T NO. 71-69
RT FILE

Industrial BIO-TEST Laboratories, Inc.
1810 FRONTAGE ROAD
NORTHBROOK, ILLINOIS 60062

#2

November 12, 1971

Mr. Elmer P. Wheeler
Monsanto Company
800 North Lindbergh Boulevard
St. Louis, Missouri 63166

Dear Mr. Wheeler:

Re: IBT No. B7298 - Two-Year Chronic Oral Toxicity Study with Aroclor 1242 in Albino Rats

We are submitting herewith our laboratory report dated November 12, 1971, prepared in connection with the above study.

Very truly yours,

J C Calandra

J. C. Calandra
President

JCC/kjl

DSW 036119

REPORT TO

MONSANTO COMPANY

TWO-YEAR CHRONIC ORAL TOXICITY WITH AROCLOR 1242 IN ALBINO RATS

NOVEMBER 12, 1971

IBT NO. B7298

I. Introduction

At the request of Monsanto Company, a two-year chronic oral toxicity study was conducted using albino rats to determine the potential toxicity of Aroclor 1242, Lot No. AK-255. The following report presents the results of this investigation.

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II. Summary

A two-year chronic toxicity study was conducted using albino rats fed diets containing 1 (T-I), 10 (T-II) or 100 (T-III) ppm Aroclor 1242.

Food consumption and body weight gains were not altered at any level of Aroclor 1242 fed. The number of animals dying and the time at which the deaths occurred did not vary among the test and control groups.

Hematological and clinical blood chemistry studies conducted after 3, 6, 9, 12, 18 or 24 months did not reveal any affects related to Aroclor 1242. Urine analyses failed to reveal any differences between test and control animals.

At sacrifice after 3, 6 or 12 months on test, organ weights, organ to body weight and organ to brain weight ratios disclosed several randomly occurring intergroup differences. The lack of any consistent dose related response and the absence of any deleterious histopathologic change confirm that these differences were not related to the ingestion of Aroclor 1242.

At the final sacrifice after 24 months on test, the liver weights and liver to body weight or brain weight ratios were significantly elevated in females from the T-III group. Histologic examination of the livers from the T-III group revealed several animals with vacuolar change. This lesion is morphologically indicative of fatty degeneration. Specific fat stains confirmed the presence of fat in these vacuoles. Focal hypertrophy and focal hyperplasia were also found in the livers from animals fed Aroclor 1242.

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Hyperplasia of the urinary bladder was found in animals from the control group and from each of the test groups. This hyperplasia was usually associated with cystitis.

The incidences and types of all tumors were about the same in all groups, including the control group, and are considered normal for rats of this age.

Respectfully submitted,

INDUSTRIAL BIO-TEST LABORATORIES, INC.

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III. Procedure

A. Experimental Animals

The animals employed in the test were Charles River strain* albino rats. Four hundred rats (200 male and 200 female) were selected for the experiment, ear-punched with the animal number assigned and housed individually in standard wire-bottomed steel rat cages. Each cage bore a color-coded card identifying the rat with respect to project number, dietary level assignment, individual animal number and sex.

B. Organization of Groups

A structural outline of the experiment is given in Table I.

TABLE I

TEST MATERIAL: Aroclor 1242

Two-Year Chronic Oral Toxicity Study - Albino Rats

Outline of Experiment

Group	Number of Animals Male	Female	Dietary Level (ppm)
Control	50	50	None Administered
T-I	50	50	1
T-II	50	50	10
T-III	50	50	100

* Charles River Breeding Laboratories, North Wilmington, Mass.

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C. Diets, Feeding and Food Consumption

All diets were prepared in the central diet room of this laboratory. The basic ration from which all diets were constructed was a standard, pulverized stock rat ration*. The diet for any given test group was prepared by blending the calculated amount of Aroclor 1242 with a pre-weighed portion of the stock ration in a Hobart mixer.

Fresh diets were prepared each week and every rat was offered an amount of food sufficient for ad libitum feeding.

Food consumption was recorded for five rats of each sex in every group weekly for the first three months and monthly for the next nine months. Thereafter, periodic spot checks were made.

D. Body Weights and Weight Gains

Initially, the body weight of each rat in every group was determined and recorded. Thereafter, individual weighings were made weekly for the first 13 weeks and monthly thereafter until the conclusion of the investigation.

E. Mortality and Reactions

Checks for mortality and abnormal behavioral reactions were made daily throughout the investigation.

F. Hematologic Studies and Urine Analyses

Blood studies, including determinations of hemoglobin concentration, hematocrit value, erythrocyte count and both total and differential

* Purina Rat Chow, Ralston Purina Company, St. Louis, Missouri.

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leukocyte counts, were conducted upon five males and five females from both the control and 100 ppm groups.

Urine analyses for the presence of glucose, albumin, microscopic elements, and determinations of pH and specific gravity were conducted upon urine samples at the same time intervals and from the same animals as those employed for the blood studies.

These studies were conducted after 3, 6, 9, 12, 18, and 24 months of feeding.

G. Clinical Blood Chemistry Studies

Determinations of blood urea nitrogen concentration (BUN), serum alkaline phosphatase activity (SAP), fasted blood glucose concentration and serum glutamic-pyruvic transaminase activity (SGPT) were conducted after 3, 6, 9, 12, 18, and 24 months of feeding upon the same rats as were the routine blood studies.

H. Pathologic Studies

When an animal succumbed during the test period, a gross autopsy was performed. In those cases when postmortem autolysis was not advanced, representative tissues were taken and preserved in ten percent formalin solution for possible future histopathologic study.

After 3, 6, and 12 months of testing, five animals of each sex from each group were sacrificed and subjected to complete gross pathologic examinations.

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Absolute organ weights were recorded and organ to body weight and organ to brain weight ratios computed. The following organs were included: liver, kidneys, spleen, gonads, heart and brain. These data were then subjected to statistical analysis. An Analysis of Variance was conducted first and significant effects disclosed by that treatment were further studied by "t"-tests.

Complete microscopic examinations were conducted upon the tissues and organs from all control and 100 ppm group rats sacrificed after 3, 6, or 12 months of testing. The following tissues and organs were included in the examinations: heart, trachea, lungs, liver, pancreas, esophagus, stomach, small intestine (duodenum, jejunum and ileum), caecum, colon, spleen, lymph nodes, kidneys, urinary bladder, gonads, prostate gland, seminal vesicles, uterus, pituitary gland, adrenal glands, salivary glands, thyroid gland, parathyroid glands, skeletal muscle, sternum, bone, peripheral nerve, spinal cord and brain (cerebrum, cerebellum and pons).

The aforementioned tissues were prepared and stained with Hematoxylin-Eosin stain.

After two years of feeding, all surviving animals were sacrificed and subjected to complete gross pathologic examination.

The absolute weights of the liver, kidneys, spleen, gonads, heart and brain were recorded immediately after sacrifice.

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Microscopic examinations were conducted upon tissues and organs from selected animals dying during the experiment and upon all animals from the final sacrifice.

Tissues and organs examined were the same as those previously mentioned.

I. Tumor Incidence and Classification

A tabulation of the incidence of tumor formation in each group was made at the conclusion of the investigation. In addition, tumor data for individual animals including location, weight, size and pathologic classification were recorded.

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IV. Results

A. Body Weights and Weight Gains

The male and female body weight data are assembled in Table II. The data in this table also include the 3, 12 and 24 month total weight gains. There were no significant effects attributable to the ingestion of the compound.

