PROJECT NO. Y-70-1
REPORT NO.

YOUNGER LABORATORIES
INCORPORATED
Consulting and Analytical Services
CHEMICAL . . . MICROBIOLOGICAL . . . BIOLOGICAL

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Certificate of Analysis

February 4th, 1970

SUBJECT -

Toxicological Investigation Of: Aroclor 5430

Monsanto Sample Number 4

Monsanto Project Number Y-70-1

STUDY CONDUCTED FOR -

Monsanto Company, St. Louis, Missouri

EXPERIMENTAL PROCEDURE -

A) Oral LD_{50} (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 five levels designed to blanket the toxicity range thereby supplying data for calculation of the LD_{50} which was done according to a modification of the method of E. J. de Beer.

Observations were made for toxic signs and the viscera of the test animals 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 undiluted 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 treated areas were covered with plastic strips and the animals held in wooden stocks for periods up to twenty-four hours, after which time they were assigned to individual cages.

Observations were made for toxic signs and the viscera of the test animals were examined macroscopically.

The data are shown in Table II.

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Younger Laboratories Certificate of Analysis - Page 2 (2/4/70) - Y-70-1

EXPERIMENTAL PROCEDURE - (Continued)

C) Skin Irritation (Rabbits, Mixed Sex)

The undiluted compound was applied to the clipped, intact skin of albino male and female rabbits and removed after twenty-four hours. The application was covered with plastic strips to retard evaporation and avoid contamination.

Observations were made over a period of several days for irritation.

The data, scored according to the method of Draize, Woodard and Calvery (Journal of Pharm. and Exp. Therapeutics, Volume 82, December, 1944) are shown in Table III.

D) Eye Irritation (Rabbits, Mixed Sex)

0.1 Milliliter of undiluted sample was placed in the conjunctival sac of the right eye of each of three albino male and female rabbits and observations made over a period of several days for inflammation.

The eyes were rinsed with warm isotonic saline solution after twenty-four hours.

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

SUMMARY -

Aroclor 5430

A) Oral LD_{50} (Rats, Mixed Sex)

The Oral LD_{50} for male and female rats was placed at 6100 milligrams per kilogram with lower and upper limits of 5550 to 6700 milligrams per kilogram.

The compound was classed as practically non-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 1260 milligrams per kilogram and less than 2000 milligrams per kilogram. Lack of sample prevented further dosing.

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

C) Skin Irritation (Rabbits, Mixed Sex)

The compound was classed as a mild to moderate irritant when applied undiluted to intact skin of male and female rabbits.

The average maximum score was 3.6 out of a possible 8 in forty-eight hours.

D) Eye Irritation (Rabbits, Mixed Sex)

The compound was classed as a slight eye irritant in male and female rabbits.

The average maximum score was 3.3 out of a possible 110 in one hour.

YOUNGER LABORATORIES, INC.

BY: MELVIN D. BIRCH

DSW 295729

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TABLE I

THE ORAL LD_{50} OF 'Aroclor 5430' FOR RATS

Sample Fed As A 75.0% Solution-Suspension In Corn Oil

Animal No. - Sex	Weight Gm.	Dose Mg./Kg.	Fate
1- Female	235	3160	Survived
2- Male	255	3160	Survived
3- Female	250	3160	Survived
4- Male	245	3160	Survived
5- Female	250	3160	Survived
6- Male	260	3980	Survived
7- Female	230	3980	Survived
8- Male	245	3980	Survived
9- Female	220	3980	Died
10- Male	250	3980	Survived
11- Female	240	5010	Died
12- Male	250	5010	Survived
13- Female	230	5010	Survived
14- Male	260	5010	Survived
15- Female	210	5010	Survived
16- Male	245	6310	Survived
17- Female	225	6310	Survived
18- Male	240	6310	Survived
19- Female	230	6310	Died
20- Male	230	6310	Died
21- Female	240	7940	Died
22- Male	240	7940	Died
23- Female	230	7940	Died
24- Male	235	7940	Survived
25- Female	220	7940	Died

DISCUSSION -

The Oral LD_{50} for male and female rats was placed at 6100 milligrams per kilogram with lower and upper limits of 5550 to 6700 milligrams per kilogram.

