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INITIAL SUBMISSION: TOXICOLOGICAL INVESTIGATION OF: ACL 53 WITH COVER LETTER DATED 081792		
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Chemical Category		
ACL 53		

8(e)

# CAP

(COMPLIANCE AUDIT PROGRAM)

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NOTE: Peter provides data entry in CBITS for the 8(e) CAP Documents.

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# Monsanto

92 AUG 28 PM 2:39

ENVIRONMENT, SAFETY & HEALTH

Monsanto Company  
800 N. Lindbergh Boulevard  
St. Louis, Missouri 63167  
Phone: (314) 694-1000  
August 17, 1992

8EHQ-0892-9222



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88920007550

Attention: Section 8(e) Coordinator (CAP Agreement)

This submission is pursuant to the TSCA Section 8(e) Compliance Audit Program and CAP Agreement #8ECAP-0036.

The information included herein is characterized as follows:

Chemical Identity - ACL 53

Chemical CAS No. - 000108805

Information/Study Type - II,B,2,b/Acute Toxicity/Irritation Study

Information/Study Identification - Toxicological Investigation of: ACL 53  
YO-64-076A

Identification of Reportable Endpoint: SKIN CORROSIVE

Previous TSCA 8(e) or PMN submissions, if any, for the reference chemical can be found in Appendix A.

It should be noted that this summary is not all inclusive. Therefore, it may not highlight all adverse effects that EPA may judge to meet TSCA 8(e) reportability. This submission/report does not contain confidential business information.

Sincerely,

J. R. Condray  
Director, Regulatory Management  
(314) 694-8883

APPENDIX A

Material Name	Monosodium Cyanurate
CAS No.	000108805
PMN Submission	
PMN Number	
Monsanto Study Number:	

Previous 8(e) Submissions:

<u>Monsanto Study No.</u>	<u>EPA Numbers</u>
IR-81-202	FIFRA MRID 00105168
IR-81-364	FIFRA MRID 00150286

# YOUNGER LABORATORIES

*Biochemists ... Pharmacologists ... Analysts*

128 CLIFF CAVE ROAD  
SAINT LOUIS, MO., 63129  
PHONE: TILDEN 6-2540

## Certificate of Analysis

July 22nd, 1964

**SUBJECT -**

Toxicological Investigation Of: ACL 53

Monsanto Sample Number 86

Monsanto Project Number Y-64-76

**STUDY CONDUCTED FOR -**

Monsanto Company, St. Louis, Missouri

**EXPERIMENTAL PROCEDURE -**

The tests were conducted in accordance with the Federal Hazardous Substances Labeling Act.

**A) Oral LD<sub>50</sub> (Rats, Mixed Sex)**

The diluted compound was fed by stomach tube to Sprague-Dawley strain albino male and female rats.

After the approximate Minimum Lethal Dose was determined, groups of male and female rats were fed in increasing doses at increments of 0.1 fractional log intervals at four levels designed to blanket the toxicity range thereby supplying data for calculation of the LD<sub>50</sub> which was done according to a modification of the method of E. J. de Beer.

Observations were made for toxic symptoms and the viscera of the animals that succumbed were examined macroscopically.

The data, together with the dilution at which the compound was fed, are shown in Table I.

**B) Skin Absorption MLD (Rabbits, Mixed Sex)**

The diluted compound was applied in increasing doses at increments of 0.2 fractional log intervals to the closely clipped, intact skin of New Zealand white male and female rabbits. The application was kept moist throughout the twenty-four hour exposure period.

The treated areas were covered with plastic strips and the animals placed in wooden stocks for periods up to twenty-four hours, after which time they were assigned to individual cages.

Observations were made for toxic symptoms and the viscera of the animal that succumbed was examined macroscopically.

The data, together with the dilution at which the compound was applied, are shown in Table II.

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 St. Louis, Missouri  
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EXPERIMENTAL PROCEDURE - (Continued)

C) Skin Irritation - Intact and Abraded (Rabbits)

The diluted compound was applied to the clipped, intact and abraded skin of six albino rabbits and removed after twenty-four hours. The treated areas were kept moist during the twenty-four hour exposure period.

The applications were covered with plastic strips to retard evaporation and avoid contamination.

