

## **Summary of Studies Supporting USDA Product Licensure**

Establishment Name	Elanco US Inc.
USDA Vet Biologics Establishment Number	196
Product Code	2668.05
True Name	Leptospira Canicola-Grippotyphosa-Icterohaemorrhagiae- Pomona Bacterial Extract
Tradename(s) / Distributor or Subsidiary (if different from manufacturer)	Elanco US Inc. Guard-Vac LCI/GP - Zoetis Industria Produtos Veterinarios Ltda Elanco US Inc. LeptoVax 4 - 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.

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Study Type	Efficacy
Pertaining to	Leptospira canicola
Study Purpose	To demonstrate effectiveness against <i>Leptospira canicola</i> in 6
	week old dogs.
<b>Product Administration</b>	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.
<b>Challenge Description</b>	Twenty-one (21) days after second vaccination all animals were
	challenged with <i>Leptospira canicola</i> 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/µL and the count was less than 50%
	of the baseline value.
	of the buseline 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	April 3, 1998

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		21DPC																		
		100PC 11DPC 12DPC 13DPC 14DPC 15DPC 16DPC 17DPC 18DPC 19DPC 20DPC 21DPC		9	8															
		19DPC			8									e						
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erved Po		9DPC									9								perved	
Signs Obs	SC Vaccinates	8DPC												3.0-103.9°F)	4.0-104.9°F)	5.0-105.9°F)			Blank - no clinical signs observed	
Leptospira canicola Clinical Signs Observed Post Challenge	SC	7DPC									9			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 cli	
spira canio		6DPC				9						А								
Lepto		SDPC									9	9		G - Ocular Discharge Mucoid	H - Nasal Discharge Serous	I - Nasal Discharge Mucoid	J - Diarrhea Mild (loose stool)	K - Diarrhea Severe (bloody stool)	ē	
		4DPC						9	A		9			G - Ocular Disc	H - Nasal Disc	I - Nasal Disch	J - Diarrhea M	K - Diarrhea Se	L - Bloody Urine	M - Icterus
		3DPC						9				9								
		2DPC					9				g	AD				ing	ethargy	: Mild/Mc	Severe	ge Serous
		1DPC		А	A	0	0					A		tance	8	d Breath	ession/Le	unctivitis	ınctivitis	Dischar
		ODPC				9			5		9	5		A-inappetance	<b>B-Vomiting</b>	C-Labored Breathing	D - Depression/Lethargy	E1 - Conjunctivitis Mild/Moderate	E2 - Conjunctivitis Severe	F- Ocular Discharge Serous
		Dog	12	13	14	15	16	17	18	19	20	21	22							

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		10DPC   11DPC   12DPC   13DPC   15DPC   15DPC   17DPC   18DPC   19DPC   20DPC   21DPC				8																
		DPC 201													ſ		7					
		3DPC 19											g			enge						
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		16DPC 1								9						y posi						
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		14DPC		۵	9											DPC						
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_		12DPC			1 D	D'C				9	Ь		ŋ	G,K								
allenge		C 11DP(	Ь		A,D,N1	9							ŋ	G,K								
ost Cha		10DP											A,K	A,K								
erved Po		9DPC			Q	A,D							A,D,G,K,L	A,D,G,K,L							bserved	
Signs Obs	Controls	8DPC			А	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)			ical signs o	
ola Clinical	0) (0	5DPC 6DPC 7DPC 8		C,D,G,L,N4	A,G	A,G,K	A,D,G			9			A,D,G,K,L	A,D,K,L,N1		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	
Leptospira canicola Clinical Signs Observed Post Challenge				A,D,K	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		_	_	_	_			
Lept				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'T	A,B,J	9		narge 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	1′9	A,G			G - Ocular Discharge Mucoid	H - Nasal Discharge Serous	I - Nasal Discharge Mucoid	J - Diarrhea Mild (loose	K - Diarrhea Se	L - Bloody Urine	M - Icterus
		3DPC			8	D,G,N1	А	А	J,K		G,K	9	A,G,N1	A,G,N2								
		2DPC		D,G,N3	N2	D,G,N1	N1	GN2	D,N2	N2	N2	N1	G,N2	A,N1				ing	ethargy	E1 - Conjunctivitis Mild/Moderate	Severe	F- Ocular Discharge Serous
		1DPC				A,G		A		9			9			tance	50	d Breath	ssion/L	unctivitis	unctivitis	Dischar
		0DPC									н		g			A-inappetance	<b>B-Vomiting</b>	C-Labored Breathing	D - Depression/Lethargy	:1 - Conju	E2 - Conjunctivitis Severe	- Ocular
		Dog	23	24	25	26	27	28	59	30	31	32	33	34		4						

