Summary of Studies Supporting USDA Product Licensure

Establishment Name	Ceva Animal Health, LLC
USDA Vet Biologics Establishment Number	368
Product Code	49A5.23
True Name	Mink Enteritis Vaccine, Killed Virus, Clostridium Botulinum Type C-Pseudomonas Aeruginosa Bacterin-Toxoid
Tradename(s) / Distributor or Subsidiary (if different from manufacturer)	Biomune Company United Vaccines, Inc.
Date of Compilation Summary	January 20, 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	*Clostridium botulinum* Type C Bacterin-Toxoid
Study Purpose	To demonstrate efficacy against Type C botulism
Product Administration	
Study Animals	Ferret
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. Study data, however, are no longer available.
USDA Approval Date	15 May 1975

Study Type	Efficacy
Pertaining to	Mink Enteritis Virus Type 1 Mink Enteritis Virus Type 2
Study Purpose	To demonstrate efficacy against virus enteritis, types 1 and 2
Product Administration	
Study Animals	Ferret
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. Study data, however, are no longer available.
USDA Approval Date	07 June 1989

Study Type	Efficacy
Pertaining to	*Pseudomonas aeruginosa* Serotype 5
Study Purpose	To demonstrate efficacy against hemorrhagic pneumonia caused by *P. aeruginosa* Serotype 5
Product Administration	One (1) dose administered subcutaneously
Study Animals	Eight (8)-week old mink, 20 vaccinates and 20 controls
Challenge Description	All mink were challenged 21 days after vaccination with *Pseudomonas aeruginosa* Serotype 5
Interval observed after challenge	Seven (7) days for mortality (death)
Results	**Mortality After Challenge** Vaccinates 0/20 (0%) Controls 15/20 (75%) Raw data in following tables
USDA Approval Date	06/DEC/2012

Control Animals

ID	Healthy	Sick	Dead
4	No	No	Yes
5	Yes	No	No
6	No	No	Yes
10	No	No	Yes
11	Yes	No	No
12	No	No	Yes
13	No	No	Yes
14	No	No	Yes
17	No	No	Yes
18	Yes	No	No
20	No	No	Yes
22	No	No	Yes
24	No	No	Yes
28	Yes	No	No
32	No	No	Yes
33	No	No	Yes
34	No	No	Yes
35	No	No	Yes
36	No	No	Yes
44	No	Yes	No

Vaccinated Animals

ID	Healthy	Sick	Dead
1	Yes	No	No
2	Yes	No	No
3	Yes	No	No
8	Yes	No	No
9	Yes	No	No
15	Yes	No	No
16	Yes	No	No
19	Yes	No	No
21	Yes	No	No
23	Yes	No	No
25	Yes	No	No
27	Yes	No	No
37	Yes	No	No
38	Yes	No	No
39	Yes	No	No
40	Yes	No	No
42	Yes	No	No
43	Yes	No	No
45	Yes	No	No
46	Yes	No	No

Study Type	Efficacy
Pertaining to	*Pseudomonas aeruginosa* Serotype 6
Study Purpose	To demonstrate efficacy against hemorrhagic pneumonia caused by *P. aeruginosa* Serotype 6
Product Administration	One (1) dose administered subcutaneously
Study Animals	Twelve (12)-week old mink, 20 vaccinates and 20 controls
Challenge Description	All mink were challenged 22 days after vaccination with *Pseudomonas aeruginosa* Serotype 6
Interval observed after challenge	Seven (7) days for mortality (death)
Results	**Mortality After Challenge** Vaccinates 3/20 (15%) Controls 18/20 (90%) Raw data shown on attached pages.
USDA Approval Date	06/DEC/2012

Control Animals

ID	Healthy	Sick	Dead
99	No	No	Yes
107	No	No	Yes
108	No	No	Yes
109	No	No	Yes
112	No	No	Yes
115	No	No	Yes
116	Yes	No	No
117	No	No	Yes
118	No	No	Yes
119	No	No	Yes
122	No	No	Yes
127	No	No	Yes
129	No	No	Yes
132	No	No	Yes
134	No	No	Yes
137	No	No	Yes
138	No	No	Yes
140	No	No	Yes
141	No	No	Yes
144	Yes	No	No

