Summary of Studies Supporting USDA Product Licensure

Establishment Name	Boehringer Ingelheim Animal Health USA Inc.
USDA Vet Biologics Establishment Number	124
Product Code	19A1.00
True Name	Salmonella Choleraesuis Vaccine, Avirulent Live Culture
Tradename(s) / Distributor or Subsidiary (if different from manufacturer)	Enterisol SC-54 - Boehringer Ingelheim Animal Health Mexico Enterisol SC-54 - Boehringer Ingelheim Animal Health Philippines, Inc. Enterisol SC-54 - Boehringer Ingelheim Animal Health do Brasil Ltda Enterisol SC-54 - No distributor specified
Date of Compilation Summary	November 22, 2021

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	*Salmonella choleraesuis*
Study Purpose	To demonstrate efficacy against *Salmonella choleraesuis*
Product Administration	Single dose, Intranasal
Study Animals	41 pigs divided into 21 vaccinates and 20 controls
Challenge Description	Challenged with *Salmonella choleraesuis* 14 days after vaccination
Interval observed after challenge	Pigs were observed daily and tissues examined 14 days 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 require publication of data submitted after that date.
USDA Approval Date	February 25, 1993

Study Type	Efficacy
Pertaining to	*Salmonella choleraesuis*
Study Purpose	To demonstrate efficacy against *Salmonella choleraesuis*
Product Administration	Single dose, in Water
Study Animals	36 pigs divided into 24 vaccinates and 12 controls
Challenge Description	Challenged with *Salmonella choleraesuis* 2 weeks after vaccination
Interval observed after challenge	Pigs were observed daily for 14 days and tissues examined 14 days 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 require publication of data submitted after that date.
USDA Approval Date	April 4, 1994

Study Type	Efficacy
Pertaining to	*Salmonella choleraesuis*
Study Purpose	To demonstrate efficacy against *Salmonella choleraesuis*
Product Administration	Single dose, Intranasal; supporting both intranasal and oral (via drinking water) routes
Study Animals	30 pigs, 1 day old, divided into 20 vaccinates and 10 controls
Challenge Description	Challenged with *Salmonella choleraesuis* when pigs were 35 days of age
Interval observed after challenge	Pigs were observed daily for 14 days and tissues examined 14 days 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 require publication of data submitted after that date.
USDA Approval Date	October 19, 1995

Study Type	Safety
Pertaining to	ALL
Study Purpose	To demonstrate safety in field conditions
Product Administration	Single dose, Intranasal
Study Animals	3-week-old pigs
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 require publication of data submitted after that date.
USDA Approval Date	May 27, 1993

Study Type	Safety
Pertaining to	ALL
Study Purpose	To demonstrate safety in typical field conditions
Product Administration	Single dose, Intranasal; supporting both intranasal and oral (via drinking water) routes
Study Animals	1-day-old pigs
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 require publication of data submitted after that date.
USDA Approval Date	August 22, 1996