DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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National Institute of
Environmental Health Sciences
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FYI_1097_1318

October 22, 1997

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Re: Oleic Acid Diethanolamine Condensate Chronic Study

In compliance with the National Toxicology Program's (NTP) mission to keep our colleagues informed of the current NTP findings during on-going studies, a copy of the Pathology Working Group (PWG) report and the Summary Tables for the chronic dermal studies on Oleic Acid Diethanolamide (CAS No. 93-83-4) in B6C3F1 mice are enclosed for your review.

The NTP assembles a Pathology Working Group to review every study and to resolve any differences between the study laboratory and quality assessment pathology evaluations. Please note that the PWG conclusion of the study results is based solely on the pathology for this study and may not reflect final NTP conclusions. In determining final conclusions, the NTP assesses a broad array of information that includes other results from this study and historical control data.

The Summary Tables contain the Incidence Rates of Neoplastic and Non-neoplastic Lesion data and the Statistical Analysis of Primary Tumors data pertaining to the laboratory animals. All study data are subject to an NTP retrospective audit and the interpretation may be modified based on the findings.

A wide variety of NTP information is also available in electronic format on the world-wide web, for example, the NTP Annual Plan, abstracts of NTP Reports, study data, and the status of all NTP studies. To view this information requires access to the internet and a Web browser such as Netscape Navigator or Internet Explorer. To access the NTP home page, use the URL http://ntp-server.niehs.nih.gov/. Comments on the usefulness of this site and suggestions for improvement are encouraged.

Please contact Central Data Management (CDM) at (919)541-3419 if you have any questions. You may also fax your requests for information to CDM at (919)541-3687 or send them via e-mail to cdm@niehs.nih.gov.

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Hard copies of documents such as NTP Technical Reports, short-term Toxicity Reports, and the Report on Carcinogens are available from the Environmental Health Information Service (EHIS). You can contact EHIS by phone at (919) 541-3841, by fax at (919)541-0273, or by e-mail at ehis@niehs.nih.gov.

Sincerely,

William Eastin

William Eastin, Ph.D.
Head, Information Systems & Central Files
Environmental Toxic gy Program

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97 OCT 29 PM 2:41

Encls: B6C3F1 Mice, PWG, Pathology Summary Tables
c.: Dr. J. Bucher
Dr. J. Roycroft
Central Data Management

CHAIRPERSON'S REPORT
PATHOLOGY WORKING GROUP (PWG) OF THE CHRONIC TOXICITY STUDY OF OLEIC ACID DIETHANOLAMINE CONDENSATE (C91014) ADMINISTERED VIA DERMAL APPLICATION TO B6C3F1 MICE PERFORMED BY BATTELLE COLUMBUS LABORATORIES

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Date of PWG: July 08, 1997

Site of PWG: National Toxicology Program
Research Triangle Institute, NC

PWG Participants:	Paul K. Hildebrandt, D.V.M., Chairperson,	PATHCO
	Ronald Herbert, D.V.M., Ph.D.	NIEHS
	Joel Leininger, D.V.M.,Ph.D.	NIEHS
	Abraham Nyska, D.V.M., Ph.D.	NIEHS
	Ann Radovsky, D.V.M., Ph.D.	NIEHS
	Douglas Wolf, D.V.M., Ph.D.	Wolf Consulting
	Suzanne Botts, D.V.M., Ph.D.	EPL
	Stefan Platz, D.V.M., Ph.D. (observer)	Boehringer Ingelheim

Study Pathologist: Dr. Donald M. Sells

Reviewing Pathologist: Dr. Deborah A. Banas

I. Summary and Conclusion

1) Oleic Acid Diethanolomine Condensate administration via dermal application for two years did not produce a carcinogenic effect when applied to the skin of male and female mice.

2) Dermatitis characterized by chronic/active inflammation, hyperkeratosis, epithelial hyperplasia, and sebaceous gland hyperplasia occurred at the site of application in essentially all high dose animals. The incidence of these lesions was slightly less in low dose mice and the severity was much less compared to high dose lesions.

3) The incidence of total liver neoplasms among the various dose groups was within the range of historical control data. It was the opinion of the PWG that no treatment effect was present.

4) The incidence of ovarian follicular cysts and pariovarian cysts was increased over controls; however, because these cysts were variable in size and are so common in older female mice, a compound effect was not considered to be present.

II. Study Design

Male and female B6C3F1 mice were administered 15mg/kg and 30 mg/kg via dermal application for up to two years. Control mice had 95% ethanol applied to the skin. There were 55 mice per sex per dose group. After 14 weeks of dermal administration, 5 mice/sex/group were randomly selected and subjected to full necropsy and histopathological examination.

III. Animal Disposition Summary

A. Chronic Toxicity/Carcinogenicity Study

1. 14-Week Interim Sacrifice

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FEMALE MICE

	0mg/kg	15mg/kg	30 mg/kg
Animals Initially In Study	55	55	55
Survivors-Scheduled Sacrifice	5	5	5
Animals Examined Microscopically	5	5	5

MALE MICE

	0 mg/kg	15 mg/kg	30 mg/kg
Animals Initially in Study	55	55	55
Survivors-Scheduled Sacrifice	5	5	5
Animals Examined Microscopically	5	5	5

A. Chronic Toxicity/Carcinogenicity Study, cont'd

2. Core Sacrifice

FEMALE MICE

	0mg/kg	15mg/kg	30 mg/kg
Animals Initially In Study	55	55	55
Early Deaths			
Natural Death	8	8	6
Moribund Sacrifice	8	12	8
Accidentally Killed			1
Survivors-Terminal Sacrifice	34	30	35
Animals Examined Microscopically	50	50	50

MALE MICE

	0mg/kg	15mg/kg	30 mg/kg
Animals Initially In Study	55	55	55
Early Deaths			
Natural Death	5	7	5
Moribund Sacrifice	3	8	11
Other	1*		
Survivors-Terminal Sacrifice	41	35	34
Animals Examined Microscopically	49	50	50

*One animal missing

IV. Conduct of the PWG

Prior to the PWG, the Chairperson reviewed the pathology incidence tables, the study pathologist's narrative, the report prepared by the reviewing pathologist, and microscopic slides of potential target organs and selected lesions with discrepancies in diagnoses between the study pathologist (SP) and reviewing pathologist (RP). All tumors were also reviewed by the Chairperson.

Potential target organs in this study were considered to be

Male Mice	Female Mice
Skin	Skin
Skin, SOA	Skin, SOA
Liver	Liver

In addition, all ovaries in female mice were examined and any ovary with a lesion considered to be cyst, follicle-cyst, or periovarian tissue, cyst were included in the RP's and Chairperson's review.

All pituitary and thyroid gland with a diagnosis of hyperplasia and/or adenoma (no site designated) were also reviewed.

Tumors in all organs from all animals in each group were examined during the RP's review and by the Chairperson.

At the PWG, the Chairperson led a short discussion in the form of introductory remarks which included:

1) Study design
2) Survival data
3) Clinical signs
4) Body/organ weights
5) Gross necropsy lesions

Skin

The Chairperson prepared and presented a number of photomicrographs of lesions of the skin from this study. These served as examples of the types of lesions that were present in the skin of respective dose groups including the 14-week interim sacrifice animals.

There were very few discrepancies in diagnosis between the SP and RP. A series of slides with skin lesions (site of application) were presented to the PWG for review.

The skin lesions were characterized by chronic/active inflammation of the dermis with epidermal hyperplasia, hyperkeratosis, and sebaceous gland hyperplasia. Dermal thickening with mild pigmentation (hemosiderin and melanin) was present in some skin lesions of high dose mice.

Occasionally, a small focus of acute inflammation and/or a small ulcer was present in the epidermis. Also, a minimal amount of cellular debris (exudate) was sometimes noted on the surface of the skin at the SOA in treated mice. Near the edge of a small ulcer or a focus of acute inflammation, the surface epithelium was usually hyperkeratotic with nuclei of epithelial cells still observable. These nuclei often appeared quite slender, with some fields almost degenerate; however, the diagnosis of parakeratosis was rendered either by the SP or RP in a number of treated mice. The PWG recognized this was not a major feature of the skin lesion but that there was sufficient retention of nuclei at the surface to accept a diagnosis of parakeratosis. Almost all of this parakeratosis was graded minimal degree of severity and the incidence was low.

The PWG examined a number of skin sections from low dose and interim sacrifice mice and confirmed the lesions diagnosed by the SP and reviewed by the RP and Chairperson. Save for an occasional minimal lesion, no discrepancies in diagnoses existed. It was noted that skin lesions were present in low dose mice but were much less severe, and not all mice were affected.

Liver

The liver was selected as a potential target organ due to a slight increase in total hepatic neoplasms in the 30 mg/kg male dose group and the 15 mg/kg female dose group. The PWG examined all livers where a discrepancy existed regarding hepatic tumor versus no tumor. Discrepancies in multiplicity or hepatocellular adenoma versus carcinoma were not presented to the PWG. The criteria utilized in diagnosing foci of cellular alteration and hepatocellular adenoma were those of Maronpot, et al. The results are presented in the PWG Chairperson's Report (Appendix).

The PWG noted that the incidence of hepatocellular tumors was within the range of historical control data and agreed with the SP and RP that a treatment affect was not present.

Ovary

A number of follicular cysts and cysts in periovarian tissue was diagnosed in this study. A series of slides with ovarian cysts were presented to the PWG for verification and characterization. The cysts varied in size and were considered to be no different than ovarian cysts commonly encountered in female mice of advancing age. The PWG noted the increase in

incidence of ovarian cysts in the high dose; however, there were no ovarian cystadenomas in the high dose. Because the ovarian cysts were quite dissimilar, and no cyst adenomas were present in the high dose, the PWG did not consider that a treatment effect existed with regard to ovarian cysts.

Several interesting and unusual lesions were presented to the PWG for evaluation. Results of these are found in the PWG Chairperson's Report (Appendix).

Paul K. Hildebrandt, D.V.M.
Diplomate, American College
of Veterinary Pathologists

NTP Experiment-Test: 91014-04
Study Type: CHRONIC
Route: SKIN APPLICATION

INCIDENCE RATES OF NONNEOPLASTIC LESIONS BY ANATOMIC SITE (a)
OLEIC ACID DIETHANOLAMINE CONDENSATE

14 WEEK SSAC

Report: PEIRPT03
Date: 09/23/97
Time: 09:32:07

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Facility: Battelle Columbus Laboratory

Chemical CAS #: 93-83-4

Lock Date: 01/02/96

Cage Range: All

Reasons For Removal: 25017 Scheduled Sacrifice

Removal Date Range: All

Treatment Groups:

Include 002	0 MG/KG
Include 004	15 MG/KG
Include 006	30 MG/KG
Include 001	0 MG/KG
Include 003	15 MG/KG
Include 005	30 MG/KG

a Number of animals examined microscopically at site and number of animals with lesion

INCIDENCE RATES OF NONNEOPLASTIC LESIONS BY ANATOMIC SITE (a)
OLEIC ACID DIETHANOLAMINE CONDENSATE

B6C3F1 MICE FEMALE	0 MG/KG	15 MG/KG	30 MG/KG
DISPOSITION SUMMARY			
Animals Initially In Study	55	55	55
Scheduled Sacrifice	5	5	5
Early Deaths			
Survivors			
Animals Examined Microscopically	5	5	5
ALIMENTARY SYSTEM			
None			
CARDIOVASCULAR SYSTEM			
None			
ENDOCRINE SYSTEM			
None			
GENERAL BODY SYSTEM			
None			
GENITAL SYSTEM			
Ovary	(1)		
Follicle, Cyst	1 (100%)		
HEMATOPOIETIC SYSTEM			
None			
INTEGUMENTARY SYSTEM			
Skin	(5)	(5)	(5)
Dermis, Skin, Site of Application, Inflammation, Chronic Active		4 (80%)	4 (80%)
Epidermis, Skin, Site of Application,			

a Number of animals examined microscopically at site and number of animals with lesion

INCIDENCE RATES OF NONNEOPLASTIC LESIONS BY ANATOMIC SITE (a)
OLEIC ACID DIETHANOLAMINE CONDENSATE

B6C3F1 MICE FEMALE	0 MG/KG	15 MG/KG	30 MG/KG
INTEGUMENTARY SYSTEM - CONT			
Hyperplasia		5 (100%)	4 (80%)
Sebaceous Gland, Skin, Site of Application, Hyperplasia		5 (100%)	5 (100%)
Skin, Site of Application, Hyperkeratosis		2 (40%)	3 (60%)
MUSCULOSKELETAL SYSTEM			
None			
NERVOUS SYSTEM			
None			
RESPIRATORY SYSTEM			
None			
SPECIAL SENSES SYSTEM			
None			
URINARY SYSTEM			
None			

a Number of animals examined microscopically at site and number of animals with lesion

INCIDENCE RATES OF NONNEOPLASTIC LESIONS BY ANATOMIC SITE (a)
OLEIC ACID DIETHANOLAMINE CONDENSATE

B6C3F1 MICE MALE	0 MG/KG	15 MG/KG	30 MG/KG
DISPOSITION SUMMARY			
Animals Initially In Study	55	55	55
Scheduled Sacrifice	5	5	5
Early Deaths			
Survivors			
Animals Examined Microscopically	5	5	5
Skin	(5)	(5)	(5)
Dermis, Skin, Site of Application, Inflammation, Chronic Active		5 (100%)	5 (100%)
Epidermis, Skin, Site of Application, Hyperplasia		5 (100%)	5 (100%)
Epidermis, Skin, Site of Application, Inflammation, Suppurative			1 (20%)
Epidermis, Skin, Site of Application, Parakeratosis		1 (20%)	4 (80%)
Sebaceous Gland, Skin, Site of Application, Hyperplasia		[illegible] (100%)	5 (100%)
Skin, Site of Application, Hyperkeratosis		[illegible] (80%)	4 (80%)
Skin, Site of Application, Ulcer			1 (20%)

a Number of animals examined microscopically at site and number of animals with lesion

