



## Summary of Studies Supporting USDA Product Licensure

Establishment Name	Boehringer Ingelheim Animal Health USA Inc.
USDA Vet Biologics Establishment Number	124
Product Code	19S1.23
True Name	Porcine Reproductive & Respiratory Syndrome Vaccine, Respiratory Form, Modified Live Virus
Tradename(s) / Distributor or Subsidiary (if different from manufacturer)	
Date of Compilation Summary	November 10, 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.**

<b>Study Type</b>	Efficacy																		
<b>Pertaining to</b>	Porcine Reproductive and Respiratory Syndrome Virus (PRRSV)																		
<b>Study Purpose</b>	To demonstrate efficacy of the PRRSV, respiratory form																		
<b>Product Administration</b>	Administration of one dose intramuscularly																		
<b>Study Animals</b>	Forty pigs, 22-24 days old, divided into 20 vaccinates and 20 controls																		
<b>Challenge Description</b>	Challenged with virulent PRRS virus 28 days after vaccination																		
<b>Interval observed after challenge</b>	Pigs were observed for 14 days after challenge, and tissues were examined for lung lesions																		
<b>Results</b>	<p>The percentage of lung consolidation was evaluated.</p> <p>Summary of Results:</p> <table border="1"> <thead> <tr> <th>Treatment Group</th> <th>Minimum</th> <th>25<sup>th</sup> Percentile</th> <th>Median</th> <th>75<sup>th</sup> Percentile</th> <th>Maximum</th> </tr> </thead> <tbody> <tr> <td>Vaccinates</td> <td>0</td> <td>1</td> <td>1</td> <td>4</td> <td>27</td> </tr> <tr> <td>Controls</td> <td>2</td> <td>13</td> <td>28</td> <td>55</td> <td>81</td> </tr> </tbody> </table> <p>See tables on the following pages for data. The total percent lung lesion score was defined as the sum of the % lung pathology for the right and left apical, right and left cardiac, right and left diaphragmatic and intermediate lobes.</p>	Treatment Group	Minimum	25 <sup>th</sup> Percentile	Median	75 <sup>th</sup> Percentile	Maximum	Vaccinates	0	1	1	4	27	Controls	2	13	28	55	81
Treatment Group	Minimum	25 <sup>th</sup> Percentile	Median	75 <sup>th</sup> Percentile	Maximum														
Vaccinates	0	1	1	4	27														
Controls	2	13	28	55	81														
<b>USDA Approval Date</b>	June 18, 2009																		

### Lung Lesions Percent Pathology for Vaccinates

ID#	R. Apical	R. Cardiac	R. Diaphragmatic	L. Apical	L. Cardiac	L. Diaphragmatic	Intermediate	Total
477	0.2	0.5	0	0	0.2	0	0	0.9
482	0	0.2	0	0.2	0	0	0	0.4
485	0	0.2	0	0	0	0	0	0.2
486	0	0.5	0	0	1	0	0	1.5
487	0.2	0.5	0	0.1	0.5	0	0	1.3
488	0.1	0.2	0	0	0.5	0	0.1	0.9
489	0.5	3	0	1	3	0	0.5	8
490	0.2	1	0.5	2	1	1.25	0.5	6.45
491	0	0	0	0	0	0	0	0
492	0	0.5	0	0	0.2	0	0	0.7
505	0	0.2	0	0	0.5	0	0.5	1.2
507	0	0.5	0	0	0.2	0.25	0	0.95
516	0.2	0.1	0.25	0	0	0.25	0	0.8
517	0	0.5	0	0	0.2	0	0	0.7
518	0	1	1.25	0	0.1	0	0.5	2.85
524	0	0.5	0.5	0	0.2	0	0.2	1.4
525	0.2	1.5	0	5	8	12.5	0.2	27.4
526	4	5	2.5	3	3	5	3	25.5
528	0.5	5	2.5	0.2	0.5	0.5	0.5	9.7
529	0	0	0	0	0	0	0	0