The compound was classed as practically non-toxic by oral ingestion in male and female rats.

Survival time was two to four days.

Toxic signs included reduced appetite and activity for two to five days, increasing weakness, collapse, and death.

At autopsy there was acute gastrointestinal inflammation, hemorrhagic lungs, and jaundiced and mottled liver.

Surviving animals were sacrificed seven days after dosing. The viscera appeared normal by macroscopic examination.

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T A B L E II

THE MINIMUM LETHAL DOSE OF 'Aroclor 5430'
BY SKIN ABSORPTION IN RABBITS

Sample Applied Undiluted

Animal No. - Sex	Weight Kg.	Dose Mg./Kg.	Weight Change 5 Days Later Kg.	Fate
1 - Male	2.3	794	+ 0.1	Survived
2 - Female	2.7	1260	0.0	Survived
3 - Male	2.6	2000	- 0.3	Died -- 9 Days
4 - Female	2.6	3160	-----	Died -- 3 Days
5 - Female	2.3	3160	- 0.2	Survived
6 - Male	2.1	5010	- 0.3	Died -- 7 Days

DISCUSSION -

The Minimum Lethal Dose by Skin Absorption in male and female rabbits was found to be greater than 1260 milligrams per kilogram and less than 2000 milligrams per kilogram. Lack of sample prevented further dosing.

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

Survival time was three to nine days.

Toxic signs included reduced appetite and activity, lethargy, increasing weakness, collapse, and death.

At autopsy there were hemorrhagic lungs, discolored and mottled liver, and enlarged gall bladder.

Surviving animals were sacrificed fourteen days after dosing. Animal #5 showed lung congestion, enlarged gall bladder, slight liver discoloration, and slight gastrointestinal inflammation. The viscera of animals #1 and #2 appeared normal by macroscopic examination.

DSW 295731

T A B L E IV

EYE IRRITATION IN RABBITS AFTER APPLICATION OF 'Aroclor 5430'

Sample (0.1 Milliliter) Applied Undiluted

Animal No. - Sex	Numerical Evaluation At The End Of					
	1 Hour	24 Hours	48 Hours	72 Hours	120 Hours	168 Hours
1 - Male	4	0	0	0	0	0
2 - Female	4	0	0	0	0	0
3 - Male	2	0	0	0	0	0
Average	3.3	0.0	0.0	0.0	0.0	0.0

DISCUSSION -

The compound was classed as a slight eye irritant in male and female rabbits. The average maximum score was 3.3 out of a possible 110 in one hour.

Observations following application --

Immediate:	Very slight discomfort
10-Minutes:	Mild to moderate discharge; no erythema or edema
1-Hour:	Barely perceptible erythema, slight discharge; no edema There was no corneal cloudiness and iris reaction to light was normal
24-Hours:	Eyes normal; zero reading
48- 168-Hours:	Eyes normal; zero reading

DSW 295732

T A B L E III

SKIN IRRITATION IN RABBITS AFTER APPLICATION OF 'Aroclor 5430'

Sample Applied Undiluted

Animal No. - Sex	Numerical Evaluation At The End Of					
	1 Hour	24 Hours	48 Hours	72 Hours	120 Hours	168 Hours
1 - Male	0	0	3	2	1	0
2 - Male	0	1	4	2	1	0
3 - Female	0	0	4	2	1	0
Average	0.0	0.3	3.6	2.0	1.0	0.0

DISCUSSION -

The compound was classed as a mild to moderate irritant when applied undiluted to intact skin of male and female rabbits.

The average maximum score was 3.6 out of a possible 8 in forty-eight hours.

OBservations following application --

1-Hour:	No skin changes; zero reading
24-Hours:	Barely perceptible erythema in one instance; no edema
48-Hours:	Slight to well-defined erythema, slight edema
72-Hours:	Very slight erythema and edema
120-Hours:	Very slight erythema; no edema
168-Hours:	Skin normal; zero reading

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