

Historical Control Data  
on Histological Findings in shorter than 21 days  
Studies  
in RccHan<sup>TM</sup>: WIST, Wistar Hannover Rats  
Recovery

**Compiled from shorter than 21 days Bioassays performed at Harlan Laboratories Ltd. Itingen/Switzerland**

**Study identification**

Study Number	ID Number	Data of Performance	Recovery	Duration of Study (days)	Study type	Age at Delivery (weeks)	Pretest Acclimatization (days)	Body Weight at Delivery (g)		Housing	Diet	Vehicle	Pathologist
								M	F				
814994	1	22 May - 09 July 2001	<input type="checkbox"/>	5	Inhalation	♂: 6-8; ♀: 10-12	7	not exceed (±20%)	not exceed (±20%)	Groups	Kliba 3433	aerosol concentration	WEK
794788	2	11 April - 03 May 2001	<input type="checkbox"/>	14	Gavage	7	7	190 (±20%)	140 (±20%)	Groups	Kliba 3433	bi- distilled water	WEK
826650	3	20 Nov. 2001 - 03 Jan. 2002	<input type="checkbox"/>	7	Inhalation	♂: 6-8; ♀: 8-10	5	180-200	180-200	Groups	Kliba 3433	aerosol concentration	WEK
A57881	4	22 March - Sept. 2006	<input type="checkbox"/>	7	Inhalation	♂: 8-10; ♀: 10-12	5	not exceed (±20%)	not exceed (±20%)	Groups	Kliba 3433	Estimated atmosphere concentration	JAG
B89076**	5	25.03. 2008 - 06 Jan. 2009	<input type="checkbox"/>	7	intrahepatic injection	6	7	172,4 - 193,9	128,2 - 158,9	Individual	Kliba 3433	NaCl 0.9%	TAT
733803	6	29 Dec. - March 2000	<input type="checkbox"/>	5	Inhalation	♂: 6-8; ♀: 8-10	8	180-200	180-200	Groups	Kliba 3433	aerosol concentration	WEK
829337	7	20 Sept. - Nov. 2001	<input type="checkbox"/>	5	Inhalation	8-12	14	not exceed (±20%)	not exceed (±20%)	Groups	Kliba 3433	bi- distilled water	WEK
714058	8	06 Jan. - 15 Feb. 1999	<input checked="" type="checkbox"/>	5	Inhalation	♂: 7 - 9	7	180-200	180-200	Groups	Kliba 3433	20% pure ethanol and 80% distilled water	WEK
835266	9	25 Sept. - 08. Oct. 2001	<input type="checkbox"/>	7	Intravenous	6	6	150 (±20%)	125 (±20%)	Individual	Kliba 3433	sheep erythrocytes	WEK
818550	10	6 June - 31 Aug. 2001	<input type="checkbox"/>	7	Intranasal	♂: 7-9 ; ♀: 10-12	6	not exceed (±20%)	not exceed (±20%)	Groups	Kliba 3433	Tween 80	WEK
697770	11	17 Feb. - 09 March 1999	<input type="checkbox"/>	7	Inhalation	♂: 6-8; ♀: 10-12	13	180-200	180-200	Groups	Kliba 3433	Target atmosphere concentration	WEK
809177	12	28.June - 12.July 2001	<input type="checkbox"/>	n.d.	Inhalation	n.d	n.d	n.d	n.d	Groups	n.d	n.d.	WEK
707760	13	19 Nov. - 10 Dec. 1998	<input type="checkbox"/>	7	Inhalation	♂: 8-10; ♀: 10-12	5	180-200	180-200	Groups	Kliba 3433	target atmosphere concentration	WEK
830452	14	17 - 25 Sept. 2001	<input type="checkbox"/>	7	Toxicogenomics	11-12	7	300 (±20%)	-	Individual	Kliba 3433	7.5% Gelantine solution	WEK
841480	15	07.- 17. Jan. 2002	<input type="checkbox"/>	7	Toxicogenomics	12	6	300 (±20%)	-	Individual	Kliba 3433	Corn Oil	WEK
841481	16	16. - 24. Jan. 2002	<input type="checkbox"/>	7	Toxicogenomics	12	7	300 (±20%)	-	Individual	Kliba 3433	Saline	WEK
848191	17	05. - 30. May 2003	<input type="checkbox"/>	7	Inhalation	♂: 8-10; ♀: 10-12	7	200-225	200-225	Groups	Kliba 3433	aerosol concentration	JAG
844258	18	21.June - 12. July 2002	<input type="checkbox"/>	14	Intravenous	6	7	150 (±20%)	125 (±20%)	Individual	Kliba 3433	physiological saline	WEK
843808	19	07. - 28. Aug. 2002	<input type="checkbox"/>	14	Inhalation	♂: 6-8; ♀: 10-12	7	180-200	180-200	Groups	Kliba 3433	aerosol concentration	WEK
816445	20	07. Aug. - 20. Sept. 2001	<input checked="" type="checkbox"/>	14	Gavage	6	7	150 (±20%)	125 (±20%)	Groups	Kliba 3433	PEG 300	WEK
809166	21	19.July -06.Aug. 2001	<input type="checkbox"/>	n.d.	Inhalation	n.d	n.d	n.d	n.d	Groups	n.d	n.d.	WEK

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Study Number	ID Number	Data of Performance	Recovery	Duration of Study (days)	Study type	Age at Delivery (weeks)	Pretest Acclimatization (days)	Body Weight at Delivery (g)		Housing	Diet	Vehicle	Pathologist
								M	F				
704226	22	03. Sept. - 01. Oct. 1998	<input type="checkbox"/>	21	Implantation	7	7	190 (±20%)	-	Individual	Kliba 3433	-	WEK
716578	23	10. Dec. 1998 - 07. Jan. 1999	<input type="checkbox"/>	21	Implantation	7	6	190 (±20%)	-	Individual	Kliba 3433	-	WEK
722496	24	16. Feb. - 16. March 1999	<input type="checkbox"/>	21	Implantation	7	6	190 (±20%)	-	Individual	Kliba 3433	-	WEK
729134	25	23. March - 20. April 1999	<input type="checkbox"/>	21	Implantation	7	6	190 (±20%)	-	Individual	Kliba 3433	-	WEK
692706	26	22. April - 13. May 1998	<input type="checkbox"/>	21	Implantation	7	7	190 (±20%)	-	Individual	Kliba 3433	-	WEK
789816	27	08. - 29. Nov. 2000	<input type="checkbox"/>	21	Intraocular	5	7	150 (±20%)	-	Individual	Kliba 3433	Physiological Saline	WEK
846804***	28	10.-17. Dec. 2002	<input type="checkbox"/>	7	Gavage/ Intravenous	7	7	180-210 (±20%)	-	Groups	Kliba 3433	5% Glucose	WEK
797905	29	15.Feb.- 14 March 2001	<input checked="" type="checkbox"/>	21	Intraocular	6	7	150 (±20%)	125 (±20%)	Individual	Kliba 3433	Physiological Saline	WEK
846842*	30	10.-31. Jan. 2003	<input type="checkbox"/>	21	Feeding	6	7	150 (±20%)	125 (±20%)	Groups	Kliba 3433	Feed and Pellets	WEK
772121	31	18.May - 09. June 2000	<input type="checkbox"/>	7	Gavage	6	5	150 (±20%)	125 (±20%)	Pairs	Kliba 3433	bi- distilled water	WEK
331683	32	May 1993	<input checked="" type="checkbox"/>	7	Gavage	n.d.	n.d.	n.d.	n.d.	n.d.	Kliba 3433	corn oil	WEK
819955	33	Oct. 2001	<input type="checkbox"/>	n.d.	Inhalation	n.d.	n.d.	n.d.	n.d.	n.d.	Kliba 3433	n.d.	WEK
B36112	34	05.-30. April 2007	<input type="checkbox"/>	14	Inhalation	8-12	7	not exceed (±20%)	not exceed (±20%)	Groups	Kliba 3433	air filtered	BDK
677430	35	August 1998	<input type="checkbox"/>	7	Inhalation	n.d.	n.d.	n.d.	n.d.	n.d.	Kliba 3433	HFA	WEK
733871	36	August 1999	<input type="checkbox"/>	7	Inhalation	n.d.	n.d.	n.d.	n.d.	n.d.	Kliba 3433	n.d.	WEK
751948	37	October 2000	<input type="checkbox"/>	14	Inhalation	n.d.	n.d.	n.d.	n.d.	n.d.	Kliba 3433	aerosol concentration	WEK
765325	38	December 2000	<input type="checkbox"/>	14	Inhalation	n.d.	n.d.	n.d.	n.d.	n.d.	Kliba 3433	air filtered	WEK
765538	39	March 2001	<input type="checkbox"/>	14	Inhalation	n.d.	n.d.	n.d.	n.d.	Groups	n.d.	n.d.	WEK
771412	40	01. Nov 00	<input type="checkbox"/>	7	Infusion	n.d.	n.d.	n.d.	n.d.	Groups	n.d.	n.d.	WEK
780107	41	February 2001	<input type="checkbox"/>	7	Inhalation	n.d.	n.d.	n.d.	n.d.	Groups	n.d.	n.d.	WEK
780120	42	March 2001	<input type="checkbox"/>	14	Inhalation	n.d.	n.d.	n.d.	n.d.	Groups	n.d.	n.d.	WEK
794788	43	September 2001	<input type="checkbox"/>	n.d.	Gavage	n.d.	n.d.	n.d.	n.d.	Groups	n.d.	bi-distilled water	WEK
C11827	44	27.Oct.2008-14.May 2009	<input checked="" type="checkbox"/>	14	Gavage	7	7	190 (±20%)	150 (±20%)	Groups	Kliba 3433	0.5% Methylcellulose/ 0.05% Polyoxyethylene	KRG

