

Reproductive Toxicology

Historical Control Data in Rats



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Sprague Dawley and Wistar Rats

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¹ The HCD period is from Jan 2019 through Dec 2020, with the exception of GD 20 Reproductive Indices which is from Jan 2016 through Dec 2020. Additional HCD endpoints and years are available upon request.

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¹ The HCD period is from Jan 2016 through Dec 2020. Additional HCD endpoints and years are available upon request.

REPRODUCTIVE INDICES
SPRAGUE DAWLEY [CrI:CD(SD)] RATS
GESTATION DAY 13 CAESAREAN-SECTION

PERIOD: 2019 THROUGH 2020

	FULL STUDIES			DOSE RANGE STUDIES		
NO. OF STUDIES INCLUDED	46			2		
NO. OF RATS TESTED	1009			18		
NO. OF RATS PREGNANT	930			16		
NO. FOUND DEAD	0			0		
NO. DELIVERED	2			0		
CAESAREAN-SECTIONED ON GD 13	930			16		
	<u>MEAN</u>	<u>MIN</u>	<u>MAX</u>	<u>MEAN</u>	<u>MIN</u>	<u>MAX</u>
PREGNANT (%)	92.2	80.0	100.0	91.7	83.3	100.0
CORPORA LUTEA	17.5	15.2	19.8	14.7	14.0	15.4
IMPLANTATIONS	15.7	13.8	18.6	13.3	11.7	14.9
PREIMPLANTATION LOSS (%)	9.3	4.0	18.5	9.9	3.2	16.7
LITTER SIZES						
VIALE EMBRYOS	14.8	12.6	17.6	12.4	10.3	14.4
NONVIALE EMBRYOS	0.9	0.3	2.0	0.3	0.0	0.5
POSTIMPLANTATION LOSS (%)	6.1	2.5	13.3	6.5	3.6	9.3
DAMS WITH ANY NONVIALE EMBRYOS (%)	52.8	27.8	75.0	15.0	0.0	30.0
DAMS WITH ALL NONVIALE EMBRYOS (%)	0.1	0.0	5.3	0.0	0.0	0.0
DAMS WITH ONE OR MORE VIALE EMBRYOS (%)	99.9	94.7	100.0	100.0	100.0	100.0
PLACENTAE APPEARED NORMAL (%)	99.7	95.2	100	100.0	100.0	100.0

Updated June 2021

REPRODUCTIVE INDICES
SPRAGUE DAWLEY [CrI:CD(SD)] RATS
GESTATION DAY 20 CAESAREAN-SECTION

PERIOD: 2016 THROUGH 2020

	FULL STUDIES			DOSE RANGE STUDIES		
NO. OF STUDIES INCLUDED	4			3		
NO. OF RATS TESTED	88			21		
NO. OF RATS PREGNANT	78			21		
NO. FOUND DEAD	0			0		
NO. ABORTED	0			0		
NO. DELIVERED	0			0		
CAESAREAN-SECTIONED ON GD 20	78			21		
NO. OF RATS WITH SINGLE CONCEPTUS LITTER						
LIVE:	0			0		
RESORBED:	0			0		
ABORTED:	0			0		
	<u>MEAN</u>	<u>MIN</u>	<u>MAX</u>	<u>MEAN</u>	<u>MIN</u>	<u>MAX</u>
PREGNANT (%)	88.6	77.3	95.4	100.0	100.0	100.0
CORPORA LUTEA	15.9	15.1	17.3	15.8	13.8	17.6
IMPLANTATIONS	14.8	14.5	15.2	15.0	13.0	16.6
PREIMPLANTATION LOSS (%)	7.0	1.3	12.8	4.5	3.3	5.3
LITTER SIZES						
LIVE FETUSES	14.1	13.9	14.2	14.2	11.6	16.2
DEAD FETUSES	0.0	0.0	0.0	0.0	0.0	0.0
TOTAL RESORPTIONS	1.2	1.2	1.2	0.8	0.4	1.4
EARLY RESORPTIONS	0.7	0.4	1.1	0.8	0.4	1.4
LATE RESORPTIONS	0.0	0.0	0.1	0.0	0.0	0.0
POSTIMPLANTATION LOSS (%)	5.1	2.8	8.7	5.4	2.2	11.0
DAMS WITH ANY RESORPTIONS (%)	61.9	61.9	61.9	45.0	37.5	60.0

Updated June 2021

REPRODUCTIVE INDICES
SPRAGUE DAWLEY [CrI:CD(SD)] RATS
GESTATION DAY 20 CAESAREAN-SECTION

PERIOD: 2016 THROUGH 2020

NO. OF STUDIES INCLUDED	FULL STUDIES 4			DOSE RANGE STUDIES 3		
	<u>MEAN</u>	<u>MIN</u>	<u>MAX</u>	<u>MEAN</u>	<u>MIN</u>	<u>MAX</u>
DAMS WITH ALL CONCEPTUSES RESORBED (%)	0.0	0.0	0.0	0.0	0.0	0.0
DAMS WITH ONE OR MORE VIABLE FETUSES (%)	100.0	100.0	100.0	100.0	100.0	100.0
SEX RATIO (% MALES/LITTER)	53.5	47.8	56.2	44.4	41.2	47.9
LIVE FETAL BODY WEIGHTS GRAMS/LITTER						
MALE FETUSES:	3.87	3.77	4.03	4.01	3.69	4.57
FEMALE FETUSES:	3.68	3.56	3.79	3.76	3.41	4.33
DAMS WITH NORMAL PLACENTAE (%)	97.6	90.5	100	100	100	100

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REPRODUCTIVE INDICES
SPRAGUE DAWLEY [CrI:CD(SD)] RATS
GESTATION DAY 21 CAESAREAN-SECTION

PERIOD: 2019 THROUGH 2020

	FULL STUDIES 29			DOSE RANGE STUDIES 27		
NO. OF STUDIES INCLUDED	29			27		
NO. OF RATS TESTED	621			192		
NO. OF RATS PREGNANT	609			188		
NO. FOUND DEAD	0			0		
NO. ABORTED	0			0		
NO. DELIVERED	0			0		
CAESAREAN-SECTIONED ON GD 21	609			188		
NO. OF RATS WITH SINGLE CONCEPTUS LITTER						
LIVE:	0			0		
RESORBED:	0			0		
ABORTED:	0			0		
	<u>MEAN</u>	<u>MIN</u>	<u>MAX</u>	<u>MEAN</u>	<u>MIN</u>	<u>MAX</u>
PREGNANT (%)	98.0	90.0	100.0	98.1	83.3	100.0
CORPORA LUTEA	14.4	12.7	18.9	13.5	12.0	15.4
IMPLANTATIONS	12.9	11.8	16.9	12.6	11.2	14.0
PREIMPLANTATION LOSS (%)	9.0	1.6	15.1	6.4	0.0	15.1
LITTER SIZES						
LIVE FETUSES	12.2	10.9	15.2	12.1	10.3	14.0
DEAD FETUSES	0.04	0.0	0.8	0.01	0.0	0.2
TOTAL RESORPTIONS	0.65	0.1	1.1	0.52	0.0	1.2
EARLY RESORPTIONS	0.61	0.1	1.1	0.49	0.0	1.2
LATE RESORPTIONS	0.04	0.0	0.3	0.03	0.0	0.2
POSTIMPLANTATION LOSS (%)	5.4	0.8	11.0	4.3	0.0	10.1
DAMS WITH ANY RESORPTIONS (%)	41.6	10.0	70.0	38.8	0.0	66.7

Updated June 2021

REPRODUCTIVE INDICES
SPRAGUE DAWLEY [CrI:CD(SD)] RATS
GESTATION DAY 21 CAESAREAN-SECTION

PERIOD: 2019 THROUGH 2020

NO. OF STUDIES INCLUDED	FULL STUDIES 29			DOSE RANGE STUDIES 27		
	<u>MEAN</u>	<u>MIN</u>	<u>MAX</u>	<u>MEAN</u>	<u>MIN</u>	<u>MAX</u>
DAMS WITH ALL CONCEPTUSES RESORBED (%)	0.0	0.0	0.0	0.0	0.0	0.0
DAMS WITH ONE OR MORE VIABLE FETUSES (%)	99.8	94.4	100.0	100.0	100.0	100.0
SEX RATIO (% MALES/LITTER)	50.1	40.5	57.9	50.6	43.3	62.8
LIVE FETAL BODY WEIGHTS GRAMS/LITTER:	5.90	5.46	6.15	5.94	4.88	6.47
MALE FETUSES:	6.06	5.64	6.35	6.08	5.02	6.54
FEMALE FETUSES:	5.72	5.29	6.08	5.79	4.77	6.45

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FETAL EXTERNAL ABNORMALITIES
SPRAGUE DAWLEY [CrI:CD(SD)] RATS
GESTATION DAY 21 CAESAREAN-SECTION
DOSE RANGE FINDING STUDIES

PERIOD: 2019 THROUGH 2020

NO. OF STUDIES INCLUDED 2

NO. LITTERS EXAMINED 17

NO. LIVE FETUSES EXAMINED 202

	ABNORMALITIES		N	RANGE/STUDY	
				N	%
TRUNK	: Anus, small	L	1	0-1	(0-12.5)
		F	1	0-1	(0-1.1)
	: Genital tubercle, absent	L	1	0-1	(0-11.1)
		F	1	0-1	(0-1.1)
FORE AND/OR HINDLIMB(S)	: Hindlimb, short, both	L	1	0-1	(0-11.1)
		F	1	0-1	(0-1.1)
PAW/DIGIT(S)	: Forepaw, adactyly	L	1	0-1	(0-11.1)
		F	1	0-1	(0-1.1)
	: Hindpaw, adactyly	L	1	0-1	(0-11.1)
		F	1	0-1	(0-1.1)
TAIL	: Tail, absent	L	1	0-1	(0-12.5)
		F	1	0-1	(0-1.1)
GENERAL	: Entire subcutis, edema	L	1	0-1	(0-11.1)
		F	1	0-1	(0-1.1)

L: LITTER INCIDENCE

F: FETAL INCIDENCE

Note: All summary values are based on studies with fetal findings.

Updated June 2021

FETAL EXTERNAL ABNORMALITIES
SPRAGUE DAWLEY [Ctrl:CD(SD)] RATS
GESTATION DAY 21 CAESAREAN-SECTION
FULL STUDIES

PERIOD: 2019 THROUGH 2020

NO. OF STUDIES INCLUDED	15
NO. LITTERS EXAMINED	326
NO. LIVE FETUSES EXAMINED	3933

			RANGE/STUDY		
	ABNORMALITIES		N	N	%
HEAD/NECK	: Domed head	L	3	0-1	(0-5.0)
		F	4	0-2	(0-1.0)
	: Cranial meningocele	L	1	0-1	(0-4.3)
		F	1	0-1	(0-0.3)
EAR	: Pinna, malpositioned	L	1	0-1	(0-5.3)
		F	1	0-1	(0-0.4)
FACE	: Eye, open eye (previously Eye, lids open)	L	1	0-1	(0-5.3)
		F	1	0-1	(0-0.4)
	: Snout, cleft	L	1	0-1	(0-4.0)
		F	1	0-1	(0-0.4)
	: Jaw, lower (mandible), small (previously micrognathia)	L	1	0-1	(0-4.5)
		F	1	0-1	(0-0.4)
	: Jaw, lower (mandible), absent (previously agnathia)	L	1	0-1	(0-5.3)
		F	1	0-1	(0-0.4)
MOUTH	: Palate, cleft	L	1	0-1	(0-4.0)
		F	1	0-1	(0-0.4)
	: Tongue, protruding	L	1	0-1	(0-4.8)
		F	1	0-1	(0-0.3)
GENERAL	: Entire subcutis, edema (previously Entire body, subcutaneous edema - generalized)	L	4	0-1	(0-4.8)
		F	4	0-1	(0-0.5)
	: Skin, tag	L	1	0-1	(0-4.3)
		F	1	0-1	(0-0.3)

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FETAL EXTERNAL ABNORMALITIES
SPRAGUE DAWLEY [CrI:CD(SD)] RATS
GESTATION DAY 21 CAESAREAN-SECTION
FULL STUDIES

			RANGE/STUDY		
	ABNORMALITIES		N	N	%
TRUNK					
	: Umbilicus, herniated	L	1	0-1	(0-5.0)
		F	1	0-1	(0-0.4)
	: Anus, absent	L	4	0-1	(0-5.0)
		F	4	0-1	(0-0.5)
	: Trunk, short	L	1	0-1	(0-5.0)
		F	1	0-1	(0-0.4)
	: Gastroschisis	L	1	0-1	(0-4.5)
		F	1	0-1	(0-0.5)
	: Genital tubercle, misshapen	L	1	0-1	(0-4.8)
	F	1	0-1	(0-0.3)	
FORE AND/OR HINDLIMBS(S)					
	: Forelimb, short	L	1	0-1	(0-4.0)
		F	1	0-1	(0-0.3)
	: Hindlimb, short	L	1	0-1	(0-4.0)
		F	1	0-1	(0-0.3)
PAW/DIGIT(S)					
	: Forepaw, syndactyly	L	1	0-1	(0-4.0)
	(previously Forepaw, fused)	F	1	0-1	(0-0.3)
	: Hindpaw, syndactyly	L	1	0-1	(0-4.0)
	(previously Hindpaw, fused)	F	1	0-1	(0-0.3)
TAIL					
	: Tail, curled tail	L	1	0-1	(0-4.0)
		F	1	0-1	(0-0.3)
	: Tail, thread-like	L	4	0-1	(0-5.3)
		F	4	0-1	(0-0.5)

L: LITTER INCIDENCE

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Note: All summary values are based on studies with fetal findings.

