Industrial BIO-TEST Laboratories, Inc.

REPORT TO

MONSANTO COMPANY

TOXICITY, REPRODUCTION AND RESIDUE STUDY WITH
MCS 1016
IN WHITE LEGHORN CHICKENS

JUNE 20, 1972

IBT NO. J899

I. Introduction

At the request of Monsanto Company, a toxicity, reproduction and residue study with MCS 1016 in White Leghorn chickens was initiated. This report presents the results of the investigation conducted at Wedge's Creek Research Farm, Industrial BIO-TEST Laboratories, Inc.



ADM C04700

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II. Summary

A toxicity, reproduction and residue study was conducted in White Leghorn chickens with MCS 1016. The levels fed were 1 (T-I), 3 (T-II) and 10 (T-III) ppm in the diet. The results of the study are as follows:

The body weights and food consumption of adult birds were normal. Six females died; one in the control group, two in the T-I group, one in the T-II group and two in the T-III group. There were no significant gross pathological changes in any of the birds.

No abnormalities or systemic signs of toxicity attributable to the ingestion of MCS 1016 were observed during the investigation.

Egg production and quality in all groups, including controls, were normal. The hatchability of eggs in the T-II group (61.4%) was lower than the hatchability in the control group (85.0%) or the other two test groups (T-I - 84.9%, T-III - 83.7%).

Specific gravity and shell thickness of eggs revealed no significant differences between the control and three test groups.

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The body weight and viability data for chicks from the control group and three test groups compared favorably. No gross pathologic changes were noted in any of the chicks at the time of sacrifice.

Respectfully submitted,

INDUSTRIAL BIO-TEST LABORATORIES, INC.

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III. Procedure

A. Experimental Animals

The animals employed in the study were White Leghorn chickens. A total of 80 hens and 16 roosters was used.

B. Organization of Groups

Ninety-six chickens were divided into one control group (C) and three test groups (T-I, T-II and T-III). A structural outline of the experiment is presented in Table I.

TABLE I

TEST MATERIAL: MCS 1016

Toxicity, Reproduction and Residue Study - White Leghorn Chickens

Outline of Experiment

Group	Number of Animals Male	Female	Dose Level (ppm)
Control	4	20	None
T-I	4	20	1.0
T-II	4	20	3.0
T-III	4	20	10.0

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C. Dosage and Feeding

All groups received the same basal feed*. Test diets were prepared weekly. The test materials were diluted with acetone before addition to the feed to assure even distribution throughout the ration. An equal amount of acetone, without test material, was added to the control feed and the feed blended in the same manner as the test feeds.

All animals were allowed water and their respective control or test feed ad libitum. Dosing began when the birds were 25 weeks of age and was continued for 16 weeks when hatching results were available.

D. Observations

Observations were made daily to ascertain the presence or absence of clinical signs of toxicity indicative of test material effect. All chickens were individually weighed and the group food consumption was determined weekly. As each group began laying, the eggs were collected daily and the egg weights recorded. When the egg weights were consistently between 50 and 60 grams and at least 50 percent of the hens in the group were laying, egg collection for that group was started. The time required to meet these criteria was recorded for each group.

* Purina Flock Chow, Ralston Purina Co., St. Louis, Mo.

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The eggs were collected for the following paramcters:

1. Egg Production and Quality

Eggs were collected, weighed and candled for a number of seven-day periods. The total number, the individual weights of eggs collected and the total number of uncracked and umblemished eggs were recorded.

2. Hatchability

Three-fourths of all non-defective eggs were randomly selected for hatching. These eggs were turned twice daily during the seven-day collection period, then placed in an incubator maintained at 99° to 100°F, with a wet bulb reading of 85°. This procedure was followed until a minimum of 100 eggs from the control group and each test group had been set for hatching. The following were recorded:

a. Number hatched.
b. Number unhatched.
c. Viability of chicks over a 30-day period, during which period feed and water were permitted ad libitum.
d. Examination of unhatched eggs for fertility and stage of development.
e. Weight of chicks after Day 1 and Day 30.

3. Physical Characteristics of Eggs

One-fourth of the non-defective eggs and all of the defective eggs were examined to determine the following:

a. Specific gravity
b. Thickness of shells at equatorial circumference (three measurements/egg)

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4. Residue Studies

The non-defective eggs examined for physical characteristics were quick-frozen and shipped to Monsanto Company for residue analysis (shells and frozen contents separated).

After hatching results were available, one-half of the chickens in each group were sacrificed, defeathered and subjected to a gross pathological examination. Individual samples of muscle, liver, fat and kidney from each group were collected and shipped to Monsanto Company for analysis.

The remaining chickens were fed the base diet without test material for 30 days. The eggs were collected, weighed and candled during the recovery period. Ten eggs (minimum) per group per week were quick-frozen and shipped to Monsanto Company for analysis. At the end of the recovery regimen, the remaining chickens were sacrificed and handled in the same manner as at the end of the test feeding period.

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IV. Results

A. Parental Generation

1. Body Weight Data

The average male and female body weights during the test diet period are shown in Table II. The average male and female body weights during the recovery period are shown in Table III. These data are summarized Table IV. Body weights were considered normal for all test groups when compared to the control group.

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TABLE II

TEST MATERIAL: MCS 1016

Toxicity, Reproduction and Residue Study - White Leghorn Chickens

Test Diet Period Body Weight Data

		Mean Body Weight in Kilograms Week:																
up	Sex	0	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16
	M	2.05	2.06	2.09	2.12	2.14	2.16	2.16	2.18	2.20	2.22	2.22	2.25	2.26	2.27	2.25	2.26	2.26
	F	1.71	1.71	1.73	1.76	1.76	1.79	1.84	1.84	1.84	1.84	1.90	1.93	1.93	1.95	1.95	1.94	1.87
	M	2.17	2.18	2.19	2.22	2.25	2.27	2.30	2.28	2.30	2.35	2.36	2.37	2.40	2.42	2.38	2.38	2.38
	F	1.81	1.82	1.85	1.85	1.88	1.88	1.93	1.93	1.96	1.97	1.99	2.06	2.02	2.03	2.00	2.00	1.95
I	M	2.08	2.15	2.20	2.24	2.29	2.28	2.32	2.35	2.39	2.45	2.47	2.50	2.57	2.56	2.56	2.58	2.58
	F	1.66	1.68	1.71	1.71	1.72	1.76	1.77	1.79	1.80	1.83	1.83	1.84	1.85	1.87	1.85	1.88	1.85
II	M	1.96	1.93	2.02	2.04	2.09	2.15	2.17	2.18	2.23	2.21	2.22	2.24	2.24	2.25	2.26	2.25	2.24
	F	1.64	1.66	1.68	1.73	1.74	1.75	1.77	1.77	1.82	1.81	1.83	1.85	1.85	1.86	1.88	1.90	1.85

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TABLE III

TEST MATERIAL: MCS 1016

Toxicity, Reproduction and Residue Study - White Leghorn Chickens

Recovery Period Body Weight Data

Group	Sex	Mean Body Weight in Kilograms Week: 1	2	3	4
C	M	2.26	2.23	2.24	2.25
	F	1.86	1.89	1.91	1.92
T-I	M	2.26	2.17	2.19	2.25
	F	1.94	1.93	1.91	1.94
T-II	M	2.64	2.63	2.59	2.71
	F	1.85	1.82	1.83	1.84
T-III	M	2.04	2.03	2.01	2.02
	F	1.84	1.83	1.82	1.84

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TABLE IV

TEST MATERIAL: MCS 1016

Toxicity, Reproduction and Residue Study - White Leghorn Chickens

Summary of Mean Body Weight Data (kilograms)

	Pretest		Test Period		Sacrifice	
Group	Male	Female	Male	Female	Male	Female
C	2.05	1.71	2.18	1.84	2.25	1.92
T-I	2.17	1.81	2.31	1.94	2.25	1.94
T-II	2.08	1.66	2.39	1.79	2.71	1.84
T-III	1.96	1.64	2.16	1.79	2.02	1.84

ACM 004710

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2. Food Consumption

The food consumption data are presented in Table V. The food consumption data were considered normal for all test groups when compared to the control group.

