

REPORT TO
MONSANTO COMPANY

TWO-YEAR CHRONIC ORAL TOXICITY WITH
AROCLOL 1260
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 1260, Lot No. AK-3. 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 1260.

Food consumption and body weight gains were not altered at any level of Aroclor 1260 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 effects related to Aroclor 1260. 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 1260.

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 the rats 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 1260.

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Hyperplasia of the urinary bladder was found in an animal from the control group but not in any of the test animals.

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 males and 200 females) 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, dose 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 1260

Two-Year Chronic Oral Toxicity Study - Albino Rats

Outline of Experiment

Group	Number of Animals		Dietary Level (ppm)
	Male	Female	
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 1260 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 concentrations, hemotocrit value, erythrocyte count and both total and differential

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

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.

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.

L 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.

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 due to ingestion of the compound

TABLE II

TEST MATERIAL: Aroclor 1260

Two-Year Chronic Oral Toxicity Study - Albino Rats

Body Weight and Total Weight Gain Data

Summary of Mean Values

Dietary Level of Aroclor 1260 (ppm)	Sex	Body Weight (grams) Week:														90-Day Total Weight Gain (grams/rat)
		0	1	2	3	4	5	6	7	8	9	10	11	12	13	
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	192	250	322	361	374	394	416	428	448	450	474	479	490	357
	F	136	167	189	218	241	252	256	261	268	273	277	281	290	288	152
10	M	133	204	245	317	368	382	400	417	436	448	461	467	475	481	348
	F	136	174	190	217	242	254	260	263	268	274	281	279	285	288	152
100	M	133	208	247	319	363	375	394	425	437	451	460	479	486	500	367
	F	136	173	188	222	240	253	258	262	265	267	270	275	275	280	144

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TABLE II continued

TEST MATERIAL: Aroclor 1260

Two-Year Chronic Oral Toxicity Study - Albino Rats

Body Weight and Total Weight Gain Data

Summary of Mean Values

Dietary Level of Aroclor 1260 (ppm)	Sex	Body Weight (grams) Month:									12-Month Total Weight Gain (grams/rat)
		4	5	6	7	8	9	10	11	12	
Control	M	498	533	565	593	622	642	667	688	701	568
	F	297	310	322	333	345	359	374	383	390	254
1	M	516	547	578	600	628	643	668	688	699	566
	F	298	307	314	321	333	340	353	367	379	243
10	M	496	526	551	581	606	633	660	685	709	576
	F	291	306	314	331	340	358	370	381	388	252
100	M	522	555	580	607	633	650	681	707	717	584
	F	289	302	307	314	326	333	342	347	363	227

TABLE II continued

TEST MATERIAL: Aroclor 1260

Two-Year Chronic Oral Toxicity Study - Albino Rats

Body Weight and Total Weight Gain Data

Summary of Mean Values

Dietary Level of Aroclor 1260 (ppm)	Sex	Body Weight (grams) Month:												24-Month Total Weight Gain (grams/rat)
		13	14	15	16	17	18	19	20	21	22	23	24	
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	721	740	760	768	776	774	762	753	733	718	715	654	521
	F	390	427	466	433	445	476	481	493	514	530	484	525	385
10	M	728	745	776	761	768	780	774	761	735	715	683	645	512
	F	416	434	482	449	473	508	519	530	536	542	536	584	448
100	M	746	760	772	775	774	769	760	750	733	714	711	641	508
	F	380	386	417	414	435	453	471	481	500	507	485	537	401

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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 II.

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 1260

Two-Year Chronic Oral Toxicity Study - Albino Rats

Food Consumption Data

Summary of Mean Values

Dietary Level of Aroclor 1260 (ppm)	Sex	Food Consumption (grams/rat/seven days)													Average Food Consumption (grams/rat/seven days)
		1	2	3	4	5	6	7	8	9	10	11	12	13	
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	118	154	151	169	201	116	200	198	201	193	189	187	194	175
	F	95	118	97	139	160	107	162	139	165	149	150	143	147	136
10	M	106	146	144	142	190	136	196	214	214	192	191	199	200	175
	F	94	124	128	124	179	90	190	167	155	151	150	149	152	143
100	M	121	150	156	117	187	124	121	190	196	186	184	199	189	163
	F	89	93	123	151	151	101	193	136	140	144	144	147	146	135

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TABLE III continued

TEST MATERIAL: Aroclor 1260

Two-Year Chronic Oral Toxicity Study - Albino Rats

Food Consumption Data

Summary of Mean Values

Dietary Level of Aroclor 1260 (ppm)	Sex	Food Consumption (grams/rat/seven days) Month:										Average Food Consumption (grams/rat/seven days)
		4	5	6	7	8	9	10	11	12		
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	196	200	189	192	179	181	182	172	184	186	
	F	148	163	141	163	160	153	157	143	132	151	
10	M	186	191	188	193	197	197	168	164	196	186	
	F	142	138	145	144	144	151	136	139	141	142	
100	M	179	170	180	188	186	166	181	188	180	180	
	F	156	127	147	144	134	132	162	149	139	143	

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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 1260

Two-Year Chronic Oral Toxicity Study - Albino Rats

Mortality Data

Frequency Distribution of Deaths

Dietary Level (ppm)	Sex	Frequency Distribution of Deaths Months:								Total Dead Number Tested
		1-3	4-6	7-9	10-12	13-15	16-18	19-21	22-24	
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	0	0	1	1	4	7	5	8	26/35
	F	0	0	0	2	3	3	6	5	19/35
10	M	1	1	0	2	4	7	8	6	29/35
	F	0	0	0	3	2	4	5	3	17/35
100	M	1	0	0	2	2	8	6	9	29/35
	F	0	2	2	0	3	5	7	4	23/35

* 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 1260

Two-Year Chronic Oral Toxicity Study - Albino Rats

Hematologic Data

Summary of Mean Values

Dietary Level (ppm)	Sex	Total Leukocyte Count (thousands/mm ³)						Erythrocyte Count (millions/mm ³)					
		Month:						Month:					
		3	6	9	12	18	24	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	10.8	13.1	7.9	12.8	8.6	8.4	7.5	8.1	8.0	7.6	8.0	7.6
	F	13.2	8.2	7.9	6.5	7.8	7.4	7.3	7.5	7.3	7.5	7.4	6.4

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TABLE VI

TEST MATERIAL: Aroclor 1260

Two-Year Chronic Oral Toxicity Study - Albino Rats

Hematologic Data

Summary of Mean Values

Dietary Level (ppm)	Sex	Hemoglobin Concentration (g/100 ml)						Hematocrit Value (%)					
		Month:						Month:					
		3	6	9	12	18	24	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	16.1	17.2	14.0	15.3	15.9	14.5	49	47	43	43	41	38
	F	16.3	17.0	13.7	15.6	15.3	12.9	48	47	41	44	39	32

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TABLE VII

TEST MATERIAL: Aroclor 1260

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:						Neutrophils Month:					
		3	6	9	12	18	24	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	85.8	85.4	83.4	72.4	73.8	66.6	12.6	13.8	15.8	22.6	24.6	31.6
	F	92.0	89.6	78.8	82.2	80.6	65.6	7.6	10.0	19.4	17.0	17.4	34.2

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TABLE VII continued

TEST MATERIAL: Aroclor 1260

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						Eosinophils					
		3	6	9	12	18	24	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	0.0	0.0	0.0	0.0	0.4	0.8	1.4	0.8	0.8	1.0	1.2	1.0
	F	0.0	0.0	0.0	0.0	0.4	0.2	0.4	0.4	0.8	0.8	1.6	0.0

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TABLE VII continued

TEST MATERIAL: Aroclor 1260

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	0.2	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 1260

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:						Blood Urea Nitrogen Concentration (mgs %) Month:					
		3	6	9	12	18	24	3	6	9	12	18	24
Control	M	38	48	45	45	42	36	17	15	12	10	14	15
	F	33	39	38	42	32	30	14	16	15	9	13	11
100	M	33	39	42	43	31	36	14	15	17	16	16	15
	F	29	37	50	40	32	33	15	15	14	13	12	14

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TABLE IX

TEST MATERIAL: Aroclor 1260

Two-Year Chronic Oral Toxicity Study - Albino Rats

Clinical Blood Chemistry Data

Summary of Mean Values

Dietary Level (ppm)	Sex	Fasted Blood Glucose Concentration (mg%) Month:						Serum Alkaline Phosphatase Activity (King-Armstrong Units) Month:					
		3	6	9	12	18	24	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	118	118	116	135	146	98	37.8	21.8	21.9	23.9	11.9	16.1
	F	117	116	115	138	146	94	12.0	12.1	7.6	11.7	7.8	12.4

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E. Urine Analyses

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

Determinations for glucose concentration were negative for all rats at every interval of examination.

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 1260

Two-Year Chronic Oral Toxicity Study - Albino Rats

Urine Analyses Data

Summary of Mean Values

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

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 1260

Two-Year Chronic Oral Toxicity Study - Albino Rats

Urine Analyses Data

Summary of Mean Values

Dietary Level (ppm)	Sex	Microscopic Elements						pH					
		3	6	9	12	18	24	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	6	7	6	6
	F	N	N	N	N	t	t	7	8	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 1260
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	1.025	1.031	1.030	1.043	1.039
	F	1.016	1.023	1.035	1.029	1.028	1.045

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F. Pathologic Studies**1. Three-Month Sacrifice****a. Gross Pathologic Findings**

No outstanding differences were noted between test and control rats upon gross pathological examination.

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

The results of the statistical analyses conducted on absolute organ weights, organ to body weight and organ to brain weight ratios are summarized in Tables XIII through XVIII.

Significant differences between a test group and the control group are designated by asterisks following the test values.

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 1260.

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TABLE XIII

TEST MATERIAL: Aroclor 1260

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 1260 (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	20.4	13.2	3.90	4.59	9.98	6.86
10	24.0**	12.2	4.48	3.61	11.8	6.38
100	29.5**	14.5	5.73**	4.58	14.4**	7.72

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

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TABLE XIV

TEST MATERIAL: Aroclor 1260

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 1260 (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	4.37	2.62	0.838	0.911	2.14	1.36
10	4.00	2.61	0.747	0.782	1.96	1.37
100	4.00	2.52	0.779	0.793	1.96	1.35

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TABLE XV

TEST MATERIAL: Aroclor 1260

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 1260 (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	0.846	0.516	0.161	0.180	0.412	0.269
10	0.838	0.632	0.156	0.189	0.411	0.331
100	0.718	0.556	0.140	0.177	0.352	0.297

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TABLE XVI

TEST MATERIAL: Aroclor 1260

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 1260 (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	3.67	0.128	0.704	0.0450	1.80	0.0666
10	3.83	0.121	0.715	0.0368	1.89	0.0636
100	3.71	0.138	0.725	0.0429	1.81	0.0728

HM917

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ADM 00375

TABLE XVII

TEST MATERIAL: Aroclor 1260

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 1260 (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	1.57	1.01	0.300	0.353	0.765	0.526
10	1.58	1.04	0.296	0.311	0.781	0.546
100	1.52	0.946	0.298	0.297	0.743	0.505

FORM 178

ADN 00375

31-1 TEST MATERIALS, Inc.

TABLE XVIII
TEST MATERIAL: Aroclor 1260
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 1260 (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	2.07	1.91	0.402	0.616	518	314
1	2.05	1.92	0.392	0.672	523	287
10	2.04	1.91	0.380	0.572	536	337
100	2.05	1.89	0.400	0.593	517	321

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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 1260.

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TABLE XIX

TEST MATERIAL: Aroclor 1260

Two-Year Chronic Oral Toxicity Study - Albino Rats

Histopathologic Changes

Three-Month Sacrifices

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

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TABLE XX

TEST MATERIAL: Aroclor 1260

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	4	1.0
	Lung	Chronic respiratory disease	2	1.0
5 Females	Trachea	Tracheitis	3	1.0
	Lung	Chronic respiratory disease	2	1.0
	Kidney	Focal lymphoid infiltration	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

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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 analyses 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 1260.

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TABLE XXI

TEST MATERIAL: Aroclor 1260

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 1260 (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	14.8**	15.1	2.92**	3.74	7.05**	7.86
10	19.0*	10.5**	3.31*	3.08*	9.45*	6.07
100	24.4	11.6	4.69*	4.03	12.3	6.17

* Statistically significant difference at the 95 percent confidence level.

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

FORM 92A

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TABLE XXII

TEST MATERIAL: Aroclor 1260

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 1260 (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	3.64	2.73	0.716	0.674*	1.73	1.42
10	3.85	2.35	0.670	0.684*	1.92	1.36
100	3.92	2.35	0.753	0.814	1.97	1.25

* Statistically significant difference at the 95 percent confidence level.

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TABLE XXIII

TEST MATERIAL: Aroclor 1260

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 1260 (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	0.908	0.148*	0.220	0.359	0.472
10	0.836	0.566*	0.146*	0.167	0.416	0.327
100	0.636	0.443*	0.122	0.151	0.320	0.236*

* Statistically significant difference at the 95 percent confidence level.

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TABLE XXIV

TEST MATERIAL: Aroclor 1260

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 1260 (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	3.23	0.120*	0.636	0.0297	1.54	0.0625*
10	3.56	0.0968	0.620	0.0287	1.77	0.0560
100	3.53	0.0710*	0.686	0.0250	1.77	0.0378*

* Statistically significant difference at the 95 percent confidence level.

