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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.

ADM 006290

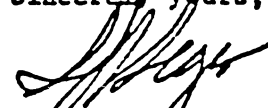
Within 14 days of receipt of this letter, your company must provide all information concerning your current status and activities and covering the twelve month period immediately preceding receipt of this letter.

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. Stephens
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.

different

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. *Sargent + White (Ct period)*
- 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. *Can do schedule*

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. Not

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:

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.

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.

*Koenig
Records*

Difficult

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.

Monsanto

FROM NAME & LOCATION: David Wood-St. Louis-B2SD

DATE: October 30, 1975

cc: f-EPA

SUBJECT:

~~REDACTED~~

REFERENCE:

COMMENTS ON EPA LETTER REC'D 10-17

TO:

W. B. Papageorge
B2SK

1. Bill, this seems to be a new version.
2. Page 1. Cl. Terphenyls specifically mentioned.
3. a) Production records answer 1(a).
b) Remember we warehoused PCBs for short period 1974 ahead labor contract renewal.
c) Question 1c raises a problem that has been at back of my mind. #2 report is supposed to show "ship to" address, but if this is case, why do 3rd party W/GE shipments appear under "bill to" locations.
4. Q2 a) No problem
b) No problem
c) No problem
d) No problem
e) Policy - Hanley level?
5. Q3-No problem except 71/72
6. Q4-No reclamation.
7. Q5-a) No problem
b) Difficult. Can split Dielec/HT/Pydraul
But some returns mixtures of oil/PCB, etc.
c) Can do.
d) Difficult
e) Difficult
8. Q6 - Available
9. Q7 - a) Guess we have
b) Guess we have
c) Guess we have
10. Q8 - a) Bulk Rail
Bulk R - 3 accounts
Drum - Specify drum construction
b) E. M. Potter

ADM 006288

11. Q9 - Should answer from our activity?

12. Q10 - None? Yusho? Cloracne years ago - Dangerous Question.

13. Q11 - a) Might get HUB again?

b) Should write this one very carefully - can make
some positive points in this section.

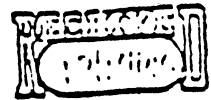
David Wood

/deb

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3

Monsanto



MONSANTO INDUSTRIAL CHEMICALS CO.
800 N. Lindbergh Boulevard
St. Louis, Missouri 63106
Phone: (314) 684-1000

December 11, 1975

Mr. Earl J. Stephenson
Director, Enforcement Division
Environmental Protection Agency
1735 Baltimore
Kansas City, Missouri 64108

Dear Mr. Stephenson:

Attached is a response to the questionnaire which accompanied
Mr. Stanley Legro's letter dated October 17, 1975.

To the best of my knowledge and belief, the information contained
in this response represents the best information available to Monsanto.

If I can be of further assistance, please let me know.

Sincerely,

W. B. Papageorge
Manager, Product Acceptability
Process Chemicals Division

ajt

Attachment

CC: Mr. Stanley W. Legro
US Environmental Protection Agency
401 "M" Street, SW
Washington, D.C. 20460

POLYCHLORINATED BIPHENYL (PCB) COMPOUNDS OR MIXTURES

In this response the phrase "PCB compound or mixture" includes those materials listed under Base Products in Exhibit A.

1. (a) Monsanto Industrial Chemicals Company does not import PCB compounds or mixtures. Amounts produced for 1971, 1972, 1973, 1974 and the first three quarters of 1975 are included in Exhibit C.

- (b) Production facilities:

For 1971 and 1972

Monsanto Company
Box 249
Anniston, Alabama 36201

For 1971 to present

Monsanto Company
Route 3
Sauget, Illinois 62201

The amounts produced at the Anniston, Alabama plant are shown on Exhibit D. The Sauget, Illinois unit produced the amounts shown on Exhibit E. Wholesale and retail outlets are not used.

- (c) See Exhibit F for 1971, Exhibit G for 1972, Exhibit H for 1973 and 1974 and Exhibit I for 1975. The PCB compounds or mixtures from the Anniston, Alabama facility are listed in Exhibit D. The remaining were shipped from the Sauget, Illinois facility.
2. (a) See Exhibit A - pages 2, 3 and 4 and Exhibit B.
 - (b) See Exhibit A - pages 2, 3 and 4.
 - (c) The PCB compounds or mixtures used were produced by Monsanto. See 1(b).
 - (d) Production facilities are those shown under 1(b) and for 1971 and 1972 also included Monsanto Company, 1700 South Second Street, St. Louis, Missouri 63177. Products distributed through Monsanto's Anniston, Alabama unit are shown on Exhibit D. All Pyral products were distributed through the St. Louis, Missouri facility. Remainder of products distributed through the Sauget, Illinois unit. Amounts distributed are shown on the exhibits listed in 2c below.

- (e) See Exhibit F for 1971, Exhibit G for 1972, Exhibit H for 1973 and 1974 and Exhibit I for 1975. The products obtained from the Anniston, Alabama facility are listed in Exhibit D. The Pydraul products originated at the St. Louis, Missouri unit. The remaining were shipped from the Sauget, Illinois facility. We do not manufacture consumer products containing PCB compounds or mixtures.
3. (a) During 1971 and 1972 PCB compounds or mixtures were used as heat transfer fluids, hydraulic fluids and in transformers and capacitors. During the latter part of 1972, 1973, 1974 and 1975 PCB compounds or mixtures are only present in transformers and capacitors.
- (b) See Exhibit J. Amounts shown are for total Monsanto Company usage. No records are available to determine specific company facility. Inertene was used in transformers. Pydrauls in air compressors. Therminols in industrial heat transfer systems.
- (c) The PCB products were all produced by Monsanto Company. The specific sources are shown on Exhibit J.
4. PCB compounds or mixtures are not reclaimed.
5. (a) During 1971 and 1972 solid waste material contaminated with PCB compounds or mixtures were buried in a secure landfill located within a fenced area on property owned by Monsanto Company at the Anniston, Alabama facility. Similar waste has also been buried in a secure landfill located on Monsanto Company property at the Sauget, Illinois facility during the period 1971 - 1975. Liquid wastes have been disposed by incineration for the period 1971 - 1975 in a high temperature unit located at the Sauget, Illinois facility. During 1975 solid waste was sent to Texas Ecologists, P. O. Box 307, Robstown, Texas 78420.
- (b) Waste materials containing PCB compounds or mixtures are received from many sources. The type of PCB compound or mixture in the waste is unknown. The concentration is also unknown. Solid waste is estimated as containing levels ranging from the ppm level to 50% by weight. Liquid waste is estimated to contain about 90% PCB compound or mixture.
- For amounts disposed see Exhibit K. Note the amounts shown refer to the total weight of waste. The actual PCB content is unknown.
- (c) See Exhibit K for total waste disposed. Concentration and type of PCB compound or mixture are unknown.

- (d) See Exhibit L. Total amounts of waste are shown. Concentration and type of PCB compound or mixture are unknown.
- (e) See 5a for name and location. See Exhibit K for amount disposed.
6. See Exhibit A. Monsanto Company does not import or reclaim PCB compounds or mixtures. Composition of disposed material is unknown but can range from ppm level to 100% by weight PCB.
7. (a) See Exhibit M for Sauget, Illinois facility waste effluent analyses. See Exhibit N for Anniston, Alabama facility water effluent analyses. For PCB emissions to the atmosphere at the Sauget, Illinois facility see Exhibit O. Analyses of air emissions were not made at the Anniston, Alabama facility.
- (b) See Exhibits M, N and O.
- (c) No information is available regarding the Anniston, Alabama facility. No information is available relating to PCB concentration in the air in the area of the Sauget, Illinois facility. Samples of the Mississippi River were taken in 1972. Results were as follows:

<u>*Sample Date</u>	<u>Location</u>	<u>mg/l PCB</u>
10/30/72	T.B. Bridge (downstream)	0.00012
12/13/72	Chain of Rocks Bridge (upstream)	0.0002 - 0.0004
12/12/72	N. of Ill. River (upstream)	0.0002 - 0.0004

*Analytical blank value at 0.00005-0.00017

8. (a) PCB compounds or mixtures are liquids and are transported in bulk or in steel drums.
- (b) See Exhibit P for transporters of PCB compounds or mixtures from Monsanto facilities. Transporters of material returned for disposal can be any common carrier serving the St. Louis, Missouri area.

9. Monsanto Company is not aware of any occasion in which PCB compounds or mixtures were introduced into the environment which is not already known to representatives of the Environmental Protection Agency. Examples include the contamination of fish meal in North Carolina, the drainage of fluid from a transformer in transit in Tennessee and the leakage of fluid from a damaged transformer in the Duwamish waterway in Washington.
10. Monsanto Company is not aware of any health or environmental effects resulting from the introduction of PCB compounds or mixtures into the environment which has not been reported in the scientific and popular press and already known to representatives of the Environmental Protection Agency.
11. (a) Monsanto Company has received reports that about 1800 drums of PCB compounds or mixtures are being offered by a company located in the northeastern U.S. for sale for any application. This information was received from Mr. Robert Laham, Hub Fabric Leather Company, 7 Charlton Street, Everett, Massachusetts 02149. This has been discussed with a representative of the Environmental Protection Agency.

Recently Pyramid Chemical Sales Company, 1035 Virginia Drive, Fort Washington, Pennsylvania 19034 has advertised the availability for any application of Aroclor 1221, Aroclor 1232 and Aroclor 5460. A representative of the Environmental Protection Agency has been informed.

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REPORT TO
MONSANTO COMPANY

TWO-YEAR CHRONIC ORAL TOXICITY WITH
AROCOR 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 at which the deaths occurred did not vary among the test and control groups.

Hematological and clinical blood chemistry studies conducted after 3, 6, 9, 12, 18, or 24 months did not reveal any effects related to Aroclor 1260. Urine analyses failed to reveal any differences between test and control animals.

At sacrifice after 3, 6, or 12 months on test organ weights, organ to body weight and organ to brain weight ratios disclosed several randomly occurring intergroup differences. The lack of any consistent dose related response and the absence of any deleterious histopathologic change confirm that these differences were not related to the ingestion of Aroclor 1260.