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TABLE V

TEST MATERIAL: MCS 1016

Toxicity, Reproduction and Residue Study - White Leghorn Chickens

Average Food Consumption (grams/bird/day)

Week	Group C	T-I	T-II	T-III
		Test Period		
1	148.0	136.0	125.0	117.0
2	141.0	135.0	110.0	104.0
3	173.0	162.0	148.0	152.0
4	166.0	177.0	154.0	145.0
5	183.0	198.0	180.0	142.0
6	166.0	216.0	213.0	194.0
7	156.0	161.0	134.0	175.0
8	166.0	229.0	156.0	175.0
9	166.0	138.0	145.0	133.0
10	218.0	202.0	211.0	177.0
11	211.0	219.0	218.0	151.0
12	213.0	209.0	214.0	164.0
13	226.0	170.0	216.0	205.0
14	201.0	156.0	190.0	168.0
15	149.0	152.0	181.0	154.0
16	130.0	128.0	132.0	137.0
		Recovery Period		
1	110.0	128.0	120.0	111.0
2	142.0	132.0	138.0	158.0
3	128.0	132.0	124.0	144.0
4*	135.0	150.0	123.0	125.0

* Figured on a 9 day basis.

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3. Mortality and Reactions

No abnormalities attributable to feeding MCS 1016 or systematic signs of toxicity were observed in any of the test groups when compared to the control group.

Mortality, chronology and diagnoses are presented in Tables VI and VII.

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TABLE VI

TEST MATERIAL: MCS 1016

Toxicity, Reproduction and Residue Study - White Leghorn Chickens

Mortality, Chronology and Diagnoses

Group	Animal Number	Sex	Week Died	Clinical Diagnoses
C	440	F	9	Lymphomatosis
T-I	438	F	16	Lymphomatosis
T-I	483	F	16	Prolasped Rectum
T-II	441	F	5	Lymphomatosis
T-III	467	F	2	Unknown
T-III	470	F	8	Lymphomatosis

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TABLE VII

TEST MATERIAL: MCS 1016

Toxicity, Reproduction and Residue Study - White Leghorn Chickens

Mortality Data

Group	Number Tested M	Number Tested F	Number Dead M	Number Dead F	Total Dead / Total Tested	Percent Dead
C	4	20	0	1	1/24	4.2
T-I	4	20	0	2	2/24	8.3
T-II	4	20	0	1	1/24	4.2
T-III	4	20	0	2	2/24	8.3

M = Male
F = Female

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4. Gross Pathology

Postmortem examination of all birds revealed no gross pathological tissue alterations attributable to effects of the test material.

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B. Eggs

1. Egg Production and Quality

The weekly egg production data are presented in Table VIII. The age of the hens in all groups when collection was started was 30 weeks and 36 weeks when hatching collection ended.

The egg quality data are presented in Table IX.

Egg production and quality were considered normal for all test groups when compared to the control group.

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TABLE VIII

TEST MATERIAL: MCS 1016

Toxicity, Reproduction and Residue Study - White Leghorn Chickens

Egg Production Data

	Control		T-I		T-II		T-III	
Neck	Average Weight (grams)	Percent Production/Day	Average Weight (grams)	Percent Production/Day	Average Weight (grams)	Percent Production/Day	Average Weight (grams)	Percent Production/Day
				Test Period				
1	52.8	62.8	51.5	64.2	50.5	57.1	51.2	64.2
2	53.9	75.0	53.8	80.0	52.6	73.7	53.1	75.0
3	54.6	69.2	54.7	85.0	52.0	62.1	54.6	61.4
4	55.8	70.0	55.4	77.1	54.2	62.1	55.5	81.2
5	56.7	75.7	56.3	75.0	55.4	67.8	55.6	69.9
6	57.0	66.4	56.7	72.8	55.4	71.4	55.9	81.2
7	57.4	62.8	57.2	71.4	55.8	60.9	56.1	78.9
8	58.3	63.5	58.0	71.4	55.6	64.6	56.5	78.1
9	58.6	72.8	58.6	72.1	57.1	68.4	57.6	84.1
10	59.2	66.9	58.8	70.7	57.7	66.9	58.1	73.0
11	60.5	68.9	59.7	68.1	58.2	59.8	58.0	68.0
12	59.4	56.5	60.3	67.5	58.7	64.0	57.7	66.6
13	60.6	57.1	60.1	65.0	58.5	65.4	57.9	74.6
14	60.6	58.6	60.5	55.7	58.5	54.8	58.9	69.0
15	59.8	45.8	60.9	61.4	57.1	54.1	59.2	75.3
16	59.9	46.6	60.4	46.4	57.4	48.8	58.9	66.6
				Recovery Period				
1	58.6	65.4	57.8	55.0	57.5	51.6	58.0	60.1
2	58.5	68.2	55.7	73.2	57.8	61.9	58.9	71.4
3	58.5	68.2	57.0	58.9	57.8	69.8	58.1	80.3
4*	59.4	71.0	57.3	76.0	57.8	72.0	57.3	67.5

ADM 004718

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TABLE IX

TEST MATERIAL: MCS 1016

Toxicity, Reproduction and Residue Study - White Leghorn Chickens

Egg Quality Data

Group	Defective Eggs Number	Defective Eggs Percent	Normal Eggs Number	Normal Eggs Percent	Total Number
C	869	53.4	760	46.6	1629
T-I	961	55.8	762	44.2	1723
T-II	743	47.6	818	52.4	1561
T-III	810	46.6	929	53.4	1739

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2. Hatchability

The hatchability data are presented in Table X. The percent of eggs hatched was lower in group T-II due to greater infertility. The percent of eggs hatched in groups T-I and T-III was considered normal when compared to the control group.

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TABLE X

TEST MATERIAL: MCS 1016

Toxicity, Reproduction and Residue Study - White Leghorn Chickens

Hatchability Data

Group	Eggs Set	Eggs Hatched	Percent Hatched	Eggs Unhatched	Stages of Incubation: Full Term	Mid-Term	One Week	Infertile	Percent* Infertile
C	114	97	85.0	17	10	1	2	4	3.5
T-I	113	96	84.9	17	10	1	2	4	3.5
T-II	114	70	61.4	44	6	5	4	29	25.4
T-III	123	103	83.7	20	8	3	4	5	4.1

* Percent of total set.

ADM 004721

STLCOPCB4028174

3. Specific Gravity

The specific gravity data of the eggs collected and candled are presented in Table XI. Test group data were considered normal when compared to the control group.

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TABLE XI

TEST MATERIAL: MCS 1016

Toxicity, Reproduction and Residue Study - White Leghorn Chickens

Specific Gravity Data

	Normal Eggs		Defective Eggs		Total Eggs	
Group	Number	Average Specific Gravity	Number	Average Specific Gravity	Number	Average Specific Gravity
C	221	1.078	869	1.074	1090	1.076
T-I	216	1.077	961	1.073	1177	1.075
T-II	232	1.078	743	1.074	975	1.076
T-III	254	1.081	810	1.077	1064	1.079

ADM OC4723

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4. Egg Shell Thickness

The shell thickness data are presented in Table XII. The shell thickness was considered normal for all test groups when compared to the control group.

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TABLE XII

TEST MATERIAL: MCS 1016

Toxicity, Reproduction and Residue Study - White Leghorn Chickens

Egg Shell Thickness (inches)

	Normal Eggs		Defective Eggs		Total Eggs	
Group	Number	Average Thickness (10^{-3})	Number	Average Thickness (10^{-3})	Number	Average Thickness (10^{-3})
C	221	0.013	869	0.012	1090	0.012
T-I	216	0.012	961	0.012	1177	0.012
T-II	232	0.012	743	0.012	975	0.012
T-III	254	0.013	810	0.013	1064	0.013

ADM 004725

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C. F1 Gereration

1. Mean Body Weights and Viability

The mean body weights and viability data are presented in Table XIII. Body weight data and viability data were considered normal for all test groups when compared to the control group.

2. Gross Pathology

Postmortem examination of all birds revealed no gross pathological tissue alterations.

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TABLE XIII

TEST MATERIAL: MCS 1016

Toxicity, Reproduction and Residue Study - White Leghorn Chickens

Mean Body Weight and Viability Data

Group	Number of Chicks Day 1	Mean Body Weight Day 1 (grams)	Number of Chicks Day 30	Mean Body Weight Day 30 (grams)	Percent Viability
C	97	41.6	93	279.3	95.9
T-I	96	40.9	92	285.9	95.8
T-II	70	41.0	67	311.6	95.7
T-III	103	39.8	98	280.7	95.1

ACM 004727

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generation related response and the absence of any deleterious histopathologic change confirm that these differences were not related to the ingestion of Aroclor 1254.