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TABLE XXV
TEST MATERIAL: Aroclor 1260

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 1260 (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	1.45	1.12	0.286	0.277	0.690	0.583
10	1.63	1.05	0.283	0.307	0.810	0.606
100	1.49	1.06	0.286	0.368**	0.749	0.564

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

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TABLE XXVI

TEST MATERIAL: Aroclor 1260

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 1260 (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	2.10	1.92	0.412*	0.474*	509	405
10	2.01	1.73	0.349	0.504	575	343
100	1.99	1.88	0.382	0.650*	522	289

* Statistically significant difference at the 95 percent confidence level.

Final

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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 1260.

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TABLE XXVII

TEST MATERIAL: Aroclor 1260

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 inflammation	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

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TABLE XXVIII

TEST MATERIAL: Aroclor 1260

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	2.0
		Focal tracheitis	1	0.5
	Lung	Focal pneumonitis	4	1.0
		Hyperemia	4	1.5
	Liver	Hyperemia	1	1.0
		Focal pericholangitis	1	0.5
5 Females	Trachea	Focal tracheitis	2	0.5
		Focal pneumonitis	2	1.0
	Lung	Hyperemia	1	3.0
		Hyperemia	2	1.5
	Liver	Focal pericholangitis	1	0.5
		Focal nephritis	3	0.5

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

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3. Twelve-Month Sacrifice

a. Gross Pathologic Findings

Gross pathologic findings among test animals were significantly different from those noted in control animals.

b. Organ Weight and Ratio Data

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

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

Organ weights, organ to body weight and organ to body 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 1260.

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TABLE XXIX

TEST MATERIAL: Aroclor 1260

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	17.1*	10.7*	2.79**	3.01*	9.23	5.76
10	20.0	13.6	3.30	3.54	10.8	7.28
100	28.8*	14.1	4.26	3.79	13.4*	8.52

Statistically significant difference at the 95 percent confidence level.

Statistically significant difference at the 99 percent confidence level.

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TABLE XXX

TEST MATERIAL: Aroclor 1260

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	3.84	2.58**	0.625	0.724	2.06	1.39
10	4.00	2.78*	0.660	0.736	2.16	1.48
100	5.11*	2.81	0.758	0.755	2.38*	1.69

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

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TABLE XXXI

TEST-MATERIAL: Aroclor 1260

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	0.778	0.796	0.133	0.183	0.380	0.396
1	0.756	0.460*	0.122	0.129*	0.408	0.247*
10	0.836	0.578	0.139	0.150	0.457	0.308
100	0.785	0.474*	0.116	0.127*	0.365	0.284

* Statistically significant difference at the 95 percent confidence level.

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TABLE XXXII

TEST MATERIAL: Aroclor 1260

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	3.38	0.103	0.551	0.0287	1.82	0.0552
10	3.51	0.112	0.578	0.0294	1.89	0.0584
100	4.03**	0.088*	0.598	0.0238	1.88	0.0527

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

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TABLE XXXIII

TEST MATERIAL: Aroclor 1260

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	0.287	0.835	0.611
1	1.68	1.07	0.273	0.301	0.902	0.575
10	1.59	1.16	0.261	0.307	0.845	0.620
100	1.86	1.27	0.275	0.340	0.868	0.760

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TABLE XXXIV

TEST MATERIAL: Aroclor 1260

Two-Year Chronic Oral Toxicity Study - Albino Rats

Organ Weight and Ratio Data

Twelve-Month Sacrifice

Summary of Mean Values

Organ: Brain

Dietary Level (ppm)	Organ Weight (g)		Organ/Body Weight Ratio (g/100 g)		Final Body Weight of Sacrificed Rats (grams)	
	Males	Females	Males	Females	Males	Females
Control	2.04	2.02	0.349	0.460	584	439
1	1.87	1.86	0.304	0.522	616	356
10	1.88	1.90	0.310	0.493	607	385
100	2.15	1.67**	0.318	0.449	675	372

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

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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 hisopathologic 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 contr as well as the rats fed Aroclor 1260.

TABLE XXXV

TEST MATERIAL: Aroclor 1260

Two-Year Chronic Oral Toxicity Study - Albino Rats

Histopathologic Changes

Twelve-Month Sacrifice

Group: Control

Number of Animals	Organ Examined	Findings	Incidence	Ave. Gr.
5 Males	Trachea	Tracheitis	1	1.
	Lung	Chronic respiratory disease	2	1.
	Urinary Bladder	Calculus	1	1.
5 Females	Trachea	Tracheitis	1	1.
	Lung	Chronic respiratory disease	1	1.
	Colon	Parasites	1	1.

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

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TABLE XXXVI

TEST MATERIAL: Aroclor 1260

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	3	1.0
	Kidney	Focal lymphoid infiltration	1	1.0
	Liver	Vacuolar change of random cells	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

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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.

Absolute liver weights and liver to body weight or liver to brain weight ratios were significantly elevated in those rats fed 100 ppm Aroclor 1260. 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 and the absence of any deleterious histopathologic change confirm that these differences were not related to the ingestion of Aroclor 1260.

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TABLE XXXIX

TEST MATERIAL: Aroclor 1260

Two-Year Chronic Oral Toxicity Study - Albino Rats

Organ Weight and Ratio Data

Summary of Mean Values

Final Sacrifice

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	1.15	0.96	0.182	0.181	0.520	0.492
1	1.17	0.72	0.178	0.148	0.529	0.370
10	1.09	0.83	0.131	0.142	0.509	0.428
100	0.89	0.75	0.138	0.146	0.400	0.379

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TABLE XL

TEST MATERIAL: Aroclor 1260

Two-Year Chronic Oral Toxicity Study - Albino Rats

Organ Weight and Ratio Data

Summary of Mean Values

Final Sacrifice

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	2.52	0.123	0.397	0.0222	1.15	0.0628
1	3.56*	0.140	0.550*	0.0317	1.61*	0.0718
10	3.36*	0.177	0.400	0.0338	1.56*	0.0900
100	2.97	0.113	0.464	0.0229	1.33	0.0584

* Statistically significant difference at the 95 percent confidence level.

TABLE XLI

TEST MATERIAL: Aroclor 1260

Two-Year Chronic Oral Toxicity Study - Albino Rats

Organ Weight and Ratio Data

Summary of Mean Values

Final Sacrifice

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	1.87	1.54	0.294	0.288	0.860	0.795
1	1.98	1.45	0.304	0.294	0.893	0.747
10	1.90	1.58	0.225**	0.279	0.884	0.809
100	2.00	1.49	0.313	0.288	0.904	0.764

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

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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 1260 (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 livers from T-I (1 ppm) and T-II (10 ppm) animals. It was frequent 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. 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 appear as nodular growths with limited compression of the surrounding normal hepatic tissue.

The minor lesions of degeneration, hepatitis, ductule 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 1260. This level of liver disease is not unusual in old animals.

Hyperplasia of the urinary bladder was found in an animal from the control group. This finding was not present in any of the rats of Aroclor 1260. All of the other lesions in other tissues found in these animals are related to spontaneous disease and they are not unusual for old rats.


Donovan E. Gordon, D. V. M., Ph. D.
Diplomate, American College of
Veterinary Pathologists

TABLE XLII

TEST MATERIAL: Aroclor 1260

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	2.21	1.94	0.343	0.407	654	525
10	2.15	1.96	0.255**	0.347	845**	584
100	2.22	1.95	0.346	0.378	641	644

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

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TABLE XLIII

TEST MATERIAL: Aroclor 1260

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
		Inflammation	1	1.0
	Prostate	Telangiectasis	1	1.0
	Adrenal Gland	Nodular hyperplasia	1	1.0
		Focal fatty change	1	1.0
		Focal encephalitis	1	1.0
	Brain	Inflammation	2	1.0
	Eye			

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TABLE XLIII continued

TEST MATERIAL: Aroclor 1260

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
		Chronic gastritis	3	1.0
	Stomach	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
	Adrenal Gland	Telangiectasia	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

Industrial Biological Test Laboratories, Inc.

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TABLE XLIV

TEST MATERIAL: Aroclor 1260

Two-Year Chronic Oral Toxicity Study - Albino Rats

Histopathologic Changes

Final Sacrifice

Group: 1 ppm

Number of Animals	Organ Examined	Findings	Incidence	Average Grade
11 Males	Heart	Chronic focal myocarditis	4	1.0
	Trachea	Tracheitis	7	1.0
	Lung	Chronic respiratory disease	10	2.0
	Liver	Focal hepatitis	1	1.0
		Focal scarring	1	1.0
		Hemosiderosis	1	1.0
	Pancreas	Chronic focal pancreatitis	2	1.0
	Stomach	Acute focal gastritis	1	3.0
	Spleen	Hemosiderosis	1	1.0
	Lymph Node	Congestion	1	1.0
	Kidney	Chronic nephritis	7	2.0
	Testes	Testicular degeneration	1	2.0
		Periarteritis	2	1.0
		Inflammation	4	2.0
	Prostate	Inflammation	1	2.0
	Seminal Vesicle	Inflammation	1	2.0

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TABLE XLIV continued

TEST MATERIAL: Aroclor 1260

Two-Year Chronic Oral Toxicity Study - Albino Rats

Histopathologic Changes

Final Sacrifice

Group: 1 ppm

Number of Animals	Organ Examined	Findings	Incidence	Average Grade
11 Males	Adrenal Gland	Nodular hyperplasia	2	1.0
		Focal fatty change	2	1.0
14 Females	Heart	Chronic focal myocarditis	3	1.0
		Chronic focal myocarditis	1	3.0
	Trachea	Tracheitis	9	1.0
	Lung	Chronic respiratory disease	13	1.0
		Focal fibrosis	1	1.0
	Liver	Focal lymphoid infiltration	1	1.0
		Ductile hyperplasia	1	0.5
		Congestion	1	1.0
		Vacuolar change (fatty)	1	2.0
	Stomach	Chronic gastritis	1	1.0
		Acanthosis	2	1.0

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TABLE XLIV continued

TEST MATERIAL: Aroclor 1260

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	Stomach	Ulceration and acanthosis	1	1.0
	Colon	Parasites	1	1.0
	Spleen	Hemosiderosis	11	1.0
		Hyperplasia	1	1.0
	Lymph Node	Congestion	1	1.0
	Kidney	Chronic nephritis	3	2.0
		Vacuolar change (fatty)	1	1.0
	Uterus	Metritis	4	1.0
	Adrenal Gland	Telangiectasia	9	1.0
		Nodular hyperplasia	3	1.0
		Congestion	1	1.0

All other tissues and organs were normal histologically.

Grading System

0.5 = minimal

2.0 = mild

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TABLE XLV

TEST MATERIAL: Aroclor 1260

Two-Year Chronic Oral Toxicity Study - Albino Rats

Histopathologic Changes

Final Sacrifice

Group: 10 ppm

Number of Animals	Organ Examined	Findings	Incidence	Average Grade
7 Males	Heart	Chronic focal myocarditis	3	1.0
	Trachea	Tracheitis	2	1.0
	Lung	Chronic respiratory disease	5	1.0
		Suppurative pneumonia	1	3.0
	Liver	Vacuolar change (fatty)	2	1.0
	Stomach	Chronic gastritis	1	1.0
		Acanthosis	2	1.0
	Spleen	Hemosiderosis	3	1.0
	Kidney	Chronic nephritis	6	1.0
	Prostate	Inflammation	2	1.0
	Adrenal Gland	Nodular hyperplasia	1	1.0
14 Females	Heart	Chronic focal myocarditis	3	1.0
	Trachea	Tracheitis	8	1.0
	Lung	Chronic respiratory disease	14	1.0

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TABLE XLV continued

TEST MATERIAL: Aroclor 1260

Two-Year Chronic Oral Toxicity Study - Albino Rats

Histopathologic Changes

Final Sacrifice

Group: 10 ppm

Number of Animals	Organ Examined	Findings	Incidence	Average Grade
14 Females	Liver	Vacuolar change (fatty)	1	1.0
		Focal hyperplasia	1	1.0
	Pancreas	Chronic focal pancreatitis	1	3.0
		Periarteritis	1	3.0
	Stomach	Acanthosis	1	1.0
	Spleen	Hemosiderosis	12	1.0
	Kidney	Chronic nephritis	10	1.0
	Uterus	Metritis	7	2.0
	Pituitary	Congestion	1	1.0
	Adrenal Gland	Telangiectasis	7	1.0
		Nodular hyperplasia	1	1.0
		Congestion	1	1.0

All other tissues and organs were normal histologically.