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TABLE II

TEST MATERIAL: Aroclor 1242

Two-Year Chronic Oral Toxicity Study - Albino Rats

Body Weight and Total Weight Gain Data

Summary of Mean Values

Dietary Level of Aroclor 1242 (ppm)	Sex	Body Weight (grams) Week: 0	1	2	3	4	5	6	7	8	9	10	11	12	13	90-Day Total Weight Gain (grams/rat)
Control	M	133	203	245	313	362	373	391	409	424	440	440	449	467	474	341
	F	136	178	190	219	244	254	259	265	270	276	281	278	290	288	152
1	M	133	205	254	329	367	377	397	417	432	451	462	481	493	508	375
	F	136	173	197	226	240	253	268	292	278	280	284	284	288	292	156
10	M	133	202	251	332	362	372	392	414	428	454	475	481	500	509	376
	F	136	176	196	226	244	254	268	288	276	280	281	284	280	285	149
100	M	133	203	248	320	365	376	398	416	427	439	453	467	478	487	354
	F	136	173	194	225	251	264	272	290	274	275	279	285	283	286	150

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TABLE II continued

TEST MATERIAL: Aroclor 1242

Two-Year Chronic Oral Toxicity Study - Albino Rats

Body Weight and Total Weight Gain Data

Summary of Mean Values

ietary Level of Aroclor 1242 (ppm)	Sex	Body Weight (grams) Month: 4	5	6	7	8	9	10	11	12	12-Month Total Weight Gain (grams/rat)
ontrol	M	498	533	565	593	622	642	667	688	701	568
	F	297	310	322	333	345	359	374	383	390	254
1	M	525	555	580	614	640	665	690	707	743	610
	F	302	321	326	333	342	355	367	381	388	252
10	M	525	553	579	600	627	641	674	693	706	573
	F	299	312	328	333	346	354	365	375	384	248
100	M	504	533	551	580	608	633	662	686	711	578
	F	290	307	321	333	347	360	374	388	379	243

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TABLE II continued

TEST MATERIAL: Aroclor 1242

Two-Year Chronic Oral Toxicity Study - Albino Rats

Body Weight and Total Weight Gain Data

Summary of Mean Values

Dietary Level of Aroclor 1242 (ppm)	Sex	Body Weight (grams) Month: 13	14	15	16	17	18	19	20	21	22	23	24	24-Month Total Weight Gain (grams/rat)
Control	M	728	746	759	768	769	767	760	758	739	726	687	642	509
	F	426	444	466	481	500	515	533	547	551	550	564	551	415
1	M	767	785	805	800	804	810	800	804	802	800	808	759	626
	F	428	443	479	468	500	514	523	531	535	538	535	532	396
10	M	740	750	763	780	784	780	785	783	780	774	796	734	601
	F	393	406	422	441	462	480	500	519	529	533	537	547	411
100	M	724	728	723	735	728	736	733	730	725	715	743	652	519
	F	428	447	463	467	472	484	481	484	485	490	487	485	349

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B. Food Consumption

The data obtained from the food consumption measurements conducted during the first 12 months of feeding are summarized in Table III.

These data revealed no significant difference between test and control rats. The periodic checks conducted during the remainder of the investigation also revealed no outstanding differences between test and control animals.

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TABLE III

TEST MATERIAL: Aroclor 1242

Two-Year Chronic Oral Toxicity Study - Albino Rats

Food Consumption Data

Summary of Mean Values

ietary Level of Aroclor 1242 (ppm)	Sex	Food Consumption (grams/rat/seven days) Week: 1	2	3	4	5	6	7	8	9	10	11	12	13	Average Food Consumption (grams/rat/seven days)
Control	M	94	160	175	163	137	137	225	197	204	188	191	194	196	174
	F	73	140	144	107	104	133	208	154	165	151	146	150	151	140
1	M	129	154	165	201	120	191	206	210	232	185	188	189	190	167
	F	91	109	120	164	110	166	124	137	172	140	145	148	145	136
10	M	113	132	142	201	120	193	183	184	184	192	196	191	193	171
	F	96	114	147	131	110	149	102	124	166	144	143	138	144	131
100	M	117	149	185	230	161	172	199	172	227	192	186	190	190	182
	F	89	118	129	189	98	114	142	135	180	145	142	139	140	135

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TABLE III continued

TEST MATERIAL: Aroclor 1242

Two-Year Chronic Oral Toxicity Study - Albino Rats

Food Consumption Data

Summary of Mean Values

etary Level of Aroclor 1242 (ppm)	Sex	Food Consumption (grams/rat/seven days) Month: 4	5	6	7	8	9	10	11	12	Average Food Consumption (grams/rat/seven days)
Control	M	196	189	168	147	163	184	179	170	187	176
	F	148	154	136	121	138	152	160	141	127	142
1	M	180	181	170	189	190	189	196	192	208	188
	F	152	159	141	154	150	148	143	145	159	150
10	M	184	164	168	197	193	188	191	186	177	183
	F	139	147	136	151	144	145	138	142	130	141
100	M	179	192	189	200	196	186	184	187	167	187
	F	163	141	160	148	145	144	147	146	145	149

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C. Mortality and Reactions

A frequency distribution of natural deaths occurring during the investigation appears in Table IV.

No untoward behavioral reactions were noted among any of the animals employed in the investigation.

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TABLE IV

TEST MATERIAL: Aroclor 1242

Two-Year Chronic Oral Toxicity Study - Albino Rats

Mortality Data

Frequency Distribution of Deaths

Dietary Level (ppm)	Sex	Frequency Distribution of Deaths Months: 1-3	4-6	7-9	10-12	13-15	16-18	19-21	22-24	Total Dead Number Tested*
Control	M	0	0	0	2	1	7	6	9	25/35
	F	0	0	0	1	3	5	7	3	19/35
1	M	2	0	1	1	3	3	7	8	25/35
	F	1	0	0	1	3	2	4	5	16/35
10	M	0	0	0	2	1	7	5	8	23/35
	F	0	1	1	2	0	2	5	5	16/35
100	M	0	0	0	3	3	6	7	10	29/35
	F	0	1	0	1	2	4	8	9	25/35

* Does not include the five animals of each sex from every group sacrificed for interim pathologic studies.

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D. Hematologic and Clinical Blood Chemistry Studies

Mean male and female hematologic and clinical blood chemistry data are summarized in Tables V through IX.

Values for all parameters investigated were within the normal range for the albino rat. No significant differences between test and control values were observed.

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TABLE V

TEST MATERIAL: Aroclor 1242

Two-Year Chronic Oral Toxicity Study - Albino Rats

Hematologic Data

Summary of Mean Values

Dietary Level (ppm)	Sex	Total Leukocyte Count (thousands/mm^3) Month: 3	6	9	12	18	24	Erythnocyte Count (millions/mm^3) Month: 3	6	9	12	18	24
Control	M	14.0	15.4	10.1	11.1	9.9	11.2	8.1	8.2	8.7	8.8	7.6	6.5
	F	9.1	9.4	6.7	7.6	8.8	7.6	7.5	7.7	7.3	7.8	7.7	6.8
100	M	15.6	10.4	9.7	12.5	9.4	9.3	7.7	8.0	8.0	7.6	7.9	7.0
	F	15.6	9.0	7.7	7.8	6.2	6.4	7.4	7.6	7.6	7.1	7.7	7.2

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TABLE VI

TEST MATERIAL: Aroclor 1242

Two-Year Chronic Oral Toxicity Study - Albino Rats

Hematologic Data

Summary of Mean Values

Dietary Level (ppm)	Sex	Hemoglobin Concentration (g/100 ml) Month: 3	6	9	12	18	24	Hematocrit Value (%) Month: 3	6	9	12	18	24
Control	M	17.1	17.7	15.7	17.6	16.1	13.6	51	49	48	50	41	35
	F	16.9	17.4	14.1	16.7	16.4	14.6	50	47	43	46	42	38
100	M	16.8	16.9	14.2	15.4	15.6	14.6	50	48	43	44	41	37
	F	15.8	16.1	13.6	15.7	15.5	14.8	46	48	41	41	40	37

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TABLE VII

TEST MATERIAL: Aroclor 1242

Two-Year Chronic Oral Toxicity Study - Albino Rats

Hematologic Data

Summary of Mean Values

Dietary Level (ppm)	Sex	Differential Leukocyte Count (Number of Cells per Hundred) Lymphocytes Month: 3	6	9	12	18	24	Neutrophils Month: 3	6	9	12	18	24
Control	M	82.0	86.6	80.4	78.8	79.0	65.4	16.0	11.4	18.6	20.6	20.0	32.2
	F	83.0	86.6	86.8	89.0	70.2	61.4	15.4	11.6	11.8	10.0	29.2	36.0
100	M	89.6	84.4	79.8	87.0	66.0	58.4	9.6	15.2	18.8	13.2	33.0	38.8
	F	91.4	86.0	82.8	88.4	75.6	65.2	8.4	13.6	17.2	11.2	23.0	33.6

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TABLE VII continued

TEST MATERIAL: Aroclor 1242

Two-Year Chronic Oral Toxicity Study - Albino Rats

Hematologic Data

Summary of Mean Values

Dietary Level (ppm)	Sex	Differential Leukocyte Count (Number of Cells per Hundred) Monocytes Month: 3	6	9	12	18	24	Eosinophils Month: 3	6	9	12	18	24
Control	M	0.6	0.0	0.0	0.4	0.2	1.2	1.4	2.0	1.0	0.2	0.8	1.6
	F	0.6	0.0	0.0	0.0	0.2	1.0	1.0	1.8	1.4	0.2	0.6	1.6
100	M	0.2	0.0	0.0	0.4	0.0	0.8	0.6	0.4	1.4	1.4	1.0	2.0
	F	0.0	0.0	0.0	0.2	0.0	0.2	0.2	0.4	0.0	0.2	1.4	1.0

