Summary of Studies Supporting USDA Product Licensure

Establishment Name	Intervet Inc.
USDA Vet Biologics Establishment Number	311
Product Code	7280.00
True Name	Clostridium Chauvoei-Septicum-Haemolyticum-Novyi-Tetani-Perfringens Types C & D Bacterin-Toxoid
Tradename(s) / Distributor or Subsidiary (if different from manufacturer)	Covexin 8 - Intervet, Inc. Covexin 8 - 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.

Study Type	Efficacy
Pertaining to	*Clostridium chauvoei, Clostridium septicum, Clostridium haemolyticum, Clostridium novyi, Clostridium tetani, Clostridium perfringens* Types C & D
Study Purpose	To demonstrate effectiveness against disease caused by *C. chauvoei, C. septicum, C. haemolyticum, C. novyi, C. tetani, C. perfringens* Types C & D
Product Administration	Subcutaneous and intramuscularly
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	January 29, 1996

Study Type	Efficacy
Pertaining to	*Clostridium chauvoei, Clostridium septicum, Clostridium haemolyticum, Clostridium novyi, Clostridium tetani, Clostridium perfringens* Types C & D
Study Purpose	To demonstrate effectiveness against disease caused by *C. chauvoei, C. septicum, C. haemolyticum, C. novyi, C. tetani, C. perfringens* Types C & 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	January 29, 1996

Study Type	Efficacy
Pertaining to	*Clostridium chauvoei, Clostridium septicum, Clostridium haemolyticum, Clostridium novyi, Clostridium tetani, Clostridium perfringens* Types C & D
Study Purpose	To demonstrate effectiveness against disease caused by *C. chauvoei, C. septicum, C. haemolyticum, C. novyi, C. tetani, C. perfringens* Types C & D
Product Administration	Subcutaneous, 1st dose prior to breeding, 2nd dose 2-6 weeks prior to lambing
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	September 30, 1996

Study Type	Safety
Pertaining to	ALL
Study Purpose	Demonstrate safety under typical field conditions
Product Administration	Subcutaneous & Intramuscular
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	June 18, 1996

Study Type	Safety
Pertaining to	ALL
Study Purpose	Demonstrate safety under typical 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.
USDA Approval Date	June 18, 1996

Study Type	Safety
Pertaining to	ALL
Study Purpose	Demonstrate safety in pregnant ovine 2-6 weeks prior to lambing under typical field conditions
Product Administration	Subcutaneous
Study Animals	Pregnant ovine 2-6 weeks prior to lambing
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	September 30, 1996