



Summary of Studies Supporting USDA Product Licensure

Establishment Name	Boehringer Ingelheim Animal Health USA Inc.
USDA Vet Biologics Establishment Number	124
Product Code	19A2.00
True Name	Salmonella Choleraesuis-Typhimurium Vaccine, Avirulent Live Culture
Tradename(s) / Distributor or Subsidiary (if different from manufacturer)	Enterisol Salmonella T/C - Boehringer Ingelheim (Canada) Ltd. Enterisol Salmonella T/C - No distributor specified
Date of Compilation Summary	March 04, 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 Choleraesuis-Typhimurium Vaccine, Avirulent Live Culture
Study Purpose	Demonstration of efficacy against <i>Salmonella enterica</i> serovar Choleraesuis
Product Administration	Administration of one dose in the drinking water
Study Animals	40 pigs, 2 weeks of age, divided into 20 vaccinates and 20 controls
Challenge Description	Challenged with virulent <i>Salmonella enterica</i> serovar Choleraesuis 28 days after vaccination
Interval observed after challenge	Pigs observed for 14 days for clinical signs of Salmonella and mortality then tissues were examined.
Results	<p>An animal was considered affected if at least one of the following criteria were met:</p> <ul style="list-style-type: none"> • Macroscopic lesions of intestines or lymphoid tissues (Score >0). • Mortality due to <i>S. typhimurium</i>. • Clinical signs classified as diarrhea (Score >0) for 2 or more days. <p>Summary of Results Following Challenge: Controls 18/20 affected Vaccinates 8/20 affected</p> <p>Summary of the Observations for each pig and raw data are included on the following pages.</p>
USDA Approval Date	January 03, 2014

Summary of Clinical Findings which indicate an affected pig

Vaccinates:

Pig #	Dead*	Diarrhea**	Pathology Findings***	Affected
138	No	No	No	No
139	No	No	No	No
143	No	No	No	No
144	No	Yes	No	Yes
110	No	No	No	No
111	No	Yes	No	Yes
114	No	No	Yes	Yes
115	No	Yes	Yes	Yes
119	No	No	No	No
123	No	No	No	No
125	No	No	No	No
126	No	No	Yes	Yes
146	No	No	No	No
149	No	No	No	No
150	No	No	Yes	Yes
153	No	No	No	No
105	No	No	Yes	Yes
106	No	No	No	No
107	No	Yes	No	Yes
109	No	No	No	No

*Found dead or humanely euthanized prior to the conclusion of the study

**For 2 or more days

***Lesions in Tonsils, Lungs, Spleen, Liver or Spiral Colon

Summary of Clinical Findings which indicate an affected pig

Controls (Treatment Group C):

Pig #	Dead*	Diarrhea**	Pathology Findings***	Affected
137	No	Yes	Yes	Yes
141	No	Yes	No	Yes
142	No	Yes	Yes	Yes
145	No	No	Yes	Yes
112	No	Yes	Yes	Yes
113	Yes	No	Yes	Yes
117	No	Yes	Yes	Yes
118	No	Yes	Yes	Yes
121	No	No	No	No
122	No	Yes	No	Yes
124	No	Yes	Yes	Yes
127	No	Yes	No	Yes
147	No	Yes	Yes	Yes
148	No	No	No	Yes
151	No	Yes	Yes	Yes
152	No	Yes	Yes	Yes
101	No	Yes	No	Yes
102	No	Yes	No	Yes
104	No	Yes	Yes	Yes
108	Yes	No	Yes	Yes

*Found dead or humanely euthanized prior to the conclusion of the study

**For 2 or more days

***Lesions in Tonsils, Lungs, Spleen, Liver or Spiral Colon

**Lesions Observed at Necropsy
(increasing score indicates increased severity of the lesion observed)**

Vaccinates

ID	Tonsil	Lung	Liver	Spleen	Spiral Colon
105	0	1	0	0	0
106	0	0	0	0	0
107	0	0	0	0	0
109	0	0	0	0	0
110	0	0	0	0	0
111	0	0	0	0	0
114	0	2	0	0	0
115	0	1	0	0	0
119	0	0	0	0	0
123	0	0	0	0	0
125	0	0	0	0	0
126	0	0	0	0	1
138	0	0	0	0	0
139	0	0	0	0	0
143	0	0	0	0	0
144	0	0	0	0	0
146	0	0	0	0	0
149	0	0	0	0	0
150	0	1	0	0	0
153	0	0	0	0	0

Controls

ID	Tonsil	Lung	Liver	Spleen	Spiral Colon
101	0	0	0	0	0
102	0	0	0	0	0
104	0	2	0	0	3
108	2	0	0	0	3
112	0	0	0	0	3
113	0	2	2	1	2
117	0	0	0	0	1
118	0	1	0	0	0
121	0	0	0	0	0
122	0	0	0	0	0
124	0	1	2	0	0
127	0	0	0	0	0
137	0	1	0	0	0
141	0	0	0	0	0
142	1	2	0	0	3
145	0	0	0	0	2
147	0	3	0	0	3
148	0	0	0	0	0
151	0	3	0	0	3
152	0	1	0	0	0