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TABLE XLVI

TEST MATERIAL: Aroclor 1260

Two-Year Chronic Oral Toxicity Study - Albino Rats

Histopathologic Changes

Final Sacrifice

Group: 100 ppm

Number of Animals	Organ Examined	Findings	Incidence	Average Grade
10 Males	Heart	Chronic focal myocarditis	5	1.0
		Tracheitis	8	1.0
	Lung	Chronic respiratory disease	9	2.0
		Congestion	1	1.0
	Liver	Vacuolar change (fatty)	2	2.0
		Focal degeneration	1	1.0
		Congestion	3	2.0
		Centrilobular hypertrophy	2	1.0
	Pancreas	Telangiectasis	1	1.0
		Chronic focal pancreatitis	2	1.0
	Stomach	Inflammation	2	2.0
		Acanthosis	2	1.0
	Spleen	Hemosiderosis	7	1.0
	Kidney	Focal lymphoid infiltration	1	1.0
		Calcified concretions in pelvis	1	1.0

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TABLE XLVI continued

TEST MATERIAL: Aroclor 1260

Two-Year Chronic Oral Toxicity Study - Albino Rats

Histopathologic Changes

Final Sacrifice

Group: 100 ppm

Number of Animals	Organ Examined	Findings	Incidence	Average Grade
10 Males	Kidney (continued)	Calcified concretions in pelvis	1	1.0
	Testes	Aspermia	1	1.0
	Prostate	Inflammation	1	1.0
	Thymus	Cyst	1	1.0
	Adrenal Gland	Telangiectasis	3	1.0
		Nodular hyperplasia	1	1.0
15 Females	Heart	Chronic focal myocarditis	5	1.0
	Trachea	Tracheitis	8	1.0
	Lung	Chronic respiratory disease	11	1.0
		Congestion	1	1.0
		Edema	1	1.0
	Liver	Vacuolar change (fatty)	5	1.0

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TABLE XLVI continued

TEST MATERIAL: Aroclor 1260

Two-Year Chronic Oral Toxicity Study - Albino Rats

Histopathologic Changes

Final Sacrifice

Group: 100 ppm

Number of Animals	Organ Examined	Findings	Incidence	Average Grade
15 Females	Liver (continued)	Focal hyperplasia	4	1.0
		Chronic inflammation of liver capsule	1	1.0
		Centrolobular hypertrophy	5	1.0
		Necrosis	2	2.0
		Ductile cell hyperplasia, portal fibrosis and widespread eosinophil inclusions in hepatocyte cytoplasm	1	1.0
	Pancreas	Chronic focal pancreatitis and periarteritis	1	3.0
	Spleen	Hemosiderosis	9	2.0
	Kidney	Chronic nephritis	8	1.0
	Uterus	Metritis	7	1.0
	Pituitary	Congestion	1	1.0
	Adrenal Gland	Telangiectasis	6	1.0
		Nodular hyperplasia	1	1.0
		Congestion	1	1.0
	Parathyroid	Hyperplasia	1	1.0

All other tissues and organs

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TABLE XLVII

TEST MATERIAL: Aroclor 1260

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	1.0
T-I (1 ppm)	M	10	Proteinaceous plug (86, 105, and 107)	3	-
	F	11	None	-	-
T-II (10 ppm)	M	7	Proteinaceous plug (187)	1	-
	F	14	None	-	-
T-III (100 ppm)	M	10	Proteinaceous plug (271)	1	-
	F	14	None	-	-

* Individual animal numbers are shown in parentheses.

Grading System

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

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None of these tumors could be related to the ingestion of Aroclor 1260 and are considered normal for a random population of rats this age.

None of these tumors could be related to the ingestion of Aroclor 1260 and are considered normal for a random population of rats this age.

TABLE XLVIII

TEST MATERIAL: Aroclor 1260

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
46-F	Abdomen	64.98	8 x 1 x 2	Mammary fibroadenoma	24
		35.09	5 x 2 x 2	Mammary fibroadenoma	
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	-	-	Mammary fibroadenoma	24
	Adrenal gland	-	-	Pheochromocytoma	
64-F	Abdomen	88.92	13 x 11 x 4	Fibroadenoma	24

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TABLE XLIX

TEST MATERIAL: Aroclor 1260

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
99-M	Pituitary	-	-	✓ Chromophobe adenoma	20
127-F	Pituitary Abdomen	- 25.00	- 6 x 3 x 1	✓ Chromophobe adenoma ✓ Mammary fibroadenoma	24
128-F	Pituitary Abdomen	- 60.80	- 5 x 6 x 2	✓ Chromophobe adenoma ✓ Mammary fibroadenoma	21
138-F	Abdomen Pituitary	20.07 -	- -	✓ Mammary fibroadenoma ✓ Chromophobe adenoma	24
141-F	Ovary	-	-	✓ Adenoma	24
151-F	Abdomen	14.89	-	✓ Mammary fibroadenoma	24
152-F	Abdomen	540.00	13 x 15 x 2	✓ Mammary fibroadenoma	22

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TABLE L

TEST MATERIAL: Aroclor 1260

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
205-F	Abdomen	190.00	9 x 5 x 4	✓ Mammary fibroadenoma	24
208-F	Pituitary	-	-	✓ Chromophobe adenoma	24
213-F	Abdomen	-	-	✓ Mammary fibroadenoma	24
216-F	Right shoulder	138.00	-	✓ Subcutaneous tumor	23
220-F	Abdomen	9.57	-	✓ Mammary fibroadenoma	24
	Pituitary	-	-	✓ Chromophobe adenoma	
221-F	Submaxillary region	14.44	2 x 3 x 1	✓ Fibroadenoma	24
	Abdomen	29.0	3 x 5 x 2	✓ Mammary fibroadenoma	

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TABLE L continued

TEST MATERIAL: Aroclor 1260

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
22-F	Left femoral region	56.00	6 x 8 x 2	✓ Subcutaneous tumor	6
233-F	Pituitary	-	-	✓ Chromophobe adenoma	24
234-F	Abdomen Pancreas	60.82 -	6 x 4 x 3 -	✓ Mammary fibroadenoma ✓ Islet cell adenoma	24

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TABLE LI

TEST MATERIAL: Aroclor 1260

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
244-M	Pancreas	-	-	Adenoma	24
264-M	Pancreas	-	-	✓ Islet cell adenoma	21
281-F	Abdomen	-	-	✓ Mammary fibroadenoma	24
293-F	Liver	35.04	6 x 4 x 2	Lymphosarcoma	23
294-F	Abdominal cavity	50.75	6 x 4 x 3	✓ Fibroma	24
301-F	Liver	-	-	Lymphosarcoma	23

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TABLE LI continued

TEST MATERIAL: Aroclor 1260

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
302-F	Lymph node	-	-	✓ Lymphosarcoma	24
308-F	Pituitary	-	-	✓ Chromophobe adenoma	24
311-F	Abdomen	14.00	4 x 3 x 2 1 x 2 x 1	✓ Mammary fibroadenoma ✓ Mammary fibroadenoma	24
312-M	Pituitary	-	-	✓ Chromophobe adenoma	24
314-F	Abdomen	26.00	5 x 4 x 3	✓ Mammary fibroadenoma	24

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REPORT TO
MONSANTO COMPANY
TWO-YEAR CHRONIC ORAL TOXICITY WITH
AROCLOR 1254
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 1254, Lot No. AK-38. The following report represents 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 1254. Food consumption was not altered in any test group. Body weight gains of test and control animals did not differ after 3 or 12 months of testing. After 24 months females fed 100 ppm Aroclor 1254 had gained less weight than the control females. Weight gains of the male rats did not differ from the controls. The number of animals dying and the time at which death occurred did not differ among test and control groups.

Hematological and clinical blood chemistry studies conducted after 3, 6, 9, 12, 18, or 24 months did not reveal any effects related to Aroclor 1254. Urine analyses failed to reveal any difference between test and control rats.

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 1254.

At the final sacrifice after 24 months on test, the absolute liver weight and liver to body weight or brain weight ratios were significantly elevated in both T-III males and females. Histologic examinations of the livers from the T-III group revealed several animals with vacuolar change.

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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 1254.

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.

None of the tumors found could be related to the ingestion of Aroclor 1254 and are considered normal for a random population of rats this age.

Respectfully submitted,

INDUSTRIAL BIO-TEST LABORATORIES, INC.

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M. L. Keplinger
M. L. Keplinger, Ph.D.
Manager, Toxicology

November 12, 1971

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III. Procedure

A. Experimental Animals

The animals employed in the test were Charles River Strain^a 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 number and sex.

B. Organization of Groups

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

TABLE I

TEST MATERIAL: Aroclor 1254

Two-Year Chronic Oral Toxicity Study - Albino Rats

Outline of Experiment

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

^a 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 1254 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 Co. St. Louis, Mo.

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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 case 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.

Absolute organ weights were recorded and organ to body weight and organ to brain weight ratios computed. The following organs were

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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 studies by "t"-tests.

Complete microscopic examinations were conducted upon the tissues and organs from all control and 100 ppm group animals 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.

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

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

L. 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.

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TABLE II

TEST MATERIAL: Aroclor 1254

Two-Year Chronic Oral Toxicity Study - Albino Rats

Body Weight and Total Weight Gain Data

Summary of Mean Values

Dietary Level of Aroclor 1254 (ppm)	Sex	Body Weight (grams) Week:														90-Day Total Weight Gain (grams/rat)
		0	1	2	3	4	5	6	7	8	9	10	11	12	13	
Control	M	133	203	245	313	362	373	391	409	424	440	440	449	467	474	311
	F	136	178	190	219	244	254	259	265	270	276	281	278	290	288	152
1	M	133	206	253	322	364	373	396	425	436	457	470	483	490	509	376
	F	136	171	190	213	235	246	248	250	259	270	270	274	279	285	149
10	M	133	209	251	325	375	394	402	410	432	453	470	488	494	508	376
	F	136	171	194	220	243	263	289	293	281	272	276	274	280	288	152
100	M	133	207	260	324	365	375	295	419	428	440	450	469	480	486	353
	F	136	174	197	223	242	254	276	290	281	268	270	274	277	280	144

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TABLE II continued

TEST MATERIAL: Aroclor 1254

Two-Year Chronic Oral Toxicity Study - Albino Rats

Body Weight and Total Weight Gain Data

Summary of Mean Values

Dietary Level of Aroclor 1254 (ppm)	Sex	Body Weight (grams) Month:									12-Month Total Weight Gain (grams/rat)
		4	5	6	7	8	9	10	11	12	
Control	M	498	533	565	593	622	642	667	688	701	568
	F	297	310	322	333	345	359	374	383	390	254
1	M	522	550	581	604	633	658	680	715	725	592
	F	289	295	307	322	333	340	354	367	380	244
10	M	529	567	593	621	642	667	681	700	726	593
	F	300	308	321	330	341	354	367	380	392	256
100	M	495	521	541	562	586	608	627	642	664	531
	F	292	300	306	316	321	326	332	340	347	211

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TABLE II continued

TEST MATERIAL: Aroclor 1254

Two-Year Chronic Oral Toxicity Study - Albino Rats

Body Weight and Total Weight Gain Data

Summary of Mean Values

Dietary Level of Aroclor 1254 (ppm)	Sex	Body Weight (grams) Month:												24-Month Total Weight Gain (grams/rat)
		13	14	15	16	17	18	19	20	21	22	23	24	
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
I	M	760	780	807	800	802	795	786	769	750	728	715	656	523
	F	401	426	476	483	493	510	521	532	537	542	553	540	404
10	M	746	774	824	780	804	826	823	821	813	800	767	762	629
	F	421	433	485	466	475	481	485	492	298	500	471	500	364
100	M	688	714	735	730	733	726	716	700	685	652	628	656	523
	F	360	367	392	374	381	394	393	398	401	400	395	411	275*

* Statistically significant at the 99 percent confidence limit.

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 1254

Two-Year Chronic Oral Toxicity Study - Albino Rats

Food Consumption Data

Summary of Mean Values

Dietary Level of Aroclor 1254 (ppm)	Sex	Food Consumption (grams/rat/seven days) Week:													Average Food Consumption (grams/rat/seven days)
		1	2	3	4	5	6	7	8	9	10	11	12	13	
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	112	148	156	168	148	214	160	193	218	186	184	187	189	174
	F	87	117	108	118	113	203	105	137	149	144	144	147	146	132
10	M	116	139	148	164	163	221	201	199	216	191	192	200	199	181
	F	90	109	107	114	121	193	159	134	144	150	151	152	149	136
100	M	116	172	163	185	231	185	189	198	185	197	189	189	121	187
	F	89	141	98	129	129	190	146	146	145	139	137	146	193	152

Indicates BIC TEST Laboratory, Inc.

