

Summary of Studies Supporting USDA Product Licensure

Establishment Name	Boehringer Ingelheim Animal Health USA Inc.
USDA Vet Biologics Establishment Number	124
Product Code	46E5.28
True Name	Canine Coronavirus Vaccine, Killed Virus, Leptospira Canicola-Grippotyphosa-Icterohaemorrhagiae-Pomona Bacterial Extract
Tradename(s) / Distributor or Subsidiary (if different from manufacturer)	
Date of Compilation Summary	June 02, 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	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 <i>Leptospira canicola</i> 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 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 <i>Leptospira canicola</i> organisms.
Interval observed after challenge	Dogs were observed daily for 21 days after challenge for clinical signs associated with <i>L. canicola</i> . 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.
	See the next page for data.
USDA Approval Date	April 3, 1998

		21DPC																		
		19DPC 20DPC		U	8															
		19DPC			80															
		18DPC				g								e						
		100PC 11DPC 12DPC 13DPC 14DPC 15DPC 15DPC 17DPC 18DPC							AG					DPC = Dav post-challenge						
		16DPC				G							т	ost-ch						
		C 150PC			₫	AG			4					Jav Do						
		C 14DP(4					C = 1						
		C 13DP									_			 ď						
		C 12DP									_									
alleng		C 11DF																		
ost		100				4														
erved P		90PC									9								bserved	
Signs Obs	SC Vaccinates	8DPC												3.0-103.9 ⁴ F)	4.0-104.9 ⁴ F)	5.0-105.9 ¹ F)			nical signs of	
Leptospira canicola Clinical Signs Observed Post Challenge	SCV	7DPC									9			M1 - Fever (103.0-103.9 ¹ F)	N2 - Fever (104.0-104.9 ¹ F)	N3 - Fever (105.0-105.9 ¹ F)	N4 - <99.6 ¹ F	P - Death	Blank - no clinical signs observed	
pira canic		60PC				9						A					-	-		
Leptos		PC D												fucoid	erous	ucoid	e stool)	oody stool)		
		SOPC									9	9		scharge N	charge Se	harge Mu	fild (loos	evere (bl	e L	
		4DPC						9	A		9			G - Ocular Discharge Mucoid	H - Nasal Discharge Serous	I - Nasal Discharge Mucoid	J - Diarrhea Mild (loose stool)	K - Diarrhea Severe (bloody stool)	L - Bloody Urine	M - Icterus
		3DPC						5				5			-			derate h		
		2DPC					U				9	AD				2	chargy	E1 - Conjunctivitis Mild/Moderate	Severe	F- Ocular Discharge Serous
		1DPC		A	A	0	0					A		ance	5.0	Breathin	ssion/Let	nctivitis	nctivitis.	Discharg
		0DPC 1				ڻ			U		U	U		A-inappetance	B-Vomiting	C-Labored Breathing	D - Depression/Lethargy	1 - Conjui	E2 - Conjunctivitis Severe	- Ocular I
		Dog	12	13	14	15	16	17	18	19	20	21	2	4	œ	ن	0	ũ	ш	ú.

