REPORT TO

MONSANTO COMPANY

TWO-YEAR CHRONIC ORAL TOXICITY WITH
AROCLOR 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.

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 a which the deaths occurred did not vary among the test and control grou

Hematological and clinical blood chemistry studies conducted after 3, 6, 9, 12, 18, or 24 months did not reveal any affects related to Aro 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 body weight and organ to brain weight ratios disclosed several randomly occurring intergroup differences. The lack of any consistent dose relat response and the absence of any deleterious histopathologic change conf 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. T lesion is morphologically indicative of fatty degeneration. Specific fat stains confirmed the presence of fat in these vacuoles. Focal hypertroph and focal hyperplasia were also found in the livers from animals fed Aro 1260.

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.

Report prepared by: Philip S. Smith
Philip Smith, B. S.
Assistant Toxicologist
Rat Toxicity

Report approved by: James B. Plank
James B. Plank
Senior Group Leader
Rat Toxicity

Paul L. Wright
Paul L. Wright, Ph. D.
Section Head, Toxicology

M. L. Kepling
M. L. Kepling, 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* 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 Male	Female	Dietary Level (ppm)
Control	50	50	None Administered
T-I	50	50	1
T-II	50	50	10
T-III	50	50	100

* Charles River Breeding Laboratories, North Wilmington, Mass.

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 ever 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 Variante 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 wer 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.

Tissues and organs examined were the same as those previous 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 dat 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: 0	1	2	3	4	5	6	7	8	9	10	11	12	13	90-Day Total Weight Gain (grams/rat)
Control	M	133	203	245	313	362	373	391	409	424	440	440	449	467	474	341
	F	136	178	190	219	244	254	259	265	270	276	281	278	290	288	152
1	M	133	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

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: 4	5	6	7	8	9	10	11	12	12-Month Total Weight Gain (grams/rat)
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: 13	14	15	16	17	18	19	20	21	22	23	24	24-Month Total Weight Gain (grams/rat
Control	M	728	746	759	768	769	767	760	758	739	726	687	642	509
	F	426	444	466	481	500	515	533	547	551	550	564	551	415
1	M	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

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.

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) Week: 1	2	3	4	5	6	7	8	9	10	11	12	13	Average Food Consumption (grams/rat/seven days)
Control	M	94	160	175	163	137	137	225	197	204	188	191	194	196	174
	F	73	140	144	107	104	133	208	154	165	151	146	150	151	140
1	M	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

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: 4	5	6	7	8	9	10	11	12	Average Food Consumption (grams/rat/seven days)
Control	M	196	189	168	147	163	184	179	170	187	176
	F	148	154	136	121	138	152	160	141	127	142
1	M	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

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.

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: 1-3	4-6	7-9	10-12	13-15	16-18	19-21	22-24	Total Dead / Number Tested
Control	M	0	0	0	2	1	7	6	9	25/35
	F	0	0	0	1	3	5	7	3	19/35
1	M	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.

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 contr values were observed.

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) Month: 3	6	9	12	18	24	Erythrocyte Count (millions/mm^3) Month: 3	6	9	12	18	24
Control	M	14.0	15.4	10.1	11.1	9.9	11.2	8.1	8.2	8.7	8.8	7.6	6.5
	F	9.1	9.4	6.7	7.6	8.8	7.6	7.5	7.7	7.3	7.8	7.7	6.8
100	M	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

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) Month: 3	6	9	12	18	24	Hematocrit Value (%) Month: 3	6	9	12	18	24
Control	M	17.1	17.7	15.7	17.6	16.1	13.6	51	49	48	50	41	35
	F	16.9	17.4	14.1	16.7	16.4	14.6	50	47	43	46	42	38
100	M	16.1	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

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: 3	6	9	12	18	24	Neutrophils Month: 3	6	9	12	18	24
Control	M	82.0	86.6	80.4	78.8	79.0	65.4	16.0	11.4	18.6	20.6	20.0	32.2
	F	83.0	86.6	86.8	89.0	70.2	61.4	15.4	11.6	11.8	10.0	29.2	36.0
100	M	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

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 Month: 3	6	9	12	18	24	Eosinophils Month: 3	6	9	12	18	24
Control	M	0.6	0.0	0.0	0.4	0.2	1.2	1.4	2.0	1.0	0.2	0.8	1.6
	F	0.6	0.0	0.0	0.0	0.2	1.0	1.0	1.8	1.4	0.2	0.6	1.6
100	M	0.0	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

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

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: 3	6	9	12	18	24	Blood Urea Nitrogen Concentration (mgs %) Month: 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

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 (mgs%) Month: 3	6	9	12	18	24	Serum Alkaline Phosphatase Activity (King-Armstrong Units) Month: 3	6	9	12	18	24
Control	M	128	123	89	88	138	99	28.6	24.7	21.5	20.3	16.2	22.3
	F	130	118	115	92	134	109	18.9	17.8	10.6	11.9	16.8	20.2
100	M	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

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.

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: 3	6	9	12	18	24	Albumin Month: 3	6	9	12	18	24
Control	M	n	n	n	n	n	n	n	n	t	t	+2	+3
	F	n	n	n	n	n	n	n	n	n	n	t	+2
100	M	n	n	n	n	n	n	n	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

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 Month: 3	6	9	12	18	24	pH Month: 3	6	9	12	18	24
Control	M	N	N	N	N	N	+1	7	7	6	7	7	6
	F	N	N	N	N	t	t	8	8	7	8	6	6
100	M	N	N	N	N	N	t	7	7	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

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

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.

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.

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

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

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

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

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

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.

TABLE XIX

TEST MATERIAL: Aroclor 1260

Two-Year Chronic Oral Toxicity Study - Albino Rats

Histopathologic Changes

Three-Month Sacrifice

Group: Control

Number of Animals	Organ Examined	Findings	Incidence	Averag 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

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

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.

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.

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.

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.

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.

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.

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.

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 contr as well as the rats fed Aroclor 1260.

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

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	Averag 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
	Lung	Focal pneumonitis	2	1.0
		Hyperemia	1	3.0
	Liver	Hyperemia	2	1.5
		Focal pericholangitis	1	0.5
	Kidney	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

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 t 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 br 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.

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.

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.

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.

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.

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

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.

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

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	Aver. Gra
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

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

TABLE XXXVII

TEST MATERIAL: Aroclor 1260

Two-Year Chronic Oral Toxicity Study - Albino Rats

Organ Weight and Ratio Data

Summary of Mean Values

Final Sacrifice

Organ: Liver

ietary Level (ppm)	Organ Weight (g)		Organ/Body Weight Ratio (g/100 g)		Organ/Brain Weight Ratio (g/g)	
	Males	Females	Males	Females	Males	Females
ontrol	22.0	16.3	3.47	3.05	10.10	8.42
1	22.0	16.6	3.40	3.35	9.93	8.62
10	24.1	18.1	2.87*	3.19	11.20	9.26
00	29.9**	22.7**	4.67**	4.42**	13.40*	11.60*

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

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

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.

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 cha noted. Table XLVII contains the results of the histopathologic examinat of the urinary bladders.

Significant liver injury was found in animals fed 100 pp Aroclor 1260 (T-III). The compound associated lesions consisted of vac change, focal hypertrophy and focal hyperplasia. In addition, there were lesions of inflammation, necrosis, fibrosis and minor degeneration in thi group which, although seen in the controls and lower test groups, were m severe and frequent in the T-III group.

The vacuolar change was not seen in the control animal 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 morphologi indicative of fatty degeneration. Formalin-frozen sections of livers from represenative animals which displayed vacuolar changes were stained wit Oil Red O to reveal the presence of fat. The vacuolar lesion in the cytopla 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 swolle to two or three times their normal size with clear pink homogenous cytopl 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 contro animals and the T-I and T-II groups are lesions of spontaneous disease a are not related to the Aroclor 1260. This level of liver disease is not un in old animals.

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

D. E. Gordon

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.

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
	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

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
	Stomach	Chronic gastritis	3	1.0
		Acanthosis - squamous epithelium	5	1.0
	Colon	Parasites	1	1.0
	Spleen	Hemosiderosis	4	1.0
	Uterus	Metritis	3	2.0
	Kidney	Chronic nephritis	6	1.0
		Focal lymphoid infiltration	1	1.0
	Ovary	Cyst	1	1.0
	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.

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
	Prostate	Inflammation	4	2.0
	Seminal Vesicle	Inflammation	1	2.0

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 hyperoplasia	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

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	Telangiectasis	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

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	Thracheitits	8	1.0
	Lung	Chronic respiratory disease	14	1.0

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.

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
	Trachea	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
		Centrolobular hypertrophy	2	1.0
		Telangiectasis	1	1.0
	Pancreas	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
				1.0

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

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

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

* Individual animal numbers are shown in parentheses.

Grading System

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

G. Detailed Description of Tumor Findings

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

None of these tumors could be related to the ingestion of Aroclo 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
16-F	Abdomen	64.98	8 x 1 x 2	Mammary fibroadenoma	24
		35.09	5 x 2 x 2	Mammary fibroadenoma	
17-F	Lymph node	-	-	Reticulum cell sarcoma	24
38-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	-

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	-	-	Chromophobe adenoma	24
	Abdomen	25.00	6 x 3 x 1	Mammary fibroadenoma	
128-F	Pituitary	-	-	Chromophobe adenoma	21
	Abdomen	60.80	5 x 6 x 2	Mammary fibroadenoma	
138-F	Abdomen	20.07	-	Mammary fibroadenoma	24
	Pituitary	-	-	Chromophobe adenoma	
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

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	-	-	Chomophobe adenoma	
221-F	Submaxillary region	14.44	2 x 3 x 1	Fibroadenoma	24
	Abdomen	29.0	3 x 5 x 2	Mammary fibroadenoma	

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	60.82	6 x 4 x 3	✓ Mammary fibroadenoma	24
	Pancreas	-	-	✓ Islet cell adenoma	

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

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	Mammary fibroadenoma	24
		-	1 x 2 x 1	Mammary fibroadenoma	
312-M	Pituitary	-	-	Chromophobe adenoma	24
314-F	Abdomen	26.00	5 x 4 x 3	Mammary fibroadenoma	24

Industrial BIO TEST Laboratories, Inc.

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 represe the results of this investigation.

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 deat 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 affects 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.

This lesion is morphologically indicative of fatty degeneration. Specific fat stains confirmed the presence of fat in these vacuoles. Focal hypertro 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 cont 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.

Report prepared by:

Philip S. Smith, B.S.
Assistant Toxicologist
Rat Toxicity

Report approved by:

James B. Plank
Senior Group Leader
Rat Toxicity

Paul L. Wright, Ph.D.
Section Head, Toxicology

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

November 12, 1971

bb:hp

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

* Charles River Breeding Laboratories, North Wilmington, Mass.

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 mad 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.

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

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.

Tissues and organs examined were the same as those previous 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.

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: 0	1	2	3	4	5	6	7	8	9	10	11	12	13	90-Day Total Weight Gain (grams/rat)
Control	M	133	203	245	313	362	373	391	409	424	440	440	449	467	474	341
	F	136	178	190	219	244	254	259	265	270	276	281	278	290	288	152
1	M	133	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

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: 4	5	6	7	8	9	10	11	12	12-Month Total Weight Gain (grams/rat)
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	496	521	541	562	586	608	627	642	664	531
	F	292	300	306	316	321	326	332	340	347	211

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: 13	14	15	16	17	18	19	20	21	22	23	24	24-Month Total Weight Gain (grams/rat)
Control	M	728	746	759	768	769	767	760	758	739	726	687	642	509
	F	426	444	466	481	500	515	533	547	551	550	564	551	415
1	M	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.

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: 1	2	3	4	5	6	7	8	9	10	11	12	13	Average Food Consumption (grams/rat/seven days)
Control	M	94	160	175	163	137	137	225	197	204	188	191	194	196	174
	F	73	140	144	107	104	133	208	154	165	151	146	150	151	140
1	M	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

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: 4	5	6	7	8	9	10	11	12	Average Food Consumption (grams/rat/seven days)
Control	M	196	189	168	147	163	184	179	170	187	176
	F	148	154	136	121	138	152	160	141	127	142
1	M	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	198	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.

TABLE IV

TEST MATERIAL: Aroclor 1254

Two-Year Chronic Oral Toxicity Study - Albino Rats

Mortality Data

Frequency Distribution of Deaths

Dietary Level (ppm)	Sex	Frequency Distribution of Deaths Months: 1-3	4-6	7-9	10-12	13-15	16-18	19-21	22-24	Total Dead Number Tested*
Control	M	0	0	0	2	1	7	6	9	25/35
	F	0	0	0	1	3	5	7	3	19/35
1	M	0	0	0	2	5	6	8	9	30/35
	F	2	0	0	1	2	1	5	3	14/35
10	M	0	0	0	1	3	5	8	10	27/35
	F	0	1	1	4	2	3	4	7	22/35
100	M	0	0	1	3	2	5	7	9	27/35
	F	1	0	2	4	4	2	4	6	23/35

* 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.

TABLE V

TEST MATERIAL: Aroclor 1254

Two-Year Chronic Oral Toxicity Study - Albino Rats

Hematologic Data

Summary of Mean Values

Dietary Level (ppm)	Sex	Total Leukocyte Count (thousands/mm^3) Month: 3	6	9	12	18	24	Erythrocyte Count (millions/mm^3) Month: 3	6	9	12	18	24
Control	M	14.0	15.4	10.1	11.1	9.9	11.2	8.1	8.2	8.7	8.8	7.6	6.5
	F	9.1	9.4	6.7	7.6	8.8	7.6	7.5	7.7	7.3	7.8	7.7	6.8
100	M	15.1	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

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) Month: 3	6	9	12	18	24	Hematocrit Value (%) Month: 3	6	9	12	18	24
Control	M	17.1	17.7	15.7	17.6	16.1	13.6	51	49	48	50	41	35
	F	16.9	17.4	14.1	16.7	16.4	14.6	50	47	43	46	42	38
100	M	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

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 Month: 3	6	9	12	18	24	Neutrophils Month: 3	6	9	12	18	24
Control	M	82.0	86.6	80.4	78.8	79.0	65.4	16.0	11.4	18.6	20.6	20.0	32.2
	F	83.0	86.6	86.8	89.0	70.2	61.4	15.4	11.6	11.8	10.0	29.2	36.0
100	M	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

		Differential Leukocyte Count (Number of Cells per Hundred)											
		Monocytes Month:						Eosinophils Month:					
Dietary Level (ppm)	Sex	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

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

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 (Dado Units) Month: 3	6	9	12	18	24	Blood Urea Nitrogen Concentration (mgs %) Month: 3	6	9	12	18	24
Control	M	38	48	45	45	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

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: 3	6	9	12	18	24	Serum Alkaline Phosphatase Activity (King-Armstrong Units) Month: 3	6	9	12	18	24
Control	M	128	123	89	88	138	99	28.6	24.7	21.5	20.3	16.2	22.3
	F	130	118	115	92	134	109	18.9	17.8	10.6	11.9	16.8	20.2
100	M	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

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.

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: 3	6	9	12	18	24	Albumin Month: 3	6	9	12	18	24
Control	M	n	n	n	n	n	n	n	n	t	t	+2	+3
	F	n	n	n	n	n	n	n	n	n	n	t	+2
100	M	n	n	n	n	n	n	n	n	t	t	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

TABLE XI

TEST MATERIAL: Aroclor 1254

Two-Year Chronic Oral Toxicity Study - Albino Rats

Urine Analyses Data

Summary of Mean Values

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

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

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.

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

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

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

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

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.

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.(
	Lung	Chronic respiratory disease	1	1.(
	Urinary Bladder	Hyperplasia	3	1.(
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

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

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.

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*	1.39
10	3.22*	2.50	0.703	0.780	1.57*	1.31
100	3.23*	2.43	0.700	0.861	1.68*	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.

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

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

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.

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	Avera Grad
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

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	Averag 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

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.

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.

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.

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.

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

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.

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.

e. Histopathologic Findings

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

Tables XXXV and XXXVI list all histopathologic changes noted.

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 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

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	Avera Grad
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

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.

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.

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

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	0.0283	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.

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.

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 chan noted. Table XLVII contains the results of the histopathologic examinatic of the urinary bladders.

Significant liver injury was found in animals fed 100 ppr 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 cytopla 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

to be an extension of the hypertrophic lesion. The hyperplastic cells were also usually hypertrophic. The most severe examples of hyperplasi 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 disea 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.

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

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

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
	Stomach	Chronic gastritis	3	1.0
		Acanthosis - squamous epithelium	5	1.0
	Colon	Parasites	1	1.0
	Spleen	Hemosiderosis	4	1.0
	Uterus	Metritis	3	2.0
	Kidney	Chronic nephritis	6	1.0
		Focal lymphoid infiltration	1	1.0
	Ovary	Cyst	1	1.0

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

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
	Pancreas	Chronic focal pancreatitis	2	1.0
		Periarteritis	1	2.0
	Stomach	Chronic gastritis	2	1.0
		Acanthosis	2	1.0
		Ulcer	1	1.0
	Spleen	Hemosiderosis	5	2.0
	Kidney	Chronic nephritis	8	2.0
	Testes	Testicular degeneration	2	1.0

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

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.

Grading System

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

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

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
		Telangiectasis	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
	Uterus	Metritis	1	1.0
	Pituitary	Adenoma	3	1.0
		Hyperplasia	1	1.0
	Adrenal Gland	Telangiectasis	9	1.0
	Parathyroid Gland	Hyperplasia	1	1.0
	Thymus	Abscess	1	1.0

All other tissues and organs were normal histologically.

Grading System

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
	Trachea	Tracheitis	4	1.0
	Lung	Chronic respiratory disease	10	1.0
		Edema	3	2.0
	Liver	Focal degeneration	2	1.0
		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
	Small Intestine	Focal inflammation	1	1.0
	Spleen	Hemosiderosis	2	1.0
	Lymph Node	Congestion	1	1.0

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

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

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
			Focal epithelial hyperplasia (5)	1	1
	F	17	None	-	-

* Individual animal numbers are shown in parenthesis.

Grading System

1.0 = minimal or trace 4.0 = severe

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.

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	[illegible]	

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 sheets
** No 405 in new data sheets
*** Single No 382 on new data sheets

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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 fibro[illegible]	

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
0-F	Adrenal gland	7.8	-	Telangioma	24

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

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

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.

II. Summary

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

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

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

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

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

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.

Report prepared by:

Philip S Smith

Philip S. Smith, B. S.
Assistant Toxicologist
Rat Toxicity

Report approved by:

James B. Plank

James B. Plank
Senior Group Leader
Rat Toxicity

Paul L. Wright

Paul L. Wright, Ph. D.
Section Head, Toxicology

M. L. Keplinger

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

November 12, 1971
lm:bb:hp:kjl

III. Procedure

A. Experimental Animals

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

B. Organization of Groups

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

TABLE I

TEST MATERIAL: Aroclor 1242

Two-Year Chronic Oral Toxicity Study - Albino Rats

Outline of Experiment

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

* Charles River Breeding Laboratories, North Wilmington, Mass.

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 mont 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 autops 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 pathologi 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 wer 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.

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.

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

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: 4	5	6	7	8	9	10	11	12	12-Month Total Weight Gain (grams/rat)
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

TABLE II continued

TEST MATERIAL: Aroclor 1242

Two-Year Chronic Oral Toxicity Study - Albino Rats

Body Weight and Total Weight Gain Data

Summary of Mean Values

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

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.