Daily Observations of Diarrhea

Vaccinates

ID	Day of Study																
	26	27	28	29	30	31	32	33	34	35	36	37	38	39	40	41	42
105	0	0	0	0	0	0	0	0	1	0	0	0	0	0	0	0	0
106	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
107	0	0	0	0	0	0	0	0	0	1	0	0	0	0	0	1	0
109	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
110	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
111	0	0	0	0	0	0	0	0	0	1	0	1	0	1	0	1	0
114	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
115	0	0	0	0	0	0	0	0	0	1	1	0	0	0	0	0	0
119	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
123	0	0	0	0	0	0	0	0	0	0	1	0	0	0	0	0	0
125	0	0	0	0	0	0	0	0	0	0	1	0	0	0	0	0	0
126	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
138	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
139	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
143	0	0	0	0	0	0	0	0	0	0	1	0	0	0	0	0	0
144	0	0	0	0	1	0	0	0	0	0	1	1	0	1	0	0	0
146	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
149	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
150	0	0	0	0	1	0	0	0	0	0	0	0	0	0	0	0	0
153	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0

Daily Observations of Diarrhea

Controls

ID	Day of Study																
	26	27	28	29	30	31	32	33	34	35	36	37	38	39	40	41	42
101	0	0	0	0	0	1	0	0	0	0	1	1	0	0	1	0	0
102	0	0	0	0	0	0	0	0	1	1	1	1	0	0	0	0	0
104	0	0	0	0	0	0	0	1	1	1	1	0	0	1	0	0	0
108	0	0	0	0	0	1	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
112	0	0	0	0	0	0	0	0	0	0	1	1	1	1	0	0	0
113	0	0	0	0	0	0	0	0	0	0	1	0	0	0	NA	NA	NA
117	0	0	0	0	0	1	0	0	0	1	1	0	0	1	1	0	1
118	0	0	0	0	0	0	0	0	0	1	1	1	1	1	0	0	0
121	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
122	0	0	0	0	0	0	0	0	0	1	0	0	0	1	1	0	1
124	0	0	0	0	1	0	0	0	1	1	0	0	0	1	0	0	0
127	0	0	0	0	1	0	0	0	1	1	0	0	0	0	0	0	0
137	0	0	0	0	0	0	0	0	0	1	1	1	0	0	0	0	1
141	0	0	0	0	0	0	0	0	0	0	1	0	0	0	1	0	0
142	0	0	0	0	0	0	0	0	0	1	1	0	0	1	0	1	1
145	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
147	0	0	0	0	0	0	0	0	0	0	1	0	1	0	0	0	0
148	0	0	0	0	0	0	0	1	0	0	0	0	0	0	0	0	0
151	0	0	0	0	0	0	0	0	0	0	0	0	0	1	1	1	0
152	0	0	0	0	0	0	0	0	0	1	1	0	0	0	0	0	0

Study Type	Efficacy									
Pertaining to	Salmonella Choleraesuis-Typhimurium Vaccine, Avirulent Live Culture									
Study Purpose	Demonstration of efficacy against <i>Salmonella enterica</i> serovar Typhimurium									
Product Administration	Oral administration of one dose									
Study Animals	24 pigs, 2.5 weeks of age, divided into 24 vaccinates and 24 controls									
Challenge Description	Challenged with virulent <i>Salmonella enterica</i> serovar Typhimurium 28 days after vaccination									
Interval observed after challenge	Pigs observed for 10 days for clinical signs of Salmonella and mortality then tissues were examined.									
Results	<p>Case definition: An animal was considered affected if at least one of the following criteria were met:</p> <ul style="list-style-type: none"> • Macroscopic lesions of intestines or lymphoid tissues. • Mortality due to <i>S. typhimurium</i>. • Diarrhea for more than 2 days OR diarrhea for 2 days along with depression. <p>Case positive/negative:</p> <table border="1"> <thead> <tr> <th></th> <th>Positive</th> <th>Negative</th> </tr> </thead> <tbody> <tr> <td>Vaccinates (N=24)</td> <td>8</td> <td>16</td> </tr> <tr> <td>Controls (N=24)</td> <td>19</td> <td>5</td> </tr> </tbody> </table>		Positive	Negative	Vaccinates (N=24)	8	16	Controls (N=24)	19	5
	Positive	Negative								
Vaccinates (N=24)	8	16								
Controls (N=24)	19	5								
USDA Approval Date	January 02, 2013									

Summary of Clinical Findings which indicate an affected pig

Vaccinates:

Pig ID	Dead*	Abnormal LN	Lesions in Cecum or Spiral Colon	Diarrhea**	Depression	Affected
901	no	no	no	yes	yes	Yes
905	no	no	no	yes	no	Yes
910	no	no	no	no	no	No
913	no	no	yes	yes	yes	Yes
918	no	yes	no	no	no	Yes
920	no	no	yes	yes	no	Yes
924	no	yes	yes	yes	no	Yes
928	no	no	no	no	yes	No
931	no	no	no	no	no	No
933	no	no	no	no	no	No
938	no	no	no	no	no	No
939	no	no	no	no	no	No
943	no	no	no	no	no	No
946	no	yes	no	no	no	Yes
950	no	no	no	yes	no	Yes
951	no	no	no	no	no	No
958	no	no	no	no	no	No
962	no	no	no	no	no	No
966	no	no	no	no	no	No
970	no	no	no	no	no	No
976	no	yes	no	no	no	Yes
977	no	no	no	no	yes	No
980	no	no	no	no	yes	No
981	no	yes	no	yes	no	Yes