At the final sacrifice after 24 months on test, the liver weights and liver to body weight or brain weight ratios were significantly elevated in the rats from the T-III group. Histologic examination of the livers from the T-III group revealed several animals with vacuolar change. This lesion is morphologically indicative of fatty degeneration. Specific fat stains confirmed the presence of fat in these vacuoles. Focal hypertrophy and focal hyperplasia were also found in the livers from animals fed Aroclor 1260.

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

lam:sjn

ADM 003722

III. Procedure

A. Experimental Animals

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

B. Organization of Groups

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

TABLE I
TEST MATERIAL: Aroclor 1260
Two-Year Chronic Oral Toxicity Study - Albino Rats
Outline of Experiment

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

* Charles River Breeding Laboratories, North Wilmington, Mass.

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C. Diets, Feeding and Food Consumption

All diets were prepared in the central diet room of this laboratory. The basic ration from which all diets were constructed was a standard, pulverized stock rat ration*. The diet for any given test group was prepared by blending the calculated amount of Aroclor 1260 with a pre-weighed portion of the stock ration in a Hobart mixer.

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

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

D. Body Weights and Weight Gains

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

E. Mortality and Reactions

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

F. Hematologic Studies and Urine Analyses

Blood studies, including determinations of hemoglobin concentrations, hemotocrit value, erythrocyte count and both total and differential

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

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

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

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

G. Clinical Blood Chemistry Studies

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

H. Pathologic Studies

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

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

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

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

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

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

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

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

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

L Tumor Incidence and Classification

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

IV. Results

A. Body Weights and Weight Gains

The male and female body weight data are assembled in Table II. The data in this table also include the 3, 12 and 24 month total weight gains.

There were no significant effects due to ingestion of the compound

TABLE II

TEST MATERIAL: Aroclor 1260

Two-Year Chronic Oral Toxicity Study - Albino Rats

Body Weight and Total Weight Gain Data

Summary of Mean Values

Dietary Level of Aroclor 1260 (ppm)	Sex	Body Weight (grams) Week:														90-Day Total Weight Gain (grams/rat)
		0	1	2	3	4	5	6	7	8	9	10	11	12	13	
Control	M	133	203	245	313	362	373	391	409	424	440	440	449	467	474	341
	F	136	178	190	219	244	254	259	265	270	276	281	278	290	288	152
1	M	133	192	250	322	361	374	394	416	428	448	450	474	479	490	357
	F	136	167	189	218	241	252	256	261	268	273	277	281	290	288	152
10	M	133	204	245	317	368	382	400	417	436	448	461	467	475	481	348
	F	136	174	190	217	242	254	260	263	268	274	281	279	285	288	152
100	M	133	208	247	319	363	375	394	425	437	451	460	479	486	500	367
	F	136	173	188	222	240	253	258	262	265	267	270	275	275	280	144

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TABLE II continued

TEST MATERIAL: Aroclor 1260

Two-Year Chronic Oral Toxicity Study - Albino Rats

Body Weight and Total Weight Gain Data

Summary of Mean Values

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

TABLE II continued

TEST MATERIAL: Aroclor 1260

Two-Year Chronic Oral Toxicity Study - Albino Rats

Body Weight and Total Weight Gain Data

Summary of Mean Values

Dietary Level of Aroclor 1260 (ppm)	Sex	Body Weight (grams) Month:												24-Month Total Weight Gain (grams/rat)
		13	14	15	16	17	18	19	20	21	22	23	24	
Control	M	728	746	759	768	769	767	760	758	739	726	687	642	509
	F	426	444	466	481	500	515	533	547	551	550	564	551	415
1	M	721	740	760	768	776	774	762	753	733	718	715	654	521
	F	390	427	466	433	445	476	481	493	514	530	484	525	385
10	M	728	745	776	761	768	780	774	761	735	715	683	645	512
	F	416	434	482	449	473	508	519	530	536	542	536	584	448
100	M	746	760	772	775	774	769	760	750	733	714	711	641	508
	F	380	386	417	414	435	453	471	481	500	507	485	537	401

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)													Average Food Consumption (grams/rat/seven days)
		Week:													
		1	2	3	4	5	6	7	8	9	10	11	12	13	
Control	M	94	160	175	163	137	137	225	197	204	188	191	194	196	174
	F	73	140	144	107	104	133	208	154	165	151	146	150	151	140
1	M	118	154	151	169	201	116	200	198	201	193	189	187	194	175
	F	95	118	97	139	160	107	162	139	165	149	150	143	147	136
10	M	106	146	144	142	190	136	196	214	214	192	191	199	200	175
	F	94	124	128	124	179	90	190	167	155	151	150	149	152	143
100	M	121	150	156	117	187	124	121	190	196	186	184	199	189	163
	F	89	93	123	151	151	101	193	136	140	144	144	147	146	135

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)										Average Food Consumption (grams/rat/seven days)
		Month:										
		4	5	6	7	8	9	10	11	12		
Control	M	196	189	168	147	163	184	179	170	187	176	
	F	148	154	136	121	138	152	160	141	127	142	
1	M	196	200	189	192	179	181	182	172	184	186	
	F	148	163	141	163	160	153	157	143	132	151	
10	M	186	191	188	193	197	197	168	164	196	186	
	F	142	138	145	144	144	151	136	139	141	142	
100	M	179	170	180	188	186	166	181	188	180	180	
	F	156	127	147	144	134	132	162	149	139	143	

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C. Mortality and Reactions

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

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

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TABLE IV

TEST MATERIAL: Aroclor 1260

Two-Year Chronic Oral Toxicity Study - Albino Rats

Mortality Data

Frequency Distribution of Deaths

Dietary Level (ppm)	Sex	Frequency Distribution of Deaths Months:								Total Dead Number Tested
		1-3	4-6	7-9	10-12	13-15	16-18	19-21	22-24	
Control	M	0	0	0	2	1	7	6	9	25/35
	F	0	0	0	1	3	5	7	3	19/35
1	M	0	0	1	1	4	7	5	8	26/35
	F	0	0	0	2	3	3	6	5	19/35
10	M	1	1	0	2	4	7	8	6	29/35
	F	0	0	0	3	2	4	5	3	17/35
100	M	1	0	0	2	2	8	6	9	29/35
	F	0	2	2	0	3	5	7	4	23/35

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

D. Hematologic and Clinical Blood Chemistry Studies

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

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

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TABLE V

TEST MATERIAL: Aroclor 1260

Two-Year Chronic Oral Toxicity Study - Albino Rats

Hematologic Data

Summary of Mean Values

Dietary Level (ppm)	Sex	Total Leukocyte Count (thousands/mm ³)						Erythrocyte Count (millions/mm ³)					
		Month:						Month:					
		3	6	9	12	18	24	3	6	9	12	18	24
Control	M	14.0	15.4	10.1	11.1	9.9	11.2	8.1	8.2	8.7	8.8	7.6	6.5
	F	9.1	9.4	6.7	7.6	8.8	7.6	7.5	7.7	7.3	7.8	7.7	6.8
100	M	10.8	13.1	7.9	12.8	8.6	8.4	7.5	8.1	8.0	7.6	8.0	7.6
	F	13.2	8.2	7.9	6.5	7.8	7.4	7.3	7.5	7.3	7.5	7.4	6.4

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TABLE VI
TEST MATERIAL: Aroclor 1260
Two-Year Chronic Oral Toxicity Study - Albino Rats
Hematologic Data
Summary of Mean Values

Dietary Level (ppm)	Sex	Hemoglobin Concentration (g/100 ml)						Hematocrit Value (%)					
		3	6	9	12	18	24	3	6	9	12	18	24
Control	M	17.1	17.7	15.7	17.6	16.1	13.6	51	49	48	50	41	35
	F	16.9	17.4	14.1	16.7	16.4	14.6	50	47	43	46	42	38
100	M	16.1	17.2	14.0	15.3	15.9	14.5	49	47	43	43	41	38
	F	16.3	17.0	13.7	15.6	15.3	12.9	48	47	41	44	39	32

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						Neutrophils					
		Month:						Month:					
		3	6	9	12	18	24	3	6	9	12	18	24
Control	M	82.0	86.6	80.4	78.8	79.0	65.4	16.0	11.4	18.6	20.6	20.0	32.2
	F	83.0	86.6	86.8	89.0	70.2	61.4	15.4	11.6	11.8	10.0	29.2	36.0
100	M	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						Eosinophils					
		3	6	9	12	18	24	3	6	9	12	18	24
Control	M	0.6	0.0	0.0	0.4	0.2	1.2	1.4	2.0	1.0	0.2	0.8	1.6
	F	0.6	0.0	0.0	0.0	0.2	1.0	1.0	1.8	1.4	0.2	0.6	1.6
100	M	0.0	0.0	0.0	0.0	0.4	0.8	1.4	0.8	0.8	1.0	1.2	1.0
	F	0.0	0.0	0.0	0.0	0.4	0.2	0.4	0.4	0.8	0.8	1.6	0.0

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

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TABLE IX

TEST MATERIAL: Aroclor 1260

Two-Year Chronic Oral Toxicity Study - Albino Rats

Clinical Blood Chemistry Data

Summary of Mean Values

Dietary Level (ppm)	Sex	Fasted Blood Glucose Concentration (mg%) Month:						Serum Alkaline Phosphatase Activity (King-Armstrong Units) Month:					
		3	6	9	12	18	24	3	6	9	12	18	24
Control	M	128	123	89	88	138	99	28.6	24.7	21.5	20.3	16.2	22.3
	F	130	118	115	92	134	109	18.9	17.8	10.6	11.9	16.8	20.2
100	M	118	118	116	135	146	98	37.8	21.8	21.9	23.9	11.9	16.1
	F	117	116	115	138	146	94	12.0	12.1	7.6	11.7	7.8	12.4

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.

Industrial Bio-Test Laboratories, Inc.

TABLE X

TEST MATERIAL: Aroclor 1260

Two-Year Chronic Oral Toxicity Study - Albino Rats

Urine Analyses Data

Summary of Mean Values

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

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

Industrial Bio-1551 Laboratories, Inc.

