

# **Summary of Studies Supporting USDA Product Licensure**

Establishment Name	Zoetis Inc.
USDA Vet Biologics Establishment Number	190
Product Code	49K5.R7
True Name	Porcine Circovirus Vaccine, Type 1 -Type 2 Chimera, Killed Virus, Mycoplasma Hyopneumoniae Bacterin
Tradename(s) / Distributor or Subsidiary (if different from manufacturer)	CircoMax Myco - Zoetis Korea Fostera Gold PCV MH - No distributor specified Fostera Gold PCV MH - Zoetis (Thailand) Limited Fostera Gold PCV MH - Zoetis Argentina Fostera Gold PCV MH - Zoetis Australia Pty Ltd Fostera Gold PCV MH - Zoetis Industria Produtos Veterinarios Ltda. Fostera Gold PCV MH - Zoetis Japan Inc. Fostera Gold PCV MH - Zoetis Mexico
Date of Compilation Summary	September 07, 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.

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Study Type	Efficacy								
Pertaining to	Circovirus, porcine, type 2 (PCV2)								
Study Purpose	Efficacy against Porcine Circovirus type 2b								
Product	Two doses administered intramuscularly 3 weeks apart.								
Administration	<u> </u>								
Study Animals	PCV2 serologically negative, commercial pigs, 3 days of age at first administration; 24 vaccinates and 25 controls.								
Challenge	Porcine Circovirus 2 (PCV2b)		vaccination.						
Description	1 0101110 01100 (1 0 (20)	, o weeks wheel seesing w	<b>W V III W I</b>						
Interval	PCV2 viremia (virus in serum	) and PCV2 shedding in	feces were evaluated						
observed after	twice weekly post challenge for	or 3 weeks.							
challenge	Lymphoid tissues were evalua	tad 2 waaks nost challer	aga for the presence of						
	PCV2 and characteristic change	-	_						
	depletion).	ges attributable to 1 C v 2	a miceuon (rymphola						
	depiction).								
Results		<b>X</b> 7• 4							
	Variable	Vaccinates Ever Positive*	Controls Ever Positive*						
	Viremia (PCV2 detection in serum)	3/24 (13%)	19/25 (76%)						
	Fecal Shedding (PCV2 detection in feces)	0/24 (0%)	20/25 (80%)						
	Lymphoid Depletion (PCV2 lesions)	1/24 (4%)	8/25 (32%)						
	Lymphoid Colonization (PCV2 in lymphoid tissues)	1/24 (4%)	11/25 (44%)						
	*A pig was considered positive for result at any sampling point.  Raw data to follow:	PCV2 detection in serum or	feces if it had a positive						

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Results		د د		ے
(continued)		viremia fecal shedding lymphoid colonization lymphoid depletion		viremia fecal shedding lymphoid colonization lymphoid depletion
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		viremia fecal sheddin lymphoid colonization lymphoid dep		viremia fecal sheddin lymphoid colonization lymphoid dep
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	16	+ + + -	10	
	2	+ +	11	
	29		12	
	30	<u></u>	14	
	31	+ +	15	
	33	- +	23	
	34	+ + + +	26	
	35	+ + + +	27	
	38	+ + + +	28	
	4	+ +	36	
	48	<u>+ </u>	43	
	5	+ + - +	50	
	52	+ + + -	51	
	6	- <u></u>	55	<u> </u>
	60	- + + +	65	+ - + +
	62	+ + + -	66	
	68	+ + + +	67	
	69	+ + + -	7	
	70	<u>+</u>	72	
	76 70	+ +	74	
	78	+ + + +	79	
	8	- 4	86	
	83	+ + + +	9	
	88	+ + -		

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Control	Day 42-46	Day 46-50	Day 49-53	Day 54-58	Day 56-60	Day 60-64
13	-	-	+	-	+	-
16	-	+	+	+	+	+
2	-	+	+	-	+	-
29	-	-	-	-	-	-
30	-	-	-	-	-	-
31	-	-	+	-	-	-
33	-	-	-	-	-	-
34	-	+	+	+	+	+
35	-	-	+	+	-	-
38	-	-	+	+	+	-
4	-	+	+	+	-	-
48	-	-	+	-	-	-
5	-	+	+	+	+	-
52	-	-	+	+	-	-
6	-	-	-	-	-	-
60	-	-	-	-	-	-
62	-	+	+	+	+	-
68	-	+	+	+	+	-
69	-	+	+	+	+	-
70	-	-	-	+	-	-
76	-	-	+	+	+	-
78	-	-	+	+	+	+
8	=	-	-	-	-	-
83	=	-	+	+	+	-
88	-	+	+	+	+	-

Vaccinate	Day 42-46	Day 46-50	Day 49-53	Day 54-58	Day 56-60	Day 60-64
1	-	-	-	-	-	-
10	-	-	-	-	-	-
11	-	-	-	-	-	-
12	-	-	-	-	-	-
14	-	-	-	-	-	-
15	-	-	-	-	-	-
23	-	-	-	-	-	-
26	-	-	-	-	-	-
27	-	-	-	-	-	-
28	-	-	-	-	-	-
36	-	-	-	-	-	-
43	-	-	-	-	-	-
50	-	-	-	-	-	-

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51	_	_	_	_	_	_
55	_	_	_	_	_	_
65	_	_	-	+	+	_
66	_	_	+	-	+	_
67					_	_
7	-	+	-	+	-	
72		-	-			=
74	-	-	-	-	-	-
	-	-	-	-	-	-
79	-	-	-	-	-	-
86 9	-	-	-	-	-	-
ecal sheddi Control	ing, observ Day 42-46	ved over ti Day 46-50	Day 49-53	Day 54-58	Day 56-60	Day 60-64
13						
16	-	-	+	+	-	-
2	-	+	+	+	+	+
	-	-	+	+	-	-
29	-	=	-	-	-	-
30	-	-	-	-	-	
31	-	-	+	+	-	-
33	-	-	+	-	-	+
34	-	+	+	+	+	+
35	-	-	+	+	+	-
38	-	-	+	+	+	-
4	=	+	+	+	-	+
48	-	-	-	-	-	-
5	-	-	-	+	+	-
52	-	-	+	+	+	+
6	-	-	-	-	-	-
60	-	-	-	+	-	-
62	-	-	+	+	+	+
68	-	-	-	+	+	+
69	-	-	+	+	+	+
	1		-	-	-	-
70	-	-				
	-	-	+	+	+	+
70				+	+	+
70 76	-	-	+			
70 76 78	-	+	+	+	+	+

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USDA Approval April 07, 2017

Date

Study Type	Efficacy
Pertaining to	Circovirus, porcine, type 2 (PCV2)
<b>Study Purpose</b>	Pivotal efficacy against Porcine Circovirus type 2b
Product	One dose, administered intramuscularly
Administration	
<b>Study Animals</b>	PCV2 serologically negative, commercial pigs, 21 days of age
	at administration; 26 vaccinates and 14 controls.
Challenge	Porcine Circovirus 2 (PCV2b), 3 weeks after vaccination
Description	
Interval	PCV2 viremia (virus in serum) and PCV2 fecal shedding were evaluated
observed after	twice weekly post challenge for 3 weeks.
challenge	Lymphoid tissues were evaluated 3 weeks post challenge for the presence of PCV2 and characteristic changes attributable to PCV2 infection (lymphoid depletion).