Updated June 2021

FETAL SOFT TISSUE ABNORMALITIES
SPRAGUE DAWLEY [CrI:CD(SD)] RATS
GESTATION DAY 21 CAESAREAN-SECTION
DOSE RANGE FINDING STUDIES

PERIOD: 2019 THROUGH 2020

NO. OF STUDIES INCLUDED	4
NO. LITTERS EXAMINED	30
NO. FETUSES EXAMINED	368

EYE(S)	ABNORMALITIES		RANGE/STUDY		
			N	N	%
	: Eye, small	L	1	0-1	(0-12.5)
	(previously microphthalmia)	F	1	0-1	(0-1.1)
	: Eye, absent	L	1	0-1	(0-12.5)
		F	1	0-1	(0-1.1)
GENERAL	: General, situs inversus	L	1	0-1	(0-12.5)
		F	1	0-1	(0-1.0)
HEART	: Membranous ventricular septal defect	L	1	0-1	(0-12.5)
	(previously Interventricular septal defect)	F	1	0-1	(0-2.1)
VESSELS	: Aortic arch, retroesophageal	L	1	0-1	(0-16.7)
		F	1	0-1	(0-1.1)
	: Carotid artery, malpositioned	L	1	0-1	(0-16.7)
		F	1	0-1	(0-1.1)

L: LITTER INCIDENCE

F: FETAL INCIDENCE

Note: All summary values are based on studies with fetal findings.

Updated June 2021

FETAL SOFT TISSUE ABNORMALITIES
SPRAGUE DAWLEY [CrI:CD(SD)] RATS
GESTATION DAY 21 CAESAREAN-SECTION
FULL STUDIES

PERIOD: 2019 THROUGH 2020

NO. OF STUDIES INCLUDED	16
NO. LITTERS EXAMINED	331
NO. FETUSES EXAMINED	1900

ABNORMALITIES		RANGE/STUDY		
		N	N	%
BRAIN				
: Lateral ventricles, dilatation, minimal	L	2	0-1	(0-4.5)
	F	2	0-1	(0-0.9)
: Lateral ventricles, dilatation, moderate	L	3	0-1	(0-5.0)
	F	3	0-1	(0-1.0)
: Brain, misshapen	L	1	0-1	(0-4.3)
	F	1	0-1	(0-0.5)
: Brain, small	L	1	0-1	(0-4.3)
	F	1	0-1	(0-0.5)
EYE(S)				
: Retina, right, retinal fold	L	3	0-2	(0-10.0)
	F	4	0-3	(0-2.7)
: Retina, left, retinal fold	L	1	0-1	(0-5.0)
	F	1	0-1	(0-0.7)
: Eye, small (previously microphthalmia)	L	1	0-1	(0-4.5)
	F	1	0-1	(0-0.9)
: Eye, absent	L	3	0-1	(0-4.5)
	F	5	0-2	(0-1.8)
: Eye, left, large	L	1	0-1	(0-5.0)
	F	1	0-1	(0-1.0)
HEART				
: Membranous ventricular septal defect	L	2	0-1	(0-5.0)
	F	3	0-2	(0-2.0)
LUNG				
: Lung, small	L	1	0-1	(0-5.0)
	F	1	0-1	(0-0.8)
: Lobe, caudate process, absent	L	1	0-1	(0-4.8)
	F	1	0-1	(0-0.6)
LIVER				
: Liver, malpositioned	L	1	0-1	(0-5.0)
	F	1	0-1	(0-0.8)

L: LITTER INCIDENCE

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Updated June 2021

FETAL SOFT TISSUE ABNORMALITIES
SPRAGUE DAWLEY [CrI:CD(SD)] RATS
GESTATION DAY 21 CAESAREAN-SECTION
FULL STUDIES

	ABNORMALITIES		RANGE/STUDY		
			N	N	%
VESSELS	: Innominate artery, absent	L	5	0-2	(0-10.0)
		F	6	0-3	(0-2.4)
	: Aortic arch, dilatation	L	1	0-1	(0-5.0)
		F	2	0-2	(0-1.7)
	: Caroid artery, malpositioned	L	1	0-1	(0-5.0)
		F	1	0-1	(0-0.8)
	: Great vessels, fused	L	1	0-1	(0-5.0)
		F	2	0-2	(0-1.7)
	: Subclavian artery, right, retroesophageal	L	1	0-1	(0-5.0)
		F	1	0-1	(0-0.7)
	: Subclavian artery origin, right, malpositioned	L	1	0-1	(0-5.0)
		F	1	0-1	(0-0.7)
DIAPHRAGM	: Hernia	L	1	0-1	(0-5.0)
		F	1	0-1	(0-0.8)
STOMACH	: Malpositioned	L	1	0-1	(0-5.0)
		F	1	0-1	(0-0.8)
INTESTINES	: Intestine, malpositioned	L	1	0-1	(0-5.0)
		F	1	0-1	(0-0.8)
KIDNEYS	: Renal papilla, right, small, moderate	L	1	0-1	(0-5.3)
		F	1	0-1	(0-0.8)
URETER	: Dilatation, severe, both	L	1	0-1	(0-4.8)
		F	1	0-1	(0-0.6)
GENERAL	: General, situs inversus	L	2	0-1	(0-5.3)
		F	2	0-1	(0-1.1)

L: LITTER INCIDENCE

F: FETAL INCIDENCE

Note: All summary values are based on studies with fetal findings.

Updated June 2021

FETAL SKELETAL ABNORMALITIES
SPRAGUE DAWLEY [CrI:CD(SD)] RATS
GESTATION DAY 21 CAESAREAN-SECTION
DOSE RANGE FINDING STUDIES

PERIOD: 2019 THROUGH 2020

NO. OF STUDIES INCLUDED 4

NO. LITTERS EXAMINED 29

NO. FETUSES EXAMINED 275

	ABNORMALITIES		N	RANGE/STUDY	
				N	%
SKULL	Frontal	: Incomplete ossification, both	L	1	0-1 (0-12.5)
			F	1	0-1 (0-1.8)
	Nasal	: Incomplete ossification, both	L	1	0-1 (0-12.5)
			F	1	0-1 (0-2.1)
	Zygomatic	: Arch, incomplete ossification, both	L	4	0-3 (0-37.5)
			F	4	0-3 (0-5.1)
		: Arch, incomplete ossification, right	L	1	0-1 (0-12.5)
			F	1	0-1 (0-1.8)
	Squamosal	: Incomplete ossification, both	L	2	0-1 (0-12.5)
			F	2	0-1 (0-1.8)
		: Incomplete ossification, right	L	1	0-1 (0-12.5)
			F	1	0-1 (0-1.6)
	Parietal	: Incomplete ossification	L	3	0-1 (0-16.7)
			F	3	0-1 (0-2.1)
VERTEBRAE	Cervical	: Arch, misshapen	L	1	0-1 (0-14.3)
			F	1	0-1 (0-0.9)
		: Supernumerary rib, cervical, short	L	1	0-1 (0-12.5)
			F	1	0-1 (0-1.8)
	Thoracic	: Centrum, incomplete ossification	L	3	0-1 (0-16.7)
		(Previously: Centrum, bifid or bipartite)	F	4	0-2 (0-2.2)
STERNUM	Sternebra	: Incomplete ossification	L	1	0-1 (0-12.5)
			F	1	0-1 (0-2.5)
PELVIC GIRDLE	Pubis	: Unossified, both	L	1	0-1 (0-12.5)
			F	1	0-1 (0-2.1)

L: LITTER INCIDENCE

F: FETAL INCIDENCE

Note: All summary values are based on studies with fetal findings.

Updated June 2021

FETAL SKELETAL ABNORMALITIES
SPRAGUE DAWLEY [CrI:CD(SD)] RATS
GESTATION DAY 21 CAESAREAN-SECTION
FULL STUDIES

PERIOD: 2019 THROUGH 2020

NO. OF STUDIES INCLUDED 28

NO. LITTERS EXAMINED 590

NO. FETUSES EXAMINED 3724

SKULL	ABNORMALITIES		N	RANGE/STUDY	
				N	%
SKULL	Frontals				
	: Incomplete ossification, both	L	23	0-5	(0-23.8)
		F	31	0-6	(0-4.7)
	: Incomplete ossification, right	L	1	0-1	(0-4.5)
		F	1	0-1	(0-0.7)
	Nasal				
	: Hole, both	L	1	0-1	(0-4.5)
		F	1	0-1	(0-0.8)
	Parietal				
	: Incomplete ossification, both	L	49	0-7	(0-33.3)
		F	69	0-10	(0-7.0)
	: Incomplete ossification, left	L	2	0-1	(0-5.0)
		F	2	0-1	(0-0.8)
	: Incomplete ossification, right	L	6	0-2	(0-10.5)
		F	6	0-2	(0-1.5)
	Interparietals				
	: Incomplete ossification	L	1	0-1	(0-4.5)
		F	1	0-1	(0-0.7)
	Mandible				
	: Absent, both	L	1	0-1	(0-5.3)
		F	1	0-1	(0-0.7)
	: Incomplete ossification, both	L	1	0-1	(0-4.0)
		F	1	0-1	(0-0.8)
	Squamosal				
	: Misshapen, both	L	2	0-1	(0-5.3)
		F	2	0-1	(0-0.8)
	: Incomplete ossification, both	L	49	0-4	(0-21.1)
		F	68	0-9	(0-6.8)
	: Incomplete ossification, left	L	15	0-3	(0-12.0)
		F	16	0-3	(0-2.3)
	: Incomplete ossification, right	L	18	0-3	(0-15.8)
		F	20	0-4	(0-3.4)
	Supraoccipital				
	: Incomplete ossification	L	2	0-1	(0-5.0)
		F	2	0-1	(0-1.0)
	Suture Bone				
	: Supernumerary site	L	2	0-1	(0-5.0)
		F	2	0-1	(0-0.7)
	Zygomatic Arch				
	: Incomplete ossification, both	L	82	0-7	(0-36.8)
		F	121	0-11	(0-10.0)
	: Incomplete ossification, left	L	27	0-4	(0-16.0)
		F	29	0-5	(0-3.3)
	: Incomplete ossification, right	L	33	0-3	(0-15.0)
		F	34	0-4	(0-3.1)
	: Misshapen, both	L	2	0-1	(0-5.3)
		F	2	0-1	(0-0.7)

L: LITTER INCIDENCE

F: FETAL INCIDENCE

Note: All summary values are based on studies with fetal findings.

Updated June 2021

FETAL SKELETAL ABNORMALITIES
SPRAGUE DAWLEY [Cr:CD(SD)] RATS
GESTATION DAY 21 CAESAREAN-SECTION
FULL STUDIES

	ABNORMALITIES		N	RANGE/STUDY	
				N	%
SKULL (CONTINUED)	Tympanic Annulus				
	<i>(Previously: Tympanic Rings)</i>				
	: Malpositioned, both	L	1	0-1	(0-5.3)
		F	1	0-1	(0-0.7)
	: Misshapen, both	L	1	0-1	(0-5.3)
		F	1	0-1	(0-0.7)
	Presphenoid				
	<i>(Previously: Sphenoid)</i>				
	: Pterygoid, misshapen, both	L	1	0-1	(0-5.3)
		F	1	0-1	(0-0.7)
	Basisphenoid				
	: Misshapen	L	1	0-1	(0-5.3)
		F	1	0-1	(0-0.7)
VERTEBRAE	Cervical				
	: Arch, incomplete ossification	L	27	0-3	(0-15.8)
		F	32	0-4	(0-3.3)
	: Arch, fused	L	1	0-1	(0-4.2)
		F	2	0-2	(0-1.2)
	: Arch, misshapen	L	25	0-3	(0-13.6)
		F	31	0-4	(0-3.3)
	: Hemivertebra	L	1	0-1	(0-4.5)
		F	1	0-1	(0-0.7)
	: Supernumerary rib, cervical, full	L	3	0-1	(0-5.0)
		F	3	0-1	(0-0.9)
	: Supernumerary rib, cervical, short	L	22	0-3	(0-15.0)
		F	24	0-4	(0-2.7)
	Thoracic				
	: Centrum, incomplete ossification	L	74	1-6	(4.0-27.3)
	<i>(Previously: Centrum, bipartite ossification)</i>	F	84	1-6	(0.6-4.9)
	: Centrum, unossified	L	1	0-1	(0-4.5)
		F	1	0-1	(0-0.9)
	: Arch, incomplete ossification	L	1	0-1	(0-4.5)
		F	1	0-1	(0-0.7)
	: Arch, fused	L	1	0-1	(0-4.2)
		F	1	0-1	(0-0.6)
	: Arch, misshapen	L	1	0-1	(0-4.2)
		F	1	0-1	(0-0.6)
	: Vertebra, absent	L	1	0-1	(0-4.5)
		F	1	0-1	(0-0.9)
	: Hemivertebra	L	1	0-1	(0-4.5)
		F	1	0-1	(0-0.9)
	Lumbar				
	: Centrum, misshapen	L	1	0-1	(0-4.5)
		F	2	0-2	(0-1.8)
	: Centrum, incomplete ossification	L	3	0-1	(0-5.0)
		F	3	0-1	(0-0.9)
	: Centrum, fused	L	1	0-1	(0-4.5)
		F	1	0-1	(0-0.8)
	: Arch, incomplete ossification	L	1	0-1	(0-4.5)
		F	1	0-1	(0-0.7)
	: Vertebra, fused	L	1	0-1	(0-4.5)
		F	1	0-1	(0-0.9)

L: LITTER INCIDENCE

F: FETAL INCIDENCE

Note: All summary values are based on studies with fetal findings.

