Summary of Studies Supporting USDA Product Licensure

Establishment Name	Medgene Labs
USDA Vet Biologics Establishment Number	474
Product Code	19A5.R9
True Name	Swine Influenza Vaccine, H3, Killed Baculovirus Vector
Tradename(s) / Distributor or Subsidiary (if different from manufacturer)	
Date of Compilation Summary	August 11, 2021

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 Vaccine, H3, Killed Baculovirus Vector
Study Purpose	To demonstrate efficacy against swine influenza virus (H3)
Product Administration	2 doses, given intramuscularly, 3 weeks apart
Study Animals	3-4-week-old pigs, 30 vaccinates and 14 controls
Challenge Description	Swine Influenza Virus (A/Swine/IA/A01566613/2014-H3N2) was administered 14 days following 2nd vaccination.
Interval observed after challenge	Pigs were evaluated for clinical signs for 5 days post challenge. Lung lesions were evaluated at 5 days post challenge.
Results	Lung lesion scoring was performed 5 days post challenge and total lung lesion percentage was calculated for every animal.

5-number summary for Lung Lesion (%)

Treatment	n	Min	25th Pctl	Median	75th Pctl	Max
Controls	14	0.00	0.75	2.68	3.99	10.86
Vaccinates	30	0.00	0.00	0.00	0.00	1.60

Summary of the Number of Affected Pigs in Each Group:

Treatment	Positive Lesion Score[1]	Negative Lesion Score[1]	Total
Controls	13	1	14
Vaccinates	6	24	30

[1] Lung Lesion % >0 = positive, otherwise negative

Raw data shown on attached page.

USDA Approval Date	June 28, 2019

Lung Lesion Scores (%), in order of rank:

Vaccinate	Control
0	0
0	0.2
0	0.5
0	0.75
0	0.85
0	1.15
0	1.8
0	3.55
0	3.625
0	3.8
0	3.9875
0	4.475
0	4.75
0	10.8625
0	
0	
0	
0	
0	
0	
0	
0	
0	
0	
0.05	
0.1	
0.25	
0.35	
0.7625	
1.6	

<table>
<tr><td>Study Type</td><td>Safety</td></tr>
<tr><td>Pertaining to</td><td>Swine Influenza Vaccine, H3</td></tr>
<tr><td>Study Purpose</td><td>To demonstrate safety under field conditions</td></tr>
<tr><td>Product Administration</td><td>2 doses, given intramuscularly, 3 weeks apart</td></tr>
<tr><td>Study Animals</td><td>899 pigs at 4 sites in 3 distinct geographical regions. Minimum age 28 days</td></tr>
<tr><td>Challenge Description</td><td>Not applicable</td></tr>
<tr><td>Interval observed after challenge</td><td>Not applicable</td></tr>
<tr><td>Results</td><td>Pigs were observed immediately after each vaccination and daily through 14 days after the last vaccination.

Injection Site Reactions

<table>
<tr><th rowspan="2">Site</th><th rowspan="2">Total # of Animals</th><th colspan="3">Maximum Size of Injection Site Reaction (cm)</th><th rowspan="2">Total # of Animals with Injection Site Reactions</th><th rowspan="2">Animals with No Injection Site Reaction</th></tr>
<tr><th><1.5</th><th>1.5-5.0</th><th>>5.0</th></tr>
<tr><td>Site 1</td><td>230</td><td>26</td><td>10</td><td>0</td><td>36</td><td>194</td></tr>
<tr><td>Site 2</td><td>217</td><td>36</td><td>1</td><td>0</td><td>37</td><td>180</td></tr>
<tr><td>Site 3</td><td>223</td><td>123</td><td>21</td><td>0</td><td>144</td><td>79</td></tr>
<tr><td>Site 4</td><td>229</td><td>11</td><td>2</td><td>0</td><td>13</td><td>216</td></tr>
<tr><td colspan="5">Totals</td><td>230</td><td>669</td></tr>
</table>

All injection site reactions resolved within 3 weeks of vaccination.</td></tr>
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Adverse Events

Clinical Observation	Number of Clinical Observations Post-Vaccination			
	Site 1	Site 2	Site 3	Site 4
Abdominal Cavity Hernia	6	0	0	1
Bacterial Skin Infection	0	0	0	1
Cough	0	0	0	1
Cyst on Rump	0	0	0	1
Depression	1	0	0	0
Ear sore	0	0	0	3
Facial Scar	0	0	0	1
Facial Swelling	0	0	0	1
Fainting	1	0	0	0
Hair Change	2	0	0	5
Injection Site Abscess	2	0	0	0
Injection Site Reddening	5	0	0	0
Injection Site Scratching	1	0	0	0
Joint Swelling	1	0	0	0
Labored Breathing	1	0	0	0
Lameness	2	0	0	3
Anorexia	4	3	0	6
Puncture Wound	1	0	0	0
Rash (not at injection site)	0	1	0	0
Scrotal oedema	0	0	0	1
Skin Scab (not at injection site)	2	0	0	0
Smaller Pig	0	0	0	1
Swollen Limb	0	0	0	2
Tiredness	4	3	0	0
Unable to Stand/Ataxia	1	0	0	0
Unthrifty	1	6	0	13
Weakness	8	0	0	0
Death	0	1	0	0

USDA Approval Date	06/09/2020