

**HISTORICAL CONTROL DATA
ON REPRODUCTION /DEVELOPMENTAL TOXICITY
STUDIES
IN HsdRccHanTM: WIST, Wistar Hannover Rats**

**COMPILED FROM BIOASSAYS PERFORMED AT RCC LTD.
ITINGEN / SWITZERLAND**

Contents Tables:

Table 2: Type and Number of the Lesions of the Brain.	4
Table 3: Type and Number of the Lesions of the Cerebrum.	4
Table 4: Type and Number of the Lesions of the Spinal Cord.	4
Table 5: Type and Number of the Lesions of the Sciatic Nerve.	4
Table 6: Type and Number of the Lesions of the Heart.	4
Table 7: Type and Number of the Lesions of the Trachea.	4
Table 8: Type and Number of the Lesions of the Lungs.	5
Table 9: Type and Number of the Lesions of the Thyroid Glands.	5
Table 10: Type and Number of the Lesions of the Parathyroid Glands.	5
Table 11: Type and Number of the Lesions of the Adrenal Glands.	5
Table 12: Type and Number of the Lesions of the Adrenal Cortex.	5
Table 13: Type and Number of the Lesions of the Liver.	6
Table 14: Type and Number of the Lesions of the Stomach.	6
Table 15: Type and Number of the Lesions of the ForeStomach.	6
Table 16: Type and Number of the Lesions of the Glandular Stomach.	6
Table 17: Type and Number of the Lesions of the Duodenum.	7
Table 18: Type and Number of the Lesions of the Jejunum.	7
Table 19: Type and Number of the Lesions of the Ileum.	7
Table 20: Type and Number of the Lesions of the Cecum.	7
Table 21: Type and Number of the Lesions of the Colon.	7
Table 22: Type and Number of the Lesions of the Rectum.	7
Table 23: Type and Number of the Lesions of the Peyer's Patches.	8
Table 24: Type and Number of the Lesions of the Urinary Bladder.	8
Table 25: Type and Number of the Lesions of the Kidneys.	8
Table 26: Type and Number of the Lesions of the Skin.	8
Table 27: Type and Number of the Lesions of the Testes.	9
Table 28: Type and Number of the Lesions of the Epididymides.	9
Table 29: Type and Number of the Lesions of the Prostate.	9
Table 30: Type and Number of the Lesions of the Seminal Vesicles.	9
Table 31: Type and Number of the Lesions of the Ovaries.	10
Table 32: Type and Number of the Lesions of the Uterus.	10
Table 33: Type and Number of the Lesions of the Vagina.	10
Table 34: Type and Number of the Lesions of the Mesentric Lymph Node.	11
Table 35: Type and Number of the Lesions of the Mandibular Lymph Node.	11
Table 36: Type and Number of the Lesions of the Other Lymph Nodes.	11
Table 37: Type and Number of the Lesions of the Thymus.	11
Table 38: Type and Number of the Lesions of the Spleen.	11
Table 39: Type and Number of the Lesions of the Bone Marrow.	11
Table 40: Type and Number of the Lesions of the Femur (Bone marrow).	12
Synonyms used in Pathology report	13
Appendix: Statistics	18

Table 1: Study Identification

Study Number	ID Number	Data of Performance	Study type	Age at Delivery (weeks)	Pretest Acclimatization (days)	Body Weight at Delivery (g)		Housing	Diet	Vehicle	Pathologist
						M	F				
A42366	1	March - June 2007	Toxicity Screening Study	10	7	275 - 325	175 - 225	groups	Kliba 3433	Corn oil	SPH
A42412	2	March - June 2007	Sreening Study	♂8 : ♀10	7	240 - 280	175 - 215	groups	Kliba 3433	1% CMC	PAV
A33816	3	Nov. 2005 - Febuary 2006	Toxicity Screening Study	11	7	280 - 340	180 - 240	groups	Kliba - Nafag 3433	Corn oil	SPH
857096	4	January 2005 - March 2005	Toxicity Screening Study	11	7	280 - 340	180 - 240	groups	Kliba - Nafag 3433	Corn oil	KHE
B64620	5	Nov. 2007 - January 2008	Dose Range - Finding Study	8 - 9	7	220 - 280	150 - 190	groups	Kliba - Nafag 3433	0,25% Methyl cellulose	WEK
857738	6	April 2007 - August 2007	Dose Toxity Study	8 - 9	7	230 - 280	160 - 190	groups	Kliba - Nafag 3433	Corn oil	KHE

Pathologists:

KHE: Dr. K. Heider

WEK: Dr. Klaus Weber

SPH/PSC: Dr. Phillipe Schätti

PAV: Dr. Virgilio Pace

Historical Control Data of Developmental Toxicity Studies in HsdRccHan™: WIST, Wistar Hannover Rats

Table 2: Type and Number of the Lesions of the Brain.

Study identification	1		2		3		4		5		6		7		8		9		10	
Sex	M	F	M	F	M	F	M	F	M	F	M	F	M	F	M	F	M	F	M	F
Brain																				
Numbers of rats examined	0	0	10	10	0	0	0	0	0	0	10	10	0	0	0	0	0	0	0	0

Table 3: Type and Number of the Lesions of the Cerebrum.

Study identification	1		2		3		4		5		6		7		8		9		10	
Sex	M	F	M	F	M	F	M	F	M	F	M	F	M	F	M	F	M	F	M	F
Cerebrum																				
Numbers of rats examined	0	0	0	0	0	0	0	0	0	0	10	10	0	0	0	0	0	0	0	0
Ventricular Dilation	0	0	0	0	0	0	0	0	0	0	0	1	0	0	0	0	0	0	0	0

Table 4: Type and Number of the Lesions of the Spinal Cord.

Study identification	1		2		3		4		5		6		7		8		9		10	
Sex	M	F	M	F	M	F	M	F	M	F	M	F	M	F	M	F	M	F	M	F
Spinal Cord																				
Numbers of rats examined	0	0	10	10	0	0	0	0	0	0	10	10	0	0	0	0	0	0	0	0

Table 5: Type and Number of the Lesions of the Sciatic Nerve.

Study identification	1		2		3		4		5		6		7		8		9		10	
Sex	M	F	M	F	M	F	M	F	M	F	M	F	M	F	M	F	M	F	M	F
Sciatic Nerve																				
Numbers of rats examined	0	0	0	0	0	0	0	0	0	0	10	10	0	0	0	0	0	0	0	0

Table 6: Type and Number of the Lesions of the Heart.

Study identification	1		2		3		4		5		6		7		8		9		10	
Sex	M	F	M	F	M	F	M	F	M	F	M	F	M	F	M	F	M	F	M	F
Heart																				
Numbers of rats examined	0	0	5	10	0	0	0	0	16	8	10	10	0	0	0	0	0	0	0	0
Mononuclear cell foci	0	0	0	0	0	0	0	0	3	1	0	0	0	0	0	0	0	0	0	0
Inflammatory cell foci	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Myocardial necrosis	0	0	0	0	0	0	0	0	1	0	0	0	0	0	0	0	0	0	0	0

Table 7: Type and Number of the Lesions of the Trachea.

Study identification	1		2		3		4		5		6		7		8		9		10	
Sex	M	F	M	F	M	F	M	F	M	F	M	F	M	F	M	F	M	F	M	F
Trachea																				
Numbers of rats examined	0	0	10	10	0	0	0	0	0	0	10	10	0	0	0	0	0	0	0	0
Glandular dilation	0	0	0	0	0	0	0	0	0	0	1	1	0	0	0	0	0	0	0	0
Mononuclear cell foci	0	0	0	0	0	0	0	0	0	0	1	0	0	0	0	0	0	0	0	0

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Table8: Type and Number of the Lesions of the Lungs.

Study identification	1		2		3		4		5		6		7		8		9		10	
Sex	M	F	M	F	M	F	M	F	M	F	M	F	M	F	M	F	M	F	M	F
Lungs																				
Numbers of rats examined	0	0	5	5	0	0	0	0	0	0	10	10	0	0	0	0	0	0	0	0
Osseous metaplasia	0	0	0	0	0	0	0	0	0	0	1	1	0	0	0	0	0	0	0	0
Hemorrhage	0	0	0	0	0	0	0	0	0	0	1	1	0	0	0	0	0	0	0	0
Alveolar histiocytosis	0	0	0	0	0	0	0	0	0	0	1	1	0	0	0	0	0	0	0	0

Table 9: Type and Number of the Lesions of the Thyroid Glands.

Study identification	1		2		3		4		5		6		7		8		9		10	
Sex	M	F	M	F	M	F	M	F	M	F	M	F	M	F	M	F	M	F	M	F
Thyroid Glands																				
Numbers of rats examined	0	0	10	10	0	0	0	0	0	0	10	10	0	0	0	0	0	0	0	0
Follicular cell hypertrophy	0	0	0	0	0	0	0	0	0	0	3	1	0	0	0	0	0	0	0	0

Table 10: Type and Number of the Lesions of the Parathyroid Glands.

Study identification	1		2		3		4		5		6		7		8		9		10	
Sex	M	F	M	F	M	F	M	F	M	F	M	F	M	F	M	F	M	F	M	F
Parathyroid Glands																				
Numbers of rats examined	0	0	0	0	0	0	0	0	0	0	10	10	0	0	0	0	0	0	0	0

Table 11: Type and Number of the Lesions of the Adrenal Glands.

Study identification	1		2		3		4		5		6		7		8		9		10	
Sex	M	F	M	F	M	F	M	F	M	F	M	F	M	F	M	F	M	F	M	F
Adrenal Glands																				
Numbers of rats examined	0	0	5	5	0	0	0	0	16	8	10	10	0	0	0	0	0	0	0	0
Vacuolation	0	0	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0

Table 12: Type and Number of the Lesions of the Adrenal Cortex.

Study identification	1		2		3		4		5		6		7		8		9		10	
Sex	M	F	M	F	M	F	M	F	M	F	M	F	M	F	M	F	M	F	M	F
Adrenal Cortex																				
Numbers of rats examined	0	0	0	0	0	0	0	0	16	8	10	10	0	0	0	0	0	0	0	0
Extra-adrenal tissue	0	0	0	0	0	0	0	0	1	0	0	0	0	0	0	0	0	0	0	0
Vacuolation	0	0	0	0	0	0	0	0	12	0	3	0	0	0	0	0	0	0	0	0
Mononuclear cell foci	0	0	0	0	0	0	0	0	2	0	0	0	0	0	0	0	0	0	0	0
Hypertrophy, fasciculata	0	0	0	0	0	0	0	0	3	2	0	0	0	0	0	0	0	0	0	0

Historical Control Data of Developmental Toxicity Studies in HsdRccHan™: WIST, Wistar Hannover Rats

Table 13: Type and Number of the Lesions of the Liver.

Study identification	1		2		3		4		5		6		7		8		9		10	
Sex	M	F	M	F	M	F	M	F	M	F	M	F	M	F	M	F	M	F	M	F
Liver																				
Numbers of rats examined	0	0	5	5	0	0	0	0	16	8	10	10	0	0	0	0	0	0	0	0
Increased glycogen	0	0	0	0	0	0	0	0	0	1	0	0	0	0	0	0	0	0	0	0
Fatty change	0	0	0	0	0	0	0	0	0	0	3	3	0	0	0	0	0	0	0	0
Hematopoiesis	0	0	0	0	0	0	0	0	0	0	1	2	0	0	0	0	0	0	0	0
Inflammatory cell foci	0	0	5	1	0	0	0	0	8	2	8	7	0	0	0	0	0	0	0	0
Single cell necrosis	0	0	0	0	0	0	0	0	0	0	1	1	0	0	0	0	0	0	0	0
Hepatocellular hypertrophy	1	2	0	0	0	0	0	0	0	2	0	0	0	0	0	0	0	0	0	0

Table 14: Type and Number of the Lesions of the Stomach.

Study identification	1		2		3		4		5		6		7		8		9		10	
Sex	M	F	M	F	M	F	M	F	M	F	M	F	M	F	M	F	M	F	M	F
Stomach																				
Numbers of rats examined	0	0	5	5	0	0	0	0	0	0	10	10	0	0	0	0	0	0	0	0

Table 15: Type and Number of the Lesions of the ForeStomach.

Study identification	1		2		3		4		5		6		7		8		9		10	
Sex	M	F	M	F	M	F	M	F	M	F	M	F	M	F	M	F	M	F	M	F
ForeStomach																				
Numbers of rats examined	0	0	0	0	0	0	0	0	0	0	10	10	0	0	0	0	0	0	0	0
Hyperkeratosis	0	0	0	0	0	0	0	0	0	0	2	3	0	0	0	0	0	0	0	0

Table 16: Type and Number of the Lesions of the Glandular Stomach.

Study identification	1		2		3		4		5		6		7		8		9		10	
Sex	M	F	M	F	M	F	M	F	M	F	M	F	M	F	M	F	M	F	M	F
Glandular Stomach																				
Numbers of rats examined	0	0	0	0	0	0	0	0	0	0	10	10	0	0	0	0	0	0	0	0
Erosion	0	0	0	0	0	0	0	0	0	0	1	0	0	0	0	0	0	0	0	0

Historical Control Data of Developmental Toxicity Studies in HsdRccHan™: WIST, Wistar Hannover Rats

Table 17: Type and Number of the Lesions of the Duodenum.

Study identification	1		2		3		4		5		6		7		8		9		10	
Sex	M	F	M	F	M	F	M	F	M	F	M	F	M	F	M	F	M	F	M	F
Duodenum																				
Numbers of rats examined	0	0	5	5	0	0	0	0	0	0	10	10	0	0	0	0	0	0	0	0
Mucosal hyperplasia	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0

Table 18: Type and Number of the Lesions of the Jejunum.