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TABLE VII continued

TEST MATERIAL: Aroclor 1242

Two-Year Chronic Oral Toxicity Study - Albino Rats

Hematologic Data

Summary of Mean Values

Dietary Level (ppm)	Sex	Differential Leukocyte Count (Number of Cells per Hundred) Basophils Month 3	6	9	12	18	24
Control	M	0.0	0.0	0.0	0.0	0.0	0.0
	F	0.0	0.0	0.0	0.0	0.0	0.0
100	M	0.0	0.0	0.0	0.0	0.0	0.0
	F	0.0	0.0	0.0	0.0	0.0	0.0

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TABLE VIII

TEST MATERIAL: Aroclor 1242

Two-Year Chronic Oral Toxicity Study - Albino Rats

Clinical Blood Chemistry Data

Summary of Mean Values

Dietary Level (ppm)	Sex	Serum Glutamic-Pyruvic Transaminase Activity (Dade Units) Month: 3	6	9	12	18	24	Blood Urea Nitrogen Concentration (mgs %) Month: 3	6	9	12	18	24
Control	M	38	48	45	45	31	36	17	15	12	10	14	15
	F	33	39	38	42	32	30	14	16	15	9	13	11
100	M	33	35	36	57	39	32	15	15	13	14	12	20
	F	39	41	53	40	52	46	17	14	14	11	11	14

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TABLE IX

TEST MATERIAL: Aroclor 1242

Two-Year Chronic Oral Toxicity Study - Albino Rats

Clinical Blood Chemistry Data

Summary of Mean Values

Dietary Level (ppm)	Sex	Fasted Blood Glucose Concentration (mgs %) Month: 3	6	9	12	18	24	Serum Alkaline Phosphatase Activity (King-Armstrong Units) Month: 3	6	9	12	18	24
Control	M	128	123	89	88	138	99	28.6	24.7	21.5	20.3	16.2	22.3
	F	130	118	115	92	134	109	18.9	17.8	10.6	11.9	16.8	20.2
100	M	121	123	129	145	125	115	26.4	23.2	17.4	25.8	16.7	13.2
	F	125	118	124	121	135	116	27.6	20.3	9.6	11.7	11.6	14.2

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E. Urine Analyses

Mean male and female urine analyses data are summarized in Tables X through XII.

No differences were noted between the urine from control and test animals at the intervals of examination.

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TABLE X

TEST MATERIAL: Aroclor 1242

Two-Year Chronic Oral Toxicity Study - Albino Rats

Urine Analyses Data

Summary of Mean Values

Dietary Level (ppm)	Sex	Glucose Month: 3	6	9	12	18	24	Albumin Month: 3	6	9	12	18	24
Control	M	n	n	n	n	n	n	n	n	t	t	+2	+3
	F	n	n	n	n	n	n	n	n	n	n	t	+2
100	M	n	n	n	n	n	n	n	n	t	t	+1	+4
	F	n	n	n	n	n	n	n	n	t	t	t	+3

Key:
n = negative
t = trace; less than 30 mg/100 ml urine
+1 = 30 to 100 mg/100 ml urine
+2 = 100 to 300 mg/100 ml urine
+3 = 300 to 500 mg/100 ml urine
+4 = more than 500 mg/100 ml urine

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TABLE XI

TEST MATERIAL: Aroclor 1242

Two-Year Chronic Oral Toxicity Study - Albino Rats

Urine Analyses Data

Summary of Mean Values

Dietary Level (ppm)	Sex	Microscopic Elements Month: 3	6	9	12	18	24	pH Month: 3	6	9	12	18	24
Control	M	N	N	N	N	N	+1	7	7	6	7	7	6
	F	N	N	N	N	t	t	8	8	7	8	6	6
100	M	N	N	N	N	N	t	7	7	7	8	6	6
	F	N	N	N	N	N	t	7	7	6	7	6	6

Key:
N= Normal
t = trace; less than 5 per low power field
+1 = 5 to 10 per low power field
+2 = 10 to 15 per low power field
+3 = more than 15 per low power field

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TABLE XII

TEST MATERIAL: Aroclor 1242

Two-Year Chronic Oral Toxicity Study - Albino Rats

Urine Analyses Data

Summary of Mean Values

Dietary Level (ppm)	Sex	Specific Gravity Month: 3	6	9	12	18	24
Control	M	1.029	1.022	1.033	1.027	1.042	1.051
	F	1.020	1.019	1.025	1.024	1.032	1.039
100	M	1.021	1.028	1.032	1.024	1.043	1.030
	F	1.022	1.019	1.029	1.029	1.027	1.038

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F. Pathologic Studies

1. Three-Month Sacrifice

a. Gross Pathologic Findings

Gross pathologic findings among test animals were not significantly different from those noted in control animals.

b. Organ Weight and Ratio Data

The mean organ weight and ratio data collected at the three-month sacrifice are presented in Tables XIII through XVIII.

Statistically significant differences are designated by asterisks following the test group value.

Organ weights, organ to body weight and organ to brain weight ratios disclosed several randomly occurring intergroup differences. The lack of any consistent dose related response and the absence of any deleterious histopathologic change confirm that these differences were not related to the ingestion of Aroclor 1242.

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TABLE XIII

TEST MATERIAL: Aroclor 1242

Two-Year Chronic Oral Toxicity Study - Albino Rats

Organ Weight and Ratio Data

Three-Month Sacrifice

Summary of Mean Values

Organ: Liver

Dietary Level of Aroclor 1242 (ppm)	Organ Weight (g)		Organ/Body Weight Ratio (g/100 g)		Organ/Brain Weight Ratio (g/g)	
	Males	Females	Males	Females	Males	Females
Control	21.4	13.0	4.13	4.16	10.3	6.82
1	22.3	12.4	4.31	3.92	10.6	6.59
10	23.3	14.4	4.41	4.31	11.9	7.93
100	25.5	14.0	4.80	4.39	15.1	7.65

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TABLE XIV

TEST MATERIAL: Aroclor 1242

Two-Year Chronic Oral Toxicity Study - Albino Rats

Organ Weight and Ratio Data

Three-Month Sacrifice

Summary of Mean Values

Organ: Kidneys

Dietary Level of Aroclor 1242 (ppm)	Organ Weight (g)		Organ/Body Weight Ratio (g/100 g)		Organ/Brain Weight Ratio (g/g)	
	Males	Females	Males	Females	Males	Females
Control	4.03	2.49	0.782	0.802	1.95	1.31
1	4.06	2.46	0.784	0.772	1.93	1.30
10	4.14	2.75	0.786	0.827	2.11	1.52
100	4.24	2.61	0.795	0.817	2.47	1.42

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TABLE XV

TEST MATERIAL: Aroclor 1242

Two-Year Chronic Oral Toxicity Study - Albino Rats

Organ Weight and Ratio Data

Three-Month Sacrifice

Summary of Mean Values

Organ: Spleen

Dietary Level of Aroclor 1242 (ppm)	Organ Weight (g)		Organ/Body Weight Ratio (g/100 g)		Organ/Brain Weight Ratio (g/g)	
	Males	Females	Males	Females	Males	Females
Control	0.766	0.578	0.150	0.184	0.371	0.302
1	0.768	0.544	0.148	0.171	0.364	0.287
10	0.756	0.596	0.143	0.179	0.385	0.328
100	0.814	0.528	0.154	0.166	0.468	0.288

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DSM 036152

STLCOPCB4019976

TABLE XVI

TEST MATERIAL: Aroclor 1242

Two-Year Chronic Oral Toxicity Study - Albino Rats

Organ Weight and Ratio Data

Three-Month Sacrifice

Summary of Mean Values

Organ: Gonads

Dietary Level of Aroclor 1242 (ppm)	Organ Weight (g)		Organ/Body Weight Ratio (g/100 g)		Organ/Brain Weight Ratio (g/g)	
	Males	Females	Males	Females	Males	Females
Control	3.60	0.114	0.698	0.0370	1.74	0.0599
1	3.51	0.143*	0.681	0.0452	1.66	0.0758
10	3.50	0.112	0.666	0.0336	1.78	0.0616
100	3.49	0.112	0.656	0.0356	2.06	0.0619

* Statistically significant difference at the 95 percent confidence level.

