



## Summary of Studies Supporting USDA Product Licensure

Establishment Name	Zoetis Inc.
USDA Vet Biologics Establishment Number	190
Product Code	2642.02
True Name	Erysipelothrix Rhusiopathiae-Leptospira Canicola-Grippytyphosa-Hardjo-Icterohaemorrhagiae-Pomona Bacterin
Tradename(s) / Distributor or Subsidiary (if different from manufacturer)	ER Bac/L5 - No distributor specified ER Bac/L5 Gold - No distributor specified
Date of Compilation Summary	June 05, 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>Erysipelothrix rhusiopathiae</i>
<b>Study Purpose</b>	Demonstrate effectiveness against <i>Erysipelothrix rhusiopathiae</i>
<b>Product Administration</b>	
<b>Study Animals</b>	Swine
<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>	February 12, 2002

<b>Study Type</b>	Efficacy
<b>Pertaining to</b>	<i>Erysipelothrix rhusiopathiae</i>
<b>Study Purpose</b>	Demonstrate a duration of immunity of at least 18 weeks against <i>Erysipelothrix rhusiopathiae</i>
<b>Product Administration</b>	
<b>Study Animals</b>	Swine
<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>	November 17, 2005

<b>Study Type</b>	Efficacy
<b>Pertaining to</b>	<i>Leptospira canicola</i>
<b>Study Purpose</b>	Demonstrate effectiveness against <i>Leptospira canicola</i>
<b>Product Administration</b>	
<b>Study Animals</b>	Swine
<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>	March 15, 1978

<b>Study Type</b>	Efficacy
<b>Pertaining to</b>	<i>Leptospira grippotyphosa</i>
<b>Study Purpose</b>	Demonstrate effectiveness against <i>Leptospira grippotyphosa</i>
<b>Product Administration</b>	
<b>Study Animals</b>	Swine
<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>	March 15, 1978

<b>Study Type</b>	Efficacy
<b>Pertaining to</b>	<i>Leptospira hardjo</i>
<b>Study Purpose</b>	Demonstrate effectiveness against <i>Leptospira hardjo</i>
<b>Product Administration</b>	
<b>Study Animals</b>	Swine
<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>	March 15, 1978

<b>Study Type</b>	Efficacy
<b>Pertaining to</b>	<i>Leptospira icterohaemorrhagiae</i>
<b>Study Purpose</b>	Demonstrate effectiveness against <i>Leptospira icterohaemorrhagiae</i>
<b>Product Administration</b>	
<b>Study Animals</b>	Swine
<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>	March 15, 1978

<b>Study Type</b>	Efficacy
<b>Pertaining to</b>	<i>Leptospira pomona</i>
<b>Study Purpose</b>	Demonstrate effectiveness against <i>Leptospira pomona</i>
<b>Product Administration</b>	
<b>Study Animals</b>	Swine
<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>	March 15, 1978

<b>Study Type</b>	Safety
<b>Pertaining to</b>	ALL
<b>Study Purpose</b>	Demonstrate safety under field conditions
<b>Product Administration</b>	
<b>Study Animals</b>	Swine
<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>	February 24, 2006