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		0	14DPC	16.6	9.1	15.7	9.4	10.5	12.3	17.6	13.4	12.7	21.7	11.5
		04407	ISDPC	19.6	6.7	23.2	10.2	10.8	6.6	17.2	12.3	9.7	14.7	11
		00000	12DPC	17.2	10.2	14	9.2	10.1	10.3	11.7	7.3	9.3	13.2	9.2
		00000	110PC	10.7	12.7	15.3	13.1	6.3	9.5	11.6	8.8	13	16.5	10.2
9		00000	100PC	19.3	8.8	16.9	8.5	11.3	8.8	9.1	7	7	11.7	1.7
Leptospira canicola White Blood Cell Count Post Challenge		0000	306	19.4	10.4	19.3	8.5	6.7	7.3	9.3	8.2	11.4	14.9	11.7
ount Post		0	8DFC	16.5	11.8	19.2	11.8	11.4	8.6	9.3	6.4	10.5	20.7	8.3
ood Cell C	SC Vaccinates	i i	700	20.7	12.5	17.4	13.1	9.4	12.5	6.7	7.5	9.2	13.4	7.3
White Bl	SC Vac	0	906	20	8	13.6	12.2	10.2	13.2	11.7	7.2	6	13.9	11
canicola		i i	SUPC	19.3	6	15.5	11.5	10.1	10.7	9.4	9.9	8	14.1	12.7
eptospira		000	40kC	20.3	10.5	14	8.2	8.4	12.2	10.2	8.4	7.6	14.6	9.5
<b>-</b>		c c	3DPC	17	9.6	12.9	12.7	7.6	11.8	10.1	9.1	9.1	15.1	12.1
		040	20PC	15.1	9.3	12.3	9.6	9.5	12.8	10.6	8	10.7	9.5	9.4
		000	JOEC	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
		ć	900 0	12	13	14	15	16	17	18	19	20	21	22

DPC = Day post-challenge. Values reported as  $k/\mu L$ .

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		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
Challenge		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 Co	rols	7DPC		20.5	17		21			11.1			13	12
White Blo	Controls	бррс		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	7.9	10.3	9.9	4.4	3.8
eptospira		4DPC	21.7	11.5	10	5.7	5.2	7	5	6.1	9	9	5.3	5.6
Le		ЗОРС	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

DPC = Day post-challenge. Values reported as  $k/\mu L$ .