### Lung Lesions Percent Pathology for Controls

ID#	R. Apical	R. Cardiac	R. Diaphragmatic	L. Apical	L. Cardiac	L. Diaphragmatic	Intermediate	Total
476	0	3	1.25	0	0.5	0.5	1	6.25
478	7	8	15	9	9	15	7	70
483	8	9	17.5	8	9	20	8	79.5
484	9	9	7.5	3	6	5	5	44.5
493	2	5	1.25	1	2	1.25	1	13.5
494	3	6	5	2	6	7.5	5	34.5
495	1	5	0.5	0	1	2.5	5	15
497	0.5	7	1.25	2	3	1.25	6	21
499	7	7	7.5	5	8	12.5	7	54
500	3	6	15	8	8	12.5	6	58.5
503	2.5	6	1.25	3	6	2.5	8	29.25
508	0.5	5	1.25	9.5	10	2.5	0.5	29.25
509	8	8	22.5	9	8	17.5	8	81
513	2	6	2.5	1	3	2.5	5	22
514	0.2	1	0.5	0	2	0.25	0.5	4.45
515	4	8	1.25	5	7	1.25	1	27.5
519	0	0.2	0.5	0.1	0.2	0.5	0.5	2
520	0.2	1	0.5	0.2	0.5	0.5	1.5	4.4
521	6	8	12.5	5	8	15	5	59.5
522	0.2	1.5	0.5	0.2	1.5	0.25	0	4.15

<b>Study Type</b>	Efficacy
<b>Pertaining to</b>	Porcine Reproductive and Respiratory Syndrome Virus (PRRS)
<b>Study Purpose</b>	Demonstration of a Duration of Immunity of at least 4 months against the respiratory form of PRRS disease
<b>Product Administration</b>	Administration of one dose intramuscularly to 1 month old pigs
<b>Study Animals</b>	
<b>Challenge Description</b>	Challenged with PRRS 110 days after vaccination
<b>Interval observed after challenge</b>	
<b>Results</b>	Study data were evaluated by USDA-APHIS prior to product licensure and met regulatory standards for acceptance at the time of submission. No data are published because this study was submitted to USDA-APHIS prior to January 1, 2007, and APHIS only requires publication of data submitted after that date.
<b>USDA Approval Date</b>	March 11, 1994

<b>Study Type</b>	Efficacy
<b>Pertaining to</b>	Porcine Reproductive and Respiratory Syndrome Virus (PRRS)
<b>Study Purpose</b>	Demonstration of minimum protective dose against the respiratory form of PRRS disease
<b>Product Administration</b>	Administration of one dose intramuscularly to 3-5 week old pigs
<b>Study Animals</b>	
<b>Challenge Description</b>	
<b>Interval observed after challenge</b>	
<b>Results</b>	Study data were evaluated by USDA-APHIS prior to product licensure and met regulatory standards for acceptance at the time of submission. No data are published because this study was submitted to USDA-APHIS prior to January 1, 2007, and APHIS only requires publication of data submitted after that date.
<b>USDA Approval Date</b>	March 11, 1994

<b>Study Type</b>	Safety
<b>Pertaining to</b>	Porcine Reproductive and Respiratory Syndrome Virus (PRRS)
<b>Study Purpose</b>	Demonstrate safety of product in non-pregnant gilts/sows under typical field conditions
<b>Product Administration</b>	Administration of one dose intramuscularly
<b>Study Animals</b>	
<b>Challenge Description</b>	
<b>Interval observed after challenge</b>	
<b>Results</b>	Study data were evaluated by USDA-APHIS prior to product licensure and met regulatory standards for acceptance at the time of submission. No data are published because this study was submitted to USDA-APHIS prior to January 1, 2007, and APHIS only requires publication of data submitted after that date.
<b>USDA Approval Date</b>	July 8, 1996