Updated June 2021

FETAL SKELETAL ABNORMALITIES
SPRAGUE DAWLEY [CrI:CD(SD)] RATS
GESTATION DAY 21 CAESAREAN-SECTION
FULL STUDIES

	ABNORMALITIES		N	RANGE/STUDY	
				N	%
VERTEBRAE (CONTINUED)					
	Sacral				
	: Arch, incomplete ossification	L	2	0-1	(0-5.3)
		F	2	0-1	(0-0.8)
	: Centrum, misshapen	L	1	0-1	(0-5.0)
		F	1	0-1	(0-0.7)
	: Centrum, fused	L	1	0-1	(0-4.5)
		F	1	0-1	(0-0.8)
	: Vertebra, absent	L	1	0-1	(0-5.0)
		F	1	0-1	(0-0.7)
	Caudal				
	: Vertebra, absent	L	1	0-1	(0-5.0)
		F	1	0-1	(0-0.7)
	: Centrum, fused	L	1	0-1	(0-4.5)
		F	1	0-1	(0-0.8)
RIBS					
	: Wavy	L	3	0-1	(0-5.0)
		F	3	0-1	(0-0.8)
	: Incomplete ossification	L	10	0-2	(0-10.0)
		F	14	0-4	(0-3.0)
	: Fused	L	3	0-1	(0-5.0)
		F	3	0-1	(0-0.9)
	: Short	L	16	0-4	(0-19.0)
		F	18	0-5	(0-3.8)
	: Misshapen	L	2	0-1	(0-5.0)
		F	3	0-2	(0-1.2)
	: Absent	L	1	0-1	(0-4.5)
		F	1	0-1	(0-0.9)
	: Nodule	L	10	0-2	(0-9.1)
	<i>(Previously: Nodulated or Thickened)</i>	F	10	0-2	(0-2.2)
STERNUM					
	Sternebra				
	: Incomplete ossification	L	20	0-2	(0-10.5)
		F	21	0-2	(0-1.9)
	: Unossified	L	1	0-1	(0-4.5)
		F	1	0-1	(0-0.7)
	: Misshapen	L	15	0-4	(0-16.7)
		F	15	0-4	(0-2.8)
	: Fused	L	2	0-1	(0-4.5)
		F	3	0-2	(0-1.2)
	: Sternoschisis	L	3	0-1	(0-5.3)
	<i>(Previously: Split)</i>	F	4	0-2	(0-1.8)
	: Isolated ossification site	L	1	0-1	(0-5.0)
		F	1	0-1	(0-0.7)

L: LITTER INCIDENCE

F: FETAL INCIDENCE

Note: All summary values are based on studies with fetal findings.

Updated June 2021

FETAL SKELETAL ABNORMALITIES
SPRAGUE DAWLEY [CrI:CD(SD)] RATS
GESTATION DAY 21 CAESAREAN-SECTION
FULL STUDIES

	ABNORMALITIES		N	RANGE/STUDY	
				N	%
PELVIC GIRDLE <i>(Previously: PELVIS)</i>	Pubis	: Incomplete ossification, both	L	10	0-2 (0-10.5)
			F	11	0-3 (0-2.6)
		: Incomplete ossification, right	L	4	0-1 (0-5.3)
			F	4	0-1 (0-1.0)
		: Unossified, left	L	1	0-1 (0-4.5)
			F	1	0-1 (0-0.7)
	Ischium	: Incomplete ossification, both	L	6	0-2 (0-9.1)
			F	7	0-2 (0-1.6)
		: Incomplete ossification, left	L	1	0-1 (0-4.2)
			F	1	0-1 (0-0.6)
		: Incomplete ossification, right	L	2	0-1 (0-5.3)
			F	2	0-1 (0-1.1)
HINDLIMB(S)	Femur	: Incomplete ossification, both	L	1	0-1 (0-4.0)
			F	2	0-2 (0-1.6)

L: LITTER INCIDENCE

F: FETAL INCIDENCE

Note: All summary values are based on studies with fetal findings.

Updated June 2021

FETAL SKELETAL OSSIFICATION SITES
SPRAGUE DAWLEY [CrI:CD(SD)] RATS
GESTATION DAY 21 CAESAREAN-SECTION
DOSE RANGE FINDING STUDIES

PERIOD: 2019 THROUGH 2020

NO. OF STUDIES INCLUDED 4

NO. LITTERS EXAMINED 29

NO. FETUSES EXAMINED 275

	MEAN	MINIMUM	MAXIMUM
HYOID	1.00	1.00	1.00
VERTEBRAE			
CERVICAL	7.00	7.00	7.00
THORACIC	13.08	13.05	13.11
LUMBAR	5.92	5.89	5.95
SACRAL	4.00	4.00	4.00
CAUDAL	6.82	6.45	7.07
RIBS (pairs)	13.06	13.03	13.10
STERNUM			
MANUBRIUM	1.00	1.00	1.00
STERNAL CENTERS	3.99	3.94	4.00
XIPHOID	1.00	0.98	1.00
FOREPAWS ^a			
CARPALS	0.00	0.00	0.00
METACARPALS	3.99	3.96	4.00
DIGITS	5.00	5.00	5.00
PHALANGES	8.51	8.41	8.74
HINDPAWS ^a			
TARSALS	0.07	0.00	0.13
METATARSALS	4.93	4.85	4.98
DIGITS	5.00	5.00	5.00
PHALANGES	7.02	6.67	7.50

a. Calculated as mean per limb

Note: All summary values are based on studies with fetal findings.

Updated June 2021

FETAL SKELETAL OSSIFICATION SITES
SPRAGUE DAWLEY [CrI:CD(SD)] RATS
GESTATION DAY 21 CAESAREAN-SECTION
FULL STUDIES

PERIOD: 2019 THROUGH 2020

NO. OF STUDIES INCLUDED 28

NO. LITTERS EXAMINED 590

NO. FETUSES EXAMINED 3724

	MEAN	MINIMUM	MAXIMUM
HYOID	0.99	0.93	1.08
VERTEBRAE			
CERVICAL	7.00	7.00	7.00
THORACIC	13.07	13.02	13.17
LUMBAR	5.93	5.84	5.97
SACRAL	4.00	4.00	4.00
CAUDAL	6.72	6.22	7.26
RIBS (pairs)	13.05	13.01	13.12
STERNUM			
MANUBRIUM	1.00	1.00	1.00
STERNAL CENTERS	4.00	3.98	4.02
XIPHOID	1.00	0.98	1.00
FOREPAWS ^a			
CARPALS	0.00	0.00	0.00
METACARPALS	3.99	3.96	4.00
DIGITS	5.00	5.00	5.00
PHALANGES	8.26	7.87	8.65
HINDPAWS ^a			
TARSALS	0.05	0.01	0.15
METATARSALS	4.91	4.76	4.97
DIGITS	5.00	5.00	5.00
PHALANGES	6.87	6.01	7.43

a. Calculated as mean per limb

Note: All summary values are based on studies with fetal findings.

Updated June 2021

REPRODUCTIVE ORGAN WEIGHTS, MATING, AND FERTILITY
SPRAGUE DAWLEY [CrI:CD(SD)] RATS
MALE

PERIOD: 2019 THROUGH 2020

NO. OF STUDIES INCLUDED- ORGAN WEIGHTS	37
NO. OF RATS TESTED- ORGAN WEIGHTS	776

ABSOLUTE REPRODUCTIVE ORGAN WEIGHTS

	<u>MEAN</u>	<u>MIN</u>	<u>MAX</u>	<u>NO. STUDIES INCLUDED</u>
TERMINAL BODY WEIGHT (TBW)	599.1	521.8	713.2	37
TESTIS				
LEFT	1.879	1.641	2.018	27
RIGHT	1.874	1.648	2.067	27
PAIRED	3.778	3.570	3.960	10
LEFT, MINUS TUNICA ALBUGINEA/VAGINALIS	1.739	1.634	1.810	5
EPIDIDYMIS				
LEFT	0.771	0.660	0.918	27
RIGHT	0.788	0.668	0.928	27
PAIRED	1.573	1.376	1.700	10
CAUDA EPIDIDYMIS				
LEFT	0.348	0.302	0.423	21
PROSTATE	1.394	1.170	1.640	35
SEMINAL VESICLES				
WITH FLUID	2.348	1.912	2.791	33
WITHOUT FLUID	1.142	0.983	1.328	3

Note: All summary values are based on all males with reproductive data (P, F1, F2 generation and all ages).
All organ weights are measured in grams.

Updated June 2021

REPRODUCTIVE ORGAN WEIGHTS, MATING, AND FERTILITY
SPRAGUE DAWLEY [CrI:CD(SD)] RATS
MALE

PERIOD: 2019 THROUGH 2020

REPRODUCTIVE ORGAN WEIGHTS RELATIVE TO TERMINAL BODY WEIGHT (TBW)

	<u>MEAN</u>	<u>MIN</u>	<u>MAX</u>	NO. STUDIES <u>INCLUDED</u>
TERMINAL BODY WEIGHT (TBW)	599.1	521.8	713.2	37
TESTIS (% TBW)				
LEFT	0.318	0.269	0.365	27
RIGHT	0.317	0.270	0.369	27
PAIRED	0.629	0.585	0.677	10
LEFT, MINUS TUNICA ALBUGINEA/VAGINALIS	0.304	0.279	0.340	5
EPIDIDYMIS (% TBW)				
LEFT	0.130	0.112	0.148	27
RIGHT	0.133	0.109	0.152	27
PAIRED	0.261	0.243	0.275	10
CAUDA EPIDIDYMIS (% TBW)				
LEFT	0.059	0.051	0.066	21
PROSTATE (% TBW)	0.235	0.171	0.283	35
SEMINAL VESICLES (% TBW)				
WITH FLUID	0.393	0.329	0.471	33
WITHOUT FLUID	0.192	0.184	0.206	3

REPRODUCTIVE ORGAN WEIGHTS RELATIVE TO BRAIN WEIGHT (BRW)

	<u>MEAN</u>	<u>MIN</u>	<u>MAX</u>	NO. STUDIES <u>INCLUDED</u>
BRAIN WEIGHT (BRW)	2.32	2.27	2.39	5
TESTIS (% BRW)				
LEFT	81.7	80.1	82.7	3
RIGHT	80.4	78.9	83.6	3
PAIRED	160.6	157.9	163.3	2
EPIDIDYMIS (% BRW)				
LEFT	33.9	29.1	38.4	3
RIGHT	34.7	29.5	38.9	3
PAIRED	68.2	66.8	69.6	2
CAUDA EPIDIDYMIS (% BRW)				
LEFT	16.0	13.6	17.7	3
PROSTATE (% BRW)	56.0	51.6	66.3	4
SEMINAL VESICLES (% BRW)				
WITH FLUID	100.6	87.4	115.4	3
WITHOUT FLUID	45.9	43.2	48.7	2

Note: All summary values are based on all males with reproductive data (P, F1, F2 generation and all ages).
All organ weights are measured in grams.

Updated June 2021

REPRODUCTIVE ORGAN WEIGHTS, MATING, AND FERTILITY
SPRAGUE DAWLEY [CrI:CD(SD)] RATS
MALE

PERIOD: 2019 THROUGH 2020

MATING AND FERTILITY EVALUATIONS

NO. OF STUDIES INCLUDED- COHABITATION	37			
NO. MALE RATS IN COHABITATION	776			
	<u>MEAN</u>	<u>MIN</u>	<u>MAX</u>	<u>NO. STUDIES INCLUDED</u>
DAYS IN COHABITATION	2.7	2.4	3.3	18
RATS THAT MATED (%) ¹	96.6	86.4	100.0	37
RATS WITH CONFIRMED MATING DATES (%) ²	99.2	90.0	100.0	37
FERTILITY INDEX (%) ³	94.4	81.0	100.0	37
RATS MATING (%)				
DAYS 1-7	99.1	88.9	100.0	18
DAYS 8-14	11.1	11.1	11.1	1
RATS PREGNANT/RATS IN COHABITATION (%)	91.2	77.3	100.0	37

¹ (Number of rats that mated/number of rats paired)*100

² (Number of rats with confirmed mating dates/number of rats that mated)*100

³ (Number of pregnancies/number of rats that mated)*100

Note: All summary values are based on all males with reproductive data (P, F1, F2 generation and all ages).
All organ weights are measured in grams.