DSM 036153

STLCOPCB4019977

TABLE XVII

TEST MATERIAL: Aroclor 1242

Two-Year Chronic Oral Toxicity Study - Albino Rats

Organ Weight and Ratio Data

Three-Month Sacrifice

Summary of Mean Values

Organ: Heart

Dietary Level of Aroclor 1242 (ppm)	Organ Weight (g)		Organ/Body Weight Ratio (g/100 g)		Organ/Brain Weight Ratio (g/g)	
	Males	Females	Males	Females	Males	Females
Control	1.59	1.05	0.307	0.339	0.767	0.551
1	1.58	1.02	0.307	0.320	0.752	0.540
10	1.55	1.10	0.295	0.331	0.788.	0.608
100	1.61	1.05	0.302	0.330	0.943	0.573

DSM 036154

STLCOPCB4019978

TABLE XVIII

TEST MATERIAL: Aroclor 1242

Two-Year Chronic Oral Toxicity Study - Albino Rats

Organ Weight and Ratio Data

Three-Month Sacrifice

Summary of Mean Values

Organ: Brain

Dietary Level of Aroclor 1242 (ppm)	Organ Weight (g)		Organ/Body Weight Ratio (g/100 g)		Total Body Weights of Sacrificed Rats (g)	
	Males	Females	Males	Females	Males	Females
Control	2.07	1.91	0.402	0.616	518	314
1	2.12	1.89	0.410	0.597	520	318
10	1.97	1.81	0.375	0.545	527	334
100	1.82	1.83	0.345	0.576	534	319

DSM 036155

STLCOPCB4019979

c. Histopathologic Findings

Histopathologic examination of tissues and organs taken from all animals from both the control and 100 ppm groups was conducted.

Tables XIX and XX list all histopathologic changes noted.

All of the lesions noted in the microscopic examination of tissues were those of spontaneous disease and are not unusual for the albino rat. The most frequent findings were lesions in the trachea and lungs, indicating chronic murine pneumonia. These occurred in the control as well as the rats fed Aroclor 1242.

STLCOPCB4019980

TABLE XIX

TEST MATERIAL: Aroclor 1242

Two-Year Chronic Oral Toxicity Study - Albino Rats

Histopathologic Changes

Three-Month Sacrifice

Group: Control

Number of Animals	Organ Examined	Findings	Incidence	Average Grade
5 Males	Trachea	Tracheitis	1	1.0
	Lung	Chronic respiratory disease	1	1.0
	Urinary Bladder	Hyperplasia	3	1.0
5 Females	Lung	Chronic respiratory disease	1	1.0

All other tissues and organs were normal histologically.

Grading System

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

STLCOPCB4019981

TABLE XX

TEST MATERIAL: Aroclor 1242

Two-Year Chronic Oral Toxicity Study - Albino Rats

Histopathologic Changes

Three-Month Sacrifice

Group: 100 ppm

Number of Animals	Organ Examined	Findings	Incidence	Average Grade
5 Males	Trachea	Tracheitis	2	1.0
5 Females	Lung	Chronic respiratory disease	2	1.0
		Focal interstitial pneumonia	1	1.0

All other tissues and organs were normal histologically.

Grading System

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

DSW 036158

2. Six-Month Sacrifice

a. Gross Pathologic Findings

No outstanding differences were noted between test and control animals.

b. Organ Weight and Organ to Body and Organ to Brain Weight Ratio Data

The results of the statistical anlayses conducted on absolute organ weights, organ to body weight and organ to brain weight ratios are summarized in Tables XXI through XXVI.

Organ weights, organ to body weight and organ to brain weight ratios disclosed several randomly occurring intergroup differences. The lack of any consistent dose related response and the absence of any deleterious histopathologic change confirm that these differences were not related to the ingestion of Aroclor 1242.

STLCOPCB4019983

TABLE XXI

TEST MATERIAL: Aroclor 1242

Two-Year Chronic Oral Toxicity Study - Albino Rats

Organ Weight and Ratio Data

Six-Month Sacrifice

Summary of Mean Values

Organ: Liver

Dietary Level of Aroclor 1242 (ppm)	Organ Weight (g)		Organ/Body Weight Ratio (g/100 g)		Organ/Brain Weight Ratio (g/g)	
	Males	Females	Males	Females	Males	Females
Control	22.9	13.1	3.74	3.77	11.7	6.71
1	13.8**	9.98*	2.85**	3.15	6.86**	5.76
10	22.3	13.2	4.08	4.23	11.0	6.95
100	22.0	11.7	4.58*	3.70	10.8	5.94

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

DSW 036160

STLCOPCB4019984

TABLE XXII

TEST MATERIAL: Aroclor 1242

Two-Year Chronic Oral Toxicity Study - Albino Rats

Organ Weight and Ratio Data

Six-Month Sacrifice

Summary of Mean Values

Organ: Kidneys

Dietary Level of Aroclor 1242 (ppm)	Organ Weight (g)		Organ/Body Weight Ratio (g/100 g)		Organ/Brain Weight Ratio (g/g)	
	Males	Females	Males	Females	Males	Females
Control	4.04	2.79	0.664	0.806	2.06	1.43
1	3.51	2.44*	0.728	0.774	1.75	1.41
10	3.75	2.49*	0.686	0.790	1.86	1.31
100	3.54	2.33*	0.730	0.757	1.74	1.18

* Statistically significant difference at the 95 percent confidence level.

DSM 036161

STLCOPCB4019985

TABLE XXIII

TEST MATERIAL: Aroclor 1242

Two-Year Chronic Oral Toxicity Study - Albino Rats

Organ Weight and Ratio Data

Six-Month Sacrifice

Summary of Mean Values

Organ: Spleen

Dietary Level of Aroclor 1242 (ppm)	Organ Weight (g)		Organ/Body Weight Ratio (g/100 g)		Organ/Brain Weight Ratio (g/g)	
	Males	Females	Males	Females	Males	Females
Control	0.752	0.684	0.122	0.196	0.384	0.350
1	0.754	0.542*	0.154	0.172	0.375	0.313
10	0.796	0.622	0.142	0.199	0.394	0.327
100	0.584	0.488*	0.120	0.159	0.288	0.248

* Statistically significant difference at the 95 percent confidence level.

DSW 036162

STLCOPCB4019986

TABLE XXIV

TEST MATERIAL: Aroclor 1242

Two-Year Chronic Oral Toxicity Study - Albino Rats

Organ Weight and Ratio Data

Six-Month Sacrifice

Summary of Mean Values

Organ: Gonads

Dietary Level of Aroclor 1242 (ppm)	Organ Weight (g)		Organ/Body Weight Ratio (g/100 g)		Organ/Brain Weight Ratio (g/g)	
	Males	Females	Males	Females	Males	Females
Control	3.55	0.0960	0.593	0.0279	1.81	0.0492
1	3.44	0.0810	0.716	0.0253	1.71	0.0468
10	3.55	0.106	0.652	0.0335	1.76	0.0558
100	3.35	0.0772	0.697	0.0251	1.65	0.0392

DSM 036163

STLCOPCB4019987

TABLE XXV

TEST MATERIAL: Aroclor 1242

Two-Year Chronic Oral Toxicity Study - Albino Rats

Organ Weight and Ratio Data

Six-Month Sacrifice

Summary of Mean Values

Organ: Heart

Dietary Level of Aroclor 1242 (ppm)	Organ Weight (g)		Organ/Body Weight Ratio (g/100 g)		Organ/Brain Weight Ratio (g/g)	
	Males	Females	Males	Females	Males	Females
Control	1.70	1.05	0.282	0.302	0.867	0.538
1	1.49	1.03	0.309	0.325	0.741	0.595
10	1.46	1.06	0.267	0.335	0.722	0.558
100	1.42	0.970	0.293	0.314	0.700	0.492

DSW 036164

STLCOPCB4019988

TABLE XXVI

TEST MATERIAL: Aroclor 1242

Two-Year Chronic Oral Toxicity Study - Albino Rats

Organ Weight and Ratio Data

Six-Month Sacrifice

Summary of Mean Values

Organ: Brain

Dietary Level of Aroclor 1242 (ppm)	Organ Weight (g)		Organ/Body Weight Ratio (g/100 g)		Final Body Weights of Sacrificed Rats (g)	
	Males	Females	Males	Females	Males	Females
Control	1.96	1.95	0.320	0.560	613	348
1	2.01	1.73	0.415	0.546	484	317
10	2.02	1.90	0.369	0.597	548	318
100	2.03	1.97	0.416	0.635	488	310

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DSW 036165

STLCOPCB4019989

c. Histopathologic Findings

Histopathologic examination of tissues and organs taken from all animals from both the control and 100 ppm groups was conducted.