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TABLE III continued
 TEST MATERIAL: Aroclor 1254
 Two-Year Chronic Oral Toxicity Study - Albino Rats

Food Consumption Data

Summary of Mean Values

Dietary Level of Aroclor 1254 (ppm)	Sex	Food Consumption (grams/rat/seven days) Month:										Average Food Consumption (grams/rat/seven days)
		4	5	6	7	8	9	10	11	12		
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	189	181	184	198	190	190	197	152	190	186	
	F	141	159	147	162	145	150	151	123	126	145	
10	M	190	191	189	196	190	188	191	186	163	187	
	F	139	138	148	148	150	145	138	142	149	144	
100	M	179	168	190	179	187	182	197	180	188	183	
	F	148	141	144	162	163	151	148	141	137	148	

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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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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TEST MATERIAL: Aroclor 1254

Hematologic Data

Dietary Level (ppm)	Sex	Total Leukocyte Count (thousands/mm ³)						Erythrocyte Count (millions/mm ³)					
		Month:						Month:					
		3	6	9	12	18	24	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	15.1	15.2	10.9	11.0	9.8	10.2	7.5	7.7	8.1	7.7	8.0	8.0
	F	11.6	12.2	7.3	8.7	6.6	11.8	7.5	7.6	7.7	6.9	7.3	6.4

Annex 1

TABLE VI

TEST MATERIAL: Aroclor 1254

Two-Year Chronic Oral Toxicity Study - Albino Rats

Hematologic Data

Summary of Mean Values

Dietary Level (ppm)	Sex	Hemoglobin Concentration (g/100 ml)						Hematocrit Value (%)					
		Month:						Month:					
		3	6	9	12	18	24	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	15.6	17.6	13.8	15.6	15.7	15.3	47	47	42	44	41	40
	F	16.5	17.8	13.9	14.5	14.5	12.7	48	47	42	40	37	32

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TABLE VII

TEST MATERIAL: Aroclor 1254

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						Neutrophils					
		Month:			Month:			Month:			Month:		
		3	6	9	12	18	24	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	88.2	79.6	85.8	85.2	69.8	68.0	10.8	20.2	13.8	14.2	29.0	30.2
	F	92.2	92.0	79.6	84.6	79.0	61.0	7.4	7.8	20.2	15.0	20.4	37.6

TABLE VII continued

TEST MATERIAL: Aroclor 1254

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						Eosinophils					
		Month:						Month:					
		3	6	9	12	18	24	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	0.0	0.0	0.0	0.0	0.0	0.8	1.0	0.2	0.4	0.6	1.2	1.0
	F	0.0	0.0	0.0	0.0	0.0	1.0	0.4	0.2	0.2	0.4	0.6	0.4

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TABLE VII continued

TEST MATERIAL: Aroclor 1254

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 1254
Two-Year Chronic Oral Toxicity Study - Albino Rats
Hematologic Data
Summary of Mean Values

Dietary Level (ppm)	Sex	Serum Glutamic-Pyruvic Transaminase Activity (Dade Units) Month:						Blood Urea Nitrogen Concentration (mgs %) Month:					
		3	6	9	12	18	24	3	6	9	12	18	24
Control	M	38	48	45	45	42	36	17	15	12	10	14	15
	F	33	39	38	42	32	30	14	16	15	9	13	11
100	M	33	32	43	50	38	41	14	15	13	12	11	15
	F	32	46	49	61	46	78	16	15	13	14	13	15

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TABLE IX

TEST MATERIAL: Aroclor 1254

Two-Year Chronic Oral Toxicity Study - Albino Rats

Hematologic Data

Summary of Mean Values

Dietary Level (ppm)	Sex	Fasted Blood Glucose Concentration (mgs %) Month:						Serum Alkaline Phosphatase Activity (King-Armstrong Units) Month:					
		3	6	9	12	18	24	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	109	113	129	128	124	115	35.4	23.2	27.4	27.1	14.6	23.5
	F	120	107	124	113	132	107	17.1	18.1	19.3	16.7	10.0	21.6

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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 1254

Two-Year Chronic Oral Toxicity Study - Albino Rats

Urine Analyses Data

Summary of Mean Values

Dietary Level (ppm)	Sex	Glucose Month:						Albumin Month:					
		3	6	9	12	18	24	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	t	+2
	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

Page 10

TABLE XI

TEST MATERIAL: Aroclor 1254

Two-Year Chronic Oral Toxicity Study - Albino Rats

Urine Analyses Data

Summary of Mean Values

Dietary Level	Sex	Microscopic Elements						pH					
		Month:						Month:					
10000		3	6	9	12	18	24	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
	M	n	n	n	n	t	t	7	7	6	7	6	6
	F	n	n	N	N	t	t	8	8	7	7	6	6

Key:

N - Normal

n = negative

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 1254

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	1.018	1.021	1.029	1.027	1.037	1.027
	F	1.020	1.018	1.023	1.022	1.029	1.031

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F. Pathologic Studies

1. Three-Month Sacrifice

a. Gross Pathologic Findings

No outstanding differences were noted between test and control rats upon gross pathological examination.

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

The results of the statistical analyses conducted on absolute organ weights, organ to body weight and organ to brain weight ratios are summarized in Tables XIII through XVIII.

Significant differences between a test group and the control group are designated by asterisks following the test values.

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 1254.

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TABLE XIII

TEST MATERIAL: Aroclor 1254

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 1254 (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	24.0	13.5	4.34	4.34	11.7	6.85
10	22.8	13.1	4.59	4.29	10.9	6.85
100	28.0*	13.8	5.25	4.89	14.6**	7.11

* Statistically significant difference at the 95 percent confidence level.

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

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TABLE XIV

TEST MATERIAL: Aroclor 1254

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 1254 (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	4.30	2.62	0.778	0.845	2.09	1.32
10	4.05	2.61	0.821	0.852	1.94	1.36
100	4.21	2.74	0.792	0.975	2.19	1.42

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TABLE XV

TEST MATERIAL: Aroclor 1254

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 1254 (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	0.942	0.668	0.167	0.217	0.454	0.338
10	0.766	0.586	0.154	0.191	0.368	0.308
100	0.814	0.542	0.153	0.192	0.425	0.281

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TABLE XVI

TEST MATERIAL: Aroclor 1254

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 1254 (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	3.50	0.134	0.637	0.0431	1.70	0.0675
10	3.55	0.110	0.720	0.0361	1.70	0.0568
100	3.82	0.120	0.718	0.0426	1.99	0.0618

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TABLE XVII

TEST MATERIAL: Aroclor 1254

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 1254 (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	1.56	1.02	0.283	0.332	0.756	0.516
10	1.49	0.984	0.302	0.322	0.713	0.515
100	1.58	0.992	0.297	0.352	0.817	0.512

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TABLE XVIII

TEST MATERIAL: Aroclor 1254

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 1254 (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	2.07	1.91	0.402	0.616	518	314
1	2.07	1.99	0.376	0.647	553	311
10	2.09	1.91	0.424	0.625	499	307
100	1.95	1.94	0.366	0.688	434	281

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 1254.

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TABLE XIX

TEST MATERIAL: Aroclor 1254

Two-Year Chronic Oral Toxicity Study - Albino Rats

Histopathologic Changes

Three-Month Sacrifice

Group: Control

Number of Animals	Organ Examined	Findings	Incidence	Aver Gra
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

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TABLE XX

TEST MATERIAL: Aroclor 1254

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	1	1.0
	Lung	Chronic respiratory disease	3	1.0
5 Females	Trachea	Tracheitis	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

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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 analyses 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 1254.

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TABLE XXII
 TEST MATERIAL: Aroclor 1254
 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 1254 (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	3.80	2.58	0.715	0.784	1.75 ^d	1.39
10	3.22 ^d	2.50	0.703	0.780	1.57 ^d	1.31
100	3.23 ^d	2.43	0.700	0.861	1.68 ^d	1.25

Statistically significant difference at the 95 percent confidence level.

TABLE XXI

TEST MATERIAL: Aroclor 1254

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 1254 (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	16.1 ^{**}	10.3 [†]	3.01 ^{**}	3.11 [†]	7.45 [†]	5.54 [†]
10	12.9 [†]	9.54 [†]	2.81 ^{**}	2.94 ^{**}	6.29 ^{**}	4.99 [†]
100	19.2	12.4	4.14	4.40	10.0	6.39

* Statistically significant difference at the 95 percent confidence level.

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

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TABLE XXIII
TEST MATERIAL: Aroclor 1254
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 1254 (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	0.830	0.602	0.155	0.182	0.384	0.324
10	0.588	0.594	0.128	0.184	0.287	0.311
100	0.684	0.512	0.150	0.180	0.356	0.264

TABLE XXIV

TEST MATERIAL: Aroclor 1254

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 1254 (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	3.67	0.0922	0.691	0.0280	1.70	0.0496
10	3.30	0.0868	0.724	0.0272	1.61	0.0454
100	3.44	0.104	0.747	0.0364	1.79	0.0536

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TABLE XXV
 TEST MATERIAL: Aroclor 1254
 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 1254 (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	1.58	1.04	0.298	0.316	0.731	0.559
10	1.44	1.03	0.314	0.320	0.702	0.539
100	1.40	1.02	0.301	0.361	0.729	0.526

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TABLE XXVI
 TEST MATERIAL: Aroclor 1254
 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 1254 (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	2.16	1.86	0.404*	0.562	534	331
10	2.05	1.91	0.447**	0.593	459	322
100	1.92	1.94	0.414**	0.681*	464	285

* Statistically significant difference at the 95 percent confidence level.

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

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 1254.

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TABLE XXVII

TEST MATERIAL: Aroclor 1254

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 inflammation	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

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TABLE XXVIII

TEST MATERIAL: Aroclor 1254

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	2.0
		Focal tracheitis	1	1.0
	Lung	Focal pneumonitis	3	0.5
	Liver	Focal pericholangitis	1	2.0
	Kidney	Focal nephritis	1	0.5
5 Females	Heart	Myocarditis	1	0.5
	Trachea	Focal tracheitis	3	0.5
	Lung	Focal pneumonitis	4	1.0
		Hyperemia	1	1.0
	Kidney	Focal nephritis	2	3.0

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

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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 12-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 1254.

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TABLE XXIX

TEST MATERIAL: Aroclor 1254

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	20.6	12.9	3.09*	3.41	9.89	7.29
10	23.5	14.6	3.52	4.34	11.2	7.34
100	27.1*	12.2	4.58*	3.43	12.7	6.30

* Statistically significant difference at the 95 percent confidence level.

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TABLE XXX

TEST MATERIAL: Aroclor 1254

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	4.09	2.75	0.618	0.728	1.98	1.55
10	4.64	2.76*	0.697	0.817	2.21	1.39
100	4.39	2.78*	0.740	0.796	2.06	1.44

* Statistically significant difference at the 95 percent confidence level.

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TABLE XXXI

TEST MATERIAL: Aroclor 1254

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	0.778	0.796	0.133	0.183	0.380	0.396
1	0.714	0.484*	0.107	0.129	0.344	0.271
10	0.904	0.548	0.135	0.161	0.430	0.275
100	0.754	0.976	0.126	0.280	0.352	0.517

* Statistically significant difference at the 95 percent confidence level.

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TABLE XXXII

TEST MATERIAL: Aroclor 1254

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	0.592	0.0275	1.70	0.0574
1	3.68	0.111	0.557	0.0294	1.78	0.0624
10	3.68	0.0918	0.550	0.0270	1.75	0.0461
100	3.56	0.121	0.603	0.0334	1.67	0.0624

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TABLE XXXIII

TEST MATERIAL: Aroclor 1254

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	1.68	1.13	0.255	0.301	0.812	0.635
10	1.84	1.08**	0.275	0.322	0.875	0.544*
100	1.69	1.14	0.284	0.325	0.795	0.589

* Statistically significant difference at the 95 percent confidence level.

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

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TABLE XXXIV

TEST MATERIAL: Aroclor 1254

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	Female	Males	Females
Control	2.04	2.02	0.35	0.474	584	439
1	2.08	1.78	0.315	0.475	665	380
10	2.10	1.99	0.315	0.591	669*	338*
100	2.14	1.93	0.361	0.552	596	355

* Statistically significant difference at the 95 percent confidence level.

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c. Histopathologic Findings

Histopathologic examination of tissues taken from each rat sacrificed from the control and 100 ppm groups after 12 months of testing was conducted.

Tables XXXV and XXXVI list all histopathologic changes noted.

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TABLE XXXV

TEST MATERIAL: Aroclor 1254

Two-Year Chronic Oral Toxicity Study - Albino Rats

Histopathologic Changes

Twelve-Month Sacrifice

Group: Control

Number of Animals	Organ Examined	Findings	Incidence	Ave Gra
5 Males	Trachea	Tracheitis	1	1.
	Lung	Chronic respiratory disease	2	1.
	Urinary Bladder	Calculus	1	1.
5 Females	Trachea	Tracheitis	1	1.
	Lung	Chronic respiratory disease	1	1.
	Colon	Parasites	1	1.

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

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TABLE XXXVI

TEST MATERIAL: Aroclor 1254

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	Lung	Chronic respiratory disease	4	1.0
5 Females	Heart	Focal myocarditis	1	1.0
	Trachea	Tracheitis	1	1.0
	Lung	Chronic respiratory disease	1	1.0
	Adrenal	Congestion	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

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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.

Absolute liver weight, liver to body weight and liver to brain weight ratios were significantly elevated in both male and female rats fed 100 ppm Aroclor 1254. 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 and the absence of any deleterious histopathologic change confirm that these differences were not related to the ingestion of Aroclor 1254.

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TABLE XXXVII

TEST MATERIAL: Aroclor 1254

Two-Year Chronic Oral Toxicity Study - Albino Rats

Organ Weight and Ratio Data

Summary of Mean Values

Final Sacrifice

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	22.0	16.3	3.47	3.05	10.10	8.42
1	19.5	16.1	2.99	3.10	8.76*	8.31
10	23.9	19.5	3.21	3.84*	11.40*	10.30
100	30.2**	32.1**	4.75**	8.62**	14.10**	17.10**

* Statistically significant difference at the 95 percent confidence level.

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

TABLE XXXVIII

TEST MATERIAL: Aroclor 1254

Two-Year Chronic Oral Toxicity Study - Albino Rats

Organ Weight and Ratio Data

Summary of Mean Values

Final Sacrifice

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	5.57	3.48	0.877	0.646	2.57	1.79
1	5.52	3.68	0.868	0.706	2.48	1.88
10	5.63	3.47	0.761	0.717	2.70	1.84
100	4.74	3.44	0.749	0.899*	2.21	1.82

* Statistically significant difference at the 95 percent confidence level.

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TABLE XXXIX

TEST MATERIAL: Aroclor 1254

Two-Year Chronic Oral Toxicity Study - Albino Rats

Organ Weight and Ratio Data

Summary of Mean Values

Final Sacrifice

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	1.15	0.96	0.182	0.181	0.520	0.492
1	1.26	1.06	0.189	0.237	0.568	0.562
10	1.57	0.86	0.220	0.175	0.749	0.462
100	1.04	0.66	0.164	0.174	0.489	0.352

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TABLE XL

TEST MATERIAL: Aroclor 1254

Two-Year Chronic Oral Toxicity Study - Albino Rats

Organ Weight and Ratio Data

Summary of Mean Values

Final Sacrifice

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	2.52	0.123	0.397	0.0222	1.15	0.0628
1	3.19	0.204	0.482	0.0390	1.43	0.1010
10	3.28	0.135	0.445	0.0281	1.58*	0.0707
100	3.44	0.128	0.547	0.0316	1.60*	0.0666

* Statistically significant difference at the 95 percent confidence level.