TABLE XI

TEST MATERIAL: Aroclor 1260

Two-Year Chronic Oral Toxicity Study - Albino Rats

Urine Analyses Data

Summary of Mean Values

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

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

Industrial Division, Inc.

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 difference. The lack of any consistent dose related response and the absence of any deleterious histopathologic change confirm that these differences were not related to the ingestion of Aroclor 1260.

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TABLE XIII

TEST MATERIAL: Aroclor 1260

Two-Year Chronic Oral Toxicity Study - Albino Rats

Organ Weight and Ratio Data

Three-Month Sacrifice

Summary of Mean Values

Organ: Liver

Dietary Level of Aroclor 1260 (ppm)	Organ Weight (g)		Organ/Body Weight Ratio (g/100 g)		Organ/Brain Weight Ratio (g/g)	
	Males	Females	Males	Females	Males	Females
Control	21.4	13.0	4.13	4.16	10.3	6.82
1	20.4	13.2	3.90	4.59	9.98	6.86
10	24.0**	12.2	4.48	3.61	11.8	6.38
100	29.5**	14.5	5.73**	4.58	14.4**	7.72

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

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TABLE XIV

TEST MATERIAL: Aroclor 1260

Two-Year Chronic Oral Toxicity Study - Albino Rats

Organ Weight and Ratio Data

Three-Month Sacrifice

Summary of Mean Values

Organ: Kidneys

Dietary Level of Aroclor 1260 (ppm)	Organ Weight (g)		Organ/Body Weight Ratio (g/100 g)		Organ/Brain Weight Ratio (g/g)	
	Males	Females	Males	Females	Males	Females
Control	4.03	2.49	0.782	0.802	1.95	1.31
1	4.37	2.62	0.838	0.911	2.14	1.36
10	4.00	2.61	0.747	0.782	1.96	1.37
100	4.00	2.52	0.779	0.793	1.96	1.35

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

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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 1250.

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	Average Grade
5 Males	Trachea	Tracheitis	1	1.0
	Lung	Chronic respiratory disease	1	1.0
	Urinary bladder	Hyperplasia	3	1.0
5 Females	Lung	Chronic respiratory disease	1	1.0

All other tissues and organs were normal histologically.

Grading System

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

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TABLE XX

TEST MATERIAL: Aroclor 1260

Two-Year Chronic Oral Toxicity Study - Albino Rats

Histopathologic Changes

Three-Month Sacrifice

Group: 100 ppm

Number of Animals	Organ Examined	Findings	Incidence	Average Grade
5 Males	Trachea	Tracheitis	4	1.0
	Lung	Chronic respiratory disease	2	1.0
5 Females	Trachea	Tracheitis	3	1.0
	Lung	Chronic respiratory disease	2	1.0
	Kidney	Focal lymphoid infiltration	1	1.0

All other tissues and organs were normal histologically.

Grading System

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

2. Six-Month Sacrifice

a. Gross Pathologic Findings

No outstanding differences were noted between test and control animals.

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

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

Organ weights, organ to body weight and organ to brain weight ratios disclosed several randomly occurring intergroup differences. The lack of any consistent dose related response and the absence of any deleterious histopathologic change confirm that these differences were not related to the ingestion of Aroclor 1260.

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TABLE XXI

TEST MATERIAL: Aroclor 1260

Two-Year Chronic Oral Toxicity Study - Albino Rats

Organ Weight and Ratio Data

Six-Month Sacrifice

Summary of Mean Values

Organ: Liver

Dietary Level of Aroclor 1260 (ppm)	Organ Weight (g)		Organ/Body Weight Ratio (g/100 g)		Organ/Brain Weight Ratio (g/g)	
	Males	Females	Males	Females	Males	Females
Control	22.9	13.1	3.74	3.77	11.7	6.71
1	14.8**	15.1	2.92**	3.74	7.05**	7.86
10	19.0*	10.5**	3.31*	3.08*	9.45*	6.07
100	24.4	11.6	4.69*	4.03	12.3	6.17

* Statistically significant difference at the 95 percent confidence level.

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

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TABLE XXII

TEST MATERIAL: Aroclor 1260

Two-Year Chronic Oral Toxicity Study - Albino Rats

Organ Weight and Ratio Data

Six-Month Sacrifice

Summary of Mean Values

Organ: Kidneys

Dietary Level of Aroclor 1260 (ppm)	Organ Weight (g)		Organ/Body Weight Ratio (g/100 g)		Organ/Brain Weight Ratio (g/g)	
	Males	Females	Males	Females	Males	Females
Control	4.04	2.79	0.664	0.806	2.06	1.43
1	3.64	2.73	0.716	0.674*	1.73	1.42
10	3.85	2.35	0.670	0.684*	1.92	1.36
100	3.92	2.35	0.753	0.814	1.97	1.25

* Statistically significant difference at the 95 percent confidence level.

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TABLE XXIII

TEST MATERIAL: Aroclor 1260

Two-Year Chronic Oral Toxicity Study - Albino Rats

Organ Weight and Ratio Data

Six-Month Sacrifice

Summary of Mean Values

Organ: Spleen

Dietary Level of Aroclor 1260 (ppm)	Organ Weight (g)		Organ/Body Weight Ratio (g/100 g)		Organ/Brain Weight Ratio (g/g)	
	Males	Females	Males	Females	Males	Females
Control	0.752	0.684	0.122	0.196	0.384	0.350
1	0.754	0.908	0.148*	0.220	0.359	0.472
10	0.836	0.566*	0.146*	0.167	0.416	0.327
100	0.636	0.443*	0.122	0.151	0.320	0.236*

* Statistically significant difference at the 95 percent confidence level.

TABLE XXIV

TEST MATERIAL: Aroclor 1260

Two-Year Chronic Oral Toxicity Study - Albino Rats

Organ Weight and Ratio Data

Six-Month Sacrifice

Summary of Mean Values

Organ: Gonads

Dietary Level of Aroclor 1260 (ppm)	Organ Weight (g)		Organ/Body Weight Ratio (g/100 g)		Organ/Brain Weight Ratio (g/g)	
	Males	Females	Males	Females	Males	Females
Control	3.55	0.0960	0.593	0.0279	1.81	0.0492
1	3.23	0.120*	0.636	0.0297	1.54	0.0625*
10	3.56	0.0968	0.620	0.0287	1.77	0.0560
100	3.53	0.0710*	0.686	0.0250	1.77	0.0378*

* Statistically significant difference at the 95 percent confidence level.

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TABLE XXV

TEST MATERIAL: Aroclor 1260

Two-Year Chronic Oral Toxicity Study - Albino Rats

Organ Weight and Ratio Data

Six-Month Sacrifice

Summary of Mean Values

Organ: Heart

Dietary Level of Aroclor 1260 (ppm)	Organ Weight (g)		Organ/Body Weight Ratio (g/100 g)		Organ/Brain Weight Ratio (g/g)	
	Males	Females	Males	Females	Males	Females
Control	1.70	1.05	0.282	0.302	0.867	0.538
1	1.45	1.12	0.286	0.277	0.690	0.583
10	1.63	1.05	0.283	0.307	0.810	0.606
100	1.49	1.06	0.286	0.368**	0.749	0.564

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

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TABLE XXVI

TEST MATERIAL: Aroclor 1260

Two-Year Chronic Oral Toxicity Study - Albino Rats

Organ Weight and Ratio Data

Six-Month Sacrifice

Summary of Mean Values

Organ: Brain

Dietary Level of Aroclor 1260 (ppm)	Organ Weight (g)		Organ/Body Weight Ratio (g/100 g)		Final Body Weights of Sacrificed Rats (g)	
	Males	Females	Males	Females	Males	Females
Control	1.96	1.95	0.320	0.560	613	348
1	2.10	1.92	0.412*	0.474*	509	405
10	2.01	1.73	0.349	0.504	575	343
100	1.99	1.88	0.382	0.650*	522	289

* Statistically significant difference at the 95 percent confidence level.

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c. Histopathologic Findings

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

Tables XXVII and XXVIII list all histopathologic changes noted.

All of the lesions noted in the microscopic examination of tissues were those of spontaneous disease and are not unusual for the albino rat. The most frequent findings were lesions in the trachea and lungs, indicating chronic murine pneumonia. These occurred in the control as well as the rats fed Aroclor 1260.

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

All other tissues and organs were normal histologically.

Grading System

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

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 the twelve month sacrifice are presented in Tables XXXIX through XXXIV.

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

Organ weights, organ to body weight and organ to body weight ratios disclosed several randomly occurring intergroup differences. The lack of any consistent dose related response and the absence of any deleterious histopathologic change confirm that these differences were not related to the ingestion of Aroclor 1260.

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

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TABLE XXXIV

TEST MATERIAL: Aroclor 1260

Two-Year Chronic Oral Toxicity Study - Albino Rats

Organ Weight and Ratio Data

Twelve-Month Sacrifice

Summary of Mean Values

Organ: Brain

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

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

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c. Histopathologic Findings

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

Tables XXXV and XXXVI list all hisopathologic changes noted.

All of the lesions noted in the microscopic examination of tissues were those of spontaneous disease and are not unusual for the albino rat. The most frequent findings were lesions in the trachea and lungs, indicating chronic murine pneumonia. These occurred in the contr as well as the rats fed Aroclor 1260.

TABLE XXXV

TEST MATERIAL: Aroclor 1260

Two-Year Chronic Oral Toxicity Study - Albino Rats

Histopathologic Changes

Twelve-Month Sacrifice

Group: Control

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

All other tissues and organs were normal histologically.

Grading System

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

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TABLE XXXVI

TEST MATERIAL: Aroclor 1260

Two-Year Chronic Oral Toxicity Study - Albino Rats

Histopathologic Changes

Twelve-Month Sacrifice

Group: 100 ppm

Number of Animals	Organ Examined	Findings	Incidence	Average Grade
5 Males	Trachea	Tracheitis	1	1.0
	Lung	Chronic respiratory disease	3	1.0
	Kidney	Focal lymphoid infiltration	1	1.0
	Liver	Vacuolar change of random cells	1	1.0
5 Females	Trachea	Tracheitis	1	1.0
	Lung	Chronic respiratory disease	1	1.0

All other tissues and organs were normal histologically.