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								M	F				
B96726	45	10.Sep.-21.Oct. 2008	<input type="checkbox"/>	4	Intraperitoneal	12-13	7	225-250	-	Groups	Kliba 3433	Phosphate buffered saline	WEK
C54307	46	09.Jul.-11.Sep. 2009	<input type="checkbox"/>	14	Inhalation	8-10	14	n.d	n.d	Groups	Kliba 3433	air filtered	HJC
B49768	47	19.Aug.-16.Dec. 2009	<input checked="" type="checkbox"/>	21	Intravenous	7	n.d.	190 (±20%)	150 (±20%)	Individual	Kliba 3433	NaCl 0.9% steril / Aqueous micellar solution	IHI
C63061	48	16.Sep. 2009-01.Feb. 2010	<input checked="" type="checkbox"/>	14	Gavage	7	7	190 (±20%)	150 (±20%)	Groups	Kliba 3433	0.5% CMC in bi-distilled water	KOD
B12846	49	28.Jan.-20.Aug. 2008	<input checked="" type="checkbox"/>	14	Intravenous	6	7	150 (±20%)	125 (±20%)	Individual	Kliba 3433	Physiological Saline	KOD
C33675	50	15.Apr.-03.Dec. 2009	<input type="checkbox"/>	14	Intravenous	8-12	n.d.	242-294	191-223	Groups	Kliba 3433	sterile 0.9% Sodium chloride	HJC
C67976	51	15.Oct. 2009-16.Feb. 2010	<input type="checkbox"/>	1	Intravenous	6	6	150 (±20%)	125 (±20%)	Individual	Kliba 3433	0.9% Saline	IHI
C58471	52	06.Oct.-23.Nov. 2009	<input type="checkbox"/>	7	Gavage	7	n.d.	190 (±20%)	150 (±20%)	Groups	Kliba 3433	Corn oil	KHE
C20467	53	26.Jan.-25.Apr. 2009	<input type="checkbox"/>	21	Gavage	7	7	190 (±20%)	150 (±20%)	Groups	Kliba 3433	Bidistilled water	HJC
C56895	54	26.Aug.-27.Oct. 2009	<input type="checkbox"/>	1	Gavage	5	7	110 (±20%)	95 (±20%)	Individual	Kliba 3433	Polyethylene glycol (PEG-) 300	WEK
C54656	55	29.Jul.-25.Nov 2009	<input checked="" type="checkbox"/>	14	Intravenous	6	7	150 (±20%)	125 (±20%)	Individual	Kliba 3433	Hydroxypropyl-β-cyclodextrin (HP-β-CD) 5%, mannitol 4%	KRG
B78625	56	16.Apr.-14.May 2008	<input type="checkbox"/>	1	Inhalation	8-12	5	n.d	n.d	Groups	Kliba 3433	FAT 75808 Placebo	HJC
B74248	57	18.Dec. 2007-17.Jul. 2008	<input type="checkbox"/>	14	Gavage	7	7	190 (±20%)	150 (±20%)	Groups	Kliba 3433	Acetate buffer, pH 4.0	KRG
C23810	58	17.Nov. 2008-22.Jul. 2009	<input checked="" type="checkbox"/>	14	Intravenous	7	7	190 (±20%)	150 (±20%)	Individual	Kliba 3433	Ro 502-8442/F02-01	KRG
C28714	59	25.Feb.-21.Oct. 2009	<input type="checkbox"/>	7	Intradermal	8-12	7	180-220 (±20%)	180-220 (±20%)	Groups	Kliba 3433	DMEM	WEK
C35846	60	27.Feb.-03.May 2009	<input type="checkbox"/>	7	Intravenous	6	7	150 (±20%)	125 (±20%)	Individual	Kliba 3433	D-mannitol	KRG
C688810	61	05.Nov. 2009-n.d.	<input type="checkbox"/>	14	Gavage	7	7	190 (±20%)	150 (±20%)	Groups	Kliba 3433	Bidistilled water	WEK
B96682	62	06.May-13.Nov 2008	<input type="checkbox"/>	14	Gavage	6	7	150 (±20%)	125 (±20%)	Groups	Kliba 3433	Tap water	WEK
B71368	63	03.Jan.-07.Jul. 2008	<input type="checkbox"/>	14	Intravenous	6	7	150 (±20%)	125 (±20%)	Individual	Kliba 3433	Water for injection	ROL
C07125	64	16.Dec. 2008-17.Feb. 2009	<input type="checkbox"/>	14	Inhalation	8-10	5	n.d	n.d	Groups	Kliba 3433	Ethanol/Purified water	HJC
C15372	65	05.Dec. 2008-14.Apr. 2009	<input type="checkbox"/>	7	Inhalation	8-10	5	n.d	n.d	Groups	Kliba 3433	air filtered	TAT
C47478	66	28.May-26.Jul. 2009	<input type="checkbox"/>	14	Inhalation	8-10	5	n.d	n.d	Groups	Kliba 3433	air filtered	HJC
844170	67	29.May 2002-12.June 2002	<input type="checkbox"/>	7	Gavage	6	7	150 (±20%)	125 (±20%)	Groups	Kliba 3433	Methocel MC	WEK

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								M	F				
B78737	68	17.Jan.-12.Apr. 2008	<input type="checkbox"/>	7	Gavage	7	7	190 (±20%)	150 (±20%)	Groups	Kliba 3433	0.5% Methylcellulose/ 0.05% Polyoxyethylene	KRG
B96693	69	13.May-13.Nov. 2008	<input type="checkbox"/>	14	Gavage	6	6	150 (±20%)	125 (±20%)	Groups	Kliba 3433	Tap water	WEK
B84374	70	13.May-13.Jul. 2008	<input type="checkbox"/>	14	Gavage	7	6	190 (±20%)	150 (±20%)	Groups	Kliba 3433	Na-acetate/acetic acid/methocel buffer pH 4.5	HJC
B85206	71	05.Feb.-15.Apr. 2008	<input type="checkbox"/>	15	Gavage	8-12	7	-	180-200	Groups	Kliba 3433	Polyethylene glycol 300 (PEG 300)	ROL
A88018	72	27.Oct.-12.Dec. 2009	<input type="checkbox"/>	14	Intravenous	6-7	n.d.	150 (±20%)	125 (±20%)	Individual	Kliba 3433	10mM Sodium citrate, pH 5,7/0.9% NaCl/Tween 80	KHE
B74250	73	25.Feb.-17.Dec. 2008	<input type="checkbox"/>	14	Intravenous	8-12	7	220 (±20%)	180 (±20%)	Groups	Kliba 3433	10mM sodium citrate/10mM disodium hydrogen	JAG
B84082	74	10.Mar.-21.Oct. 2008	<input type="checkbox"/>	14	Gavage	7	7	190 (±20%)	150 (±20%)	Groups	Kliba 3433	Na-acetate Buffer, pH 4.5	KRG
A42726	79	02.Mar.-16.Jun. 2006	<input type="checkbox"/>	14	Inhalation	♂: 6-8; ♀: 8-10	14	n.d	n.d	Groups	Kliba 3433	Phosphate buffered saline (PBS)	MAM
C11816	80	10.Sep. 2008-11.Feb. 2009	<input type="checkbox"/>	14	Gavage	7	7	-	150 (±20%)	Groups	Kliba 3433	Na-acetate Buffer, pH 4.5	KRG

