

**APPENDIX XI**  
**Pathology Report**

**Effect of Oxybenzone on Fertility and Early Embryonic Development in  
Sprague-Dawley rats (Segment I)**

**NCTR Protocol Number E02186.01  
(Study Number E02186.02)**

**PATHOLOGY REPORT**

**PREPARED  
BY**

**TOXICOLOGIC PATHOLOGY ASSOCIATES  
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**FOR**

**NATIONAL CENTER FOR TOXICOLOGICAL RESEARCH  
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**November 6, 2014**

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## Effect of Oxybenzone on Fertility and Early Embryonic Development in Sprague-Dawley rats (Segment I)

### NCTR Protocol Number E02186.01 (Study Number E02186.02)

#### INTRODUCTION

This report by Toxicologic Pathology Associates for the National Center for Toxicological Research (NCTR), Jefferson, Arkansas 72079, represents the results of pathology support to examine the reproductive toxicity of oxybenzone in male and female Sprague-Dawley rats and is designed to focus specifically on fertility and early embryonic development to implantation. Oxybenzone (HMB) is used in sunscreen and many commercial products to absorb UV radiation and prevent UV-induced photodecomposition in plastics and cosmetics.

#### EXPERIMENT DESIGN AND METHODS

The number of animals used and their allocation to their respective dose groups is shown in the following table:

**Table 1 – Treatment Groups**

Group #		Treatment Text*	Treatment	Dose Level (ppm)	Animals	
Male	Female				Male	Female
1	2	CTRL.0 PPM	None	0	25	25
3	4	OX2 3,000	HMB	3,000	25	25
5	6	OX3 10,000	HMB	10,000	25	25
7	8	OX6 30,000	HMB	30,000	25	25
9	10	EE2 0.05	EE2	0.05	25	25

HMB = Oxybenzone

EE2 – Ethinylestradiol

\*Treatment Text depicted in NCTR Micropathology Data Collection System

Male rats approximately 5-7 weeks old and female rats approximately 9-11 weeks old were delivered to NCTR and assigned to one of five treatment groups. Males were dosed for 10 weeks and females for 2 weeks prior to mating. Dosing was continued until Gestation Day (GD)6 for all animals; from GD6 to GD15 dams were placed on control chow. All dams were sacrificed on GD15; males soon after breeding (~ GD6).

At study termination, surviving animals were euthanized by exposure to carbon dioxide and a complete necropsy of the thoracic and abdominal cavities was performed. At sacrifice, all protocol-designated tissues were examined grossly, removed and preserved in 10% neutral buffered formalin (NBF) except testes, prostate, seminal vesicle, coagulating gland, epididymis and bulbourethral gland which were fixed in

modified Davidson's fixative. Gross findings were captured electronically in the Gross Pathology System (GPS). The protocol-designated tissues were trimmed, processed and embedded in infiltrating media (Formula R<sup>®</sup>), sectioned at 5 microns and stained with hematoxylin and eosin (except testes and epididymides) and examined microscopically by light microscopy. The testes and epididymides were stained with PAS per the Pathology Procedures Worksheet. Microscopic findings were recorded in the NCTR Micropathology Data Collection System. When applicable, non-neoplastic lesions were graded for severity as 1 (minimal), 2 (mild), 3 (moderate) or 4 (marked).

## RESULTS AND DISCUSSION

### Mortality

There were no early deaths or moribund animals in this study.

### Gross Observations

There were no meaningful treatment related gross observations except for an increase in kidney lesions in the male high dose group.

### Histopathology

Microscopic findings are summarized by treatment group and anatomic site in Pathology Report 1 (Neoplastic) and Pathology Report 2 (Non-neoplastic). They are also tabulated by individual animal in Pathology Reports 3 (Tumor) and 4 (Non-Tumor). These compilations are in Appendices I-IV, respectively, of this report.

### Neoplastic Findings

A mammary gland adenocarcinoma was present in the female control group.

### Non-neoplastic Findings

Protocol designated select tissues were examined with the mammary gland and kidneys in males being the only tissues with a possible treatment effect. Alveolar mammary gland hyperplasia was determined by density per unit area of the mammary fat pad as shown in Table 2. Kidney changes in the high dose group were characterized by protein casts, dilated renal tubules, regeneration of renal tubules and inflammation. These types of renal changes have been well documented in previous studies with HMB. Common background changes were evident in most groups.


**Table 2 – Mammary Gland Hyperplasia – Males**

	CTRL. 0PPM	OX2 3,000	OX3 10,000	OX6 30,000	EE2 0.05
Hyperplasia, Alveolus	8(1.5)*	20(1.2)	28(1.4)	8(1.5)	40(1.5)

\*% incidence; ( ) average severity

**SUMMARY**

The only notable pathology findings in this Segment I study of oxybenzone in Sprague-Dawley rats was a mild increased incidence in mammary gland alveolar hyperplasia in the 3,000 and 10,000 ppm male groups and kidney changes present in the male 30,000 ppm group.

