



Summary of Studies Supporting USDA Product Licensure

Establishment Name	Intervet Inc.
USDA Vet Biologics Establishment Number	165A
Product Code	19A5.RD
True Name	Swine Influenza Vaccine, H1, RNA Particle
Tradename(s) / Distributor or Subsidiary (if different from manufacturer)	Merck Animal Health
Date of Compilation Summary	December 04, 2024

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	Efficacy																																				
Pertaining to	Swine Influenza Virus, H1																																				
Study Purpose	To demonstrate efficacy against swine influenza virus, H1N1																																				
Product Administration	Two doses, administered intradermally 3 weeks apart,																																				
Study Animals	Commercial pigs, 3 weeks of age, 32 vaccinates and 32 controls (placebo vaccinated)																																				
Challenge Description	All pigs were challenged 29 days post second vaccination with swine influenza strain A/swine/Iowa/A01778877/2016 (H1N1).																																				
Interval observed after challenge	Lung lesion scores were assessed 5 days post challenge on a subgroup of 20 vaccinates and 20 controls. Nasal swabs were collected daily 14 days post challenge from 12 vaccinates and 12 controls.																																				
Results	Five number summary for lung lesion scores*: <table><tr><th>Group</th><th>Min</th><th>Q1</th><th>Med</th><th>Q3</th><th>Max</th></tr><tr><td>vaccinates</td><td>0</td><td>0</td><td>0</td><td>1</td><td>8</td></tr><tr><td>placebo controls</td><td>5</td><td>10</td><td>14</td><td>18</td><td>24</td></tr></table> *Lesion scores were calculated as the percentage of total lung area Five number summary for duration of nasal shedding (days): <table><tr><th>Group</th><th>Min</th><th>Q1</th><th>Med</th><th>Q3</th><th>Max</th></tr><tr><td>vaccinates</td><td>0</td><td>0</td><td>0</td><td>0</td><td>0</td></tr><tr><td>placebo controls</td><td>1</td><td>2</td><td>3</td><td>4</td><td>5</td></tr></table> Raw data are shown below.	Group	Min	Q1	Med	Q3	Max	vaccinates	0	0	0	1	8	placebo controls	5	10	14	18	24	Group	Min	Q1	Med	Q3	Max	vaccinates	0	0	0	0	0	placebo controls	1	2	3	4	5
Group	Min	Q1	Med	Q3	Max																																
vaccinates	0	0	0	1	8																																
placebo controls	5	10	14	18	24																																
Group	Min	Q1	Med	Q3	Max																																
vaccinates	0	0	0	0	0																																
placebo controls	1	2	3	4	5																																
USDA Approval Date	March 29, 2022																																				

