

Reproductive Toxicology

Historical Control Data In Rabbits



Tranent, Edinburgh, EH33 2NE, United Kingdom • 44.1875.628323 • FAX 44.1875.614555

TABLE OF CONTENTS

Rabbits

<u>HCD Data¹</u>	<u>Date Range</u>	<u>Page</u>
TABLE OF CONTENTS.....		2
RABBIT (HsdIf:NZW)	1999-2018	3
RABBIT (KBL:NZW).....	2008-2014.....	5

Contact:

Stephanie Clubb
Functional Manager
Developmental, Reproductive and Juvenile Toxicology
Charles River Laboratories, Preclinical Services, Edinburgh

Phone: 44.1875.618306
Fax: 44.1875.614555
Email: stephanie.clubb@crl.com

¹Additional HCD endpoints and years are available upon request.

HISTORICAL CONTROL DATA
RABBIT (Hsdlf:NZW) 1999-2018
CHARLES RIVER, PRECLINICAL SERVICES EDINBURGH

Developmental Toxicity Studies in the Rabbit			
<i>Parameter</i>	<i>Mean</i>	<i>Minimum</i>	<i>Maximum</i>
Pregnancy Data			
Corpora Lutea	9.6	7.6	11.2
Implants	8.5	5.3	10.0
Early Deaths	0.6	0.1	2.3
Late Deaths	0.2	0.0	0.7
Dead fetuses	0.1	0.0	1.0
Total Deaths	1.0	0.3	2.6
Live Implants	7.6	4.8	9.0
Uterus weight (g)	493.0	382.0	589.0
Mean foetal weight (g)	43.4	38.8	49.9

Foetal examination (5752 fetuses from 749 litters, typically 3-24 litters per study)			
<i>Parameter</i>	<i>Mean</i>	<i>Minimum</i>	<i>Maximum</i>
Major abnormality (litter incidence per study)	3.1	0.0	8.0
Major abnormality (foetus incidence per study)	3.7	0.0	10.0
Minor visceral abnormality (litter incidence per study)	8.6	1.0	19.0
Minor visceral abnormality (foetus incidence per study)	16.2	1.0	43.0
Minor skeletal abnormality (litter incidence per study)	15.8	6.0	22.0
Minor skeletal abnormality (foetus incidence per study)	55.8	13.0	90.0

Data from Provantis

Foetal examination (1036 foetuses from 136 litters, typically 6-24 litters per study)			
<i>Parameter</i>	<i>Mean</i>	<i>Minimum</i>	<i>Maximum</i>
Malformation external (number of foetuses)	1.4	0.0	5.0
Malformation external (number of litters)	1.2	0.0	4.0
Variation external (number of foetuses)	0.0	0.0	0.0
Variation external (number of litters)	0.0	0.0	0.0
Foetal examination (518 foetuses from 124 litters)			
Malformation visceral (number of foetuses)	0.9	0.0	2.0
Malformation visceral (number of litters)	0.9	0.0	2.0
Variation visceral (number of foetuses)	2.3	0.0	6.0
Variation visceral (number of litters)	2.3	0.0	6.0
Foetal examination (484 foetuses from 119 litters)			
Malformation skeletal (number of foetuses)	1.2	0.0	3.0
Malformation skeletal (number of litters)	1.2	0.0	3.0
Variation skeletal (number of foetuses)	66.7	57.0	77.0
Variation skeletal (number of litters)	19.7	18.0	22.0

HISTORICAL CONTROL DATA
RABBIT (KBL:NZW) 2008-2014
CHARLES RIVER, PRECLINICAL SERVICES EDINBURGH

Developmental Toxicity Studies in the Rabbit			
<i>Parameter</i>	<i>Mean</i>	<i>Minimum</i>	<i>Maximum</i>
Pregnancy Data			
Corpora Lutea	10.8	10.2	11.5
Implants	10.0	9.4	11.1
Early Deaths	0.4	0.2	0.7
Late Deaths	0.4	0.2	0.6
Dead fetuses	0.0	0.0	0.2
Total Deaths	0.8	0.3	1.1
Live Implants	9.3	8.6	10.4
Uterus weight (g)	561.1	499.0	628.0
Mean foetal weight (g)	40.4	37.3	43.1

Foetal examination (873 fetuses from 95 litters, typically 15-23 litters per study)			
<i>Parameter</i>	<i>Mean</i>	<i>Minimum</i>	<i>Maximum</i>
Major abnormality (litter incidence per study)	2.8	1.0	6.0
Major abnormality (foetus incidence per study)	3.4	1.0	9.0
Minor visceral abnormality (litter incidence per study)	11.0	7.0	13.0
Minor visceral abnormality (foetus incidence per study)	21.8	13.0	29.0
Minor skeletal abnormality (litter incidence per study)	17.8	14.0	23.0
Minor skeletal abnormality (foetus incidence per study)	69.0	47.0	102.0