Summary of Studies Supporting USDA Product Licensure

Establishment Name	Intervet Inc.
USDA Vet Biologics Establishment Number	165A
Product Code	19H1.20
True Name	Porcine Rotavirus-Transmissible Gastroenteritis Vaccine, Modified Live Virus
Tradename(s) / Distributor or Subsidiary (if different from manufacturer)	ProSystem TGE/Rota - Merck Animal Health ProSystem TGE/Rota - No distributor specified
Date of Compilation Summary	March 01, 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	Transmissible Gastroenteritis (TGE)
Study Purpose	Establish efficacy against TGE Virus 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	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
Study Purpose	Demonstrate safety under typical field conditions
Product Administration	Total 3 doses: 1 dose via oral route given at 5 and 3 weeks before farrowing followed by 1 dose intramuscular route at 1 week pre-farrow.
Study Animals	Sows and gilts
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	April 6, 1984

Study Type	Safety
Pertaining to	All
Study Purpose	Demonstrate safety under typical field conditions
Product Administration	One dose at 5 weeks before farrowing, repeat at 2 weeks pre-farrow
Study Animals	Sows and gilts
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	April 6, 1984