Study identification	1		2		3		4		5		6		7		8		9		10	
Sex	M	F	M	F	M	F	M	F	M	F	M	F	M	F	M	F	M	F	M	F
Jejunum																				
Numbers of rats examined	0	0	5	5	0	0	0	0	0	0	10	10	0	0	0	0	0	0	0	0

Table 19: Type and Number of the Lesions of the Ileum.

Study identification	1		2		3		4		5		6		7		8		9		10	
Sex	M	F	M	F	M	F	M	F	M	F	M	F	M	F	M	F	M	F	M	F
Ileum																				
Numbers of rats examined	0	0	5	10	0	0	0	0	0	0	10	10	0	0	0	0	0	0	0	0

Table 20: Type and Number of the Lesions of the Cecum.

Study identification	1		2		3		4		5		6		7		8		9		10	
Sex	M	F	M	F	M	F	M	F	M	F	M	F	M	F	M	F	M	F	M	F
Cecum																				
Numbers of rats examined	0	0	10	10	0	0	0	0	0	0	10	10	0	0	0	0	0	0	0	0

Table 21: Type and Number of the Lesions of the Colon.

Study identification	1		2		3		4		5		6		7		8		9		10	
Sex	M	F	M	F	M	F	M	F	M	F	M	F	M	F	M	F	M	F	M	F
Colon																				
Numbers of rats examined	0	0	10	10	0	0	0	0	0	0	10	10	0	0	0	0	0	0	0	0
Dilation	0	0	0	0	0	0	0	0	0	0	1	0	0	0	0	0	0	0	0	0
Nematodes	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0

Table 22: Type and Number of the Lesions of the Rectum.

Study identification	1		2		3		4		5		6		7		8		9		10	
Sex	M	F	M	F	M	F	M	F	M	F	M	F	M	F	M	F	M	F	M	F
Rectum																				
Numbers of rats examined	0	0	10	10	0	0	0	0	0	0	10	10	0	0	0	0	0	0	0	0
Dilation	0	0	0	0	0	0	0	0	0	0	1	0	0	0	0	0	0	0	0	0

Historical Control Data of Developmental Toxicity Studies in HsdRccHan™: WIST, Wistar Hannover Rats

Table 23: Type and Number of the Lesions of the Peyer's Patches.

Study identification	1		2		3		4		5		6		7		8		9		10	
Sex	M	F	M	F	M	F	M	F	M	F	M	F	M	F	M	F	M	F	M	F
Peyer's patches																				
Numbers of rats examined	0	0	5	5	0	0	0	0	0	0	10	10	0	0	0	0	0	0	0	0

Table 24: Type and Number of the Lesions of the Urinary Bladder.

Study identification	1		2		3		4		5		6		7		8		9		10	
Sex	M	F	M	F	M	F	M	F	M	F	M	F	M	F	M	F	M	F	M	F
Urinary Bladder																				
Numbers of rats examined	0	0	5	10	0	0	0	0	0	0	10	10	0	0	0	0	0	0	0	0

Table 25: Type and Number of the Lesions of the Kidneys.

Study identification	1		2		3		4		5		6		7		8		9		10	
Sex	M	F	M	F	M	F	M	F	M	F	M	F	M	F	M	F	M	F	M	F
Kidneys																				
Numbers of rats examined	0	0	5	5	0	0	0	0	16	8	10	10	0	0	0	0	0	0	0	0
Hyaline inclusions	0	0	0	0	0	0	0	0	11	0	3	0	0	0	0	0	0	0	0	0
Cortical mineralization	0	0	0	0	0	0	0	0	2	1	0	0	0	0	0	0	0	0	0	0
Medulla mineralization	0	0	0	0	0	0	0	0	1	0	0	0	0	0	0	0	0	0	0	0
Tubular basophilia	0	0	2	1	0	0	0	0	11	1	0	0	0	0	0	0	0	0	0	0
Tubular cast(s)	0	0	0	0	0	0	0	0	2	1	0	0	0	0	0	0	0	0	0	0
Tubular degeneration	0	0	0	0	0	0	0	0	0	0	3	1	0	0	0	0	0	0	0	0
Mononuclear cell foci	0	0	0	0	0	0	0	0	4	3	1	0	0	0	0	0	0	0	0	0
Mixed cell Infiltration	0	0	1	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0

Table 26: Type and Number of the Lesions of the Skin.

*only gross lesions examined

Study identification	1		2		3		4		5		6		7		8		9		10	
Sex	M	F	M	F	M	F	M	F	M	F	M	F	M	F	M	F	M	F	M	F
Skin																				
Numbers of rats examined	0	1	0	0	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Hair follicle atrophy	0	1	0	0	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0

Historical Control Data of Developmental Toxicity Studies in HsdRccHan™: WIST, Wistar Hannover Rats

Table 27: Type and Number of the Lesions of the Testes.

