



## Summary of Studies Supporting USDA Product Licensure

Establishment Name	Zoetis Inc.
USDA Vet Biologics Establishment Number	190
Product Code	19U5.20
True Name	Porcine Epidemic Diarrhea Vaccine, Killed Virus
Tradename(s) / Distributor or Subsidiary (if different from manufacturer)	
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	Safety																																																																		
Pertaining to	All																																																																		
Study Purpose	Demonstrate safety under field conditions in pregnant sows and pre-bred gilts																																																																		
Product Administration	An intramuscular dose administered at 5 weeks and 2 weeks pre-farrowing or pre-breeding in gilts (3 weeks apart).																																																																		
Study Animals	Commercial pigs at one location, a total of 60 pregnant sows including pre-breeding gilts were enrolled (50 vaccinates and 10 controls)																																																																		
Challenge Description	N/A																																																																		
Interval observed after challenge	Animals were monitored daily for 42 days. Injection site reactions monitored for 28 days.																																																																		
Results	<p>Injection site reactions (ISR)</p> <table><tr><th rowspan="3">Summary of Injection Site Reactions on Right Side of Neck</th><th colspan="4">Ever present right neck (first injection)</th><th rowspan="2">Total observations</th></tr><tr><th colspan="2">No</th><th colspan="2">Yes</th></tr><tr><th>number</th><th>%</th><th>number</th><th>%</th><th>number</th></tr><tr><td>Treatment</td><td></td><td></td><td></td><td></td><td></td></tr><tr><td>Control</td><td>10</td><td>100.0</td><td>0</td><td>0.0</td><td>10</td></tr><tr><td>Vaccinate</td><td>45</td><td>90.0</td><td>5</td><td>10.0</td><td>50</td></tr></table> <p>Only one animal had an ISR observed on day 2 and resolved by Day 7 (red-purple swelling that was not abscessed or painful).</p> <table><tr><th rowspan="3">Summary of Injection Site Reactions on Left Side of Neck</th><th colspan="4">Ever present left neck (second injection)</th><th rowspan="2">Total observations</th></tr><tr><th colspan="2">No</th><th colspan="2">Yes</th></tr><tr><th>number</th><th>%</th><th>number</th><th>%</th><th>number</th></tr><tr><td>Treatment</td><td></td><td></td><td></td><td></td><td></td></tr><tr><td>Control</td><td>10</td><td>100.0</td><td>0</td><td>0.0</td><td>10</td></tr><tr><td>Vaccinate</td><td>44</td><td>89.8</td><td>5</td><td>10.2</td><td>49</td></tr></table> <p>Four sows had an ISR that appeared as red or red-purple swellings that were not abscessed or painful; three were resolved in less than 4 days and all were resolved by 7 days.</p>	Summary of Injection Site Reactions on Right Side of Neck	Ever present right neck (first injection)				Total observations	No		Yes		number	%	number	%	number	Treatment						Control	10	100.0	0	0.0	10	Vaccinate	45	90.0	5	10.0	50	Summary of Injection Site Reactions on Left Side of Neck	Ever present left neck (second injection)				Total observations	No		Yes		number	%	number	%	number	Treatment						Control	10	100.0	0	0.0	10	Vaccinate	44	89.8	5	10.2	49
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### Post Vaccination Adverse Events

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

\*None were considered attributable to vaccination as affirmed by licensee.  
NOS: Not otherwise specified

### Reproductive Summary

Treatment	N*	Number of piglets	Number of piglets born alive/normal**	Number of piglets born with low viability	Number of piglets still born	Number of piglets born as mummies
<b>Controls</b>	6	68	51	0	4	13
<b>Vaccinates</b>	29	362	318	0	26	18