Results	Results:							
	Variable	Vaccinates Ever Positive*	Controls Ever Positive*					
	Viremia (PCV2 detection in serum)	3/26 (12%)	10/14 (71%)					
	Fecal Shedding (PCV2 detection in feces)	7/26 (27%)	12/14 (86%)					
	Lymphoid Depletion (PCV2 lesions)	6/26 (23%)	11/14 (79%)					
	Lymphoid Colonization (PCV2 in lymphoid tissues)	Lymphoid Colonization 8/26 (31%) 12/14 (86						
	*A pig was considered positive for I result at any sampling point.	CV2 detection in serum of its	eces ii it nau a positive					

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Results (Continued)	Control ID  122 146 153 167 188 193 202 214 25 358 368 378 48 78	- + + + + + + + + + + + + + + + + + + +	Vaccinate ID  121 123 142 147 152 155 156 158 166 170 183 187 192 201 205 21 213 357 369 372 377 41	+
	368	+ + + -	183	- +
	48		192	
			205	
			213	+ + +
			369	
			46 77	- + + -
			84 89	
	Raw data	, by study day, shown below.		
USDA Approval Date	09/15/2017	7		

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## Viremia, observed over time:

			Study Day					
	Animal	24	28	31	35	38	42	
Control	25	-	+	+	+	+	+	
Control	48	-	+	+	+	+	+	
Control	78	-	-	-	-	-	-	
Control	122	-	-	+	+	+	-	
Control	146	-	-	+	+	+	-	
Control	153	-	-	+	+	+	+	
Control	167	-	-	+	+	+	+	
Control	188	-	-	-	+	+	+	
Control	193	-	-	-	-	-	-	
Control	202	-	-	-	-	-	-	
Control	214	-	-	+	+	+	+	
Control	358	-	-	-	-	-	-	
Control	368	-	-	+	-	-	-	
Control	378	-	-	-	+	+	-	
Vaccinate	21	-	-	-	-	-	-	
Vaccinate	41	-	-	-	-	-	-	
Vaccinate	46	-	-	-	-	-	-	
Vaccinate	77	-	-	-	-	-	-	
Vaccinate	84	-	-	-	-	-	-	
Vaccinate	89	-	-	-	-	-	-	
Vaccinate	121	-	-	-	-	-	-	
Vaccinate	123	-	-	-	-	-	-	
Vaccinate	142	-	-	-	-	-	-	
Vaccinate	147	-	-	-	-	-	-	
Vaccinate	152	-	-	-	-	-	-	
Vaccinate	155	-	-	-	-	-	-	
Vaccinate	156	-	-	-	-	-	-	
Vaccinate	158	-	-	-	-	-	-	
Vaccinate	166	-	-	-	-	-	-	

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			Study Day					
	Animal	24	28	31	35	38	42	
Vaccinate	170	•	-	+	-	-	-	
Vaccinate	183	-	-	-	-	-	-	
Vaccinate	187	-	+	+	-	-	-	
Vaccinate	192	•	-	-	-	-	-	
Vaccinate	201	1	1	-	-	-	-	
Vaccinate	205	1	1	-	-	-	-	
Vaccinate	213	•	-	+	-	-	-	
Vaccinate	357	1	ı	-	-	-	-	
Vaccinate	369	-	-	-	-	-	-	
Vaccinate	372	-	-	-	-	-	-	
Vaccinate	377	-	-	-	-	-	-	

## Fecal shedding, observed over time:

			Study Day					
	Animal	24	28	31	35	38	42	
Control	25	-	+	+	+	+	+	
Control	48	-	+	+	+	+	+	
Control	78	-	-	+	+	+	+	
Control	122	-	-	+	-	+	-	
Control	146	-	-	-	-	+	+	
Control	153	-	-	-	+	+	+	
Control	167	-	-	+	+	+	+	
Control	188	-	-	-	+	+	-	
Control	193	-	-	-	-	-	-	
Control	202	-	-	-	+	-	-	
Control	214	-	-	+	+	+	+	
Control	358	-	-	-	-	-	-	
Control	368	-	-	+	+	-	-	
Control	378	-	-	-	+	+	+	

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				Study	y Day		
	Animal	24	28	31	35	38	42
Vaccinate	21	-	-	-	-	+	-
Vaccinate	41	-	-	-	-	-	-
Vaccinate	46	+	-	-	-	-	-
Vaccinate	77	-	-	-	-	-	-
Vaccinate	84	-	-	-	-	-	-
Vaccinate	89	-	-	-	-	-	-
Vaccinate	121	-	-	-	-	-	-
Vaccinate	123	-	-	-	-	-	-
Vaccinate	142	-	-	-	-	-	-
Vaccinate	147	1	-	-	-	1	-
Vaccinate	152	-	-	-	-	-	-
Vaccinate	155	-	-	-	-	-	+
Vaccinate	156	-	-	-	-	-	-
Vaccinate	158	-	-	-	-	-	-
Vaccinate	166	-	-	-	-	-	-
Vaccinate	170	-	-	+	-	-	+
Vaccinate	183	-	-	-	-	-	+
Vaccinate	187	-	-	+	-	-	-
Vaccinate	192	-	-	_	-	-	_
Vaccinate	201	-	-	-	-	-	-
Vaccinate	205	-	-	_	_	-	_
Vaccinate	213	-	-	-	-	-	-
Vaccinate	357	-	-	-	-	-	-
Vaccinate	369	-	-	-	-	-	-
Vaccinate	372	-	-	-	+	-	-
Vaccinate	377	-	-	-	-	-	-

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Study Type	Efficacy										
Pertaining to	Circovirus, porcine, type 2 (PC	(V2)									
Study Purpose	Pivotal efficacy against Porcine										
Product	Two doses, administered intramuscularly, 3 weeks apart										
Administration	1 wo doses, administered intramusediarry, 5 weeks apart										
Study Animals	PCV2 serologically negative, commercial pigs, 3 days of age at first										
Study Allillais	administration; 30 vaccinates a	10.	age at mst								
Challenge	Porcine Circovirus 2 (PCV2a),		cination								
Description	Toreme cheovitus 2 (1 e v 2a),	5 weeks after second vac	Cination								
Interval	PCV2 viremia (virus in serum)	and PCV2 shedding in fo	eces were evaluated								
observed after	twice weekly post challenge for		oces were evaluated								
challenge											
	Lymphoid tissues were evaluate	1 0	•								
	PCV2 and characteristic change		ntection (lymphoid								
	depletion and histiocytic replac	ement).									
Results											
	Results:										
	Variable	Vaccinates	Controls								
	Variable	Ever Positive*	Ever Positive*								
	Viremia	1/30 (3%)	24/29 (83%)								
	(PCV2 detection in serum)		(3233)								
	Fecal Shedding (PCV2 detection in feces)	5/30 (17%)	25/29 (86%)								
	Lymphoid Depletion										
	(PCV2 lesions)	1/30 (3%)	12/29 (41%)								
	Lymphoid Colonization	2/20 (7%)	14/20 (490/)								
	(PCV2 in lymphoid tissues)	2/30 (7%)	14/29 (48%)								
	*A pig was considered positive for l	PCV2 detection in serum or fe	eces if it had a positive								
	result at any sampling point.										

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Results		چ		c
(Continued)		letio g		g
(Continued)	Control	depl	Vaccinate	depl
	ID	shec shec zatid	ID	a shec oid zatii
		viremia fecal shedding lymphoid colonization lymphoid depletion		viremia fecal shedding lymphoid colonization lymphoid depletion
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	21	+ + + +	10	- 🕶
		+ + + +		
	23	+ + + +	11	
	26	• • · <u>·</u>	12	- + + -
	27	+ + - +	16	
	28	+ + + +	17	
	3	+ + + +	18	
	31	+ +	19	- 🕶
	32		20	
	35	+ + + +	25	- <u>-</u>
	36	+ + - +	29	- 🕶
	39	<b>.</b>	30	
	4	+ + + +	37	
	45	+ +	38	
	5	+ +	40	
	52		47	
	53		49	
	57	+ + + -	50	
	58	+ + + +	55	
	59	+ + + -	56	
	60	+ + + -	6	
	63	+ + + -	61	
	66	+ +	64	
	68		65	
	69	+ +	67	
	71	+ + + +	70	
	73	<b>+ +</b>	72	
	80	- 4	8	
	9		83	
			84	
			U <del>-1</del>	<b>-</b>
	Raw Data.	by sampling day, presented below		
		F87, F		
USDA Approval	August 25,	2017		
Date				

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## Viremia, observed over time:

					Study Day	1		
	Animal	43-47	47-51	51-55	55-58	58-62	61-65	64-68
Control	2	-	-	+	+	+	+	+
Control	3	-	-	+	+	+	+	+
Control	4	-	-	+	+	+	+	+
Control	5	-	-	+	-	-	-	+
Control	9	-	-	+	+	+	+	+
Control	21	-	-	+	+	+	+	+
Control	23	-	-	-	+	+	-	-
Control	26	-	-	+	+	-	-	-
Control	27	-	+	+	+	-	-	-
Control	28	-	-	+	+	-	-	-
Control	31	-	-	+	+	-	-	-
Control	32	-	-	-	-	-	-	-
Control	35	-	-	+	+	-	-	-
Control	36	-	-	+	+	-	-	-
Control	39	-	-	-	+	-	-	-
Control	45	-	-	-	+	-	+	-
Control	52	-	-	-	-	-	-	-
Control	53	-	-	-	-	-	-	-
Control	57	-	-	+	+	+	+	+
Control	58	-	-	+	+	-	-	-
Control	59	-	-	+	+	+	+	+
Control	60	-	-	+	+	-	+	-
Control	63	-	-	+	+	+	-	+
Control	66	-	-	+	+	+	+	+
Control	68	-	-	-	-	-	-	-
Control	69	-	-	-	-	-	+	+
Control	71	-	-	+	+	+	+	+
Control	73	-	-	+	+	-	-	-
Control	80	-	-	-	-	-	-	-