*Found dead or humanely euthanized prior to the conclusion of the study

**For 2 or more days

Summary of Clinical Findings which indicate an affected pig (cont'd)

Controls:

Pig ID	Dead*	Abnormal LN	Lesions in Cecum or Spiral Colon	Diarrhea**	Depression	Affected
903	no	yes	no	yes	no	Yes
906	no	yes	yes	yes	yes	Yes
912	no	yes	yes	yes	no	Yes
914	yes	yes	yes	no	no	Yes
915	no	yes	no	yes	no	Yes
916	no	yes	no	yes	no	Yes
923	no	no	no	yes	yes	Yes
925	yes	no	yes	no	yes	Yes
930	yes	yes	yes	no	no	Yes
932	no	no	no	yes	yes	Yes
936	no	yes	yes	yes	no	Yes
937	no	no	yes	yes	no	Yes
947	no	no	no	yes	no	Yes
949	no	yes	no	yes	yes	Yes
954	no	no	no	no	no	No
955	no	no	no	no	no	No
957	no	yes	no	no	no	Yes
961	no	no	no	yes	no	Yes
964	no	no	no	yes	no	Yes
965	no	no	no	yes	no	Yes
974	yes	yes	yes	yes	yes	Yes
975	no	yes	yes	yes	yes	Yes
978	no	no	yes	yes	yes	Yes
979	no	no	no	yes	yes	Yes

*Found dead or humanely euthanized prior to the conclusion of the study

**For 2 or more days

**Lesions Observed at Necropsy
(Increasing score indicates increased severity of the lesion observed)**

Vaccinates

Pig ID	Mesenteric Lymph Node	Ileocecal Lymph Node	Cecum	Spiral Colon
901	0	0	0	0
905	0	0	0	0
910	0	0	0	0
913	0	0	3	2
918	1	0	0	0
920	0	0	0	1
924	1	1	0	1
928	0	0	0	0
931	0	0	0	0
933	0	0	0	0
938	0	0	0	0
939	0	0	0	0
943	0	0	0	0
946	0	1	0	0
950	0	0	0	0
951	0	0	0	0
958	0	0	0	0
962	0	0	0	0
966	0	0	0	0
970	0	0	0	0
976	1	0	0	0
977	0	0	0	0
980	0	0	0	0
981	0	1	0	0

Lesions Observed at Necropsy (cont'd)
(Increasing score indicates increased severity of the lesion observed)

Controls

Pig ID	Mesenteric Lymph Node	Ileocecal Lymph Node	Cecum	Spiral Colon
903	0	1	0	0
906	0	1	1	2
912	1	1	1	1
914	1	1	2	2
915	0	1	0	0
916	1	1	0	0
923	0	0	0	0
925	0	0	3	3
930	1	1	2	2
932	0	0	0	0
936	0	1	2	2
937	0	0	1	0
947	0	0	0	0
949	0	1	0	0
954	0	0	0	0
955	0	0	0	0
957	0	1	0	0
961	0	0	0	0
964	0	0	0	0
965	0	0	0	0
974	1	0	3	3
975	0	1	1	2
978	0	0	1	0
979	0	0	0	0

Daily Observations of Diarrhea

Vaccinates

Day of Study												
Pig ID	27	28	29	30	31	32	33	34	35	36	37	38
901	0	0	0	0	1	1	0	0	0	0	0	0
905	0	0	1	1	0	0	0	0	0	0	0	0
910	0	0	0	0	1	0	0	0	0	0	0	0
913	0	0	0	1	0	0	0	0	1	0	1	0
918	0	0	0	0	0	0	0	0	0	0	0	0
920	0	0	0	1	1	0	0	0	0	0	0	0
924	0	0	0	0	0	1	0	0	0	0	1	0
928	0	0	0	0	0	0	0	0	0	0	0	0
931	0	0	0	0	0	0	0	0	0	0	0	0
933	0	0	0	0	0	0	0	0	0	0	0	0
938	0	0	0	0	1	0	0	0	0	0	0	0
939	0	0	0	0	0	0	0	0	1	0	0	0
943	0	0	0	0	0	0	0	0	0	0	0	0
946	0	0	0	0	0	0	0	0	0	0	0	0
950	0	0	0	0	0	0	0	0	0	1	0	1
951	0	0	0	0	0	0	0	0	0	0	0	0
958	0	0	0	0	1	0	0	0	0	0	0	0
962	0	0	0	0	0	0	0	0	0	0	0	0
966	0	0	0	0	0	0	0	0	0	0	0	0
970	0	0	0	0	0	0	0	0	0	0	0	0
976	0	0	0	0	1	0	0	0	0	0	0	0
977	0	0	0	0	0	0	0	0	0	0	0	0
980	0	0	0	0	0	0	0	0	0	0	0	0
981	0	0	0	1	0	0	0	1	1	1	0	0