	100PC 11DPC 12DPC 13DPC 15DPC 16DPC 17DPC 18DPC 20DPC 21DPC				8	A A,G			99			G,L A,G G			DPC = Day post-challenge					
	4DPC 151			U								9			DPC =	_				
	13DPC 1		ď				d	٩			d					_				
	12DPC			0	D,G				U	d		U	G,K							
	11DPC	a.		A,D,N1	9							U	G,K							
	10DP(A,K	A,K							
	9DPC			D	A,D							A,D,G,K,L	A,D,G,K,L							ranad
Controls	8DPC			A	A,D,K				G,K			A,D,G,K,L	A,D,G,L,N1		-103.9°F))-104.9°F))-105.9°F)			al cione ob
Con	7DPC		C,D,G,L,N4	A,G	A,G,K	A,D,G			9			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	Black on clinical signs observed
	6DPC		A,D,K C	A,K	A,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 A		U.	N2	N3	7N		ā
	SDPC		A,D,G		D	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	U	0	harge Mucoid	arge Serous	arge Mucoid	d (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	C,L	A,G			G - Ocular Discharge Mucoid	H - Nasal Discharge Serous	I - Nasal Discharge Mucoid	J - Diarrhea Mild (loose	K - Diarrhea Sev	L. Blondullring
	3DPC			8	D,G,N1	A	A	J,K		G,K	9	A,G,N1	A,G,N2			_				
	2DPC		D,G,N3	N2	D,G,N1	N	GN2	D,N2	N2	N2	N	G,N2	A,N1				Bui	ethargy	E1 - Conjunctivitis Mild/Moderate	Cauara
	1DPC				A,G		A		9			9			tance	8	C-Labored Breathing	D - Depression/Lethargy	Inctivitis	62 - Conjunctinitie Cauara
	ODPC									Ŧ		U			A-inappetance	B-Vomiting	Clabore	0 - Depre	1-Conju	in Coni
	Dog	23	24	25	26	27	28	50	30	31	32	33	34							

1 E.				-	eptospira	Leptospira canicola White Blood Cell Count Post Challenge	White Blo	od Cell C	ount Post	Challeng					
							SC Vaccinates	cinates							
Baseline Avg -2DPC, -1DPC, 0DPC)		1DPC	2DPC	3DPC	4DPC	SDPC	60PC	7DPC	SDPC	9DPC	100PC	11DPC	12DPC	13DPC	14DPC
22.1	\vdash	25.8	15.1	17	20.3	19.3	20	20.7	16.5	19.4	19.3	10.7	17.2	19.6	16.6
12.3		12.4	9.3	9.6	10.5	6	80	12.5	11.8	10.4	8.8	12.7	10.2	9.7	9.1
21.7		19.8	12.3	12.9	14	15.5	13.6	17.4	19.2	19.3	16.9	15.3	14	23.2	15.7
13.3		8.8	9.6	12.7	8.2	11.5	12.2	13.1	11.8	8.5	8.5	13.1	9.2	10.2	9.4
14		13.2	9.5	7.6	8.4	10.1	10.2	9.4	11.4	9.7	11.3	9.3	10.1	10.8	10.5
14.3		16.1	12.8	11.8	12.2	10.7	13.2	12.5	9.8	7.3	8.8	9.5	10.3	9.9	12.3
=		11.4	10.6	10.1	10.2	9.4	11.7	9.7	9.3	9.3	9.1	11.6	11.7	17.2	17.6
8.9		8.4	80	9.1	8.4	6.6	7.2	7.5	6.4	8.2	7	8.8	7.3	12.3	13.4
11.2		15.8	10.7	9.1	7.6	89	6	9.2	10.5	11.4	7	13	9.3	7.6	12.7
=		10.5	9.5	15.1	14.6	14.1	13.9	13.4	20.7	14.9	11.7	16.5	13.2	14.7	21.7
10.2		15.6	9.4	12.1	9.5	12.7	11	7.3	8.3	11.7	7.7	10.2	9.2	11	11.5