Table 1: Lung Lesion Score (LLS) by 1st Scorer

Pig ID	Treatment	DLA	DLC	DLD	DRA	DRC	DRD	VLA	VLC	VLD	VRA	VRC	VRD	INT	Total Score	LLS
684	Placebo	9	14	16	6	24	15.5	15.5	16	20.5	8	34	15.5	7.5	201.5	17.06
687	Placebo	7.5	27.5	28	16.5	21.5	14.5	14.5	33	23	25	44	14	13.5	282.5	23.92
692	Placebo	3.5	19	8.5	14	22	13.5	7.5	13	12.5	17	37	14.5	4.5	186.5	15.79
693	Placebo	2	13.5	11.5	3.5	13.5	6.5	4	14	8	9.5	26	5.5	1	118.5	10.03
700	Placebo	2.5	5	3	7.5	16.5	8.5	4.5	4	2.5	5	19.5	3	1.5	83	7.03
707	Placebo	4.5	29.5	24	1.5	21	9.5	9	39.5	23.5	3	39	7.5	5	216.5	18.33
709	Placebo	8	21	8.5	7.5	19	1.5	9.5	22.5	3	13	40	5	2	160.5	13.59
714	Placebo	10	13	2.5	22	16.5	1.5	13	15.5	1	29.5	23	1.5	2.5	151.5	12.83
722	Placebo	2	19.5	22	13.5	25.5	16.5	3	24.5	19.5	10	46	8	12	222	18.8
726	Placebo	8.5	35	27.5	31.5	29	4.5	12.5	28	23.5	20	44	5	9.5	278.5	23.58
727	Placebo	6	23.5	20.5	3.5	25	4.5	11	19.5	15.5	1.5	33.5	3.5	2.5	170	14.39
728	Placebo	3.5	38	15.5	11	23	8.5	8	44	17.5	20.5	41	7.5	4.5	242.5	20.53
734	Placebo	0.5	11.5	12	6	25.5	11	2	9	10	6.5	27.5	6	4	131.5	11.13
736	Placebo	0	29	15.5	3	13	4	0	22.5	23	6.5	18.5	4.5	1	140.5	11.9
737	Placebo	3	17	9.5	0	10	2.5	2.5	11	8	0	14	1.5	3	82	6.94
739	Placebo	6.5	19	1.5	10	8.5	2	7	15	4.5	9	21	1.5	1.5	107	9.06
741	Placebo	0.5	5.5	1.5	3	8.5	2.5	2.5	6	0	2.5	11	2	0.5	46	3.9
748	Placebo	9	28	6	10	18.5	12.5	16.5	29	8.5	10.5	34.5	12	9.5	204.5	17.32
754	Placebo	5.5	22	16.5	22.5	24	9	7.5	11.5	14.5	19	54	14.5	9.5	230	19.48
757	Placebo	3.5	29.5	16	28	30	24	7.5	31	16.5	24.5	58	12	1	281.5	23.84
685	Vaccinate	0	0.5	0.5	1.5	1	0	0	0.5	0.5	0	0.5	0	0	5	0.42
688	Vaccinate	0	4.5	12	10	5.5	10.5	0	9.5	13.5	4	5.5	33.5	6.5	115	9.74
691	Vaccinate	0	0.5	0	0	1	0	0	0	0	0	1.5	0	0	3	0.25
698	Vaccinate	0	0	0	0	0	0	0	0.5	0	0	0	0	0	0.5	0.04
702	Vaccinate	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
703	Vaccinate	0	0.5	0	0	0	0	0	0.5	0	0	0	0	0	1	0.08
712	Vaccinate	0	0.5	0	2	0	0	0	0.5	0	2	0	0	0	5	0.42
718	Vaccinate	0	2	1.5	0	0	0	0	0.5	0.5	0	0	0.5	0	5	0.42
720	Vaccinate	0	1	1.5	0	0.5	0.5	0	1	1	0	1	0.5	0	7	0.59
721	Vaccinate	0	2	0.5	0	2	0.5	0	2.5	1.5	0	2	0	0	11	0.93
723	Vaccinate	0	5	0	0	1.5	0	0	4.5	0	0	1.5	0	0	12.5	1.06
729	Vaccinate	0	0.5	2	0	0.5	0	0	1.5	0.5	0	1	2	0	8	0.68
731	Vaccinate	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
733	Vaccinate	0	0	0	0	0.5	0	0	0.5	0	0	0.5	0	0	1.5	0.13
735	Vaccinate	0	0	0	0	1.5	0	0	0.5	0	0	1	0	0	3	0.25
738	Vaccinate	0	2	0	0	0	0	0	1.5	0	0	0	0	0	3.5	0.3
747	Vaccinate	0	2	1	0	0	0	0	2	0.5	0	0	0	0	5.5	0.47
749	Vaccinate	0	2	0	0	1	0	0	1	0	0	0	0	0	4	0.34
755	Vaccinate	0	0.5	0	0	0	0	0	0.5	0	0	0	0	0	1	0.08
758	Vaccinate	0	1	0	0	1.5	0	0	1.5	0	0	2	0	0	6	0.51

Code

DLA = Dorsal Left Apical Lobe	VLA = Ventral Left Apical Lobe
DLC = Dorsal Left Cardiac Lobe	VLC = Ventral Left Cardiac Lobe
DLD = Dorsal Left Diaphragmatic Lobe	VLD = Ventral Left Diaphragmatic Lobe
DRA = Dorsal Right Apical Lobe	VRA = Ventral Right Apical Lobe
DRC = Dorsal Right Cardiac Lobe	VRC = Ventral Right Cardiac Lobe
DRD = Dorsal Right Diaphragmatic Lobe	VRD = Ventral Right Diaphragmatic Lobe
INT = Intermediate Lobe	