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

TABLE III continued

TEST MATERIAL: Aroclor 1242

Two-Year Chronic Oral Toxicity Study - Albino Rats

Food Consumption Data

Summary of Mean Values

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

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C. Mortality and Reactions

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

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

TABLE IV

TEST MATERIAL: Aroclor 1242

Two-Year Chronic Oral Toxicity Study - Albino Rats

Mortality Data

Frequency Distribution of Deaths

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

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

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D. Hematologic and Clinical Blood Chemistry Studies

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

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

TABLE V

TEST MATERIAL: Aroclor 1242

Two-Year Chronic Oral Toxicity Study - Albino Rats

Hematologic Data

Summary of Mean Values

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

TABLE VI

TEST MATERIAL: Aroclor 1242

Two-Year Chronic Oral Toxicity Study - Albino Rats

Hematologic Data

Summary of Mean Values

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

TABLE VII

TEST MATERIAL: Aroclor 1242

Two-Year Chronic Oral Toxicity Study - Albino Rats

Hematologic Data

Summary of Mean Values

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

TABLE VII continued

TEST MATERIAL: Aroclor 1242

Two-Year Chronic Oral Toxicity Study - Albino Rats

Hematologic Data

Summary of Mean Values

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

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

TABLE VIII

TEST MATERIAL: Aroclor 1242

Two-Year Chronic Oral Toxicity Study - Albino Rats

Clinical Blood Chemistry Data

Summary of Mean Values

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

TABLE IX

TEST MATERIAL: Aroclor 1242

Two-Year Chronic Oral Toxicity Study - Albino Rats

Clinical Blood Chemistry Data

Summary of Mean Values

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

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.

TABLE X

TEST MATERIAL: Aroclor 1242

Two-Year Chronic Oral Toxicity Study - Albino Rats

Urine Analyses Data

Summary of Mean Values

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

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

TABLE XI

TEST MATERIAL: Aroclor 1242

Two-Year Chronic Oral Toxicity Study - Albino Rats

Urine Analyses Data

Summary of Mean Values

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

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

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

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.

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

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

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.

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

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

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.

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	Avera Grad
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

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	Aver Gra
5 Males	Trachea	Tracheitis	2	1.(
5 Females	Lung	Chronic respiratory disease	2	1.(
		Focal interstitial pneumonia	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

2. Six-Month Sacrifice

a. Gross Pathologic Findings

No outstanding differences were noted between test and control animals.

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

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

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

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.

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.

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.

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

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

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

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 contro as well as the rats fed Aroclor 1242.

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	1.5
		Focal tracheitis	2	1.0
	Lung	Focal pneumonitis	1	0.5
		Hyperemia	2	1.0
	Liver	Focal pericholangitis	1	1.0
	Skeletal Muscle	Focal inflammation	1	1.0
5 Females	Trachea	Focal tracheitis	1	1.0
	Lung	Hyperemia	2	2.5
	Liver	Hyperemia	1	1.0
		Pericholangitis	1	0.5
	Kidney	Focal pneumonitis	1	1.0

All other tissues and organs were normal histologically.

Grading System

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

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	Avera Grad
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

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.

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

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.

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.

TABLE XXXII

TEST MATERIAL: Aroclor 1242

Two-Year Chronic Oral Toxicity Study - Albino Rats

Twelve-Month Sacrifice

Organ Weight and Ratio Data

Summary of Mean Values

Organ: Gonads

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

* Statistically significant difference at the 95 percent confidence level.

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

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.

c. Histopathologic Findings

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

Tables XXXV and XXXVI list all histopathologic cha noted.

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

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
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

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

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.

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

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	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.

TABLE XXXVIII

TEST MATERIAL: Aroclor 1242

Two-Year Chronic Oral Toxicity Study - Albino Rats

Organ Weight and Ratio Data

Summary of Mean Values

Final Sacrifice

Organ: Kidneys

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

TABLE XXXIX

TEST MATERIAL: Aroclor 1242

Two-Year Chronic Oral Toxicity Study - Albino Rats

Organ Weight and Ratio Data

Summary of Mean Values

Final Sacrifice

Organ: Spleen

etary Level (ppm)	Organ Weight (g)		Organ/Body Weight Ratio (g/100 g)		Organ/Brain Weight Rat (g/g)	
	Males	Females	Males	Females	Males	Femal
Control	1.15	0.96	0.182	0.181	0.520	0.49
1	1.26	0.81	0.169	0.158	0.572	0.14
10	1.08	0.82	0.158	0.153	0.495	0.40
100	1.07	0.65	0.165	0.140	0.499	0.33

TABLE XL

TEST MATERIAL: Aroclor 1242

Two-Year Chronic Oral Toxicity Study - Albino Rats

Organ Weight and Ratio Data

Summary of Mean Values

Final Sacrifice

Organ: Gonads

etary Level (ppm)	Organ Weight (g)		Organ/Body Weight Ratio (g/100 g)		Organ/Brain Weight Ratio (g/g)	
	Males	Females	Males	Females	Males	Females
Control	2.52	0.123	0.397	0.0222	1.15	0.062
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

TABLE XLI

TEST MATERIAL: Aroclor 1242

Two-Year Chronic Oral Toxicity Study - Albino Rats

Organ Weight and Ratio Data

Summary of Mean Values

Final Sacrifice

Organ: Heart

:tary Level (ppm)	Organ Weight (g)		Organ/Body Weight Ratio (g/100 g)		Organ/Brain Weight Ratio (g/g)	
	Males	Females	Males	Females	Males	Females
Control	1.87	1.54	0.294	0.288	0.860	0.79[illegible]
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

c. Histopathologic Findings

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

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

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

The vacuolar change was not seen in the control animals but was observed occasionally in liver from T-I (1 ppm) and T-II (10 ppm. animals. The vacuolar change was observed frequently in the T-III anima 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 fa The vacuolar lesion in the cytoplasm of these cells was positively identifie as fat.

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

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 a 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 o 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.

D. E. Gordon

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

TABLE XLIII

TEST MATERIAL: Aroclor 1242

Two-Year Chronic Oral Toxicity Study - Albino Rats

Histopathologic Changes

Final Sacrifice

Group: Control

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

TABLE XLIII continued

TEST MATERIAL: Aroclor 1242

Two-Year Chronic Oral Toxicity Study - Albino Rats

Histopathologic Changes

Final Sacrifice

Group: Control

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

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

TABLE XLIV

TEST MATERIAL: Aroclor 1242

Two-Year Chronic Oral Toxicity Study - Albino Rats

Histopathologic Changes

Final Sacrifice

Group: 1 ppm

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

TABLE XLIV continued

TEST MATERIAL: Aroclor 1242

Two-Year Chronic Oral Toxicity Study - Albino Rats

Histopathologic Changes

Final Sacrifice

Group: 1 ppm

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

All other tissues and organs were normal histologically.

TABLE XLV

TEST MATERIAL: Aroclor 1242

Two-Year Chronic Oral Toxicity Study - Albino Rats

Histopathologic Changes

Final Sacrifice

Group: 10 ppm

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

TABLE XLV continued

TEST MATERIAL: Aroclor 1242

Two-Year Chronic Oral Toxicity Study - Albino Rats

Histopathologic Changes

Final Sacrifice

Group: 10 ppm

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

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

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

TABLE XLVI continued

TEST MATERIAL: Aroclor 1242

Two-Year Chronic Oral Toxicity Study - Albino Rats

Histopathologic Changes

Final Sacrifice

Group: 100 ppm

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

All other tissues and organs were normal histologically.

Grading System

0.5 = minimal

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

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

TABLE XLVIII

TEST MATERIAL: Aroclor 1242

Two-Year Chronic Oral Toxicity Study - Albino Rats

Description of Tumor Findings

Group: Control

Animal Number and Sex	Location	Weight (grams)	Size (cm)	Classification	Months on Test
1-M	Abdomen	-	-	Mammary fibroadenoma	24
2-M	Pancreas	11.76	-	Adenocarcinoma	24
16-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
1-F	Abdomen	88.92	13 x 11 x 4	Fibroadenoma	24

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

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	

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

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

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

Monsanto

ACHIEVEMENT AWARD DATA

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

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

Award Category	Category
Technical - Accomplishment of significant results	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 obser that Monsanto's toxicologists were held in high regard at EPA. Howev since it lacked an in-house toxicology facility, Monsanto as a compan not as highly regarded overall as duPont, Carbide, or Dow.

Dr. Wright's professional and personal characteristics have contribut nificantly to Monsanto's image at EPA. He has shown unusual persever and dedication, frequently involving his own time, to review and inte large volumes of data which he subsequently organized for presentatio EPA officials. Particularly noteworthy were his efforts on polychlor biphenyls (Aroclors) and chlorinated isocyanurates (ACL products). I former instance, his excellent analysis and synthesis of widely scatt observations played a prominent role in forestalling EPA's promulgati unrealistic regulations to limit discharges of polychlorinated biphen EPA's proposed regulations would have precluded the use of these mate by Monsanto's customers. With respect to chlorinated isocyanurates, Dr. Wright has had several contacts with individual scientists at EPA answer specific questions that they had raised or to inform them of t status of additional studies which had been undertaken.

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

F001144

Recommended By: Date	Award Amount Recommended:	Approved By: Date	Awa
[signature] 16 July '76		[signature] 7.4.81	71

C-2532 (Rev. 10/74)

001 522 SCM 0587

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:

R. E. Lewis
General Manufacturing Superintendent

W R Richard
Research & Development Manager

J R Fairey
Manufacturing Manager

Issued: January 1972

Copy 9 of 15

DEPARTMENT 246 - STANDARD MANUFACTURING PROCESS

AROCLOR

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.

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.

Year	Injuries	No. of Men
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
   Chromic Local: U
7. Fire Hazard: Definitely when exposed to heat or flame; can react with oxidizing materials.
8. Fire Fighting: CO_2 or dry chemical.
9. Formula: $C_6H_5C_6H_5$

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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°C.;B.P. - 34.5°C.; Density 1.47 @ 0°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 mucou membranes of the eyes and respiratory tract. It combines with moisture to liberate nascent oxygen and from hydrochloric acid.

   Both of these substances, if present in quantity, cause inflammation of the tissues with which they come in contac If the lung tissues are attacked, pulmonary edema may resu 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 exposu 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 affec In cases where this is impossible, the initial irritation

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 exposur 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 powdere metals.

7. Explosion Hazard: Present by reaction with reducing agen

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 Chlo
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 mucou membranes of the eyes and respiratory tract. Concentratio of 35 ppm causes irritation of the throat after short expo 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 denydrating effect.

7. See Hygienic Guide Series on "Hydrogen Chloride".

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: U
   Chronic Local: Irritant 1
   Chronic Systemic: U
5. Fire Hazard: There is no fire hazard under normal condit 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 approve 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 38600) (Calcium Oxide)

1. Description: Fine white or slightly gray powder, Rhomeri Trigonal 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 t skin. As a dust it can cause dermatitis and irritation of the eyes and mucous membranes. It is a general nuisan 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 cove apron and full cover plastic goggles should be used when

SAFETY AND TOXICITY DATA (Cont'd)

E. 7. (Cont'd)

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

Lime is added to the stills to neutralize any liberated HC 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").

Monsanto

MONSANTO INDUSTRIAL CHEMICALS CO.
800 N. Lindbergh Boulevard
St. Louis, Missouri 63166
Phone: (314) 694-1000

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

/jf

Attachment

PLAINTIFF'S EXHIBIT 325

F001152

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

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.

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. Putzell

Monsanto

MONSANTO INDUSTRIAL CHEMICALS CO.
800 N. Lindbergh Boulevard
St. Louis, Missouri 63166
Phone: (314) 694-1000

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

/jf

Attachment

F001156
100399

Monsanto

MONSANTO INDUSTRIAL CHEMICALS CO.
800 N. Lindbergh Boulevard
St. Louis, Missouri 63166
Phone: (314) 694-1000

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, employes 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.

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. Schlotterbeck

TITLE: Vice President and Corporate Counsel

DATE: January 21, 1972

MONSANTO COMPANY

BY:

Monsanto

MONSANTO INDUSTRIAL CHEMICALS CO.
800 N. Lindbergh Boulevard
St Louis, Missouri 63166
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.

PLAINTIFF'S EXHIBIT 332

F001159

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ADM 00245

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.

/bi

Enclosures

Monsanto

MONSANTO INDUSTRIAL CHEMICALS CO.
800 N. Lindbergh Boulevard
St. Louis, Missouri 63166
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

T. L. Gossage
Marketing Director
Specialty Products Group

/jf

Monsanto

MONSANTO INDUSTRIAL CHEMICALS CO.
800 N. Lindbergh Boulevard
St. Louis, Missouri 63166
Phone: (314) 694-1000

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
Marketing Director
Specialty Products

/bi

cc: Purchasing Agent

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

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

/jf

Enclosure

cc: Mr. Charles H. Sommer/Monsanto

MITSUBISHI MONSANTO CHEMICAL COMPANY

FROM LOCATION: Tokyo

DATE: March 22, 1972

SUBJECT: PCB IN JAPAN

REFERENCE:

W16A

cc: Messrs.
J. R. Durland - Tok
W. R. Corey - St.
H. S. Berger -
T. L. Gossage -
C. Paton -
J. Mason - Bru
P. J. A. Marsh -
W. R. Richard - St.
R. H. Munch -
W. B. Papageorge -
C. R. Coleman - New

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

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:

a. No electrical machinery and equipment which contain PCB must be manufactured after Sep. 1, 1972.

b. No heat exchange equipment must be produced after July 1, 1972 which use PCB as a transfer medium.

c. 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 registe in the official list to insure strict supervis in the future.

d. Import of such machinery and equipment will be possible only if permission is granted by the Government after September 1, 1972.

e. 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 336

F001165 100527

W 108

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!

WIOC

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

Monsanto

MONSANTO INDUSTRIAL CHEMICALS CO.
800 N Lindbergh Boulevard
St Louis, Missouri 63166
Phone (314) 694-1000

April, 1972

Dear Sir:

Since early 1970 we have been advising your company of significant developments relating to the polychlorinated biphenyl (PCB) environmental situation.

As you know, many pollution control agencies conduct monitoring programs to evaluate the presence and impact of many materials on the environment. Some of these programs include PCB.

Recently a representative of a governmental pollution control agency contacted Monsanto requesting information concerning PCB sales. Specifically, he asked for names and addresses of PCB customers in his area, with the quantities of PCB product sold to each. He stated that this information was being requested because significant amounts of PCB were being detected in the discharge from sewage treatment facilities in his area.

He was informed that Monsanto considers information of this type confidential and, therefore, does not disclose it outside the Company. He subsequently informed us that the request for information was being sent to the local federal district attorney for appropriate action.

As we have pointed out on numerous occasions to representatives of government and of private groups, Monsanto has long had a policy, which it continues to follow, of treating information concerning its customers as confidential information. However, you should be aware that, because of governmental or judicial orders or requirements or because of a change in circumstances resulting from the unique nature of the PCB problem, Monsanto may at some future date be obligated to disclose such information to qualified persons.

F001168

PLAINTIFF'S EXHIBIT 337

We wish to strongly re-emphasize with you the importance of avoiding direct or accidental PCB contamination of feed, food and packaging material and of preventing PCB's from escaping into the environment. We direct your attention to the recent FDA notice of proposed rule making on PCB's published in the Federal Register, Vol. 37, No. 54, pp 5705 and following, dated March 18, 1972.

If PCB's are still present at your locations you are urged to thoroughly review your procedures and inspect your facilities to insure that extreme care is taken in the handling, use, storage, and disposal of these materials.

Sincerely,

W B Papageorge

W. B. Papageorge
Manager
Environmental Protection

F001169

ADM 002492

PRESENTATION

To The

INTERDEPARTMENTAL TASK FORCE ON PCBs

WASHINGTON, D. C.

May 15, 1972

by

MONSANTO COMPANY

Introduction

By

W. B. Papageorge

Considerable interest has been and continues to be expressed by many involved in studies of PCBs and the environment concerning their degradability. Monsanto has received many inquiries relating to results of our studies. We now have accumulated some meaningful data which we believe would be appropriate to present in a status report to the Interdepartmental PCB Task Force. We sincerely appreciate this opportunity to share this information with you this afternoon.

Slide #1 - We plan to discuss current results of laboratory biodegration studies of PCBs and the levels of PCB residues observed in the tissues of laboratory animals which were used in our toxicity studies. We will review briefly actions Monsanto has taken to reduce PCB usage and environmental losses. We will also discuss the application of our laboratory findings to the development of a modified more readily degradable PCB mixture for use by the capacitor industry as a dielectric fluid. As many of you are aware, we have designated this material as Aroclor 1016.

Slide #2 - Our presentation will begin with Dr. Tucker discussing primary bacterial degradation and PCB residues in fish, fowl and mammal tissues. Dr. Munch will review evidence that demonstrates disappearance of PCBs from the environment and Dr. Paton will discuss Monsanto's PCB sales and use actions and the impact these actions will have on the environment.

Because of the limited time available, may I suggest that questions be held until all the speakers have completed their reports. Following the presentations there will be opportunity for further discussion of information which may be of particular interest to you.

Dr. Tucker, Research Group Leader, will now present a status report of his laboratory results.

OBJECTIVES

- PROGRESS REPORT ON LABORATORY BIODEGRADATION OF PCB'S
- RESIDUE ACCUMULATION STUDIES IN FISH, BIRDS AND MAMMALS
- TO SHOW REDUCTION IN LESS BIODEGRADABLE PCB'S AS A RESULT OF MONSANTO ACTIONS ON SALES AND PRODUCTS

AGENDA

- INTRODUCTION — W. B. PAPAGEORGE
- PCB STUDIES — E. S. TUCKER
  - PRIMARY BACTERIAL DEGRADATION
  - RESIDUES IN FISH, FOWL AND MAMMALS
- EVIDENCE FOR LOSS OF PCB FROM THE ENVIRONMENT — R. H. MUNCH
- MONSANTO PCB ACTIONS — C. PATON
- DISCUSSION

ASSESSMENT OF THE BIOLOGICAL PERSISTENCE OF POLYCHLORINATED BIPHENYLS

By

Dr. E. S. Tucker

The research-I will review today will focus upon one aspect of Monsanto's efforts to understand the environmental impact and behavior of our polychlorinated biphenyl or PCB products.

This research was initiated early in 1969 after development of the necessary PCB analytical methodology and subsequent confirmation of Dr. Soren Jensen's identification of PCB residues in fish and birds in Sweden.

At this point in time, PCB residue data from Monsanto and external environmental monitoring programs indicated that at the previous rate of use and release of these products that some PCB homologs were beginning to reach detectable levels in fish, birds and mammals. Conversely, these data indicated to us that with the exception of localized, controllable contamination, PCB homologs with less than five chlorine atoms per molecule had not accumulated to detectable levels; even though it was known that significantly greater amounts of the PCB homologs with less than 5 chlorine atoms per molecule had been manufactured and used over the years.

Now, before discussing our biological studies, I would like to review for you the gross homolog composition of our Aroclor products and then in a very brief fashion, try and illustrate to you the complexity of these materials and hence the complexity of the problem.

In the first slide (#1), is shown the most recent data on the weight % composition of four of our Aroclor products as a function of each detectable PCB homolog. The first column on the left lists the homolog in question and the subsequent columns under each product show the weight % distribution of each PCB homolog in each product.

As most of you probably know, with the exception of Aroclor 1016, the last two digits of each product number refer to the degree of chlorination. For example, Aroclor 1221 contains 21% chlorine by weight, and so on.

Aroclor 1016 is a special case in that while it contains about 41% chlorine by weight, its penta, hexa, and heptachloro biphenyl content has been significantly reduced with respect to Aroclor 1242, a product produced by direct chlorination, containing 42% by weight chlorine. Please note that the penta, hexa, and heptachloro biphenyl homologs in Aroclor 1016 have been reduced by factors of about 8, 10, and 10, respectively, with reference to Aroclor 1242.

As you can also see, the chief constituents of Aroclor 1221 are the mono- and dichloro biphenyls, while Aroclor 1016 and Aroclor 1242 contain predominantly di-, tri-, and tetrachloro biphenyls, and Aroclor 1254, tetra, penta, and hexachloro biphenyls.