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					Study Day	,		
	Animal	43-47	47-51	51-55	55-58	58-62	61-65	64-68
Vaccinate	1	-	-	-	-	-	-	-
Vaccinate	6	-	-	-	-	-	-	-
Vaccinate	8	-	-	•	-	-	-	-
Vaccinate	10	-	-	-	-	-	-	-
Vaccinate	11	-	-	•	-	-	-	-
Vaccinate	12	-	-	-	-	-	-	-
Vaccinate	16	-	-	-	-	-	-	-
Vaccinate	17	-	-	-	-	-	-	-
Vaccinate	18	-	-	-	-	-	-	-
Vaccinate	19	-	-	-	-	-	-	-
Vaccinate	20	-	-	-	-	-	-	-
Vaccinate	25	-	-	-	-	-	-	-
Vaccinate	29	-	-	-	-	-	-	-
Vaccinate	30	-	-	-	-	-	-	-
Vaccinate	37	-	-	-	-	-	-	-
Vaccinate	38	-	-	-	-	-	-	-
Vaccinate	40	-	-	-	-	-	-	-
Vaccinate	47	-	-	-	-	-	-	-
Vaccinate	49	-	-	-	-	-	-	-
Vaccinate	50	-	-	-	-	-	-	-
Vaccinate	55	-	-	-	-	-	-	-
Vaccinate	56	-	-	-	-	-	-	-
Vaccinate	61	-	-	-	-	-	-	-
Vaccinate	64	-	-	-	-	-	-	-
Vaccinate	65	-	-	-	-	-	-	-
Vaccinate	67	-	-	-	-	-	-	-
Vaccinate	70	-	-	-	-	-	-	-
Vaccinate	72	-	-	-	-	-	-	-
Vaccinate	83	-	-	-	+	-	-	-
Vaccinate	84	-	-	-	-	-	-	-

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## Fecal Shedding, observed over time:

					Study Day			
	Animal	43-47	47-51	51-55	55-58	58-62	61-65	64-68
Control	2	-	-	+	+	+	+	+
Control	3	-	-	+	+	+	+	+
Control	4	-	-	+	+	+	+	+
Control	5	-	-	+	+	+	+	+
Control	9	-	-	+	+	+	+	+
Control	21	-	-	+	+	+	+	+
Control	23	-	-	+	+	+	+	-
Control	26	-	-	+	+	+	+	+
Control	27	-	+	+	+	+	-	+
Control	28	-	+	+	+	+	+	+
Control	31	-	-	+	+	+	-	+
Control	32	-	-	-	-	-	-	-
Control	35	-	-	+	+	+	-	-
Control	36	-	-	+	+	-	+	+
Control	39	-	-	-	-	-	-	-
Control	45	-	-	-	+	+	+	-
Control	52	-	-	-	-	-	-	-
Control	53	-	-	-	-	-	-	-
Control	57	-	-	+	+	+	+	+
Control	58	-	-	+	+	-	-	-
Control	59	-	-	+	+	+	+	+
Control	60	-	-	-	+	+	-	+
Control	63	-	-	+	+	+	+	+
Control	66	-	-	+	+	+	+	+
Control	68	-	-	-	-	+	+	+
Control	69	-	-	+	+	+	+	+
Control	71	-	-	+	+	+	+	+
Control	73	-	-	+	-	+	-	-
Control	80	-	+	+	-	+	-	-

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					Study Day			
	Animal	43-47	47-51	51-55	55-58	58-62	61-65	64-68
Vaccinate	1	-	-	+	-	-	-	-
Vaccinate	6	-	-	-	-	-	-	-
Vaccinate	8	-	-	-	-	-	-	-
Vaccinate	10	-	-	-	-	-	-	-
Vaccinate	11	-	-	-	-	-	-	-
Vaccinate	12	-	-	-	-	+	-	-
Vaccinate	16	ı	-	-	-	-	-	-
Vaccinate	17	-	-	-	-	-	-	-
Vaccinate	18	-	-	-	-	-	-	
Vaccinate	19	-	-	+	-	-	-	-
Vaccinate	20	-	-	-	-	-	-	-
Vaccinate	25	-	-	-	-	-	-	-
Vaccinate	29	-	+	-	-	-	-	-
Vaccinate	30	-	-	-	-	-	-	-
Vaccinate	37	-	-	-	-	-	-	-
Vaccinate	38	ı	•	-	-	-	-	-
Vaccinate	40	ı	-	-	-	-	-	•
Vaccinate	47	ı	•	-	-	-	-	-
Vaccinate	49	ı	-	+	+	ı	-	-
Vaccinate	50	-	-	-	-	-	-	-
Vaccinate	55	ı	-	-	-	-	-	-
Vaccinate	56	ı	-	-	-	-	-	-
Vaccinate	61	ı	-	-	-	-	-	•
Vaccinate	64	•	-	-	-	-	-	-
Vaccinate	65	•	-	-	-	-	-	-
Vaccinate	67	•	-	-	-	-	-	-
Vaccinate	70	-	-	-	-	-	-	-
Vaccinate	72	•	-	-	-	-	-	-
Vaccinate	83	•	-	-	-	-	-	-
Vaccinate	84	-	-	-	-	-	-	-

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Study Type	Efficacy										
Pertaining to	Circovirus, porcine, type 2 (P	CV2)									
Study Purpose	Efficacy against Porcine Circo										
Product	One dose, administered intramuscularly.										
Administration											
Study Animals		PCV2 serologically negative, commercial pigs, 3 weeks of age at									
		administration; 28 vaccinates and 29 controls.									
Challenge	Porcine Circovirus 2 (PCV2a)	), 3 weeks after vaccinate	ion.								
Description											
Interval	PCV2 viremia (virus in serum		ing were evaluated								
observed after	twice weekly post challenge f	for 3 weeks.									
challenge											
	Lymphoid tissues were evalua	-	_								
	PCV2 and characteristic chan	ges attributable to PCV2	infection (lymphoid								
D 14	depletion).										
Results		<b>T</b> 7•	Cartaila								
	Variable	Vaccinates Ever Positive*	Controls Ever Positive*								
	Viremia										
	(PCV2 detection in serum)	1 1//8/4%) 1 ////9///%)									
	Fecal Shedding	7/20 (250()	22/20 (7(0))								
	(PCV2 detection in feces)										
	<b>Lymphoid Depletion</b> 0/28 (0%) 9/29 (31%)										
	(PCV2 lesions)	0/20 (0/0)	7/27 (31/0)								
	Lymphoid Colonization (PCV2 in lymphoid tissues)	0/28 (0%)	13/29 (45%)								
	*A pig was considered positive fo	r PCV2 detection in serum or	feces if it had a positive								
	result at any sampling point.										
	D. L. CH										
	Raw data to follow:										

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Results (continued)	Control ID		tecal shedding lymphoid colonization	lymphoid depletion	Vaccinate ID	viremia	fecal shedding	lymphoid colonization	lymphoid depletion
	2457		+ +	+	2463	-	-	-	-
	2464		+ +	-	4851	-	+	-	-
	4850	+	-	-	4852	-	-	-	-
	5638	-		-	5644	-	-	-	-
	5645	+		-	5649	-	-	-	-
	5647		+ -	-	5654	-	-	-	-
	5650	+	+ +	+	5679	-	+	-	-
	5652		+ +	+	5686	-	-	-	-
	5653		+ +	-	5699	-	-	-	-
	5658		-	_	5705	-	-	-	-
	5684	+	+ -	+	5717	-	_	-	-
	5700	+	+ +	-	5719	-	+	-	-
	5707			-	5720	-	-	-	-
	5710	+	+ +	+	5725	-	+	-	-
	5713		+ -	-	5760	-	-	-	-
	5716		+ -	-	5761	-	-	-	-
	5723	+	+ +	+	5766	-	+	-	-
	5726	-		-	5767	-	-	-	-
	5762	+		-	6519	-	-	-	-
	6503	-		-	6524	-	-	-	-
	6515	-		-	6527	-	-	-	-
	6526	-	-	-	6534	-	+	-	-
	6542		+ +	-	6540	-	-	-	-
	6552		+ -	-	6545	+	-	-	-
	6564	-	+ +	+	6560	-	-	-	-
	6565		+ +	+	6568	-	-	-	-
	6572		+ +	١-	6581	-	-	-	-
	6589		+ -	-	6582	-	+	-	-
	6599		+ +	+					
USDA Approval	Septembe	er 26,	2016						
Date									