TABLE XLI
TEST MATERIAL: Aroclor 1254
Two-Year Chronic Oral Toxicity Study - Albino Rats

Organ Weight and Ratio Data

Summary of Mean Values

Final Sacrifice

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	1.87	1.54	0.294	0.288	0.860	0.795
1	1.98	1.55	0.303	0.302	0.889	0.805
10	2.08	1.37	0.279	0.282	0.998*	0.727
100	1.94	1.50	0.304	0.386**	0.909	0.803

* Statistically significant difference at the 95 percent confidence level.

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

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TABLE XLII

TEST MATERIAL: Aroclor 1254

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	2.22	1.94	0.347	0.376	656	540
10	2.08	1.88	0.279	0.388	762	500
100	2.13	1.88	0.340	0.486**	656	411**

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

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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 1254 (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, 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 livers from T-I (1 ppm) and T-II (10 ppm) animals. It was frequent in the T-III animals. This lesion is morphologic 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 changes 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. The hyperplasia was associated with the same cells and appeared

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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 1254. This level of liver disease is not unusual in rats of this age.

Hyperplasia of the transitional epithelium was present in the urinary bladder of animals from the control group and each of the test groups. This lesion was usually associated with cystitis. The most severe changes were associated with the presence of mineralized calculi in the bladder lumen.

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


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TABLE XLIII

TEST MATERIAL: Aroclor 1254

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 1254

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	3	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
		Chronic gastritis	3	1.0
	Stomach	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
	Ovary	Focal lymphoid infiltration	1	1.0
		Cyst	1	1.0

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TABLE XLIII continued

TEST MATERIAL: Aroclor 1254

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	Telangiectasia	9	1.0
		Nodular hyperplasia	4	1.0
		Pheochromocytoma	1	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

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TABLE XLIV.

TEST MATERIAL: Aroclor 1254

Two-Year Chronic Oral Toxicity Study - Albino Rats

Histopathologic Changes

Final Sacrifice

Group: 1 ppm

Number of Animals	Organ Examined	Findings	Incidence	Average Grade
11 Males	Heart	Chronic focal myocarditis	5	1.0
	Trachea	Tracheitis	6	1.0
	Lung	Chronic respiratory disease	9	1.0
		Congestion	1	1.0
	Liver	Ductile hyperplasia	1	0.5
		Vacuolar change (fatty)	1	1.0
		Necrosis	1	3.0
		Chronic focal pancreatitis	2	1.0
	Pancreas	Periarteritis	1	2.0
	Stomach	Chronic gastritis	2	1.0
		Acanthosis	2	1.0
		Ulcer	1	1.0
		Hemosiderosis	5	2.0
	Spleen	Chronic nephritis	8	2.0
	Kidney	Testicular degeneration	2	1.0
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TABLE XLIV continued

TEST MATERIAL: Aroclor 1254

Two-Year Chronic Oral Toxicity Study - Albino Rats

Histopathologic Changes

Final Sacrifice

Group: 1 ppm

Number of Animals	Organ Examined	Findings	Incidence	Average Grade
11 Males	Testes (continued)	Periarteritis	2	1.0
		Focal calcification	2	2.0
	Prostate	Inflammation	6	2.0
	Seminal Vesicle	Inflammation	2	2.0
	Pituitary	Congestion	1	1.0
	Adrenal Gland	Nodular hyperplasia	1	1.0
	Parathyroid Gland	Hyperplasia	1	1.0
22 Females	Heart	Chronic focal myocarditis	12	1.0
	Trachea	Tracheitis	16	1.0
	Lung	Chronic respiratory disease	17	2.0
	Liver	Focal lymphoid infiltration	3	1.0

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TABLE XLIV continued

TEST MATERIAL: Aroclor 1254

Two-Year Chronic Oral Toxicity Study - Albino Rats

Histopathologic Changes

Final Sacrifice

Group: 1 ppm

Number of Animals	Organ Examined	Findings	Incidence	Average Grade
22 Females	Liver (continued)	Ductile hyperplasia	2	1.0
		Vacuolar change (fatty)	3	2.0
		Congestion	1	1.0
		Necrosis	1	1.0
	Stomach	Focal inflammation and acanthosis	4	2.0
	Colon	Parasites	2	1.0
	Spleen	Hemosiderosis	8	2.0
	Lymph Node	Abscesses	1	1.0
	Kidney	Chronic nephritis	8	1.0
		Focal calcification	3	1.0
	Uterus	Metritis	6	1.0
	Pituitary	Hyperplasia	4	1.0
	Adrenal Gland	Telangiectasis	17	1.0
		Nodular hyperplasia	1	1.0
		Congestion	1	1.0
		Focal fatty change	3	1.0

All other tissues and organs were normal histologically.

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Reference: U.S. - 1521 - Microscopic, Inc.

TABLE XLV

TEST MATERIAL: Aroclor 1254

Two-Year Chronic Oral Toxicity Study - Albino Rats

Histopathologic Changes

Final Sacrifice

Group: 10 ppm

Number of Animals	Organ Examined	Findings	Incidence	Average Grade
12 Males	Heart	Chronic focal myocarditis	7	1.0
	Trachea	Tracheitis	9	2.0
	Lung	Chronic respiratory disease	11	1.0
		Pneumonia	1	1.0
	Liver	Vacuolar change (fatty)	3	1.0
		Ductile hyperplasia	1	1.0
		Hypertrophy	1	0.5
		Focal degeneration	1	0.5
	Pancreas	Chronic focal pancreatitis	1	3.0
	Stomach	Chronic gastritis and acanthosis	1	1.0
	Spleen	Hemosiderosis	2	1.0
	Kidney	Chronic nephritis	7	1.0
	Testes	Testicular degeneration	1	2.0

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TABLE XLV continued

TEST MATERIAL: Aroclor 1254

Two-Year Chronic Oral Toxicity Study - Albino Rats

Histopathologic Changes

Final Sacrifice

Group: 10 ppm

Number of Animals	Organ Examined	Findings	Incidence	Average Grade
12 Males	Testes (continued)	Periarteritis	1	3.0
	Prostate	Inflammation	2	2.0
	Seminal Vesicle	Inflammation	2	1.0
	Adrenal Gland	Telangiectasis	2	1.0
		Focal fatty change	1	1.0
	Thyroid Gland	Focal hyperplasia	1	1.0
12 Females	Heart	Chronic focal myocarditis	3	1.0
	Trachea	Tracheitis	7	1.0
	Lung	Chronic respiratory disease	12	1.0
	Liver	Focal lymphoid infiltration	4	1.0
		Vacuolar change (fatty)	1	1.0
		Nodular hyperplasia	1	3.0

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TABLE XLV continued

TEST MATERIAL: Aroclor 1254

Two-Year Chronic Oral Toxicity Study - Albino Rats

Histopathologic Changes

Final Sacrifice

Group: 10 ppm

Number of Animals	Organ Examined	Findings	Incidence	Average Grade
12 Females	Liver (continued)	Ductile hyperplasia	2	1.0
		Telangiectasia	1	1.0
		Hepatoma	1	1.0
	Colon	Parasites	1	1.0
	Spleen	Hemosiderosis	2	1.0
	Lymph Node	Congestion	1	1.0
	Kidney	Chronic nephritis	3	2.0
		Focal calcification	2	1.0
		Metritis	1	1.0
	Pituitary	Adenoma	3	1.0
		Hyperplasia	1	1.0
	Adrenal Gland	Telangiectasia	9	1.0
	Parathyroid Gland	Hyperplasia	1	1.0
	Thymus	Abscess	1	1.0

All other tissues and organs were normal histologically.

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TABLE XLVI

TEST MATERIAL: Aroclor 1254

Two-Year Chronic Oral Toxicity Study - Albino Rats

Histopathologic Changes

Final Sacrifice

Group: 100 ppm

Number of Animals	Organ Examined	Findings	Incidence	Average Grade
11 Males	Heart	Chronic focal myocarditis	3	2.0
		Tracheitis	4	1.0
		Chronic respiratory disease	10	1.0
	Lung	Edema	3	2.0
		Focal degeneration	2	1.0
	Liver	Vacuolar change (fatty)	3	1.0
		Ductile hyperplasia	3	1.0
		Hypertrophy	3	2.0
		Focal lymphoid infiltration	1	1.0
		Portal fibrosis	1	2.0
		Focal inflammation	1	1.0
		Hemosiderosis	2	1.0
		Congestion	1	1.0
	Small Intestine			
	Spleen			
	Lymph Node			

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TABLE XLVI continued

TEST MATERIAL: Aroclor 1254

Two-Year Chronic Oral Toxicity Study - Albino Rats

Histopathologic Changes

Final Sacrifice

Group: 100 ppm

Number of Animals	Organ Examined	Findings	Incidence	Average Grade
11 Males	Kidney	Chronic nephritis	8	1.0
	Testes	Periarteritis	1	1.0
	Prostate	Inflammation	5	2.0
	Adrenal Gland	Telangiectasis	2	1.0
		Congestion	1	1.0
	Thyroid Gland	Hyperplasia	1	1.0
15 Females	Heart	Chronic focal myocarditis	5	1.0
	Trachea	Tracheitis	6	1.0
	Lung	Chronic respiratory disease	13	2.0
		Edema	1	2.0
	Liver	Focal hypertrophy	1	1.0
		Hypertrophy	5	3.0
		Focal hyperplasia	1	1.0

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TABLE XLVI continued

TEST MATERIAL: Aroclor 1254

Two-Year Chronic Oral Toxicity Study - Albino Rats

Histopathologic Changes

Final Sacrifice

Group: 100 ppm

Number of Animals	Organ Examined	Findings	Incidence	Average Grade
15 Females	Liver (continued)	Ductile hyperplasia	2	1.0
		Vacuolar change (fatty)	10	1.0
		Nodular hyperplasia	1	1.0
		Hepatoma	1	1.0
	Stomach	Chronic gastritis	2	1.0
		Acanthosis	4	1.0
		Inflammation	1	1.0
	Spleen	Hemosiderosis	5	1.0
	Kidney	Chronic nephritis	5	1.0
		Focal calcification	1	1.0
	Uterus	Metritis	3	1.0
	Pituitary	Hyperplasia	4	1.0
	Pituit	Nodular hyperplasia	1	1.0
	Adrenal Gland	Telangiectasis	3	1.0
		Nodular hyperplasia	1	1.0
		Congestion	1	1.0

All other tissues and organs were normal histologically.

Grading System

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TABLE XLVII

TEST MATERIAL: Aroclor 1254

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	10	Proteinaceous plug (326)	1	-
	F	19	Diffuse epithelial hyperplasia associated with diffuse cystitis (377)	1	3
T-II (10 ppm)	M	13	Diffuse epithelial hyperplasia and papilloma associated with focal cystitis (417)	1	4
			Diffuse epithelial hyperplasia associated with diffuse cystitis (419)	1	2
	F	13	None	-	-
T-III (100 ppm)	M	10	Focal epithelial hyperplasia associated with focal cystitis (497)	1	2
	F	17	Focal epithelial hyperplasia (5) None	1 -	1 -

* Individual animal numbers are shown in parenthesis.

Grading System

1.0 = minimal or trace

4.0 = severe

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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 LL

None of these tumors could be related to the ingestion of Aroclor 1254 and are considered normal for a random population of rats this age.