\*Number of bred animals that were pregnant and farrowed

\*\*All animals born alive were born normal

This herd did have a PRRS outbreak

**USDA Approval Date** 26AUG2014

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Study Purpose	Demonstrate safety under field conditions in pregnant sows and pre-bred gilts																																																																		
Product Administration	An intramuscular dose administered at 5 weeks and 2 weeks pre-farrowing or pre-breeding in gilts (3 weeks apart).																																																																		
Study Animals	Commercial pigs at two geographical locations, a total of 500 pregnant sows including gilts were enrolled (400 vaccinates and 100 controls)																																																																		
Challenge Description	N/A																																																																		
Interval observed after challenge	Animals were monitored through farrowing (49 days). Injection site reactions monitored for 42 days.																																																																		
Results	<p>Injection site reactions (ISR) ISR was calculated as frequency of abnormal 0, 1, 2, 3</p> <table><tr><th rowspan="3">Summary of Injection Site Reactions on the Right Side of Neck</th><th colspan="4">Ever present right neck (first injection)</th><th rowspan="2">Total observations</th></tr><tr><th colspan="2">No</th><th colspan="2">Yes</th></tr><tr><th>number</th><th>%</th><th>number</th><th>%</th><th>number</th></tr><tr><td>Treatment</td><td></td><td></td><td></td><td></td><td></td></tr><tr><td>Control</td><td>99</td><td>99.0</td><td>1</td><td>1.0</td><td>100</td></tr><tr><td>Vaccinate</td><td>276</td><td>69.0</td><td>124</td><td>31.0</td><td>400</td></tr></table> <p>No ISR scores of 3 (severe) were observed on the right neck.</p> <table><tr><th rowspan="3">Summary of Injection Site Reactions on Left Side of Neck</th><th colspan="4">Ever present left neck (second injection)?</th><th rowspan="2">Total observations</th></tr><tr><th colspan="2">No</th><th colspan="2">Yes</th></tr><tr><th>number</th><th>%</th><th>number</th><th>%</th><th>number</th></tr><tr><td>Treatment</td><td></td><td></td><td></td><td></td><td></td></tr><tr><td>Control</td><td>89</td><td>89.9</td><td>10</td><td>10.1</td><td>99</td></tr><tr><td>Vaccinate</td><td>249</td><td>63.4</td><td>144</td><td>36.6</td><td>393</td></tr></table> <p>ISR scores of 3 were observed in the left neck (second dose) in all treatment groups (Controls=4, Vaccinates=2); all were observed on only 1 day. One vaccinated bred sow had an ISR &gt;0 for 3 days (first observed pre-1<sup>st</sup> vaccination and continuing until Day 2), One pre-breeding gilt had an ISR &gt;0 for 8 days (post 2<sup>nd</sup> vaccination), and one bred sow had an ISR &gt;0 for a maximum of 28 days (post 1<sup>st</sup> vaccination). All other ISR of any score &gt;0 resolved in less than two days and the majority were only observed on one day.</p>	Summary of Injection Site Reactions on the Right Side of Neck	Ever present right neck (first injection)				Total observations	No		Yes		number	%	number	%	number	Treatment						Control	99	99.0	1	1.0	100	Vaccinate	276	69.0	124	31.0	400	Summary of Injection Site Reactions on Left Side of Neck	Ever present left neck (second injection)?				Total observations	No		Yes		number	%	number	%	number	Treatment						Control	89	89.9	10	10.1	99	Vaccinate	249	63.4	144	36.6	393
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	Reproductive Summary						
	Treatment	N*	Number of piglets	Number of piglets born alive/normal**	Number of piglets born with low viability	Number of piglets still born	Number of piglets born as mummies
	Controls	67	962	869	28	62	31
	Vaccinates	270	3873	3499	110	228	146
	*Number of bred animals that were pregnant and farrowed						
	Post Vaccination Adverse Events by Treatment						
	Events*		Treatment				
			Controls	Vaccinates			
	Normal		78	336			
	Abortion		0	1			
	Active Labor		2	2			
	Early labor		1	1			
	Vaginal discharge		0	1			
	Skin sore		1	3			
	Cough		5	9			
	Death during farrowing		0	1			
	Diarrhea		0	1			
	Labored breathing		2	0			
	Euthanized		0	1			
	Swollen limb		0	2			
	Lameness		2	10			
	Depression		2	13			
	Trembling		1	0			
	Mammary gland disorder		0	1			
	Dystocia		0	1			
	Decreased appetite		9	30			
	Systemic disorder		0	1			
	Emesis		1	0			
	*None were considered attributable to vaccination. The observations were within the expectations for within the herd.						
USDA Approval Date		18DEC2014					