Summary of Studies Supporting USDA Product Licensure

Establishment Name	Ceva Animal Health, LLC
USDA Vet Biologics Establishment Number	368
Product Code	16J1.R4
True Name	Fowl Laryngotracheitis-Marek's Disease Vaccine, Serotypes 2 & 3, Live Virus, Live Marek's Disease Vector
Tradename(s) / Distributor or Subsidiary (if different from manufacturer)	Biomune Company CEVAC MD SB1 - Biomune Company Vectormune HVT LT - Biomune Company
Date of Compilation Summary	August 23, 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.

Study Type	Efficacy
Pertaining to	Infectious Laryngotracheitis Virus (ILTV)
Study Purpose	Demonstrate efficacy against Infectious Laryngotracheitis Virus
Product Administration	One dose administered *in ovo* at 18 days of embryonation
Study Animals	Embryos from specific pathogen free chickens divided into 3 groups Group F – vaccinated with product and challenged. Group E– vaccinated with placebo and challenged. Group D – vaccinated with placebo and not challenged.
Challenge Description	LTV administered at 6 weeks and 1 days post vaccination. Group D was not challenged.
Interval observed after challenge	Observed daily for 10 days for mortality or clinical signs associated with ILTV.
Results	Vaccinates and controls were evaluated individually for clinical signs associated with ILTV per the criteria in 9 CFR 113.328(c)(5). Birds with observable lesions: Group F: 2/30 Group E: 30/30 Group D: 0/30 Requirements of 9 CFR 113.328 were met. Raw data on attached page
USDA Approval Date	November 3, 2017

Raw Data for Birds Classified as Positive. All other birds are normal.

Group / Bird	Clinical Signs of LT
Group F/164	NE[1]
Group F/341	WE[2]
Group E/153	NE,WE, SE[3]
Group E/155	WE,SE
Group E/156	WE,SE, SH[4], NE
Group E/158	WE,NE, SE
Group E/165	WE,NE,SH
Group E/166	WE,SE,SH, NE
Group E/167	WE,SE
Group E/171	WE,SE,SH
Group E/185	NE
Group E/186	WE,SE,NE,SH
Group E/188	WE,NE, SE,SH,GA[5],DP[6]
Group E/192	WE,SE
Group E/193	WE,SE,SH, GA, D[7]
Group E/198	NE
Group E/200	WE,NE,SH
Group E/327	NE,SH
Group E/328	WE,SE,SH
Group E/329	WE,SE,SH
Group E/335	WE,SE,SH, NE
Group E/339	WE
Group E/351	NE,SH
Group E/352	WE,SE,SH
Group E/353	WE,SE
Group E/362	WE,NE,SH
Group E/365	WE,SE
Group E/368	WE,NE,SH
Group E/370	WE,NE,SH
Group E/374	WE,SE
Group E/377	WE,SE, FE[8]
Group E/378	WE,SE, D

[1] NE = nasal exudates [2] WE = watery eye(s)
[3] SE = swollen eye(s) [4] SH = swollen head
[5] GA = gasping [6] DP = Depression
[7] D = Dead [8] FE = foamy eye(s)

Study Type	Efficacy
Pertaining to	Marek's Disease Virus (MDV)
Study Purpose	Demonstrate efficacy against very virulent MDV
Product Administration	One dose administered *in ovo* at 18 days of embryonation
Study Animals	Group G: 43 SPF chicken embryos per treatment group vaccinated by the *in vivo* route at 18 days of incubation with product. Group E: 45 SPF chickens per treatment group vaccinated by the subcutaneous route at day of age with Marek's Serotype 3 vaccine (Marek's Serotype 3 control). Group H: 43 SPF chickens per treatment group vaccinated by the *in vivo* route at 18 days of incubation with placebo-matched vaccine (positive control). Group F: 44 SPF chickens per treatment group vaccinated by the subcutaneous route at at day of age with placebo-matched vaccine, non-challenged (negative control).
Challenge Description	Serotype-1 RB1B strain administered at 5 days post vaccination. Group F was not challenged.
Interval observed after challenge	Observed daily for till 49 days of age then evaluated for grossly observable lesions of MDV.
Results	A chicken was considered affected by the challenge (positive) if grossly observable lesions caused by the MDV challenge were present. Birds with observable lesions: Group G: 7/43 were affected by the challenge. Group E: 17/45 Marek's Serotype 3 controls were affected by the challenge. Group H: 43/43 positive controls were affected by the challenge. Group F: 0/44 negative controls were affected by the challenge. Requirements of 9 CFR 113.330(c)(4) & (5) were met. Raw data on attached page
USDA Approval Date	August 29, 2017