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TABLE XLVIII

TEST MATERIAL: Aroclor 1254

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
46-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
-F	Abdomen	88.92	13 x 11 x 4	Fibroadenoma	24
-F	Abdomen	230.00	13 x 11 x 4		

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TABLE XLIX continued

TEST MATERIAL: Aroclor 1254

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
11-F ♀	Abdomen	-	-	✓ Mammary adenocarcinoma	24
12-F ♀	Abdomen	-	-	✓ Mammary fibroadenoma	24
13-F ♀	Abdomen	-	-	✓ Lipoma	24

* No 371 in new data file
 *** No 405 in new data file
 ** maybe no 382 in new data file

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TABLE XLIX

TEST MATERIAL: Aroclor 1254

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
1-M	Parathyroid gland	-	-	Adenoma	24
2-M	Pituitary	-	-	Chromophobe adenoma	23
3-F	Abdomen	-	-	Mammary fibroadenoma	24
4-F	Abdomen	-	-	Mammary fibroadenoma	24
5-F	Abdomen	8.97	2 x 2 x 2	Mammary adenoma	24
	Parathyroid gland	-	-	Adenoma	
6-F	Abdomen	8.86	3 x 2 x 2	Mammary fibroadenoma	24
7-F	Abdomen	65.0		Mammary fibroadenoma	24
	Dorsal cervical region	209	13 x 8 x 2	Fibroadenoma	
8-F	Pituitary	-	-	Chromophobe adenoma	24
	Abdomen	-	-	Mammary fibroadenoma	
9-F	Abdomen	-	-	Mammary fibroadenoma	

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TABLE L

TEST MATERIAL: Aroclor 1254

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
1-M	Pancreas	-	-	✓ Adenoma ✓	24
2-M	Parathyroid gland	-	-	✓ Adenoma ✓	24
3-F	Abdomen	-	-	✓ Mammary fibroadenoma ✓	24
4-F	Thyroid	-	-	✓ Adenoma ✓	24
	Abdomen	-	-	✓ Mammary fibroadenoma ✓	
5-F	Abdomen	-	-	✓ Mammary fibroadenoma ✓	24
6-F	Abdomen	86	7 x 8 x 3	✓ Fibroadenoma ✓	24
	Abdomen	29	5 x 5 x 2	✓ Fibroadenoma ✓	
7-F	Pituitary	-	-	✓ Chromophobe adenoma ✓	24
8-F	Abdomen	28	6 x 5 x 3	✓ Fibroadenoma ✓	24
9-F	Pituitary	-	-	✓ Chromophobe adenoma ✓	22
10-F	Adrenal gland	7.8	-	✓ Telangioma ✓	24

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TABLE LI

TEST MATERIAL: Aroclor 1254

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
1-F	Abdomen	48.12	5 x 4 x 3	✓ Fibroma ✓	24
2-F	Abdomen	-	-	✓ Mammary fibroadenoma ✓	24
3-F	Abdomen	-	18 x 4 x 3	✓ Mammary fibroadenoma ✓	24
4-M	Pancreas	-	-	✓ Adenoma ✓	24
5-M	Abdomen	-	1 x 2 x 1	✓ Fibroadenoma ✓	24
6-F	Abdomen	-	-	✓ Mammary fibroadenoma ✓	24
7-M	Lymph node	-	-	✓ Reticulum cell sarcoma ✓	13
8-F	Pancreas	13.0	3 x 3 x 3	✓ Adenocarcinoma ✓	24
9-F	Lymph node	-	-	✓ Lymphosarcoma ✓	24
10-F	Abdomen	52.0	8 x 5 x 2	✓ Fibroadenoma ✓	24

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TABLE LI continued

TEST MATERIAL: Aroclor 1254

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
11-F	Abdomen	141.9	8 x 8 x 2	✓ Mammary fibroadenoma ✓	24
12-F	Abdomen	42	6 x 4 x 2	✓ Mammary fibroadenoma ✓	24
13-F	Abdomen	-	-	✓ Fibroadenoma ✓	24
14-F	Abdomen	209.0	10 x 9 x 3	✓ Mammary fibroadenoma ✓	24
15-F	Abdomen	14.63	-	✓ Fibroadenoma ✓	24

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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 effects 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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Manager, Toxicology

November 12, 1971

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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		Dietary Level (ppm)
	Male	Female	
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.

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.

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.

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:														90-Day Total Weight Gain (grams/rat)
		0	1	2	3	4	5	6	7	8	9	10	11	12	13	
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

Dietary Level of Aroclor 1242 (ppm)	Sex	Body Weight (grams) Month:									12-Month Total Weight Gain (grams/rat)
		4	5	6	7	8	9	10	11	12	
Control	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:											24-Month Total Weight Gain (grams/rat)	
		13	14	15	16	17	18	19	20	21	22	23	24	
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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BIO 1531 Laboratory Inc

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

Dietary Level of Aroclor 1242 (ppm)	Sex	Food Consumption (grams/rat/seven days)													Average Food Consumption (grams/rat/seven days)
		1	2	3	4	5	6	7	8	9	10	11	12	13	
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

Dietary Level of Aroclor 1242 (ppm)	Sex	Food Consumption (grams/rat/seven days)										Average Food Consumption (grams/rat/seven days)
		Month:										
		4	5	6	7	8	9	10	11	12		
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	

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

Dietary Level (ppm)	Sex	Frequency Distribution of Deaths Months:								Total Dead Number Tested
		1-3	4-6	7-9	10-12	13-15	16-18	19-21	22-24	
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.

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)						Erythrocyte Count (millions/mm ³)					
		Month:						Month:					
		3	6	9	12	18	24	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)						Hematocrit Value (%)					
		3	6	Month:		18	24	3	6	Month:		18	24
				9	12					9	12		
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						Neutrophils					
		3	6	9	12	18	24	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						Eosinophils					
		Month:						Month:					
		3	6	9	12	18	24	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)						Blood Urea Nitrogen Concentration (mgs %)					
		Month:						Month:					
		3	6	9	12	18	24	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 %)						Serum Alkaline Phosphatase Activity (King-Armstrong Units)					
		3	6	9	12	18	24	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:						Albumin Month:					
		3	6	9	12	18	24	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:						pH Month:					
		3	6	9	12	18	24	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

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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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.

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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

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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

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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.

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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

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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

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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 analyses 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.

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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.

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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.

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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.

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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

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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

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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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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.

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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	Aver Gra
5 Males	Trachea	Tracheitis	2	1.0
		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

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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

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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.

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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

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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.

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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.

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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: Conads

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.

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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

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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.

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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.

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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	A C
5 Males	Trachea	Tracheitis	1	
	Lung	Chronic respiratory disease	2	
	Urinary Bladder	Calculus	1	
5 Females	Trachea	Tracheitis	1	
	Lung	Chronic respiratory disease	1	
	Colon	Parasites	1	

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

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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	Av C
5 Males	Trachea	Tracheitis	1	1
	Lung	Chronic respiratory disease	4	1
	Liver	Congestion	1	1
	Pancreas	Focal atrophy	1	1
	Kidney	Focal lymphoid infiltration	1	1
	Pituitary	Chromophobe hyperplasia	1	1
	Adrenal	Nodular hyperplasia	1	1
		Hematocyst	1	1
5 Females	Trachea	Tracheitis	1	1
	Lung	Chronic respiratory disease	1	1

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.

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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 Aroclor 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.

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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

Dose 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.

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Organ: Kidneys

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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

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	1.15	0.96	0.182	0.181	0.520	0.497
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

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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

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	2.52	0.123	0.397	0.0222	1.15	0.062
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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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

Dose 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.

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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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 animal 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.

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

The minor lesions of degeneration, hepatitis, ductule 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 the animals are related to spontaneous disease and they are not unusual for rats of this age.


Donovan E. Gordon, D. V. M., Ph. D.
Diplomate, American College of
Veterinary Pathologists

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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
		Focal encephalitis	1	1.0
	Brain			
	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		
	Stomach	Chronic gastritis	3	1.0
		Acanthosis - squamous epithelium	5	1.0
		Colon		
	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

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

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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
		Tracheitis	9	2.0
		Chronic respiratory disease	12	1.0
		Focal lymphoid infiltration	1	1.0
	Liver	Cirrhosis	1	1.0
		Congestion	1	1.0
		Chronic gastritis and acanthosis	2	1.0
		Hemosiderosis	4	2.0
	Spleen	Chronic nephritis	9	2.0
		Calcification	1	1.0
		Periarteritis	2	2.0
		Testicular degeneration	1	1.0
	Kidney	Inflammation	1	4.0
		Telangiectasis	2	1.0
		Nodular hyperplasia	1	2.0

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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	Chronic 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

All other tissues and organs were normal histologically.

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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
		Tracheitis	7	1.0
		Chronic respiratory disease	9	2.0
		Focal hypertrophy and hyperplasia	1	1.0
		Hypertrophy	1	1.0
		Vacuolar change (fatty)	2	1.0
		Ductile hyperplasia	1	2.0
		Chronic focal pancreatitis	3	1.0
	Pancreas	Acanthosis	6	1.0
		Inflammation, ulceration and necrosis	1	1.0
		Hemosiderosis	7	1.0
	Kidney	Chronic nephritis	10	2.0
		Testicular degeneration	2	3.0
	Testes	Periarteritis	3	3.0

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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
		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

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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

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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

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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
		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

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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 4.0 = severe

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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 Arocl 1242 and are considered normal for a random population of rats this age.

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Two-Year Chronic Oral Toxicity Study - Albino Rats

Group: Control

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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	5 x 3 x 1	Fibroadenoma	24
		35.00	1 x 1 x 1	Fibroadenoma	
613-F	Ovary	-	3 x 2 x 1	Granulosa cell tumor	24
	Abdomen	-	-	Fibroadenoma	
615-F	Abdomen	335.00	13 x 10 x 5	Mammary fibroadenoma	23

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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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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	
700-F	Abdomen	175.0	8 x 7 x 5	Mammary fibroadenoma	24
701-F	Parathyroid gland	-	-	Adenoma	24

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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

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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

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Monsanto

ACHIEVEMENT AWARD DATA

Name of Nominee Paul L. Wright			Location Creve
Company Unit or Staff Dept. Med. & Env. Hlth.	Division	Business Group	Department
Position Title Toxicology Manager	Salary Grade 19	Annual Salary \$31,800	Date of Last Increase 2/1/76
Performance		Growth	Date Last Employee Review

Type of Award (Select the award category from the opposite side of this sheet which most appropriately describes the award and enter the code below.)

Award Category Technical - Accomplishment of significant results	Category 106
--	------------------------

Describe the achievement and its significance to Monsanto below:

At a recent meeting in Creve Coeur, Glenn Schweitzer, head of the Off Toxic Substances of EPA, offered some interesting comments. He observed that Monsanto's toxicologists were held in high regard at EPA. However since it lacked an in-house toxicology facility, Monsanto as a company not as highly regarded overall as duPont, Carbide, or Dow.

Dr. Wright's professional and personal characteristics have contributed significantly to Monsanto's image at EPA. He has shown unusual perseverance and dedication, frequently involving his own time, to review and integrate large volumes of data which he subsequently organized for presentation to EPA officials. Particularly noteworthy were his efforts on polychlorinated biphenyls (Aroclors) and chlorinated isocyanurates (ACL products). In former instance, his excellent analysis and synthesis of widely scattered observations played a prominent role in forestalling EPA's promulgation of unrealistic regulations to limit discharges of polychlorinated biphenyls. EPA's proposed regulations would have precluded the use of these materials by Monsanto's customers. With respect to chlorinated isocyanurates, Dr. Wright has had several contacts with individual scientists at EPA to answer specific questions that they had raised or to inform them of the status of additional studies which had been undertaken.

Overall, by virtue of the qualities of leadership which Dr. Wright has played, he has made an important contribution to Monsanto's image at EPA. That favorable image will become increasingly important to Monsanto in areas of interaction with EPA multiply.

F001144

Recommended By <i>Ed Leimbach</i>	Date <i>16 July '76</i>	Award Amount Recommended	Approved By <i>Leimbach</i>	Date <i>8/4/76</i>	Award Amount <i>771</i>
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MONSANTO INDUSTRIAL CHEMICALS COMPANY
FUNCTIONAL PRODUCTS GROUP

STANDARD MANUFACTURING PROCESS
for

AROCLORS (Take-over distilled)

Department 246

Supercedes: Standard Manufacturing Process for Aroclors -
Department 246, dated October 1966, and all
amendments A through L.

Tentative Process for the Continuous Manufacture
of Aroclor 1242, dated 9/16/68, and designated
Report No. P-1504.

Prepared by: R. M. McCutchan

Approved by

A. E. Lewis

General Manufacturing Superintendent

W R Richard

Research & Development Manager

A R Fairclough

Manufacturing Manager

Issued: January 1972

Copy 9 of 15

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E001145

123

10M 0026

DEPARTMENT 246 - STANDARD MANUFACTURING PROCESS

AROCOR

APPENDIX J

SAFETY AND TOXICITY DATA

I. SAFETY EQUIPMENT

A. Fire Extinguishers.

1. Carbon dioxide - 1st floor, NE of lean-to
2. Dry chemical - 1st floor, SE of lean-to
3. Dry chemical - 2nd floor, west wall
4. Dry chemical - 2nd floor, west wall

B. Gas Masks.

1. 1st floor, on sprinkler house
2. 1st floor, outside west wall of repair room
3. 2nd floor, on west wall
4. Control room, east wall
5. 4th floor, on handrail by #1 chlorinator
6. 4th platform, Aroclor column (2)

C. Scott Air Pak.

1. Outside west wall of lean-to

D. Emergency Clothing.

1. Box on 2nd floor, west wall.

E. Safety Showers With Eye Wash.

1. Batch department, 1st floor,
2. Batch department, 2nd floor.
3. Batch department, 3rd floor.
4. Continuous department, 1st floor.
5. Continuous department, 2nd floor.
6. Continuous department, 3rd floor.
7. West side of tank farm (alarm in control room).
8. Control room (eye batch only).

F. Personal Safety Equipment Available.

1. Hard hat.
2. Safety glasses.
3. Safety shoes.
4. Goggles.
5. Rubber or canvas gloves.
6. Rubber overshoes.

E001146

DEPARTMENT 246 - STANDARD MANUFACTURING PROCESS

AROCLOR (Cont'd)

APPENDIX J (Cont'd)

SAFETY AND TOXICITY DATA (Cont'd)

II. DEPARTMENT SAFETY RECORD (246/259).

- A. Lost time accidents - Last occurred on January 28, 1948.
- B. Serious injuries - The last two serious injuries were:
- 1) 8/5/70 - See Attached informal investigation report.
 - 2) 12/2/68 - Refer to formal investigation report L-17-20-68
- C. Minor injuries.

