Summary of Studies Supporting USDA Product Licensure

Establishment Name	Boehringer Ingelheim Animal Health USA Inc.
USDA Vet Biologics Establishment Number	124
Product Code	19T1.20
True Name	Porcine Reproductive & Respiratory Syndrome Vaccine, Reproductive & Respiratory Forms, Modified Live Virus
Tradename(s) / Distributor or Subsidiary (if different from manufacturer)	Ingelvac PRRS MLV - Boehringer Ingelheim (Canada) Ltd. Ingelvac PRRS MLV - Boehringer Ingelheim (Thai) Ltd. Ingelvac PRRS MLV - Boehringer Ingelheim Animal Health Korea, Ltd. Ingelvac PRRS MLV - Boehringer Ingelheim Animal Health Mexico Ingelvac PRRS MLV - Boehringer Ingelheim Animal Health Philippines, Inc. Ingelvac PRRS MLV - Boehringer Ingelheim S.A. Ingelvac PRRS MLV - Boehringer Ingelheim Vetmedica GmbH Ingelvac PRRS MLV - No distributor specified Ingelvac PRRS MLV - PT Boehringer Ingelheim Indonesia Ingelvac PRRS vet. - No distributor specified
Date of Compilation Summary	September 30, 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.

Study Type	Efficacy
Pertaining to	Porcine Reproductive and Respiratory Syndrome Virus (PRRS)
Study Purpose	Demonstration of minimum protective dose against the respiratory form of PRRS disease
Product Administration	Administration of one dose intramuscularly to 3-5 week old pigs
Study Animals	
Challenge Description	
Interval observed after challenge	
Results	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.
USDA Approval Date	March 11, 1994

Study Type	Efficacy
Pertaining to	Porcine Reproductive and Respiratory Syndrome Virus (PRRS)
Study Purpose	Demonstration of efficacy against the reproductive form of PRRS disease
Product Administration	Administration of one dose intramuscularly
Study Animals	Ten gilts, divided into 5 vaccinates and 5 controls
Challenge Description	Pregnant gilts were challenged with PRRS virus 88 days after insemination
Interval observed after challenge	Through parturition for sow and piglet condition
Results	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.
USDA Approval Date	July 8, 1996

Study Type	Efficacy
Pertaining to	Porcine Reproductive and Respiratory Syndrome Virus (PRRS)
Study Purpose	Demonstration of efficacy against the reproductive form of PRRS disease
Product Administration	Administration of one dose intramuscularly
Study Animals	12 pre-breeding sows, divided into 8 vaccinates and 4 controls
Challenge Description	Challenged with PRRS 118 days after vaccination (90 days of gestation)
Interval observed after challenge	Through parturition for sow and piglet condition
Results	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.
USDA Approval Date	October 6, 1995

<table>
<tr><td>Study Type</td><td>Efficacy</td></tr>
<tr><td>Pertaining to</td><td>Porcine Reproductive and Respiratory Syndrome Virus (PRRSV)</td></tr>
<tr><td>Study Purpose</td><td>To demonstrate efficacy of the PRRSV, respiratory form</td></tr>
<tr><td>Product Administration</td><td>Administration of one dose intramuscularly</td></tr>
<tr><td>Study Animals</td><td>Forty pigs, 22-24 days old, divided into 20 vaccinates and 20 controls</td></tr>
<tr><td>Challenge Description</td><td>Challenged with virulent PRRS virus 28 days after vaccination</td></tr>
<tr><td>Interval observed after challenge</td><td>Pigs were observed for 14 days after challenge, and tissues were examined for lung lesions</td></tr>
<tr><td>Results</td><td>The percentage of lung consolidation was evaluated.

Summary of Results:
<table><tr><th>Treatment Group</th><th>Minimum</th><th>25th Percentile</th><th>Median</th><th>75th Percentile</th><th>Maximum</th></tr><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></table>
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.</td></tr>
<tr><td>USDA Approval Date</td><td>June 18, 2009</td></tr>
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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

Study Type	Efficacy
Pertaining to	Porcine Reproductive and Respiratory Syndrome Virus (PRRS)
Study Purpose	Demonstration of a Duration of Immunity of at least 4 months against the respiratory form of PRRS disease
Product Administration	Administration of one dose intramuscularly to 1 month old pigs
Study Animals	
Challenge Description	Challenged with PRRS 110 days after vaccination
Interval observed after challenge	
Results	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.
USDA Approval Date	March 11, 1994

Study Type	Safety
Pertaining to	Porcine Reproductive and Respiratory Syndrome Virus (PRRS)
Study Purpose	Demonstrate safety of product in pregnant gilts / and or sows under typical field conditions
Product Administration	Administration of one dose intramuscularly
Study Animals	Six hundred and eleven sows/gilts, divided into 308 vaccinates and 303 controls
Challenge Description	NA
Interval observed after challenge	Sows/ gilts were examined two hours after treatment and once daily until farrowing. Piglets were observed daily up to weaning.
Results	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.
USDA Approval Date	August 27, 2003

Study Type	Safety
Pertaining to	Porcine Reproductive and Respiratory Syndrome Virus (PRRS)
Study Purpose	Demonstrate safety of product in non-pregnant gilts/sows under typical field conditions
Product Administration	Administration of one dose intramuscularly
Study Animals	
Challenge Description	
Interval observed after challenge	
Results	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.
USDA Approval Date	July 8, 1996