



Summary of Studies Supporting USDA Product Licensure

Establishment Name	Intervet Inc.
USDA Vet Biologics Establishment Number	165A
Product Code	1431.5E
True Name	Coccidiosis Vaccine, Live Oocysts
Tradenname(s) / Distributor or Subsidiary (if different from manufacturer)	Coccivac-D - Merck Sharp & Dohme Saude Animal Ltda. Coccivac-D - No distributor specified Coccivac-D2 - International Free Trade Co. Coccivac-D2 - International Free Trade Co. - Merck Sharpe and Dohme (MSD) Coccivac-D2 - Intervet Israel Ltd - Merck Sharpe and Dohme (MSD) Coccivac-D2 - Intervet Mexico S.A. de C.V. Coccivac-D2 - Intervet Mexico S.A. de C.V. - Merck Sharpe and Dohme (MSD) Coccivac-D2 - MSD Salud Animal Columbia S.A.S. - Merck Sharpe and Dohme (MSD) Coccivac-D2 - Merck Animal Health Coccivac-D2 - No distributor specified Merck Animal Health Merck Sharpe and Dohme (MSD)
Date of Compilation Summary	October 15, 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	Coccidiosis Vaccine, Live Oocysts, Chicken Isolates
Study Purpose	To demonstrate effectiveness against Coccidiosis
Product Administration	Coarse Spray
Study Animals	Chickens
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	November 24, 1998

Study Type	Efficacy
Pertaining to	Coccidiosis Vaccine, Live Oocysts, Chicken Isolates
Study Purpose	To demonstrate effectiveness against Coccidiosis
Product Administration	Feed Spray
Study Animals	Chickens
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	August 8, 1996

Study Type	Safety
Pertaining to	Coccidiosis Vaccine, Live Oocysts, Chicken Isolates
Study Purpose	Demonstrate safety under typical field conditions
Product Administration	Feed Spray
Study Animals	Chickens
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	1996

Study Type	Safety					
Pertaining to	All fractions					
Study Purpose	Field Safety					
Product Administration	Single dose, administered via spray cabinet					
Study Animals	Commercial Broilers at one day of age. 4 independent study sites.					
Challenge Description	NA					
Interval observed after challenge	Chicks were followed through grow-out to slaughter.					
Results		Number of chickens	Mortality (%)		Condemnation (%)	
	Site		Vaccinates	Controls	Vaccinates	Controls
	1	43,119	4.78	3.23	0.27	0.07
	2	44,600	4.14	4.66	0.20	0.37
	3	43,400	5.40	5.02	0.34	0.27
	4	90,437	1.17	1.78	0.09	0.13
*Mortality and condemnation rates were within normal limits for each site						
USDA Approval Date	November 23, 2010					