



Summary of Studies Supporting USDA Product Licensure

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| Establishment Name | Boehringer Ingelheim Animal Health USA Inc. |
| USDA Vet Biologics Establishment Number | 124 |
| Product Code | 2863.01 |
| True Name | Campylobacter Fetus-Leptospira Canicola-Grippotyphosa-Hardjo-Icterohaemorrhagiae-Pomona Bacterin |
| Tradename(s) / Distributor or Subsidiary (if different from manufacturer) | Citadel VL5 - No distributor specified Citadel VL5 HB - No distributor specified |
| Date of Compilation Summary | November 27, 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.

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|--|---|
| Study Type | Efficacy |
| Pertaining to | <i>Campylobacter fetus</i> |
| Study Purpose | Demonstration of efficacy against infertility, delayed conception, or abortion caused by <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. 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 | August 20, 1971 |

| | |
|--|---|
| 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. |
| USDA Approval Date | July 14, 1981 |

| 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% |
| 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% | | | | | | | | | | | | | | | | | | | | | | | | | | |
| 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. |
| USDA Approval Date | July 14, 1981 |

| | |
|--|---|
| 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 | November 16, 2006 |