<u>Year</u>	<u>Injuries</u>	<u>No. of Men</u>
1969	12	20
1970	12	20
1971	13	24

III. TOXICITY

The following toxic rating code will be used in describing the toxicity of these materials:

- 0 - none
1 - slight
2 - moderate
3 - high
U - unknown

A. Biphenyl (Code 82601)

1. Synonyms: Diphenyl.
2. Description: White flakes or solid off white mass; somewhat pleasant odor.
3. Constants: Mol. Wt. 154.2; M.P. 69°C.; B.P. 255°C.; Density .9910 @ 75°/4°C.
4. Flash Point: 235° F. (C.C.).
5. Auto Ignition Temperature: 1004°F.
6. Toxic Hazard Rating:
Acute Local: U
Acute Systematic: Ingestion 3, Inhalation 3
Chronic Local: U
7. Fire Hazard: Definitely when exposed to heat or flame; can react with oxidizing materials.
8. Fire Fighting: CO₂ or dry chemical.
9. Formula: C₆H₅C₆H₅

E001147

DEPARTMENT 246 - STANDARD MANUFACTURING PROCESS

AROCLOR

APPENDIX J (Cont'd)

SAFETY AND TOXICITY DATA (Cont'd)

III. (Cont'd)

A. (Cont'd)

10. Biphenyl vapors are irritating to the upper respiratory tract. Workers should not be exposed to vapor levels throughout their shift in excess of the threshold limit value of 1 milligram per cubic meter of air (or about 0.2 ppm). The compound, or organic solutions of the compound can absorb through the intact skin; therefore, repeated skin contact should be avoided.
11. See Hygienic Guide Series on "Diphenyl".

B. Chlorine (Code 81059).

1. Description: Greenish yellow gas.
2. Formula: Cl_2
3. Constants: Mol. Wt. 70.914; M.P. = $-101^{\circ}C.$; B.P. = $-34.5^{\circ}C.$; Density 1.47 @ $0^{\circ}C.$
4. Toxic Hazard Rating:
 - Acute local: Irritant 3; Inhalation 3
 - Acute systemic: 0
 - Chronic local: U
 - Chronic systemic: U
 - M.A.C. = 1 ppm in air per 8 hour day
5. Toxicology: Chlorine is extremely irritating to the mucous membranes of the eyes and respiratory tract. It combines with moisture to liberate nascent oxygen and form hydrochloric acid.

Both of these substances, if present in quantity, cause inflammation of the tissues with which they come in contact. If the lung tissues are attacked, pulmonary edema may result. A concentration of 3.5 ppm produces a detectable odor; 15 PPM causes immediate irritation of the throat. Concentrations of 50 PPM are dangerous for even short exposure; 1000 PPM may be fatal even when the exposure is brief.

Because of its intensely irritating properties, severe industrial exposure seldom occurs, as the workman is forced to leave the area before he can be seriously affected. In cases where this is impossible, the initial irritation

E001148

DEPARTMENT 246 - STANDARD MANUFACTURING PROCESS

AROCOR

APPENDIX J (Cont'd)

SAFETY AND TOXICITY DATA (Cont'd)

III. B. 5. (Cont'd)

of the eyes and mucous membranes of the nose and throat is followed by cough, a feeling of suffocation and later pain and a feeling constriction in the chest. If exposure has been severe, pulmonary edema may follow with rales being heard over the chest.

6. Fire Hazard: Moderate - can react to cause fire or explosion upon contact with turpentine, ether, ammonia gas, illuminating gas, hydrocarbons, hydrogen and powdered metals.
7. Explosion Hazard: Present by reaction with reducing agents.
8. Disaster Control: Dangerous; emits highly toxic fumes; will react with water to form toxic and corrosive fumes of HCl; is heavier than air - gas will hug the ground. People without adequate protection should go across wind until out of the affected area.

C. HCl Off-Gas (Code 828.51)

1. Synonyms: Muriatic acid, Chlorohydric Acid, Hydrogen Chloride
2. Description: Colorless gas.
3. Formula: HCl.
4. Toxic Hazard Rating:
 - Acute local: Irritant 3, Ingestion 3, Inhalation 3
 - Acute Systemic: U
 - Chronic local: Irritant 2
 - Chronic Systemic: U
5. M.A.C.: 5 ppm in air for 8 hr. day.
6. Toxicology: Hydrogen chloride is an irritant to the mucous membranes of the eyes and respiratory tract. Concentration of 35 ppm causes irritation of the throat after short exposure. Concentrations of 50 to 100 ppm are tolerable for 1 hour. More serious exposures result in pulmonary edema and often laryngeal spasm. Concentrations of 1000 to 2000 ppm are dangerous even for brief exposures. Mists of HCl are considered less harmful than the anhydrous form since the droplets have no dehydrating effect.
7. See Hygienic Guide Series on "Hydrogen Chloride".

FM01149

DEPARTMENT 246 - STANDARD MANUFACTURING PROCESS

AROCLOR

APPENDIX J (Cont'd)

SAFETY AND TOXICITY DATA (Cont'd)

III. (Cont'd)

D. Ferric Chloride (Code 33500)

1. Description: Granular solid.
2. Formula: FeCl_3 (Anhydrous)
3. Constants: Mol. Wgt. = 166.22, Melting Pt. = sublimes, solubility in H_2O = very soluble with heat rise.
4. Toxic Hazard Rating:
Acute Local: Irritant 1; Ingestion 1
Acute Systemic: 0
Chronic Local: Irritant 1
Chronic Systemic: 0
5. Fire Hazard: There is no fire hazard under normal conditions but it will emit toxic fumes at high temperatures.
6. Handling: Protect the skin with approved protective clothing, avoid the breathing of FeCl_3 dust, wear approved respirator with adequate cartridge, and protect the eyes with approved goggles. There are no storage regulations; however, it should be stored in a dry place as heat is released upon solution in water and wet ferric chloride will not catalyze the chlorination reaction.

E. Lime (Code 38800) (Calcium Oxide)

1. Description: Fine white or slightly gray powder, Rhombohedral Trigonial Crystals.
2. Formula: CaO .
3. Toxic Hazard Rating:
Acute Local: Irritant 3; Ingestion 1; Inhalation 3.
Acute Systemic: Ingestion 2; Inhalation 3; skin absorption 0.
Chronic Local: Irritant 3; Inhalation 2.
Chronic Systemic: Ingestion 2; Inhalation 3; Skin absorption 0.
4. Toxicology:
Has a caustic reaction and, therefore, is irritating to the skin. As a dust it can cause dermatitis and irritation of the eyes and mucous membranes. It is a general nuisance type of dust.
5. Fire Hazard: None.
6. Explosion Hazard: Virtually none.
7. Handling: Dust respirator, adequate protective clothing, including rubber coated gloves, optional rubber full cover apron and full cover plastic goggles should be used when

ENC1150

DEPARTMENT 246 - STANDARD MANUFACTURING PROCESS

AROCLOL

APPENDIX J (Cont'd)

SAFETY AND TOXICITY DATA (Cont'd)

E. 7. (Cont'd)

handling lime (dust). Adequate ventilation and dust removal equipment should be used in the handling area.

Lime is added to the stills to neutralize any liberated HCl prevent sublimation of the FeCl_3 catalyst. It is handled in 50# bags.

F. Nitrogen (Code 43099)

1. Description: Colorless gas
2. Formula: N_2
3. Constants: Mol. Wt. 28.02; M.P. - 210°C ; B.P. - 195.8°C .,
Density 1.2506 gr/liter at 0°C .
4. Toxicity: None. In high concentrations it is an asphyxiant.

G. Aroclors.

(See Hygienic Guide Series on "Chlorodiphenyls").

EQ01151

Monsanto

MONSANTO INDUSTRIAL CHEMICALS CO.
800 N. Lindbergh Boulevard
St. Louis, Missouri 63166
Phone: (314) 684-1000

January 20, 1972

Westinghouse Electric Corp.
Box 341
Bloomington, Indiana 47402

Gentlemen,

As we have previously notified you by way of correspondence since early 1970, the material described on the attached acknowledgement of your order contains polychlorinated biphenyls (PCB). Polychlorinated biphenyls are highly stable chemical compounds and are not readily biodegradable. Therefore, when placed in the environment they may be considered contaminants and may adversely affect some species of animal and marine life.

You must take every precaution to prevent any entry of polychlorinated biphenyls into the environment through spills, usage, leakage, disposal, vaporization or otherwise.

This material should not be used by you or your customer in equipment, packaging materials or products involved in the processing, handling, or storage of food, food related products, animal feeds, food wrapping or container materials, potable waters or pharmaceuticals.

Very truly yours,

Howard S. Bergen, Jr.
Howard S. Bergen, Jr.
Director
Specialty Products Group

/js

Attachment



EC01152

10 104

(Typed from Original)

January 15, 1972

Monsanto Industrial Chemicals Co.
800 N. Lindbergh Boulevard
St. Louis, Missouri 63166

Gentlemen:

Monsanto Company ("Monsanto") manufactures certain polychlorinated biphenyl products ("PCB's") which Westinghouse Electric Corporation ("Buyer") desires to purchase. While Buyer desires to purchase PCB's because of certain desirable flame resistant and insulator properties, Buyer acknowledges that it is aware and has been advised by Monsanto that PCB's tend to persist in the environment; that care is required in their handling, possession, use and disposition; that tolerance limits have been or are being established for PCB's in various food products.

Monsanto has therefore adopted certain restrictive policies with respect to its further production, sale and delivery of PCB's, including the receipt of undertakings from its customers as set forth below, and Buyer is willing to agree to such undertakings with respect to sales and/or deliveries of PCB's by Monsanto to Buyer.

Accordingly, Buyer hereby covenants and agrees that, with respect to any and all PCB's sold or delivered by or on behalf of Monsanto to or for the account of Buyer on or after the date hereof, and in consideration of any such sale or delivery, Buyer shall defend, indemnify and hold harmless Monsanto, its present, past and future directors, officers, employees and agents, from and against any and all liabilities, claims, damages, penalties, actions, suits, losses, costs and expenses arising out of or in connection with the receipt, purchase, possession, handling, use, sale or disposition of



Ex001153

Monsanto Industrial Chemicals Co.

Page Two

January 15, 1972

such PCB's by, through or under Buyer, whether alone or in combination with other substances, including, without implied limitation, any contamination of or adverse effect on humans, marine and wildlife, food, animal feed or the environment by reason of such PCB's.

The point at and after which the provisions of this agreement shall apply to PCB's sold or delivered by or on behalf of Monsanto to or for the account of Buyer on or after the date hereof, and the point at which title and risk of loss with respect to such PCB's shall pass from Monsanto to Buyer, shall be the F.O.B. point at the location from which delivery to Buyer is initiated by Monsanto, and shall refer to the point of transfer of possession of the drum, tank car, tank truck, or other container for such PCB's, from Monsanto to Buyer or the first receiving carrier utilized to effect delivery of such PCB's to Buyer.

The provisions of this agreement shall not be applicable to any PCB's delivered to Buyer prior to the date hereof; and nothing herein shall create or imply any duty or obligation: (i) of Monsanto to sell or deliver any PCB's to Buyer; or (ii) of Buyer to defend, indemnify or hold harmless Monsanto or any other corporation, or any person, for any damages resulting from the negligence of Monsanto (in the absence of negligence of Buyer) in its packaging or shipping of PCB's or from the failure of PCB's to comply with the contract specifications applicable to such PCB's. No conditions, understandings or agreements purporting to modify or vary the terms hereof shall be binding unless hereafter made in writing specifically referring to this agreement and signed by the party to be bound and no modification or variance of this agreement shall be effected by the acknowledgment or acceptance of any sale document, purchase order, shipping instruction or other forms containing terms or conditions at variance herewith.

F001154

Monsanto Industrial Chemicals Co.

Page Two

January 15, 1972

In the event of litigation to which these indemnity provisions shall apply, Monsanto will make available to Buyer such information as Monsanto has (excluding trade secrets or proprietary information of Monsanto, or any other information which Monsanto is not legally free to disclose) which may reasonably be required by Buyer in the defense of such litigation, and otherwise will cooperate with Buyer in connection therewith.

This agreement shall be governed by and be construed according to the laws of the State of Missouri.

All existing contracts for the sale of PCB's by Monsanto to Buyer for delivery in the future are hereby amended to contain the provisions set forth herein.

WESTINGHOUSE ELECTRIC CORPORATION

By (Signature)

Title Vice President

Date JANUARY 15, 1972

MONSANTO COMPANY

ORIGINAL SIGNED BY:

By E. J. Putzeli

EQ01155

Monsanto

MONSANTO INDUSTRIAL CHEMICALS CO.
800 N. Lindbergh Boulevard
St. Louis, Missouri 63166
Phone: (314) 594-1000

January 20, 1972

Westinghouse Electric Corp.
Box 341
Bloomington, Indiana 47402

Gentlemen,

As we have previously notified you by way of correspondence since early 1970, the material described on the attached acknowledgement of your order contains polychlorinated biphenyls (PCB). Polychlorinated biphenyls are highly stable chemical compounds and are not readily biodegradable. Therefore, when placed in the environment they may be considered contaminants and may adversely affect some species of animal and marine life.

You must take every precaution to prevent any entry of polychlorinated biphenyls into the environment through spills, usage, leakage, disposal, vaporization or otherwise.

This material should not be used by you or your customer in equipment, packaging materials or products involved in the processing, handling, or storage of food, food related products, animal feeds, food wrapping or container materials, potable waters or pharmaceuticals.

Very truly yours,



Howard S. Bergen, Jr.
Director
Specialty Products Group

/jef

Attachment



E001156
100599

Monsanto

MONSANTO INDUSTRIAL CHEMICALS CO.
800 N. Lindbergh Boulevard
St. Louis, Missouri 63166
Phone: (314) 684-1000

SPECIAL UNDERTAKING BY PURCHASERS OF POLYCHLORINATED BIPHENYLS

Monsanto Company ("Monsanto") manufactures certain polychlorinated biphenyl products ("PCB's") which General Electric Company ("Buyer") desires to purchase. While Buyer desires to purchase PCB's because of certain desirable flame resistant and insulator properties, Buyer acknowledges that it is aware and has been advised by Monsanto that PCB's tend to persist in the environment; that care is required in their handling, possession, use and disposition; that tolerance limits have been or are being established for PCB's in various food products.