Grading System

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

4. Final Sacrifice

a. Gross Pathologic Findings

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

b. Organ Weight and Ratio Data

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

Absolute liver weights and liver to body weight or liver to brain weight ratios were significantly elevated in those rats fed 100 ppm Aroclor 1260. Other organ weights, organ to body weight and organ to brain weight ratios disclosed several randomly occurring intergroup differences. The lack of any consistent dose related response and the absence of any deleterious histopathologic change confirm that these differences were not related to the ingestion of Aroclor 1260.

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TABLE 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

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	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
100	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.

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TABLE XXXIX

TEST MATERIAL: Aroclor 1260

Two-Year Chronic Oral Toxicity Study - Albino Rats

Organ Weight and Ratio Data

Summary of Mean Values

Final Sacrifice

Organ: Spleen

Dietary Level (ppm)	Organ Weight (g)		Organ/Body Weight Ratio (g/100 g)		Organ/Brain Weight Ratio (g/g)	
	Males	Females	Males	Females	Males	Females
Control	1.15	0.96	0.182	0.181	0.520	0.492
1	1.17	0.72	0.178	0.148	0.529	0.370
10	1.09	0.83	0.131	0.142	0.509	0.428
100	0.89	0.75	0.138	0.146	0.400	0.379

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 changes noted. Table XLVII contains the results of the histopathologic examination of the urinary bladders.

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

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

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

extension of the hypertrophic lesion. The hyperplastic cells were also usually hypertrophic. The most severe examples of hyperplasia appear as nodular growths with limited compression of the surrounding normal hepatic tissue.

The minor lesions of degeneration, hepatitis, ductule proliferation, necrosis and focal lymphoid infiltration seen in the control animals and the T-I and T-II groups are lesions of spontaneous disease and are not related to the Aroclor 1260. This level of liver disease is not unusual in old animals.

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


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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
		Parasites	1	1.0
	Colon	Hemosiderosis	4	1.0
	Spleen	Metritis	3	2.0
	Uterus	Chronic nephritis	6	1.0
	Kidney	Focal lymphoid infiltration	1	1.0
		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
		Chronic focal pancreatitis	2	1.0
		Acute focal gastritis	1	3.0
	Spleen	Hemosiderosis	1	1.0
	Lymph Node	Congestion	1	1.0
	Kidney	Chronic nephritis	7	2.0
	Testes	Testicular degeneration	1	2.0
		Periarteritis	2	1.0
		Inflammation	4	2.0
	Prostate	Inflammation	1	2.0
	Seminal Vesicle	Inflammation	1	2.0

TABLE XLIV continued

TEST MATERIAL: Aroclor 1260

Two-Year Chronic Oral Toxicity Study - Albino Rats

Histopathologic Changes

Final Sacrifice

Group: 1 ppm

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

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TABLE XLV

TEST MATERIAL: Aroclor 1260

Two-Year Chronic Oral Toxicity Study - Albino Rats

Histopathologic Changes

Final Sacrifice

Group: 10 ppm

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

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
		Centrilobular 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

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
		Vacuolar change (fatty)	5	1.0
	Liver			

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TABLE XLVI continued

TEST MATERIAL: Aroclor 1260

Two-Year Chronic Oral Toxicity Study - Albino Rats

Histopathologic Changes

Final Sacrifice

Group: 100 ppm

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

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TABLE XLVII

TEST MATERIAL: Aroclor 1260

Two-Year Chronic Oral Toxicity Study - Albino Rats

Histopathologic Changes of the Urinary Bladder

Final Sacrifice

Group	Sex	Number Examined	Findings*	Incidence	Average Grade
C	M	11	Proteinaceous plug (34)	1	-
	F	14	Focal epithelial hyperplasia (62)	1	1.0
T-I (1 ppm)	M	10	Proteinaceous plug (86, 105, and 107)	3	-
	F	11	None	-	-
T-II (10 ppm)	M	7	Proteinaceous plug (187)	1	-
	F	14	None	-	-
T-III (100 ppm)	M	10	Proteinaceous plug (271)	1	-
	F	14	None	-	-

* Individual animal numbers are shown in parentheses.

Grading System

1.0 = minimal or trace

4.0 = severe

2.0 = mild

5.0 = extreme

3.0 = moderate

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 Aroclor 1260 and are considered normal for a random population of rats this age

TABLE XLVIII

TEST MATERIAL: Aroclor 1260

Two-Year Chronic Oral Toxicity Study - Albino Rats

Description of Tumor Findings

Group: Control

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

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TABLE XLIX

TEST MATERIAL: Aroclor 1260

Two-Year Chronic Oral Toxicity Study - Albino Rats

Description of Tumor Findings

Group: 1 ppm

Animal Number and Sex	Location	Weight (grams)	Size (cm)	Classification	Months on Test
99-M	Pituitary	-	-	✓ Chromophobe adenoma	20
127-F	Pituitary Abdomen	- 25.00	- 6 x 3 x 1	✓ Chromophobe adenoma ✓ Mammary fibroadenoma	24
128-F	Pituitary Abdomen	- 60.80	- 5 x 6 x 2	✓ Chromophobe adenoma ✓ Mammary fibroadenoma	21
138-F	Abdomen Pituitary	20.07 -	- -	✓ Mammary fibroadenoma ✓ Chromophobe adenoma	24
141-F	Ovary	-	-	✓ Adenoma	24
151-F	Abdomen	14.89	-	✓ Mammary fibroadenoma	24
152-F	Abdomen	540.00	13 x 15 x 2	✓ Mammary fibroadenoma	22

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TABLE L

TEST MATERIAL: Aroclor 1260

Two-Year Chronic Oral Toxicity Study - Albino Rats

Description of Tumor Findings

Group: 10 ppm

Animal Number and Sex	Location	Weight (grams)	Size (cm)	Classification	Months on Test
205-F	Abdomen	190.00	9 x 5 x 4	✓ Mammary fibroadenoma	24
208-F	Pituitary	-	-	✓ Chromophobe adenoma	24
213-F	Abdomen	-	-	✓ Mammary fibroadenoma	24
216-F	Right shoulder	138.00	-	✓ Subcutaneous tumor	23
220-F	Abdomen	9.57	-	✓ Mammary fibroadenoma	24
	Pituitary	-	-	✓ Chromophobe adenoma	
221-F	Submaxillary region	14.44	2 x 3 x 1	✓ Fibroadenoma	24
	Abdomen	29.0	3 x 5 x 2	✓ Mammary fibroadenoma	

TABLE L continued

TEST MATERIAL: Aroclor 1260

Two-Year Chronic Oral Toxicity Study - Albino Rats

Description of Tumor Findings

Group: 10 ppm

Animal Number and Sex	Location	Weight (grams)	Size (cm)	Classification	Months on Test
✓ 22-F	Left femoral region	56.00	6 x 8 x 2	✓ Subcutaneous tumor	6
233-F	Pituitary	-	-	✓ Chromophobe adenoma	24
234-F	Abdomen Pancreas	60.82 -	6 x 4 x 3 -	✓ Mammary fibroadenoma ✓ Islet cell adenoma	24

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

REPORT TO
MONSANTO COMPANY
TWO-YEAR CHRONIC ORAL TOXICITY WITH
AROCOR 1254
IN ALBINO RATS

NOVEMBER 12, 1971

IBT NO. B7298

I. Introduction

At the request of Monsanto Company, a two-year chronic oral toxicity study was conducted using albino rats to determine the potential toxicity of Aroclor 1254, Lot No. AK-38. The following report represents the results of this investigation.

II. Summary

A two-year chronic toxicity study was conducted using albino rats fed diets containing 1 (T-I), 10 (T-II) or 100 (T-III) ppm Aroclor 1254. Food consumption was not altered in any test group. Body weight gains of test and control animals did not differ after 3 or 12 months of testing. After 24 months females fed 100 ppm Aroclor 1254 had gained less weight than the control females. Weight gains of the male rats did not differ from the controls. The number of animals dying and the time at which death occurred did not differ among test and control groups.

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

At sacrifice after 3, 6, or 12 months on test, organ weights, organ to body weight and organ to brain weight ratios disclosed several randomly occurring intergroup differences. The lack of any consistent dose related response and the absence of any deleterious histopathologic change confirm that these differences were not related to the ingestion of Aroclor 1254.

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

This lesion is morphologically indicative of fatty degeneration. Specific fat stains confirmed the presence of fat in these vacuoles. Focal hypertrophy and focal hyperplasia were also found in the livers from animals fed Aroclor 1254.

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

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

Respectfully submitted,

INDUSTRIAL BIO-TEST LABORATORIES, INC.

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November 12, 1971

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III. Procedure

A. Experimental Animals

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

B. Organization of Groups

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

TABLE I

TEST MATERIAL: Aroclor 1254

Two-Year Chronic Oral Toxicity Study - Albino Rats

Outline of Experiment

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

* 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 made daily throughout the investigation.

F. Hematologic Studies and Urine Analyses

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

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

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 previously mentioned.

L. Tumor Incidence and Classification

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

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TABLE II

TEST MATERIAL: Aroclor 1254

Two-Year Chronic Oral Toxicity Study - Albino Rats

Body Weight and Total Weight Gain Data

Summary of Mean Values

Dietary Level of Aroclor 1254 (ppm)	Sex	Body Weight (grams) Week:														90-Day Total Weight Gain (grams/rat)
		0	1	2	3	4	5	6	7	8	9	10	11	12	13	
Control	M	133	203	245	313	362	373	391	409	424	440	440	449	467	474	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:									12-Month Total Weight Gain (grams/rat)
		4	5	6	7	8	9	10	11	12	
Control	M	498	533	565	593	622	642	667	688	701	568
	F	297	310	322	333	315	359	374	383	390	254
1	M	522	550	581	604	633	658	680	715	725	592
	F	289	295	307	322	333	340	354	367	380	244
10	M	529	567	593	621	642	667	681	700	726	593
	F	300	308	321	330	341	354	367	380	392	256
100	M	495	521	541	562	586	608	627	642	664	531
	F	292	300	306	316	321	326	332	340	347	211

TABLE II continued

TEST MATERIAL: Aroclor 1254

Two-Year Chronic Oral Toxicity Study - Albino Rats

Body Weight and Total Weight Gain Data

Summary of Mean Values

Dietary Level of Aroclor 1254 (ppm)	Sex	Body Weight (grams) Month:											24-Month Total Weight Gain	
		13	14	15	16	17	18	19	20	21	22	23	24	(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.

