

Summary of Studies Supporting USDA Product Licensure

Establishment Name	Elanco US Inc.
USDA Vet Biologics Establishment Number	196
Product Code	46E5.21
True Name	Canine Coronavirus Vaccine, Killed Virus, Leptospira Canicola-Grippotyphosa-Icterohaemorrhagiae-Pomona Bacterial Extract
Tradename(s) / Distributor or Subsidiary (if different from manufacturer)	CvK/LCIGP - Elanco US Inc.
Date of Compilation Summary	December 19, 2019

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
Study Type	
Pertaining to	Canine coronavirus
Study Purpose	To demonstrate effectiveness against intestinal disease due to
	canine coronavirus
Product Administration	
Study Animals	
Challenge Description	
Interval observed after	
challenge	
Results	Study data were evaluated by USDA-APHIS prior to product licensure and met regulatory standards for acceptance. Study data, however, are no longer available.
USDA Approval Date	December 3, 1984

Study Type	Efficacy
Pertaining to	Leptospira canicola
Study Purpose	To demonstrate effectiveness against Leptospira canicola in 6
	week old dogs.
Product Administration	Two doses were administered subcutaneously (SC) 3 weeks
	apart.
Study Animals	Twenty-three (23) 6 week old puppies serologically negative for
	Leptospira were randomized into one group of 11 SC vaccinates
	and one group of 12 controls.
Challenge Description	Twenty-one (21) days after second vaccination all animals were
	challenged with Leptospira canicola organisms.
Interval observed after	Dogs were observed daily for 21 days after challenge for clinical
challenge	signs associated with L. canicola. Blood samples were collected
	through 14 days after challenge.
Results	Efficacy was determined by comparing vaccinates versus
	controls in clinical signs, thrombocytopenia, and leukopenia.
	A dog was considered to have thrombocytopenia if the platelet
	count dropped below 200 k/ μ L and the count was less than 50%
	of the baseline value.
	A dog was considered to have leukopenia if the platelet count
	dropped below 6 k/ μ L and the count was less than 50% of the
	baseline value.
	Data tables are appended to the end of this summary.
USDA Approval Date	April 3, 1998

		21DPC																		
		20DPC		9	8															
		19DPC			8									0	7					
		18DPC				œ								 llenge	– د					
		17DPC							AG					st-cha						
		16DPC				U							т	IV DOS	-					
		15DPC			A	AG			A					DPC = Day post-challenge						
		14DPC							A					DPC						
		13DPC																		
		10DPC 11DPC 12DPC 13DPC 14DPC 15DPC 16DPC 17DPC 18DPC 19DPC 20DPC 21DPC																		
enge		11DPC																		
		10DPC				A														
Leptospira canicola Clinical Signs Observed Fost Challenge		9DPC									9								erved	
Sus Obse	inates	8DPC												103.9°F)	104.9°F)	105.9°F)			Blank - no clinical signs observed	
	SC Vaccinates													r (103.0-	r (104.0-	r (105.0-	۲.		o clinica	
		7DPC									U			N1 - Fever (103.0-103.9°F)	N2 - Fever (104.0-104.9°F)	N3 - Fever (105.0-105.9°F)	N4 - <99.6°F	P - Death	Blank - n	
pira canid		6DPC				9						A								
eptos																	()	stool)		
		5DPC									9	9		narge Mucoi	arge Serous	arge Mucoid	d (loose stool)	/ere (bloody		
		4DPC						9	A		IJ			G - Ocular Discharge Mucoid	H - Nasal Discharge Serous	I - Nasal Discharge Mucoid	 J - Diarrhea Mild (loose 	K - Diarrhea Severe (bloody stool)	L - Bloody Urine	M - Icterus
		3DPC						9				9		-	-	_	_		_	_
												6					NBV	Id/Modt	/ere	erous
		C 2DPC					9				9	AD		a		athing	D - Depression/Lethargy	E1 - Conjunctivitis Mild/Moderate	E2 - Conjunctivitis Severe	F- Ocular Discharge Serous
		1DPC		A	A	0	٥					A		A-inappetance	B-Vomiting	C-Labored Breathing	pressio	onjuncti	onjuncti	lar Disc
		ODPC				U			9		U	g		A-inap	B-Von	C-Lab(D - De	E1 - C0	E2 - Cc	F- Ocu
		Dog	12	13	14	15	16	17	18	19	20	21	22							