Updated June 2021

ESTROUS CYCLING, MATING, AND FERTILITY
SPRAGUE DAWLEY [CrI:CD(SD)] RATS
FEMALE

PERIOD: 2019 THROUGH 2020

NO. OF STUDIES INCLUDED- ESTROUS	40
NO. OF RATS EVALUATED- ESTROUS	873

PREDOSE ESTROUS EVALUATIONS

NO. RATS EVALUATED: PREDOSE ESTROUS	22
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	<u>MEAN</u>	<u>MIN</u>	<u>MAX</u>	<u>NO. STUDIES INCLUDED</u>
ESTROUS STAGES/14 DAYS	3.5	3.5	3.5	1
RATS WITH 6 OR MORE CONSEC. DAYS OF DIESTRUS	0.0	0	0	1
RATS WITH 6 OR MORE CONSEC. DAYS OF ESTRUS	0.0	0	0	1

PRECOHABITATION ESTROUS EVALUATIONS

NO. RATS EVALUATED: PRECOHABITATION ESTROUS	873
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	<u>MEAN</u>	<u>MIN</u>	<u>MAX</u>	<u>NO. STUDIES INCLUDED</u>
ESTROUS STAGES/14 DAYS	2.6	1.7	3.5	35
ESTROUS STAGES/15 DAYS	2.4	2.4	2.5	2
ESTROUS STAGES/18 DAYS	2.7	2.7	2.7	1
ESTROUS STAGES/21 DAYS	4.4	4.3	4.4	2
CYCLE LENGTHS (DAYS)	4.2	3.8	4.9	27
RATS WITH 6 OR MORE CONSEC. DAYS OF DIESTRUS	0.5	0	3	12
RATS WITH 6 OR MORE CONSEC. DAYS OF ESTRUS	0.0	0	0	12

Updated June 2021

ESTROUS CYCLING, MATING, AND FERTILITY
SPRAGUE DAWLEY [CrI:CD(SD)] RATS
FEMALE

PERIOD: 2019 THROUGH 2020

NO. OF STUDIES INCLUDED- MATING AND FERTILITY 55

MATING AND FERTILITY EVALUATIONS

NO. RATS IN COHABITATION 1192

	<u>MEAN</u>	<u>MIN</u>	<u>MAX</u>	<u>NO. STUDIES INCLUDED</u>
DAYS IN COHABITATION	2.7	2.0	3.7	55
RATS THAT MATED (%) ¹	98.7	90.9	100.0	55
RATS WITH CONFIRMED MATING DATES (%) ²	98.4	90.0	100.0	55
RATS MATED BY FIRST MALE (%)				
DAYS 1-7	98.0	90.0	100.0	55
DAYS 8-14	6.7	4.0	10.0	12
RATS MATED BY SECOND MALE (%)				
DAYS 8-14	5.4	4.0	9.1	5
FERTILITY INDEX (%) ³	93.0	70.0	100.0	55
RATS PREGNANT/RATS IN COHABITATION (%)	91.7	70.0	100.0	55

¹ (Number of rats that mated/number of rats paired)*100

² (Number of rats with confirmed mating dates/number of rats that mated)*100

³ (Number of pregnancies/number of rats that mated)*100

Updated June 2021

HAMILTON-THORNE SPERM EVALUATION
SPRAGUE DAWLEY [CrI:CD(SD)] RATS

PERIOD: 2019 THROUGH 2020¹

NO. OF RATS INCLUDED	594			NO. STUDIES INCLUDED
<u>VAS DEFERENS SPERM MOTILITY</u>	<u>MEAN</u>	<u>MINIMUM</u>	<u>MAXIMUM</u>	
NUMBER MOTILE	304.8	255.6	354.0	2
MOTILE PERCENT	84.0	77.5	91.7	30
STATIC COUNT (NONMOTILE)	59.3	44.8	73.7	2
TOTAL COUNT	364.1	329.3	398.8	2
<u>CAUDA EPIDIDYMAL SPERM COUNT</u>				
SPERM COUNT (20 fields evaluated)	436.2	375.9	496.4	2
SPERM DENSITY ²	1637.3	1148.7	2406.1	30
<u>TESTICULAR SPERM COUNT</u>				
SPERMATID COUNT (20 fields evaluated)	324.1	324.1	324.1	1
SPERMATID DENSITY ³	278.5	214.2	351.7	5

¹ IIVOS Version 12.2L or later

² Million sperm/gram of tissue

³ Million spermatid/gram of tissue

Updated June 2021

SPERM MORPHOLOGY
SPRAGUE DAWLEY [CrI:CD(SD)] RATS

PERIOD: 2019 THROUGH 2020

NO. OF STUDIES INCLUDED	13
NO. OF RATS INCLUDED	254

CAUDA EPIDIDYMAL SPERM MORPHOLOGY

	<u>MEAN</u>	<u>MINIMUM</u>	<u>MAXIMUM</u>
Normal	190.1	169.3	195.6
Percent abnormal	5.1	2.3	15.7
No hook	0.0	0.0	0.2
Excessive hook	0.0	0.0	0.0
No head	3.1	1.4	10.0
Detached head	6.3	2.5	17.8
Amorphous	0.0	0.0	0.1
Pin head	0.0	0.0	0.0
Two heads & tails	0.0	0.0	0.0
Short sperm head	0.0	0.0	0.0
Banana	0.0	0.0	0.2
Broken flagellum	0.6	0.0	3.7
Coiled flagellum	0.0	0.0	0.2
Bent flagellum	0.1	0.0	0.5
Bent flagellum tip	0.0	0.0	0.1
Other	0.0	0.0	0.0

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NATURAL DELIVERY AND LITTER PARAMETERS
SPRAGUE DAWLEY [CrI:CD(SD)] RATS
(STUDIES WITH CULLING)

PERIOD: 2019 THROUGH 2020

NO. OF RATS ASSIGNED TO NATURAL DELIVERY	125			
NO. OF RATS PREGNANT	122			
NO. OF RATS DELIVERED LITTERS	121			
	<u>MEAN or %</u>	<u>MINIMUM</u>	<u>MAXIMUM</u>	<u>NO. STUDIES INCLUDED</u>
PREGNANT (%)	97.8	90.9	100.0	6
DELIVERED LITTERS (%)	100.0	100.0	100.0	6
DURATION OF GESTATION IN DAYS	21.9	21.3	22.7	6
IMPLANTATION SITES PER DELIVERED LITTER	13.1	12.2	15.1	6
DAMS WITH STILLBORN PUPS (%)	6.5	0.0	20.0	6
DAMS WITH NO LIVEBORN PUPS (%)	0.0	0.0	0.0	6
GESTATION INDEX (NO. RATS WITH LIVEBORN/NO. PREGNANT RATS) (%)	100.0	100.0	100.0	6
DAMS WITH ALL PUPS DYING DAYS 1-4 POSTPARTUM (%)	0.0	0.0	0.0	2
DAMS WITH ALL PUPS DYING DAYS 5-21 POSTPARTUM (%)	0.0	0.0	0.0	2
PUPS DELIVERED (TOTAL)	11.6	11.4	11.8	2
LIVEBORN	12.1	10.9	13.6	6
LIVEBORN (%)	99.5	98.3	100.0	6
STILLBORN	0.4	0.0	1.7	6
STILLBORN (%)	0.5	0.0	1.7	6
POSTIMPLANTATION LOSS / LITTER (%)	7.2	2.9	10.1	4

PND or DAY(s) = Postnatal Day(s)

Updated June 2021

NATURAL DELIVERY AND LITTER PARAMETERS
SPRAGUE DAWLEY [Ctrl:CD(SD)] RATS
(STUDIES WITH CULLING)

PERIOD: 2019 THROUGH 2020

	<u>MEAN or %</u>	<u>MINIMUM</u>	<u>MAXIMUM</u>	<u>NO. STUDIES INCLUDED</u>
PUPS FOUND DEAD OR PRESUMED CANNIBALIZED (%)				
DAY 1	0.2	0.0	0.4	2
DAYS 2-4	0.4	0.4	0.4	2
DAYS 5-7	0.0	0.0	0.0	2
DAYS 8-14	0.0	0.0	0.0	2
DAYS 11-14	0.3	0.0	0.5	2
DAYS 15-17	0.0	0.0	0.0	2
DAYS 18-21	0.0	0.0	0.0	2
VIABILITY INDEX (%) (No. Live pups PND 4 / No. Live pups PND 1)	95.2	88.9	99.6	6
LACTATION INDEX (%) (No. Live pups PND 21 / No. Live pups PND 4)	99.6	99.3	100.0	5
SURVIVING PUPS/LITTER				
Day 1	11.6	11.3	11.8	2
Day 4 (Preculling)	11.5	11.3	11.7	2
Day 4 (Postculling)	8.0	7.9	8.0	2
Day 7	8.0	7.9	8.0	2
Day 10	8.0	7.9	8.0	2
Day 14	8.0	7.9	8.0	2
Day 17	8.0	7.9	8.0	2
Day 21	8.0	7.9	8.0	2

PND or DAY(s) = Postnatal Day(s)

Updated June 2021

NATURAL DELIVERY AND LITTER PARAMETERS
SPRAGUE DAWLEY [CrI:CD(SD)] RATS
(STUDIES WITH CULLING)

PERIOD: 2019 THROUGH 2020

	<u>MEAN or %</u>	<u>MINIMUM</u>	<u>MAXIMUM</u>	<u>NO. STUDIES INCLUDED</u>
PERCENT MALE PUPS PER NUMBER OF PUPS SEXED				
Birth	50.4	44.8	53.9	4
Day 1	47.9	46.9	48.8	2
Day 4 (Preculling)	48.1	47.1	49.1	2
Day 4 (Postculling)	48.4	47.6	49.1	2
Day 7	48.4	47.6	49.1	2
Day 10	48.4	47.6	49.1	2
Day 14	48.2	47.6	48.8	2
Day 17	48.2	47.6	48.8	2
Day 21	49.3	47.6	50.7	5
LIVE LITTER SIZE AT WEIGHING				
Day 1	11.5	11.3	11.7	2
Day 4 (Preculling)	11.5	11.3	11.7	2
Day 4 (Postculling)	8.0	7.9	8.0	2
Day 7	8.0	7.9	8.0	2
Day 10	8.0	7.9	8.0	2
Day 14	8.0	7.9	8.0	2
Day 17	8.0	7.9	8.0	2
Day 21	8.0	7.9	8.0	2

PND or DAY(s) = Postnatal Day(s)

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NATURAL DELIVERY AND LITTER PARAMETERS
SPRAGUE DAWLEY [CrI:CD(SD)] RATS
(STUDIES WITH CULLING)

PERIOD: 2019 THROUGH 2020

	<u>MEAN or %</u>	<u>MINIMUM</u>	<u>MAXIMUM</u>	<u>NO. STUDIES INCLUDED</u>
PUP WEIGHT/LITTER (GRAMS)				
Day 0	6.7	6.3	7.2	2
Day 1	7.2	6.7	7.6	4
Day 4 (Preculling)	10.5	9.6	11.4	6
Day 4 (Postculling)	10.5	9.7	11.4	6
Day 5	13.6	13.6	13.6	1
Day 7	16.8	15.7	18.2	5
Day 9	22.9	22.9	22.9	1
Day 10	23.9	21.9	25.4	4
Day 13	32.9	32.4	33.4	2
Day 14	34.2	30.8	36.5	4
Day 17	40.7	37.4	43.4	3
Day 18	45.8	45.6	45.9	2
Day 21	56.3	50.3	59.0	5

PND or DAY(s) = Postnatal Day(s)

Updated June 2021

NATURAL DELIVERY AND LITTER PARAMETERS
SPRAGUE DAWLEY [CrI:CD(SD)] RATS
(STUDIES WITHOUT CULLING)

PERIOD: 2019 THROUGH 2020

NO. OF RATS ASSIGNED TO NATURAL DELIVERY	520			
NO. OF RATS PREGNANT	490			
NO. OF RATS THAT DELIVERED LITTERS	473			
	<u>MEAN or %</u>	<u>MINIMUM</u>	<u>MAXIMUM</u>	<u>NO. STUDIES INCLUDED</u>
PREGNANT (%)	94.9	70.0	100.0	25
DELIVERED LITTERS (%)	98.6	92.3	100.0	25
DURATION OF GESTATION IN DAYS	22.2	21.0	23.0	25
IMPLANTATION SITES PER DELIVERED LITTER	13.3	11.4	17.0	25
DAMS WITH STILLBORN PUPS (%)	9.2	0.0	42.9	25
DAMS WITH NO LIVEBORN PUPS (%)	0.0	0.0	0.0	25
GESTATION INDEX (NO. RATS WITH LIVEBORN/NO. PREGNANT RATS) (%)	98.6	92.3	100.0	25
DAMS WITH ALL PUPS DYING DAYS 1-4 POSTPARTUM (%)	0.7	0.0	8.3	18
DAMS WITH ALL PUPS DYING DAYS 5-21 POSTPARTUM (%)	0.0	0.0	0.0	17
PUPS DELIVERED (TOTAL)	11.9	10.0	15.8	18
LIVEBORN	12.2	10.0	15.8	25
LIVEBORN (%)	98.7	90.7	100.0	25
STILLBORN	0.6	0.0	9.3	25
STILLBORN (%)	1.3	0.0	9.3	25
UNKNOWN VITAL STATUS (N)	0.2	0.0	1.0	13
POSTIMPLANTATION LOSS / LITTER (%)	6.8	3.6	10.6	7

PND or DAY(s) = Postnatal Day(s)

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NATURAL DELIVERY AND LITTER PARAMETERS
SPRAGUE DAWLEY [CrI:CD(SD)] RATS
(STUDIES WITHOUT CULLING)

