

Summary of Studies Supporting USDA Product Licensure

Establishment Name	Zoetis Inc.
USDA Vet Biologics Establishment Number	190
Product Code	8601.02
True Name	Tetanus Toxoid
Tradename(s) / Distributor or Subsidiary (if different from manufacturer)	Zoetis (Thailand) Limited Zoetis Mexico
Date of Compilation Summary	May 26, 2023

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.

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Study Type	Efficacy				
Pertaining to	Tetanus Toxoid				
Study Purpose	Efficacy against Clostridum tetani in cows, horses, pigs, and sheep				
Product Administration					
Study Animals	Guinea pigs				
Challenge Description	NA				
Interval observed after	NA				
challenge					
Results	Efficacy requirements were evaluated by USDA-APHIS prior to product licensure and met regulatory standards for acceptance per 9 CFR 113.114.				
USDA Approval Date	04/19/1984				

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Study Type	Safety			
Pertaining to	All fractions			
Study Purpose	To demonstrate safety under field conditions.			
Product Administration				
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. 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 19, 1992			

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Study Type	Safety			
Pertaining to	All fractions			
Study Purpose	To demonstrate safety under field conditions.			
Product Administration				
Study Animals	Swine and Sheep			
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	12/10/1992			

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Study Type	Safety					
Pertaining to	ALL					
Study Purpose		in pregnant mare	es in the third	trimester under field		
study 1 di post	To demonstrate safety in pregnant mares in the third trimester under field conditions.					
Product	Single dose administered intramuscularly during the third trimester of					
Administration	pregnancy.	ica miramascara	if during the	unia uninester or		
Study Animals		nregnant mares i	n their third tr	imester were enrolled		
Study Allillais	A total of 282 healthy pregnant mares in their third trimester were enrolled in one of two treatment groups in two distinct geographical locations. The					
	in one of two treatment groups in two distinct geographical locations. The animals were distributed as follows: Controls, $n = 57$, Vaccinated, $n = 225$.					
Challenge	N/A	ca as follows. Co	mirois, ii 37	, vaccinated, ii 223.		
Description	1071					
Interval	Clinical observations v	were performed o	n all mares fo	er at least 30 minutes		
observed after	following vaccination.					
last treatment	daily for general health					
last treatment	weekly until foaling.	11 101 21 days 1011	owing vaccina	ation and at least once		
	Mares were observed	-				
	weekly for general hea	alth until they we	re at least 21 o	lays of age.		
Results	Mare Abnormal Heal	th Events				
	Number of	Mares				
	Total Enrolled	282	Mares with			
			no AE* (%)			
	Controls	57	54 (94.7%)	` '		
	Vaccinated	225 214 (95.1) 11 (4.9%)		
	*AE= Adverse Events					
		1				
	Treatment /	Mare Abnorm	nal Health	Number of Mares /		
	Number of	Mare Abnorm		Percent of		
		Even	ts	Percent of Vaccinations		
	Number of Vaccinations	Even Agalac	ts etia	Percent of Vaccinations 1 / 1.75%		
	Number of Vaccinations Controls	Even Agalad Death	ts etia	Percent of Vaccinations 1 / 1.75% 1 / 1.75%		
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	Number of Vaccinations Controls	Agalac Death Dystoc Fractu	etia n ¹ cia	Percent of Vaccinations 1 / 1.75% 1 / 1.75% 1 / 1.75% 1 / 1.75%		