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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	260	302	261	480	414	601	521	200
	10DPC	512	501	267	482	519	270	405	381	493	501	492
	9DPC	631	470	695	497	512	288	483	476	662	581	597
	8DPC	478	565	693	576	655	314	463	379	704	650	473
inates	7DPC	582	636	604	633	558	351	247	375	706	514	469
SC Vac	6DPC	531	467	497	612	555	389	542	376	538	441	517
	5DPC	512	539	536	503	492	329	453	375	523	469	576
	4DPC	473	576	444	421	456	324	398	403	483	447	478
	3DPC	452	573	202	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
	SC Vaccinates	Baseline	Baseline (Awg -2DPC, -1DPC, ODPC)         1DPC (Awg -2DPC, -1DPC, -1DPC)         3DPC (AWg -2DPC, -1DPC, -1DPC, -1DPC)         5DPC (AWg -2DPC, -1DPC, -1DPC, -1DPC, -1DPC, -1DPC, -1DPC)         3DPC (AWg -2DPC, -1DPC, -1DPC	Baseline (Avg -2DPC, 1DPC, 1DPC)         2DPC (Avg -2DPC, 1DPC)         3DPC (Avg -2DPC, 1DPC, 1DPC)         3DPC (Avg -2DPC, 1DPC, 1DPC)         3DPC (Avg -2DPC, 1DPC, 1DPC, 1DPC)         3DPC (Avg -2DPC, 1DPC, 1DPC, 1DPC, 1DPC)         3DPC (Avg -2DPC, 1DPC, 1DPC	Baseline (AVG -2DPC)         SC Vaccinates           (AVG -2DPC) (AVG -1DPC)         1DPC (AVG -2DPC)         3DPC (AVG -2DPC)         4DPC (AVG -	Baseline (Avg -2DPC, 1DPC, -1DPC, -	Baseline (Avg - 2DPC, 1DPC, -1DPC,	Baseline (Awg-2DPC, -1DPC)         1DPC         3DPC         4DPC         5DPC         6DPC         7DPC         8DPC         4DPC         4DPC <th< td=""><td>Baseline (Awg-2DPC, -1DPC)         2DPC (Ang2DPC, -1DPC)         3DPC (ANG2DPC, -1DPC)         3DPC (ANG2DPC, -1DPC)         3DPC (ANG2DPC, -1DPC, -1DPC)         3DPC (ANG2DPC, -1DPC, -1DPC, -1DPC)         3DPC (ANG2DPC, -1DPC, -1DPC,</td><td>Baseline (Avg2DPC, -1DPC)         3DPC (Avg2DPC, -1DPC)         3DPC (Avg2DPC, -1DPC)         3DPC (Avg2DPC, -1DPC, -1DPC)         3DPC (Avg2DPC, -1DPC, -1DP</td><td>Baseline (AWg2DPC, -1DPC)         3DPC 4DPC -1DPC, -1DPC, -1DPC         3DPC 4Ng -2DPC -1DPC, -1DPC</td><td>Baseline (Avg. 2DPC, 1DPC)         2DPC (Avg. 2DPC, 1DPC)         3DPC (Avg. 2DPC, 1DPC)         3DPC (Avg. 2DPC, 1DPC)         3DPC (Avg. 2DPC, 1DPC)         3DPC (Avg. 2DPC, 1DPC, 1DPC)         3DPC (Avg. 2DPC, 1DPC, 1DPC, 1DPC)         3DPC (Avg. 2DPC, 1DPC, 1DPC,</td></th<>	Baseline (Awg-2DPC, -1DPC)         2DPC (Ang2DPC, -1DPC)         3DPC (ANG2DPC, -1DPC)         3DPC (ANG2DPC, -1DPC)         3DPC (ANG2DPC, -1DPC, -1DPC)         3DPC (ANG2DPC, -1DPC, -1DPC, -1DPC)         3DPC (ANG2DPC, -1DPC,	Baseline (Avg2DPC, -1DPC)         3DPC (Avg2DPC, -1DPC)         3DPC (Avg2DPC, -1DPC)         3DPC (Avg2DPC, -1DPC, -1DPC)         3DPC (Avg2DPC, -1DPC, -1DP	Baseline (AWg2DPC, -1DPC)         3DPC 4DPC -1DPC, -1DPC, -1DPC         3DPC 4Ng -2DPC -1DPC, -1DPC	Baseline (Avg. 2DPC, 1DPC)         2DPC (Avg. 2DPC, 1DPC)         3DPC (Avg. 2DPC, 1DPC)         3DPC (Avg. 2DPC, 1DPC)         3DPC (Avg. 2DPC, 1DPC)         3DPC (Avg. 2DPC, 1DPC, 1DPC)         3DPC (Avg. 2DPC, 1DPC, 1DPC, 1DPC)         3DPC (Avg. 2DPC, 1DPC,

DPC = Day post-challenge. Values reported as  $k/\mu L$ .

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					Leptos	pira canic	Leptospira canicola Platelet Counts Post Challenge	et Counts	s Post Cha	llenge					
							Controls	rols							
Dog	Baseline (Avg2DPC, -1DPC, 0DPC)	1DPC	2DPC	3DPC	4DPC	5DPC	ЭФО9	7DPC	8DPC	90РС	10DPC	11DPC	12DPC	13DPC	14DPC
23	300	238	148	11	7.7	O	Q	D	O	O	O	O	Q	O	D
24	342	204	161	64.1	40.5	45.3	123	207	D	Q	D	D	Q	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	22	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	Q	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	Q	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															

DPC = Day post-challenge. Values reported as  $k/\mu L$ .