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Study Type	Efficacy										
Pertaining to	Circovirus, porcine, type 2 (Po	CV2)									
Study Purpose	Pivotal efficacy against Porcin	**									
Product	Two doses, administered intramuscularly, 3 weeks apart.										
Administration											
<b>Study Animals</b>		PCV2 serologically negative, commercial pigs, 3 weeks of age at first									
	administration; 29 vaccinates										
Challenge	Porcine Circovirus 2 (PCV2a)	, 3 weeks after second va	accination.								
Description											
Interval	PCV2 viremia (virus in serum		ng were evaluated								
observed after	weekly post challenge for 3 w	eeks.									
challenge											
	Lymphoid tissues were evalua	-	_								
	PCV2 and characteristic change		intection (lymphoid								
Dogulta	depletion and histiocytic repla	cement).									
Results		Vaccinates	Controls								
	Variable	vaccinates Ever Positive*	Ever Positive*								
	Viremia										
	(PCV2 detection in serum)	0/29 (0%)	25/27 (93%)								
	Fecal Shedding	7/20 (240/)	25/27 (020/)								
	(PCV2 detection in feces)	7/29 (24%)	25/27 (93%)								
	Lymphoid Depletion	0/29 (0%)	4/27 (15%)								
	(PCV2 lesions)	0/2/ (0/0)	1/2/ (15/0)								
	Lymphoid Colonization (PCV2 in lymphoid tissues)	0/29 (0%)	3/27 (11%)								
	*A pig was considered positive for	PCV2 detection in serum or	feces if it had a positive								
	result at any sampling point.		_								
	Raw data to follow:										
Results											

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(continued)	<u> </u>									
(continued)	Control ID	viremia	recal shedding	colonization	lymphoid depletion	Vaccinate ID	viremia	fecal shedding	lymphoid colonization	lymphoid depletion
	1102	+ -		-	-	1101	-	+	-	-
	1103	+ +	F	-	-	1104	-	+	-	-
	1107	+ +	F	-	-	1105	-	-	-	-
	1108	+ +	F		-	1106	-	-	-	-
	1111	+ +	F	+	-	1112	-	-	-	-
	1114	+ +	F	-	-	1115	-	-	-	-
	1117	+ +	F	-	+	1118	-	-	-	-
	1121	+ +	F	-	-	1123	-	+	-	-
	1125	<u> </u>		-	-	1124	-	-	-	-
	1126	+ +	F	-	+	1127	-	+	-	-
	1131	+ +	F	+	+	1132	-	-	-	-
	1135	+ +	H	-	-	1133	-	+	-	-
	1138	+ +	F	-	-	1134	-	-	-	-
	1145	+ +	F	+	+	1143	-	-	-	-
	1146	+ +	H	-	-	1147	-	-	-	-
	1150	+ +	H	-	-	1148	-	-	-	-
	1153		H	-	-	1149	-	+	-	-
	1154	+ +	H	-	-	1151	-	-	-	-
	1159	+ +	H	-	-	1155	-	-	-	-
	1169	+ +	F	-	-	1156	-	-	-	-
	1170	+		-	-	1158	-	-	-	-
	1176	+ +	H	-	-	1167	-	-	-	-
	1178	+ +	H	-	-	1171	-	-	-	-
	1181	+ +	F	-	-	1172	-	+	-	-
	1188	+ +	F	-	-	1177	-	-	-	-
	1195	+ +	F	-	-	1180	-	-	-	-
	1199	+ +	F	-	-	1191	-	-	-	-
						1194	-	-	-	-
						1198	-	-	-	-
USDA Approval Date	Septembe	r 13, 2	201	3						

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Study Type	Efficacy										
Pertaining to	Circovirus, porcine, type 2 (P										
Study Purpose	Duration of immunity against										
Product	One dose, administered intramuscularly.										
Administration											
<b>Study Animals</b>		PCV2 serologically negative, commercial pigs, 3 weeks of age at									
Cl. II.	administration; 28 vaccinates		-4:								
Challenge	Porcine Circovirus 2 (PCV2b	), 23 weeks after vaccin	ation.								
Description	DCV2 vinamia (vinus in samu	a) was avaluated twice v	waaldy and facal								
Interval	PCV2 viremia (virus in serun		•								
observed after	shedding was evaluated week	ary, for 50 days after cha	menge.								
challenge	I swamp oid tissues sugar sugle	oto d 20 dove most shallo	for the museum of								
	Lymphoid tissues were evaluated of PCV2 and characteristic charact		-								
	(lymphoid depletion and histi	•	V Z IIII CCIIOII								
Results	(Tymphold depletion and mstr	ocytic replacement).									
Results		Vaccinates	Controls								
	Variable	Ever Positive*	Ever Positive*								
	Viremia										
	(PCV2 detection in serum)	0/28 (0%)	15/26 (58%)								
	Fecal Shedding	5/28 (18%)	16/26 (62%)								
	(PCV2 detection in feces)	3/20 (1070)	10/20 (02%)								
	Lymphoid Colonization (PCV2 in lymphoid tissues)	1/28 (4%)	9/26 (35%)								
	*A pig was considered positive fo	or PCV2 detection in serum o	or feces if it had a								
	positive result at any sampling poi		1 10005 11 11 1140 4								
	Raw data to follow:										

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Results						
(continued)		D			D	
(continued)	Control	ddin	Vaccinate		ddin	on
	ID	she sherizati	ID	<u>.</u>	she	oid izati
		viremia fecal shedding lymphoid colonization		viremia	fecal shedding	lymphoid colonization
	502	+ + +	501	-	-	<u> -</u>
	505	+ + -	503	_	_	_
	506	<u> </u>	504	_	_	_
	507	- 🕶 -	508	_	_	_
	509	+ + +	510	_	_	-
	512		511	-	+	-
	513		514	-	-	-
	515	+ + +	516	-	-	-
	517		518	-	-	-
	522	+ + -	519	-	+	-
	524	+ + +	521	-	-	-
	526	+ + -	523	-	+	+
	527		525	-	-	-
	528	+ + +	529	-	-	-
	531	- + -	530	-	-	-
	533	- 🚺 -	532	-	-	-
	538	<u>•</u> -	536	-	-	-
	545	+ + -	539	-	-	-
	546	<u></u>	540	-	-	-
	547	+ + +	542	-	_	-
	548	+ - +	543	-	+	-
	550	<u></u> -	544	-	-	_
	552	+ + -	549	-	+	-
	558		551	-	-	-
	559	+ + +	553	-	-	-
	560	+ + +	554	-	-	-
			555	-	-	-
			556	-	-	-
USDA Approval	June 6, 20	14				
Date						

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Study Type	Efficacy			
Pertaining to	Circovirus, porcine, type 2 (Po	CV2)		
Study Purpose	Duration of Immunity against	Porcine Circovirus T	Type 2b	
Product	One dose, administered intran	nuscularly.		
Administration				
<b>Study Animals</b>	PCV2 serologically negative,	commercial pigs, 3 w	eeks of age at	
	administration; 25 vaccinates	and 25 controls.		
Challenge	Porcine Circovirus Type 2b, 2	3 weeks after vaccina	ation	
Description				
Interval observed	PCV2 viremia and PCV2 Feca	al Shedding were eva	luated twice weekly po	ost
after challenge	challenge for 3 weeks.			
	Lymphoid tissues were evalual PCV2 in lymphoid tissues and disease (lymphoid depletion a	l characteristic lesion	s attributable to PCV2	
Results				_
	Variable	Vaccinates Ever Positive*	Controls Ever Positive*	
	Viremia (PCV2 detection in serum)	4/25 (16%)	13/25 (52%)	
	Fecal Shedding (PCV2 detection in feces)	3/25 (12%)	20/25 (80%)	
	Lymphoid Depletion (PCV2 lesions)	3/25 (12%)	11/25 (44%)	
	Lymphoid Colonization (PCV2 in lymphoid tissues)	0/25 (0%)	6/25 (24%)	
	*A pig was considered positive for positive result at any sampling poin		n or feces if it had a	
	Raw data to follow:			
<b>USDA Approval Date</b>	04/12/17			

