YOUNGER LABORATORIES
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September 20th, 1972

Certificate of Analysis

SUBJECT -

Toxicological Investigation Of: MCS 1330 -- OR:198850-6

Monsanto Sample Number 246

Monsanto Project Number Y-72-246

STUDY CONDUCTED FOR -

Monsanto Company, St. Louis, Missouri

EXPERIMENTAL PROCEDURE -

A) Acute Oral Toxicity (Rats, Mixed Sex)

The undiluted compound was fed by stomach tube to Sprague-Dawley strain albino male and female rats in increasing doses at increments of 0.1 fractional log intervals.

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

The data are shown in Table I.

B) Acute Skin Absorption Minimal Lethal Dose (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 the twenty-four hour reading. The left eye served as a control.

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

SUMMARY -

MCS 1330 - OR:198850-6

A) Acute Oral Toxicity (Rats, Mixed Sex)

The Acute Oral Minimal Lethal Dose for male and female rats was found to be greater than 7,940 milligrams per kilogram and less than 10,000 milligrams per kilogram.

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

B) Acute Skin Absorption Minimal Lethal Dose (Rabbits, Mixed Sex)

The Acute Skin Absorption Minimal Lethal Dose for male and female rabbits was found to be greater than 7,940 milligrams per kilogram.

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 mild irritant when applied undiluted to intact skin of male and female rabbits.

The average maximum score was 2.6 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 6.0 out of a possible 110 in one hour.

YOUNGER LABORATORIES, INC.

BY: MELVIN D. BIRCH

DSW 586486

TABLE I

THE ACUTE ORAL MINIMAL LETHAL DOSE OF

'MCS 1330 -- OR:198850-6'

FOR RATS

Sample Fed Undiluted

Animal No. - Sex	Weight Gm.	Dose Mg./Kg.	Fate
1- Female	215	7,940	Survived
2- Male	250	7,940	Survived
3- Female	245	7,940	Survived
4- Male	255	7,940	Survived
5- Female	230	7,940	Survived
6- Male	260	10,000	Survived
7- Female	230	10,000	Survived
8- Male	235	10,000	Survived
9- Female	240	10,000	Survived
10- Male	240	10,000	Died
11- Female	240	12,600	Survived
12- Male	230	12,600	Died
13- Female	235	12,600	Survived
14- Male	230	12,600	Survived
15- Female	225	12,600	Survived
16- Male	230	15,800	Died
17- Female	235	15,800	Survived
18- Male	235	15,800	Survived
19- Female	245	15,800	Died
20- Male	230	15,800	Died

DISCUSSION -

The Acute Oral Minimal Lethal Dose for male and female rats was found to be greater than 7,940 milligrams per kilogram and less than 10,000 milligrams per kilogram.

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

Toxic signs included reduced appetite and activity and lethargy (lasting two to five days in survivors), increasing weakness, collapse, and death.

Survival time was one to three days.

At autopsy there was lung hyperemia, liver discoloration, and acute gastro-intestinal inflammation.

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

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TABLE II

THE ACUTE SKIN ABSORPTION MINIMAL LETHAL DOSE OF 'MCS 1330 -- OR: 198850-6' FOR RABBITS

Sample Applied Undiluted

Animal No. - Sex	Weight Kg.	Dose Mg. / Kg.	Weight Change 5 Days Later Kg.	Fate
1 - Female	2.0	3160	0.0	Survived
2 - Male	1.9	5010	+ 0.1	Survived
3 - Female	1.9	7940	0.0	Survived
4 - Male	1.8	7940	0.0	Survived

DISCUSSION -

The Acute Skin Absorption Minimal Lethal Dose for male and female rabbits was found to be greater than 7940 milligrams per kilogram.

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

There was no weakness or other outward signs of systemic toxicity.

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

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T A B L E III

SKIN IRRITATION IN RABBITS AFTER APPLICATION OF

'MCS 1330 -- OR: 198850-6'

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	3	3	2	0	0
2 - Female	0	2	2	1	0	0
3 - Male	0	3	2	2	0	0
Average	0.0	2.6	2.3	1.6	0.0	0.0

DISCUSSION -

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

The average maximum score was 2.6 out of a possible 8 in twenty-four hours.

Observations following application --

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

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T A B L E IV

EYE IRRITATION IN RABBITS AFTER APPLICATION OF

'MCS 1330 -- OR: 198850-6'

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 - Female	6	0	0	0	0	0
2 - Male	6	0	0	0	0	0
3 - Female	6	0	0	0	0	0
Average	6.0	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 6.0 out of a possible 110 in one hour.

Observations following application --

Immediate:	Discomfort was slight
10-Minutes:	Slight erythema, copious discharge; no edema
1-Hour:	Slight erythema, moderate discharge; no edema
24-Hours:	Eyes normal; zero readings
48- 168-Hours:	Eyes normal; zero readings

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