



Summary of Studies Supporting USDA Product Licensure

Establishment Name	Zoetis Inc.
USDA Vet Biologics Establishment Number	190
Product Code	1831.00
True Name	Streptococcus Equi Vaccine, Live Culture
Tradename(s) / Distributor or Subsidiary (if different from manufacturer)	Pinnacle I.N. - No distributor specified Pinnacle I.N. - Zoetis Mexico
Date of Compilation Summary	January 21, 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	<i>Streptococcus equi</i>									
Study Purpose	To demonstrate effectiveness against <i>S. equi</i> (strangles)									
Product Administration	Two doses, administered intranasally, 3 weeks apart									
Study Animals	Horses; Vaccinates (Group B; n=20) and Controls (n=15)									
Challenge Description	Vaccinates and controls were challenged with virulent <i>S. equi</i> intranasally 23 days post second vaccination									
Interval observed after challenge	Animals were observed daily for 3 weeks post challenge for clinical signs consistent with strangles. Nasal secretions were sampled to measure shedding daily for 3 weeks. Animals without ruptured lymph nodes were observed additionally up to 5 weeks post challenge.									
Results	<p>An animal was considered affected if it had enlarged or ruptured lymph nodes. The rate of mortality was evaluated.</p> <p>Table 1. Frequency of death/euthanasia and enlarged or ruptured lymph nodes</p> <table border="1"> <thead> <tr> <th>Treatment</th> <th>Death or Humane Euthanasia post challenge</th> <th>Enlarged or Ruptured Lymph Node(s)</th> </tr> </thead> <tbody> <tr> <td>Group B</td> <td>2/20</td> <td>13/20</td> </tr> <tr> <td>Controls</td> <td>9/15</td> <td>15/15</td> </tr> </tbody> </table> <p>The raw data can be found on the attached pages. dpc or DPC is Day Post Challenge</p>	Treatment	Death or Humane Euthanasia post challenge	Enlarged or Ruptured Lymph Node(s)	Group B	2/20	13/20	Controls	9/15	15/15
Treatment	Death or Humane Euthanasia post challenge	Enlarged or Ruptured Lymph Node(s)								
Group B	2/20	13/20								
Controls	9/15	15/15								
USDA Approval Date	December 11, 1997									

Table 2: Daily Clinical Signs of Each Animal from 2 Days before Challenge to 10 Days Post Challenge (dpc)

Group	Horse ID	-2dpc	-1dpc	0dpc	1dpc	2dpc	3dpc	4dpc	5dpc	6dpc	7dpc	8dpc	9dpc	10dpc
B	1	A	M1	F	DF	A	A	D	A	M1	H	DFH	H	H
B	11	A	A	A	A	A	A	A	A	A	M1	A	M1	M1
B	16	D	M1	A	A	A	A	A	A	A	A	A	D	A
B	19	D	A	A	E	E	DF	EH	H M3	H M3	FH M2	EH M2	EH M2	EH M1
B	22	D	A	D	A	D	A	A	H	DH M3	H M2	EFH M1	H M2	J M3
B	26	A	A	A	A	A	A	A	A	A	F	EFH	H	DH
B	31	D	M1	D	A	A	D	D	D	M1	D	EFH M1	EH M1	HL M2
B	35	A	A	A	A	A	A	M1	M4	M3	A M3	E M2	L M4	FHL M3
B	39	D	A	A	D	D	A	D	D	A	A	A	D	DF
B	41	D	A	A	A	A	E	D	A	M1	A	M1	E M2	E M1
B	48	A	A	A	A	A	A	A	H M2	H M1	H M2	DFH M1	FH M2	DH M2
B	58	F	A	A	A	A	A	A	A	M1	A M1	M1	M2	M1
B	127	E	A	D	EF	H	A	F	A	A	D F	E M2	D M1	D M1
B	131	A	A	A	A	A	A	D	A	F M1	A	E	A	A
B	132	D	M1	A	A	A	A	E	A	A	DF M1	EFH M1	EFH M1	DH M2
B	135	A M1	A	A	D	E	A	A	A	A	A	DF M1	DF M1	M1
B	141	D	A	A	DF	A	A	A	M3	M3	H M2	DH M1	EFH M1	EH M2
B	142	D	A	D	A	A	A	A	M2	A	A	A	A	A
B	143	A	A	M1	M1	M1	A	A	D M3	M2	D M2	E M2	EHL M3	H M3
B	149	A	A	A	A	D M2	F	A	A	M1	A	D	M1	E M2

