

Summary of Studies Supporting USDA Product Licensure

Establishment Name	Elanco US Inc.
USDA Vet Biologics Establishment Number	196
Product Code	2668.02
True Name	Leptospira Canicola-Grippotyphosa-Icterohaemorrhagiae- Pomona Bacterial Extract
Tradename(s) / Distributor or Subsidiary (if different from manufacturer)	Elanco US Inc. Ultra Duramune 4L - 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
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		U	8															
		19DPC			•									U						
		18DPC				U								alleng	0					
		17DPC							AG					st-ch						
		16DPC				U							н	av po	-					
		15DPC			A	AG			A					D = D						
		14DPC							A					DPC						
		13DPC																		
		12DPC																		
lenge		11DPC																		
st Chal		10DPC				A														
erved Po:		9DPC									9								berved	
Signs Obs	accinates	8DPC												.0-103.9°F)	.0-104.9°F)	.0-105.9°F)			ical signs ot	
a Clinical	SC Va	7DPC									9			- Fever (103	- Fever (104	- Fever (105	- <99.6°F	Death	ank - no clin	
anicol														 N1	N2	ŝ	R	à	819	
ospira c		6DPC				9						A						()		
Lept		SDPC									ŋ	9		charge Mucoid	harge Serous	arge Mucoid	id (loose stool)	evere (bloody stoc	Ð	
		4DPC						9	A		9			G - Ocular Disc	H - Nasal Disc	I - Nasal Disch	J - Diarrhea Mi	K - Diarrhea Se	L - Bloody Urin	M - Icterus
		3DPC						9				9						oderate		s
		2DPC					U				U	AD				ning	ethargy	s Mild/M	s Severe	rge Serou
		1DPC		A	A	٥	٥					A		tance	e	d Breath	ssion/L	unctiviti:	unctiviti:	Dischar
		ODPC				ن			5		œ	ن		-inappe	P-Vomiti	-Labore) - Depre	1 - Conju	2 - Conju	- Ocular
		Dog	12	13	14	15	16	17	18	19	20	21	22	₫	8	0				<u>u</u>

Leptospira canicola Clinical Signs Observed Post Challenge	Controls	4DPC 5DPC 5DPC 7DPC 8DPC 9DPC 10DPC 11DPC 12DPC 14DPC 15DPC 15DPC 15DPC 14DPC 15DPC 12DPC 12DPC 20DPC 20DPC 20DPC 21DPC	A,D,K,M,N4	A,D,G,J A,D,G A,D,K C,D,G,L,N4	G A, A, A, A, B, A, B, A, B, A, B, B, C,	G D A,D,J A,G,K A,D,K A,D G D,G B B	A A,N1 A,K A,D,G A A,G A	A,G,L A,D,G,K,L,M,N4 A,D,E2,M,N4 P	A,B,D,G,L D,G,K,L,N4 A,D,E1,K,L,M,N4 P	G,K A,D,G,K G G,K G G G G G	B,D,K,L D,G,K,L,N4 P	G,L D,K,L A,D,G,K,L,M,N4 P	A,G A,B,J A,D,G,K,L A,D,G,K,	G A,D,G,K,L A,D,K,L,N1 A,D,G,K,L A,K G,K G,K G,K C		DPC = Day post-challenge	H - Nasal Discharge Serous N2 - FEVEr (104: U-104:9°F)	I - Nasal Discharge Mucoid N3 - Fever (105.0-105.9°F)	J - Diarrhea Mild (loose stool) N4 - <99.6°F	K - Diarrhea Severe (bloody stool) P - Death	L - Bloody Urine Blank - no clinical signs observed	M - Icterus
Leptospira ca		PC 5DPC 6DPC	M,N4	G,J A,D,G A,D,K	A,K	L,D,A D	A,N1 A,K	;J A,D,G,K,L,M,N4 A,D,E2,M,N	,G,L D,G,K,L,N4 A,D,E1,K,L,M,I	G,K A,D,G,K	K,L D,G,K,L,N4	L D,K,L A,D,G,K,L,M,N	G A,B,J A,D,G,K,L	G A,D,G,K,L	as Discharge Mussia		al Discharge Serous	al Discharge Mucoid	hea Mild (loose stool)	rhea Severe (bloody stool)	dy Urine	rus
		C 4DP	A,D,K,N	A,D,(9	11 G	A	A,G	A,B,D,		B,D,)	G,I	11 A,G	12			H - Nas	I - Nasa	J - Diarr	e K-Diarr	L - Bloo	M - Ictel
		3DP(8	l D,G,N	A	A	J,K		G,K	9	A,G,N	A,G,N	_				~	Moderat	e.	SNO
		2DPC		D,G,NB	N2	D,G,N1	N1	GN2	D,N2	N2	N2	N1	G,N2	A,N1				athing	//Letharg	itis Mild/	itis Sever	large Ser(
		1DPC				A,G		A		9			G			pperarice.	Buting	ored Brea	pression	onjunctivi	onjunctivi	ular Disch
		0DPC									т		G		v i n	PI-H	P-Von	C-Lab	D-De	E1 - C(E2 - C(F- Ocu
		Dog	23	24	25	26	27	28	29	30	31	32	33	34								