PERIOD: 2019 THROUGH 2020

	<u>MEAN or %</u>	<u>MINIMUM</u>	<u>MAXIMUM</u>	<u>NO. STUDIES INCLUDED</u>
PUPS FOUND DEAD OR PRESUMED CANNIBALIZED (%)				
DAY 1	1.1	0.0	11.6	17
DAYS 2-4	1.7	0.0	9.3	17
DAYS 5-6	0.0	0.0	0.0	1
DAYS 5-7	0.3	0.0	0.9	16
DAY 7	0.0	0.0	0.0	1
DAYS 8-10	0.2	0.0	2.3	16
DAYS 11-14	0.1	0.0	0.4	16
DAYS 15-17	0.0	0.0	0.0	8
DAYS 15-18	0.0	0.0	0.0	7
DAYS 15-21	0.0	0.0	0.0	1
DAYS 18-21	0.3	0.0	0.9	8
DAYS 19-21	0.2	0.0	1.1	7
DAYS 22-28	0.9	0.9	0.9	1
VIABILITY INDEX (%) (No. Live pups PND 4 / No. Live pups PND 1)	97.5	79.3	100.0	25
LACTATION INDEX (%) (No. Live pups PND 21 / No. Live pups PND 4)	98.8	93.7	100.0	19

PND or DAY(s) = Postnatal Day(s)

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NATURAL DELIVERY AND LITTER PARAMETERS
SPRAGUE DAWLEY [CrI:CD(SD)] RATS
(STUDIES WITHOUT CULLING)

PERIOD: 2019 THROUGH 2020

	<u>MEAN or %</u>	<u>MINIMUM</u>	<u>MAXIMUM</u>	<u>NO. STUDIES INCLUDED</u>
SURVIVING PUPS/LITTER				
Day 1	11.8	10.0	15.5	18
Day 4	11.5	8.0	15.2	18
Day 6	13.0	13.0	13.0	1
Day 7	11.0	6.0	15.0	18
Day 10	11.4	6.9	15.0	16
Day 14	11.4	7.6	15.0	16
Day 17	11.2	7.6	14.4	8
Day 18	11.5	10.6	12.3	7
Day 21	11.3	7.6	14.4	16
Day 28	11.8	11.8	11.8	1
PERCENT MALE PUPS PER NUMBER OF PUPS SEXED				
Birth	49.6	44.7	55.2	7
Day 1	50.8	43.2	55.5	18
Day 4	50.1	39.0	54.8	18
Day 6	45.4	43.2	47.6	2
Day 7	50.1	39.0	54.9	21
Day 10	50.2	37.2	54.9	16
Day 14	50.3	38.7	54.4	16
Day 17	48.8	38.7	54.4	8
Day 18	51.8	49.2	54.3	7
Day 21	49.9	38.7	54.4	19
Day 28	54.1	54.1	54.1	1

PND or DAY(s) = Postnatal Day(s)

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NATURAL DELIVERY AND LITTER PARAMETERS
SPRAGUE DAWLEY [CrI:CD(SD)] RATS
(STUDIES WITHOUT CULLING)

PERIOD: 2019 THROUGH 2020

	<u>MEAN or %</u>	<u>MINIMUM</u>	<u>MAXIMUM</u>	<u>NO. STUDIES INCLUDED</u>
LIVE LITTER SIZE AT WEIGHING				
Day 1	11.8	9.2	15.4	17
Day 4	11.6	8.8	15.2	17
Day 6	13.0	13.0	13.0	1
Day 7	11.2	6.0	15.0	17
Day 10	11.5	8.4	15.0	16
Day 14	11.5	8.5	15.0	16
Day 17	11.3	8.5	14.4	8
Day 18	11.6	11.0	12.3	7
Day 21	11.4	8.5	14.4	16
Day 28	11.8	11.8	11.8	1
PUP WEIGHT/LITTER (GRAMS)				
Day 0	6.7	6.7	6.7	1
Day 1	7.0	6.5	7.7	23
Day 4	10.1	9.2	11.0	24
Day 6	13.2	12.8	13.7	2
Day 7	14.8	13.3	17.4	23
Day 10	20.3	18.0	25.3	19
Day 13	33.5	33.5	33.5	1
Day 14	27.8	24.7	30.4	18
Day 17	33.9	29.4	43.2	10
Day 18	35.4	33.8	39.6	8
Day 21	45.7	38.8	60.2	19
Day 28	82.6	82.6	82.6	1

PND or DAY(s) = Postnatal Day(s)

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SEXUAL MATURATION
SPRAGUE DAWLEY [CrI:CD(SD)] RATS

PERIOD: 2019 THROUGH 2020

SEXUAL MATURATION

TOTAL MALE RATS	984				NO. STUDIES
	MEAN	MINIMUM	MAXIMUM		INCLUDED
Preputial Separation (Days Postpartum)	43.6	40.6	46.7		39
Body Weight (g) on day of sexual maturity	235.2	215.2	252.2		39
TOTAL FEMALE RATS	965				NO. STUDIES
	MEAN	MINIMUM	MAXIMUM		INCLUDED
Vaginal Patency (Days Postpartum)	31.7	29.3	34.1		39
Body Weight (g) on day of sexual maturity	108.9	95.5	129.2		39

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REPRODUCTIVE INDICES
WISTAR (CrI:WI[Han]) RATS
GESTATION DAY 13 CAESAREAN-SECTION
FULL STUDIES

PERIOD: 2016 THROUGH 2020

NO. OF STUDIES INCLUDED	11
NO. OF RATS TESTED	229
NO. OF RATS PREGNANT	216

NO. FOUND DEAD	0
NO. PREMATURE DELIVERY	0

NO. OF RATS PREGNANT AT CAESAREAN-SECTIONING	216
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		<u>MEAN</u>	<u>MINIMUM</u>	<u>MAXIMUM</u>
PREGNANT	(%)	94.8	77.3	100.0
CORPORA LUTEA		13.4	12.2	14.0
IMPLANTATIONS		12.1	11.4	13.1
PREIMPLANTATION LOSS	(%)	9.4	5.7	17.4
LITTER SIZES				
VIALE EMBRYOS		11.2	10.0	12.1
NONVIALE EMBRYOS		0.9	0.4	1.4
POSTIMPLANTATION LOSS	(%)	7.7	4.3	14.5
DAMS WITH ANY NONVIALE EMBRYOS	(%)	47.8	23.5	68.2
DAMS WITH ALL NONVIALE EMBRYOS	(%)	0.0	0.0	0.1
DAMS WITH ONE OR MORE VIALE EMBRYO	(%)	100.0	100.0	100.0
PLACENTAE APPEARED NORMAL	(%)	100.0	100.0	100.0

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REPRODUCTIVE INDICES
WISTAR (CrI:WI[Han]) RATS
GESTATION DAY 20 CAESAREAN-SECTION

PERIOD: 2016 THROUGH 2020

	FULL STUDIES			DOSE RANGE STUDIES		
NO. OF STUDIES INCLUDED	3			0		
NO. OF RATS TESTED	66			--		
NO. OF RATS PREGNANT	61			--		
NO. FOUND DEAD	0			--		
NO. ABORTED	0			--		
NO. DELIVERED	0			--		
CAESAREAN-SECTIONED ON GD 20	61			--		
NO. OF RATS WITH SINGLE CONCEPTUS LITTER						
LIVE:	0			--		
RESORBED:	0			--		
ABORTED:	0			--		
	<u>MEAN</u>	<u>MIN</u>	<u>MAX</u>	<u>MEAN</u>	<u>MIN</u>	<u>MAX</u>
PREGNANT (%)	92.4	81.8	100.0	--	--	--
CORPORA LUTEA	13.7	12.7	14.5	--	--	--
IMPLANTATIONS	12.4	11.4	13.2	--	--	--
PREIMPLANTATION LOSS (%)	9.6	8.5	10.9	--	--	--
LITTER SIZES						
LIVE FETUSES	11.8	10.9	12.8	--	--	--
DEAD FETUSES	0.0	0.0	0.0	--	--	--
TOTAL RESORPTIONS	0.6	0.4	0.9	--	--	--
EARLY RESORPTIONS	0.6	0.3	0.9	--	--	--
LATE RESORPTIONS	0.0	0.0	0.1	--	--	--
POSTIMPLANTATION LOSS (%)	5.7	4.5	7.8	--	--	--
DAMS WITH ANY RESORPTIONS (%)	36.2	31.5	38.9	--	--	--

REPRODUCTIVE INDICES
WISTAR (CrI:WI[Han]) RATS
GESTATION DAY 20 CAESAREAN-SECTION

PERIOD: 2016 THROUGH 2020

NO. OF STUDIES INCLUDED	FULL STUDIES 3			DOSE RANGE STUDIES 0		
	<u>MEAN</u>	<u>MIN</u>	<u>MAX</u>	<u>MEAN</u>	<u>MIN</u>	<u>MAX</u>
DAMS WITH ALL CONCEPTUSES RESORBED (%)	0.0	0.0	0.0	--	--	--
DAMS WITH ONE OR MORE VIABLE FETUSES (%)	100.0	100.0	100.0	--	--	--
SEX RATIO (% MALES/LITTER)	49.2	44.1	51.9	--	--	--
LIVE FETAL BODY WEIGHTS GRAMS/LITTER:	--	--	--	--	--	--
MALE FETUSES:	3.81	3.76	3.86	--	--	--
FEMALE FETUSES:	3.60	3.53	3.69	--	--	--

REPRODUCTIVE INDICES
WISTAR (CrI:WI[Han]) RATS
GESTATION DAY 21 CAESAREAN-SECTION

PERIOD: 2016 THROUGH 2020

	FULL STUDIES			DOSE RANGE STUDIES		
NO. OF STUDIES INCLUDED	13			12		
NO. OF RATS TESTED	280			86		
NO. OF RATS PREGNANT	269			80		
NO. FOUND DEAD	0			0		
NO. ABORTED	0			0		
NO. DELIVERED	0			1		
CAESAREAN-SECTIONED ON GD 21	269			79		
NO. OF RATS WITH SINGLE CONCEPTUS LITTER						
LIVE:	0			0		
RESORBED:	0			0		
ABORTED:	0			0		
	<u>MEAN</u>	<u>MIN</u>	<u>MAX</u>	<u>MEAN</u>	<u>MIN</u>	<u>MAX</u>
PREGNANT (%)	96.2	87.5	100.0	93.1	71.4	100.0
CORPORA LUTEA	11.3	10.3	13.7	11.9	10.9	13.5
IMPLANTATIONS	10.3	9.6	12.8	10.8	9.4	13.3
PREIMPLANTATION LOSS (%)	8.6	2.1	13.8	9.1	1.1	20.3
LITTER SIZES						
LIVE FETUSES	9.7	8.5	12.0	10.1	8.3	13.3
DEAD FETUSES	0.0	0.0	0.0	0.0	0.0	0.0
TOTAL RESORPTIONS	0.6	0.3	1.1	0.7	0.0	2.2
EARLY RESORPTIONS	0.6	0.3	1.1	0.7	0.0	2.2
LATE RESORPTIONS	0.0	0.0	0.1	0.0	0.0	0.1
POSTIMPLANTATION LOSS (%)	6.6	2.4	12.8	8.1	0.0	19.4
DAMS WITH ANY RESORPTIONS (%)	42.9	25.0	65.0	38.8	0.0	100.0

REPRODUCTIVE INDICES
WISTAR (CrI:WI[Han]) RATS
GESTATION DAY 21 CAESAREAN-SECTION

PERIOD: 2016 THROUGH 2020

NO. OF STUDIES INCLUDED	FULL STUDIES 13			DOSE RANGE STUDIES 12		
	<u>MEAN</u>	<u>MIN</u>	<u>MAX</u>	<u>MEAN</u>	<u>MIN</u>	<u>MAX</u>
DAMS WITH ALL CONCEPTUSES RESORBED (%)	0.0	0.0	0.1	1.2	0.0	14.3
DAMS WITH ONE OR MORE VIALE FETUSES (%)	99.6	95.0	100.0	98.8	85.7	100.0
SEX RATIO (% MALES/LITTER)	51.1	45.6	55.6	48.8	39.4	65.3
LIVE FETAL BODY WEIGHTS GRAMS/LITTER:	5.30	5.16	5.48	5.34	5.20	5.50
MALE FETUSES:	5.45	5.30	5.65	5.46	5.21	5.79
FEMALE FETUSES:	5.20	5.00	5.55	5.19	5.01	5.55

FETAL EXTERNAL ABNORMALITIES
WISTAR (CrI:WI[Han]) RATS
GESTATION DAY 21 CAESAREAN-SECTION
FULL STUDIES

PERIOD: 2016 THROUGH 2020

NO. OF STUDIES INCLUDED	5
NO. LITTERS EXAMINED	98
NO. LIVE FETUSES EXAMINED	845

		RANGE/STUDY		
ABNORMALITIES		N	N	%
HEAD/NECK				
: Head, domed	L	1	0-1	(0-5.3)
	F	1	0-1	(0-0.6)
FACE				
: Eye bulge depression	L	2	0-1	(0-5.3)
	F	2	0-1	(0-0.6)
MOUTH				
: Palate, cleft	L	2	0-2	(0-10.5)
	F	2	0-2	(0-1.1)
TRUNK				
: Umbilicus, herniated	L	3	0-2	(0-10.0)
	F	3	0-2	(0-1.0)
: Genital tubercle, absent	L	1	0-1	(0-5.0)
	F	1	0-1	(0-0.5)
GENERAL				
: Entire subcutis, edema	L	3	0-1	(0-5.3)
<i>(previously Entire body, subcutaneous edema - generalized)</i>	F	3	0-1	(0-0.6)
FORE AND/OR HINDLIMBS(S)				
: Hindlimb, short	L	1	0-1	(0-5.0)
	F	1	0-1	(0-0.5)
PAW/DIGIT				
: Forepaw, short	L	1	0-1	(0-5.0)
	F	1	0-1	(0-0.5)
: Forepaw, adactyly	L	1	0-1	(0-5.6)
	F	1	0-1	(0-0.7)
: Forepaw, polydactyly	L	1	0-1	(0-5.3)
	F	1	0-1	(0-0.6)
: Hindpaw, adactyly	L	1	0-1	(0-5.0)
	F	1	0-1	(0-0.5)
: Hindpaw, polydactyly	L	1	0-1	(0-5.3)
	F	1	0-1	(0-0.6)
TAIL				
: Tail, short	L	1	0-1	(0-5.3)
	F	1	0-1	(0-0.6)

L: LITTER INCIDENCE

F: FETAL INCIDENCE

Note: All summary values are based on studies with fetal findings.

