

Summary of Studies Supporting USDA Product Licensure

Establishment Name	Zoetis Inc.
USDA Vet Biologics Establishment Number	190
Product Code	2785.00
True Name	Salmonella Enteritidis Bacterin
Tradename(s) / Distributor or Subsidiary (if different from manufacturer)	Poulvac SE - No distributor specified Poulvac SE - Zoetis (Thailand) Limited Poulvac SE - Zoetis Colombia S.A.S. Poulvac SE - Zoetis Industria de Produtos Poulvac SE - Zoetis Mexico Poulvac SE - Zoetis Panama
Date of Compilation Summary	March 27, 2020

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	Salmonella enteritidis
Study Purpose	Demonstrate efficacy against S. enteritidis colonization of
	internal organs, including reproductive tract and intestines
Product Administration	
Study Animals	Chicken
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	1 June 1999

Study Type	Efficacy
Pertaining to	Salmonella enteritidis
Study Purpose	Demonstrate efficacy against S. enteritidis colonization of
	internal organs, including the reproductive tract and intestines
Product Administration	
Study Animals	Chicken
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	10 September 1998

Study Type	Efficacy
Pertaining to	Salmonella enteritidis
Study Purpose	Demonstrate efficacy against S. enteritidis colonization of
	internal organs, including the reproductive tract and intestines
Product Administration	
Study Animals	Chicken
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	19 October 1998

Study Type	Safety
Pertaining to	ALL
Study Purpose	Demonstrate safety under field conditions
Product Administration	
Study Animals	Chicken
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	25 January 1999