  
Greg R. Olson, DVM, PhD.

11/6/14  
Date



Effect of Oxybenzone on Fertility and Early Embryonic Development in  
Sprague-Dawley Rats (Segment I)

NCTR Protocol Number E02186.01  
NCTR Study Number E02186.02

**QUALITY ASSURANCE STATEMENT**

The portions of this study conducted by Toxicologic Pathology Associates (TPA) have been inspected and audited by the TPA Quality Assurance Unit (QAU) as required by the Good Laboratory Practice (GLP) regulations promulgated by the U.S. Food and Drug Administration Federal Register (21 CFR Part 58). The following table is a record of the inspections/audits performed and reported by the QAU.

<u>DATE OF INSPECTION</u>	<u>PHASE INSPECTED</u>	<u>DATE FINDINGS REPORTED TO MANAGEMENT AND STUDY PATHOLOGIST</u>
May 17, 2013	Critical Phase Inspection – Necropsy	May 20, 2013
Sept 20, 2013	Sperm Analysis Data	Sept 23, 2013
Sept 18-24, 2013	Clinical Pathology Data	Sept 24, 2013
Oct 8, 2013	Vaginal Cytology Data	Oct 8, 2013
Oct 30, 2013	Receiving Weights and Organ Weights	Oct 30, 2013
Oct 7-29, 2013	IANRs and P14s	Nov 1, 2013
Nov 10-13, 2013	Draft Pathology Report	Nov 13, 2013
Oct 8, 2014	Final Pathology Report	Oct 8, 2014
Nov 6, 2014	Final Pathology Report (post NCTR QAU)	Nov 6, 2014

[Redacted Signature]

Quality Assurance Manager  
Toxicologic Pathology Associates

*Nov 6, 2014*  
Date

3900 NCTR Road, Jefferson, AR 72079 • [Redacted] • FAX: [Redacted]



Appendix I Neoplastic Morphologies by Anatomic Site (Pathology Report 1)

Report Parameters

Report Type	Neoplastic Morphologies by Anatomic Site
Agency	04
Exp Test	0218602
Removal Date Range	No Removal Date Range Selected
Treatment Range	No Treatment Range Selected
Treatment Exclusions	

Rem Reason Exclusions

FEMALE Sprague Dawley -- Harlan	2 CTRL. 0 PPM FEM.	4 OX2 3,00 0 FEM.	6 OX3 10,0 00 FEM.	8 OX6 30,0 00 FEM.	10 EE2 0.05 FEMALE
<b>DISPOSITION SUMMARY</b>					
ANIMALS INITIALLY IN STUDY	25	25	25	25	25
SCHEDULED SACRIFICE	0	0	0	0	0
SURVIVORS					
TERMINAL SACRIFICE	25	25	25	25	25
ANIMALS EXAMINED MICROSCOPICALLY	25	1	2	25	25
<b>Integumentary System</b>					
Mammary Gland	(25)	(1)	(1)	(25)	(25)
Adenocarcinoma	1 (4%)				

NEOPLASTIC MORPHOLOGIES BY ANATOMIC SITE  
PATHOLOGY REPORT 01

MALE Sprague Dawley -- Harlan	1 CTRL. 0 PPM MALE	3 OX2 3,00 0 MALE	5 OX3 10,0 00 MALE	7 OX6 30,0 00 MALE	9 EE2 0.05 MALE
DISPOSITION SUMMARY					
ANIMALS INITIALLY IN STUDY	25	25	25	25	25
SCHEDULED SACRIFICE	0	0	0	0	0
SURVIVORS					
TERMINAL SACRIFICE	25	25	25	25	25
ANIMALS EXAMINED MICROSCOPICALLY	25	25	25	25	25

Appendix II Non-neoplastic Morphologies by Anatomic Site (Pathology Report 2)

Report Parameters

Report Type	Non-Neoplastic Morphologies by Anatomic Site
Agency	04
Exp Test	0218602
Removal Date Range	No Removal Date Range Selected
Treatment Range	No Treatment Range Selected
Treatment Exclusions	

