



Summary of Studies Supporting USDA Product Licensure

Establishment Name	Intervet Inc.
USDA Vet Biologics Establishment Number	165A
Product Code	1631.10
True Name	Marek's Disease Vaccine, Serotype 2, Live Virus
Tradename(s) / Distributor or Subsidiary (if different from manufacturer)	Marexine SB VAX - No distributor specified
Date of Compilation Summary	February 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	Marek's Disease Virus, Serotype 2 (SB-1)
Study Purpose	To demonstrate effectiveness against disease caused by very virulent Marek's Disease Virus.
Product Administration	One dose administered <i>in ovo</i> at 18 days of embryonation.
Study Animals	Group 2: 35 embryos, vaccinates Group 3: 34 embryos, HVT inoculated challenged controls Group 4: 34 embryos, diluent inoculated challenged controls Group 5: 25 embryos, diluent inoculated non-challenged controls
Challenge Description	Challenged with very virulent Marek's disease virus RB1B strain at 5 days of age.
Interval observed after challenge	Observed for clinical signs through 49 days of age. All birds were necropsied at the end of the observation period.
Results	Summary of results: Birds positive for Marek's Disease: Group 2: 4/35 Group 3: 7/34 Group 4: 32/34 Group 5: 0/25 Requirements per 9 CFR 113.330(c) were met. Raw data attached
USDA Approval Date	April 20, 2020

Group 2: Vaccinated by the *in*

Count	Wing Tag No.	Isolator	Heart	Liver	Spleen	Gonads	Kidneys	Prov.	Paralysis	Result	End of Study Status	Comments
1	504	187	0	0	0	0	0	0	0	0	Alive	
2	505	187	0	0	0	0	0	0	0	0	Alive	
3	507	187	0	0	0	0	0	0	0	0	Alive	
4	513	187	0	0	0	0	0	0	0	0	Alive	
5	526	187	0	0	0	0	0	0	0	0	Alive	
6	529	187	0	0	0	0	0	0	0	0	Alive	
7	530	187	0	0	0	0	0	0	0	0	Alive	
8	531	187	0	0	0	0	0	0	0	0	Alive	
9	534	187	0	0	0	0	0	0	0	0	Alive	
10	535	187	0	0	0	1	0	0	0	1	Alive	
11	540	187	0	0	0	0	0	0	0	0	Alive	
12	541	187	0	0	0	0	0	0	0	0	Alive	
13	542	182	0	0	0	0	0	0	0	0	Alive	
14	548	182	0	1	0	0	0	0	0	1	Alive	One small lesion on liver
15	553	182	0	0	0	0	0	0	0	0	Alive	
16	557	182	0	0	0	1	0	0	0	1	Alive	
17	558	182	0	0	0	0	0	0	0	0	Alive	
18	559	182	0	0	0	0	0	0	0	0	Alive	
19	563	182	0	0	0	0	0	0	0	0	Alive	
20	566	182	0	0	0	0	0	0	0	0	Alive	
21	567	182	0	0	0	0	0	0	0	0	Alive	
22	571	182	0	0	0	0	0	0	0	0	Alive	
23	573	182	0	0	0	0	0	0	0	0	Alive	
24	577	182	0	0	0	0	0	0	0	0	Alive	
25	584	184	0	0	0	0	0	0	0	0	Alive	
26	586	184	0	0	0	0	0	0	0	1	Alive	Breast Tumor
27	598	184	0	0	0	0	0	0	0	0	Alive	
28	606	184	0	0	0	0	0	0	0	0	Alive	
29	614	184	0	0	0	0	0	0	0	0	Alive	
30	627	184	0	0	0	0	0	0	0	0	Alive	
31	637	184	0	0	0	0	0	0	0	0	Alive	
32	639	184	0	0	0	0	0	0	0	0	Alive	
33	644	184	0	0	0	0	0	0	0	0	Alive	
34	645	184	0	0	0	0	0	0	0	0	Alive	
35	660	184	0	0	0	0	0	0	0	0	Alive	

