



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 | 1281.R1 |
| True Name | Bursal Disease-Marek's Disease Vaccine, Serotypes 1 & 3, Live Virus, Live Marek's Disease Vector |
| Tradename(s) / Distributor or Subsidiary (if different from manufacturer) | Biomune Company VECTORMUNE HVT IBD & RISPENS - Ceva Saude Animal LTDA VECTORMUNE HVT IBD & RISPENS - No distributor specified |
| Date of Compilation Summary | July 09, 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 | Infectious Bursal Disease Virus (IBDV) Standard and Variant types |
| Study Purpose | To demonstrate efficacy against IBDV Standard and Variant types |
| Product Administration | Subcutaneous |
| Study Animals | |
| 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 31, 2002 |

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|--|---|
| Study Type | Efficacy |
| Pertaining to | Marek's Disease Virus (MDV) |
| Study Purpose | To demonstrate efficacy against Marek's Disease Virus (MDV) RB1/B |
| Product Administration | Chickens were vaccinated at day of age via the subcutaneous (SQ) 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 16, 2007 |

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|--|---|
| Study Type | Efficacy |
| Pertaining to | Marek's Disease Virus (MDV) |
| Study Purpose | To demonstrate efficacy against MDV RB1/B |
| Product Administration | Subcutaneous |
| 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 16, 2007 |

| Study Type | Safety | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
|--|---|--------------------|---------------|------|----------|-----------------|--------------------|-----------|--|---------------|---|---|-----------|--------|-----|------|---------|--------|-----|------|---|-----------|--------|-----|------|---------|--------|-----|------|---|-----------|--------|-------|------|---------|--------|-----|------|
| Pertaining to | All | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Study Purpose | To demonstrate safety under typical field conditions | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Product Administration | Subcutaneous | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Study Animals | Commercial chickens at day of age 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 rowspan="2">Number of Chickens</th> <th colspan="2">Mortality</th> </tr> <tr> <th>No. of Deaths</th> <th>%</th> </tr> </thead> <tbody> <tr> <td rowspan="2">1</td> <td>Vaccinate</td> <td>30,700</td> <td>444</td> <td>1.45</td> </tr> <tr> <td>Control</td> <td>14,600</td> <td>261</td> <td>1.79</td> </tr> <tr> <td rowspan="2">2</td> <td>Vaccinate</td> <td>13,000</td> <td>282</td> <td>2.17</td> </tr> <tr> <td>Control</td> <td>13,000</td> <td>318</td> <td>2.45</td> </tr> <tr> <td rowspan="2">3</td> <td>Vaccinate</td> <td>20,907</td> <td>1,006</td> <td>4.81</td> </tr> <tr> <td>Control</td> <td>20,778</td> <td>960</td> <td>4.62</td> </tr> </tbody> </table> <p>No adverse reactions were observed in any treatment group following vaccination or throughout the observation period.</p> | | | | Location | Treatment Group | Number of Chickens | Mortality | | No. of Deaths | % | 1 | Vaccinate | 30,700 | 444 | 1.45 | Control | 14,600 | 261 | 1.79 | 2 | Vaccinate | 13,000 | 282 | 2.17 | Control | 13,000 | 318 | 2.45 | 3 | Vaccinate | 20,907 | 1,006 | 4.81 | Control | 20,778 | 960 | 4.62 |
| Location | Treatment Group | Number of Chickens | Mortality | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| | | | No. of Deaths | % | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| 1 | Vaccinate | 30,700 | 444 | 1.45 | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| | Control | 14,600 | 261 | 1.79 | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| 2 | Vaccinate | 13,000 | 282 | 2.17 | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| | Control | 13,000 | 318 | 2.45 | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| 3 | Vaccinate | 20,907 | 1,006 | 4.81 | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| | Control | 20,778 | 960 | 4.62 | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| USDA Approval Date | October 8, 2009 | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |