

Historical Control Data in New Zealand White Rabbits



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Covance - [Hra:(NZW)SPF] Rabbits

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¹ Additional HCD endpoints and years are available upon request.

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Historical Control Range-Finding Developmental Toxicity Data
New Zealand White Rabbit - Covance Research Products
1 Dec 2014 to 1 Dec 2019

Pregnancy Data	Total
No. Control Groups	4
No. Females	32
No. Pregnant	32
No. Not Pregnant	0
No. Pregnant By Stain	0
No. Aborted	0
No. Died Pregnant	0
No. Females with All Resorptions	0
No. Early Deliveries	0
No. Females with Viable Fetuses	32

Maternal and Developmental Observations at Uterine Examination and Fetal Body Weight Values	Mean	Minimum	Maximum
Pregnancy Index (%)	100.00	100.0	100.0
Corpora Lutea (Mean No. per Animal)	10.15	9.1	11.0
Implantation Site (Mean No. per Animal)	8.60	8.0	9.3
Preimplantation Loss (Mean % per Animal)	15.090	10.06	22.71
Viable Fetus (Mean No. per Animal)	8.25	7.2	9.0
Fetal Sex Ratio (Mean % Males per Animal)	51.43	50.7	52.2
Postimplantation Loss (Mean % per Animal)	4.218	0.00	10.37
Nonviable Fetuses (Mean No. per Animal)	0.00	0.0	0.0
Resorptions: Early and Late (Mean No. per Animal)	0.35	0.0	0.8
Resorptions: Early (Mean No. per Animal)	0.25	0.0	0.5
Resorptions: Late (Mean No. per Animal)	0.10	0.0	0.3
Mean Fetal Body Weight Male (grams)	40.205	38.00	41.83
Mean Fetal Body Weight Female (grams)	40.724	38.78	42.99
Mean Fetal Body Weight Males and Females (grams)	40.780	38.73	42.78

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Historical Control Range-Finding Developmental Toxicity Data
New Zealand White Rabbit - Covance Research Products
1 Dec 2014 to 1 Dec 2019

Litter Data	Total
No. Litters Evaluated	32
No. External Fetuses Evaluated	267
No. Visceral Fetuses Evaluated	224
No. Skeletal Fetuses Evaluated	224

	Total Number		Maximum %	
	Fetuses	Litters	Fetuses	Litters
External Malformations				
Body, umbilicus, omphalocele	1	1	1.1	10.0
Head, eye(s), open eye	1	1	1.1	10.0
Visceral Pathological				
Thoracic cavity, thymus, smaller than normal	1	1	1.1	10.0
Visceral Variations				
Abdominal cavity, ureter, malpositioned	5	3	4.3	20.0
Thoracic cavity, common carotid artery, arising from innominate artery	1	1	1.4	12.5
Thoracic cavity, right lung, azygous lobe absent	9	7	6.7	40.0
Skeletal Malformations				
Cervical vertebra(e), centra, misshapen	1	1	1.1	10.0
Rib(s), absent	1	1	1.6	12.5
Rib(s), misshapen	2	2	3.1	25.0
Skull, jugal, fused	3	2	3.3	20.0
Sternum, sternebra(e), fused	5	5	3.1	25.0
Thoracic vertebra(e), centra, misshapen	1	1	1.6	12.5
Thoracic vertebra(e), neural arch(es), misshapen	1	1	1.6	12.5
Skeletal Variations				
Caudal vertebra(e), centra, additional ossification center	1	1	1.1	10.0
Caudal vertebra(e), hemivertebra(e)	1	1	1.1	10.0
Cervical vertebra(e), centra, additional ossification center	1	1	1.1	10.0
Cervical vertebra(e), neural arch(es), additional ossification center	1	1	1.6	12.5
Rib(s), absent, 12th rib	1	1	1.6	12.5
Rib(s), rudimentary	49	21	24.4	87.5
Rib(s), smaller than normal	1	1	1.6	12.5
Rib(s), unilateral full rib	29	19	15.6	80.0
Skull, frontal bone, additional ossification center	1	1	1.1	10.0
Skull, hyoid arch, bent	10	7	8.9	50.0
Skull, hyoid body, not ossified	1	1	1.1	10.0
Skull, interparietal bone, bipartite	1	1	1.6	12.5
Skull, interparietal bone, misshapen	1	1	1.6	12.5
Skull, nasal bone, additional ossification center	2	2	1.4	12.5
Skull, parietal bone, additional ossification center	1	1	1.1	10.0
Sternum, sternebra(e), additional ossification center	4	3	3.1	25.0
Sternum, sternebra(e), misaligned	2	2	1.4	12.5
Sternum, sternebra(e), not ossified	30	11	26.6	50.0

