Summary of Studies Supporting USDA Product Licensure

Establishment Name	Boehringer Ingelheim Animal Health USA Inc.
USDA Vet Biologics Establishment Number	124
Product Code	27H8.00
True Name	Mycoplasma Hyorhinis Bacterin
Tradename(s) / Distributor or Subsidiary (if different from manufacturer)	Ingelvac MycoMax - No distributor specified
Date of Compilation Summary	October 28, 2020

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>Efficacy</td></tr>
<tr><td>Pertaining to</td><td>Mycoplasma Hyorhinis Bacterin</td></tr>
<tr><td>Study Purpose</td><td>Demonstration of efficacy</td></tr>
<tr><td>Product Administration</td><td>Single intramuscular administration of vaccine</td></tr>
<tr><td>Study Animals</td><td>56 pigs, 3 weeks of age, divided into 28 vaccinates and 28 controls. 27 vaccinates and 27 controls were challenged</td></tr>
<tr><td>Challenge Description</td><td>Challenged with virulent M. hyorhinis, consecutively for 3 days on days 22, 23 and 24 after vaccination</td></tr>
<tr><td>Interval observed after challenge</td><td>Pigs were observed daily for 3 weeks after challenge</td></tr>
<tr><td>Results</td><td>Summary of Results Following Challenge:
<table>
<tr><th>Observation</th><th>Vaccinates (N=27)</th><th>Controls (n=27)</th></tr>
<tr><td>Pre-mortem Lameness[1]</td><td>4</td><td>15</td></tr>
<tr><td>Pre-mortem Respiratory Signs[2]</td><td>3</td><td>5</td></tr>
<tr><td>Pericarditis[3]</td><td>11</td><td>26</td></tr>
<tr><td>Pleuritis[3]</td><td>8</td><td>11</td></tr>
<tr><td>Arthritis</td><td>5</td><td>26</td></tr>
<tr><td>Peritonitis</td><td>6</td><td>14</td></tr>
<tr><td>Affected[4]</td><td>14</td><td>27</td></tr>
</table>
[1]Lameness was defined as visible lameness for 2 or more consecutive days.
[2]Respiratory signs were any observations of abnormal respiration or cough.
[3]Pleuritis and/or Pericarditis were coded as “Respiratory Distress”.
[4]A pig was considered affected following challenge if lameness was observed for 2 or more consecutive days or if respiratory distress (pleuritis or pericarditis), arthritis, or peritonitis was observed at necropsy.

Raw Data: shown on the following pages.</td></tr>
<tr><td>USDA Approval Date</td><td>February 10, 2016</td></tr>
</table>

Controls:

Pig #	Total Days Lame	>=2 consecutive days with lameness	Pericarditis Score 1=mild 2=moderate 3=severe	Pleuritis	Arthritis 1=positive	Peritonitis
8	18	yes	2	No	1	No
9	0	No	2	Yes	1	Yes
24	2	Yes	2	No	1	Yes
29	5	Yes	2	No	1	No
31	0	No	3	Yes	1	Yes
35	2	Yes	2	Yes	1	Yes
38	11	Yes	2	Yes	1	Yes
39	6	Yes	2	No	1	Yes
44	0	No	2	No	1	No
47	1	No	3	Yes	1	Yes
49	12	Yes	2	No	1	Yes
52	5	Yes	3	Yes	1	No
53	9	Yes	2	No	1	Yes
56	8	Yes	2	No	1	No
65	0	No	2	No	1	No
74	3	Yes	0	No	1	Yes
75	0	No	2	No	1	No
86	4	Yes	2	No	1	No
88	14	Yes	3	No	1	Yes
89	11	Yes	2	Yes	1	Yes
93	2	No	2	Yes	1	No
95	0	No	2	No	1	No
98	0	No	3	No	1	No
101	1	No	3	No	1	No
116	0	No	3	Yes	0	No
117	0	No	2	Yes	1	Yes
118	14	Yes	2	Yes	1	Yes

Vaccinates:

Pig #	Total Days Lame	>=2 consecutive days with lameness	Pericarditis Score 1=mild 2=moderate 3=severe	Pleuritis	Arthritis 1=positive	Peritonitis
2	0	No	2	No	0	No
7	0	No	0	No	0	No
12	2	No	2	No	1	Yes
18	7	Yes	2	Yes	0	No
20	0	No	0	No	0	No
21	0	No	0	No	0	No
22	0	No	0	No	0	No
27	0	No	0	No	0	No
34	0	No	0	No	0	No
40	0	No	0	No	0	No
42	0	No	3	Yes	0	Yes
57	0	No	0	Yes	0	No
58	0	No	2	Yes	1	Yes
60	0	No	2	Yes	1	No
61	0	No	3	No	0	No
69	1	No	0	No	1	Yes
77	0	No	0	No	0	No
79	0	No	0	No	0	No
81	0	No	0	No	0	No
85	4	Yes	3	Yes	0	Yes
90	0	No	3	Yes	0	Yes
102	1	No	2	No	0	No
104	3	Yes	2	Yes	1	No
106	5	Yes	0	No	0	No
112	0	No	0	No	0	No
114	0	No	0	No	0	No
120	0	No	0	No	0	No

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<tr><td>Study Type</td><td>Efficacy</td></tr>
<tr><td>Pertaining to</td><td>Mycoplasma Hyorhinis Bacterin</td></tr>
<tr><td>Study Purpose</td><td>Demonstration of duration of immunity</td></tr>
<tr><td>Product Administration</td><td>Single intramuscular administration of vaccine</td></tr>
<tr><td>Study Animals</td><td>64 pigs, 3 weeks of age, divided into 32 vaccinates and 32 controls (31 controls were challenged)</td></tr>
<tr><td>Challenge Description</td><td>Challenged with virulent M. hyorhinis, consecutively for 3 days 7 weeks after vaccination</td></tr>
<tr><td>Interval observed after challenge</td><td>Pigs were observed daily for 3 weeks after challenge</td></tr>
<tr><td>Results</td><td>Summary of Results Following Challenge:

<table>
<tr><th>Observation</th><th>Vaccinates (N=32)</th><th>Controls (n=31)</th></tr>
<tr><td>Pre-mortem Lameness[1]</td><td>6</td><td>19</td></tr>
<tr><td>Pre-mortem Respiratory Signs[2]</td><td>2</td><td>4</td></tr>
<tr><td>Pericarditis[3]</td><td>1</td><td>8</td></tr>
<tr><td>Arthritis</td><td>3</td><td>19</td></tr>
<tr><td>Affected[4]</td><td>11</td><td>26</td></tr>
</table>
[1]Lameness was defined as visible lameness for 2 or more consecutive days.
[2]Respiratory signs were any observations of abnormal respiration or cough.
[3] Pericarditis was coded as an indicator of Respiratory Disease and coded as “Respiratory Distress”.
[4] An animal was considered affected following challenge if, lameness was observed for 2 or more consecutive days, or respiratory distress, or pericarditis or arthritis were observed at necropsy.

Raw Data: shown on the following pages.</td></tr>
<tr><td>USDA Approval Date</td><td>October 14, 2016</td></tr>
</table>

Controls:

Pig ID	Respiratory signs (days duration)	Total Days Lame	Lameness >=2 consecutive days 1=yes, 0=no	Pericarditis Score 1=mild 2=moderate 3=severe	Arthritis 1=positive
21	0	0	0	2	0
24	0	0	0	0	1
33	0	0	0	0	0
36	0	0	0	0	0
37	0	4	1	0	1
41	0	7	1	0	1
44	AR (3)	15	1	0	1
45	AR (1)	15	1	2	1
49	0	13	1	0	1
56	0	13	1	0	0
64	0	5	1	0	1
66	0	6	1	0	1
68	0	7	1	0	1
70	0	0	0	2	1
72	0	14	1	0	1
75	0	0	0	0	0
77	0	22*	1	0	0
88	0	1	0	0	0
89	0	14	1	0	0
95	0	0	0	0	1
98	0	0	0	2	0
101	0	10	1	0	1
103	AR (1)	20	1	2	1
107	0	0	0	0	0
108	AR (1)	15	1	2	1
114	0	11	1	0	0
115	0	0	0	3	1
119	0	8	1	2	1
122	0	0	0	0	1
136	0	8	1	0	0
139	0	12	1	0	1

*lameness also observed prior to challenge
AR=Abnormal Respiration

Vaccinates:

Pig ID	Respiratory signs (days duration)	Total Days Lame	Lameness >=2 consecutive days 1=yes, 0=no	Pericarditis Score 1=mild 2=moderate 3=severe	Arthritis 1=positive
3	0	14	1	0	1
19	0	0	0	0	0
30	0	0	0	0	0
32	0	0	0	0	0
39	0	0	0	0	0
47	0	4	1	0	0
51	0	0	0	0	0
53	0	2	1	0	0
57	0	0	0	0	0
58	C (1)	0	0	0	0
61	0	13	1	0	0
71	0	0	0	0	0
79	0	0	0	0	0
82	0	0	0	0	0
84	0	0	0	0	0
86	0	5	1	0	0
92	C (2)	0	0	0	0
93	0	0	0	0	0
94	0	0	0	0	0
99	0	0	0	0	0
100	0	0	0	0	1
104	0	0	0	0	1
109	0	0	0	0	0
111	0	0	0	0	0
116	0	0	0	0	0
120	0	0	0	0	0
124	0	0	0	1	0
125	0	0	0	0	0
130	0	0	0	0	0
131	0	7	1	0	0
133	0	0	0	0	0
135	0	0	0	0	0

C=Cough

Study Type	Safety
Pertaining to	Mycoplasma Hyorhinis Bacterin
Study Purpose	To demonstrate safety under field conditions
Product Administration	Single intramuscular administration of vaccine
Study Animals	767 weaned pigs approximately 3 weeks of age
Challenge Description	Not applicable
Interval observed after challenge	Pigs were observed daily for 14 days following vaccination
Results	Number of pigs by site with any listed clinical observations, occurring at least once during the 14 day study duration: A total of 109 adverse events were observed. Four animals showed both injection site reactions and systemic reactions.

Clinical Observation	**IL Site N=242**	**MO Site N=250**	**NC Site 1 N=81**	**NC Site 2[1] N=194**	**Total Animals N=767**
Normal[2]	**206**	**239**	**60**	**157**	**662**
Loss of condition	24	2	6	14	46
Injection site rxn[3]	6	0	7	6	19
Mortality[4]	3	4	2	6	15
Diarrhea	3	0	0	11	14
Dyspnea	1	5	3	2	11
Cough	3	0	1	5	9
Lameness	1	4	2	2	9
Anaphylaxis[5]	0	1	6	1	8
Lethargy	5	0	1	1	7
Emesis[5]	0	0	0	6	6
Recumbency[5]	1	0	0	4	5
Ataxia[4]	1	0	0	3	4
Aural hematoma	0	0	2	0	2
Poor Coat Condition	1	0	1	0	2
Nystagmus	1	0	0	0	1
Paddling	1	0	0	0	1
Pallor	1	0	0	0	1
Pinnal reddening	0	0	0	1	1
Sneezing	0	0	1	0	1
Tachypnea	1	0	0	0	1

[1]Site 2 in North Carolina is an antibiotic free herd, treatment is limited.
[2]For "normal" a pig had to be observed to be without adverse events for the entire 14 days of the study.
[3]rxn= reaction. All injections site swellings observed were <1 inch in

	size. Swellings resolved within 1-3 days. [4]One death was attributed to anaphylactic reaction post vaccination. Two deaths attributed to *M. hyorhinis* systemic infection. Other deaths affirmed by investigator to have cause other than vaccination or *M. hyorhinis* infection. [5]These observations generally occurred immediately following vaccination. The majority recovered within 15 minutes, without intervention.
USDA Approval Date	October 5, 2017