



Summary of Studies Supporting USDA Product Licensure

Establishment Name	HIPRA USA, LLC
USDA Vet Biologics Establishment Number	449A
Product Code	2852.00
True Name	Staphylococcus Aureus Bacterin
Tradename(s) / Distributor or Subsidiary (if different from manufacturer)	VIMCO - No distributor specified
Date of Compilation Summary	September 12, 2018

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>Staphylococcus aureus</i>																																	
Study Purpose	Efficacy against mastitis																																	
Product Administration	Two doses administered intramuscularly at approximately 35 and 14 days before kidding																																	
Study Animals	Pregnant goats, primiparous and multiparous, randomly divided into 17 vaccinates and 15 controls.																																	
Challenge Description	All goats were challenged with <i>S. aureus</i> 36 days after final vaccination.																																	
Interval observed after challenge	Observed for 14 days																																	
Results	<table border="1"> <thead> <tr> <th colspan="3">Clinical Signs of Mastitis after Challenge</th> </tr> <tr> <th></th> <th>Vaccinates</th> <th>Controls</th> </tr> </thead> <tbody> <tr> <td>Udder swelling</td> <td>3/17</td> <td>13/15</td> </tr> <tr> <td>Udder edema</td> <td>0/17</td> <td>3/15</td> </tr> <tr> <td>Udder sclerosis</td> <td>5/17</td> <td>14/15</td> </tr> <tr> <td>Udder gangrene</td> <td>0/17</td> <td>1/15</td> </tr> <tr> <td>Blood in milk</td> <td>0/17</td> <td>1/15</td> </tr> <tr> <td>Clots in milk</td> <td>3/17</td> <td>13/15</td> </tr> <tr> <td>Aggregates in milk</td> <td>1/17</td> <td>7/15</td> </tr> <tr> <td>Abnormal milk color</td> <td>5/17</td> <td>14/15</td> </tr> <tr> <td>Abnormal milk density</td> <td>1/17</td> <td>3/15</td> </tr> </tbody> </table> <p>Raw data shown on attached page.</p>	Clinical Signs of Mastitis after Challenge				Vaccinates	Controls	Udder swelling	3/17	13/15	Udder edema	0/17	3/15	Udder sclerosis	5/17	14/15	Udder gangrene	0/17	1/15	Blood in milk	0/17	1/15	Clots in milk	3/17	13/15	Aggregates in milk	1/17	7/15	Abnormal milk color	5/17	14/15	Abnormal milk density	1/17	3/15
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		Clinical signs of Mastitis after Challenge								
ID	Treatment	Swelling	Edema	Sclerosis	Gangrene	Blood	Clots	Aggregates	Color	Density
3	vaccinate	no	no	no	no	no	no	no	yes	no
18	vaccinate	yes	no	yes	no	no	yes	no	yes	no
21	vaccinate	no	no	yes	no	no	yes	no	yes	no
22	vaccinate	no	no	no	no	no	no	no	no	no
24	vaccinate	no	no	no	no	no	no	no	no	no
32	vaccinate	no	no	no	no	no	no	no	no	no
34	vaccinate	yes	no	yes	no	no	no	no	no	no
36	vaccinate	no	no	no	no	no	no	no	no	no
42	vaccinate	no	no	no	no	no	no	no	no	no
46	vaccinate	no	no	yes	no	no	no	no	no	no
47	vaccinate	no	no	no	no	no	no	no	no	no
49	vaccinate	yes	no	yes	no	no	yes	yes	yes	yes
53	vaccinate	no	no	no	no	no	no	no	no	no
58	vaccinate	no	no	no	no	no	no	no	no	no
59	vaccinate	no	no	no	no	no	no	no	no	no
73	vaccinate	no	no	no	no	no	no	no	yes	no
75	vaccinate	no	no	no	no	no	no	no	no	no
2	control	yes	no	yes	no	no	yes	no	yes	no
7	control	yes	no	yes	no	no	no	yes	yes	no
9	control	yes	no	yes	no	no	yes	no	yes	no
10	control	yes	no	yes	no	no	yes	no	yes	no
16	control	yes	yes	yes	yes	yes	no	yes	yes	yes
20	control	yes	no	yes	no	no	yes	no	yes	no
25	control	yes	no	yes	no	no	yes	yes	yes	no
26	control	yes	no	yes	no	no	yes	no	yes	no
33	control	no	no	no	no	no	yes	no	no	no
39	control	no	no	yes	no	no	yes	yes	yes	no
40	control	yes	no	yes	no	no	yes	no	yes	no
66	control	yes	yes	yes	no	no	yes	no	yes	yes
69	control	yes	no	yes	no	no	yes	yes	yes	yes
70	control	yes	yes	yes	no	no	yes	yes	yes	no
78	control	yes	no	yes	no	no	yes	yes	yes	no

Study Type	Safety																																														
Pertaining to	ALL																																														
Study Purpose	Observe safety of product under typical use conditions																																														
Product Administration	Two doses administered intramuscularly at approximately 35 and 14 days before kidding																																														
Study Animals	203 pregnant goats total at 2 geographical sites. 1/3 were primiparous (minimum age of ≥ 7 months old) and 2/3 were multiparous.																																														
Challenge Description	NA																																														
Interval observed after challenge	Animals were observed for 1 hour after each injection and then daily until parturition.																																														
Results	<table border="1"> <thead> <tr> <th rowspan="2">Site</th> <th rowspan="2">Group at site</th> <th rowspan="2">Total number animals</th> <th colspan="4">Max size of injection site reaction</th> <th rowspan="2">Adverse events affirmed by licensee to have possible cause other than vaccine</th> </tr> <tr> <th>< 1.5 cm</th> <th>1.5-5.0 cm</th> <th>> 5.0 cm</th> <th>None observed</th> </tr> </thead> <tbody> <tr> <td rowspan="2">1</td> <td>1</td> <td>47</td> <td>7</td> <td>24</td> <td>0</td> <td>16</td> <td rowspan="2">7</td> </tr> <tr> <td>2</td> <td>44</td> <td>8</td> <td>21</td> <td>1</td> <td>14</td> </tr> <tr> <td rowspan="2">2</td> <td>1</td> <td>57</td> <td>22</td> <td>11</td> <td>0</td> <td>24</td> <td rowspan="2">10</td> </tr> <tr> <td>2</td> <td>55</td> <td>22</td> <td>9</td> <td>0</td> <td>24</td> </tr> </tbody> </table> <p>All local reactions were resolved by the conclusion of the study except for swelling in one animal.</p>							Site	Group at site	Total number animals	Max size of injection site reaction				Adverse events affirmed by licensee to have possible cause other than vaccine	< 1.5 cm	1.5-5.0 cm	> 5.0 cm	None observed	1	1	47	7	24	0	16	7	2	44	8	21	1	14	2	1	57	22	11	0	24	10	2	55	22	9	0	24
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