



Summary of Studies Supporting USDA Product Licensure

Establishment Name	Intervet Inc.
USDA Vet Biologics Establishment Number	165A
Product Code	19U5.P1
True Name	Porcine Epidemic Diarrhea Vaccine, RNA Particle Platform
Tradename(s) / Distributor or Subsidiary (if different from manufacturer)	Intervet Mexico S.A. de C.V. Merck Animal Health Merck Sharpe and Dohme (MSD)
Date of Compilation Summary	December 28, 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	Safety			
Pertaining to	All			
Study Purpose	Demonstrate safety of product under typical use conditions.			
Product Administration	2 doses administered intramuscularly (IM) 3 weeks apart.			
Study Animals	400 pigs, 3 weeks of age, distributed among 2 study sites.			
Challenge Description	Not applicable			
Interval observed after challenge	Animals were observed one hour after administration for immediate adverse reactions, at 48-72 hours and on 7 days post-vaccination for local or systemic reactions after each administration. 21 days post-vaccination the injection sites were palpated for all animals.			
Results	Frequency of adverse events out of 799* possible (400 pigs)		Number	
	Injection site swelling**		7	
	Lethargy		6	
	Death***		7	
	Anorexia		5	
	Lameness		4	
	Swollen join		3	
	Loss of condition		6	
	Cough		1	
	No Adverse Events		755	
	*1 pig died prior to 2 nd vaccination **3 resolved by the end of study, 5 were reported at the end of the study after 2 nd vaccination ***Deaths affirmed by study cooperator as not attributable to vaccine.			
	USDA Approval Date	May 15, 2014		