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Control ID	viremia	fecal shedding	lymphoid colonization	lymphoid depletion	Vaccinate ID	viremia	fecal shedding	lymphoid colonization	lymphoid depletion
622	+	+	-	-	624	+	-	-	-
617	+	+	-	-	618	-	-	-	-
623	-	+	-	-	620	-	-	-	
664	+	+	+	+	625	-	-	-	+
668	+	+	-	+	665	-	+	-	-
986	-	+	-	-	670	-	-	-	-
610	-	+	-	+	675	-	-	-	-
611	-	-	-	-	995	-	+	-	-
612	-	-	-	-	606	+	-	-	-
615	+	+	-	+	607	-	-	-	
616	-	+	-	+	613	-	-	-	+
990	-	-	-	+	614	-	-	-	-
994	-	-	-	-	991	-	-	-	-
673	+	+	+	+	992	+	-	-	-
674	+	+	+	+	667	-	-	-	-
741	-	-	-	-	669	-	-	-	-
979	-	+	-	-	672	-	-	-	-
981	+	+	-	-	977	-	-	-	-
982	+	+	-	-	978	-	-	-	-
985	-	+	-	-	983	-	-	-	+
744	-	+	-	-	742	-	-	-	-
746	+	+	+	+	743	-	-	-	-
748	+	+	+	+	745	-	-	-	-
750	+	+	+	+	747		+	-	-
976	+	+	-	-	749	+	-	-	-

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Study Type	Efficacy
Pertaining to	Circovirus, porcine, type 2 (PCV2)
<b>Study Purpose</b>	23-week Duration of immunity against Porcine Circovirus 2.
<b>Product Administration</b>	One dose, administered intramuscularly at 3 weeks of age or
	two doses, administered intramuscularly 21 days apart at 3 days
	of age
<b>Study Animals</b>	Pigs
<b>Challenge Description</b>	
Interval observed after	
challenge	
Results	Study data are not available.

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Study Type	Effic	cacv						
Pertaining to			a hvor	пеин	noniae (N	MH)		
Study Purpose							aused	by <i>Mycoplasma</i>
		пеитог		F				5 y 2.5 y 2.5 p 2.2.2.2.2.
Product	Two	doses,	admir	nister	ed intram	nuscul	arly, 3	weeks apart
Administration							•	•
Study Animals	MH	serolog	ically	nega	tive, con	nmerc	ial pig	s, 3 days of age at first
	adm	inistrati	on; 59	vac	cinates ar	nd 56	contro	ols.
Challenge		•	a hyop	neur	noniae, a	dmini	stered	3 weeks after second
Description		ination						
Interval	1	_						ge for the presence of
observed after	Мус	oplasmo	a hyop	neur	noniae-sp	pecific	lung	lesions.
challenge								
Results				lung	g that was	s abno	rmal (	(consolidated) was calculated
	for e	every an	imal.					
	_					,		(0/)
					for lung o			on (%):
	Tre	atment	Min	Q1	Median	Q3	Max	
	Co	ontrols	0.35	7.0	15.3	20.1	62.4	
	Vac	ccinates	0.05	2.7	7.9	14.1	54.8	
				on s	cores (%	), in o	rder (	of rank:
		g conso		on s	cores (% Controls	), in o	order (	of rank:
		Vaccinat % Lı	es		Controls % Lun	ıg	order (	of rank:
		Vaccinat	es	on so	Controls	ıg	order (	of rank:
		Vaccinat % Lı	es ing dation		Controls % Lun	ıg	order (	of rank:
	ID	Vaccinat % Lu Consolie	es ung dation	ID	Controls % Lun Consolida	ıg	order (	of rank:
	ID 318	Vaccinat % Lu Consolid	ing dation 5	ID 286	Controls % Lun Consolida 0.35	ıg	order (	of rank:
	ID 318 320	Vaccinat % Lu Consolid 0.0 0.2	es ing dation 5 5	ID 286 247	Controls % Lun Consolida 0.35 1.00	ıg	order (	of rank:
	ID 318 320 323	% Lu Consolid  0.0  0.2  0.6	nng dation 5 5 0	ID 286 247 255	Controls % Lun Consolida 0.35 1.00 1.65	ıg	order (	of rank:
	ID  318  320  323  204	% Lu Consolid  0.0  0.2  0.6  0.7	dation  5  0  0  3	ID 286 247 255 304	Controls % Lun Consolida 0.35 1.00 1.65 2.90	ıg	order (	of rank:
	318 320 323 204 361	% Lu Consolid  0.0  0.2  0.6  0.7	tes ing dation 5 0 0 3	286 247 255 304 299	Controls % Lun Consolida 0.35 1.00 1.65 2.90 3.45	ıg	order (	of rank:
	318 320 323 204 361 334	% Lu Consolid  0.0  0.2  0.6  0.7  1.1	tes ing dation 5 5 0 0 3 0 0	286 247 255 304 299 289	Controls % Lun Consolida 0.35 1.00 1.65 2.90 3.45 4.95	ıg	order (	of rank:
	318 320 323 204 361 334 319	% Lu Consolid  0.0  0.2  0.6  0.7  1.1  1.3	tes ing dation 5 5 0 0 0 3 0 0 5	286 247 255 304 299 289 309	Controls % Lun Consolida 0.35 1.00 1.65 2.90 3.45 4.95 5.15	ıg	order (	of rank:
	318 320 323 204 361 334 319 313	Vaccinat           % Lu           Consolid           0.0           0.2           0.6           0.7           1.1           1.3	tes ing dation 5 5 0 0 0 3 0 0 5 0 0	286 247 255 304 299 289 309 370	Controls % Lun Consolida 0.35 1.00 1.65 2.90 3.45 4.95 5.15 5.18	ıg	order (	of rank:
	318 320 323 204 361 334 319 313 205	Vaccinat           % Lu           Consolid           0.0           0.2           0.6           0.7           1.1           1.3           1.4	es ing dation 5 5 0 0 0 5 0 0 0 0 0 0 0 0 0 0 0 0 0	286 247 255 304 299 289 309 370 206	Controls % Lun Consolida 0.35 1.00 1.65 2.90 3.45 4.95 5.15 5.18 5.55	ıg	order (	of rank:
	318 320 323 204 361 334 319 313 205 336	Vaccinat  % Lu Consolid  0.0  0.2  0.6  0.7  1.1  1.3  1.4  1.7	es ing dation 5 5 0 0 0 5 0 0 0 8	286 247 255 304 299 289 309 370 206 202	Controls % Lun Consolida 0.35 1.00 1.65 2.90 3.45 4.95 5.15 5.18 5.55 5.70	ıg	order (	of rank:

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6.55

371

2.70

333

325	2.73	261	7.40
222	2.75	310	7.55
218	3.00	337	7.65
339	3.08	287	8.30
315	3.15	321	9.00
212	3.75	209	9.05
236	3.85	335	10.13
283	4.20	250	11.85
228	4.60	211	12.80
268	4.95	316	13.25
356	5.48	301	13.60
203	5.80	201	13.85
207	5.88	217	14.45
294	5.90	226	14.90
290	6.28	326	15.70
237	7.90	330	16.20
303	8.00	340	16.25
285	8.23	305	16.95
314	8.95	302	17.05
244	9.05	219	17.05
214	9.03	369	17.13
243	10.35	249	17.25
253	10.33	281	17.55
282	10.55	252	18.15
296	10.65	269	18.90
241	10.80	293	18.90
273	10.90	353	19.30
267	12.00	327	19.85
232	12.40	256	20.40
245	13.40	231	21.00
297	14.10	224	21.60
372	14.40	317	22.15
329	15.45	350	22.50
275	17.50	291	23.50
264	19.40	238	24.80

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	366	19.65	266	24.95
	251	20.25	239	25.80
	274	22.60	230	26.25
	233	24.15	234	38.10
	279	24.60	278	38.50
	235	25.15	364	41.75
	262	26.90	365	62.35
	223	34.40		
	367	44.25		
	242	54.80		
USDA Approval Date	April 1	8, 2017		
Daic				