[redacted] efforts at determining the homolog distribution of [redacted] and as such a number of you may have seen estimations of the homolog content of these products which are significantly different. The analytical methodology used is currently in a very dynamic state and our understanding of the contents of these products increases as the methodology is improved. At this point in time, we regard these numbers as the most accurate ones currently available.

In the next slide (#2) are shown examples of low resolution - packed column electron capture chromatograms of Aroclor 1221, Aroclor 1242, Aroclor 1254, and Aroclor 1260. This is what these products look like to a residue analyst using the most commonly employed detection system.

From these chromatograms, it can be readily seen that we are dealing with multi-component products, which of course, increases the complexity of assessing every aspect of this problem - relative to a well defined single component system such as DDT.

I should mention at this point, that the PCB residues generally found in wildlife are most similar to Aroclor 1254 and Aroclor 1260 chromatograms.

The next slide (#3) demonstrates that in reality, these materials are even more complex than is generally realized. In the upper right portion of this slide is again shown a low resolution electron capture gas chromatogram of Aroclor 1242 under the optimum conditions normally employed by residue analysts. Under these conditions, Aroclor 1242 would appear to be a 15 component system.

In the lower portion of this slide is a flame ionization gas chromatogram of the same material using a high resolution S.C.O.T. column. If one carefully inspects this chromatogram, our simple 15 component product has now been resolved into 55 different components.

These facts simply indicate that all PCB products cannot be lumped together in terms of either their environmental impact or persistence.

The type of biological studies which we have carried out to date are shown in the next slide (#5). For discussion purposes, they can be conveniently divided into two categories: "Primary Bacterial Degradation Studies", an area in which research on PCBs is just beginning, and "Residue Accumulation Studies". Most of our bacterial degradation work has been centered around the fairly well known semi-continuous activated sludge degradation test.

Our residue accumulation studies have been fairly extensive and have involved the exposure of better than 2100 fish, chickens, rats and dogs to the various Aroclor products; resulting in the collection of over 1200 samples of which approximately 500 pooled samples were eventually analyzed for PCB residues.

The prime objective of these studies is given on Slide #6.

Slide 47. The semi-continuous activated sludge test procedure we used to evaluate the primary bacterial degradation rates of the Aroclor products is the test method recommended by the Soap and Detergents Association for the evaluation of the biodegradability of linear alkyl benzene sulfonate type surfactants [JAOCS 42, 986 (1965) & 46, 432 (1969)].

> Primary Biodegradation - Minimum alternation of the chemical structure of the material in question to an extent that characteristic properties of the original material are no longer evident.

This procedure employs sludge from a sewage treatment plant as the source of microorganisms to which a specific amount of the material being evaluated and a synthetic sewage mixture are fed on a periodic basis in a specially designed aeration chamber. The next slide (#8) graphically illustrates what the aeration chamber looks like. It is simply a large glass cylinder with provisions for aeration, auxiliary stirring, a siphon for periodic removal of the supernatant and a septum for introduction of the test material.

The mixed liquor (sludge + water) obtained from the sewage treatment plant is initially adjusted with tap water to a suspended solids concentration of about 2500 mg/l, and 1500 ml of this mixture is then charged to the aeration chamber.

The mechanical cycle employed is shown in the next slide (#9). Each cycle is initiated by the addition of the synthetic sewage and 1 mg of the PCB product being tested.

Since the PCBs are quite water insoluble, they are fed to the unit via injection of 200 µls of a concentrated ethanol solution. In this manner, homogenous dispersion of the PCBs on the bacterial sludge is obtained.

After about one hour of aeration an aliquot of the mixed liquor is withdrawn from the chamber and analyzed for PCBs via UV spectrophotometry and/or electron capture gas chromatography. Aeration is continued for about 48 hours and a second sample is withdrawn for analysis. At this point, the aeration is stopped and the sludge allowed to settle, the sludge volume and pH are then checked to insure that the unit is operating satisfactorily. Two-thirds of the supernatant is withdrawn and replaced with tap water; aeration is then resumed. The cycle is re-initiated by the addition of the synthetic sewage and Aroclor in question. This cycle is continuously repeated until a steady state and consistent degradation rates are obtained.

The per cent degradation rate is calculated as shown in the equation on the slide from the amounts found in the samples analyzed during each cycle.

Degradation testing of the Aroclor products shown in the next slide (#10) have been carried out over an eight month period in our laboratories. In this slide, we have shown graphically the results observed to date. Here we have plotted the mean per cent degradation

rates for Biphenyl, Aroclor 1221, MCS 1043, a research material containing 30% by weight chlorine, Aroclor 1016 (41% chlorine), Aroclor 1242, and Aroclor 1254 versus the weight per cent chlorine present in each. The actual mean per cent degradation rates and 95% confidence limits for each material are shown in the lower left portion of the slide. These data were all obtained by UV spectrophotometry which in essence follows the decrease in the aromatic ring content and is indicative of bacterial ring cleavage. The important point to note here is that as the degree of chlorination decreases the degradation rate increases.

In order to give you a feeling for the degradation rates observed with other materials, Aroclor 1221 degrades at about the same rate as a non-linear ABS surfactant.

We have also used this technique to study p,p'-DDT and have at this point in time noted no significant primary degradation.

The next slide (#11) shows the changes in homolog distribution observed for Aroclor 1242 via electron capture gas chromatographic analyses. The upper chromatogram shows the character of the residue one hour after addition. The numbers above each peak indicate the dominant homolog or homologs present in each. The lower chromatogram is of the residue after 72 hours of exposure to the bacterial sludge. It can be readily seen by comparing the two chromatograms that all the dichloro biphenyls, most of the trichloro biphenyls, and a significant portion of the tetrachloro biphenyls are degraded in 48 hours under these test conditions.

The conclusions which we draw from this preliminary data are shown in the next slide (#12).

Next, I will discuss our "Aroclor Residue Studies" (Slide #13).

Our white leghorn chicken studies (Slide #14) have consisted of a 90 day oral exposure of Aroclor 1242, Aroclor 1254, and Aroclor 1260 at 1, 10, and 100 ppm feed levels and a repeat 90 day study of Aroclor 1242 at the 2, 4, and 8 ppm feed levels. 336 Chickens were employed from which a total of 521 tissue, chick, and egg samples were collected. Of these 112 pooled samples were analyzed for PCB residues.

In the next slide (#15) are shown the results of the 90 day oral exposure of white leghorn chickens to Aroclor 1242. On the left side, we have shown the oral exposure levels which were 1, 10, and 100 ppm, the theoretical residue in ppm, which would have been found in the lipid if the chickens had retained all of the Aroclor 1242 which they orally injested. As you can see, these levels are ~125, 1250, and 12,500 ppm. Next is shown the actual average level in ppm found in the lipid of the muscle, fat, and liver samples and then the levels found after 30 days on a PCB free diet. The important points to note are that ~90% of all the Aroclor 1242 consumed is directly excreted and/or metabolized and that after 30 days on a PCB free diet 35%, 44%, and 57% of the PCBs retained after 90 days of continuous exposure at the 1, 10, and 100 ppm levels was excreted and/or metabolized.

On the right hand side of this slide is shown the homolog distribution of the product fed and that of the residues isolated from the tissues after 90 days of exposure and 30 days on a PCB free diet. The numbers across the top simply refer to the number of chlorine atoms per biphenyl molecule. As you can see, Aroclor 1242 contains dominant amounts of the di- through pentachlorobiphenyls and a minor amount of hexachlorobiphenyl. After 90 days of exposure the dichlorobiphenyl was no longer observable and the dominant components were the tri- through pentachloro biphenyl homologs. After 30 days on a PCB free recovery diet, the hexachloro biphenyl is now a dominant component because of continued excretion and/or metabolism of the lower chlorinated homologs.

In the next slide (#16) are shown the results for the 90 day oral exposure of Aroclor 1254 in white leghorn chickens at the 1, 10, and 100 ppm exposure levels. The theoretical residues are the same as before and we have again shown the actual levels found in the tissues after 90 days of continuous exposure and 30 days on a PCB free diet. In this instance, ~70-72% of the Aroclor 1254 ingested was directly excreted and/or metabolized and after 30 days on a PCB free diet, ~45% of the residues retained were excreted and/or metabolized.

The homolog distribution of the product and residues is shown on the right of the slide, the product Aroclor 1254 contains minor amounts of the tri- and heptachloro homologs and dominant amounts of the tetra-, penta-, and hexachloro biphenyls. The residue after 90 days of exposure did not contain detectable amounts of the trichloro biphenyls and the tetrachloro biphenyls were no longer a dominant component. The dominant homologs were penta- and hexachloro biphenyls. After 30 days on a PCB free diet, the tetrachloro biphenyls were now not detectable, the pentachloro biphenyls were a minor component, and the hexachloro biphenyls the dominant component.

In the next slide (#17) are the results for Aroclor 1260. Again, the oral exposure level and theoretical residue levels are the same and the PCB residues found in the tissues after 90 days of continuous exposure and 30 days on a PCB free recovery diet are shown. After 90 days of exposure, 57-52% of all Aroclor 1260 consumed was directly excreted and/or metabolized and after 30 days on a PCB free diet ~40% of the residues retained were excreted and/or metabolized.

As shown on the right, Aroclor 1260 contains dominant amounts of penta-, hexa-, and heptachloro biphenyls and a minor amount of octachloro biphenyl. The residues after 90 days of exposure and 30 days on a PCB free recovery diet contain minor amounts of the penta- and octachloro homologs. In both cases, the dominant homologs were the hexa- and heptachloro biphenyls.

Our albino rat work (Slide #18) has consisted of 30 day oral, 2 year chronic oral and a 3 generation rat reproduction exposure study with Aroclor 1242, Aroclor 1254, and Aroclor 1260 and a 90 day subacute

[redacted] Approximately 2100 animals were used for these exposure studies from which about 400 necropsy liver and fat samples were collected. Two hundred of these samples were analyzed for PCB residues.

In the next slide (#19) are shown the results of our two year chronic oral exposure study of Aroclor 1242 in albino rats. The oral exposure levels were 1, 10, and 100 ppm and the theoretical residues were ~800, 8000, 80,000 ppm, respectively. The actual residues found in the tissue lipid are shown after 3, 12, and 24 months of exposure. Comparison of the residues found after 24 months to the theoretical residue levels indicates that 99% of the Aroclor 1242 fed was directly excreted and/or metabolized at all exposure levels.

As is shown on the right, Aroclor 1242 contains dominant amounts of the di- through pentachloro biphenyl homologs and a minor amount of the hexa-. The residues after two years did not contain a significant amount of the dichloro biphenyls and the dominant components were the tri-, tetra-, and pentachloro biphenyl homologs.

In the next slide (#20) are shown the results of the two year chronic oral exposure of albino rats to Aroclor 1254. The exposure and theoretical residue levels are the same as with Aroclor 1242. The residues found after 3, 12, and 24 months of exposure are also shown. Comparison of the residues after two years to the amount ingested demonstrates that 95-98% of the Aroclor 1254 consumed is directly excreted and/or metabolized.

The homolog distribution of Aroclor 1254 and the residues are shown on the right. Aroclor 1254 contains minor amounts of the tri- and heptachloro biphenyl homologs and dominant amounts of the tetra-, penta-, and hexachloro biphenyl homologs. The residues did not contain detectable levels of the trichloro homologs and the tetrachloro biphenyls were no longer a dominant component. The dominant homologs were the penta- and hexachloro biphenyls.

The next slide (#21) shows the the results for the two year exposure of Aroclor 1260 in albino rats. Again, the exposure and theoretical residue levels are the same and the residues found in the tissues after 3, 12, and 24 months of exposure are shown. In this case 93-95% of all Aroclor 1260 ingested was directly excreted and/or metabolized.

The dominant homologs in Aroclor 1260 and the residues isolated from the tissues were similar in all cases.

In order to demonstrate the relationship between residue storage levels and the degree of chlorination of the product fed (slide #22). I have plotted the average ppm PCB found in the lipid vs the weight per cent chlorine in the product fed. These data were taken from our 90 day subacute albino rat studies with Aroclor 1221, Aroclor 1242, Aroclor 1254, and Aroclor 1260 at an exposure level of 100 ppm. As you can see, the residue storage levels decrease exponentially as the weight per cent chlorine decreases, simply demonstrating the relationship between the higher homolog content of an Aroclor product and the tissue storage level.

Our beagle dog studies (Slide #23) have consisted of a two year chronic exposure of Aroclor 1242, Aroclor 1254, and Aroclor 1260 and a 90 day subacute study of Aroclor 1221. In these studies, 108 beagle dogs were used, resulting in the collection of 263 samples, and the analyses of 146 for PCB residues.

The next slide (#24) shows the results of one two year study of Aroclor 1242 at exposure levels of 1, 10, and 100 ppm. In this study, the theoretical residue levels are ~500, 5000, and 50,000 ppm respectively. We have also shown on this slide the residue levels found after two years of exposure and after 30 and 60 day periods on PCB free recovery diets. The beagle dogs directly excreted and/or metabolized 99.6% of the Aroclor 1242 consumed and after 60 days on PCB free diets, 50-60% of PCB residue retained after two years of exposure was excreted and/or metabolized.

Aroclor 1242 contains dominant amounts of the di-, tri-, tetra-, and pentachloro homologs and a minor amount of the hexa- homolog. The residue found after two years of exposure contained no detectable levels of the dichloro homologs and dominant levels of the tri-, tetra-, hepta-, and octachloro biphenyls. The pentachloro homolog, although dominant in the product fed, was not a dominant component of the residue. After 30 days on a PCB free recovery diet, the di-, tri-, and tetrachloro biphenyls were not detectable components of the residue. At this point, the dominant components were the hexa-, hepta-, and octachloro biphenyls. The trend toward excretion and/or metabolism of the lower chlorinated homologs continued to the extent that after 60 days on the recovery diet the hexachloro biphenyl was no longer a dominant component, and the hepta- and octachloro biphenyls became the dominant constituents in the residue.

In the next slide (#25) are the results for the two year exposure of beagle dogs to Aroclor 1254. The oral exposure and theoretical residue levels are the same and the PCB residue levels found in the tissues after two years of exposure and after 30 and 60 day periods on PCB free recovery diets are again shown.

In this instance, the dogs excreted and/or metabolized 98-99% of all Aroclor 1254 consumed over a two year period. After 60 days on a PCB free recovery diet, 30-40% of the residues retained were excreted and/or metabolized. The product fed, Aroclor 1254, contains minor amounts of the tri- and heptachloro biphenyls and dominant amounts of the tetra-, penta-, and hexachloro homologs. After two years of exposure, the residue retained from the product did not contain detectable levels of the tri- or tetrachloro biphenyls, the penta-, and hexachloro biphenyls remained dominant components, and the heptachloro biphenyls became dominant constituents.

After 30 days on the PCB free recovery diet, the pentachloro homologs became a minor component of the residue, the hexa- and heptachloro biphenyls remained dominant components and the octachloro homologs became a minor component. After 60 days on the PCB free recovery diet, the pentachloro biphenyls were excreted and/or metabolized to the extent that the octachloro homologs became a dominant constituent of the residue.

The next slide (#26) shows the results for the two year oral exposure residue study of Aroclor 1260 in beagle dogs. The exposure and theoretical residue levels are the same as those for the Aroclor 1242 and Aroclor 1254 studies. Next is shown the residues which accumulated after two years of continuous exposure and the residues retained after 30 and 60 day recovery periods on PCB free diets. With this Aroclor 98-99% of the amount consumed over two years was directly excreted and/or metabolized. After 60 days on the recovery diet ~13% of the retained residues were excreted and/or metabolized.

The homolog distribution of Aroclor 1260 is as shown, dominant amounts of the penta-, hexa-, and heptachloro biphenyls with a minor amount of the octachloro homologs. After two years, the PCB residue contains no detectable level of the pentachloro homologs, a minor amount of the heptachloro biphenyls, and dominant amounts of the hexachloro and octachloro homologs. After 30 days on the recovery diet, the dominant homologs are now the hexa-, hepta-, and octachloro biphenyls becoming a dominant component of the residue via loss of some of the hexachloro biphenyls. After 60 days on the recovery diet, the hexachloro biphenyls are no longer dominant components of the residue and it is now mainly the hepta- and octachloro biphenyls.

The next slide (#27) illustrates the residue fall off as a function of Aroclor and recovery period. These data are from the two year beagle dog studies and the exposure level is 1 ppm. In this graph, I have plotted the average ppm PCB found in the lipid for Aroclor 1260, Aroclor 1254, and Aroclor 1242 after two years of continuous oral exposure and then after 1 month and 2 month recovery periods on PCB free diets. This plot simply demonstrates that the PCB residues retained from Aroclor 1242 fall off more quickly than those retained from Aroclor 1254 and Aroclor 1260.

The table in the next slide (#28) shows the relative ability of fowl, small mammals, and large mammals to retain orally ingested PCBs. These data are for Aroclor 1242 at the exposure levels and periods shown. The concentration factor is calculated by dividing the maximum PCB level found in the lipid by the exposure level. As you can see from the factors, chickens retain PCBs to a greater extent than do rats or dogs.

Our fish residue work is not very extensive at this point - primarily because we have had problems in finding consulting laboratories capable of carrying out dynamic low level fish exposure studies, and secondly, because government laboratories such as those in Duluth, Minnesota, Columbia, Missouri, and Gulf Breeze, Florida were, and are, still in better positions to carry out and evaluate these types of studies.

We have done some very preliminary 21 day dynamic exposures of catfish and bluegill fingerlings to some of our Aroclor products and it generally supports the conclusions which can be drawn from literature data.

The general conclusions which we draw from these residue studies are shown in the next three slides.

Slide #29 - Build-Up - Conclusions

Slide #30 - Fall-Off - Conclusions

Slide #31 - Alteration of Homolog Distribution - Conclusions

In summary, we feel that the results of our preliminary research support, what has and is being observed via residue analysis of environmental samples; that is to say, from a residue viewpoint, that the bulk of the PCB homologs released to the environment (PCBs with less than 5 chlorines) are subject to environmental degradation of one sort or another at measurable rates and as such have not accumulated.

E. S. Tucker

OPERATING INSTRUCTIONS

DEPARTMENT 246

STILL OPERATOR

October, 1974

SECTION V

MATERIAL HANDLING & TOXICITY DATA

SECTION VI

A. BATCH BLOW TANKS

B. VACUUM JETS

C. #3 AND 4 STILLS

D. POROCEL TREATMENT

E. THERMINOL FURNACE

Written by: T.N. Carrico

Revieved by: G.L. Johnson

/tm

SECTION V - MATERIAL HANDLING AND TOXICITY DATA

AROCLORS

Aroclors as manufactured in Department 246 are non-flammable liquids which may vary greatly in viscosity at room temperature. Contact with the skin should be avoided. In case of spills on the body, wash the affected areas with soap and water. Inhalation of Aroclor and Montar fumes should be avoided as they are highly toxic. Protect the skin, lungs, and eyes by wearing protective clothing, respirator, and goggles. If spilled on clothing, change to clean clothes.

BIPHENYL

Biphenyl is a flammable liquid received in tank cars from our Anniston, Alabama, plant. It is heated to 95°C and unloaded to the East BiØ storage tank. It is transferred daily to the continuous chlorinators, the catalyst mix tank, and when necessary, to the head tank for the batch chlorinators. The system is essentially closed.

Biphenyl is a solid at ambient temperature, the flash point is 113°C, the X-point is 68°C. The fumes are not dangerously deadly, but they are poisonous over a prolonged time. Breathing large amounts of vapor or dust can cause damage to respiratory passages. Wear goggles when transferring or sampling BiØ from tank cars or storage tanks.

If molten Biphenyl is spilled on the skin it should be absorbed with a clean cloth and then washed with alcohol followed by large quantities of water, or if allowed to solidify it should be scraped off and then washed with water. If spilled on clothing, change to clean clothes.

CHLORINE

Chlorine is delivered by pipeline from the chlorine department, and is used to chlorinate biphenyl to produce various Aroclors. It is a gas under normal conditions and is very toxic. A concentration of 1,000 ppm would be fatal.