Tables XXVII and XXVIII list all histopathologic changes noted.

All of the lesions noted in the microscopic examination of tissues were those of spontaneous disease and are not unusual for the albino rat. The most frequent findings were lesions in the trachea and lungs, indicating chronic murine pneumonia. These occurred in the control as well as the rats fed Aroclor 1242.

STLCOPCB4019990

TABLE XXVII

TEST MATERIAL: Aroclor 1242

Two-Year Chronic Oral Toxicity Study - Albino Rats

Histopathologic Changes

Six-Month Sacrifice

Group: Control

Number of Animals	Organ Examined	Findings	Incidence	Average Grade
5 Males	Trachea	Tracheitis	2	1.5
		Focal tracheitis	2	1.0
	Lung	Focal pneumonitis	1	0.5
		Hyperemia	2	1.0
	Liver	Focal pericholangitis	1	1.0
	Skeletal Muscle	Focal inflammation	1	1.0
5 Females	Trachea	Focal tracheitis	1	1.0
	Lung	Hyperemia	2	2.5
	Liver	Hyperemia	1	1.0
		Pericholangitis	1	0.5
	Kidney	Focal pneumonitis	1	1.0

All other tissues and organs were normal histologically.

Grading System

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

STLCOPCB4019991

TABLE XXVIII

TEST MATERIAL: Aroclor 1242

Two-Year Chronic Oral Toxicity Study - Albino Rats

Histopathologic Changes

Six-Month Sacrifice

Group: 100 ppm

Number of Animals	Organ Examined	Findings	Incidence	Average Grade
5 Males	Trachea	Tracheitis	2	1.0
		Focal tracheitis	2	0.5
	Lung	Focal pneumonitis	3	1.5
		Hyperemia	2	1.0
5 Females	Trachea	Focal tracheitis	1	1.0
	Lung	Focal pneumonitis	1	0.5
		Hyperemia	1	2.0

All other tissues and organs were normal histologically.

Grading System

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

STLCOPCB4019992

3. Twelve-Month Sacrifice

a. Gross Pathologic Findings

Gross pathologic findings among test animals were not significantly different from those noted in control animals.

b. Organ Weight and Ratio Data

The mean organ weight and ratio data collected at the twelve-month sacrifice are presented in Tables XXIX through XXXIV.

Statistically significant differences are designated by asterisks following the test group value.

Organ weights, organ to body weight and organ to brain weight ratios disclosed several randomly occurring intergroup differences. The lack of any consistent dose related response and the absence of any deleterious histopathologic change confirm that these differences were not related to the ingestion of Aroclor 1242.

STLCOPCB4019993

TABLE XXIX

TEST MATERIAL: Aroclor 1242

Two-Year Chronic Oral Toxicity Study - Albino Rats

Twelve-Month Sacrifice

Organ Weight and Ratio Data

Summary of Mean Values

Organ: Liver

Dietary Level (ppm)	Organ Weight (g)		Organ/Body Weight Ratio (g/100 g)		Organ/Brain Weight Ratio (g/g)	
	Males	Females	Males	Females	Males	Females
Control	22.1	15.5	3.79	3.52	10.8	7.72
1	22.7	13.7	3.45	3.33	10.4	7.05
10	22.4	14.4	3.48	3.44	10.6	7.39
100	26.3	14.4	3.78	3.59	12.4	7.16

DSW 036170

STLCOPCB4019994

TABLE XXX

TEST MATERIAL: Aroclor 1242

Two-Year Chronic Oral Toxicity Study - Albino Rats

Twelve-Month Sacrifice

Organ Weight and Ratio Data

Summary of Mean Values

Organ: Kidneys

Dietary Level (ppm)	Organ Weight (g)		Organ/Body Weight Ratio (g/100 g)		Organ/Brain Weight Ratio (g/g)	
	Males	Females	Males	Females	Males	Females
Control	4.04	3.19	0.692	0.738	1.97	1.58
1	4.31	2.93	0.656	0.735	1.97	1.51
10	4.27	3.24	0.662	0.779	2.02	1.66
100	4.98*	3.01	0.716	0.745	2.33	1.50

* Statistically significant difference at the 95 percent confidence level.

DSM 036171

STLCOPCB4019995

TABLE XXXI

TEST MATERIAL: Aroclor 1242

Two-Year Chronic Oral Toxicity Study - Albino Rats

Twelve-Month Sacrifice

Organ Weight and Ratio Data

Summary of Mean Values

Organ: Spleen

Dietary Level (ppm)	Organ Weight (g)		Organ/Body Weight Ratio (g/100 g)		Organ/Brain Weight Ratio (g/g)	
	Males	Females	Males	Females	Males	Females
Control	0.788	0.796	0.133	0.183	0.380	0.396
1	1.000*	0.600	0.152	0.153	0.458	0.307
10	0.868	0.664	0.136	0.160	0.412	0.341
100	0.968	0.570	0.138	0.145	0.454	0.285

* Statistically significant difference at the 95 percent confidence level.

DSM 036172

STLCOPCB4019996

TABLE XXXII

TEST MATERIAL: Aroclor 1242

Two-Year Chronic Oral Toxicity Study - Albino Rats

Twelve-Month Sacrifice

Organ Weight and Ratio Data

Summary of Mean Values

Organ: Gonads

Dietary Level (ppm)	Organ Weight (g)		Organ/Body Weight Ratio (g/100 g)		Organ/Brain Weight Ratio (g/g)	
	Males	Females	Males	Females	Males	Females
Control	3.46	0.116	0.596	0.0275	1.70	0.0574
1	3.47	0.0938	0.529	0.0239	1.59	0.0483
10	3.00	0.141	0.457	0.0332	1.40	0.0719
100	3.67*	0.122	0.531	0.0305	1.72	0.0608

* Statistically significant difference at the 95 percent confidence level.

DSW 036173

STLCOPCB4019997

TABLE XXXIII

TEST MATERIAL: Aroclor 1242

Two-Year Chronic Oral Toxicity Study - Albino Rats

Twelve-Month Sacrifice

Organ Weight and Ratio Data

Summary of Mean Values

Organ: Heart

Dietary Level (ppm)	Organ Weight (g)		Organ/Body Weight Ratio (g/100 g)		Organ/Brain Weight Ratio (g/g)	
	Males	Females	Males	Females	Males	Females
Control	1.71	1.23	0.293	0.286	0.835	0.609
1	1.69	1.18	0.258	0.298	0.776	0.610
10	1.68	1.29	0.263	0.312	0.799	0.663
100	1.87	1.19	0.268	0.298	0.878	0.591

DSM 036174

STLCOPCB4019998

TABLE XXXIV

TEST MATERIAL: Aroclor 1242

Two-Year Chronic Oral Toxicity Study - Albino Rats

Twelve-Month Sacrifice

Organ Weight and Ratio Data

Summary of Mean Values

Organ: Brain

Dietary Level (ppm)	Organ Weight (g)		Organ/Body Weight Ratio (g/100 g)		Final Body Weight of Sacrificed Animals (grams)	
	Males	Females	Males	Females	Males	Females
Control	2.04	2.02	0.351	0.474	584	439
1	2.19	1.95	0.334	0.516	660	431
10	2.11	1.95	0.329	0.473	642	425
100	2.14	2.00	0.310	0.508	698*	409

* Statistically significant difference at the 95 percent confidence level.

DSM 036175
STLCOPCB4019999

c. Histopathologic Findings

Histopathologic examination of tissues taken from each rat sacrificed from the control and 100 ppm groups after twelve months of testing was conducted.

Tables XXXV and XXXVI list all histopathologic changes noted.

All of the lesions noted in the microscopic examination were those of spontaneous disease and cannot be related to the ingestion of Aroclor 1242.

STLCOPCB4020000

TABLE XXXV

TEST MATERIAL: Aroclor 1242

Two-Year Chronic Oral Toxicity Study - Albino Rats

Histopathologic Changes

Twelve-Month Sacrifice

Group: Control

Number of Animals	Organ Examined	Findings	Incidence	Average Grade
5 Males	Trachea	Tracheitis	1	1.0
	Lung	Chronic respiratory disease	2	1.0
	Urinary Bladder	Calculus	1	1.0
5 Females	Trachea	Tracheitis	1	1.0
	Lung	Chronic respiratory disease	1	1.0
	Colon	Parasites	1	1.0

All other tissues and organs were normal histologically.