	10DPC 11DPC 12DPC 14DPC 15DPC 16DPC 17DPC 18DPC 19DPC 20DPC 21DPC					A,G			9			A,G G		DPC = Day post-challenge	,					
	5DPC 160					A			9			G,L		= Day						
	4DPC 1		٩	ۍ										DPC						ł
	13DPC 1						<u>م</u>	4			۹.			_						İ
	12DPC			٥	D,G				9	4		G	G,K							Ī
0	11DPC	Ь		A,D,N1	9							9	G,K							
	10DPC											A,K	A,K							
	9DPC			۵	A,D							A,D,G,K,L	A,D,G,K,L						served	
Controls	8DPC			A	A,D,K				G,K			A,D,G,K,L	A,D,G,L,N1	0-103.9°F)	0-104.9°F)	0-105.9°F)			cal signs ob	,
8	7DPC		C,D,G,L,N4	A,G	A,G,K	A,D,G			6			A,D,G,K,L	A,D,K,L,N1 A	N1 - Fever (103.0-103.9°F)	N2 - Fever (104.0-104.9°F)	N3 - Fever (105.0-105.9°F)	N4 - <99.6°F	P - Death	Blank - no clinical signs observed	
Controls	6DPC		A,D,K	A,K	L,D,J	A,K	A,D,E2,M,N4	A,D,E1,K,L,M,N4	A,D,G,K		A,D,G,K,L,M,N4	A,D,G,K,L	A,D,G,K,L	Z	Z	Z	Z		80	
	SDPC		A,D,G		Q	A,N1	A,D,G,K,L,M,N4	D,G,K,L,N4 A,	G,K	D,G,K,L,N4	D,K,L A	A,B,J	IJ	harge Mucoid	large Serous	arge Mucoid	J - Diarrhea Mild (loose stool)	K - Diarrhea Severe (bloody stool)		
	4DPC	A,D,K,M,N4	A,D,G,J	9	9	A	A,G,L	A,B,D,G,L		B,D,K,L	G,L	A,G		G - Ocular Discharge Mucoid	H - Nasal Discharge Ser	I - Nasal Discharge Mucoid	I - Diarrhea Mi	K - Diarrhea Se	L - Bloody Urine	-
	3DPC			•	D,G,N1	A	A	J,K		G,K	G	A,G,N1	A,G,N2							Í
	2DPC		D,G,N3	N2	D,G,N1	N1	GN2	D,N2	N2	N2	IJ	G,N2	A,N1			ß	ethargy	E1 - Conjunctivitis Mild/Moderate	Severe	
	1DPC				A,G		A		9			ن		tance	20	C-Labored Breathing	D - Depression/Lethargy	Inctivitis	E2 - Conjunctivitis Severe	
	ODPC									Ŧ		ۍ		A-inappetance	B-Vomiting	Labored	- Depre	- Conju	- Conju	