At times, leaks do occur which will liberate chlorine gas into the air. Gas masks are provided in the department and are sufficient for small leaks. A Scot-Air-Pak is provided for large gas releases.

SECTION V - MATERIAL HANDLING AND TOXICITY DATA

NATURAL GAS

Natural Gas is supplied by Illinois Power and is a mixture of Methane, Ethane, and a small amount of Propane. Natural gas is essentially odorless, however, a small amount of Mercaptan is added to give it a characteristic, pungent odor. It is lighter than air and colorless, and very flammable.

HCl OFF-GAS

Hydrogen chloride is a by-product of the chlorination of biphenyl. The gas is carried by pipeline to Dept. 217. It is a gas under normal conditions and is very toxic. A concentration of 1500-2000 ppm would be fatal in a few minutes. Do not remain in an area where enough HCl gas is present to cause discomfort in breathing. Gas masks are provided in the department and are sufficient for small leaks. A Scot-Air-Pak is provided for large gas releases.

If skin irritations persist, wash the area with large amounts of water, then report to the dispensary.

FERRIC CHLORIDE

Ferric chloride is purchased in two pound plastic bottles for use as a catalyst in the chlorinators. It is a solid under normal conditions and is not considered toxic. Some people may be allergic and develop a skin rash. Gloves should be worn to protect the hands and the eyes must be protected to keep Ferric Chloride dust from blowing in them. Large amounts of water should be used to wash any irritated areas.

LIME

Lime is handled in bags and is not dangerously toxic, and is regarded as more of a nuisance. It is very hazardous to the eyes, therefore, goggles should be worn when handling it. Large quantities of water should be used to flush lime from the eyes and further treatment should be given at the dispensary. Gloves should be worn for general sanitation to keep lime off the skin and clothing.

ATTAPULGUS EARTH

Attapulgus earth is handled in bags and is not toxic. As a matter of general cleanliness, it should be kept off the skin and clothing.

POROCEL

Porocel is handled in bags and is not considered toxic or dangerous. It is used as the material to upgrade electrical properties of Aroclor passed thru the absorbers. Handling would present a hazard to the eyes, therefore, goggles should be worn when handling this material.

BULLETIN NO. IC-FF 38R
(Revised March, 1975)

TRANSFORMER

Askarel

Inspection & Maintenance Guide

Monsanto

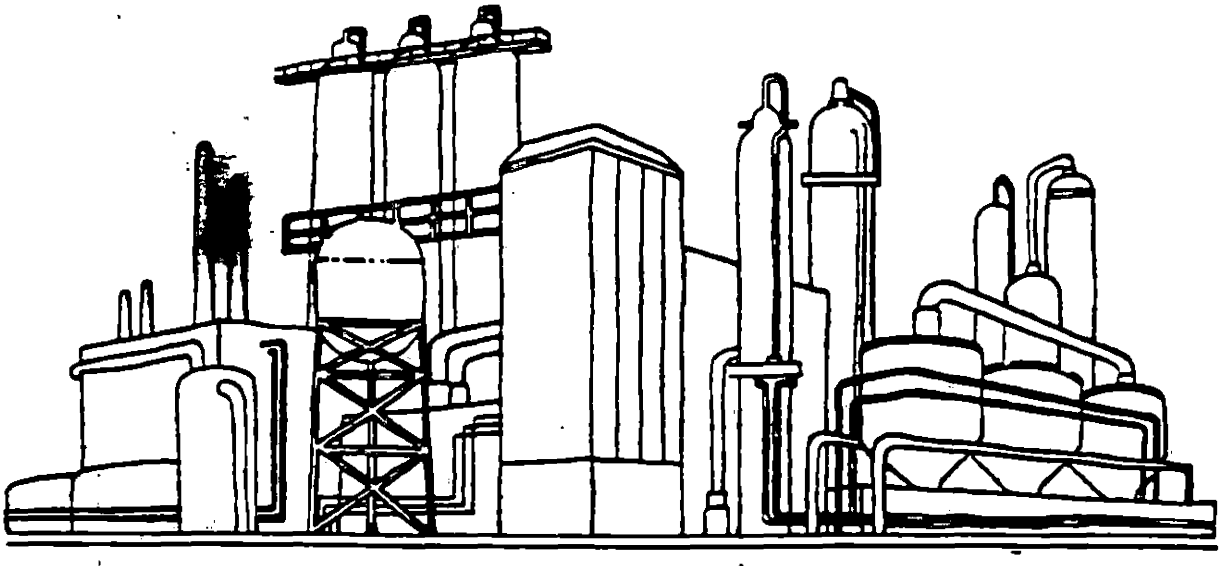


Table of Contents

by swelling and cracking of the exposed edge. In cases of severe deterioration, liquid seepage is usually present.

6. Check for leakage at packing gland of switching shaft. If leaking, repack with a Silastic ring type gasket.

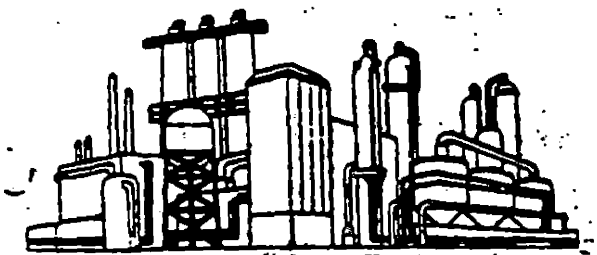
VI. Askarel Under Excessive Temperature or Fault Conditions

The IEEE Guide also points out that,

"Chlorobenzenes used in transformer askarels begin to boil at temperatures of about 205°C, under atmospheric conditions. If the material is heated to such high temperature in a sealed system, pressure develops. Pressure will also develop in the system if the askarel is arced sufficiently to generate copious hydrogen chloride gas.

"Therefore, it is recommended that wherever possible, sealed askarel-filled equipment be provided with pressure relief devices. These devices must be large enough to provide immediate relief at a definite pressure, and to prevent further build up of pressure if decomposition continues. It must be remembered that the presence of devices of this sort does not necessarily preclude the rupturing of containing vessels, since pressure build up can be extremely rapid under violent arcing conditions."

Section C
Toxicity & Safe Handling



I. Inhalation

At ordinary temperatures the chlorinated biphenyls in Askarel have not presented industrial toxicological problems. The hazard of potential toxic exposure varies with their volatility: the lower-chlorinated, more-volatile ones present more of a potential problem from the standpoint of both inhalation and skin contact. When Askarel fluids are used at elevated temperatures, engineering controls must be applied, either by the use of closed systems or by effective local-exhaust ventilation together with general workroom exhaust.

Vapors of Askarel at room temperature should not be breathed in a confined space, and no vapor of any fluid evolved at elevated temperatures should be allowed to be dispersed into the general workroom.

Inhalation tests on animals indicate that the maximum safe concentration of vapor is in the range of from 0.5 to 1.0 milligram per cubic meter of air. The threshold limit value (maximum allowable concentration of an 8-hour working day) set by the American Conference of Government Hygienists are 1.0 milligram of the lower-chlorinated biphenyl compounds per cubic meter of air and 0.5 milligram of the more-highly-chlorinated compounds, per cubic meter of air.

II. Skin Contact

Prolonged or repeated skin contact with the Askarel fluids must be avoided by the use of gloves and protective garments, because of the possible occurrence of a condition called chloracne. Although reports of this condition caused by Askarel are rare, it can be produced by excessive skin contact. If the fluid is spilled on the skin the skin should be washed in the usual manner with a soap solution.

A burn caused by contact with a hot Askarel should be treated like any ordinary burn.

For disposal instructions of Askarel fluids, see Section A - VIII, page 8.

Monsanto

SPECIALTY CHEMICALS DIVISION

MONSANTO INDUSTRIAL CHEMICALS CO.
800 N. Lindbergh Boulevard
St. Louis, Missouri 63166
Phone. (314) 694-1000

September 22, 1977

Mr. Dick Jones, Senior Buyer
Westinghouse Electric Corporation
469 Sharpsville Avenue
Sharon, Pa. 16416

Dear Mr. Jones:

As you know, Monsanto will completely withdraw as a supplier of PCB dielectrics October 31, 1977. Concurrent with this withdrawal date, Monsanto will stop making available to askarel users the "Transformer Askarel Inspection and Maintenance Guide", Bulletin No. IC/FF-38R-2. Although operators of askarel transformers have used this askarel guide as a reference manual in the past, environmental regulations on PCB's are changing rapidly and have made the bulletin obsolete. This bulletin will not be updated. (May I suggest that you destroy all copies in your files and offices so we don't inadvertently supply obsolete information to the industry.)

If your company has ever used our bulletin as a supplement to your own literature, we want you to be aware of our decision. Equally, we ask you to note that in your own use of this bulletin you recognize that the last edition was issued August 1976. It should not be relied upon now or in the future.

Sincerely,

J. A. Alley

J. A. Alley
Industry Specialist
Dielectrics

tmc

F001190

100324

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OCT 17 1975

OFFICE OF ENFORCEMENT

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

OCT 22 1975

Gentlemen:

Recent governmental sampling data indicate the presence of Polychlorinated Biphenyls (PCBs) and comparable chemical substances in the air, in water bodies, and in fish in several areas of the country. In order to determine the nature and extent of the possible adverse effects resulting from the presence of PCB compounds in the environment, the Environmental Protection Agency (EPA), in cooperation with other federal and State agencies, is attempting to determine the sources and amounts of PCBs entering the environment. It is important that this effort be carried out without delay.

It is our understanding that your company handles PCB compounds or mixtures or comparable chemical substances in its operations. I am therefore requesting, pursuant to the authority provided by Section 308 of the Federal Water Pollution Control Act, as amended, 33 U.S.C. 1318, and Section 114 of the Clean Air Act, as amended, 42 U.S.C. 1857c-9, that your company furnish EPA with information pertaining to your use and handling of PCBs and comparable chemical substances. In addition to a general description, which should include information as to sources, quantities, uses, and ultimate disposition, you should respond in detail to the enclosed questions. If any question is not applicable to your company or operations, please so indicate by responding "not applicable."

The information requested herein must be provided notwithstanding its possible characterization as confidential information or trade secrets. Should you so request, however, any information (other than effluent or emission data) which the Administrator of this Agency determines to constitute methods or processes entitled to protection as trade secrets will be maintained as confidential, pursuant to procedures specified in 40 CFR Part 2.

E001191

ADM 006290

Within 14 days of receipt of this letter, your company must provide all information concerning your current status and activities and covering the twelve month period immediately preceding receipt of this letter.

Within 30 days following receipt of this letter, your company must provide all information for all of the prior years indicated.

The information required herein should be sent directly to the address indicated below. If you have any questions you may call the person indicated below or Mr. Blake A. Biles of our office at (202) 755-8731.

We appreciate your prompt cooperation in this matter.

Sincerely yours,

Stanley W. Legro
Assistant Administrator
for Enforcement

Enclosure

Regional Contact:
Mr. Earl J. Stephenson
Director, Enforcement Division
Environmental Protection Agency
1735 Baltimore
Kansas City, Missouri 64108
Telephone: (816) 374-2576

POLYCHLORINATED BIPHENYL (PCB) COMPOUNDS OR MIXTURES

Within 14 days of receipt of this letter, your company must provide all information concerning your current status and activities and covering the twelve month period immediately preceding receipt of this letter.

Within 30 days following receipt of this letter, your company must provide all information for all of the prior years indicated.

FOR PURPOSES OF THIS LETTER, THE PHRASE "PCB COMPOUND OR MIXTURE" INCLUDES ALL CHEMICAL SUBSTANCES KNOWN OR BELIEVED BY YOU TO BE PCB COMPOUNDS OR MIXTURES OR OF A SIMILAR CHEMICAL NATURE, IRRESPECTIVE OF TRADE NAME, AND SPECIFICALLY INCLUDING CHLORINATED TERPHENYLS.

1. For each PCB compound or mixture produced or imported by your company, for each company facility, during each year of 1971, 1972, 1973, 1974, and the first two quarters of 1975:

   a. The total amount of each PCB compound or mixture produced or imported.

   b. The name and address of each of your company's facilities which handle PCB compounds or mixtures (including production facilities and wholesale and retail outlets), and the amount of each PCB compound or mixture distributed through each facility.

   c. The name and address of each customer of each PCB compound or mixture, the amount of each PCB compound or mixture obtained by each customer from each facility, and each customer's delivery point(s) for the receipt of each PCB compound or mixture.

2. For each PCB compound or mixture incorporated by your company into its products, for each company facility, during each year of 1971, 1972, 1973, 1974, and the first two quarters of 1975:

   a. A description of each product.

   b. For each product the total amount incorporated of each PCB compound or mixture.

2. (continued)

c. For each product the name and address of each source from which your company obtained each PCB compound or mixture, and the amount of each PCB compound or mixture obtained from each source.

d. The name and address of each of your company's facilities which handle such products (including production facilities and wholesale and retail outlets), and the amount of each product distributed through each facility.

e. The name and address of each customer of each product, and the amount of each product obtained by each customer from each facility. For consumer products list only the total production of each product at each facility and the total number of customers. Do not provide the name and address of each customer of consumer products.

3. For each PCB compound or mixture used by your company in its operations other than for incorporation into its products, for each company facility, during each year of 1971, 1972, 1973, 1974, and the first two quarters of 1975:

a. A description of each use.

b. For each use the total amount of each PCB compound or mixture.

c. For each use the name and address of each source from which your company obtained each PCB compound or mixture, and the amount of each PCB compound or mixture obtained from each source.

4. For each PCB compound or mixture reclaimed by your company, for each company facility, during each year of 1971, 1972, 1973, 1974, and the first two quarters of 1975:

a. A description of each method of reclamation.

b. For each method of reclamation, the total amount of each PCB compound or mixture reclaimed.

c. The total amount of each PCB compound or mixture reclaimed.

d. The name and address of each source from which your company obtained PCB compounds or mixtures, and the amount of each PCB compound or mixture obtained from each source.

e. For each method of reclamation, the location of every reclamation site, the name and address of each party involved in the reclamation of each PCB compound or mixture, and the amount of each PCB compound or mixture reclaimed by each party.

5. For each PCB compound or mixture disposed of by your company (with or without the involvement of other parties), for each company facility, during each year of 1971, 1972, 1973, 1974, and the first two quarters of 1975:

Koenig Records

a. A description of each method of disposal.

b. For each method of disposal the total amount of each PCB compound or mixture disposed.

c. The total amount of each PCB compound or mixture disposed.

d. The name and address of each source from which your company obtained PCB compounds or mixtures, and the amount of each PCB compound or mixture obtained from each source.

Difficult

e. For each method of disposal, the location of every disposal site, the name and address of each party involved in the disposal of each PCB compound or mixture, and the amount of each PCB compound or mixture disposed of by each party.

6. The composition by chemical name and percent by weight of each PCB compound or mixture produced, imported, sold, reclaimed, used, and/or disposed of by your company since January 1, 1971.

7. The results of any and all sampling and analysis performed by your company, its agents or contractors since January 1, 1971, concerning the following:

a. Concentrations of PCB compounds or mixtures in the effluent of any discharges by the company (into waters of the United States or Publicly Owned Treatment Works) or in the emissions of the company into the air.

b. The flow and/or composition of any discharges or emissions by the company (into waters of the United States or Publicly Owned Treatment Works, or into the air) which contain PCB compounds or mixtures.

c. Concentrations of PCB compounds or mixtures in receiving waters (both upstream and downstream) of any discharges by the company which contain PCB compounds or mixtures and concentrations of PCB compounds or mixtures in the air in the area of the company.

8. The methods by which PCB compounds or mixtures are transported to, by, and/or from your company, including:

a. A description of each method of transportation, and the form in which PCB compounds or mixtures are transported by each method. Where different methods of transportation are used at different facilities specify which transportation method is used at each facility.

b. The names and addresses of all known transportors of PCB compounds or mixtures.

9. All occasions (including spills) of which you are aware on which PCB compounds or mixtures have or may have been introduced into the environment. In particular, describe such occasions insofar as they involved PCB compounds or mixtures in their liquid state, as incorporated into closed systems, or as incorporated into open systems. For each occasion, indicate name and address of party involved; dates, time, and location of the discharge or spill; and the amounts involved.

10. A description of any adverse health or environmental effects which you know or believe to have resulted from the introduction of PCB compounds or mixtures into the environment. Indicate any specific occasions including dates, times, locations, amounts, and parties involved for which such effects are known.

11. Any and all other information which you possess concerning:

a. The production, importation, reclamation, use, distribution, and disposal of PCB compounds or mixtures.

b. The discharge of PCB compounds or mixtures into the environment.

In addition to the above, EPA would appreciate receiving any other information which you possess concerning the distribution and discharge of PCB compounds or mixtures by sources other than your company, including your company's customers and sources.

P. O. M.
J. Zapp

Monsanto

MONSANTO INDUSTRIAL CHEMICALS CO
800 N. Lindbergh Boulevard
St. Louis, Missouri 63166
Phone: (314) 694-1000

June 6, 1973

McGraw Edison Power Systems Div.
P.O Box 160 Central Plant
12th & Madison Avenue
South Milwaukee, Wisconsin 53172

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

/jk
Attachment

PLAINTIFF'S EXHIBIT 339

F001198

ME 000243

Monsanto

MONSANTO INDUSTRIAL CHEMICALS CO.
800 N. Lindbergh Boulevard
St. Louis, Missouri 63166
Phone: (314) 694-1000

July 13, 1973

Dr. Martha Sager, Chairman
Effluent Standards and Water Quality
Information Advisory Committee
Environmental Protection Agency
Room 821, Crystal Mall, Building 2
Washington, D.C. 20460

Re: Effluent Standards and Water Quality
Information Advisory Committee
Agenda and Notice of Public Hearings
Federal Register, Vol. 38, No. 116, Page 11868
Monday, June 18, 1973

Dear Dr. Sager:

Monsanto Company, as an interested party and a manufacturer of polychlorinated biphenyl (PCB), would like to take this opportunity to share with the Committee, and present for the record, our experiences regarding the manufacture, sale and handling of PCB and its relationship to the environment.

We hope this information, along with the attached exhibits, will be helpful to the Committee and the Administrator when proposing effluent standards for toxic pollutants.

BACKGROUND

Monsanto Company has been a major manufacturer of chemical products since 1901. These products are used in numerous American industries, and in fact, through our research department, we have played a role in developing new products to meet the needs of industry and the consumer.

On some occasions a chemical compound with specific properties is developed to meet a need in a certain application. In other cases a chemical compound with unique properties is developed first -- possibly through innovative research or even by happenstance -- and then an end-use is found.

The chemical structure of PCB has been known for nearly 100 years. It was not until the late 1920s that a use for PCB was found -- as a dielectric fluid in transformers and capacitors. The properties of PCB -- inertness, fire resistance and a nonconductor of electricity -- seemed to be perfectly suited to these electrical applications where high-voltage arcing could occur, possibly resulting in serious fires or damage to the equipment.

Monsanto began commercial production of PCB in 1929. As the unique properties of the material became known new uses were found. For example, their fire-resistant nature made them excellent choices for use in heat-transfer fluids. Their inertness gave long-lasting qualities to lubricants. Their use in surface coatings improved waterproofing characteristics.

Handling of the product at the manufacturing level has not presented problems so long as the proper industrial hygiene practices were followed and PCB has always been considered less hazardous than many other chemicals in everyday use.

Therefore, it appeared that PCBs were a very suitable product which met the needs of industry.

Late in the 1960s, sophisticated analytical procedures were developed which could detect very minute quantities of PCB in nature. Following this analytical breakthrough, researchers discovered that PCB could possibly be affecting certain forms of aquatic, marine, terrestrial and avian wildlife.

The persistent nature and stability of PCB, while so desirable from the standpoint of many industrial applications, appeared to be undesirable in terms of our environment.

