



## Summary of Studies Supporting USDA Product Licensure

Establishment Name	Ceva Animal Health, LLC
USDA Vet Biologics Establishment Number	368
Product Code	16L1.06
True Name	Marek's Disease Vaccine, Serotype 3, Live Virus
Tradename(s) / Distributor or Subsidiary (if different from manufacturer)	Biomune Company CEVA Salud Animal S.A.C.-Peru CEVAC MD HVT - Biomune Company CEVAC MD HVT - Ceva Saude Animal LTDA CEVAC MD HVT - No distributor specified
Date of Compilation Summary	February 10, 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>	Marek's Disease Virus (MDV)
<b>Study Purpose</b>	To demonstrate efficacy against MDV
<b>Product Administration</b>	<i>In ovo</i> route and Subcutaneous route
<b>Study Animals</b>	Chickens
<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>	March 14, 2002

<b>Study Type</b>	Efficacy
<b>Pertaining to</b>	Marek's Disease Virus (MDV)
<b>Study Purpose</b>	To demonstrate efficacy against MDV GA strain
<b>Product Administration</b>	<i>In ovo</i> and subcutaneous
<b>Study Animals</b>	Chickens
<b>Challenge Description</b>	
<b>Interval observed after challenge</b>	
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<b>Study Type</b>	Safety																
<b>Pertaining to</b>	ALL																
<b>Study Purpose</b>	To demonstrate safety under field conditions																
<b>Product Administration</b>	One dose by the subcutaneous (SQ) route																
<b>Study Animals</b>	Commercial chicks at day of age at one site																
<b>Challenge Description</b>	Not Applicable																
<b>Interval observed</b>	Commercial chickens were observed daily through 21 days of age.																
<b>Results</b>	<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%
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<b>USDA Approval Date</b>	November 19, 2008																

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<b>Study Animals</b>	Commercial chicken embryos at 18 to 19 days of incubation at three independent sites																																																							
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