Summary of Studies Supporting USDA Product Licensure

Establishment Name	Zoetis Inc.
USDA Vet Biologics Establishment Number	190
Product Code	2775.00
True Name	Mycoplasma Hyopneumoniae Bacterin
Tradename(s) / Distributor or Subsidiary (if different from manufacturer)	RespiSure - No distributor specified RespiSure - Zoetis Argentina RespiSure - Zoetis Australia Pty Ltd RespiSure - Zoetis Colombia S.A.S. RespiSure - Zoetis Industria de Produtos RespiSure - Zoetis Japan Inc. RespiSure - Zoetis Korea RespiSure - Zoetis New Zealand Ltd RespiSure - Zoetis Russia Zoetis Mexico
Date of Compilation Summary	November 28, 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	*Mycoplasma hyopneumoniae*
Study Purpose	Demonstrate effectiveness against *Mycoplasma hyopneumoniae*
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	June 04, 1990

Study Type	Safety
Pertaining to	All
Study Purpose	Demonstrate safety under field conditions in piglets and pregnant sows/gilts
Product Administration	Two doses administered intramuscularly
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	April 25, 1991

Study Type	Safety
Pertaining to	All
Study Purpose	Demonstrate safety under field conditions in pregnant sows
Product Administration	Two doses administered intramuscularly at 6 weeks and 2 weeks prior to farrow
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	April 25, 1991

Study Type	Safety
Pertaining to	All
Study Purpose	Demonstrate safety under field conditions in piglets, and pregnant sows or gilts
Product Administration	Two doses administered intramuscularly
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	September 18, 1991

Study Type	Safety
Pertaining to	All
Study Purpose	Demonstrate safety under field conditions in piglets
Product Administration	Two doses administered intramuscularly
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	October 12, 1990