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		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
		10DPC	19.3	8.8	16.9	8.5	11.3	8.8	9.1	7	7	11.7	7.7
Challenge		9DPC	19.4	10.4	19.3	8.5	9.7	7.3	9.3	8.2	11.4	14.9	11.7
unt Post		8DPC	16.5	11.8	19.2	11.8	11.4	9.8	9.3	6.4	10.5	20.7	8.3
od Cell Co	inates	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 Vacc	6DPC	20	80	13.6	12.2	10.2	13.2	11.7	7.2	6	13.9	11
canicola V		SDPC	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
Le		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	
		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	
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	Cont	6DPC		14.6	13.6	8	19.4	13.2	17.5	10.6		15.8	8.7	6	
canicola		5DPC		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	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	

				_	_		_	_	_			_		2
		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 Vaco	6DPC	531	467	497	612	555	389	542	376	538	441	517	
pira canic		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	

Platelet Counts Post Challenge 4 . .

		14DPC	D	D	717	588	435	D	D	551	D	D	714	564		
		13DPC	D	D	810	590	428	D	D	596	D	D	726	475		
		12DPC	٥	D	738	599	528	D	D	632	D	D	701	479		
		11DPC	٥	D	823	648	552	D	D	504	D	D	744	383		
		10DPC	D	D	714	721	492	D	D	697	D	D	417	310		
llenge		9DPC	D	D	710	441	455	D	D	518	D	D	235	273		
s Post Cha		8DPC	D	D	497	302	405	D	D	412	D	D	87.1	142		
let Counts	trols	7DPC	D	207	285	ND	157	D	D	242	D	D	11.4	82.8		
ola Platel	Cont	6DPC	D	123	160	194	100	11.3	42.2	122	D	44.1	2.4	6.8		
pira canic		SDPC	D	45.3	117	172	49.9	11.1	15.8	81.6	14	14.2	8.5	8.3		
Leptos		4DPC	1.7	40.5	134	150	55	3.9	37.6	61.7	38	33.3	67.1	41.6		
		3DPC	11	64.1	187	196	119	45.9	195	107	80.2	103	115	64.5		
		2DPC	148	161	213	279	225	60.4	305	167	150	195	182	150		
		1DPC	238	204	267	278	281	209	521	292	327	329	409	174		
		Baseline (Avg -2DPC, -1DPC, 0DPC)	300	342	519.7	404.7	482.7	242.3	529.7	329.3	432.7	395.7	563.7	232.7	ata	
		Dog	23	24	25	26	27	28	29	30	31	32	33	34	ND= No Dá	D = dead

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 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

						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 Leptospira
	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/ 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	March 31, 1998

						, al	otospira lct	ero Clinical	Signs Obse	erved Post	Challe	nge		-							
								SC	Vaccinates			I									
Dog	ODPC	1DPC	2DPC	3DPC	4DPC	SDPC	6DPC	7DPC	8DPC	DPPC	10DPC	11DPC	2DPC 13	DPC 14DP	C 15DPC	16DPC	17DPC	18DPC	19DPC 2	0DPC 21	IDPC
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12																					
13				ш		D								ш			ш	٥		ш	
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17																					
18																		٥			
19							ш														
20			٥	٥		D	D					٥		E		ш					
	A-inapp	etance			F - Nasal Disc	harge Serous		K - Bloody Un	ine												
	B-Vomit	ting			G - Nasal Dis(harge Mucoid		L - Fever >103	3.0°F												
	C - Depr	'ession/l	Lethargy		H- Diarrhea N	(ild (loose stool)		M - Death													
	D- Oculà	ar Discha	arge Sero	SU	I- Diarrhea M	oderate (Watery si	tool)	Blank - no cli	inical Sign ob.	served											
	E - Ocul	ar Disch	arge Muc	oid	J - Diarrhea S(evere (bloody stoc	()														
DPC =	E Day	post-c	hallen	e e																	

