Summary of Studies Supporting USDA Product Licensure

Establishment Name	Zoetis Inc.
USDA Vet Biologics Establishment Number	190
Product Code	19A5.2P
True Name	Swine Influenza Vaccine, pH1N1, Killed Virus
Tradename(s) / Distributor or Subsidiary (if different from manufacturer)	FluSure Pandemic - No distributor specified FluSure Pandemic - Zoetis Industria de Produtos
Date of Compilation Summary	December 06, 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.

Study Type	Efficacy
Pertaining to	Influenza A Virus of Swine (IAV-S)
Study Purpose	Efficacy against respiratory disease due to IAV-S, pH1N1
Product Administration	Intramuscular dose administered two weeks apart
Study Animals	IAV-S serologically negative commercial pigs 3 weeks of age at administration, 20 vaccinates and 20 controls.
Challenge Description	Influenza A/Swine/MX/4108/2009 pH1N1, administered 10 days after last vaccination
Interval observed after challenge	Observed daily for 10 days. Lung lesions were evaluated 5 days after challenge from 9 controls and 11 vaccinates. Remaining animals necropsied 10 days after challenge. Nasal swabs were collected daily from day 1 until day 6 then on days 8 and 10.
Results	Lung lesions were calculated and reported. If any lung lesions were observed, an animal was considered positive: Controls: 8 out 9 (89%) Vaccinates: 2 out of 11 (89%) Virus shedding after challenge (nasal swabs). An animal is positive if virus was detected (viral isolation) any day post-challenge: Controls: 19 out of 20 (95%) through day 10 post-challenge Vaccinates: 1 out of 20 (5%) though day 10 post-challenge Individual animal data provided below:
USDA Approval Date	29JUN2010

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

Control ID	Control % Lung Consolidation
6623	0.0
6637	10.6
6644	16.1
6569	16.3
6581	25.8
6615	27.3
6629	35.0
6588	40.8
6610	45.5

Vaccinate ID	Vaccinate % Lung Consolidation
6572	0.0
6582	0.0
6587	0.0
6605	0.0
6608	0.0
6616	0.0
6631	0.0
6649	0.0
6651	0.0
6635	0.2
6628	0.5

Summary of Quantitative Post Challenge Virus Shedding, Individual Animal Listing "If Ever Positive" Post-Challenge

*****An animal was considered positive for "if ever virus shed post challenge" if virus was detected (viral isolation).*

Treatment	Animal	If Ever Virus Shed Post Challenge
Controls	6567	+
	6569	+
	6579	+
	6581	+
	6588	+
	6589	+
	6595	+
	6610	+
	6612	+
	6614	+
	6615	+
	6621	+
	6623	-
	6625	+
	6626	+
	6629	+
	6637	+
	6640	+
	6644	+
	6648	+

Treatment	Animal	If Ever Virus Shed Post Challenge
Vaccinates	6572	-
	6575	-
	6580	-
	6582	-
	6587	-
	6593	-
	6594	-
	6605	-
	6606	-
	6608	-
	6616	-
	6619	-
	6620	+
	6628	-
	6631	-
	6635	-
	6638	-
	6643	-
	6649	-
	6651	-

Summary of Quantitative Post Challenge Virus Shedding, Individual Animal Listing

		Day of Study								
Treatment	**Animal**	**23**	**25**	**26**	**27**	**28**	**29**	**30**	**32**	**34**
Controls	6567	-	-	+	-	-	-	-	-	-
	6569	-	-	+	+	+	-	-	-	-
	6579	-	+	+	+	+	+	-	-	-
	6581	-	-	+	+	+	+	-	-	-
	6588	-	-	+	+	+	+	-	-	-
	6589	-	-	+	+	+	+	-	-	-
	6595	-	+	+	+	+	+	-	-	-
	6610	-	-	+	+	+	+	-	-	-
	6612	-	-	-	+	+	+	-	-	-
	6614	-	-	+	+	+	+	-	-	-
	6615	-	+	+	+	+	+	-	-	-
	6621	-	-	+	+	+	+	-	-	-
	6623	-	-	-	-	-	-	-	-	-
	6625	-	+	+	+	+	+	-	-	-
	6626	-	+	+	+	+	+	-	-	-
	6629	-	-	+	+	+	+	-	-	-
	6637	-	-	-	+	+	+	-	-	-
	6640	-	-	+	+	+	+	-	-	-
	6644	-	+	+	+	+	+	-	-	-
	6648	-	+	+	+	+	+	-	-	-
Vaccinates	6572	-	-	-	-	-	-	-	-	-
	6575	-	-	-	-	-	-	-	-	-
	6580	-	-	-	-	-	-	-	-	-
	6582	-	-	-	-	-	-	-	-	-
	6587	-	-	-	-	-	-	-	-	-
	6593	-	-	-	-	-	-	-	-	-
	6594	-	-	-	-	-	-	-	-	-
	6605	-	-	-	-	-	-	-	-	-
	6606	-	-	-	-	-	-	-	-	-
	6608	-	-	-	-	-	-	-	-	-
	6616	-	-	-	-	-	-	-	-	-
	6619	-	-	-	-	-	-	-	-	-
	6620	-	-	-	-	-	-	-	+	-
	6628	-	-	-	-	-	-	-	-	-
	6631	-	-	-	-	-	-	-	-	-
	6635	-	-	-	-	-	-	-	-	-
	6638	-	-	-	-	-	-	-	-	-
	6643	-	-	-	-	-	-	-	-	-
	6649	-	-	-	-	-	-	-	-	-
	6651	-	-	-	-	-	-	-	-	-

<table>
<tr><td>Study Type</td><td>Safety</td></tr>
<tr><td>Pertaining to</td><td>All</td></tr>
<tr><td>Study Purpose</td><td>Abbreviated safety evaluation in piglets</td></tr>
<tr><td>Product Administration</td><td>Intramuscular dose administered two weeks apart</td></tr>
<tr><td>Study Animals</td><td>Commercial pigs ~ 4 weeks of age (50 vaccinates and 4 sterile saline vaccinated controls)</td></tr>
<tr><td>Challenge Description</td><td>N/A</td></tr>
<tr><td>Interval observed after challenge</td><td>Daily for the duration of the study</td></tr>
<tr><td>Results</td><td>No immediate post-vaccination systemic health events

Summary of Animals Ever Having Each Clinical Sign After the First Vaccination
<table>
<tr><td rowspan="2">Treatment</td><td colspan="6">Number (and Percentage) of Animals Ever Positive for Each Clinical Sign</td></tr>
<tr><td>Labored breathing</td><td>Lameness</td><td>Lethargy</td><td>Off-feed</td><td>vomiting</td><td>Other*</td></tr>
<tr><td>Control</td><td>0/4</td><td>0/4</td><td>0/4</td><td>0/4</td><td>0/4</td><td>2/4 (50%)</td></tr>
<tr><td>Vaccinates</td><td>0/50</td><td>2/50 (4%)</td><td>3/50 (6%)</td><td>0/50</td><td>0/50</td><td>21/50 (42%)</td></tr>
</table>
*Other included pre-existing conditions at the time of arrival majority included coughing and sneezing

Summary of Animals Ever Having Each Clinical Sign After the Second Vaccination
<table>
<tr><td rowspan="2">Treatment</td><td colspan="6">Number (and Percentage) of Animals Ever Positive for Each Clinical Sign</td></tr>
<tr><td>Labored breathing</td><td>Lameness</td><td>Lethargy</td><td>Off-feed</td><td>vomiting</td><td>Other*</td></tr>
<tr><td>Control</td><td>0/4</td><td>0/4</td><td>0/4</td><td>0/4</td><td>0/4</td><td>0/4</td></tr>
<tr><td>Vaccinates</td><td>0/50</td><td>2/50 (4%)</td><td>10/50 (20%)</td><td>0/50</td><td>0/50</td><td>2/50 (4%)</td></tr>
</table></td></tr>
</table>

Injection Site Injections Summary

Treatment	Number (and Percentage) of Animals Ever Positive for Site Reactions after each vaccination			
	Left Neck- Vac #1		Right Neck- Vac #2	
	Pos	Neg	Pos	Neg
Control	0/4	4/4	0/4	4/4
Vaccinates	4/50 (8%)	46/50 (92%)	10/50 (20%)	40/50 (80%)

Study Days On Which Injection Site Reactions Were Present For Each Animal

Injection Site Location	Animal ID	Number of Positive Findings	Day(s) of Study Injection Site Reactions were Present
Left Neck (Vac #1)	6829	1	Day 3
	6847	1	Day 2
	6857	1	Day 7
	6879	1	Day 3
Right Neck (Vac #2)	6825	1	Day 15
	6829	1	Day 14 (1 hour post-vac)
	6842	1	Day 15
	6843	1	Day 14 (4-6 hours post-vac)
	6847	1	Day 15
	6849	1	Day 16
	6857	4	Days 15, 17, 18, 19
	6859	1	Day 15
	6861	2*	Day 14 (1 hour post-vac) Day 14 (4-6 hours post-vac)
	6880	1	Day 16

*Injection sites were evaluated at 3 time-points on Day 14; therefore, Pig #6861 had 2 detectable injection site reactions, but the reaction did not persist beyond a single day.

All injection site reactions were < 1.5 cm size

USDA Approval Date	29JUN2010

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	February 12, 2002

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.
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USDA Approval Date	February 12, 2002

Study Type	Safety
Pertaining to	All
Study Purpose	Demonstrate safety under field conditions in pregnant sows
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 29, 2002

Study Type	Safety
Pertaining to	All
Study Purpose	Demonstrate safety under field conditions in pregnant sows
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 29, 2002

Study Type	Safety
Pertaining to	All
Study Purpose	Demonstrate safety under field conditions in pregnant sows
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 29, 2002