



## Summary of Studies Supporting USDA Product Licensure

Establishment Name	Zoetis Inc.
USDA Vet Biologics Establishment Number	190
Product Code	4995.2C
True Name	Swine Influenza Vaccine, H1N1 & H1N2 & H3N2, Killed Virus, Mycoplasma Hyopneumoniae Bacterin
Tradename(s) / Distributor or Subsidiary (if different from manufacturer)	FluSure XP/RespiSure - No distributor specified
Date of Compilation Summary	September 09, 2022

**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.**

<b>Study Type</b>	Efficacy
<b>Pertaining to</b>	Swine Influenza Virus H1N1
<b>Study Purpose</b>	To demonstrate efficacy against respiratory disease due to Swine Influenza Virus H1N1
<b>Product Administration</b>	Two doses administered intramuscularly
<b>Study Animals</b>	Swine
<b>Challenge Description</b>	Minnesota SIV isolate 01-10597H1 (H1N1)
<b>Interval observed after challenge</b>	
<b>Results</b>	<p>Study data were evaluated by USDA-APHIS prior to product licensure and met regulatory standards for acceptance at the time of submission.</p> <p>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.</p>
<b>USDA Approval Date</b>	12FEB2002

<b>Study Type</b>	Efficacy
<b>Pertaining to</b>	Swine Influenza A virus
<b>Study Purpose</b>	Efficacy against respiratory disease due to Swine Influenza A H1N1, H1N2, and H3N2
<b>Product Administration</b>	
<b>Study Animals</b>	
<b>Challenge Description</b>	
<b>Interval observed after challenge</b>	
<b>Results</b>	This product class allows the manufacturer to update microorganisms in this vaccine under expedited procedures to respond to emerging needs. Abbreviated data to support influenza strain updates to the product composition were evaluated by USDA-APHIS and found to be acceptable based on regulations and policies at the time of approval. Full vaccination challenge studies may not have been required for these updates.
<b>USDA Approval Date</b>	Apr 03 2015

Study Type	Efficacy																					
Pertaining to	Swine Influenza																					
Study Purpose	Efficacy against respiratory disease due to Swine Influenza Virus, H3N2																					
Product Administration	Intramuscular dose administered two weeks apart																					
Study Animals	Swine influenza virus serologically negative commercial pigs 3 weeks of age at administration, 20 vaccinates and 21 controls																					
Challenge Description	Influenza A/Swine/Indiana/853/2012 H3N2, administered 14 days after last vaccination																					
Interval observed after challenge	Observed daily for 5 days. Lung lesions were evaluated 5 days after challenge																					
Results	<p><b>Lung lesions was calculated with &gt;5% lung lesions defined as a positive case</b></p> <p><b>Five number summary of Lung Consolidation (%):</b></p> <table><tr><th>Treatment</th><th>n</th><th>Min</th><th>Q1</th><th>Median</th><th>Q3</th><th>Max</th></tr><tr><td>Controls</td><td>21</td><td>1.4</td><td>12.0</td><td>16.5</td><td>19.9</td><td>34.5</td></tr><tr><td>Vaccinates</td><td>20</td><td>0</td><td>0.8</td><td>6.0</td><td>9.9</td><td>15.4</td></tr></table> <p>Individual animal data provided below:</p>	Treatment	n	Min	Q1	Median	Q3	Max	Controls	21	1.4	12.0	16.5	19.9	34.5	Vaccinates	20	0	0.8	6.0	9.9	15.4
Treatment	n	Min	Q1	Median	Q3	Max																
Controls	21	1.4	12.0	16.5	19.9	34.5																
Vaccinates	20	0	0.8	6.0	9.9	15.4																
USDA Approval Date	13JUN2016																					

**Percentage of Total Lung with Lesions, in order of rank:**

<b>Control ID</b>	<b>Control % Lung Consolidation</b>
118	1.40
108	8.75
180	9.90
147	10.00
185	11.45
131	12.00
178	13.25
111	15.00
167	15.00
122	16.25
143	16.50
134	17.00
126	17.75
177	19.50
113	19.75
169	19.90
136	20.50
188	23.25
102	24.75
140	28.50
103	34.50

<b>Vaccinate ID</b>	<b>Vaccinate % Lung Consolidation</b>
170	0.00
179	0.30
187	0.45
101	0.50
174	0.50
104	1.15
145	1.55
186	3.30
127	3.80
144	5.50
130	6.50
112	7.50
137	7.50
117	8.45
123	9.25
176	10.50
107	12.20
138	12.50
115	13.50
172	15.45