Group 3: Vaccinated by the *in ovo* route with HVT

Count	Wing Tag No.	Isolator	Heart	Liver	Spleen	Gonads	Kidneys	Prov.	Paralysis	Result	End of Study Status	Comments
1	502	188	0	0	0	0	0	0	0	0	Alive	
2	512	188	0	0	0	1	0	0	0	1	Alive	Enlarged Testes
3	515	188	0	0	0	0	0	1	0	1	Alive	
4	516	188	0	0	0	0	0	0	0	0	Alive	
5	519	188	0	0	0	0	0	0	0	0	Alive	
6	523	188	0	0	1	0	0	0	0	1	Alive	
7	525	188	0	0	0	0	0	0	0	0	Alive	
8	528	188	0	0	0	0	0	0	0	0	Alive	
9	532	188	0	0	0	0	0	0	1	1	Alive	Enlarged sciatic nerve
10	538	188	0	0	0	0	0	0	0	0	Alive	
11	544	188	0	0	0	0	0	0	0	0	Alive	
12	550	188	0	0	0	0	0	0	0	0	Alive	
13	551	196	0	0	0	0	0	0	0	0	Alive	
14	554	196	0	0	0	0	0	0	0	0	Alive	
16	569	196	0	0	0	0	0	0	0	0	Alive	
17	579	196	0	0	0	0	0	0	0	0	Alive	
18	582	196	0	0	0	0	0	0	0	0	Alive	
20	595	196	0	0	0	0	0	0	0	0	Alive	
21	607	196	0	0	0	0	0	0	0	1	Alive	Multiple Breast Tumors
22	610	196	0	0	0	0	0	0	0	0	Alive	
23	618	196	0	0	0	0	0	0	0	0	Alive	
24	619	196	0	0	0	0	0	0	0	0	Alive	
25	623	197	0	0	0	0	0	0	0	0	Alive	
26	624	197	0	0	0	0	0	0	0	0	Alive	
27	628	197	0	0	0	0	0	1	0	1	Alive	
28	629	197	0	0	0	0	0	0	0	0	Alive	
29	630	197	0	0	0	0	0	0	0	0	Alive	
30	634	197	0	0	0	0	0	0	0	0	Alive	
31	647	197	0	0	0	0	0	0	0	0	Alive	
32	651	197	0	0	0	0	0	0	0	0	Alive	
33	659	197	1	0	0	1	0	0	0	1	Alive	
34	661	197	0	0	0	0	0	0	0	0	Alive	
35	665	197	0	0	0	0	0	0	0	0	Alive	

Group 4: Inoculated by the *in ovo* route with Diluent Placebo

Count	Wing Tag No.	Isolator	Heart	Liver	Spleen	Gonads	Kidneys	Prov.	Paralysis	Result	End of Study Status	Comments
2	511	186	0	0	0	0	1	1	0	1	Dead	
3	514	186	0	1	1	1	1	0	0	1	Alive	
4	518	186	0	0	1	1	1	0	1	1	Dead	Sick, uncoordinated
5	522	187	0	0	0	0	0	0	0	0	Alive	
6	539	187	1	1	1	1	1	1	0	1	Dead	Small, sick, uncoordinated
7	552	187	0	1	1	1	1	1	0	1	Alive	
8	555	187	1	1	0	0	1	1	0	1	Dead	
9	564	188	1	1	1	0	1	1	1	1	Dead	
10	572	188	1	1	1	1	1	1	1	1	Dead	Sick, uncoordinated
11	574	188	0	0	1	1	0	1	0	1	Dead	Sick, uncoordinated
12	585	188	1	1	1	1	1	1	0	1	Dead	Sick, uncoordinated
13	587	198	0	0	0	0	0	0	0	0	Alive	
14	590	198	1	1	1	0	1	1	0	1	Dead	
15	591	198	1	0	0	0	1	0	0	1	Alive	
16	593	198	1	0	1	1	1	1	0	1	Dead	Uncoordinated, red legs
17	597	182	0	0	0	1	0	0	0	1	Dead	Sick, uncoordinated
18	602	182	1	1	0	0	0	0	0	1	Alive	
19		182	1	1	1	0	0	0	0	1	Alive	Emaciated, immobile, severely depressed, uncoordinated
20	603											
21	604	182	1	0	1	0	0	0	0	1	Dead	Sick, uncoordinated
22	608	196	1	1	0	1	1	1	0	1	Dead	Sick, uncoordinated
23	609	196	0	1	0	0	1	1	0	1	Alive	Sick, uncoordinated
24	611	196	0	1	1	0	1	1	0	1	Dead	Sick, uncoordinated
25	615	196	0	1	1	1	1	1	1	1	Dead	Sick, uncoordinated
26	620	151	0	1	0	1	1	1	1	1	Dead	Sick, uncoordinated
27	632	151	1	1	1	0	1	1	0	1	Dead	Breast Tumor
28	635	151	0	1	1	1	1	1	0	1	Dead	Sick, uncoordinated
29	636	151	1	1	1	0	1	0	0	1	Dead	Sick
30	638	184	1	1	1	0	0	0	0	1	Alive	Sick, emaciated, uncoordinated, black comb
31	642	184	1	0	0	0	0	1	1	1	Dead	Uncoordinated
32	649	184	1	0	1	0	0	1	1	1	Dead	Sick, uncoordinated, down
33	650	184	1	1	1	0	1	1	0	1	Dead	Sick, uncoordinated
34	653	197	0	1	1	0	0	1	0	1	Dead	Sick
35	657	197	0	0	0	0	1	1	0	1	Dead	Sick, uncoordinated, emaciated
36	663	197	0	1	1	0	1	1	0	1	Dead	Sick, uncoordinated