\* = MTD/DRF

\*\* = no control group; group 1 injection volume 0.02 ml

\*\*\* = Effect on renal function in the rat

n.d. = no data

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**Pathologists**

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Sublingual salivary glands	16		
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**Brain**

Males	Total n	Total %	Mean %	STDEV %	MIN %	MAX %
Numbers of rats examined	54					

Females	Total n	Total %	Mean %	STDEV %	MIN %	MAX %
Numbers of rats examined	49					

**Cerebrum**

Males	Total n	Total %	Mean %	STDEV %	MIN %	MAX %
Numbers of rats examined	54					
Mononuclear cell foci	1	1.85	1.00	3.16	0.00	10.00

Females	Total n	Total %	Mean %	STDEV %	MIN %	MAX %
Numbers of rats examined	49					
Mononuclear cell foci	0	0.00	0.00	0.00	0.00	0.00

**Brain stem/midbrain**

Males	Total n	Total %	Mean %	STDEV %	MIN %	MAX %
Number of rats examined	15					

Females	Total n	Total %	Mean %	STDEV %	MIN %	MAX %
Number of rats examined	10					

**Medulla oblongata**

Males	Total n	Total %	Mean %	STDEV %	MIN %	MAX %
Numbers of rats examined	54					
Hemorrhage	1	1.85	1.00	3.16	0.00	10.00

Females	Total n	Total %	Mean %	STDEV %	MIN %	MAX %
Numbers of rats examined	49					
Hemorrhage	0	0.00	0.00	0.00	0.00	0.00

**Spinal cord**

Males	Total n	Total %	Mean %	STDEV %	MIN %	MAX %
Numbers of rats examined	54					

Females	Total n	Total %	Mean %	STDEV %	MIN %	MAX %
Numbers of rats examined	49					



### Sciatic Nerve

Males	Total n	Total %	Mean %	STDEV %	MIN %	MAX %
Numbers of rats examined	54					
Nerve fiber degeneration	7	12.96	13.00	31.29	0.00	100.00

Females	Total n	Total %	Mean %	STDEV %	MIN %	MAX %
Numbers of rats examined	49					
Nerve fiber degeneration	4	8.16	8.89	17.64	0.00	40.00

### Sural Nerve

Males	Total n	Total %	Mean %	STDEV %	MIN %	MAX %
Numbers of rats examined	5					
Nerve fiber degeneration	4	80.00	80.00	0.00	80.00	80.00

Females	Total n	Total %	Mean %	STDEV %	MIN %	MAX %
Numbers of rats examined	0					
Nerve fiber degeneration	0	0.00	0.00	0.00	0.00	0.00

### Tibial Nerve

Males	Total n	Total %	Mean %	STDEV %	MIN %	MAX %
Numbers of rats examined	5					
Nerve fiber degeneration	1	20.00	20.00	0.00	20.00	20.00

Females	Total n	Total %	Mean %	STDEV %	MIN %	MAX %
Numbers of rats examined	0					
Nerve fiber degeneration	0	0.00	0.00	0.00	0.00	0.00

### Optic Nerve

Males	Total n	Total %	Mean %	STDEV %	MIN %	MAX %
Numbers of rats examined	39					
Degeneration	0	0.00	0.00	0.00	0.00	0.00

Females	Total n	Total %	Mean %	STDEV %	MIN %	MAX %
Numbers of rats examined	39					
Degeneration	0	0.00	0.00	0.00	0.00	0.00

**Eyes**

<b>Males</b>	<b>Total n</b>	<b>Total %</b>	<b>Mean %</b>	<b>STDEV %</b>	<b>MIN %</b>	<b>MAX %</b>
Numbers of rats examined	44					
Hemorrhage	3	6.82	3.75	10.61	0.00	30.00
Corneal mineralization	1	2.27	2.50	7.07	0.00	20.00
Retinal rosettes	2	4.55	3.75	7.44	0.00	20.00
Inflammatory cell foci	0	0.00	0.00	0.00	0.00	0.00
Retinal degeneration	0	0.00	0.00	0.00	0.00	0.00
Periorbital inflammation	2	4.55	2.50	7.07	0.00	20.00
Peristal hyal. artery	0	0.00	0.00	0.00	0.00	0.00
Corneal vacuolation	0	0.00	0.00	0.00	0.00	0.00

<b>Females</b>	<b>Total n</b>	<b>Total %</b>	<b>Mean %</b>	<b>STDEV %</b>	<b>MIN %</b>	<b>MAX %</b>
Numbers of rats examined	44					
Hemorrhage	4	9.09	5.00	14.14	0.00	40.00
Corneal mineralization	0	0.00	0.00	0.00	0.00	0.00
Retinal rosettes	2	4.55	4.38	9.04	0.00	25.00
Inflammatory cell foci	0	0.00	0.00	0.00	0.00	0.00
Retinal degeneration	0	0.00	0.00	0.00	0.00	0.00
Periorbital inflammation	3	6.82	3.75	10.61	0.00	30.00
Peristal hyal. artery	1	2.27	1.25	3.54	0.00	10.00
Corneal vacuolation	1	2.27	2.50	7.07	0.00	20.00

**Harderian glands**

<b>Males</b>	<b>Total n</b>	<b>Total %</b>	<b>Mean %</b>	<b>STDEV %</b>	<b>MIN %</b>	<b>MAX %</b>
Numbers of rats examined	24					
Inflammation	2	8.33	10.00	22.36	0.00	50.00
Inflammation cell infiltration	0	0.00	0.00	0.00	0.00	0.00
Necrosis	1	4.17	4.00	8.94	0.00	20.00

<b>Females</b>	<b>Total n</b>	<b>Total %</b>	<b>Mean %</b>	<b>STDEV %</b>	<b>MIN %</b>	<b>MAX %</b>
Numbers of rats examined	24					
Inflammation	0	0.00	0.00	0.00	0.00	0.00
Inflammation cell infiltration	1	4.17	4.00	8.94	0.00	20.00
Necrosis	2	8.33	8.00	17.89	0.00	40.00

**Exorbital Lacrimal Glands**

<b>Males</b>	<b>Total n</b>	<b>Total %</b>	<b>Mean %</b>	<b>STDEV %</b>	<b>MIN %</b>	<b>MAX %</b>
Numbers of rats examined	5					

<b>Females</b>	<b>Total n</b>	<b>Total %</b>	<b>Mean %</b>	<b>STDEV %</b>	<b>MIN %</b>	<b>MAX %</b>
Numbers of rats examined	5					

**Aorta**

<b>Males</b>	<b>Total n</b>	<b>Total %</b>	<b>Mean %</b>	<b>STDEV %</b>	<b>MIN %</b>	<b>MAX %</b>
Numbers of rats examined	44					

<b>Females</b>	<b>Total n</b>	<b>Total %</b>	<b>Mean %</b>	<b>STDEV %</b>	<b>MIN %</b>	<b>MAX %</b>
Numbers of rats examined	44					

**Heart**

<b>Males</b>	<b>Total n</b>	<b>Total %</b>	<b>Mean %</b>	<b>STDEV %</b>	<b>MIN %</b>	<b>MAX %</b>
Numbers of rats examined	49					
Mononuclear cell foci	7	14.29	12.22	15.63	0.00	40.00
Myocarditis	1	2.04	2.22	6.67	0.00	20.00
Lymphoid cell infiltration	1	2.04	2.78	8.33	0.00	25.00