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<b>Study Type</b>	Effic	cacy						
Pertaining to	$\overline{Myc}$	oplasm	a hyop	neur	noniae (N	MH)		
<b>Study Purpose</b>				espir	atory dise	ease c	aused	by <i>Mycoplasma</i>
		oneumoi						
Product	One	dose ac	lminis	terec	l intramus	scular	ly.	
Administration								
<b>Study Animals</b>		·	•	_				s, 3 weeks of age at
					cinates ar			
Challenge	Мус	oplasm	a hyop	neur	noniae, a	dmini	stered	3 weeks after vaccination.
Description								
Interval	1	_						ge for the presence of
observed after	Myc	oplasm	a hyop	neui	noniae-sp	pecific	lung	lesions.
challenge	TDI		C .1	1	.1 .		1 /	
Results		-		lun	g that was	s abno	ormal (	consolidated) was calculated
	for e	every an	ımaı.					
	- NT		g		e T	•	. 1. 1	4 (0/)
					_			tion (%):
	Tre	eatment	Min	Q1	Median	Q3	Max	
		ontrols	<b>Min</b> 4.4	<b>Q1</b> 7.5	Median 13.2	<b>Q3</b> 18.0	Max 26.3	
	Co			-		-		
	Co	ontrols	4.4	7.5	13.2	18.0	26.3	
	Vac	ontrols	4.4	7.5	13.2	18.0	26.3	r of Rank:
	Vac	ontrols	4.4 0	7.5	13.2	18.0	26.3	r of Rank:
	Vac	ontrols ccinates g Cons Vaccinat	4.4 0 olidat	7.5 2.0	13.2 5.3 Scores (% Controls	18.0 10.5	26.3	r of Rank:
	Vac	ontrols ccinates  g Cons Vaccinat	4.4 0 olidat	7.5	13.2 5.3 Scores (% Controls % Lun	18.0 10.5	26.3	r of Rank:
	Lun ID	ontrols ccinates G Cons Vaccinat % La Consoli	4.4 0 olidates	7.5 2.0 ion \$	13.2 5.3 Scores (% Controls % Lun Consolida	18.0 10.5	26.3	r of Rank:
	Lun ID 272	controls  g Cons Vaccinate  % Li Consoli	4.4 0 olidates ung dation	7.5 2.0 ion \$ ID	13.2 5.3 Scores (% Controls % Lun Consolida 4.4	18.0 10.5	26.3	r of Rank:
	Co   Vac   Lun     ID     272   234	yaccinates Vaccinate Consoli  0.0	4.4 0 olidates ung dation	7.5 2.0 ion \$ ID 216 242	13.2 5.3  Scores (% Controls % Lun Consolida 4.4 4.7	18.0 10.5	26.3	r of Rank:
	Lun  1D  272  234  271	y Consoli  Consoli  0.6	4.4 0 olidates ung dation	7.5 2.0 ion S ID 216 242 240	13.2 5.3 Scores (% Controls % Lun Consolida 4.4 4.7 5.3	18.0 10.5	26.3	r of Rank:
	Lun  1D  272  234  271  277	y Consoli  Consoli  0.6  0.6	4.4 0  olidates ung dation 0 5	7.5 2.0 ion \$\frac{9}{2}\$ 216 242 240 223	13.2 5.3 Scores (% Controls % Lun Consolida 4.4 4.7 5.3 5.4	18.0 10.5	26.3	r of Rank:
	Lun  ID  272  234  271  277  251	y Consoli  Consoli  0.6  0.6  0.8	4.4 0  olidates  ung dation  5 5 6 8	7.5 2.0 ion \$ 1D 216 242 240 223 235	13.2 5.3 Scores (% Controls % Lun Consolida 4.4 4.7 5.3 5.4 6.8	18.0 10.5	26.3	r of Rank:
	Co   Vao	### Consoli	4.4 0 olidates ung dation 0 5 6 8	7.5 2.0 ion S 1D 216 242 240 223 235 239	13.2 5.3 Scores (% Controls % Lun Consolida 4.4 4.7 5.3 5.4 6.8 6.9	18.0 10.5	26.3	r of Rank:
	Lun  ID  272  234  271  277  251	### Consoli	4.4 0 olidates ung dation 0 5 6 8	7.5 2.0 ion \$ 1D 216 242 240 223 235	13.2 5.3 Scores (% Controls % Lun Consolida 4.4 4.7 5.3 5.4 6.8	18.0 10.5	26.3	r of Rank:
	Co   Vao	### Consoli	4.4 0 olidates ung dation 0 5 6 8	7.5 2.0 ion S 1D 216 242 240 223 235 239	13.2 5.3 Scores (% Controls % Lun Consolida 4.4 4.7 5.3 5.4 6.8 6.9	18.0 10.5	26.3	r of Rank:
	Lun  1D  272  234  271  277  251  207  226	© Consoli  Consoli  0.6  0.6  0.8  0.9	4.4 0 olidates ung dation 0 5 6 8 9	7.5 2.0 ion S 1D 216 242 240 223 235 239 219	13.2 5.3 Scores (% Controls % Lun Consolida 4.4 4.7 5.3 5.4 6.8 6.9 7.2	18.0 10.5	26.3	r of Rank:
	Lun  272 234 271 277 251 207 226 256	© Consoli	4.4 0 olidates ung dation 0 5 5 6 8 9	7.5 2.0 ion \$\frac{9}{2}\$ 216 242 240 223 235 239 219 264	13.2 5.3 Scores (% Controls % Lun Consolida 4.4 4.7 5.3 5.4 6.8 6.9 7.2 7.5	18.0 10.5	26.3	r of Rank:

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10.1

11.5

11.8

13.0

268

258

278

253

215

275

250

203

3.3

4.5

5.2

5.3

	238	5.3	252	13.2		
	246	6.0	225	13.7		
	214	6.7	211	13.7		
	217	8.1	273	14.0		
	243	8.6	248	15.0		
	230	9.8	227	16.9		
	274	10.0	237	17.8		
	261	10.5	257	18.0		
	220	12.1	205	18.8		
	247	14.0	244	19.0		
	218	15.6	222	19.1		
	255	16.0	209	21.0		
	208	16.6	206	21.5		
	249	19.2	228	22.0		
	212	20.8	254	26.3		
JSDA Approval Date	Octobe	er 26, 2016				

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Study Type	Effic							
Pertaining to	•				noniae (N			
<b>Study Purpose</b>					-	igains	st respi	ratory disease caused by
<b>D</b> 1 .		oplasm						
Product	One	dose ac	lmınıs	terec	l intramus	scular	ly.	
Administration	3.411	1	• 11		· ·		. 1 .	2 1 6
<b>Study Animals</b>					itive, com ccinates a			s, 3 weeks of age at
Challenge								23 weeks after vaccination.
<b>Description</b>	WIYC	opiasmi	л пуор	meur	noniue, a	umm	stereu	23 weeks after vaccination.
Interval	Lune	os were	evalu	ated	4 weeks a	after c	hallen	ge for the presence of
observed after		-			noniae-sp			
challenge	1,190	ориали	ипуор	,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,	nomine sp	,001110	7 14116	e de la companya de l
Results	The	percent	of the	lung	g that was	abno	rmal (	consolidated) was calculated for
		y anima		`				,
	5-Nı	ımber S	Sumn	ary	for Lung	g Con	solida	tion (%):
	Tre	atment	Min	Q1	Median	Q3	Max	
	Co	ontrols	0	1.4	2.7	5.8	18.2	
	Vac	cinates	0	0.5	1.8	3.8	8.6	
	Lun	g Cons	olidat	ion S	Scores (%	6), In	Orde	r of Rank:
					Controls			
		% Lı	าทฐ		% Lun	σ ·		
	ID	Consoli	_	ID	, v 23411			
		00110011	dation		Consolida	-		
	232	0.0			Consolida	-		
	232	0.0	)	248	0.0	-		
	293	0.0	)	248	0.0	-		
	293 295	0.0	)	248 385 184	0.0 0.5 0.6	-		
	293 295 357	0.0	) ) )	248 385 184 288	0.0 0.5 0.6 0.6	-		
	293 295 357 379	0.0 0.0 0.1	) ) ) 1	248 385 184 288 383	0.0 0.5 0.6 0.6 0.7	-		
	293 295 357 379 183	0.0 0.0 0.1 0.2	) ) ) 1 3	248 385 184 288 383 363	0.0 0.5 0.6 0.6 0.7	-		
	293 295 357 379 183 277	0.0 0.0 0.2 0.2	) ) ) 1 3 4	248 385 184 288 383 363 289	0.0 0.5 0.6 0.6 0.7 0.8	-		
	293 295 357 379 183 277 191	0.0 0.0 0.1 0.2 0.2 0.2	) ) ) 1 3 4 4 4	248 385 184 288 383 363 289 372	0.0 0.5 0.6 0.6 0.7 0.8 1.0	-		
	293 295 357 379 183 277	0.0 0.0 0.2 0.2	) ) ) 1 3 4 4 4 5 5	248 385 184 288 383 363 289	0.0 0.5 0.6 0.6 0.7 0.8	-		