4. Reproductive Performance

Reproductive indices of rats fed 1 or 10 ppm did not differ from those of the controls during any of the three generations. During the second generation (F2a and F2b litters), rats fed 100 ppm had lowered mating indices and a reduced incidence of pregnancy. The other indices were normal.

B. Progeny

1. Population Data

The number of live pups born per litter was not affected at any level of Aroclor 1254 tested. The number of pups weaned per litter was reduced in all three generations in the group fed 100 ppm (T-III). The average number weaned per litter was normal for the groups fed 1 or 10 ppm. No external abnormalities were present that could be attributed to treatment. No untoward behavioral reactions were observed among test or control progeny.

2. Survival

Pup survival was lower in litters from dams fed 100 ppm Aroclor 1254 than for any other group. Pup survival was not reduced when 1 or 10 ppm was fed.

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3. Body Weights

Body weights for all progeny were normal at weaning.

4. Pathologic Studies

At autopsy of the F3b weanlings no gross or microscopic tissue changes were present which could be associated with the ingestion of Aroclor 1254.

Respectfully submitted,

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III. Procedure

A. Experimental Animals

The animals employed were weanling Charles River albino rats*. A total of 96 weanling rats (32 males and 64 females) was selected to form three test groups and a control group of Fo generation animals. Parental animals were allowed to reach maturity, mate and produce two litters. Eight males and 16 females from the second litters of each dietary group (F1b and F2b) were selected at weaning as parental animals for the succeeding generations. The study terminated following the weaning of the F3b litters.

B. Organization of Groups

A structural outline of the experiment is given in Table I. A flow chart depicting the three generations is shown in Figure I.

* Charles River Breeding Laboratories, Inc., North Wilmington, Mass.

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TABLE I

TEST MATERIAL: Aroclor 1254

Three-Generation Reproduction Study - Albino Rats

Outline of Experiment

Fo Generation

Group	Dietary Level (ppm)	Number of Animals Male	Female
C	None	8	16
T-I	1	8	16
T-II	10	8	16
T-III	100	8	16

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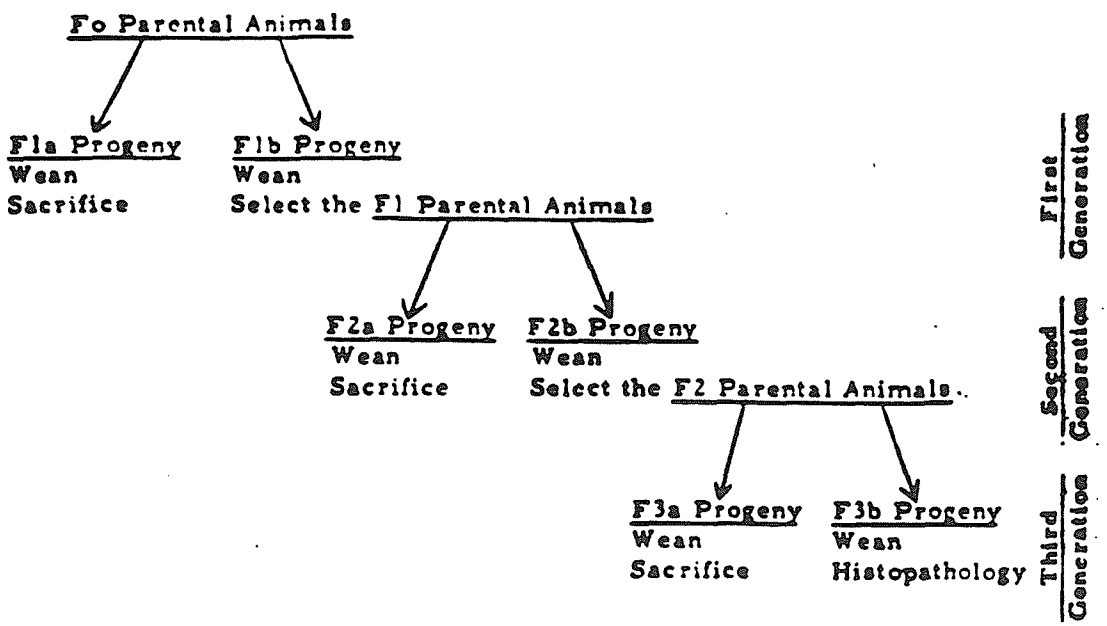
FIGURE 1

TEST MATERIAL: Aroclor 1254

Design of Experiment



Gross and histopathologic examinations were conducted upon parental animals of all three generations following the weaning of the second (b) litters.

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C. Diets and Feeding

Diets were prepared in the central diet room of this laboratory. The diet for any given test group was prepared by incorporating a calculated weight of Aroclor 1254 into a standard pulverized stock ration*, so that the final concentrations of test material in the diets were 1, 10 and 100 parts per million respectively. The animals in the control group were fed the basic ration without test material. Animals in all groups were maintained on their respective diets without interruption until their sacrifice, which followed the weaning of the second litters. Feeding was conducted on an ad libitum basis; fresh diets were prepared weekly.

D. Body Weights and Weight Gains

Initially, the body weight of each rat was determined and recorded at 21 days of age. All animals were then weighed weekly until mating trials commenced. No further body weight data were obtained until the sacrifice of each parental generation, at which time final body weights were recorded.

E. Mortality, Reactions and General Observations

Observations among animals of each generation for mortality and abnormal behavioral reactions were made daily. In addition, these animals were observed for fertility, length of gestation and lactation performance.

* Special Mix Mouse Chow, Ralston Purina Company, St. Louis, Mo.

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All pups were examined for physical abnormalities at birth and the numbers of viable and stillborn members of each litter were recorded. Records of survival at designated intervals during the lactation period were maintained and a final examination for physical abnormalities was made at the weaning of each litter. Litters of more than ten pups were reduced to that number by random sacrifice on the fifth day of the lactation period.

F. Mating Procedure

Mating trials were initiated when the parental animals were 100 days old. Females were caged in pairs and mated with a male from within the same treatment group. Daily examinations were conducted to determine if copulation had occurred. Males were rotated within their dietary group at ten day intervals until conception was confirmed or until each female had been paired with a maximum of three males.

The first litters (F1a, F2a, and F3a) obtained were weaned at 21 days post-partum. The parental females were then given a ten-day rest period and again mated, the above procedure being repeated in order to obtain second litters (F1b, F2b, and F3b). Females failing to become pregnant during the first mating trials were not rebred.

Eight males and 16 females from the second litters of each group were selected at weaning on the basis of health and body weight as parental animals for each succeeding generation.

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C. Gross and Microscopic Pathologic Studies

Whenever a parental animal succumbed during the test period, a gross autopsy was performed. In those instances when postmortem changes were not advanced, representative tissues were taken for microscopic study.

After the second litters were weaned, all surviving males and eight females from each group were sacrificed and subjected to gross pathologic examination. The weights of the liver, kidneys, spleen, gonads, heart, brain, adrenal glands and thyroid gland were recorded, along with the final body weight of each rat.

Statistical analyses were conducted upon the absolute organ weights of the sacrificed animals and upon the corresponding organ to body weight and organ to brain weight ratios. An Analysis of Variance was conducted first and significant effects disclosed by that treatment were further studied by "t"-tests.

Microscopic pathologic studies were conducted upon five males and five females from the control and T-III groups.

The following tissues and organs were examined:

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Tissues and Organs Examined Grossly	Tissues and Organs Examined Microscopically
Skin	Heart (right and left ventricles)
Heart	Trachea
Trachea	Lung
Lungs	Liver
Liver	Pancreas
Pancreas	Stomach (cardiac, fundic and pyloric regions)
Esophagus	Small Intestine (duodenum, jejunum and ileum)
Stomach	Caecum
Intestinal Tract	Colon
Spleen	Spleen
Lymph Nodes	Lymph Node (cervical and mesenteric)
Kidneys	Kidney
Urinary Bladder	Urinary Bladder
Testes	Testis
Ovaries	Ovary
Prostate	Prostate
Seminal Vesicles	Uterus
Uterus	Pituitary Gland
Vagina	Adrenal Gland
Pituitary Gland	Salivary Gland (submaxillary)
Adrenal Glands	Thyroid Gland
Salivary Glands	Parathyroid Gland
Thyroid Gland	Skeletal Muscle
Skeletal Muscle	Bone Marrow (sternum and femur)
Bone	Peripheral Nerve (sciatic)
Peripheral Nerve	Brain (cerebrum, cerebellum and pons)
Eyes	Seminal Vesicles
Brain	Esophagus
Thymus	Spinal Cord
Optic Nerve	
Aorta	

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IV. Results

A. Parental Animals

1. Body Weights

Body weight data are presented in Tables II and III. Included in the data on these tables are total weight gains over the first 77 days of the feeding period.

