



Summary of Studies Supporting USDA Product Licensure

Establishment Name	Elanco US Inc.
USDA Vet Biologics Establishment Number	196
Product Code	8081.01
True Name	Clostridium Perfringens Type A Toxoid
Tradename(s) / Distributor or Subsidiary (if different from manufacturer)	Elanco US Inc.
Date of Compilation Summary	February 07, 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	Safety																					
Pertaining to	All																					
Study Purpose	To demonstrate safety under typical field conditions																					
Product Administration	Two doses administered 2-4 weeks apart																					
Study Animals	1,954 pigs were used in this study. 1,364 bred sow and gilts and 590 feeder pigs approximately 6 weeks of age at the time of first vaccination. Six independent sites were used in the study.																					
Challenge Description	NA																					
Interval observed after challenge	Animals were observed immediately after injection, 24 and 48 hours post vaccination, and then weekly for 21 days.																					
Results	<p>Frequency of Adverse Events:</p> <table border="1"> <thead> <tr> <th></th> <th>Number Sows/Gilts</th> <th>Number Pigs ~6wks of age</th> </tr> </thead> <tbody> <tr> <td>No Adverse Events</td> <td>1340</td> <td>578</td> </tr> <tr> <td>injection site reactions†</td> <td>11</td> <td>0</td> </tr> <tr> <td>Decreased appetite</td> <td>1</td> <td>0</td> </tr> <tr> <td>Abortion</td> <td>11*</td> <td>0</td> </tr> <tr> <td>Death</td> <td>1*</td> <td>0</td> </tr> <tr> <td>Other</td> <td>0</td> <td>12**</td> </tr> </tbody> </table> <p>*Abortions and Deaths were not attributed to the vaccine as affirmed by licensee.</p> <p>** 12 pigs were removed or euthanized due to other causes unrelated to the vaccine as affirmed by licensee.</p> <p>†Injection site reactions 4 animals had 3-4cm swellings of which 3 resolved before the second vaccination and the other resolved before the end of the observation period. 3 animals had 2cm swellings of which 2 resolved by 48 hours and the other within 14 days. 3 animals had a soft swelling that resolved within 14 days.</p>		Number Sows/Gilts	Number Pigs ~6wks of age	No Adverse Events	1340	578	injection site reactions†	11	0	Decreased appetite	1	0	Abortion	11*	0	Death	1*	0	Other	0	12**
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USDA Approval Date	June 13, 2006																					