

Summary of Studies Supporting USDA Product Licensure

Establishment Name	Epitopix, LLC
USDA Vet Biologics Establishment Number	365
Product Code	27A6.00
True Name	Escherichia Coli-Salmonella Enteritidis Bacterial Extract
Tradename(s) / Distributor or Subsidiary (if different from manufacturer)	Vaxxon SRP E.coli-SE - No distributor specified
Date of Compilation Summary	April 11, 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	Escherichia	ı coli						
Study Purpose	To demonst	trate effectives	ness ag	ainst <i>Esc</i>	cherichia	<i>coli</i> ir	chickens.	
Product		Two doses administered at an 8-week interval by subcutaneous injection.						
Administration								
Study Animals	Ten week o	Ten week old chickens were randomly assigned to one of two treatments,						
Study 1 minus		vaccinates (25 birds) or placebo (25 birds).						
Challenge		All chickens were challenged with <i>Escherichia coli</i> 14 days following						
Description		second vaccination.						
Interval observed		The chickens were monitored for 7 days after challenge then tissues were						
after challenge		examined.						
Results		A chicken was considered positive for <i>E. coli</i> if mortality occurred and						and
Results		nization was d						
		ilization was c	iciccicc	i iii uic i	ivei, iieai	ı, spic	cii, aii sac,	oviduci,
	or ovary.							
	Summary							
	Summary:							
			Vac	ain atas	Control			
	Dagitiya fa	E sali		<u>cinates</u>		.5		
	Positive fo	or E.coll	0/25		19/25			
					`			
	Raw Data ((negative sam						Ι ο
	Vaccinates	Mortality	Liver	Heart	Spleen	Air	Oviduct	Ovary
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	701							
		+						
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	712							
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	719				+	+	+	+
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	719 720 721 722 723 728 731 733 735 736				+		+	
	719 720 721 722 723 728 731 733 735 736 738				+		+	
	719 720 721 722 723 728 731 733 735 736				+		+	

Study Type

Efficacy

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	743							
	745							
	746							
	748				+		+	
			ı	T	T	ı	T	
	Controls	Mortality	Liver	Heart	Spleen		Oviduct	Ovary
	ID#					Sac		
	703							
	704	+	+	+	+	+	+	+
	705	+	+	+	+	+	+	+
	707	+	+	+	+	+	+	+
	708							
	710	+	+	+	+	+	+	+
	713	+	+	+	+	+	+	+
	714	+	+	+	+	+	+	+
	717	+	+	+	+	+	+	+
	718	+	+	+	+	+	+	+
	724	+	+	+	+	+	+	+
	725	+	+	+	+	+	+	+
	726						+	+
	727	+	+	+	+	+	+	+
	729	+	+	+	+	+	+	+
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	747	+	+	+	+	+	+	+
	750						+	7
	130							
USDA Approval	August 31,	2018						
Date	August 31,	2010						

