



Summary of Studies Supporting USDA Product Licensure

Establishment Name	Boehringer Ingelheim Animal Health USA Inc.
USDA Vet Biologics Establishment Number	124
Product Code	2665.00
True Name	Leptospira Canicola-Grippotyphosa-Hardjo-Icterohaemorrhagiae-Pomona Bacterin
Tradename(s) / Distributor or Subsidiary (if different from manufacturer)	Citadel L5 - No distributor specified Citadel L5 HB - No distributor specified Lepto 5 Citadel - Boehringer Ingelheim Animal Health Mexico
Date of Compilation Summary	November 02, 2020

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>Leptospira canicola</i>
Study Purpose	Demonstration of efficacy against leptospirosis caused by <i>Leptospira canicola</i>
Product Administration	
Study Animals	Bovine and Porcine
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	July 14, 1981

Study Type	Efficacy
Pertaining to	<i>Leptospira grippotyphosa</i>
Study Purpose	Demonstration of efficacy against leptospirosis caused by <i>Leptospira grippotyphosa</i>
Product Administration	
Study Animals	Bovine and Porcine
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	July 14, 1981

Study Type	Efficacy
Pertaining to	<i>Leptospira hardjo</i>
Study Purpose	Demonstration of efficacy against leptospirosis caused by <i>Leptospira hardjo</i>
Product Administration	
Study Animals	Bovine and Porcine
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.
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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	32 bovine (21 vaccinates, 11 controls), 6 months of age																											
Challenge Description	Challenged with <i>Leptospira borgpetersenii</i> serovar <i>hardjo-bovis</i> on 84, 85 and 86 days after the second vaccination																											
Interval observed after challenge	Cattle were observed daily after challenge. Urine samples were taken weekly for 8 weeks. On day 56 and 57 after challenge, kidneys, ovaries, and uterine tissues were cultured for <i>Leptospira</i> isolation.																											
Results	<p>An animal was considered affected if urine cultures were positive at one or more points after challenge.</p> <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> </tr> </thead> <tbody> <tr> <td>Vaccinates</td> <td>0 / 21</td> <td>0%</td> </tr> <tr> <td>Controls</td> <td>11 / 11</td> <td>100%</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> </tr> </thead> <tbody> <tr> <td>Vaccinates</td> <td>0 / 21</td> <td>0%</td> </tr> <tr> <td>Controls</td> <td>10 / 11</td> <td>91%</td> </tr> </tbody> </table> <p>Ovary 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> </tr> </thead> <tbody> <tr> <td>Vaccinates</td> <td>0 / 21</td> <td>0%</td> </tr> <tr> <td>Controls</td> <td>2 / 11</td> <td>18%</td> </tr> </tbody> </table> <p>No <i>Leptospira</i> was cultured from the uterine tissue of any of the vaccinated or control heifers at necropsy.</p> <p>See tables on the following pages for data.</p>	Group	# Positive / Total	% Affected	Vaccinates	0 / 21	0%	Controls	11 / 11	100%	Group	# Positive / Total	% Affected	Vaccinates	0 / 21	0%	Controls	10 / 11	91%	Group	# Positive / Total	% Affected	Vaccinates	0 / 21	0%	Controls	2 / 11	18%
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USDA Approval Date	April 5, 2010																											

Urine, Kidney and Ovary Cultures:

Vaccinates:

Animal #	Weekly Urine Observations								Overall Urine Outcome	Kidney Outcome	Ovary Outcome
	1	2	3	4	5	6	7	8			
2	-	-	-	-	-	-	-	-	Negative	Negative	Negative
7	-	-	-	-	-	-	-	-	Negative	Negative	Negative
10	-	-	-	-	-	-	-	-	Negative	Negative	Negative
11	-	-	-	-	-	-	-	-	Negative	Negative	Negative
12	-	-	-	-	-	-	-	-	Negative	Negative	Negative
13	-	-	-	-	-	-	-	-	Negative	Negative	Negative
14	-	-	-	-	-	-	-	-	Negative	Negative	Negative
15	-	-	-	-	-	-	-	-	Negative	Negative	Negative
16	-	-	-	-	-	-	-	-	Negative	Negative	Negative
17	-	-	-	-	-	-	-	-	Negative	Negative	Negative
30	-	-	-	-	-	-	-	-	Negative	Negative	Negative
32	-	-	-	-	-	-	-	-	Negative	Negative	Negative
37	-	-	-	-	-	-	-	-	Negative	Negative	Negative
41	-	-	-	-	-	-	-	-	Negative	Negative	Negative
42	-	-	-	-	-	-	-	-	Negative	Negative	Negative
43	-	-	-	-	-	-	-	-	Negative	Negative	Negative
49	-	-	-	-	-	-	-	-	Negative	Negative	Negative
50	-	-	-	-	-	-	-	-	Negative	Negative	Negative
51	-	-	-	-	-	-	-	-	Negative	Negative	Negative
53	-	-	-	-	-	-	-	-	Negative	Negative	Negative
54	-	-	-	-	-	-	-	-	Negative	Negative	Negative

Controls:

Animal #	Weekly Urine Observations								Overall Urine Outcome	Kidney Outcome	Ovary Outcome
	1	2	3	4	5	6	7	8			
4	-	-	+	+	+	+	+	-	Positive	Negative	Negative
5	-	-	+	+	+	+	+	+	Positive	Positive	Positive
6	-	-	+	+	+	+	+	+	Positive	Positive	Negative
9	-	-	-	+	+	+	+	+	Positive	Positive	Negative
23	-	-	-	+	+	-	+	+	Positive	Positive	Negative
27	-	-	+	+	+	-	-	+	Positive	Positive	Negative
28	-	-	+	+	+	+	+	-	Positive	Positive	Positive
31	-	-	-	-	-	+	+	-	Positive	Positive	Negative
34	-	-	+	-	+	+	+	+	Positive	Positive	Negative
35	-	-	-	+	+	-	+	+	Positive	Positive	Negative
52	-	-	-	+	+	+	+	-	Positive	Positive	Negative

Weekly Urine Observations:

- = Urine sample was negative for *Leptospira*

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

Overall Urine / Kidney / Ovary Outcome:

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

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

Study Type	Efficacy
Pertaining to	<i>Leptospira icterohaemorrhagiae</i>
Study Purpose	Demonstration of efficacy against leptospirosis caused by <i>Leptospira icterohaemorrhagiae</i>
Product Administration	
Study Animals	Bovine and Porcine
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	July 14, 1981

Study Type	Efficacy
Pertaining to	<i>Leptospira pomona</i>
Study Purpose	Demonstration of efficacy against leptospirosis caused by <i>Leptospira pomona</i>
Product Administration	
Study Animals	Bovine and Porcine
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.
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Study Type	Safety
Pertaining to	All fractions
Study Purpose	Safety by the intramuscular and subcutaneous route in bovine and by the intramuscular route in porcine
Product Administration	
Study Animals	
Challenge Description	
Interval observed after challenge	
Results	Study data not available