Daily Observations of Diarrhea

Controls

Pig ID	Study Day											
	27	28	29	30	31	32	373	34	35	36	37	38
903	0	0	0	0	1	1	1	0	0	0	0	0
906	0	0	0	0	1	1	1	0	1	1	0	0
912	0	0	0	1	1	1	1	0	1	1	1	0
914	0	0	0	NA	NA	NA	NA	NA	NA	NA	NA	NA
915	0	0	0	1	1	1	0	1	0	0	0	0
916	0	0	0	1	1	1	0	1	0	0	0	0
923	0	0	1	1	1	1	1	1	0	0	0	0
925	0	0	0	0	0	NA	NA	NA	NA	NA	NA	NA
930	0	0	1	NA	NA	NA	NA	NA	NA	NA	NA	NA
932	0	0	0	0	1	1	0	0	0	0	0	0
936	0	0	0	0	1	0	0	0	0	0	0	1
937	0	0	0	0	1	0	0	0	0	0	0	1
947	0	0	0	1	1	1	1	1	0	0	0	1
949	0	0	0	1	1	0	1	0	1	1	0	0
954	0	0	0	1	0	0	0	0	0	0	0	0
955	0	0	0	0	0	0	0	0	0	0	0	0
957	0	0	0	0	1	0	0	0	0	0	0	0
961	0	0	0	0	1	0	1	0	0	0	0	0
964	0	0	0	1	2	0	0	0	0	0	0	0
965	0	0	0	0	1	0	1	1	0	0	0	0
974	0	0	1	1	1	1	1	0	NA	NA	NA	NA
975	0	0	0	1	2	1	0	0	1	1	1	0
978	0	0	1	1	0	1	0	0	0	0	0	0
979	0	0	0	0	1	1	2	0	0	0	0	1

Daily Observations of Depression

Vaccinates

Pig ID	Study Day											
	27	28	29	30	31	32	33	34	35	36	37	38
901	0	0	0	0	0	0	0	1	1	0	0	0
905	0	0	0	0	0	0	0	0	0	0	0	0
910	0	0	0	0	0	0	0	0	0	0	0	0
913	0	0	1	0	0	0	0	0	0	0	0	0
918	0	0	0	0	0	0	0	0	0	0	0	0
920	0	0	0	0	0	0	0	0	0	0	0	0
924	0	0	0	0	0	0	0	0	0	0	0	0
928	0	0	0	0	0	0	1	0	0	0	0	0
931	0	0	0	0	0	0	0	0	0	0	0	0
933	0	0	0	0	0	0	0	0	0	0	0	0
938	0	0	0	0	0	0	0	0	0	0	0	0
939	0	0	0	0	0	0	0	0	0	0	0	0
943	0	0	0	0	0	0	0	0	0	0	0	0
946	0	0	0	0	0	0	0	0	0	0	0	0
950	0	0	0	0	0	0	0	0	0	0	0	0
951	0	0	0	0	0	0	0	0	0	0	0	0
958	0	0	0	0	0	0	0	0	0	0	0	0
962	0	0	0	0	0	0	0	0	0	0	0	0
966	0	0	0	0	0	0	0	0	0	0	0	0
970	0	0	0	0	0	0	0	0	0	0	0	0
976	0	0	0	0	0	0	0	0	0	0	0	0
977	0	0	1	0	0	0	0	0	0	0	0	0
980	0	0	0	1	0	0	0	0	0	0	0	0
981	0	0	0	0	0	0	0	0	0	0	0	0

Daily Observations of Depression

Controls

Pig ID	Study Day											
	27	28	29	30	31	32	33	34	35	36	37	38
903	0	0	0	0	0	0	0	0	0	0	0	0
906	0	0	0	0	0	0	0	0	1	1	2	1
912	0	0	0	0	0	0	0	0	0	0	0	0
914	0	0	0	NA	NA	NA	NA	NA	NA	NA	NA	NA
915	0	0	0	0	0	0	0	0	0	0	0	0
916	0	0	0	0	0	0	0	0	0	0	0	0
923	0	0	0	0	0	0	1	0	0	0	0	0
925	0	0	0	0	1	NA	NA	NA	NA	NA	NA	NA
930	0	0	0	NA	NA	NA	NA	NA	NA	NA	NA	NA
932	0	0	0	0	0	1	0	0	0	0	0	0
936	0	0	0	0	0	0	0	0	0	0	0	0
937	0	0	0	0	0	0	0	0	0	0	0	0
947	0	0	0	0	0	0	0	0	0	0	0	0
949	0	0	0	1	0	0	0	0	0	0	0	0
954	0	0	0	0	0	0	0	0	0	0	0	0
955	0	0	0	0	0	0	0	0	0	0	0	0
957	0	0	0	0	0	0	0	0	0	0	0	0
961	0	0	0	0	0	0	0	0	0	0	0	0
964	0	0	0	0	0	0	0	0	0	0	0	0
965	0	0	0	0	0	0	0	0	0	0	0	0
974	0	0	0	0	0	0	0	2	NA	NA	NA	NA
975	0	0	0	0	0	0	0	0	0	0	0	1
978	0	0	0	1	0	1	0	0	0	0	0	0
979	0	0	0	1	1	1	0	0	0	0	0	0

