



## Summary of Studies Supporting USDA Product Licensure

Establishment Name	Elanco US Inc.
USDA Vet Biologics Establishment Number	196
Product Code	2774.00
True Name	Mycoplasma Gallisepticum Bacterin
Tradename(s) / Distributor or Subsidiary (if different from manufacturer)	AviPro 104 MG - No distributor specified AviPro 104 MG Bacterin - Elanco (Thailand) Ltd. - Lohmann Animal Health International AviPro 104 MG Bacterin - Elanco Animal Health - Lohmann Animal Health International AviPro 104 MG Bacterin - Elanco Salud Animal, S.A. de C.V. AviPro 104 MG Bacterin - Eli Lilly Philippines, Inc. AviPro 104 MG Bacterin - International Science Solution Co. LTD. - Lohmann Animal Health International AviPro 104 MG Bacterin - Lohmann Animal Health International AviPro 104 MG Bacterin - Lohmann Saude Animal Ltda AviPro 104 MG Bacterin - No distributor specified
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.**

<b>Study Type</b>	Efficacy
<b>Pertaining to</b>	<i>Mycoplasma gallisepticum</i>
<b>Study Purpose</b>	To demonstrate effectiveness against <i>M. gallisepticum</i>
<b>Product Administration</b>	Subcutaneous injection
<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>	October 22, 1987

<b>Study Type</b>	Safety
<b>Pertaining to</b>	<i>Mycoplasma gallisepticum</i>
<b>Study Purpose</b>	To demonstrate safety under field conditions
<b>Product Administration</b>	Subcutaneous injection
<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>	October 13, 1988