Rem Reason Exclusions

FEMALE Sprague Dawley -- Harlan	2 CTRL. 0 PPM FEM.	4 OX2 3,00 0 FEM.	6 OX3 10,0 00 FEM.	8 OX6 30,0 00 FEM.	10 EE2 0.05 FEMALE
<b>DISPOSITION SUMMARY</b>					
ANIMALS INITIALLY IN STUDY	25	25	25	25	25
SCHEDULED SACRIFICE	0	0	0	0	0
<b>SURVIVORS</b>					
TERMINAL SACRIFICE	25	25	25	25	25
ANIMALS EXAMINED MICROSCOPICALLY	25	1	2	25	25
<b>Alimentary System</b>					
Liver	(2)	(1)	(2)	(2)	(1)
Hemorrhage, Marked				1 (50%)	
Hepatodiaphragmatic Nodule	1 (50%)				
Infiltration Cellular, Polymorphonuclear, Marked			1 (50%)	1 (50%)	
Necrosis, Marked			1 (50%)	1 (50%)	
<b>Integumentary System</b>					
Mammary Gland	(25)	(1)	(1)	(25)	(25)
Dilatation, Moderate, Alveolus				1 (4%)	
Hyperplasia, Marked, Alveolus				1 (4%)	
Hyperplasia, Mild, Alveolus	1 (4%)			1 (4%)	

MALE Sprague Dawley -- Harlan	1 CTRL. 0 PPM MALE	3 OX2 3,00 0 MALE	5 OX3 10,0 00 MALE	7 OX6 30,0 00 MALE	9 EE2 0.05 MALE
<b>DISPOSITION SUMMARY</b>					
ANIMALS INITIALLY IN STUDY	25	25	25	25	25
SCHEDULED SACRIFICE	0	0	0	0	0
<b>SURVIVORS</b>					
TERMINAL SACRIFICE	25	25	25	25	25
ANIMALS EXAMINED MICROSCOPICALLY	25	25	25	25	25
<b>Alimentary System</b>					
<b>Liver</b>	(4)	(1)	(2)	(4)	(1)
Congestion, Moderate Deformity	1 (25%)		1 (50%)		
Fibrosis, Moderate				1 (25%)	
Hepatodiaphragmatic Nodule	2 (50%)			1 (25%)	
Hyperplasia, Mild, Bile Duct	1 (25%)				
Inflammation, Chronic, Mild	1 (25%)		1 (50%)	1 (25%)	
Necrosis, Mild, Hepatocyte			1 (50%)		
Pigmentation, Moderate	1 (25%)			1 (25%)	
<b>Endocrine System</b>					
<b>Adrenal Cortex</b>	(25)	(1)	(1)	(25)	(25)
Accessory Adrenal Cortical Nodule					1 (4%)
<b>Pituitary Gland</b>	(25)	(1)	(1)	(25)	(25)
Cyst, Minimal, Pars Distalis	2 (8%)			1 (4%)	
<b>Thyroid Gland</b>	(25)	(1)	(1)	(25)	(25)
Ultimobranchial Cyst, Mild				2 (8%)	1 (4%)
Ultimobranchial Cyst, Minimal	2 (8%)			5 (20%)	6 (24%)
<b>Genital System</b>					
<b>Epididymis</b>	(25)	(1)	(1)	(25)	(25)
Exfoliated Germ Cell, Minimal	1 (4%)				
Spermatocoele, Marked					1 (4%)
<b>Prostate - Ventral Lobe</b>	(25)	(1)	(1)	(25)	(25)
Infiltration Cellular, Lymphocyte, Minimal	1 (4%)			1 (4%)	3 (12%)
<b>Prostate- Dorsal/Lateral Lobe</b>	(25)	(1)	(1)	(25)	(25)
Infiltration Cellular, Lymphocyte, Minimal	1 (4%)				
<b>Testes</b>	(25)	(1)	(1)	(25)	(25)
Degeneration, Minimal, Seminiferous Tubule	1 (4%)				
<b>Integumentary System</b>					
<b>Mammary Gland</b>	(25)	(25)	(25)	(25)	(25)
Hyperplasia, Mild, Alveolus	1 (4%)	1 (4%)	3 (12%)	1 (4%)	5 (20%)
Hyperplasia, Minimal, Alveolus	1 (4%)	4 (16%)	4 (16%)	1 (4%)	5 (20%)