		0												
		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
		10DPC			36.6	16.6	11.3			11.4			20.5	15.3
eptospira canicola White Blood Cell Count Post Challenge		9DPC			28.1	13.8	7.9			8.7			22.8	17.3
ount Post		8DPC			26	11.7	16.2			10.4			22.8	12.6
od Cell C	rols	7DPC		20.5	17		21			11.1			13	12
White Blo	Controls	6DPC		14.6	13.6	8	19.4	13.2	17.5	10.6		15.8	8.7	9
canicola		SDPC		15.6	12.6	6.7	8.6	19.4	5.3	7.9	10.3	6.6	4.4	3.8
eptospira		4DPC	21.7	11.5	10	5.7	5.2	7	5	6.1	6	6	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
	110PC	381	616	568	560	302	261	480	414	601	521	500
	10DPC	512	501	567	482	519	270	405	381	493	501	492
llenge	90PC	631	470	695	497	512	288	483	476	662	581	597
Post Cha	8DPC	478	565	693	576	655	314	463	379	704	650	473
<mark>et Counts</mark> cínates	7DPC	582	636	604	633	558	351	247	375	706	514	469
ola Platelet Cou SC Vaccinates	60PC	531	467	497	612	555	389	542	376	538	441	517
Leptospira canicola Platelet Counts Post Challenge SC Vaccinates	SDPC	512	539	536	503	492	329	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	pira canic	Leptospira canicola Platelet Counts Post Challenge	et Counts	Post Cha	llenge					
							Controls	rols							
Dog	Baseline (Avg -20PC, -10PC, 00PC)	1DPC	2DPC	3DPC	4DPC	SDPC	6DPC	7DPC	BDPC	9DPC	10DPC	11DPC	12DPC	13DPC	14DPC
23	300	238	148	11	7.7	٥	٥	٥	٥	٥	D	D	D	٥	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	Data														
D = dead															

Study Type	Efficac	у												
Pertaining to	Leptos	pira	grip	opot	yph	osa								
Study Purpose					fecti	iven	ess a	agai	nst	Lepi	tospir	a grip	potyp	<i>hosa</i> in
Product Administration												,		
Study Animals													to one	group
							_		-					
Challenge Description		·	/	•										
		-			-	-	0				-			
Interval observed after	Twenty (20) 6-week-old puppies were randomized into one group of 10 SC vaccinates and one group of 10 controls.otionFifteen (15) days after second vaccination all animals were challenged with Leptospira grippotyphosa organisms.													
challenge														
Results		-								-	iroche	etemia	1 n	
	vaccina	utes	wne	en co	omp	arec	u to	con	rol	5.				
	Lentos	nira	wa	- n 0	tico	late	d in	anv	of	the 1	vaccir	nates r	eceivi	na
		-				face	um	any	01		accii	lates I		ng
	vacenit	JOy	50	IUu	ic.									
	Leptos	oira	was	s iso	late	d fr	om ł	oloo	d co	ollec	ted fr	om do	ogs in	the
		0	-				0						U	
	ation Two doses were administered subcutaneously (SC) 3 weeks apart. Twenty (20) 6-week-old puppies were randomized into one group of 10 SC vaccinates and one group of 10 controls. ion Fifteen (15) days after second vaccination all animals were challenged with <i>Leptospira grippotyphosa</i> organisms. after Dogs were observed daily for 21 days after challenge Efficacy was based on the reduction in spirochetemia in vaccinates when compared to controls. Leptospira was not isolated in any of the vaccinates receiving vaccine by SC route. Leptospira was isolated from blood collected from dogs in the control group after challenge): Dog 0 3 4 5 6 7 8 9 10 11 12 13 14 1 4 1 4 4 4 4 4 4 4 4 4 4 4 4 4 4													
	ationTwo doses were administered subcutaneously (SC) 3 weeks apart.Twenty (20) 6-week-old puppies were randomized into one group of 10 SC vaccinates and one group of 10 controls.ionFifteen (15) days after second vaccination all animals were challenged with Leptospira grippotyphosa organisms.fferDogs were observed daily for 21 days after challengeEfficacy was based on the reduction in spirochetemia in vaccinates when compared to controls.Leptospira was not isolated in any of the vaccinates receiving vaccine by SC route.Leptospira was isolated from blood collected from dogs in the control group after challenge; as shown in the following table for Days 0 – 14 (post-challenge):Dog034567891011121314144+44442+++++NANANA7++++++NANANA													
	Twenty (20) 6-week-old puppies were randomized into one group of 10 SC vaccinates and one group of 10 controls.Fifteen (15) days after second vaccination all animals were challenged with Leptospira grippotyphosa organisms.Dogs were observed daily for 21 days after challengeEfficacy was based on the reduction in spirochetemia in vaccinates when compared to controls.Leptospira was not isolated in any of the vaccinates receiving vaccine by SC route.Leptospira was isolated from blood collected from dogs in the control group after challenge):Dog034567891011121314144444444444454444444444447444444ANANA													
	4					+	+							
	5				+	+	+							
	6						+	+	+	+	+	NA	NA	NA
	7				+	+	+	+	+	+	NA	NA	NA	NA
	8					+	+	+	+	+	+	NA	NA	NA
	9				+	+	+	+	+	+	+	NA	NA	NA
	10					+	+	+	+	+	+	NA	NA	NA
	NA is Ar	nima	l Dea	d or	euth	naniz	ed /	no sa	amp	le tak	en		1	1
	+ is Posi						-							
				•	•									
USDA Approval Date	January	/ 12	, 19	99										