Observations were made over a period of several days.

The data, scored according to the method of Draize, Woodard and Calvery (Journal of Pharm. and Exp. Therapeutics, Volume 82, December, 1944), together with the dilution at which the compound was applied, are shown in Table III.

D) Eye Irritation (Rabbits)

One Hundred (100.0) milligrams of finely ground sample were placed in the conjunctival sac of the right eye of each of six albino rabbits and observations made over a period of several days for inflammation.

The eyes of animals #1 and #2 were rinsed with warm isotonic saline solution after twenty-four hours exposure, the eyes of animals #3 and #4 were rinsed after two seconds exposure, and the eyes of animals #5 and #6 were rinsed after four seconds exposure.

The left eye served as the control.

The data, scored according to the method of Draize, et al, are shown in Table IV.

SUMMARY -

ACL 53

A) Oral LD<sub>50</sub> (Rats, Mixed Sex)

The Oral LD<sub>50</sub> for male and female rats was placed at 1510 milligrams per kilogram with lower and upper limits of 1330 to 1720 milligrams per kilogram.

The compound was classed as slightly toxic by oral ingestion in male and female rats.

B) Skin Absorption MLD (Rabbits, Mixed Sex)

The Minimum Lethal Dose by Skin Absorption in male and female rabbits was found to be greater than 2510 milligrams per kilogram and less than 3980 milligrams per kilogram.

The compound was classed as slightly toxic by skin absorption in male and female rabbits.

C) Skin Irritation - Intact and Abraded (Rabbits)

PRIMARY IRRITATION SCORE (FEDERAL HAZARDOUS SUBSTANCES LABELING ACT) --

Primary Irritation Score = 0.0

ACL 53 was classed as a 'corrosive skin irritant' under the grading system as outlined in the Act.

A 'corrosive substance' is one that causes visible destruction or irreversible alterations in the tissue at the site of contact; the structure of the tissue at the site of contact is destroyed or changed irreversibly in twenty-four hours or less.

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Younger Laboratories Certificate of Analysis - Page 3 (7/22/64) - Y-64-76

SUMMARY - (Continued)

C) Skin Irritation - Intact and Abraded Skin (Rabbits) - Continued

The compound was classed as a corrosive skin irritant when applied as a 25.0% aqueous solution to INTACT rabbit skin.  
The average maximum score was 8.0 out of a possible 8 in twenty-four hours.  
The compound was classed as a corrosive skin irritant when applied as a 25.0% aqueous solution to ABRADED rabbit skin.  
The average maximum score was 8.0 out of a possible 8 in twenty-four hours.

D) Eye Irritation (Rabbits)

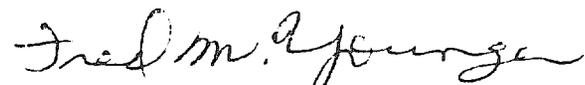
EYE IRRITATION (FEDERAL HAZARDOUS SUBSTANCES LABELING ACT) --

ACL 53 was classed as a 'corrosive eye irritant' under the grading system as outlined in the Act.

A 'corrosive substance' is one that causes visible destruction or irreversible alterations in the tissue at the site of contact.

The compound was classed as a corrosive eye irritant.  
The average maximum score was 110 out of a possible 110 in twenty-four hours.

YOUNGER LABORATORIES



BY: FRED M. YOUNGER

The material in this report is to be used in development of the product and may be given to responsible sales contacts, but it is not to be used by them in advertising copy. The source of this material is not to be divulged until it appears in formal publications. It is recommended that a written rule may be made without the approval of the Medical Department in St. Louis. Customer inquiries regarding matters of toxicity are to be referred as before to the Medical Department in St. Louis for reply.

