

Establishment Name	Epitopix, LLC
USDA Vet Biologics Establishment Number	365
Product Code	264E.01
True Name	Escherichia Coli Bacterial Extract
Tradename(s) / Distributor or Subsidiary (if different from manufacturer)	
Date of Compilation Summary	July 11, 2018

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	Escherichia coli O157 (E. coli O157)										
Study Purpose	To demonstrate efficacy against fecal shedding of <i>E. coli</i> O157 in cattle.										
Product	Three doses admin	istere	d at 3-4 wee	k intervals	by subcutan	eous route.					
Administration					•						
Study Animals	Commercial yearli	ng fee	edlot cattle v	vere enrolle	ed. Each of 5	feedyards included					
	20 pens in 10 matc	20 pens in 10 matched pairs, with one pen randomized to vaccine and the other to									
	placebo. The pens housed a total of 8,584 head of cattle, 4,298 vaccinates, and										
	4,286 placebo controls.										
	_										
Challenge	The challenge was	throu	gh natural e	xposure of	<i>E. coli</i> O157	in the environment.					
Description	_										
Interval	Cattle were observ	ed dai	ily. Thirty f	ecal sample	es were colle	cted from each pen					
observed after	on day 0 and at the	end of	of the observ	ation perio	d (95-126 da	ays after the first					
challenge	vaccination).										
Results											
	Number of matche	d pen	pairs with the	he higher p	revalence of	<i>E. coli</i> O157 positive					
	fecal specimens.										
	Feedyard	Ν	Vaccine	Placebo	Equal						
	0700.1	10	Higher	Higher	Prevalence						
	0/08-1	10	0	<u>6</u>	4						
	1008-2	10	<u> </u>	<u> </u>	0						
	1008-3	10	3	5	2						
	1008-4	10	3	6	1						
	$\begin{array}{c ccccccccccccccccccccccccccccccccccc$										
			-	_,							
	Raw data on fecal	sampl	e testing are	shown on	the next pag	e					
USDA	November 4, 2011										
Approval Date											

Table. Number of *E. coli* O157 positive samples out of 30 tested from each pen at enrollment and the end of the observation period.

