



Summary of Studies Supporting USDA Product Licensure

Establishment Name	Boehringer Ingelheim Animal Health USA Inc.
USDA Vet Biologics Establishment Number	124
Product Code	19J1.00
True Name	Haemophilus Parasuis Vaccine, Avirulent Live Culture
Tradenname(s) / Distributor or Subsidiary (if different from manufacturer)	ParaSail - No distributor specified
Date of Compilation Summary	June 19, 2019

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	Haemophilus Parasuis Vaccine, Avirulent Live Culture																					
Study Purpose	Demonstration of efficacy																					
Product Administration	Single intramuscular administration of vaccine																					
Study Animals	69 pigs, 3 weeks of age, divided into 24 vaccinates and 20 controls.																					
Challenge Description	Challenged with virulent <i>H. parasuis</i> , on day 20 after vaccination																					
Interval observed after challenge	Pigs were observed daily for up to 4 days after challenge for clinical signs of Glasser's Disease. Tissues were examined day 4 post challenge for lesions of Glasser's Disease.																					
Results	<p>Summary of Results Following Challenge:</p> <table border="1"> <thead> <tr> <th>Observation</th> <th>Vaccinates (N=24)</th> <th>Controls (N=20)</th> </tr> </thead> <tbody> <tr> <td>Dead*</td> <td>5</td> <td>15</td> </tr> <tr> <td>Pleuritis</td> <td>6</td> <td>10</td> </tr> <tr> <td>Pericarditis</td> <td>3</td> <td>5</td> </tr> <tr> <td>Peritonitis</td> <td>8</td> <td>8</td> </tr> <tr> <td>Arthritis (swollen joints)</td> <td>1</td> <td>6</td> </tr> <tr> <td>Any lesion indicative of Glasser's</td> <td>8</td> <td>15</td> </tr> </tbody> </table> <p>*Found dead or humanely euthanized prior to the completion of the observation time</p> <p>Raw Data provided on the following pages</p>	Observation	Vaccinates (N=24)	Controls (N=20)	Dead*	5	15	Pleuritis	6	10	Pericarditis	3	5	Peritonitis	8	8	Arthritis (swollen joints)	1	6	Any lesion indicative of Glasser's	8	15
Observation	Vaccinates (N=24)	Controls (N=20)																				
Dead*	5	15																				
Pleuritis	6	10																				
Pericarditis	3	5																				
Peritonitis	8	8																				
Arthritis (swollen joints)	1	6																				
Any lesion indicative of Glasser's	8	15																				
USDA Approval Date	February 8, 2008																					

Lesions in Vaccinates:

Pig #	Dead*	Pleuritis	Pericarditis	Peritonitis	Arthritis
857	No	No	No	No	No
847	No	Yes	Yes	Yes	No
5983	Yes	Yes	No	Yes	No
810	No	Yes	Yes	Yes	No
852	Yes	Yes	No	Yes	No
838	Yes	No	No	Yes	No
801	No	Yes	Yes	Yes	No
5924	No	No	No	No	No
844	No	No	No	No	No
854	No	No	No	No	No
860	No	No	No	No	No
832	No	No	No	No	No
813	No	No	No	No	No
803	No	No	No	No	No
826	No	No	No	No	No
814	No	No	No	No	No
850	No	No	No	No	No
829	No	No	No	No	No
806	No	No	No	No	No
817	No	No	No	No	No
835	No	No	No	No	No
841	No	No	No	No	No
823	Yes	No	No	Yes	No
851	Yes	Yes	No	Yes	Yes

*Found dead or humanely euthanized prior to the conclusion of the study

Lesions in Controls:

Pig #	Dead	Pleuritis	Pericarditis	Peritonitis	Arthritis
845	Yes	Yes	Yes	Yes	No
839	Yes	Yes	Yes	Yes	No
855	Yes	Yes	No	Yes	No
804	Yes	Yes	Yes	Yes	Yes
827	No	No	No	No	No
848	Yes	Yes	Yes	Yes	No
811	Yes	Yes	Yes	No	No
833	Yes	No	No	No	Yes
836	No	No	No	No	No
5925	No	No	No	No	No
5922	No	No	No	No	No
815	No	No	No	No	No
5950	Yes	No	No	No	Yes
818	Yes	Yes	No	No	Yes
821	Yes	Yes	No	Yes	No
824	Yes	Yes	No	No	Yes
807	yes	Yes	No	Yes	No
5985	Yes	No	No	Yes	No
842	Yes	No	No	Yes	No
830	yes	No	No	No	No

*Found dead or humanely euthanized prior to the conclusion of the study

Daily Observation of Vaccinates Following Challenge

Pig ID	Day 0	Day1	Day 2	Day 3	Day 4
801	OK	OK	OK	OK	OK
803	OK	OK	OK	OK	OK
806	OK	OK	OK	OK	OK
810	OK	OK	OK	OK	OK
813	OK	OK	OK	OK	OK
814	OK	OK	OK	OK	OK
817	OK	OK	OK	OK	OK
823	OK	OK	Lethargy	Dead	NA
826	OK	OK	OK	OK	OK
829	OK	OK	OK	OK	OK
832	OK	OK	OK	OK	OK
835	OK	OK	OK	OK	OK
838	OK	OK	Lame (hind)	OK	RH Lame (Euth.)
841	OK	OK	OK	OK	OK
844	OK	OK	OK	OK	OK
847	OK	OK	OK	OK	OK
850	OK	OK	OK	OK	OK
851	OK	OK	Laterally recumbent (Euth.)	NA	NA
852	OK	OK	OK	OK	Gaunt (Euth.)
854	OK	OK	OK	OK	OK
857	OK	OK	OK	OK	OK
860	OK	OK	OK	OK	OK
5924	OK	OK	OK	OK	OK
5983	OK	OK	OK	OK	Dead

