



Summary of Studies Supporting USDA Product Licensure

Establishment Name	Boehringer Ingelheim Animal Health USA Inc.
USDA Vet Biologics Establishment Number	124
Product Code	4990.00
True Name	Trichomonas Foetus Vaccine, Killed Protozoa-Campylobacter Fetus-Leptospira Canicola-Grippotyphosa-Hardjo-Icterohaemorrhagiae-Pomona Bacterin
Tradename(s) / Distributor or Subsidiary (if different from manufacturer)	TrichGuard V5L - Zoetis Inc. TrichGuard V5L HB - No distributor specified
Date of Compilation Summary	October 07, 2019

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>Campylobacter fetus</i>
Study Purpose	Demonstration of efficacy against <i>Campylobacter fetus</i>
Product Administration	
Study Animals	Bovine
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 7, 1992

Study Type	Efficacy
Pertaining to	<i>Leptospira canicola</i>
Study Purpose	Demonstration of efficacy against <i>Leptospira canicola</i>
Product Administration	
Study Animals	Bovine
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 7, 1992

Study Type	Efficacy
Pertaining to	<i>Leptospira grippotyphosa</i>
Study Purpose	Demonstration of efficacy against <i>Leptospira grippotyphosa</i>
Product Administration	
Study Animals	Bovine
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 7, 1992

Study Type	Efficacy
Pertaining to	<i>Leptospira hardjo</i>
Study Purpose	Demonstration of efficacy against <i>Leptospira hardjo</i>
Product Administration	
Study Animals	Bovine
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 7, 1992

Study Type	Efficacy																								
Pertaining to	<i>Leptospira hardjo</i>																								
Study Purpose	Demonstration of efficacy against <i>Leptospira borgpetersenii</i> serovar <i>hardjo-bovis</i>																								
Product Administration	Two doses, 21 days apart, Subcutaneously																								
Study Animals	27 bovine (14 vaccinates, 13 controls), 6-10 month old heifers																								
Challenge Description	Challenged with <i>Leptospira borgpetersenii</i> serovar <i>hardjo-bovis</i> on 62, 63 and 64 days after the second vaccination																								
Interval observed after challenge	Cattle were observed daily for 10 days after challenge, then three times weekly for 7 weeks. Urine samples were taken weekly for 8 weeks. On day 62 and 63 after challenge, kidneys were cultured for <i>Leptospira</i> isolation.																								
Results	<p>Results of the study are summarized as follows:</p> <p>Urine cultures were positive for <i>Leptospira</i> on at least one day:</p> <table border="1"> <thead> <tr> <th>Group</th> <th># Positive / Total</th> <th>% Affected</th> <th>% Unaffected</th> </tr> </thead> <tbody> <tr> <td>Vaccinates</td> <td>0 / 14</td> <td>0%</td> <td>100%</td> </tr> <tr> <td>Controls</td> <td>13 / 13</td> <td>100%</td> <td>0%</td> </tr> </tbody> </table> <p>Kidney cultures were positive for <i>Leptospira</i> at necropsy:</p> <table border="1"> <thead> <tr> <th>Group</th> <th># Positive / Total</th> <th>% Affected</th> <th>% Unaffected</th> </tr> </thead> <tbody> <tr> <td>Vaccinates</td> <td>0 / 14</td> <td>0%</td> <td>100%</td> </tr> <tr> <td>Controls</td> <td>13 / 13</td> <td>100%</td> <td>0%</td> </tr> </tbody> </table> <p>See tables on the following pages for data.</p>	Group	# Positive / Total	% Affected	% Unaffected	Vaccinates	0 / 14	0%	100%	Controls	13 / 13	100%	0%	Group	# Positive / Total	% Affected	% Unaffected	Vaccinates	0 / 14	0%	100%	Controls	13 / 13	100%	0%
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USDA Approval Date	January 14, 2015																								

Urine and Kidney Cultures:

Vaccinates:

Animal #	Weekly Urine Observations								Overall Urine Outcome	Overall Kidney Outcome
	1	2	3	4	5	6	7	8		
1	-	-	-	-	-	-	-	-	Negative	Negative
4	-	-	-	-	-	-	-	-	Negative	Negative
13	-	-	-	-	-	-	-	-	Negative	Negative
16	-	-	-	-	-	-	-	-	Negative	Negative
19	-	-	-	-	-	-	-	-	Negative	Negative
25	-	-	-	-	-	-	-	-	Negative	Negative
31	-	-	-	-	-	-	-	-	Negative	Negative
35	-	-	-	-	-	-	-	-	Negative	Negative
48	-	-	-	-	-	-	-	-	Negative	Negative
54	-	-	-	-	-	-	-	-	Negative	Negative
57	-	-	-	-	-	-	-	-	Negative	Negative
61	-	-	-	-	-	-	-	-	Negative	Negative
65	-	-	-	-	-	-	-	-	Negative	Negative
66	-	-	-	-	-	-	-	-	Negative	Negative

Controls:

Animal #	Weekly Urine Observations								Overall Urine Outcome	Overall Kidney Outcome
	1	2	3	4	5	6	7	8		
6	-	+	+	+	+	+	+	+	Positive	Positive
10	-	+	+	+	+	+	+	+	Positive	Positive
18	-	+	+	+	+	+	+	+	Positive	Positive
28	-	+	+	+	+	+	+	+	Positive	Positive
32	-	-	+	+	+	+	+	+	Positive	Positive
41	-	-	+	+	+	+	+	+	Positive	Positive
43	-	+	+	+	+	+	+	+	Positive	Positive
49	-	+	+	+	+	+	+	+	Positive	Positive
50	-	-	+	+	+	+	-	+	Positive	Positive
59	-	+	+	+	+	+	+	+	Positive	Positive
60	-	+	+	+	+	+	+	+	Positive	Positive
67	-	-	+	+	+	+	+	+	Positive	Positive
68	-	+	+	+	+	+	+	+	Positive	Positive

Weekly Urine Observations:

- = Urine sample was negative for *Leptospira*

+ = Urine sample was positive for *Leptospira* (highlighted yellow)

Overall Urine / Kidney Outcome:

Negative = All urine / kidney samples were negative for *Leptospira*

Positive = At least one urine / kidney sample was positive for *Leptospira* (highlighted yellow)

Study Type	Efficacy
Pertaining to	<i>Leptospira icterohaemorrhagiae</i>
Study Purpose	Demonstration of efficacy against <i>Leptospira icterohaemorrhagiae</i>
Product Administration	
Study Animals	Bovine
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 7, 1992

Study Type	Efficacy
Pertaining to	<i>Leptospira pomona</i>
Study Purpose	Demonstration of efficacy against <i>Leptospira pomona</i>
Product Administration	
Study Animals	Bovine
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 7, 1992

Study Type	Efficacy
Pertaining to	<i>Trichomonas foetus</i>
Study Purpose	Demonstration of efficacy against disease caused by <i>Trichomonas foetus</i> including shedding of <i>T. foetus</i>
Product Administration	
Study Animals	Bovine
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	May 17, 1991

Study Type	Safety
Pertaining to	All fractions
Study Purpose	To demonstrate safety under field conditions
Product Administration	
Study Animals	Bovine
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	January 7, 1992