<b>Females</b>	<b>Total n</b>	<b>Total %</b>	<b>Mean %</b>	<b>STDEV %</b>	<b>MIN %</b>	<b>MAX %</b>
Numbers of rats examined	49					
Mononuclear cell foci	2	4.08	4.44	13.33	0.00	40.00
Myocarditis	0	0.00	0.00	0.00	0.00	0.00
Lymphoid cell infiltration	1	2.04	2.22	6.67	0.00	20.00

**Nasal cavities**

<b>Males</b>	<b>Total n</b>	<b>Total %</b>	<b>Mean %</b>	<b>STDEV %</b>	<b>MIN %</b>	<b>MAX %</b>
Numbers of rats examined	15					

<b>Females</b>	<b>Total n</b>	<b>Total %</b>	<b>Mean %</b>	<b>STDEV %</b>	<b>MIN %</b>	<b>MAX %</b>
Numbers of rats examined	10					

**Nasal cavity, level 2**

<b>Males</b>	<b>Total n</b>	<b>Total %</b>	<b>Mean %</b>	<b>STDEV %</b>	<b>MIN %</b>	<b>MAX %</b>
Numbers of rats examined	15					

<b>Females</b>	<b>Total n</b>	<b>Total %</b>	<b>Mean %</b>	<b>STDEV %</b>	<b>MIN %</b>	<b>MAX %</b>
Numbers of rats examined	15					

**Larynx**

<b>Males</b>	<b>Total n</b>	<b>Total %</b>	<b>Mean %</b>	<b>STDEV %</b>	<b>MIN %</b>	<b>MAX %</b>
Numbers of rats examined	29					
Lymphoid cell infiltration	2	6.90	8.33	20.41	0.00	50.00

<b>Females</b>	<b>Total n</b>	<b>Total %</b>	<b>Mean %</b>	<b>STDEV %</b>	<b>MIN %</b>	<b>MAX %</b>
Numbers of rats examined	24					
Lymphoid cell infiltration	2	8.33	10.00	22.36	0.00	50.00

**Larynx level 2**

<b>Males</b>	<b>Total n</b>	<b>Total %</b>	<b>Mean %</b>	<b>STDEV %</b>	<b>MIN %</b>	<b>MAX %</b>
Numbers of rats examined	10					

<b>Females</b>	<b>Total n</b>	<b>Total %</b>	<b>Mean %</b>	<b>STDEV %</b>	<b>MIN %</b>	<b>MAX %</b>
Numbers of rats examined	10					

**Larynx level 3**

<b>Males</b>	<b>Total n</b>	<b>Total %</b>	<b>Mean %</b>	<b>STDEV %</b>	<b>MIN %</b>	<b>MAX %</b>
Numbers of rats examined	5					

<b>Females</b>	<b>Total n</b>	<b>Total %</b>	<b>Mean %</b>	<b>STDEV %</b>	<b>MIN %</b>	<b>MAX %</b>
Numbers of rats examined	5					

**Larynx level 6**

<b>Males</b>	<b>Total n</b>	<b>Total %</b>	<b>Mean %</b>	<b>STDEV %</b>	<b>MIN %</b>	<b>MAX %</b>
Numbers of rats examined	5					

<b>Females</b>	<b>Total n</b>	<b>Total %</b>	<b>Mean %</b>	<b>STDEV %</b>	<b>MIN %</b>	<b>MAX %</b>
Numbers of rats examined	5					

**Trachea**

<b>Males</b>	<b>Total n</b>	<b>Total %</b>	<b>Mean %</b>	<b>STDEV %</b>	<b>MIN %</b>	<b>MAX %</b>
Numbers of rats examined	54					
Mononuclear cell foci	15	27.78	28.00	37.06	0.00	100.00
Glandular dilation	5	9.26	8.00	19.32	0.00	60.00
Inflammation infiltrate	9	16.67	18.00	38.24	0.00	100.00

<b>Females</b>	<b>Total n</b>	<b>Total %</b>	<b>Mean %</b>	<b>STDEV %</b>	<b>MIN %</b>	<b>MAX %</b>
Numbers of rats examined	49					
Mononuclear cell foci	12	24.49	22.78	30.73	0.00	80.00
Glandular dilation	1	2.04	1.11	3.33	0.00	10.00
Inflammation infiltrate	9	18.37	20.00	40.00	0.00	100.00

**Lungs**

<b>Males</b>	<b>Total n</b>	<b>Total %</b>	<b>Mean %</b>	<b>STDEV %</b>	<b>MIN %</b>	<b>MAX %</b>
Numbers of rats examined	54					
Alveolar histiocytosis	16	29.63	31.00	29.98	0.00	100.00
Emphysema	0	0.00	0.00	0.00	0.00	0.00
Hemorrhage	6	11.11	10.00	14.14	0.00	40.00
Mononuclear cell foci	5	9.26	10.50	17.39	0.00	40.00
Osseous metaplasia	5	9.26	9.00	9.94	0.00	20.00
Vascular calcification	18	33.33	28.00	28.60	0.00	80.00
Granuloma(s)	1	1.85	2.00	6.32	0.00	20.00
Inflammatory infiltration	1	1.85	2.00	6.32	0.00	20.00
Mixed cell inflammation	0	0.00	0.00	0.00	0.00	0.00
Squamous cyst	1	1.85	2.00	6.32	0.00	20.00

<b>Females</b>	<b>Total n</b>	<b>Total %</b>	<b>Mean %</b>	<b>STDEV %</b>	<b>MIN %</b>	<b>MAX %</b>
Numbers of rats examined	49					
Alveolar histiocytosis	19	38.78	37.22	26.35	0.00	75.00
Emphysema	1	2.04	2.22	6.67	0.00	20.00
Hemorrhage	2	4.08	4.44	8.82	0.00	20.00
Mononuclear cell foci	8	16.33	18.33	33.91	0.00	100.00
Osseous metaplasia	0	0.00	0.00	0.00	0.00	0.00
Vascular calcification	10	20.41	20.00	20.00	0.00	60.00
Granuloma(s)	0	0.00	0.00	0.00	0.00	0.00
Inflammatory infiltration	1	2.04	2.22	6.67	0.00	20.00
Mixed cell inflammation	2	4.08	4.44	13.33	0.00	40.00
Squamous cyst	0	0.00	0.00	0.00	0.00	0.00

**Tracheal bifurcation, carina & mainstem bronchi**

Males	Total n	Total %	Mean %	STDEV %	MIN %	MAX %
Numbers of rats examined	5					

Females	Total n	Total %	Mean %	STDEV %	MIN %	MAX %
Numbers of rats examined	0					

**Pituitary**

Males	Total n	Total %	Mean %	STDEV %	MIN %	MAX %
Numbers of rats examined	49					
Cystic Rathke`s cleft	1	2.04	2.22	6.67	0.00	20.00
P. distal. hypertrophy	3	6.12	7.22	14.81	0.00	40.00

Females	Total n	Total %	Mean %	STDEV %	MIN %	MAX %
Numbers of rats examined	49					
Cystic Rathke`s cleft	1	2.04	1.11	3.33	0.00	10.00
P. distal. hypertrophy	0	0.00	0.00	0.00	0.00	0.00

**Adrenals NOS**

Males	Total n	Total %	Mean %	STDEV %	MIN %	MAX %
Numbers of rats examined	5					
Vacuolation	5	100.00	100.00	0.00	100.00	100.00

Females	Total n	Total %	Mean %	STDEV %	MIN %	MAX %
Numbers of rats examined	0					
Vacuolation	0	0.00	0.00	0.00	0.00	0.00

**Adrenal cortex**

Males	Total n	Total %	Mean %	STDEV %	MIN %	MAX %
Numbers of rats examined	49					
Mononuclear cell foci	0	0.00	0.00	0.00	0.00	0.00
Vacuolation	15	30.61	32.78	29.06	0.00	80.00

Females	Total n	Total %	Mean %	STDEV %	MIN %	MAX %
Numbers of rats examined	49					
Mononuclear cell foci	2	4.08	4.44	13.33	0.00	40.00
Vacuolation	1	2.04	2.78	8.33	0.00	25.00