Study Type	Efficacy
Pertaining to	Leptospira icterohaemorrhagiae
Study Purpose	To demonstrate effectiveness against <i>Leptospira</i>
in a second s	icterohaemorrhagiae in 6 week old dogs.
Product Administration	Two doses were administered subcutaneously (SC) 3 weeks
Study Animals	apart. Twenty-two (22) 6-week-old puppies serologically negative for <i>Leptospira icterohaemorrhagiae</i> 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 <i>Leptospira icterohaemorrhagiae</i> organisms.
Interval observed after challenge	Dogs were observed daily for 21 days after challenge for clinical signs associated with <i>L. icterohaemorrhagiae</i> . 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.
	See the next page for data.
USDA Approval Date	March 31, 1998

						[a]	Leptospira Ictero Clinical Signs Observed Post Challenge	ro Cinical S	Signs Obse	rved Post	Challe	agui									
								SCV	SC Vaccinates												
Dog	00PC	10PC	20PC	30PC	40PC	SDPC	60PC	70PC	8DPC	90PC	100PC	100PC 11DPC 12DPC 14DPC 15DPC 15DPC 17DPC 18DPC 29DPC 200PC 21DPC	12DPC 15	IDPC 14	DPC 150	PC 16DP	C 17DPC	C 180PC	19DPC	200PC	21DPC
Ħ							A														
11																					
8						0											•••	0		-	
1									u.									0	•••		
ä		AE											0							ш	
16																			۲		
11																					
18																		0			
61							H														
8			-	•		0	٥					٩			_						
	A-inapp	A-inappetance			F - Nasal Disc	F - Nasal Discharge Serous		K - Bloody Urine	ne												
	B-Vomiting	ting			G - Nasal Dis	G - Nasal Discharge Mucoid		L-Fever>103.0 ¹ F	0'F												
	C-Dept	ression	C - Depression/Lethargy		H-Diarrhea M	H- Diarrhea Mild (loose stool)		M - Death													
	D-Oal	ar Disch	D- Ocular Discharge Serous	S	I-Diarrhea M	I- Diarrhea Moderate (Watery stool)	(loot)	Blank - no clinical Sign observed	nical Sign obs	served											
	E - Ocul	lar Disch	E - Ocular Discharge Mucoid	Did	J - Diarrhea Si	 J - Diarrhea Severe (bloody stool) 	0														
DPC	= Dav	post-e	DPC = Dav post-challenge	ae																	
					_																