Table 2: Lung Lesion Score (LLS) by 2nd Scorer

Pig ID	Treatment	DLA	DLC	DLD	DRA	DRC	DRD	VLA	VLC	VLD	VRA	VRC	VRD	INT	Total Score	LLS
684	Placebo	5.5	20	11.5	8	25	8.5	8.5	13	10	11	28	15	7.5	171.5	14.52
687	Placebo	6.5	20	14.5	12.5	16	8	14.5	24.5	21	20	30.5	10	14.5	212.5	17.99
692	Placebo	3.5	12	13	11	24.5	10	6	16	10	13	28.5	19	4.5	171	14.48
693	Placebo	2.5	12.5	10	5	13.5	4	3	13	5.5	9.5	22	6	1.5	108	9.14
700	Placebo	2.5	7.5	3.5	5	15	7.5	6	5	3.5	7.5	23.5	7	2	95.5	8.09
707	Placebo	4.5	27	22	2.5	28	6.5	8.5	33.5	22	2.5	37.5	10	2.5	207	17.53
709	Placebo	8.5	12.5	7	7	19.5	0.5	9.5	19	3	9	32	5	0.5	133	11.26
714	Placebo	10	18.5	3	22.5	15.5	0.5	10	18	2.5	23.5	26	1.5	2	153.5	13
722	Placebo	2	30	15	12	23	10.5	3.5	20.5	11	10	41.5	7.5	16.5	203	17.19
726	Placebo	10.5	29	30.5	16.5	28.5	2.5	10	22	20.5	25	40	5	15	255	21.59
727	Placebo	4.5	17.5	12	1.5	26	0	7	15	16	1	28	1.5	0.5	130.5	11.05
728	Placebo	5	37.5	13	9.5	25	7	8	39	10.5	16.5	31	6	3	211	17.87
734	Placebo	1	9	6	4	21	10	1.5	7.5	6.5	5	29	5.5	2	108	9.14
736	Placebo	1	26	12	6.5	12	2.5	1.5	14.5	18	7	12.5	2.5	1	117	9.91
737	Placebo	2	25	7.5	0	9.5	2.5	2	15	6.5	0.5	23	3	2.5	99	8.38
739	Placebo	7	14.5	1	5.5	12	1	8.5	15	3	8.5	22	1.5	1.5	101	8.55
741	Placebo	1.5	11.5	1	3.5	9	1	3.5	7	0	3	15.5	4	0.5	61	5.17
748	Placebo	9	29	5.5	8	23	10.5	13	21.5	6	10	35	10	4.5	185	15.66
754	Placebo	8	22	12	14.5	27	9.5	7	15	9	16	37	10	7.5	194.5	16.47
757	Placebo	3	30.5	20.5	29	36.5	15	8.5	25	14	31	49.5	7	3	272.5	23.07
685	Vaccinate	0	1	0	1	0	0	0	0.5	0	0.5	0.5	0	0	3.5	0.3
688	Vaccinate	0.5	3.5	10.5	8	6	8	1	8	4.5	3.5	5	12	0.5	71	6.01
691	Vaccinate	0	0.5	0	0	0.5	0	0	1	0	0.5	0.5	0	0	3	0.25
698	Vaccinate	0	0.5	0	0	0	0	0	0	0	0	0.5	0	0	1	0.08
702	Vaccinate	0	1	0	0	0	0	0	0	0	0	0	0	0	1	0.08
703	Vaccinate	0	0.5	0	0	0	0	0	0.5	0	0	0	0	0	1	0.08
712	Vaccinate	0	0.5	0	1	0	0	0	1	0	1	0	0	0	3.5	0.3
718	Vaccinate	0	2	1	0	0	0	0	1.5	0	0	0	1	0	5.5	0.47
720	Vaccinate	0	0.5	1.5	0	0.5	0	0	0.5	0.5	0.5	1.5	0.5	0	6	0.51
721	Vaccinate	0.5	3	1.5	0	1.5	0.5	0	2.5	1	0	3	0.5	0	14	1.19
723	Vaccinate	0	7	0	0	1	0	0	7.5	0	0	1.5	0	0.5	17.5	1.48
729	Vaccinate	0	3	2.5	0	0	0	0	1	2	0	1	1	0	10.5	0.89
731	Vaccinate	0	0.5	0	0.5	0.5	0	0	0	0	0	0	0	0	1.5	0.13
733	Vaccinate	0	0	0	0.5	0.5	0	0	1	0	0	0	0	0	2	0.17
735	Vaccinate	0	0.5	0	0	0.5	0	0	0	0	0	0.5	0	0	1.5	0.13
738	Vaccinate	0	2	0	0	0	0	0	3	0	0	0	0	0	5	0.42
747	Vaccinate	0	1.5	0.5	0	0.5	0.5	0.5	1.5	0.5	0	0.5	0	0	6	0.51
749	Vaccinate	0	1	0.5	0	1	0	0	1	0	0	0.5	0	0.5	4.5	0.38
755	Vaccinate	0	0.5	0	0	0	0	0	1.5	0	0	0	0	0	2	0.17
758	Vaccinate	0	1.5	0	0	2	0	0	1	0	0.5	2.5	0	0	7.5	0.64

