# Summary of Studies Supporting USDA Product Licensure

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|---|---|
| Establishment Name | Intervet Inc. |
| USDA Vet Biologics Establishment Number | 165A |
| Product Code | 2775.02 |
| True Name | Mycoplasma Hyopneumoniae Bacterin |
| Tradename(s) / Distributor or Subsidiary (if different from manufacturer) | Myco Silencer ONCE - Intervet Argentina S.A.<br>Myco Silencer ONCE - Merck Animal Health<br>Myco Silencer ONCE - No distributor specified<br>Porcilis Myco Silencer ONCE - Intervet Mexico S.A. de C.V.<br>Porcilis Myco Silencer ONCE - Intervet Mexico S.A. de C.V. - Merck Sharpe and Dohme (MSD)<br>Porcilis Myco Silencer ONCE - Intervet Thailand Ltd |
| Date of Compilation Summary | October 27, 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.**

<table>
<tr><td>Study Type</td><td>Efficacy</td></tr>
<tr><td>Pertaining to</td><td>Mycoplasma hyopneumoniae</td></tr>
<tr><td>Study Purpose</td><td>Demonstrate 23 weeks DOI against pneumonia caused by Mycoplasma hyopneumoniae</td></tr>
<tr><td>Product Administration</td><td>One dose IM</td></tr>
<tr><td>Study Animals</td><td>Total of 48 three-week-old pigs, grouped into 24 vaccinated and 24 control group</td></tr>
<tr><td>Challenge Description</td><td>Pigs were challenged 23 weeks post vaccination, intranasally with virulent Mycoplasma hyopneumoniae.</td></tr>
<tr><td>Interval observed after challenge</td><td>At 3 weeks post challenge, lung lesions were evaluated.</td></tr>
<tr><td>Results</td><td>
<table>
<tr><th colspan="7">Five number summary of lung lesion scores</th></tr>
<tr><td>Groups</td><td>N</td><td>Minimum</td><td>25th percentile</td><td>Median</td><td>75th percentile</td><td>Maximum</td></tr>
<tr><td>Vaccinated (Group 1)</td><td>24</td><td>0</td><td>0</td><td>0.2</td><td>7.7</td><td>32.7</td></tr>
<tr><td>Control (Group 2)</td><td>24</td><td>0</td><td>1.9</td><td>8.3</td><td>25.3</td><td>48.1</td></tr>
</table>
<br>Raw data is presented in tables below.
</td></tr>
<tr><td>USDA Approval Date</td><td>June 6, 2001</td></tr>
</table>

**Lung Lesion Score (LLS):**

**Group 1 Vaccinated**

| Group | Pig | LLS |
|---|---|---|
| 1 | 2169 | 0 |
| 1 | 2170 | 5 |
| 1 | 2171 | 0 |
| 1 | 2172 | 0 |
| 1 | 2173 | 3.8 |
| 1 | 2174 | 20.6 |
| 1 | 2175 | 9.4 |
| 1 | 2176 | 5.9 |
| 1 | 2177 | 2.4 |
| 1 | 2178 | 0 |
| 1 | 2179 | 19.8 |
| 1 | 2180 | 0 |
| 1 | 2181 | 0.4 |
| 1 | 2182 | 0 |
| 1 | 2183 | 13.5 |
| 1 | 2184 | 0 |
| 1 | 2185 | 32.7 |
| 1 | 2186 | 0 |
| 1 | 2187 | 0 |
| 1 | 2189 | 0 |
| 1 | 2190 | 2.1 |
| 1 | 2191 | 0 |
| 1 | 2192 | 0 |
| 1 | 2193 | 9.7 |