Date

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Study Type	Efficacy							
Pertaining to	Salmonella Er	nteritidis						
Study Purpose		te effectivenes	s agains	t Salmono	olla Enteriti	dis in chi	ckens	
Product								
Administration	I wo doses adi	Two doses administered at a 10-week interval by subcutaneous injection.						
Study Animals	Ten week old chickens were randomly assigned to one of two treatments,							
Study Allinais		vaccinates (37 birds) or placebo (36 birds).						
Challenge		All chickens were challenged with <i>Salmonella enterica</i> serovar Enteritidis						
Description	days following second vaccination.						iterrials i	
Interval observed		The chickens were monitored for 14 days after challenge then tissues were						
after challenge	examined.	were monitore	u 101 1 1	aays are	r enamenge	then tibb	acs were	
Results		s considered at	ffected i	f the tissu	e had a bac	terial cou	int of	
	Salmonella Er			1 1110 1122 11	- 1100			
	Summary							
	Samples	Positive		Positive				
		Vaccinat		Controls				
	Oviduct/Ova	ry 3/36		10/35				
	Liver/Spleen	•	4	4/36				
	Livel/ Spiceli	2/30		16/35				
	Cecal Junction			16/35				
	Cecal Junction			16/35 20/36				
	Cecal Junction Any Tissue	on 7/36	,	20/36				
	Cecal Junction Any Tissue *One bird died at Raw Data	on 7/36 9/36	nd prior t	20/36 o challenge		s (negativ	ves left	
	Cecal Junction Any Tissue *One bird died a Raw Data Salmonella Er	on 7/36 9/36 fter vaccination a	nd prior t	20/36 o challenge			Cecal	
	Cecal Junction Any Tissue *One bird died at Raw Data Salmonella Err blank)	on 7/36 9/36 fter vaccination a nteritidis Cultu	nd prior t	20/36 o challenge of Individ	lual Tissues		Cecal	
	Cecal Junction Any Tissue *One bird died at Raw Data Salmonella Err blank)	on 7/36 9/36 fter vaccination a the restriction of	nd prior t	20/36 o challenge of Individ	lual Tissues		Cecal Junction	
	Cecal Junction Any Tissue *One bird died at Raw Data Salmonella Err blank)	on 7/36 9/36 fter vaccination a the restriction of	nd prior t	20/36 o challenge of Individ	lual Tissues		Cecal Junction	
	Cecal Junction Any Tissue *One bird died at Raw Data Salmonella Err blank)	on 7/36 9/36 fter vaccination a the restriction of	nd prior t	20/36 o challenge of Individ	lual Tissues		Cecal Junction	
	Cecal Junction Any Tissue *One bird died at Raw Data Salmonella Err blank)	7/36 9/36 fter vaccination a Chicken ID # 501 502 503 505	nd prior t	20/36 o challenge of Individ	lual Tissues		Cecal Junction	
	Cecal Junction Any Tissue *One bird died at Raw Data Salmonella Err blank)	on 7/36 9/36 fter vaccination a the restriction of	nd prior t	20/36 o challenge of Individ	lual Tissues		Cecal Junction + +	
	Cecal Junction Any Tissue *One bird died at Raw Data Salmonella Err blank)	7/36 9/36 fter vaccination a hteritidis Cultu Chicken ID # 501 502 503 505 506 508	nd prior t	20/36 o challenge of Individ	lual Tissues		Cecal Junction + +	
	Cecal Junction Any Tissue *One bird died at Raw Data Salmonella Err blank)	7/36 9/36 fter vaccination a hteritidis Cultu Chicken ID # 501 502 503 505 506	nd prior t	20/36 o challenge of Individ	lual Tissues		Cecal Junction + +	
	Cecal Junction Any Tissue *One bird died at Raw Data Salmonella Err blank)	7/36 9/36 fter vaccination a hteritidis Cultu Chicken ID # 501 502 503 505 506 508	nd prior t	20/36 o challenge of Individ	lual Tissues		Cecal Junction + +	
	Cecal Junction Any Tissue *One bird died at Raw Data Salmonella Err blank)	7/36 9/36 fter vaccination a hteritidis Cultu Chicken ID # 501 502 503 505 506 508 509	nd prior t	20/36 o challenge of Individ	lual Tissues		Cecal Junction + +	
	Cecal Junction Any Tissue *One bird died at Raw Data Salmonella Err blank)	7/36 9/36 fter vaccination a hteritidis Cultu Chicken ID # 501 502 503 505 506 508 509 511	nd prior t	20/36 o challenge of Individ	lual Tissues		Cecal Junction + +	
	Cecal Junction Any Tissue *One bird died at Raw Data Salmonella Err blank)	7/36 9/36 fter vaccination a hteritidis Cultu Chicken ID # 501 502 503 505 506 508 509 511 513	nd prior t	20/36 o challenge of Individ	lual Tissues		Cecal Junction + +	
	Cecal Junction Any Tissue *One bird died at Raw Data Salmonella Err blank)	7/36 9/36 fter vaccination a meteritidis Cultu Chicken ID # 501 502 503 505 506 508 509 511 513 515	nd prior t	20/36 o challenge of Individ	lual Tissues		Cecal Junction + +	

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Controls Chicken ID Liver Spleen Oviduct Ovary Cecal Junction
Controls Chicken ID Liver Spleen Oviduct Ovary Cecal Junction
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		571	+		+	+	+
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		573					
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USDA Approval	April 12, 201	9					
Date							

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Study Type	Safety
Pertaining to	ALL
Study Purpose	To demonstrate safety of the product under field conditions.
Product Administration	Two doses administered at an 8 to 10-week interval by a
	subcutaneous route of injection.
Study Animals	A total of 103,404 chickens were enrolled in the study and
Study Timinus	housed at commercial egg or layer operations in three
	geographically distinct regions of the United States. The
	chickens were vaccinated with a test vaccine (Serial 1 or Serial
	2) or left as non-vaccinated controls.
	Birds ranged in age from 9 weeks to 12 weeks at first
	vaccination.
Challenge Description	Not applicable
Interval observed after	Chickens were observed for adverse events and mortality for 21
challenge	days after each of two vaccinations given 5 weeks apart.
Results	No adverse events were observed in any chickens after
	vaccination. See summary table by region below.
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TIOD A A	F.1 22 2021
USDA Approval Date	February 22, 2021

Tables show the number of mortality of chickens at each site after each vaccination.

Region 1

Treatment	Starting	21-day	Mortality Rate
	Population	Mortality	(%)
1st Vaccination			
Control	15,287	16	0.10
Vaccine Serial 1	15,288	7	0.05
Vaccine Serial 2	15,288	6	0.04
2 nd Vaccination			
Control	15,251	24	0.16
Vaccine Serial 1	15,251	22	0.14
Vaccine Serial 2	15,255	26	0.17

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Region 2

Treatment	Starting	21-day	Mortality Rate
	Population	Mortality	(%)
1st Vaccination	•		
Control	19,365	47	0.24
Vaccine Serial 1	10,880	42	0.39
2 nd Vaccination	<u> </u>		
Control	19, 280	63	0.33
Vaccine Serial 1	10,474	31	0.30

Region 3

Treatment	Starting	21-day	Mortality Rate
	Population	Mortality	(%)
1st Vaccination			
Control	13,648	14	0.10
Vaccine Serial 2	13,648	12	0.09
2 nd Vaccination	•		
Control	13,627	3	0.02
Vaccine Serial 2	13,629	4	0.03

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