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Historical Control Developmental Toxicity Data
New Zealand White Rabbit - Covance Research Products
1 Jan 2015 to 1 Jan 2020

Pregnancy Data	Total
No. of Studies	37
No. Females	811
No. Pregnant	776
No. Not Pregnant	35
No. Died Pregnant or Pregnant Euthanized Moribund	4
No. of Abortions	1
No. of Early Deliveries	2
No. with all Resorptions	0
No. Pregnant By Stain	0
No. of Females with Viable Fetuses Day 29 Gestation	769

Maternal and Developmental Observations at Uterine Examination and Fetal Body Weight Values	Mean	Minimum	Maximum
Pregnancy Index (%)	95.64	82.6	100.0
Corpora Lutea (Mean No. per Animal)	10.14	8.5	11.0
Implantation Site (Mean No. per Animal)	8.94	7.7	9.7
Preimplantation Loss (Mean % per Animal)	11.457	6.04	20.65
Viable Fetus (Mean No. per Animal)	8.57	7.3	9.4
Fetal Sex Ratio (Mean % Males per Animal)	50.77	41.8	59.0
Postimplantation Loss (Mean % per Animal)	4.288	0.42	11.65
Nonviable Fetuses (Mean No. per Animal)	0.00	0.0	0.0
Resorptions: Early and Late (Mean No. per Animal)	0.38	0.1	0.8
Resorptions: Early (Mean No. per Animal)	0.28	0.0	0.7
Resorptions: Late (Mean No. per Animal)	0.11	0.0	0.5
Mean Fetal Body Weight Male (grams)	42.977	41.23	44.51
Mean Fetal Body Weight Female (grams)	41.874	39.21	44.20
Mean Fetal Body Weight Males and Females (grams)	42.467	40.86	44.48

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Historical Control Developmental Toxicity Data
New Zealand White Rabbit - Covance Research Products
1 Jan 2015 to 1 Jan 2020

Litter Data	Total
No. Litter Evaluated	769
No. External Fetuses Evaluated	6586
No. Visceral Fetuses Evaluated	6586
No. Skeletal Fetuses Evaluated	6586

	Total Number		Maximum %	
	Fetuses	Litters	Fetuses	Litters
External Malformations				
Body, abdomen, gastroschisis	1	1	0.7	5.9
Body, anus, absent	2	2	0.7	5.9
Body, umbilicus, omphalocele	5	4	1.4	5.9
Forelimb(s), digits, brachydactyly	3	2	1.0	5.0
Forelimb(s), entire, abnormal flexure	1	1	0.6	5.6
Forelimb(s), forepaw, abnormal flexure	4	4	1.4	11.8
Head, entire, dome shaped	1	1	0.5	4.3
Head, entire, exencephaly	1	1	0.7	5.3
Head, entire, microcephaly	4	4	0.7	5.9
Head, eye(s), microphthalmia	3	3	0.7	5.9
Head, incisors, absent	1	1	0.7	5.9
Head, incisors, fused	1	1	0.7	5.3
Head, jaw(s), micrognathia	1	1	0.7	5.9
Head, nares, misshapen	1	1	0.7	5.9
Head, tongue, smaller than normal	1	1	0.5	4.5
Hind limb(s), entire, malrotated	2	2	0.7	5.3
Hind limb(s), entire, misshapen	1	1	0.7	5.9
Hind limb(s), hind paw, abnormal flexure	2	2	0.7	5.9
Tail, entire, absent	1	1	0.7	5.9
Tail, entire, filamentous	1	1	0.7	5.9
Tail, entire, short	3	3	0.7	5.3
External Pathological				
Body, abdomen, distended	1	1	0.7	5.3
Body, entire, discolored	1	1	0.5	4.5
Body, skin, focus/foci	1	1	0.5	4.3
Placenta, entire, discolored	4	4	0.7	5.3