There were no differences between test and control animals which could be related to the ingestion of Aroclor 1254.

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TABLE II

TEST MATERIAL: Aroclor 1254

Three-Generation Reproduction Study - Albino Rats

Mean Body Weight and Weight Gain Data

Parental Male Rats

Group	Generation	Mean Body Weight (grams) Day Number: 0	7	14	21	28	35	42	49	56	63	70	77	Total Weight Gain (grams)	Final Body Weight at Sacrifice
C	Fo	-	95	142	202	253	309	354	393	426	456	480	492	397	709
	F1	47	77	112	152	192	234	271	316	349	382	416	438	391	636
	F2	49	77	108	140	164	200	234	265	295	319	345	354	305	592
T-I	Fo	-	95	136	192	240	293	354	375	404	432	453	468	373	681
(1 ppm)	F1	47	79	122	164	203	247	288	329	362	389	405	422	375	642
	F2	55	97	135	184	232	279	317	348	375	400	425	445	390	679
T-II	Fo	-	95	135	184	230	280	339	361	391	417	446	460	365	661
(10 ppm)	F1	47	78	124	171	202	240	278	314	347	373	396	412	365	650
	F2	56	88	118	157	193	206	264	297	325	350	373	389	333	579
T-III	Fo	-	95	135	186	231	285	353	376	417	449	479	496	401	678
(100 ppm)	F1	42	73	111	160	201	242	283	306	343	374	397	421	376	640
	F2	47	77	118	157	167	228	278	300	313	339	368	386	339	569

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13

164

ADM 005438

STLCOPCB4028191

TABLE III

TEST MATERIAL: Aroclor 1254

Three-Generation Reproduction Study - Albino Rats

Mean Body Weight and Weight Gain Data

Parental Female Rats

Group	Generation	Mean Body Weight (grams) Day Number: 0	7	14	21	28	35	42	49	56	63	70	77	Total Weight Gain (grams)	Final Body Weight at Sacrifice
C	Fo	-	95	142	202	253	309	354	393	426	456	480	492	397	709
	F1	47	77	112	152	192	234	271	316	349	382	416	438	391	636
	F2	49	77	108	140	164	200	234	265	295	319	345	354	305	592
I-I	Fo	-	95	136	192	240	293	354	375	404	432	453	468	373	681
(1 ppm)	F1	47	79	122	164	203	247	288	329	362	389	405	422	375	642
	F2	55	97	135	184	232	279	317	348	375	400	425	445	390	679
I-II	Fo	-	95	135	184	230	280	339	361	391	417	446	460	365	661
(10 ppm)	F1	47	78	124	171	202	240	278	314	347	373	396	412	365	650
	F2	56	88	118	157	193	206	264	297	325	350	373	389	333	579
I-III	Fo	-	95	135	186	231	285	353	376	417	449	479	496	401	678
(100 ppm)	F1	42	73	111	160	201	242	283	306	343	374	397	421	379	640
	F2	47	77	118	157	167	228	278	300	313	339	368	386	339	569

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2. Mortality

Mortality data are presented in Tables IV and V.

Gross autopsy performed on animals which succumbed during the test period failed to reveal any relationship between the ingestion of Aroclor 1254 and the death of the animal.

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TABLE IV

TEST MATERIAL: Aroclor 1254

Three-Generation Reproduction Study - Albino Rats

Mortality Data

Parental Generation Males

Group	Generation	First Mating			Second Mating		
		Pre-M	M	Post-M	M	Post-M	Total
C	Fo	0	0	0	0	0	0
	F1	0	0	0	0	0	0
	F2	0	0	0	0	1	1
T-I	Fo	0	0	0	0	0	0
(1 ppm)	F1	0	0	0	0	0	0
	F2	0	0	0	0	0	0
T-II	Fo	0	0	0	0	0	0
(10 ppm)	F1	0	0	0	0	0	0
	F2	0	0	0	0	0	0
T-III	Fo	0	0	0	0	0	0
(100 ppm)	F1	0	0	0	0	0	0
	F2	0	1	0	0	0	1

Pre-M = Pre-Mating Period
M = Mating Period
Post-M = Post-Mating Period

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TABLE V

TEST MATERIAL: Aroclor 1254

Three-Generation Reproduction Study - Albino Rats

Mortality Data

Parental Generation Females

Group	Generation	First Mating Pre-M	M	G	P	L	R	Second Mating M	G	P	L	Post-W	Total
C	Fo	0	0	0	1	0	0	0	0	0	0	0	1
	F1	0	0	0	0	0	0	0	0	0	0	0	0
	F2	0	0	0	0	0	1	0	0	0	0	0	1
T-I	Fo	0	0	0	0	0	0	0	0	0	0	1	1
(1 ppm)	F1	0	0	0	0	0	0	0	0	0	0	0	0
	F2	0	0	0	0	0	0	0	0	0	0	0	0
T-II	Fo	0	0	0	0	0	0	0	1	0	0	0	1
(10 ppm)	F1	0	0	0	0	0	0	0	0	0	1	1	2
	F2	0	0	0	0	0	0	0	0	1	1	0	2
T-III	Fo	0	0	0	0	0	0	0	0	0	0	0	0
(100 ppm)	F1	0	0	0	0	0	0	0	0	0	0	0	0
	F2	0	0	0	1	0	0	0	0	0	0	0	1

Pre-M = Pre-Mating Period
M = Mating Period
G = Gestation Period
P = Parturition
L = Lactation Period
R = Resting Period
Post-W = Post-Weaning Period

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17

ADM 005482

STLCOPCB4028195

3. Reactions

No untoward reactions were noted among the parental animals during the investigation.

4. Pathologic Findings

a. Gross Pathologic Findings

There were no gross pathologic findings which could be correlated with ingestion of the test material. Findings among test animals were comparable to those noted among control animals.

b. Organ Weights and Ratios

Mean organ weights, organ to body weight ratios and organ to brain weight ratios are assembled in Tables VI through XIII.

Liver weights and liver to body or brain weight ratios of males fed diets containing 100 ppm Aroclor 1254 were elevated. The absolute liver weights for females in the same group (T-III) were not elevated; however, liver to brain weight ratios were significantly higher than the control values for these females. Statistical evaluation of other organ weights, organ to body weight and organ to brain weight ratios disclosed several randomly occurring intergroup differences. The lack of any consistent dose or generation related response and the absence of any deleterious histopathologic change confirm that these differences were not related to the ingestion of Aroclor 1254.

Statistical evaluations of other organ weights, organ to body weight and organ to brain weight ratios disclosed several randomly

STLCOPCB4028196

occurring intergroup differences. The lack of any consistent dose or generation related response and the absence of any deleterious histopathologic change confirm that these differences were not related to the ingestion of Aroclor 1254.

STLCOPCB4028197

TABLE VI

TEST MATERIAL: Aroclor 1254

Three-Generation Reproduction Study - Albino Rats

Mean Organ Weights and Ratios

Parental Animals

Organ: Liver

Group	Generation	Organ Weight (g)		Organ/Body Weight Ratio (g/100 g)		Organ/Brain Weight Ratio (g/g)	
		Males	Females	Males	Females	Males	Females
C	Fo	28.0	16.3	3.96	4.26	12.9	8.68
	F1	24.7	15.2	3.90	4.41	11.9	7.92
	F2	23.6	12.2	3.97	3.87	11.6	6.97
T-I	Fo	24.2**	14.6	3.56*	4.00	11.5	7.79
(1 ppm)	F1	25.5	15.3	3.95	4.66	11.9	7.82
	F2	27.9	17.1**	4.16	4.73	12.5	8.48
T-II	Fo	23.6*	15.8	3.55*	4.16	11.8	8.34
(10 ppm)	F1	27.9	14.3	4.25	4.04	13.4	7.84
	F2	21.5	14.2	3.72	4.21	10.1	7.50
T-III	Fo	33.4**	17.3	4.95**	4.90*	15.9**	9.28
(100 ppm)	F1	32.8*	17.3	5.14**	4.85	17.5**	10.70**
	F2	32.8	17.4	5.79	5.20	15.7	9.11**

* Statistically significant difference at the 95 percent confidence level.
** Statistically significant difference at the 99 percent confidence level.

