



Summary of Studies Supporting USDA Product Licensure

Establishment Name	Medgene Labs
USDA Vet Biologics Establishment Number	474
Product Code	1R00.R1
True Name	Rabbit Hemorrhagic Disease Vaccine, Serotype 2, Killed Baculovirus Vector
Tradename(s) / Distributor or Subsidiary (if different from manufacturer)	
Date of Compilation Summary	February 27, 2025

Disclaimer: Do not use the following studies to compare one product to another. Slight differences in study design and execution can render the comparisons meaningless.

Study Type	Safety																											
Pertaining to	ALL																											
Study Purpose	Demonstration of safety under typical field conditions																											
Product Administration	One dose administered subcutaneously, followed by a second dose 3 weeks later																											
Study Animals	638 vaccinated rabbits, 8 weeks of age or younger (270 rabbits) and 9 weeks of age or older (368 rabbits), at three different geographical locations. The control group consisted of 135 unvaccinated rabbits 8 weeks of age or younger.																											
Challenge Description	Not applicable																											
Interval observed after challenge	Rabbits were observed daily through study day 34-35. Injection site palpations were conducted on study days 1, 21, 22, and 34 or 35.																											
Results	Table 1: Size of injection site reactions: <table><tr><td>Vaccination</td><td>< 1.5 cm in size</td><td>1.5 – 5 cm in size</td></tr><tr><td>1st</td><td>6</td><td>0</td></tr><tr><td>2nd</td><td>14</td><td>1</td></tr></table> Table 2: Duration of injection site reactions by group: <table><tr><td>Vaccination</td><td>Min</td><td>Q1</td><td>Median</td><td>Q3</td><td>Max</td></tr><tr><td>1st</td><td>1.0</td><td>2.5</td><td>9.0</td><td>14.0</td><td>14.0</td></tr><tr><td>2nd</td><td>1.0</td><td>1.0</td><td>3.0</td><td>7.0</td><td>14.0</td></tr></table> See adverse events in Tables 3a and 3b below for numbers of rabbits by site, age, and treatment group with specific clinical observations post-vaccination. Site 1: South Dakota (2 locations) Site 2: Texas (7 locations) Site 3: Colorado (5 locations) Group A: Adults, vaccinated Group K: Kits, vaccinated Group C: Control Kits, unvaccinated * not attributable to the vaccine ** deaths were due to heat stroke resulting from a mechanical failure of the air conditioning unit	Vaccination	< 1.5 cm in size	1.5 – 5 cm in size	1 st	6	0	2 nd	14	1	Vaccination	Min	Q1	Median	Q3	Max	1 st	1.0	2.5	9.0	14.0	14.0	2 nd	1.0	1.0	3.0	7.0	14.0
Vaccination	< 1.5 cm in size	1.5 – 5 cm in size																										
1 st	6	0																										
2 nd	14	1																										
Vaccination	Min	Q1	Median	Q3	Max																							
1 st	1.0	2.5	9.0	14.0	14.0																							
2 nd	1.0	1.0	3.0	7.0	14.0																							
USDA Approval Date	October 25, 2022																											