Vaccinated Animals

ID	Healthy	Sick	Dead
97	Yes	No	No
98	Yes	No	No
100	Yes	No	No
101	Yes	No	No
102	Yes	No	No
103	Yes	No	No
104	No	No	Yes
105	Yes	No	No
110	Yes	No	No
111	No	No	Yes
121	Yes	No	No
123	Yes	No	No
125	Yes	No	No
128	Yes	No	No
130	Yes	No	No
131	Yes	No	No
133	Yes	No	No
135	Yes	No	No
136	Yes	No	No
139	No	No	Yes

Study Type	Efficacy
Pertaining to	*Pseudomonas aeruginosa* Serotype 7-8
Study Purpose	To demonstrate efficacy against hemorrhagic pneumonia caused by *P. aeruginosa* Serotype 7-8
Product Administration	One (1) dose administered subcutaneously
Study Animals	Ten (10)-week old mink, 20 vaccinates and 20 controls
Challenge Description	All mink were challenged 21 days after vaccination with *Pseudomonas aeruginosa* Serotype 7-8
Interval observed after challenge	Seven (7) days for mortality (death)
Results	**Mortality After Challenge** Vaccinates 1/20 (5%) Controls 9/20 (45%) Raw data shown on attached pages
USDA Approval Date	06/DEC/2012

Control Animals

ID	Healthy	Sick	Dead
50	No	No	Yes
51	Yes	No	No
52	No	No	Yes
61	No	No	Yes
66	No	Yes	No
67	Yes	No	No
69	No	No	Yes
70	Yes	No	No
74	Yes	No	No
75	Yes	No	No
79	Yes	No	No
80	Yes	No	No
84	No	No	Yes
86	No	No	Yes
87	No	No	Yes
90	No	No	Yes
91	No	No	Yes
94	Yes	No	No
95	No	Yes	No
96	Yes	No	No

Vaccinated Animals

ID	Healthy	Sick	Dead
54	Yes	No	No
57	Yes	No	No
58	Yes	No	No
59	Yes	No	No
60	Yes	No	No
62	Yes	No	No
63	Yes	No	No
64	Yes	No	No
65	Yes	No	No
68	Yes	No	No
71	Yes	No	No
72	No	No	Yes
73	Yes	No	No
76	Yes	No	No
78	Yes	No	No
85	Yes	No	No
88	Yes	No	No
89	Yes	No	No
92	Yes	No	No
93	No	Yes	No

<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 (1) dose subcutaneously under the loose skin of the armpit</td></tr>
<tr><td>Study Animals</td><td>350 mink, minimum age of six (6) weeks, at seven (7) sites</td></tr>
<tr><td>Challenge Description</td><td>Not applicable</td></tr>
<tr><td>Interval observed after vaccination</td><td>Animals were observed at the time of vaccination and were physically examined on Days 1, 10, and 21 post-vaccination</td></tr>
<tr><td>Results</td><td>
<table>
<tr><th>Site ID</th><th>A</th><th>B</th><th>C</th><th>D</th><th>E</th><th>F</th><th>G</th></tr>
<tr><td>Injection Site Swelling (< 1.5 cm to 5.0 cm) that resolved within 21 days</td><td>0</td><td>0</td><td>0</td><td>5</td><td>27</td><td>0</td><td>0</td></tr>
<tr><td>Anorexia</td><td>2</td><td>0</td><td>0</td><td>0</td><td>0</td><td>0</td><td>0</td></tr>
<tr><td>Abnormal Pain / Discomfort Upon Vaccination</td><td>0</td><td>0</td><td>0</td><td>0</td><td>1</td><td>0</td><td>0</td></tr>
<tr><td>Anaphylaxis</td><td>0</td><td>0</td><td>0</td><td>0</td><td>0</td><td>0</td><td>0</td></tr>
<tr><td>No Adverse Events</td><td>48[1]</td><td>50</td><td>50</td><td>45</td><td>22</td><td>50</td><td>50</td></tr>
<tr><td>Total Number of Animals</td><td>50</td><td>50</td><td>50</td><td>50</td><td>50</td><td>50</td><td>50</td></tr>
</table>
[1] One (1) animal died post-vaccination due to causes not attributable to the vaccine as affirmed by licensee
</td></tr>
<tr><td>USDA Approval Date</td><td>19/MAR/2013</td></tr>
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