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TABLE VII

TEST MATERIAL: Aroclor 1254

Three-Generation Reproduction Study - Albino Rats

Mean Organ Weights and Ratios

Parental Animals

Organ: Kidneys

Group	Generation	Organ Weight (g)		Organ/Body Weight Ratio (g/100 g)		Organ/Brain Weight Ratio (g/g)	
		Males	Females	Males	Females	Males	Females
C	Fo	4.82	2.77	0.680	0.724	2.22	1.48
	F1	4.44	2.68	0.709	0.771	2.14	1.40
	F2	4.01	2.43	0.681	0.774	1.99	1.39
T-I	Fo	4.25*	2.82	0.625	0.776	2.00	1.50
(1 ppm)	F1	4.44	2.87*	0.693	0.878	2.08	1.45
	F2	4.54	2.98**	0.677	0.821	2.03	1.47
T-II	Fo	4.02**	2.79	0.614	0.734	2.00	1.47
(10 ppm)	F1	4.56	2.79	0.697	0.793	2.20	1.53
	F2	3.84	2.56	0.667	0.752	1.82	1.34
T-III	Fo	4.68	2.75	0.697	0.782	2.23	1.48
(100 ppm)	F1	4.08	2.61	0.638	0.735	2.14	1.62
	F2	3.90	2.51	0.700	0.754	1.87	1.31

*Statistically significant difference at the 95 percent confidence level.
**Statistically significant difference at the 99 percent confidence level.

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TABLE VIII

TEST MATERIAL: Aroclor 1254

Three-Generation Reproduction Study - Albino Rats

Mean Organ Weights and Ratios

Parental Animals

Organ: Spleen

Group	Generation	Organ Weight (g)		Organ/Body Weight Ratio (g/100 g)		Organ/Brain Weight Ratio (g/g)	
		Males	Females	Males	Females	Males	Females
C	Fo	0.83	0.63	0.12	0.16	0.38	0.33
	F1	0.74	0.61	0.12	0.18	0.36	0.32
	F2	0.96	0.63	0.16	0.20	0.48	0.36
T-I	Fo	0.93	0.58	0.14	0.16	0.44	0.31
(1 ppm)	F1	0.72	0.48	0.11	0.15	0.34	0.24
	F2	0.91	0.63	0.14	0.17*	0.41	0.31*
T-II	Fo	0.78	0.54	0.12	0.14	0.39	0.29
(10 ppm)	F1	0.87	0.50	0.13	0.14	0.42	0.28
	F2	0.76	0.73	0.13	0.21	0.36	0.38
T-III	Fo	0.78	0.56	0.12	0.16	0.37	0.30
(100 ppm)	F1	0.72	0.48	0.11	0.13	0.38	0.30
	F2	0.77	0.57	0.14	0.17*	0.37	0.30*

* Statistically significant difference at the 99 percent confidence level.

ADM 005467

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TABLE IX

TEST MATERIAL: Aroclor 1254

Three-Generation Reproduction Study - Albino Rats

Mean Organ Weights and Ratios

Parental Animals

Organ: Gonads

Group	Generation	Organ Weight (g)		Organ/Body Weight Ratio (g/100 g)		Organ/Brain Weight Ratio (g/g)	
		Males	Females	Males	Females	Males	Females
C	Fo	3.62	0.117	0.510	0.0302	1.67	0.0627
	F1	3.57	0.099	0.576	0.0283	1.72	0.0524
	F2	3.18	0.132	0.530	0.0424	1.57	0.0757
T-I (1 ppm)	Fo	3.74	0.126	0.551	0.0344	1.76	0.0668
	F1	3.17*	0.092	0.492*	0.0280	1.48**	0.0469
	F2	3.78	0.127	0.563	0.0356	1.69	0.0636
T-II (10 ppm)	Fo	3.41	0.122	0.523	0.0322	1.69	0.0641
	F1	4.03**	0.108	0.624	0.0313	1.96**	0.0615
	F2	3.11	0.148	0.543	0.0439	1.47	0.0781
T-III (100 ppm)	Fo	3.52	0.111	0.525	0.0313	1.67	0.0587
	F1	3.68	0.105	0.577	0.0303	1.97	0.0665
	F2	3.52	0.135	0.623	0.0410	1.68	0.0705

* Statistically significant difference at the 95 percent confidence level.
** Statistically significant difference at the 99 percent confidence level.

ADM 005466
STLCOPCB4028201

TABLE X

TEST MATERIAL: Aroclor 1254

Three-Generation Reproduction Study - Albino Rats

Mean Organ Weights and Ratios

Parental Animals

Organ: Heart

Group	Generation	Organ Weight (g)		Organ/Body Weight Ratio (g/100 g)		Organ/Brain Weight Ratio (g/g)	
		Males	Females	Males	Females	Males	Females
C	Fo	1.86	1.28	0.261	0.332	0.858	0.684
	F1	1.74	1.24	0.276	0.360	0.844	0.647
	F2	1.84	1.19	0.314	0.379	0.914	0.682
T-I	Fo	1.93	1.29	0.283	0.355	0.910	0.688
(1 ppm)	F1	1.71	1.24	0.266	0.376	0.804	0.630
	F2	2.01	1.43**	0.301	0.394	0.909	0.706
T-II	Fo	1.69	1.23	0.258	0.325	0.838	0.650
(10 ppm)	F1	1.81	1.10**	0.279	0.314*	0.881	0.608
	F2	1.66*	1.16	0.292	0.343	0.788	0.610
T-III	Fo	1.84	1.24	0.271	0.352	0.877	0.605
(100 ppm)	F1	1.87	1.41**	0.292	0.401	0.990*	0.854**
	F2	1.68*	1.23	0.298	0.369	0.805	0.649

*Statistically significant difference at the 95 percent confidence level.
**Statistically significant difference at the 99 percent confidence level.

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TABLE XI

TEST MATERIAL: Aroclor 1254

Three-Generation Reproduction Study - Albino Rats

Mean Organ Weights and Ratios

Parental Animals

Organ: Brain

Group	Generation	Organ Weight (g) Males	Organ Weight (g) Females	Organ/Body Weight Ratios (g/100 g) Males	Organ/Body Weight Ratios (g/100 g) Females
C	Fo	2.17	1.90	0.307	0.509
	F1	2.07	1.93	0.334	0.566
	F2	2.01	1.74	0.345	0.557
T-I (1 ppm)	Fo	2.13	1.89	0.313	0.521
	F1	2.13	1.97	0.335	0.607
	F2	2.23*	2.03**	0.332	0.560
T-II (10 ppm)	Fo	2.02	1.90	0.310	0.502
	F1	2.05	1.82	0.317	0.525
	F2	2.10	1.90**	0.370	0.564
T-III (100 ppm)	Fo	2.11	1.86	0.316	0.530
	F1	1.89*	1.62**	0.296*	0.461
	F2	2.09	1.91**	0.370	0.581

*Statistically significant difference at the 95 percent confidence level.
**Statistically significant difference at the 99 percent confidence level.

ADM 005470

STLCOPCB4028203

TABLE XII

TEST MATERIAL: Aroclor 1254

Three-Generation Reproduction Study - Albino Rats

Mean Organ Weights and Ratios

Parental Animals

Organ: Adrenal Glands

Group	Generation	Organ Weight (g) Males	Organ Weight (g) Females	Organ/Body Weight Ratio (g/100 g) Males	Organ/Body Weight Ratio (g/100 g) Females	Organ/Brain Weight Ratio (g/g) Males	Organ/Brain Weight Ratio (g/g) Females
C	Fo	0.072	0.095	0.010	0.025	0.033	0.050
	F1	0.066	0.091	0.010	0.026	0.032	0.047
	F2	0.071	0.083	0.012	0.025	0.035	0.049
T-I (1 ppm)	Fo	0.077	0.092	0.011	0.025	0.036	0.049
	F1	0.077*	0.092	0.012*	0.028	0.036	0.046
	F2	0.084	0.012*	0.012	0.032	0.037	0.058
T-II (10 ppm)	Fo	0.059	0.087	0.008	0.022	0.029	0.046
	F1	0.056	0.075	0.009*	0.021	0.027	0.042
	F2	0.064	0.073	0.011	0.021	0.030*	0.038
T-III (100 ppm)	Fo	0.070	0.082	0.010	0.023	0.033	0.044
	F1	0.069	0.083	0.012	0.023	0.037*	0.051
	F2	0.058	0.074	0.010	0.022	0.027**	0.038

* Statistically significant difference at the 95 percent confidence level.
** Statistically significant difference at the 99 percent confidence level.

ADM 005471

STLCOPCB4028204

TABLE XIII

TEST MATERIAL: Aroclor 1254

Three-Generation Reproduction Study - Albino Rats

Mean Organ Weights and Ratios

Parental Animals

Organ: Thyroid Gland

Group	Generation	Organ Weight (g)		Organ/Body Weight Ratio (g/100 g)		Organ/Brain Weight Ratio (g/g)	
		Males	Females	Males	Females	Males	Females
C	Fo	0.035	0.028	0.0050	0.0075	0.016	0.015
	F1	0.025	0.025	0.0040	0.0074	0.012	0.013
	F2	0.033	0.028	0.0056	0.0089	0.016	0.016
T-I	Fo	0.031	0.025	0.0045	0.0069	0.014	0.013
(1 ppm)	F1	0.042**	0.034**	0.0066**	0.0104**	0.020**	0.018**
	F2	0.034	0.031	0.0051	0.0088	0.015	0.015
T-II	Fo	0.034	0.029	0.0052	0.0076	0.017	0.015
(10 ppm)	F1	0.035**	0.023	0.0054*	0.0066	0.017**	0.013
	F2	0.040	0.024	0.0069	0.0073	0.019	0.012
T-III	Fo	0.047*	0.023*	0.0069*	0.0067	0.022	0.013
(100 ppm)	F1	0.044**	0.044**	0.0068**	0.0123**	0.023**	0.027**
	F2	0.035	0.021	0.0062	0.0066	0.016	0.011

* Statistically significant difference at the 95 percent confidence level.
** Statistically significant difference at the 99 percent confidence level.

ACM 005472

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c. Histopathologic Findings

Histopathologic findings among sacrificed animals are summarized in Tables XIV through XVI. Table XVII summarizes the histopathologic examination of the urinary bladder conducted on all animals sacrificed from the final generation.

Three animals with epithelial hyperplasia of the urinary bladder were present in the T-III group of the F2 generation. All three of these rats were from the same litter. One control rat had similar urinary bladder hyperplasia.

The changes found in the other organs examined for each of the three generations did not differ from those present in the control group.

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TABLE XIV

TEST MATERIAL: Aroclor 1254

Three-Generation Reproduction Study - Albino Rats

Histopathologic Changes

Control Group - Fo Generation

Organ	Number of Animals Examined	Findings	Incidence	Average Grade
Trachea	5 Males	Focal inflammation	3	0.5
		Tracheitis	1	2.0
	5 Females	Focal inflammation	1	1.0
Lung	5 Males	Focal inflammation	2	1.0
		Hyperemia	5	2.0
	5 Females	Focal inflammation	2	0.5
		Hyperemia	5	1.0
Pancreas	5 Males	Prominent islands of Langerhans	1	1.0
Kidney	5 Males	Focal inflammation	1	0.5
		Hyperemia	1	0.5
	5 Females	Hyperemia	2	1.0
Adrenal glands	5 Males	Hyperemia	3	1.0

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TABLE XIV continued

TEST MATERIAL: Aroclor 1254

Three-Generation Reproduction Study - Albino Rats

Histopathologic Changes

Test Group III - Fo Generation

Organ	Number of Animals Examined	Findings	Incidence	Average Grade
Heart	5 Males	Focal inflammation	1	1.0
Trachea	5 Males	Focal inflammation	2	2.0
		Tracheitis	1	2.0
	5 Females	Tracheitis	3	2.0
Lung	5 Males	Focal inflammation	4	1.0
		Hyperemia	2	1.0
	5 Females	Focal inflammation	1	0.5
		Hyperemia	5	3.0

ADM 005475

STLCOPCB4028208

TABLE XIV continued

TEST MATERIAL: Aroclor 1254

Three-Generation Reproduction Study - Albino Rats

Histopathologic Changes

Test Group III - Fo Generation

Organ	Number of Animals Examined	Findings	Incidence	Average Grade
Liver	5 Males	Focal vacuolization	2	1.0
		Hyperemia	1	0.5
Kidney	5 Males	Nephritis	1	1.0
	5 Females	Focal inflammation	1	1.0
Thyroid	5 Males	Thyroiditis	3	1.0
Thymus	5 Females	Hyperemia	1	2.0

All other tissues and organs examined were normal histologically.

Grading System
0.5 = minimal
1.0 = slight
2.0 = mild
3.0 = moderate
4.0 = severe
5.0 = extreme

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TABLE XV

TEST MATERIAL: Aroclor 1254

Three-Generation Reproduction Study - Albino Rats

Histopathologic Changes

Control Group - F1 Generation

Organ	Number of Animals Examined	Findings	Incidence	Average Grade
Trachea	5 Males	Tracheitis	3	2.0
		Focal inflammation	1	1.0
	5 Females	Tracheitis	3	2.0
Lung	5 Males	Focal inflammation	5	2.0
	5 Females	Focal inflammation	4	1.0
		Focal inflammation with abscess	1	5.0
		Hyperemia	1	2.0
Liver	5 Females	Hyperemia	1	0.5
Kidney	5 Males	Nephrosis	2	0.5
		Nephritis	1	0.5
	5 Females	Nephrosis	1	0.5
Prostate	5 Males	Focal inflammation	1	0.5

ADM 005477

STLCOPCB4028210

TABLE XV continued

TEST MATERIAL: Aroclor 1254

Three-Generation Reproduction Study - Albino Rats

Histopathologic Changes

Test Group III - F1 Generation

Organ	Number of Animals Examined	Findings	Incidence	Average Grade
Trachea	5 Males	Focal inflammation	3	0.5
Lung	5 Males	Hyperemia	3	1.0
		Focal inflammation	4	1.0
	5 Females	Hyperemia	5	3.0
		Focal inflammation	2	1.0
Liver	5 Females	Hyperemia	1	2.0
Kidney	5 Males	Nephritis	1	0.5
	5 Females	Nephritis	1	0.5

All other tissues and organs examined were normal histologically.

Grading System
0.5 = minimal
1.0 = slight
2.0 = mild
3.0 = moderate
4.0 = severe
5.0 = extreme

ADM 005478

STLCOPCB4028211

TABLE XVI

TEST MATERIAL: Arocior 1254

Three-Generation Reproduction Study - Albino Rats

Histopathologic Changes

Control Group - F2 Generation

Organ	Number of Animals Examined	Findings	Incidence	Average Grade
Trachea	5 Males	Focal inflammation	1	0.5
		Inflammation	2	3.0
	5 Females	Focal inflammation	1	0.5
		Inflammation	1	1.0
Lung	5 Males	Focal inflammation	4	1.0
		Inflammation with abscess	1	3.0
		Hyperemia	2	1.0
	5 Females	Focal inflammation	1	2.0
		Inflammation with abscess	1	4.0
		Hyperemia	3	2.0

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TABLE XVI continued

TEST MATERIAL: Aroclor 1254

Three-Generation Reproduction Study - Albino Rats

Histopathologic Changes

Control Group - F2 Generation

Organ	Number of Animals Examined	Findings	Incidence	Average Grade
Colon	5 Males	Focal inflammation	2	0.5
Liver	5 Females	Hyperemia	1	0.5
Kidney	5 Males	Focal inflammation	1	0.5
	5 Females	Nephrocalcinosis	1	0.5

ADM 005480

STLCOPCB4028213

TABLE XVI continued

TEST MATERIAL: Aroclor 1254

Three-Generation Reproduction Study - Albino Rats

Histopathologic Changes

Test Group III - F2 Generation

Organ	Number of Animals Examined	Findings	Incidence	Average Grade
Trachea	7 Males	Focal inflammation	1	2.0
		Inflammation	1	2.0
	8 Females	Focal inflammation	4	0.5
		Inflammation	1	1.0
Lung	7 Males	Focal inflammation	5	1.0
		Hyperemia	5	2.0
	8 Females	Focal inflammation	5	1.0
		Hyperemia	5	2.0
Liver	7 Males	Focal inflammation	2	2.0
	8 Females	Hyperemia	2	2.0
		Mononuclear cell infiltration	1	0.5
		Focal vacuolization	1	0.5

ADM 005481

STLCOPCB4028214

TABLE XVI continued

TEST MATERIAL: Aroclor 1254

Three-Generation Reproduction Study - Albino Rats

Histopathologic Changes

Test Group III - F2 Generation

Organ	Number of Animals Examined	Findings	Incidence	Average Grade
Colon	7 Males	Focal inflammation	2	1.0
	8 Females	Focal inflammation	1	0.5
Testis	7 Males	Atrophied	1	4.0
		Focal inflammation	1	2.0
Kidney	7 Males	Focal inflammation, pyelonephritis	1	4.0
	8 Females	Nephrocalcinosis	1	0.5

All other tissues and organs examined were normal histologically.