			İ.										
		14DPC	16.6	9.1	15.7	9.4	10.5	12.3	17.6	13.4	12.7	21.7	11.5
		13DPC	19.6	9.7	23.2	10.2	10.8	9.9	17.2	12.3	7.6	14.7	11
		12DPC	17.2	10.2	14	9.2	10.1	10.3	11.7	7.3	9.3	13.2	9.2
		11DPC	10.7	12.7	15.3	13.1	9.3	9.5	11.6	8.8	13	16.5	10.2
a		10DPC	19.3	8.8	16.9	8.5	11.3	8.8	9.1	7	7	11.7	7.7
Challeng		9DPC	19.4	10.4	19.3	8.5	9.7	7.3	9.3	8.2	11.4	14.9	11.7
Leptospira canicola White Blood Cell Count Post Challenge		8DPC	16.5	11.8	19.2	11.8	11.4	9.8	9.3	6.4	10.5	20.7	8.3
ood Cell C	SC Vaccinates	7DPC	20.7	12.5	17.4	13.1	9.4	12.5	9.7	7.5	9.2	13.4	7.3
White Blo	SC Vao	50PC	20	8	13.6	12.2	10.2	13.2	11.7	7.2	9	13.9	11
canicola		5DPC	19.3	6	15.5	11.5	10.1	10.7	9.4	6.6	8	14.1	12.7
eptospira		4DPC	20.3	10.5	14	8.2	8.4	12.2	10.2	8.4	7.6	14.6	9.5
		3DPC	17	9.6	12.9	12.7	7.6	11.8	10.1	9.1	9.1	15.1	12.1
		2DPC	15.1	9.3	12.3	9.6	9.5	12.8	10.6	8	10.7	9.5	9.4
		1DPC	25.8	12.4	19.8	8.8	13.2	16.1	11.4	8.4	15.8	10.5	15.6
		Baseline (Avg -2DPC, -1DPC, 0DPC)	22.1	12.3	21.7	13.3	14	14.3	11	8.9	11.2	11	10.2
		Dog	12	13	14	15	16	17	18	19	20	21	22

		14DPC			21.9	13.9	13.3			12.2			16.9	20.2
		13DPC			29.4	12.7	11.5			16.7			17.4	15.9
		12DPC			26.2	11.5	15			12.69			26.3	15.7
		11DPC			36.7	9.6	13.9			9.2			31.5	10.9
a		10DPC			36.6	16.6	11.3			11.4			20.5	15.3
Challeng		9DPC			28.1	13.8	7.9			8.7			22.8	17.3
ptospira canicola White Blood Cell Count Post Challenge		8DPC			26	11.7	16.2			10.4			22.8	12.6
od Cell C	Controls	7DPC		20.5	17		21			11.1			13	12
White Blo	Cont	6DPC		14.6	13.6	8	19.4	13.2	17.5	10.6		15.8	8.7	9
canicola		5DPC		15.6	12.6	6.7	8.6	19.4	5.3	6.7	10.3	6.6	4.4	3.8
Leptospira		4DPC	21.7	11.5	10	5.7	5.2	7	5	6.1	9	9	5.3	5.6
		3DPC	7.4	6.1	8.3	5.6	4.1	3.9	4.2	3.2	4	5.3	2.6	3.4
		2DPC	14.2	16.7	13	9.6	5.5	6.4	7.8	9.5	6.4	11.5	6.1	10.1
		1DPC	21.7	20	11.3	7.9	8.9	18.4	19.4	11.9	10.6	12.2	17.5	9.6
		Baseline (Avg -2DPC, -1DPC, 0DPC)	18.3	16.1	17.1	6	10.4	9.6	12.2	9.5	8.9	11.9	11.8	7
		Dog	23	24	25	26	27	28	29	30	31	32	33	34

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		14DPC	470	467	640	461	390	278	572	524	469	583	593
		13DPC	511	510	802	463	399	257	554	516	464	474	495
		12DPC	483	550	508	438	428	232	406	418	462	429	497
		11DPC	381	616	568	560	302	261	480	414	601	521	500
		10DPC	512	501	567	482	519	270	405	381	493	501	492
llenge		9DPC	631	470	695	497	512	288	483	476	662	581	597
s Post Cha		8DPC	478	565	693	576	655	314	463	379	704	650	473
let Count:	cinates	7DPC	582	636	604	633	558	351	247	375	706	514	469
ola Plate	SC Vaccinates	6DPC	531	467	497	612	555	389	542	376	538	441	517
Leptospira canicola Platelet Counts Post Challenge		5DPC	512	539	536	503	492	32 9	453	375	523	469	576
Leptos		4DPC	473	576	444	421	456	324	398	403	483	447	478
		3DPC	452	573	505	543	452	311	381	324	530	476	581
		2DPC	480	559	452	381	409	247	356	353	497	354	455
		1DPC	538	679	571	407	377	243	331	330	494	332	413
		Baseline (Avg -2DPC, -1DPC, 0DPC)	444.3	551.3	473.3	459.7	477.3	318	425.7	348.7	555.3	378.3	469.3
		Dog	12	13	14	15	16	17	18	19	20	21	22