Samples Samples Samples Study Feedyard Pair Vaccinates Placebo Vaccinates Placebo 0708 1 2 1 0 1 7 0708 1 2 1 0 1 7 0708 1 3 1 7 0 4 0708 1 5 4 4 0 0 0708 1 6 0 0 0 5 0708 1 7 3 2 1 1 1 0708 1 9 4 0 0 1 1 0708 1 10 3 1 1 1 1 1 1008 2 11 7 5 5 7 1 1008 2 13 22 19 3 7 1008 2 16 0 0<				Enrollr	nent	Final		
StudyFeedyardPairVaccinatesPlaceboVaccinatesPlacebo070811530007081210170708131704070814620007081544000708160005070817321107081800240708194001070819400107081103111007081103111007081103111007081103111010082132219371008215315910082160013161008219107141008219100010083230100100832421001008325001010083260000 <t< td=""><td></td><td></td><td></td><td>Samp</td><td>les</td><td>Sampl</td><td>es</td></t<>				Samp	les	Sampl	es	
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$\begin{array}{c c c c c c c c c c c c c c c c c c c $	0708	1	2	1	0	1	7	
$\begin{array}{c c c c c c c c c c c c c c c c c c c $	0708	1	3	1	7	0	4	
$\begin{array}{c c c c c c c c c c c c c c c c c c c $	0708	1	4	6	2	0	0	
$\begin{array}{c c c c c c c c c c c c c c c c c c c $	0708	1	5	4	4	0	0	
$\begin{array}{c ccccccccccccccccccccccccccccccccccc$	0708	1	6	0	0	0	5	
$\begin{array}{c ccccccccccccccccccccccccccccccccccc$	0708	1	7	3	2	1	1	
$\begin{array}{c ccccccccccccccccccccccccccccccccccc$	0708	1	8	0	0	2	4	
$\begin{array}{c ccccccccccccccccccccccccccccccccccc$	0708	1	9	4	0	0	1	
10082117557 1008 2122496 1008 213221937 1008 2145081 1008 2153159 1008 216001316 1008 216011116 1008 21701010 1008 21910714 1008 22011418 1008 2201100 1008 3210000 1008 3220100 1008 3230100 1008 3242100 1008 3250012 1008 3260000 1008 3292216 1008 3292216 1008 4310010 1008 4350115 1008 4350115 1008 4361263 1008 438004 <td< td=""><td>0708</td><td>1</td><td>10</td><td>3</td><td>1</td><td>1</td><td>10</td></td<>	0708	1	10	3	1	1	10	
10082 12 2496 1008 2 13 22 19 3 7 1008 2 14 5 0 8 1 1008 2 15 3 1 5 9 1008 2 16 0 0 13 16 1008 2 17 0 1 0 10 1008 2 18 0 1 11 16 1008 2 19 1 0 7 14 1008 2 20 1 1 4 18 1008 3 21 0 0 0 0 1008 3 22 0 1 0 0 1008 3 22 0 1 0 0 1008 3 24 2 1 0 0 1008 3 25 0 0 15 0 1008 3 26 0 0 0 0 1008 3 29 2 2 1 6 1008 3 29 2 2 1 0 1008 4 31 0 0 0 0 1008 4 35 0 1 1 5 1008 4 37 0 1 0 5 1008 4 37 0 1 0 4 1008 <td>1008</td> <td>2</td> <td>11</td> <td>7</td> <td>5</td> <td>5</td> <td>7</td>	1008	2	11	7	5	5	7	
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10082145081 1008 2153159 1008 216001316 1008 21701010 1008 218011116 1008 21910714 1008 22011418 1008 3210000 1008 3220100 1008 3220100 1008 3230100 1008 32500150 1008 3260000 1008 3292216 1008 3292216 1008 3292210 1008 3300000 1008 4331303 1008 4350115 1008 4350115 1008 4361263 1008 4370105 1008 4380040	1008	2	13	22	19	3	7	
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1008216001316 1008 21701010 1008 218011116 1008 21910714 1008 22011418 1008 3210000 1008 3220100 1008 3220100 1008 3230100 1008 3242100 1008 32500150 1008 3260000 1008 3292216 1008 3292216 1008 3300000 1008 3300000 1008 3300000 1008 4310010 1008 4350115 1008 4350115 1008 4361263 1008 4361263 1008 4361263 1008 436126	1008	2	15	3	1	5	9	
10082 17 01010 1008 2 18 01 11 16 1008 2 19 107 14 1008 2 20 114 18 1008 3 21 0000 1008 3 22 0100 1008 3 22 0100 1008 3 22 0100 1008 3 23 0100 1008 3 25 00150 1008 3 26 0007 1008 3 27 0012 1008 3 29 2 216 1008 3 29 2 2 16 1008 3 30 0002 1008 4 31 0010 1008 4 35 0115 1008 4 35 0115 1008 4 36 1 2 6 3 1008 4 37 0105 1008 4 38 0040 1008 4 39 2104	1008	2	16	0	0	13	16	
1008218011116 1008 21910714 1008 22011418 1008 3210000 1008 3220100 1008 3220100 1008 3230100 1008 3242100 1008 32500150 1008 3260007 1008 3270012 1008 3292216 1008 3292216 1008 3300000 1008 4310010 1008 4350115 1008 4350115 1008 4361263 1008 4361263 1008 4380040	1008	2	17	0	1	0	10	
100821910714 1008 22011418 1008 3210000 1008 3220100 1008 3230100 1008 3242100 1008 32500150 1008 3260007 1008 3270012 1008 3292216 1008 3292216 1008 3300002 1008 3300002 1008 3300000 1008 4310010 1008 4331303 1008 4350115 1008 4361263 1008 4370105 1008 4380040	1008	2	18	0	1	11	16	
100822011418 1008 3210000 1008 3220100 1008 3230100 1008 3242100 1008 32500150 1008 3260007 1008 3270012 1008 3280000 1008 3292216 1008 3300002 1008 3300000 1008 4310010 1008 4350115 1008 4361263 1008 4361263 1008 436104 1008 4370105 1008 4380040	1008	2	19	1	0	7	14	
$\begin{array}{c ccccccccccccccccccccccccccccccccccc$	1008	2	20	1	1	4	18	
$\begin{array}{c ccccccccccccccccccccccccccccccccccc$	1008	3	21	0	0	0	0	
10083 23 0100 1008 3 24 2100 1008 3 25 00150 1008 3 26 0007 1008 3 27 0012 1008 3 28 0000 1008 3 29 2 2 16 1008 3 29 2 2 16 1008 3 30 000 2 1008 4 31 0010 1008 4 32 0000 1008 4 35 0115 1008 4 36 1 2 6 3 1008 4 36 1 2 6 3 1008 4 36 1 2 6 3 1008 4 37 010 5 1008 4 38 00 4 0 1008 4 39 2 1 0 4	1008	3	22	0	1	0	0	
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10083 25 00150 1008 3 26 0007 1008 3 27 0012 1008 3 28 0000 1008 3 29 2 2 16 1008 3 29 2 2 16 1008 3 30 000 2 1008 4 31 0010 1008 4 32 0000 1008 4 34 3100 1008 4 35 0115 1008 4 36 1 2 63 1008 4 37 0105 1008 4 38 0040 1008 4 39 2 104	1008	3	24	2	1	0	0	
$\begin{array}{c ccccccccccccccccccccccccccccccccccc$	1008	3	25	0	0	15	0	
$\begin{array}{c ccccccccccccccccccccccccccccccccccc$	1008	3	26	0	0	0	7	
$\begin{array}{c ccccccccccccccccccccccccccccccccccc$	1008	3	27	0	0	1	2	
$\begin{array}{c ccccccccccccccccccccccccccccccccccc$	1008	3	28	0	0	0	0	
$\begin{array}{c ccccccccccccccccccccccccccccccccccc$	1008	3	29	2	2	1	6	
$\begin{array}{c ccccccccccccccccccccccccccccccccccc$	1008	3	30	0	0	0	2	
$\begin{array}{c ccccccccccccccccccccccccccccccccccc$	1008	4	31	0	0	1	0	
$\begin{array}{c ccccccccccccccccccccccccccccccccccc$	1008	4	32	0	0	0	0	
$\begin{array}{c ccccccccccccccccccccccccccccccccccc$	1008	4	33	1	3	0	3	
$\begin{array}{c ccccccccccccccccccccccccccccccccccc$	1008	4	34	3	1	0	0	
1008 4 36 1 2 6 3 1008 4 37 0 1 0 5 1008 4 38 0 0 4 0 1008 4 39 2 1 0 4	1008	4	35	0	1	1	5	
1008 4 37 0 1 0 5 1008 4 38 0 0 4 0 1008 4 39 2 1 0 4	1008	4	36	1	2	6	3	
1008 4 38 0 0 4 0 1008 4 39 2 1 0 4	1008	4	37	0	1	0	5	
1008 4 39 2 1 0 4	1008	4	38	0	0	4	0	
	1008	4	39	2	1	0	4	