Grading System
0.5 = minimal
1.0 = slight
2.0 = mild
3.0 = moderate
4.0 = severe
5.0 = extreme

ADM 005482

STLCOPCB4028215

TABLE XVII

TEST MATERIAL: Aroclor 1254

Three-Generation Reproduction Study - Albino Rats

Histopathologic Changes of the Urinary Bladder

F2 Generation

Group	Sex	Number Examined	Findings*	Incidence	Average Grade
C	M	7	None	-	-
	F	10	Focal epithelial hyperplasia associated with focal cystitis (11)	1	1.0
T-I (1 ppm)	M	8	Proteinaceous plug (103)	1	-
	F	14	None	-	-
T-II (10 ppm)	M	8	Proteinaceous plug (123 and 124)	2	-
	F	13	None	-	-
T-III (100 ppm)	M	7	Diffuse epithelial hyperplasia associated with focal cystitis and mineralized calculi (152)	1	4.0
	F	10	Focal epithelial hyperplasia (167 and 168)	2	1.0

* Individual animal numbers are shown in parenthesis.

Grading System
1.0 = minimal or trace
2.0 = mild
3.0 = moderate
4.0 = severe
5.0 = extreme

ADM 005483

STLCOPCB402821

4. Reproductive Data

Reproductive data for parental animals are presented in Table XVIII.

The indices employed are defined below:

$$\text{Mating Index} = \frac{\text{Number of Copulations}^{*}}{\text{Number of Estrus Cycles Required}} \times 100$$

$$\text{Fertility Index} = \frac{\text{Number of Pregnancies}}{\text{Number of Copulations}} \times 100$$

$$\text{Incidence of Pregnancy} = \frac{\text{Number of Pregnancies}}{\text{Number of Females Mated}} \times 100$$

$$\text{Incidence of Parturition} = \frac{\text{Number of Parturitions}}{\text{Number of Pregnancies}} \times 100$$

The addition of 1 or 10 ppm Aroclor 1254 to the diet did not affect the reproductive performance of rats during the three-generation study. During the second generation (F2a and F2b litters), rats fed 10 (T-II) or 100 ppm (T-III) had lowered mating indices. The other indices were normal. During the third generation (F3a and F3b litters) the reproductive performance of all treatment groups was equal to that of the contemporary control.

* Only one copulation counted per estrus cycle. Five days equal one estrus cycle.

STLCOPCB4028217

TABLE XVIII

TEST MATERIAL: Aroclor 1254

Three-Generation Reproduction Study - Albino Rats

General Data

Parental Animals

Reproductive Performance

Litter	Mating Index Fraction	Mating Index Percent	Incidence of Pregnancy Fraction	Incidence of Pregnancy Percent	Fertility Index Fraction	Fertility Index Percent	Incidence of Parturition Fraction	Incidence of Parturition Percent	Gestation Time (Days) Mean	Gestation Time (Days) Range
F1a	17/25	68.0	16/16	100.0	16/17	94.1	15/16	93.8	22	19-22
F1b	15/20	75.0	15/15	100.0	15/15	100.0	15/15	100.0	22	21-22
F2a	16/37	43.2	14/16	87.5	14/16	87.5	14/14	100.0	21	20-22
F2b	14/26	53.8	14/14	100.0	14/14	100.0	14/14	100.0	22	21-23
F3a	15/66	22.7	13/16	81.2	13/15	86.7	11/13	84.6	22	21-22
F3b	12/16	75.0	12/12	100.0	12/12	100.0	11/12	91.6	22	20-22
F1a	16/29	55.2	16/16	100.0	16/16	100.0	16/16	100.0	22	21-22
F1b	16/29	55.2	16/16	100.0	16/16	100.0	15/16	93.8	22	20-23
F2a	16/42	38.1	12/16	75.0	12/16	75.0	12/12	100.0	21	20-22
F2b	11/28	39.3	11/12	91.7	11/11	100.0	11/11	100.0	22	20-23
F3a	18/58	31.0	12/18	66.7	12/16	75.0	9/12	75.0	22	22-23
F3b	14/24	58.3	11/14	78.6	11/12	91.7	11/11	100.0	22	21-23

ADM 005485

STLCOPCB4028218

TABLE XVIII continued

TEST MATERIAL: Aroclor 1254

Three-Generation Reproduction Study - Albino Rats

General Data

Parental Animals

Reproductive Performance

	Litter	Mating Index Fraction	Mating Index Percent	Incidence of Pregnancy Fraction	Incidence of Pregnancy Percent	Fertility Index Fraction	Fertility Index Percent	Incidence of Parturition Fraction	Incidence of Parturition Percent	Gestation Time (Days) Mean	Gestation Time (Days) Range
[illegible]	F1a	16/23	69.6	16/16	100.0	16/16	100.0	16/16	100.0	22	21-23
[illegible] ppm)	F1b	16/21	76.2	16/16	100.0	16/16	100.0	15/16	93.8	22	20-23
	F2a	14/63	22.2	11/16	68.8	11/14	78.6	10/11	90.9	22	21-23
	F2b	11/32	34.4	10/11	90.9	10/11	90.9	9/10	90.0	23	22-23
	F3a	16/54	29.6	14/16	87.5	14/16	87.5	12/14	85.7	22	21-22
	F3b	14/35	40.0	13/14	92.9	13/14	92.9	13/13	100.0	22	20-23
[illegible]	F1a	16/28	57.1	16/16	100.0	16/16	100.0	15/16	93.8	22	21-23
[illegible] ppm)	F1b	16/26	61.5	16/16	100.0	16/16	100.0	13/16	81.3	21	19-22
	F2a	14/73	18.2	13/16	81.2	13/14	92.9	13/13	100.0	22	22-24
	F2b	10/52	19.2	9/13	69.2	9/10	90.0	9/9	100.0	22	-
	F3a	11/36	30.6	11/11	100.0	11/11	100.0	10/11	90.9	22	22-23
	F3b	8/31	25.8	8/8	100.0	8/8	100.0	8/8	100.0	22	-

ADM 005486

STLCOPCB4028219

B. Progeny

1. Population Data

Population data for all litters are presented in Tables XIX and XX. The number of live pups born per litter was not affected by feeding 1, 10 or 100 ppm Aroclor 1254. The number of pups weaned per litter was reduced in all three generations in the group fed 100 ppm (T-III). The average number of pups weaned per litter for the groups fed 1 or 10 ppm was not lowered.

All pups delivered appeared outwardly normal and displayed normal growth through the lactation period. At weaning, an examination of each pup for external abnormalities was conducted and all pups were judged to be free of gross external abnormalities.