Leptospira Ictero Clinical Signs Observed Post Challenge Controls	4DPC 5DPC 5DPC 5DPC 7DPC 8DPC 3DPC 140PC 120PC 130PC 140PC 15DPC 15DPC 15DPC 15DPC 15DPC 15DPC 15DPC 20DPC 20DPC 21DPC	P P						D E D D	,cp,i		A,E M	A E D		Saal Discharze Serous K - Bloody Urine K		H-Diarrhea Mild (loose stool) M - Death	- Diarrhea Moderate (Watery stool) Blank - no clinical Sign observed	J - Diarrhea Severe (bloody stool)
Leptospira Ictero Clini		A						-				A	ш					y stool)
	4DPC 5DPC	u.	-						A,C,D,J	0	A,E			F - Nasal Discharge Serous	G - Nasal Discharge Mucoid	H- Diarrhea Mild (loose s	I- Diarrhea Moderate (Wa	J - Diarrhea Severe (blood
	3DPC			-	1			0	K		L,D	ш						
	2DPC			_	_			_	L,E	_		_				Lethargy	arge Serou	arge Muco
	0DPC 1DPC													A-inappetance	8-Vomiting	C - Depression/Lethargy	D- Ocular Discharge Serous	E - Ocular Discharge Mucoid
	Dog	21	22	23	24	25	26	27	28	29	30	31	32					

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	
		120PC	9.6	6	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	
hallenge		9DPC	8.5	8.6	8.3	80	7.5	7.7	7.6	80	8.2	8.7	
unt Post C		8DPC	6.4	11.1	9.6	11.8	80	10.1	11.4	7.4	7.5	9.1	
od Cell Cou	inates	7DPC	6.4	8.2	9.2	7.3	10.2	8.4	9.4	8.4	10.5	6.4	
/hite Bloo	SC Vaccinates	6DPC	6.4	15.2	8.8	9.3	11.2	9.4	10.5	7.1	6.7	14.4	
a ictero M		SDPC	10.1	12.4	14.2	11.3	8.3	9.1	7.2	7.3	8.7	14.8	Г
Leptospira ictero White Blood Cell Count Post Challenge		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	6	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.	9.9	
		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	

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					Leptospin	a ictero V	Leptospira ictero White Blood Cell Count Post Challenge	od Cell Co	unt Post (Challenge					
Dog	Baseline (Avg -2DPC, -1DPC, 0DPC)	10PC	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	6	7.1
26	8.4	8.6	6	3.9	11.8	12.2	15.4	11.3	11.8	6	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	0				
30	8.8	7.6	5	7.2	7.8	7.5	7.8	6.2	9.9	8	10.3	10.1	6.6	9.4	9.6
31	11	8.1	8.3	4.2	19					D	0				
32	8.3	9.3	6.2	5	10.7	12.6	10.6	13.5	14.5	9.6	14.1	6.6	10	10.1	9.3
D = dead															
						Г									
PC =	DPC = Day post-challenge. Values reported as	hallenge.	Values re		k/μL.	_									

