



Summary of Studies Supporting USDA Product Licensure

Establishment Name	Elanco US Inc.
USDA Vet Biologics Establishment Number	196
Product Code	2775.01
True Name	Mycoplasma Hyopneumoniae Bacterin
Tradename(s) / Distributor or Subsidiary (if different from manufacturer)	PneumoSTAR Myco - No distributor specified
Date of Compilation Summary	June 10, 2021

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>Mycoplasma hyopneumoniae</i>
Study Purpose	To demonstrate effectiveness against <i>Mycoplasma hyopneumoniae</i>
Product Administration	
Study Animals	Swine
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 require publication of data submitted after that date.
USDA Approval Date	August 22, 2002

Study Type	Safety								
Pertaining to	All								
Study Purpose	To demonstrate safety under typical field conditions								
Product Administration	Two doses administered 2 weeks apart								
Study Animals	1,990 pigs 3-5 weeks of age at the time of first vaccination.								
Challenge Description	NA								
Interval observed after challenge	Animals were observed immediately after injection, 24 and 48 hours after each vaccination. Pigs were observed 1 week after first vaccination and then once weekly for three weeks after second vaccination.								
Results	<p>Frequency of Adverse Events:</p> <table border="1"> <thead> <tr> <th></th> <th>Number of pigs</th> </tr> </thead> <tbody> <tr> <td>No Adverse Reaction</td> <td>1982</td> </tr> <tr> <td>Injection site reactions / abscess</td> <td>7</td> </tr> <tr> <td>Staph infection</td> <td>1</td> </tr> </tbody> </table> <p>Abscesses were identified after the administration of the first or second vaccination and ranged in size from 1cm to 7cm.</p>		Number of pigs	No Adverse Reaction	1982	Injection site reactions / abscess	7	Staph infection	1
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No Adverse Reaction	1982								
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USDA Approval Date	September 4, 2003								