<table>
<thead>
<tr>
<th>Establishment Name</th>
<th>Intervet Inc.</th>
</tr>
</thead>
<tbody>
<tr>
<td>USDA Vet Biologics Establishment Number</td>
<td>165A</td>
</tr>
<tr>
<td>Product Code</td>
<td>2775.01</td>
</tr>
<tr>
<td>True Name</td>
<td>Mycoplasma Hyopneumoniae Bacterin</td>
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| Tradename(s) / Distributor or Subsidiary (if different from manufacturer) | M+Pac - Intervet Argentina S.A. - Merck Sharpe and Dohme (MSD)  
M+Pac - Intervet Ecuador S.A. - Merck Sharpe and Dohme (MSD)  
M+Pac - Intervet Mexico S.A. de C.V. - Merck Sharpe and Dohme (MSD)  
M+Pac - Intervet Thailand Ltd  
M+Pac - Intervet Veterinaria Chile Ltda.  
M+Pac - MSD Salud Animal Columbia S.A.S.  
M+Pac - Merck Animal Health  
M+Pac - Merck Sharp & Dohme Sundo Animal Ltda.  
M+Pac - Merck Sharp and Dohme (MSD)  
M+Pac - No distributor specified  
M+Pac - Schering Canada Inc.  
Myco-Pac - No distributor specified |
| 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>
<thead>
<tr>
<th>Study Type</th>
<th>Efficacy</th>
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<tbody>
<tr>
<td>Pertaining to</td>
<td>Mycoplasma hyopneumoniae</td>
</tr>
<tr>
<td>Study Purpose</td>
<td>To establish duration of immunity of 4 months with administration of 1 dose</td>
</tr>
<tr>
<td>Product Administration</td>
<td>1 dose, administered IM</td>
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<tr>
<td>Study Animals</td>
<td>Total of 42 pigs, 6 weeks of age, 20 non-vaccinates (Group A controls) and 21 vaccinates (Group B)</td>
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<tr>
<td>Challenge Description</td>
<td>All pigs were challenged 4 months after vaccination. Challenge material was Mycoplasma hyopneumoniae</td>
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<tr>
<td>Interval observed after challenge</td>
<td>Pigs were observed daily for 28 days post challenge then lung tissues were examined.</td>
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<td>Results</td>
<td>Primary criterion for vaccine efficacy was lung consolidation scoring (weighted scores).</td>
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<tr>
<td></td>
<td>Group Minimum Q1 Median Q3 Maximum</td>
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<td>Controls Group A</td>
<td>0.4 2.3 6.2 9.8 23.4</td>
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<td>Vaccinates Group B</td>
<td>0.0 0.4 0.8 3.2 12.6</td>
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Raw data found on tables below.

| USDA Approval Date         | Feb 11, 2002                                |
### Mycoplasma hyopneumoniae Lung Consolidation Scores, Nonvaccinated Group A

<table>
<thead>
<tr>
<th>Pig ID</th>
<th>% Lung Consolidation For Each Lobe (weighted scores)</th>
<th>Total Consolidation</th>
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<tbody>
<tr>
<td></td>
<td>Right Cranial</td>
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<tr>
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<td>8492</td>
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### Mycoplasma hyopneumoniae Lung Consolidation Scores, Vaccinate Group B

<table>
<thead>
<tr>
<th>Pig ID</th>
<th>% Lung Consolidation For Each Lobe (weighted scores)</th>
<th>Total Consolidation</th>
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<tr>
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<tr>
<td>Study Purpose</td>
<td>Efficacy against pneumonia caused by <em>Mycoplasma hyopneumoniae</em></td>
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<tr>
<td>Product Administration</td>
<td>2 doses: first dose administered IM then second dose administered IM 14 days after 1st dose.</td>
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<tr>
<td>Study Animals</td>
<td>Total of 57, pigs 7-10 day old, 20 vaccinates and 10 nonvaccinated control</td>
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<tr>
<td>Challenge Description</td>
<td>Pigs were challenged 21 days after the 2nd administration with <em>Mycoplasma hyopneumoniae</em></td>
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<tr>
<td>Interval observed after challenge</td>
<td>Pigs were observed daily for 23 days post-challenge then lung tissues were examined on day 56 post-challenge.</td>
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<tr>
<td>Results</td>
<td>Primary criterion for vaccine efficacy was lung consolidation scoring (weighted scores).</td>
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<tr>
<td></td>
<td><strong>Group</strong></td>
<td><strong>Minimum</strong></td>
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<tr>
<td></td>
<td>Controls</td>
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<td>Vaccinates</td>
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<tr>
<td></td>
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<tr>
<td>USDA Approval Date</td>
<td>Nov 14, 1996</td>
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# Lung Scores for Vaccinate Group

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<th>ID #</th>
<th>Lung Scores</th>
<th>% Total Lung Involvement</th>
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<tr>
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<td>7</td>
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</table>

A = left apical lung lobe  
B = left cardiac lung lobe  
C = left diaphragmatic lung lobe  
D = right apical lung lobe  
E = right cardiac lung lobe  
F = right diaphragmatic lung lobe  
G = intermediate lung lobe  
Lung Scores for Nonvaccinate Control Group

<table>
<thead>
<tr>
<th>ID #</th>
<th>Lung Scores</th>
<th>% Total Lung Involvement</th>
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<tbody>
<tr>
<td>5</td>
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<tr>
<td>55</td>
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</tbody>
</table>

A = left apical lung lobe  
B = left cardiac lung lobe  
C = left diaphragmatic lung lobe  
D = right apical lung lobe  
E = right cardiac lung lobe  
F = right diaphragmatic lung lobe  
G = intermediate lung lobe  

% Total lung involvement = A(.10)+B(.10)+C(.10)+D(.10)+E(.10)+F(.25)+G(.10)
<table>
<thead>
<tr>
<th><strong>Study Type</strong></th>
<th>Safety</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Pertaining to</strong></td>
<td>Mycoplasma hyopneumoniae</td>
</tr>
<tr>
<td><strong>Study Purpose</strong></td>
<td>Establish safety in young pigs under field conditions</td>
</tr>
<tr>
<td><strong>Product Administration</strong></td>
<td>2 doses: first dose administered IM then second dose administered IM 14 days after 1st dose</td>
</tr>
<tr>
<td><strong>Study Animals</strong></td>
<td></td>
</tr>
<tr>
<td><strong>Challenge Description</strong></td>
<td></td>
</tr>
<tr>
<td><strong>Interval observed after challenge</strong></td>
<td></td>
</tr>
<tr>
<td><strong>Results</strong></td>
<td>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.</td>
</tr>
<tr>
<td><strong>USDA Approval Date</strong></td>
<td>November 14, 1996</td>
</tr>
<tr>
<td>Study Type</td>
<td>Safety</td>
</tr>
<tr>
<td>---------------------</td>
<td>------------------------------------------------------</td>
</tr>
<tr>
<td>Pertaining to</td>
<td>Mycoplasma hyopneumoniae</td>
</tr>
<tr>
<td>Study Purpose</td>
<td>Establish safety of in young pigs under field conditions</td>
</tr>
<tr>
<td>Product Administration</td>
<td>One IM dose</td>
</tr>
<tr>
<td>Study Animals</td>
<td>Pigs, 6 weeks of age and older</td>
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<tr>
<td>Challenge Description</td>
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<td>Interval observed after challenge</td>
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</tr>
<tr>
<td>Results</td>
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