TABLE XIX

TEST MATERIAL: Aroclor 1254

Three-Generation Reproduction Study - Albino Rats

Population Data

Progeny

Litter	Number of Pups Delivered		Number of Pups Stillborn		Number of Pups Cannibalised		Number of Viable Pups Born	
	Total	Mean/Litter	Total	Mean/Litter	Total	Mean/Litter	Total	Mean/Litter
F1a	178	11.9	13	0.9	0	-	165	11.0
F1b	191	12.7	12	0.8	1	0.1	178	11.9
F2a	147	10.5	7	0.5	0	-	140	10.0
F2b	164	11.7	0	-	0	-	164	11.7
F3a	102	9.3	10	0.9	0	-	92	8.4
F3b	109	9.9	15	1.4	1	0.1	93	8.5
F1a	187	11.7	1	0.1	0	-	186	11.6
F1b	207	13.8	4	0.3	1	0.1	202	13.4
F2a	132	11.0	0	-	0	-	132	11.0
F2b	124	11.3	3	0.3	0	-	121	11.0
F3a	85	9.4	12	1.3	1	0.1	70	7.8
F3b	120	10.9	8	0.7	1	0.1	111	10.1

ADM 005468

STLCOPCB4028221

TABLE XIX continued

TEST MATERIAL: Aroclor 1254

Three-Generation Reproduction Study - Albino Rats

Population Data

Progeny

	Litter	Number of Pups Delivered Total	Number of Pups Delivered Mean/Litter	Number of Pups Stillborn Total	Number of Pups Stillborn Mean/Litter	Number of Pups Cannibalized Total	Number of Pups Cannibalized Mean/Litter	Number of Viable Pups Born Total	Number of Viable Pups Born Mean/Litter
	F1a	163	10.2	11	0.7	4	0.2	148	9.2
	F1b	192	12.8	14	0.9	5	0.3	173	11.5
	F2a	97	9.7	5	0.5	0	-	92	9.2
	F2b	88	9.8	1	0.1	0	-	87	9.7
	F3a	99	8.2	6	0.5	-	-	93	7.8
	F3b	118	9.1	15	1.2	-	-	105	8.1
	F1a	167	11.1	0	-	0	-	167	11.1
ppm)	F1b	163	12.5	8	0.6	3	0.2	152	11.7
	F2a	115	8.8	8	0.6	5	0.4	102	7.8
	F2b	97	10.8	3	0.3	12*	1.3	82	9.1
	F3a	95	9.5	14	1.4	4	0.4	77	7.7
	F3b	83	10.4	2	0.2	-	-	79	9.9

*Eleven pups cannibalized from one litter.

ADM 005489

STLCOPCB4028222

TABLE XX

TEST MATERIAL: Aroclor 1254

Three-Generation Reproduction Study - Albino Rats

Population Data

Progeny

Litter	Number of Pups at Lactation Day 1 Total	Mean/Litter	Number of Pups at Lactation Day 5 Total	Mean/Litter	Number of Pups Retained at Lactation Day 5 Total	Mean/Litter	Number of Weanlings Male	Female	Total	Mean/Litter
F1a	146	9.7	70	4.7	66	4.4	34	28	62	4.1
F1b	176	11.7	117	7.8	103	6.9	31	35	66	4.4
F2a	132	9.4	90	6.4	78	5.6	30	34	64	4.6
F2b	163	11.6	135	9.6	115	8.2	39	46	85	6.1
F3a	90	8.2	69	6.3	65	5.9	26	25	51	4.6
F3b	91	8.3	79	7.2	75	6.8	16	26	42	3.8
F1a	182	11.4	165	10.3	144	9.0	74	60	134	8.4
F1b	159	10.6	150	10.0	131	8.7	55	57	112	7.5
F2a	131	10.9	119	9.9	88	7.3	30	43	73	6.1
F2b	120	10.9	103	9.4	84	7.6	35	39	74	6.7
F3a	59	6.5	57	6.3	53	5.9	18	29	47	5.2
F3b	111	10.1	106	9.6	95	8.6	37	49	86	7.8

ADM 005490

STLCOPCB4028223

TABLE XX continued

TEST MATERIAL: Aroclor 1254

Three-Generation Reproduction Study - Albino Rats

Population Data

Progeny

Litter	Number of Pups at Lactation Day 1 Total	Mean/Litter	Number of Pups at Lactation Day 5 Total	Mean/Litter	Number of Pups Retained at Lactation Day 5 Total	Mean/Litter	Number of Weanlings Male	Female	Total	Mean/Litter
F1a	163	8.9	114	7.1	104	6.5	45	42	87	5.4
F1b	159	10.6	150	10.0	131	8.7	55	57	112	7.5
F2a	66	6.6	54	5.4	50	5.0	18	24	42	4.2
F2b	66	7.3	40	5.0*	37	4.6	20	18	38	4.4
F3a	92	7.7	89	7.4	82	6.8	31	35	66	5.5
F3b	99	7.6	93	7.2	76	5.8	36	28	64	4.9
F1a	158	10.5	98	6.5	92	6.1	38	26	64	4.3
F1b	148	11.4	110	8.5	101	7.8	13	13	26	2.0
F2a	90	6.9	66	5.1	59	4.5	11	26	37	2.8
F2b	61	6.8	44	4.9	40	4.4	13	12	25	2.8
F3a	54	5.4	14	1.4	14	1.4	6	3	9	0.9
F3b	77	9.6	39	4.9	39	4.9	10	10	20	2.5

...n per litter from day 5 of lactation through weaning reported on eight females due to death of one female and ...sacrifice of progeny.

ADM 005491

STLCOPCB4028224

2. Survival Data

Survival data for progeny are presented in Table XXI.

The indices employed are defined below.

$$\text{Live Birth Index} = \frac{\text{Number of Viable Pups Born}}{\text{Total Number of Pups Born}} \times 100$$

$$\text{24-Hour Survival Index} = \frac{\text{Number of Pups Viable at Lactation Day 1}}{\text{Number of Viable Pups Born}} \times 100$$

$$\text{5-Day Survival Index} = \frac{\text{Number of Pups Viable at Lactation Day 5}}{\text{Number of Viable Pups Born}} \times 100$$

$$\text{Lactation Index} = \frac{\text{Number of Pups Viable at Lactation Day 21}}{\text{Number of Pups Viable at Lactation Day 5}} \times 100$$

Pup survival was lower in litters from dams fed 100 ppm Aroclor 1254 than for any other group. Pup survival was not reduced when 1 or 10 ppm was fed.

ADM C05492

STLCOPCB4028225

TABLE XXI

TEST MATERIAL: Aroclor 1254

Three-Generation Reproduction Study - Albino Rats

Survival Indices

Progeny

Group	Litter	Live Birth Index	24-Hour Survival Index	5-Day Survival Index	Lactation Index
C	F1a	92.7	88.5	42.4	93.9
	F1b	93.2	98.9	65.7	64.1
	F2a	95.2	94.3	64.3	82.1
	F2b	100.0	99.3	82.3	73.9
	F3a	90.2	97.8	75.0	78.5
	F3b	85.3	97.8	84.9	56.0
T-I (1 ppm)	F1a	99.5	97.8	88.7	93.1
	F1b	97.6	78.7	91.6	78.8
	F2a	100.0	99.2	98.2	83.0
	F2b	97.6	99.1	85.1	88.1
	F3a	82.4	84.3	81.4	88.7
	F3b	92.5	100.0	95.5	90.5
T-II (10 ppm)	F1a	90.8	96.6	77.0	83.7
	F1b	90.1	91.9	86.7	85.5
	F2a	94.8	71.7	58.7	84.0
	F2b	98.9	75.8	50.0*	94.6
	F3a	93.9	98.9	95.7	80.5
	F3b	89.0	94.3	88.6	84.2
T-III (100 ppm)	F1a	100.0	94.6	58.7	69.6
	F1b	93.3	97.4	72.4	25.7
	F2a	88.7	88.2	64.7	62.7
	F2b	84.5	74.4	53.7	62.5
	F3a	81.1	70.1	18.2	64.3
	F3b	95.2	97.5	49.4	51.3

* Five-day survival index corrected to allow for sacrificed progeny due to the death of one female.

ADM 005493

STLCOPCB4028226

2. Body Weight Data

Body weight data for weanlings are presented in Table XXII. There were no significant differences between test and control weanling body weights.

STLCOPCB4028227

TABLE XXII

TEST MATERIAL: Aroclor 1254

Three-Generation Reproduction Study - Albino Rats

Progeny

Weanling Body Weight Data

Group	Litter	Mean Body Weight (grams) Male	Female
C	F1a	48	44
	F1b	47	43
	F2a	46	43
	F2b	41	39
	F3a	45	44
	F3b	42	42
T-I (1 ppm)	F1a	49	46
	F1b	45	45
	F2a	52	45
	F2b	48	47
	F3a	47	41
	F3b	50	48
T-II (10 ppm)	F1a	51	48
	F1b	51	47
	F2a	52	48
	F2b	45	49
	F3a	45	42
	F3b	48	45
T-III (100 ppm)	F1a	46	42
	F1b	43	40
	F2a	40	42
	F2b	47	46
	F3a	43	37
	F3b	40	32

ABM 005495

STLCOPCB4028228

4. Pathologic Studies

At autopsy of the F3b weanlings no gross or microscopic tissue changes were present which could be associated with the ingestion of Aroclor 1254.

STLCOPCB4028229