**Adrenal medulla**

<b>Males</b>	<b>Total n</b>	<b>Total %</b>	<b>Mean %</b>	<b>STDEV %</b>	<b>MIN %</b>	<b>MAX %</b>
Numbers of rats examined	49					

<b>Females</b>	<b>Total n</b>	<b>Total %</b>	<b>Mean %</b>	<b>STDEV %</b>	<b>MIN %</b>	<b>MAX %</b>
Numbers of rats examined	49					

**Thyroid glands**

<b>Males</b>	<b>Total n</b>	<b>Total %</b>	<b>Mean %</b>	<b>STDEV %</b>	<b>MIN %</b>	<b>MAX %</b>
Numbers of rats examined	49					
Ductal remnant	1	2.04	1.11	3.33	0.00	10.00
Follicular cell hypertrophy	10	20.41	23.89	38.87	0.00	100.00
Thymic ectopia	1	2.04	2.22	6.67	0.00	20.00

<b>Females</b>	<b>Total n</b>	<b>Total %</b>	<b>Mean %</b>	<b>STDEV %</b>	<b>MIN %</b>	<b>MAX %</b>
Numbers of rats examined	49					
Ductal remnant	2	4.08	2.22	6.67	0.00	20.00
Follicular cell hypertrophy	0	0.00	0.00	0.00	0.00	0.00
Thymic ectopia	1	2.04	2.22	6.67	0.00	20.00

**Parathyroid glands**

<b>Males</b>	<b>Total n</b>	<b>Total %</b>	<b>Mean %</b>	<b>STDEV %</b>	<b>MIN %</b>	<b>MAX %</b>
Numbers of rats examined	49					

<b>Females</b>	<b>Total n</b>	<b>Total %</b>	<b>Mean %</b>	<b>STDEV %</b>	<b>MIN %</b>	<b>MAX %</b>
Numbers of rats examined	49					

**Pancreas**

<b>Males</b>	<b>Total n</b>	<b>Total %</b>	<b>Mean %</b>	<b>STDEV %</b>	<b>MIN %</b>	<b>MAX %</b>
Numbers of rats examined	49					
Exocrine atrophy	7	14.29	17.78	33.83	0.00	100.00
Islet hyperplasia	3	6.12	7.22	10.93	0.00	25.00
Mononuclear cell foci	2	4.08	3.33	7.07	0.00	20.00
Cytoplas. vacuolation	0	0.00	0.00	0.00	0.00	0.00
Acinar cell vacuolation	3	6.12	8.33	25.00	0.00	75.00
Congestion	2	4.08	4.44	13.33	0.00	40.00

<b>Females</b>	<b>Total n</b>	<b>Total %</b>	<b>Mean %</b>	<b>STDEV %</b>	<b>MIN %</b>	<b>MAX %</b>
Numbers of rats examined	49					
Exocrine atrophy	3	6.12	7.78	17.16	0.00	50.00
Islet hyperplasia	3	6.12	7.78	17.16	0.00	50.00
Mononuclear cell foci	4	8.16	7.78	13.94	0.00	40.00
Cytoplas. vacuolation	3	6.12	6.67	20.00	0.00	60.00
Acinar cell vacuolation	0	0.00	0.00	0.00	0.00	0.00
Congestion	0	0.00	0.00	0.00	0.00	0.00



**Liver**

<b>Males</b>	<b>Total n</b>	<b>Total %</b>	<b>Mean %</b>	<b>STDEV %</b>	<b>MIN %</b>	<b>MAX %</b>
Numbers of rats examined	49					
Erythropoiesis	0	0.00	0.00	0.00	0.00	0.00
Bile duct hyperplasia	1	2.04	2.22	6.67	0.00	20.00
Fatty change	19	38.78	40.00	31.62	0.00	100.00
Increased glycogen	5	10.20	11.11	33.33	0.00	100.00
Hematopoiesis	0	0.00	0.00	0.00	0.00	0.00
Hemosiderin deposits	1	2.04	1.11	3.33	0.00	10.00
Inflammatory cell foci	29	59.18	55.56	44.19	0.00	100.00
Peri-/ bile duct inflammation	1	2.04	2.22	6.67	0.00	20.00
Hemopoietic foci	2	4.08	3.33	7.07	0.00	20.00
Mononuclear cell foci	10	20.41	22.22	44.10	0.00	100.00
Congestion	1	2.04	1.11	3.33	0.00	10.00
Cytopl. Inclusions	1	2.04	2.22	6.67	0.00	20.00
Mixed cell infiltration	4	8.16	8.89	26.67	0.00	80.00

<b>Females</b>	<b>Total n</b>	<b>Total %</b>	<b>Mean %</b>	<b>STDEV %</b>	<b>MIN %</b>	<b>MAX %</b>
Numbers of rats examined	49					
Erythropoiesis	1	2.04	2.22	6.67	0.00	20.00
Bile duct hyperplasia	0	0.00	0.00	0.00	0.00	0.00
Fatty change	28	57.14	61.11	34.08	0.00	100.00
Increased glycogen	12	24.49	28.33	36.74	0.00	100.00
Hematopoiesis	2	4.08	4.44	13.33	0.00	40.00
Hemosiderin deposits	0	0.00	0.00	0.00	0.00	0.00
Inflammatory cell foci	20	40.82	35.56	38.44	0.00	100.00
Peri-/ bile duct inflammation	0	0.00	0.00	0.00	0.00	0.00
Hemopoietic foci	3	6.12	5.56	8.82	0.00	20.00
Mononuclear cell foci	10	20.41	22.22	44.10	0.00	100.00
Congestion	0	0.00	0.00	0.00	0.00	0.00
Cytopl. Inclusions	0	0.00	0.00	0.00	0.00	0.00
Mixed cell infiltration	5	10.20	11.11	33.33	0.00	100.00

**Tongue**

<b>Males</b>	<b>Total n</b>	<b>Total %</b>	<b>Mean %</b>	<b>STDEV %</b>	<b>MIN %</b>	<b>MAX %</b>
Numbers of rats examined	24					
Inflammatory all foci	0	0.00	0.00	0.00	0.00	0.00

<b>Females</b>	<b>Total n</b>	<b>Total %</b>	<b>Mean %</b>	<b>STDEV %</b>	<b>MIN %</b>	<b>MAX %</b>
Numbers of rats examined	24					
Inflammatory all foci	1	4.17	4.00	8.94	0.00	20.00

## Esophagus

<b>Males</b>	<b>Total n</b>	<b>Total %</b>	<b>Mean %</b>	<b>STDEV %</b>	<b>MIN %</b>	<b>MAX %</b>
Numbers of rats examined	34					

<b>Females</b>	<b>Total n</b>	<b>Total %</b>	<b>Mean %</b>	<b>STDEV %</b>	<b>MIN %</b>	<b>MAX %</b>
Numbers of rats examined	24					

## Stomach

<b>Males</b>	<b>Total n</b>	<b>Total %</b>	<b>Mean %</b>	<b>STDEV %</b>	<b>MIN %</b>	<b>MAX %</b>
Numbers of rats examined	49					
Glandular cyst	1	2.04	2.78	8.33	0.00	25.00
Hyaline droplets	9	18.37	20.00	36.06	0.00	100.00
Mononuclear cell foci	5	10.20	11.11	22.61	0.00	60.00
Lymphoid follicles	0	0.00	0.00	0.00	0.00	0.00
Vacuolation	0	0.00	0.00	0.00	0.00	0.00
Congestion	4	8.16	9.44	20.68	0.00	60.00
Hemorrhage	0	0.00	0.00	0.00	0.00	0.00
Inflammatory infiltration	3	6.12	4.44	8.82	0.00	20.00
Cystic glands	0	0.00	0.00	0.00	0.00	0.00