Study identification	1	2	3	4	5	6	7	8	9	10
Sex	M	M	M	M	M	M	M	M	M	M
Testes										
Numbers of rats examined	10	10	10	10	16	10	0	0	0	0
Cellular debris	1	0	1	0	0	0	0	0	0	0
Single cell pyknosis *	3	0	0	0	0	0	0	0	0	0
Tubular degeneration	2	0	7	1	4	0	0	0	0	0

Table 28: Type and Number of the Lesions of the Epididymides.

Study identification	1	2	3	4	5	6	7	8	9	10
Sex	M	M	M	M	M	M	M	M	M	M
Epididymides										
Numbers of rats examined	10	10	10	10	16	10	0	0	0	0
Inflammatory cell foci	0	1	0	0	0	0	0	0	0	0
Cellular Debris	1	0	0	0	0	0	0	0	0	0

Table 29: Type and Number of the Lesions of the Prostate.

Study identification	1	2	3	4	5	6	7	8	9	10
Sex	M	M	M	M	M	M	M	M	M	M
Prostate										
Numbers of rats examined	0	10	0	0	0	10	0	0	0	0

Table 30: Type and Number of the Lesions of the Seminal Vesicles.

Study identification	1	2	3	4	5	6	7	8	9	10
Sex	M	M	M	M	M	M	M	M	M	M
Seminal Vesicles										
Numbers of rats examined	1	10	0	0	0	10	0	0	0	0
Inspissated Secretion	1	0	0	0	0	0	0	0	0	0

Table 31: Type and Number of the Lesions of the Ovaries.

Study identification	1	2	3	4	5	6	7	8	9	10
Sex	F	F	F	F	F	F	F	F	F	F
Ovaries										
Numbers of rats examined	10	10	10	10	8	10	0	0	0	0
Cyst(s)	0	0	2	0	0	0	0	0	0	0
Atrophy	0	0	0	0	6	0	0	0	0	0
Stroma cell hyperplasia	0	0	2	0	0	0	0	0	0	0

Table 32: Type and Number of the Lesions of the Uterus.

Study identification	1	2	3	4	5	6	7	8	9	10
Sex	F	F	F	F	F	F	F	F	F	F
Uterus										
Numbers of rats examined	0	5	0	0	8	10	0	0	0	0
Dilation	0	0	0	0	0	1	0	0	0	0
Implantation site	0	0	0	0	5	0	0	0	0	0
Atrophy	0	0	0	0	8	0	0	0	0	0

Table 33: Type and Number of the Lesions of the Vagina.

Study identification	1	2	3	4	5	6	7	8	9	10
Sex	F	F	F	F	F	F	F	F	F	F
Vagina										
Numbers of rats examined	0	5	0	0	8	0	0	0	0	0
Anestrus	0	0	0	0	8	0	0	0	0	0
Cycle: Metestrus	0	5	0	0	0	0	0	0	0	0
Mucification	0	0	0	0	2	0	0	0	0	0
Mucosa atrophy	0	0	0	0	8	0	0	0	0	0
Cystic degeneration, mucosal	0	0	0	0	2	0	0	0	0	0

Table 34: Type and Number of the Lesions of the Mesenteric Lymph Node.

Study identification	1		2		3		4		5		6		7		8		9		10	
Sex	M	F	M	F	M	F	M	F	M	F	M	F	M	F	M	F	M	F	M	F
Mesenteric Lymph Nodes																				
Numbers of rats examined	0	0	4	5	0	0	0	0	0	0	10	10	0	0	0	0	0	0	0	0

Table 35: Type and Number of the Lesions of the Mandibular Lymph Node.

Study identification	1		2		3		4		5		6		7		8		9		10	
Sex	M	F	M	F	M	F	M	F	M	F	M	F	M	F	M	F	M	F	M	F
Mandibular Lymph Nodes																				
Numbers of rats examined	0	0	10	10	0	0	0	0	0	0	10	10	0	0	0	0	0	0	0	0
Congestion	0	0	0	0	0	0	0	0	0	0	1	0	0	0	0	0	0	0	0	0

Table 36: Type and Number of the Lesions of the Other Lymph Nodes.

Study identification	1		2		3		4		5		6		7		8		9		10	
Sex	M	F	M	F	M	F	M	F	M	F	M	F	M	F	M	F	M	F	M	F
Other Lymph nodes																				
Numbers of rats examined	0	0	0	0	0	0	0	0	0	0	10*	10*	0	0	0	0	0	0	0	0

* Inguinal

Table 37: Type and Number of the Lesions of the Thymus.