Group 5: Vaccinated with Diluent Placebo (Non-challenged Controls)

Count	Wing Tag No.	Isolator	Heart	Liver	Spleen	Gonads	Kidneys	Prov.	Paralysis	Result	End of Study Status	Comments
1	517	88	0	0	0	0	0	0	0	0	Alive	
2	521	88	0	0	0	0	0	0	0	0	Alive	
3	527	88	0	0	0	0	0	0	0	0	Alive	
4	543	88	0	0	0	0	0	0	0	0	Alive	
5	546	88	0	0	0	0	0	0	0	0	Alive	
6	549	88	0	0	0	0	0	0	0	0	Alive	
7	556	88	0	0	0	0	0	0	0	0	Alive	
8	561	88	0	0	0	0	0	0	0	0	Alive	
9	562	89	0	0	0	0	0	0	0	0	Alive	
10	570	89	0	0	0	0	0	0	0	0	Alive	
11	575	89	0	0	0	0	0	0	0	0	Alive	
12	581	89	0	0	0	0	0	0	0	0	Alive	
13	599	89	0	0	0	0	0	0	0	0	Alive	
14	605	89	0	0	0	0	0	0	0	0	Alive	
15	612	89	0	0	0	0	0	0	0	0	Alive	
16	616	89	0	0	0	0	0	0	0	0	Alive	
17	621	90	0	0	0	0	0	0	0	0	Alive	
18	622	90	0	0	0	0	0	0	0	0	Alive	
19	626	90	0	0	0	0	0	0	0	0	Alive	
20	633	90	0	0	0	0	0	0	0	0	Alive	
21	643	90	0	0	0	0	0	0	0	0	Alive	
22	646	90	0	0	0	0	0	0	0	0	Alive	
23	648	90	0	0	0	0	0	0	0	0	Alive	
24	658	90	0	0	0	0	0	0	0	0	Alive	
25	662	90	0	0	0	0	0	0	0	0	Alive	

Study Type	Safety																																							
Pertaining to	ALL																																							
Study Purpose	To demonstrate safety of product under typical field conditions																																							
Product Administration	One dose was administered <i>in ovo</i> to 18-19 day old chicken embryos.																																							
Study Animals	A total of 2,366,613 chickens, representing 3 distinct geographical locations.																																							
Challenge Description	N/A																																							
Interval observed after challenge	Chicks were observed daily for mortality through 14 days post-hatch.																																							
Results	<table border="1"> <thead> <tr> <th>Site</th> <th>Group</th> <th>Total Placed</th> <th>% Hatchability</th> <th>% Mortality</th> <th>Condemnation Rates</th> </tr> </thead> <tbody> <tr> <td rowspan="2">1</td> <td>Vaccinate</td> <td>681,138</td> <td>69.1-92.1</td> <td>0.99-3.57</td> <td>0.36-1.37</td> </tr> <tr> <td>Control</td> <td>702,801</td> <td>65.5-92.1</td> <td>0.93-2.36</td> <td>0.65-1.15</td> </tr> <tr> <td rowspan="2">2</td> <td>Vaccinate</td> <td>343,155</td> <td>73.0-93.4</td> <td>2.61-5.38*</td> <td>0.37-0.47*</td> </tr> <tr> <td>Control**</td> <td>--</td> <td>73.7-87.5</td> <td>--</td> <td>--</td> </tr> <tr> <td rowspan="2">3</td> <td>Vaccinate</td> <td>1,342,320</td> <td>72.9-91.3</td> <td>4.50-5.17</td> <td>0.78-1.12</td> </tr> <tr> <td>Control</td> <td>1,436,083</td> <td>70.3-91.2</td> <td>0.79-1.58</td> <td>0.79-1.58</td> </tr> </tbody> </table> <p>*8 total houses that had test vaccinated birds, however only 2 has all test birds. Percent mortality and condemnation rates were determined based on the 2 houses with test birds only.</p> <p>** Percent hatchability for Site 2 controls was the "Standard Hatch" value provided by the site.</p> <p>No adverse reactions attributable to vaccination with the test article were reported.</p>	Site	Group	Total Placed	% Hatchability	% Mortality	Condemnation Rates	1	Vaccinate	681,138	69.1-92.1	0.99-3.57	0.36-1.37	Control	702,801	65.5-92.1	0.93-2.36	0.65-1.15	2	Vaccinate	343,155	73.0-93.4	2.61-5.38*	0.37-0.47*	Control**	--	73.7-87.5	--	--	3	Vaccinate	1,342,320	72.9-91.3	4.50-5.17	0.78-1.12	Control	1,436,083	70.3-91.2	0.79-1.58	0.79-1.58
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USDA Approval Date	April 13, 2009																																							

Study Type	Safety
Pertaining to	ALL
Study Purpose	To demonstrate safety of product under typical field conditions
Product Administration	<i>In ovo</i>
Study Animals	Chicken
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 18, 2007