



## Summary of Studies Supporting USDA Product Licensure

Establishment Name	Ceva Animal Health, LLC
USDA Vet Biologics Establishment Number	368
Product Code	1045.30
True Name	Avian Reovirus Vaccine, Killed Virus
Tradename(s) / Distributor or Subsidiary (if different from manufacturer)	Reomune 3 - ACI Limited, Bangladesh Reomune 3 - Axis Agency Services Ltd. Reomune 3 - Axis Agency Services Ltd. - Biomune Company Reomune 3 - Biomune Company Reomune 3 - CEVA Animal Health (Thailand) Ltd Reomune 3 - CEVA Sante Animale S.A. (Argentina) Reomune 3 - Ceva Hayvan Sagligi A.S. Reomune 3 - Ceva Salud Animal SRL - Biomune Company Reomune 3 - Ceva Salud Animal SpA (Chile) - Biomune Company Reomune 3 - Ceva Sante Animale (Russia) - Biomune Company Reomune 3 - Chemie S.A. Reomune 3 - MAS Veterinary Services Reomune 3 - No distributor specified Reomune 3 - Productos Swissagro C.A., Torre KLM
Date of Compilation Summary	January 14, 2022

**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 Reovirus
<b>Study Purpose</b>	Efficacy against tenosynovitis and malabsorption in progeny caused by avian reovirus standard and variant (SS412) strains when administered to breeder hens
<b>Product Administration</b>	Subcutaneous
<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>	February 3, 1993

<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>	Subcutaneous
<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>	February 3, 1993