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---------- END OF REPORT ----------

INCIDENCE RATES OF NEOPLASMS BY ANATOMIC SITE (SYSTEMIC LESIONS ABRIDGED) (a)
OLEIC ACID DIETHANOLAMINE CONDENSATE

14 WEEK SSAC

Facility: Battelle Columbus Laboratory

Chemical CAS #: 93-83-4

Lock Date: 01/02/96

Cage Range: All

Reasons For Removal: 25017 Scheduled Sacrifice

Removal Date Range: All

Treatment Groups:

Include 002	0 MG/KG
Include 004	15 MG/KG
Include 006	30 MG/KG
Include 001	0 MG/KG
Include 003	15 MG/KG
Include 005	30 MG/KG

a Number of animals examined microscopically at site and number of animals with lesion

B6C3F1 MICE FEMALE	0 MG/KG	15 MG/KG	30 MG/KG
DISPOSITION SUMMARY			
Animals Initially in Study	55	55	55
Scheduled Sacrifice	5	5	5
Early Deaths			
Survivors			
Animals Examined Microscopically	5	5	5
ALIMENTARY SYSTEM			
None			
CARDIOVASCULAR SYSTEM			
None			
ENDOCRINE SYSTEM			
None			
GENERAL BODY SYSTEM			
None			
GENITAL SYSTEM			
None			
HEMATOPOIETIC SYSTEM			
None			
INTEGUMENTARY SYSTEM			
None			

B6C3F1 MICE FEMALE	0 MG/KG	15 MG/KG	30 MG/KG

MUSCULOSKELETAL SYSTEM

None

NERVOUS SYSTEM

None

RESPIRATORY SYSTEM

None

SPECIAL SENSES SYSTEM

None

URINARY SYSTEM

None

B6C3F1 MICE MALE	0 MG/KG	15 MG/KG	30 MG/KG
DISPOSITION SUMMARY			
Animals Initially in Study	55	55	55
Scheduled Sacrifice	5	5	5
Early Deaths			
Survivors			
Animals Examined Microscopically	5	5	5
ALIMENTARY SYSTEM			
None			
CARDIOVASCULAR SYSTEM			
None			
ENDOCRINE SYSTEM			
None			
GENERAL BODY SYSTEM			
None			
GENITAL SYSTEM			
None			
HEMATOPOIETIC SYSTEM			
None			
INTEGUMENTARY SYSTEM			
None			

B6C3F1 MICE MALE	0 MG/KG	15 MG/KG	30 MG/KG

MUSCULOSKELETAL SYSTEM

None

NERVOUS SYSTEM

None

RESPIRATORY SYSTEM

None

SPECIAL SENSES SYSTEM

None

URINARY SYSTEM

None

---------- END OF REPORT ----------

INCIDENCE RATES OF NONNEOPLASTIC LESIONS BY ANATOMIC SITE (a)
OLEIC ACID DIETHANOLAMINE CONDENSATE

2 YEAR CHRONIC

Facility: Battelle Columbus Laboratory

Chemical CAS #: 93-83-4

Lock Date: 01/02/96

Cage Range: All

Reasons For Removal: 25022 Accidently Killed
25019 Moribund Sacrifice
25021 Terminal Sacrifice
25023 Missing
25020 Natural Death

Removal Date Range: All

Treatment Groups:

Include 002	0 MG/KG
Include 004	15 MG/KG
Include 006	30 MG/KG
Include 001	0 MG/KG
Include 003	15 MG/KG
Include 005	30 MG/KG

a Number of animals examined microscopically at site and number of animals with lesion

INCIDENCE RATES OF NONNEOPLASTIC LESIONS BY ANATOMIC SITE (a)
OLEIC ACID DIETHANOLAMINE CONDENSATE

B6C3F1 MICE FEMALE	0 MG/KG	15 MG/KG	30 MG/KG
DISPOSITION SUMMARY			
Animals Initially In Study	55	55	55
Early Deaths			
Moribund Sacrifice	8	12	8
Natural Death	8	8	6
Accidently Killed			1
Survivors			
Terminal Sacrifice	34	30	35
Animals Examined Microscopically	50	50	50
ALIMENTARY SYSTEM			
Intestine Small, Duodenum	(49)	(50)	(50)
Inflammation, Suppurative			1 (2%)
Intestine Small, Jejunum	(50)	(49)	(50)
Peyer's Patch, Hyperplasia	1 (2%)		
Liver	(50)	(50)	(50)
Angiectasis			1 (2%)
Basophilic Focus		1 (2%)	1 (2%)
Clear Cell Focus	3 (6%)	2 (4%)	3 (6%)
Cyst	1 (2%)	1 (2%)	
Eosinophilic Focus	11 (22%)	5 (10%)	10 (20%)
Eosinophilic Focus, Multiple	4 (8%)	8 (16%)	4 (8%)
Infarct		1 (2%)	
Mixed Cell Focus	6 (12%)	6 (12%)	6 (12%)
Mixed Cell Focus, Multiple	2 (4%)	2 (4%)	1 (2%)
Necrosis	2 (4%)	1 (2%)	
Pigmentation		1 (2%)	
Vacuolization Cytoplasmic			1 (2%)
Bile Duct, Cyst	1 (2%)		
Mesentery	(12)	(7)	(9)
Inflammation, Suppurative			1 (11%)
Necrosis	2 (17%)	2 (29%)	1 (11%)
Fat, Necrosis	9 (75%)	5 (71%)	5 (56%)
Pancreas	(49)	(50)	(50)
Basophilic Focus		1 (2%)	
Acinus, Atrophy			1 (2%)
Duct, Cyst	1 (2%)		
Stomach, Forestomach	(50)	(50)	(50)
Hyperkeratosis	1 (2%)	1 (2%)	
Hyperplasia		3 (6%)	
Stomach, Glandular	(50)	(50)	(50)
Cyst	1 (2%)		
Inflammation, Acute	1 (2%)		
Mineralization			2 (4%)

a Number of animals examined microscopically at site and number of animals with lesion

NTP Experiment-Test: 91014-04
Study Type: CHRONIC
Route: SKIN APPLICATION

INCIDENCE RATES OF NONNEOPLASTIC LESIONS BY ANATOMIC SITE (a)
OLEIC ACID DIETHANOLAMINE CONDENSATE

Report: PEIRPT03
Date: 09/23/97
Time: 09:41:16

B6C3F1 MICE FEMALE	0 MG/KG	15 MG/KG	30 MG/KG
CARDIOVASCULAR SYSTEM			
Blood Vessel	(50)	(50)	(50)
Aorta, Mineralization	2 (4%)		
Heart	(50)	(50)	(50)
Degeneration			1 (2%)
Inflammation, Suppurative		1 (2%)	
Mineralization	4 (8%)		1 (2%)
Thrombosis		1 (2%)	
Artery, Inflammation, Chronic Active	1 (2%)		
Artery, Mineralization	1 (2%)		
Pericardium, Inflammation, Chronic Active	2 (4%)		
ENDOCRINE SYSTEM			
Adrenal Cortex	(50)	(50)	(50)
Angiectasis	1 (2%)		
Hyperplasia	1 (2%)		1 (2%)
Hypertrophy	1 (2%)	1 (2%)	
Zona Fasciculata, Vacuolization Cytoplasmic	1 (2%)		1 (2%)
Adrenal Medulla	(50)	(50)	(50)
Hyperplasia	1 (2%)		2 (4%)
Islets, Pancreatic	(49)	(50)	(50)
Hyperplasia	7 (14%)	8 (16%)	6 (12%)
Pituitary Gland	(50)	(50)	(50)
Angiectasis	4 (8%)		1 (2%)
Hypertrophy	1 (2%)		
Pars Distalis, Hyperplasia	9 (18%)	6 (12%)	7 (14%)
Thyroid Gland	(50)	(50)	(50)
Atrophy		1 (2%)	
Inflammation, Chronic Active	1 (2%)		
C-Cell, Hyperplasia	1 (2%)		
Follicle, Cyst			1 (2%)
Follicular Cell, Hyperplasia	14 (28%)	15 (30%)	15 (30%)
GENERAL BODY SYSTEM			
None			

a Number of animals examined microscopically at site and number of animals with lesion

INCIDENCE RATES OF NONNEOPLASTIC LESIONS BY ANATOMIC SITE (a)
OLEIC ACID DIETHANOLAMINE CONDENSATE

B6C3F1 MICE FEMALE	0 MG/KG	15 MG/KG	30 MG/KG
GENITAL SYSTEM			
Ovary	(50)	(50)	(50)
Angiectasis			1 (2%)
Atrophy	5 (10%)		5 (10%)
Hemorrhage	1 (2%)		
Follicle, Cyst	7 (14%)	11 (22%)	14 (28%)
Periovarian Tissue, Angiectasis	1 (2%)		
Periovarian Tissue, Cyst			3 (6%)
Oviduct	(1)	(1)	
Atrophy	1 (100%)		
Uterus	(50)	(50)	(50)
Angiectasis		1 (2%)	
Cyst		1 (2%)	
Inflammation, Acute	1 (2%)		
Endometrium, Hyperplasia			9 (18%)
Endometrium, Hyperplasia, Cystic	35 (70%)	20 (40%)	28 (56%)
HEMATOPOIETIC SYSTEM			
Bone Marrow	(50)	(50)	(50)
Hyperplasia	3 (6%)	1 (2%)	2 (4%)
Myelofibrosis	11 (22%)	9 (18%)	8 (16%)
Lymph Node	(2)	(5)	(8)
Lumbar, Hyperplasia, Histiocytic	1 (50%)		
Renal, Angiectasis			1 (13%)
Renal, Hyperplasia, Lymphoid			1 (13%)
Lymph Node, Mandibular	(49)	(49)	(47)
Hyperplasia		1 (2%)	
Hyperplasia, Lymphoid	1 (2%)	2 (4%)	3 (6%)
Lymph Node, Mesenteric	(49)	(47)	(49)
Hyperplasia, Lymphoid	1 (2%)		2 (4%)
Spleen	(50)	(50)	(50)
Hematopoietic Cell Proliferation	22 (44%)	27 (54%)	15 (30%)
Hyperplasia, Lymphoid	4 (8%)	3 (6%)	5 (10%)
Thymus	(41)	(45)	(47)
Atrophy	6 (15%)	4 (9%)	5 (11%)
Hyperplasia, Lymphoid		2 (4%)	2 (4%)
INTEGUMENTARY SYSTEM			
Mammary Gland	(49)	(50)	(49)
Dilatation		1 (2%)	
Hyperplasia, Cystic	1 (2%)		
Inflammation, Acute	1 (2%)		
Skin	(50)	(50)	(50)

a Number of animals examined microscopically at site and number of animals with lesion

INCIDENCE RATES OF NONNEOPLASTIC LESIONS BY ANATOMIC SITE (a)
OLEIC ACID DIETHANOLAMINE CONDENSATE

B6C3F1 MICE FEMALE	0 MG/KG	15 MG/KG	30 MG/KG
INTEGUMENTARY SYSTEM - CONT			
Fibrosis	1 (2%)		
Dermis, Skin, Site of Application, Inflammation, Chronic Active		40 (80%)	49 (98%)
Epidermis, Skin, Site of Application, Hyperplasia		43 (86%)	50 (100%)
Epidermis, Skin, Site of Application, Parakeratosis			4 (8%)
Sebaceous Gland, Skin, Site of Application, Hyperplasia		39 (78%)	46 (92%)
Skin, Site of Application, Exudate			6 (12%)
Skin, Site of Application, Hyperkeratosis		36 (72%)	42 (84%)
MUSCULOSKELETAL SYSTEM			
Bone	(50)	(50)	(50)
Arthrosis	1 (2%)		
Fibrous Osteodystrophy	1 (2%)		2 (4%)
Femur, Fibrous Osteodystrophy	1 (2%)		
Maxilla, Fibrous Osteodystrophy	1 (2%)		
Vertebra, Fibrous Osteodystrophy	1 (2%)		
NERVOUS SYSTEM			
Brain	(50)	(50)	(50)
Necrosis			1 (2%)
RESPIRATORY SYSTEM			
Lung	(50)	(50)	(50)
Hemorrhage			1 (2%)
Alveolar Epithelium, Hyperplasia	2 (4%)		1 (2%)
SPECIAL SENSES SYSTEM			
None			
URINARY SYSTEM			
Kidney	(50)	(50)	(50)
Accumulation, Hyaline Droplet	3 (6%)	3 (6%)	3 (6%)
Mineralization	9 (18%)	2 (4%)	2 (4%)
Nephropathy	11 (22%)	6 (12%)	16 (32%)

a Number of animals examined microscopically at site and number of animals with lesion

INCIDENCE RATES OF NONNEOPLASTIC LESIONS BY ANATOMIC SITE (a)
OLEIC ACID DIETHANOLAMINE CONDENSATE

B6C3F1 MICE FEMALE	0 MG/KG	15 MG/KG	30 MG/KG
URINARY SYSTEM - CONT			
Pigmentation		1 (2%)	
Pelvis, Dilatation	1 (2%)		
Renal Tubule, Dilatation	3 (6%)		

a Number of animals examined microscopically at site and number of animals with lesion

