Summary of Studies Supporting USDA Product Licensure

Establishment Name	Zoetis Inc.
USDA Vet Biologics Establishment Number	190
Product Code	2775.01
True Name	Mycoplasma Hyopneumoniae Bacterin
Tradename(s) / Distributor or Subsidiary (if different from manufacturer)	RespiSure 1One - No distributor specified RespiSure 1One - Zoetis Argentina RespiSure 1One - Zoetis Colombia S.A.S. RespiSure 1One - Zoetis Industria de Produtos RespiSure 1One - Zoetis Korea RespiSure 1One - Zoetis Mexico RespiSure 1One - Zoetis Panama RespiSure 1One - Zoetis South Africa Ltd RespiSure One - No distributor specified RespiSure One - Zoetis Australia Pty Ltd RespiSure One - Zoetis Japan Inc. RespiSure One - Zoetis Korea
Date of Compilation Summary	February 07, 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.

Study Type	Efficacy
Pertaining to	*Mycoplasma hyopneumoniae*
Study Purpose	Demonstrate a duration of immunity of at least 8 weeks against *Mycoplasma hyopneumoniae*
Product Administration	
Study Animals	Swine
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	November 18, 1999

Study Type	Efficacy
Pertaining to	*Mycoplasma hyopneumoniae*
Study Purpose	Demonstrate a duration of immunity of at least 18 weeks against *Mycoplasma hyopneumoniae*
Product Administration	
Study Animals	Swine
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	November 18, 1999

Study Type	Efficacy
Pertaining to	*Mycoplasma hyopneumoniae*
Study Purpose	Demonstrate a duration of immunity of at least 25 weeks against *Mycoplasma hyopneumoniae*
Product Administration	
Study Animals	Swine
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	November 14, 2001

Study Type	Efficacy
Pertaining to	*Mycoplasma hyopneumoniae*
Study Purpose	Demonstrate a duration of immunity of at least 23 weeks against *Mycoplasma hyopneumoniae*
Product Administration	
Study Animals	Swine
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	May 10, 2000

<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 effectiveness against Mycoplasma hyopneumoniae</td></tr>
<tr><td>Product Administration</td><td>Two doses administered intramuscularly, 14 days apart</td></tr>
<tr><td>Study Animals</td><td>41 vaccinated and 41 control piglets, 1 day of age</td></tr>
<tr><td>Challenge Description</td><td>M. hyopneumoniae administered two weeks post-vaccination</td></tr>
<tr><td>Interval observed after challenge</td><td>Animals were observed for four weeks post-challenge. Lung consolidation (%) was evaluated at four weeks post-challenge.</td></tr>
<tr><td>Results</td><td>Lung consolidation (%) was the primary variable.

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>0.13</td><td>5.13</td><td>16.00</td><td>25.38</td><td>44.20</td></tr>
<tr><td>Vaccinates</td><td>0</td><td>0.05</td><td>0.70</td><td>8.50</td><td>53.25</td></tr>
</table>

See individual data attached.</td></tr>
<tr><td>USDA Approval Date</td><td>March 28, 2013</td></tr>
</table>

Lung Consolidation (%) by Treatment and Animal

Controls

Animal	Lung Consolidation (%)
92	0.13
84	1.00
150	2.25
121	3.28
75	3.35
61	3.55
124	4.18
99	4.80
159	5.45
144	5.75
86	8.10
147	9.50
70	9.50
138	12.20
07	13.00
109	16.00
51	16.75
154	17.75
98	19.00
11	19.75
132	20.20
73	20.50
71	25.00
57	25.75
127	27.25
03	29.75
58	32.25
40	34.25
134	39.25
13	41.75
114	44.20

Vaccinates

Animal	Lung Consolidation (%)
119	0.00
123	0.00
125	0.00
146	0.00
50	0.00
60	0.00
77	0.00
90	0.00
102	0.05
110	0.05
142	0.05
148	0.10
128	0.13
01	0.20
74	0.20
82	0.20
56	0.40
152	0.65
117	0.70
105	0.83
55	1.00
34	1.15
52	1.90
47	3.55
33	6.10
81	6.10
94	7.25
143	8.50
38	9.00
137	10.30
112	12.25
155	15.00
35	16.00
06	23.25
05	42.45
02	49.85
04	53.25

Study Type	Safety
Pertaining to	All
Study Purpose	Demonstrate safety under field conditions in piglets and pregnant sows/gilts
Product Administration	Two doses administered intramuscularly
Study Animals	Swine
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	April 25, 1991

Study Type	Safety
Pertaining to	All
Study Purpose	Demonstrate safety under field conditions in pregnant sows
Product Administration	Two doses administered intramuscularly at 6 weeks and 2 weeks prior to farrow
Study Animals	Swine
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	April 25, 1991

Study Type	Safety
Pertaining to	All
Study Purpose	Demonstrate safety under field conditions in piglets, and pregnant sows or gilts
Product Administration	Two doses administered intramuscularly
Study Animals	Swine
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	September 18, 1991

Study Type	Safety
Pertaining to	All
Study Purpose	Demonstrate safety under field conditions in piglets
Product Administration	Two doses administered intramuscularly
Study Animals	Swine
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	October 12, 1990

Study Type	Safety
Pertaining to	All
Study Purpose	Demonstrate safety under field conditions in day of age piglets
Product Administration	Intramuscular
Study Animals	One dose administered intramuscularly 2 weeks apart
Challenge Description	Commercial pigs at one location, a total of 300 pigs were vaccinated (238 vaccinates and 62 controls) at 1 day of age
Interval observed after challenge	N/A
Results	Animals were monitored daily for 34-35 days and injection sites palpated three times during the week after each vaccination. No injection site reactions were noted.

Table 1 Post Vaccination Adverse Events which required Treatment

	Adverse Event*							
	NORMAL number	COUGH number	DIARRHEA number	LAMENESS number	RUNT number	SKIN LESION NOS number	SYSTEMIC DISORDERS NOS number	Total observations number
Treatment								
Control	48	3	1	0	8	10	0	70
Vaccinate	189	5	5	1	37	31	1	269
Total	237	8	6	1	45	41	1	339

*None were considered attributable to vaccination as affirmed by the Investigator to the vaccination.

Individual pigs with clinical observations (Tables 2 and 3) may also be included in Table 1 (if treatment was required)

Table 2 Clinical Observations Ever Present

	Normal	Abnormal	anorexia	Body condition	depression	Other*	Total Observations
	number	number	number	number	number	number	number
Treatment							
Control	51	11	0	1	1	11	62
Vaccinates	185	53	1	4	0	51	238

*Piglets observed as abnormal may exhibit more than one clinical sign. None of the abnormal observations were attributed by the Investigator to the vaccination.

Table 3 Additional details for "Other" clinical observation category*

Description	Control	Vaccinates
	number	number
Face Scars	7	25
Small Size, Runt, Thin	12	44
Lameness	1	2
Rupture/Hernia	0	4
Dead (Laid on, Stepped on)	0	4
Splay Leg	0	1

*Individual piglets may have more than one condition, however each condition was counted once. None of these conditions were attributed by the Investigator to the to the vaccination.

USDA Approval Date	01NOV2013