Grading System

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

STLCOPCB4020001

DSW 036178

TABLE XXXVI

TEST MATERIAL: Aroclor 1242

Two-Year Chronic Oral Toxicity Study - Albino Rats

Histopathologic Changes

Twelve-Month Sacrifice

Group: 100 ppm

Number of Animals	Organ Examined	Findings	Incidence	Average Grade
5 Males	Trachea	Tracheitis	1	1.0
	Lung	Chronic respiratory disease	4	1.0
	Liver	Congestion	1	1.0
	Pancreas	Focal atrophy	1	1.0
	Kidney	Focal lymphoid infiltration	1	1.0
	Pituitary	Chromophobe hyperplasia	1	1.0
	Adrenal	Nodular hyperplasia	1	1.0
		Hematocyst	1	1.0
5 Females	Trachea	Tracheitis	1	1.0
	Lung	Chronic respiratory disease	1	1.0

All other tissues and organs were normal histologically.

Grading System

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

STLCOPCB4020003

4. Final Sacrifice

a. Gross Pathologic Findings

Gross pathologic findings among test animals were not significantly different from those noted in control animals.

b. Organ Weight and Ratio Data

The mean organ weight and ratio data collected at the final sacrifice are presented in Tables XXXVII through XLII. Statistically significant differences are designated by asterisks following the test group value.

The absolute liver weight and liver to body or brain weight ratios were significantly evaluated in female rats fed 100 ppm Arpclor 1242. Statistical evaluations 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 related response indicates that these differences were not related to the ingestion of Aroclor 1242.

STLCOPCB4020004

TABLE XXXVII

TEST MATERIAL: Aroclor 1242

Two-Year Chronic Oral Toxicity Study - Albino Rats

Organ Weight and Ratio Data

Summary of Mean Values

Final Sacrifice

Organ: Liver

etary Level (ppm)	Organ Weight (g)		Organ/Body Weight Ratio (g/100 g)		Organ/Brain Weight Ratio (g/g)	
	Males	Females	Males	Females	Males	Females
Control	22.0	16.3	3.47	3.05	10.10	8.42
1	21.9	15.7	2.93	3.00	9.97	8.03
10	22.3	17.1	3.18	3.19	10.20	8.50
100	25.6	22.4**	3.95	4.82**	11.90	11.60**

* Statistically significant difference at the 99 percent confidence level.

DSW 036181

STLCOPCB4020005

TABLE XXXVIII

TEST MATERIAL: Aroclor 1242

Two-Year Chronic Oral Toxicity Study - Albino Rats

Organ Weight and Ratio Data

Summary of Mean Values

Final Sacrifice

Organ: Kidneys

etary Level (ppm)	Organ Weight (g)		Organ/Body Weight Ratio (g/100 g)		Organ/Brain Weight Ratio (g/g)	
	Males	Females	Males	Females	Males	Females
Control	5.57	3.48	0.877	0.646	2.57	1.79
1	6.13	3.45	0.820	0.670	2.78	1.76
10	5.63	3.43	0.816	0.644	2.56	1.71
100	5.44	3.43	0.835	0.725	2.52	1.79

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DSM 036182

STLCOPCB4020006

TABLE XXXIX

TEST MATERIAL: Aroclor 1242

Two-Year Chronic Oral Toxicity Study - Albino Rats

Organ Weight and Ratio Data

Summary of Mean Values

Final Sacrifice

Organ: Spleen

etary Level (ppm)	Organ Weight (g)		Organ/Body Weight Ratio (g/100 g)		Organ/Brain Weight Ratio (g/g)	
	Males	Females	Males	Females	Males	Females
Control	1.15	0.96	0.182	0.181	0.520	0.492
1	1.26	0.81	0.169	0.158	0.572	0.145
10	1.08	0.82	0.158	0.153	0.495	0.409
100	1.07	0.65	0.165	0.140	0.499	0.339

STLCOPCB4020007

TABLE XL

TEST MATERIAL: Aroclor 1242

Two-Year Chronic Oral Toxicity Study - Albino Rats

Organ Weight and Ratio Data

Summary of Mean Values

Final Sacrifice

Organ: Gonads

etary Level (ppm)	Organ Weight (g)		Organ/Body Weight Ratio (g/100 g)		Organ/Brain Weight Ratio (g/g)	
	Males	Females	Males	Females	Males	Females
Control	2.52	0.123	0.397	0.0222	1.15	0.0628
1	3.20	0.102	0.424	0.0205	1.46	0.0523
10	3.00	0.126	0.437	0.0237	1.40	0.0625
100	3.31	0.129	0.514	0.0278	1.55	0.0671

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DSW 036184

STLCOPCB402008

TABLE XLI

TEST MATERIAL: Aroclor 1242

Two-Year Chronic Oral Toxicity Study - Albino Rats

Organ Weight and Ratio Data

Summary of Mean Values

Final Sacrifice

Organ: Heart

:tary Level (ppm)	Organ Weight (g)		Organ/Body Weight Ratio (g/100 g)		Organ/Brain Weight Ratio (g/g)	
	Males	Females	Males	Females	Males	Females
Control	1.87	1.54	0.294	0.288	0.860	0.795
1	2.30*	1.51	0.307	0.292	1.040**	0.770
10	2.08*	1.59	0.303	0.298	0.959*	0.788
100	2.19*	1.41	0.335	0.303	1.010**	0.741

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

DSW 036185

STLCOPCB4020009

TABLE XLII

TEST MATERIAL: Aroclor 1242

Two-Year Chronic Oral Toxicity Study - Albino Rats

Organ Weight and Ratio Data

Summary of Mean Values

Final Sacrifice

Organ: Brain

Dietary Level (ppm)	Organ Weight (g)		Organ/Body Weight Ratio (g/100 g)		Final Body Weight of Sacrificed Animals (grams)	
	Males	Females	Males	Female	Males	Females
Control	2.18	1.95	0.342	0.362	642	551
1	2.20	1.96	0.294	0.388	759	532
10	2.18	2.01	0.313	0.379	734	547
100	2.14	1.91	0.330	0.415	652	485

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DSM 036186

STLCOPCB4020010

c. Histopathologic Findings

Histopathologic examination of tissues and organs taken from all animals sacrificed after 24 months on test was conducted.

Tables XLIII through XLVI list all histopathologic changes noted. Table XLVII contains the results of the histopathologic examination of the urinary bladders.

Significant liver injury was found in animals fed 100 ppm Aroclor 1242 (T-III). The compound associated lesions consisted of vacuolar change, focal hypertrophy and focal hyperplasia. In addition, there were lesions of inflammation, necrosis, fibrosis and minor degeneration in this group which, although seen in the controls and lower test groups, were more severe and frequent in the T-III group.

The vacuolar change was not seen in the control animals but was observed occasionally in liver from T-I (1 ppm) and T-II (10 ppm) animals. The vacuolar change was observed frequently in the T-III animals. This lesion is morphologically indicative of fatty degeneration. Formalin-frozen sections of livers from representative animals which displayed vacuolar changes were stained with Oil Red O to reveal the presence of fat. The vacuolar lesion in the cytoplasm of these cells was positively identified as fat.

The hypertrophic change found in the liver was focal and often limited to the central lobular area where groups of cells were swollen to two or three times their normal size with clear pink homogeneous cytoplasm.

STLCOPCB4020011

The hyperplasia was associated with the same cells and appeared to be an extension of the hypertrophic lesion. The hyperplastic cells were also usually hypertrophic. The most severe examples of hyperplasia appeared as nodular growths with limited compression of the surrounding normal hepatic tissue.

The minor lesions of degeneration, hepatitis, ductule cell proliferation, necrosis and focal lymphoid infiltration seen in the control animals and the T-I and T-II groups are lesions of spontaneous disease and are not related to the Aroclor 1242. This level of liver disease is not unusual in old animals.

Hyperplasia of the transitional epithelium was present in the urinary bladder of animals from the control group and from each of the test groups. This lesion was usually associated with cystitis.

All of the other lesions in the other tissues found in these animals are related to spontaneous disease and they are not unusual for rats of this age.