					Leptos	Leptospira canicola Platelet Counts Post Challenge	ola Platel	et Counts	Post Cha	llenge					
							Controls	rols		1					
Dog	Baseline (Avg -2DPC, -1DPC, 0DPC)	1DPC	2DPC	3DPC	4DPC	SDPC	6DPC	7DPC	8DPC	9DPC	10DPC	11DPC	12DPC	13DPC	14DPC
23	300	238	148	11	7.7	D	D	D	D	D	D	D	D	D	٥
24	342	204	161	64.1	40.5	45.3	123	207	D	D	D	D	D	D	D
25	519.7	267	213	187	134	117	160	285	497	710	714	823	738	810	717
26	404.7	278	279	196	150	172	194	ND	302	441	721	648	599	590	588
27	482.7	281	225	119	55	49.9	100	157	405	455	492	552	528	428	435
28	242.3	209	60.4	45.9	3.9	11.1	11.3	D	D	D	D	D	D	D	D
29	529.7	521	305	195	37.6	15.8	42.2	D	D	D	D	D	D	D	D
30	329.3	292	167	107	61.7	81.6	122	242	412	518	697	504	632	596	551
31	432.7	327	150	80.2	38	14	D	D	D	D	D	D	D	D	D
32	395.7	329	195	103	33.3	14.2	44.1	D	D	D	D	D	D	D	D
33	563.7	409	182	115	67.1	8.5	2.4	11.4	87.1	235	417	744	701	726	714
34	232.7	174	150	64.5	41.6	8.3	6.8	82.8	142	273	310	383	479	475	564
ND= No Data	ata														
D = dead															

Study Type	Efficacy
Pertaining to	Leptospira grippotyphosa
Study Purpose	To demonstrate effectiveness against <i>Leptospira grippotyphosa</i>
Study I dipose	in 6-week-old dogs.
Product Administration	Two doses were administered subcutaneously (SC) 3 weeks apart.
Study Animals	Twenty (20) 6-week-old puppies were randomized into one group of 10 SC vaccinates and one group of 10 controls.
Challenge Description	Fifteen (15) days after second vaccination all animals were
	challenged with Leptospira grippotyphosa organisms.
Interval observed after	Dogs were observed daily for 21 days after challenge
challenge	
Results	Efficacy was based on the reduction in spirochetemia in vaccinates when compared to controls.
	A data table is appended to the end of this summary.
USDA Approval Date	January 12, 1999

				•	-p	Contro	l Animals						
Dog	ODPC	3DPC	4DPC	5DPC	6DPC	7DPC	8DPC	9DPC	10DPC	11DPC	12DPC	13DPC	14DPC
1						+							
2					+		+	+					
3				+	+								
4					+	+							
5				+	+	+							
6						+	+	+	+	+	NA	NA	NA
7				+	+	+	+	+	+	NA	NA	NA	NA
8					+	+	+	+	+	+	NA	NA	NA
9				+	+	+	+	+	+	+	NA	NA	NA
10					+	+	+	+	+	+	NA	NA	NA

Isolation of Leptospira from Blood Collected from Dogs Post Challenge

NA - Animal Dead or euthanized / no sample taken

+ - Positive for Leptospira

*Leptospira was not isolated in any of the SC vaccinates

Study Type	Efficacy
Pertaining to	Leptospira icterohaemorrhagiae
Study Purpose	To demonstrate effectiveness against <i>Leptospira</i>
	icterohaemorrhagiae in 6 week old dogs.
Product Administration	Two doses were administered subcutaneously (SC) 3 weeks
	apart.
Study Animals	Twenty-two (22) 6 week old puppies serologically negative for
·	Leptospira icterohaemorrhagiae were randomized into one
	group of 10 SC vaccinates and one group of 12 controls.
Challenge Description	Twenty-one (21) days after second vaccination all animals were
	challenged with Leptospira icterohaemorrhagiae organisms.
Interval observed after	Dogs were observed daily for 21 days after challenge for clinical
challenge	signs associated with L. icterohaemorrhagiae. Blood samples
	were collected through 14 days after challenge.
Results	Efficacy was determined by comparing vaccinates versus
	controls in clinical signs, thrombocytopenia, and leukopenia.
	A dog was considered to have thrombocytopenia if the platelet
	count dropped below 200 k/ μ L and the count was less than 50% of the baseline value.
	A dog was considered to have leukopenia if the platelet count dropped below 6 $k/\mu L$ and the count was less than 50% of the baseline value.
	Data tables are appended to the end of this summary.
USDA Approval Date	March 31, 1998