Study Type	Efficacy									
Pertaining to	Salmonella Choleraesuis-Typhimurium Vaccine, Avirulent Live Culture									
Study Purpose	Demonstration of onset of immunity against <i>Salmonella enterica</i> serovar Typhimurium									
Product Administration	Administration of one dose in the drinking water									
Study Animals	48 pigs, 2 weeks of age, divided into 24 vaccinates and 24 controls. One control was removed before challenge for reasons unrelated to the study.									
Challenge Description	Challenged with virulent <i>Salmonella enterica</i> serovar Typhimurium 14 days after vaccination									
Interval observed after challenge	Pigs observed for 21 days for clinical signs of Salmonella and mortality then tissues were examined.									
Results	<p>Case definition: An animal was considered affected if at least one of the following criteria were met:</p> <ul style="list-style-type: none"> • Macroscopic lesions of intestines or lymphoid tissues. • Diarrhea for 2 or more days • Depression OR dehydration for one or more day. <p>Case positive/negative:</p> <table border="1"> <thead> <tr> <th></th> <th>Positive</th> <th>Negative</th> </tr> </thead> <tbody> <tr> <td>Vaccinates</td> <td>12</td> <td>12</td> </tr> <tr> <td>Controls</td> <td>20</td> <td>3</td> </tr> </tbody> </table> <p>Raw Data are provided on the following pages</p>		Positive	Negative	Vaccinates	12	12	Controls	20	3
	Positive	Negative								
Vaccinates	12	12								
Controls	20	3								
USDA Approval Date	August 4, 2014									

Summary of Clinical Findings which indicate an affected pig

Vaccinates:

Pig ID	Abnormal LN		Intestinal Lesions		Diarrhea*	Depression**	Dehydration**	Affected
	MLN	ILN	Cecum	Spiral Colon				
4	Yes	No	No	No	No	No	No	Yes
5	Yes	Yes	No	Yes	No	No	No	Yes
6	No	No	No	No	No	No	No	No
7	No	No	No	Yes	No	No	No	Yes
11	No	No	Yes	Yes	No	No	No	Yes
13	No	No	No	Yes	No	No	No	Yes
14	No	Yes	Yes	No	No	No	No	Yes
16	No	No	No	No	No	No	No	No
20	No	No	No	Yes	No	No	No	Yes
21	No	No	No	No	No	No	No	No
24	No	No	No	No	No	No	No	No
26	No	No	No	No	No	No	No	No
28	No	No	No	No	No	No	No	No
31	No	No	Yes	No	No	No	No	Yes
33	No	No	No	No	No	No	No	No
35	No	No	No	No	No	No	No	No
41	No	No	No	No	No	No	No	No
43	Yes	No	No	No	No	No	No	Yes
44	No	Yes	No	No	No	No	No	Yes
45	Yes	Yes	No	Yes	No	No	No	Yes
46	Yes	No	No	No	No	No	Yes	Yes
47	No	No	No	No	No	No	No	No
49	No	No	No	No	No	No	No	No
50	No	No	No	No	No	No	No	No

MLN= Mesenteric Lymph nodes ILN = Ileocecal Lymph Nodes

*Observed for 2 or more days following challenge

**Observed on at least one day following challenge

Summary of Clinical Findings which indicate an affected pig (Cont'd)

Controls:

Pig ID	Abnormal LN		Intestinal Lesions		Diarrhea*	Depression**	Dehydration**	Affected
	MLN	ILN	Cecum	Spiral Colon				
1	No	No	No	No	No	No	No	No
2	No	Yes	No	No	No	Yes	Yes	Yes
8	No	No	No	No	No	No	No	No
9	No	No	Yes	Yes	Yes	Yes	Yes	Yes
10	No	No	No	Yes	Yes	No	No	Yes
12	No	No	No	Yes	No	No	No	Yes
15	Yes	Yes	Yes	Yes	Yes	Yes	No	Yes
18	Yes	Yes	No	Yes	No	No	No	Yes
22	No	Yes	Yes	Yes	No	Yes	No	Yes
23	Yes	No	Yes	Yes	No	No	No	Yes
25	No	Yes	No	No	No	No	No	Yes
27	No	No	No	No	No	No	No	No
29	Yes	No	Yes	Yes	Yes	Yes	Yes	Yes
30	No	No	No	Yes	No	No	No	Yes
32	No	No	No	Yes	Yes	Yes	Yes	Yes
36	Yes	Yes	Yes	Yes	No	No	Yes	Yes
37	No	No	Yes	Yes	Yes	No	No	Yes
39	No	Yes	Yes	Yes	Yes	Yes	No	Yes
40	No	No	No	Yes	No	Yes	No	Yes
42	No	Yes	No	Yes	No	No	No	Yes
48	No	Yes	No	No	No	No	No	Yes
51	No	No	No	No	Yes	No	No	Yes
53	Yes	No	No	No	No	No	No	Yes

