



Summary of Studies Supporting USDA Product Licensure

Establishment Name	Intervet Inc.
USDA Vet Biologics Establishment Number	165A
Product Code	2775.01
True Name	Mycoplasma Hyopneumoniae Bacterin
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 Saude Animal Ltda. M+Pac - Merck Sharpe 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.

Study Type	Efficacy																		
Pertaining to	<i>Mycoplasma hyopneumoniae</i>																		
Study Purpose	To establish duration of immunity of 4 months with administration of 1 dose																		
Product Administration	1 dose, administered IM																		
Study Animals	Total of 42 pigs, 6 weeks of age, 20 non-vaccinates (Group A controls) and 21 vaccinates (Group B)																		
Challenge Description	All pigs were challenged 4 months after vaccination. Challenge material was <i>Mycoplasma hyopneumoniae</i>																		
Interval observed after challenge	Pigs were observed daily for 28 days post challenge then lung tissues were examined.																		
Results	<p>Primary criterion for vaccine efficacy was lung consolidation scoring (weighted scores).</p> <table border="1"> <thead> <tr> <th>Group</th> <th>Minimum</th> <th>Q1</th> <th>Median</th> <th>Q3</th> <th>Maximum</th> </tr> </thead> <tbody> <tr> <td>Controls Group A</td> <td>0.4</td> <td>2.3</td> <td>6.2</td> <td>9.8</td> <td>23.4</td> </tr> <tr> <td>Vaccinates Group B</td> <td>0.0</td> <td>0.4</td> <td>0.8</td> <td>3.2</td> <td>12.6</td> </tr> </tbody> </table> <p>Raw data found on tables below.</p>	Group	Minimum	Q1	Median	Q3	Maximum	Controls Group A	0.4	2.3	6.2	9.8	23.4	Vaccinates Group B	0.0	0.4	0.8	3.2	12.6
Group	Minimum	Q1	Median	Q3	Maximum														
Controls Group A	0.4	2.3	6.2	9.8	23.4														
Vaccinates Group B	0.0	0.4	0.8	3.2	12.6														
USDA Approval Date	Feb 11, 2002																		

***Mycoplasma hyopneumoniae* Lung Consolidation Scores, Nonvaccinated Group A**

Pig ID	% Lung Consolidation For Each Lobe (weighted scores)						Total Consolidation
	Right Cranial	Right Middle	Right Caudal	Accessory	Left Cranial	Left Caudal	
8495	0.22	0.1	0	0.1	0	0	0.42
8469	0	0	0	1	0	0	1
8471	0.55	0.5	0	0	0.22	0	1.27
8505	0	0.2	0.68	0	0.55	0.58	2.01
8485	0.55	1	0.34	0.1	0.22	0	2.21
8496	0.11	0.5	0.68	0.5	0.55	0	2.34
8483	0.55	2	0	0.1	0	0	2.65
8510	0	2	0	2.5	0	0	4.5
8509	1.65	1	0	0.25	1.1	0.58	4.58
8474	0.55	4	0	0	1.1	0	5.65
8497	1.1	0	0.34	2.5	2.75	0	6.69
8490	0	3	0	1.5	2.75	0.29	7.54
8506	0.11	1	5.1	1	0.11	0.29	7.61
8476	1.65	0	0	3	3.3	0	7.95
8499	2.2	2	1.7	1	1.65	0.58	9.13
8470	0.55	4	0.68	2	3.3	0	10.53
8468	0.55	7	0.68	1	2.75	0	11.98
8494	2.2	5	0	3.5	3.3	0.29	14.29
8500	2.75	5	1.7	1.5	4.4	0.58	15.93
8492	5.5	6	3.4	3.5	4.4	0.58	23.38

***Mycoplasma hyopneumoniae* Lung Consolidation Scores, Vaccinate Group B**

Pig ID	% Lung Consolidation For Each Lobe (weighted scores)						Total Consolidation
	Right Cranial	Right Middle	Right Caudal	Accessory	Left Cranial	Left Caudal	
8488	0	0	0	0	0	0	0
8498	0	0.1	0	0	0	0	0.1
8472	0	0	0	0	0.11	0	0.11
8482	0	0	0	0	0.22	0	0.22
8478	0	0.2	0	0	0.11	0	0.31
8484	0.11	0.1	0	0	0.22	0	0.43
8512	0	0.5	0	0	0.11	0	0.61
8493	0	0.1	0	0	0.55	0	0.65
8513	0	0.1	0	0	0.55	0	0.65
8507	0	0.5	0	0	0.22	0	0.72
8477	0.11	0.1	0	0.05	0.55	0	0.81
8487	0	0.1	0	0	1.1	0	1.2
8489	0.11	1	0.34	0	0.22	0	1.67
8479	1.65	0	0	0	0.11	0	1.76
8491	0	0.1	0	2.5	0.11	0	2.71
8475	0.55	2	0.34	0.1	0.22	0	3.21
8502	0	3	0	0	1.1	0	4.1
8511	1.65	4	0	0	0	0	5.65
8481	0.55	3	0	0.25	2.2	0	6
8503	2.75	1	0	1.5	1.65	0	6.9
8501	1.65	5	1.7	1.5	2.2	0.58	12.63

