Summary of Studies Supporting USDA Product Licensure

Establishment Name	Boehringer Ingelheim Animal Health USA Inc.
USDA Vet Biologics Establishment Number	124
Product Code	19T1.21
True Name	Porcine Reproductive & Respiratory Syndrome Vaccine, Reproductive & Respiratory Forms, Modified Live Virus
Tradename(s) / Distributor or Subsidiary (if different from manufacturer)	Ingelvac PRRS ATP - Boehringer Ingelheim (Canada) Ltd. Ingelvac PRRS ATP - No distributor specified
Date of Compilation Summary	March 05, 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 (PRRSV)
Study Purpose	Demonstration of efficacy against the respiratory form of PRRSV disease
Product Administration	Administration of one dose intramuscularly
Study Animals	Forty-four pigs, 3-5 weeks of age, divided into 22 vaccinates and 22 controls
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	February 24, 1999

Study Type	Efficacy
Pertaining to	Porcine Reproductive and Respiratory Syndrome Virus (PRRSV)
Study Purpose	Demonstration of a duration of immunity against respiratory form of at least 4 months
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	October 20, 1999

Study Type	Efficacy
Pertaining to	Porcine Reproductive and Respiratory Syndrome Virus (PRRSV)
Study Purpose	Demonstration of efficacy against the respiratory form of PRRSV disease
Product Administration	Administration of one dose intramuscularly
Study Animals	Forty pigs, 3 – 4 weeks of age, divided into 20 vaccinates and 20 controls
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	October 20, 1999

Study Type	Efficacy
Pertaining to	Porcine Reproductive and Respiratory Syndrome Virus (PRRSV)
Study Purpose	Demonstration of efficacy against the reproductive form of PRRSV disease
Product Administration	Administration of one dose intramuscularly 23 days prior to breeding
Study Animals	Thirty-nine pre-breeding sows, divided into 26 vaccinates, and 13 controls
Challenge Description	Sows were challenged intranasally with virulent heterologous PRRS virus at 88-92 days of gestation
Interval observed after challenge	Sows were observed daily through farrowing. Piglets were observed daily from farrowing until 14 days of age.
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 9, 2000

Study Type	Safety
Pertaining to	Porcine Reproductive and Respiratory Syndrome Virus (PRRSV)
Study Purpose	Demonstrate safety of product 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	May 17, 2005