MALE Sprague Dawley -- Harlan	1 CTRL. 0 PPM MALE	3 OX2 3,00 0 MALE	5 OX3 10,0 00 MALE	7 OX6 30,0 00 MALE	9 EE2 0.05 MALE
Urinary System					
Kidney	(1)	(1)	(1)	(7)	(1)
Casts Protein,Marked				1 (14%)	
Casts Protein,Mild	1 (100%)	1 (100%)		2 (29%)	1 (100%)
Casts Protein,Moderate			1 (100%)	1 (14%)	
Cyst,Marked,Renal Tubule				1 (14%)	
Cyst,Multiple,Marked				2 (29%)	
Dilatation,Marked,Renal Tubule				5 (71%)	
Dilatation,Mild,Renal Tubule	1 (100%)	1 (100%)		1 (14%)	1 (100%)
Dilatation,Moderate,Renal Tubule			1 (100%)		
Infiltration Cellular,Histiocytic,Marked				1 (14%)	
Infiltration Cellular,Lymphocyte,Mild				1 (14%)	
Infiltration Cellular,Lymphocyte,Moderate				2 (29%)	
Inflammation,Suppurative,Marked				2 (29%)	
Inflammation,Suppurative,Mild				1 (14%)	
Inflammation,Suppurative,Minimal				1 (14%)	
Regeneration,Marked,Renal Tubule				3 (43%)	
Regeneration,Mild,Renal Tubule			1 (100%)		
Regeneration,Moderate,Renal Tubule				1 (14%)	

Appendix III Individual Animal Tumor Pathology Table (Pathology Report 3)

Report Parameters

Report Type	Individual Animal Tumor Pathology Table
Agency	04
Exp Test	0218602
Removal Date Range	No Removal Date Range Selected
Treatment Range	No Treatment Range Selected
Treatment Exclusions	

Rem Reason Exclusions



INDIVIDUAL ANIMAL TUMOR PATHOLOGY TABLE  
 PATHOLOGY REPORT 3

	DAYS ON	0			
	TEST	0			
		5			
		4			
Sprague Dawley -- Harlan		0			T
FEMALE	CARCASS ID	0			I
		2			S
		6			U
OX2 3,000 FEM.	4	6			O
					E
					R
					S
					S
Alimentary System					
Liver		+			1
Integumentary System					
Mammary Gland		+			1

+ : TISSUE EXAMINED MICROSCOPICALLY  
 X : LESION PRESENT BUT NOT QUALIFIED  
 I : INSUFFICIENT TISSUE

M : MISSING TISSUE  
 A : AUTOLYSIS PRECLUDES EXAMINATION  
 BLANK : NOT EXAMINED

1-4 : LESION QUALIFIED AS:  
 1) MINIMAL 3) MODERATE  
 2) MILD 4) MARKED

INDIVIDUAL ANIMAL TUMOR PATHOLOGY TABLE  
PATHOLOGY REPORT 3

	DAYS ON	0   0			
	TEST	0   0			
		5   5			
		9   4			
Sprague Dawley -- Harlan		0   0		T	
FEMALE	CARCASS ID	0   0		I	T
		2   2		S	U
OX3 10,000 FEM. 6		1   2		S	M
		8   2		U	O
				E	R
				S	S

Alimentary System

Liver		+ +			2
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Integumentary System

Mammary Gland		+			1
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+ : TISSUE EXAMINED MICROSCOPICALLY  
X : LESION PRESENT BUT NOT QUALIFIED  
I : INSUFFICIENT TISSUE

M : MISSING TISSUE  
A : AUTOLYSIS PRECLUDES EXAMINATION  
BLANK : NOT EXAMINED

1-4 : LESION QUALIFIED AS:  
1) MINIMAL 3) MODERATE  
2) MILD 4) MARKED







INDIVIDUAL ANIMAL TUMOR PATHOLOGY TABLE  
PATHOLOGY REPORT 3

DAYS ON TEST		PATHOLOGY REPORT 3																								
Sprague Dawley -- Harlan MALE	CARCASS ID	0   0																								T
		0   0   1   1   1   1   1   1   0   1   0   0   0   1   0   1   1   0   1   1   1   1   0   1   1																								I
CTRL. 0 PPM MALE 1		9   9   0   0   1   1   1   0   9   0   9   9   9   0   9   0   0   9   0   1   0   9   0   0   0																								S
		5   4   8   8   3   2   2   7   5   1   4   2   3   8   9   9   5   8   5   5   2   8   7   8   1																								S

Alimentary System

Liver	+ +																								4
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Endocrine System

Adrenal Cortex	+ +																								25
Adrenal Medulla	+ +																								25
Pituitary Gland	+ +																								25
Thyroid Gland	+ +																								25

Genital System

Coagulating Gland	+ +																								25
Epididymis	+ +																								25
Prostate - Ventral Lobe	+ +																								25
Prostate- Dorsal/Lateral Lobe	+ +																								25
Seminal Vesicle	+ +																								25
Testes	+ +																								25

Integumentary System

Mammary Gland	+ +																								25
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Urinary System

Kidney	+ +																								1
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+ : TISSUE EXAMINED MICROSCOPICALLY      M : MISSING TISSUE      1-4 : LESION QUALIFIED AS:  
X : LESION PRESENT BUT NOT QUALIFIED      A : AUTOLYSIS PRECLUDES EXAMINATION      1) MINIMAL      3) MODERATE  
I : INSUFFICIENT TISSUE      BLANK : NOT EXAMINED      2) MILD      4) MARKED