Raw Data for Birds Classified as Positive. All other birds are normal.

	Lesions in				
Group/Bird	**Kidney**	**Heart**	**Gonad**	**Spleen**	**Liver**
Group G/279	X				
Group G/340	X	X	X		
Group G/363	X	X	X	X	
Group G/366			X		
Group G/386			X		
Group G/409	X			X	X
Group G/416		X	X		
Group E/238	X		X	X	
Group E/257	X			X	
Group E/260	X				
Group E/263				X	
Group E/268	X				X
Group E/283	X	X			
Group E/312			X		
Group E/315	X	X	X		X
Group E/317	X		X		
Group E/333	X				X
Group E/344	X		X		
Group E/356	X	X			
Group E/375			X		
Group E/390	X				X
Group E/402			X		
Group E/407			X		
Group E/408	X	X	X		
Group H/227	X	X			
Group H/229	X	X	X	X	X
Group H/232		X			
Group H/236		X			
Group H/240		X		X	X
Group H/243		X		X	
Group H/248		X		X	
Group H/250				X	
Group H/252	X		X	X	X
Group H/253		X			
Group H/254				X	X
Group H/256		X	X		
Group H/269			X		

	Lesions in				
Group/Bird	**Kidney**	**Heart**	**Gonad**	**Spleen**	**Liver**
Group H/274	X	X	X	X	
Group H/280	X	X	X	X	
Group H/282		X		X	
Group H/285		X		X	
Group H/287	X		X		
Group H/289	X	X			
Group H/290	X		X		
Group H/299	X		X		
Group H/306	X	X		X	
Group H/309	X	X			
Group H/313		X			
Group H/318	X	X			X
Group H/320		X		X	
Group H/321	X	X	X		
Group H/324		X		X	X
Group H/325	X	X			
Group H/336	X	X	X	X	X
Group H/349	X	X	X	X	
Group H/362		X		X	X
Group H/373	X	X		X	
Group H/379	X	X	X	X	
Group H/382	X	X	X		
Group H/383	X	X			
Group H/389	X			X	X
Group H/391	X	X		X	X
Group H/394		X			
Group H/396		X		X	
Group H/398		X	X	X	X
Group H/406	X	X		X	X
Group H/419		X		X	

<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 under field conditions</td></tr>
<tr><td>Product Administration</td><td>One dose administered via the in ovo route</td></tr>
<tr><td>Study Animals</td><td>Commercial chicken embryos at 18 days of incubation in two groups: vaccinate or control</td></tr>
<tr><td>Challenge Description</td><td>Not Applicable</td></tr>
<tr><td>Interval observed</td><td>Animals were observed daily for mortality, morbidity, and adverse reactions through 21 days of age (in ovo vaccination)</td></tr>
<tr><td>Results</td><td>
<table>
<tr><th>Treatment</th><th>% Hatchability</th><th>Number of Chicks Placed</th><th>% Mortality</th><th>Morbidity</th><th>Observations</th></tr>
<tr><td>In ovo Vaccinate</td><td>84</td><td>37,900</td><td>1.46</td><td>None</td><td>No adverse reactions</td></tr>
<tr><td>Control</td><td>72</td><td>37,600</td><td>1.97</td><td>None</td><td>No adverse reactions</td></tr>
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Adverse events, including morbidity, were not observed post-vaccination in any group.
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<tr><td>USDA Approval Date</td><td>July 25, 2019</td></tr>
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