PROJECT NO. Y-70-74

YOUNGER LABORATORIES
INCORPORATED

Consulting and Analytical Services

CHEMICAL ... MICROBIOLOGICAL ... BIOLOGICAL

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Certificate of Analysis

August 17th, 1970

SUBJECT -

Toxicological Investigation Of: Aroclor 6062 -- Lot GH 1304

Monsanto Sample Number 80

Monsanto Project Number Y-70-74

Y-10-74
8-17-70

STUDY CONDUCTED FOR -

Monsanto Company, St. Louis, Missouri

EXPERIMENTAL PROCEDURE -

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

The undiluted 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 six levels designed to blanket the toxicity range thereby supplying data for calculation of the LD_{50} which was done according to 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 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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EXPERIMENTAL PROCEDURE - (Continued)

C) Skin Irritation (Rabbits, Mixed Sex)

0.5 Milliliter of undiluted sample was applied to the clipped, intact skin of New Zealand white male and female rabbits under a one inch by one inch square patch, two single layers thick. The patches were held in place with adhesive tape. The trunk of each animal was wrapped with plastic strips, to retard evaporation and avoid contamination, for the twenty-four hour exposure period.

Observations were made over a period of seven 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 seven 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 5062 -- Lot GM 1304

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

The Oral LD_{50} for male and female rats was placed at 8050 milligrams per kilogram with lower and upper limits of 7320 to 8850 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 highest application of 7940 milligrams per kilogram was found to be non-lethal by skin absorption in male and female rabbits.

The compound was classed as practically non-toxic by skin absorption in male and female rabbits.

C) Skin Irritation (Rabbits, Mixed Sex)

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

The average maximum score was 1.3 out of a possible 8 in twenty-four 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 11.3 out of a possible 110 in one hour.

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BY: MELVIN D. BIRCH

To: Monsanto Company
St. Louis, Missouri
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TABLE I

THE ORAL LD_{50} OF 'Aroclor 6062 -- Lot QM 1304' FOR RATS

Sample Fed Undiluted

Animal No. - Sex	Weight Gm.	Dose Mg./Kg.	Rate
1- Female	200	3980	Survived
2- Male	255	3980	Survived
3- Female	195	3980	Survived
4- Male	225	3980	Survived
5- Female	200	3980	Survived
6- Male	210	5010	Died
7- Female	200	5010	Survived
8- Male	255	5010	Survived
9- Female	210	5010	Survived
10- Male	220	5010	Survived
11- Female	220	6310	Survived
12- Male	255	6310	Died
13- Female	230	6310	Died
14- Male	250	6310	Survived
15- Female	205	6310	Survived
16- Male	245	7940	Died
17- Female	210	7940	Survived
18- Male	265	7940	Survived
19- Female	225	7940	Died
20- Male	260	7940	Survived
21- Female	220	10000	Survived
22- Male	270	10000	Died
23- Female	215	10000	Died
24- Male	255	10000	Died
25- Female	220	10000	Died
26- Male	235	12600	Died
27- Female	205	12600	Died
28- Male	250	12600	Died
29- Female	215	12600	Died
30- Male	270	12600	Died

DISCUSSION -

The Oral LD_{50} for male and female rats was placed at 8050 milligrams per kilogram with lower and upper limits of 7320 to 8850 milligrams per kilogram.

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

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DISCUSSION -- TABLE I (Continued)

Survival time was one to four days with most deaths occurring within two days.

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

At autopsy there was lung and liver hyperemia and gastrointestinal inflammation.

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

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TABLE II

THE MINIMUM LETHAL DOSE OF 'Aroclor 6062 -- Lot QH 1304'
BY SKIN ABSORPTION IN RABBITS

Sample Applied Undiluted

Animal No. - Sex	Weight Kg.	Dose Mg./Kg.	Weight Change 5 Days Later Kg.	Fate
1 - Female	2.4	2000	0.0	Survived
2 - Male	2.7	3160	- 0.1	Survived
3 - Female	2.6	5010	+ 0.1	Survived
4 - Male	2.2	7940	- 0.1	Survived
5 - Female	2.4	7940	- 0.1	Survived

DISCUSSION -

The highest application of 7940 milligrams per kilogram was found to be non-lethal by skin absorption in male and female rabbits.

The compound was classed as practically non-toxic by skin absorption in male and female rabbits.

Toxic signs included reduced appetite and activity for three to five days.

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

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TABLE III

SKIN IRRITATION IN RABBITS AFTER APPLICATION OF
'Aroclor 6062 -- Lot GM 1304'

Sample (0.5 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	0	1	1	0	0	0
2 - Female	0	1	0	0	0	0
3 - Female	0	2	1	0	0	0
Average	0.0	1.3	0.6	0.0	0.0	0.0

DISCUSSION -

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

The average maximum score was 1.3 out of a possible 8 in twenty-four hours.

Observations following application --

1-Hour:	No skin changes; zero readings
24-Hours:	Very slight to well-defined erythema; no edema
48-Hours:	Very slight erythema in two instances; no edema
72-Hours:	No erythema or edema; zero readings
120-Hours: - 168-Hours:	No erythema or edema; zero readings

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TABLE IV

EYE IRRITATION IN RABBITS AFTER APPLICATION OF
'Aroclor 6062 — Lot #1304'

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	12	2	0	0	0	0
2 - Female	12	2	0	0	0	0
3 - Male	10	2	0	0	0	0
Average	11.3	2.0	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 11.3 out of a possible 110 in one hour.

Observations following application —

Immediate:	Discomfort was mild with the eyes closed
10-Minutes:	Slight erythema, barely perceptible edema, copious discharge
1-Hour:	Moderate erythema, slight edema, moderate discharge
24-Hours:	Slight erythema; no edema or discharge
48-Hours:	Eyes normal; zero readings
72- 168-Hours:	Eyes normal; zero readings