<b>Study Type</b>	Efficacy
<b>Pertaining to</b>	Swine Influenza Virus H3N2
<b>Study Purpose</b>	To demonstrate short term efficacy after vaccination against respiratory disease due to Swine Influenza Virus H3N2
<b>Product Administration</b>	Two doses administered intramuscularly
<b>Study Animals</b>	Swine
<b>Challenge Description</b>	NADC SIV isolate 3 (H3N2)
<b>Interval observed after challenge</b>	
<b>Results</b>	<p>Study data were evaluated by USDA-APHIS prior to product licensure and met regulatory standards for acceptance at the time of submission.</p> <p>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.</p>
<b>USDA Approval Date</b>	November 15, 2001

<b>Study Type</b>	Efficacy
<b>Pertaining to</b>	Swine Influenza Virus H3N2
<b>Study Purpose</b>	To demonstrate efficacy 10 weeks after vaccination against respiratory disease due to Swine Influenza Virus H3N2
<b>Product Administration</b>	Two doses administered intramuscularly
<b>Study Animals</b>	Swine
<b>Challenge Description</b>	NADC Swine Influenza Virus Isolate 3 (H3N3)
<b>Interval observed after challenge</b>	
<b>Results</b>	<p>Study data were evaluated by USDA-APHIS prior to product licensure and met regulatory standards for acceptance at the time of submission.</p> <p>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.</p>
<b>USDA Approval Date</b>	21OCT2003

<b>Study Type</b>	Efficacy
<b>Pertaining to</b>	<i>Mycoplasma hyopneumoniae</i> , <i>Erysipelothrix rhusiopathiae</i> , and swine influenza virus
<b>Study Purpose</b>	Demonstrate lack of interference between swine influenza virus, <i>M. hyopneumoniae</i> , and <i>E. rhusiopathiae</i>
<b>Product Administration</b>	
<b>Study Animals</b>	Swine
<b>Challenge Description</b>	
<b>Interval observed after challenge</b>	
<b>Results</b>	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.
<b>USDA Approval Date</b>	November 05, 2001



<b>Study Type</b>	Efficacy
<b>Pertaining to</b>	<i>Mycoplasma hyopneumoniae</i>
<b>Study Purpose</b>	Demonstrate effectiveness against <i>Mycoplasma hyopneumoniae</i>
<b>Product Administration</b>	
<b>Study Animals</b>	
<b>Challenge Description</b>	
<b>Interval observed after challenge</b>	
<b>Results</b>	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.
<b>USDA Approval Date</b>	June 04, 1990

<b>Study Type</b>	Safety
<b>Pertaining to</b>	All
<b>Study Purpose</b>	Demonstrate safety under field conditions in piglets
<b>Product Administration</b>	Two doses administered intramuscularly
<b>Study Animals</b>	Swine
<b>Challenge Description</b>	
<b>Interval observed after challenge</b>	
<b>Results</b>	<p>Study data were evaluated by USDA-APHIS prior to product licensure and met regulatory standards for acceptance at the time of submission.</p> <p>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.</p>
<b>USDA Approval Date</b>	February 12, 2002

<b>Study Type</b>	Safety
<b>Pertaining to</b>	All
<b>Study Purpose</b>	Demonstrate safety under field conditions in piglets
<b>Product Administration</b>	Two doses administered intramuscularly
<b>Study Animals</b>	Swine
<b>Challenge Description</b>	
<b>Interval observed after challenge</b>	
<b>Results</b>	<p>Study data were evaluated by USDA-APHIS prior to product licensure and met regulatory standards for acceptance at the time of submission.</p> <p>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.</p>
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<b>USDA Approval Date</b>	February 12, 2002

<b>Study Type</b>	Safety
<b>Pertaining to</b>	All
<b>Study Purpose</b>	Demonstrate safety under field conditions in pregnant sows
<b>Product Administration</b>	Two doses administered intramuscularly
<b>Study Animals</b>	Swine
<b>Challenge Description</b>	
<b>Interval observed after challenge</b>	
<b>Results</b>	<p>Study data were evaluated by USDA-APHIS prior to product licensure and met regulatory standards for acceptance at the time of submission.</p> <p>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.</p>
<b>USDA Approval Date</b>	April 29, 2002

<b>Study Type</b>	Safety
<b>Pertaining to</b>	All
<b>Study Purpose</b>	Demonstrate safety under field conditions in pregnant sows
<b>Product Administration</b>	Two doses administered intramuscularly
<b>Study Animals</b>	Swine
<b>Challenge Description</b>	
<b>Interval observed after challenge</b>	
<b>Results</b>	<p>Study data were evaluated by USDA-APHIS prior to product licensure and met regulatory standards for acceptance at the time of submission.</p> <p>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.</p>
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<b>Product Administration</b>	Two doses administered intramuscularly
<b>Study Animals</b>	Swine
<b>Challenge Description</b>	
<b>Interval observed after challenge</b>	
<b>Results</b>	<p>Study data were evaluated by USDA-APHIS prior to product licensure and met regulatory standards for acceptance at the time of submission.</p> <p>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.</p>
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