Study identification	1		2		3		4		5		6		7		8		9		10	
Sex	M	F	M	F	M	F	M	F	M	F	M	F	M	F	M	F	M	F	M	F
Thymus																				
Numbers of rats examined*	0	0	6	10	0	1	0	0	16	8	10	10	0	0	0	0	0	0	0	0
Cyst(s)	0	0	0	0	0	0	0	0	1	3	1	4	0	0	0	0	0	0	0	0
Congestion	0	0	1	0	0	0	0	0	0	0	1	2	0	0	0	0	0	0	0	0
Hemorrhage	0	0	0	0	0	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Atrophy	0	0	0	0	0	0	0	0	8	8	0	0	0	0	0	0	0	0	0	0
Hyperplastic Epithelium	0	0	0	0	0	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0

*gross lesions only

Table 38: Type and Number of the Lesions of the Spleen.

Study identification	1		2		3		4		5		6		7		8		9		10	
Sex	M	F	M	F	M	F	M	F	M	F	M	F	M	F	M	F	M	F	M	F
Spleen																				
Numbers of rats examined	0	0	5	5	0	0	0	0	16	8	10	10	0	0	0	0	0	0	0	0
Congestion	0	0	0	0	0	0	0	0	0	0	7	4	0	0	0	0	0	0	0	0
Erythropoiesis	0	0	0	0	0	0	0	0	11	8	10	10	0	0	0	0	0	0	0	0
Hemosiderin	0	0	0	0	0	0	0	0	16	8	5	9	0	0	0	0	0	0	0	0

Table 39: Type and Number of the Lesions of the Bone Marrow.

Study identification	1		2		3		4		5		6		7		8		9		10	
Sex	M	F	M	F	M	F	M	F	M	F	M	F	M	F	M	F	M	F	M	F
Bone Marrow																				
Numbers of rats examined	0	0	5	5	0	0	0	0	0	0	10	10	0	0	0	0	0	0	0	0

Table 40: Type and Number of the Lesions of the Femur (Bone marrow).

Study identification	1		2		3		4		5		6		7		8		9		10	
Sex	M	F	M	F	M	F	M	F	M	F	M	F	M	F	M	F	M	F	M	F
Femur (Bone marrow)																				
Numbers of rats examined	0	0	0	0	0	0	0	0	0	0	10	10	0	0	0	0	0	0	0	0

Synonyms used in Pathology Reports

Adrenal Cortex:

Extra-adrenal tissue:	Accessory Cortical Tissue, Accessory tissue
Angiectasis:	Focal angiectasis
Inflammatory cell foci:	Focal cortical inflammator cell infiltration
Mononuclear cell foci:	Lymphoid foci, Mononuclear focus/ foci
Vacuolation:	Diffuse cortical coarse vacuolation, Diffuse fatty change, Fasciculata vacuolization

Adrenal Glands:

Mononuclear cell foci:	Lymphoid cell infiltration
Vacuolation:	Change fatty, Change fatty cortical

Bone marrow:

Decreased Erythropoiesis:	Reduced Erythropoiesis
Fatty replacement:	Atrophy fatty, Fatty change
Increased Myelopoiesis:	Increased granulopoiesis, Leftshifted myelopoiesis, Rightshifted Myelopoiesis

Brain:

Mononuclear cell foci:	Infiltration lymphoid
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Colon:

Mononuclear cell foci:	Mononuclear foci
Nematodes:	Nematodes in lumen, Parasites

Epididymides:

Inflammatory cell foci	Infiltration Lymphocytic, Lymphoid cell infiltration, Lymphoid foci, Lymphoid infiltration, Mononuclear cell infiltration, Mononuclear cells, Mononuclear infiltration, Round cell infiltration, Mixed cell Infiltration
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Exorbital Lacrimal Glands:

Mononuclear cell foci:	Infiltration lymphoid, Mononuclear foci
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Eyes:

Mononuclear cell foci:	Infiltration lymphoid
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Harderian Glands:

Inflammation:	Chronic adenitis
Mononuclear cell foci:	Mononuclear foci
Porphyryn granulomas:	Granuloma porphyrin, Porphyrin, Porphyrin pigment

Heart:

Inflammation:	Focal myocarditis, Lymphocytic inflammation
Inflammatory cell foci:	Inflammatory cell infiltration, Infiltration Inflammatory cell, Lymphoid cell foci, Lymphoid foci, Mononuclear foci
Mononuclear cell foci:	Infiltration lymphoid
Myocardial fibrosis:	Fibrosis, Interstitial fibrosis, Myodegeneration/ fibrosis, Myofibrosis
Myofibrosis/necrosis:	Fibromuscular degeneration, Myodegeneration, Fibrinoid degeneration, Myocytolysis/fibrosis
Myolysis/ Myonecrosis:	Focal myonecrosis, Myocardial necrosis, Myolysis/ Myonecrosis, Myonecrosis, Necrosis/ cytolysis

Ileum:

Lymphoid hyperplasia:	Follicular hyperplasia
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Historical Control Data of Developmental Toxicity Studies in HsdRccHan™: WIST, Wistar Hannover Rats

Jejunum:

Mineralization: Mineralization: lymph follicles

Kidneys:

Cyst(s): Cortical cyst(s)
 Fibrosis: Fibrotic foci, Interstitial fibrosis
 Hyaline inclusion: Change hyaline tubular, Hyaline inclusions, Hyaline resorption bodies, Intraepithelial hyaline droplets, Intratubular hyaline droplets, Tubular hyaline droplets, Hyaline droplets
 Hydronephrosis: Bilateral hydronephrosis, Unilateral hydronephrosis
 Inflammation: Chronic inflammation, Embolic nephritis, Inflammation mononuclear, Inflammation polymorpheous, Inflammation suppurative, Interstitial nephritis, Mononuclear inflammation, Nephritis, Purulent nephritis, Pyelonephritis, Suppurative nephritis, Suppurative pyelonephritis
 Lipofuscin pigment: Lipofuscin deposition
 Mononuclear cell foci: Infiltration lymphoid, Lymphoid cell foci, Lymphoid cell infiltration, Lymphoid foci, Mononuclear cell infiltration, Mononuclear cells, Mononuclear foci
 Papillary mineralization: Mineralization papillary
 Pelvic dilation: Dilatation, Dilated pelvis, Pelvic dilatation
 Pelvic mineralization: Mineral deposits: pelvis& papilla, Urothelial mineralization
 Pyelitis: Pyelitis chronic, Suppurative pyelitis
 Tubular basophilia: Basophilic tubule(s)
 Tubular casts: Proteinaceous cast, Proteinaceous tubular casts
 Tubular degeneration: Tubular atrophy
 Tubular dilation: Cystic dilatation, Cystic dilation, Dilated tubules, Tubular dilatation
 Urothelial hyperplasia: Pelvic epithelial hyperplasia, Transitional cell hyperplasia, Transitional cell proliferation

Liver:

Bile duct proliferation: Bile duct hyperplasia, Biliar proliferation
 Erythropoiesis: Extramedullary haematopoiesis, Extramedullary hemopoiesis, Granulopoiesis, Hematopoiesis, Hemopoiesis, Hemopoietic cells, Hemopoietic foci
 Fatty change: Diffuse (fat) vacuolation, Fatty change/ centrilobular, Fatty change/ diffuse, Fatty change/ patchy, Fatty change/ periportal, Focal fatty change, Hepatocyte fat vacuolar, Lipidosis, Lipid storage, Periportal fat vacuolation
 Hepatocellular hypertrophy: Centrilobular Hypertrophy, Hypertrophy, Hypertrophy perilobular,
 Increased glycogen: Glycogen contents, Hepatocytic glycogen deposits, Increased glycogen deposits
 Necrosis: Focal coagulative necrosis, Infarction lobular, Necrosis coagulative
 Single Cell Necrosis: Necrosis Individual Cells, Unicellular necrosis, Hepatocellular Necrosis
 Vacuolation: Centrilobular vacuolation, Midzonal vacuolation, Patchy vacuolation, Portal vacuolation, mfocal vacuolation

Historical Control Data of Developmental Toxicity Studies in HsdRccHanTM: WIST, Wistar Hannover Rats

Lungs:

Alveolar crystals:	Intra-alveolar crystals
Alveolar edema:	Edema, Intra-alveolar edema, Oedema
Alveolar histiocytosis:	Alveolar macrophages, Foam cell aggregates, Foam cells, Histiocytosis, Intra-alveolar histiocytosis, Macrophages accumulation
Alveolitis:	Alveolar inflammation
Congestion:	Agonal congestion
Emphysema	Emphysema acute
Granulomas:	Microgranulomas
Hemorrhage:	Alveolar hemorrhage
Inflammatory foci:	Infiltration Inflammatory Cell
Lymphoid hyperplasia:	Lymphoid infiltration peribronchial, Peribronchial lymphoid hyperplasia
Mononuclear cell foci:	Infiltration Lymphocytic, Infiltration lymphoid, Lymphoid infiltrate, Lymphoid cell foci
Osseous metaplasia:	Alveolar bone, Alveolar bony metaplasia, Intra-alveolar bone, Ossification, Pneumoliths
Perivascular cuffing:	Lymphoid cuffing, Lymphoid infiltration perivascular, Perivascular lymphoid, Perivascular Infiltrate
Perivascular Inflammation:	Perivasculitis

Mandibular lymph nodes:

Erythrophagocytosis/ Congestion	Erythrophagocytosis
Histiocytosis:	Sinus histiocytosis
Lymphoid hyperplasia:	Hyperplasia, Hyperplastic reaction chronic, Reactive hyperplasia
Plasmacytosis:	Plasma cell hyperplasia, Plasma cells
Sinusoidal dilation:	Cyst, Cystic degeneration, Cystic sinus dilation, Lymphangiectasis, Sinus dilation, Sinus ectasia, Sinusoidal cysts, Sinusoidal ectasia

Mesenteric lymph nodes:

Histiocytosis:	Histiocytic conglomerates, Macrophage accumulation, Sinus histiocytosis, increased histiocytosis
Lymphoid hyperplasia:	Hyperplasia, Reactive hyperplasia
Sinus dilation:	Cystic degeneration, Cystic sinus dilation, Cystic sinusoids, Lymphangiectasis, Sinus ectasia, Sinusoidal cysts, Sinusoidal dilation, Sinusoidal ectasia, Sinusoidal mastcells
Sinusoidal plasma cells	Plasmocytosis

Oral Cavity:

Periodontitis	Parodontitis:
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Other Lymph nodes:

Hemosiderin:	Hemosiderosis
Sinusoidal dilation:	Dilated sinusoidal cyst

Historical Control Data of Developmental Toxicity Studies in HsdRccHanTM: WIST, Wistar Hannover Rats

Ovaries:

Bursa dilation: Bursal distension, Cystic bursa, Cyst(s)/ bursa dilation, Dilated bursa, Distended bursa
Interstitial cell hyperplasia: Focal interstitial hyperplasia, Interstitial glandular hyperplasia, Interstitial hyperplasia, Stromal hyperplasia, Stromal cell hyperplasia

Pancreas:

Apoptosis: Exocrine apoptosis
Exocrine atrophy: Atrophy, Atrophy acinar, Exocrine degeneration
Islet cell hyperplasia: Hyperplasia islet
Mononuclear foci: Lymphoid foci

Peyer's Patches:

Mineralization: Calcification

Pituitary Glands:

Cyst: Developmental cyst
Cystic Rathke's cleft: Dilation hypophyseal cleft
Stromatodeal Remnants: Craniopharyngeal Structures

Rectum:

Mononuclear cell foci: Mononuclear foci
Nematodes: Nematodes in lumen, Parasites

Seminal vesicles:

Reduced colloid: Reduced content

Skin:

Inflammation: Subcutaneous inflammation, Inflammatory foci, Dermal inflammation
Fibrosis: Subepidermal fibrosis
Mononuclear cell foci: Lymphoid foci; Mononuclear infiltration
Hair follicle atrophy

Historical Control Data of Developmental Toxicity Studies in HsdRccHanTM: WIST, Wistar Hannover Rats

Spleen:

Hemopoiesis: Extramedullary hemopoiesis, Exmedullary hematopoiesis, Hemopoiesis, Increased hematopoiesis, Red pulp hyperplasia,
Hemosiderin: Hemosiderin pigment, Hemosiderosis, Hemosiderin deposits
Lymphoid hyperplasia: Follicular hyperplasia, Hyperplasia, Lymphoid cell proliferation, Reactive hyperplasia
Congestion

Testes:

Tubular degeneration: Bilateral degeneration of the germinal epithelium, Degeneration, Seminiferous tubular atrophy, Tubular atrophy, Tubular degeneration

Thymus:

Atrophy: Advanced atrophy, Cortical atrophy, Involution, Lymphoid atrophy, Lymphoid depletion, Thymic atrophy, Thymic involution
Congestion: Hyperemia
Cyst(s): Cystic change, Epithelial cysts, Medullary Cyst(s), Multiloculated cysts, Squamous Cystic, Tubular structures

Lymphocytolysis: Increased lymphocytolysis, Phagocytic cells
Histiocytosis: Starry sky cells, Tingated body macrophages

Thyroid Glands:

Ductal remnants: Persistent thyroglossal duct, Thyroglossal cast/ducts, Cyst(s), Ultimobranchial cyst(s)
Dysplasia: Epithelial dysplasia
Follicular cell hypertrophy: Hypertrophy follicular
Mononuclear cell foci: Infiltration Lymphocytic, Mononuclear foci
Thymic remnants: Accessory thymus, Ectopic thymus

Tongue:

Mononuclear cell foci: Infiltration lymphoid, Lymphoid cell infiltration, Mononuclear foci

Trachea:

Distended glands: Cystic glands, Dilated glands, Glandular dilation
Inflammatory foci: Mixed cell foci
Hyaline inclusions: Eosinophile inclusions

Uterus:

Cornual dilation: Dilatation, Dilated lumen, Dilated horns, Distended lumen, Distension, Estrus/ Proestrus: Cyclic dilation (present), Luminal dilatation
Squamous cyst(s): Epidermal cyst(s), Epithelial cyst(s), Inclusion cyst(s)

Appendix

Statistic