<b>Females</b>	<b>Total n</b>	<b>Total %</b>	<b>Mean %</b>	<b>STDEV %</b>	<b>MIN %</b>	<b>MAX %</b>
Numbers of rats examined	49					
Glandular cyst	2	4.08	5.56	16.67	0.00	50.00
Hyaline droplets	14	28.57	31.11	47.02	0.00	100.00
Mononuclear cell foci	1	2.04	2.22	6.67	0.00	20.00
Lymphoid follicles	1	2.04	2.22	6.67	0.00	20.00
Vacuolation	3	6.12	6.67	20.00	0.00	60.00
Congestion	3	6.12	6.67	14.14	0.00	40.00
Hemorrhage	1	2.04	2.22	6.67	0.00	20.00
Inflammatory infiltration	4	8.16	7.78	19.86	0.00	60.00
Cystic glands	1	2.04	1.11	3.33	0.00	10.00

## Duodenum

<b>Males</b>	<b>Total n</b>	<b>Total %</b>	<b>Mean %</b>	<b>STDEV %</b>	<b>MIN %</b>	<b>MAX %</b>
Numbers of rats examined	49					

<b>Females</b>	<b>Total n</b>	<b>Total %</b>	<b>Mean %</b>	<b>STDEV %</b>	<b>MIN %</b>	<b>MAX %</b>
Numbers of rats examined	49					

**Jejunum**

Males	Total n	Total %	Mean %	STDEV %	MIN %	MAX %
Numbers of rats examined	44					

Females	Total n	Total %	Mean %	STDEV %	MIN %	MAX %
Numbers of rats examined	44					

**Ileum**

Males	Total n	Total %	Mean %	STDEV %	MIN %	MAX %
Numbers of rats examined	44					

Females	Total n	Total %	Mean %	STDEV %	MIN %	MAX %
Numbers of rats examined	44					

**Peyer's patches – jejunum**

Males	Total n	Total %	Mean %	STDEV %	MIN %	MAX %
Number of rats examined	41					
Lymphoid hyperplasia	5	12.20	12.50	26.73	0.00	75.00
Mineralization	2	4.88	6.25	11.57	0.00	25.00

Females	Total n	Total %	Mean %	STDEV %	MIN %	MAX %
Number of rats examined	41					
Lymphoid hyperplasia	7	17.07	15.36	30.12	0.00	80.00
Mineralization	2	4.88	5.00	9.26	0.00	20.00

**Peyer's patches – ileum**

Males	Total n	Total %	Mean %	STDEV %	MIN %	MAX %
Number of rats examined	44					
Lymphoid hyperplasia	11	25.00	18.75	34.82	0.00	80.00
Congestion	4	9.09	10.00	28.28	0.00	80.00

Females	Total n	Total %	Mean %	STDEV %	MIN %	MAX %
Number of rats examined	44					
Lymphoid hyperplasia	9	20.45	16.25	31.14	0.00	80.00
Congestion	1	2.27	2.50	7.07	0.00	20.00

**Caecum**

<b>Males</b>	<b>Total n</b>	<b>Total %</b>	<b>Mean %</b>	<b>STDEV %</b>	<b>MIN %</b>	<b>MAX %</b>
Numbers of rats examined	49					
Congestion	1	2.04	2.22	6.67	0.00	20.00

<b>Females</b>	<b>Total n</b>	<b>Total %</b>	<b>Mean %</b>	<b>STDEV %</b>	<b>MIN %</b>	<b>MAX %</b>
Numbers of rats examined	49					
Congestion	0	0.00	0.00	0.00	0.00	0.00

**Colon**

<b>Males</b>	<b>Total n</b>	<b>Total %</b>	<b>Mean %</b>	<b>STDEV %</b>	<b>MIN %</b>	<b>MAX %</b>
Numbers of rats examined	49					

<b>Females</b>	<b>Total n</b>	<b>Total %</b>	<b>Mean %</b>	<b>STDEV %</b>	<b>MIN %</b>	<b>MAX %</b>
Numbers of rats examined	49					

**Rectum**

<b>Males</b>	<b>Total n</b>	<b>Total %</b>	<b>Mean %</b>	<b>STDEV %</b>	<b>MIN %</b>	<b>MAX %</b>
Numbers of rats examined	49					
Dilation	4	8.16	8.89	14.53	0.00	40.00

<b>Females</b>	<b>Total n</b>	<b>Total %</b>	<b>Mean %</b>	<b>STDEV %</b>	<b>MIN %</b>	<b>MAX %</b>
Numbers of rats examined	49					
Dilation	4	8.16	8.89	17.64	0.00	40.00

**Parotid salivary glands**

<b>Males</b>	<b>Total n</b>	<b>Total %</b>	<b>Mean %</b>	<b>STDEV %</b>	<b>MIN %</b>	<b>MAX %</b>
Numbers of rats examined	15					
Cytoplas. vacuolation	3	20.00	20.00	34.64	0.00	60.00
Secretory depletion	0	0.00	0.00	0.00	0.00	0.00

<b>Females</b>	<b>Total n</b>	<b>Total %</b>	<b>Mean %</b>	<b>STDEV %</b>	<b>MIN %</b>	<b>MAX %</b>
Numbers of rats examined	15					
Cytoplas. vacuolation	3	20.00	20.00	34.64	0.00	60.00
Secretory depletion	1	6.67	6.67	11.55	0.00	20.00

**Sublingual salivary glands**

<b>Males</b>	<b>Total n</b>	<b>Total %</b>	<b>Mean %</b>	<b>STDEV %</b>	<b>MIN %</b>	<b>MAX %</b>
Numbers of rats examined	49					
Parotid glandular ectopia	0	0.00	0.00	0.00	0.00	0.00

<b>Females</b>	<b>Total n</b>	<b>Total %</b>	<b>Mean %</b>	<b>STDEV %</b>	<b>MIN %</b>	<b>MAX %</b>
Numbers of rats examined	49					
Parotid glandular ectopia	1	2.04	1.11	3.33	0.00	10.00

**Submand. salivary glands**

<b>Males</b>	<b>Total n</b>	<b>Total %</b>	<b>Mean %</b>	<b>STDEV %</b>	<b>MIN %</b>	<b>MAX %</b>
Numbers of rats examined	49					
Mononuclear foci	1	2.04	2.22	6.67	0.00	20.00
Fatty atrophy	2	4.08	5.56	16.67	0.00	50.00

<b>Females</b>	<b>Total n</b>	<b>Total %</b>	<b>Mean %</b>	<b>STDEV %</b>	<b>MIN %</b>	<b>MAX %</b>
Numbers of rats examined	49					
Mononuclear foci	0	0.00	0.00	0.00	0.00	0.00
Fatty atrophy	0	0.00	0.00	0.00	0.00	0.00

**Urinary bladder**

<b>Males</b>	<b>Total n</b>	<b>Total %</b>	<b>Mean %</b>	<b>STDEV %</b>	<b>MIN %</b>	<b>MAX %</b>
Numbers of rats examined	45					
Mononuclear cell foci	1	2.22	11.11	33.33	0.00	100.00

<b>Females</b>	<b>Total n</b>	<b>Total %</b>	<b>Mean %</b>	<b>STDEV %</b>	<b>MIN %</b>	<b>MAX %</b>
Numbers of rats examined	44					
Mononuclear cell foci	2	4.55	5.00	9.26	0.00	20.00

**Ureter**

<b>Males</b>	<b>Total n</b>	<b>Total %</b>	<b>Mean %</b>	<b>STDEV %</b>	<b>MIN %</b>	<b>MAX %</b>
Numbers of rats examined	34					

<b>Females</b>	<b>Total n</b>	<b>Total %</b>	<b>Mean %</b>	<b>STDEV %</b>	<b>MIN %</b>	<b>MAX %</b>
Numbers of rats examined	34					

## Kidneys

Males	Total n	Total %	Mean %	STDEV %	MIN %	MAX %
Numbers of rats examined	49					
Cortical mineralization	0	0.00	0.00	0.00	0.00	0.00
Hyaline droplets	25	51.02	54.44	43.33	0.00	100.00
Medullary mineralization	1	2.04	1.11	3.33	0.00	10.00
Interstitial inflammation	5	10.20	11.11	33.33	0.00	100.00
Pelvic dilation	5	10.20	11.11	16.91	0.00	50.00
Pyelitis	1	2.04	2.22	6.67	0.00	20.00
Tubular basophilia	23	46.94	45.56	38.44	0.00	100.00
Tubular casts	5	10.20	11.11	33.33	0.00	100.00
Urothelial hyperplasia	1	2.04	2.22	6.67	0.00	20.00
Tubular mineraliz.	1	2.04	2.22	6.67	0.00	20.00
Mononuclear cell foci	10	20.41	21.11	31.00	0.00	80.00
Lymphoid foci	2	4.08	4.44	13.33	0.00	40.00
Tubular cyst(s)	0	0.00	0.00	0.00	0.00	0.00
Cortical scar	1	2.04	1.11	3.33	0.00	10.00
Tubular vacuolation	9	18.37	22.22	44.10	0.00	100.00