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	Total Number		Maximum %	
	Fetuses	Litters	Fetuses	Litters
External Variations				
Body, skin, thin/underdeveloped	1	1	0.7	5.3
Visceral Malformations				
Abdominal cavity, abdominal muscle, discontinuous	1	1	0.7	5.3
Abdominal cavity, adrenal, absent	1	1	0.7	5.9
Abdominal cavity, epididymis, smaller than normal	1	1	1.3	5.6
Abdominal cavity, gallbladder, absent	19	14	2.3	11.8
Abdominal cavity, kidney, absent	2	2	0.7	5.9
Abdominal cavity, kidney, fused	2	2	0.7	5.9
Abdominal cavity, kidney, malpositioned	3	3	0.7	5.9
Abdominal cavity, kidney, malrotated	2	2	0.6	5.3
Abdominal cavity, spleen, smaller than normal	1	1	0.7	5.9
Abdominal cavity, testis, malpositioned	1	1	1.5	5.9
Abdominal cavity, testis, smaller than normal	2	2	1.5	5.9
Abdominal cavity, ureter, absent	2	2	0.7	5.9
Brain, entire, hydrocephaly	1	1	0.7	5.9
Brain, lateral ventricle, hydrocephaly	3	3	0.7	5.9
Head, eye(s), microphthalmia	1	1	0.5	5.0
Thoracic cavity, aortic arch, constricted	1	1	0.5	4.5
Thoracic cavity, aortic arch, dilated	15	14	2.0	15.8
Thoracic cavity, aortic arch, discontinuous	1	1	0.6	5.6
Thoracic cavity, aortic arch, smaller than normal	1	1	0.7	5.9
Thoracic cavity, diaphragm, diaphragmatic hernia	4	4	0.7	5.9
Thoracic cavity, ductus arteriosus, absent	1	1	0.5	4.5
Thoracic cavity, ductus arteriosus, constricted	3	3	0.7	5.3
Thoracic cavity, heart - entire, transposition of great vessels	3	3	0.7	5.9
Thoracic cavity, interventricular septum, discontinuous	15	14	2.0	15.8
Thoracic cavity, left lung, abnormal lobulation	1	1	0.7	5.9
Thoracic cavity, pulmonary artery, arising from aortic arch	1	1	0.6	5.6
Thoracic cavity, pulmonary trunk, constricted	7	6	1.0	5.3
Thoracic cavity, pulmonary trunk, dilated	2	2	0.7	5.9
Thoracic cavity, pulmonary trunk, smaller than normal	6	6	0.7	5.3
Thoracic cavity, right lung, abnormal lobulation	1	1	0.7	5.9
Thoracic cavity, trachea, misshapen	1	1	0.5	4.5
Thoracic cavity, ventricle, larger than normal	5	5	0.6	5.3
Visceral Pathological				
Abdominal cavity, abdomen, fluid filled	2	2	1.3	10.5
Abdominal cavity, kidney, white foreign material	1	1	0.6	4.5
Abdominal cavity, liver, thickened	1	1	0.5	4.5
Abdominal cavity, spleen, discolored	1	1	0.6	4.8
Head, eye(s), discolored	4	1	2.1	4.5
Head, eye(s), hemorrhagic	34	32	2.2	18.2
Head, eye(s), opaque	1	1	0.5	4.3