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		21DPC																	
		DDPC 2																	
		19DPC 2		ш	ш														
		8DPC 1			ш						٥		0	•					
		IZDPC 1			ш														
		16DPC			ш								ш						
		15DPC							٥										
		14DPC																	
		13DPC																	
		12DPC			ш				ш										
agu		11DPC										_	ш						
Challer		10DPC								~		~							
Post (PC																_	
erved		6																bserved	
ns Obs	rols	8DPC							A									al Sign o	
cal Sig	Cont														/Urine	103.0°F	_	o clinica	
Clinic		7DPC							-						- Blood	- Fever >	- Deat	lank - ni	
Icter															×	<u> </u>	2		
ospira		6DPC	A										A	ш				ol)	
Lept															s	p	tool)	tery sto	y stool)
		5DPC							ш		D				e Serou	e Muco	loose s	ate (Wa	(blood
															ischarg	Discharg	a Mild (Moder	a Severe
		4DPC	ш	u.					٥	A,C,D,J		A,E			Nasal D	Nasal [Diarrhe	iarrhea	Diarrhei
		ç													ii.	ம்	÷	-	Ξ
		3DP			_	_			0	×		Ľ	ш					sno	coid
		2DPC			-	-			-	Ľ,E	_		-				ethargy	irge Seri	arge Mu.
		1DPC													stance	B	ssion/L	r Discha	r Discha
		ODPC													-inappe	-Vomiti	- Depre	- Ocula	- Ocula
		ß	1	2		4	2	9	2		6		1	2	Ā	è	U		ш
		8	2	2	2	2	2	7	2	28	2	3	3	3.					

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	9	7.7	12.5	
Challenge		9DPC	8.5	8.6	8.3	8	7.5	7.7	7.6	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	cinates	7DPC	6.4	8.2	9.2	7.3	10.2	8.4	9.4	8.4	10.5	6.4	
Vhite Bloc	SC Vaco	6DPC	6.4	15.2	8.8	9.3	11.2	9.4	10.5	7.1	6.7	14.4	
a ictero V		SDPC	10.1	12.4	14.2	11.3	8.3	9.1	7.2	7.3	8.7	14.8	
Leptospir		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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		14DPC	6.2	9.4	11.8	12.3	7.1	10.5	9.5	7.7		9.6		9.3		
		13DPC	6.5	7.6	11	24.4	6	8.9	7.4	7.8		9.4		10.1		
		12DPC	8.5	7.7	9.6	13.3	8.3	8.6	11.4	8.3		9.9		10		
		11DPC	6.4	10.1	7	24.9	9.4	13.3	8.3	14		10.1		9.9		
		10DPC	10.4	13.4	11.9	19.2	13.9	10.2	8.6	11.7		10.3		14.1		
hallenge		9DPC	8.1	8.2	7.1	13.7	10	6	12.1	11.6		8	D	9.6		
unt Post C		8DPC	6.5	7.2	6.5	16	9.6	11.8	8.6	10		9.9		14.5		
od Cell Cou	rols	7DPC	6.7	9.4	7	19.8	12.8	11.3	7.5	14.7		6.2		13.5		
/hite Bloc	Cont	6DPC	8.6	13.4	10	16.7	10.9	15.4	9.8	8.8		7.8		10.6		
a ictero V		SDPC	6.2	7.3	6	15.3	7	12.2	10.7	7.3		7.5		12.6		
Leptospin		4DPC	8.2	6.5	7.1	11.8	9.1	11.8	14.6	7.3	26.4	7.8	19	10.7		
		3DPC	6.7	8.2	11.6	7.8	6.9	3.9	15.8	4.5	4.1	7.2	4.2	5		
		2DPC	9.6	9.3	9.4	10.6	5.8	6	9.4	6.7	5.8	5	8.3	6.2		
		1DPC	6.6	8.5	12.2	19.6	13.9	8.6	7.5	8.8	6.7	7.6	8.1	9.3		:
		Baseline (Avg -2DPC, -1DPC, 0DPC)	7.4	7.4	9.3	13.7	10	8.4	7.8	7.8	7.8	8.8	11	8.3		
		Dog	21	22	23	24	25	26	27	28	29	30	31	32	D = dead	