Code

DLA = Dorsal Left Apical Lobe	VLA = Ventral Left Apical Lobe
DLC = Dorsal Left Cardiac Lobe	VLC = Ventral Left Cardiac Lobe
DLD = Dorsal Left Diaphragmatic Lobe	VLD = Ventral Left Diaphragmatic Lobe
DRA = Dorsal Right Apical Lobe	VRA = Ventral Right Apical Lobe
DRC = Dorsal Right Cardiac Lobe	VRC = Ventral Right Cardiac Lobe
DRD = Dorsal Right Diaphragmatic Lobe	VRD = Ventral Right Diaphragmatic Lobe
INT = Intermediate Lobe	

Table 3: Nasal Shedding Titer ($\log_{10}$ TCID₅₀ per mL)

Note: Titer of 0.5 $\log_{10}$ TCID₅₀/mL is IAV-S (Swine Influenza A Virus) negative. NA = not applicable

Pig ID	Treatment	Days post challenge								
		-1DPC	1DPC	2DPC	3DPC	4DPC	5DPC	6DPC	7DPC	8DPC
682	Placebo	0.5	5	5	5.8	4.5	0.5	0.5	0.5	0.5
683	Placebo	0.5	0.5	4	6	5	0.5	0.5	0.5	0.5
694	Placebo	0.5	0.5	0.5	4.8	0.5	0.5	0.5	0.5	0.5
695	Placebo	0.5	0.5	4.8	4	4.5	0.5	0.5	0.5	0.5
704	Placebo	0.5	0.5	4	5.8	0.5	0.5	0.5	0.5	0.5
706	Placebo	0.5	0.5	5.5	5.5	5.5	3	0.5	0.5	0.5
710	Placebo	0.5	0.5	0.5	0.5	0.5	0.5	4.5	0.5	0.5
713	Placebo	0.5	0.5	0.5	5.3	4.8	4.8	0.5	0.5	0.5
745	Placebo	0.5	0.5	4.8	6	0.5	0.5	0.5	0.5	0.5
750	Placebo	0.5	0.5	5.5	6.5	4.8	3	0.5	0.5	0.5
756	Placebo	0.5	3.5	3.5	4.5	4	2.8	0.5	0.5	0.5
760	Placebo	0.5	0.5	4.5	5.5	5	3.3	0.5	0.5	0.5
684	Placebo	0.5	NA	NA	NA	NA	NA	NA	NA	NA
687	Placebo	0.5	NA	NA	NA	NA	NA	NA	NA	NA
692	Placebo	0.5	NA	NA	NA	NA	NA	NA	NA	NA
693	Placebo	0.5	NA	NA	NA	NA	NA	NA	NA	NA
700	Placebo	0.5	NA	NA	NA	NA	NA	NA	NA	NA
707	Placebo	0.5	NA	NA	NA	NA	NA	NA	NA	NA
709	Placebo	0.5	NA	NA	NA	NA	NA	NA	NA	NA
714	Placebo	0.5	NA	NA	NA	NA	NA	NA	NA	NA
722	Placebo	0.5	NA	NA	NA	NA	NA	NA	NA	NA
726	Placebo	0.5	NA	NA	NA	NA	NA	NA	NA	NA
727	Placebo	0.5	NA	NA	NA	NA	NA	NA	NA	NA
728	Placebo	0.5	NA	NA	NA	NA	NA	NA	NA	NA
734	Placebo	0.5	NA	NA	NA	NA	NA	NA	NA	NA
736	Placebo	0.5	NA	NA	NA	NA	NA	NA	NA	NA
737	Placebo	0.5	NA	NA	NA	NA	NA	NA	NA	NA
739	Placebo	0.5	NA	NA	NA	NA	NA	NA	NA	NA
741	Placebo	0.5	NA	NA	NA	NA	NA	NA	NA	NA
748	Placebo	0.5	NA	NA	NA	NA	NA	NA	NA	NA
754	Placebo	0.5	NA	NA	NA	NA	NA	NA	NA	NA
757	Placebo	0.5	NA	NA	NA	NA	NA	NA	NA	NA