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1.8

1.9

2.0

2.2

182

243

284

298

0.9

1.4

1.5

1.7

389

187

273

354

Results	384	1.8	189	2.3
(continued)	299	1.8	190	2.5
	356	1.8	227	2.7
	246	1.9	239	2.7
	279	1.9	358	2.8
	225	2.0	282	2.8
	376	2.1	374	3.0
	381	3.2	297	3.1
	359	3.3	377	3.9
	362	3.6	274	4.7
	360	4.0	364	5.5
	387	4.7	286	5.8
	301	5.1	235	6.3
	244	5.4	388	7.0
	231	6.3	355	8.1
	378	7.8	236	9.2
	281	8.5	386	9.8
	238	8.6	304	10.0
			237	11.5
			306	18.2
USDA	Octob	er 03, 201	6	
<b>Approval Date</b>				

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Study Type	Effica	acv						
Pertaining to			a hvop	пеито	oniae (MF	<del>I</del> )		
Study Purpose		•					e caus	ed by <i>Mycoplasm</i>
				,		,		or of may represent
Product Administration				stered	intramus	cularly	2 week	s apart.
Study Animals	MH s	erolog	ically	negati	ve, comm	ercial p	igs, 21	days of age at
	first a	dminis	stration	ı; 32 v	accinates	and 31	contro	ls.
Challenge Description	Мусо	plasmo	a hyop	neumo	<i>oniae</i> , adn	ninister	ed 3 we	eeks after second
	vacci	nation.	1					
Interval observed after	_						_	or the presence of
challenge	Мусо	plasmo	a hyopi	neumo	oniae-spec	cific lun	g lesio	ns.
Results				_				olidated) for all
	lung l	lobes v	vas cal	culate	d for ever	y anima	al.	
			~					(0.4)
	5-Nu	mber (			or Lung (			(%):
	Trea	tment	Min	Q1	Median	Q3	Max	
	Cor	Controls		3.1	10.89	14.8	35.0	
	Vacc	inates	0.1	0.3	0.6	2.0	33.3	
	Lung	Cons	olidati	on So	amag (0/ )	<b>T</b> 0		D 1
	Lune	Lung Consolidation Scores (%), In Order of Ra						
				on sc		, In Oro	der of .	Kank:
		Vaccina	tes	on sc	Controls		der of .	Kank:
		Vaccina % I	tes Lung	ID	Controls % Lun	g	der of .	Kank:
	V	Vaccina % I Consol	tes	ID	Controls	g	der of .	Kank:
	ID	Vaccina % I Consol	tes Lung lidation	ID	Controls % Lun Consolida	g	der of .	Kank:
	ID 3265	% I Consol	tes Lung lidation	ID 3242	Controls % Lun Consolida 0.00	g	der of .	Kank:
	ID 3265 3295	% I Consol  0. 0.	tes Lung lidation 10	ID 3242 3252	Controls % Lun Consolida 0.00 0.18	g	der of .	Kank:
	ID 3265 3295 3293	% I Consol 0. 0. 0.	Lung lidation 10 10	ID  3242 3252 3297	Controls  % Lun Consolida  0.00  0.18  0.40	g	der of .	Kank:
	3265 3295 3293 3232	% I Consol  0. 0. 0. 0. 0.	Lung lidation 10 10 18 20	ID 3242 3252 3297 3282	Controls  % Lun Consolida  0.00  0.18  0.40  0.70	g	der of .	Kank:
	3265 3295 3293 3232 3241	% I Consol 0. 0. 0. 0. 0. 0.	tes Lung lidation 10 10 18 20 25	3242 3252 3297 3282 3251	Controls  % Lun Consolida  0.00  0.18  0.40  0.70  1.05	g	der of .	Kank:
	3265 3295 3293 3232 3241 3243	% I Consol 0. 0. 0. 0. 0. 0. 0.	Lung lidation 10 10 18 20 25 25	3242 3252 3297 3282 3251 3249	Controls  % Lun Consolida  0.00  0.18  0.40  0.70  1.05  1.28	g	der of	Kank:
	3265 3295 3293 3232 3241 3243 3221	% I Consol 0. 0. 0. 0. 0. 0. 0. 0. 0.	tes Lung lidation 10 10 18 20 25 25 30	3242 3252 3297 3282 3251 3249 3264	Controls  % Lun Consolida  0.00  0.18  0.40  0.70  1.05  1.28  1.78	g	der of	Kank:
	3265 3295 3293 3232 3241 3243 3221 3250	% I Consol  0. 0. 0. 0. 0. 0. 0. 0. 0. 0. 0.	tes Lung lidation 10 10 18 20 25 25 30 33	3242 3252 3297 3282 3251 3249 3264 3291	Controls  % Lun Consolida  0.00  0.18  0.40  0.70  1.05  1.28  1.78  2.90	g	der of	Kank:
	3265 3295 3293 3232 3241 3243 3250 3224	% I Consol 0. 0. 0. 0. 0. 0. 0. 0. 0. 0. 0. 0. 0.	tes Lung lidation 10 10 18 20 25 25 30 33 35	3242 3252 3297 3282 3251 3249 3264 3291 3225	Controls  % Lun Consolida  0.00  0.18  0.40  0.70  1.05  1.28  1.78  2.90  3.20	g	der of	Kank:

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3246

3210

3272

3299

7.20

7.95

8.60

9.88

3247

3269

3248

3267

0.45

0.45

0.48

0.55

Results	3217 0.60	3286 10.25	
(continued)	3219 0.65	3212 11.90	
	3226 0.70	3213 12.20	
	3270 0.70	3222 12.50	
	3218 0.75	3235 13.50	
	3294 0.98	3266 13.70	
	3233 1.85	3227 14.25	
	3230 1.95	3287 15.25	
	3283 2.05	3216 16.20	
	3231 2.45	3236 16.65	
	3240 3.30	3229 19.00	
	3253 4.00	3239 20.00	
	3215 5.48	3289 27.50	
	3288 8.30	3296 33.70	
	3238 27.35	3245 35.00	
	3292 33.25		
<b>USDA Approval Date</b>	September 27, 2013	3	

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Efficacy
Mycoplasma hyopneumoniae (MH)
23-week Duration of immunity against respiratory disease
caused by Mycoplasma hyopneumoniae
Two doses, administered intramuscularly 21 days apart at 3 days
of age
Pigs
Study data are not available.

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Study Type	Safety	Safety						
Pertaining to	ALL							
Study Purpose	To demons	trate safety	under	field condition	ns.			
Product	Two doses,	administer	ed intr	amuscularly 2	2 weeks ap	art.		
Administratio								
n								
<b>Study Animals</b>	Commercia	l pigs at thi	ee diff	erent geograp	hical locat	ions, 3 w	eeks of ag	ge at
	first admini	stration; 60	2 vacc	inates and 14	8 controls	were enro	olled.	
Challenge	N/A							
Description								
Interval	Animals we	ere observe	d daily	as a group an	nd individu	ally post	vaccinatio	on(s)
observed after	until three	weeks after	the fin	al vaccination	1.			
challenge								
Results	All 3 sites v	were combi	ned for	this summar	у.			
					-			
	Number of	Animals v	vith C	inical Signs				
		$\underset{\gamma}{\textbf{Abnormal}}$	Cough	Depression	Diarrhea	Thin	Other **	Death ***
	Control	14 (10%)	0 (0%)	2 (1%)	4 (3%)	7 (5%)	6 (4%)	0 (0%)
	Vaccinate	48 (8%)	0 (0%)		17 (3%)	24 (4%)	14 (2%)	8 (1%)
			"abnori	nal;" specific cli	inical observ	ations were	marked	
	or described			1 1	· C' 1 "	.1 "		
				to stand were cla have cause other				
		•		whole number.	i man vaccin	ation.		
				.,				
	Number of	Animals v	vith In	jection Site I	Reactions			
		1st Vaccina		2 <sup>nd</sup> Vaccination				
	Control	0 (0%)	)	0 (0%)				
	Vaccinate	2 (1%)		10 (2%)				
				t whole number	•			
TICDA		solved within	3 days.					
USDA	September	27, 2013						
Approval Date								