Control	64	A	A	M1	A	E M2	A	A	A	EH M3	EGH M2	H M2	FHL M2	FH M1
Control	66	A	A	A	M1	A	A	A	M2	H M1	H	H	HL	HL
Control	73	A	E	A	M1	M1	M1	D M3	M4	A M3	CDFL M2	L M2	DH M1	EL M2
Control	74	A	A	M2	M2	E M2	M1	D	D M2	DH M3	CFH M2	EFH M2	EHL M2	EH M1
Control	75	A	M1	A	A	DF	A	A	A	M1	DFH M2	FH M1	H M2	FH M1
Control	82	A	A	M2	A	M1	A	A	A	M1	E M1	EF M1	M1	EH M1
Control	91	A	A	F	A	A	A	A	F M1	M2	DF M3	M3	EFH M2	EH M1
Control	97	A	A	M1	A	A	E	H M1	M3	H M3	H M1	EFH M2	EFH M1	EH M2
Control	99	A	M1	D M2	A	A	F	DF	A	F M1	DF	EH	FH	EFH
Control	101	A	M1	F	A	F	A	A	A	A	M1	EF M2	D M2	H M3
Control	103	F	A	A	A	A	A	A	M1	H M2	M3	M2	FH M2	DH M3
Control	107	F	F	M2	M1	E M2	A	A	H	H M2	EH M1	EFH M3	EJ	CJ M1
Control	108	A	A	A	M1	M1	M1	M1	M2	H M2	H M1	H M2	HL M1	J M1
Control	109	A	M1	A	A	A	A	M1	M3	H M2	DGH M2	EH M1	HL M1	EH M1
Control	112	A	A	F	A	A	A	D	A	A	M1	E M2	M2	M1

Key

- A - Normal
- B - Sneezing
- C - Depression
- D - Serous Nasal Discharge
- E - Mucopurulent Nasal Discharge
- F - Ocular Discharge
- G - Coughing
- H - Enlarged Local Lymph Nodes
- I - Swollen Disseminated Lymph Node
- J - Abscessed Local Lymph Node
- K - Death/Humane euthanasia
- L - Labored Breathing
- M1 - Fever (103-103.9⁰F)
- M2 - Fever (104-104.9⁰F)
- M3 - Fever (105-105.9⁰F)
- M4 - Fever (106-106.9⁰F)

Table 3. Daily Clinical Signs of Each Animal from 11 Days Post Challenge (dpc) to 21 dpc and Lymph Node and Abscess Information

Group	Horse ID	11dpc	12dpc	13dpc	14dpc	15dpc	16dpc	17dpc	18dpc	19dpc	20dpc	21dpc	Total Swollen Lymph Nodes	Total Abscess
B	1	DH M3	H	FH	J	FJ	FJ M1	DJM1	J	EFJ M1	J	J	+	+
B	11	M2	A	A	M1	M2	A	M1	EF	A	E	A	-	-
B	16	A	A	EF	D	A	A	A	A	M1	M2	M4	-	-
B	19	IJ M2	IJ M2	EIJ M3	EIJ M2	IJ M1	EFIL M3	EFIJ	EIJ M1	EFIJ M1	EIJ	DFIJ M1	+	+
B	22	EJ M1	H M1	EH M2	J	EHM3	DJ M1	EFJ M1	FJ M1	EFJ M1	J M1	E	+	+
B	26	FH	H	EFH M3	EFH M1	DFH M1	FI	DFJ M1	EFJ	EFJ	EJ	EJ	+	+
B	31	DH M3	EH M1	EH M2	EH M1	DJ M1	EFJ	J	DEFJ	DH	H	FJ M3	+	+
B	35	EH M3	EH M1	DH M1	EH M1	FH M1	EH M1	FH M2	H	FH M2	J M1	HJ M1	+	+
B	39	D M1	A	D	DF	DF	EF	DF	A	A	A	A	-	-
B	41	EL M2	E M1	M2	D M3	E M2	D	E M1	EF M1	E	F	DF	-	-
B	48	H M2	EF	EH M2	EH M2	EFJ M1	EJ	EFJ M1	FJ	DJ	FJ	FJ	+	+
B	58	M2	EF M1	F M3	EF M1	E	E	E	E	E	EH	EH	+	-
B	127	D M2	D M3	E M3	E M2	DF M1	D	DHM1	H	DH	DH M1	DH M1	+	-
B	131	F	A	A	M3	DF M2	F	DF	A	A	A	A	-	-
B	132	DH M3	H M2	EH M2	EFH M2	EFH M1	EFJ	DH	EJ	J M1	FJ M2	FHJ M3	+	+
B	135	D M3	F M1	A M2	EF	DE	DF	EF	E	A	E	D	-	-
B	141	EH	FH M2	FH	ECH	EF1 M2	EFHL M1	EFJ	DFJ M2	EFJ	FJ M1	EFJ	+	+
B	142	M1	D M2	M3	DF M3	EF	G	M1	A	D	A	A	-	-
B	143	EFH M3	H M3	I M3	EIJ M2	IJ M1	EJ	FJI	I M1	FJ	J M1	DFJ M1	+	+
B	149	D M1	E M1	F M2	D M2	F	A	DF	F	A	M1	F M1	-	-