INDIVIDUAL ANIMAL TUMOR PATHOLOGY TABLE  
PATHOLOGY REPORT 3

DAYS ON TEST	0   0
	0   0   0   0   0   0   1   1   1   1   0   1   1   1   0   1   0   1   1   1   1   1   1   1   0
	9   9   9   9   9   9   0   0   0   0   9   0   0   1   9   0   9   0   0   1   0   1   1   0   9
	8   5   5   3   2   5   5   9   2   7   4   8   9   3   8   1   8   8   0   2   8   4   2   5   8

Sprague Dawley -- Harlan MALE	CARCASS ID	0   0	T
		0   0	I
		0   0   0   0   0   0   0   0   0   0   0   0   0   0   0   0   1   1   1   1   1   1   1   1	S
OX3 10,000 MALE	5	1   1   1   2   2   2   2   5   5   5   6   6   6   6   6   0   0   0   0   0   0   0   0	U
		7   8   9   0   1   2   3   4   7   8   9   0   1   2   3   4   1   2   3   4   5   6   7   8   9	O
			E
			S

Alimentary System

Liver		+		+		2	
-------	--	---	--	---	--	---	--

Endocrine System

Adrenal Cortex		+		1	
Adrenal Medulla		+		1	
Pituitary Gland		+		1	
Thyroid Gland		+		1	

Genital System

Coagulating Gland		+		1	
Epididymis		+		1	
Prostate - Ventral Lobe		+		1	
Prostate- Dorsal/Lateral Lobe		+		1	
Seminal Vesicle		+		1	
Testes		+		1	

Integumentary System

Mammary Gland		+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+		25	
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Urinary System

Kidney		+		1	
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+ : TISSUE EXAMINED MICROSCOPICALLY  
X : LESION PRESENT BUT NOT QUALIFIED  
I : INSUFFICIENT TISSUE

M : MISSING TISSUE  
A : AUTOLYSIS PRECLUDES EXAMINATION  
BLANK : NOT EXAMINED

1-4 : LESION QUALIFIED AS:  
1) MINIMAL 3) MODERATE  
2) MILD 4) MARKED



INDIVIDUAL ANIMAL TUMOR PATHOLOGY TABLE  
 PATHOLOGY REPORT 3

PAGE: 10  
 DATE: 11/13/2013  
 TIME: 09:06:23.5

	DAYS ON TEST	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0				
		0	0	1	1	1	1	0	1	0	0	1	1	0	1	1	1	1	1	1	1	1	1	0	1	1	0		
		9	9	0	1	0	0	9	0	9	9	0	0	9	0	0	1	1	0	0	0	0	9	0	1	9			
		5	5	2	4	2	9	3	1	2	4	1	7	8	1	8	4	4	5	9	5	8	8	2	4	8			
Sprague Dawley -- Harlan MALE	CARCASS ID	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	T		
		0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	I	T
		0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	1	1	1	1	1	1	1	1	1	1	S	U
		3	3	3	3	3	3	4	7	7	7	7	7	7	7	8	2	2	2	2	2	2	2	2	2	2	2	S	M
EE2 0.05 MALE	9	3	4	5	6	7	8	9	0	3	4	5	6	7	8	9	0	1	2	3	4	5	6	7	8	9	U	O	
		3	4	5	6	7	8	9	0	3	4	5	6	7	8	9	0	1	2	3	4	5	6	7	8	9	E	R	
																											S	S	

Alimentary System  
 Liver | + | 1 |

Endocrine System  
 Adrenal Cortex | + | 25 |  
 Adrenal Medulla | + | 25 |  
 Pituitary Gland | + | 25 |  
 Thyroid Gland | + | 25 |

Genital System  
 Coagulating Gland | + | 25 |  
 Epididymis | + | 25 |  
 Prostate - Ventral Lobe | + | 25 |  
 Prostate- Dorsal/Lateral Lobe | + | 25 |  
 Seminal Vesicle | + | 25 |  
 Testes | + | 25 |

Integumentary System  
 Mammary Gland | + | 25 |

Urinary System  
 Kidney | + | 1 |

+ : TISSUE EXAMINED MICROSCOPICALLY      M : MISSING TISSUE      1-4 : LESION QUALIFIED AS:  
 X : LESION PRESENT BUT NOT QUALIFIED      A : AUTOLYSIS PRECLUDES EXAMINATION      1) MINIMAL      3) MODERATE  
 I : INSUFFICIENT TISSUE      BLANK : NOT EXAMINED      2) MILD      4) MARKED