**Group 2 Control**

| Group | Pig | LLS |
|---|---|---|
| 2 | 2094 | 30.6 |
| 2 | 2095 | 14.4 |
| 2 | 2096 | 0 |
| 2 | 2097 | 32.6 |
| 2 | 2098 | 2.8 |
| 2 | 2099 | 20.1 |
| 2 | 2100 | 17.2 |
| 2 | 2101 | 48.1 |
| 2 | 2102 | 2.3 |
| 2 | 2103 | 0.4 |
| 2 | 2104 | 0 |
| 2 | 2105 | 11.5 |
| 2 | 2106 | 8 |
| 2 | 2107 | 24 |
| 2 | 2108 | 3.7 |
| 2 | 2109 | 7.6 |
| 2 | 2110 | 0 |
| 2 | 2111 | 26.9 |
| 2 | 2112 | 27 |
| 2 | 2114 | 7.6 |
| 2 | 2115 | 8.6 |
| 2 | 2116 | 1.4 |
| 2 | 2117 | 0.8 |
| 2 | 2118 | 26.5 |

| | |
|---|---|
| **Study Type** | Efficacy |
| **Pertaining to** | *Mycoplasma hyopneumoniae* |
| **Study Purpose** | Efficacy against pneumonia caused by *Mycoplasma hyopneumoniae* |
| **Product Administration** | IM |
| **Study Animals** | 3-week-old pigs |
| **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** | December 18, 2001 |

| | |
|---|---|
| **Study Type** | Safety |
| **Pertaining to** | *Mycoplasma hyopneumoniae* |
| **Study Purpose** | To demonstrate field safety of product |
| **Product Administration** | Single dose, IM |
| **Study Animals** | A total of 1,317 pigs, 3-weeks-of-age were vaccinated and monitored from four herds in distance geographical areas. Pigs were observed for systemic events, localized injection site events, and palpable lesions. |
| **Challenge Description** | N/A |
| **Interval observed after challenge** | N/A |
| **Results** | Out of 1,317 pigs, vaccinated only one systemic type event was noted and no mortalities were reported attributable to vaccination. Localized injection site swellings and/or redness were observed.<br><br>See the summary table below. |
| **USDA Approval Date** | November 14, 2001 |

**Adverse Event Summary Table**

| Herd | PL Serial | + Animals | EVENTS: Systemic | Local | PALPATION: Animals | Nodules |
|---|---|---|---|---|---|---|
| 1 | 7881501 | 195 | 0 | 11[b] | -- | |
| | 7881502 | 186 | 1[a] | 10[b] | -- | |
| 2 | 7881501 | 170 | 0 | 1[c] | 42 | 1[c] |
| | 7881502 | 179 | 0 | 1[b] | 42 | 1[f] |
| 3 | 7881501 | 125 | 0 | 0 | 35[e] | 1[f] |
| | 7881502 | 133 | 0 | 0 | 42[e] | 1[f] |
| 4 | 7881501 | 162 | 0 | 0 | 36 | 2[f] |
| | 7881502 | 167 | 0 | 1[d] | 36 | 0 |
| Serials: | 7881501 | 652 | 0 | 12 | 113 | 4 |
| | 7881502 | 665 | 1 | 12 | 120 | 2 |
| | **Totals** | 1,317 | 1 (0.08) | 24 (1.8%) | 233 | 6 (2.6%) |

a – allergic like paddling event, resolved untreated within 2 minutes

b – transient redness or swelling at 24 hours post-injection, most resolved by 48 hours

c – reddened spot noted at 14 days, along with BB-sized palpable nodule (same pig)

d – swelling noted at 7 days, resolved by 14 days

e – 7 head per pen estimate

f – 0.5 – 1.0 cm firm palpable nodules noted at 14 days

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|---|---|
| **Study Type** | Safety |
| **Pertaining to** | *Mycoplasma hyopneumoniae* |
| **Study Purpose** | To demonstrate field safety of product |
| **Product Administration** | 2 doses: 1 mL dose at 3 weeks of age or older followed by a second 1 mL dose 21 days later |
| **Study Animals** | Pigs 3-4 weeks of age |
| **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. |
| **USDA Approval Date** | 2005 |