INCIDENCE RATES OF NONNEOPLASTIC LESIONS BY ANATOMIC SITE (a)
OLEIC ACID DIETHANOLAMINE CONDENSATE

B6C3F1 MICE MALE	0 MG/KG	15 MG/KG	30 MG/KG
DISPOSITION SUMMARY			
Animals Initially In Study	55	55	55
Early Deaths			
Moribund Sacrifice	3	8	11
Natural Death	5	7	5
Survivors			
Terminal Sacrifice	41	35	34
Missing	1		
Animals Examined Microscopically	49	50	50
ALIMENTARY SYSTEM			
Intestine Small, Duodenum	(48)	(50)	(50)
Ulcer		1 (2%)	1 (2%)
Intestine Small, Jejunum	(49)	(50)	(50)
Hyperplasia, Lymphoid	2 (4%)		
Peyer's Patch, Hyperplasia, Lymphoid		1 (2%)	1 (2%)
Liver	(49)	(50)	(50)
Basophilic Focus	4 (8%)	3 (6%)	3 (6%)
Clear Cell Focus	3 (6%)	3 (6%)	6 (12%)
Clear Cell Focus, Multiple	1 (2%)	4 (8%)	2 (4%)
Eosinophilic Focus	7 (14%)	5 (10%)	8 (16%)
Eosinophilic Focus, Multiple	5 (10%)	4 (8%)	1 (2%)
Infarct	3 (6%)		
Mixed Cell Focus	3 (6%)	6 (12%)	5 (10%)
Mixed Cell Focus, Multiple	1 (2%)	9 (18%)	5 (10%)
Necrosis	7 (14%)	1 (2%)	9 (18%)
Vacuolization Cytoplasmic	1 (2%)	1 (2%)	1 (2%)
Bile Duct, Cyst			1 (2%)
Mesentery	(4)	(4)	(3)
Necrosis, Focal			1 (33%)
Fat, Necrosis	2 (50%)	3 (75%)	2 (67%)
Pancreas	(49)	(50)	(50)
Basophilic Focus		1 (2%)	
Necrosis	1 (2%)		
Duct, Cyst		1 (2%)	1 (2%)
Stomach, Forestomach	(49)	(50)	(50)
Cyst	1 (2%)		1 (2%)
Hyperkeratosis		1 (2%)	
Hyperplasia		2 (4%)	1 (2%)
Inflammation, Suppurative			1 (2%)
Ulcer		1 (2%)	
Stomach, Glandular	(49)	(50)	(50)
Cyst	3 (6%)		1 (2%)
Erosion			(2%)

a Number of animals examined microscopically at site and number of animals with lesion

INCIDENCE RATES OF NONNEOPLASTIC LESIONS BY ANATOMIC SITE (a)
OLEIC ACID DIETHANOLAMINE CONDENSATE

B6C3F1 MICE MALE	0 MG/KG	15 MG/KG	30 MG/KG
ALIMENTARY SYSTEM - CONT			
Hyperplasia, Focal	1 (2%)		
Inflammation, Chronic Active			1 (2%)
Mineralization	1 (2%)		2 (4%)
CARDIOVASCULAR SYSTEM			
Heart	(49)	(50)	(50)
Cardiomyopathy			1 (2%)
Necrosis		1 (2%)	
Artery, Inflammation, Chronic Active		1 (2%)	
ENDOCRINE SYSTEM			
Adrenal Cortex	(49)	(50)	(50)
Hyperplasia	2 (4%)	1 (2%)	5 (10%)
Hypertrophy	22 (45%)	12 (24%)	10 (20%)
Capsule, Hyperplasia	11 (22%)	7 (14%)	7 (14%)
Adrenal Medulla	(49)	(50)	(50)
Hyperplasia	1 (2%)		2 (4%)
Islets, Pancreatic	(49)	(50)	(50)
Hyperplasia	30 (61%)	28 (56%)	26 (52%)
Parathyroid Gland	(45)	(42)	(42)
Hyperplasia		1 (2%)	
Pituitary Gland	(49)	(47)	(50)
Pars Distalis, Hyperplasia	1 (2%)		1 (2%)
Thyroid Gland	(49)	(50)	(50)
Cyst			1 (2%)
Inflammation, Chronic Active		1 (2%)	
Follicle, Cyst	1 (2%)		
Follicular Cell, Hyperplasia	8 (16%)	7 (14%)	9 (18%)
GENERAL BODY SYSTEM			
None			
GENITAL SYSTEM			
Preputial Gland	(48)	(50)	(50)
Angiectasis	1 (2%)		
Cyst	17 (35%)	12 (24%)	10 (20%)
Inflammation			1 (2%)
Inflammation, Chronic Active	5 (10%)	1 (2%)	2 (4%)
Seminal Vesicle	(49)	(50)	(50)

a Number of animals examined microscopically at site and number of animals with lesion

INCIDENCE RATES OF NONNEOPLASTIC LESIONS BY ANATOMIC SITE (a)
OLEIC ACID DIETHANOLAMINE CONDENSATE

B6C3F1 MICE MALE	0 MG/KG	15 MG/KG	30 MG/KG
GENITAL SYSTEM - CONT			
Cyst		2 (4%)	
Hypertrophy	1 (2%)		
Testes	(49)	(50)	(50)
Atrophy	1 (2%)	3 (6%)	
HEMATOPOIETIC SYSTEM			
Bone Marrow	(49)	(50)	(50)
Hyperplasia	4 (8%)	4 (8%)	6 (12%)
Myelofibrosis		3 (6%)	
Lymph Node, Mandibular	(48)	(46)	(47)
Hyperplasia, Lymphoid	1 (2%)		
Lymph Node, Mesenteric	(47)	(48)	(48)
Angiectasis	1 (2%)		2 (4%)
Ectasia		1 (2%)	
Hematopoietic Cell Proliferation		1 (2%)	
Hyperplasia, Lymphoid	2 (4%)		
Inflammation, Chronic Active			1 (2%)
Spleen	(49)	(50)	(50)
Angiectasis		1 (2%)	
Hematopoietic Cell Proliferation	10 (20%)	12 (24%)	16 (32%)
Hyperplasia, Lymphoid		1 (2%)	2 (4%)
Inflammation, Chronic Active		1 (2%)	
Thymus	(45)	(36)	(39)
Atrophy	5 (11%)		5 (13%)
Epithelial Cell, Hyperplasia			1 (3%)
INTEGUMENTARY SYSTEM			
Skin	(49)	(50)	(50)
Hyperkeratosis			2 (4%)
Dermis, Skin, Site of Application, Inflammation, Chronic Active		34 (68%)	50 (100%)
Epidermis, Skin, Site of Application, Hyperplasia	1 (2%)	40 (80%)	47 (94%)
Epidermis, Skin, Site of Application, Inflammation, Suppurative			3 (6%)
Epidermis, Skin, Site of Application, Parakeratosis		2 (4%)	8 (16%)
Sebaceous Gland, Hyperplasia		1 (2%)	
Sebaceous Gland, Skin, Site of Application, Hyperplasia	1 (2%)	21 (42%)	34 (68%)
Skin, Site of Application, Exudate	1 (2%)	3 (6%)	9 (18%)
Skin, Site of Application, Hyperkeratosis	1 (2%)	38 (76%)	37 (74%)
Skin, Site of Application, Ulcer			7 (14%)

a Number of animals examined microscopically at site and number of animals with lesion

INCIDENCE RATES OF NONNEOPLASTIC LESIONS BY ANATOMIC SITE (a)
OLEIC ACID DIETHANOLAMINE CONDENSATE

B6C3F1 MICE MALE	0 MG/KG	15 MG/KG	30 MG/KG
INTEGUMENTARY SYSTEM - CONT			
Subcutaneous Tissue, Edema		1 (2%)	
MUSCULOSKELETAL SYSTEM			
Bone	(49)	(50)	(50)
Hyperostosis			1 (2%)
NERVOUS SYSTEM			
None			
RESPIRATORY SYSTEM			
Lung	(49)	(50)	(50)
Hemorrhage		1 (2%)	
Hyperplasia		3 (6%)	
Alveolar Epithelium, Hyperplasia	5 (10%)	3 (6%)	8 (16%)
Nose	(49)	(50)	(50)
Lateral Wall, Inflammation, Chronic Active	1 (2%)		
SPECIAL SENSES SYSTEM			
Eye			(1)
Cornea, Degeneration			1 (100%)
Harderian Gland	(2)	(1)	(5)
Hyperplasia			1 (20%)
Lacrimal Gland			(1)
Mineralization			1 (100%)
URINARY SYSTEM			
Kidney	(49)	(50)	(50)
Accumulation, Hyaline Droplet		1 (2%)	
Cyst	3 (6%)	1 (2%)	3 (6%)
Mineralization	37 (76%)	39 (78%)	28 (56%)
Nephropathy	44 (90%)	38 (76%)	38 (76%)
Pigmentation			1 (2%)

a Number of animals examined microscopically at site and number of animals with lesion

INCIDENCE RATES OF NONNEOPLASTIC LESIONS BY ANATOMIC SITE (a)
OLEIC ACID DIETHANOLAMINE CONDENSATE

B6C3F1 MICE MALE	0 MG/KG	15 MG/KG	30 MG/KG
URINARY SYSTEM - CONT			
Vacuolization Cytoplasmic			1 (2%)

a Number of animals examined microscopically at site and number of animals with lesion

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---------- END OF REPORT ----------

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2 YEAR CHRONIC

Facility: Battelle Columbus Laboratory

Chemical CAS #: 93-83-4

Lock Date: 01/02/96

Cage Range: All

Reasons For Removal: 25022 Accidently Killed; 25019 Moribund Sacrifice; 25021 Terminal Sacrifice; 25023 Missing; 25020 Natural Death

Removal Date Range: All

Treatment Groups:

Include 002	0 MG/KG
Include 004	15 MG/KG
Include 006	30 MG/KG
Include 001	0 MG/KG
Include 003	15 MG/KG
Include 005	30 MG/KG

a Number of animals examined microscopically at site and number of animals with lesion

B6C3F1 MICE FEMALE	0 MG/KG	15 MG/KG	30 MG/KG
DISPOSITION SUMMARY			
Animals Initially in Study	55	55	55
Early Deaths			
Moribund Sacrifice	8	12	8
Natural Death	8	8	6
Accidently Killed			1
Survivors			
Terminal Sacrifice	34	30	35
Animals Examined Microscopically	50	50	50
ALIMENTARY SYSTEM			
Gallbladder	(46)	(46)	(49)
Intestine Large, Colon	(50)	(50)	(50)
Intestine Large, Cecum	(50)	(50)	(50)
Leiomyoma		1 (2%)	
Intestine Small, Jejunum	(50)	(49)	(50)
Liver	(50)	(50)	(50)
Hepatoblastoma	1 (2%)		
Hepatocellular Carcinoma	4 (8%)	8 (16%)	7 (14%)
Hepatocellular Carcinoma, Multiple	1 (2%)	2 (4%)	
Hepatocellular Adenoma	12 (24%)	13 (26%)	10 (20%)
Hepatocellular Adenoma, Multiple	14 (28%)	17 (34%)	18 (36%)
Histiocytic Sarcoma	3 (6%)	2 (4%)	1 (2%)
Ito Cell Tumor Benign, Multiple		1 (2%)	
Mesentery	(12)	(7)	(9)
Hemangioma			1 (11%)
Sarcoma	1 (8%)		
Pancreas	(49)	(50)	(50)
Histiocytic Sarcoma			1 (2%)
Salivary Glands	(50)	(50)	(50)
Stomach, Forestomach	(50)	(50)	(50)
Squamous Cell Carcinoma	1 (2%)		
Squamous Cell Papilloma	2 (4%)	2 (4%)	4 (8%)
Squamous Cell Papilloma, Multiple	1 (2%)		
Stomach, Glandular	(50)	(50)	(50)
Sarcoma, Metastatic, Mesentery	1 (2%)		
Tongue	(1)		
Squamous Cell Papilloma	1 (100%)		

B6C3F1 MICE FEMALE	0 MG/KG	15 MG/KG	30 MG/KG
CARDIOVASCULAR SYSTEM			
Heart	(50)	(50)	(50)
ENDOCRINE SYSTEM			
Adrenal Cortex	(50)	(50)	(50)
Adrenal Medulla	(50)	(50)	(50)
Pheochromocytoma Benign	2 (4%)		
Islets, Pancreatic	(49)	(50)	(50)
Adenoma	1 (2%)		1 (2%)
Carcinoma		1 (2%)	
Pituitary Gland	(50)	(50)	(50)
Pars Distalis, Adenoma	9 (18%)	6 (12%)	3 (6%)
Pars Intermedia, Adenoma		3 (6%)	1 (2%)
Thyroid Gland	(50)	(50)	(50)
Adenoma		1 (2%)	1 (2%)
Follicular Cell, Adenoma	2 (4%)		
GENERAL BODY SYSTEM			
None			
GENITAL SYSTEM			
Ovary	(50)	(50)	(50)
Cystadenoma	3 (6%)	2 (4%)	
Granulosa Cell Tumor Benign			1 (2%)
Hemangioma		1 (2%)	1 (2%)
Histiocytic Sarcoma	2 (4%)		
Luteoma			1 (2%)
Teratoma Benign		2 (4%)	
Periovarian Tissue, Plasma Cell Tumor Malignant, Metastatic, Lymph Node, Mesenteric			1 (2%)
Uterus	(50)	(50)	(50)
Adenocarcinoma	1 (2%)		
Hemangioma		2 (4%)	
Histiocytic Sarcoma	2 (4%)	1 (2%)	
Leiomyoma		1 (2%)	
Polyp Stromal	1 (2%)	2 (4%)	
Sarcoma Stromal	1 (2%)		
Cervix, Histiocytic Sarcoma	1 (2%)		
Vagina		(1)	

