Summary of Studies Supporting USDA Product Licensure

Establishment Name	Ceva Animal Health, LLC
USDA Vet Biologics Establishment Number	368
Product Code	16J1.R1
True Name	Fowl Laryngotracheitis-Marek's Disease Vaccine, Serotype 3, Live Marek's Disease Vector
Tradename(s) / Distributor or Subsidiary (if different from manufacturer)	Biomune Company Vectormune HVT LT - Biomune Company Vectormune HVT LT - CEVA Saude Animal Ltda. (Brazil) - Biomune Company Vectormune HVT LT - No distributor specified
Date of Compilation Summary	February 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.

Study Type	Efficacy
Pertaining to	Infectious Laryngotracheitis Virus (ILTV)
Study Purpose	Demonstrate efficacy against Laryngotracheitis
Product Administration	1. One dose administered via the *in ovo* 2. One dose administered via the subcutaneous (SQ)
Study Animals	30 SPF chicken embryos per treatment group (vaccinates and positive controls) vaccinated at 18 days of embryonation 30 SPF chicks (vaccinates) vaccinated SQ at day of age 10 SPF chicks (negative controls) vaccinated SQ at day of age
Challenge Description	USDA challenge strain of ILTV at six weeks of age
Interval observed after challenge	Daily observation for ten days post challenge
Results	A chicken was considered affected by the challenge (positive) if clinical signs caused by the ILTV challenge were present. *In ovo* vaccination: 3/30 vaccinates and 26/30 positive controls were affected by the challenge SQ vaccination: 0/30 SQ vaccinates were affected by the challenge 0/10 negative controls were affected by the challenge. Raw data are shown on the attached page.
USDA Approval Date	June 5, 2009

In ovo Vaccinate ID	Clinical Signs of LT[1]	Positive Control ID	Clinical Signs of LT[1]
314	NE, SE, WE	303	NE, SE, WE
278	NE,WE	339	NE, SE, WE
273	NE, SE, WE	256	NE
		295	NE
		285	NE
		324	NE
		288	NE, SE, WE
		291	NE, SE, WE
		272	NE, SE, WE
		356	NE, SE, WE
		259	NE, WE
		304	WE
		336	NE
		341	NE, WE
		292	NE,SE
		275	NE
		306	NE, SE,WE
		263	SE,WE
		331	SE,WE
		258	SE,WE
		361	NE
		277	NE
		254	NE, SE, WE
		310	NE, SE, WE
		287	NE,SF
		269	NE, SE, WE

[1] Clinical Signs of LT: NE=nasal exudate, SE=swollen eye, WE=watery eye, SF=swollen face

Study Type	Efficacy
Pertaining to	Marek's Disease Virus (MDV)
Study Purpose	To demonstrate efficacy against MDV GA strain
Product Administration	1. One dose administered via the *in ovo* route 2. One dose administered via the subcutaneous (SQ) route
Study Animals	35 SPF chicken embryos per treatment group (vaccinates and positive controls) vaccinated at 18 days of embryonation. 35 SPF chicks (vaccinates) vaccinated SQ at day of age. 25 SPF chicks (negative controls) vaccinated SQ at day of age.
Challenge Description	MDV GA strain at five days of age
Interval observed after challenge	Daily observation for 44 days post challenge; tissues examined at 44 days post challenge.
Results	A chicken was considered affected by the challenge (positive) if grossly observable lesions caused by the MDV GA challenge were present. *In ovo* Vaccination: 4/34 *in ovo* vaccinates and 32/35 positive controls were affected by the challenge, MDV GA strain SQ Vaccination: 3/34[1] SQ vaccinates were affected by the challenge, MDV GA strain [1]One bird died before challenge. This death was due to a bacterial infection. 0/25 negative controls were affected by the challenge Raw data are shown on the attached page.
USDA Approval Date	June 4, 2009

In ova Vaccinate ID	Marek's Lesions[1]	SQ Vaccinate ID	Marek's Lesions	Positive Control ID	Marek's Lesions
351	K,S,H,G	356	K,L,H,G	332	S,L,H
317	K,S,L,H	347	N	344	K,S,L,H
271	G	348	H	256	K,S,L,H
309	S			326	K,S,H
				360	S,L
				362	S,L
				279	K,S,L
				330	S
				304	K,H
				378	K,H
				303	K,S,L
				257	K,S,L,H
				331	K,S,H
				338	K,L,H
				369	K,S,L,H
				294	K,H
				282	K,S,H
				276	H
				264	H
				367	K,S,L,H
				268	K,S,L,H
				342	H
				343	S,H
				286	K,S,L,H
				319	S,L,H
				335	K,L,H
				293	G
				364	K,L,H
				323	H,P
				315	P
				292	S,L
				289	L,H,P

[1] Tissue with lesion: K=kidney, S=spleen, L=liver, H=heart, G=gonad, N=nerves, Ski=skin, E=eye, P=proventriculus

Study Type	Safety
Pertaining to	ALL
Study Purpose	To demonstrate safety under field conditions
Product Administration	1. One dose administered via the *in ovo* route 2. One dose administered via the subcutaneous (SQ) route
Study Animals	1. Commercial chicken embryos at 18 to 19 days of embryonation at two independent sites 2. Commercial chickens at day of age at two independent sites
Challenge Description	Not Applicable
Interval observed after challenge	Animals were observed daily for mortality through 21 days of age (*in ovo* vaccination) and 21 days post vaccination (SQ vaccination).
Results	

Location	Treatment	% Hatchability	Number of Chicks Placed	% Mortality	Observations
1	*In ovo* Vaccinate	80	30,600	1.13	No adverse reactions
	Control	79	30,600	1.31	No adverse reactions
2	*In ovo* Vaccinate	85	53,800	2.46	No adverse reactions
	Control	84	26,900	2.47	No adverse reactions
3	SQ Vaccinate	Not Applicable	3,000	1.43	No adverse reactions
	Control	Not Applicable	3,000	1.47	No adverse reactions
4	SQ Vaccinate	Not Applicable	1,000	1.10	No adverse reactions
	Control	Not Applicable	1,000	1.30	No adverse reactions

USDA Approval Date	August 22, 2011