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Study Type	Safety							
Pertaining to	ALL	ALL						
Study Purpose	To demon	Γο demonstrate safety under field conditions.						
Product	One dose	One dose administered intramuscularly.						
Administratio		, and the second						
n								
<b>Study Animals</b>	Commerci	ial pigs at t	three diffe	erent geogra	phical loc	ations, 3 v	weeks of a	ge at
				nd 632 vacc				
Challenge	N/A							
Description								
Interval	Animals w	vere observ	ved daily	as a group a	nd individ	dually post	vaccinati	on(s)
observed after				l vaccination				
challenge								
Results	All 3 sites	were com	bined for	this summa	ıry.			
					·			
	Number o	of Animals	s with Cli	nical Signs	5			
		Abnormal <sup>γ</sup>	Anorexia	Depression	Diarrhea	Dyspnea	Other **	Death ***
	Control	20 (13%)	8 (5%)	3 (2%)	6 (4%)	2 (1%)	9 (6%)	0 (0%)
	Vaccinate	108 (17%)	29 (5%)	13 (2%)	17 (3%)	3 (1%)	81 (13%)	2 (0%)
			"abnormal;"	specific clinica	l observation	s were marke	d or	
	described as		lethargy rou	gh coat, jowl al	hscess were c	lassified as "c	other"	
				cause other tha			otilei.	
	Percent was	rounded to th	e nearest wh	ole number.				
	Number o	of Animala	s with Ini	ection Site	Reaction	C		
	Number		s Ever with		Reaction	3		
	Control		0 (0%)	Reaction				
	Vaccinat		7 (1%)					
		rounded to th	· /	ole number.				
		esolved within						
USDA	June 14, 2	013						
Approval Date	1							
Approvar Dacc								

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Study Type	Safety								
Pertaining to	ALL								
Study Purpose	To demonstrate safety under field conditions.								
Product	One dose administered intramuscularly at 3 weeks of age or two doses								
Administration	administered intramuscularly 3 weeks apart with first dose at 3 days of age.								
<b>Study Animals</b>	Commercial pigs at three different geographical locations, a total of 600								
<b>J</b>	vaccinates (200 receiving one-dose and 400 receiving two-doses) and 150								
		non-treated controls (50 per site) were enrolled.							
Challenge	N/A	•							
Description									
Interval	Animals were observe	d daily	as a gro	up and ind	ividually po	st			
observed after	vaccination(s) until the	•	_	-					
challenge	, ,								
Results	Site A – One dose adn	ninistrat	ion						
	Sites B & C –Two dos	se admin	istratio	n					
	Injection Site Reaction	ons Eve	r Prese	nt (# of Ar	nimals (% o	of Anin	nals))		
		Sit			e B +		te C		
		1 <sup>st</sup>	2 <sup>nd</sup>	1 <sup>st</sup>	2 <sup>nd</sup>	1 <sup>st</sup>	2 <sup>nd</sup>		
	Non-Treated Control	0	n/a	2 (4%)	8 (17%)	0	0		
	Vaccinate Injection site reactions range	0 d from 0.5	n/a to 5.0 cm	11 (6%)	38 (20%)	days of f	2 (1%)		
	vaccination and within 14 da				sorved within 7	days of 1	1130		
	Percent was rounded to the n								
	n/a = Not Applicable + All site B animals were dos	ed with an	autogeno	us vaccine in t	he same targete	d vaccina	ntion site		
	prior to the 2 <sup>nd</sup> dose. Some an								
	reactions at the site of vaccin	ation prior	to the 2 <sup>nd</sup>	dose. Therefo					
	reactions were attributable to	the test ar	ticle at sit	e B.					

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<b>Observations Ever P</b>	resent (	# of Anin	nals (%	of Anima	ls))	
	Si	te A	Si	te B	Si	te C
	Control	Vaccinate	Control	Vaccinate	Control	Vaccinate
None	38 (76)	166 (83)	40 (80)	144 (72)	37 (74)	146 (73)
Cough	2 (4)	4(2)	1(2)	4(2)		
Incoordination	3 (6)	6 (3)				•
Increased respiratory rate	8 (16)	16 (8)				2 (1)
Joint swelling	5 (10)	4(2)		•	1(2)	1(1)
Lameness	5 (10)	16 (8)	1(2)	3 (2)	1(2)	3 (2)
Lethargy	3 (6)	7 (4)	1(2)	6 (3)	1(2)	8 (4)
Not eating	2 (4)	1(1)				
Swollen limb	2 (4)	1(1)				
Unthrifty	2 (4)	1(1)	5 (10)	38 (19)	1(2)	12 (6)
Central nervous system disorder		2 (1)		•		
Depression		1(1)				
Other ear disorder		2(1)		•		
Abdominal cavity hernia			1 (2)	•		2(1)
Abrasion			1 (2)	•		1(1)
Diarrhea			3 (6)	17 (9)	6 (12)	22 (11)
Scar			1 (2)	6 (3)		
Sore Eye			1(2)	•		
Claw / hoof / nail disorder				1 (1)		
Dermatitis				•	1(2)	1(1)
Head tilt - neurological disorder					2 (4)	
Infectious disease					1(2)	3 (2)
Scour				•	7 (14)	25 (13)
Fracture						1(1)
Paraplegia						1(1)
Weakness				•		1(1)
Found Dead*	1 (2)	2(1)		•	1 (2)	11 (6)
Death by Euthanasia*			2 (4)	9 (5)		2(1)
Uncoded Sign						1(1)
All observations were VeDI Percent was rounded to the i * All deaths were affirmed b	nearest who	le number.	•	J		s).
November 1, 2017	,ge	2 22 2 . 9 2		P1		

Date

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Study Type	Safety								
Pertaining to	ALL								
Study Purpose	To demonstrate safety under field conditions.								
Product Administration	One dose administered in		υ.						
			1. ! 1						
Study Animals	Commercial sows and gil								
	locations, in each of three								
	enrolled.								
Challenge Description	Not applicable								
Interval observed after	No challenge. Animals were observed approximately four hours								
vaccination	post-vaccination, one day	No challenge. Animals were observed approximately four hours post-vaccination, one day post-vaccination and daily from 2 to 14							
	days post-vaccination for	any health observa	ation, and for any						
	veterinary interventions f								
	days post-farrowing. Inje								
	day 1. Reproductive perfe		-						
	evaluated. Piglets were of		_						
Results									
resuits		Controls (%)	Vaccinates (%)						
	Total Number	60 (100)	299 (100)						
	Normal Cough	47 (78.3) 1 (1.7)	268 (89.6)						
	Decreased Appetite	2 (3.3)	13 (4.3)						
	Depression	6 (10)	17 (5.7)						
	Joint stiffness*** 2 (3.3) 4 (1.3)								
	Joint Swelling***	3 (1)							
	Lameness***  Metritis	1 (1.7) 3 (5)	10 (3.3)						
	Vaginal Hemorrhage	0	1 (0.3)						
	Abortion	1 (1.7)	2 (0.7)						
	Rectal Prolapse	1 (1.7)	2 (0.7)						
	Dystocia Found dead**	1 (1.7)	4 (1.3)						
	Vaginal Prolapse	0	3 (1) 2 (0.7)						
	Mammary Gland Edema	1 (1.7)	0						
	Mastitis NOS	1 (1.7)	0						
	Adverse Health Events*								
	* Pigs observed as abnormal may								
	** The Investigator affirmed that								
	*** Nine of these events were obs	served at one site followi	ng nousing changes on day						

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### Injection Site Reactions

Injection sites were observed on Day 0 and 1. Since there were no injection site reactions observed on Day 1, further observations were not necessary.

	Score 0 (normal)	Score 1 (≥ 0.5 cm and ≤ 1.5 cm)	Score 2 (≥ 1.6 cm and ≤ 3 cm)	Score 3 (> 3 cm)
Controls	60	0	0	0
Vaccinates	299	0	0	0

### Reproductive Outcomes -Sow Outcome

	Controls (%)	Vaccinates (%)
Total Number	60 (100)	299 (100)
Farrowed	57 (95)	286 (95.7)
Abortion*+	1 (1.7)	2 (0.7)
Not Pregnant*	2 (3.3)	8 (2.7)
Culled/ Dead+	0	3 (1)

<sup>\*</sup> Events occurred at one site

### Farrowing Outcomes

	Controls (%)	Vaccinates (%)
Total Number of Piglets	876	4557
Born Normal	698 (80)	3740 (82)
Low viability	38 (4)	191 (4)
Stillborn	123 (14)	510 (11)
Mummies	17 (2)	116 (3)

#### **Litter Health Observations**

Five number summary of percent of litter that is Normal (not mummified, stillborn, or low viability)

Group	Min	Q1	Median	Q3	Max
Vaccinates	26.3	75.0	84.4	93.3	100.0
Controls	0.0	71.4	83.3	88.2	100.0

**USDA Approval Date** 

February 10, 2022

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<sup>+</sup>Same as reported on the Adverse Events table