

Reproductive Toxicology

Historical Control Data in Guinea Pigs



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CHARLES RIVER LABORATORIES PRECLINICAL SERVICES, PENNSYLVANIA
SUMMARY OF REPRODUCTIVE INDICES
CrI:(HA)BR-Hartley GUINEA PIGS
SOURCE: CHARLES RIVER LABORATORIES, INC.

PERIOD: 2003 - 2004

NUMBER OF STUDIES 6

NUMBER OF GUINEA PIGS:

TESTED	52
PREGNANT	41
FOUND DEAD	1
ABORTED	1
DELIVERED PREMATURELY	0

NUMBER OF GUINEA PIGS WITH
SINGLE CONCEPTUS LITTER:

LIVE	1
RESORBED	0
ABORTED	0

NUMBER OF GUINEA PIGS PREGNANT
AT DG60 CAESAREAN-SECTIONING 39

	MEAN or %	RANGE/STUDY MEAN or %
% PREGNANT	80.1	(50.0-100)
AVERAGE NO. CORPORA LUTEA	5.7	(3.0-6.2)
AVERAGE NO. IMPLANTATIONS	4.9	(3.0-6.0)
AVERAGE LITTER SIZE		
AVERAGE NO. LIVE FETUSES	4.7	(2.0-5.1)
AVERAGE NO. DEAD FETUSES	0.0	---
AVERAGE NO. RESORPTIONS	0.2	(0-3.0)
AVERAGE NO. EARLY RESORPTIONS	0.2	(0-3.0)
AVERAGE NO. LATE RESORPTIONS	0.0	(0-0.1)

CHARLES RIVER LABORATORIES PRECLINICAL SERVICES, PENNSYLVANIA
SUMMARY OF REPRODUCTIVE INDICES
CrI:(HA)BR-Hartley GUINEA PIGS
SOURCE: CHARLES RIVER LABORATORIES, INC.

	MEAN or %	RANGE/STUDY MEAN or %
AVERAGE % SOWS WITH ANY RESORPTIONS	15.4	(0-100)
AVERAGE % SOWS WITH ALL CONCEPTUSES RESORBED	0.0	---
AVERAGE % SOWS WITH ONE OR MORE LIVE FETUSES	100.0	---
AVERAGE SEX RATIO, (% MALES/LITTER)	50.0	(40.4-66.7)
AVERAGE FETAL BODY WEIGHT (G)	64.49	(56.64-67.76)
AVERAGE FOR MALES (G)	65.90	(51.20-68.46)
AVERAGE FOR FEMALES (G)	62.86	(62.05-68.50)
AVERAGE % DEAD OR RESORBED CONCEPTUSES/LITTER	3.7	(0-50.0)

CHARLES RIVER LABORATORIES PRECLINICAL SERVICES, PENNSYLVANIA
SUMMARY OF FETAL EXTERNAL ALTERATIONS
CrI:(HA)BR (Hartley) GUINEA PIGS
SOURCE: CHARLES RIVER LABORATORIES, INC.

PERIOD: 2003 - 2004

NO. OF STUDIES	6
NO. LITTERS EXAMINED	39
NO. LIVE FETUSES EXAMINED	185

ALTERATION				RANGE /STUDY	
		N	%	N	%
BODY	Umbilical hernia	L	1 2.56	0-1	(0-9.1)
		F	1 0.54	0-1	(0-1.8)

L: LITTER INCIDENCE
F: FETUS INCIDENCE

CHARLES RIVER LABORATORIES PRECLINICAL SERVICES, PENNSYLVANIA
SUMMARY OF FETAL SOFT TISSUE ALTERATIONS
CrI:(HA)BR (Hartley) GUINEA PIGS
SOURCE: CHARLES RIVER LABORATORIES, INC.