MLN= Mesenteric Lymph nodes

ILN = Ileocecal Lymph Nodes

*Observed for 2 or more days following challenge

**Observed on at least one day following challenge

**Lesions Observed at Necropsy
(increasing score indicates increased severity of the lesion observed)**

Vaccinates

Pig ID	Mesenteric Lymph Node	Ileocecal Lymph Node	Cecum	Spiral Colon
4	1	0	0	0
5	1	1	0	1
6	0	0	0	0
7	0	0	0	1
11	0	0	1	1
13	0	0	0	2
14	0	1	1	0
16	0	0	0	0
20	0	0	0	3
21	0	0	0	0
24	0	0	0	0
26	0	0	0	0
28	0	0	0	0
31	0	0	1	0
33	0	0	0	0
35	0	0	0	0
41	0	0	0	0
43	1	0	0	0
44	0	1	0	0
45	1	1	0	1
46	1	0	0	0
47	0	0	0	0
49	0	0	0	0
50	0	0	0	0

Controls

ID	Mesenteric Lymph Node	Ileocecal Lymph Node	Cecum	Spiral Colon
1	0	0	0	0
2	0	1	0	0
8	0	0	0	0
9	0	0	1	3
10	0	0	0	3
12	0	0	0	2
15	1	1	1	1
18	1	1	0	2
22	0	1	3	3
23	1	0	2	3
25	0	1	0	0
27	0	0	0	0
29	1	0	2	2
30	0	0	0	2
32	0	0	0	2
36	1	1	3	2
37	0	0	3	2
39	0	1	1	2
40	0	0	0	3
42	0	1	0	1
48	0	1	0	0
51	0	0	0	0
53	1	0	0	0

Daily Observations of Diarrhea

Vaccinates

Pig ID	Study Day									
	12	13	14	15	16	17	18	19	20	21
4	0	0	0	0	0	0	0	0	0	0
5	0	0	0	0	0	0	0	0	0	0
6	0	0	0	0	0	0	0	0	0	0
7	0	0	0	0	0	0	0	0	0	0
11	0	0	0	0	0	0	0	0	0	0
13	0	0	0	0	0	0	0	0	0	0
14	0	0	0	0	0	0	0	0	0	0
16	0	0	0	0	0	0	0	0	0	0
20	0	0	0	0	0	0	0	0	0	0
21	0	0	0	0	0	0	0	0	0	0
24	0	0	0	0	0	0	0	0	0	0
26	0	0	0	0	0	0	0	0	0	0
28	0	0	0	0	0	0	0	0	0	0
31	0	0	0	0	0	0	0	0	0	0
33	0	0	0	0	0	0	0	1	0	0
35	0	0	0	0	0	0	0	0	0	0
41	0	0	0	0	0	0	0	0	0	0
43	0	0	0	0	0	0	0	0	0	0
44	0	0	0	0	0	0	0	0	0	0
45	0	0	0	0	0	0	0	1	0	0
46	0	0	0	0	0	0	0	0	0	0
47	0	0	0	0	0	0	0	0	0	0
49	0	0	0	0	0	0	0	0	0	0
50	0	0	0	0	0	0	0	0	0	0

Controls

Pig ID	Study Day									
	12	13	14	15	16	17	18	19	20	21
1	0	0	0	0	0	1	0	0	0	0
2	0	0	0	0	0	0	0	0	0	0
8	0	0	0	0	0	1	0	0	0	0
9	0	0	0	0	0	1	1	1	1	0
10	0	0	0	0	1	1	1	0	0	0
12	0	0	0	0	1	0	0	0	0	0
15	0	0	0	1	0	1	1	2	0	1
18	0	0	0	0	1	0	0	0	0	0
22	0	0	0	0	0	0	0	0	0	0
23	0	0	0	0	0	1	0	0	0	0
25	0	0	0	0	0	0	0	0	0	0
27	0	0	0	0	1	0	0	0	0	0
29	0	0	0	0	1	1	1	0	1	1
30	0	0	0	0	1	0	0	0	0	0
32	0	0	0	0	0	1	1	2	1	1
36	0	0	0	0	0	0	0	0	0	0
37	0	0	0	0	1	1	0	0	1	1
39	0	0	0	0	0	1	1	1	1	1
40	0	0	0	0	0	1	0	0	0	0
42	0	0	0	0	0	0	0	0	0	0
48	0	0	0	0	0	0	0	0	0	0
51	0	0	0	1	1	1	0	0	0	0
53	0	0	0	0	0	0	0	0	0	0

