Summary of Studies Supporting USDA Product Licensure

Establishment Name	Intervet Inc.
USDA Vet Biologics Establishment Number	165A
Product Code	48C5.21
True Name	Parvovirus Vaccine, Killed Virus, Erysipelothrix Rhusiopathiae-Leptospira Canicola-Grippotyphosa-Hardjo-Icterohaemorrhagiae-Pomona Bacterin
Tradename(s) / Distributor or Subsidiary (if different from manufacturer)	Magestic 7 - Intervet South Africa (Pty) Ltd. Magestic 7 - Merck Animal Health Magestic 7 - No distributor specified
Date of Compilation Summary	January 31, 2022

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	*Erysipelothrix rhusiopathiae*
Study Purpose	Establish efficacy against *Erysipelothrix rhusiopathiae*
Product Administration	2 dose IM route: 1st dose 6 weeks before breeding and 2nd dose (booster) 14-28 days later
Study Animals	Breeding pigs including sow, gilts, and boars
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.
USDA Approval Date	May 19, 2004

Study Type	Efficacy
Pertaining to	*Erysipelothrix rhusiopathiae*
Study Purpose	Establish duration of immunity of 121 days against *Erysipelothrix rhusiopathiae*
Product Administration	2 dose IM route: 1st dose 6 weeks before breeding and 2nd dose (booster) 14 -28 days later
Study Animals	Breeding pigs including sow, gilts, and boars
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.
USDA Approval Date	May 19, 2004

Study Type	Efficacy
Pertaining to	*Leptospira interrogans var canicola*
Study Purpose	Establish efficacy against *Leptospira interrogans var canicola*
Product Administration	2 dose IM route: 1st dose 6 weeks before breeding and 2nd dose (booster) 14 -28 days later
Study Animals	Breeding pigs including sow, gilts, and boars
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.
USDA Approval Date	May 19, 2004

Study Type	Efficacy
Pertaining to	*Leptospira interrogans var grippotyhposa*
Study Purpose	Establish efficacy against *Leptospira interrogans var grippotyhposa*
Product Administration	2 dose IM route: 1st dose 6 weeks before breeding and 2nd dose (booster) 14 -28 days later
Study Animals	Breeding pigs including sow, gilts, and boars
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.
USDA Approval Date	May 19, 2004

Study Type	Efficacy
Pertaining to	*Leptospira interrogans var hardjo*
Study Purpose	Establish efficacy against *Leptospira interrogans var hardjo*
Product Administration	2 dose IM route: 1st dose 6 weeks before breeding and 2nd dose (booster) 14 -28 days later
Study Animals	Breeding pigs including sow, gilts, and boars
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.
USDA Approval Date	May 19, 2004

Study Type	Efficacy
Pertaining to	*Leptospira interrogans var icterohaemorrhagiae*
Study Purpose	Establish efficacy against *Leptospira interrogans var icterohaemorrhagiae*
Product Administration	2 dose IM route: 1st dose 6 weeks before breeding and 2nd dose (booster) 14 -28 days later
Study Animals	Breeding pigs including sow, gilts, and boars
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.
USDA Approval Date	May 19, 2004

Study Type	Efficacy
Pertaining to	*Leptospira interrogans var pomona*
Study Purpose	Establish efficacy against *Leptospira interrogans var pomona*
Product Administration	2 dose IM route: 1st dose 6 weeks before breeding and 2nd dose (booster) 14 -28 days later
Study Animals	Breeding pigs including sow, gilts, and boars
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.
USDA Approval Date	May 19, 2004

Study Type	Efficacy
Pertaining to	*Parvovirus*
Study Purpose	Establish efficacy against Parvovirus
Product Administration	2 dose IM route: 1st dose 6 weeks before breeding and 2nd dose (booster) 14 -28 days later
Study Animals	Breeding pigs including sow, gilts, and boars
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.
USDA Approval Date	May 19, 2004

Study Type	Safety
Pertaining to	All fractions
Study Purpose	Establish field safety of vaccine under typical field conditions to breeding pigs
Product Administration	2 dose IM route: 1st dose 6 weeks before breeding and 2nd dose (booster) 14 -28 days later
Study Animals	Breeding pigs including sows, gilts, and boars
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.
USDA Approval Date	May 19, 2004