



Summary of Studies Supporting USDA Product Licensure

Establishment Name	Huvepharma, Inc.
USDA Vet Biologics Establishment Number	605
Product Code	1431.56
True Name	Coccidiosis Vaccine, Live Oocysts
Tradename(s) / Distributor or Subsidiary (if different from manufacturer)	Inovocox EM1 - No distributor specified
Date of Compilation Summary	December 04, 2020

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	<i>Eimeria acervulina</i> , <i>Eimeria tenella</i> , and <i>Eimeria maxima</i>
Study Purpose	To demonstrate the efficacy against <i>E. acervulina</i> , <i>E. tenella</i> , and <i>E. maxima</i>
Product Administration	Spray application
Study Animals	Chickens one day of age: 30 non-vaccinated controls per treatment group, TG 01-TG 03 (water spray); and 30 administered product per treatment group, TG 07-TG09
Challenge Description	<i>E. acervulina</i> , <i>E. tenella</i> , or <i>E. maxima</i> given 28 days post vaccination
Interval observed after challenge	6 days
Results	<p>A chicken was considered affected by challenge if the lesion score was 2-4 (positive) and not affected by challenge if the lesion score was 0-1 (negative).</p> <p>Raw data is shown on the following page.</p> <p>No adverse reactions were observed during the study.</p>
USDA Approval Date	November 19, 2013

Treatment Group	Treatment	Challenge	Lesion Score					% Scores ≥ 2
			0	1	2	3	4	
TG 01	Non-vaccinated	<i>E. acervulina</i>	1	9	17	3	0	67%
TG 07	Vaccinated	<i>E. acervulina</i>	26	4	0	0	0	0%
TG 03	Non-vaccinated	<i>E. tenella</i>	3	5	1	21	0	73%
TG 08	Vaccinated	<i>E. tenella</i>	17	6	4	3	0	23%
TG 02	Non-vaccinated	<i>E. maxima</i>	2	2	10	5	11	87%
TG 09	Vaccinated	<i>E. maxima</i>	25	4	1	0	0	3%

Vaccinates and Non-Vaccinates challenged with *E. acervulina*

Chicken ID	Lesion Score	Treatment Group T01	Chicken ID	Lesion Score	Treatment Group T07
390	0	Non-vaccinated	46	0	Vaccinated
406	1	Non-vaccinated	47	0	Vaccinated
407	2	Non-vaccinated	48	1	Vaccinated
408	3	Non-vaccinated	49	0	Vaccinated
409	2	Non-vaccinated	50	0	Vaccinated
410	2	Non-vaccinated	51	0	Vaccinated
411	2	Non-vaccinated	52	0	Vaccinated
412	1	Non-vaccinated	53	0	Vaccinated
413	3	Non-vaccinated	54	0	Vaccinated
414	2	Non-vaccinated	55	0	Vaccinated
415	1	Non-vaccinated	56	0	Vaccinated
416	1	Non-vaccinated	57	0	Vaccinated
418	3	Non-vaccinated	58	0	Vaccinated
419	1	Non-vaccinated	59	0	Vaccinated
420	2	Non-vaccinated	60	0	Vaccinated
586	2	Non-vaccinated	466	0	Vaccinated
587	2	Non-vaccinated	467	0	Vaccinated
588	2	Non-vaccinated	468	0	Vaccinated
589	2	Non-vaccinated	469	1	Vaccinated
590	2	Non-vaccinated	470	0	Vaccinated
591	1	Non-vaccinated	471	0	Vaccinated
592	2	Non-vaccinated	472	0	Vaccinated
593	2	Non-vaccinated	473	0	Vaccinated
594	2	Non-vaccinated	474	0	Vaccinated
595	2	Non-vaccinated	475	0	Vaccinated
596	2	Non-vaccinated	476	0	Vaccinated
597	1	Non-vaccinated	477	1	Vaccinated
598	2	Non-vaccinated	478	0	Vaccinated
599	1	Non-vaccinated	479	1	Vaccinated
600	1	Non-vaccinated	480	0	Vaccinated

Lesion scores determined by Johnson and Reid (1970) 0 – 4 scoring system.

