>a</sup></u>
	6427 M	275	291	16	336	61
	6405 M	291	293	2	334	43
	6409 M	298	292	-6	347	49
	6393 M	274	282	8	324	50
	6440 M	294	322	28	379	85
	6470 F	256	261	5	292	36
	6487 F	264	267	3	301	37
	6483 F	241	247	6	283	42
	6480 F	243	250	7	269	26
	5199 F	227	236	9	266	39

<sup>a</sup>Weight change from prefasted body weight.

TABLE II  
 ACUTE ORAL TOXICITY STUDY IN RATS  
 TEST MATERIAL: Zonester® 85, DB-3012  
 Summary of In-Life Observations<sup>a</sup>

Dose Level g/kg	Observations	Time Interval							
		Hours		Days					
		0-2	4-6	1	2	3	4	5-7	8-14
5.0	NOA	2	0	0	1	7	6	9	10
	Dead	0	0	0	0	0	0	0	0
	Red Nasal Discharge	0	6	0	0	0	0	0	0
	Clear Oral Discharge	1	1	0	0	0	0	0	0
	Respiratory Rate Increase	0	0	0	0	0	0	1	0
	Respiratory Rate Decrease	0	0	1	0	0	0	0	0
	Labored Breathing (Gasping)	1	0	0	0	0	0	0	0
	Urinary Staining	0	10	5	3	1	1	1	0
	Fecal Staining	7	10	3	0	0	1	0	0
	Soft Stool	5	10	0	0	0	0	0	0
	Piloerection	0	5	0	1	1	3	9	4
	Abdominal Griping	0	0	0	0	0	1	0	0
	Motor Activity Increase	0	0	1	0	0	0	2	0
	Motor Activity Decrease	1	4	7	9	3	1	2	0
	Irregular breathing	2	0	0	0	0	0	0	0
	Ocular opacity right eye	0	1	0	0	0	0	0	0
	Alopecia Ano-genital Region	0	0	0	0	0	0	1	0

<sup>a</sup>Numbers represent number of animals (out of 10) exhibiting indicated finding.

TABLE III

## ACUTE ORAL TOXICITY STUDY IN RATS

TEST MATERIAL: Zonester® 85, DB-3012

## Necropsy Observations

<u>Dose Level</u> g/kg	<u>Day of Death</u>	<u>Observations</u>
5.0		
6427 M	TE	Lungs: dark red foci; adrenals: pale red; stomach: thick green material; intestines: viscous white fluid.
6405 M	TE	Adrenal: pale red; stomach and intestines: thick green substance.
6409 M	TE	Lungs: dark red foci; adrenals: pale red; stomach and intestines: thick green substance.
6393 M	TE	Lungs: mottled tan, dark red foci; adrenals: pale red; spleen: roughened; stomach and intestines: vascularized, thick green material.
6440 M	TE	Lungs: dark red foci throughout; stomach: thick green material; intestines: viscous white fluid.
6470 F	TE	Adrenals: pale red; stomach: thick green material; intestines: viscous white fluid.
6487 F	TE	Lungs: mottled dark red, bright red foci; kidneys: mottled grey; adrenals: pale; stomach and intestines: thick green substance.
6483 F	TE	Lungs: dark red foci; adrenals: pale red; spleen: roughened; stomach and intestines: thick green substance.
6480 F	TE	Adrenals: pale red; stomach: thick green material; intestines: viscous yellow fluid.
5199 F	TE	Lungs: pale, dark red foci; adrenals: dark red; stomach and intestines: thick green substance.

TE - Terminal Euthanasia, Day 14.

APPENDIX A

STUDY PROTOCOL

PROJECT NO. 5787-79

I. INTRODUCTION

PROJECT NO. 5787-79

STUDY: Acute Oral Toxicity Study in Rats with Zonester<sup>R</sup> 85

PURPOSE: This study is designed to determine the oral LD<sub>50</sub> of the test substance or to establish a non-lethal dose level of 5 grams of test substance per kilogram of body weight, which represents the maximum dose which can be administered.

TESTING FACILITY:

Bio/dynamics Inc.,  
East Millstone, New Jersey 08873

SPONSOR: American Cyanamid Company  
Wayne, N.J.  
Attention: David R. Brown, Sc.D.

DATE OF AUTHORIZATION:

May 24, 1979

PROPOSED STUDY DATES:

June 7 - 21, 1979

II. MATERIALS:

TEST ANIMALS: Albino Rats

Strain: Sprague-Dawley

Supplier: Charles River Breeding Laboratories, Inc.  
Wilmington, Mass

Number: Single dose level (5 g/kg): Ten (five/sex)  
Range-finding Screen: Ten (one/sex/dose level)  
Note: additional animals may be used if indicated.  
LD<sub>50</sub> Determination: Fifty (five/sex/dose level)

Age/Weight: Young Adults - Males: Approximately 230-360 g.;  
Females approximately 180-250 g. at time of dosing.

Husbandry: Housing: Individual, in suspended stainless steel cage  
Food: Purina Laboratory Chow, ad libitum  
Water: Elizabethtown Water Co., ad libitum

Equilibration Period: At least one week

II. MATERIALS (cont.):

Identification: Each animal is identified with a monel ear tag prior to testing.

Selection: The animals are randomly selected for each study.

TEST SUBSTANCE: Zonester<sup>R</sup> 85 DB3012

Handling Information:

As described in Appendix A (toxicity data sheet)

III. METHODS:

Test Design:

Because this material is expected to be non-toxic, the highest attainable dose (5 g/kg) will be administered initially to 10 animals (5/sex). If no animals die during the fourteen day post-dose observation period, no additional testing is required.