INDUSTRY ACTIONS

When questions about the effect of PCB on the environment first surfaced, Monsanto Company reviewed its product line and the applications for these products. As more data were developed and the environmental controversy grew, Monsanto took steps intended to reduce the entry of PCB into the environment. The company stopped the sale of PCB for use in various applications, except where no acceptable alternatives were available.

Today, PCB manufactured by Monsanto Company is sold to the electrical industry where it is used in closed systems as a dielectric fluid in transformers and capacitors -- applications for which we understand there continue to be no acceptable substitutes.

Our manufacturing and sales reduction program was a unilateral action taken by Monsanto and was based on our evaluation of developing environmental data.

Recognizing the need for proper controls in the handling and use of PCBs, representatives of the transformer and capacitor industries, utilities, and governmental agencies under the initial auspices of the National Electrical Manufacturers Association formed American National Standards Institute Committee C-107. A copy of the Committee's recently issued proposed guidelines for the handling and disposal of dielectric fluids is attached. These guidelines reflect the industry's understanding of the need for proper control and should contribute significantly toward this objective.

TOXICITY IN PERSPECTIVE

In Section 502 (13) of the current Federal Water Pollution Control Act, the term "toxic pollutant" is defined as "those pollutants or combinations of pollutants including disease causing agents, which after discharge or upon exposure, ingestion, inhalation or assimilation into any organism, either directly from the environment or indirectly by ingestion through food chains will, on the basis of information available to the Administrator, cause death, disease, behavioral abnormalities, cancer, genetic mutations, physiological malfunctions (including malfunctions in reproduction) or physical deformations in such organisms or their offspring."

While the breadth of this definition can be so construed as to permit the inclusion of many substances on a list of "toxic pollutant(s)," we concur with the recent suggestion of the EPA's Acting Administrator (Federal Register Vol. 38, No. 129, page 18044) that Congress intended the Administrator under the Act "... to be selective in determining which of the potentially large number of candidate substances

actually should be listed at various times." Although not spelled out in the definition, we feel it important to consider the degree of toxicity of the substance; differences in biological species' sensitivity; and whether or not the substance poses a threat to man, animals, birds, the aquatic environment or some other aspect of the ecosystem.

For example, there is a material difference between the threat to human health posed by equal amounts of the "cyanide ion" and "PCBs," both of which substances appear on your proposed list of pollutants. We feel certain the members of your committee will agree that these two substances should not be considered on the same basis merely because they are both suggested for inclusion in the same list.

We trust that comparative differences in the potential hazard to health and our environment of the various substances proposed for your list will be an important factor in your deliberations and determinations.

On the basis of available evidence, it would appear that PCBs pose less of an acute toxic health hazard than many substances not proposed for your list, and at the levels found in the total environment are not a threat to public health. We believe these views agree with the conclusions reached by the Interdepartmental Task Force on PCBs in its report dated May, 1972 (CCM-72-10419).

We sincerely believe, because of Monsanto's sales policies discussed elsewhere, and actions of others throughout the world, that the levels of PCB in the aquatic environment are even lower now than at the time the Task Force report was prepared.

BIODEGRADATION

A valid assessment of the environmental impact of polychlorinated biphenyls must include consideration of the persistence of these materials. Certain reports have been made that PCBs are non-degradable. However, although much work remains to be done, an analysis of available information and information from studies by Monsanto indicate beyond any reasonable doubt that the many PCB

isomers degrade in the environment at different rates. This information indicates that under the proper conditions of use and control, some of the commercial PCBs, which are mixtures of several isomers, can be utilized and their safety benefits can be realized without serious adverse consequences to the environment.

In May, 1972 we shared with members of the Federal Interdepartmental Task Force on PCBs the results of studies of residual PCBs in animal tissues and biodegradation by activated sludges. A copy of this presentation is attached for review by your Committee. Articles describing in more detail the results of the degradation studies in activated sludges and soils are being prepared for publication. Copies of these reports will be mailed to your Committee when they are completed.

EFFLUENT STANDARDS

The worldwide interest in PCBs and their environmental impact has resulted in an abundance of published articles. To assist the Committee we have attached a bibliography of some of the pertinent literature, copies of selected articles and a copy of the Interdepartmental Task Force report. This report, in our opinion, is an excellent reference document and we recommend it to the Committee as a valuable source of information as you consider possible effluent standards.

Although much has been published, much more scientific information is required. This critical need for more knowledge was recognized by the Task Force and is highlighted in its report under "Findings, Conclusions and Recommendations".

It is our considered opinion that in the absence of critical basic scientific data any attempt to establish a PCB standard for water effluents at point sources would be premature at this time.

Pending the availability of the data which would contribute to the establishment of a realistic effluent standard, it is appropriate to consider that the restricted use and proper control of PCBs have and will continue to result in a diminished impact on the environment. Furthermore, the recent ruling by the Food and Drug Administration

(Federal Register, Volume 38, Number 129, July 6, 1973) provides for temporary PCB tolerances in food, animal feeds and food packaging materials, thereby limiting exposure to humans and domestic animals.

We appreciate the opportunity the Committee has provided for interested parties to contribute information. If you have any questions concerning our comments or any of the attachments we will be pleased to supply further explanations or information upon request.

Respectfully submitted,

W. B. Papageorge
Manager
Product Acceptability

WBP/bt

Enclosures

MINUTES OF MEETING

ON

PROPOSED PCB EFFLUENT STANDARDS

February 28, 1974

Monsanto Company
St. Louis, Mo.

Chairman: Mr. W. B. Papageorge
Manager, Product Acceptability
Monsanto Industrial Chemicals Co.

Objective:

The purpose of the meeting was to share information, experiences and impressions to help each of the participating companies in taking appropriate actions which are mutually supportive and effective in persuading the Administration of EPA to modify the proposed PCB Effluent Standard.

PARTICIPANTS

PCB STANDARDS MEETING

February 28, 1974

CERTIFIED BALLAST MANUFACTURERS

Mr. N. R. Clark	Universal Manufacturing Co.

E.I.A.

Mr. Arnold S. Doty	P. R. Mallory & Co., Inc.
Dr. E. M. Moore	Electrical Utilities Co.
Mr. Rudy Carlson	Electrical Utilities Co.

GENERAL ELECTRIC COMPANY

Mr. James S. Nelson
Mr. Stuart Richel
Dr. Edward L. Simons

JARD COMPANY, INC.

Mr. Richard Rollins

NATIONAL ELECTRICAL MANUFACTURERS ASSOCIATION (NEMA)

Mr. A. M. Salazar

WESTINGHOUSE CORPORATION

Mr. H. Sheppard
Mr. M. H. Smith

MONSANTO COMPANY

P. G. Benignus	Market Manager
H. S. Bergen	Business Director
D. B. Hosmer	Utilities and Environmental Protection Director
R. H. Munch	Senior Science Fellow
W. B. Papageorge	Manager, Product Acceptability
W. W. Withers	Attorney
C. Paton	Product Manager
W. R. Richard	Manager, Research and Development
J. R. Savage	Manager, Manufacturing
E. S. Tucker	Research Group Leader
P. L. Wright	Manager, Toxicology

AGENDA

PCB EFFLUENT STANDARDS MEETING

February 28, 1974

9:00 AM	1. Welcome - H. S. Bergen
9:10 AM	2. Introductory Remarks - W. B. Papageorge
	a. Brief Review of Proposed Standard
	b. Critical Action Dates
	c. Objectives of Meeting
	3. Discussion Topics
9:15 AM	a. PCB Characteristics - Realistic Definition chemical, physical, biodegradation
9:45 AM	b. Sampling and Analytical Methodology
10:15 AM	Break
10:30 AM	c. Toxicity Acute Chronic
11:30 AM	d. Bioaccumulation - Biomagnification
12:00 Noon	e. Dilution - Stream Size
12:30 PM	Lunch
1:15 PM	f. Proposed Effluent Standard
2:00 PM	g. Control at Manufacturing and Use Sites Current losses Background
2:45 PM	Break
3:00 PM	h. Economic Considerations
3:30 PM	i. Action Plans
4:00 PM	Adjourn

MINUTES OF PCB EFFLUENT STANDARDS MEETING

1. Mr. Howard S. Bergen, Jr., Director, Specialty Products Business Group of Monsanto Industrial Chemicals Company, welcomed the participants.

2. Introduction - W. B. Papageorge

   Mr. Papageorge summarized the timetable past and future on toxic pollutants:

   July 6, 1973 - Toxic Pollutants list published

   September 7, 1973 - Final toxic pollutants list published including PCBs and 8 other chemical classes (e.g. cyanide, mercury, DDT, cadmium, etc.)

   December 27, 1973 - Proposed Effluent Standards published

   January 18, 1974 - Filing date for status as participant at proposed EPA Hearing on Standards

   January 25, 1974 -

   (i) Prehearing Conference with EPA

   (ii) NEMA, Monsanto, G.E. and Westinghouse recognized as participants.

   (iii) A total of 38 objectors expressed an interest. They represented industry or trade associations with the exception of the Michigan Water Research Commission and two powerful environmental groups (Environmental Defense Fund and National Resources Defense Council).

   (iv) Presiding officer made it clear that Hearings will be strictly for cross-examination of participants' testimonies in affidavit form only.

March 15, 1974 - Written testimony by 38 objectors to be submitted in affidavit form.

April 8, 1974 - Hearings open for cross-examination and rebuttal evidence. CN^-/Cd/Hg - first three. PCBs are 7th (third from last).

Mid-May, 1974 - Hearings completed. (Evenings/week-ends may be used.)

June 25, 1974 - Final standards published - effective in one year.

It should be noted that others who are affected by these standards can still comment by March 25 to:

Dr. C. Hugh Thompson,
Chairman-Hazardous and Toxic Substances
Regulation Task Force
Office of Water Protection Agency,
Environmental Protection Agency
Washington D. C. 20460

Industry representatives still wishing to comment and who need more background information can contact any of the industry participants (see attached list) or Mr. W. B. Papageorge of Monsanto (314-694-4051).

Mr. Richel (G.E.):

(i) Made a plea for greater industry participation. Comments can still be made up to March 25 with sound excuse for tardiness.

(ii) EPA at January 25 prehearing Conference were reluctant to expose themselves to cross-examination. Dr. Hugh Thompson to be available for cross-examination at Hearings.

(iii) Many objectors had common interest (e.g. environmentalists). EPA suggested a common counsel for this group.

(iv) On each of first 3 pollutants, EPA would offer 2 witnesses.

Mr. Doty (P.R. Mallory) asked about bearing of economic factors on standards.

Mr. Richel (G.E.) stated:

(i) Law is clear-economic factors are not relevant in establishing standards.

(ii) EPA is somewhat of a split personality on this. The

Presiding Officer at the Prehearing Conference ruled that economics are relevant. NRDC (National Resources Defense Council) objected and was over-ruled.

(iii) Industry can and should therefore introduce relevant economic data. EPA would be wise not to expressly refer to such data in the published standard otherwise NRDC could go to court and EPA over-ruled.

Department of Commerce

It was pointed out that Sidney R. Gallier, Deputy Assistant Secretary for Environmental Affairs at the Department of Commerce wrote Monsanto on January 15 asking their views on the proposed effluent standards. Copies of Dr. Gallier's letter and Monsanto's response were circulated at the meeting. Industry should contact the Dept. of Commerce. Their legal counsel (Mr. Morland) has been active on the side of industry in other environmental hearings.

Mr. Salazar (NEMA) pointed out that the PCB Task Force had recommended a standard for PCBs of 0.01 ppb in the main body of water. (EPA was a member of that task force). ANSI C-119 proposes to use this Task Force recommendation and print this as a standard of 0.01 ppb in main body of water.

Mr. Sheppard (Westinghouse) queried if plant effluent standards could be set to meet 0.01 ppb.

Dr. Simons (G.E.) said this implied an acceptance of ANSI C-119 by industry.

There seemed to be some doubt on this..

PCB Characteristics

Dr. Tucker (Monsanto) presented hand-outs on:

(a) Monsanto's proposed definition of PCBs

(b) Comments on EPA's proposed analytical methodology

(c) Monsanto's pre-publication paper on biodegradation of PCBs.

(a) Definition of PCBs

1-4 chlorobiphenyls do not have long residence time. PCBs up to tetrachlorobiphenyl are not of concern on environmental persistence or biomagnification. Dr. Tucker proposed the following definition:

"Polychlorinated biphenyls (PCBs) means materials containing the biphenyl group which is chlorinated and which have been shown to persist and rapidly bioaccumulate in the aquatic environment. These chlorinated biphenyls are identified as those components having gas chromatographic retention times greater than 54, relative to p, p-DDE = 100, under the standard conditions recommended in the EPA PCB test method."

Mr. Sheppard (Westinghouse) said Monsanto's proposed definition was relevant to persistence but was it relevant for standards directed toward toxic materials? Are persistent materials non-toxic?

Mr. Wright (Monsanto) stated the proposed effluent standard had two parts:

(i) acute limits directed to toxicity of materials and specifically limits PCB concentrations on that basis.

(ii) daily load in effluent - based solely on bio-magnification (relevant to persistence).

Dr. Simons (G.E.) pointed out that section 307-A of the proposed standard refers to persistence as being a critical factor to be considered.

Dr. Tucker (Monsanto) stated we were badly hurt if all PCBs are regarded as persistent and if biomagnification factors of 200,000 are used. Researchers other than Monsanto have found bacterial degradation of PCBs and that PCBs have been found to undergo metabolism in both aviarian and mammalian animals.

Mr. Nelson (G.E.) asked if proposed PCB definition would exclude Aroclor 1016.

Dr. Tucker (Monsanto) Aroclor 1016 would be excluded for the most part (98.9% is lower than pentachlorobiphenyl). Aroclor 1242 would be excluded to 65% or better. Aroclor 1254 however would not be excluded.

Mr. Papageorge (Monsanto) pointed out that of the factors listed as being critical in determining which pollutants made the EPA list of 9/7/73 only biomagnification appeared relevant to PCBs.

Dr. Simons (G.E.) agreed.

Mr. Wright (Monsanto) stated that an acute toxicological level is defined in the EPA Basis & Purpose document as ≤ 10 ppm (96 hour LC-50). He also believes that differences in toxicity among PCBs are minor until chlorinated as high as Aroclor 1260.

Mr. Nelson (G.E.) stated that words should be used in a discourse on definition to properly screen us on acute toxicity.

In reference to a comment that Aroclor 1254 would not be excluded by the proposed definition, Dr. Tucker (Monsanto) offered the opinion that transformer fluids were easier to recover than capacitors.

(b) Analytical Methodology

Dr. Tucker (Monsanto) stated the EPA's proposed method for PCB analysis was being submitted to ASTM. He thought the method was well written and capable of detection to ppt (parts per trillion) but it was untried and the quantitative accuracy is in question. The method was not submitted for round-robin testing before EPA adopted it. Monsanto has found that by spiking distilled water with 500,000 ppt or 500 ppb of PCBs we get values for PCB that vary by ± 55%. The EPA, however, claims a capability of detecting absolute values at 50 ppt. The EPA method ignores interfering substances.

Mr. Clark (Universal Manufacturing) said that with a proposed upper limit for PCB discharge of 0.0648 lb./day the sensitivity of the analytical method would vary "all over the lot" depending on the size of the water "reservoir" into which the PCBs discharge.

Mr. Sheppard (Westinghouse) commented that if the analytical techniques on determining PCB levels are so difficult, how valid are the determination of toxic values for PCBs.

Mr. Clark (Universal Manufacturing) asked if analytical techniques differentiate between different chlorine levels. Dr. Tucker (Monsanto) said it would depend on the PCB mixture. Aroclor 1242 could probably be identified quantitatively in a mixture with Aroclor 1260 but addition of Aroclor 1254 to the mixture would prevent identification because Aroclor 1254 contains PCB homologs that overlap both Aroclor 1242 and 1260.

Dr. Munch (Monsanto) said that the proposed EPA method does not use high resolution and hence handicaps identification of individual peaks.

Dr. Simons (G.E.) mentioned that after EPA set automotive emission standards (NIOX) the analytical methodology was found faulty and the standards were delayed. In this case, EPA is not setting the effluent standard on analytical methodology but

on factors such as toxicity and persistence. The methodology is relevant in enforcement and monitoring. This then leads to the possible argument that the effluent standard is correct and justified on the basis of toxicology et al, but is not enforceable due to lack of an accurate method for absolute value determination of PCB discharge.

Mr. Richel (G.E.) pointed out that EPA won't buy an answer to that argument which seeks to raise the effluent standard to a level that can be accurately measured. Mr. Savage (Monsanto) felt strongly, however, that this dilemma needed to be in the record. Others agreed.

Dr. Tucker (Monsanto) said ASTM would hold a round-robin on the EPA method and that Monsanto would participate. He will send the name of the ASTM contact to the participants so that they can decide if they want to join the round-robin test.

Mr. Sheppard (Westinghouse) said he was not prepared to accept that the proposed EPA method for determining quantities and types of PCB in samples and animals was accurate enough so that toxic limits could be defined on the basis of PCB levels of questionable accuracy.

Toxicity

Mr. Hosmer (Monsanto) stated that the original EPA publication on Water Quality Criteria came from a publication by McKee and Wolfe for the State of California. The McKee/Wolfe volume was well done and EPA did not change much of it. There is now a new 2-volume EPA edition extracted from the work of 10 committees of the National Academy of Sciences.

The toxicity of PCBs is related to salmon egg studies and Monsanto doubts the validity of this. Monsanto has made their feelings known to Dr. Thompson of EPA but he thought the criteria were sound. Since then Russell Train has been sued by NRDC and other groups on the grounds that the toxic pollutants list is not long enough and the proposed standards are too lenient.

Mr. Wright (Monsanto) went through the rationale used by EPA in arriving at a PCB discharge maximum of 0.0648 lb./day. He also showed how the standard could be changed and yet be consistent with published data on PCBs. Details follow.

(a) FDA set arbritary proposed tolerances:

5 ppm in fish for human consumption
5 ppm in components for animal feed
0.5 ppm in complete animal feed

(b) Monsanto would not disagree with these tolerances.

(c) FDA has presented - acute toxicity limits (point sources)
- chronic toxicity limits (daily load)

Acute toxicity limits:

96 hour LC-50 studies for PCBs show:

~280 ppb in fresh water (bluegill)
~10 ppb in coastal or seawater (pink shrimp/oysters)

Published data based on materials leaving an outlet and going into a body of water. Acute limits have no direct relation to chronic limits.

Chronic toxicity limits:

The EPA equation is:

Chronic limit X water flow rate X safety factor = gm/day discharge

In Marine organisms the chronic limit is set as

$$\frac{0.5 \text{ ppm}}{30{,}000} = 0.0167 \text{ ppb}$$

In fresh water the chronic limit has been determined by using 0.5 ppm as toxic limit for salmon eggs and a 200,000 biomagnification factor. This gives a chronic limit of

$$\frac{0.5}{200{,}000} = \underline{0.0025 \text{ ppb}}$$

The biomagnification level of 200,000 is based on unpublished data from Stalling & Meyer (Fish Pesticide Lab, U. S. Dept. of Interior, Colombia, Mo.). Dr. Simons said that in response to repeated requests by G.E. to the Columbia Lab the only reference they have been given is a Stalling & Meyer paper presented in Carolina in 1971 and which contains no mention of a 200,000 factor. Mr. Wright (Monsanto) stated he has seen only one literature reference to an accumulation factor of ~200,000 and that was in the hepato pancreas of a pink shrimp. If the PCB level was calculated on the basis of the total shrimp then the accumulation factor was only 22,000. Other references give accumulation factors of 1000-75,000 for whole tissues of various fresh water organisms. Accordingly, Mr. Wright proposes that a biomagnification factor of 30,000 and not 200,000 be used. He also proposes that we retain the chronic limit of 0.5 ppm without debating the salmon egg issue.