Individual BIC TEST Laboratories, Inc.

TABLE III

TEST MATERIAL: Aroclor 1254

Two-Year Chronic Oral Toxicity Study - Albino Rats

Food Consumption Data

Summary of Mean Values

Dietary Level of Aroclor 1254 (ppm)	Sex	Food Consumption (grams/rat/seven days) Week:													Average Food Consumption (grams/rat/seven days)
		1	2	3	4	5	6	7	8	9	10	11	12	13	
Control	M	94	160	175	163	137	137	225	197	204	188	191	194	196	174
	F	73	140	144	107	104	133	208	154	165	151	146	150	151	140
1	M	112	148	156	168	148	214	160	193	218	186	184	187	189	174
	F	87	117	108	118	113	203	105	137	149	144	144	147	146	132
10	M	116	139	148	164	163	221	201	199	216	191	192	200	199	181
	F	90	109	107	114	121	193	159	134	144	150	151	152	149	136
100	M	116	172	163	185	231	185	189	198	185	197	189	189	121	187
	F	89	141	98	129	129	190	146	146	145	139	137	146	193	152

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)										Average Food Consumption (grams/rat/seven days)
		Month:										
		4	5	6	7	8	9	10	11	12		
Control	M	196	189	168	147	163	184	179	170	187	176	
	F	148	154	136	121	138	152	160	141	127	142	
1	M	189	181	184	198	190	190	197	152	190	186	
	F	141	159	147	162	145	150	151	123	126	145	
10	M	190	191	189	196	190	188	191	186	163	187	
	F	139	138	148	148	150	145	138	142	149	144	
100	M	179	168	190	179	187	182	197	180	188	183	
	F	148	141	144	162	163	151	148	141	137	148	

C. Mortality and Reactions

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

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

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:								Total Dead Number Tested
		1-3	4-6	7-9	10-12	13-15	16-18	19-21	22-24	
Control	M	0	0	0	2	1	7	6	9	25/35
	F	0	0	0	1	3	5	7	3	19/35
1	M	0	0	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)						Erythrocyte Count (millions/mm ³)					
		Month:						Month:					
		3	6	9	12	18	24	3	6	9	12	18	24
Control	M	14.0	15.4	10.1	11.1	9.9	11.2	8.1	8.2	8.7	8.8	7.6	6.5
	F	9.1	9.4	6.7	7.6	8.8	7.6	7.5	7.7	7.3	7.8	7.7	6.8
100	M	15.1	15.2	10.9	11.0	9.8	10.2	7.5	7.7	8.1	7.7	8.0	8.0
	F	11.6	12.2	7.3	8.7	6.6	11.8	7.5	7.6	7.7	6.9	7.3	6.4

TABLE VI
TEST MATERIAL: Aroclor 1254
Two-Year Chronic Oral Toxicity Study - Albino Rats
Hematologic Data

Summary of Mean Values

Dietary Level (ppm)	Sex	Hemoglobin Concentration (g/100 ml)						Hematocrit Value (%)					
		Month:						Month:					
		3	6	9	12	18	24	3	6	9	12	18	24
Control	M	17.1	17.7	15.7	17.6	16.1	13.6	51	49	48	50	41	35
	F	16.9	17.4	14.1	16.7	16.4	14.6	50	47	43	46	42	38
100	M	15.6	17.6	13.8	15.6	15.7	15.3	47	47	42	44	41	40
	F	16.5	17.8	13.9	14.5	14.5	12.7	48	47	42	40	37	32

TABLE VII
TEST MATERIAL: Aroclor 1254
Two-Year Chronic Oral Toxicity Study - Albino Rats
Hematologic Data

Summary of Mean Values

Dietary Level (ppm)	Sex	Differential Leukocyte Count (Number of Cells per Hundred)											
		Lymphocytes						Neutrophils					
		Month:						Month:					
		3	6	9	12	18	24	3	6	9	12	18	24
Control	M	82.0	86.6	80.4	78.8	79.0	65.4	16.0	11.4	18.6	20.6	20.0	32.2
	F	83.0	86.6	86.8	89.0	70.2	61.4	15.4	11.6	11.8	10.0	29.2	36.0
100	M	88.2	79.6	85.8	85.2	69.8	68.0	10.8	20.2	13.8	14.2	29.0	30.2
	F	92.2	92.0	79.6	84.6	79.0	61.0	7.4	7.8	20.2	15.0	20.4	37.6

TABLE VII continued
 TEST MATERIAL: Aroclor 1254
 Two-Year Chronic Oral Toxicity Study - Albino Rats
 Hematologic Data
 Summary of Mean Values

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

TABLE VII continued

TEST MATERIAL: Aroclor 1254

Two-Year Chronic Oral Toxicity Study - Albino Rats

Hematologic Data

Summary of Mean Values

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

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

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 %)						Serum Alkaline Phosphatase Activity (King-Armstrong Units)					
		Month:						Month:					
		3	6	9	12	18	24	3	6	9	12	18	24
Control	M	128	123	89	88	138	99	28.6	24.7	21.5	20.3	16.2	22.3
	F	130	118	115	92	134	109	18.9	17.8	10.6	11.9	16.8	20.2
100	M	109	113	129	128	124	115	35.4	23.2	27.4	27.1	14.6	23.5
	F	120	107	124	113	132	107	17.1	18.1	19.3	16.7	10.0	21.6

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.

Individual BIO-TEST Laboratories, Inc.

TABLE X

TEST MATERIAL: Aroclor 1254

Two-Year Chronic Oral Toxicity Study - Albino Rats

Urine Analyses Data

Summary of Mean Values

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

Key:

n = negative

t = trace; less than 30 mg/100 ml urine

+1 = 30 to 100 mg/100 ml urine

+2 = 100 to 300 mg/100 ml urine

+3 = 300 to 500 mg/100 ml urine

+4 = more than 500 mg/100 ml urine

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

Key:

N = Normal

n = negative

t = trace; less than 5 per low power field

+1 = 5 to 10 per low power field

+2 = 10 to 15 per low power field

+3 = more than 15 per low power field

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TABLE XII

TEST MATERIAL: Aroclor 1254

Two-Year Chronic Oral Toxicity Study - Albino Rats

Urine Analyses Data

Summary of Mean Values

Dietary Level (ppm)	Sex	Specific Gravity Month:					
		3	6	9	12	18	24
Control	M	1.029	1.022	1.033	1.027	1.042	1.051
	F	1.020	1.019	1.025	1.024	1.032	1.039
100	M	1.018	1.021	1.029	1.027	1.037	1.027
	F	1.020	1.018	1.023	1.022	1.029	1.031

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.

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. Histonathologic 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	1.0
	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 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.

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TABLE XXII
TEST MATERIAL: Aroclor 1254
Two-Year Chronic Oral Toxicity Study - Albino Rats
Organ Weight and Ratio Data
Six-Month Sacrifice
Summary of Mean Values
Organ: Kidneys

Dietary Level of Aroclor 1254 (ppm)	Organ Weight (g)		Organ/Body Weight Ratio (g/100 g)		Organ/Brain Weight Ratio (g/g)	
	Males	Females	Males	Females	Males	Females
Control	4.04	2.79	0.664	0.806	2.06	1.43
1	3.80	2.58	0.715	0.784	1.75*	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.

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TABLE XXVII

TEST MATERIAL: Aroclor 1254

Two-Year Chronic Oral Toxicity Study - Albino Rats

Histopathologic Changes

Six-Month Sacrifice

Group: Control

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

All other tissues and organs were normal histologically.

Grading System

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

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TABLE XXVIII

TEST MATERIAL: Aroclor 1254

Two-Year Chronic Oral Toxicity Study - Albino Rats

Histopathologic Changes

Six-Month Sacrifice

Group: 100 ppm

Number of Animals	Organ Examined	Findings	Incidence	Average Grade
5 Males	Trachea	Tracheitis	2	2.0
		Focal tracheitis	1	1.0
	Lung	Focal pneumonitis	3	0.5
	Liver	Focal pericholangitis	1	2.0
	Kidney	Focal nephritis	1	0.5
5 Females	Heart	Myocarditis	1	0.5
	Trachea	Focal tracheitis	3	0.5
	Lung	Focal pneumonitis	4	1.0
		Hyperemia	1	1.0
	Kidney	Focal nephritis	2	3.0

All other tissues and organs were normal histologically.

Grading System

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

3. Twelve-Month Sacrifice

a. Gross Pathologic Findings

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

b. Organ Weight and Ratio Data

The mean organ weight and ratio data collected at the 12-month sacrifice are presented in Tables XXIX through XXXIV.

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

Organ weights, organ to body weight and organ to brain weight ratios disclosed several randomly occurring intergroup differences. The lack of any consistent dose related response and the absence of any deleterious histopathologic change confirm that these differences were not related to the ingestion of Aroclor 1254.

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TABLE XXIX

TEST MATERIAL: Aroclor 1254

Two-Year Chronic Oral Toxicity Study - Albino Rats

Twelve-Month Sacrifice

Organ Weight and Ratio Data

Summary of Mean Values

Organ: Liver

Dietary Level (ppm)	Organ Weight (g)		Organ/Body Weight Ratio (g/100 g)		Organ/Brain Weight Ratio (g/g)	
	Males	Females	Males	Females	Males	Females
Control	22.1	15.5	3.79	3.52	10.8	7.72
1	20.6	12.9	3.09*	3.41	9.89	7.29
10	23.5	14.6	3.52	4.34	11.2	7.34
100	27.1*	12.2	4.58*	3.43	12.7	6.30

* Statistically significant difference at the 95 percent confidence level.