						- F	Leptospira Ictero Clinical Signs Observed Post Challenge	tro Clinical	Signs Obse	erved Post	Challe	agu									
								SCV	SC Vaccinates												
Dog	ODPC	1DPC	2DPC	3DPC	4DPC	5DPC	6DPC	7DPC	8DPC	9DPC	10DPC	11DPC	12DPC 1	3DPC 14	DPC 150	PC 16DF	10DPC 11DPC 12DPC 13DPC 14DPC 15DPC 15DPC 17DPC 19DPC 20DPC 21DPC	18DPC	19DPC	20DPC	21DPC
11							А														
12																					
13				ш		0								ш			ш	0		ш	
14				ш			ш		Ŀ									0	ш		
15		A,E							ш				0							ш	
16																			A		
17																					
18																		0			
19							ш														
8			_	0		٥	D					0		ш		ш					
	A-inappetance	etance			F - Nasal Discharge Serous	narge Serous		K - Bloody Urine	ne												
	B-Vomiting	ing			G - Nasal Disc	G - Nasal Discharge Mucoid		L - Fever >103.0°F	.0°F												
	C - Depr	C - Depression/Lethargy	ethargy		H- Diarrhea Mild (loose	ild (loose stool)		M - Death													
	D- Ocula	ar Discha	D- Ocular Discharge Serous	2	I- Diarrhea Moderate (W	derate (Watery stool)	(lool)	Blank - no clinical Sign observed	nical Sign ob:	served											
	E - Ocula	ar Discha	E - Ocular Discharge Mucoid	.p	J - Diarrhea Se	J - Diarrhea Severe (bloody stool)	()														
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Leptospira Ictero Clinical Signs Observed Post Challenge	Controls	6DPC 7DPC 8DPC 9DPC 10DPC 11DPC 12DPC 13DPC 14DPC 15DPC 14DPC 15DPC 14DPC 12DPC 20DPC 20DPC 20DPC 21DPC	A	8					J A E D	M		M	A E D E			K - Bloody Urine	L - Fever >103.0°F	M - Death	tool) Blank - no clinical Sign observed	
		2DPC 1			ш				ш											
e B		1DPC 1											ш							
Challen		10DPC 1								M		M								
rved Post (8															served	
Signs Obse	Controls	8DPC							A							ne	1.0°F		inical Sign ob:	
aro Clinical		7DPC							[K - Bloody Uri	L - Fever >103	M - Death	Blank - no cli	
ptospira lcte		6DPC	A										A	ш					tool)	()
þ		SDPC							ш		D					harge Serous	G - Nasal Discharge Mucoid	(ild (loose stool)	oderate (Watery stool)	J - Diarrhea Severe (bloody stool)
		4DPC	F	F					Q	A,C,D,J		A,E				F - Nasal Discharge Serous	G - Nasal Disc	H- Diarrhea Mild (loose	I- Diarrhea Moderate (W	J - Diarrhea Sé
		3DPC			_	_			٥	К		L,D	Ц						10	
		2DPC				_				L,E	_		_					hargy	D- Ocular Discharge Serous	E - Ocular Discharge Mucoid
		1DPC														ance	p.c	sion/Let	Discharg	Discharg
		0DPC 1														A-inappetance	B-Vomiting	C - Depression/Lethargy	Ocular [Ocular I
		Dog 0				24	25	26	27	28	29	30	31	32	-	Ą	÷	ن	Ċ	ú

