Summary of Studies Supporting USDA Product Licensure

Establishment Name	Epitopix, LLC
USDA Vet Biologics Establishment Number	365
Product Code	27A5.02
True Name	Salmonella Enteritidis Bacterial Extract
Tradename(s) / Distributor or Subsidiary (if different from manufacturer)	Vaxxon SRP SE - No distributor specified
Date of Compilation Summary	January 10, 2020

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	*Salmonella* Enteritidis
Study Purpose	To demonstrate effectiveness against *Salmonella* Enteritidis in chickens.
Product Administration	Two doses administered at an 8-week interval by subcutaneous injection.
Study Animals	Ten week old chickens were randomly assigned to one of two treatments, vaccinates (21 birds) or placebo (29 birds).
Challenge Description	All chickens were challenged with *Salmonella enterica* Enteritidis 28 days following second vaccination.
Interval observed after challenge	The chickens were monitored for 14 days after challenge then tissues were examined.
Results	A chicken was considered affected if the ovary or oviduct had a bacterial count of *Salmonella* Enteritidis $\geq$0.

Summary

	Salmonella Enteritidis Negative	*Salmonella* Enteritidis Positive
Placebo	22	7
Vaccinates	21	0

Raw Data

Salmonella Enteritidis Culture Data (CFU/gram) of Ovary/Oviduct

Placebo Animal ID	Culture Data	Placebo Animal ID	Culture Data	Placebo Animal ID	Culture Data
111	2000	152	0	186	0
113	0	155	50	187	0
118	0	167	0	188	10
122	0	173	0	190	0
127	0	174	0	196	0
129	0	175	0	197	0
133	0	176	300	198	10
136	0	177	11000	199	0
143	0	180	10	200	0
147	0	181	0		
All vaccinates were negative for culture of *Salmonella* Enteritidis.					

USDA Approval Date	November 1, 2016

Study Type	Safety
Pertaining to	ALL
Study Purpose	To demonstrate safety of the product under field conditions.
Product Administration	Two doses administered at a 3-8 week interval by a subcutaneous route of injection.
Study Animals	A total of 111,058 chickens were enrolled in the study and housed at commercial egg or layer operations in three geographically distinct regions of the United States. The chickens were vaccinated with the test vaccine or left as non-vaccinated controls. Birds ranged in age from 8 weeks to 15 weeks at first vaccination.
Challenge Description	Not applicable
Interval observed after challenge	Chickens were observed for adverse events and mortality for 21 days after each of two vaccinations given 3-8 weeks apart.
Results	No adverse events were observed in any chickens after vaccination. Mortality rates are listed in tables by region below.
USDA Approval Date	July 10, 2019

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

Region 1

Treatment	Starting Population	21-day Mortality	Mortality Rate (%)
1st Vaccination			
Vaccine Serial	22,748	43	0.19
Control	22,939	35	0.15
2nd Vaccination			
Vaccine Serial	22,671	39	0.17
Control	22,889	18	0.08

Region 2

Treatment	Starting Population	21-day Mortality	Mortality Rate (%)
1st Vaccination			
Vaccine Serial	12,885	46	0.36
Control	12,947	26	0.20
2nd Vaccination			
Vaccine Serial	12,839	51	0.40
Control	12,921	23	0.18

Region 3

Treatment	Starting Population	21-day Mortality	Mortality Rate (%)
1st Vaccination			
Vaccine Serial	19,811	74	0.37
Control	19,728	80	0.41
2nd Vaccination			
Vaccine Serial	19,710	37	0.19
Control	19,516	48	0.25