

Reproductive Toxicology

Historical Control Data In Mice



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Mice

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¹Additional HCD endpoints and years are available upon request.

HISTORICAL CONTROL DATA
MOUSE (CrI:CD-1) 2017
CHARLES RIVER, PRECLINICAL SERVICES EDINBURGH

Fertility Studies			
<i>Parameter</i>	<i>Mean</i>	<i>Minimum</i>	<i>Maximum</i>
Male Fertility Index (%)	96	96	96
Female Fertility Index (%)	98	96	100
Pregnancy Data			
Corpora Lutea	12.9	12.2	13.6
Implants	12.6	11.8	13.3
Early Deaths	0.5	0.2	0.7
Late Deaths	0.0	0.0	0.0
Total Deaths	0.5	0.2	0.7
Live Implants	12.1	11.6	12.6
Male absolute organ weights (g)			
Testes	0.2598	0.2598	0.2598
Epididymides	0.1098	0.1098	0.1098
Prostate	0.0205	0.0205	0.025
Organ Weights relative to terminal body weight (g)			
Terminal body weight	35.88	35.88	35.88
Testes	0.72459	0.72459	0.72459
Epididymides	0.30657	0.30657	0.30657
Prostate	0.05732	0.05732	0.05732

Data from 1 male fertility study.

HISTORICAL CONTROL DATA
MOUSE (CrI:CD-1) 2017-2018
CHARLES RIVER, PRECLINICAL SERVICES EDINBURGH

Day 17.5 of Gestation

Developmental Toxicity Studies in the Mouse			
<i>Parameter</i>	<i>Mean</i>	<i>Minimum</i>	<i>Maximum</i>
Pregnancy Data			
Corpora Lutea	13.7	13.6	13.8
Implants	13.3	13.2	13.3
Early Deaths	0.7	0.3	1.0
Late Deaths	0.1	0.0	0.1
Dead fetuses	0.0	0.0	0.0
Total Deaths	0.7	0.3	1.1
Live Implants	12.5	12.2	12.8
Uterus weight (g)	19.6	19.1	20.2
Mean foetal weight (g)	1.1	1.1	1.2

Data from 2 developmental toxicity studies.

Day 18 of Gestation

Developmental Toxicity Studies in the Mouse			
<i>Parameter</i>	<i>Mean</i>	<i>Minimum</i>	<i>Maximum</i>
Pregnancy Data			
Corpora Lutea	12.6	11.8	13.3
Implants	12.2	11.3	13.0
Early Deaths	0.3	0.0	0.7
Late Deaths	0.0	0.0	0.0
Dead fetuses	0.0	0.0	0.0
Total Deaths	0.3	0.0	0.7
Live Implants	11.9	11.0	13.0
Uterus weight (g)	21.2	19.6	24.0
Mean foetal weight (g)	1.4	1.4	1.5

Data from 4 developmental toxicity studies.

Data from Provantis

Day 17.5 of Gestation.

Foetal examination (320 fetuses from 26 litters, typically 6-20 litters per study)			
<i>Parameter</i>	<i>Mean</i>	<i>Minimum</i>	<i>Maximum</i>
Malformation external (number of fetuses)	0.5	0.0	1.0
Malformation external (number of litters)	0.5	0.0	1.0
Variation external (number of fetuses)	0.0	0.0	0.0
Variation external (number of litters)	0.0	0.0	0.0
Foetal examination (126 fetuses from 20 litter)			
Malformation visceral (number of fetuses)	1.0	1.0	1.0
Malformation visceral (number of litters)	1.0	1.0	1.0
Variation visceral (number of fetuses)	9.0	9.0	9.0
Variation visceral (number of litters)	9.0	9.0	9.0
Foetal examination (166 fetuses from 26 litter)			
Malformation skeletal (number of fetuses)	0.0	0.0	0.0
Malformation skeletal (number of litters)	0.0	0.0	0.0
Variation skeletal (number of fetuses)	77.0	40.0	114.0
Variation skeletal (number of litters)	13.0	6.0	20.0

Data from 2 developmental toxicity studies.

Day 18 of Gestation.

Foetal examination (675 fetuses from 60 litters, typically 5-43 litters per study)			
<i>Parameter</i>	<i>Mean</i>	<i>Minimum</i>	<i>Maximum</i>
Malformation external (number of fetuses)	3.0	0.0	11.0
Malformation external (number of litters)	1.3	0.0	4.0
Variation external (number of fetuses)	0.0	0.0	0.0
Variation external (number of litters)	0.0	0.0	0.0
Foetal examination (98 fetuses from 11 litters)			
Malformation visceral (number of fetuses)	0.0	0.0	0.0
Malformation visceral (number of litters)	0.0	0.0	0.0
Variation visceral (number of fetuses)	1.0	1.0	1.0
Variation visceral (number of litters)	1.0	1.0	1.0
Foetal examination (289 fetuses from 49 litters)			
Malformation skeletal (number of fetuses)	1.3	0.0	4.0
Malformation skeletal (number of litters)	0.7	0.0	2.0
Variation skeletal (number of fetuses)	78.0	0.0	203.0
Variation skeletal (number of litters)	15.0	0.0	39.0

Data from 4 developmental toxicity studies.