Appendix IV Individual Animal Non-Tumor Pathology Table (Pathology Report 4)

Report Parameters

Report Type	Individual Animal Non-Tumor Pathology Table
Agency	04
Exp Test	0218602
Removal Date Range	No Removal Date Range Selected
Treatment Range	No Treatment Range Selected
Treatment Exclusions	

Rem Reason Exclusions





INDIVIDUAL ANIMAL NON-TUMOR PATHOLOGY TABLE  
 PATHOLOGY REPORT 4

	DAYS ON TEST	0     0     5     4			
				O	S
				T	B
				I	S
				S	E
Sprague Dawley -- Harlan FEMALE	CARCASS ID	0     0     2     6     6		S	R
				E	E
OX2 3,000 FEM. 4				U	V
				E	E
				S	D

Alimentary System

Liver	+			1	
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Integumentary System

Mammary Gland	+			1	
---------------	---	--	--	---	--

+ : TISSUE EXAMINED MICROSCOPICALLY  
 X : LESION PRESENT BUT NOT QUALIFIED  
 I : INSUFFICIENT TISSUE

M : MISSING TISSUE  
 A : AUTOLYSIS PRECLUDES EXAMINATION  
 BLANK : NOT EXAMINED

1-4 : LESION QUALIFIED AS:  
 1) MINIMAL 3) MODERATE  
 2) MILD 4) MARKED

INDIVIDUAL ANIMAL NON-TUMOR PATHOLOGY TABLE  
PATHOLOGY REPORT 4

DAYS ON | 0 | 0 |  
TEST | 0 | 0 |  
| 5 | 5 |  
| 9 | 4 |

Sprague Dawley -- Harlan  
FEMALE CARCASS ID  
OX3 10,000 FEM. 6

0	0
0	0
2	2
1	2
8	2

O S |  
T B E |  
I S V |  
S E E |  
S R R |  
U V I |  
E E T |  
S D Y |

Alimentary System

Liver | + +  
Infiltration Cellular, Polymorphonuclear | 4  
Necrosis | 4

| 2 |  
| 1 4.0 |  
| 1 4.0 |

Integumentary System

Mammary Gland | +

| 1 |

+ : TISSUE EXAMINED MICROSCOPICALLY  
X : LESION PRESENT BUT NOT QUALIFIED  
I : INSUFFICIENT TISSUE

M : MISSING TISSUE  
A : AUTOLYSIS PRECLUDES EXAMINATION  
BLANK : NOT EXAMINED

1-4 : LESION QUALIFIED AS:  
1) MINIMAL 3) MODERATE  
2) MILD 4) MARKED

INDIVIDUAL ANIMAL NON-TUMOR PATHOLOGY TABLE
PATHOLOGY REPORT 4

Table with 25 columns and 4 rows of data. Header row: DAYS ON TEST. Data rows contain numerical values in a grid format.

O S I
T B E I
I S V I
S E E I
S R R I
U V I I
E E T I
S D Y I

Sprague Dawley -- Harlan
FEMALE
OX6 30,000 FEM. 8
CARCASS ID

Table with 25 columns and 4 rows of data. Header row: CARCASS ID. Data rows contain numerical values in a grid format.

Alimentary System

Table with 4 rows of data for Alimentary System. Rows include: Liver (with '+' sign), Hemorrhage, Infiltration Cellular, Polymorphonuclear, and Necrosis. Values include 2, 4, 1 4.0, and 1 4.0.

Integumentary System

Table with 4 rows of data for Integumentary System. Rows include: Mammary Gland, Dilatation, Alveolus, and Hyperplasia, Alveolus. Values include 25, 1 3.0, and 2 3.0.

+ : TISSUE EXAMINED MICROSCOPICALLY
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A : AUTOLYSIS PRECLUDES EXAMINATION
BLANK : NOT EXAMINED
1-4 : LESION QUALIFIED AS:
1) MINIMAL 3) MODERATE
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INDIVIDUAL ANIMAL NON-TUMOR PATHOLOGY TABLE  
PATHOLOGY REPORT 4

DAYS ON TEST	0   0
	5   4   7   6   7   7   6   6   6   7   7   7   8   7   6   7   6   5   5   6   6   6   5   6   5   6   5
	3   9   7   7   1   6   7   1   9   1   6   1   2   0   9   2   1   5   8   8   1   5   7   6   6   6

Sprague Dawley -- Harlan FEMALE	CARCASS ID	0   0	O T I S S E S R U E S D Y	S E V E R I T Y
EE2 0.05 FEMALE 10		2   2   2   2   2   2   2   2   2   2   2   2   2   2   2   2   2   3   3   3   3   3   3   3   3   3   3   3		
		3   3   3   3   3   3   3   3   4   7   7   7   7   7   7   8   2   2   2   2   2   2   2   2   2   2   2		
		3   4   5   6   7   8   9   0   3   4   5   6   7   8   9   0   1   2   3   4   5   6   7   8   9   0   1   2   3		