	_												
		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	
allenge		9DPC	442	505	508	331	285	253	436	424	489	358	
Post Ch		8DPC	488	480	416	376	314	281	513	327	378	392	
Counts	nates	7DPC	447	435	517	335	400	268	457	419	500	352	
Platelet	SC Vacci	6DPC	457	645	445	344	435	308	542	393	459	555	
ictero		5DPC	667	526	580	374	282	278	214	351	417	515	
otospira		4DPC	440	428	424	457	275	264	332	397	52 9	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	

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		14DPC	410	367	535	451	409	388	474	383		427		301				
		13DPC	414	386	583	658	432	452	372	467		421		287				
		12DPC	399	369	422	461	427	513	540	495		411		337				
		11DPC	434	421	444	635	519	578	461	618		494		360				
		10DPC	575	520	546	618	660	467	469	622		642		529				
allenge		9DPC	537	412	447	480	466	444	575	612		516		430				
Post C		8DPC	529	340	369	440	458	421	465	467		549		525				
Counts	ols	7DPC	506	288	361	497	611	381	437	332		512		347				
Platelet	Contro	6DPC	545	261	393	312	483	361	386	307		379		257				
i ictero		SDPC	341	184	362	189	288	210	335	213		231		196		[
ptospira		4DPC	301	126	289	116	189	84.5	413	128	11.2	119	11.9	88.8			I.	
Lej		3DPC	207	168	265	99.5	146	94.9	483	60.5	6.7	53.9	36.7	7.7			orted as k/	
		2DPC	315	250	307	130	220	213	423	93.5	101	80.9	94.4	55		_	Jues rend	der centre
		1DPC	291	238	374	251	401	302	399	214	136	204	163	184			llence V	* .~Suvu
		Baseline (Avg -2DPC, -1DPC, 0DPC)	534.3	428.7	411.3	344.7	566	392	475.7	411.7	332	421.9	319.3	267	p		Dav nost-cha	Luy poor the
		Dog	21	22	23	24	25	26	27	28	29	30	31	32	D = Dea		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
	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 Leptospira pomona 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

	Control Animals														
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											
Study Purpose	Demonstrate safety of product under	r typical use co	onditions									
Product Administration	Two doses were administered subcu	taneously appr	roximately two									
	weeks apart.											
Study Animals	A total of 675 dogs, privately owned	and from con	nmercial kennels									
	were enrolled in the study. From these dogs 234 were 6 weeks of											
	age or younger, at first vaccination. Three geographical sites were											
	represented.											
Challenge Description	NA											
Interval observed after	Animals were observed 30 minutes after each vaccination and daily											
challenge	for two (2) weeks after each vaccination.											
Kesults	Frequency of adverse events:											
		Ni	Deve end of									
		Number of	Percent of									
		Amiliais	Ammais									
	No observed adverse events	628	93.0%									
	Injection Site Lesion	1	0.1%									
	Diarrhea-one day of loose	23	3.4%									
	stools	1	0.10/									
	Heavy Breathing	1	0.1%									
	Death-Hit by Car *	1	0.1%									
	Death-depression, decreased	1	0.1%									
	appetite, weight loss **	1	0.10/									
	Lameness (leg cramp) *	1	0.1%									
	Decreased appetite, weight	4	0.60									
	loss, diarrnea, and	4	0.6%									
	Contropatoritie (versities) *	2	0.20/									
	Locartice *	∠ 1	0.3%									
			0.1%									
	Protapsed nictitan gland *	/	1.0%									
	Pyoderma *	5	0.7%									
	*Affirmed by study investigator to h vaccination	nave cause othe	er than									
	**Cause of death was not determine appeared 4 days after vaccination ar	ed by study inv nd death 8 days	estigator. Signs a later.									
	The injection site lesion was detected after the second vaccination and resolved within 15 days.											
USDA Approval Date	13 Jan 2011											
Contra philotai Date	1.5 5411 2011											