Table 3(continued): Nasal Shedding Titer (log₁₀ TCID₅₀ per mL)

Note: Titer of 0.5 log₁₀ TCID₅₀/mL is IAV-S (Swine Influenza A Virus) negative. NA = not applicable

Pig ID	Treatment	Days post challenge								
		-1DPC	1DPC	2DPC	3DPC	4DPC	5DPC	6DPC	7DPC	8DPC
679	Vaccinate	0.5	0.5	0.5	0.5	0.5	0.5	0.5	0.5	0.5
686	Vaccinate	0.5	0.5	0.5	0.5	0.5	0.5	0.5	0.5	0.5
690	Vaccinate	0.5	0.5	0.5	0.5	0.5	0.5	0.5	0.5	0.5
697	Vaccinate	0.5	0.5	0.5	0.5	0.5	0.5	0.5	0.5	0.5
701	Vaccinate	0.5	0.5	0.5	0.5	0.5	0.5	0.5	0.5	0.5
705	Vaccinate	0.5	0.5	0.5	0.5	0.5	0.5	0.5	0.5	0.5
711	Vaccinate	0.5	0.5	0.5	0.5	0.5	0.5	0.5	0.5	0.5
716	Vaccinate	0.5	0.5	0.5	0.5	0.5	0.5	0.5	0.5	0.5
743	Vaccinate	0.5	0.5	0.5	0.5	0.5	0.5	0.5	0.5	0.5
746	Vaccinate	0.5	0.5	0.5	0.5	0.5	0.5	0.5	0.5	0.5
753	Vaccinate	0.5	0.5	0.5	0.5	0.5	0.5	0.5	0.5	0.5
759	Vaccinate	0.5	0.5	0.5	0.5	0.5	0.5	0.5	0.5	0.5
685	Vaccinate	0.5	NA	NA	NA	NA	NA	NA	NA	NA
688	Vaccinate	0.5	NA	NA	NA	NA	NA	NA	NA	NA
691	Vaccinate	0.5	NA	NA	NA	NA	NA	NA	NA	NA
698	Vaccinate	0.5	NA	NA	NA	NA	NA	NA	NA	NA
702	Vaccinate	0.5	NA	NA	NA	NA	NA	NA	NA	NA
703	Vaccinate	0.5	NA	NA	NA	NA	NA	NA	NA	NA
712	Vaccinate	0.5	NA	NA	NA	NA	NA	NA	NA	NA
718	Vaccinate	0.5	NA	NA	NA	NA	NA	NA	NA	NA
720	Vaccinate	0.5	NA	NA	NA	NA	NA	NA	NA	NA
721	Vaccinate	0.5	NA	NA	NA	NA	NA	NA	NA	NA
723	Vaccinate	0.5	NA	NA	NA	NA	NA	NA	NA	NA
729	Vaccinate	0.5	NA	NA	NA	NA	NA	NA	NA	NA
731	Vaccinate	0.5	NA	NA	NA	NA	NA	NA	NA	NA
733	Vaccinate	0.5	NA	NA	NA	NA	NA	NA	NA	NA
735	Vaccinate	0.5	NA	NA	NA	NA	NA	NA	NA	NA
738	Vaccinate	0.5	NA	NA	NA	NA	NA	NA	NA	NA
747	Vaccinate	0.5	NA	NA	NA	NA	NA	NA	NA	NA
749	Vaccinate	0.5	NA	NA	NA	NA	NA	NA	NA	NA
755	Vaccinate	0.5	NA	NA	NA	NA	NA	NA	NA	NA
758	Vaccinate	0.5	NA	NA	NA	NA	NA	NA	NA	NA

