



Summary of Studies Supporting USDA Product Licensure

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|---|--|
| Establishment Name | Ceva Animal Health, LLC |
| USDA Vet Biologics Establishment Number | 368 |
| Product Code | 16L1.02 |
| True Name | Marek's Disease Vaccine, Serotypes 1 & 3, Live Virus |
| Tradename(s) / Distributor or Subsidiary (if different from manufacturer) | Biomune Company CEVAC MD HVT & RISPENS - Biomune Company CEVAC MD HVT & RISPENS - No distributor specified |
| Date of Compilation Summary | August 30, 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 | Marek's Disease Virus (MDV) |
| Study Purpose | To demonstrate efficacy against MDV |
| Product Administration | <i>In ovo</i> route and Subcutaneous route |
| Study Animals | Chickens |
| 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 | March 14, 2002 |

| Study Type | Safety | | | | | | | | | | | | | | | | | | | |
|-------------------------------|--|--------------------|-----------|---------|----------|-----------------|--------------------|-----------|--|-------|---------|---|-----------|--------|-----|-------|----------|--------|-----|-------|
| Pertaining to | ALL | | | | | | | | | | | | | | | | | | | |
| Study Purpose | To demonstrate safety under field conditions | | | | | | | | | | | | | | | | | | | |
| Product Administration | One dose by the subcutaneous (SQ) route | | | | | | | | | | | | | | | | | | | |
| Study Animals | Commercial chicks at day of age at one site | | | | | | | | | | | | | | | | | | | |
| Challenge Description | Not Applicable | | | | | | | | | | | | | | | | | | | |
| Interval observed | Commercial chickens were observed daily through 21 days of age. | | | | | | | | | | | | | | | | | | | |
| Results | <table border="1"> <thead> <tr> <th rowspan="2">Location</th> <th rowspan="2">Treatment Group</th> <th rowspan="2">Number of Chickens</th> <th colspan="2">Mortality</th> </tr> <tr> <th>Total</th> <th>Percent</th> </tr> </thead> <tbody> <tr> <td rowspan="2">1</td> <td>Vaccinate</td> <td>25,800</td> <td>331</td> <td>1.28%</td> </tr> <tr> <td>Control*</td> <td>25,800</td> <td>688</td> <td>2.67%</td> </tr> </tbody> </table> <p>*Other commercially available vaccine</p> <p>No adverse reactions or clinical signs of Marek's disease were noted in either group during post-challenge observation.</p> <p>Raw data found below.</p> | | | | Location | Treatment Group | Number of Chickens | Mortality | | Total | Percent | 1 | Vaccinate | 25,800 | 331 | 1.28% | Control* | 25,800 | 688 | 2.67% |
| Location | Treatment Group | Number of Chickens | Mortality | | | | | | | | | | | | | | | | | |
| | | | Total | Percent | | | | | | | | | | | | | | | | |
| 1 | Vaccinate | 25,800 | 331 | 1.28% | | | | | | | | | | | | | | | | |
| | Control* | 25,800 | 688 | 2.67% | | | | | | | | | | | | | | | | |
| USDA Approval Date | November 19, 2008 | | | | | | | | | | | | | | | | | | | |

| Study Type | Safety | | | | | | | | | | | | | | | | | | | | | | | | | | | |
|--|---|-----------------|-------------|----------|-----------|-----------------|-------------|---|--------------|--------|------|---------|--------|------|---|--------------|--------|------|---------|--------|------|---|--------------|--------|------|---------|--------|------|
| Pertaining to | ALL | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Study Purpose | To demonstrate safety under field conditions | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Product Administration | One dose administered via the subcutaneous (SQ) route | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Study Animals | Commercial chicks at day of age | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Challenge Description | Not Applicable | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Interval observed after challenge | No challenge. Animals were observed daily for 21 days for clinical signs of Marek's disease, adverse events, and mortality. | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Results | <table border="1"> <thead> <tr> <th>Location</th> <th>Treatment</th> <th>Number of Birds</th> <th>% Mortality</th> </tr> </thead> <tbody> <tr> <td rowspan="2">1</td> <td>SQ Vaccinate</td> <td>25,800</td> <td>1.28</td> </tr> <tr> <td>Control</td> <td>25,800</td> <td>2.67</td> </tr> <tr> <td rowspan="2">2</td> <td>SQ Vaccinate</td> <td>13,000</td> <td>1.27</td> </tr> <tr> <td>Control</td> <td>13,000</td> <td>1.51</td> </tr> <tr> <td rowspan="2">3</td> <td>SQ Vaccinate</td> <td>20,907</td> <td>3.01</td> </tr> <tr> <td>Control</td> <td>20,778</td> <td>4.62</td> </tr> </tbody> </table> <p>No adverse reactions or clinical signs of Marek's disease were noted in any group during post-challenge observation.</p> | | | Location | Treatment | Number of Birds | % Mortality | 1 | SQ Vaccinate | 25,800 | 1.28 | Control | 25,800 | 2.67 | 2 | SQ Vaccinate | 13,000 | 1.27 | Control | 13,000 | 1.51 | 3 | SQ Vaccinate | 20,907 | 3.01 | Control | 20,778 | 4.62 |
| Location | Treatment | Number of Birds | % Mortality | | | | | | | | | | | | | | | | | | | | | | | | | |
| 1 | SQ Vaccinate | 25,800 | 1.28 | | | | | | | | | | | | | | | | | | | | | | | | | |
| | Control | 25,800 | 2.67 | | | | | | | | | | | | | | | | | | | | | | | | | |
| 2 | SQ Vaccinate | 13,000 | 1.27 | | | | | | | | | | | | | | | | | | | | | | | | | |
| | Control | 13,000 | 1.51 | | | | | | | | | | | | | | | | | | | | | | | | | |
| 3 | SQ Vaccinate | 20,907 | 3.01 | | | | | | | | | | | | | | | | | | | | | | | | | |
| | Control | 20,778 | 4.62 | | | | | | | | | | | | | | | | | | | | | | | | | |
| USDA Approval Date | October 8, 2009 | | | | | | | | | | | | | | | | | | | | | | | | | | | |