Vaccinates and Non-Vaccinates challenged with *E. tenella*

Chicken ID	Lesion Score	Treatment Group T03	Chicken ID	Lesion Score	Treatment Group T08
361	3	Non-vaccinated	1	3	Vaccinated
362	3	Non-vaccinated	2	1	Vaccinated
363	3	Non-vaccinated	3	1	Vaccinated
364	3	Non-vaccinated	4	0	Vaccinated
365	1	Non-vaccinated	5	0	Vaccinated
366	3	Non-vaccinated	6	2	Vaccinated
367	1	Non-vaccinated	7	3	Vaccinated
368	3	Non-vaccinated	8	0	Vaccinated
369	2	Non-vaccinated	9	2	Vaccinated
370	3	Non-vaccinated	10	0	Vaccinated
371	3	Non-vaccinated	11	0	Vaccinated
372	3	Non-vaccinated	12	0	Vaccinated
373	0	Non-vaccinated	13	0	Vaccinated
374	1	Non-vaccinated	14	0	Vaccinated
375	3	Non-vaccinated	15	0	Vaccinated
541	0	Non-vaccinated	421	0	Vaccinated
542	3	Non-vaccinated	422	0	Vaccinated
543	3	Non-vaccinated	423	1	Vaccinated
544	3	Non-vaccinated	424	0	Vaccinated
545	3	Non-vaccinated	425	3	Vaccinated
546	3	Non-vaccinated	426	0	Vaccinated
547	0	Non-vaccinated	427	0	Vaccinated
548	1	Non-vaccinated	428	1	Vaccinated
549	3	Non-vaccinated	429	2	Vaccinated
550	3	Non-vaccinated	430	1	Vaccinated
551	3	Non-vaccinated	431	0	Vaccinated
552	3	Non-vaccinated	432	2	Vaccinated
553	1	Non-vaccinated	433	0	Vaccinated
554	3	Non-vaccinated	434	0	Vaccinated
555	3	Non-vaccinated	435	1	Vaccinated

Lesion scores determined by Johnson and Reid (1970) 0 – 4 scoring system.

Vaccinates and Non-Vaccinates challenged with *E. maxima*

Chicken ID	Lesion Score	Treatment Group T02	Chicken ID	Lesion Score	Treatment Group T09
391	2	Non-vaccinated	31	1	Vaccinated
392	4	Non-vaccinated	32	0	Vaccinated
393	2	Non-vaccinated	33	1	Vaccinated
394	4	Non-vaccinated	34	0	Vaccinated
395	2	Non-vaccinated	35	0	Vaccinated
396	4	Non-vaccinated	36	0	Vaccinated
397	3	Non-vaccinated	37	2	Vaccinated
398	4	Non-vaccinated	38	0	Vaccinated
399	0	Non-vaccinated	39	0	Vaccinated
400	4	Non-vaccinated	40	0	Vaccinated
401	4	Non-vaccinated	41	0	Vaccinated
402	2	Non-vaccinated	42	0	Vaccinated
403	4	Non-vaccinated	43	0	Vaccinated
404	4	Non-vaccinated	44	0	Vaccinated
405	1	Non-vaccinated	45	0	Vaccinated
571	3	Non-vaccinated	451	0	Vaccinated
572	3	Non-vaccinated	452	0	Vaccinated
573	3	Non-vaccinated	453	0	Vaccinated
574	4	Non-vaccinated	454	1	Vaccinated
575	1	Non-vaccinated	455	0	Vaccinated
576	0	Non-vaccinated	456	0	Vaccinated
577	4	Non-vaccinated	457	0	Vaccinated
578	2	Non-vaccinated	458	0	Vaccinated
579	2	Non-vaccinated	459	0	Vaccinated
580	3	Non-vaccinated	460	0	Vaccinated
581	2	Non-vaccinated	461	0	Vaccinated
582	4	Non-vaccinated	462	0	Vaccinated
583	2	Non-vaccinated	463	0	Vaccinated
584	2	Non-vaccinated	464	1	Vaccinated
585	2	Non-vaccinated	465	0	Vaccinated

Lesion scores determined by Johnson and Reid (1970) 0 – 4 scoring system.