Study Type	Efficacy																		
Pertaining to	<i>Mycoplasma hyopneumoniae</i>																		
Study Purpose	Efficacy against pneumonia caused by <i>Mycoplasma hyopneumoniae</i>																		
Product Administration	2 doses: first dose administered IM then second dose administered IM 14 days after 1 st dose.																		
Study Animals	Total of 57, pigs 7-10 day old, 20 vaccinates and 10 nonvaccinated control																		
Challenge Description	Pigs were challenged 21 days after the 2 nd administration with <i>Mycoplasma hyopneumoniae</i>																		
Interval observed after challenge	Pigs were observed daily for 23 days post-challenge then lung tissues were examined on day 56 post-challenge.																		
Results	<p>Primary criterion for vaccine efficacy was lung consolidation scoring (weighted scores).</p> <table border="1"> <thead> <tr> <th>Group</th> <th>Minimum</th> <th>Q1</th> <th>Median</th> <th>Q3</th> <th>Maximum</th> </tr> </thead> <tbody> <tr> <td>Controls</td> <td>0.1</td> <td>1.8</td> <td>3.4</td> <td>9.8</td> <td>37.3</td> </tr> <tr> <td>Vaccinates</td> <td>0.0</td> <td>0.1</td> <td>0.8</td> <td>3.6</td> <td>11.5</td> </tr> </tbody> </table> <p>Raw data found on tables below.</p>	Group	Minimum	Q1	Median	Q3	Maximum	Controls	0.1	1.8	3.4	9.8	37.3	Vaccinates	0.0	0.1	0.8	3.6	11.5
Group	Minimum	Q1	Median	Q3	Maximum														
Controls	0.1	1.8	3.4	9.8	37.3														
Vaccinates	0.0	0.1	0.8	3.6	11.5														
USDA Approval Date	Nov 14, 1996																		

Lung Scores for Vaccinate Group

ID #	Lung Scores							% Total Lung Involvement
	A (.10)	B (.10)	C (.25)	D (.10)	E (.10)	F (.25)	G (.10)	
1	0	20	1	10	15	0	0	4.75
6	0	7	0	30	5	0	0	4.20
7	0	0	2	0	2	0	0	0.70
10	0	5	0	0	3	0	0	0.80
18	0	25	1	5	5	0	0	3.75
22	0	6	0	10	7	0	0	2.30
24	0	1	0	0	2	0	1	0.40
27	0	1	0	2	1	0	0	0.40
30	0	0	0	0	0	0	0	0.00
32	0	0	0	0	0	0	0	0.00
34	0	20	1	1	10	1	0	3.60
37	0	1	0	20	7	0	0	2.80
40	0	5	0	5	0	0	0	1.00
45	0	0	0	0	1	0	0	0.10
47	0	1	0	0	0	0	0	0.10
54	0	3	0	0	1	0	0	0.40
57	0	0	0	0	0	0	0	0.00
59	20	60	0	20	15	0	0	11.50

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 = $A(.10)+B(.10)+C(.10)+D(.10)+E(.10)+F(.25)+G(.10)$

Lung Scores for Nonvaccinate Control Group

ID #	Lung Scores							% Total Lung Involvement
	A (.10)	B (.10)	C (.25)	D (.10)	E (.10)	F (.25)	G (.10)	
5	0	7	1	2	10	1	2	2.60
14	0	30	2	0	5	0	0	4.00
19	8	75	3	25	25	1	0	14.30
21	0	5	0	7	3	0	0	1.50
25	0	2	1	5	40	0	0	4.95
29	0	1	0	0	0	0	0	0.10
38	0	2	0	3	15	15	40	9.75
43	0	50	2	70	90	25	95	37.25
48	0	20	1	2	3	0	0	2.75
56	0	7	0	10	1	0	0	1.80

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 = $A(.10)+B(.10)+C(.10)+D(.10)+E(.10)+F(.25)+G(.10)$

Study Type	Safety
Pertaining to	Mycoplasma hyopneumoniae
Study Purpose	Establish safety in young pigs under field conditions
Product Administration	2 doses: first dose administered IM then second dose administered IM 14 days after 1 st dose
Study Animals	
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. Study data, however, are no longer available.
USDA Approval Date	November 14, 1996

Study Type	Safety
Pertaining to	Mycoplasma hyopneumoniae
Study Purpose	Establish safety of in young pigs under field conditions
Product Administration	One IM dose
Study Animals	Pigs, 6 weeks of age and older
Challenge Description	
Interval observed after challenge	
Results	Study data are not available.