Females	Total n	Total %	Mean %	STDEV %	MIN %	MAX %
Numbers of rats examined	49					
Cortical mineralization	10	20.41	16.67	21.21	0.00	50.00
Hyaline droplets	0	0.00	0.00	0.00	0.00	0.00
Medullary mineralization	2	4.08	2.22	6.67	0.00	20.00
Interstitial inflammation	5	10.20	11.11	33.33	0.00	100.00
Pelvic dilation	3	6.12	7.22	14.81	0.00	40.00
Pyelitis	1	2.04	2.22	6.67	0.00	20.00
Tubular basophilia	13	26.53	26.67	17.32	0.00	60.00
Tubular casts	1	2.04	2.22	6.67	0.00	20.00
Urothelial hyperplasia	1	2.04	2.22	6.67	0.00	20.00
Tubular mineraliz.	4	8.16	8.89	17.64	0.00	40.00
Mononuclear cell foci	8	16.33	16.67	33.91	0.00	100.00
Lymphoid foci	1	2.04	2.22	6.67	0.00	20.00
Tubular cyst(s)	0	0.00	0.00	0.00	0.00	0.00
Cortical scar	0	0.00	0.00	0.00	0.00	0.00
Tubular vacuolation	9	18.37	22.22	44.10	0.00	100.00

## Skin

Males	Total n	Total %	Mean %	STDEV %	MIN %	MAX %
Numbers of rats examined	44					
Mononuclear cell foci	0	0.00	0.00	0.00	0.00	0.00

Females	Total n	Total %	Mean %	STDEV %	MIN %	MAX %
Numbers of rats examined	44					
Mononuclear cell foci	2	4.55	5.00	14.14	0.00	40.00

### **Mammary glands**

<b>Males</b>	<b>Total n</b>	<b>Total %</b>	<b>Mean %</b>	<b>STDEV %</b>	<b>MIN %</b>	<b>MAX %</b>
Numbers of rats examined	48					
Glandular hyperplasia	0	0.00	0.00	0.00	0.00	0.00
Lobular development	9	16.67	21.11	32.57	0.00	80.00
Secretory activity	8	14.81	19.44	30.46	0.00	75.00
Adipose tissue only	6	11.11	8.89	17.64	0.00	40.00
Vacuolation	1	1.85	2.78	8.33	0.00	25.00

<b>Females</b>	<b>Total n</b>	<b>Total %</b>	<b>Mean %</b>	<b>STDEV %</b>	<b>MIN %</b>	<b>MAX %</b>
Numbers of rats examined	49					
Glandular hyperplasia	13	26.53	31.11	47.02	0.00	100.00
Lobular development	0	0.00	0.00	0.00	0.00	0.00
Secretory activity	8	16.33	20.00	36.06	0.00	100.00
Adipose tissue only	0	0.00	0.00	0.00	0.00	0.00
Vacuolation	0	0.00	0.00	0.00	0.00	0.00

### **Testes**

<b>Males</b>	<b>Total n</b>	<b>Total %</b>	<b>Mean %</b>	<b>STDEV %</b>	<b>MIN %</b>	<b>MAX %</b>
Numbers of rats examined	49					
Sertoli cell vacuolation	3	6.12	5.56	13.33	0.00	40.00
Tubular degeneration	3	6.12	6.67	20.00	0.00	60.00

### **Epididymides**

<b>Males</b>	<b>Total n</b>	<b>Total %</b>	<b>Mean %</b>	<b>STDEV %</b>	<b>MIN %</b>	<b>MAX %</b>
Numbers of rats examined	49					
Mononuclear cell foci	7	14.29	11.11	22.61	0.00	60.00
Sperm granuloma	1	2.04	2.22	6.67	0.00	20.00
Lymphoid cell infiltrate	1	2.04	2.78	8.33	0.00	25.00

### **Prostate**

<b>Males</b>	<b>Total n</b>	<b>Total %</b>	<b>Mean %</b>	<b>STDEV %</b>	<b>MIN %</b>	<b>MAX %</b>
Numbers of rats examined	49					
Inflammation	1	2.04	1.11	3.33	0.00	10.00

### **Coagulating gland**

<b>Males</b>	<b>Total n</b>	<b>Total %</b>	<b>Mean %</b>	<b>STDEV %</b>	<b>MIN %</b>	<b>MAX %</b>
Numbers of rats examined	39					

**Seminal vesicles**

Males	Total n	Total %	Mean %	STDEV %	MIN %	MAX %
Numbers of rats examined	49					

**Ovaries**

Females	Total n	Total %	Mean %	STDEV %	MIN %	MAX %
Numbers of rats examined	49					
Congestion	2	4.08	4.44	13.33	0.00	40.00

**Oviducts**

Females	Total n	Total %	Mean %	STDEV %	MIN %	MAX %
Numbers of rats examined	19					
Congestion	1	5.26	5.00	10.00	0.00	20.00

**Uterus**

Females	Total n	Total %	Mean %	STDEV %	MIN %	MAX %
Numbers of rats examined	49					
Estrus	1	2.04	2.22	6.67	0.00	20.00
Cornual dilation	3	6.12	4.44	8.82	0.00	20.00
Diestrus	2	4.08	4.44	13.33	0.00	40.00
Proestrus	2	4.08	4.44	13.33	0.00	40.00

**Cervix**

Females	Total n	Total %	Mean %	STDEV %	MIN %	MAX %
Numbers of rats examined	20					

**Vagina**

Females	Total n	Total %	Mean %	STDEV %	MIN %	MAX %
Numbers of rats examined	49					
Diestrus	9	18.37	14.44	24.04	0.00	60.00
Estrus	4	8.16	7.78	13.94	0.00	40.00
Metestrus	8	16.33	14.44	18.10	0.00	40.00
Proestrus	4	8.16	7.78	19.86	0.00	60.00
Cyst	1	2.04	2.22	6.67	0.00	20.00



**Bone marrow – sternal**

Males	Total n	Total %	Mean %	STDEV %	MIN %	MAX %
Numbers of rats examined	4					
Fatty atrophy	4	100.00	100.00	0.00	100.00	100.00

Females	Total n	Total %	Mean %	STDEV %	MIN %	MAX %
Numbers of rats examined	5					
Fatty atrophy	4	80.00	80.00	0.00	80.00	80.00

**Bone marrow – femoral**

Males	Total n	Total %	Mean %	STDEV %	MIN %	MAX %
Numbers of rats examined	44					
Fatty atrophy	11	25.00	29.38	40.57	0.00	80.00
Fatty replacement	11	25.00	15.00	35.05	0.00	100.00

Females	Total n	Total %	Mean %	STDEV %	MIN %	MAX %
Numbers of rats examined	44					
Fatty atrophy	6	13.64	15.00	35.05	0.00	100.00
Fatty replacement	8	18.18	10.00	28.28	0.00	80.00

**Mesentric lymph node**

Males	Total n	Total %	Mean %	STDEV %	MIN %	MAX %
Numbers of rats examined	49					
Histiocytosis	4	8.16	11.11	33.33	0.00	100.00
Histiocytic aggregation	0	0.00	0.00	0.00	0.00	0.00
Lymphoid hyperplasia	21	42.86	44.44	48.76	0.00	100.00
Mastocytosis	4	8.16	8.89	26.67	0.00	80.00
Sinusoidal dilation	0	0.00	0.00	0.00	0.00	0.00