Study Type	Efficacy
Pertaining to	<i>Eimeria maxima</i> , <i>E. tenella</i> , and <i>E. acervulina</i>
Study Purpose	Efficacy against coccidiosis caused by <i>E. maxima</i> , <i>E. acervulina</i> or <i>E. maxima</i>
Product Administration	<i>In ovo</i>
Study Animals	Chickens at 18 days embryonation; 24 non-vaccinated controls per treatment group; and 24 administered product per treatment group
Challenge Description	<i>E. acervulina</i> , <i>E. tenella</i> , or <i>E. maxima</i> challenge by oral gavage between 27 and 29 days of age
Interval observed after challenge	6 days
Results	<p>Birds with lesion scores of 2 or above were considered positive for coccidiosis.</p> <p>Scoring was in accordance with the Johnson and Reid coccidial scoring system, as described in Experimental Parasitology, Vol. 28, P. 30-36, 1970.</p> <p>Summary data below.</p>
USDA Approval Date	April 26, 2010

Treatment	Challenge	Lesion Score					% Scores ≥ 2
		0	1	2	3	4	
Vaccine	<i>E. acervulina</i> 1	21	3	0	0	0	0
Vaccine	<i>E. maxima</i> 1	17	7	0	0	0	0
Vaccine	<i>E. maxima</i> 2	15	9	0	0	0	0
Vaccine	<i>E. tenella</i> 1	19	5	0	0	0	0
Non-vaccinates	<i>E. acervulina</i> 1	0	9	10	5	0	62.5
Non-vaccinates	<i>E. maxima</i> 1	0	9	8	4	3	62.5
Non-vaccinates	<i>E. maxima</i> 2	0	6	10	5	3	75
Non-vaccinates	<i>E. tenella</i> 1	0	5	11	7	1	79

Vaccinates and Non-Vaccinates challenged with *E. acervulina*

Chicken ID	Lesion Score	Treatment	Chicken ID	Lesion Score	Treatment
1	2	Non-vaccinated	1	0	Vaccinated
2	2	Non-vaccinated	2	0	Vaccinated
3	2	Non-vaccinated	3	0	Vaccinated
4	3	Non-vaccinated	4	0	Vaccinated
5	2	Non-vaccinated	5	0	Vaccinated
6	3	Non-vaccinated	6	0	Vaccinated
7	1	Non-vaccinated	7	0	Vaccinated
8	1	Non-vaccinated	8	0	Vaccinated
9	2	Non-vaccinated	9	0	Vaccinated
10	1	Non-vaccinated	10	0	Vaccinated
11	2	Non-vaccinated	11	1	Vaccinated
12	2	Non-vaccinated	12	0	Vaccinated
13	2	Non-vaccinated	13	1	Vaccinated
14	1	Non-vaccinated	14	0	Vaccinated
15	1	Non-vaccinated	15	0	Vaccinated
16	3	Non-vaccinated	16	0	Vaccinated
17	2	Non-vaccinated	17	0	Vaccinated
18	1	Non-vaccinated	18	0	Vaccinated
19	1	Non-vaccinated	19	1	Vaccinated
20	2	Non-vaccinated	20	0	Vaccinated
21	3	Non-vaccinated	21	0	Vaccinated
22	1	Non-vaccinated	22	0	Vaccinated
23	3	Non-vaccinated	23	0	Vaccinated
24	1	Non-vaccinated	24	0	Vaccinated

Vaccinates and Non-Vaccinates challenged with *E. tenella*

Chicken ID	Lesion Score	Treatment	Chicken ID	Lesion Score	Treatment
1	3	Non-vaccinated	1	0	Vaccinated
2	2	Non-vaccinated	2	1	Vaccinated
3	2	Non-vaccinated	3	0	Vaccinated
4	3	Non-vaccinated	4	0	Vaccinated
5	2	Non-vaccinated	5	0	Vaccinated
6	3	Non-vaccinated	6	0	Vaccinated
7	4	Non-vaccinated	7	0	Vaccinated
8	3	Non-vaccinated	8	1	Vaccinated
9	2	Non-vaccinated	9	0	Vaccinated
10	2	Non-vaccinated	10	0	Vaccinated
11	2	Non-vaccinated	11	0	Vaccinated
12	3	Non-vaccinated	12	0	Vaccinated
13	1	Non-vaccinated	13	1	Vaccinated
14	1	Non-vaccinated	14	0	Vaccinated
15	3	Non-vaccinated	15	0	Vaccinated
16	2	Non-vaccinated	16	0	Vaccinated
17	2	Non-vaccinated	17	0	Vaccinated
18	2	Non-vaccinated	18	1	Vaccinated
19	1	Non-vaccinated	19	0	Vaccinated
20	1	Non-vaccinated	20	0	Vaccinated
21	2	Non-vaccinated	21	1	Vaccinated
22	1	Non-vaccinated	22	0	Vaccinated
23	2	Non-vaccinated	23	0	Vaccinated
24	3	Non-vaccinated	24	0	Vaccinated

Vaccinates and Non-Vaccinates challenged with *E. maxima* 1

Chicken ID	Lesion Score	Treatment	Chicken ID	Lesion Score	Treatment
1	1	Non-vaccinated	1	0	Vaccinated
2	1	Non-vaccinated	2	0	Vaccinated
3	2	Non-vaccinated	3	0	Vaccinated
4	1	Non-vaccinated	4	0	Vaccinated
5	1	Non-vaccinated	5	0	Vaccinated
6	2	Non-vaccinated	6	0	Vaccinated
7	2	Non-vaccinated	7	1	Vaccinated
8	1	Non-vaccinated	8	0	Vaccinated
9	1	Non-vaccinated	9	0	Vaccinated
10	1	Non-vaccinated	10	0	Vaccinated
11	1	Non-vaccinated	11	1	Vaccinated
12	2	Non-vaccinated	12	0	Vaccinated
13	4	Non-vaccinated	13	0	Vaccinated
14	2	Non-vaccinated	14	0	Vaccinated
15	3	Non-vaccinated	15	1	Vaccinated
16	3	Non-vaccinated	16	1	Vaccinated
17	3	Non-vaccinated	17	1	Vaccinated
18	2	Non-vaccinated	18	1	Vaccinated
19	1	Non-vaccinated	19	0	Vaccinated
20	3	Non-vaccinated	20	1	Vaccinated
21	2	Non-vaccinated	21	0	Vaccinated
22	4	Non-vaccinated	22	0	Vaccinated
23	2	Non-vaccinated	23	0	Vaccinated
24	4	Non-vaccinated	24	0	Vaccinated

Vaccinates and Non-Vaccinates challenged with *E. maxima* 2

Chicken ID	Lesion Score	Treatment	Chicken ID	Lesion Score	Treatment
1	1	Non-vaccinated	1	1	Vaccinated
2	2	Non-vaccinated	2	0	Vaccinated
3	2	Non-vaccinated	3	0	Vaccinated
4	2	Non-vaccinated	4	1	Vaccinated
5	2	Non-vaccinated	5	0	Vaccinated
6	1	Non-vaccinated	6	0	Vaccinated
7	1	Non-vaccinated	7	0	Vaccinated
8	1	Non-vaccinated	8	0	Vaccinated
9	2	Non-vaccinated	9	1	Vaccinated
10	4	Non-vaccinated	10	0	Vaccinated
11	2	Non-vaccinated	11	0	Vaccinated
12	3	Non-vaccinated	12	1	Vaccinated
13	2	Non-vaccinated	13	0	Vaccinated
14	2	Non-vaccinated	14	1	Vaccinated
15	1	Non-vaccinated	15	0	Vaccinated
16	3	Non-vaccinated	16	0	Vaccinated
17	3	Non-vaccinated	17	0	Vaccinated
18	2	Non-vaccinated	18	0	Vaccinated
19	1	Non-vaccinated	19	0	Vaccinated
20	2	Non-vaccinated	20	1	Vaccinated
21	3	Non-vaccinated	21	0	Vaccinated
22	3	Non-vaccinated	22	1	Vaccinated
23	4	Non-vaccinated	23	1	Vaccinated
24	4	Non-vaccinated	24	1	Vaccinated