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

Baseline (Avg2DPC, -1DPC, 0DPC) IDPC 1DPC, 0DPC) IDPC 2DPC 3DPC 3DPC 4DPC 5DPC 5DPC 5DPC 7DPC 8 21 534.3 291 315 207 301 341 545 506 1 22 438.7 238 250 168 126 184 261 288 497 1 23 441.3 374 230 245 116 189 312 497 1 24 344.7 251 130 99.5 116 189 312 497 1 25 556 401 220 146 189 243 611 1 2	Controls	
534.3 291 315 207 301 341 545 506 428.7 238 250 168 126 184 261 288 411.3 374 307 265 186 126 184 261 288 344.7 251 130 99.5 116 189 362 361 344.7 251 130 99.5 116 189 362 361 344.7 251 130 99.5 116 189 362 361 361 344.7 251 130 94.9 84.5 210 361 381 347.7 392 302 213 94.9 84.5 210 361 381 475.7 399 423 413 335 386 437 381 471.7 214 93.5 60.5 128 213 307 332 332 131.5 214	7DPC 8DPC 9DPC 10DPC	11DPC 12DPC 13DPC 14DPC
428.7 238 250 168 126 184 261 288 361 288 361 288 361 288 361 288 361 288 361 288 361 288 361 288 361 288 361 289 361 289 361 289 361 289 361 289 361 289 361 289 361 289 361 289 361 289 361 289 361 381 361 381 361 381 361 381 361 381 361 381 361 381 361 381 361 381 361 381 361 381 361 381 </td <td>506 529 537 575</td> <td>434 399 414 410</td>	506 529 537 575	434 399 414 410
411.3 374 307 265 289 362 393 361 361 344.7 251 130 99.5 116 189 312 497 361 344.7 251 130 99.5 116 189 312 497 361 566 401 220 146 189 288 483 611 381 392 302 213 94.9 84.5 210 361 381 </td <td>-</td> <td>421 369 386 367</td>	-	421 369 386 367
344.7 251 130 99.5 116 189 312 497 1 566 401 220 146 189 288 483 611 1 392 302 213 94.9 84.5 210 361 381 1 475.7 399 423 483 413 335 386 437 1 475.7 399 423 483 413 335 386 437 1 411.7 214 93.5 60.5 128 213 307 332 332 332 136 101 6.7 11.2 379 372 1 332 163 53.9 119 231 379 512 1 319.3 163 36.7 11.2 11.2 1 1 1 1 319.3 163 53.9 119 231 379 512 1 319.3 </td <td>361 369 447 546</td> <td>444 422 583 535</td>	361 369 447 546	444 422 583 535
566 401 220 146 189 288 483 611 611 392 302 213 94.9 84.5 210 361 381 475.7 399 423 483 413 335 386 437 475.7 399 423 483 413 335 386 437 411.7 214 93.5 60.5 128 213 307 332 332 136 101 6.7 11.2 213 307 332 332 132 11.2 213 307 332 332 332 132 11.2 213 307 332 332 319.3 163 94.4 36.7 11.2 231 379 512 319.3 163 94.4 36.7 11.9 267 347 347	497 440 480 618	635 461 658 451
392 302 213 94.9 84.5 210 361 381 381 475.7 399 423 483 413 335 386 437 475.7 399 423 483 413 335 386 437 411.7 214 93.5 60.5 128 213 307 332 332 136 101 6.7 11.2 379 332 332 136 53.9 119 231 379 512 319.3 163 94.4 36.7 11.9 231 379 512 257 184 55 7.7 88.8 196 347 347	611 458 466 660	519 427 432 409
475.7 399 423 483 413 335 386 437 411.7 214 93.5 60.5 128 213 307 332 411.7 214 93.5 60.5 128 213 307 332 332 136 101 6.7 11.2 332 332 421.9 204 80.9 53.9 119 231 379 512 319.3 163 94.4 36.7 11.9 231 379 512 267 184 55 7.7 88.8 196 257 347	_	578 513 452 388
411.7 214 93.5 60.5 128 213 307 332 332 136 101 6.7 11.2 379 332 421.9 204 80.9 53.9 119 231 379 512 319.3 163 94.4 36.7 11.9 231 379 512 267 184 55 7.7 88.8 196 257 347		461 540 372 474
332 136 101 6.7 11.2 421.9 204 80.9 53.9 119 231 379 512 319.3 163 94.4 36.7 11.9 231 379 512 267 184 55 7.7 88.8 196 257 347	332 467 612 622	618 495 467 383
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Study Type	Efficac	ey (
Pertaining to	Leptos		por	non	a											
Study Purpose	To den	nons	strat	e ef	fect	iver	ness	aga	inst	Lep	otos	pira	poi	mon	a in	6
	week o	ld d	logs	•				_		_			-			
Product Administration	Two do	oses	we	re a	dmi	niste	ered	sul	ocut	aneo	ousl	y (S	C)	3 we	eeks	apart
Study Animals	Twenty															
	Leptos											ofo	ne g	grou	p of	f 10
	SC vac															
Challenge Description	Twenty												all a	nim	als	were
	challen															
Interval observed after	Dogs v					-			-				_			d
challenge	sample															
Results	Efficac	-								-	oiro	chet	em	a in		
	vaccina	ates	wh	en c	omp	bare	d to	cor	trol	s.						
	Tantaa			~	. :	1.4.	16		1.1 .				6 4 1.		:	
	Leptos receivi								0100	od 11	n an	iy oi	the	e va	ccin	ates
	IECEIVI	ng v	acc	inc	Uy S		out									
	Leptospira was isolated from blood collected from dogs in the control group after challenge, as shown in the following table															
	control group after challenge, as shown in the following table															
	control group after challenge, as shown in the following table for Days $0 - 14$ (post-challenge):															
	for Days 0 - 14 (post-challenge):															
	Dog 0 1 2 3 4 5 6 7 8 9 10 11 12 13 14 1 + + + + + -<											10	11	12	13	14
		0	1		3	4	5	Ē ,	7	8	9	10	11	12	13	14
	1	0	1		3	4	5	Ē ,	7	8	9	10	11	12	13	14
	1 2	0	1	+	3 +	4 +	5	Ē ,	7	8	9	10	11	12	13	14
	1 2 3	0	1		3 + + +	4 + +	5	Ē ,	7	8	9	10	11	12	13	14
	1 2 3 4	0	1	+ +	3 + + +	4 + + + +	5 +	Ē ,	7	8	9	10	11	12	13	14
	1 2 3 4 5	0	1	+ + + +	3 + + + +	4 + +	5	Ē ,	7	8	9	10	11	12	13	14
	1 2 3 4			+ + + + +	3 + + + + + +	4 + + + +	5 +	Ē ,	7	8	9	10	11	12	13	14
	1 2 3 4 5		1	+ + + + + +	3 + + + + + + +	4 + + + + +	5 +	Ē ,	7	8	9	10	11	12	13	
	1 2 3 4 5 6			+ + + + +	3 + + + + + + + + +	4 + + + +	5 +	Ē ,	7	8	9	10	11	12	13	
	1 2 3 4 5 6 7			+ + + + + +	3 + + + + + + +	4 + + + + +	5 +	Ē ,	7	8	9	10	11	12	13	
	1 2 3 4 5 6 7 8		+	+ + + + + + +	3 + + + + + + + + +	4 + + + + + + + +	5 +	Ē ,	7	8	9		11	12	13	
	1 2 3 4 5 6 7 8 9		+++++++++++++++++++++++++++++++++++++++	+ + + + + + + + + +	3 + + + + + + + + + + + + +	4 + + + + + + + + + + + + + + + + + + +	5 +	Ē ,	7	8	9				13	
	1 2 3 4 5 6 7 8 9 10	itive	+ + + for l	+ + + + + + +	3 + + + + + + + + + + + + +	4 + + + + + + + + + + + + + + + + + + +	5 +	Ē ,	7	8	9				13	