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	Total Number		Maximum %	
	Fetuses	Litters	Fetuses	Litters
Thoracic cavity, fluid filled	3	3	1.3	10.5
Thoracic cavity, pericardial sac, fluid filled	3	2	1.0	4.5
Thoracic cavity, sternum, discolored	1	1	0.5	4.3
Thoracic cavity, thymus, discolored	1	1	0.5	4.8
Thoracic cavity, thymus, hemorrhagic	3	3	0.6	5.3
Visceral Variations				
Abdominal cavity, gallbladder, smaller than normal	37	34	2.4	17.4
Abdominal cavity, kidney, increased renal pelvic cavitation	6	6	0.7	5.9
Abdominal cavity, kidney, renal papillae undeveloped	4	3	1.0	4.5
Abdominal cavity, ureter, dilated	1	1	0.5	4.5
Abdominal cavity, ureter, malpositioned	108	86	4.0	25.0
Thoracic cavity, common carotid artery, arising from innominate artery	31	23	2.4	16.7
Thoracic cavity, ductus arteriosus, smaller than normal	8	8	1.2	10.5
Thoracic cavity, innominate artery, absent	18	16	1.8	15.0
Thoracic cavity, right lung, azygous lobe absent	142	107	6.4	33.3
Thoracic cavity, subclavian artery, retroesophageal	17	16	1.7	15.0
Skeletal Malformations				
Caudal vertebra(e), absent	3	3	1.4	11.8
Caudal vertebra(e), one or more, absent	2	2	0.7	5.3
Caudal vertebra(e), one or more, fused	1	1	0.7	5.3
Cervical vertebra(e), absent	1	1	0.7	5.9
Cervical vertebra(e), centra, misshapen	1	1	0.7	5.9
Cervical vertebra(e), neural arch(es), fused	1	1	0.5	4.5
Cervical vertebra(e), neural arch(es), misaligned	1	1	0.5	4.3
Cervical vertebra(e), neural arch(es), misshapen	6	6	0.7	5.9
Lumbar vertebra(e), absent	1	1	0.7	5.9
Lumbar vertebra(e), centra, extra	1	1	0.6	5.3
Lumbar vertebra(e), centra, fused	5	5	0.7	5.9
Lumbar vertebra(e), neural arch(es), absent	3	3	0.7	5.9
Lumbar vertebra(e), neural arch(es), extra	1	1	0.6	5.3
Lumbar vertebra(e), neural arch(es), fused	1	1	0.7	5.3
Lumbar vertebra(e), neural arch(es), misaligned	7	7	1.4	11.8
Lumbar vertebra(e), neural arch(es), misshapen	2	2	0.7	5.9
Pelvic girdle, ilium, fused	1	1	0.7	5.9
Rib(s), absent	6	5	2.1	11.8
Rib(s), branched	3	3	0.6	5.6
Rib(s), costal cartilage, branched	2	2	0.6	5.0
Rib(s), costal cartilage, fused	3	3	1.1	9.5
Rib(s), fused	9	9	1.4	11.8
Rib(s), misshapen	6	6	1.4	11.8
Sacral vertebra(e), absent	1	1	0.7	5.9
Sacral vertebra(e), centra, fused	2	2	0.7	5.6
Sacral vertebra(e), fused	1	1	0.7	5.9
Sacral vertebra(e), neural arch(es), fused	1	1	0.7	5.3