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

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TABLE XXXIII

TEST MATERIAL: Aroclor 1254

Two-Year Chronic Oral Toxicity Study - Albino Rats

Twelve-Month Sacrifice

Organ Weight and Ratio Data

Summary of Mean Values

Organ: Heart

Dietary Level (ppm)	Organ Weight (g)		Organ/Body Weight Ratio (g/100 g)		Organ/Brain Weight Ratio (g/g)	
	Males	Females	Males	Females	Males	Females
Control	1.71	1.23	0.293	0.286	0.835	0.609
1	1.68	1.13	0.255	0.301	0.812	0.635
10	1.84	1.08**	0.275	0.322	0.875	0.544*
100	1.69	1.14	0.284	0.325	0.795	0.589

* Statistically significant difference at the 95 percent confidence level.

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

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.

c. Histopathologic Findings

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

Tables XXXV and XXXVI list all histopathologic changes noted.

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TABLE XXXV

TEST MATERIAL: Aroclor 1254

Two-Year Chronic Oral Toxicity Study - Albino Rats

Histopathologic Changes

Twelve-Month Sacrifice

Group: Control

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

All other tissues and organs were normal histologically.

Grading System

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

TABLE XXXVI

TEST MATERIAL: Aroclor 1254

Two-Year Chronic Oral Toxicity Study - Albino Rats

Histopathologic Changes

Twelve-Month Sacrifice

Group: 100 ppm

Number of Animals	Organ Examined	Findings	Incidence	Average Grade
5 Males	Lung	Chronic respiratory disease	4	1.0
5 Females	Heart	Focal myocarditis	1	1.0
	Trachea	Tracheitis	1	1.0
	Lung	Chronic respiratory disease	1	1.0
	Adrenal	Congestion	1	1.0

All other tissues and organs were normal histologically.

Grading System

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

4. Final Sacrifice

a. Gross Pathologic Findings

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

b. Organ Weight and Ratio Data

The mean organ weight and ratio data collected at the final sacrifice are presented in Tables XXXVII through XLII.

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

Absolute liver weight, liver to body weight and liver to brain weight ratios were significantly elevated in both male and female rats fed 100 ppm Aroclor 1254. Other organ weights, organ to body weight and organ to brain weight ratios disclosed several randomly occurring intergroup differences. The lack of any consistent dose related response and the absence of any deleterious histopathologic change confirm that these differences were not related to the ingestion of Aroclor 1254.

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TABLE XXXVII

TEST MATERIAL: Aroclor 1254

Two-Year Chronic Oral Toxicity Study - Albino Rats

Organ Weight and Ratio Data

Summary of Mean Values

Final Sacrifice

Organ: Liver

Dietary Level (ppm)	Organ Weight (g)		Organ/Body Weight Ratio (g/100 g)		Organ/Brain Weight Ratio (g/g)	
	Males	Females	Males	Females	Males	Females
Control	22.0	16.3	3.47	3.05	10.10	8.42
1	19.5	16.1	2.99	3.10	8.76*	8.31
10	23.9	19.5	3.21	3.84*	11.40*	10.30
100	30.2**	32.1**	4.75**	8.62**	14.10**	17.10**

* Statistically significant difference at the 95 percent confidence level.

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

TABLE XXXVIII

TEST MATERIAL: Aroclor 1254

Two-Year Chronic Oral Toxicity Study - Albino Rats

Organ Weight and Ratio Data

Summary of Mean Values

Final Sacrifice

Organ: Kidneys

Dietary Level (ppm)	Organ Weight (g)		Organ/Body Weight Ratio (g/100 g)		Organ/Brain Weight Ratio (g/g)	
	Males	Females	Males	Females	Males	Females
Control	5.57	3.48	0.877	0.646	2.57	1.79
1	5.52	3.68	0.868	0.706	2.48	1.88
10	5.63	3.47	0.761	0.717	2.70	1.84
100	4.74	3.44	0.749	0.899*	2.21	1.82

* Statistically significant difference at the 95 percent confidence level.

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TABLE XXXIX

TEST MATERIAL: Aroclor 1254

Two-Year Chronic Oral Toxicity Study - Albino Rats

Organ Weight and Ratio Data

Summary of Mean Values

Final Sacrifice

Organ: Spleen

Dietary Level (ppm)	Organ Weight (g)		Organ/Body Weight Ratio (g/100 g)		Organ/Brain Weight Ratio (g/g)	
	Males	Females	Males	Females	Males	Females
Control	1.15	0.96	0.182	0.181	0.520	0.492
1	1.26	1.06	0.189	0.237	0.568	0.562
10	1.57	0.86	0.220	0.175	0.749	0.462
100	1.04	0.66	0.164	0.174	0.489	0.352

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TABLE XL

TEST MATERIAL: Aroclor 1254

Two-Year Chronic Oral Toxicity Study - Albino Rats

Organ Weight and Ratio Data

Summary of Mean Values

Final Sacrifice

Organ: Gonads

Dietary Level (ppm)	Organ Weight (g)		Organ/Body Weight Ratio (g/100 g)		Organ/Brain Weight Ratio (g/g)	
	Males	Females	Males	Females	Males	Females
Control	2.52	0.123	0.397	0.0222	1.15	0.0628
1	3.19	0.204	0.482	0.0390	1.43	0.1010
10	3.28	0.135	0.445	0.0283	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.

TEST MATERIAL: Aroclor 1254

TABLE XLI
TEST MATERIAL: Aroclor 1254
Two-Year Chronic Oral Toxicity Study - Albino Rats
Organ Weight and Ratio Data
Summary of Mean Values
Final Sacrifice
Organ: Heart

Dietary Level (ppm)	Organ Weight (g)		Organ/Body Weight Ratio (g/100 g)		Organ/Brain Weight Ratio (g/g)	
	Males	Females	Males	Females	Males	Females
Control	1.87	1.54	0.294	0.288	0.860	0.795
1	1.98	1.55	0.303	0.302	0.889	0.805
10	2.08	1.37	0.279	0.282	0.998*	0.727
100	1.94	1.50	0.304	0.386**	0.909	0.803

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

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TABLE XLII

TEST MATERIAL: Aroclor 1254

Two-Year Chronic Oral Toxicity Study - Albino Rats

Organ Weight and Ratio Data

Summary of Mean Values

Final Sacrifice

Organ: Brain

Dietary Level (ppm)	Organ Weight (g)		Organ/Body Weight Ratio (g/100 g)		Final Body Weight of Sacrificed Animals (grams)	
	Males	Females	Males	Female	Males	Females
Control	2.18	1.95	0.342	0.362	642	551
1	2.22	1.94	0.347	0.376	656	540
10	2.08	1.88	0.279	0.388	762	500
100	2.13	1.88	0.340	0.486**	656	411**

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

c. Histopathologic Findings

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

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

Significant liver injury was found in animals fed 100 ppm Aroclor 1254 (T-III). The compound associated lesions consisted of vacuolar change, focal hypertrophy and focal hyperplasia. In addition, there were lesions of inflammation, necrosis, fibrosis and minor degeneration, were more severe and frequent in the T-III group.

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

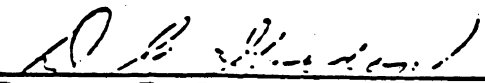
The hypertrophic changes found in the liver was focal and often limited to the central lobular area where groups of cells were swollen to two or three times their normal size with clear pink homogeneous cytoplasm. The hyperplasia was associated with the same cells and appeared

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

The minor lesions of degeneration, hepatitis, ductule cell proliferation, necrosis and focal lymphoid infiltration seen in the control animals and the T-I and T-II groups are lesions of spontaneous disease and are not related to the Aroclor 1254. This level of liver disease is not unusual in rats of this age.

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

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


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

Institution 810-TEST Laboratories, Inc

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 encephallitis	1	1.0
	Eye	Inflammation	2	1.0

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TABLE XLIII continued
 TEST MATERIAL: Aroclor 1254 ,
 Two-Year Chronic Oral Toxicity Study - Albino Rats
 Histopathologic Changes
 Final Sacrifice
 Group: Control

Number of Animals	Organ Examined	Findings	Incidence	Average Grade
14 Females	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.

<u>Grading System</u>		
0.5 = minimal	2.0 = mild	4.0 = severe
1.0 = slight	3.0 = moderate	5.0 = extreme

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TABLE XLIV

TEST MATERIAL: Aroclor 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

Reference: DUC-1531-1-10-1961

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

Histopathologic Changes

Final Sacrifice

Group: 1 ppm

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

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Industrial BIO-TEST Laboratories, Inc.

TABLE XLIV continued

TEST MATERIAL: Aroclor 1254

Two-Year Chronic Oral Toxicity Study - Albino Rats

Histopathologic Changes

Final Sacrifice

Group: 1 ppm

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

All other tissues and organs were normal histologically.

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TABLE XLV

TEST MATERIAL: Aroclor 1254

Two-Year Chronic Oral Toxicity Study - Albino Rats

Histopathologic Changes

Final Sacrifice

Group: 10 ppm

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

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TABLE XLV continued

TEST MATERIAL: Aroclor 1254

Two-Year Chronic Oral Toxicity Study - Albino Rats

Histopathologic Changes

Final Sacrifice

Group: 10 ppm

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

TABLE XLV continued

TEST MATERIAL: Aroclor 1254

Two-Year Chronic Oral Toxicity Study - Albino Rats

Histopathologic Changes

Final Sacrifice

Group: 10 ppm

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

All other tissues and organs were normal histologically.

Grading System

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TABLE XLVI

TEST MATERIAL: Aroclor 1254

Two-Year Chronic Oral Toxicity Study - Albino Rats

Histopathologic Changes

Final Sacrifice

Group: 100 ppm

Number of Animals	Organ Examined	Findings	Incidence	Average Grade
11 Males	Heart	Chronic focal myocarditis	3	2.0
	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

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TABLE XLVI continued

TEST MATERIAL: Aroclor 1254

Two-Year Chronic Oral Toxicity Study - Albino Rats

Histopathologic Changes

Final Sacrifice

Group: 100 ppm

Number of Animals	Organ Examined	Findings	Incidence	Average Grade
11 Males	Kidney	Chronic nephritis	8	1.0
	Testes	Periarteritis	1	1.0
	Prostate	Inflammation	5	2.0
	Adrenal Gland	Telangiectasia	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	Telangiectasia	3	1.0
		Nodular hyperplasia	1	1.0
		Congestion	1	1.0

All other tissues and organs were normal histologically.