Study Type	Efficacy
Pertaining to	<i>Eimeria acervulina</i> , <i>Eimeria tenella</i> and <i>Eimeria maxima</i>
Study Purpose	Lack of interference when administered with Est. 124, Code 1271.0A, Bursal Disease Vaccine, Live Virus
Product Administration	<i>In ovo</i>
Study Animals	Chickens at 18 days of embryonation.
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	June 25, 2004

Study Type	Efficacy
Pertaining to	<i>Eimeria acervulina</i> , <i>Eimeria tenella</i> and <i>Eimeria maxima</i>
Study Purpose	Lack of interference when administered with Est. 124, Code 1651.01, Marek's Disease Vaccine, Serotypes 2 and 3, Live Virus
Product Administration	<i>In ovo</i>
Study Animals	Chickens at 18 days of embryonation.
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	February 23, 2004

Study Type	Safety
Pertaining to	All
Study Purpose	To demonstrate safety under field conditions
Product Administration	<i>In ovo</i>
Study Animals	Chickens - Commercial broilers 18-19-day-old embryos
Challenge Description	Not Applicable
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	December 14, 2006

Study Type	Safety																																		
Pertaining to	All																																		
Study Purpose	To demonstrate safety under field conditions																																		
Product Administration	Spray																																		
Study Animals	Approximately 300,000 day-of-age commercial broiler chickens, distributed equally into vaccinates and controls at three independent sites. Controls received a commercially available coccidiosis vaccine.																																		
Challenge Description	Not applicable																																		
Interval observed after challenge	No challenge. Chickens were observed daily for at least 21 days post vaccination.																																		
Results	<p>Total Mortality for Vaccinates and Controls 21 days post vaccination</p> <table border="1"> <thead> <tr> <th rowspan="2">Site</th> <th rowspan="2">Treatment Group</th> <th rowspan="2">Total Number of Chickens</th> <th colspan="2">21-day Mortality</th> </tr> <tr> <th>Number</th> <th>Percent</th> </tr> </thead> <tbody> <tr> <td rowspan="2">1</td> <td>Vaccinates</td> <td>86204</td> <td>2035</td> <td>2.4</td> </tr> <tr> <td>Controls</td> <td>86204</td> <td>2080</td> <td>2.4</td> </tr> <tr> <td rowspan="2">2</td> <td>Vaccinates</td> <td>105524</td> <td>1568</td> <td>1.9</td> </tr> <tr> <td>Controls</td> <td>122823</td> <td>1893</td> <td>1.5</td> </tr> <tr> <td rowspan="2">3</td> <td>Vaccinates</td> <td>191711</td> <td>2847</td> <td>1.5</td> </tr> <tr> <td>Controls</td> <td>124926</td> <td>3325</td> <td>2.6</td> </tr> </tbody> </table>	Site	Treatment Group	Total Number of Chickens	21-day Mortality		Number	Percent	1	Vaccinates	86204	2035	2.4	Controls	86204	2080	2.4	2	Vaccinates	105524	1568	1.9	Controls	122823	1893	1.5	3	Vaccinates	191711	2847	1.5	Controls	124926	3325	2.6
Site	Treatment Group				Total Number of Chickens	21-day Mortality																													
		Number	Percent																																
1	Vaccinates	86204	2035	2.4																															
	Controls	86204	2080	2.4																															
2	Vaccinates	105524	1568	1.9																															
	Controls	122823	1893	1.5																															
3	Vaccinates	191711	2847	1.5																															
	Controls	124926	3325	2.6																															
USDA Approval Date	May 7, 2013																																		