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	Total Number		Maximum %	
	Fetuses	Litters	Fetuses	Litters
Sacral vertebra(e), neural arch(es), misaligned	1	1	0.7	5.3
Sacral vertebra(e), neural arch(es), misshapen	1	1	0.7	5.3
Skull, frontal bone, fused	6	6	1.2	10.5
Skull, frontal bone, misshapen	1	1	0.7	5.3
Skull, nasal bone, fused	2	2	0.7	5.9
Skull, nasal bone, misshapen	1	1	0.5	4.3
Skull, parietal bone, misshapen	2	2	0.7	5.9
Skull, premaxilla, fused	2	2	0.7	5.9
Skull, premaxilla, misshapen	2	2	0.7	5.9
Skull, premaxilla, short	1	1	0.7	5.9
Skull, squamosal, misshapen	1	1	0.7	5.3
Skull, supra occipital bone, bipartite	1	1	0.5	4.2
Sternum, entire, sternoschisis	1	1	0.5	4.5
Sternum, sternebra(e), fused	109	82	4.9	22.7
Thoracic vertebra(e), absent	1	1	0.7	5.9
Thoracic vertebra(e), centra, absent	2	2	0.7	5.9
Thoracic vertebra(e), centra, extra	1	1	0.5	4.5
Thoracic vertebra(e), centra, fused	14	14	1.8	15.8
Thoracic vertebra(e), neural arch(es), absent	6	6	1.4	11.8
Thoracic vertebra(e), neural arch(es), extra	4	4	0.7	5.3
Thoracic vertebra(e), neural arch(es), fused	5	5	1.4	11.8
Thoracic vertebra(e), neural arch(es), misaligned	7	7	1.3	10.5
Thoracic vertebra(e), neural arch(es), misshapen	10	10	1.4	11.8
Skeletal Variations				
Caudal vertebra(e), hemivertebra(e)	49	46	2.6	21.1
Caudal vertebra(e), misaligned	2	2	0.7	5.3
Cervical vertebra(e), centra, additional ossification center	24	19	1.6	13.0
Cervical vertebra(e), centra, hemicentric	1	1	0.5	4.3
Cervical vertebra(e), centra, malpositioned	1	1	0.6	4.8
Cervical vertebra(e), centra, misaligned	1	1	0.5	4.3
Cervical vertebra(e), neural arch(es), additional ossification center	141	97	6.8	30.0
Cervical vertebra(e), neural arch(es), cervical ribs	3	3	1.1	9.5
Cervical vertebra(e), neural arch(es), irregular ossification	1	1	0.5	4.3
Forelimb(s), phalanges, short	2	1	1.0	4.2
Hind limb(s), talus, not ossified	8	5	2.0	5.3
Lumbar vertebra(e), centra, hemicentric	7	7	1.4	11.8
Lumbar vertebra(e), centra, misaligned	7	7	1.4	11.8
Pectoral girdle, clavicle, irregular ossification	1	1	0.5	4.3
Pelvic girdle, pubis, not ossified	3	2	1.0	4.5
Rib(s), bent	1	1	0.5	4.3
Rib(s), costal cartilage, misaligned	2	2	0.6	4.8
Rib(s), extra	4	4	0.7	5.3
Rib(s), interrupted ossification	6	5	1.0	5.3
Rib(s), irregular ossification	3	3	0.6	5.3
Rib(s), knobby	2	2	0.6	4.5

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Historical Control Developmental Toxicity Data
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	Total Number		Maximum %	
	Fetuses	Litters	Fetuses	Litters
Rib(s), rudimentary	1880	675	38.6	100.0
Rib(s), short	1	1	0.5	4.5
Rib(s), smaller than normal	1	1	0.5	4.5
Rib(s), unilateral full rib	855	483	20.6	90.0
Sacral vertebra(e), centra, additional ossification center	1	1	0.6	5.6
Skull, basisphenoid, irregular ossification	1	1	0.7	5.9
Skull, frontal bone, additional ossification center	13	11	1.8	11.1
Skull, hyoid arch, bent	236	170	10.9	56.5
Skull, hyoid arch, misshapen	1	1	0.6	5.3
Skull, hyoid arch, not ossified	3	2	1.0	5.3
Skull, hyoid body, not ossified	14	12	2.0	13.0
Skull, interparietal bone, bipartite	25	22	2.1	11.8
Skull, interparietal bone, misshapen	3	3	0.7	5.3
Skull, interparietal bone, smaller than normal	4	4	0.7	5.9
Skull, jugal, bipartite	1	1	0.6	5.3
Skull, jugal, fused	98	65	4.5	20.0
Skull, nasal bone, additional ossification center	36	30	2.0	15.8
Skull, parietal bone, additional ossification center	42	37	2.1	11.8
Skull, parietal bone, additional suture line	1	1	0.6	4.8
Skull, parietal bone, irregular ossification	3	3	0.6	5.3
Skull, pterygoid process, irregular ossification	1	1	0.7	5.9
Skull, supra occipital bone, incompletely ossified	1	1	0.7	5.3
Skull, supra occipital bone, misshapen	1	1	0.7	5.9
Sternum, sternebra(e), additional ossification center	185	122	6.1	28.6
Sternum, sternebra(e), bipartite	1	1	0.5	4.3
Sternum, sternebra(e), extra	10	9	1.7	10.0
Sternum, sternebra(e), misaligned	35	31	2.3	11.8
Sternum, sternebra(e), misshapen	1	1	0.6	5.0
Sternum, sternebra(e), not ossified	768	369	19.2	64.7
Thoracic vertebra(e), centra, hemicentric	15	13	2.1	11.8
Thoracic vertebra(e), centra, misaligned	6	6	0.7	5.9