



## Summary of Studies Supporting USDA Product Licensure

Establishment Name	Diamond Animal Health, Inc.
USDA Vet Biologics Establishment Number	213
Product Code	4089.20
True Name	Bovine Rhinotracheitis Vaccine, Modified Live Virus, Leptospira Pomona Bacterin
Tradename(s) / Distributor or Subsidiary (if different from manufacturer)	Elanco Animal Health - Diamond Animal Health, Inc. Elanco US, Inc. - Diamond Animal Health, Inc. Titanium IBR LP - Elanco Animal Health - Diamond Animal Health, Inc. Titanium IBR LP - Elanco US, Inc. - Diamond Animal Health, Inc.
Date of Compilation Summary	September 24, 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.**

<b>Study Type</b>	Efficacy
<b>Pertaining to</b>	Infectious Bovine Rhinotracheitis (IBR) Virus
<b>Study Purpose</b>	To demonstrate effectiveness against disease caused by infectious bovine rhinotracheitis virus.
<b>Product Administration</b>	1 dose to calves 6-8 months of age.
<b>Study Animals</b>	Bovine
<b>Challenge Description</b>	
<b>Interval observed after challenge</b>	
<b>Results</b>	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.
<b>USDA Approval Date</b>	July 13, 1998

<b>Study Type</b>	Efficacy
<b>Pertaining to</b>	Leptospira pomonaa
<b>Study Purpose</b>	Demonstrate efficacy against L. pomona
<b>Product Administration</b>	One dose
<b>Study Animals</b>	Bovine
<b>Challenge Description</b>	
<b>Interval observed after challenge</b>	
<b>Results</b>	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.
<b>USDA Approval Date</b>	January 5, 1983

<b>Study Type</b>	Efficacy
<b>Pertaining to</b>	Leptospira pomona
<b>Study Purpose</b>	Demonstrate efficacy against L. pomona
<b>Product Administration</b>	One dose
<b>Study Animals</b>	Bovine
<b>Challenge Description</b>	
<b>Interval observed after challenge</b>	
<b>Results</b>	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.
<b>USDA Approval Date</b>	March 1, 1978

<b>Study Type</b>	Safety
<b>Pertaining to</b>	ALL
<b>Study Purpose</b>	Demonstrate safety of product under typical use conditions
<b>Product Administration</b>	One dose
<b>Study Animals</b>	Bovine
<b>Challenge Description</b>	NA
<b>Interval observed after challenge</b>	
<b>Results</b>	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.
<b>USDA Approval Date</b>	July 13, 1998

<b>Study Type</b>	Safety																																																									
<b>Pertaining to</b>	ALL																																																									
<b>Study Purpose</b>	To demonstrate safety in pregnant cows and calves nursing pregnant cows																																																									
<b>Product Administration</b>	Two doses administered subcutaneously to heifers and cows, 1 dose prior to breeding and 1 dose during pregnancy at different trimesters. Heifers and cows were confirmed to be pregnant at administration during pregnancy.																																																									
<b>Study Animals</b>	Heifers and cows-separate groups vaccinated during each trimester. Similar sized groups in each trimester were maintained as controls.																																																									
<b>Challenge Description</b>	NA																																																									
<b>Interval observed after challenge</b>	Heifers and cows observed from pre-breeding vaccination through birth of calves. Nursing calves observed through 4 weeks of age.																																																									
<b>Results</b>	<p>Summary of Calving Rates (Normal calves delivered/Total deliveries)</p> <table border="1"> <thead> <tr> <th>Trimester</th> <th>Vaccinates</th> <th>Controls</th> </tr> </thead> <tbody> <tr> <td>1</td> <td>200/208 (96%)</td> <td>205/213 (96%)</td> </tr> <tr> <td>2</td> <td>302/313 (96%)</td> <td>293/308 (95%)</td> </tr> <tr> <td>3</td> <td>193/205 (94%)</td> <td>195/208 (94%)</td> </tr> <tr> <td>Total</td> <td>695/726 (96%)</td> <td>693/729 (95%)</td> </tr> </tbody> </table> <p>First Trimester (<math>\leq 93</math> days of gestation)</p> <table border="1"> <thead> <tr> <th></th> <th>Vaccinate</th> <th>Control</th> </tr> </thead> <tbody> <tr> <td>Enrolled</td> <td>209</td> <td>213</td> </tr> <tr> <td>Excluded (not related to vaccination)</td> <td>1</td> <td>0</td> </tr> <tr> <td>Aborted or stillborn</td> <td>6</td> <td>5</td> </tr> <tr> <td>Died at or after birth</td> <td>2</td> <td>3</td> </tr> </tbody> </table> <p>Second Trimester (94-187 days of gestation)</p> <table border="1"> <thead> <tr> <th></th> <th>Vaccinate</th> <th>Control</th> </tr> </thead> <tbody> <tr> <td>Enrolled</td> <td>315</td> <td>310</td> </tr> <tr> <td>Excluded (not related to vaccination)</td> <td>2</td> <td>2</td> </tr> <tr> <td>Aborted or stillborn</td> <td>7</td> <td>9</td> </tr> <tr> <td>Died at or after birth</td> <td>4</td> <td>6*</td> </tr> </tbody> </table> <p>*one death was from a set of twins; the other was normal</p> <p>Third Trimester (188-250 days of gestation)</p> <table border="1"> <thead> <tr> <th></th> <th>Vaccinate</th> <th>Control</th> </tr> </thead> <tbody> <tr> <td>Enrolled</td> <td>205</td> <td>208</td> </tr> <tr> <td>Aborted or stillborn</td> <td>9</td> <td>9*</td> </tr> <tr> <td>Died at or after birth</td> <td>3</td> <td>4**</td> </tr> </tbody> </table> <p>*one stillborn was from a set of twins; the other was normal **one dead was from a set of twins; the other was normal</p>	Trimester	Vaccinates	Controls	1	200/208 (96%)	205/213 (96%)	2	302/313 (96%)	293/308 (95%)	3	193/205 (94%)	195/208 (94%)	Total	695/726 (96%)	693/729 (95%)		Vaccinate	Control	Enrolled	209	213	Excluded (not related to vaccination)	1	0	Aborted or stillborn	6	5	Died at or after birth	2	3		Vaccinate	Control	Enrolled	315	310	Excluded (not related to vaccination)	2	2	Aborted or stillborn	7	9	Died at or after birth	4	6*		Vaccinate	Control	Enrolled	205	208	Aborted or stillborn	9	9*	Died at or after birth	3	4**
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