Grading System

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TABLE XLVII

TEST MATERIAL: Aroclor 1254

Two-Year Chronic Oral Toxicity Study - Albino Rats

Histopathologic Changes of the Urinary Bladder

Final Sacrifice

Group	Sex	Number Examined	Findings*	Incidence	Average Grade
C	M	11	Proteinaceous plug (34)	1	-
	F	14	Focal epithelial hyperplasia (62)	1	1
T-I (1 ppm)	M	10	Proteinaceous plug (326)	1	-
	F	19	Diffuse epithelial hyperplasia associated with diffuse cystitis (377)	1	3
T-II (10 ppm)	M	13	Diffuse epithelial hyperplasia and papilloma associated with focal cystitis (417)	1	4
			Diffuse epithelial hyperplasia associated with diffuse cystitis (419)	1	2
	F	13	None	-	-
T-III (100 ppm)	M	10	Focal epithelial hyperplasia associated with focal cystitis (497)	1	2
			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

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G. Detailed Description of Tumor Findings

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

None of these tumors could be related to the ingestion of Aroclor 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	-	-	Mammary fibroadenoma	24
	Adrenal gland	-	-	Pheochromocytoma	
-F	Abdomen	88.92	13 x 11 x 4	Fibroadenoma	24
-F	Abdomen	230.00	13 x 11 x 4		

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TABLE XLIX continued

TEST MATERIAL: Aroclor 1254

Two-Year Chronic Oral Toxicity Study - Albino Rats

Description of Tumor Findings

Group: 1 ppm

Animal Number and Sex	Location	Weight (grams)	Size (cm)	Classification	Months on Test
11-F *	Abdomen	-	-	✓ Mammary adenocarcinoma	24
12-F **	Abdomen	-	-	✓ Mammary fibroadenoma	24
13-F **	Abdomen	-	-	✓ Lipoma	24

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

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NO TEST Animals

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TABLE XLIX

TEST MATERIAL: Aroclor 1254

Two-Year Chronic Oral Toxicity Study - Albino Rats

Description of Tumor Findings

Group: 1 ppm

Animal Number and Sex	Location	Weight (grams)	Size (cm)	Classification	Months on Test
1-M	Parathyroid gland	-	-	Adenoma ✓	24
2-M	Pituitary	-	-	Chromophobe adenoma ✓	23
3-F	Abdomen	-	-	Mammary fibroadenoma ✓	24
4-F	Abdomen	-	-	Mammary fibroadenoma ✓	24
5-F	Abdomen	8.97	2 x 2 x 2	Mammary adenoma ✓	24
	Parathyroid gland	-	-	Adenoma ✓	
6-F	Abdomen	8.86	3 x 2 x 2	Mammary fibroadenoma ✓	24
7-F	Abdomen	65.0		Mammary fibroadenoma ✓	24
	Dorsal cervical region	209	13 x 8 x 2	Fibroadenoma ✓	
8-F	Pituitary	-	-	Chromophobe adenoma ✓	24
	Abdomen	-	-	Mammary fibroadenoma ✓	
9-F	Abdomen	-	-	Mammary fibroadenoma ✓	

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BIO-TEST Laboratories Inc.

TABLE L

TEST MATERIAL: Aroclor 1254

Two-Year Chronic Oral Toxicity Study - Albino Rats

Description of Tumor Findings

Group: 10 ppm

Animal Number and Sex	Location	Weight (grams)	Size (cm)	Classification	Months on Test
1-M	Pancreas	-	-	✓ Adenoma ✓	24
2-M	Parathyroid gland	-	-	✓ Adenoma ✓	24
3-F	Abdomen	-	-	✓ Mammary fibroadenoma ✓	24
4-F	Thyroid	-	-	✓ Adenoma ✓	24
	Abdomen	-	-	✓ Mammary fibroadenoma ✓	
5-F	Abdomen	-	-	✓ Mammary fibroadenoma ✓	24
6-F	Abdomen	86	7 x 8 x 3	✓ Fibroadenoma ✓	24
	Abdomen	29	5 x 5 x 2	✓ Fibroadenoma ✓	
7-F	Pituitary	-	-	✓ Chromophobe adenoma ✓	24
8-F	Abdomen	28	6 x 5 x 3	✓ Fibroadenoma ✓	24
9-F	Pituitary	-	-	✓ Chromophobe adenoma ✓	22
10-F	Adrenal gland	7.8	-	✓ Telangioma ✓	24

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TABLE LI

TEST MATERIAL: Aroclor 1254

Two-Year Chronic Oral Toxicity Study - Albino Rats

Description of Tumor Findings

Group: 100 ppm

Animal Number and Sex	Location	Weight (grams)	Size (cm)	Classification	Months on Test
1-F	Abdomen	48.12	5 x 4 x 3	✓ Fibroma ✓	24
2-F	Abdomen	-	-	✓ Mammary fibroadenoma ✓	24
3-F	Abdomen	-	18 x 4 x 3	✓ Mammary fibroadenoma ✓	24
4-M	Pancreas	-	-	✓ Adenoma ✓	24
5-M	Abdomen	-	1 x 2 x 1	✓ Fibroadenoma ✓	24
6-F	Abdomen	-	-	✓ Mammary fibroadenoma ✓	24
7-M	Lymph node	-	-	✓ Reticulum cell sarcoma ✓	13
8-F	Pancreas	13.0	3 x 3 x 3	✓ Adenocarcinoma ✓	24
9-F	Lymph node	-	-	✓ Lymphosarcoma ✓	24
10-F	Abdomen	52.0	8 x 5 x 2	✓ Fibroadenoma ✓	24

TABLE LI continued

TEST MATERIAL: Aroclor 1254

Two-Year Chronic Oral Toxicity Study - Albino Rats

Description of Tumor Findings

Group: 100 ppm

Animal Number and Sex	Location	Weight (grams)	Size (cm)	Classification	Months on Test
11-F	Abdomen	141.9	8 x 8 x 2	✓ Mammary fibroadenoma ✓	24
12-F	Abdomen	42	6 x 4 x 2	✓ Mammary fibroadenoma ✓	24
13-F	Abdomen	-	-	✓ Fibroadenoma ✓	24
14-F	Abdomen	209.0	10 x 9 x 3	/ Mammary fibroadenoma ✓	24
15-F	Abdomen	14.63	-	✓ Fibroadenoma ✓	24

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REPORT TO

MONSANTO COMPANY

TWO-YEAR CHRONIC ORAL TOXICITY WITH
AROCOR 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.

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Assistant Toxicologist
Rat Toxicity

Report approved by: James B. Plank
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M. L. Keplinger, Ph.D.
Manager, Toxicology

November 12, 1971

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III. Procedure

A. Experimental Animals

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

B. Organization of Groups

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

TABLE I

TEST MATERIAL: Aroclor 1242

Two-Year Chronic Oral Toxicity Study - Albino Rats

Outline of Experiment

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

* Charles River Breeding Laboratories, North Wilmington, Mass.

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C. Diets, Feeding and Food Consumption

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

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

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

D. Body Weights and Weight Gains

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

E. Mortality and Reactions

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

F. Hematologic Studies and Urine Analyses

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

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

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

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

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

G. Clinical Blood Chemistry Studies

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

H. Pathologic Studies

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

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

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

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

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

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

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

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

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

I. Tumor Incidence and Classification

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

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IV. Results

A. Body Weights and Weight Gains

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

TABLE II

TEST MATERIAL: Aroclor 1242

Two-Year Chronic Oral Toxicity Study - Albino Rats

Body Weight and Total Weight Gain Data

Summary of Mean Values

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

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TABLE II continued
TEST MATERIAL: Aroclor 1242
Two-Year Chronic Oral Toxicity Study - Albino Rats
Body Weight and Total Weight Gain Data

Summary of Mean Values

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

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TABLE II continued
 TEST MATERIAL: Aroclor 1242
 Two-Year Chronic Oral Toxicity Study - Albino Rats
 Body Weight and Total Weight Gain Data
 Summary of Mean Values

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

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

TABLE III continued
 TEST MATERIAL: Aroclor 1242
 Two-Year Chronic Oral Toxicity Study - Albino Rats
 Food Consumption Data
 Summary of Mean Values

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

C. Mortality and Reactions

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

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

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								Total Dead Number Tested
		Months:								
		1-3	4-6	7-9	10-12	13-15	16-18	19-21	22-24	
Control	M	0	0	0	2	1	7	6	9	25/35
	F	0	0	0	1	3	5	7	3	19/35
1	M	2	0	1	1	3	3	7	8	25/35
	F	1	0	0	1	3	2	4	5	16/35
10	M	0	0	0	2	1	7	5	8	23/35
	F	0	1	1	2	0	2	5	5	16/35
100	M	0	0	0	3	3	6	7	10	29/35
	F	0	1	0	1	2	4	8	9	25/35

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

D. Hematologic and Clinical Blood Chemistry Studies

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

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

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TABLE V

TEST MATERIAL: Aroclor 1242

Two-Year Chronic Oral Toxicity Study - Albino Rats

Hematologic Data

Summary of Mean Values

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

TABLE VI
TEST MATERIAL: Aroclor 1242
Two-Year Chronic Oral Toxicity Study - Albino Rats
Hematologic Data
Summary of Mean Values

Dietary Level (ppm)	Sex	Hemoglobin Concentration (g/100 ml)						Hematocrit Value (%)					
		Month:						Month:					
		3	6	9	12	18	24	3	6	9	12	18	24
Control	M	17.1	17.7	15.7	17.6	16.1	13.6	51	49	48	50	41	35
	F	16.9	17.4	14.1	16.7	16.4	14.6	50	47	43	46	42	38
100	M	16.8	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						Neutrophils					
		3	6	9	12	18	24	3	6	9	12	18	24
Control	M	82.0	86.6	80.4	78.8	79.0	65.4	16.0	11.4	18.6	20.6	20.0	32.2
	F	83.0	86.6	86.8	89.0	70.2	61.4	15.4	11.6	11.8	10.0	29.2	36.0
100	M	89.6	84.4	79.8	87.0	66.0	58.4	9.6	15.2	18.8	13.2	33.0	38.8
	F	91.4	86.0	82.8	88.4	75.6	65.2	8.4	13.6	17.2	11.2	23.0	33.6

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

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)						Blood Urea Nitrogen Concentration (mgs %)					
		Month:						Month:					
		3	6	9	12	18	24	3	6	9	12	18	24
Control	M	38	48	45	45	31	36	17	15	12	10	14	15
	F	33	39	38	42	32	30	14	16	15	9	13	11
100	M	33	35	36	57	39	32	15	15	13	14	12	20
	F	39	41	53	40	52	46	17	14	14	11	11	14

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

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TABLE X
TEST MATERIAL: Aroclor 1242
Two-Year Chronic Oral Toxicity Study - Albino Rats
Urine Analyses Data
Summary of Mean Values

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

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

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TABLE XI
TEST MATERIAL: Aroclor 1242
Two-Year Chronic Oral Toxicity Study - Albino Rats
Urine Analyses Data

Summary of Mean Values

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

Key:

N= Normal

t = trace; less than 5 per low power field

+1 = 5 to 10 per low power field

+2 = 10 to 15 per low power field

+3 = more than 15 per low power field

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	Average Grade
5 Males	Trachea	Tracheitis	2	1.0
5 Females	Lung	Chronic respiratory disease	2	1.0
		Focal interstitial pneumonia	1	1.0

All other tissues and organs were normal histologically.