Study Type	Safety										
Pertaining to	All fractions										
Study Purpose	Demonstrate safety	of pro	duct under	typical	use cond	itions					
Product	Two doses were add	ministe	red subcut	aneous	ly (SC) at	2-3 we	ek intervals				
Administration	in dogs 6 weeks of	age or	older.		• • •						
Study Animals	A total of 624 dogs,	, privat	ely owned	and fro	om comm	ercial k	ennels,				
	were enrolled in the	study.	From thes	se dogs	, 341 were	e 6 wee	ks of age or				
	younger, at first vac	cinatic	on.								
Challenge	Not applicable										
Description											
Interval	No challenge. Dog						g each				
observed after	vaccination and dai	ly for t	wo weeks	after ea	ich vaccin	ation.					
challenge											
Results	Frequency of advert	se ever	its:								
	Post Vaccination	Reacti	on Occurre	nce by (doses. Tota	al Doses	s = 1223				
	Reaction ≤ 6 Week old > 6 Weeks old Total Doses Category Dogs Dogs										
	Category	#	Percent	#	Percent	#	Percent				
	No adverse events	673	99.26%	538	98.72%	1211	99.02%				
	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 recei	ved on	e vaccinati	ion. Eit	her thev d	id not 1	eturn for				
	follow-up or were r				•						
	cooperator to be un					5	2				
USDA Approval	November 2, 1998										
Date	, 1990										
2.000											