Females	Total n	Total %	Mean %	STDEV %	MIN %	MAX %
Numbers of rats examined	49					
Histiocytosis	2	4.08	5.00	10.00	0.00	25.00
Histiocytic aggregation	1	2.04	1.11	3.33	0.00	10.00
Lymphoid hyperplasia	20	40.82	44.44	52.70	0.00	100.00
Mastocytosis	2	4.08	4.44	13.33	0.00	40.00
Sinusoidal dilation	0	0.00	0.00	0.00	0.00	0.00

**Mandibular lymph node**

<b>Males</b>	<b>Total n</b>	<b>Total %</b>	<b>Mean %</b>	<b>STDEV %</b>	<b>MIN %</b>	<b>MAX %</b>
Numbers of rats examined	49					
Hemorrhage	2	4.08	4.44	13.33	0.00	40.00
Histiocytosis	3	6.12	8.33	25.00	0.00	75.00
Lymphoid hyperplasia	19	38.78	42.22	50.44	0.00	100.00
Plasmocytosis	19	38.78	42.22	50.44	0.00	100.00
Plasma cell infiltration	9	18.37	22.22	44.10	0.00	100.00
Hematopoiesis	0	0.00	0.00	0.00	0.00	0.00

<b>Females</b>	<b>Total n</b>	<b>Total %</b>	<b>Mean %</b>	<b>STDEV %</b>	<b>MIN %</b>	<b>MAX %</b>
Numbers of rats examined	49					
Hemorrhage	3	6.12	6.67	20.00	0.00	60.00
Histiocytosis	0	0.00	0.00	0.00	0.00	0.00
Lymphoid hyperplasia	17	34.69	37.78	46.31	0.00	100.00
Plasmocytosis	18	36.73	40.00	47.96	0.00	100.00
Plasma cell infiltration	9	18.37	22.22	44.10	0.00	100.00
Hematopoiesis	1	2.04	2.22	6.67	0.00	20.00

**Other Lymph Nodes**

<b>Males</b>	<b>Total n</b>	<b>Total %</b>	<b>Mean %</b>	<b>STDEV %</b>	<b>MIN %</b>	<b>MAX %</b>
Numbers of rats examined	29					
Congestion	1	1.85	4.00	8.94	0.00	20.00
Histiocytosis	1	1.85	5.00	11.18	0.00	25.00
Lymphoid hyperplasia	5	9.26	18.00	14.83	0.00	40.00
Pigment deposition	0	0.00	0.00	0.00	0.00	0.00
Mast cell infiltrate	3	5.56	15.00	33.54	0.00	75.00

<b>Females</b>	<b>Total n</b>	<b>Total %</b>	<b>Mean %</b>	<b>STDEV %</b>	<b>MIN %</b>	<b>MAX %</b>
Numbers of rats examined	29					
Congestion	0	0.00	0.00	0.00	0.00	0.00
Histiocytosis	0	0.00	0.00	0.00	0.00	0.00
Lymphoid hyperplasia	5	10.20	20.00	24.49	0.00	60.00
Pigment deposition	2	4.08	6.00	8.94	0.00	20.00
Mast cell infiltrate	3	6.12	15.00	33.54	0.00	75.00

### Thymus

Males	Total n	Total %	Mean %	STDEV %	MIN %	MAX %
Numbers of rats examined	49					
Involution/ Atrophy	6	12.24	11.67	20.62	0.00	60.00
Cyst(s)	7	14.29	15.00	16.96	0.00	40.00
Hemorrhage	6	12.24	11.11	20.28	0.00	60.00

Females	Total n	Total %	Mean %	STDEV %	MIN %	MAX %
Numbers of rats examined	49					
Involution/ Atrophy	4	8.16	7.78	19.86	0.00	60.00
Cyst(s)	18	36.73	34.44	33.58	0.00	80.00
Hemorrhage	5	10.20	11.67	18.03	0.00	40.00

### Spleen

Males	Total n	Total %	Mean %	STDEV %	MIN %	MAX %
Numbers of rats examined	49					
Extramedullary hematopoiesis	36	73.47	78.89	37.56	0.00	100.00
Hemosiderin pigment	6	12.24	12.22	17.16	0.00	40.00

Females	Total n	Total %	Mean %	STDEV %	MIN %	MAX %
Numbers of rats examined	49					
Extramedullary hematopoiesis	29	59.18	66.67	45.83	0.00	100.00
Hemosiderin pigment	25	51.02	44.44	45.58	0.00	100.00

### Bone sternum

Males	Total n	Total %	Mean %	STDEV %	MIN %	MAX %
Number of rats examined	39					
Chondromucinous degeneration	2	5.13	2.86	7.56	0.00	20.00

Females	Total n	Total %	Mean %	STDEV %	MIN %	MAX %
Number of rats examined	39					
Chondromucinous degeneration	0	0.00	0.00	0.00	0.00	0.00

### Bone femur

Males	Total n	Total %	Mean %	STDEV %	MIN %	MAX %
Number of rats examined	59					

Females	Total n	Total %	Mean %	STDEV %	MIN %	MAX %
Number of rats examined	59					

**Skeletal Muscle**

<b>Males</b>	<b>Total n</b>	<b>Total %</b>	<b>Mean %</b>	<b>STDEV %</b>	<b>MIN %</b>	<b>MAX %</b>
Numbers of rats examined	44					
Mononuclear cell foci	0	0.00	0.00	0.00	0.00	0.00

<b>Females</b>	<b>Total n</b>	<b>Total %</b>	<b>Mean %</b>	<b>STDEV %</b>	<b>MIN %</b>	<b>MAX %</b>
Numbers of rats examined	44					
Mononuclear cell foci	3	6.82	7.50	14.88	0.00	40.00

**Injection site**

<b>Males</b>	<b>Total n</b>	<b>Total %</b>	<b>Mean %</b>	<b>STDEV %</b>	<b>MIN %</b>	<b>MAX %</b>
Numbers of rats examined	29					
Inflammatory infiltration dermis	1	3.45	2.00	4.47	0.00	10.00
Intimal proliferation	1	3.45	2.00	4.47	0.00	10.00
Phlebitis/periphlebitis	0	0.00	0.00	0.00	0.00	0.00
Inflammation infiltrate	3	10.34	12.00	26.83	0.00	60.00
Vasular degeneration	1	3.45	4.00	8.94	0.00	20.00
Obliteration	1	3.45	5.00	11.18	0.00	25.00

<b>Females</b>	<b>Total n</b>	<b>Total %</b>	<b>Mean %</b>	<b>STDEV %</b>	<b>MIN %</b>	<b>MAX %</b>
Numbers of rats examined	29					
Inflammatory infiltration dermis	0	0.00	0.00	0.00	0.00	0.00
Intimal proliferation	0	0.00	0.00	0.00	0.00	0.00
Phlebitis/periphlebitis	1	3.45	2.00	4.47	0.00	10.00
Inflammation infiltrate	0	0.00	0.00	0.00	0.00	0.00
Vasular degeneration	1	3.45	4.00	8.94	0.00	20.00
Obliteration	2	6.90	10.00	22.36	0.00	50.00

**Tail vein**

<b>Males</b>	<b>Total n</b>	<b>Total %</b>	<b>Mean %</b>	<b>STDEV %</b>	<b>MIN %</b>	<b>MAX %</b>
Numbers of rats examined	5					
Foreign body embolus	0	0.00	0.00	0.00	0.00	0.00
Venous obliteration	0	0.00	0.00	0.00	0.00	0.00

<b>Females</b>	<b>Total n</b>	<b>Total %</b>	<b>Mean %</b>	<b>STDEV %</b>	<b>MIN %</b>	<b>MAX %</b>
Numbers of rats examined	5					
Foreign body embolus	1	20.00	20.00	0.00	20.00	20.00
Venous obliteration	2	40.00	40.00	0.00	40.00	40.00

**Tail**

<b>Males</b>	<b>Total n</b>	<b>Total %</b>	<b>Mean %</b>	<b>STDEV %</b>	<b>MIN %</b>	<b>MAX %</b>
Numbers of rats examined	5					

<b>Females</b>	<b>Total n</b>	<b>Total %</b>	<b>Mean %</b>	<b>STDEV %</b>	<b>MIN %</b>	<b>MAX %</b>
Numbers of rats examined	5					