Updated June 2021

FETAL SOFT TISSUE ABNORMALITIES
WISTAR (CrI:WI[Han]) RATS
GESTATION DAY 21 CAESAREAN-SECTION
DOSE-RANGE FINDING STUDIES

PERIOD: 2016 THROUGH 2020

NO. OF STUDIES INCLUDED 4

NO. LITTERS EXAMINED 23

NO. FETUSES EXAMINED 177

	ABNORMALITIES		N	N	RANGE/STUDY %
HEART					
	: Heart, membranous ventricular septal defect	L	1	0-1	(0-16.7)
	(previously Interventricular septal defect)	F	1	0-1	(0-1.7)
	: Heart, misshapen	L	1	0-1	(0-16.7)
		F	1	0-1	(0-1.7)
	: Heart, atrioventricular septal defect	L	1	0-1	(0-16.7)
		F	1	0-1	(0-1.7)
	: Ventricle, small	L	1	0-1	(0-16.7)
		F	1	0-1	(0-1.7)
	: Ventricular septum, misshapen	L	1	0-1	(0-16.7)
		F	1	0-1	(0-1.7)
	: Ventricular wall, thick	L	1	0-1	(0-16.7)
		F	1	0-1	(0-1.7)
VESSELS					
	: Aorta, malpositioned	L	1	0-1	(0-16.7)
		F	1	0-1	(0-1.7)
	: Aortic arch, narrow	L	1	0-1	(0-16.7)
		F	1	0-1	(0-1.7)
	: Pulmonary trunk, malpositioned	L	1	0-1	(0-16.7)
		F	1	0-1	(0-1.7)
	: Pulmonary trunk, narrow	L	1	0-1	(0-16.7)
		F	1	0-1	(0-1.7)
LIVER					
	: Lobe, misshapen	L	3	0-1	(0-20.0)
		F	3	0-1	(0-2.4)
KIDNEY					
	: Kidney, small	L	1	0-1	(0-16.7)
		F	1	0-1	(0-2.8)
GONAD					
	: Ovary, absent	L	1	0-1	(0-16.7)
		F	1	0-1	(0-2.8)
	: Oviduct, absent	L	1	0-1	(0-16.7)
		F	1	0-1	(0-2.8)
	: Uterus horn, absent	L	1	0-1	(0-16.7)
		F	1	0-1	(0-2.8)
URETER					
	: Ureter, absent	L	1	0-1	(0-16.7)
		F	1	0-1	(0-2.8)

L: LITTER INCIDENCE

F: FETAL INCIDENCE

Note: All summary values are based on studies with fetal findings.

Updated June 2021

FETAL SOFT TISSUE ABNORMALITIES
WISTAR (CrI:WI[Han]) RATS
GESTATION DAY 21 CAESAREAN-SECTION
FULL STUDIES

PERIOD: 2016 THROUGH 2020

NO. OF STUDIES INCLUDED	11
NO. LITTERS EXAMINED	221
NO. FETUSES EXAMINED	1081

	ABNORMALITIES		N	RANGE/STUDY	
				N	%
BRAIN	: Fourth ventricle, dilatation, moderate	L	1	0-1	(0-5.6)
		F	1	0-1	(0-1.4)
	: Third ventricle, dilatation, minimal	L	1	0-1	(0-5.6)
		F	1	0-1	(0-1.4)
	: Lateral ventricle, both, dilatation, moderate	L	1	0-1	(0-5.0)
		F	1	0-1	(0-1.3)
EYE(S)	: Retina, folded	L	1	0-1	(0-5.0)
		F	1	0-1	(0-1.1)
	: Lens, malpositioned	L	1	0-1	(0-4.5)
		F	1	0-1	(0-1.0)
	: Eye, both, absent	L	1	0-1	(0-5.6)
		F	1	0-1	(0-1.4)
GENERAL	: General, situs inversus (previously Total, situs inversus)	L	1	0-1	(0-5.0)
		F	1	0-1	(0-0.9)
HEART	: Heart, membranous ventricular septal defect (previously Interventricular septal defect)	L	1	0-1	(0-4.8)
		F	1	0-1	(0-0.8)
INTESTINES	: Intestine, malpositioned	L	1	0-1	(0-5.0)
		F	1	0-1	(0-1.1)
LIVER	: Lobe, misshapen	L	13	0-3	(0-15.0)
		F	17	0-4	(0-3.8)
LUNG	: Lung, small	L	1	0-1	(0-5.3)
		F	1	0-1	(0-1.1)
KIDNEY	: Renal pelvis, dilated, minimal	L	1	0-1	(0-5.0)
		F	1	0-1	(0-0.9)
GONAD	: Testis, malpositioned	L	1	0-1	(0-5.0)
		F	1	0-1	(0-0.9)
URETER	: Ureter, dilated, severe	L	1	0-1	(0-5.0)
		F	1	0-1	(0-0.9)

L: LITTER INCIDENCE

F: FETAL INCIDENCE

Note: All summary values are based on studies with fetal findings.

Updated June 2021

FETAL SKELETAL ABNORMALITIES
WISTAR (CrI:WI[Han]) RATS
GESTATION DAY 21 CAESAREAN-SECTION
DOSE-RANGE FINDING STUDIES

PERIOD: 2016 THROUGH 2020

NO. OF STUDIES INCLUDED 6
NO. LITTERS EXAMINED 42
NO. FETUSES EXAMINED 332

SKULL	ABNORMALITIES	RANGE/STUDY		
		N	N	%
SKULL	Frontal			
	: Incomplete ossification, Both	L 2	0-1	(0-12.5)
		F 4	0-3	(0-7.5)
	Parietal			
	: Incomplete ossification, Both	L 9	0-4	(0-66.7)
		F 15	0-6	(0-14.9)
	Interparietal			
	: Incomplete ossification	L 4	0-3	(0-50.0)
		F 4	0-3	(0-8.1)
	Squamosal			
	: Incomplete ossification, Both	L 5	0-2	(0-25.0)
		F 9	0-4	(0-10.0)
	: Incomplete ossification, Right	L 2	0-1	(0-12.5)
		F 2	0-1	(0-2.5)
	Zygomatic arch			
	: Incomplete ossification, Both	L 6	0-2	(0-33.3)
		F 11	0-4	(0-10.0)
	: Incomplete ossification, Right	L 1	0-1	(0-12.5)
		F 1	0-1	(0-2.5)
	: Fused	L 2	0-2	(0-33.3)
		F 2	0-2	(0-5.2)
VERTEBRAE	Cervical			
	: Arch, misshapen	L 3	0-2	(0-33.3)
		F 3	0-2	(0-6.1)
	: Supernumerary Rib, Cervical, Short	L 13	1-3	(12.5-50.0)
		F 20	1-8	(1.4-12.5)
	Thoracic			
	: Vertebra, fused	L 1	0-1	(0-16.7)
		F 1	0-1	(0-2.4)
	: Centrum, bipartite ossification (Previously: Centrum, bifid)	L 1	0-1	(0-16.7)
		F 1	0-1	(0-2.4)

L: LITTER INCIDENCE

F: FETAL INCIDENCE

Note: All summary values are based on studies with fetal findings.

Updated June 2021

FETAL SKELETAL ABNORMALITIES
WISTAR (CrI:WI[Han]) RATS
GESTATION DAY 21 CAESAREAN-SECTION
DOSE-RANGE FINDING STUDIES

RIBS	ABNORMALITIES	RANGE/STUDY		
		N	N	%
	Ribs			
	: Nodule	L 10	0-4	(0-66.7)
	<i>(Previously: Nodulated or Thickened)</i>	F 22	0-8	(0-18.0)
	: Wavy	L 2	0-1	(0-16.7)
		F 5	0-4	(0-5.6)
	Thoracolumbar			
	: Supernumerary Rib, Full	L 2	0-1	(0-16.7)
	<i>(Previously: T14 or Thoracolumbar, full)</i>	F 2	0-1	(0-2.4)
	: Supernumerary Rib, Short	L 12	0-6	(0-100.0)
	<i>(Previously: T14 or Thoracolumbar, short)</i>	F 46	0-26	(0-58.1)
STERNEBRAE				
	Sternebra			
	: Incomplete ossification	L 1	0-1	(0-16.7)
		F 1	0-1	(0-3.3)
	: Sternoschisis	L 1	0-1	(0-16.7)
	<i>(Previously: Split or Duplicated)</i>	F 1	0-1	(0-1.7)

L: LITTER INCIDENCE

F: FETAL INCIDENCE

Note: All summary values are based on studies with fetal findings.

Updated June 2021

FETAL SKELETAL ABNORMALITIES
WISTAR (CrI:WI[Han]) RATS
GESTATION DAY 21 CAESAREAN-SECTION
FULL STUDIES

PERIOD: 2016 THROUGH 2020

NO. OF STUDIES INCLUDED 13
NO. LITTERS EXAMINED 265
NO. FETUSES EXAMINED 1349

SKULL	ABNORMALITIES		RANGE/STUDY		
			N	N	%
Parietal	: Incomplete ossification, Both	L	71	0-7	(0-38.9)
		F	115	0-14	(0-15.3)
	: Incomplete ossification, Left	L	3	0-2	(0-11.1)
		F	3	0-2	(0-2.2)
	: Incomplete ossification, Right	L	3	0-2	(0-11.1)
		F	3	0-2	(0-2.2)
	: Hole	L	1	0-1	(0-5.6)
		F	1	0-1	(0-1.1)
	Interparietal	L	30	0-6	(0-30.0)
		F	45	0-13	(0-14.7)
	Squamosal	L	47	1-5	(4.5-26.3)
		F	67	1-10	(1.2-11.2)
	: Incomplete ossification, Left	L	4	0-2	(0-11.1)
		F	4	0-2	(0-2.6)
	: Incomplete ossification, Right	L	2	0-1	(0-5.6)
		F	2	0-1	(0-1.1)
	Zygomatic arch	L	1	0-1	(0-5.0)
		F	2	0-2	(0-1.7)
	: Incomplete ossification, Both	L	50	2-6	(9.1-47.6)
		F	71	2-10	(1.9-11.8)
	: Incomplete ossification, Left	L	4	0-3	(0-16.7)
		F	4	0-3	(0-3.2)
	: Incomplete ossification, Right	L	3	0-2	(0-10.0)
		F	4	0-3	(0-2.7)
	: Fused	L	3	0-1	(0-5.3)
		F	3	0-1	(0-1.1)
	Frontal	L	15	0-3	(0-15.8)
		F	21	0-7	(0-6.8)
	: Holes	L	1	0-1	(0-5.0)
		F	1	0-1	(0-1.1)
	: Misshapen	L	1	0-1	(0-5.6)
		F	1	0-1	(0-1.1)
	Supraoccipital	L	7	0-4	(0-21.1)
		F	9	0-5	(0-5.4)
	Mandible	L	1	0-1	(0-5.3)
		F	2	0-2	(0-2.2)
	Suture	L	1	0-1	(0-5.0)
		F	1	0-1	(0-0.9)
	Premaxilla	L	1	0-1	(0-5.3)
		F	2	0-2	(0-2.2)

L: LITTER INCIDENCE

F: FETAL INCIDENCE

Note: All summary values are based on studies with fetal findings.

