Summary of Studies Supporting USDA Product Licensure

Establishment Name	Intervet Inc.
USDA Vet Biologics Establishment Number	165A
Product Code	49C1.21
True Name	Porcine Rotavirus Vaccine, Modified Live Virus, Clostridium Perfringens Type C-Escherichia Coli Bacterin-Toxoid
Tradename(s) / Distributor or Subsidiary (if different from manufacturer)	Porcilis 2 4 3 - Merck Sharp & Dohme Saude Animal Ltda. ProSystem RCE - Intervet Veterinaria Chile Ltda - Merck Sharpe and Dohme (MSD) ProSystem RCE - Merck Animal Health ProSystem RCE - Merck Sharpe and Dohme (MSD) ProSystem RCE - No distributor specified ProSystem Rota - No distributor specified
Date of Compilation Summary	October 25, 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	Clostridium perfringens
Study Purpose	Establish efficacy of *Clostridium perfringens* fraction in nursing piglets when administered to pregnant swine
Product Administration	
Study Animals	Pregnant Gilts and Sows
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. Study data, however, are no longer available.
USDA Approval Date	June 10, 1988

Study Type	Efficacy
Pertaining to	*Escherichia coli* 987P
Study Purpose	Establish efficacy of *E. coli* 987P fraction in nursing piglets when administered to pregnant swine
Product Administration	
Study Animals	Pregnant Gilts and Sow
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. Study data, however, are no longer available.
USDA Approval Date	June 10, 1988

Study Type	Efficacy
Pertaining to	*Escherichia coli* F41
Study Purpose	Establish efficacy of *E. coli* F41 fraction in nursing piglets when administered to pregnant swine
Product Administration	
Study Animals	Pregnant Gilts and Sows
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. Study data, however, are no longer available.
USDA Approval Date	June 10, 1988

Study Type	Efficacy
Pertaining to	*Escherichia coli* K88
Study Purpose	Establish efficacy of *E. coli* K88 fraction in nursing piglets when administered to pregnant swine
Product Administration	
Study Animals	Pregnant Gilts and Sows
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. Study data, however, are no longer available.
USDA Approval Date	June 10, 1988

Study Type	Efficacy
Pertaining to	*Escherichia coli* K99
Study Purpose	Establish efficacy of *E. coli* K99 fraction in nursing piglets when administered to pregnant swine
Product Administration	
Study Animals	Pregnant Gilts and Sows
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. Study data, however, are no longer available.
USDA Approval Date	June 10, 1988

Study Type	Efficacy
Pertaining to	*Escherichia.coli 987P*
Study Purpose	Establish efficacy of the vaccine against colibacillosis including effect on mortality and clinical disease caused by *E. coli* in nursing piglets
Product Administration	
Study Animals	Nursing piglets farrowed from pregnant swine administered product
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	June 10, 1988

Study Type	Efficacy
Pertaining to	Rotavirus
Study Purpose	Establish efficacy against Rotavirus in nursing piglets when administered to pregnant swine
Product Administration	Pregnant Sows and gilts
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. Study data, however, are no longer available.
USDA Approval Date	January 12, 1982

Study Type	Safety
Pertaining to	*All fractions*
Study Purpose	To demonstrate safety of under field condition in pregnant swine
Product Administration	
Study Animals	Pregnant gilts and sow
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	December 27, 1993