



## Summary of Studies Supporting USDA Product Licensure

Establishment Name	Ceva Animal Health, LLC
USDA Vet Biologics Establishment Number	368
Product Code	10M1.40
True Name	Avian Encephalomyelitis-Fowl Pox Vaccine, Live Virus
Tradenname(s) / Distributor or Subsidiary (if different from manufacturer)	<p>Poximune AE - ACI Limited, Bangladesh - Biomune Company</p> <p>Poximune AE - Agroservet S.R.L.</p> <p>Poximune AE - Axis Agency Services Ltd. - Biomune Company</p> <p>Poximune AE - Biomune - Biomune Company</p> <p>Poximune AE - Biomune Company</p> <p>Poximune AE - CEVA Salud Animal S.A.C.-Peru</p> <p>Poximune AE - CEVA Saude Animal Ltda. (Brazil)</p> <p>Poximune AE - Ceva Hayvan Sagligi A.S.</p> <p>Poximune AE - Ceva Salud Animal S.A. de C.V. (Mexico)</p> <p>Poximune AE - No distributor specified</p> <p>Poximune AE - Vetiplus S.A.</p>
Date of Compilation Summary	August 31, 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.**

<b>Study Type</b>	Efficacy
<b>Pertaining to</b>	Avian Encephalomyelitis Virus
<b>Study Purpose</b>	Demonstrate efficacy against Avian Encephalomyelitis
<b>Product Administration</b>	Wing web
<b>Study Animals</b>	Chickens
<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>	April 23, 2001

<b>Study Type</b>	Efficacy
<b>Pertaining to</b>	Fowl Pox Virus
<b>Study Purpose</b>	Demonstrate efficacy against Fowl Pox Virus
<b>Product Administration</b>	Wing web
<b>Study Animals</b>	Chickens
<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>	April 23, 2001

<b>Study Type</b>	Safety
<b>Pertaining to</b>	All
<b>Study Purpose</b>	Demonstrate safety of product under typical field conditions
<b>Product Administration</b>	Wing web
<b>Study Animals</b>	
<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>	July 19, 2001