B6C3F1 MICE FEMALE	0 MG/KG	15 MG/KG	30 MG/KG
HEMATOPOIETIC SYSTEM			
Bone Marrow	(50)	(50)	(50)
Hemangiosarcoma	1 (2%)		
Histiocytic Sarcoma			1 (2%)
Lymph Node	(2)	(5)	(8)
Lumbar, Histiocytic Sarcoma	1 (50%)		
Renal, Fibrosarcoma, Metastatic, Skeletal Muscle			1 (13%)
Lymph Node, Mandibular	(49)	(49)	(47)
Hemangioma	1 (2%)		
Plasma Cell Tumor Malignant, Metastatic, Lymph Node, Mesenteric			1 (2%)
Lymph Node, Mesenteric	(49)	(47)	(49)
Plasma Cell Tumor Malignant			1 (2%)
Spleen	(50)	(50)	(50)
Histiocytic Sarcoma			1 (2%)
Thymus	(41)	(45)	(47)
INTEGUMENTARY SYSTEM			
Skin	(50)	(50)	(50)
Fibrosarcoma	1 (2%)	1 (2%)	2 (4%)
Histiocytic Sarcoma	1 (2%)		
Pinna, Melanoma Malignant		1 (2%)	
Skin, Site of Application, Fibrosarcoma	1 (2%)	2 (4%)	
MUSCULOSKELETAL SYSTEM			
Bone	(50)	(50)	(50)
Osteosarcoma		1 (2%)	
Skeletal Muscle	(1)		(1)
Fibrosarcoma			1 (100%)
Osteosarcoma	1 (100%)		
NERVOUS SYSTEM			
Brain	(50)	(50)	(50)

B6C3F1 MICE FEMALE	0 MG/KG	15 MG/KG	30 MG/KG
RESPIRATORY SYSTEM			
Lung	(50)	(50)	(50)
Alveolar/Bronchiolar Adenoma	1 (2%)	1 (2%)	3 (6%)
Alveolar/Bronchiolar Adenoma, Multiple			1 (2%)
Alveolar/Bronchiolar Carcinoma	3 (6%)	2 (4%)	3 (6%)
Hepatocellular Carcinoma, Metastatic, Liver	3 (6%)	4 (8%)	6 (12%)
Histiocytic Sarcoma	1 (2%)		1 (2%)
Osteosarcoma, Metastatic, Uncertain Primary Site		1 (2%)	
Plasma Cell Tumor Malignant, Metastatic, Lymph Node, Mesenteric			1 (2%)
Nose	(50)	(50)	(50)
SPECIAL SENSES SYSTEM			
Harderian Gland	(3)	(2)	
Adenoma	3 (100%)	1 (50%)	
Carcinoma		1 (50%)	
URINARY SYSTEM			
Kidney	(50)	(50)	(50)
Histiocytic Sarcoma			1 (2%)
Plasma Cell Tumor Malignant, Metastatic, Lymph Node, Mesenteric			1 (2%)
Urinary Bladder	(50)	(50)	(50)
SYSTEMIC LESIONS			
Multiple Organs	*(50)	*(50)	*(50)
Histiocytic Sarcoma	3 (6%)	2 (4%)	1 (2%)
Leukemia Granulocytic	1 (2%)		
Lymphoma Malignant	3 (6%)	9 (18%)	11 (22%)

* Number of animals with any tissue examined microscopically

B6C3F1 MICE FEMALE	0 MG/KG	15 MG/KG	30 MG/KG
TUMOR SUMMARY			
Total Animals with Primary Neoplasms (b)	46	45	36
Total Primary Neoplasms	77	86	72
Total Animals with Benign Neoplasms	37	40	31
Total Benign Neoplasms	53	56	46
Total Animals with Malignant Neoplasms	22	23	21
Total Malignant Neoplasms	24	30	26
Total Animals with Metastatic Neoplasms	4	5	8
Total Metastatic Neoplasm	4	5	11
Total Animals with Malignant Neoplasms Uncertain Primary Site		1	
Total Animals with Neoplasms Uncertain-Benign or Malignant			
Total Uncertain Neoplasms			

a Number of animals examined microscopically at site and number of animals with lesion
b Primary tumors: all tumors except metastatic tumors

INCIDENCE RATES OF NEOPLASMS BY ANATOMIC SITE (SYSTEMIC LESIONS ABRIDGED) (a)
OLEIC ACID DIETHANOLAMINE CONDENSATE

B6C3F1 MICE MALE	0 MG/KG	15 MG/KG	30 MG/KG
DISPOSITION SUMMARY			
Animals Initially in Study	55	55	55
Early Deaths			
Moribund Sacrifice	3	8	11
Natural Death	5	7	5
Survivors			
Terminal Sacrifice	41	35	34
Missing	1		
Animals Examined Microscopically	49	50	50
ALIMENTARY SYSTEM			
Intestine Small, Duodenum	(48)	(50)	(50)
Hepatocholangiocarcinoma, Metastatic, Liver		1 (2%)	
Intestine Small, Jejunum	(49)	(50)	(50)
Carcinoma	2 (4%)		
Hepatocholangiocarcinoma, Metastatic, Liver		2 (4%)	
Intestine Small, Ileum	(49)	(50)	(50)
Hepatocholangiocarcinoma, Metastatic, Liver		1 (2%)	
Liver	(49)	(50)	(50)
Fibrous Histiocytoma	1 (2%)		
Hemangiosarcoma		2 (4%)	1 (2%)
Hemangiosarcoma, Multiple	1 (2%)	2 (4%)	1 (2%)
Hepatoblastoma			1 (2%)
Hepatocellular Carcinoma	5 (10%)	9 (18%)	12 (24%)
Hepatocellular Carcinoma, Multiple	4 (8%)		1 (2%)
Hepatocellular Adenoma	13 (27%)	14 (28%)	14 (28%)
Hepatocellular Adenoma, Multiple	9 (18%)	8 (16%)	8 (16%)
Hepatocholangiocarcinoma		2 (4%)	1 (2%)
Histiocytic Sarcoma		1 (2%)	
Mesentery	(4)	(4)	(3)
Fibrous Histiocytoma, Metastatic, Liver	1 (25%)		
Pancreas	(49)	(50)	(50)
Fibrous Histiocytoma, Metastatic, Liver	1 (2%)		
Hepatocholangiocarcinoma, Metastatic, Liver		1 (2%)	
Salivary Glands	(49)	(50)	(50)
Fibrous Histiocytoma, Metastatic, Liver	1 (2%)		
Stomach, Forestomach	(49)	(50)	(50)
Squamous Cell Carcinoma		1 (2%)	
Squamous Cell Papilloma		2 (4%)	
Stomach, Glandular	(49)	(50)	(50)
Adenoma		1 (2%)	

B6C3F1 MICE MALE	0 MG/KG	15 MG/KG	30 MG/KG
CARDIOVASCULAR SYSTEM			
Blood Vessel	(49)	(50)	(50)
Fibrous Histiocytoma, Metastatic, Liver	1 (2%)		
Heart	(49)	(50)	(50)
Fibrous Histiocytoma, Metastatic, Liver	1 (2%)		
Hemangiosarcoma, Metastatic, Spleen		1 (2%)	
Hepatocholangiocarcinoma, Metastatic, Liver			1 (2%)
ENDOCRINE SYSTEM			
Adrenal Cortex	(49)	(50)	(50)
Adenoma	2 (4%)		
Hepatocholangiocarcinoma, Metastatic, Liver		1 (2%)	
Adrenal Medulla	(49)	(50)	(50)
Islets, Pancreatic	(49)	(50)	(50)
Adenoma		2 (4%)	2 (4%)
Thyroid Gland	(49)	(50)	(50)
Adenoma			1 (2%)
Follicular Cell, Adenoma	2 (4%)		1 (2%)
Follicular Cell, Carcinoma	1 (2%)		
GENERAL BODY SYSTEM			
None			
GENITAL SYSTEM			
Epididymis	(49)	(50)	(50)
Alveolar/Bronchiolar Carcinoma, Metastatic, Lung		1 (2%)	
Preputial Gland	(48)	(50)	(50)
Hemangioma		1 (2%)	
Prostate	(49)	(50)	(50)
Seminal Vesicle	(49)	(50)	(50)
Testes	(49)	(50)	(50)
Hemangioma			1 (2%)
Interstitial Cell, Adenoma		1 (2%)	1 (2%)

B6C3F1 MICE MALE	0 MG/KG	15 MG/KG	30 MG/KG
HEMATOPOIETIC SYSTEM			
Bone Marrow	(49)	(50)	(50)
Fibrous Histiocytoma, Metastatic, Liver	1 (2%)		
Hemangiosarcoma			2 (4%)
Hemangiosarcoma, Metastatic, Spleen		1 (2%)	
Lymph Node	(3)	(4)	(1)
Lumbar, Fibrous Histiocytoma, Metastatic, Liver	1 (33%)		
Mediastinal, Alveolar/Bronchiolar Carcinoma, Metastatic, Lung		1 (25%)	
Pancreatic, Hepatocellular Carcinoma, Metastatic, Liver	1 (33%)		
Renal, Fibrous Histiocytoma, Metastatic, Liver	1 (33%)		
Lymph Node, Mandibular	(48)	(46)	(47)
Fibrous Histiocytoma, Metastatic, Liver	1 (2%)		
Lymph Node, Mesenteric	(47)	(48)	(48)
Spleen	(49)	(50)	(50)
Hemangioma			1 (2%)
Hemangiosarcoma	3 (6%)	4 (8%)	2 (4%)
Hemangiosarcoma, Multiple		1 (2%)	
Thymus	(45)	(36)	(39)
Hemangioma			1 (3%)
INTEGUMENTARY SYSTEM			
Skin	(49)	(50)	(50)
Fibrosarcoma			1 (2%)
Fibrous Histiocytoma, Metastatic, Liver	1 (2%)		
Hemangiosarcoma, Metastatic, Spleen		1 (2%)	
Schwannoma Benign		1 (2%)	
Subcutaneous Tissue, Hemangiosarcoma			1 (2%)
MUSCULOSKELETAL SYSTEM			
Skeletal Muscle		(1)	
Hepatocholangiocarcinoma, Metastatic, Liver		1 (100%)	
NERVOUS SYSTEM			
None			

B6C3F1 MICE MALE	0 MG/KG	15 MG/KG	30 MG/KG
RESPIRATORY SYSTEM			
Lung	(49)	(50)	(50)
Alveolar/Bronchiolar Adenoma	6 (12%)	8 (16%)	4 (8%)
Alveolar/Bronchiolar Adenoma, Multiple	1 (2%)		1 (2%)
Alveolar/Bronchiolar Carcinoma	6 (12%)	8 (16%)	9 (18%)
Alveolar/Bronchiolar Carcinoma, Multiple	1 (2%)	2 (4%)	
Fibrous Histiocytoma, Metastatic, Liver	1 (2%)		
Hemangiosarcoma, Metastatic, Spleen			1 (2%)
Hepatocellular Carcinoma, Metastatic, Liver	3 (6%)	2 (4%)	5 (10%)
Hepatocholangiocarcinoma, Metastatic, Liver		2 (4%)	3 (6%)
Mediastinum, Hemangioma			1 (2%)
Nose	(49)	(50)	(50)
Fibrous Histiocytoma, Metastatic, Liver	1 (2%)		
SPECIAL SENSES SYSTEM			
Harderian Gland	(2)	(1)	(5)
Adenoma	2 (100%)	1 (100%)	4 (80%)
URINARY SYSTEM			
Kidney	(49)	(50)	(50)
Fibrous Histiocytoma, Metastatic, Liver	1 (2%)		
Hepatocholangiocarcinoma, Metastatic, Liver			1 (2%)
Urinary Bladder	(49)	(50)	(50)
Fibrous Histiocytoma, Metastatic, Liver	1 (2%)		
Leiomyosarcoma	1 (2%)		
SYSTEMIC LESIONS			
Multiple Organs	*(49)	*(50)	*(50)
Histiocytic Sarcoma		1 (2%)	
Lymphoma Malignant	1 (2%)	6 (12%)	2 (4%)

* Number of animals with any tissue examined microscopically

NTP Experiment-Test: 91014-04 INCIDENCE RATES OF NEOPLASMS BY ANATOMIC SITE (SYSTEMIC LESIONS ABRIDGED) (a)
Study Type: CHRONIC OLEIC ACID DIETHANOLAMINE CONDENSATE
Route: SKIN APPLICATION

Report: PEIRPT05
Date: 09/23/97
Time: 09:41:47

B6C3F1 MICE MALE	0 MG/KG	15 MG/KG	30 MG/KG
TUMOR SUMMARY			
Total Animals with Primary Neoplasms (b)	42	43	44
Total Primary Neoplasms	61	77	74
Total Animals with Benign Neoplasms	28	30	32
Total Benign Neoplasms	35	39	40
Total Animals with Malignant Neoplasms	24	29	25
Total Malignant Neoplasms	26	38	34
Total Animals with Metastatic Neoplasms	5	6	9
Total Metastatic Neoplasm	18	16	11
Total Animals with Malignant Neoplasms Uncertain Primary Site			
Total Animals with Neoplasms Uncertain-Benign or Malignant			
Total Uncertain Neoplasms			

a Number of animals examined microscopically at site and number of animals with lesion
b Primary tumors: all tumors except metastatic tumors

---------- END OF REPORT ----------

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2 YEAR CHRONIC

REASONS FOR REMOVAL:
25022 Accidently Killed
25023 Missing
25019 Moribund Sacrifice
25020 Natural Death
25021 Terminal Sacrifice

REMOVAL DATE RANGE: ALL

TREATMENT GROUPS:

INCLUDE	001	0 MG/KG
INCLUDE	002	0 MG/KG
INCLUDE	003	15 MG/KG
INCLUDE	004	15 MG/KG
INCLUDE	005	30 MG/KG
INCLUDE	006	30 MG/KG

NTP
LAB: Battelle Columbus
EXPERIMENT: 91014 TEST: 04
TEST TYPE: CHRONIC
CONT: N01-ES-15314
PATHOLOGIST: SELLS, D.