Alimentary System

Liver		+	1	
-------	--	---	---	--

Integumentary System

Mammary Gland	+ +	25	
---------------	---	----	--

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1-4 : LESION QUALIFIED AS:  
1) MINIMAL 3) MODERATE  
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INDIVIDUAL ANIMAL NON-TUMOR PATHOLOGY TABLE  
PATHOLOGY REPORT 4

DAYS ON TEST	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	0	0	1	1	1	1	1	1	0	1	0	0	1	0	1	1	0	1	1	1	0	1	1	1	1
	9	9	0	0	1	1	1	0	9	0	9	9	9	0	9	0	0	9	0	1	0	9	0	0	0
	5	4	8	8	3	2	2	7	5	1	4	2	3	8	9	9	5	8	5	5	2	8	7	8	1
Sprague Dawley -- Harlan MALE	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
CTRL. 0 PPM MALE 1	1	2	3	4	5	6	7	8	9	0	1	2	3	4	5	6	1	2	3	4	5	6	7	8	9
CARCASS ID	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
	0	0	0	0	0	0	0	4	5	5	5	5	5	5	5	9	9	9	9	9	9	9	9	9	9
	1	2	3	4	5	6	7	8	9	0	1	2	3	4	5	6	1	2	3	4	5	6	7	8	9

O S  
T B E  
I S V  
S E E  
S R R  
U V I  
E E T  
S D Y

Alimentary System

Liver																										
Congestion																										
Hepatodiaphragmatic Nodule																										
Hyperplasia, Bile Duct																										
Inflammation, Chronic																										
Pigmentation																										

Endocrine System

Adrenal Cortex	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	25
Adrenal Medulla	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	25
Pituitary Gland	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	25
Cyst, Pars Distalis																										1
Thyroid Gland	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	25
Ultimobranchial Cyst																										1

Genital System

Coagulating Gland	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	25
Epididymis	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	25
Exfoliated Germ Cell																										1
Prostate - Ventral Lobe	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	25
Infiltration Cellular, Lymphocyte																										1
Prostate- Dorsal/Lateral Lobe	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	25
Infiltration Cellular, Lymphocyte																										1
Seminal Vesicle	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	25
Testes	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	25
Degeneration, Seminiferous Tubule																										1

Integumentary System

Mammary Gland	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	25
Hyperplasia, Alveolus																										2

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       2) MILD       4) MARKED

INDIVIDUAL ANIMAL NON-TUMOR PATHOLOGY TABLE  
PATHOLOGY REPORT 4

DAYS ON TEST	0   0		
	0   0   1   1   1   1   1   1   0   1   0   0   0   1   0   1   1   1   0   1   1   1   0   1   1		
	9   9   0   0   1   1   1   0   9   0   9   9   9   0   9   0   0   9   0   1   0   1   0   9   0   0		
	5   4   8   8   3   2   2   7   5   1   4   2   3   8   9   9   5   8   5   5   2   8   7   8   1		
			O S
			T B E
Sprague Dawley -- Harlan MALE	0   0		I S V
CARCASS ID	0   0		S E E
	0   0		S R R
	0   0   0   0   0   0   0   0   4   5   5   5   5   5   9   9   9   9   9   9   9   9   9   9		U V I
CTRL. 0 PPM MALE 1	1   2   3   4   5   6   7   8   9   0   1   2   3   4   5   6   1   2   3   4   5   6   7   8   9		E E T
			S D Y

Urinary System

Kidney		+	1	
Casts Protein		2		1 2.0
Dilatation, Renal Tubule		2		1 2.0

+ : TISSUE EXAMINED MICROSCOPICALLY                      M : MISSING TISSUE                                      1-4 : LESION QUALIFIED AS:  
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 I : INSUFFICIENT TISSUE                                      BLANK : NOT EXAMINED    2) MILD                                      4) MARKED

