



## Summary of Studies Supporting USDA Product Licensure

Establishment Name	Elanco US Inc.
USDA Vet Biologics Establishment Number	196
Product Code	7054.01
True Name	Bordetella Bronchiseptica-Erysipelothrix Rhusiopathiae-Pasteurella Multocida Bacterin-Toxoid
Tradename(s) / Distributor or Subsidiary (if different from manufacturer)	Rhini Shield TX4 - Elanco Salud Animal, S.A. de C.V. - Elanco US Inc. Rhini Shield TX4 - Elanco US Inc.
Date of Compilation Summary	January 23, 2023

**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.**

<b>Study Type</b>	Efficacy
<b>Pertaining to</b>	<i>Bordetella bronchiseptica</i>
<b>Study Purpose</b>	To demonstrate passive immunity against <i>Bordetella bronchiseptica</i>
<b>Product Administration</b>	Pregnant pigs - Two doses IM 5 weeks and 3 weeks prior to farrowing
<b>Study Animals</b>	Unvaccinated piglets, born from vaccinated pigs
<b>Challenge Description</b>	
<b>Interval observed after challenge</b>	
<b>Results</b>	Study data were evaluated by USDA-APHIS prior to product licensure and met regulatory standards for acceptance at the time of submission. No data are published because this study was submitted to USDA-APHIS prior to January 1, 2007, and APHIS only require publication of data submitted after that date.
<b>USDA Approval Date</b>	April 23, 1984

<b>Study Type</b>	Efficacy
<b>Pertaining to</b>	<i>Erysipelothrix rhusiopathiae</i>
<b>Study Purpose</b>	To demonstrate effectiveness against <i>Erysipelothrix rhusiopathiae</i>
<b>Product Administration</b>	
<b>Study Animals</b>	Piglets
<b>Challenge Description</b>	
<b>Interval observed after challenge</b>	
<b>Results</b>	Study data were evaluated by USDA-APHIS prior to product licensure and met regulatory standards for acceptance at the time of submission. No data are published because this study was submitted to USDA-APHIS prior to January 1, 2007, and APHIS only require publication of data submitted after that date.
<b>USDA Approval Date</b>	April 23, 1984

<b>Study Type</b>	Efficacy
<b>Pertaining to</b>	Pasteurella Multocida Type A
<b>Study Purpose</b>	To demonstrate effectiveness against Pasteurella Multocida Type A
<b>Product Administration</b>	
<b>Study Animals</b>	
<b>Challenge Description</b>	
<b>Interval observed after challenge</b>	
<b>Results</b>	Study data were evaluated by USDA-APHIS prior to product licensure and met regulatory standards for acceptance at the time of submission. No data are published because this study was submitted to USDA-APHIS prior to January 1, 2007, and APHIS only require publication of data submitted after that date.
<b>USDA Approval Date</b>	April 23, 1984

<b>Study Type</b>	Efficacy
<b>Pertaining to</b>	Pasteurella Multocida
<b>Study Purpose</b>	To demonstrate effectiveness against <i>Pasteurella multocida</i> Type D
<b>Product Administration</b>	Piglets – 2 doses 2 weeks apart farrowed from pregnant gilts that received 2 doses 3 weeks apart
<b>Study Animals</b>	Piglets
<b>Challenge Description</b>	
<b>Interval observed after challenge</b>	
<b>Results</b>	Study data were evaluated by USDA-APHIS prior to product licensure and met regulatory standards for acceptance at the time of submission. No data are published because this study was submitted to USDA-APHIS prior to January 1, 2007, and APHIS only requires publication of data submitted after that date.
<b>USDA Approval Date</b>	October 24, 1996

<b>Study Type</b>	Safety
<b>Pertaining to</b>	All fractions
<b>Study Purpose</b>	Safety by intramuscular route and subcutaneous route in swine
<b>Product Administration</b>	Swine including pregnant swine
<b>Study Animals</b>	
<b>Challenge Description</b>	
<b>Interval observed after challenge</b>	
<b>Results</b>	Scientific data were evaluated by USDA-APHIS prior to product licensure and met regulatory standards for acceptance at the time of submission.