Updated June 2021

FETAL SKELETAL ABNORMALITIES
WISTAR (CrI:WI[Han]) RATS
GESTATION DAY 21 CAESAREAN-SECTION
FULL STUDIES

SKULL (CONTINUED)		ABNORMALITIES		RANGE/STUDY			
				N	N	%	
VERTEBRAE	Tympanic	: Annulus, incomplete ossification	L	2	0-2	(0-10.5)	
			F	3	0-3	(0-3.3)	
		: Annulus, misshapen	L	1	0-1	(0-5.3)	
			F	1	0-1	(0-1.1)	
	Cervical	: Arch, incomplete ossification	L	4	0-2	(0-10.5)	
			F	5	0-3	(0-3.3)	
		: Arch, misshapen	L	8	0-3	(0-15.0)	
			F	9	0-4	(0-4.1)	
		: Arch, fused	L	2	0-1	(0-5.3)	
			F	2	0-1	(0-1.1)	
		: Arch, absent	L	1	0-1	(0-4.8)	
			F	1	0-1	(0-0.8)	
		: Supernumerary Rib, Cervical, Full	L	8	0-1	(0-5.3)	
			F	8	0-1	(0-1.3)	
		: Supernumerary Rib, Cervical, Short	L	43	0-7	(0-35.0)	
			F	54	0-8	(0-7.8)	
		: Hemivertebra	L	1	0-1	(0-5.3)	
			F	1	0-1	(0-1.1)	
		Thoracic	: Arch, absent	L	1	0-1	(0-4.8)
				F	1	0-1	(0-0.8)
			: Centrum, bipartite ossification (previously reported as centrum, bifid)	L	3	0-1	(0-5.3)
				F	3	0-1	(0-1.1)
			: Centrum, fused	L	2	0-1	(0-5.3)
				F	2	0-1	(0-1.1)
			: Centrum, incomplete ossification	L	10	0-3	(0-15.8)
				F	11	0-3	(0-3.2)
			: Centrum, unilateral ossification	L	1	0-1	(0-5.3)
				F	1	0-1	(0-1.1)
	: Hemivertebra		L	1	0-1	(0-5.3)	
			F	1	0-1	(0-1.1)	
	Lumbar	: Vertebra, supernumerary	L	3	0-1	(0-5.3)	
			F	3	0-1	(0-1.1)	
		: Vertebra, absent	L	1	0-1	(0-5.3)	
			F	1	0-1	(0-1.1)	
Caudal	: Unossified	L	2	0-1	(0-5.0)		
		F	3	0-2	(0-2.2)		
	: Incomplete ossification	L	1	0-1	(0-4.8)		
		F	1	0-1	(0-0.8)		
RIBS	Ribs	: Incomplete ossification	L	1	0-1	(0-5.0)	
			F	1	0-1	(0-0.9)	
		: Nodule (Previously: Nodulated or Thickened)	L	41	1-7	(4.0-36.8)	
			F	60	1-10	(0.7-14.8)	
		: Wavy	L	8	0-4	(0-21.1)	
			F	8	0-4	(0-3.9)	

L: LITTER INCIDENCE

F: FETAL INCIDENCE

Note: All summary values are based on studies with fetal findings.

Updated June 2021

FETAL SKELETAL ABNORMALITIES
WISTAR (CrI:WI[Han]) RATS
GESTATION DAY 21 CAESAREAN-SECTION
FULL STUDIES

RIBS (CONTINUED)	ABNORMALITIES		N	RANGE/STUDY	
				N	%
	Ribs	: Short	L	9	0-4 (0-20.0)
			F	9	0-4 (0-4.5)
		: Misshapen	L	1	0-1 (0-4.8)
			F	1	0-1 (0-0.7)
		: Fused	L	2	0-1 (0-5.3)
			F	2	0-1 (0-1.1)
	Thoracolumbar	: Supernumerary Rib, Full (Previously: T14 or Thoracolumbar, full)	L	27	0-8 (0-36.4)
			F	38	0-12 (0-10.4)
		: Supernumerary Rib, Short (Previously: T14 or Thoracolumbar, short)	L	126	0-21 (0-95.2)
			F	392	0-75 (0-63.9)
STERNEBRAE	Sternebra	: Asymmetric	L	5	0-2 (0-10.0)
			F	5	0-2 (0-1.9)
		: Fused	L	3	0-1 (0-5.0)
			F	3	0-1 (0-1.0)
		: Incomplete ossification	L	8	0-2 (0-10.5)
			F	9	0-3 (0-3.3)
		: Misshappen	L	6	0-1 (0-5.3)
			F	6	0-1 (0-1.3)
		: Extra point of ossification	L	2	0-1 (0-5.0)
			F	2	0-1 (0-0.9)
FORELIMB	Phalanges	: Unossified	L	12	0-11 (0-50.0)
			F	20	0-19 (0-17.9)
		: Absent	L	1	0-1 (0-5.0)
			F	1	0-1 (0-1.0)
	Humerus	: Misshapen	L	1	0-1 (0-5.3)
			F	1	0-1 (0-1.1)
	Metacarpal	: Unossified	L	5	0-2 (0-10.5)
			F	6	0-3 (0-3.3)
HINDLIMB	Phalanges	: Absent	L	1	0-1 (0-5.0)
			F	1	0-1 (0-1.0)
		: Small	L	1	0-1 (0-5.0)
			F	1	0-1 (0-1.0)
	Femur	: Short	L	2	0-1 (0-5.3)
			F	2	0-1 (0-1.1)
	Fibula	: Short	L	2	0-1 (0-5.3)
			F	2	0-1 (0-1.1)
	Metatarsal	: Unossified	L	1	0-1 (0-5.3)
			F	1	0-1 (0-1.1)
	Tibia	: Short	L	2	0-1 (0-5.3)
			F	2	0-1 (0-1.1)

L: LITTER INCIDENCE

F: FETAL INCIDENCE

Note: All summary values are based on studies with fetal findings.

Updated June 2021

FETAL SKELETAL OSSIFICATION SITES
WISTAR (CrI:WI[Han]) RATS
GESTATION DAY 21 CAESAREAN-SECTION
DOSE-RANGE FINDING STUDIES

PERIOD: 2016 THROUGH 2020

NO. OF STUDIES INCLUDED 4

NO. LITTERS EXAMINED 30

NO. FETUSES EXAMINED 217

	MEAN	MINIMUM	MAXIMUM
HYOID	1.00	1.00	1.00
VERTEBRAE			
CERVICAL	7.00	7.00	7.00
THORACIC	13.42	13.39	13.46
LUMBAR	5.58	5.55	5.61
SACRAL	4.00	4.00	4.00
CAUDAL	6.98	6.73	7.23
RIBS (pairs)	13.34	13.30	13.41
STERNUM			
MANUBRIUM	1.00	1.00	1.00
STERNAL CENTERS	4.00	4.00	4.00
XIPHOID	1.00	1.00	1.00
FOREPAWS ^a			
CARPALS	0.00	0.00	0.00
METACARPALS	4.00	4.00	4.00
DIGITS	5.00	5.00	5.00
PHALANGES	8.72	8.53	8.92
HINDPAWS ^a			
TARSALS	0.70	0.57	0.81
METATARSALS	5.00	4.98	5.00
DIGITS	5.00	5.00	5.00
PHALANGES	7.95	7.73	8.25

a. Calculated as mean per limb

Note: All summary values are based on studies with fetal findings.

Updated June 2021

FETAL SKELETAL OSSIFICATION SITES
WISTAR (CrI:WI[Han]) RATS
GESTATION DAY 21 CAESAREAN-SECTION
FULL STUDIES

PERIOD: 2016 THROUGH 2020

NO. OF STUDIES INCLUDED	6
NO. LITTERS EXAMINED	122
NO. FETUSES EXAMINED	607

	MEAN	MINIMUM	MAXIMUM
HYOID	1.00	0.99	1.00
VERTEBRAE			
CERVICAL	7.00	7.00	7.00
THORACIC	13.47	13.35	13.65
LUMBAR	5.53	5.35	5.68
SACRAL	4.00	4.00	4.00
CAUDAL	7.09	6.66	7.54
RIBS (pairs)	13.41	13.29	13.59
STERNUM			
MANUBRIUM	1.00	1.00	1.00
STERNAL CENTERS	4.00	3.99	4.00
XIPHOID	1.00	1.00	1.00
FOREPAWS ^a			
CARPALS	0.00	0.00	0.00
METACARPALS	4.00	4.00	4.00
DIGITS	5.00	5.00	5.00
PHALANGES	8.51	8.27	8.64
HINDPAWS ^a			
TARSALS	0.65	0.47	0.77
METATARSALS	4.99	4.97	5.00
DIGITS	5.00	5.00	5.00
PHALANGES	7.91	7.45	8.36

a. Calculated as mean per limb

Note: All summary values are based on studies with fetal findings.

Updated June 2021

REPRODUCTIVE ORGAN WEIGHTS, MATING, AND FERTILITY
WISTAR (CrI:WI[Han]) RATS
MALE

PERIOD: 2016 THROUGH 2020

NO. OF STUDIES INCLUDED - ORGAN WEIGHTS 11
NO. OF RATS EVALUATED - ORGAN WEIGHTS 198

ABSOLUTE REPRODUCTIVE ORGAN WEIGHTS

	<u>MEAN</u>	<u>MIN</u>	<u>MAX</u>	<u>NO. STUDIES INCLUDED</u>
TERMINAL BODY WEIGHT (TBW)	399.5	266.7	486.8	11
TESTIS				
LEFT	1.876	1.825	1.916	9
RIGHT	1.853	1.780	1.899	9
PAIRED	3.447	3.135	3.760	2
EPIDIDYMIS				
LEFT	0.679	0.404	0.739	8
RIGHT	0.704	0.643	0.753	9
PAIRED	1.115	0.809	1.420	2
CAUDA EPIDIDYMIS				
LEFT	0.281	0.257	0.319	9
PROSTATE	0.892	0.424	1.062	10
SEMINAL VESICLES				
WITH FLUID	1.421	0.636	1.649	8
WITHOUT FLUID	0.740	0.740	0.740	1

Note: All summary values are based on all males with reproductive data (P, F1, F2 generation and all ages).
All organ weights are measured in grams.

Updated June 2021

REPRODUCTIVE ORGAN WEIGHTS, MATING, AND FERTILITY
WISTAR (CrI:WI[Han]) RATS
MALE

PERIOD: 2016 THROUGH 2020

REPRODUCTIVE ORGAN WEIGHTS RELATIVE TO TERMINAL BODY WEIGHT (TBW)

	<u>MEAN</u>	<u>MIN</u>	<u>MAX</u>	<u>NO. STUDIES INCLUDED</u>
TERMINAL BODY WEIGHT (TBW)	399.5	266.7	486.8	11
TESTIS (% TBW)				
LEFT	0.459	0.392	0.493	9
RIGHT	0.454	0.392	0.491	9
PAIRED	1.017	0.903	1.131	2
EPIDIDYMIS (% TBW)				
LEFT	0.166	0.098	0.189	8
RIGHT	0.172	0.152	0.185	9
PAIRED	0.316	0.292	0.340	2
CAUDA EPIDIDYMIS (% TBW)				
LEFT	0.069	0.063	0.078	9
PROSTATE (% TBW)	0.223	0.152	0.274	10
SEMINAL VESICLES (% TBW)				
WITH FLUID	0.364	0.228	0.399	8
WITHOUT FLUID	0.179	0.179	0.179	1

REPRODUCTIVE ORGAN WEIGHTS RELATIVE TO BRAIN WEIGHT (BRW)

	<u>MEAN</u>	<u>MIN</u>	<u>MAX</u>	<u>NO. STUDIES INCLUDED</u>
BRAIN WEIGHT (BRW)	2.05	2.01	2.11	4
TESTIS (% BRW)				
LEFT	92.5	91.5	93.3	3
RIGHT	92.1	90.6	93.2	3
PAIRED	161.2	161.2	161.2	1
EPIDIDYMIS (% BRW)				
LEFT	35.1	33.3	36.8	3
RIGHT	36.2	35.8	37.0	3
PAIRED	41.6	41.6	41.6	1
CAUDA EPIDIDYMIS (% BRW)				
LEFT	14.6	13.4	15.5	3
PROSTATE (% BRW)	39.3	21.9	49.9	4
SEMINAL VESICLES (% BRW)				
WITH FLUID	55.6	32.6	78.6	2

Note: All summary values are based on all males with reproductive data (P, F1, F2 generation and all ages).
All organ weights are measured in grams.