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DSW 036188

TABLE XLIII

TEST MATERIAL: Aroclor 1242

Two-Year Chronic Oral Toxicity Study - Albino Rats

Histopathologic Changes

Final Sacrifice

Group: Control

Number of Animals	Organ Examined	Findings	Incidence	Average Grade
11 Males	Heart	Chronic focal myocarditis	3	1.0
	Trachea	Tracheitis	3	1.0
	Lung	Chronic respiratory disease	9	1.0
	Liver	Focal degeneration	1	1.0
		Ductile hyperplasia	2	1.0
	Stomach	Chronic gastritis	1	1.0
	Spleen	Hemosiderosis	3	1.0
	Kidney	Chronic nephritis	8	1.0
	Testes	Testicular degeneration	2	1.0
		Periarteritis	2	1.0
	Prostate	Inflammation	1	1.0
	Adrenal Gland	Telangiectasis	1	1.0
		Nodular hyperplasia	1	1.0
		Focal fatty change	1	1.0
	Brain	Focal encephalitis	1	1.0
	Eye	Inflammation	2	1.0

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TABLE XLIII continued

TEST MATERIAL: Aroclor 1242

Two-Year Chronic Oral Toxicity Study - Albino Rats

Histopathologic Changes

Final Sacrifice

Group: Control

Number of Animals	Organ Examined	Findings	Incidence	Average Grade
14 Females	Heart	Chronic focal myocarditis	7	2.0
	Trachea	Tracheitis	9	1.0
	Lung	Chronic respiratory disease	13	1.0
	Liver	Focal lymphoid infiltration	3	1.0
		Ductile hyperplasia	2	1.0
		Focal hepatitis	1	1.0
		Non-lipid vacuolar change	2	0.5
	Stomach	Chronic gastritis	3	1.0
		Acanthosis - squamous epithelium	5	1.0
	Colon	Parasites	1	1.0
	Spleen	Hemosiderosis	4	1.0
	Uterus	Metritis	3	2.0
	Kidney	Chronic nephritis	6	1.0
		Focal lymphoid infiltration	1	1.0
	Ovary	Cyst	1	1.0

DSM 036190

STLCOPCB4020014

TABLE XLIII continued

TEST MATERIAL: Aroclor 1242

Two-Year Chronic Oral Toxicity Study - Albino Rats

Histopathologic Changes

Final Sacrifice

Group: Control

Number of Animals	Organ Examined	Findings	Incidence	Average Grade
14 Females	Adrenal Gland	Telangiectasis	9	1.0
		Nodular hyperplasia	4	1.0
	Salivary Gland	Chronic fibrosis and atrophy	1	1.0

All other tissues and organs were normal histologically.

Grading System

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

DSW 036191

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STLCOPCB402015

TABLE XLIV

TEST MATERIAL: Aroclor 1242

Two-Year Chronic Oral Toxicity Study - Albino Rats

Histopathologic Changes

Final Sacrifice

Group: 1 ppm

Number of Animals	Organ Examined	Findings	Incidence	Average Grade
13 Males	Heart	Chronic focal myocarditis	5	1.0
	Trachea	Tracheitis	9	2.0
	Lung	Chronic respiratory disease	12	1.0
	Liver	Focal lymphoid infiltration	1	1.0
		Cirrhosis	1	1.0
		Congestion	1	1.0
	Stomach	Chronic gastritis and acanthosis	2	1.0
	Spleen	Hemosiderosis	4	2.0
	Kidney	Chronic nephritis	9	2.0
		Calcification	1	1.0
	Testes	Periarteritis	2	2.0
		Testicular degeneration	1	1.0
	Prostate	Inflammation	1	4.0
	Adrenal Gland	Telangiectasis	2	1.0
		Nodular hyperplasia	1	2.0

DSM 036192

STLCOPCB4020016

TABLE XLIV continued

TEST MATERIAL: Aroclor 1242

Two-Year Chronic Oral Toxicity Study - Albino Rats

Histopathologic Changes

Final Sacrifice

Group: 1 ppm

Number of Animals	Organ Examined	Findings	Incidence	Average Grade
14 Females	Heart	Chronci focal myocarditis	6	1.0
	Trachea	Tracheitis	7	1.0
	Lung	Chronic respiratory disease	13	1.0
	Liver	Ductile hyperplasia	3	1.0
	Pancreas	Chronic focal pancreatitis	2	1.0
	Stomach	Chronic gastritis	2	1.0
		Ulcerative gastritis	1	1.0
		Acanthosis	2	1.0
	Spleen	Hemosiderosis	8	2.0
	Kidney	Chronic nephritis	6	1.0
	Uterus	Metritis	1	1.0
	Adrenal Gland	Telangiectasis	10	1.0

DSW 036193

All other tissues and organs were normal histologically.

Grading System

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

STLCOPCB4020017

TABLE XLV

TEST MATERIAL: Aroclor 1242

Two-Year Chronic Oral Toxicity Study - Albino Rats

Histopathologic Changes

Final Sacrifice

Group: 10 ppm

Number of Animals	Organ Examined	Findings	Incidence	Average Grade
13 Males	Heart	Chronic focal myocarditis	6	1.0
	Trachea	Tracheitis	7	1.0
	Lung	Chronic respiratory disease	9	2.0
	Liver	Focal hypertrophy and hyperplasia	1	1.0
		Hypertrophy	1	1.0
		Vacuolar change (fatty)	2	1.0
		Ductile hyperplasia	1	2.0
	Pancreas	Chronic focal pancreatits	3	1.0
	Stomach	Acanthosis	6	1.0
		Inflammation, ulceration and necrosis	1	1.0
	Spleen	Hemosiderosis	7	1.0
	Kidney	Chronic nephritis	10	2.0
	Testes	Testicular degeneration	2	3.0
		Periarteritis	3	3.0

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DSM 036194

STLCOPCB402018

TABLE XLV continued

TEST MATERIAL: Aroclor 1242

Two-Year Chronic Oral Toxicity Study - Albino Rats

Histopathologic Changes

Final Sacrifice

Group: 10 ppm

Number of Animals	Organ Examined	Findings	Incidence	Average Grade
13 Males	Prostate	Inflammation	2	3.0
	Adrenal Gland	Telangiectasis	4	1.0
		Medullary hyperplasia	1	1.0
		Nodular hyperplasia	2	1.0
13 Females	Heart	Chronic focal myocarditis	1	1.0
	Trachea	Tracheitis	5	1.0
	Lung	Chronic respiratory disease	9	1.0
	Tongue	Periarteritis	1	2.0
	Stomach	Chronic gastritis and acanthosis	5	1.0
		Ulceration	1	1.0
	Spleen	Hemosiderosis	5	2.0
	Lymph Node	Edema	1	1.0
	Kidney	Chronic nephritis	6	1.0
	Uterus	Metritis	2	1.0
	Adrenal Gland	Telangiectasis	8	1.0
		Nodular hyperplasia	1	1.0

All other tissues and organs were normal histologically.

Grading System

0.5 = minimal 2.0 = mild 4.0 = severe

5.0 = extreme

DSW 036195

STLCOPCB4020019

TABLE XLVI

TEST MATERIAL: Aroclor 1242

Two-Year Chronic Oral Toxicity Study - Albino Rats

Histopathologic Changes

Final Sacrifice

Group: 100 ppm

Number of Animals	Organ Examined	Findings	Incidence	Average Grade
6 Males	Heart	Chronic focal myocarditis	3	1.0
	Trachea	Tracheitis	3	2.0
	Lung	Chronic respiratory disease	6	1.0
	Liver	Focal degeneration	1	1.0
		Focal hypertrophy	1	1.0
		Hypertrophy	1	1.0
		Vacuolar change (fatty)	3	1.0
	Pancreas	Periarteritis	1	3.0
	Testes	Periarteritis	3	2.0
	Stomach	Chronic gastritis and acanthosis	1	1.0
		Periarteritis	1	2.0
	Spleen	Hemosiderosis	1	1.0
	Lymph Node	Periarteritis	1	3.0
	Kidney	Chronic nephritis	4	2.0

DSM 036196

STLCOPCB4020020

TABLE XLVI continued

TEST MATERIAL: Aroclor 1242

Two-Year Chronic Oral Toxicity Study - Albino Rats

Histopathologic Changes

Final Sacrifice

Group: 100 ppm

Number of Animals	Organ Examined	Findings	Incidence	Average Grade
6 Males	Prostate	Inflammation	1	3.0
	Adrenal Gland	Focal fatty change	1	1.0
	Salivary Gland	Focal chronic inflammation	1	1.0
	Eye	Inflammation	1	1.0
14 Females	Heart	Chronic focal myocarditis	4	1.0
	Trachea	Tracheitis	8	1.0
	Lung	Chronic respiratory disease	6	1.0
	Liver	Focal degeneration	3	1.0
		Focal hyperplasia	2	1.0
		Focal hypertrophy	2	1.0
		Hypertrophy	3	2.0
		Nodular hyperplasia	1	1.0
		Focal cholangiohepatitis	1	1.0

DSM 036197

STLCOPCB4020021

TABLE XLVI continued

TEST MATERIAL: Aroclor 1242

Two-Year Chronic Oral Toxicity Study - Albino Rats

Histopathologic Changes

Final Sacrifice

Group: 100 ppm

Number of Animals	Organ Examined	Findings	Incidence	Average Grade
14 Females	Liver (continued)	Focal hepatitis	1	1.0
		Hyperplasia	1	3.0
		Vacuolar change (fatty)	11	1.0
	Pancreas	Chronic focal pancreatitis	1	1.0
	Stomach	Chronic gastritis	2	1.0
		Acanthosis	2	1.0
		Ulcerative gastritis	1	1.0
		Ulcer	1	1.0
	Spleen	Hemosiderosis	4	2.0
	Lymph Node	Congestion	1	1.0
	Kidney	Chronic nephritis	7	1.0
	Uterus	Metritis	2	1.0
	Adrenal Gland	Telangiectasis	8	1.0
		Nodular hyperplasia	4	1.0
		Acanthosis	1	1.0

All other tissues and organs were normal histologically.

