

Summary of Studies Supporting USDA Product Licensure

Establishment Name	Zoetis Inc.
USDA Vet Biologics Establishment Number	190
Product Code	7410.02
True Name	Clostridium Chauvoei-Septicum-Novyi-Sordellii-Perfringens Types C & D Bacterin-Toxoid
Tradename(s) / Distributor or Subsidiary (if different from manufacturer)	UltraChoice 7 - No distributor specified UltraChoice 7 - Zoetis Inc. UltraChoice 7 - Zoetis Industria de Produtos UltraChoice 7 - Zoetis South Africa Ltd
Date of Compilation Summary	September 20, 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.

Study Type	Efficacy
Pertaining to	Clostridium chauvoei
Study Purpose	Demonstrate effectiveness against Clostridium chauvoei
Product Administration	Subcutaneous
Study Animals	Bovine
Challenge Description	
Interval observed after	
challenge	
Results	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.
USDA Approval Date	February 3, 1999

Study Type	Efficacy
Pertaining to	Clostridium chauvoei
Study Purpose	Demonstrate effectiveness against Clostridium chauvoei
Product Administration	Subcutaneous
Study Animals	Ovine
Challenge Description	
Interval observed after	
challenge	
Results	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.
USDA Approval Date	October 26, 1999

	D 00
Study Type	Efficacy
Pertaining to	Clostridium novyi
Study Purpose	Demonstrate effectiveness against Clostridium novyi
Product Administration	Subcutaneous
Study Animals	Bovine
Challenge Description	
Interval observed after	
challenge	
Results	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.
USDA Approval Date	February 3, 1999

Study Type	Efficacy
Pertaining to	Clostridium novyi
Study Purpose	Demonstrate effectiveness against Clostridium novyi
Product Administration	Subcutaneous
Study Animals	Ovine
Challenge Description	
Interval observed after	
challenge	
Results	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.
USDA Approval Date	October 26, 1999

G4 L T	
Study Type	Efficacy
Pertaining to	Clostridium perfringens Type C
Study Purpose	Demonstrate effectiveness against Clostridium perfringens Type
	С
Product Administration	Subcutaneous
Study Animals	Bovine
Challenge Description	
Interval observed after	
challenge	
Results	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.
USDA Approval Date	February 3, 1999

64 J T	
Study Type	Efficacy
Pertaining to	Clostridium perfringens Type C
Study Purpose	Demonstrate effectiveness against Clostridium perfringens Type
	С
Product Administration	Subcutaneous
Study Animals	Ovine
Challenge Description	
Interval observed after	
challenge	
Results	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.
USDA Approval Date	October 26, 1999

64 J T	
Study Type	Efficacy
Pertaining to	Clostridium perfringens Type D
Study Purpose	Demonstrate effectiveness against Clostridium perfringens Type
	D
Product Administration	Subcutaneous
Study Animals	Bovine
Challenge Description	
Interval observed after	
challenge	
Results	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.
USDA Approval Date	February 3, 1999

64 J T	
Study Type	Efficacy
Pertaining to	Clostridium perfringens Type D
Study Purpose	Demonstrate effectiveness against Clostridium perfringens Type
	D
Product Administration	Subcutaneous
Study Animals	Ovine
Challenge Description	
Interval observed after	
challenge	
Results	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.
USDA Approval Date	October 26, 1999

	F 00
Study Type	Efficacy
Pertaining to	Clostridum septicum
Study Purpose	Demonstrate effectiveness against Clostridium septicum
Product Administration	Subcutaneous
Study Animals	Ovine
Challenge Description	
Interval observed after	
challenge	
Results	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.
USDA Approval Date	October 26, 1999

Study Type	Efficacy
Pertaining to	Clostridium septicum
Study Purpose	Demonstrate effectiveness against Clostridium septicum
Product Administration	Subcutaneous
Study Animals	Bovine
Challenge Description	
Interval observed after	
challenge	
Results	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.
USDA Approval Date	February 3, 1999

	19.00
Study Type	Efficacy
Pertaining to	Clostridium sordelli
Study Purpose	Demonstrate effectiveness against Clostridium sordelli
Product Administration	Subcutaneous
Study Animals	Bovine
Challenge Description	
Interval observed after	
challenge	
Results	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.
USDA Approval Date	February 3, 1999

	7.00
Study Type	Efficacy
Pertaining to	Clostridium sordelli
Study Purpose	Demonstrate effectiveness against Clostridium sordelli
Product Administration	Subcutaneous
Study Animals	Ovine
Challenge Description	
Interval observed after	
challenge	
Results	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.
USDA Approval Date	October 26, 1999

Study Type	Safety
Pertaining to	ALL
Study Purpose	Demonstrate safety in sheep under field conditions
Product Administration	Subcutaneous
Study Animals	Ovine
Challenge Description	
Interval observed after	
challenge	
Results	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.
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Study Type	Safety
Pertaining to	ALL
Study Purpose	Demonstrate safety in sheep under field conditions
Product Administration	Subcutaneous
Study Animals	Ovine
Challenge Description	
Interval observed after	
challenge	
Results	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.
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Pertaining to	ALL
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Product Administration	Subcutaneous
Study Animals	Ovine
Challenge Description	
Interval observed after	
challenge	
Results	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.
USDA Approval Date	October 26, 1999

G4 1 T	
Study Type	Safety
Pertaining to	ALL
Study Purpose	Demonstrate safety in cattle under field conditions
Product Administration	Subcutaneous
Study Animals	Bovine
Challenge Description	
Interval observed after	
challenge	
Results	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.
USDA Approval Date	May 27, 1999

G4 1 T	
Study Type	Safety
Pertaining to	ALL
Study Purpose	Demonstrate safety in cattle under field conditions
Product Administration	Subcutaneous
Study Animals	Bovine
Challenge Description	
Interval observed after	
challenge	
Results	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.
USDA Approval Date	May 27, 1999

G4 1 T	
Study Type	Safety
Pertaining to	ALL
Study Purpose	Demonstrate safety in cattle under field conditions
Product Administration	Subcutaneous
Study Animals	Bovine
Challenge Description	
Interval observed after	
challenge	
Results	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.
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