DPC = Day post-challenge

	14DPC	6.4	12.3	8.4	9.1	10.9	8.3	7.3	6.4	6.7	8.9
	13DPC	7.2	9.1	7.8	12.8	7.5	8.3	7.5	7.8	8.8	8.1
	12DPC	9.6	9	7.8	10	11.1	10	10.2	6.5	7	7.6
	11DPC	9.7	10.2	6.7	9.8	7.7	9.5	7.1	8.1	7.8	12.6
	10DPC	8.9	7.7	10.6	13.2	10.4	8.7	11.7	6	7.7	12.5
	9DPC	8.5	8.6	8.3	8	7.5	7.7	7.6	8	8.2	8.7
	8DPC	6.4	11.1	9.6	11.8	8	10.1	11.4	7.4	7.5	9.1
inates	7DPC	6.4	8.2	9.2	7.3	10.2	8.4	9.4	8.4	10.5	6.4
SC Vacc	6DPC	6.4	15.2	8.8	9.3	11.2	9.4	10.5	7.1	6.7	14.4
	5DPC	10.1	12.4	14.2	11.3	8.3	9.1	7.2	7.3	8.7	14.8
	4DPC	6.8	9.1	9.1	12.6	8	8.1	7.5	6.6	11.7	11.9
	3DPC	7.9	8.9	13.2	8.2	9	6.8	8.1	9.1	11.7	9.1
	2DPC	12.4	10.4	9.6	12.6	9.8	9.5	7.8	10.5	8.4	5.3
	1DPC	7.3	13.9	15.4	7.6	11.4	8.8	7.1	7.7	13.8.	6.6
	Baseline (Avg -2DPC, -1DPC, 0DPC)	7.2	10	7.6	13.4	9.8	9.1	9.1	7.2	9.5	13.1
	Dog	11	12	13	14	15	16	17	18	19	20
	SC Vaccinates	Baseline (Avg -2DPC, -1DPC, 0DPC) 1DPC 2DPC 3DPC 4DPC 5DPC 6DPC 7DPC 8DPC 9DPC 11DPC 11DPC 12DPC 13DPC	Baseline (Avg -2DPC, -1DPC, 0DPC) IDPC 3DPC 4DPC 5DPC 6DPC 7DPC 8DPC 1DPC 12DPC 13DPC 13	Baseline (Avg - 2DPC, -1DPC, 0DPC) IDPC IDPC	Baseline (Awg-2DPC, -1DPC, 0DPC) IDPC IDPC	Baseline (Awg-2DPC, -1DPC, 0DPC) IDPC 2DPC 4DPC 5DPC 6DPC 7DPC 8DPC 9DPC 11DPC 11DPC 12DPC 13DPC 12DPC 12D	Baseline (Awg-2DPC, -1DPC, 0DPC) IDPC 3DPC 4DPC 5DPC 6DPC 7DPC 8DPC 9DPC 11DPC 13DPC 13D	Baseline (Awg-2DPC, -1DPC, 0DPC) IDPC Solution S	Baseline (Avg -2DPC, -1DPC, 0DPC) IDPC Solution Solution	Solution Baseline (Awg -2DPC, 1DPC, 1DPC, 1DPC, IC Ancinates Baseline (Awg -2DPC, 1DPC, 1DPC, 1DPC, 1DPC 3DPC 4DPC 5DPC 6DPC 7DPC 9DPC 11DPC 12DPC 1DPC, 1DPC, 1DPC, 139 12.4 70 6DPC 7DPC 8DPC 9DPC 910 13DPC 10 13.9 10.4 8.9 91 12.4 15.2 82 11.1 86 7.7 10.2 9 9.1 10 13.9 10.4 8.9 11.3 9.3 7.3 11.8 8 7.7 10.2 9 9.1 7.8 11.4 9.6 11.3 9.3 7.3 11.8 8 7.7 10.2 9 7.8 13.4 7.6 11.4 9.8 7.3 11.8 8 7.3 11.8 7.8 7.8 7.8 13.4 7.6 11.4 8.6 7.7 11.1 7.7 11.1 7.	Baseline Baseline Baseline CVaccinates (Age 2DPC, 1DPC, 1DPC, 0DPC) 2DPC 3DPC 6DPC 7DPC 8DPC 1DPC 11DPC 11DPC

