



## Summary of Studies Supporting USDA Product Licensure

Establishment Name	Elanco US Inc.
USDA Vet Biologics Establishment Number	196
Product Code	19C1.01
True Name	Salmonella Typhimurium Vaccine, Live Culture
Tradename(s) / Distributor or Subsidiary (if different from manufacturer)	AviPro Megan Vac 1 - Elanco Salud Animal, S.A. de C.V. - Elanco US Inc. AviPro Megan Vac 1 - Elanco Salud Animal, S.A. de C.V. - Lohmann Animal Health International AviPro Megan Vac 1 - Elanco US Inc. AviPro Megan Vac 1 - Lohmann Animal Health International AviPro Megan Vac 1 - No distributor specified Elanco US Inc. Lohmann Animal Health International
Date of Compilation Summary	February 14, 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.**

<b>Study Type</b>	Efficacy
<b>Pertaining to</b>	<i>Salmonella</i> Typhimurium
<b>Study Purpose</b>	To demonstrate efficacy against <i>S. enteritidis</i> for colonization of the crop, digestive system, including the ceca
<b>Product Administration</b>	Coarse spray at day-of-age followed by a second vaccination at 2 weeks of age by the drinking water route
<b>Study Animals</b>	Chicken
<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>	September 5, 2005

<b>Study Type</b>	Efficacy
<b>Pertaining to</b>	<i>Salmonella</i> Typhimurium
<b>Study Purpose</b>	To demonstrate efficacy against <i>S. enteritidis</i> for colonization of internal organs
<b>Product Administration</b>	Coarse spray at day-of-age followed by a second vaccination at 2 weeks of age by the drinking water route
<b>Study Animals</b>	Chicken
<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>	May 21, 1997

<b>Study Type</b>	Efficacy
<b>Pertaining to</b>	<i>Salmonella</i> Typhimurium
<b>Study Purpose</b>	To demonstrate efficacy against <i>S. heidelberg</i> for colonization of internal organs
<b>Product Administration</b>	Coarse spray at day-of-age followed by a second vaccination at 2 weeks of age by the drinking water route
<b>Study Animals</b>	Chicken
<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>	May 21, 1997

<b>Study Type</b>	Efficacy
<b>Pertaining to</b>	<i>Salmonella</i> Typhimurium
<b>Study Purpose</b>	To demonstrate efficacy against <i>S. typhimurium</i> colonization of internal organs
<b>Product Administration</b>	Coarse spray at day-of-age followed by a second vaccination at 2 weeks of age by the drinking water route
<b>Study Animals</b>	Chicken
<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>	May 21, 1997

<b>Study Type</b>	Safety
<b>Pertaining to</b>	<i>Salmonella</i> Typhimurium
<b>Study Purpose</b>	To demonstrate safety under field conditions
<b>Product Administration</b>	Coarse spray and drinking water
<b>Study Animals</b>	Chicken
<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, 1998