Summary of Studies Supporting USDA Product Licensure

Establishment Name	Zoetis Inc.
USDA Vet Biologics Establishment Number	190
Product Code	8699.00
True Name	Mannheimia Haemolytica Toxoid
Tradename(s) / Distributor or Subsidiary (if different from manufacturer)	One Shot - No distributor specified
Date of Compilation Summary	January 28, 2023

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.

<table>
<tr><td>Study Type</td><td>Efficacy</td></tr>
<tr><td>Pertaining to</td><td>Mannheimia haemolytica</td></tr>
<tr><td>Study Purpose</td><td>Demonstrate efficacy against respiratory disease caused by M. haemolytica</td></tr>
<tr><td>Product Administration</td><td>One dose administered subcutaneously</td></tr>
<tr><td>Study Animals</td><td>20 vaccinated and 19 control calves, six months of age</td></tr>
<tr><td>Challenge Description</td><td>M. haemolytica administered 21 days post-vaccination</td></tr>
<tr><td>Interval observed after challenge</td><td>Animals were observed daily for six days following challenge then lung lesions were evaluated</td></tr>
<tr><td>Results</td><td>Lung lesions (%) and mortality were efficacy variables.

Lung lesions:
<table>
<tr><th></th><th>Minimum</th><th>25th Percentile</th><th>Median</th><th>75th Percentile</th><th>Maximum</th></tr>
<tr><td>Controls</td><td>8.7</td><td>23.3</td><td>41.5</td><td>47.4</td><td>55.2</td></tr>
<tr><td>Vaccinates</td><td>1.1</td><td>6.1</td><td>13.8</td><td>19.0</td><td>59.1</td></tr>
</table>
Mortality:
Controls: 9/19 (47.4%)
Vaccinates: 1/20 (5%)

See individual data attached.</td></tr>
<tr><td>USDA Approval Date</td><td>January 18, 2012</td></tr>
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Lung Lesions and Mortality by Treatment and Animal

Controls

Animal	Lung Lesions (%)	Mortality (prior to 6 days post-challenge)
2024	46.5	No
2026	55.2	Yes
2037	44.8	Yes
2045	38.86	No
2046	26.28	No
2050	41.23	Yes
2052	17.31	No
2061	46.37	No
2065	18.55	No
2066	9.25	No
2085	48.7	Yes
2098	26.9	Yes
2108	48.25	Yes
2111	20.29	No
2117	41.47	Yes
2120	54.25	Yes
2123	46.5	Yes
2125	8.71	No
2128	49.82	No

Vaccinates

Animal	Lung Lesions (%)	Mortality (prior to 6 days post-challenge)
2023	16.71	No
2028	59.06	Yes
2031	11.84	No
2039	8.88	No
2040	16.25	No
2042	3.27	No
2051	19.9	No
2059	18.13	No
2072	15.05	No
2082	22.72	No
2084	1.26	No
2090	1.11	No
2091	1.54	No
2093	21.1	No
2106	11.83	No
2107	12.61	No
2116	17.75	No
2124	11.61	No
2127	2.4	No
2132	28.35	No

Study Type	Safety
Pertaining to	ALL
Study Purpose	Demonstrate safety in cattle under field conditions
Product Administration	Subcutaneous
Study Animals	Bovine
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 15, 1992