PERIOD: 2003 - 2004

NO. STUDIES INCLUDED	2
NO. LITTERS EXAMINED	39
NO. FETUSES EXAMINED	185

ALTERATION			RANGE / STUDY	
	N	%	N	%
INTESTINES				
Portion protruded through umbilicus	L 1	2.56	0-1	(0-9.1)
	F 1	0.54	0-1	(0-1.8)

L: LITTER INCIDENCE
F: FETUS INCIDENCE

CHARLES RIVER LABORATORIES PRECLINICAL SERVICES, PENNSYLVANIA
SUMMARY OF FETAL SKELETAL ALTERATIONS
CrI:(HA)BR (Hartley) GUINEA PIGS
SOURCE: CHARLES RIVER LABORATORIES, INC.

PERIOD: 2003 - 2004

NO. STUDIES	2
NO. LITTERS EXAMINED	2
NO. FETUSES EXAMINED	5

ALTERATION		N	%	RANGE / STUDY	
				N	%
STERNEBRAE					
Irregularly shaped	L	1	50.00	0-1	(0-100)
	F	2	40.00	0-2	(0-66.7)

L: LITTER INCIDENCE
F: FETUS INCIDENCE

CHARLES RIVER LABORATORIES PRECLINICAL SERVICES, PENNSYLVANIA
SUMMARY OF FETAL OSSIFICATION SITES
SKELETAL AVERAGES
Crl:(HA)BR (Hartley) GUINEA PIGS
SOURCE: CHARLES RIVER LABORATORIES, INC.

PERIOD: 2003 - 2004

NO. STUDIES INCLUDED	2
NO. LITTERS EXAMINED	2
NO. FETUSES EXAMINED	5

SKELETAL AVERAGES	FETUS / LITTER	
	MEAN	RANGE
HYOID	0.85	(0.70-1.00)
VERTEBRAE:		
CERVICAL	7.00	---
THORACIC	13.15	(13.00-13.30)
LUMBAR	5.85	(5.70-6.00)
SACRAL	3.00	---
CAUDAL	7.85	(7.70-8.00)
RIBS (pairs)	13.15	(13.00-13.30)
STERNUM		
MANUBRIUM	1.00	---
STERNAL CENTERS	3.00	---
XIPHOID	1.00	---
FORELIMBS ^a		
CARPALS	10.65	(10.30-11.00)
METACARPALS	4.00	---
DIGITS	4.00	---
PHALANGES	12.00	---
HINDLIMBS ^a		
TARSALS	8.75	(8.50-9.00)
METATARSALS	3.00	---
DIGITS	3.00	---
PHALANGES	9.00	---

a. Calculated as average per limb

CHARLES RIVER LABORATORIES PRECLINICAL SERVICES, PENNSYLVANIA
SUMMARY OF REPRODUCTIVE INDICES
Hra:(DH)fBR (Dunkin Hartley) GUINEA PIGS
SOURCE: COVANCE RESEARCH PRODUCTS, INC.

PERIOD: 2003 - 2004

NUMBER OF STUDIES 6

NUMBER OF GUINEA PIGS:

TESTED	52
PREGNANT	44
FOUND DEAD	2*
ABORTED	1**
DELIVERED PREMATURELY	0

NUMBER OF GUINEA PIGS WITH
SINGLE CONCEPTUS LITTER:

LIVE	0
RESORBED	0
ABORTED	0

NUMBER OF GUINEA PIGS PREGNANT
AT DG60 CAESAREAN-SECTIONING

42

	MEAN or %	RANGE/STUDY MEAN or %
% PREGNANT	89.3	(25.0-100)
AVERAGE NO. CORPORA LUTEA	5.0	(3.0-5.5)
AVERAGE NO. IMPLANTATIONS	4.5	(3.0-5.5)
AVERAGE LITTER SIZE		
AVERAGE NO. LIVE FETUSES	4.3	(3.0-5.5)
AVERAGE NO. DEAD FETUSES	0.0	---
AVERAGE NO. RESORPTIONS	0.2	(0-0.5)
AVERAGE NO. EARLY RESORPTIONS	0.1	(0-0.2)
AVERAGE NO. LATE RESORPTIONS	0.1	(0-0.5)

* One was attributed to an intubation accident

** Attributed to an intubation accident

CHARLES RIVER LABORATORIES PRECLINICAL SERVICES, PENNSYLVANIA
SUMMARY OF REPRODUCTIVE INDICES
Hra:(DH)fBR (Dunkin Hartley) GUINEA PIGS
SOURCE: COVANCE RESEARCH PRODUCTS, INC.