			Enrolln	nent	Fina	l	
			Samp	les	Samples		
Study	Feedyard	Pair	Vaccinates	Placebo	Vaccinates	Placebo	
1008	4	40	14	17	1	8	
1008	5	41	1	1	3	3	
1008	5	42	3	3	6	7	
1008	5	43	0	1	2	11	
1008	5	44	0	0	11	8	
1008	5	45	0	0	5	6	
1008	5	46	0	2	8	2	
1008	5	47	2	0	4	8	
1008	5	48	0	0	8	1	
1008	5	49	0	0	3	4	
1008	5	50	2	4	0	1	

Study Type	Safety
Pertaining to	ALL
Study Purpose	To demonstrate safety of the product under field conditions.
Product	Three doses administered at 3-4 week intervals by subcutaneous route.
Administration	
Study Animals	655 head of commercial feedlot cattle between 4 and 10 months of age were
	housed at three separate commercial feedyards in three geographically distinct
	regions. At least 1/3 of the aimals vaccinated in each region were the minimum
	age recommended for product administration. Region 1 included 246 cattle.
	Region 2 included 211 cattle. Region 3 included 198 cattle.
Challenge	Not applicable
Description	
Interval	On day of vaccination cattle were observed for local and systemic reactions and
observed after	then palpated weekly to monitor any local swelling until resolution.
challenge	