STATISTICAL ANALYSIS OF PRIMARY TUMORS
OLEIC ACID DIETHANOLAMINE CONDENSATE

CAGES FROM 0000 TO LAST CAGE
ROUTE: SKIN APPLICATION

REPORT: PEIRPT08
DATE: 09/23/97
TIME: 09:44:37

NTP C#: C91014
CAS: 93-83-4

MICE(B6C3F1)

FOR ALL DOSES THE TUMOR RATES IN THE FOLLOWING TISSUES/ORGANS ARE BASED ON NUMBER OF TISSUES EXAMINED.
IN OTHER TISSUES/ORGANS, RATES ARE BASED ON NUMBER OF ANIMALS NECROPSIED.

Adrenal Cortex
Adrenal Medulla
Bone Marrow
Brain
Clitoral Gland
Epididymis
Gallbladder
Heart
Islets, Pancreatic
Kidney
Liver
Lung
Nose
Ovary
Pancreas
Parathyroid Gland
Pituitary Gland
Preputial Gland
Prostate
Salivary Glands
Spleen
Testes
Thymus
Thyroid Gland
Urinary Bladder

NTP
LAB: Battelle Columbus
EXPERIMENT: 91014 TEST: 04
TEST TYPE: CHRONIC
CONT: N01-ES-15314
PATHOLOGIST: SELLS, D.

STATISTICAL ANALYSIS OF PRIMARY TUMORS
OLEIC ACID DIETHANOLAMINE CONDENSATE

CAGES FROM 0000 TO LAST CAGE
ROUTE: SKIN APPLICATION

REPORT: PEIRPT08
DATE: 09/23/97
TIME: 09:44:37

NTP C#: C91014
CAS: 93-83-4

SUMMARY OF STATISTICALLY SIGNIFICANT (P<=.05) RESULTS
IN THE ANALYSIS OF THE STUDY OF OLEIC ACID DIETHANOLAMINE CONDENSATE

	MALE MICE
ORGAN	MORPHOLOGY
All Organs	Hemangioma

	FEMALE MICE
ORGAN	MORPHOLOGY
Pituitary Gland: Pars Distalis or Unspecified Site	Adenoma
All Organs	Malignant Lymphoma: Histiocytic, Lymphocytic, Mixed, NOS, or Undifferentiated Cell Type
	Malignant and Benign Tumors

STATISTICAL ANALYSIS OF PRIMARY TUMORS IN MICE(B6C3F1) -- OLEIC ACID DIETHANOLAMINE CONDENSATE

TERMINAL SACRIFICE AT 105 WEEKS

	MALES			FEMALES		
DOSE	0 MG/KG	15 MG/KG	30 MG/KG	0 MG/KG	15 MG/KG	30 MG/KG
Adrenal Cortex Adenoma						
TUMOR RATES						
OVERALL (a)	2/49 (4%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
ADJUSTED (b)	4.9%	0.0%	0.0%	0.0%	0.0%	0.0%
TERMINAL (d)	2/41 (5%)	0/35 (0%)	0/34 (0%)	0/34 (0%)	0/30 (0%)	0/35 (0%)
FIRST INCIDENCE (DAYS)	729 (T)	---	---	---	---	---
STATISTICAL TESTS (f)						
LIFE TABLE	P=0.118N	P=0.274N	P=0.280N	(e)	(e)	(e)
INCIDENTAL TUMOR	P=0.118N	P=0.274N	P=0.280N	(e)	(e)	(e)
LOGISTIC REGRESSION	P=0.118N	P=0.274N	P=0.280N	(e)	(e)	(e)
COCHRAN-ARMITAGE	P=0.093N			(e)		
FISHER EXACT		P=0.242N	P=0.242N		(e)	(e)
Adrenal Medulla Pheochromocytoma Benign						
TUMOR RATES						
OVERALL (a)	0/49 (0%)	0/50 (0%)	0/50 (0%)	2/50 (4%)	0/50 (0%)	0/50 (0%)
ADJUSTED (b)	0.0%	0.0%	0.0%	5.9%	0.0%	0.0%
TERMINAL (d)	0/41 (0%)	0/35 (0%)	0/34 (0%)	2/34 (6%)	0/30 (0%)	0/35 (0%)
FIRST INCIDENCE (DAYS)	---	---	---	730 (T)	---	---
STATISTICAL TESTS (f)						
LIFE TABLE	(e)	(e)	(e)	P=0.098N	P=0.266N	P=0.232N
INCIDENTAL TUMOR	(e)	(e)	(e)	P=0.098N	P=0.266N	P=0.232N
LOGISTIC REGRESSION	(e)	(e)	(e)	P=0.098N	P=0.266N	P=0.232N
COCHRAN-ARMITAGE	(e)			P=0.095N		
FISHER EXACT		(e)	(e)		P=0.247N	P=0.247N

STATISTICAL ANALYSIS OF PRIMARY TUMORS IN MICE(B6C3F1) -- OLEIC ACID DIETHANOLAMINE CONDENSATE

TERMINAL SACRIFICE AT 105 WEEKS

	MALES			FEMALES		
DOSE	0 MG/KG	15 MG/KG	30 MG/KG	0 MG/KG	15 MG/KG	30 MG/KG
Bone Marrow Hemangiosarcoma						
TUMOR RATES						
OVERALL (a)	0/49 (0%)	0/50 (0%)	2/50 (4%)	1/50 (2%)	0/50 (0%)	0/50 (0%)
ADJUSTED (b)	0.0%	0.0%	5.9%	2.9%	0.0%	0.0%
TERMINAL (d)	0/41 (0%)	0/35 (0%)	2/34 (6%)	1/34 (3%)	0/30 (0%)	0/35 (0%)
FIRST INCIDENCE (DAYS)	---	---	729 (T)	730 (T)	---	---
STATISTICAL TESTS (f)						
LIFE TABLE	P=0.080	(e)	P=0.198	P=0.271N	P=0.525N	P=0.494N
INCIDENTAL TUMOR	P=0.080	(e)	P=0.198	P=0.271N	P=0.525N	P=0.494N
LOGISTIC REGRESSION	P=0.080	(e)	P=0.198	P=0.271N	P=0.525N	P=0.494N
COCHRAN-ARMITAGE	P=0.097			P=0.269N		
FISHER EXACT		(e)	P=0.253		P=0.500N	P=0.500N
Harderian Gland Adenoma						
TUMOR RATES	#	#	#	#	#	#
OVERALL (a)	2/49 (4%)	1/50 (2%)	4/50 (8%)	3/50 (6%)	1/50 (2%)	0/50 (0%)
ADJUSTED (b)	4.9%	2.9%	10.7%	8.1%	3.3%	0.0%
TERMINAL (d)	2/41 (5%)	1/35 (3%)	2/34 (6%)	2/34 (6%)	1/30 (3%)	0/35 (0%)
FIRST INCIDENCE (DAYS)	729 (T)	729 (T)	638	621	730 (T)	---
STATISTICAL TESTS (f)						
LIFE TABLE	P=0.186	P=0.555N	P=0.264	P=0.062N	P=0.338N	P=0.120N
INCIDENTAL TUMOR	P=0.248	P=0.555N	P=0.393	P=0.068N	P=0.326N	P=0.143N
LOGISTIC REGRESSION	P=0.218	P=0.555N	P=0.316	P=0.060N	P=0.308N	P=0.120N
COCHRAN-ARMITAGE	P=0.245			P=0.060N		
FISHER EXACT		P=0.492N	P=0.349		P=0.309N	P=0.121N

STATISTICAL ANALYSIS OF PRIMARY TUMORS IN MICE(B6C3F1) -- OLEIC ACID DIETHANOLAMINE CONDENSATE

TERMINAL SACRIFICE AT 105 WEEKS

	MALES			FEMALES		
DOSE	0 MG/KG	15 MG/KG	30 MG/KG	0 MG/KG	15 MG/KG	30 MG/KG
Harderian Gland Carcinoma or Adenoma						
TUMOR RATES	#	#	#	#	#	#
OVERALL (a)	2/49 (4%)	1/50 (2%)	4/50 (8%)	3/50 (6%)	2/50 (4%)	0/50 (0%)
ADJUSTED (b)	4.9%	2.9%	10.7%	8.1%	6.7%	0.0%
TERMINAL (d)	2/41 (5%)	1/35 (3%)	2/34 (6%)	2/34 (6%)	2/30 (7%)	0/35 (0%)
FIRST INCIDENCE (DAYS)	729 (T)	729 (T)	638	621	730 (T)	---
STATISTICAL TESTS (f)						
LIFE TABLE	P=0.186	P=0.555N	P=0.264	P=0.083N	P=0.543N	P=0.120N
INCIDENTAL TUMOR	P=0.248	P=0.555N	P=0.393	P=0.090N	P=0.532N	P=0.143N
LOGISTIC REGRESSION	P=0.218	P=0.555N	P=0.316	P=0.082N	P=0.509N	P=0.120N
COCHRAN-ARMITAGE	P=0.245			P=0.082N		
FISHER EXACT		P=0.492N	P=0.349		P=0.500N	P=0.121N
Intestine Small: Jejunum Carcinoma						
TUMOR RATES	#	#	#	#	#	#
OVERALL (a)	2/49 (4%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
ADJUSTED (b)	4.9%	0.0%	0.0%	0.0%	0.0%	0.0%
TERMINAL (d)	2/41 (5%)	0/35 (0%)	0/34 (0%)	0/34 (0%)	0/30 (0%)	0/35 (0%)
FIRST INCIDENCE (DAYS)	729 (T)	---	---	---	---	---
STATISTICAL TESTS (f)						
LIFE TABLE	P=0.118N	P=0.274N	P=0.280N	(e)	(e)	(e)
INCIDENTAL TUMOR	P=0.118N	P=0.274N	P=0.280N	(e)	(e)	(e)
LOGISTIC REGRESSION	P=0.118N	P=0.274N	P=0.280N	(e)	(e)	(e)
COCHRAN-ARMITAGE	P=0.093N			(e)		
FISHER EXACT		P=0.242N	P=0.242N		(e)	(e)

STATISTICAL ANALYSIS OF PRIMARY TUMORS IN MICE(B6C3F1) -- OLEIC ACID DIETHANOLAMINE CONDENSATE

TERMINAL SACRIFICE AT 105 WEEKS

	MALES			FEMALES		
DOSE	0 MG/KG	15 MG/KG	30 MG/KG	0 MG/KG	15 MG/KG	30 MG/KG
Intestine Small: Site Unspecified Carcinoma						
TUMOR RATES	#	#	#	#	#	#
OVERALL (a)	2/49 (4%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
ADJUSTED (b)	4.9%	0.0%	0.0%	0.0%	0.0%	0.0%
TERMINAL (d)	2/41 (5%)	0/35 (0%)	0/34 (0%)	0/34 (0%)	0/30 (0%)	0/35 (0%)
FIRST INCIDENCE (DAYS)	729 (T)	---	---	---	---	---
STATISTICAL TESTS (f)						
LIFE TABLE	P=0.118N	P=0.274N	P=0.280N	(e)	(e)	(e)
INCIDENTAL TUMOR	P=0.118N	P=0.274N	P=0.280N	(e)	(e)	(e)
LOGISTIC REGRESSION	P=0.118N	P=0.274N	P=0.280N	(e)	(e)	(e)
COCHRAN-ARMITAGE	P=0.093N			(e)		
FISHER EXACT		P=0.242N	P=0.242N		(e)	(e)
Islets, Pancreatic Adenoma						
TUMOR RATES						
OVERALL (a)	0/49 (0%)	2/50 (4%)	2/50 (4%)	1/49 (2%)	0/50 (0%)	1/50 (2%)
ADJUSTED (b)	0.0%	5.7%	5.9%	2.9%	0.0%	2.6%
TERMINAL (d)	0/41 (0%)	2/35 (6%)	2/34 (6%)	1/34 (3%)	0/30 (0%)	0/35 (0%)
FIRST INCIDENCE (DAYS)	---	729 (T)	729 (T)	730 (T)	---	692
STATISTICAL TESTS (f)						
LIFE TABLE	P=0.140	P=0.204	P=0.198	P=0.655N	P=0.525N	P=0.751N
INCIDENTAL TUMOR	P=0.140	P=0.204	P=0.198	P=0.670N	P=0.525N	P=0.757N
LOGISTIC REGRESSION	P=0.140	P=0.204	P=0.198	P=0.664N	P=0.525N	P=0.758N
COCHRAN-ARMITAGE	P=0.180			P=0.665N		
FISHER EXACT		P=0.253	P=0.253		P=0.495N	P=0.747N