If deaths occur in animals dosed with 5 g/kg a preliminary range-finding screen will be performed by administering five different dose levels (0.05, 0.1, 0.5, 1.0 and 2.0 g/kg) to ten rats (one male; one female per dose level). If results do not provide adequate information for selecting doses for the LD<sub>50</sub> determination, additional screening will be performed. Animals are observed for viability for seven days after dosing. Based on the results of this screen, five geometrically spaced dose levels are selected and each dose is administered to ten animals (5/sex) for a determination of the LD<sub>50</sub>.

Preparation of Animals:

Animals are fasted for approximately eighteen hours prior to treatment.

Preparation of Test and/or Control Substance:

The test substance will be administered as a 10 percent suspension in corn oil.

IV. EXPERIMENTAL EVALUATION:

VIALIBILTY CHECK: Twice Daily

OBSERVATIONS OF PHARMACOLOGIC AND TOXICOLOGIC SIGNS:

Approximately 1, 2, and 4 hours after dosing, and daily thereafter for fourteen days.

IV. EXPERIMENTAL EVALUATION (cont.):BODY WEIGHTS:

Pre-fast

Post-fast (just prior to dosing)

Day 7 and Day 14

Terminal: Any animals which do not survive for 14 days are weighed at the time of death or at the time they are found dead.

V. POST MORTEM:Necropsy:

Gross post mortem examinations are performed on all surviving animals on Day 14 and on all animals which die or are found dead during the study. All abnormalities are recorded but no tissues are saved.

VI. REPORT:

A report containing tabulations of numbers of animals dying, time of death, in-life observations, necropsy observations and the LD<sub>50</sub> with 95% confidence limits is provided following the termination of the study. Note: Data from preliminary range-finding screens are not reported but are placed with the raw data which is retained permanently on file at Bio/dynamics.

VII. REFERENCES:

<sup>1</sup>Miller, Lloyd C. and M.L. Tainter., Estimation of the ED<sub>50</sub> and Its Error by Means of Logarithmic-Probit Graph Paper., Proc. Soc. Exp. Bio. Med., 57, 261-264, (1944)

VIII. PROTOCOL REVIEWED AND ACCEPTED:

By: Carol J. Ametta Date: June 5, 1979  
For: Bio/dynamics, Inc.

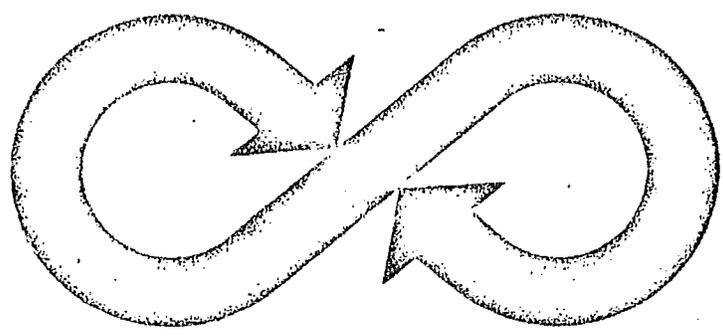
By: David R. Brown Date: June 10, 1979  
For: American Cyanamid Company

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file: Tox-  
Rosin, glycerol ester B

79-03



Eio/dynamics Inc.

Division of Biology and Safety Evaluation

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PROJECT NO. 5788-79

ACUTE ORAL TOXICITY STUDY IN RATS

TEST MATERIAL: *glycerol ester of Rosin*  
Zonester® 85 NF-7015 8050-31-S

Submitted to: The American Cyanamid Company  
Wayne, N.J.

Date: August 28, 1979

## I. INTRODUCTION

This study was conducted for The American Cyanamid Company in order to evaluate the acute oral toxicity of Zonester® 85, NF-7015. The study was performed at Bio/dynamics, Inc., East Millstone, New Jersey, and was designed to determine the oral LD<sub>50</sub> of the test substance or to establish a non-lethal dose level of 5.0 grams of test substance per kilogram of body weight, which represents the maximum dose which can be administered.

## II. MATERIALS AND METHODS

This study was performed as described in the study protocol submitted June 5, 1979, which is presented as Appendix A of this report.

Information which applies specifically to this study is as follows:

Bio/dynamics Project No.: 5788-79

Dates of Study:

Initiation of Study: July 5, 1979.

Termination of Study: July 19, 1979.

Test Material:

Label Information: Zonester® 85, Gum Grade, LO-5-14, NF-7015.

Description: Amber crystalline solid.

Date of Receipt: May 29, 1979.

Storage: Room temperature

Test Material Preparation:

Concentration: 10% w/v suspension.

Vehicle: Corn oil.

Temperature of dosing mixture: Ambient.

### III. RESULTS

#### A. Mortality

A single dose of 5.0 g/kg was administered to ten rats. No mortality occurred. The LD<sub>50</sub> of Zonester® 85, NF-7015 can therefore be considered to be greater than 5.0 g/kg.

#### B. Body Weights (Table I)

The majority of the animals on this study exhibited moderate weight gains during the first week of the two-week post-dose observation period. During the second week of the study larger weight gains were exhibited by all animals, the result being a net body weight gain in all animals.

#### C. Physical Observations (Table II)

Urinary and fecal staining of the abdomen, soft stool, piloerection and motor activity decrease were noted in many of the animals during the first week of the observation period, most notably within the 24 hours following intubation. Other signs were noted sporadically in one to five animals during the first week of the study as outlined in Table II. Motor activity decrease and piloerection were the only signs noted during the second week of the observation period in two and one animals respectively.

#### D. Necropsy Observations (Table III)

The observations of the terminal gross necropsy performed on each animal are presented in Table III.