— Monsanto Chemical Company

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St. Louis, Missouri  
Younger Laboratories Certificate of Analysis - Page 4 (7/22/64) - Y-64-76

T A B L E I

THE ORAL LD<sub>50</sub> OF 'ACL 53' FOR RATS

Sample Fed As A 25.0% Aqueous Solution

<u>Animal No. - Sex</u>	<u>Weight Gm.</u>	<u>Dose Mg. / Kg.</u>	<u>Fate</u>
1- Female	225	1000	Survived
2- Female	230	1000	Survived
3- Male	245	1000	Survived
4- Male	260	1000	Survived
5- Female	220	1000	Survived
6- Female	235	1260	Survived
7- Male	245	1260	Survived
8- Male	250	1260	Survived
9- Female	215	1260	Survived
10- Female	230	1260	Survived
11- Male	240	1580	Died
12- Male	230	1580	Survived
13- Female	215	1580	Died
14- Female	225	1580	Survived
15- Male	250	1580	Died
16- Male	240	2000	Died
17- Female	225	2000	Died
18- Female	220	2000	Died
19- Male	235	2000	Died
20- Male	245	2000	Died

DISCUSSION -

The Oral LD<sub>50</sub> for male and female rats was placed at 1510 milligrams per kilogram with lower and upper limits of 1330 to 1720 milligrams per kilogram.

The compound was classed as slightly toxic by oral ingestion in male and female rats.

Survival time was several hours to three days with most deaths occurring overnight.

Toxic symptoms included collapse within minutes usually followed by temporary recovery, salivation, severe diarrhea, tremors, and dyspnea.

At autopsy there was severe inflammation of the gastrointestinal tract and renal hyperemia macroscopically.

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 St. Louis, Missouri  
 Younger Laboratories Certificate of Analysis - Page 5 (7/22/64) - Y-64-76

T A B L E II

THE MINIMUM LETHAL DOSE OF 'ACL 53'  
 BY SKIN ABSORPTION IN RABBITS

Sample Applied As A 25.0% Aqueous Solution

<u>Animal No. - Sex</u>	<u>Weight Kg.</u>	<u>Dose Mg./Kg.</u>	<u>Weight Change 5 Days Later Kg.</u>	<u>Fate</u>
1 - Female	2.3	398	+ 0.1	Survived
2 - Male	2.5	631	0.0	Survived
3 - Female	2.2	1000	0.0	Survived
4 - Male	2.5	1580	+ 0.1	Survived
5 - Female	2.4	2510	- 0.2	Survived
6 - Male	2.7	3980	-----	Died -- 2 Days

DISCUSSION -

The Minimum Lethal Dose by Skin Absorption in male and female rabbits was found to be greater than 2510 milligrams per kilogram and less than 3980 milligrams per kilogram.

The compound was classed as slightly toxic by skin absorption in male and female rabbits.

Survival time was two days.

Toxic symptoms included marked discomfort, dyspnea, and increasing weakness. Pain due to the corrosive nature of the application may have been a factor in the death of animal #6.

At autopsy there was pulmonary hyperemia in addition to eschar formation where the application covered the skin.

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Younger Laboratories Certificate of Analysis - Page 6 (7/22/64) - Y-64-76

T A B L E III

'ACL 53' -- SKIN IRRITATION STUDY IN RABBITS

Sample (0.5 Gram) Applied As A 25.0% Aqueous Solution

<u>Animal Number</u>	<u>Numerical Evaluation At The End Of</u>					
	<u>1 Hour</u>	<u>24 Hours</u>	<u>48 Hours</u>	<u>72 Hours</u>	<u>120 Hours</u>	<u>168 Hours</u>
<b>INTACT SKIN</b>						
1	3	8	8	8	8	8
2	4	8	8	8	8	8
3	4	8	8	8	8	8
4	5	8	8	8	8	8
5	3	8	8	8	8	8
6	4	8	8	8	8	8
Average (Intact)	3.8	8.0	8.0	8.0	8.0	8.0
<b>ABRADED SKIN</b>						
1	6	8	8	8	8	8
2	5	8	8	8	8	8
3	5	8	8	8	8	8
4	6	8	8	8	8	8
5	6	8	8	8	8	8
6	6	8	8	8	8	8
Average (Abraded)	5.6	8.0	8.0	8.0	8.0	8.0

DISCUSSION -

PRIMARY IRRITATION SCORE (FEDERAL HAZARDOUS SUBSTANCES LABELING ACT) --

	<u>Exposure Time</u> <u>Hours</u>	<u>Exposure Unit</u> <u>Value</u>
<b>Erythema and Eschar Formation:</b>		
Intact skin .....	24	4.0
Do .....	72	4.0
Abraded skin .....	24	4.0
Do .....	72	4.0
Subtotal .....		<u>16.0</u>
<b>Edema Formation:</b>		
Intact skin .....	24	4.0
Do .....	72	4.0
Abraded skin .....	24	4.0
Do .....	72	4.0
Subtotal .....		<u>16.0</u>
Total .....		<u>32.0</u>