STATISTICAL ANALYSIS OF PRIMARY TUMORS IN MICE(B6C3F1) -- OLEIC ACID DIETHANOLAMINE CONDENSATE

TERMINAL SACRIFICE AT 105 WEEKS

DOSE	MALES 0 MG/KG	MALES 15 MG/KG	MALES 30 MG/KG	FEMALES 0 MG/KG	FEMALES 15 MG/KG	FEMALES 30 MG/KG
Islets, Pancreatic Carcinoma or Adenoma						
TUMOR RATES						
OVERALL (a)	0/49 (0%)	2/50 (4%)	2/50 (4%)	1/49 (2%)	1/50 (2%)	1/50 (2%)
ADJUSTED (b)	0.0%	5.7%	5.9%	2.9%	3.3%	2.6%
TERMINAL (d)	0/41 (0%)	2/35 (6%)	2/34 (6%)	1/34 (3%)	1/30 (3%)	0/35 (0%)
FIRST INCIDENCE (DAYS)	---	729 (T)	729 (T)	730 (T)	730 (T)	692
STATISTICAL TESTS (f)						
LIFE TABLE	P=0.140	P=0.204	P=0.198	P=0.626N	P=0.734	P=0.751N
INCIDENTAL TUMOR	P=0.140	P=0.204	P=0.198	P=0.635N	P=0.734	P=0.757N
LOGISTIC REGRESSION	P=0.140	P=0.204	P=0.198	P=0.633N	P=0.734	P=0.758N
COCHRAN-ARMITAGE	P=0.180			P=0.634N		
FISHER EXACT		P=0.253	P=0.253		P=0.747N	P=0.747N
Liver Hemangiosarcoma						
TUMOR RATES						
OVERALL (a)	1/49 (2%)	4/50 (8%)	2/50 (4%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
ADJUSTED (b)	2.4%	11.4%	5.0%	0.0%	0.0%	0.0%
TERMINAL (d)	1/41 (2%)	4/35 (11%)	1/34 (3%)	0/34 (0%)	0/30 (0%)	0/35 (0%)
FIRST INCIDENCE (DAYS)	729 (T)	729 (T)	468	---	---	---
STATISTICAL TESTS (f)						
LIFE TABLE	P=0.341	P=0.135	P=0.459	(e)	(e)	(e)
INCIDENTAL TUMOR	P=0.364	P=0.135	P=0.490	(e)	(e)	(e)
LOGISTIC REGRESSION	P=0.416	P=0.135	P=0.572	(e)	(e)	(e)
COCHRAN-ARMITAGE	P=0.415			(e)		
FISHER EXACT		P=0.187	P=0.508		(e)	(e)

STATISTICAL ANALYSIS OF PRIMARY TUMORS IN MICE(B6C3F1) -- OLEIC ACID DIETHANOLAMINE CONDENSATE

TERMINAL SACRIFICE AT 105 WEEKS

	MALES			FEMALES		
DOSE	0 MG/KG	15 MG/KG	30 MG/KG	0 MG/KG	15 MG/KG	30 MG/KG
Liver Hepatocellular Adenoma						
TUMOR RATES						
OVERALL (a)	22/49 (45%)	22/50 (44%)	22/50 (44%)	26/50 (52%)	30/50 (60%)	28/50 (56%)
ADJUSTED (b)	50.9%	57.7%	55.8%	64.7%	76.2%	71.7%
TERMINAL (d)	20/41 (49%)	19/35 (54%)	17/34 (50%)	20/34 (59%)	21/30 (70%)	24/35 (69%)
FIRST INCIDENCE (DAYS)	456	660	356	578	501	659
STATISTICAL TESTS (f)						
LIFE TABLE	P=0.251	P=0.330	P=0.301	P=0.443	P=0.143	P=0.476
INCIDENTAL TUMOR	P=0.357	P=0.316	P=0.477	P=0.356	P=0.225	P=0.382
LOGISTIC REGRESSION	P=0.469	P=0.563	P=0.566	P=0.376	P=0.247	P=0.423
COCHRAN-ARMITAGE	P=0.505N			P=0.381		
FISHER EXACT		P=0.545N	P=0.545N		P=0.273	P=0.421
Liver Hepatocellular Carcinoma						
TUMOR RATES						
OVERALL (a)	9/49 (18%)	9/50 (18%)	13/50 (26%)	5/50 (10%)	10/50 (20%)	7/50 (14%)
ADJUSTED (b)	19.3%	21.7%	31.9%	13.2%	26.1%	18.2%
TERMINAL (d)	4/41 (10%)	4/35 (11%)	7/34 (21%)	3/34 (9%)	4/30 (13%)	4/35 (11%)
FIRST INCIDENCE (DAYS)	452	547	537	562	585	659
STATISTICAL TESTS (f)						
LIFE TABLE	P=0.122	P=0.514	P=0.148	P=0.362	P=0.112	P=0.400
INCIDENTAL TUMOR	P=0.289	P=0.315N	P=0.344	P=0.269	P=0.173	P=0.331
LOGISTIC REGRESSION	P=0.393	P=0.423N	P=0.516	P=0.338	P=0.131	P=0.381
COCHRAN-ARMITAGE	P=0.208			P=0.336		
FISHER EXACT		P=0.584N	P=0.251		P=0.131	P=0.380

STATISTICAL ANALYSIS OF PRIMARY TUMORS IN MICE(B6C3F1) -- OLEIC ACID DIETHANOLAMINE CONDENSATE

TERMINAL SACRIFICE AT 105 WEEKS

	MALES			FEMALES		
DOSE	0 MG/KG	15 MG/KG	30 MG/KG	0 MG/KG	15 MG/KG	30 MG/KG
Liver Hepatocellular Carcinoma or Hepatoblastoma						
TUMOR RATES						
OVERALL (a)	9/49 (18%)	9/50 (18%)	13/50 (26%)	6/50 (12%)	10/50 (20%)	7/50 (14%)
ADJUSTED (b)	19.3%	21.7%	31.9%	15.1%	26.1%	18.2%
TERMINAL (d)	4/41 (10%)	4/35 (11%)	7/34 (21%)	3/34 (9%)	4/30 (13%)	4/35 (11%)
FIRST INCIDENCE (DAYS)	452	547	537	562	585	659
STATISTICAL TESTS (f)						
LIFE TABLE	P=0.122	P=0.514	P=0.148	P=0.465	P=0.180	P=0.516
INCIDENTAL TUMOR	P=0.289	P=0.315N	P=0.344	P=0.363	P=0.266	P=0.428
LOGISTIC REGRESSION	P=0.393	P=0.423N	P=0.516	P=0.446	P=0.207	P=0.502
COCHRAN-ARMITAGE	P=0.208			P=0.445		
FISHER EXACT		P=0.584N	P=0.251		P=0.207	P=0.500
Liver Hepatocellular Carcinoma or Hepatocellular Adenoma						
TUMOR RATES						
OVERALL (a)	29/49 (59%)	27/50 (54%)	30/50 (60%)	28/50 (56%)	35/50 (70%)	29/50 (58%)
ADJUSTED (b)	60.3%	65.5%	69.5%	67.9%	80.8%	72.4%
TERMINAL (d)	22/41 (54%)	21/35 (60%)	21/34 (62%)	21/34 (62%)	22/30 (73%)	24/35 (69%)
FIRST INCIDENCE (DAYS)	452	547	356	562	501	659
STATISTICAL TESTS (f)						
LIFE TABLE	P=0.174	P=0.455	P=0.206	P=0.518	P=0.063	P=0.553
INCIDENTAL TUMOR	P=0.418	P=0.487N	P=0.547	P=0.398	P=0.094	P=0.445
LOGISTIC REGRESSION	P=0.458	P=0.388N	P=0.561	P=0.459	P=0.097	P=0.504
COCHRAN-ARMITAGE	P=0.506			P=0.459		
FISHER EXACT		P=0.376N	P=0.548		P=0.107	P=0.500

STATISTICAL ANALYSIS OF PRIMARY TUMORS IN MICE(B6C3F1) -- OLEIC ACID DIETHANOLAMINE CONDENSATE

TERMINAL SACRIFICE AT 105 WEEKS

	MALES			FEMALES		
DOSE	0 MG/KG	15 MG/KG	30 MG/KG	0 MG/KG	15 MG/KG	30 MG/KG
Liver Hepatocellular Carcinoma, Hepatocellular Adenoma, or Hepatoblastoma						
TUMOR RATES						
OVERALL (a)	29/49 (59%)	27/50 (54%)	30/50 (60%)	28/50 (56%)	35/50 (70%)	29/50 (58%)
ADJUSTED (b)	60.3%	65.5%	69.5%	67.9%	80.8%	72.4%
TERMINAL (d)	22/41 (54%)	21/35 (60%)	21/34 (62%)	21/34 (62%)	22/30 (73%)	24/35 (69%)
FIRST INCIDENCE (DAYS)	452	547	356	562	501	659
STATISTICAL TESTS (f)						
LIFE TABLE	P=0.174	P=0.455	P=0.206	P=0.518	P=0.063	P=0.553
INCIDENTAL TUMOR	P=0.418	P=0.487N	P=0.547	P=0.398	P=0.094	P=0.445
LOGISTIC REGRESSION	P=0.458	P=0.388N	P=0.561	P=0.459	P=0.097	P=0.504
COCHRAN-ARMITAGE	P=0.506			P=0.459		
FISHER EXACT		P=0.376N	P=0.548		P=0.107	P=0.500
Liver Hepatocholangiocarcinoma						
TUMOR RATES						
OVERALL (a)	0/49 (0%)	2/50 (4%)	1/50 (2%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
ADJUSTED (b)	0.0%	4.9%	2.3%	0.0%	0.0%	0.0%
TERMINAL (d)	0/41 (0%)	0/35 (0%)	0/34 (0%)	0/34 (0%)	0/30 (0%)	0/35 (0%)
FIRST INCIDENCE (DAYS)	---	686	572	---	---	---
STATISTICAL TESTS (f)						
LIFE TABLE	P=0.326	P=0.227	P=0.496	(e)	(e)	(e)
INCIDENTAL TUMOR	P=0.476	P=0.362	P=0.872	(e)	(e)	(e)
LOGISTIC REGRESSION	P=0.395	P=0.244	P=0.592	(e)	(e)	(e)
COCHRAN-ARMITAGE	P=0.366			(e)		
FISHER EXACT		P=0.253	P=0.505		(e)	(e)

STATISTICAL ANALYSIS OF PRIMARY TUMORS IN MICE(B6C3F1) -- OLEIC ACID DIETHANOLAMINE CONDENSATE

TERMINAL SACRIFICE AT 105 WEEKS

DOSE	MALES 0 MG/KG	MALES 15 MG/KG	MALES 30 MG/KG	FEMALES 0 MG/KG	FEMALES 15 MG/KG	FEMALES 30 MG/KG
Lung Alveolar/Bronchiolar Adenoma						
TUMOR RATES						
OVERALL (a)	7/49 (14%)	8/50 (16%)	5/50 (10%)	1/50 (2%)	1/50 (2%)	4/50 (8%)
ADJUSTED (b)	16.4%	21.2%	13.6%	2.3%	3.3%	11.4%
TERMINAL (d)	6/41 (15%)	6/35 (17%)	4/34 (12%)	0/34 (0%)	1/30 (3%)	4/35 (11%)
FIRST INCIDENCE (DAYS)	452	621	416	615	730 (T)	730 (T)
STATISTICAL TESTS (f)						
LIFE TABLE	P=0.456N	P=0.390	P=0.493N	P=0.110	P=0.749	P=0.187
INCIDENTAL TUMOR	P=0.367N	P=0.448	P=0.456N	P=0.097	P=0.758N	P=0.164
LOGISTIC REGRESSION	P=0.316N	P=0.511	P=0.328N	P=0.102	P=0.762	P=0.180
COCHRAN-ARMITAGE	P=0.315N			P=0.101		
FISHER EXACT		P=0.517	P=0.365N		P=0.753N	P=0.181
Lung Alveolar/Bronchiolar Carcinoma						
TUMOR RATES						
OVERALL (a)	7/49 (14%)	10/50 (20%)	9/50 (18%)	3/50 (6%)	2/50 (4%)	3/50 (6%)
ADJUSTED (b)	17.1%	25.5%	25.7%	8.0%	5.4%	8.3%
TERMINAL (d)	7/41 (17%)	7/35 (20%)	8/34 (24%)	2/34 (6%)	1/30 (3%)	2/35 (6%)
FIRST INCIDENCE (DAYS)	729 (T)	547	691	578	585	723
STATISTICAL TESTS (f)						
LIFE TABLE	P=0.212	P=0.204	P=0.244	P=0.575N	P=0.526N	P=0.649N
INCIDENTAL TUMOR	P=0.291	P=0.350	P=0.253	P=0.548	P=0.506N	P=0.627
LOGISTIC REGRESSION	P=0.274	P=0.292	P=0.255	P=0.587N	P=0.501N	P=0.662N
COCHRAN-ARMITAGE	P=0.363			P=0.588N		
FISHER EXACT		P=0.314	P=0.410		P=0.500N	P=0.661N

STATISTICAL ANALYSIS OF PRIMARY TUMORS IN MICE(B6C3F1) -- OLEIC ACID DIETHANOLAMINE CONDENSATE

TERMINAL SACRIFICE AT 105 WEEKS

	MALES			FEMALES		
DOSE	0 MG/KG	15 MG/KG	30 MG/KG	0 MG/KG	15 MG/KG	30 MG/KG
Lung Alveolar/Bronchiolar Carcinoma or Alveolar/Bronchiolar Adenoma						
TUMOR RATES						
OVERALL (a)	12/49 (24%)	18/50 (36%)	13/50 (26%)	4/50 (8%)	3/50 (6%)	7/50 (14%)
ADJUSTED (b)	28.3%	44.3%	35.6%	10.1%	8.7%	19.4%
TERMINAL (d)	11/41 (27%)	13/35 (37%)	11/34 (32%)	2/34 (6%)	2/30 (7%)	6/35 (17%)
FIRST INCIDENCE (DAYS)	452	547	416	578	585	723
STATISTICAL TESTS (f)						
LIFE TABLE	P=0.260	P=0.070	P=0.308	P=0.212	P=0.530N	P=0.278
INCIDENTAL TUMOR	P=0.395	P=0.146	P=0.340	P=0.167	P=0.503N	P=0.226
LOGISTIC REGRESSION	P=0.423	P=0.141	P=0.471	P=0.196	P=0.501N	P=0.263
COCHRAN-ARMITAGE	P=0.481			P=0.195		
FISHER EXACT		P=0.152	P=0.523		P=0.500N	P=0.262
Ovary Cystadenoma						
TUMOR RATES						
OVERALL (a)				3/50 (6%)	2/50 (4%)	0/50 (0%)
ADJUSTED (b)				7.0%	6.5%	0.0%
TERMINAL (d)				1/34 (3%)	1/30 (3%)	0/35 (0%)
FIRST INCIDENCE (DAYS)				150	711	---
STATISTICAL TESTS (f)						
LIFE TABLE				P=0.086N	P=0.532N	P=0.124N
INCIDENTAL TUMOR				P=0.132N	P=0.477N	P=0.280N
LOGISTIC REGRESSION				P=0.093N	P=0.525N	P=0.142N
COCHRAN-ARMITAGE				P=0.082N		
FISHER EXACT					P=0.500N	P=0.121N

