Summary of Studies Supporting USDA Product Licensure

Establishment Name	Intervet Inc.
USDA Vet Biologics Establishment Number	165A
Product Code	9PP0.01
True Name	Prescription Product, RNA Particle
Tradename(s) / Distributor or Subsidiary (if different from manufacturer)	Merck Animal Health
Date of Compilation Summary	March 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.

<table>
<tr><td>Study Type</td><td>Safety</td></tr>
<tr><td>Pertaining to</td><td>All</td></tr>
<tr><td>Study Purpose</td><td>Demonstrate safety of product under typical use conditions.</td></tr>
<tr><td>Product Administration</td><td>2 doses administered intramuscularly (IM) 3 weeks apart.</td></tr>
<tr><td>Study Animals</td><td>776 pregnant sows, between two study sites, separated into three treatment groups. Group 1 and 2 received one of two vaccine serials, Group 3 was non-vaccinated control. 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).</td></tr>
<tr><td>Challenge Description</td><td>Not Applicable</td></tr>
<tr><td>Interval observed after challenge</td><td>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.</td></tr>
<tr><td>Results</td><td>Summary of Sow Injection Site Reactions

<table>
<tr><td rowspan="2">Site</td><td rowspan="2">Total Number Animals</td><td colspan="5">Max. Size of Injection Site Reaction</td><td rowspan="2">IVP or Control (C)</td></tr>
<tr><td>No Swellings</td><td>Draining Abscess</td><td><1.5 cm</td><td>1.5 – 5 cm</td><td>>5 – 10 cm</td></tr>
<tr><td rowspan="2">1</td><td>283</td><td>282</td><td>0</td><td>1</td><td>0</td><td>0</td><td>IVP</td></tr>
<tr><td>144</td><td>144</td><td>0</td><td>0</td><td>0</td><td>0</td><td>C</td></tr>
<tr><td rowspan="2">2</td><td>234</td><td>146</td><td>0</td><td>67</td><td>21</td><td>0</td><td>IVP</td></tr>
<tr><td>115</td><td>105</td><td>0</td><td>9</td><td>1</td><td>0</td><td>C</td></tr>
<tr><td rowspan="2">Total All Sites</td><td>517</td><td>428</td><td>0</td><td>68</td><td>21</td><td>0</td><td>IVP</td></tr>
<tr><td>259</td><td>249</td><td>0</td><td>9</td><td>1</td><td>0</td><td>C</td></tr>
</table>

The mean duration of injection site reactions was 4.2 days after the first vaccination and 1.7 days after the second vaccination.</td></tr>
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Table 1: Sows Incidence of Occurrence of Adverse Events

VeDDRA Code	Total Vaccinated Animals (N=517)	Total Control Animals (N=259)	Percent of All Animals (N=776)
No Adverse Events	361	187	70.6%
Return to estrus	27	26	6.8%
Bacterial skin infection	23	13	4.6%
Lactation change	16	4	2.6%
Death*	8	3	1.4%
Hyperthermia	4	7	1.4%
Anorexia	4	4	1.0%
Retained placenta	5	3	1.0%
Lameness	2	4	0.8%
Rectal prolapse	2	2	0.5%
Behavioral disorder NOS (b)	0	2	0.3%
Cough	2	0	0.3%
Trauma NOS (b)	1	1	0.3%
Abortion	0	1	0.1%
Abscess NOS (b)	0	1	0.1%
Dermal cyst	1	0	0.1%
Dermal mass	1	0	0.1%
Emesis	1	0	0.1%
Erythema	1	0	0.1%
Loss of condition	0	1	0.1%
Mastitis NOS (b)	1	0	0.1%
Paralysis	1	0	0.1%
Recumbency	1	0	0.1%
Salivary gland disorder	0	1	0.1%
Skin disorders NOS (b)	1	0	0.1%
Ulceration NOS (b)	0	1	0.1%
Uterine prolapse	1	0	0.1%
Vaginal prolapse	1	0	0.1%

*Deaths not attributable to vaccine as affirmed by licensee

(b) NOS = Not otherwise specified

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	Birth Events by Gestation One sow aborted 10 piglets.

Gestation	Serial Group	Born Alive	Dead	Stillborn	Mummified	Weak	Aborted
Early (30-40 days)	1	1110	35	68	21	16	0
Early (30-40 days)	2	1160	40	88	28	20	0
Early (30-40 days)	Control	1082	32	80	24	17	0
Mid (50-60 days)	1	1124	35	58	13	9	0
Mid (50-60 days)	2	1072	38	69	19	25	0
Mid (50-60 days)	Control	1008	36	65	16	18	1
Late (70-80 days)	1	1132	44	80	15	11	0
Late (70-80 days)	2	1148	23	80	20	24	0
Late (70-80 days)	Control	1024	36	74	29	15	0

USDA Approval Date	February 15, 2024

Study Type	Safety
Pertaining to	Prescription Platform Product
Study Purpose	Safety
Product Administration	Intramuscular
Study Animals	Swine
Results	This product was qualified as a prescription production platform based on demonstrated safety as shown in the Product Summary for Establishment 165A, Product Code 19A5.RC. As a prescription platform product, the manufacturer may update the gene insert in this vaccine under expedited procedures to respond to emerging needs per Veterinary Services Memorandum 800.214. Study data to support these updates were evaluated by USDA-APHIS and found acceptable based on regulations and policies at the time of approval. Additional safety studies may not have been required for these updates. An identifier for the gene sequence found in a given serial (numbered batch) of vaccine is listed on the product labeling.