Daily Observations of Depression

Vaccinates

Pig ID	Study Day									
	12	13	14	15	16	17	18	19	20	21
4	0	0	0	0	0	0	0	0	0	0
5	0	0	0	0	0	0	0	0	0	0
6	0	0	0	0	0	0	0	0	0	0
7	0	0	0	0	0	0	0	0	0	0
11	0	0	0	0	0	0	0	0	0	0
13	0	0	0	0	0	0	0	0	0	0
14	0	0	0	0	0	0	0	0	0	0
16	0	0	0	0	0	0	0	0	0	0
20	0	0	0	0	0	0	0	0	0	0
21	0	0	0	0	0	0	0	0	0	0
24	0	0	0	0	0	0	0	0	0	0
26	0	0	0	0	0	0	0	0	0	0
28	0	0	0	0	0	0	0	0	0	0
31	0	0	0	0	0	0	0	0	0	0
33	0	0	0	0	0	0	0	0	0	0
35	0	0	0	0	0	0	0	0	0	0
41	0	0	0	0	0	0	0	0	0	0
43	0	0	0	0	0	0	0	0	0	0
44	0	0	0	0	0	0	0	0	0	0
45	0	0	0	0	0	0	0	0	0	0
46	0	0	0	0	0	0	0	0	0	0
47	0	0	0	0	0	0	0	0	0	0
49	0	0	0	0	0	0	0	0	0	0
50	0	0	0	0	0	0	0	0	0	0

Controls

ID	Study Day									
	12	13	14	15	16	17	18	19	20	21
1	0	0	0	0	0	0	0	0	0	0
2	0	0	0	0	1	0	0	1	0	0
8	0	0	0	0	0	0	0	0	0	0
9	0	0	0	1	1	1	1	0	1	1
10	0	0	0	0	0	0	0	0	0	0
12	0	0	0	0	0	0	0	0	0	0
15	0	0	0	0	0	0	1	0	0	0
18	0	0	0	0	0	0	0	0	0	0
22	0	0	0	1	0	0	0	0	0	0
23	0	0	0	0	0	0	0	0	0	0
25	0	0	0	0	0	0	0	0	0	0
27	0	0	0	0	0	0	0	0	0	0
29	0	0	0	0	1	1	0	0	0	0
30	0	0	0	0	0	0	0	0	0	0
32	0	0	0	0	1	1	1	2	1	1
36	0	0	0	0	0	0	0	0	0	0
37	0	0	0	0	0	0	0	0	0	0
39	0	0	0	0	0	0	0	1	0	0
40	0	0	0	0	0	0	1	0	0	0
42	0	0	0	0	0	0	0	0	0	0
48	0	0	0	0	0	0	0	0	0	0
51	0	0	0	0	0	0	0	0	0	0
53	0	0	0	0	0	0	0	0	0	0

Daily Observations of Dehydration

Vaccinates

ID	Study Day									
	12	13	14	15	16	17	18	19	20	21
4	0	0	0	0	0	0	0	0	0	0
5	0	0	0	0	0	0	0	0	0	0
6	0	0	0	0	0	0	0	0	0	0
7	0	0	0	0	0	0	0	0	0	0
11	0	0	0	0	0	0	0	0	0	0
13	0	0	0	0	0	0	0	0	0	0
14	0	0	0	0	0	0	0	0	0	0
16	0	0	0	0	0	0	0	0	0	0
20	0	0	0	0	0	0	0	0	0	0
21	0	0	0	0	0	0	0	0	0	0
24	0	0	0	0	0	0	0	0	0	0
26	0	0	0	0	0	0	0	0	0	0
28	0	0	0	0	0	0	0	0	0	0
31	0	0	0	0	0	0	0	0	0	0
33	0	0	0	0	0	0	0	0	0	0
35	0	0	0	0	0	0	0	0	0	0
41	0	0	0	0	0	0	0	0	0	0
43	0	0	0	0	0	0	0	0	0	0
44	0	0	0	0	0	0	0	0	0	0
45	0	0	0	0	0	0	0	0	0	0
46	0	0	0	0	0	0	0	0	1	0
47	0	0	0	0	0	0	0	0	0	0
49	0	0	0	0	0	0	0	0	0	0
50	0	0	0	0	0	0	0	0	0	0

Controls

ID	Study Day									
	12	13	14	15	16	17	18	19	20	21
1	0	0	0	0	0	0	0	0	0	0
2	0	0	0	0	0	1	0	0	1	0
8	0	0	0	0	0	0	0	0	0	0
9	0	0	0	0	0	0	0	0	1	0
10	0	0	0	0	0	0	0	0	0	0
12	0	0	0	0	0	0	0	0	0	0
15	0	0	0	0	0	0	0	0	0	0
18	0	0	0	0	0	0	0	0	0	0
22	0	0	0	0	0	0	0	0	0	0
23	0	0	0	0	0	0	0	0	0	0
25	0	0	0	0	0	0	0	0	0	0
27	0	0	0	0	0	0	0	0	0	0
29	0	0	0	0	0	0	0	0	1	0
30	0	0	0	0	0	0	0	0	0	0
32	0	0	0	0	0	1	1	1	1	1
36	0	0	0	0	0	0	0	1	0	0
37	0	0	0	0	0	0	0	0	0	0
39	0	0	0	0	0	0	0	0	0	0
40	0	0	0	0	0	0	0	0	0	0
42	0	0	0	0	0	0	0	0	0	0
48	0	0	0	0	0	0	0	0	0	0
51	0	0	0	0	0	0	0	0	0	0
53	0	0	0	0	0	0	0	0	0	0

