



## Summary of Studies Supporting USDA Product Licensure

Establishment Name	Zoetis Inc.
USDA Vet Biologics Establishment Number	190
Product Code	7423.00
True Name	Clostridium Chauvoei-Septicum-Novyi-Sordellii-Perfringens Types C & D-Haemophilus Somnus Bacterin-Toxoid
Tradename(s) / Distributor or Subsidiary (if different from manufacturer)	Ultrabac 7/Somubac - No distributor specified Ultrabac 7/Somubac - Zoetis Mexico
Date of Compilation Summary	September 02, 2021

**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>Clostridium chauvoei</i>
<b>Study Purpose</b>	Demonstrate effectiveness against <i>Clostridium chauvoei</i>
<b>Product Administration</b>	
<b>Study Animals</b>	Bovine
<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>	July 1, 1997

<b>Study Type</b>	Efficacy
<b>Pertaining to</b>	<i>Clostridium novyi</i>
<b>Study Purpose</b>	Demonstrate effectiveness against <i>Clostridium novyi</i>
<b>Product Administration</b>	
<b>Study Animals</b>	Bovine
<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>	July 1, 1997

<b>Study Type</b>	Efficacy
<b>Pertaining to</b>	<i>Clostridium perfringens</i> Type C
<b>Study Purpose</b>	Demonstrate effectiveness against <i>Clostridium perfringens</i> Type C
<b>Product Administration</b>	
<b>Study Animals</b>	Bovine
<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>	July 1, 1997

<b>Study Type</b>	Efficacy
<b>Pertaining to</b>	<i>Clostridium perfringens</i> Type D
<b>Study Purpose</b>	Demonstrate effectiveness against <i>Clostridium perfringens</i> Type D
<b>Product Administration</b>	
<b>Study Animals</b>	Bovine
<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>	July 1, 1997

<b>Study Type</b>	Efficacy
<b>Pertaining to</b>	<i>Clostridium septicum</i>
<b>Study Purpose</b>	Demonstrate effectiveness against <i>Clostridium septicum</i>
<b>Product Administration</b>	
<b>Study Animals</b>	Bovine
<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>	July 1, 1997

<b>Study Type</b>	Efficacy
<b>Pertaining to</b>	<i>Clostridium sordelli</i>
<b>Study Purpose</b>	Demonstrate effectiveness against <i>Clostridium sordelli</i>
<b>Product Administration</b>	
<b>Study Animals</b>	Bovine
<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>	July 1, 1997

<b>Study Type</b>	Efficacy
<b>Pertaining to</b>	<i>Haemophilus somnus</i>
<b>Study Purpose</b>	Demonstrate effectiveness against <i>Haemophilus somnus</i>
<b>Product Administration</b>	
<b>Study Animals</b>	Bovine
<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 25, 1980



<b>Study Type</b>	Safety
<b>Pertaining to</b>	ALL
<b>Study Purpose</b>	Demonstrate safety under typical field conditions
<b>Product Administration</b>	Subcutaneous
<b>Study Animals</b>	Bovine
<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>	July 1, 1997

<b>Study Type</b>	Safety
<b>Pertaining to</b>	ALL
<b>Study Purpose</b>	Demonstrate safety under typical field conditions
<b>Product Administration</b>	Subcutaneous
<b>Study Animals</b>	Bovine
<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>	July 1, 1997