INDIVIDUAL ANIMAL NON-TUMOR PATHOLOGY TABLE  
PATHOLOGY REPORT 4

	DAYS ON TEST	0   0		
		9   9   9   0   0   1   0   1   0   1   0   9   0   1   0   0   9   9   9   9   0   0   0   9   0   9		
		4   4   2   1   9   2   7   2   1   5   8   4   7   9   4   2   9   4   9   0   2   2   8   8   5		
				O S
				T B E
				I S V
Sprague Dawley -- Harlan	CARCASS ID	0   0		
MALE		0   0		
		0   0   0   0   0   0   0   0   0   0   0   0   0   0   0   0   1   1   1   1   1   1   1   1		S E E S R R U V I E E T S D Y
OX2 3,000 MALE	3	9   0   1   2   3   4   5   6   5   6   7   8   9   0   1   2   1   2   3   4   5   6   7   8   9		
Alimentary System				
Liver			+	1
Endocrine System				
Adrenal Cortex			+	1
Adrenal Medulla			+	1
Pituitary Gland			+	1
Thyroid Gland			+	1
Genital System				
Coagulating Gland			+	1
Epididymis			+	1
Prostate - Ventral Lobe			+	1
Prostate- Dorsal/Lateral Lobe			+	1
Seminal Vesicle			+	1
Testes			+	1
Integumentary System				
Mammary Gland		+ +		25
Hyperplasia, Alveolus		1     1     2     1         1     + + + + + + + + +		5 1.2
Urinary System				
Kidney			+	1
Casts Protein			2	1 2.0
Dilatation, Renal Tubule			2	1 2.0

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DAYS ON TEST	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
	0	0	1	1	0	1	0	0	1	1	1	1	1	1	1	1	1	0	1	0	0	1	1	1	0	1	1	1	0	1	1	1	0	1	0
	9	9	1	0	9	0	9	9	0	0	0	1	0	0	1	1	9	0	9	9	9	0	1	1	9	9	9	0	1	1	1	9	9	9	
	8	4	2	0	2	1	5	3	9	0	9	4	1	2	4	2	8	1	3	3	4	8	5	2	5										

Sprague Dawley -- Harlan MALE	CARCASS ID	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
		0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
		0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
		2	2	2	2	2	3	3	3	4	4	4	4	4	4	4	4	8	8	8	8	8	8	8	8	8	8	8	8	8	8	8	8	8

O S  
T B E  
I S V  
S E E  
S R R  
U V I  
E E T  
S D Y

Alimentary System

Liver														+	+	+								+	4		
Fibrosis																		3					1	3.0			
Hepatodiaphragmatic Nodule																								1			
Inflammation, Chronic																		2					1	2.0			
Pigmentation																		3					1	3.0			

Endocrine System

Adrenal Cortex	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	25	
Adrenal Medulla	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	25	
Pituitary Gland	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	25	
Cyst, Pars Distalis																								1					1	1.0						
Thyroid Gland	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	25	
Ultimobranchial Cyst						2	1	1						2	1	1								1					7	1.2						

Genital System

Coagulating Gland	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	25	
Epididymis	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	25	
Prostate - Ventral Lobe	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	25	
Infiltration Cellular, Lymphocyte																				1					1	1.0										
Prostate- Dorsal/Lateral Lobe	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	25	
Seminal Vesicle	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	25	
Testes	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	25	

Integumentary System

Mammary Gland	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	25	
Hyperplasia, Alveolus																		1								2					2	1.5				

Urinary System

Kidney														+	+	+	+	+								+	7								
Casts Protein																		2	3	2						4					4	2.7			
Cyst, Multiple																						4					4			2	4.0				
Cyst, Renal Tubule																		4														1	4.0		

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I : INSUFFICIENT TISSUE      BLANK : NOT EXAMINED      2) MILD        4) MARKED

INDIVIDUAL ANIMAL NON-TUMOR PATHOLOGY TABLE  
PATHOLOGY REPORT 4

DAYS ON TEST	0   0																														O	S
	0   0   1   1   0   1   0   0   1   1   1   1   1   1   1   1   0   1   0   0   0   1   1   0   0   1   1   1   0																														T	B
	9   9   1   0   9   0   9   9   0   0   1   0   0   1   1   9   0   9   9   9   0   1   1   9																														I	S
	8   4   2   0   2   1   5   3   9   0   9   4   1   2   4   2   8   1   3   3   4   8   5   2   5																														S	E
Sprague Dawley -- Harlan	0   0																														I	S
MALE	0   0																														S	E
	0   0																														S	R
OX6 30,000 MALE	2   2   2   2   2   3   3   3   4   4   4   4   4   4   4   8   8   8   8   8   8   8   8   8   8   8   8   8   8   8																														U	V
7	5   6   7   8   9   0   1   2   1   2   3   4   5   6   7   8   1   2   3   4   5   6   7   8   9																														E	T
																															S	D

Urinary System

Dilatation, Renal Tubule		4	4	4	4	2	4		6	3.6
Infiltration Cellular, Histiocytic				4					1	4.0
Infiltration Cellular, Lymphocyte		3			2		3		3	2.6
Inflammation, Suppurative		4	1	4	2				4	2.7
Regeneration, Renal Tubule		4	4		3		4		4	3.7

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