This would lead to a discharge level for PCBs:

$$\frac{0.5}{30{,}000} \times (\text{flow rate } 10{,}000) \times (\text{safety factor } 0.5) \times (\text{conversion into lb./day } 5.4) = 0.459 \text{ lb./day}$$

This compares to the proposed standard of 0.0648 lb./day.

The safety factor comes from the EPA's Basis and Purpose document supporting the proposed effluent standards. It is supposed to take account of non-point sources of PCBs and is the same as 6 of the 9 toxic pollutants proposed for EPA standards. Monsanto's Medical Department feels this safety factor is arbitrary and confers no real toxicological benefit. If deleted, the revised Wright PCB discharge level would be 0.918 lb./day.

One of the most critical parts of the discharge equation is the water flow rate. A significant number of dielectric PCB manufacturers have plants on rivers where the flow rate is under 100 cfs or 1% of the EPA cut-off flow of 10,000 cfs. Several plants discharge into sewage plants which in turn have treated liquid flowing into rivers or streams with very low flow rates. For a river with 100 cfs flow the EPA maximum discharge would drop to 0.000648 lb./day or 0.162 lb. in a 250 work-day year. Even a revised standard of 0.918 lb./day at 10,000 cfs would only be 0.00918 lb./day at 100 cfs or ~2.3 lb. per 250 work-day year. Clearly this is a staggering target to have to meet.

Mr. Doty (Mallory) pointed out that in the present language of the EPA standards municipal sewage systems are not considered point sources.

Mr. Richel (G.E.) was of the opinion that where a plant discharged into a sewage system without treatment and hence into navigable waters the plant could have to comply with effluent standards on toxic pollutants. Mr. Papageorge (Monsanto) felt we should not be complacent and regard discharge to sewage plants being the answer to problems. Mr. Hosmer (Monsanto) stated that 10,000 cfs represents the largest flow the EPA will consider on the grounds that all industry would move to the largest river. The opposite of that argument is that it encourages small plants on every stream in the country.

Mr. Sheppard (Westinghouse) raised the issue of sedimentation. Since it appears that all the experiments to establish toxic values were run without sediment effects being considered, the real-life values were questioned. PCBs attach themselves to sediment. Furthermore the sediment moves down river and so PCB would be dispersed from the point source. It was pointed out by Dr. Richard (Monsanto) that Aroclor 1254 is soluble in water up to 50 ppb and that in time partitioning between sediment and

water could take place. Mr. Wright (Monsanto) agreed that the discharge limits were extreme cases in the absence of sediment considerations and this was worth study and incorporation into arguments against the proposed levels.

Dr. Simons (G.E.) queried whether we were correct in concentrating our attacks on the criterion of toxic effects of mammals eating fish and ignoring the possible argument that fish per se must be protected. Mr. Wright (Monsanto) said the proposed standard says both. In salt water, standards are proposed that would protect the species that eat organisms containing PCB. In fresh water, if 0.5 ppm in salmon eggs correlates with <5 ppm in salmon then we are protecting salmon. He also said that the chronic limits and biomagnification limits he was proposing would protect the species themselves. We should, however, beware of arguing for higher levels in fish because we could draw EPA and FDA into conflict. The FDA levels in food, fish etc., are temporary tolerances and any arguments against their validity could lead to a reduction in these tolerances.

Mr. Savage (Monsanto) queried whether raising the level in organisms could cause possible danger to predators.

Dr. Simons (G.E.) quoted from page 39 of the Basis & Purposes document which states that the body burdens of birds and mammals should not increase over present levels. Page 51 of the same document cites a Nat. Acad. Sci. report which gives 2.0 ppm PCB as tolerable level in flesh of whole fish. $\frac{2.0}{200,000}$ = 0.1 ppm PCB is given as tolerable level in water divided by a safety factor of 5 to give a maximum PCB concentration in water of 0.002 ppm. Thus EPA accepted 2 ppm PCB level in fish but got to water concentration of 0.002 ppm by using a high level of 200,000 for biomagnification and an arbitrary factor of 5.

If we were to revise the proposed EPA standard by:

(i) using 2.0 ppm as chronic limit in fresh water species instead of 0.5 ppm;

(ii) substituting 30,000 instead of 200,000 for biomagnification factor;

and

(iii) ignoring safety factor of 0.5

then the maximum permissible discharge in lb. PCB per day would be:

$$\frac{2.0}{30,000} \times 10,000 \times 5.4 \simeq 3.6 \text{ lb.}$$

For the plant situation on a river with a flow of only 100 cfs the discharge would be 0.036 lb/day or 9.0 lb. per 250 work-day year. These levels are still far below the 5 lb./day given in ANSI C-107.

It is therefore apparent that other aspects of PCBs must be highlighted in order to get away from PCB discharge levels as low as even our "revised" proposals.

Aspects to concentrate on are:

(1) Definition of PCBs that excludes biodegradable homologs.

This could exclude 90% or better of Aroclor 1016 and 65% or better of Aroclor 1242. On that basis, discharge levels would be as follows:

PCB Type	Stream Flow (cfs)	Discharge (lb.PCB equivalent/day)		
		EPA	Wright	Simons/Wright
Any PCB	10,000	0.0648	0.918	3.6
Any PCB	100	0.000648	0.00918	0.036
Aroclor 1016	10,000	0.648	9.18	36.0
Aroclor 1016	100	0.00648	0.0918	0.36
Aroclor 1242	10,000	0.194	2.75	10.8
Aroclor 1242	100	0.0019	0.027	0.10

(2) Try to change stream flows from the present value of the flow rate in cubic feet per second (cfs) expressed as the probable low rate occurring during a 7 consecutive day period once in 10 years at the effluent point.

If the average flow rate over a period of time (to be agreed on) was used, the lowest flow rate in the equation could conceivably be raised by a factor of 10 from 100 to 1000. In the Simons/Wright version for a standard the Aroclor 1016 discharge could be raised to 3.6 lb./day at 1000 cfs flow and Aroclor 1242 to 1.0 lb./day at 1000 cfs flow.

(3) Magnitude of PCB Point-Sources

It is possible that EPA and environmentalists are totally misinformed on the number of plants still using PCBs. In the U.S. today there are:

1 PCB manufacturing plant

~18 capacitor plants using PCB

~27 transformer manufacturing plants using PCB

In the past there were probably 1500-2500* plants using PCBs. Only 2-3% of these plants continue to use PCB today.

* (Subject to closer checking if necessary)

In the past ~97% of plants using PCBs purchased ~40 million pounds of PCB per year. Monsanto's PCB sales policy has therefore

- reduced number of using plants to ~2-3% of previous total.
- eliminated ~40M lbs. PCB sales per year.

The EPA standard would limit PCB discharge per plant to 0.0648 lb./day or ~3.2 lb./day across the U.S. (~50 plants). This equates to ~800 pounds in a 250 work-day year. Since fish have survived throughout the 40+ years that PCBs have been produced and widely used, the standard proposed by EPA seems far too drastic.

Turning again to the Simons/Wright proposal we can estimate the effect in terms of annual PCB discharge into water across the U.S. at 1000 cfs:

			US Total per	As Persistent PCBs		
Discharge As	Discharge (lb./day)	No. Plants	250 days (pounds)	Discharge (lb./day)	No. Plants	US Total
Any PCB	3.6	*1	900	1.2	1	300
Aroclor 1016	3.6	18	16200	0.36	18	1620
Aroclor 1242	1.08	4	1080	0.36	4	360
Aroclor 1254	0.36	23	2070	0.36	23	2070
			20,250			4350

* Plant is on river in excess of 10,000 cfs.

Using this technique an argument can be made in favor of the ANSI C-107 proposal of 5.0 lb./day.

Proposed Effluent Standards

Dr. Simons (G.E.) summarized the points he felt had to be dealt with in trying to change the proposed standard:

1. Higher persistence of higher PCBs versus alleged lower acute toxicity

2. Background levels of PCBs

3. Written testimony of participants and correlation

Toxicity

EPA Basis & Purpose document (page 50) states that 96 hour LC-50 to fish cannot adequately measure toxicity of PCB. Where is time demarcation between acute and chronic. Chronic effects can be either lethal or non-lethal.

Why are PCBs on the list on toxic grounds?

LD-50 for PCB is such that it is not considered toxic to humans.

For protection of aquatic life the Nat. Aca. Sci. set a 96 hour LC-50 of 10 ppm or less.

In proposing a definition for PCBs, Dr. Simons (G.E.) felt we should stress:

(a) lack of persistence of homologs below tetrachlorobiphenyl.

(b) chronic toxicity does not arise for the lower homologs because they are non-persistent.

(c) ignore acute toxicity - no real differences between Aroclor 1016, 1242 and 1254.

Participants need to consider: Do we have the best definition?

In the tentative EPA analytical method we should take note that in the table on p.3-22, the percentage of PCB was not controlled.

Mr. Carlson (E.U.C.) pointed out that in its present form the standard could saddle present PCB users with all other discontinued uses. Dr. Richard (Monsanto) pointed out that FDA and Boxboard Manufacturer's Association had agreed on a protocol that protected recycle paper users from just such a situation. Mr. Bergen (Monsanto) asked that copies be circulated to participants.

We need to word our definitions to exclude residuals. Participants should exchange proposed drafts on wording regarding residuals by March 7.

G. E. stated we should not approach the hearing on the basis that things can't be done. Rather take the proposed standard and point out what it means in real life. In G.E.'s case they use X M lb./year and yet can't lost 0.5 drops per day. Stream flow rates make the matter worse. This is a point on which Dr. Thompson should be cross-examined.

Of the participants present, 5 plants discharge into sewers with outlets into rivers (very small except in 2 cases). Three plants discharge into small rivers.

No one at the meeting could cope with the EPA standard as it is proposed. Only Jard expressed an opinion on what level they could live with. (Jard stated 27 lb. Aroclor 1016 per day. This would be 2.7 lb. PCB by our proposed definition.)

Participation at EPA Hearing

Definite participation:	Monsanto G. E. Westinghouse
Undecided:	Electrical Utilities Jard NEMA
No participation:	Electronic Components Mallory

Objectors of record could adopt non-responding company as witness.

G.E.'s testimony will fall into the following areas:

- Explanation of why PCBs are used
- Consequences of ban on customers
- Inadequacy of EPA/Nat. Acad. Sci. statements
- How standards would apply to G.E.
- Inadequacies of the Standard
    - definition
    - methodology
    - logic behind the standard

Other contributory actions:

- Involve Federal Energy Office (e.g. Aerovox letter on motor-run capacitor contribution to ease energy crisis.)
- Involve F.E.O./other agencies along lines of petrochemical producers' PEC report.
- Power Systems Group of IEEE will circulate a position paper on PCBs (technical aspects) in the dielectric industry to Congress, EPA, FEO and Dept. of Commerce (target date: April).

Action Plans

1.	(W. B. Papageorge)	Circulate to participants copies of FDA/Boxboard Manufacturers protocol on PCBs in recycle paper.
2.	(Participants)	Exchange drafts on testimony regarding PCB residuals/background levels with each other by March 7. (Monsanto contact should be W. B. Papageorge.)
3.	(Participants)	Submit to W. B. Papageorge their thoughts on proposed PCB definition (to exclude 1-4 chlorine homologs).
4.	(Participants)	Communicate with each other on how best to handle sedimentation phenomenon (as raised by Mr. Sheppard of Westinghouse).
5.	(E. S. Tucker)	Send out name of ASTM contact for participation in round-robin on proposed EPA analytical method.
6.	(Participants)	Write to Dr. Galler of Commerce Dept. opposing EPA standards. (See Galler letter to Monsanto and Monsanto response.)
7.	(Participants)	Those who have not responded to EPA can still write Dr. Thompson by March 25.
8.	(A. Salazar, NEMA)	(a) Get feedback from Sangamo/McGraw Edison on the proposed standards.
		(b) Determine role NEMA will take on affidavits/testimony at EPA hearing.
9.	(W. B. Papageorge)	Obtain PEG report and send to Mr. Nelson (G.E.).
10.	(Participants)	Involve P.E.O. in EPA Hearing along lines of Aerovox letter to Secretary Simon.

Monsanto

LAW DEPA

Monsanto Company
800 N. Lindbergh Boulevard
St. Louis, Missouri 63166
Phone: (314) 694-1000

March 12, 1974

-8
-13

Mrs. Betty J. Billings
Hearing Clerk
Environmental Protection Agency
Room 1019-East Tower
401 "M" Street, S.W.
Washington, D. C. 20460

Re: Proposed Toxic Pollutant Effluent Standards for Aldrin-Dieldrin, Et Al - FWPCA (307) - Docket No. 1

Dear Mrs. Billings:

In accordance with the ORDER AND NOTICE of Judge William J. Sweeney dated February 8, 1974, enclosed are the original and three copies of the written testimony with attachments submitted on behalf of Monsanto Company in connection with the above described matter.

Yours very truly,

Phocion S. Park

Phocion S. Park
Senior Attorney

PSP/jmd

Enc.

PLAINTIFF'S EXHIBIT 342

174

E001225

1003

Monsanto

MONSANTO INDUSTRIAL CHEMICALS CO.
800 N. Lindbergh Boulevard
St. Louis, Missouri 63166
Phone: (314) 694-1000

In Re: PROPOSED TOXIC POLLUTANT EFFLUENT STANDARDS FOR ALDRIN-DIELDRIN, ET AL - FWPCA (307) - DOCKET NO. 1

State of Missouri)
County of St. Louis) ss:

W. B. Papageorge, being first duly sworn says:

My name is W. B. Papageorge and I am Manager, Product Acceptability for the Functional Product Groups, Monsanto Industrial Chemicals Company, an operating unit of Monsanto Company. I am a graduate of Washington University, St. Louis, Missouri with a Bachelor of Science degree in Chemical Engineering and have received a Master of Science degree in Chemical Engineering from the same institute. I am a Registered Professional Engineer in the state of Missouri.

I have been employed by Monsanto Company for approximately 22 years, during which period I have served as an engineer, maintenance superintendent, distribution superintendent, manufacturing superintendent, plant manager and manager of environmental protection. In my present position I am responsible for seeing that the quality of products produced by two business groups in Monsanto Company is properly maintained. One of the business groups within my area of responsibility is the Specialty Products Business Group which manufactures and markets polychlorinated biphenyl (PCB) products for use as dielectric fluids in transformers and capacitors. I am a member, and have served as chairman, of a committee of the National Electrical Manufacturers Association which has reviewed the environmental effects of PCBs and has recommended procedures to users of PCBs which should minimize the possibility of entry of PCBs into the environment.

PLAINTIFF'S EXHIBIT 343

MONSANTO COMPANY'S POSITION AND RECOMMENDATIONS

As a major producer and supplier of polychlorinated biphenyls (PCBs) to the electrical industry for fire resistant dielectric fluid applications, we have reviewed and evaluated the effluent standards for these materials in proposed Part 129, Subpart I, Chapter I of Title 40, Code of Federal Regulations. Pursuant to this review, we submit the following comments and recommendations:

1. The proposed effluent standards for PCBs are unwarranted and practically and economically unattainable.

2. Actions by Monsanto and its customers, which have resulted in limiting the use of PCBs only to electrical applications in hermetically sealed units, have dramatically reduced the quantities of the more persistent PCBs introduced directly into the environment.

3. The definition of PCBs in Section 129.09a, Subpart I should be changed to read:

   "Polychlorinated biphenyls (PCBs) means materials containing the biphenyl group which is chlorinated and which have been shown to persist and rapidly bioaccumulate in the aquatic environment. These chlorinated biphenyls are identified as those components having gas chromatographic retention times greater than 60, relative to p,p-DDE=100, under the standard conditions recommended in the EPA PCB test method."

4. The accuracy and reproducibility of results attainable between laboratories using currently available sampling and analytical techniques are questionable and further studies are recommended.

5. The proposed PCB effluent standard is based on inadequate toxicity information, on non-typical fish species and on an unusually high and artificial bioaccumulation factor. Fundamental scientifically-based data is lacking and no responsible standards can be developed at this time. We recommend that studies be conducted to obtain the relevant data and that effluent standards be established which are appropriate for the unique conditions existing at each point source.

6. We object to a limitation of 10,000 cubic feet per second being arbitrarily assigned as a maximum stream flow, without a sound technical basis demonstrating adverse effects.

7. The presence of background levels of PCBs at point sources should be considered when determining effluent levels. The following definition of "Background" should be added under Section 129.01a:

> " 'Background' means amounts of toxic pollutant (1) presently found in the waterways of the United States (including the intake waters of a discharger), or (2) arising out of operations subject to this Part that occurred before the effective date of this Part, but were not discharged to the waterways of the United States before the effective date of this Part."

8. Technology for the attainment of the proposed PCB effluent standard has not been demonstrated and is not available to the industry. Unachievement of the strict standard proposed would have the effect of a ban on the use of PCBs with serious economic and social consequences very thoroughly described in an impact statement submitted to the Agency on January 15, 1974, by the General Electric Company.

The chemical structure of polychlorinated biphenyls (PCBs) has been known for nearly 100 years. It was not until the late 1920s that a use for PCBs was found — as a dielectric fluid in transformers. The properties of PCB — inertness, fire resistance and a non-conductor of electricity — are perfectly suited to those electrical applications where high-voltage arcing could occur; possibly resulting in serious fires or damage to the equipment.

Commercial production of PCBs began in 1929. As the unique properties of the material became known, new uses were found. For example, their fire-resistant nature made them excellent choices for use in heat-transfer fluids. Their inertness gave long-lasting qualities to lubricants. Their use in surface coatings improved waterproofing characteristics.

Handling of the product at the manufacturing level has not presented problems as long as the normal industrial hygiene practices were followed and PCBs have always been considered less hazardous than many other chemicals in everyday use.

Therefore, it appeared that PCBs were a unique product which met important needs of industry.

When questions about the effect of PCBs on the environment first surfaced, Monsanto Company reviewed its product line and the applications for these products. As more data were developed concerning the effect of PCBs, Monsanto took steps to reduce the entry of PCB into the environment. The Company stopped the sale of PCBs for use in various applications, except where no acceptable alternatives were available. Today, PCBs manufactured by Monsanto Company are sold only to the electrical industry for use in closed systems as a dielectric fluid in transformers and capacitors — applications for which there exist no acceptable substitutes.

Thus the situation today is drastically different from conditions which existed only three years ago. Today about 40 million pounds per year are being carefully used in the United States by less than 50 Monsanto customers in the manufacture of sealed electrical equipment. Prior to 1971, close to 80 million pounds per year were used by thousands of customers. This lends perspective to the current debate over modest losses of PCBs to waterways.

Our manufacturing and sales reduction program was a unilateral action taken by Monsanto and was based on our evaluation of developing environmental data.

The Interdepartmental Task Force on PCBs in its report (1)* concurs that the safety benefits derived justify the continued use in dielectric applications. Recommendation 6 under Findings, Conclusions and Recommendations reads as follows:

> "6. <u>The use of PCBs should not be banned entirely</u>. Their continued use for transformers and capacitors in the near future is considered necessary because of the significantly increased risk of fire and explosion and the disruption of electrical service which would result from a ban on PCB use. Also, continued use of PCBs in transformers and capacitors presents a minimal risk of environmental contamination. The Monsanto Company, the sole domestic producer, has reported voluntarily eliminating its distribution of PCBs to all except manufacturers of electrical transformers and capacitors."

*Numbers in parentheses refer to reference list attached.

Recognizing the need for proper controls in the handling and use of PCBs, representatives of the transformer and capacitor industries, utilities and governmental agencies under the initial auspices of the National Electrical Manufacturers Association formed American National Standards Institute Committee C-107. Proposed guidelines (30) for the handling and disposal of dielectric fluids have been published. These guidelines reflect the industry's understanding of the need for proper control and have contributed significantly toward achieving this objective.

Proposals for the control of PCBs internationally were considered by the member countries of the Organization for Economic Co-operation and Development (OECD) and in February, 1973, they adopted an agreement (31 which restricts the use of PCBs to dielectric applications, non-food related heat transfer fluid applications and hydraulic fluid applications in mining equipment. This agreement is less restrictive than Monsanto's sales policy since it supports the continued use of PCBs in heat transfer and hydraulic fluids.