Grading System

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

DSM 036198

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TABLE XLVII

TEST MATERIAL: Aroclor 1242

Two-Year Chronic Oral Toxicity Study - Albino Rats

Histopathologic Changes of the Urinary Bladder

Final Sacrifice

Group	Sex	Number Examined	Findings*	Incidence	Average Grade
C	M	11	Proteinaceous plug (34)	1	-
	F	14	Focal epithelial hyperplasia (62)	1	1
T-I (1 ppm)	M	12	Proteinaceous plug (582)	1	-
			Diffuse epithelial hyperplasia associated with diffuse cystitis (566)	1	2
			Diffuse epithelial hyperplasia associated with diffuse cystitis (580)	1	1
	F	13	None	-	-
T-II (10 ppm)	M	11	Diffuse epithelial hyperplasia associated with diffuse cystitis (651)	1	3
			Diffuse epithelial hyperplasia associated with diffuse cystitis and a proteinaceous plug (655)	1	1
	F	13	None	-	-
T-III (100 ppm)	M	6	Proteinaceous plug (744)	1	-
	F	13	Focal epithelial hyperplasia (767)	1	2

* Individual animal numbers are shown in parentheses.

Grading System

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

DSM 036199

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G. Detailed Description of Tumor Findings

Tumor data for individual animals including location, weight and pathologic classification are presented in Table XLVIII through LI.

None of these tumors could be related to the ingestion of Aroclor 1242 and are considered normal for a random population of rats this age.

STLCOPCB4020024

TABLE XLVIII

TEST MATERIAL: Aroclor 1242

Two-Year Chronic Oral Toxicity Study - Albino Rats

Description of Tumor Findings

Group: Control

Animal Number and Sex	Location	Weight (grams)	Size (cm)	Classification	Months on Test
1-M	Abdomen	-	-	Mammary fibroadenoma	24
2-M	Pancreas	11.76	-	Adenocarcinoma	24
6-F	Abdomen	64.98 35.09	8 x 1 x 2 5 x 2 x 2	Mammary fibroadenoma Mammary fibroadenoma	24
47-F	Lymph node	-	-	Reticulum cell sarcoma	24
48-F	Abdomen	-	2 x 2 x 1	Mammary fibroadenoma	24
50-F	Abdomen	-	2 x 2 x 3	Mammary fibroadenoma	7
52-F	Abdomen	-	-	Mammary fibroadenoma	24
59-F	Abdomen Adrenal gland	- -	- -	Mammary fibroadenoma Pheochromocytoma	24
64-F	Abdomen	88.92	13 x 11 x 4	Fibroadenoma	24
66-F	Abdomen	230.00	13 x 11 x 4	Mammary adenoma	24

DSW 036201

STLCOPCB4020025

TABLE XLIX

TEST MATERIAL: Aroclor 1242

Two-Year Chronic Oral Toxicity Study - Albino Rats

Description of Tumor Findings

Group: 1 ppm

Animal Number and Sex	Location	Weight (grams)	Size (cm)	Classification	Months on Test
566-M	Abdomen	-	-	Adenocarcinoma	24
569-M	Spleen	-	-	Lymphosarcoma	22
604-F	Abdomen	-	-	Mammary fibroadenoma	24
609-F	Abdomen	15.00	5 x 3 x 1	Fibroadenoma	24
611-F	Abdomen	53.50 35.00	5 x 3 x 1 1 x 1 x 1	Fibroadenoma Fibroadenoma	24
613-F	Ovary Abdomen	- -	3 x 2 x 1 -	Granulosa cell tumor Fibroadenoma	24
615-F	Abdomen	335.00	13 x 10 x 5	Mammary fibroadenoma	23

DSW 03620

STLCOPCB4020026

TABLE XLIX continued

TEST MATERIAL: Aroclor 1242

Two-Year Chronic Oral Toxicity Study - Albino Rats

Description of Tumor Findings

Group: 1 ppm

Animal Number and Sex	Location	Weight (grams)	Size (cm)	Classification	Months on Test
621-F	Abdomen	18.00	1 x 3 x 3	Fibroadenoma	24
627-F	Pituitary	-	-	Chromophobe adenoma	24
628-F	Abdomen	-	6 x 3 x 3	Fibroadenoma	24
630-M	Abdomen	157.20	9 x 6 x 4	Mammary fibroadenoma	23
		117.90	7 x 6 x 2	Mammary fibroadenoma	
631-F	Uterus	-	3 x 2 x 1	Fibroma	24
	Abdomen	44.00	-	Fibroadenoma	
634-F	Abdomen	13.41	6 x 5 x 3	Fibroadenoma	24
635-F	Abdomen	39.36	6 x 5 x 4	Fibroadenoma	24
	Pituitary	-	-	Chromophobe adenoma	

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DSW 036203

STLCOPCB4020027

TABLE L

TEST MATERIAL: Aroclor 1242

Two-Year Chronic Oral Toxicity Study - Albino Rats

Description of Tumor Findings

Group: 10 ppm

Animal Number and Sex	Location	Weight (grams)	Size (cm)	Classification	Months on Test
640-M	Abdomen	129.0	9 x 7 x 3	Fibroadenoma	24
646-M	Pancreas	-	-	Islet cell adenoma	24
	Adrenal gland	-	-	Medullary tumor	
662-M	Pituitary	-	-	Chromophobe adenoma	24
	Abdomen	280.0	-	Mammary fibroadenoma	22
687-F	Pituitary	-	-	Chromophobe adenoma	24
689-F	Abdomen	-	-	Mammary adenocarcinoma	24
690-F	Pituitary	-	-	Chromophobe adenoma	24
695-F	Abdomen	3.90	3 x 3 x 2	Mammary fibroadenoma	24
	Abdomen	23.15	7 x 6 x 3	Mammary fibroadenoma	
697-F	Abdomen	175.0	8 x 7 x 5	Mammary fibroadenoma	24
703-F	Parathyroid gland	-	-	Adenoma	24

DSW 036204

STLCOPCB4020028

TABLE L continued

TEST MATERIAL: Aroclor 1242

Two-Year Chronic Oral Toxicity Study - Albino Rats

Description of Tumor Findings

Group: 10 ppm

Animal Number and Sex	Location	Weight (grams)	Size (cm)	Classification	Months on Test
707-F	Abdomen	74.6	7 x 6 x 3	Mammary fibroadenoma	24
708-F	Abdomen	189.0	5 x 4 x 1	Mammary fibroadenoma	24
711-F	Abdomen	6.96	3 x 2 x 1	Mammary fibroadenoma	24
712-F	Subcutaneous, abdominal	155.0	11 x 8 x 3	Fatty tissue fibroma	24

DSW 036205
STLCOPCB4020029

TABLE LI

TEST MATERIAL: Aroclor 1242

Two-Year Chronic Oral Toxicity Study - Albino Rats

Description of Tumor Findings

Group: 100 ppm

Animal Number and Sex	Location	Weight (grams)	Size (cm)	Classification	Months on Test
744-M	Pancreas	-	-	Islet cell adenoma	24
775-F	Ovary	-	-	Granulosa cell tumor	24
785-F	Pituitary	-	-	Chromophobe adenoma	24
789-F	Adrenal gland	-	-	Medullary tumor	24
794-F	Abdomen	260.0	10 x 10 x 5	Mammary fibroadenoma	23

DSW 036206

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