PRIMARY IRRITATION SCORE (32.0 ÷ 4) = 8.0

ACL 53 was classed as a 'corrosive skin irritant' under the grading system as outlined in the Act. \*

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Younger Laboratories Certificate of Analysis - Page 7 (7/22/64) - Y-64-76

TABLE III - DISCUSSION (Continued)

INTACT SKIN -

The compound was classed as a corrosive skin irritant when applied as a 25.0% aqueous solution to intact rabbit skin.

The average maximum score was 8.0 out of a possible 8 in twenty-four hours.

After one hour there was moderate erythema with well-defined to moderate edema for an average score of 3.8. In twenty-four hours there was severe swelling and redness with obvious tissue necrosis. Injury extended into the dermal layer.

ABRADED SKIN -

The compound was classed as a corrosive skin irritant when applied as a 25.0% aqueous solution to abraded rabbit skin.

The average maximum score was 8.0 out of a possible 8 in twenty-four hours.

Moderate to severe erythema and edema developed within one hour. The average initial score of 5.6 increased to the maximum in twenty-four hours. Severe edema and beet redness with moderate eschar formation was noted.

\* A 'corrosive substance' is one that causes visible destruction or irreversible alterations in the tissue at the site of contact; the structure of the tissue at the site of contact is destroyed or changed irreversibly in twenty-four hours or less.

T A B L E I V

'ACL 53' -- EYE IRRITATION STUDY IN RABBITS

Sample (100.0 Milligrams) Applied As Finely Ground Powder

<u>Animal Number</u>	<u>Numerical Evaluation At The End Of</u>					
	<u>1 Hour</u>	<u>24 Hours</u>	<u>48 Hours</u>	<u>72 Hours</u>	<u>120 Hours</u>	<u>168 Hours</u>
24-HOUR EXPOSURE						
1	86	110	110	110	110	110
2	79	110	110	110	110	110
Average (1-2)	92.5	110.0	110.0	110.0	110.0	110.0
2-SECOND EXPOSURE						
3	36	31	22	16	8	0
4	41	37	30	21	12	0
Average (3-4)	38.5	34.0	26.0	18.5	10.0	0.0
4-SECOND EXPOSURE						
5	44	39	32	26	17	4
6	50	46	38	31	21	8
Average (5-6)	47.0	42.5	35.0	28.5	19.0	6.0

DISCUSSION -

EYE IRRITATION (FEDERAL HAZARDOUS SUBSTANCES LABELING ACT) --

ACL 53 was classed as a 'corrosive eye irritant' under the grading system as outlined in the Act. \*\*

The compound was classed as a corrosive eye irritant.

The average maximum score was 110 out of a possible 110 in twenty-four hours.

There was intense discomfort immediately following application.

24-HOUR EXPOSURE

Swelling nearly closed the lids in ten to fifteen minutes. Best redness of the conjunctivae, opalescent cornea with pupil size barely discernible, and edema extending for a considerable distance around the eye resulted in an average score of 82.5 in one hour. Overnight the cornea was opaque and remained so throughout the seven day observation period.

2-SECOND EXPOSURE

Moderate edema and redness, copious discharge, and mild to moderate iris congestion was noted in one hour. There was continued improvement after twenty-four hours so that by the fifth day iris clarity was nearly normal.

To: Monsanto Company  
St. Louis, Missouri

Younger Laboratories Certificate of Analysis - Page 9 (7/22/64) - Y-64-76

TABLE IV - DISCUSSION (Continued)

4-SECOND EXPOSURE

Moderately severe redness, copious discharge, moderate swelling, and translucent corneal areas with iris details slightly obscured developed in one hour. The iris continued to react to light. Inflammation decreased slightly in twenty-four hours and the cornea continued to clear resulting in full iris clarity within seven days.

\*\* A 'corrosive substance' is one that causes visible destruction or irreversible alterations in the tissue at the site of contact.



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