



Summary of Studies Supporting USDA Product Licensure

Establishment Name	Elanco US Inc.
USDA Vet Biologics Establishment Number	196
Product Code	2785.00
True Name	Salmonella Enteritidis Bacterin
Tradenname(s) / Distributor or Subsidiary (if different from manufacturer)	<p>AviPro 109 SE4 - Ilender Peru S.A. AviPro 109 SE4 - Laboratories Bimex SRL AviPro 109 SE4 - No distributor specified AviPro 109 SE4 Conc - Elanco Animal Health - Lohmann Animal Health International AviPro 109 SE4 Conc - Elanco Colombia SAS - Lohmann Animal Health International AviPro 109 SE4 Conc - Elanco Salud Animal, S.A. de C.V. AviPro 109 SE4 Conc - J. Orbe Asesores S.A.C. - Lohmann Animal Health International AviPro 109 SE4 Conc - Lohmann Animal Health International AviPro 109 SE4 Conc - No distributor specified AviPro 109 SE4 Conc - TADEC CIA Ltda Ilender Bolivia S.A. Lohmann Animal Health International</p>
Date of Compilation Summary	February 28, 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	<i>Salmonella enteritidis</i>
Study Purpose	To demonstrate effectiveness against colonization of internal organs, including the reproductive tract caused by <i>Salmonella enteritidis</i>
Product Administration	Subcutaneous injection
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	February 16, 1994

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USDA Approval Date	February 16, 1994

Study Type	Safety
Pertaining to	<i>Salmonella enteritidis</i>
Study Purpose	To demonstrate safety under field conditions
Product Administration	Subcutaneous injection
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	April 14, 1995

Study Type	Safety
Pertaining to	<i>Salmonella</i> Enteritidis
Study Purpose	To demonstrate safety under field conditions
Product Administration	Subcutaneous injection
Study Animals	Chicken
Challenge Description	
Interval observed after challenge	
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