Study Type	Safety																																																																																											
Pertaining to	Salmonella Choleraesuis-Typhimurium Vaccine, Avirulent Live Culture																																																																																											
Study Purpose	Demonstration of safety under field conditions																																																																																											
Product Administration	In the drinking water or single dose by oral drench																																																																																											
Study Animals	290 neonatal pigs 3-5 days of age, and 223 3-week old pigs administered vaccine by oral drench (OD) 336 pigs administered vaccine by drinking water (DW) at weaning																																																																																											
Challenge Description	Not applicable																																																																																											
Interval observed after challenge	Pigs observed for 5 days after administration																																																																																											
Results	<p>Number of pigs by site with any listed clinical observations, occurring at least once during the observation period:</p> <table border="1"> <thead> <tr> <th>Clinical Observation</th> <th>UT Site (OD)¹ N=180</th> <th>NC Site 1 (OD)¹ N=110</th> <th>NC Site 2 (DW)² N=176</th> <th>MO Site (DW)² N=160</th> <th>IA Site (OD)² N=223</th> <th>Total N = 849</th> </tr> </thead> <tbody> <tr> <td>Normal³</td> <td>128</td> <td>98</td> <td>151</td> <td>160</td> <td>222</td> <td>759</td> </tr> <tr> <td>Diarrhea</td> <td>40⁴</td> <td>4</td> <td>15</td> <td>0</td> <td>0</td> <td>59</td> </tr> <tr> <td>Loss of condition</td> <td>15</td> <td>3</td> <td>2</td> <td>0</td> <td>0</td> <td>20</td> </tr> <tr> <td>Mortality⁵</td> <td>7</td> <td>5</td> <td>0</td> <td>0</td> <td>0</td> <td>12</td> </tr> <tr> <td>Sneezing</td> <td>0</td> <td>0</td> <td>5</td> <td>0</td> <td>0</td> <td>5</td> </tr> <tr> <td>Cough</td> <td>0</td> <td>0</td> <td>4</td> <td>0</td> <td>0</td> <td>4</td> </tr> <tr> <td>Depression</td> <td>0</td> <td>3</td> <td>0</td> <td>0</td> <td>0</td> <td>3</td> </tr> <tr> <td>Other</td> <td>0</td> <td>3</td> <td>0</td> <td>0</td> <td>0</td> <td>3</td> </tr> <tr> <td>Decreased Appetite</td> <td>0</td> <td>1</td> <td>1</td> <td>0</td> <td>0</td> <td>2</td> </tr> <tr> <td>Lameness</td> <td>2</td> <td>0</td> <td>0</td> <td>0</td> <td>0</td> <td>2</td> </tr> <tr> <td>Dyspnea</td> <td>0</td> <td>0</td> <td>1</td> <td>0</td> <td>0</td> <td>1</td> </tr> <tr> <td>Vomiting</td> <td>0</td> <td>0</td> <td>0</td> <td>0</td> <td>1</td> <td>1</td> </tr> </tbody> </table> <p>¹Pigs were 3-5 days of age ²Pigs were 17 - 29 days of age ³For “normal” a pig had to be observed to be without adverse events for the entire observation period of the study. ⁴ Includes 20 pigs with diarrhea at the time of vaccination. ⁵ No mortality at any of the sites was associated with vaccination as affirmed by licensee.</p>	Clinical Observation	UT Site (OD) ¹ N=180	NC Site 1 (OD) ¹ N=110	NC Site 2 (DW) ² N=176	MO Site (DW) ² N=160	IA Site (OD) ² N=223	Total N = 849	Normal³	128	98	151	160	222	759	Diarrhea	40 ⁴	4	15	0	0	59	Loss of condition	15	3	2	0	0	20	Mortality ⁵	7	5	0	0	0	12	Sneezing	0	0	5	0	0	5	Cough	0	0	4	0	0	4	Depression	0	3	0	0	0	3	Other	0	3	0	0	0	3	Decreased Appetite	0	1	1	0	0	2	Lameness	2	0	0	0	0	2	Dyspnea	0	0	1	0	0	1	Vomiting	0	0	0	0	1	1
Clinical Observation	UT Site (OD) ¹ N=180	NC Site 1 (OD) ¹ N=110	NC Site 2 (DW) ² N=176	MO Site (DW) ² N=160	IA Site (OD) ² N=223	Total N = 849																																																																																						
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Sneezing	0	0	5	0	0	5																																																																																						
Cough	0	0	4	0	0	4																																																																																						
Depression	0	3	0	0	0	3																																																																																						
Other	0	3	0	0	0	3																																																																																						
Decreased Appetite	0	1	1	0	0	2																																																																																						
Lameness	2	0	0	0	0	2																																																																																						
Dyspnea	0	0	1	0	0	1																																																																																						
Vomiting	0	0	0	0	1	1																																																																																						
USDA Approval Date	October 28, 2013																																																																																											