OK = No abnormal clinical signs observed

R = Right

L = Left

F = Fore

H = Hind

(Euth.) = Humanely Euthanized

Daily Observation of Controls Following Challenge

Pig ID	Day 0	Day1	Day 2	Day 3	Day 4
804	OK	OK	Increased Resp.	RH & LH Lameness	Increased Resp. Gaunt (Euth.)
807	OK	OK	Dead	Na	NA
811	OK	OK	RF Lameness	RH Lameness	Recumbent (Euth.)
815	OK	OK	OK	OK	OK
818	OK	OK	RF Lameness	LH Lameness (Euth.)	NA
821	OK	OK	Increased Resp. Lethargy (Euth.)	NA	NA
824	OK	OK	Recumbent (Euth.)	NA	NA
827	OK	OK	OK	OK	OK
830	OK	OK	Recumbent (Euth.)	NA	NA
833	OK	OK	OK	LH Lameness	LH/RH Lameness (Euth.)
836	OK	OK	OK	OK	OK
839	OK	OK	OK	LF Lameness	RH Lameness (Euth.)
842	OK	OK	Recumbent (Euth.)	NA	NA
845	OK	OK	OK	LF Lameness	Dead
848	OK	OK	Gaunt	RH Lameness Gaunt	Dead
855	OK	OK	OK	LH Lameness	RH Lameness (Euth.)
5922	OK	OK	OK	OK	OK
5925	OK	OK	OK	OK	OK
5950	OK	OK	OK	Recumbent (Euth.)	NA
5985	OK	OK	Dead	NA	NA

OK = No abnormal clinical signs observed

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Study Type	Safety																																																							
Pertaining to	All																																																							
Study Purpose	To demonstrate safety under field conditions																																																							
Product Administration	Single intramuscular administration of vaccine																																																							
Study Animals	1068 weaned pigs approximately 3 weeks of age																																																							
Challenge Description	Not applicable																																																							
Interval observed after challenge	Pigs were observed daily for 21 days following vaccination																																																							
Results	<p>Number of pigs by site with any listed clinical observations, occurring at least once during the 21 day study duration:</p> <table border="1"> <thead> <tr> <th>Clinical Observation</th> <th>MN Site N=372</th> <th>IN Site N=287</th> <th>NC Site N=409</th> <th>Total Animals N=1068</th> </tr> </thead> <tbody> <tr> <td>Normal¹</td> <td>299</td> <td>273</td> <td>401</td> <td>973</td> </tr> <tr> <td>Injection site rxn²</td> <td>67</td> <td>4</td> <td>1</td> <td>72</td> </tr> <tr> <td>Mortality⁴</td> <td>6</td> <td>0</td> <td>8</td> <td>14</td> </tr> <tr> <td>Dyspnea</td> <td>0</td> <td>0</td> <td>0</td> <td>7</td> </tr> <tr> <td>Anaphylaxis³</td> <td>0</td> <td>7</td> <td>0</td> <td>7</td> </tr> <tr> <td>Emesis³</td> <td>0</td> <td>7</td> <td>0</td> <td>7</td> </tr> <tr> <td>Recumbency³</td> <td>0</td> <td>7</td> <td>0</td> <td>7</td> </tr> <tr> <td>Ataxia³</td> <td>0</td> <td>7</td> <td>0</td> <td>7</td> </tr> <tr> <td>Tachypnea³</td> <td>0</td> <td>7</td> <td>0</td> <td>7</td> </tr> <tr> <td>Lethargy</td> <td>0</td> <td>1</td> <td>0</td> <td>1</td> </tr> </tbody> </table> <p>¹For “normal” a pig had to be observed to be without adverse events for the entire 21 days of the study.</p> <p>²All injections site swellings observed at Day 7 and resolved by Day 21, except for 1 pig (at MN Site) noted with swelling remaining at Day 21.</p> <p>³These observations generally occurred immediately following vaccination. The majority recovered within 15 minutes, without intervention.</p> <p>⁴ No mortality at any of the sites was associated with vaccination as affirmed by licensee.</p> <p>Loss of condition, poor coat condition, cough, lameness, diarrhea and sneezing were observed in the population and not associated with vaccination as affirmed by licensee. In some cases animals were affected at the time of vaccination.</p>	Clinical Observation	MN Site N=372	IN Site N=287	NC Site N=409	Total Animals N=1068	Normal¹	299	273	401	973	Injection site rxn ²	67	4	1	72	Mortality ⁴	6	0	8	14	Dyspnea	0	0	0	7	Anaphylaxis ³	0	7	0	7	Emesis ³	0	7	0	7	Recumbency ³	0	7	0	7	Ataxia ³	0	7	0	7	Tachypnea ³	0	7	0	7	Lethargy	0	1	0	1
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