Updated June 2021

REPRODUCTIVE ORGAN WEIGHTS, MATING, AND FERTILITY
WISTAR (CrI:WI[Han]) RATS
MALE

PERIOD: 2016 THROUGH 2020

MATING AND FERTILITY EVALUATIONS

NO. OF STUDIES INCLUDED - COHABITATION	10			
NO. MALE RATS IN COHABITATION	220			
	<u>MEAN</u>	<u>MIN</u>	<u>MAX</u>	<u>NO. STUDIES INCLUDED</u>
DAYS IN COHABITATION	2.6	2.0	3.6	9
RATS THAT MATED (%) ¹	98.6	95.0	100.0	10
RATS WITH CONFIRMED MATING DATES (%) ²	99.5	95.2	100.0	10
FERTILITY INDEX (%) ³	93.8	75.0	100.0	10
RATS MATING (%)				
DAYS 1-4	90.9	90.9	90.9	1
DAYS 1-7	99.3	95.4	100.0	7
DAYS 5-7	9.1	9.1	9.1	1
DAYS 8-14	4.5	4.5	4.5	1
RATS PREGNANT/RATS IN COHABITATION (%)	92.5	75.0	100.0	10

¹ (Number of rats that mated/number of rats paired)*100

² (Number of rats with confirmed mating dates/number of rats that mated)*100

³ (Number of pregnancies/number of rats that mated)*100

ESTROUS CYCLING, MATING, AND FERTILITY
WISTAR [CrI:WI(Han)] RATS
FEMALE

PERIOD: 2016 THROUGH 2020

NO. OF STUDIES INCLUDED - ESTROUS	16
NO. OF RATS EVALUATED - ESTROUS	307

PREDOSE ESTROUS EVALUATIONS

NO. RATS EVALUATED: PREDOSE ESTROUS	96			NO. STUDIES INCLUDED
	<u>MEAN</u>	<u>MINIMUM</u>	<u>MAXIMUM</u>	
ESTROUS STAGES/14 DAYS	3.5	3.4	3.7	5
RATS WITH 6 OR MORE CONSEC. DAYS OF DIESTRUS	0.0	0	0	5
RATS WITH 6 OR MORE CONSEC. DAYS OF ESTRUS	0.0	0	0	5

PRECOHABITATION ESTROUS EVALUATIONS

NO. RATS EVALUATED: PRECOHABITATION ESTROUS	307			NO. STUDIES INCLUDED
	<u>MEAN</u>	<u>MINIMUM</u>	<u>MAXIMUM</u>	
ESTROUS STAGES/14 DAYS	3.5	1.8	7.3	16
CYCLE LENGTHS (DAYS)	4.2	4.1	4.3	2
RATS WITH 6 OR MORE CONSEC. DAYS OF DIESTRUS	0.0	0	0	14
RATS WITH 6 OR MORE CONSEC. DAYS OF ESTRUS	0.1	0	1	14

ESTROUS CYCLING, MATING, AND FERTILITY
WISTAR [CrI:WI(Han)] RATS
FEMALE

PERIOD: 2016 THROUGH 2020

NO. OF STUDIES INCLUDED - MATING AND FERTILITY 17

MATING AND FERTILITY EVALUATIONS

NO. OF RATS IN COHABITATION 391

	<u>MEAN</u>	<u>MINIMUM</u>	<u>MAXIMUM</u>	<u>NO. STUDIES INCLUDED</u>
DAYS IN COHABITATION	2.6	2.0	3.6	17
RATS THAT MATED (%) ¹	99.1	93.8	100.0	17
RATS WITH CONFIRMED MATING DATES (%) ²	99.7	95.5	100.0	17
RATS MATED BY FIRST MALE (%)				
DAYS 1-4	90.9	90.9	90.9	1
DAYS 1-7	98.7	95.0	100.0	15
DAYS 5-7	9.1	9.1	9.1	1
DAYS 8-14	4.7	4.5	5.0	4
FERTILITY INDEX (%) ³	93.7	75.0	100.0	17
RATS PREGNANT/RATS IN COHABITATION (%)	92.9	75.0	100.0	17

¹ (Number of rats that mated/number of rats paired)*100

² (Number of rats with confirmed mating dates/number of rats that mated)*100

³ (Number of pregnancies/number of rats that mated)*100

HAMILTON-THORNE SPERM EVALUATION
WISTAR (CrI:WI[Han]) RATS

PERIOD: 2016 THROUGH 2020¹

SUMMARY

NO. OF RATS INCLUDED	113			
	<u>MEAN</u>	<u>MINIMUM</u>	<u>MAXIMUM</u>	<u>NO. STUDIES INCLUDED</u>
<u>VAS DEFERENS SPERM MOTILITY</u>				
MOTILE PERCENT	82.4	73.2	89.7	7
<u>CAUDA EPIDIDYMAL SPERM COUNT</u>				
SPERM DENSITY ²	1512.9	1211.0	1798.4	7

¹ IVOS Version 12.2L or later

² Million sperm/gram of tissue

Updated June 2021

CAUDA EPIDIDYMAL SPERM MORPHOLOGY
WISTAR (CrI:WI[Han]) RATS

PERIOD: 2016 THROUGH 2020

SUMMARY

NO. OF STUDIES INCLUDED

4

NO. OF RATS INCLUDED

49

	MEAN	MINIMUM	MAXIMUM
Normal	193.1	189.8	194.8
Percent abnormal	3.8	2.6	5.1
No hook	0.6	0.0	2.4
Excessive hook	0.1	0.0	0.2
No head	2.6	1.9	3.0
Detached head	3.6	2.4	4.4
Amorphous	0.0	0.0	0.0
Pin head	0.0	0.0	0.0
Two heads & tails	0.0	0.0	0.0
Short sperm head	0.0	0.0	0.0
Banana	0.1	0.0	0.2
Broken flagellum	0.8	0.2	1.6
Coiled flagellum	0.0	0.0	0.0
Bent flagellum	0.0	0.0	0.1
Bent flagellum tip	0.0	0.0	0.0
Other	0.0	0.0	0.0

Updated June 2021

NATURAL DELIVERY AND LITTER PARAMETERS
WISTAR [CrI:WI(Han)] RATS
(STUDIES WITH CULLING)

PERIOD: 2016 THROUGH 2020

NO. OF RATS ASSIGNED TO NATURAL DELIVERY	8			
NO. OF RATS PREGNANT	8			
NO. OF RATS THAT DELIVERED LITTERS	8			
	<u>MEAN or %</u>	<u>MINIMUM</u>	<u>MAXIMUM</u>	<u>NO. STUDIES INCLUDED</u>
PREGNANT (%)	100.0	100.0	100.0	1
DELIVERED LITTERS (%)	100.0	100.0	100.0	1
DURATION OF GESTATION IN DAYS	21.5	21.5	21.5	1
DAMS WITH STILLBORN PUPS (%)	0.0	0.0	0.0	1
DAMS WITH NO LIVEBORN PUPS (%)	0.0	0.0	0.0	1
GESTATION INDEX (NO. RATS WITH LIVEBORN/NO. PREGNANT RATS) (%)	100.0	100.0	100.0	1
PUPS DELIVERED (TOTAL)	8.1	8.1	8.1	1
LIVEBORN	8.1	8.1	8.1	1
LIVEBORN (%)	100.0	100.0	100.0	1
STILLBORN	0.0	0.0	0.0	1
STILLBORN (%)	0.0	0.0	0.0	1
VIABILITY INDEX (%) (No. Live pups PND 4 / No. Live pups PND 1)	98.2	98.2	98.2	1
SURVIVAL INDEX (%) (No. Live pups PND 14 / No. Live pups PND 1)	96.9	96.9	96.9	1
PERCENT MALE PUPS PER NUMBER OF PUPS SEXED				
Birth	47.7	47.7	47.7	1
PUP WEIGHT/LITTER (GRAMS)				
Day 1	6.3	6.3	6.3	1
Day 4 (Preculling)	10.1	10.1	10.1	1
Day 4 (Postculling)	10.1	10.1	10.1	1
Day 7	15.3	15.3	15.3	1
Day 14	30.1	30.1	30.1	1

PND or DAY(s) = Postnatal Day(s)

Updated June 2021

NATURAL DELIVERY AND LITTER PARAMETERS
WISTAR [CrI:WI(Han)] RATS
(STUDIES WITHOUT CULLING)

PERIOD: 2016 THROUGH 2020

NO. OF RATS ASSIGNED TO NATURAL DELIVERY	188			
NO. OF RATS PREGNANT	176			
NO. OF RATS THAT DELIVERED LITTERS	176			
	<u>MEAN or %</u>	<u>MINIMUM</u>	<u>MAXIMUM</u>	<u>NO. STUDIES INCLUDED</u>
PREGNANT (%)	93.8	75.0	100.0	8
DELIVERED LITTERS (%)	96.9	75.0	100.0	8
DURATION OF GESTATION IN DAYS	22.3	21.3	22.7	8
IMPLANTATION SITES PER DELIVERED LITTER	10.9	9.1	13.0	8
DAMS WITH STILLBORN PUPS (%)	4.7	0.0	11.1	8
DAMS WITH NO LIVEBORN PUPS (%)	0.0	0.0	0.0	8
GESTATION INDEX (NO. RATS WITH LIVEBORN/NO. PREGNANT RATS) (%)	100.0	100.0	100.0	8
DAMS WITH ALL PUPS DYING DAYS 1-4 POSTPARTUM (%)	0.6	0.0	4.3	7
DAMS WITH ALL PUPS DYING DAYS 5-21 POSTPARTUM (%)	0.0	0.0	0.0	7
PUPS DELIVERED (TOTAL)	10.4	8.5	12.5	7
LIVEBORN	10.4	8.5	12.3	8
LIVEBORN (%)	99.3	97.8	100.0	8
STILLBORN	0.1	0.0	0.5	8
STILLBORN (%)	0.7	0.0	2.2	8
UNKNOWN VITAL STATUS (N)	0.0	0.0	0.0	4
POSTIMPLANTATION LOSS / LITTER (%)	2.9	2.9	2.9	1

PND or DAY(s) = Postnatal Day(s)

Updated June 2021

NATURAL DELIVERY AND LITTER PARAMETERS
WISTAR [CrI:WI(Han)] RATS
(STUDIES WITHOUT CULLING)

PERIOD: 2016 THROUGH 2020

	<u>MEAN or %</u>	<u>MINIMUM</u>	<u>MAXIMUM</u>	<u>NO. STUDIES INCLUDED</u>
PUPS FOUND DEAD OR PRESUMED CANNIBALIZED (%)				
DAY 1	0.5	0.0	1.9	7
DAYS 2-4	1.3	0.0	4.1	7
DAYS 5-7	0.1	0.0	0.4	7
DAYS 8-10	0.0	0.0	0.0	1
DAYS 8-14	0.1	0.0	0.5	4
DAYS 11-14	0.0	0.0	0.0	1
DAYS 15-17	0.0	0.0	0.0	1
DAYS 15-21	0.0	0.0	0.0	3
DAYS 18-21	0.0	0.0	0.0	1
DAYS 22-28	0.5	0.5	0.5	1
VIABILITY INDEX (%) (No. Live pups PND 4 / No. Live pups PND 1)	98.7	95.9	100.0	7
VIABILITY INDEX (%) (No. Live pups PND 5 / No. Live pups PND 1)	100.0	100.0	100.0	1
VIABILITY INDEX (%) (No. Live pups PND 7 / No. Live pups PND 1)	95.5	95.5	95.5	1
LACTATION INDEX (%) (No. Live pups PND 21 / No. Live pups PND 4)	99.7	98.8	100.0	6
LACTATION INDEX (%) (No. Live pups PND 28 / No. Live pups PND 4)	99.5	99.5	99.5	1

PND or DAY(s) = Postnatal Day(s)

Updated June 2021

NATURAL DELIVERY AND LITTER PARAMETERS
WISTAR [CrI:WI(Han)] RATS
(STUDIES WITHOUT CULLING)

PERIOD: 2016 THROUGH 2020

	<u>MEAN or %</u>	<u>MINIMUM</u>	<u>MAXIMUM</u>	<u>NO. STUDIES INCLUDED</u>
SURVIVING PUPS/LITTER				
Day 1	10.3	8.5	12.3	7
Day 4	9.6	8.1	11.2	5
Day 7	10.1	8.1	12.3	7
Day 10	9.8	9.8	9.8	1
Day 14	9.4	8.1	11.2	5
Day 17	9.8	9.8	9.8	1
Day 21	9.4	8.1	11.2	5
Day 28	8.1	8.1	8.1	1
PERCENT MALE PUPS PER NUMBER OF PUPS SEXED				
Birth	51.2	51.2	51.2	1
Day 1	50.3	44.9	54.5	7
Day 4	50.7	46.4	54.6	5
Day 7	50.5	46.4	54.6	7
Day 10	49.4	49.4	49.4	1
Day 14	50.8	46.4	54.6	5
Day 17	49.4	49.4	49.4	1
Day 21	50.8	46.4	54.6	6
Day 28	46.9	46.9	46.9	1

PND or DAY(s) = Postnatal Day(s)

Updated June 2021

NATURAL DELIVERY AND LITTER PARAMETERS
WISTAR [CrI:WI(Han)] RATS
(STUDIES WITHOUT CULLING)

PERIOD: 2016 THROUGH 2020

	<u>MEAN or %</u>	<u>MINIMUM</u>	<u>MAXIMUM</u>	<u>NO. STUDIES INCLUDED</u>
LIVE LITTER SIZE AT WEIGHING				
Day 1	10.3	8.5	12.3	7
Day 4	9.7	8.5	11.2	5
Day 7	10.2	8.5	12.2	7
Day 10	9.8	9.8	9.8	1
Day 14	9.5	8.5	11.2	5
Day 17	9.8	9.8	9.8	1
Day 21	9.5	8.5	11.2	5
Day 28	8.4	8.4	8.4	1
PUP WEIGHT/LITTER (GRAMS)				
Day 1	5.9	5.6	6.3	8
Day 4	9.0	8.2	9.5	6
Day 7	13.5	12.6	14.1	8
Day 10	19.0	18.2	19.8	2
Day 14	26.7	25.3	28.4	6
Day 17	32.2	30.2	34.3	2
Day 21	41.0	38.0	44.2	6
Day 28	68.7	68.7	68.7	1

PND or DAY(s) = Postnatal Day(s)

Updated June 2021

SEXUAL MATURATION
WISTAR [CrI:WI(Han)] RATS

PERIOD: 2016 THROUGH 2020

SEXUAL MATURATION

SUMMARY

TOTAL MALE RATS	225			NO. STUDIES
	MEAN	MINIMUM	MAXIMUM	INCLUDED
Preputial Separation (Mean day postpartum achieved)	45.1	43.5	46.7	7
Body Weight (g) on day of sexual maturity	188.2	181.1	198.0	7
TOTAL FEMALE RATS	216			NO. STUDIES
	MEAN	MINIMUM	MAXIMUM	INCLUDED
Vaginal Patency (Mean day postpartum achieved)	30.8	29.2	32.4	8
Body Weight (g) on day of sexual maturity	86.3	75.7	90.5	8

Updated June 2021