Control	64	EH M1	EH	DFJ	EFIJ	EFJL	EFJL	CEFIJ	EFJL	FJ	J	HJ	+	+
Control	66	CEH M1	EH	EFGL M1	EJ	K	K	K	K	K	K	K	+	+
Control	73	EHL M1	EHL M1	EFH L M2	EFHL M2	EFHL M1	HL	EFI L M1	CEFG IL	HJL M1	CHL M1	CG H L M2	+	+
Control	74	EH M2	EHL M1	EH M2	EI M1	EJ M1	IJ M2	EFIJ	CIJ	EIJ	EFIJ	EIJL M1	+	+
Control	75	H M2	FJ	EJ	EFJ	J	EJ	J	DFJ M2	FJ	J	J M1	+	+
Control	82	EH M2	EH	EH M1	EH M2	EH	H	H	H	J	EJ	EFJ	+	+
Control	91	EFHL M2	EFH	H M1	CFH	EFH	EFH	EFIJ M1	IJ	EFIJ	EFHI J	EFIJ M2	+	+
Control	97	EJ M1	EFJ	HL M1	EFH	EFJ M1	EFJ M2	EFJ M2	EFJ M1	EFJ	EFIJ M1	EHJ M1	+	+
Control	99	EFH M1	H M1	EH M2	EFH M1	DFH M1	EJ	EFJ	FJ	FJ M1	FJ	EJ M1	+	+
Control	101	EFH M2	EH M2	EJ M2	EHL M2	EHI M1	H M2	EH M2	EFH	H	FJ	J M1	+	+
Control	103	EH M3	EH M2	EJ M3	EJ M3	EFJ M1	J M1	EHJ M1	FJ M1	FJ	EFJ M1	IJ M1	+	+
Control	107	EJ M1	J M1	EH	EJ M2	EFIJ M1	EFIJ	EFIJ	EIJ	EFHI J	EFIJL M1	EFIJ M1	+	+
Control	108	EJ M1	EJ M2	EJ	EJ	EJ	FJ	EJ	J	H	J	DJ	+	+
Control	109	EHL M1	EH	EH	EJ	EFJL	FJ	EFIJ	EFIJ	H M1	EHL M2	CGL M2 K	+	+
Control	112	D M2	H M2	EH M2	EFH M1	H M1	FH	EH M1	EJ	EJ	D	HJ M2	+	+

Key

- | | | | |
|----------------------------------|-------------------------------------|-----------------------------|--------------------------|
| A - Normal | F - Ocular Discharge | K - Death/Humane euthanasia | M4 - Fever (106-106.9°F) |
| B - Sneezing | G - Coughing | L - Labored Breathing | |
| C - Depression | H - Enlarged Local Lymph Nodes | M1 - fever (103-103.9 °F) | |
| D - Serous Nasal Discharge | I - Swollen Disseminated Lymph Node | M2 - Fever (104-104.9 °F) | |
| E - Mucopurulent Nasal Discharge | J - Abscessed Local Lymph Node | M3 - Fever (105-105.9 °F) | |

Table 4. Clinical Signs of Non-Abscess Horses over Extended Observation Period Post Challenge (dpc)

Group	Horse ID	25dpc	27dpc	32dpc	35dpc
B	11	A	A	A	A
B	16	A	A	A	A
B	39	A	A	A	A
B	41	E	A	A	A
B	58	DHL	K	K	K
B	127	H	H	J	J
B	131	A	DEH	H	H
B	135	A	DF	A	A
B	142	A	A	A	A
B	149	A	A	A	A

Key

- | | | |
|----------------------------------|-------------------------------------|-----------------------|
| A - Normal | F - Ocular Discharge | K – Death |
| B - Sneezing | G - Coughing | L – Labored Breathing |
| C - Depression | H - Enlarged Local Lymph Nodes | |
| D - Serous Nasal Discharge | I - Swollen Disseminated Lymph Node | |
| E - Mucopurulent Nasal Discharge | J - Abscessed Local Lymph Node | |

Table 5: Death or Humane Euthanasia Period Post Challenged (DPC)