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Study Type	Efficacy
Pertaining to	Leptospira grippotyphosa
Study Purpose	To demonstrate effectiveness against Leptospira grippotyphosa
	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 <i>Leptospira grippotyphosa</i> 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

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## Isolation of Leptospira from Blood Collected from Dogs Post Challenge

						Contro	l Animals						
Dog	0DPC	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

NA - Animal Dead or euthanized / no sample taken

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<sup>+ -</sup> Positive for Leptospira

<sup>\*</sup>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 <i>Leptospira icterohaemorrhagiae</i> 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/µL and the count was less than 50%
	of the baseline value.
	A dog was considered to have leadronesis if the platelet count
	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.
	baseline value.
	Data tables are appended to the end of this summary.
	Data tables are appended to the end of this summary.
USDA Approval Date	March 31, 1998

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		ب															
		21DP															
		20DPC			E		3										
		19DPC				п		A									
		18DPC			٥	0				0							
		17DPC			ш												
		16DPC										E					
		15DPC															
		14DPC															
		13DPC			ш							E					
		12DPC					0										
age age		11DPC										0					
Challer		100PC   110PC   120PC   130PC   140PC   150PC   160PC   170PC   180PC   190PC   200PC   210PC															
rved Post		9DPC														served	
Signs Obse	SC Vaccinates	8DPC				F	E						ne	.0°F		Blank - no clinical Sign observed	
ro Clinical	SC	7DPC											K - Bloody Urine	L - Fever >103.0°F	M - Death	Blank - no cli	
Leptospira Ictero Clinical Signs Observed Post Challenge		6DPC	А			E					3	O				stool)	()
a		SDPC			٥							0	narge Serous	harge Mucoid	H- Diarrhea Mild (loose stool)	I- Diarrhea Moderate (Watery stool)	J - Diarrhea Severe (bloody stool)
		4DPC											F - Nasal Discharge Serous	G - Nasal Discharge Mucoid	H- Diarrhea M	I- Diarrhea Mo	J - Diarrhea Se
		3DPC			ш	ш						0					ъ
		2DPC										0			hargy	e Serous	e Mucoi
		1DPC					A,E						ance		sion/Let	)ischarg	)ischarg
		0DPC 1											A-inappetance	<b>B-Vomiting</b>	C - Depression/Lethargy	D- Ocular Discharge Serous	E - Ocular Discharge Mucoid
		Dog	11	12	13	14	15	16	17	18	19	20					

DPC = Day post-challenge

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			_		_														
		21DPC																	
		20DPC																	
		19DPC		E	ш														
		18DPC			ш						0		0	8					
		17DPC			ш														
		16DPC			ш								E						
		15DPC							0										
		14DPC																	
		13DPC																	
		12DPC			ш				Б										
E		11DPC								M		M	E						
Sale Sale		10DPC 11DPC 12DPC 13DPC 14DPC 15DPC 16DPC 17DPC 18DPC 19DPC 20DPC 21DPC								_		_							
Post		9DPC		8														_	
erved		96																bserved	
Leptospira Ictero Clinical Signs Observed Post Challenge	SIO.	8DPC							A									Blank - no clinical Sign observed	
al Sig	Controls													$\dashv$	/Urine	103.0°F	_	clinica	
G		7DPC							_						K - Bloody Urine	L - Fever >103.0°F	M - Death	ank - no	
cterc															ż	ن	Σ	₩	
ospira		6DPC	A										А	Е				=	
Lep														-		ъ	(100	eny sto	(stool)
		SDPC							Б		0				Serous	e Mucoi	oose st	te (Wat	(blood)
														Ц	scharge	ischarg	I) piiM	Modera	Severe
		4DPC	ı.	F					٥	A,C,D,J		A,E			F - Nasal Discharge Serous	G - Nasal Discharge Mucoid	H- Diarrhea Mild (loose stool)	I- Diarrhea Moderate (Watery stool)	J - Diarrhea Severe (bloody stool)
														Н	-E	-6	呈	<u>-</u>	=
		3DPC			_	_			٥	×		L,D	Н					Sn	ë
		2DPC			_	_			_	L,E	_		_				thargy	ge Sero	ge Muc
		1DPC													auce	500	sion/Le	Dischar	Dischar
		0DPC 1												H	A-inappetance	<b>B-Vomiting</b>	C - Depression/Lethargy	D- Ocular Discharge Serous	E - Ocular Discharge Mucoid
														H	A-	<u>~</u>	ن	⇔	ய்
		Dog	21	22	23	24	25	26	27	28	29	30	31	32					

DPC = Day post-challenge

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		14DPC	6.4	12.3	8.4	9.1	10.9	8.3	7.3	6.4	6.7	8.9
		14[	9	12	80	9.	10	80	7.	9	9	80
		13DPC	7.2	9.1	7.8	12.8	7.5	8.3	7.5	7.8	8.8	8.1
		12DPC	9.6	6	7.8	10	11.1	10	10.2	6.5	7	9.7
		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
Leptospira ictero White Blood Cell Count Post Challenge		9DPC	8.5	9.8	8.3	8	7.5	7.7	9.7	8	8.2	8.7
unt Post		8DPC	6.4	11.1	9.6	11.8	8	10.1	11.4	7.4	7.5	9.1
od Cell Co	SC Vaccinates	7DPC	6.4	8.2	9.2	7.3	10.2	8.4	9.4	8.4	10.5	6.4
<b>White Blo</b>	SC Vac	6DPC	6.4	15.2	8.8	9.3	11.2	9.4	10.5	7.1	6.7	14.4
ra ictero \		SDPC	10.1	12.4	14.2	11.3	8.3	9.1	7.2	7.3	8.7	14.8
Leptospi		4DPC	6.8	9.1	9.1	12.6	8	8.1	7.5	9.9	11.7	11.9
		3DPC	7.9	8.9	13.2	8.2	6	8.9	8.1	9.1	11.7	9.1
		2DPC	12.4	10.4	9.6	12.6	8.6	9.5	7.8	10.5	8.4	5.3
		1DPC	7.3	13.9	15.4	9.7	11.4	8.8	1.7	1.7	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

DPC = Day post-challenge. Values reported as  $k/\mu L$ .

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				Leptospira	a ictero M	Vhite Bloc	eptospira ictero White Blood Cell Count Post Challenge	unt Post (	Challenge					
		L				Con	Controls							
1DPC 2DPC	2DPC		3DPC	4DPC	SDPC	бРРС	7DPC	8DPC	9DРС	10DPC	11DPC	12DPC	13DPC	14DPC
9.6 9.9			6.7	8.2	6.2	8.6	6.7	6.5	8.1	10.4	6.4	8.5	6.5	6.2
8.5 9.3 8		8	8.2	6.5	7.3	13.4	9.4	7.2	8.2	13.4	10.1	7.7	9.2	9.4
12.2 9.4 11		11	11.6	7.1	6	10	7	6.5	7.1	11.9	4	9.6	11	11.8
19.6 10.6 7.8		7.	8	11.8	15.3	16.7	19.8	16	13.7	19.2	24.9	13.3	24.4	12.3
13.9 8.5 6.9		9.	6	9.1	7	10.9	12.8	9.6	10	13.9	9.4	8.3	6	7.1
8.6 9 3.9		3.9		11.8	12.2	15.4	11.3	11.8	9	10.2	13.3	8.6	8.9	10.5
7.5 9.4 15.8		15.		14.6	10.7	8.6	7.5	8.6	12.1	9.8	8.3	11.4	7.4	9.5
8.8 6.7 4.5		4.5		7.3	7.3	8.8	14.7	10	11.6	11.7	14	8.3	7.8	7.7
6.7 5.8 4.1		4.	1	26.4					]	D				
7.6 5 7.		7.	7.2	7.8	7.5	7.8	6.2	6.6	8	10.3	10.1	9.9	9.4	9.6
8.1 8.3 4		4	4.2	19					]	0				
9.3 6.2	6.2		5	10.7	12.6	10.6	13.5	14.5	9.6	14.1	6.6	10	10.1	9.3

DPC = Day post-challenge. Values reported as  $k/\mu L$ .