Study Type	Safety					
Pertaining to	All					
Study Purpose	Demonstrate safety of product under typical use conditions.					
Product Administration	2 doses administered intradermally (ID) 3 weeks apart.					
Study Animals	728 pigs, 21-24 days of age, distributed among 3 study sites.					
Challenge Description	Not applicable					
Interval observed after challenge	Animals were observed for systemic and/or local injection site reactions, and various adverse events (AEs) per VeDDRA guidance for 21 days after each vaccination, or until resolution.					
Results	Site	Total Number Animals	Max. Size of Injection Site Reaction			1 st or 2 nd vaccination
			<1.5 cm	1.5 to 5 cm	<5 to 10 cm	
	1	230	0	0	0	1
		229	0	0	0	2
	2	244	29	4	0	1
		243	101	20	0	2
	3	254	6	0	0	1
		252	84	12	0	2
	Total All Sites	728	35	4	0	1
		724	185	32	0	2
	The mean duration of site reactions was 1.4 days after the first vaccination and 3.9 days after the second vaccination.					
	VEDDRA Code			Total Animals		Percent of All Animals
	No adverse events			379		52.1%
	Pneumonia			117		16.1%
	Anorexia			46		6.3%
	Death			19		2.6%
	Lameness			14		1.9%
	Diarrhea			11		1.5%
	Depression			7		1.0%
	Ataxia			5		0.7%
	Dyspnea			3		0.4%
	Internal ear disorder			2		0.3%
Lethargy			2		0.3%	
Bacterial skin infection			1		0.1%	
Paralysis			1		0.1%	
Rectal prolapse			1		0.1%	
Recumbency			1		0.1%	
USDA Approval Date	May 7, 2024					

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Study Purpose	Demonstrate safety of product under typical use conditions.																																																																																					
Product Administration	2 doses administered intradermally (ID) 3 weeks apart.																																																																																					
Study Animals	716 pregnant sows, between two study sites, separated into vaccinates and control groups. Sows were in one of three phases of gestation at the time of the first vaccination; early (30-40 days), mid (50-60 days), and late (70-80 days).																																																																																					
Challenge Description	Not Applicable																																																																																					
Interval observed after challenge	Sows were observed daily for general health for 21 days following each vaccination until 7 days post-farrowing, or until resolution of any systemic adverse events. Palpation of injection site areas were performed on Days 3, 4, and 5 following each vaccination.																																																																																					
Results	Summary of Sow Injection Site Reactions <table><tr><th rowspan="2">Site</th><th rowspan="2">Total Number Animals</th><th colspan="3">Max. Size of Injection Site Reaction</th><th rowspan="2">1st or 2nd vaccination</th><th rowspan="2">IVP or Control (C)</th></tr><tr><th><1.5 cm</th><th>1.5 to 5 cm</th><th><5 to 10 cm</th></tr><tr><td rowspan="4">1</td><td>239</td><td>1</td><td>1</td><td>0</td><td>1</td><td>IVP</td></tr><tr><td>118</td><td>1</td><td>0</td><td>0</td><td>NVC-1</td><td>C</td></tr><tr><td>235</td><td>18</td><td>2</td><td>0</td><td>2</td><td>IVP</td></tr><tr><td>117</td><td>1</td><td>0</td><td>1</td><td>NVC-2</td><td>C</td></tr><tr><td rowspan="4">2</td><td>240</td><td>131</td><td>64</td><td>0</td><td>1</td><td>IVP</td></tr><tr><td>119</td><td>1</td><td>0</td><td>0</td><td>NVC-1</td><td>C</td></tr><tr><td>234</td><td>147</td><td>66</td><td>4</td><td>2</td><td>IVP</td></tr><tr><td>117</td><td>12</td><td>0</td><td>0</td><td>NVC-2</td><td>C</td></tr><tr><td rowspan="4">Total All Sites</td><td>479</td><td>131</td><td>65</td><td>0</td><td>1</td><td>IVP</td></tr><tr><td>237</td><td>2</td><td>0</td><td>0</td><td>NVC-1</td><td>C</td></tr><tr><td>469</td><td>164</td><td>68</td><td>4</td><td>2</td><td>IVP</td></tr><tr><td>234</td><td>11</td><td>0</td><td>1</td><td>NVC-2</td><td>C</td></tr></table> NVC = non-vaccinated control The mean duration of site reactions was 8.0 days after the first vaccination and 10.1 days after the second vaccination.	Site	Total Number Animals	Max. Size of Injection Site Reaction			1st or 2nd vaccination	IVP or Control (C)	<1.5 cm	1.5 to 5 cm	<5 to 10 cm	1	239	1	1	0	1	IVP	118	1	0	0	NVC-1	C	235	18	2	0	2	IVP	117	1	0	1	NVC-2	C	2	240	131	64	0	1	IVP	119	1	0	0	NVC-1	C	234	147	66	4	2	IVP	117	12	0	0	NVC-2	C	Total All Sites	479	131	65	0	1	IVP	237	2	0	0	NVC-1	C	469	164	68	4	2	IVP	234	11	0	1	NVC-2	C
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Sow Incidence of Occurrence of Adverse Events