	MEAN or %	RANGE/STUDY MEAN or %
AVERAGE % SOWS WITH ANY RESORPTIONS	14.3	(0-50.0)
AVERAGE % SOWS WITH ALL CONCEPTUSES RESORBED	2.4	(0-4.5)
AVERAGE % SOWS WITH ONE OR MORE LIVE FETUSES	97.6	(95.4-100)
AVERAGE SEX RATIO, (% MALES/LITTER)	53.0	(33.3-65.0)
AVERAGE FETAL BODY WEIGHT (G)	55.64	(34.56-62.90)
AVERAGE FOR MALES (G)	55.32	(33.56-64.35)
AVERAGE FOR FEMALES (G)	54.78	(35.18-63.00)
AVERAGE % DEAD OR RESORBED CONCEPTUSES/LITTER	3.8	(0-12.5)

CHARLES RIVER LABORATORIES PRECLINICAL SERVICES, PENNSYLVANIA
SUMMARY OF FETAL EXTERNAL ALTERATIONS
Hra:(DH)fBR (Dunkin Hartley) GUINEA PIGS
SOURCE: COVANCE RESEARCH PRODUCTS, INC.

PERIOD: 2003 - 2004

NO. OF STUDIES	5
NO. LITTERS EXAMINED	30
NO. LIVE FETUSES EXAMINED	124

There were no fetal external alterations

CHARLES RIVER LABORATORIES PRECLINICAL SERVICES, PENNSYLVANIA
SUMMARY OF FETAL SOFT TISSUE ALTERATIONS
Hra:(DH)fBR (Dunkin Hartley) GUINEA PIGS
SOURCE: COVANCE RESEARCH PRODUCTS, INC.

PERIOD: 2003 - 2004

NO. STUDIES INCLUDED	5
NO. LITTERS EXAMINED	30
NO. FETUSES EXAMINED	124

ALTERATION			RANGE / STUDY			
			N	%	N	%
LIVER	Mottled	L	1	3.33	0-1	(0-5.6)
		F	1	0.81	0-1	(0-1.3)
	Thick	L	1	3.33	0-1	(0-5.6)
		F	1	0.81	0-1	(0-1.3)
	SPLEEN					
	Large	L	1	3.33	0-1	(0-5.6)
		F	1	0.81	0-1	(0-1.3)

L: LITTER INCIDENCE
F: FETUS INCIDENCE

CHARLES RIVER LABORATORIES PRECLINICAL SERVICES, PENNSYLVANIA
SUMMARY OF FETAL SKELETAL ALTERATIONS
Hra:(DH)fBR (Dunkin Hartley) GUINEA PIGS
SOURCE: COVANCE RESEARCH PRODUCTS, INC.

PERIOD: 2003 - 2004

NO. STUDIES	5
NO. LITTERS EXAMINED	14
NO. FETUSES EXAMINED	58

				RANGE / STUDY	
ALTERATION		N	%	N	%
SKULL					
Nasal: Contains an intranasal	L	1	7.14	0-1	(0-14.3)
	F	1	1.72	0-1	(0-3.3)
Nasal - Frontal: Irregular suture	L	3	21.43	0-2	(0-100)
	F	3	5.17	0-2	(0-28.6)
Frontals: Irregular suture	L	5	35.71	0-3	(0-100)
	F	7	12.07	0-5	(0-18.2)
VERTEBRAE					
Caudal: Fused	L	2	14.29	0-1	(0-50.0)
	F	2	3.45	0-1	(0-14.3)
: Misaligned	L	1	7.14	0-1	(0-14.3)
	F	1	1.72	0-1	(0-3.3)
RIBS					
Cervical rib(s) present	L	2	14.29	0-2	(0-28.6)
	F	2	3.45	0-2	(0-6.7)
STERNEBRAE					
Duplicated	L	5	35.71	0-3	(0-100)
	F	7	12.07	0-5	(0-28.6)
Irregularly shaped	L	6	42.86	0-3	(0-50.0)
	F	9	15.52	0-6	(0-20.0)

L: LITTER INCIDENCE
F: FETUS INCIDENCE

CHARLES RIVER LABORATORIES PRECLINICAL SERVICES, PENNSYLVANIA
SUMMARY OF FETAL OSSIFICATION SITES
SKELETAL AVERAGES
Hra:(DH)fBR (Dunkin Hartley) GUINEA PIGS
SOURCE: COVANCE RESEARCH PRODUCTS, INC.

PERIOD: 2003 - 2004

NO. STUDIES INCLUDED	5
NO. LITTERS EXAMINED	14
NO. FETUSES EXAMINED	58

SKELETAL AVERAGES	FETUS / LITTER	
	MEAN	RANGE
HYOID	1.00	---
VERTEBRAE:		
CERVICAL	7.00	---
THORACIC	13.26	(13.00-13.40)
LUMBAR	5.74	(5.60-6.00)
SACRAL	3.00	---
CAUDAL	7.66	(7.00-7.85)
RIBS (pairs)	13.22	(13.00-13.40)
STERNUM		
MANUBRIUM	1.00	---
STERNAL CENTERS	3.04	(3.00-3.08)
XIPHOID	1.00	---
FORELIMBS ^a		
CARPALS	9.91	(3.80-11.90)
METACARPALS	3.99	(3.95-4.00)
DIGITS	4.00	---
PHALANGES	12.12	(12.00-13.70)
HINDLIMBS ^a		
TARSALS	9.70	(2.00-12.00)
METATARSALS	3.00	---
DIGITS	3.00	---
PHALANGES	8.96	(8.70-9.00)

a. Calculated as average per limb

CHARLES RIVER LABORATORIES PRECLINICAL SERVICES, PENNSYLVANIA
SUMMARY OF REPRODUCTIVE INDICES
Dunkin-Hartley GUINEA PIGS
SOURCE: ELM HILL BREEDING LABORATORIES

PERIOD: 2011 - 2012

NUMBER OF STUDIES 2

NUMBER OF GUINEA PIGS:

TESTED	53
PREGNANT	51
FOUND DEAD	0
ABORTED	0
DELIVERED PREMATURELY	0

NUMBER OF GUINEA PIGS WITH
SINGLE CONCEPTUS LITTER:

LIVE	0
RESORBED	0
ABORTED	0

NUMBER OF GUINEA PIGS PREGNANT
AT DG 30 CAESAREAN-SECTIONING 51

	MEAN or %	RANGE/STUDY MEAN or %
% PREGNANT	96.4	(91.7-100)
AVERAGE NO. CORPORA LUTEA	4.9	(4.8-5.0)
AVERAGE NO. IMPLANTATIONS	4.4	---
AVERAGE % PREIMPLANTATION LOSS	10.4	(8.3-12.0)
AVERAGE LITTER SIZE		
AVERAGE NO. LIVE FETUSES	4.0	(3.9-4.0)
AVERAGE NO. DEAD FETUSES	0.0	---
AVERAGE NO. RESORPTIONS	0.4	---
AVERAGE NO. EARLY RESORPTIONS	0.4	---
AVERAGE NO. LATE RESORPTIONS	0.0	---
AVERAGE % POSTIMPLANTATION LOSS	10.4	(10.2-10.6)

CHARLES RIVER LABORATORIES PRECLINICAL SERVICES, PENNSYLVANIA
SUMMARY OF REPRODUCTIVE INDICES
Dunkin-Hartley GUINEA PIGS
SOURCE: ELM HILL BREEDING LABORATORIES

	MEAN or %	RANGE/STUDY MEAN or %
AVERAGE % SOWS WITH ANY RESORPTIONS	25.5	(24.1-27.3)
AVERAGE % SOWS WITH ALL CONCEPTUSES RESORBED	1.9	(0-3.4)
AVERAGE % SOWS WITH ONE OR MORE LIVE FETUSES	98.1	(96.6-100)

CHARLES RIVER LABORATORIES PRECLINICAL SERVICES, PENNSYLVANIA
SPERM MOTILITY AND DENSITY
HISTORICAL CONTROL DATA
Dunkin Hartley GUINEA PIGS

SUMMARY
2011 - 2012

2* = TOTAL NUMBER STUDIES
32 = TOTAL GUINEA PIGS

		AVERAGE	MINIMUM	MAXIMUM	NO. STUDIES INCLUDED
<u>VAS DEFERENS (BILATERAL) SPERM MOTILITY</u>					
NUMBER MOTILE	MEAN	291.4	161.2	421.6	2
MOTILE PERCENT	MEAN	92.1	91.6	92.5	2
STATIC COUNT (NONMOTILE)	MEAN	23.1	12.9	33.3	2
TOTAL COUNT (5 fields evaluated)	MEAN	314.5	174.0	454.9	2
<u>CAUDA EPIDIDYMAL SPERM COUNT</u>					
SPERM COUNT (20 fields evaluated)	MEAN	262.4	199.1	325.6	2
SPERM DENSITY	MEAN	730.87	643.38	818.35	2

* One was a non-glp study

CHARLES RIVER LABORATORIES PRECLINICAL SERVICES, PENNSYLVANIA
MALE REPRODUCTIVE ORGAN WEIGHTS AND RATIOS
HISTORICAL CONTROL DATA
Dunkin Hartley GUINEA PIGS

SUMMARY
2011 - 2012

2* = TOTAL NUMBER STUDIES
32 = TOTAL GUINEA PIGS

		AVERAGE	MINIMUM	MAXIMUM	NO. STUDIES INCLUDED
TERMINAL BODY WEIGHT (TBW)	MEAN	1024.3	942.3	1106.2	2
TESTIS					
LEFT	MEAN	2.3900	2.3250	2.4549	2
RIGHT	MEAN	2.3278	2.2545	2.4011	2
EPIDIDYMIS					
LEFT	MEAN	1.0020	0.8132	1.1907	2
RIGHT	MEAN	1.0895	0.8377	1.3412	2
CAUDA EPIDIDYMIS LEFT	MEAN	0.4653	0.4099	0.5207	2
PROSTATE	MEAN	1.9067	1.5680	2.2453	2
SEMINAL VESICLES WITH FLUID	MEAN	4.7794	3.3396	6.2191	2
RATIO (%) ORG. WTS. TO BODY WTS.					
TESTIS (% TBW)					
LEFT	MEAN	0.236	0.224	0.248	2
RIGHT	MEAN	0.228	0.216	0.239	2
EPIDIDYMIS (% TBW)					
LEFT	MEAN	0.097	0.085	0.108	2
RIGHT	MEAN	0.105	0.089	0.120	2
CAUDA EPIDIDYMIS LEFT (% TBW)	MEAN	0.045	0.043	0.046	2
PROSTATE (% TBW)	MEAN	0.183	0.166	0.200	2
SEMINAL VESICLES WITH FLUID (% TBW)	MEAN	0.455	0.354	0.556	2

ALL WEIGHTS ARE MEASURED IN GRAMS

* One was a non-glp study