



Summary of Studies Supporting USDA Product Licensure

Establishment Name	Intervet Inc.
USDA Vet Biologics Establishment Number	165A
Product Code	1891.R2
True Name	Pseudorabies Vaccine, Modified Live Virus
Tradenname(s) / Distributor or Subsidiary (if different from manufacturer)	PRV/Marker Gold - Merck Animal Health PRV/Marker Gold - Merck Sharpe and Dohme (MSD) PRV/Marker Gold - 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	<i>Pseudorabies virus</i>
Study Purpose	Efficacy against disease caused by pseudorabies
Product Administration	3-day old pigs, one dose, IM
Study Animals	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 requires publication of data submitted after that date.
USDA Approval Date	March 10, 1992

Study Type	Efficacy
Pertaining to	<i>Pseudorabies virus</i>
Study Purpose	Efficacy against disease caused by pseudorabies
Product Administration	3-day old pigs, Intranasal
Study Animals	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. Study data, however, are no longer available
USDA Approval Date	March 10, 1992

Study Type	Safety
Pertaining to	<i>Pseudorabies virus</i>
Study Purpose	Safety in pigs being reared under typical husbandry conditions.
Product Administration	Total of 1547 pigs, 3 day old- to 10 week old pigs and pregnant pigs , IM and IN (intranasally).
Study Animals	Nursing piglets(3-10 day old), Weaned Pigs (4-10 week old) and Pregnant pigs (various stages of gestation) from 6 states
Challenge Description	None
Interval observed after challenge	Animals were observed for 21 days following vaccination for adverse reactions
Results	Total of 1547 pigs were vaccinated and adverse reactions were not reported in any of the animals. Refer to Table 1 for nursing pigs , Table 2 for weaned pigs and Table 3 for breeding/pregnant pigs.
USDA Approval Date	March 3, 1992

TABLE 1
VACCINATION OF NURSING PIGS

Herd and Location	Age at Vaccination	Number Vaccinated	Vaccine Serial	Post-Vaccinal Reactions
Site 1	8 days	10 - I.M. 11 - I.N.	05102 05102	None None
Site 2	3-10 days	20 - I.M. 20 - I.N.	05102 05102	None None
Site 3	11 days 11-12 days	30 - I.M. 30 - I.N.	05102 05102	None None
Site 4	7-10 days	21 - I.M. 21 - I.N.	05102 05102	None None

TABLE 2
VACCINATION OF WEANED PIGS

Herd and Location	Age at Vaccination	Number Vaccinated	Vaccine Serial	Post-Vaccinal Reactions
Site 1	10 weeks	50 - I.M. 50 - I.N.	05102 05102	None None
Site 2	5-6 weeks	50 - I.M. 50 - I.N.	05102 05102	None None
Site 3	5-6 weeks	50 - I.M. 50 - I.N.	05102 05102	None None
Site 4	3 weeks	5 - I.M.	05102	None
Site 5	4-5 weeks	47 - I.M. 53 - I.N.	05102 05103	None None
Site 6	6-8 weeks	50 - I.M. 50 - I.N.	05102 05102	None None

TABLE 3
VACCINATION OF BREEDING ANIMALS

Herd and Location	Age/Parity at Vaccination	Number Vaccinated	Vaccine Serial	Post-Vaccinal Reactions
Site 1	Parity 4-8	10 sows	05102 05102	None None
Site 2	Parity 1-4	10	05102	None
Site 3	Parity 1-4	10	05102	None
Site 4	Parity 0	70	05102	None
Site 5	Parity 0-2	10	05103 05103	None None
Site 6	Parity 0-5	24	05102	None
Site 7	Parity 0-10	42	05102	None
Site 8	Parity 2-5	25	05102	None
Site 9	Parity 0-4	25	05102	None
Site 10	0-5	58	02102	None
Site 11	Parity 0-5	35	05102	None
Site 12	6-8 mo. gilts	417	05103 05103	None None
Site 13	6 mo. gilts	100	05102	None