sults	Tables show the dose of vaccine	numer	of cattle	e with	injecti	on s	site re	actions	s foll	owing th
	Region 1									
			W	/eeks	Post Va	acci	inatio	n		
		0	1	2	4		5	6	7	
	No palpable swelling	244	76	113	229		237	242	23	8
	< 1.5 cm	1	0	6	0		2	2	0	
	1.5 - 5.0 cm	1	168	125	16		6	1	7	
	> 5 cm	0	1	1	0		0	0	0	
	Total Animals palpated	246	245	245	245	/	245	245	24:	5
	Dagion 2									
	<u>Region 2</u>			Week	re Post '	Vac	cinati	on		
		0	1	2	31030	v ac		5		6
	No palpable swelling	211	26	39) 92	2	131	170	0	196
	< 1.5 cm	0	11	25	5 2	1	24	33		6
	1.5 - 5.0 cm	0	130	14	4 94	4	54	6		7
	> 5 cm	0	43	2	3	;	1	1		1
	Total Animals palpated	211	210	21	0 21	0	210	210	о <i>с</i>	210
		•						•		
	Region 3		Wo	oka D	lost Va	oin	ation			7
	-	0	1		2		<i>a</i> tion <i>1</i>		6	_
	No palpable swelling	198	68	3	165		177	1	0 94	
	< 1.5 cm	0	33	3	26	1	12		0	1
	1.5 - 5.0 cm	0	97	7	6	\uparrow	6		2	1
	> 5 cm	0	0		0	+	1		0	1
	Total Animals palpated	198	19	8	197		196	1	96	

Tables show the numer of cattle with injection site reactions following the second dose of vaccine

Region 1

	Weeks Post Vaccination								
	0	1	2	3	4	5	6		
No palpable swelling	244	98	166	228	240	244	245		
< 1.5 cm	0	1	18	2	2	1	0		
1.5 - 5.0 cm	1	145	61	15	3	0	0		
> 5 cm	0	1	0	0	0	0	0		
Total Animals palpated	245	245	245	245	245	245	245		

Region 2

	Weeks Post Vaccination								
	0	1	2	3	4	5			
No palpable swelling	210	111	190	201	208	209			
< 1.5 cm	0	28	3	6	0	0			
1.5 - 5.0 cm	0	69	17	3	1	0			
> 5 cm	0	2	0	0	0	0			
Total Animals palpated	210	210	210	210	209	209			

Region 3

	Weeks Post Vaccination							
	0	1	3	4	9			
No palpable swelling	193	48	155	170	60			
< 1.5 cm	2	17	16	7	0			
1.5 - 5.0 cm	1	128	17	12	0			
> 5 cm	1	3	8	5	0			
Total Animals palpated	197	196	196	194	60			

	Tables show the nume third dose of vaccine	er of cat	ttle wit	h injec	tion	site rea	ctions following the		
	unité dose of vacenie								
	Region 1								
		We	eks Po	st Vac	cinat	ion			
		0	1	2		3			
	No palpable swelling	238	127	18	9	240			
	< 1.5 cm	0	0	0		0			
	1.5 - 5.0 cm	7	118	56	5	5			
	> 5 cm	0	0	0		0			
	Total Animals palpated	245	245	24:	5	245			
	Region 2	-							
		W	Veeks I	Post Va	accin	ation			
		0	1	2	3	9			
	No palpable swelling	196	50	172	33	4			
	< 1.5 cm	6	1	5	0	0			
	1.5 - 5.0 cm	7	150	32	4	0			
	> 5 cm	1	8	0	0	0			
	Total Animals palpated	210	209	209	37	4			
	Region 3	1			<u>.</u>	1			
		Week	s Post	Vaccin	natior	1			
		0		1	6	5			
	No palpable swelling	194	1	55	6	0			
	< 1.5 cm	0		25	()			
	1.5 - 5.0 cm	2		13	0)			
	> 5 cm	0		1	()			
	Total Animals palpated	196]	.94	6	0			
	No systemic reactions or deaths were attributed to the vaccine at any study site. Transient swelling at the injection site is commonly observed.								
USDA	January 26, 2009								
Approval Date									