					Leptospir	Leptospira ictero White Blood Cell Count Post Challenge	Vhite Bloc	od Cell Co	unt Post (challenge					
							Cont	Controls							
Dog	Baseline (Avg -2DPC, -1DPC, 0DPC)	1DPC	2DPC	3DPC	4DPC	SDPC	6DPC	7DPC	8DPC	9DPC	10DPC	11DPC	12DPC	13DPC	14DPC
21	7.4	6.6	9.6	6.7	8.2	6.2	8.6	6.7	6.5	8.1	10.4	6.4	8.5	6.5	6.2
22	7.4	8.5	9.3	8.2	6.5	7.3	13.4	9.4	7.2	8.2	13.4	10.1	7.7	7.6	9.4
23	9.3	12.2	9.4	11.6	7.1	6	10	7	6.5	7.1	11.9	7	9.6	11	11.8
24	13.7	19.6	10.6	7.8	11.8	15.3	16.7	19.8	16	13.7	19.2	24.9	13.3	24.4	12.3
25	10	13.9	8.5	6.9	9.1	7	10.9	12.8	9.6	10	13.9	9.4	8.3	9	7.1
26	8.4	8.6	9	3.9	11.8	12.2	15.4	11.3	11.8	9	10.2	13.3	8.6	8.9	10.5
27	7.8	7.5	9.4	15.8	14.6	10.7	9.8	7.5	8.6	12.1	8.6	8.3	11.4	7.4	9.5
28	7.8	8.8	6.7	4.5	7.3	7.3	8.8	14.7	10	11.6	11.7	14	8.3	7.8	7.7
29	7.8	6.7	5.8	4.1	26.4					D					
30	8.8	7.6	5	7.2	7.8	7.5	7.8	6.2	9.9	8	10.3	10.1	9.9	9.4	9.6
31	11	8.1	8.3	4.2	19					D					
32	8.3	9.3	6.2	5	10.7	12.6	10.6	13.5	14.5	9.6	14.1	9.9	10	10.1	9.3
D = dead															
						Г									
	$DDC = D_{cirr} = 0$	1 11	Violine and	1 1 1-	-/T										

		13DPC 14DPC	471 359	461 517	337 349	351 281	290 369	284 294	373 381	391 287	406 352	340 378	
		12DPC	536	473	347	263	401	286	498	283	331	325	
		11DPC	586	453	415	330	288	258	417	388	383	501	
		10DPC	591	487	522	431	388	316	529	406	356	488	
Leptospira ictero Platelet Counts Post Challenge		9DPC	442	505	508	331	285	253	436	424	489	358	
s Post C		8DPC	488	480	416	376	314	281	513	327	378	392	
t Count	inates	7DPC	447	435	517	335	400	268	457	419	500	352	
Platele	SC Vaccinates	6DPC	457	645	445	344	435	308	542	393	459	555	
a ictero		SDPC	667	526	580	374	282	278	214	351	417	515	
ptospir		4DPC	440	428	424	457	275	264	332	397	529	525	
Le		3DPC	476	447	560	349	286	217	386	392	552	483	
		2DPC	619	456	425	413	297	298	400	569	386	506	
		1DPC	432	475	595	258	380	264	407	482	467	412	
		Baseline (Avg -2DPC, -1DPC, 0DPC)	449.7	518.3	489.3	451.7	357.7	369	473.7	506	477	502.3	
		Dog	11	12	13	14	15	16	17	18	19	20	

k/μL.
Values reported as
DPC = Day post-challenge.