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		14DPC		359	517	349	281	369	294	381	287	352	378
		13DPC		471	461	337	351	290	284	373	391	406	340
		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
hallenge		9DPC		442	505	508	331	285	253	436	424	489	358
Leptospira ictero Platelet Counts Post Challenge		8DPC		488	480	416	376	314	281	513	327	378	392
Counts	nates	7DPC		447	435	517	335	400	268	457	419	200	352
Platelet	SC Vaccinates	6DPC		457	645	445	344	435	308	542	393	459	555
ictero		SDPC		299	526	580	374	282	278	214	351	417	515
ptospira		4DPC		440	428	424	457	275	264	332	397	529	525
Le		3DPC		476	447	260	349	286	217	386	392	552	483
		2DPC		619	456	425	413	297	298	400	569	386	206
		1DPC		432	475	595	258	380	264	407	482	467	412
		Baseline (Avg -2DPC, -1DPC	ODPC)	449.7	518.3	489.3	451.7	357.7	369	473.7	905	477	502.3
		Dog		11	12	13	14	15	16	17	18	19	20

DPC = Day post-challenge. Values reported as  $k/\mu L$ .

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				Le	Leptospira ictero Platelet Counts Post Challenge	ictero	Platelet	t Counts	: Post Cl	hallenge	•				
							Controls	slo							
Dog	Baseline (Avg -2DPC, -1DPC, 0DPC)	1DPC	2DPC	3DPC	4DPC	SDPC	6DPC	7DPC	8DPC	9DPC	10DPC	11DPC	12DPC	13DPC	14DPC
21	534.3	291	315	207	301	341	545	206	529	537	575	434	399	414	410
22	428.7	238	250	168	126	184	261	288	340	412	520	421	369	386	367
23	411.3	374	307	265	289	362	393	361	369	447	546	444	422	583	535
24	344.7	251	130	99.5	116	189	312	497	440	480	618	635	461	658	451
25	266	401	220	146	189	288	483	611	458	466	660	519	427	432	409
26	392	302	213	94.9	84.5	210	361	381	421	444	467	578	513	452	388
27	475.7	399	423	483	413	335	386	437	465	575	469	461	540	372	474
28	411.7	214	93.5	60.5	128	213	307	332	467	612	622	618	495	467	383
29	332	136	101	6.7	11.2						D				
30	421.9	204	80.9	53.9	119	231	379	512	549	516	642	494	411	421	427
31	319.3	163	94.4	36.7	11.9						D				
32	267	184	55	7.7	88.8	196	257	347	525	430	529	360	337	287	301
D = Dead	ad														

DPC = Day post-challenge. Values reported as  $k/\mu L$ .

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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
	Leptospira 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	Dogs were observed daily for 21 days after challenge. Blood
challenge	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
OSDA Appiovai Date	various 12, 1777

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Isolation of Leptospira from Blood Collected from Dogs Post Challenge

							Cont	rol Anin	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		+		+	+										

DPC= Day post challenge

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<sup>\*</sup>Leptospira was not isolated from blood in any of the SC vaccinates

Study Type	Safety											
Pertaining to	All											
Study Purpose	Demonstrate safety	of pro	duct under	typica	l use cond	litions						
Product	Two doses were ad						eek					
Administration	intervals in dogs 6	weeks	of age or o	lder.								
Study Animals	A total of 624 dogs	, privat	tely owned	and fr	om comm	ercial k	tennels,					
	were enrolled in the	e study	. From 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					al Doses	s = 1223					
	Reaction		Veek old		eeks old	Tota	al Doses					
	Category	[	Dogs		ogs							
	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 rece				•							
	follow-up or were				ns confirm	ned by	the study					
	cooperator to be un	related	to vaccina	ation.								
USDA Approval												
Date	November 2, 1998											
Daic	1											

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