Monsanto has therefore adopted certain restrictive policies with respect to its further production, sale and delivery of PCB's, including the receipt of undertakings from its customers as set forth below, and Buyer is willing to agree to such undertakings with respect to sales and/or deliveries of PCB's by Monsanto to Buyer.

Accordingly, Buyer hereby covenants and agrees that, with respect to any and all PCB's sold or delivered by or on behalf of Monsanto to Buyer on or after the date hereof and in consideration of any such sale or delivery, Buyer shall defend, indemnify and hold harmless Monsanto, its present, past and future directors, officers, employees and agents, from and against any and all liabilities, claims, damages, penalties, actions, suits, losses, costs and expenses arising out of or in connection with the receipt, purchase, possession, handling, use, sale or disposition of such PCB's by, through or under Buyer, whether alone or in combination with other substances, including, without implied limitation, any contamination of or adverse effect on humans, marine and wildlife, food, animal feed or the environment by reason of such PCB's.



E001157

P. 22

All existing contracts for the sale of PCB's by Monsanto to Buyer are hereby amended to contain the provisions set forth above.

Nothing herein shall create or imply any duty or obligation of Monsanto to sell or deliver any PCB's to Buyer. No conditions, understandings or agreements purporting to modify or vary the terms hereof shall be binding unless hereafter made in writing specifically referring to this agreement and signed by the party to be bound and no modification or variance of the above undertaking shall be effected by the acknowledgment or acceptance of any sale document, purchase order, shipping instruction or other forms containing terms or conditions at variance herewith.

GENERAL ELECTRIC CO.

(Buyer)

BY:

Walter A. Schottelbach

TITLE: Vice President and
Corporate Counsel

DATE: January 21, 1972

MONSANTO COMPANY

BY:

E. J. Butz
John Brundage

E001158

R-23

IDS J000

Monsanto

MONSANTO INDUSTRIAL CHEMICALS CO.
800 N. Lindbergh Boulevard
St. Louis, Missouri 63186
Phone: (314) 694-1000

February 4, 1972

Dear Sir:

We are writing to advise you that Monsanto has adopted certain policies with respect to its further sale and delivery of all polychlorinated biphenyl (PCB) products used as dielectric fluids including but not limited to those sold under tradenames such as Aroclor [®], Inerteen [®], and Pyranol [®], and under the generic term askarel.

Effective immediately Monsanto will sell and deliver these products only to manufacturers of electrical equipment or components who utilize the products as dielectric fluids and who have entered into agreement to indemnify and hold harmless Monsanto in the use of these products. The two copies of such an agreement are attached. The acceptance by Monsanto of such an agreement is subject to receipt of financial and other information from you (such as evidence of adequate insurance protection) which, in Monsanto's opinion, makes the agreement meaningful.

As you are undoubtedly aware, studies indicate PCBs may be accumulating in the environment. In some instances, PCBs have been found in food or in the food chain. For your information, attached is an article by Carl G. Gustafson of the Federal Water Quality Administration appearing in "Environmental Science & Technology" which deals with this subject. Because of Monsanto's concern over this problem, we have discontinued sales of PCBs except for use as dielectric fluids in electrical equipment and components.

If you desire to continue purchase of these products from Monsanto, please have the attached copies of agreement signed by an authorized officer on behalf of your company and forward a fully signed copy, together with your most recent audited financial statement and any other information which you feel will assist Monsanto in its evaluation.



E001159

22

ADM 00245

Page 2

If you have any questions please telephone (314) 694-2455 or write directly to Mr. H.S. Bergen, Monsanto Company, P.O. Box 14617, St. Louis, Missouri 63178.

We sincerely regret any hardships that this decision may cause you but it is taken in an effort to continue to make available these products for these important electrical applications.

Very truly yours,

Howard Bergen

Howard Bergen, Director
Specialty Products Group
Monsanto Industrial Chemicals Co.

/b1

Enclosures

E001160

ADM 002459

Monsanto

MONSANTO INDUSTRIAL CHEMICALS CO.
800 N. Lindbergh Boulevard
St. Louis, Missouri 63186
Phone: (314) 694-1000

February 17, 1972

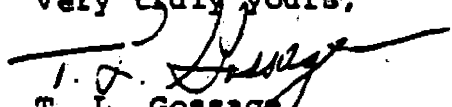
We are writing to advise you that Monsanto has adopted certain policies with respect to the further sale and delivery of all polychlorinated biphenyl (PCB's) products including those sold under tradenames such as Aroclor (®), Inerteen (®), Pyranol (®), and under the generic term askarel.

Studies have indicated PCB's may be accumulating in the environment. In some instances PCB's have been found in food or in the food chain. Because of Monsanto's concern over this problem we have discontinued sales of PCB's in all applications except as dielectric fluids for use in transformers, capacitors, and other electrical equipment and components.

In the past, Monsanto has sold these fluids direct to transformer component manufacturers and also to makers of insulation such as Kraft paper and plastic film who use only small amounts of the dielectric fluid for testing purposes. Monsanto has decided to discontinue such direct sales. For your future requirements of these dielectric fluids, we suggest you contact the Aroclor capacitor makers, or in the case of transformers contact the makers of the askarel types.

We sincerely regret any inconvenience this decision may cause you. If you have any questions relative to this decision please telephone (314) 694-2513, or write directly to Mr. Paul Benignus, Monsanto Company, P. O. Box 14617, St. Louis, Missouri 63178.

Very truly yours,


T. L. Gossage
Marketing Director
Specialty Products Group



a unit of Monsanto Company

1001161

ADM 002449

Monsanto

MONSANTO INDUSTRIAL CHEMICALS CO.
800 N. Lindbergh Boulevard
St. Louis, Missouri 63188
Phone: (314) 894-1000

February 28, 1972

Attention: Plant Engineer

Dear Sir:

We are writing to advise you that Monsanto has adopted certain policies with respect to the further sale and delivery of all polychlorinated biphenyl (PCBs) products including those sold under tradenames such as Aroclor[®], Inerteen[®], Pyranol[®], and under the generic term askarel.

Studies have indicated PCBs may be accumulating in the environment. In some instances PCBs have been found in food or in the food chain. Because of Monsanto's concern over this problem, we have discontinued sales of PCBs in all applications except as dielectric fluids for use in transformers, capacitors, and other electrical equipment and components. In the past, Monsanto has sold these fluids direct to transformer repair shops and to anyone requiring the fluid for top-up of an existing transformer. Monsanto has decided to discontinue direct sales to transformer repair shops and for transformer top-up. For your future requirements of dielectric fluids, we suggest you contact the manufacturer of the transformer for which you desire the fluid.

We sincerely regret any hardships that this decision may cause you, but it has been taken in an effort to continue to make available these products for important electrical applications. If you have any questions relative to this decision, please telephone (314) 694-2513, or write directly to Mr. Paul Benignus, Monsanto Company, P. O. Box 14617, St. Louis, Missouri 63178.

Very truly yours,

T. L. Gossage

T. L. Gossage
Marketing Director
Specialty Products

/b1

cc: Purchasing Agent

a unit of Monsanto Company



E001162

ADM 002493

Dcc: H. S. Bergen - L
C. P. Cunningham -
W. B. Papageorge - B.

March 3, 1972

Mr. Paul DeFalco, Jr.
Regional Administrator
U.S. Environmental Protection Agency
Region IX
100 California Street
San Francisco, California 94111

Dear Mr. DeFalco:

I have been asked to respond to your letter addressed to Mr. E. J. Bock, asking for certain information regarding sales of polychlorinated biphenyls by Monsanto and Central Solvents and Chemicals in the Los Angeles County area. I know that you have discussed this by telephone with Mr. W. B. Papageorge and I have reviewed the situation with him.

It has always been Monsanto's policy not to divulge the names of our customers for the products we make, nor the quantities of products these customers purchase. We consider this to be proprietary information and therefore hold it confidential. Consequently we do not feel free to comply with your request for data on customer names and quantities purchased.

On the other hand, last November we did release to governmental agencies, including the EPA, Monsanto's total production and sales figures on PCB's for the years 1960 through 1971. These statistics have been released publicly and earlier this year we discussed them in detail with members of the scientific



E001163

141 ADM 006163

Mr. Paul DeFalco, Jr.
March 3, 1972
Page 2

community and with representatives of the Washington multi-agency PCB task force of which EPA is a member. For your ready reference I am enclosing a copy of this information.

We certainly share your concern and desire to control the discharge of PCB's into the environment. It is because of this concern that we implemented a program of self-imposed curtailment of sales of these products so that now we are only offering continuing supplies for closed system dielectric applications where the potential danger of environmental contamination is carefully controlled.

Furthermore, as another step in safeguarding the environment we have informed all customers of PCB materials of the potential dangers should these materials escape and have strongly urged them to take every precaution to prevent losses through spills, usage, leakage, disposal, vaporization or otherwise.

I regret we cannot comply with your request for customer information but if we can be of assistance to you in other ways we will be glad to visit you or your designees to discuss the PCB situation further.

Sincerely,

W. R. Corey, Director
Functional Product Groups

/js

Enclosure

cc: Mr. Charles H. Soomer/Monsanto

E001164

MITSUBISHI MONSANTO CHEMICAL COMPANY

FROM LOCATION Tokyo

DATE March 22, 1972

SUBJECT PCB IN JAPAN

REFERENCE

TO Mr. P. G. Benignus
St. Louis
(B2SC)

cc, Messrs
J. R. Durland - Tokyo
W. R. Corey - St.
H. S. Berger -
T. L. Gessage -
C. Paton -
J. Mason - Brus
P. J. A. Marsh -
W. R. Richard - St.
R. H. Munch -
W. B. Papageorge -
C. R. Coleman - Newp

Dear Paul:

I am pleased to answer your questions in your letter of March 20, 1972.

The Ministry of International Trade and Industry (MITI) issued notice yesterday to almost every industrial association concerned, as summarized in the following:

- No electrical machinery and equipment which contain PCB must be manufactured after Sept. 1, 1972.
- No heat exchange equipment must be produced after July 1, 1972 which use PCB as a transfer medium.
- Exceptions to the above are those which are sold to the specific users and which can be returned after use to the producers or manufacturers for PCB disposal. They must periodically report to the ministry how PCB is used, shipped, stored, recovered, returned and disposed, including machinery, in addition to the quantity dealt with and so and so forth

Every user of PCB-containing machinery and equipment will have to be recorded and registered in the official list to insure strict supervision in the future.

- Import of such machinery and equipment will be possible only if permission is granted by the Government, after September 1, 1972.
- PCB containing machinery and equipment already in use must be identified and reported to the authorities so that the disposal of PCB is to be made complete.

PLAINTIFF'S
EXHIBIT

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You will understand that the above action is not the total ban of PCB usage. However, who can meet such stringent regulatory requirements to continue using PCB, other than non-civil organisations?

We called the MITI yesterday to learn the following:

1. The MITI foresee by the action taken yesterday the use of PCB fluid will be limited in the near future to the transformers used by the Japan National Railroad and certain electronic parts in missiles belonging to the Defense Ministry, in addition to the high voltage electro-furnace capacitors as a possibility.
2. Thermal transfer systems with PCB will sooner or later undergo change in fluid or the whole line will have to discontinue operation.
3. Kaneka agreed to follow the recommendation by the MITI to discontinue the production of PCB, probably after September of this year.
4. Those who are able and obliged to use PCB will have to import PCB, possibly from Bayer, with permission from the Government.

You rightly pointed out that the actions being taken by the Japanese Government appear out of line from the rest of the world today. - I can agree to Mr. Terasaki's statement in this respect that the folks go all the way when they decide to do something in this country.

I think the latest happening sensationally moved the Government to this direction - the analysis of mothers' milk in Osaka showed PCB level of 0.7 to 0.1 PPM, as against the FDA's 0.2 maximum level for cows' milk. - In the Diet committee the Welfare Minister was at a loss when asked if or not babies can drink milk with 0.7 PPM-PCB without any danger to their healthy growth.

You might recall Yodo River flows from Lake Biwa to Osaka Bay. Two capacitor plants are located by the Lake-Nichicon's and Nisshin Electric's. Samples of the soil were taken from the vicinity of Nichicon to run analysis of PCB with an unfortunate result showing 1,000 PPM PCB.

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People associated the contamination of the soil with the mothers' milk case. Thus Nichicon was forced to announce last week that they plan to discontinue production of PCB capacitors, after coming September.

Today the world seems to be ruled by feeling and not reason. The pressure against PCB usage is far from logical. It is quite emotional and at the same time political. It was this pressure that led Kaneka to the discontinuation.

It has not been 100% confirmed but I think you may rest assured Kaneka will not go after overseas markets after the fall of this year, although they are exporting substantially today.

The grand funeral of PCB in Japan is close at hand. What will replace PCB in the dielectric markets is yet known to nobody exactly. We only are aware a number of products ranging from silicone to polyisobutane, wax and DOP are competing. The strongest candidate on the longer term basis seems to me entirely new systems after technological innovation.

I wish you good luck.

T. Katayama

T. Katayama

TK/ym

P.S. Just before I had this letter typed, Kaneka announced that they decided to discontinue the production of Kaneclor by the end of June, which was confirmed by myself today with Kaneka.

Also Nichicon was forced to terminate their production of PCB capacitors at the end of April.

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