Group	Horse ID	Death or Humane Euthanasia (HE)	Date	Group	Horse ID	Death or Humane Euthanasia (HE)	Date
B	1	N	NA	Control	64	N	NA
B	11	N	NA	Control	66	HE	15 DPC
B	16	N	NA	Control	73	HE	25 DPC
B	19	HE	25 DPC	Control	74	HE	25 DPC
B	22	N	NA	Control	75	N	NA
B	26	N	NA	Control	82	N	NA
B	31	N	NA	Control	91	HE	25 DPC
B	35	N	NA	Control	97	Died	34 DPC
B	39	N	NA	Control	99	N	NA
B	41	N	NA	Control	101	Died	34 DPC
B	48	N	NA	Control	103	N	NA
B	58	HE	26 DPC	Control	107	HE	25 DPC
B	127	N	NA	Control	108	N	NA
B	131	N	NA	Control	109	HE	21 DPC
B	132	N	NA	Control	112	HE	33 DPC
B	135	N	NA				
B	141	N	NA				
B	142	N	NA				
B	143	N	NA				
B	149	N	NA				

Table 6: Daily Shedding Incidence of Horses from 2 Days Prior to and 21 Days Post Challenge (dpc)

Group	Horse ID	-2dpc	-1dpc	0dpc	1dpc	2dpc	3dpc	4dpc	5dpc	6dpc	7dpc	8dpc	9dpc	10dpc	11dpc	12dpc	13dpc	14dpc	15dpc	16dpc	17dpc	18dpc	19dpc	20dpc	21dpc
B	1	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
B	11	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
B	16	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
B	19	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
B	22	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
B	26	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
B	31	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
B	35	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
B	39	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
B	41	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
B	48	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
B	58	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
B	127	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
B	131	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
B	132	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
B	133	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
B	141	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
B	142	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
B	143	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
B	149	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Control	64	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Control	66	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Control	71	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Control	74	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Control	75	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Control	82	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Control	91	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Control	97	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Control	99	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Control	101	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Control	103	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Control	107	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Control	108	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Control	109	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Control	112	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-

Study Type	Safety
Pertaining to	ALL
Study Purpose	To demonstrate safety of product under field conditions
Product Administration	Two doses, administered intranasally, 2-3 weeks apart
Study Animals	Study involved 692 horses from a variety of breeds in 5 states. The animals were randomly assigned to either a control group (110 animals) or a vaccinate group (582 animals). Vaccinated horses were distributed as follows: 7 were < 4 months of age; 185 were 4-9 months of age; 390 were > 9 months of age
Challenge Description	N/A
Interval observed after challenge	No challenge. Animals were observed for 30 minutes post-vaccination for immediate adverse reactions. Horses were then evaluated once a week, for 2 weeks after each vaccination, for delayed adverse reactions.
Results	<p>99.14% (5/582) of the vaccinates had no vaccine reactions during the observation period following first and second vaccinations. There were only five vaccine-related reactions in a total of 1,164 doses administered (reaction rate 0.43%). All vaccine related reactions resolved within 48 hours without treatment.</p> <p>Controls had no vaccine reactions during the observation period.</p> <p>Raw data are shown in Table 1 attached.</p>
USDA Approval Date	December 19, 1997

Table 1: Summary of Streptococcus equi Vaccine Field Safety Study

Investigator	Total No. Animals Vaccinated	Total No. Controls	Sex (M/F)	No. Animals <4 months	No. Animals 4 - 9 months	No. Animals >9 months	Vaccine Related Reactions	Non vaccine Related Events ^y
1	235	50	87/148	0	102	133	0	28 ^a
2	56	8	24/30/2*	1	5	50	3 ^b	1 ^c
3	93	0	47/46	6	21	66	0	1 ^d
4	71	9	22/49	0	4	67	5 ^e	1 ^f
5	127	43	44/82/1*	0	53	74	2 ^g	2 ^h
Totals	582	110	224/355/3*	7	185	390	5	38

* Sex not recorded

^y As affirmed by licensee

- a. Eleven horses with mucoid discharge from eyes prior to vaccination.
Twenty four horses with crusty to clear nasal discharge prior to vaccination.
One horse had a cough prior to vaccination.
One horse required colic surgery three days post vaccination.
One horse had an upper respiratory tract infection requiring treatment.
- b. Two horses had thick bilateral nasal discharge one week post vaccination.
One horse had mild unilateral mucopurulent nasal discharge one week post vaccination.
- c. One horse was treated medically for colic 36-48 hours post vaccination.
- d. One horse became febrile, developed bilateral nasal discharge, and profuse watery diarrhea six days post vaccination.
- e. Five horses sneezed post inoculation due to mucosal irritation. These episodes were immediate.
- f. One horse had bilateral conjunctivitis at time of vaccination.
- g. Two horses had nasal discharge post vaccination.
- h. Two control horses had swollen lymph nodes.