Leptospira ictero Platelet Counts Post Challenge	Controls	Baseline Avg -2DPC, -1DPC, 0DPC) 1DPC 2DPC 3DPC 4DPC 5DPC 6DPC 7DPC 8DPC 9DPC 11DPC 12DPC 13DPC 14DPC 14DPC 10DPC 11DPC 13DPC 14DPC	534.3 291 315 207 301 341 545 506 529 537 575 434 399 414 410	428.7 238 250 168 126 184 261 288 340 412 520 421 369 386 367	411.3 374 307 265 289 362 393 361 369 447 546 444 422 583 535	3 <i>44.7</i> 251 130 99.5 116 189 312 497 440 480 618 635 461 658 451	566 401 220 146 189 288 483 611 458 466 660 519 432 409	392 302 213 94.9 84.5 210 361 381 421 444 467 578 513 452 388	475.7 399 423 483 413 335 386 437 465 575 469 461 540 372 474	411.7 214 93.5 60.5 128 213 307 332 467 612 618 495 467 383	332 136 101 6.7 11.2 D	421.9 204 80.9 53.9 119 231 379 512 549 516 642 494 411 421 427	319.3 163 94.4 36.7 11.9 D	267 184 55 7.7 88.8 196 257 347 525 430 529 360 337 287 301		DPC = Day post-challenge. Values reported as k/µL.	
															q	 Day post-challen	
		Dog	21	22	23	24	25	26	27	28	29	30	31	32	D = Dead	 DPC =	

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Study Type	Efficacy
Pertaining to	Leptospira pomona
Study Purpose	To demonstrate effectiveness against <i>Leptospira pomona</i> in 6 week old dogs.
Product Administration	Two doses were administered subcutaneously (SC) 3 weeks apart.
Study Animals	Twenty (20) 6 week old puppies serologically negative for <i>Leptospira</i> were randomized into one group of 10 SC vaccinates and one group of 10 controls.
Challenge Description	Twenty-five (25) days after second vaccination all animals were challenged with <i>Leptospira pomona</i> organisms.
Interval observed after challenge	Dogs were observed daily for 21 days after challenge. Blood samples were collected through 14 days after challenge.
Results	Efficacy was based on the reduction in spirochetemia in vaccinates when compared to controls. A Data table is appended to the end of this summary.
USDA Approval Date	January 12, 1999
USDA Approvar Date	January 12, 1777

											06310				
							Cont	rol Anir	nals						
Dog	0DPC	1DPC	2DPC	3DPC	4DPC	5DPC	6DPC	7DPC	8DPC	9DPC	10DPC	11DPC	12DPC	13DPC	14DPC
1			+	+	+	+									
2															
3			+	+	+										
4				+	+										
5			+	+	+	+									
6			+	+											
7		+	+	+											
8			+	+	+										
9		+	+	+	+										
10		+		+	+										

Isolation of Leptospira from Blood Collected from Dogs Post Challenge

DPC= Day post challenge

*Leptospira was not isolated from blood in any of the SC vaccinates

Study Type	Safety												
Pertaining to	All												
		- f	1		1	1:4:							
Study Purpose	Demonstrate safety						1						
Product	Two doses were ad				sly (SC) a	t 2-3 W	еек						
Administration	intervals in dogs 6												
Study Animals	A total of 624 dogs		•										
	were enrolled in the			se dogs	s, 341 wer	e 6 wee	eks of age						
	or younger, at first	vaccina	ation.										
Challenge	NA												
Description													
Interval observed	Dogs were observe				ng each v	accinat	ion and						
after challenge	daily for two weeks			nation.									
Results	Frequency of Adve	erse Eve	ents:										
	Post Vaccination	Reacti	on Occurre	nce by o	doses. Tota	al Doses	5 = 1223						
	Desertion	≤ 6 V	Veek old	>6 W	eeks old	Tot	al Doses						
	Reaction	[Dogs	0	Dogs	1016	al Doses						
	Category	#	Percent	#	Percent	#	Percent						
	No adverse	C7 2	00.20%	F 2 0	00 720/	1211	00.020/						
	#Percent#Percent#PercentNo adverse events67399.26%53898.72%121199.02%												
	lethargy	0	0.00%	1	0.18%	1	0.08%						
	Swelling	0	0.00%	3	0.55%	3	0.25%						
	Injection Site pain	5	0.74%	1	0.18%	6	0.49%						
	Pruritus	0	0.00%	2	0.37%	2	0.16%						
	Increased Thirst	0	0.00%	1	0.18%	1	0.08%						
	*25 dogs only rece	ived on	e vaccinat	ion. Ei	ither they	did not	return for						
	follow-up or were i												
	cooperator to be un					·	-						
USDA Approval	November 2, 1998												
Date													