We have reviewed with considerable interest the effluent standards proposed for polychlorinated biphenyls in new Part 129, Subpart I, Chapter I of Title 40, Code of Federal Regulations and have objections relating to the following:

1. Definition of polychlorinated biphenyls.

2. Sampling and analytical methods.

3. Toxicity data.

4. Bioaccumulation factors.

5. Safety factors.

6. Stream flow rates.

7. Background levels of polychlorinated biphenyls.

8. Economic considerations.

DEFINITION OF POLYCHLORINATED BIPHENYLS

Commercial polychlorinated biphenyl products, of which Aroclor® products are examples, are produced by direct chlorination of biphenyl; the degree of chlorination being chosen to provide desired properties. These products are in all cases multi-component mixtures and not single entities as implied by the commonly employed acronym "PCBs".

While it is well understood and accepted that polychlorinated biphenyl isomers have a unique set of physical and chemical properties, it is apparently not understood that they bioaccumulate, dissipate and biodegrade at different rates.

This lack of understanding is reflected in the definition proposed in the EPA Toxic Pollutant Effluent Standards (Federal Register, Vol. 38, No. 247, page 35393, Section 129.09a) and we quote:

> "As used in this Subpart, the term: Polychlorinated biphenyls (PCB's) means materials containing the biphenyl group which have been chlorinated to varying degrees. There are 210 possible different PCB compounds."

We object to this definition because it implies that all polychlorinated biphenyl isomers are of equal environmental concern, i.e., that they all persist and bioaccumulate in the same manner in our environment. It has been well established by academic, government, and industrial researchers that this is simply not true. Environmental monitoring programs have clearly demonstrated that, with the exception of direct high-level controllable release near points of manufacture or use, the PCBs found in our environment are the more highly chlorinated ones, i.e., those containing predominantly five or more chlorine atoms per biphenyl molecule (2 thru 13).

This is true even though the lower polychlorinated biphenyls have constituted more than 65% of all the PCBs manufactured over the years. This is strong evidence that the lower polychlorinated biphenyls degrade rapidly. It further demonstrates that even under conditions of unlimited use, and without special precautions to avoid release into our environment (which is not the case now), that the lower polychlorinat biphenyls degrade rapidly enough to prevent bioaccumulation (4, 5, 6, 27,

More recently, it has also been demonstrated in laboratory experiments that chlorinated biphenyl isomers, readily undergo bacterial degradation at rates dependent upon the number of chlorines per biphenyl molecule (17, 18, 19, 20, 21 and 37). There are also good indications that ambien environmental PCB levels are decreasing at rates more rapidly than predicted (14, 15, 16).

The rapid metabolism of these chlorinated isomers and their lack of importance as contributors to the chlorinated biphenyl tissue burdens is evidenced in the results of numerous studies. Risebrough (2) reported that the chlorine composition of the PCBs detected in Atlantic Ocean zooplankton was approximately 54%. He concluded "U.S. production of Aroclor 1254 in 1970 amounted to 12 million pounds -- only one quarte

of the production of 49 million pounds of Aroclor 1242. It might be expected therefore that biphenyls with fewer chlorine atoms would predominate in planktonic samples unless these compounds were selectively degraded." Similar findings in fresh water and marine fishes were reported by Zitko (3) and Jensen, et al., (4). The disappearance of the lower chlorinated homologs in extracts of tissues from birds (5, 34) and mammals (6, 33) indicate rapid metabolism or excretion of the lower chlorinated homologs. As a result of the metabolism and/or excretion of the chlorinated biphenyls containing less than five chlorine atoms per molecule, their contribution to the effluent should not be used in measuring polychlorinated biphenyl effluent from a facility.

On the basis of these data it is unrealistic to consider all polychlorinated biphenyls equivalent in terms of persistence and bioaccumulation as does the proposed regulation. Therefore, for environmental purposes, the definition of PCBs should focus upon those which are of concern and we recommend that the following definition be substituted for that proposed in Section 129.09a, Subpart I, Title 40, Code of Federal Regulations:

> "Polychlorinated biphenyls (PCBs) means materials containing the biphenyl group which is chlorinated and which have been shown to persist and rapidly bioaccumulate in the aquatic environment. These chlorinated biphenyls are identified as those components having gas chromatographic retention times greater than 60, relative to p,p-DDE = 100, under the standard conditions recommended in the EPA PCB test method."

ANALYTICAL METHODOLOGY

We have no reason to doubt that the recommended EPA PCB test method is capable of detecting parts per trillion (ppt) levels of PCBs in waste waters. However, our experience with analyzing industrial waste waters for PCBs at the parts per billion (ppb) level prompts us to be concerned about the following areas, some of which are not covered adequately in the test procedure.

1. Sampling Procedures

2. Correction for Laboratory and Reagent Background

3. Correction for Non-PCB Sample Interferences

4. Absolute Verification

5. Physical State of PCBs (Adsorbed/Dissolved)

6. Quantitation

7. Precision and Accuracy

Our concern lies in the fact that any method, especially one as complex as a PCB analytical method, which is to be used for effluent control purposes must be thoroughly evaluated and its accuracy and reproducibility proven. If this is not done, the effectiveness of any effluent limit, no matter what the level, will prove to be difficult, if not impossible to determine.

For example, we have found that if waste water streams are not sampled properly, the PCB levels found depend on the sampling procedure employed and bear no relationship to the amount of PCBs discharged. For this reason, sampling procedures used must be designed for the discharge in question and clearly stated. To our knowledge, this has not been done.

We also note that no provisions are recommended for correcting the apparent PCB level found in a sample for laboratory and reagent background. It is our experience that as one approaches the ppt level, this background can significantly affect the observed PCB level.

With regard to correction for non-PCB sample interferences, we feel that, while the procedure notes many of the possible interferences, it does not really address itself to those which are more likely to be in industrial waste water streams. For this reason, if the electron capture chromatogram does not match the PCB being manufactured or used, complete absolute verification of all components counted as PCB must be validated via an alternate technique such as gas chromatography/mass spectrometry.

We also note that the recommended EPA PCB test method does not specify a means of differentiating between dissolved and adsorbed PCBs. We believe this should be done since there is a definite difference in the toxicity and availability for bioaccumulation of dissolved and adsorbed chlorinated hydrocarbons (24, 35, 36).

While the scheme proposed for estimation (quantitation) of PCBs is logical, it suffers from the same shortcoming as do the multitude of ot procedures which have been proposed. It is an empirical estimate and only a reflection of the real PCB level. Therefore, it should be determined via an alternate, more-elaborate procedure how closely the calculated PCB levels (for each of the cases) are to the real PCB level so that they may be corrected.

Last, but not least, the precision and accuracy of any procedure propos as a standard method should undergo a thorough inter-laboratory evaluat If this has not already been done, it must be carried out prior to the use of the procedure for enforcement purposes. The accuracy and precision of the Monsanto PCB procedure has been subjected to a preliminary evaluation. Prior to this evaluation, we probably would have overestimated the precision and accuracy of our procedure. The exact details of the evaluation are available.

Briefly, samples were prepared by spiking distilled water with 500 ppb PCBs. Individual preparations include blanks (no PCBs), Aroclor® 1242 Aroclor® 1254 only, Aroclor® 1260 only, all 50-50 two-component mixture and a 1/3, 1/3, 1/3 preparation containing all three components. Six samples of each mixture were prepared and analyzed by two experienced analytical laboratories.

Each result, expressed in ppb of the individual Aroclor®, was converted to percent of the total added. Analysis of variance was run on all data taken together and on each laboratory independently.

- The 95% confidence limits observed for individual results were:

Either Lab	87.5 ± 55.2%
Lab A	81.3 ± 46.4%
Lab B	93.7 ± 19.2%

- The repeatability for the individual labs, based on repeat tests of samples having identical prepared compositions was:

Lab A	± 42.0%
Lab B	± 11.6%

We feel that these results demonstrate the importance of evaluating the precision of any PCB procedure. Note that the test did not include sampling problems, used distilled water free of interferences, and was carried out at a relatively high PCB level (500 ppb; 500,000 ppt) by two experienced laboratories. It is expected that, if sampling proble were involved, and the level of PCB present was extremely low, the accuracy and precision of any PCB method would decrease considerably.

BACKGROUND FOR PROPOSED EPA EFFLUENT STANDARD

In the establishment of the proposed effluent standard the primary basis for toxicological consideration came from the Water Quality Criteria, October, 1973, (Federal Register, Vol. 38, pages 29646 et seq., Friday, October 26, 1973). These criteria were, in turn, based on Water Quality Criteria, 1972, by the National Academy of Sciences and the National Academy of Engineering.

The Water Quality Criteria, October, 1973, have not undergone the normal review, criticism, comment and revision before final adoption. We object to the use of challengeable portions of a proposed publication in the development of critical effluent standards.

We note in Water Quality Criteria, 1972, in those sections pertaining to polychlorinated biphenyls, the frequent use of unpublished data and the disturbing use of qualifying phrases such as "...may adversely affect...", "...apparently related...", or "...the work...suggest..." In our opinion, none of the discussions present adequate data to support establishment of responsible effluent standards for PCBs.

On page 5 of Water Quality Criteria, 1972, the Committee emphasized the importance in understanding that there is a distinction between criteria and standards and that the words were not interchangeable nor or they synonyms for words such as objectives or goals. The report further states that it is necessary to establish scientifically-based recommendati for each assignable water use, implying availability of practical methods of detecting and measuring which can be applied to monitoring. Once these fundamentals are available, political, social and economical factors enter into the decision-making process to establish standards. In our opinion, these procedural steps were not followed in arriving at the proposed effluent standards for PCBs.

The maximum acceptable concentration in fresh water that would be permitted by the proposed standard is 0.002 mg/l. The rationale describec in the Statement of Basis and Purpose, Toxic Pollutant Effluent Standards is based on results of a preliminary study which have suggested (not yet proven) a threshold PCB level for salmon egg mortality. We cannot accept the selection of salmon as representing organisms which are usual or may potentially be present in water systems near facilities described in Section 129.09, Code of Federal Regulations.

The cumulative sales of PCBs in the United States since 1930 has been estimated to be about 500,000 tons and that total world production was probably 1,000,000 tons (1). About one-half of the PCBs were used in applications where containment was difficult and losses into the environment were common. With this amount of material discharged into the environment, it is of considerable importance to note that extensive harm predicted by some theories has not been found and documented.

This lack of evidence indicates that all of the PCBs do not persist in the environment as a result of factors such as the biodegration we have discussed previously. Also, the PCBs that do persist may not be available because of some factors not clearly understood at present. One characteristic which undoubtedly is of significant importance is the ability of PCBs to adsorb tenaciously to particulate matter. Under these conditions, can PCBs be rightfully considered to be environmental active and, if so, to what degree? There exists at present a critical need for data relating to partition coefficients between water and sediments and diffusion coefficients in sediment (1, 22, 39, 40).

Although many reports have been published on the subject of polychlorinated biphenyls and living organisms, the majority of these describe the presence of PCBs in the environment. Presence should not be assumed to imply adverse effect. To our knowledge, no published report exists which conclusively relates the mortality of any wildlife species to the presence of PCBs. The only reported mortalities are those achieved in laboratory studies. Not enough is known about the fate and effect of PCBs in the natural and diverse aquatic and marine environments to properly design laboratory studies. Results from such studies are not extrapolatable to the natural situations and any conclusions derived from such studies must still be considered speculative. Fundamental scientifically-based data is lacking and, in its absence, the establishment of effluent standards for polychlorinated biphenyls cannot be made intelligently and responsibly.

In the establishment of the PCB effluent standard for freshwater systems a bioaccumulation factor of 200,000 was selected. This factor has no extrapolatable relationship to either the residues of PCB in salmon eggs or to PCB residues of fresh water forage fish. The only published report (27) of an accumulation factor of the magnitude selected was that for the hepatopancreas of the pink shrimp, Penaeus durarum. Even though an accumulation of 204,000 in the hepatopancreas has occurred a nearly complete elimination of PCB from that tissue was achieved when the shrimp were placed in water free of added PCB. The equilibrium whole body accumulation plateau indicated an approximate accumulation factor of 22,000. These results are in agreement with those reported by Stallings and Mayer (29), and with the studies of Ryther (28), Greichus et al (24) and Crump-Weisner, et al (22) showing equilibrium biomagnification factors between water and fish ranging between 1,000 and 75,000 depending on the presence and absence of sediment and the specific PCB mixture present. These data would support the selection of a factor considerably lower than the factors which were applied.

Arbitrary safety factors were applied to the tolerable chronic limit to establish the so-called "critical chronic limit" which was then used to compute the maximum allowable effluent. These safety factors were proposed to account for a multitude of variables, including non-point sources, multiple discharges and industrial growth. The safety factors proposed were identical for 7 of the 9 materials for which effluent standards were prepared. These safety factors, resulting in approximate two-fold reductions, are so small as to be of no beneficial toxicologica consequence. We recommend that no safety factor be applied.

In establishing the effluent standards, an attempt was made to distinguish between types of receiving waters by classifying them as streams, lakes and impoundments, estuaries and coastal waters. We do not believe this attempt to distinguish water bodies is by any measure adequate. Water bodies are universally known to be complex systems with no two systems alike. With a complex material such as poly-chlorinated biphenyls, the determination of possible adverse effects in each water body becomes exceedingly difficult. The uniqueness of each water system at each point source must be considered.

A key parameter used to further describe the water body is the flow rate which was limited to the probable low rate of stream flow occurring during a seven-consecutive-day period once in ten years. We do not agree that this is realistic or appropriate. In our opinion, appropriat control is achieved using average stream flow rates.

Further, the maximum flow rate that can be used in calculating the daily discharge permitted has been arbitrarily set at 10,000 cubic feet per second. This limit is based on a nondegradation philosophy which tolerates limited diffusion and on a desire to discourage industry from locating facilities on large main inland waters and coastlines. This limitation deprives our society of the judicious use of an important gre natural resource. Discharge limitations should be based on the effects a material will have on a water system, giving consideration to its siz and flow rate. For PCBs, proper control will not occur by imposing maximum flow rate conditions, but by applying results from scientific studies which properly define how each water system responds to the presence of PCBs.

RESIDUAL POLYCHLORINATED BIPHENYLS

Because of their chemical and physical properties, PCBs can be found in soils and waters at point sources long after a discharge has occurred. This source of PCBs to the environment will diminish with time but its presence will distort and mask results from current control activities. To maintain control of losses, emphasis should be directed toward discharges resulting from current and future uses of PCBs.

Since this problem of background levels occurs with all materials in varying degrees, we propose the following revisions:

From Section 129.01c(b), delete the words "in intake waters for a discharger".

Add an additional definition in Section 129.01a:

" 'Background' means amounts of toxic pollutant (1) presently found in the waterways of the United States (including the intake waters of a discharger), or (2) arising out of operations subject to this Part that occurred before the effective date of this Part, but were not discharged to the waterways of the United States before the effective date of this Part."

ECONOMIC CONSIDERATIONS

At our PCB manufacturing facility, we developed and instituted an aggressive control program which we described before the Effluent Standards and Water Quality Information Advisory Committee, EPA (41). Yet, in spite of all our efforts, we cannot today meet the proposed effluent standard.

In response (42) to an inquiry from the U.S. Department of Commerce, we emphasized that technology has not been developed to the point that facilities could be designed to meet a reasonable standard. However, analytical techniques suggest a conceptual design using adsorption, settling and filtration of aqueous waste, followed by incineration of the adsorbent, probably carbon. We estimate the capital cost of such a facility, sized to handle our plant waste, at $600,000, not including a dedicated incinerator for the disposal of the adsorbent material. Annual operating cost would approximate $150,000.

The value of Monsanto's annual PCB production is about $8 million, while the value of the electrical devices made therefrom is an order of magnitude larger. If Monsanto were to cease production of PCBs, the jobs of 55 employees would be eliminated directly, while those of an additional 47 employees in a supporting facility would be in jeopardy. The total payroll involved is on the order of $1.5 million.

The impact of a PCB ban on our customers can best be described by them. However, it is apparent that capacitors or transformers made without PCBs will be less fire-resistant than present products, thus leading to an undeterminable incidence of fires, higher insurance rates, and additional protection facilities. In the case of capacitors, the replacements are likely to be larger and less efficient, thus consuming more of the resources required in their manufacture. A more complete

analysis of the consequences of a PCB ban was developed by the General Electric Company and addressed to Dr. Martha Sager, Chairman, Effluent Standards and Water Quality Advisory Committee, EPA (43). We concur with the General Electric Company's conclusions.

Our purpose in commenting on the proposed standards is to aid the Agency in the development of realistic effluent standards which will achieve the intended objectives without serious technical, social and economic disruptions. We recognize the seriousness of this endeavor and find a statement made by Mr. John R. Quarles, Jr., Deputy Administrato Environmental Protection Agency, of considerable interest. At a recent conference, Mr. Quarles (26) stated:

> "We have found it virtually impossible to devise intelligent standards which specify an appropriate degree of control over toxic pollutants irrespective of the sources of those pollutants and factors affecting the feasibility and timing of their abatement."

The difficulties which could be anticipated in establishing effluent standards were recognized by the National Academy of Science in its preparation of Water Quality Criteria, 1972. In a review which appeared in the Environmental Reporter (38) dated August 24, 1973, the following pertinent statements highlight some of the areas of concern:

> "Knowledge of local environmental conditions is essential prior to application of any water quality recommendations for marine aquatic life and wildlife..."
>
> "NAS said application of recommendations to a local situation is unique because it requires an understanding of the circulation of water and the resultant mixing and dilution of pollutants, a knowledge of biological species and determination of the most sensitive species, and an evaluation of the transport of materials through the food web."
>
> "NAS said it is not practical to make recommendations for the relatively persistent organic pollutant based on water concentration, especially when partition coefficients are unknown."

We can appreciate Mr. Quarles' concern, particularly as it applies to PCBs. Lacking good scientific information on the fate and effects of PCBs in complex water systems each having unique characteristics, we urge extreme care be taken to avoid the promulgation of effluent standards which are unattainable and unwarranted.

W. B. Papageorge.

Subscribed and sworn to before me this 14th day of March 197

Notary Public

My Commission expires July 18, 1975

E001240

Monsanto

W. B. Papageorge -- B2SK E. P. Wheeler-- A2SA

December 9, 1974

cc: H. S. Bergen
F. J. Fitzgerald
Robert Flint - 1740
D. B. Hosmer
Clarence Sweets

SUBJECT: PCBs - Minutes of Meeting with NIOSH - 11/22/74

FROM: G. L. Bratsch
W. C. Engman --- 1740
G. F. Fort
R. E. Kelly
G. J. Levinskas
J. R. Savage

The meeting was held at the request of Joseph K. Wagoner, S. D Hyg., Director, Division of Field Studies and Clinical Investigations (DFSCI), National Institute for Occupational Safety and Health (NIOSH). NIOSH reports to the Center for Disease Control (CDC) in the Department of Health, Education and Welfare (DHEW). The participants in the discussion are as shown in the attached list.

The original purpose was to explore whether Monsanto had a "suitable occupational group for study" to assess the potential chronic effects of PCBs. To be included were "PCB-exposed active and inactive workers at Monsanto in a planned retrospective cohort study." What this would involve is obtaining work histories of time spent in PCB departments, and medical records of active and still-living inactive employees.

The study would not be complete without examination of death records of those "PCB-exposed" employees who are deceased -- including those who expired while employed and those who expired after termination of employment because of retirement or for any other cause.

The proposed study was stimulated by a report from Dr. Kimbrough, Toxicologist, CDC, to NIOSH, that she had found an alarming rate of liver cancers in rats fed Aroclor 1260. Briefly, she found 15 of 180 female rats with "definite hepatic cell carcinoma" when fed Aroclor 1260 at 100 ppm in the diet for 22 months. Only one of 173 controls had the carcinoma. She then described a number of other liver tissue effects as "pre-cancerous lesions" and found these in 175 of the experimental rats and in only three of the controls.