STATISTICAL ANALYSIS OF PRIMARY TUMORS IN MICE(B6C3F1) -- OLEIC ACID DIETHANOLAMINE CONDENSATE

TERMINAL SACRIFICE AT 105 WEEKS

DOSE	MALES 0 MG/KG	MALES 15 MG/KG	MALES 30 MG/KG	FEMALES 0 MG/KG	FEMALES 15 MG/KG	FEMALES 30 MG/KG
Ovary Teratoma Benign						
TUMOR RATES						
OVERALL (a)				0/50 (0%)	2/50 (4%)	0/50 (0%)
ADJUSTED (b)				0.0%	5.5%	0.0%
TERMINAL (d)				0/34 (0%)	0/30 (0%)	0/35 (0%)
FIRST INCIDENCE (DAYS)				---	662	---
STATISTICAL TESTS (f)						
LIFE TABLE				P=0.663N	P=0.225	(e)
INCIDENTAL TUMOR				P=0.655	P=0.316	(e)
LOGISTIC REGRESSION				P=0.667	P=0.237	(e)
COCHRAN-ARMITAGE				P=0.669		
FISHER EXACT					P=0.247	(e)
Pituitary Gland: Pars Distalis or Unspecified Site Adenoma						
TUMOR RATES						
OVERALL (a)	0/49 (0%)	0/47 (0%)	0/50 (0%)	9/50 (18%)	6/50 (12%)	3/50 (6%)
ADJUSTED (b)	0.0%	0.0%	0.0%	25.4%	17.3%	8.6%
TERMINAL (d)	0/41 (0%)	0/33 (0%)	0/34 (0%)	8/34 (24%)	4/30 (13%)	3/33 (9%)
FIRST INCIDENCE (DAYS)	---	---	---	660	616	730 (T)
STATISTICAL TESTS (f)						
LIFE TABLE	(e)	(e)	(e)	P=0.044N*	P=0.363N	P=0.055N
INCIDENTAL TUMOR	(e)	(e)	(e)	P=0.049N*	P=0.328N	P=0.057N
LOGISTIC REGRESSION	(e)	(e)	(e)	P=0.044N*	P=0.302N	P=0.056N
COCHRAN-ARMITAGE	(e)			P=0.045N*		
FISHER EXACT		(e)	(e)		P=0.288N	P=0.061N

STATISTICAL ANALYSIS OF PRIMARY TUMORS IN MICE(B6C3F1) -- OLEIC ACID DIETHANOLAMINE CONDENSATE

TERMINAL SACRIFICE AT 105 WEEKS

DOSE	MALES 0 MG/KG	MALES 15 MG/KG	MALES 30 MG/KG	FEMALES 0 MG/KG	FEMALES 15 MG/KG	FEMALES 30 MG/KG
Pituitary Gland: Pars Intermedia Adenoma						
TUMOR RATES						
OVERALL (a)	0/49 (0%)	0/47 (0%)	0/50 (0%)	0/50 (0%)	3/50 (6%)	1/50 (2%)
ADJUSTED (b)	0.0%	0.0%	0.0%	0.0%	8.7%	2.9%
TERMINAL (d)	0/41 (0%)	0/33 (0%)	0/34 (0%)	0/34 (0%)	2/30 (7%)	1/35 (3%)
FIRST INCIDENCE (DAYS)	---	---	---	---	604	730 (T)
STATISTICAL TESTS (f)						
LIFE TABLE	(e)	(e)	(e)	P=0.389	P=0.111	P=0.506
INCIDENTAL TUMOR	(e)	(e)	(e)	P=0.358	P=0.117	P=0.506
LOGISTIC REGRESSION	(e)	(e)	(e)	P=0.379	P=0.120	P=0.506
COCHRAN-ARMITAGE	(e)			P=0.378		
FISHER EXACT		(e)	(e)		P=0.121	P=0.500
Skin Fibrosarcoma						
TUMOR RATES	#	#	#	#	#	#
OVERALL (a)	0/49 (0%)	0/50 (0%)	1/50 (2%)	2/50 (4%)	3/50 (6%)	2/50 (4%)
ADJUSTED (b)	0.0%	0.0%	2.2%	5.4%	7.6%	5.7%
TERMINAL (d)	0/41 (0%)	0/35 (0%)	0/34 (0%)	1/34 (3%)	0/30 (0%)	2/35 (6%)
FIRST INCIDENCE (DAYS)	---	---	549	675	585	730 (T)
STATISTICAL TESTS (f)						
LIFE TABLE	P=0.266	(e)	P=0.496	P=0.584N	P=0.476	P=0.688N
INCIDENTAL TUMOR	P=0.454	(e)	P=0.872	P=0.555	P=0.601	P=0.688
LOGISTIC REGRESSION	P=0.297	(e)	P=0.609	P=0.593N	P=0.500	P=0.693N
COCHRAN-ARMITAGE	P=0.272			P=0.594		
FISHER EXACT		(e)	P=0.505		P=0.500	P=0.691N

STATISTICAL ANALYSIS OF PRIMARY TUMORS IN MICE(B6C3F1) -- OLEIC ACID DIETHANOLAMINE CONDENSATE

TERMINAL SACRIFICE AT 105 WEEKS

	MALES			FEMALES		
DOSE	0 MG/KG	15 MG/KG	30 MG/KG	0 MG/KG	15 MG/KG	30 MG/KG
Spleen Hemangiosarcoma						
TUMOR RATES						
OVERALL (a)	3/49 (6%)	5/50 (10%)	2/50 (4%)	0/50 (0%)	0/50 (0%)	0/50 (0%)
ADJUSTED (b)	7.3%	13.6%	5.0%	0.0%	0.0%	0.0%
TERMINAL (d)	3/41 (7%)	4/35 (11%)	1/34 (3%)	0/34 (0%)	0/30 (0%)	0/35 (0%)
FIRST INCIDENCE (DAYS)	729 (T)	697	468	---	---	---
STATISTICAL TESTS (f)						
LIFE TABLE	P=0.510N	P=0.281	P=0.566N	(e)	(e)	(e)
INCIDENTAL TUMOR	P=0.482N	P=0.318	P=0.542N	(e)	(e)	(e)
LOGISTIC REGRESSION	P=0.423N	P=0.319	P=0.462N	(e)	(e)	(e)
COCHRAN-ARMITAGE	P=0.410N			(e)		
FISHER EXACT		P=0.369	P=0.490N		(e)	(e)
Stomach, Forestomach Squamous Cell Carcinoma or Papilloma Squamous						
TUMOR RATES	#	#	#	#	#	#
OVERALL (a)	0/49 (0%)	3/50 (6%)	0/50 (0%)	4/50 (8%)	2/50 (4%)	4/50 (8%)
ADJUSTED (b)	0.0%	7.9%	0.0%	11.8%	6.7%	11.4%
TERMINAL (d)	0/41 (0%)	2/35 (6%)	0/34 (0%)	4/34 (12%)	2/30 (7%)	4/35 (11%)
FIRST INCIDENCE (DAYS)	---	628	---	730 (T)	730 (T)	730 (T)
STATISTICAL TESTS (f)						
LIFE TABLE	P=0.595	P=0.104	(e)	P=0.563N	P=0.395N	P=0.629N
INCIDENTAL TUMOR	P=0.560N	P=0.178	(e)	P=0.563N	P=0.395N	P=0.629N
LOGISTIC REGRESSION	P=0.638N	P=0.125	(e)	P=0.563N	P=0.395N	P=0.629N
COCHRAN-ARMITAGE	P=0.634N			P=0.579		
FISHER EXACT		P=0.125	(e)		P=0.339N	P=0.643N

STATISTICAL ANALYSIS OF PRIMARY TUMORS IN MICE(B6C3F1) -- OLEIC ACID DIETHANOLAMINE CONDENSATE

TERMINAL SACRIFICE AT 105 WEEKS

	MALES			FEMALES		
DOSE	0 MG/KG	15 MG/KG	30 MG/KG	0 MG/KG	15 MG/KG	30 MG/KG
Stomach, Forestomach Squamous Cell Papilloma						
TUMOR RATES	#	#	#	#	#	#
OVERALL (a)	0/49 (0%)	2/50 (4%)	0/50 (0%)	3/50 (6%)	2/50 (4%)	4/50 (8%)
ADJUSTED (b)	0.0%	5.1%	0.0%	8.8%	6.7%	11.4%
TERMINAL (d)	0/41 (0%)	1/35 (3%)	0/34 (0%)	3/34 (9%)	2/30 (7%)	4/35 (11%)
FIRST INCIDENCE (DAYS)	---	628	---	730 (T)	730 (T)	730 (T)
STATISTICAL TESTS (f)						
LIFE TABLE	P=0.637	P=0.220	(e)	P=0.432	P=0.558N	P=0.516
INCIDENTAL TUMOR	P=0.552N	P=0.382	(e)	P=0.432	P=0.558N	P=0.516
LOGISTIC REGRESSION	P=0.656N	P=0.250	(e)	P=0.432	P=0.558N	P=0.516
COCHRAN-ARMITAGE	P=0.665N			P=0.417		
FISHER EXACT		P=0.253	(e)		P=0.500N	P=0.500
Thyroid Gland: Follicular Cell Adenoma						
TUMOR RATES						
OVERALL (a)	2/49 (4%)	0/50 (0%)	1/50 (2%)	2/50 (4%)	0/50 (0%)	0/50 (0%)
ADJUSTED (b)	4.9%	0.0%	2.4%	5.2%	0.0%	0.0%
TERMINAL (d)	2/41 (5%)	0/35 (0%)	0/34 (0%)	1/34 (3%)	0/30 (0%)	0/35 (0%)
FIRST INCIDENCE (DAYS)	729 (T)	---	606	615	---	---
STATISTICAL TESTS (f)						
LIFE TABLE	P=0.402N	P=0.274N	P=0.551N	P=0.098N	P=0.251N	P=0.239N
INCIDENTAL TUMOR	P=0.271N	P=0.274N	P=0.358N	P=0.108N	P=0.236N	P=0.280N
LOGISTIC REGRESSION	P=0.349N	P=0.274N	P=0.486N	P=0.096N	P=0.238N	P=0.239N
COCHRAN-ARMITAGE	P=0.355N			P=0.095N		
FISHER EXACT		P=0.242N	P=0.492N		P=0.247N	P=0.247N

DATE: 09/23/97 EXPERIMENT: 91014 TEST: 04

STATISTICAL ANALYSIS OF PRIMARY TUMORS IN MICE(B6C3F1) -- OLEIC ACID DIETHANOLAMINE CONDENSATE

TERMINAL SACRIFICE AT 105 WEEKS

DOSE	MALES 0 MG/KG	MALES 15 MG/KG	MALES 30 MG/KG	FEMALES 0 MG/KG	FEMALES 15 MG/KG	FEMALES 30 MG/KG
Thyroid Gland: Follicular Cell Carcinoma or Adenoma						
TUMOR RATES						
OVERALL (a)	3/49 (6%)	0/50 (0%)	1/50 (2%)	2/50 (4%)	0/50 (0%)	0/50 (0%)
ADJUSTED (b)	7.3%	0.0%	2.4%	5.2%	0.0%	0.0%
TERMINAL (d)	3/41 (7%)	0/35 (0%)	0/34 (0%)	1/34 (3%)	0/30 (0%)	0/35 (0%)
FIRST INCIDENCE (DAYS)	729 (T)	---	606	615	---	---
STATISTICAL TESTS (f)						
LIFE TABLE	P=0.215N	P=0.150N	P=0.364N	P=0.098N	P=0.251N	P=0.239N
INCIDENTAL TUMOR	P=0.130N	P=0.150N	P=0.210N	P=0.108N	P=0.236N	P=0.280N
LOGISTIC REGRESSION	P=0.174N	P=0.150N	P=0.303N	P=0.096N	P=0.238N	P=0.239N
COCHRAN-ARMITAGE	P=0.171N			P=0.095N		
FISHER EXACT		P=0.117N	P=0.301N		P=0.247N	P=0.247N
Uterus Hemangioma						
TUMOR RATES				#	#	#
OVERALL (a)				0/50 (0%)	2/50 (4%)	0/50 (0%)
ADJUSTED (b)				0.0%	6.7%	0.0%
TERMINAL (d)				0/34 (0%)	2/30 (7%)	0/35 (0%)
FIRST INCIDENCE (DAYS)				---	730 (T)	---
STATISTICAL TESTS (f)						
LIFE TABLE				P=0.659N	P=0.211	(e)
INCIDENTAL TUMOR				P=0.659N	P=0.211	(e)
LOGISTIC REGRESSION				P=0.659N	P=0.211	(e)
COCHRAN-ARMITAGE				P=0.669		
FISHER EXACT					P=0.247	(e)

DATE: 09/23/97

EXPERIMENT: 91014 TEST: 04
STATISTICAL ANALYSIS OF PRIMARY TUMORS IN MICE(B6C3F1) -- OLEIC ACID DIETHANOLAMINE CONDENSATE