Table 3a

Site	Group	Number Enrolled	Injection Site Hair Loss	Injection Site Crust	Injection Site Oedema	Injection Site Other	Distress	Teeth Grinding	Diarrhea	Bloated	Wry Neck	Paralysis	Dyspnea
1A	A	50	0	0	1	0	0	0	0	0	0	0	0
	K	46	0	0	0	0	0	0	1	0	0	0	0
	C	24	0	0	0	0	0	0	3	0	0	0	0
1B	A	56	0	0	1	0	0	0	0	0	0	0	0
	K	60	0	0	1	0	0	0	0	0	0	0	0
	C	33	0	0	0	0	0	0	0	0	0	0	0
2A	A	5	0	0	0	0	0	0	1	0	0	0	0
	K	2	1	0	2	0	0	0	0	0	0	0	0
	C	1	0	0	0	0	0	0	0	0	0	0	0
2B	A	22	0	0	0	0	0	0	0	0	0	0	0
	K	18	0	0	1	0	0	0	0	0	0	0	0
	C	10	0	0	0	0	0	0	0	0	0	0	0
2C	A	18	0	0	0	1	0	0	0	0	0	0	0
	K	1	0	0	0	0	0	0	0	0	0	0	0
	C	1	0	0	0	0	0	0	0	0	0	0	0
2D	A	0	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a
	K	27	0	0	3	1	0	0	2	0	0	0	0
	C	13	0	0	0	0	0	0	1	0	0	0	0
2E	A	43	0	2	3	6	0	0	0	0	0	0	0
	K	0	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a
	C	0	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a
2F	A	62	0	0	0	0	0	00	1	0	1	0	0
	K	0	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a
	C	0	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a
2G	A	10	0	0	0	0	4	0	0	0	0	0	4
	K	7	0	0	1	0	0	0	0	0	0	0	0
	C	2	0	0	0	0	0	0	0	0	0	0	0
3A	A	7	0	0	0	0	0	0	0	0	0	0	0
	K	10	0	0	0	0	0	0	3	0	0	0	0
	C	4	0	0	0	0	0	0	1	0	0	0	0
3B	A	16	0	0	0	0	0	0	0	0	0	0	0
	K	53	0	0	0	1	0	1	0	3	0	0	0
	C	25	0	0	0	0	0	1	0	4	0	0	0
3C	A	26	0	0	0	0	0	0	0	0	0	0	0
	K	2	0	0	0	0	0	0	0	0	0	0	0
	C	1	0	0	0	0	0	0	0	0	0	0	0
3D	A	37	0	0	0	0	0	0	0	0	0	1	0
	K	34	0	0	0	0	0	0	3	0	0	0	0
	C	16	0	0	0	0	0	0	1	0	0	0	0
3E	A	15	0	0	0	0	0	0	0	0	0	0	0
	K	10	0	0	0	0	0	0	0	0	0	0	0
	C	5	0	0	0	0	0	0	0	0	0	0	0

Table 3b

Site	Group	Number Enrolled	Nasal Bleeding	Sneezing	Nasal Discharge	Mortality *	Anorexia	Lethargy	Local Swelling	Loss of Condition	Unthrifty	Skin Abscess	Skin irritation
1A	A	50	0	0	0	1	0	1	0	0	0	0	0
	K	46	0	0	0	1	0	0	0	0	0	0	0
	C	23	0	0	1	2	1	0	0	0	0	0	0
1B	A	56	0	0	0	1	0	1	1	0	0	0	1
	K	60	0	0	0	0	0	0	0	0	0	0	0
	C	33	0	0	0	0	0	0	0	0	0	0	0
2A	A	5	0	0	0	0	0	0	0	0	0	0	0
	K	2	0	0	0	0	0	0	0	0	0	0	0
	C	1	0	0	0	0	0	0	0	0	0	0	0
2B	A	22	0	0	0	0	0	0	0	0	0	0	0
	K	18	0	0	0	0	0	0	0	0	0	0	0
	C	10	0	0	0	1	0	0	0	0	0	0	0
2C	A	18	0	0	0	5	1	1	0	1	0	0	0
	K	1	0	0	0	1	0	0	0	0	0	0	0
	C	1	0	0	0	1	0	0	0	0	0	0	0
2D	A	0	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a
	K	27	0	0	0	0	0	0	0	0	0	0	0
	C	13	0	0	0	0	0	0	0	0	0	0	0
2E	A	43	0	0	0	2	0	0	0	0	0	0	0
	K	0	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a
	C	0	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a
2F	A	62	0	0	0	43**	0	0	0	0	0	1	0
	K	0	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a
	C	0	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a
2G	A	10	1	4	4	0	0	0	0	0	0	0	0
	K	7	0	0	0	0	0	0	0	0	0	0	0
	C	2	0	0	0	0	0	0	0	0	0	0	0
3A	A	7	0	0	0	0	0	0	0	0	0	0	0
	K	10	0	0	0	1	0	0	0	0	0	0	0
	C	4	0	0	0	0	0	0	0	0	0	0	0
3B	A	16	0	0	0	0	0	0	0	0	0	0	0
	K	53	0	0	0	5	0	2	0	0	3	0	0
	C	25	0	0	0	5	0	3	0	0	2	0	0
3C	A	26	0	0	0	0	0	0	0	0	0	0	0
	K	2	0	0	0	0	0	0	0	0	0	0	0
	C	1	0	0	0	0	0	0	0	0	0	0	0
3D	A	37	0	0	0	1	0	0	0	0	0	0	0
	K	34	0	0	0	1	0	3	0	0	0	0	0
	C	16	0	0	0	0	0	0	0	0	0	0	0
3E	A	15	0	0	0	0	0	0	0	0	0	0	0
	K	10	0	0	0	0	0	0	0	0	0	0	0
	C	5	0	0	0	0	0	0	0	0	0	0	0