Grading System

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

2. Six-Month Sacrifice

a. Gross Pathologic Findings

No outstanding differences were noted between test and control animals.

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

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

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

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

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TABLE XXVI
 TEST MATERIAL: Aroclor 1242
 Two-Year Chronic Oral Toxicity Study - Albino Rats
 Organ Weight and Ratio Data
 Six-Month Sacrifice
 Summary of Mean Values
 Organ: Brain

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

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c. Histopathologic Findings

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

Tables XXVII and XXVIII list all histopathologic changes noted.

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

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TABLE XXVII

TEST MATERIAL: Aroclor 1242

Two-Year Chronic Oral Toxicity Study - Albino Rats

Histopathologic Changes

Six-Month Sacrifice

Group: Control

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

All other tissues and organs were normal histologically.

Grading System

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

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TABLE XXVIII

TEST MATERIAL: Aroclor 1242

Two-Year Chronic Oral Toxicity Study - Albino Rats

Histopathologic Changes

Six-Month Sacrifice

Group: 100 ppm

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

All other tissues and organs were normal histologically.

Grading System

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

3. Twelve-Month Sacrifice

a. Gross Pathologic Findings

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

b. Organ Weight and Ratio Data

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

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

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

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TABLE XXIX
 TEST MATERIAL: Aroclor 1242
 Two-Year Chronic Oral Toxicity Study - Albino Rats
 Twelve-Month Sacrifice
 Organ Weight and Ratio Data
 Summary of Mean Values
 Organ: Liver

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

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.

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TABLE XXXIII
 TEST MATERIAL: Aroclor 1242
 Two-Year Chronic Oral Toxicity Study - Albino Rats
 Twelve-Month Sacrifice
 Organ Weight and Ratio Data
 Summary of Mean Values
 Organ: Heart

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

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

Tables XXXV and XXXVI list all histopathologic changes noted.

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

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	Av C
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 1242

Two-Year Chronic Oral Toxicity Study - Albino Rats

Histopathologic Changes

Twelve-Month Sacrifice

Group: 100 ppm

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

All other tissues and organs were normal histologically.

Grading System

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

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4. Final Sacrifice

a. Gross Pathologic Findings

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

b. Organ Weight and Ratio Data

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

The absolute liver weight and liver to body or brain weight ratios were significantly evaluated in female rats fed 100 ppm Aroclor 1242. Statistical evaluations of other organ weights, organ to body weight and organ to brain weight ratios disclosed several randomly occurring intergroup differences. The lack of any consistent dose related response indicates that these differences were not related to the ingestion of Aroclor 1242.

TABLE XXXVII

TEST MATERIAL: Aroclor 1242

Two-Year Chronic Oral Toxicity Study - Albino Rats

Organ Weight and Ratio Data

Summary of Mean Values

Final Sacrifice

Organ: Liver

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

* Statistically significant difference at the 99 percent confidence level.

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

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	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

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	0.81	0.169	0.158	0.572	0.145
10	1.08	0.82	0.158	0.153	0.495	0.409
100	1.07	0.65	0.165	0.140	0.499	0.339

TABLE XL

TEST MATERIAL: Aroclor 1242

Two-Year Chronic Oral Toxicity Study - Albino Rats

Organ Weight and Ratio Data

Summary of Mean Values

Final Sacrifice

Organ: Gonads

Dietary Level (ppm)	Organ Weight (g)		Organ/Body Weight Ratio (g/100 g)		Organ/Brain Weight Ratio (g/g)	
	Males	Females	Males	Females	Males	Females
Control	2.52	0.123	0.397	0.0222	1.15	0.062
1	3.20	0.102	0.424	0.0205	1.46	0.0523
10	3.00	0.126	0.437	0.0237	1.40	0.0625
100	3.31	0.129	0.514	0.0278	1.55	0.0671

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

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	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 taken from all animals sacrificed after 24 months on test was conducted.

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

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

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

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

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 appeared as nodular growths with limited compression of the surrounding normal hepatic tissue.

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

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

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


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TABLE XLIII

TEST MATERIAL: Aroclor 1242

Two-Year Chronic Oral Toxicity Study - Albino Rats

Histopathologic Changes

Final Sacrifice

Group: Control

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

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TABLE XLIII continued

TEST MATERIAL: Aroclor 1242

Two-Year Chronic Oral Toxicity Study - Albino Rats

Histopathologic Changes

Final Sacrifice

Group: Control

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

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TABLE XLIII continued

TEST MATERIAL: Aroclor 1242

Two-Year Chronic Oral Toxicity Study - Albino Rats

Histopathologic Changes

Final Sacrifice

Group: Control

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

All other tissues and organs were normal histologically.

Grading System

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

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
			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
			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	Chronic focal myocarditis	6	1.0
	Trachea	Tracheitis	7	1.0
	Lung	Chronic respiratory disease	13	1.0
	Liver	Ductile hyperplasia	3	1.0
	Pancreas	Chronic focal pancreatitis	2	1.0
	Stomach	Chronic gastritis	2	1.0
		Ulcerative gastritis	1	1.0
		Acanthosis	2	1.0
	Spleen	Hemosiderosis	8	2.0
	Kidney	Chronic nephritis	6	1.0
	Uterus	Metritis	1	1.0
	Adrenal Gland	Telangiectasis	10	1.0

All other tissues and organs were normal histologically.

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TABLE XLV

TEST MATERIAL: Aroclor 1242

Two-Year Chronic Oral Toxicity Study - Albino Rats

Histopathologic Changes

Final Sacrifice

Group: 10 ppm

Number of Animals	Organ Examined	Findings	Incidence	Average Grade
13 Males	Heart	Chronic focal myocarditis	6	1.0
	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
		Chronic focal pancreatitis	3	1.0
	Pancreas			
	Stomach	Acanthosis	6	1.0
		Inflammation, ulceration and necrosis	1	1.0
	Spleen	Hemosiderosis	7	1.0
	Kidney	Chronic nephritis	10	2.0
	Testes	Testicular degeneration	2	3.0
		Periarteritis	3	3.0

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TABLE XIV continued

TEST MATERIAL: Aroclor 1242

Two-Year Chronic Oral Toxicity Study - Albino Rats

Histopathologic Changes

Final Sacrifice

Group: 10 ppm

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

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TABLE XLVI

TEST MATERIAL: Aroclor 1242

Two-Year Chronic Oral Toxicity Study - Albino Rats

Histopathologic Changes

Final Sacrifice

Group: 100 ppm

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

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TABLE XLVI continued

TEST MATERIAL: Aroclor 1242

Two-Year Chronic Oral Toxicity Study - Albino Rats

Histopathologic Changes

Final Sacrifice

Group: 100 ppm

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

TABLE XLVI continued

TEST MATERIAL: Aroclor 1242

Two-Year Chronic Oral Toxicity Study - Albino Rats

Histopathologic Changes

Final Sacrifice

Group: 100 ppm

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

All other tissues and organs were normal histologically.

Grading System

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TABLE XLVII

TEST MATERIAL: Aroclor 1242

Two-Year Chronic Oral Toxicity Study - Albino Rats

Histopathologic Changes of the Urinary Bladder

Final Sacrifice

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

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* 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 Arocl 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
57-F	Abdomen Adrenal gland	- -	- -	Mammary fibroadenoma Pheochromocytoma	24
51-F	Abdomen	88.92	13 x 11 x 4	Fibroadenoma	24

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TABLE XLIX

TEST MATERIAL: Aroclor 1242

Two-Year Chronic Oral Toxicity Study - Albino Rats

Description of Tumor Findings

Group: 1 ppm

Animal Number and Sex	Location	Weight (grams)	Size (cm)	Classification	Months on Test
566-M	Abdomen	-	-	Adenocarcinoma	24
569-M	Spleen	-	-	Lymphosarcoma	22
604-F	Abdomen	-	-	Mammary fibroadenoma	24
609-F	Abdomen	15.00	5 x 3 x 1	Fibroadenoma	24
611-F	Abdomen	53.50	5 x 3 x 1	Fibroadenoma	24
		35.00	1 x 1 x 1	Fibroadenoma	
613-F	Ovary	-	3 x 2 x 1	Granulosa cell tumor	24
	Abdomen	-	-	Fibroadenoma	
815-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	
700-F	Abdomen	175.0	8 x 7 x 5	Mammary fibroadenoma	24
71-F	Parathyroid gland	-	-	Adenoma	24

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TABLE L continued

TEST MATERIAL: Aroclor 1242

Two-Year Chronic Oral Toxicity Study - Albino Rats

Description of Tumor Findings

Group: 10 ppm

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

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TABLE LI

TEST MATERIAL: Aroclor 1242

Two-Year Chronic Oral Toxicity Study - Albino Rats

Description of Tumor Findings

Group: 100 ppm

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

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