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	Number of Vaccinations Controls	Agalace Death Dystoce Fractu Abdomina Decreased	ts ctia n¹ cia ire il Pain Appetite	Percent of Vaccinations 1 / 1.75% 1 / 1.75% 1 / 1.75% 1 / 1.75% 1 / 0.44% 1 / 0.44%		
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	Number of Vaccinations Controls (57 animals) Vaccinated	Agalace Death Dystoce Fractur Abdomina Decreased A Dystoce Fractur Dystoce Fractur	etia cia cia lre al Pain Appetite cia	Percent of Vaccinations 1 / 1.75% 1 / 1.75% 1 / 1.75% 1 / 1.75% 1 / 1.75% 1 / 0.44% 1 / 0.44% 3 / 1.33% 1 / 0.44%		
	Number of Vaccinations Controls (57 animals) Vaccinated (Product Code	Agalace Death Dystoce Fractur Abdomina Decreased A Dystoce Fractur Injection Site	etia etia etia etia etia etia etia etia	Percent of Vaccinations 1 / 1.75% 1 / 1.75% 1 / 1.75% 1 / 1.75% 1 / 0.44% 1 / 0.44% 3 / 1.33% 1 / 0.44% 1 / 0.44%		
	Number of Vaccinations Controls (57 animals) Vaccinated	Agalace Death Dystoce Fractu Abdomina Decreased A Dystoce Fractu Injection Site Lacerate	etia etia etia etia etia etia etia etia	Percent of Vaccinations 1 / 1.75% 1 / 1.75% 1 / 1.75% 1 / 1.75% 1 / 0.44% 1 / 0.44% 3 / 1.33% 1 / 0.44% 1 / 0.44% 1 / 0.44% 1 / 0.44%		
	Number of Vaccinations Controls (57 animals) Vaccinated (Product Code 48R5.20; 225	Agalace Death Dystoce Fracture Abdominate Decreased	etia cia cia cia lre dl Pain Appetite cia lre Swelling tion ess	Percent of Vaccinations 1 / 1.75% 1 / 1.75% 1 / 1.75% 1 / 1.75% 1 / 0.44% 1 / 0.44% 3 / 1.33% 1 / 0.44% 1 / 0.44%		
	Number of Vaccinations Controls (57 animals) Vaccinated (Product Code 48R5.20; 225	Agalace Death Dystoce Fractu Abdomina Decreased A Dystoce Fractu Injection Site Lacerate	etia etia etia etia etia etia etia etia	Percent of Vaccinations 1 / 1.75% 1 / 1.75% 1 / 1.75% 1 / 1.75% 1 / 0.44% 1 / 0.44% 3 / 1.33% 1 / 0.44% 1 / 0.44% 1 / 0.44% 2 / 0.89%		
	Number of Vaccinations Controls (57 animals) Vaccinated (Product Code 48R5.20; 225	Agalace Death Dystoce Fracture Abdomina Decreased of Dystoce Fracture Injection Site Lacerate Lamene Nasal Disc	etia cia cia cia cia cia cia cia cia cia	Percent of Vaccinations 1 / 1.75% 1 / 1.75% 1 / 1.75% 1 / 1.75% 1 / 0.44% 1 / 0.44% 3 / 1.33% 1 / 0.44% 1 / 0.44% 1 / 0.44% 2 / 0.89% 1 / 0.44%		
	Number of Vaccinations Controls (57 animals) Vaccinated (Product Code 48R5.20; 225 animals)	Agalace Death Dystoce Fractur Abdomina Decreased A Dystoce Fractur Injection Site Lacerate Lamene Nasal Disc Placental Ab Retained P	etia cia cia cia cia cia cia cia cia cia	Percent of Vaccinations 1 / 1.75% 1 / 1.75% 1 / 1.75% 1 / 1.75% 1 / 0.44% 1 / 0.44% 3 / 1.33% 1 / 0.44% 1 / 0.44% 2 / 0.89% 1 / 0.44% 1 / 0.44% 1 / 0.44%		
	Number of Vaccinations Controls (57 animals) Vaccinated (Product Code 48R5.20; 225	Agalace Death Dystoce Fractur Abdomina Decreased A Dystoce Fractur Injection Site Lacerate Lamene Nasal Disc Placental Ab Retained P	etia cia cia cia cia cia cia cia cia cia	Percent of Vaccinations 1 / 1.75% 1 / 1.75% 1 / 1.75% 1 / 1.75% 1 / 0.44% 1 / 0.44% 3 / 1.33% 1 / 0.44% 1 / 0.44% 2 / 0.89% 1 / 0.44% 1 / 0.44% 1 / 0.44%		

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	There was only one adverse event that was attributable to IVP which was an injection site reaction in a vaccinate that was observed the day after vaccination and resolved the following day. Birth Outcome Summary from Vaccinated Mares					
	Number of Foals		Live Foals	Foal died during or immediately post- parturition		
	Total Foals	280¹	273 (97.50%)	7 (2.50%)		
	Controls	56	53 (94.64%)	3 (5.36%)		
	Vaccinated	224	220 (98.21%)	4 (1.79%)		
	Two mares (one vaccinate and one control) were removed prior to foaling due to fractured legs.					
USDA Approval Date	March 02, 2022					

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