VeDDRA Code	Number of Vaccinates (N=479)	Vaccinates, Percent of All Animals (N=716)	Number of Controls (N=237)	Controls, Percent of All Animals (N=716)
No adverse events	192	26.8%	184	25.7%
Return to oestrus	18	2.5%	13	1.8%
Hyperthermia	15	2.1%	6	0.8%
Dermatitis and eczema	15	2.1%	3	0.4%
Retained placenta	10	1.4%	3	0.4%
Lameness	8	1.1%	3	0.4%
Death*	7	1.0%	3	0.4%
Dystocia	9	1.3%	1	0.1%
Abortion	6	0.8%	3	0.4%
Lactation change	6	0.8%	0	0.0%
Vaginal prolapse	4	0.6%	2	0.3%
Emesis	3	0.4%	2	0.3%
Trauma NOS ^(b)	3	0.4%	2	0.3%
Anisocoria	2	0.3%	2	0.3%
Anorexia	4	0.6%	0	0.0%
Bacterial skin infection	2	0.3%	2	0.3%
Loss of condition	2	0.3%	1	0.1%
Behavioural disorder NOS ^(b)	2	0.3%	0	0.0%
Diarrhoea	2	0.3%	0	0.0%
Rectal prolapse	0	0.0%	2	0.3%
Vulvovaginitis	1	0.1%	1	0.1%
Aggression	1	0.1%	0	0.0%
General pain	1	0.1%	0	0.0%
Internal ear disorder	1	0.1%	0	0.0%
Mastitis NOS ^(b)	0	0.0%	1	0.1%
Musculoskeletal disorder NOS ^(b)	1	0.1%	0	0.0%
Skin ulceration	1	0.1%	0	0.0%
Tachypnoea	0	0.0%	1	0.1%

* Deaths not attributable to vaccine as affirmed by licensee

(b) NOS = not otherwise specified

	Birth Events by Gestation Phase									
		Early (30-40 days)			Mid (50-60 days)			Late (70-80 days)		
		IVP	C	Total	IVP	C	Total	IVP	C	Total
	Born Alive	2277	1082	3359	2236	1101	3337	2119	1139	3258
		89.5%	88.7%	89.3%	86.1%	86.7%	86.3%	86.8%	89.3%	87.6%
	Dead	51	24	75	100	32	132	34	15	49
		2.0%	2.0%	2.0%	3.9%	2.5%	3.4%	1.4%	1.2%	1.3%
	Stillborn	165	92	257	197	115	312	156	70	226
		6.5%	7.5%	6.8%	7.6%	9.1%	8.1%	6.4%	5.5%	6.1%
	Mummified	41	19	60	38	15	53	70	33	103
		1.6%	1.6%	1.6%	1.5%	1.2%	1.4%	2.9%	2.6%	2.8%
	Weak	8	1	9	22	6	28	62	19	81
		0.3%	0.1%	0.2%	0.8%	0.5%	0.7%	2.5%	1.5%	2.2%
	Aborted	1	2	3	4	1	5	1	0	1
		0.0%	0.2%	0.1%	0.2%	0.1%	0.1%	0.0%	0.0%	0.0%
	Total	2543	1220	3763	2597	1270	3867	2442	1276	3718
	IVP = born to sows vaccinated with investigational test product									
C = born to non-vaccinated controls										
USDA Approval Date	October 4, 2024									