# Summary of Studies Supporting USDA Product Licensure

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| Establishment Name | Diamond Animal Health, Inc. |
| USDA Vet Biologics Establishment Number | 213 |
| Product Code | 4389.21 |
| True Name | Bovine Rhinotracheitis-Virus Diarrhea Vaccine, Modified Live Virus, Leptospira Pomona Bacterin |
| Tradename(s) / Distributor or Subsidiary (if different from manufacturer) | Elanco Animal Health - Diamond Animal Health, Inc.<br>Elanco US, Inc. - Diamond Animal Health, Inc.<br>Titanium 3 LP - Elanco Animal Health - Diamond Animal Health, Inc.<br>Titanium 3 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.**

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|---|---|
| **Study Type** | Efficacy |
| **Pertaining to** | Bovine Virus Diarrhea Type 1 |
| **Study Purpose** | To demonstrate effectiveness against disease caused by bovine virus diarrhea type 1 |
| **Product Administration** | 1 dose to calves 6-8 months of age. |
| **Study Animals** | Bovine |
| **Challenge Description** | BVDV NY-1 Strain non-cytopathic Type 1b |
| **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, 1998 |

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|---|---|
| **Study Type** | Efficacy |
| **Pertaining to** | Bovine Virus Diarrhea Virus (BVDV) Type 2 |
| **Study Purpose** | To demonstrate effectiveness against disease caused by bovine virus diarrhea type 2 |
| **Product Administration** | |
| **Study Animals** | Bovine |
| **Challenge Description** | BVDV Type 2a strain 890 |
| **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, 1998 |

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|---|---|
| **Study Type** | Efficacy |
| **Pertaining to** | Infectious Bovine Rhinotracheitis (IBR) Virus |
| **Study Purpose** | To demonstrate effectiveness against disease caused by infectious bovine rhinotracheitis virus. |
| **Product Administration** | 1 dose to calves 6-8 months of age. |
| **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** | July 13, 1998 |

| | |
|---|---|
| **Study Type** | Efficacy |
| **Pertaining to** | Leptospira pomonaa |
| **Study Purpose** | Demonstrate efficacy against L. pomona |
| **Product Administration** | One dose |
| **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 5, 1983 |

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|---|---|
| **Study Type** | Efficacy |
| **Pertaining to** | Leptospira pomona |
| **Study Purpose** | Demonstrate efficacy against L. pomona |
| **Product Administration** | One dose |
| **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** | March 1, 1978 |

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|---|---|
| **Study Type** | Safety |
| **Pertaining to** | ALL |
| **Study Purpose** | Demonstrate safety of product under typical use conditions |
| **Product Administration** | One dose |
| **Study Animals** | Bovine |
| **Challenge Description** | NA |
| **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 13, 1998 |

<table>
<tr><td>Study Type</td><td>Safety</td></tr>
<tr><td>Pertaining to</td><td>ALL</td></tr>
<tr><td>Study Purpose</td><td>To demonstrate safety in pregnant cows and calves nursing pregnant cows</td></tr>
<tr><td>Product Administration</td><td>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.</td></tr>
<tr><td>Study Animals</td><td>Heifers and cows-separate groups vaccinated during each trimester. Similar sized groups in each trimester were maintained as controls.</td></tr>
<tr><td>Challenge Description</td><td>NA</td></tr>
<tr><td>Interval observed after challenge</td><td>Heifers and cows observed from pre-breeding vaccination through birth of calves. Nursing calves observed through 4 weeks of age.</td></tr>
<tr><td>Results</td><td>Summary of Calving Rates<br>(Normal calves delivered/Total deliveries)<br><br>
<table>
<tr><td>Trimester</td><td>Vaccinates</td><td>Controls</td></tr>
<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>
</table>
<br>First Trimester (≤93 days of gestation)
<table>
<tr><td></td><td>Vaccinate</td><td>Control</td></tr>
<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>
</table>
<br>Second Trimester (94-187 days of gestation)
<table>
<tr><td></td><td>Vaccinate</td><td>Control</td></tr>
<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>
</table>
*one death was from a set of twins; the other was normal<br><br>Third Trimester (188-250 days of gestation)
<table>
<tr><td></td><td>Vaccinate</td><td>Control</td></tr>
<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>
</table>
*one stillborn was from a set of twins; the other was normal<br>**one dead was from a set of twins; the other was normal</td></tr>
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| **USDA Approval Date** | March 5, 2013 |