

Summary of Studies Supporting USDA Product Licensure

Establishment Name	Zoetis Inc.
USDA Vet Biologics Establishment Number	190
Product Code	4BC5.22
True Name	Parvovirus Vaccine, Killed Virus, Erysipelothrix Rhusiopathiae-Leptospira Bratislava-Canicola-Grippotyphosa- Hardjo-Icterohaemorrhagiae-Pomona Bacterin
Tradename(s) / Distributor or Subsidiary (if different from manufacturer)	FarrowSure B Gold - Zoetis Industria de Produtos FarrowSure Gold B - No distributor specified FarrowSure Gold B - Zoetis Argentina FarrowSure Gold B - Zoetis Mexico FarrowSure Gold B - Zoetis Russia FarrowSure Gold B - Zoetis South Africa Ltd Farrowsure Gold - Zoetis Colombia S.A.S. Zoetis (Thailand) Limited
Date of Compilation Summary	February 16, 2023

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.

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Study Type	Efficacy
Pertaining to	Erysipelothrix rhusiopathiae
Study Purpose	Demonstrate effectiveness against Erysipelothrix rhusiopathiae
Product Administration	
Study Animals	Swine
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 12, 2002

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Study Type	Efficacy
Pertaining to	Erysipelothrix rhusiopathiae
Study Purpose	Demonstrate a duration of immunity of at least 18 weeks against
	Erysipelothrix rhusiopathiae
Product Administration	
Study Animals	Swine
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	November 17, 2005

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Study Type	Efficacy
Pertaining to	Leptospira bratislava
Study Purpose	Demonstrate effectiveness against <i>Leptospira bratislava</i>
Product Administration	
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	August 25, 1988

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Study Type	Efficacy
Pertaining to	Leptospira canicola
Study Purpose	Demonstrate effectiveness against Leptospira canicola
Product Administration	
Study Animals	Swine
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 15, 1978

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Study Type	Efficacy
Pertaining to	Leptospira grippotyphosa
Study Purpose	Demonstrate effectiveness against Leptospira grippotyphosa
Product Administration	
Study Animals	Swine
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 15, 1978

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Study Type	Efficacy
Pertaining to	Leptospira hardjo
Study Purpose	Demonstrate effectiveness against <i>Leptospira hardjo</i>
Product Administration	
Study Animals	Swine
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 15, 1978

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Study Type	Efficacy
Pertaining to	Leptospira icterohaemorrhagiae
Study Purpose	Demonstrate effectiveness against <i>Leptospira</i>
_	icterohaemorrhagiae
Product Administration	
Study Animals	Swine
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 15, 1978

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Study Type	Efficacy
Pertaining to	Leptospira pomona
Study Purpose	Demonstrate effectiveness against <i>Leptospira pomona</i>
Product Administration	
Study Animals	Swine
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 15, 1978

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Study Type	Efficacy
Pertaining to	Porcine parvovirus
Study Purpose	Demonstrate effectiveness against porcine parvovirus
Product Administration	
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	September 15, 1980

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Study Type	Safety
Pertaining to	ALL
Study Purpose	Demonstrate safety under field conditions
Product Administration	
Study Animals	Swine
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, 2006

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