TERMINAL SACRIFICE AT 105 WEEKS

DOSE	MALES 0 MG/KG	MALES 15 MG/KG	MALES 30 MG/KG	FEMALES 0 MG/KG	FEMALES 15 MG/KG	FEMALES 30 MG/KG
Uterus Polyp Stromal						
TUMOR RATES				#	#	#
OVERALL (a)				1/50 (2%)	2/50 (4%)	0/50 (0%)
ADJUSTED (b)				2.4%	5.4%	0.0%
TERMINAL (d)				0/34 (0%)	0/30 (0%)	0/35 (0%)
FIRST INCIDENCE (DAYS)				621	641	---
STATISTICAL TESTS (f)						
LIFE TABLE				P=0.360N	P=0.493	P=0.500N
INCIDENTAL TUMOR				P=0.431N	P=0.578	P=0.581N
LOGISTIC REGRESSION				P=0.366N	P=0.498	P=0.513N
COCHRAN-ARMITAGE				P=0.360N		
FISHER EXACT					P=0.500	P=0.500N
Uterus Sarcoma Stromal or Polyp Stromal						
TUMOR RATES				#	#	#
OVERALL (a)				2/50 (4%)	2/50 (4%)	0/50 (0%)
ADJUSTED (b)				5.3%	5.4%	0.0%
TERMINAL (d)				1/34 (3%)	0/30 (0%)	0/35 (0%)
FIRST INCIDENCE (DAYS)				621	641	---
STATISTICAL TESTS (f)						
LIFE TABLE				P=0.178N	P=0.675	P=0.237N
INCIDENTAL TUMOR				P=0.210N	P=0.647N	P=0.280N
LOGISTIC REGRESSION				P=0.177N	P=0.695	P=0.238N
COCHRAN-ARMITAGE				P=0.176N		
FISHER EXACT					P=0.691N	P=0.247N

STATISTICAL ANALYSIS OF PRIMARY TUMORS IN MICE(B6C3F1) -- OLEIC ACID DIETHANOLAMINE CONDENSATE

TERMINAL SACRIFICE AT 105 WEEKS

DOSE	MALES 0 MG/KG	MALES 15 MG/KG	MALES 30 MG/KG	FEMALES 0 MG/KG	FEMALES 15 MG/KG	FEMALES 30 MG/KG
All Organs Hemangioma						
TUMOR RATES	#	#	#	#	#	#
OVERALL (a)	0/49 (0%)	1/50 (2%)	4/50 (8%)	1/50 (2%)	3/50 (6%)	2/50 (4%)
ADJUSTED (b)	0.0%	2.6%	10.8%	2.9%	9.1%	5.7%
TERMINAL (d)	0/41 (0%)	0/35 (0%)	2/34 (6%)	1/34 (3%)	2/30 (7%)	2/35 (6%)
FIRST INCIDENCE (DAYS)	---	709	638	730 (T)	659	730 (T)
STATISTICAL TESTS (f)						
LIFE TABLE	P=0.019 *	P=0.485	P=0.048 *	P=0.413	P=0.272	P=0.510
INCIDENTAL TUMOR	P=0.026 *	P=0.612	P=0.093	P=0.402	P=0.303	P=0.510
LOGISTIC REGRESSION	P=0.024 *	P=0.500	P=0.059	P=0.404	P=0.294	P=0.510
COCHRAN-ARMITAGE	P=0.027 *			P=0.399		
FISHER EXACT		P=0.505	P=0.061		P=0.309	P=0.500
All Organs Hemangiosarcoma						
TUMOR RATES	#	#	#	#	#	#
OVERALL (a)	4/49 (8%)	7/50 (14%)	4/50 (8%)	1/50 (2%)	0/50 (0%)	0/50 (0%)
ADJUSTED (b)	9.8%	19.2%	10.7%	2.9%	0.0%	0.0%
TERMINAL (d)	4/41 (10%)	6/35 (17%)	3/34 (9%)	1/34 (3%)	0/30 (0%)	0/35 (0%)
FIRST INCIDENCE (DAYS)	729 (T)	697	468	730 (T)	---	---
STATISTICAL TESTS (f)						
LIFE TABLE	P=0.450	P=0.184	P=0.552	P=0.271N	P=0.525N	P=0.494N
INCIDENTAL TUMOR	P=0.473	P=0.209	P=0.572	P=0.271N	P=0.525N	P=0.494N
LOGISTIC REGRESSION	P=0.534	P=0.216	P=0.642N	P=0.271N	P=0.525N	P=0.494N
COCHRAN-ARMITAGE	P=0.553N			P=0.269N		
FISHER EXACT		P=0.274	P=0.631N		P=0.500N	P=0.500N

STATISTICAL ANALYSIS OF PRIMARY TUMORS IN MICE(B6C3F1) -- OLEIC ACID DIETHANOLAMINE CONDENSATE

TERMINAL SACRIFICE AT 105 WEEKS

	MALES			FEMALES		
DOSE	0 MG/KG	15 MG/KG	30 MG/KG	0 MG/KG	15 MG/KG	30 MG/KG
All Organs Hemangiosarcoma or Hemangioma						
TUMOR RATES	#	#	#	#	#	#
OVERALL (a)	4/49 (8%)	8/50 (16%)	8/50 (16%)	2/50 (4%)	3/50 (6%)	2/50 (4%)
ADJUSTED (b)	9.8%	21.3%	20.8%	5.9%	9.1%	5.7%
TERMINAL (d)	4/41 (10%)	6/35 (17%)	5/34 (15%)	2/34 (6%)	2/30 (7%)	2/35 (6%)
FIRST INCIDENCE (DAYS)	729 (T)	697	468	730 (T)	659	730 (T)
STATISTICAL TESTS (f)						
LIFE TABLE	P=0.091	P=0.120	P=0.116	P=0.579N	P=0.452	P=0.685N
INCIDENTAL TUMOR	P=0.125	P=0.157	P=0.180	P=0.590N	P=0.487	P=0.685N
LOGISTIC REGRESSION	P=0.131	P=0.146	P=0.175	P=0.588N	P=0.483	P=0.685N
COCHRAN-ARMITAGE	P=0.161			P=0.594		
FISHER EXACT		P=0.188	P=0.188		P=0.500	P=0.691N
All Organs Histiocytic Sarcoma						
TUMOR RATES	#	#	#	#	#	#
OVERALL (a)	0/49 (0%)	1/50 (2%)	0/50 (0%)	3/50 (6%)	2/50 (4%)	1/50 (2%)
ADJUSTED (b)	0.0%	2.1%	0.0%	6.9%	6.7%	2.2%
TERMINAL (d)	0/41 (0%)	0/35 (0%)	0/34 (0%)	1/34 (3%)	2/30 (7%)	0/35 (0%)
FIRST INCIDENCE (DAYS)	---	567	---	435	730 (T)	552
STATISTICAL TESTS (f)						
LIFE TABLE	P=0.729	P=0.509	(e)	P=0.226N	P=0.534N	P=0.312N
INCIDENTAL TUMOR	P=0.546N	P=0.846	(e)	P=0.143N	P=0.536N	P=0.179N
LOGISTIC REGRESSION	P=0.704N	P=0.578	(e)	P=0.241N	P=0.512N	P=0.348N
COCHRAN-ARMITAGE	P=0.728N			P=0.222N		
FISHER EXACT		P=0.505	(e)		P=0.500N	P=0.309N

STATISTICAL ANALYSIS OF PRIMARY TUMORS IN MICE(B6C3F1) -- OLEIC ACID DIETHANOLAMINE CONDENSATE

TERMINAL SACRIFICE AT 105 WEEKS

	MALES			FEMALES		
DOSE	0 MG/KG	15 MG/KG	30 MG/KG	0 MG/KG	15 MG/KG	30 MG/KG
All Organs Malignant Lymphoma: Histiocytic, Lymphocytic, Mixed, NOS, or Undifferentiated Cell Type						
TUMOR RATES	#	#	#	#	#	#
OVERALL (a)	1/49 (2%)	6/50 (12%)	2/50 (4%)	3/50 (6%)	9/50 (18%)	11/50 (22%)
ADJUSTED (b)	2.3%	13.6%	4.9%	7.7%	26.5%	27.7%
TERMINAL (d)	0/41 (0%)	1/35 (3%)	1/34 (3%)	1/34 (3%)	6/30 (20%)	7/35 (20%)
FIRST INCIDENCE (DAYS)	695	176	356	603	646	604
STATISTICAL TESTS (f)						
LIFE TABLE	P=0.362	P=0.056	P=0.457	P=0.028 *	P=0.048 *	P=0.030 *
INCIDENTAL TUMOR	P=0.451N	P=0.339	P=0.740	P=0.012 *	P=0.075	P=0.014 *
LOGISTIC REGRESSION	P=0.563	P=0.085	P=0.631	P=0.019 *	P=0.059	P=0.022 *
COCHRAN-ARMITAGE	P=0.426			P=0.019 *		
FISHER EXACT		P=0.059	P=0.508		P=0.061	P=0.020 *
All Organs Benign Tumors						
TUMOR RATES	#	#	#	#	#	#
OVERALL (a)	28/49 (57%)	30/50 (60%)	32/50 (64%)	37/50 (74%)	40/50 (80%)	31/50 (62%)
ADJUSTED (b)	63.4%	71.1%	75.8%	87.9%	90.8%	77.4%
TERMINAL (d)	25/41 (61%)	23/35 (66%)	24/34 (71%)	29/34 (85%)	26/30 (87%)	26/35 (74%)
FIRST INCIDENCE (DAYS)	452	547	356	150	501	659
STATISTICAL TESTS (f)						
LIFE TABLE	P=0.055	P=0.175	P=0.068	P=0.114N	P=0.144	P=0.116N
INCIDENTAL TUMOR	P=0.178	P=0.258	P=0.217	P=0.135N	P=0.255	P=0.194N
LOGISTIC REGRESSION	P=0.218	P=0.432	P=0.163	P=0.096N	P=0.249	P=0.130N
COCHRAN-ARMITAGE	P=0.276			P=0.110N		
FISHER EXACT		P=0.466	P=0.311		P=0.318	P=0.142N

STATISTICAL ANALYSIS OF PRIMARY TUMORS IN MICE(B6C3F1) -- OLEIC ACID DIETHANOLAMINE CONDENSATE

TERMINAL SACRIFICE AT 105 WEEKS

	MALES			FEMALES		
DOSE	0 MG/KG	15 MG/KG	30 MG/KG	0 MG/KG	15 MG/KG	30 MG/KG
All Organs Malignant Tumors						
TUMOR RATES	#	#	#	#	#	#
OVERALL (a)	24/49 (49%)	29/50 (58%)	25/50 (50%)	22/50 (44%)	24/50 (48%)	21/50 (42%)
ADJUSTED (b)	50.0%	59.2%	56.1%	48.9%	59.6%	47.7%
TERMINAL (d)	17/41 (41%)	15/35 (43%)	15/34 (44%)	12/34 (35%)	14/30 (47%)	12/35 (34%)
FIRST INCIDENCE (DAYS)	452	176	356	435	585	552
STATISTICAL TESTS (f)						
LIFE TABLE	P=0.231	P=0.136	P=0.263	P=0.437N	P=0.304	P=0.474N
INCIDENTAL TUMOR	P=0.356N	P=0.547N	P=0.472N	P=0.524N	P=0.496	P=0.582N
LOGISTIC REGRESSION	P=0.462N	P=0.291	P=0.516N	P=0.494N	P=0.420	P=0.543N
COCHRAN-ARMITAGE	P=0.502			P=0.460N		
FISHER EXACT		P=0.243	P=0.540		P=0.421	P=0.500N
All Organs Malignant and Benign Tumors						
TUMOR RATES	#	#	#	#	#	#
OVERALL (a)	42/49 (86%)	43/50 (86%)	44/50 (88%)	46/50 (92%)	45/50 (90%)	36/50 (72%)
ADJUSTED (b)	85.7%	87.8%	89.8%	93.8%	93.8%	81.8%
TERMINAL (d)	34/41 (83%)	29/35 (83%)	29/34 (85%)	31/34 (91%)	27/30 (90%)	27/35 (77%)
FIRST INCIDENCE (DAYS)	452	176	356	150	501	552
STATISTICAL TESTS (f)						
LIFE TABLE	P=0.073	P=0.175	P=0.085	P=0.042N*	P=0.370	P=0.044N*
INCIDENTAL TUMOR	P=0.546	P=0.439N	P=0.615	P=0.009N**	P=0.473N	P=0.025N*
LOGISTIC REGRESSION	P=0.452	P=0.611	P=0.544	P=0.003N**	P=0.493N	P=0.008N**
COCHRAN-ARMITAGE	P=0.426			P=0.004N**		
FISHER EXACT		P=0.597	P=0.484		P=0.500N	P=0.009N**

DATE: 09/23/97 EXPERIMENT: 91014 TEST: 04

STATISTICAL ANALYSIS OF PRIMARY TUMORS IN MICE(B6C3F1) -- OLEIC ACID DIETHANOLAMINE CONDENSATE

TERMINAL SACRIFICE AT 105 WEEKS

(a) Number of tumor-bearing animals / number of animals examined at site.
(b) Kaplan-Meier estimated lifetime tumor incidence after adjustment for intercurrent mortality.
(d) Observed incidence at terminal kill.
(f) Beneath the control incidence are the P-values associated with the trend test. Beneath the dosed group incidence are the P-values corresponding to pairwise comparisons between the controls and that dosed group. The life table analysis regards tumors in animals dying prior to terminal kill as being (directly or indirectly) the cause of death. The incidental tumor test regards these lesions as non-fatal. Logistic regression is an alternative method for analyzing the incidence of non-fatal tumors. The Cochran-Armitage and Fisher's exact tests compare directly the overall incidence rates. For all tests, a negative trend is indicated by "N".
(e) Value of Statistic cannot be computed.
(I) Interim sacrifice
(T) Terminal sacrifice
\# Tumor rates based on number of animals necropsied.

* To the right of any statistical result, indicates significance at (P<=0.05).
** To the right of any statistical result, indicates significance at (P<=0.01).

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Data produced 8 (Month) 27 (Day) 98 (Year) Barbara Smith Camera Operator

Place Syracuse (City) New York (State)

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