| Study Type | Safety | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
|--|--|-------------------------|---------|--------------------|-----------|---------|----------|-----------------|--------------|--|--------------------|-----------|--|-------------------------|---------|-----------|---------|---|-----------|-----------------|--------|--------|-----|-------|---------|-----------------|--------|--------|-----|-------|---|-----------|-----------------|--------|--------|-----|-------|---------|-----------------|--------|--------|-----|-------|---|-----------|-----------------|--------|--------|-------|-------|---------|-----------------|--------|--------|-----|-------|
| Pertaining to | ALL | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Study Purpose | To demonstrate safety under field conditions | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Product Administration | One dose by the <i>in ovo</i> route | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Study Animals | Commercial chicken embryos at 18 to 19 days of incubation at three independent sites | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Challenge Description | Not Applicable | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Interval observed after challenge | No challenge. Commercial chickens were observed daily through 21 days of age. | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Results | <table border="1"> <thead> <tr> <th rowspan="2">Location</th> <th rowspan="2">Treatment Group</th> <th colspan="2">Hatchability</th> <th rowspan="2">Number of Chickens</th> <th colspan="2">Mortality</th> </tr> <tr> <th>No. hatched/embryos set</th> <th>Percent</th> <th>Total No.</th> <th>Percent</th> </tr> </thead> <tbody> <tr> <td rowspan="2">1</td> <td>Vaccinate</td> <td>19,400 / 21,870</td> <td>88.71%</td> <td>19,400</td> <td>144</td> <td>0.74%</td> </tr> <tr> <td>Control</td> <td>16,000 / 17,674</td> <td>90.53%</td> <td>16,000</td> <td>172</td> <td>1.08%</td> </tr> <tr> <td rowspan="2">2</td> <td>Vaccinate</td> <td>21,559 / 24,300</td> <td>88.72%</td> <td>21,559</td> <td>257</td> <td>1.19%</td> </tr> <tr> <td>Control</td> <td>46,871 / 53,460</td> <td>87.67%</td> <td>17,071</td> <td>168</td> <td>0.98%</td> </tr> <tr> <td rowspan="2">3</td> <td>Vaccinate</td> <td>24,700 / 27,317</td> <td>90.41%</td> <td>24,700</td> <td>1,075</td> <td>4.35%</td> </tr> <tr> <td>Control</td> <td>24,100 / 32,079</td> <td>75.12%</td> <td>24,100</td> <td>583</td> <td>2.42%</td> </tr> </tbody> </table> <p>No adverse reactions were noted in either group at any location.</p> | | | | | | Location | Treatment Group | Hatchability | | Number of Chickens | Mortality | | No. hatched/embryos set | Percent | Total No. | Percent | 1 | Vaccinate | 19,400 / 21,870 | 88.71% | 19,400 | 144 | 0.74% | Control | 16,000 / 17,674 | 90.53% | 16,000 | 172 | 1.08% | 2 | Vaccinate | 21,559 / 24,300 | 88.72% | 21,559 | 257 | 1.19% | Control | 46,871 / 53,460 | 87.67% | 17,071 | 168 | 0.98% | 3 | Vaccinate | 24,700 / 27,317 | 90.41% | 24,700 | 1,075 | 4.35% | Control | 24,100 / 32,079 | 75.12% | 24,100 | 583 | 2.42% |
| Location | Treatment Group | Hatchability | | Number of Chickens | Mortality | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| | | No. hatched/embryos set | Percent | | Total No. | Percent | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| 1 | Vaccinate | 19,400 / 21,870 | 88.71% | 19,400 | 144 | 0.74% | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| | Control | 16,000 / 17,674 | 90.53% | 16,000 | 172 | 1.08% | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| 2 | Vaccinate | 21,559 / 24,300 | 88.72% | 21,559 | 257 | 1.19% | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
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| 3 | Vaccinate | 24,700 / 27,317 | 90.41% | 24,700 | 1,075 | 4.35% | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| | Control | 24,100 / 32,079 | 75.12% | 24,100 | 583 | 2.42% | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| USDA Approval Date | October 19, 2009 | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |