

Summary of Studies Supporting USDA Product Licensure

Establishment Name	Elanco US Inc.
USDA Vet Biologics Establishment Number	196
Product Code	2703.15
True Name	Pasteurella Multocida Bacterin, Avian Isolates, Types 1, 3, 4 & 3 X 4
Tradename(s) / Distributor or Subsidiary (if different from manufacturer)	AviPro 108 FC4 - Elanco Animal Health - Lohmann Animal Health International AviPro 108 FC4 - Elanco Salud Animal, S.A. de C.V. AviPro 108 FC4 - Eli Lilly Interamerica Inc Lohmann Animal Health International AviPro 108 FC4 - Eli Lilly, Inc. AviPro 108 FC4 - Lohmann Animal Health International AviPro 108 FC4 - No distributor specified AviPro 108 PM/FC - No distributor specified
Date of Compilation Summary	March 06, 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.

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Study Type	Efficacy
Pertaining to	Pasteurella multocida
Study Purpose	To demonstrate effectiveness against Pasteurella multocida, type
	1 in chickens.
	To demonstrate effectiveness against Pasteurella multocida,
	types, 3, 4 and 3x4 in turkeys.
Product Administration	Subcutaneous injection
Study Animals	Chickens and turkeys
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	March 31, 1992

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Study Type	Safety
Pertaining to	All fractions
Study Purpose	To demonstrate safety under field conditions
Product Administration	Subcutaneous injection
Study Animals	Chickens
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	November 20, 1991

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Study Type	Safety
Pertaining to	All fractions
Study Purpose	To demonstrate safety under field conditions
Product Administration	Subcutaneous injection
Study Animals	Turkeys
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 24, 1992

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Study Type	Safety
Pertaining to	All fractions
Study Purpose	To demonstrate safety under field conditions
Product Administration	Subcutaneous injection
Study Animals	Turkeys
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	March 23, 1992

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Study Type	Safety
Pertaining to	All fractions
Study Purpose	To demonstrate safety under field conditions
Product Administration	Subcutaneous injection
Study Animals	Chickens
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 24, 1992

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Study Type	Safety
Pertaining to	All fractions
Study Purpose	To demonstrate safety under field conditions
Product Administration	Subcutaneous injection
Study Animals	Chickens
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 24, 1992

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