FEB 6 1975

Westinghouse Electric Corporation

South Boston Distribution Transformer Div
Box 920
Highway 58 West
South Boston Virginia 24592
(703) 575 7971

February 3, 1975

Dr. W. B. Papageorge
Manager Environmental Control
Monsanto Company
Organic Chemicals Division
800 North Linbergh Blvd.
St. Louis, Missouri 63166

Dear Dr. Papageorge:

Attached you will find a list of questions that have been asked by our employes regarding the use of Inerteen. Mr. Garry Wilburn, our Engineering Manager, felt if these questions could be answered you would be the man to answer them.

We have had,in the past,workplace meetings with our employes explaining proper use of Inerteen and telling them unless it is consumed, it presents no real danger to them.

In answering these questions, hopefully we will gain much needed knowledge on Inerteen and how to present it properly to our employes.

Thank you for your help.

Very truly yours,

Dan A. Albert
Staff Supervisor
Personnel Relations

mm

cc: George Hvizdos, Marvin Bowling

1. Question: Does Inerteen have permanent effects on the human body? If so, what type of permanent damage and how long a period of time does it take for this to develop? If not, explain why, if possible.

2. Question: Several hourly employes have mentioned recently that many chemicals such as Inerteen cause sterilization after a prolonged use. Is this true?

3. Question: Since Inerteen effects birds and other animals, if there is no real effects to human beings, how do you explain it to employes in such a way that they will understand why it can kill a bird and not a human?

4. Question: If an employe spills Inerteen on his clothing and later takes the clothing home to be washed with other clothes, will this have any effect on he or his family and should he carry his clothes home be be washed?

5. Question: Employes carry Inerteen home on the soles of their shoes and complain quite a bit about the effect Inerteen has on wearing out their shoes. Is this a serious problem? Will Inerteen in the soles and leather of shoes, over a long period of time, have an effect on the feet and skin since the shoe is the only protective equipment we wear on our feet and the Inerteen penetrates through the leather.

6. Question: There is one employe in our plant who had no problem whatsoever with Inerteen years ago. After six years of using, now when he works in Inerteen (which is a part of his job) he develops a swelling on the inner bicep of his left arm, only in one location. Could this be from Inerteen or not? It goes away as soon as he gets out of the Inerteen. It is similar to the swelling after taking an injection.

7. Question: Are there hand cleaning solvent materials that we should be using when working in Inerteen to coat our skin before working in it and to wash it off after we finish working in it? Please give your recommendation. Our employes working in Inerteen are not able to use gloves since it is an assembly area. Even if they could, the Inerteen would destroy the protective glove.

Summary: If there are any questions we have not brought up that you are aware of, please include in your comments, or any other information you can give us concerning the proper use of Inerteen.

I Xerox glass

E001253

GBRN 000027

Monsanto

MONSANTO INDUSTRIAL CHEMICALS CO.
800 N. Lindbergh Boulevard
St. Louis, Missouri 63166
Phone: (314) 694-1000

February 26, 1975

Mr. Dan A. Albert
Staff Supervisor
Personnel Relations
Westinghouse Electric Corporation
Box 290, Highway 58 West
South Boston, Virginia 24592

Dear Mr. Albert:

I have received your letter dated February 3 asking us to respond to a list of questions. Since these questions relate to human health considerations, I have asked our Medical Department to prepare the response. You should be hearing from us shortly, either from my office or from a representative of our Medical Department.

If I can be of further service please let me know.

Sincerely,

W. B. Papageorge

W. B. Papageorge
Manager, Product Acceptability
Specialty & Process Chemicals

WBP:pd

GBRN 000028

Monsanto

FROM (NAME & LOCATION): W. B. Papageorge — St. Louis — B2SK

DATE: March 18, 1975

cc: C. Paton
E. P. Wheeler
D. Wood

SUBJECT: WESTINGHOUSE - Inerteen

REFERENCE:

TO : H. R. Ford - 1070

Attached is the original of a letter addressed to Mr. Dan A. Albert of Westinghouse, South Boston, Virginia. The contents of this letter have been reviewed with Dave Wood and it was agreed that the letter be delivered by you personally to South Boston, giving you an opportunity to discuss with the Westinghouse representatives the proper approach that must be taken in presenting this information to avoid undue concerns and misunderstandings. Will you please deliver this letter as soon as practical.

W. B. Papageorge / pd

W. B. Papageorge

/pd

E001245

GBRN 001640

MM - 10 REV. 1/71

Monsanto

SPECIALTY & PROCESS CHEMICALS DIVISION

MONSANTO INDUSTRIAL CHEMICALS CO.
800 N. Lindbergh Boulevard
St. Louis, Missouri 63166
Phone: (314) 694-1000

March 18, 1975

Mr. Dan A. Albert
Staff Supervisor
Personnel Relations
Westinghouse Electric Corporation
Highway 58 West
South Boston, Virginia 24592

Dear Mr. Albert:

Attached are responses to the questions listed in your letter dated February 3, 1975.

In addition to the industrial hygiene practices described in our responses to your questions, I cannot overemphasize the need to properly control the use and handling of Inerteens to prevent their escape into the environment. Also, in discussing this information with your employees, I strongly recommend that the perspective gained from over 40 years of experience in which no human harm has resulted, be emphasized. In summary, the proper handling of Inerteens should pose no environmental or human health problems, permitting society's continued use of a very valuable material.

I hope the above information is useful to you. If I can be of further service please let me know.

Sincerely,

W. B. Papageorge

W. B. Papageorge
Manager, Product Acceptability
Specialty & Process Chemicals

WBP:pd

E001256

PLAINTIFF'S EXHIBIT 347

1. Question: Does Inerteen have permanent effects on the human body? If so, what type of permanent damage and how long a period of time does it take for this to develop? If not, explain why, if possible.

The polychlorinated biphenyls in Inerteen can have permanent effects on the human body.

The length of time or period of exposure necessary to develop symptoms depends on the degree or amount of exposure. In general, a single exposure for a few minutes to atmospheric concentrations that cause irritation to the eyes and/or respiratory tract would not be expected to cause either the skin eruptions or demonstrable liver injury. The problem arises from repeated and prolonged exposure to atmospheric concentrations in excess of the accepted Threshold Limit Levels or repeated and prolonged skin contact.

The polychlorinated biphenyls have not been recognized as skin "irritants" in the same sense that caustic materials or many organic chemicals are irritants. Because of their "solvent" action in removing the natural fats and oils from the skin, leaching, drying and chapping, repeated and prolonged skin contact should be avoided.

When the polychlorinated biphenyls are mixed with other chlorinated hydrocarbons, the mixture may be classified as a skin irritant.

The potential toxic effects in humans from excessive exposure to polychlorinated biphenyls include injury to the liver and chloracne. In animals, the liver effect is demonstrated by increased liver weights and injury to cellular tissue. Although chloracne is difficult to evaluate in animals, in humans, this take the form of comedones (large blackheads with typical acute pustules) and may be an external symptom of over exposure preceding serious liver injury.

Animal data and human experience indicate that the toxic effects are similar whether exposure results from ingestion, inhalation of vapors, or absorption of the liquid material through the unbroken skin.

(See AIHA Hygienic Guide Series - "Chlorodiphenyls" attached.)

2. Question: Several hourly employees have mentioned recently that many chemicals such as Inerteen cause sterilization after prolonged use. Is this true?

There is no evidence that polychlorinated biphenyls cause "sterilization" in humans.

3. Question: Since Inerteen effects birds and other animals, if there is no real effects to human beings, how do you explain it to employees in such a way that they will understand why it can kill a bird and not a human?

There is a potential real effect to humans - including death - as discussed in the answer to Question 1.

Due to differences in metabolism of food (and food contaminants) in birds and humans (and particularly the difference in the reproduction process in birds and mammals - including humans), birds are particualrly sensitive to many chlorinated hydrocarbons including polychlorinated biphenyls.

4. Question: If an employee spills Inerteen on his clothing and later takes the clothing home to be wa ed with other clothes, will this have any effect on he or his family and should be carry his clothes home to be washed?

There should not be any effect on an employee or his family from home laundering of work clothing. If washed with other clothing, there may be residual odor of the chlorinated hydrocarbons in the clothing.

5. Question: Employees carry Inerteen home on the soles of their shoes and complain quite a bit about the effect Inerteen has on wearing out their shoes. Is this a serious problem? Will Inerteen in the soles and leather of shoes, over a long period of time, have an effect on the feet and skin since the shoe is the only protective equipment we wear on our feet and the Inerteen penetrates through the leather.

There should not be polychlorinated biphenyl on the floor for workmen to contaminate their shoes to carry home. The plasticizer or solvent action will destroy or shorten the life of the shoes. More importantly, the wearing of contaminated shoes could lead to absorption of the liquid through the soles of the feet as through any other unbroken skin surface.

6. Question: There is one employee in our plant who had no problem whatsoever with Inerteen years ago. After six years of using, now when he works in Inerteen (which is a part of his job) he develops a swelling on the inner bicep of his left arm, only in one location. Could this be from Inerteen or not? It goes away as soon as he gets out of the Inerteen. It is similar to the swelling after taking an injection.

We do not believe there can be any association between "a swelling on the inner bicep" of the arm and exposure to polychlorinated biphenyls.

7. Question: Are there hand cleaning solvent materials that we should be using when working in Inerteen to coat our skin before working in it and to wash it off after we finish working in it? Please give your recommendation. Our employees working in Inerteen are not able to use gloves since it is an assembly area. Even if they could, the Inerteen would destroy the protective glove.

We assume the question refers to the use of "Barrier Creams" rather than a "hand cleaning solvent".

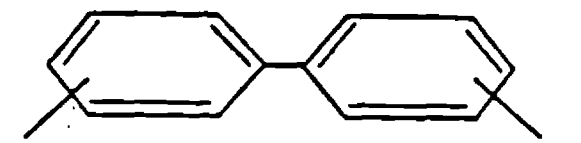
There are a number of barrier creams available to protect workers against water <u>insoluble</u> solvents. Probably the most effective include silicone "to provide an impenetrable shield". A problem with such creams is that they may offer a false sense of security.

Proper use includes a discipline which requires liberal application at the beginning of a work shift and after each washing of the hands during the work day.

HYGIENIC GUIDE SERIES

Chlorodiphenyls

(Containing 42% and 54% Chlorine)



$(x + y = 3 \text{ or } 5)$

Significant Physical Properties[1]

The chlorodiphenyls are light straw-colored mobile (42% chlorinated) and viscous (54% chlorinated) liquids with typical chlorinated aromatic odors. These compounds are chlorinated to specific weights of chlorine. Chlorodiphenyl (42%) contains 42.0 ± 0.5 chlorine, an amount corresponding to three chlorine atoms in unassigned positions. Chlorodiphenyl (51%) contains 54.5% chlorine corresponding to five chlorine atoms in unassigned positions. Both compounds are insoluble in water, but soluble in benzene, kerosene, acetone, amyl alcohol, ether and chloroform.

	Chlorodiphenyl (42%)	*Chlorodiphenyl (54%)*
Molecular weight:	247.53	326.45
Flash point (Cleveland O. C.):	176°-180°C (349°-356°F)	None
Distillation range:	325°-366°C	365°-390°C
Specific gravity:	1.381-1.392 (25°/15.5°C)	1.495-1.505 (65°/15.5°C)
Vapor pressure:		
0°C	0.001 mm	0.00006 mm
25°C	0.006 mm (est)	0.00054 mm (est)
150°C	4.3 mm	1.4 mm
200°C	29.0 mm	9.0 mm
At 25°C and 760 mm Hg:		
Saturated air contains	0.060 mg/liter	0.009 mg/liter
1 mg/liter =	98.8 ppm	74.9 ppm
1 ppm =	0.010 mg/liter	0.013 mg/liter

I. Hygienic Standards

A. RECOMMENDED MAXIMAL ATMOSPHERIC CONCENTRATIONS (8 hours): One milligram chlorodiphenyl (42%) per cubic meter of air and 0.5 milligram chlorodiphenyl (54%) per cubic meter of air.[2] This is based on the results of chronic animal inhalation studies.[3]

B. SHORT EXPOSURE TOLERANCE: Ten mg of a diphenyl of unspecified chlorine content per cubic meter of air has been reported as unbearably irritating.[4]

C. ATMOSPHERIC CONCENTRATION IMMEDIATELY HAZARDOUS TO LIFE: Not known for man. Irritation of the eyes, nose and throat at levels which have not caused acute illness preclude the likelihood of voluntary exposure to immediately hazardous concentrations.

The Committee wishes to acknowledge the preparation of the medical information section of this Guide by the Industrial Hygiene and Clinical Toxicology Committees of A. M. A., and to acknowledge also the assistance of Elmer P. Wheeler and Jack T. Garrett in the writing of this Guide.

II. Toxic Properties

A. INHALATION: Experiments with chlorodiphenyl (42% chlorine) were run at concentrations of 8.6 μg/liter and at 6.83 μg/liter of air. Cats, mice, rabbits and rats were unaffected by the higher level while guinea pigs showed poor growth after seventeen 7-hour/day exposures over 24 days. Eighty-four 7-hour/day exposures at the lower concentration had essentially no effect on similar species of animals.[3]

In the case of chlorodiphenyl (54% chlorine) eighty-three 7-hour/day exposures over 121 days to a concentration of 5.4 μg/liter resulted in injury to liver cells and increased liver weights in rats. At a concentration of 1.5 μg/liter for one hundred and fifty 7-hour/day exposures over 213 days, the rats showed distinct microscopic changes in the liver.[3]

The literature contains many references to the potential toxic effects of chlorinated diphenyls in man and animals. The early work included investigations of chlorinated naphthalenes, chlorinated diphenyls, chlorinated diphenyl oxide and various mixtures of these. An early report indicated serious toxic effects from chlorodiphenyl chlorinated to the extent of 65%.[5] A later report by the principal author properly identified the earlier sample as a mixture of chlorinated diphenyl and chlorinated diphenyl benzene.[6] However, only a few authors of subsequent papers, bulletins or textbooks have noted this correction and the original data are cited repeatedly as relating to chlorinated diphenyl alone.

B. SKIN CONTACT: Both compounds are readily absorbed through the clipped, intact skin of rabbits. The minimum lethal dose when the undiluted materials were applied to the covered clipped, intact skin of rabbits for 24 hours was approximately 1.0 gm/kg for the 42% chlorinated and 1.5 gm/kg for the 54% chlorinated.[7]

Local action on the skin is similar to that of common organic solvents where contact leads to removal of natural fats and oils with subsequent drying and cracking of the skin.

Human cases of chloracne have not been reported from the use of these two specific chlorodiphenyls. The potential undoubtedly exists because of cases which were reported from the use of chlorodiphenyls with a higher chlorine content and from mixtures with other chlorinated aromatic compounds.[3,4,8]

C. EYE CONTACT: The liquid products and their vapors are moderately irritating to eye tissues.

D. INGESTION: The acute oral toxicities of the undiluted compounds are not great as evidenced by oral LD_{50}'s in rats of approximately 8.65 gm (7.61 to 9.78 gm) per kilogram for the 42% chlorinated and 11.9 gm (10.48 to 13.45 gm) per kilogram for the 54% chlorinated.[7] Central atrophy of the liver appears to be the chief toxic effect.

III. Industrial Hygiene Practice

A. INDUSTRIAL USES: The chlorodiphenyls are used as dielectrics for condensers, capacitors and transformers, plasticizers in synthetic resins, in emulsion adhesives, as nonflammable hydraulic fluids and as transfer media.

B. EVALUATION OF EXPOSURES:

1. *Air sampling and analysis:*
   a. Direct field methods: None
   b. Laboratory methods:
      (1) Collect in secondary butyl alcohol in fritted bubbler or two large impingers in series; concentrate sample and complete analysis by one of various methods for chlorinated hydrocarbons.[9]
      (2) Sample air through combustion furnace, collect chloride ion from decomposed chlorodiphenyl in suitable alkaline solution and determine chloride ion concentration.[9]

C. HAZARDS AND THEIR RECOMMENDED CONTROL:

1. *Inhalation:* Absorption is chiefly by inhalation. Concentrations in the workroom atmosphere should be maintained below the recommended levels. Where the chlorinated diphenyls are used at room tempera-

tures, the hazard of inhalation is considered slight or absent. When these materials are subjected to elevated temperatures, the process either should be completely enclosed or other adequate mechanical exhaust ventilation must be provided to reduce concentrations to safe levels. In heat transfer media applications, the system must be designed and constructed so that it is leakproof. Special gasket materials and pump seals are available to prevent leakage. The reservoir tank should be airtight except for a vent to the outdoors. In the event of spills or leaks of hot fluids, use chemical cartridge respirators or gas masks approved by the U. S. Bureau of Mines for protection against organic vapors. These will provide good protection up to the concentrations shown on the approval labels and the odor will give ample warning if it comes through the device.

2. *Skin contact:* Operations and handling procedures should be such as to avoid the possibility of prolonged or repeated skin contact. Contaminated clothing must be laundered before reuse.
3. *Eye contact:* Eye protection should be used where there is a possibility of liquid splashes.
4. *Ingestion:* Ingestion of these materials is not a problem in industry.
5. *Fire and explosion:* The chlorodiphenyls are fire-resistant or essentially nonflammable liquids. When exposed to flame or hot surfaces they may decompose to form CO, CO_2, HCl, phenolics and aldehydes depending on the temperature, availability of oxygen, area of the heated surface, rate of application of the liquid to the surface and other variables.

IV. Medical Information

A. Emergency treatment: Skin surfaces exposed to chlorodiphenyls should be thoroughly washed with soap and water at once. If clothing has been contaminated it should be removed promptly.

If exposure to a high vapor concentration occurs, as in the case of spills at elevated temperatures, the patient should be moved from exposure and kept at rest until seen by a physician. Oxygen should be administered if breathing is difficult.

Eyes contaminated with chlorodiphenyl should be irrigated with water for at least 15 minutes and the patient should be seen by a physician. Depending on the amount of inflammation and pain present, drugs like Cortisporin® ointment and topical Pontocaine® may be indicated.

B. Special procedures: Persons who are regularly or repeatedly exposed to chlorodiphenyls should be examined periodically to detect early evidence of skin irritation and/or liver damage. Persons with known liver disease should not be exposed to repeated contact with the chlorodiphenyls.

V. References

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2. American Conference of Governmental Industrial Hygienists: Threshold Limit Values for 1964. *AMA Arch. Environ. Health 9:* 545 (1964).
3. Treon, J. F., F. P. Cleveland, J. Cappel, and R. W. Atchley: The Toxicity of the Vapors of Aroclor 1242 and Aroclor 1254. *Amer. Ind. Hyg. Assoc. Quart. 17:* 204 (1956).
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5. Drinker, C. K., M. F. Warren, and G. A. Bennet: The Problem of Possible Systemic Effects from Certain Chlorinated Hydrocarbons. *J. Ind. Hyg. Toxicol. 19:* 283 (1937).
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7. Wheeler, E. P.: Personal Communication, Monsanto Company, St. Louis, Missouri 63166.
8. Greenburg, L., M. R. Mavers, and A. R. Smith: The Systemic Effects Resulting from Exposure to Certain Chlorinated Hydrocarbons. *J. Ind. Hyg Toxicol. 21:* 29 (1939).

HYGIENIC GUIDES COMMITTEE

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Hygienic Guide sheets may be obtained from the American Industrial Hygiene Association, 14125 Prevost, Detroit 27, Michigan, at 25 cents each for two-page reprints; 30 cents each for four-page reprints. All orders for less than $2.00 must be prepaid. Discount of 20% on orders of five or more Guides; 40% discount on orders of 100 or more Guides. Special loose-leaf binders for the Guides may also be ordered from the Association office for $1.25 each.