



Summary of Studies Supporting USDA Product Licensure

Establishment Name	Hygieia Biological Laboratories
USDA Vet Biologics Establishment Number	407
Product Code	1544.00
True Name	Epizootic Bovine Abortion Agent Vaccine, Live Culture
Tradename(s) / Distributor or Subsidiary (if different from manufacturer)	
Date of Compilation Summary	September 07, 2022

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	Safety																																
Pertaining to	All fractions																																
Study Purpose	To demonstrate safety under field conditions																																
Product Administration	One dose injected subcutaneously																																
Study Animals	Cattle																																
Challenge Description	Not Applicable																																
Interval observed after challenge	<div>Variable intervals of observation by day post vaccination (DPV) based on study site</div> <table><thead><tr><th>Ranch</th><th>Observation Type</th><th>Study Day</th></tr></thead><tbody><tr><td rowspan="2">Site 1 n = 74</td><td>Group</td><td>0, 8, 15, 19, 28</td></tr><tr><td>Individuals</td><td>31 (N = 18), 34 (N = 56), 58 (N = 40), 73 (N = 34)</td></tr><tr><td rowspan="2">Site 2 n = 12</td><td>Group</td><td>0, 1, 7, 11, 17, 24, 29</td></tr><tr><td>Individuals</td><td>38, 86</td></tr><tr><td rowspan="2">Site 3 n = 31</td><td>Group</td><td>0</td></tr><tr><td>Individuals</td><td>38</td></tr><tr><td rowspan="2">Site 4 n = 157</td><td>Group</td><td>0</td></tr><tr><td>Individuals</td><td>3, 30</td></tr></tbody></table>	Ranch	Observation Type	Study Day	Site 1 n = 74	Group	0, 8, 15, 19, 28	Individuals	31 (N = 18), 34 (N = 56), 58 (N = 40), 73 (N = 34)	Site 2 n = 12	Group	0, 1, 7, 11, 17, 24, 29	Individuals	38, 86	Site 3 n = 31	Group	0	Individuals	38	Site 4 n = 157	Group	0	Individuals	3, 30									
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Results	<div>Number of animals with a reaction 40 days or less since vaccination.</div> <table><thead><tr><th>Ranch</th><th>N</th><th>Injection Site Reaction</th><th>Percent</th></tr></thead><tbody><tr><td>Site 1.a</td><td>31</td><td>10</td><td>32.3</td></tr><tr><td>Site 1.b</td><td>30</td><td>9</td><td>30.0</td></tr><tr><td>Site 1.c</td><td>13</td><td>3</td><td>23.1</td></tr><tr><td>Site 2</td><td>12</td><td>5</td><td>41.7</td></tr><tr><td>Site 3</td><td>31</td><td>5</td><td>16.1</td></tr><tr><td>Site 4.a</td><td>93</td><td>2</td><td>2.2</td></tr><tr><td>Site 4.b</td><td>64</td><td>3</td><td>4.7</td></tr></tbody></table> <div>No adverse reactions observed after 40 DPV.</div>	Ranch	N	Injection Site Reaction	Percent	Site 1.a	31	10	32.3	Site 1.b	30	9	30.0	Site 1.c	13	3	23.1	Site 2	12	5	41.7	Site 3	31	5	16.1	Site 4.a	93	2	2.2	Site 4.b	64	3	4.7
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