



Summary of Studies Supporting USDA Product Licensure

Establishment Name	Zoetis Inc.
USDA Vet Biologics Establishment Number	190
Product Code	19X5.R1
True Name	Mink Coronavirus Vaccine, Subunit
Tradename(s) / Distributor or Subsidiary (if different from manufacturer)	
Date of Compilation Summary	April 15, 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.

Study Type	Safety
Pertaining to	ALL
Study Purpose	To demonstrate safety under field conditions
Product Administration	Two doses, administered subcutaneously, 3 weeks apart.
Study Animals	The study involved 90 seronegative adult mink in total, aged 8 to 20 months old, from 3 sites in 2 different geographical locations.
Challenge Description	Not applicable
Interval observed after challenge	Animals were monitored prior to the first vaccination through 14 days following the second vaccination. Daily observations were made for visible injection site reactions, including size, redness, or ulceration.
Results	<p>No immediate reactions were observed. No injection site reactions or swellings were observed.</p> <p>Only 1 abnormal health event occurred with the animal found deceased on Study Day 33. Based on necropsy, the cause of death was determined to be cystitis and acute renal failure which is common to breeding-age females and not related to the investigational product.</p>
USDA Approval Date	20 December, 2021

Study Type	Safety																								
Pertaining to	ALL																								
Study Purpose	To demonstrate safety under field conditions during emergency use authorization.																								
Product Administration	Two doses, administered subcutaneously, 3 weeks apart.																								
Study Animals	The study involved administration in kits (6-8 weeks of age at 1 st vaccination), and adult mink (\geq 8 weeks of age at 1 st vaccination). The mink were located over 11 states in 4 geographical locations.																								
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Interval observed after challenge	Animals were monitored following vaccination according to individual farm practices for animal health observations.																								
Results	<p>In total, over three million doses were administered with emergency approval to mink in 2021.</p> <p>Table 1. Distribution of Vaccine by Geographic Location</p> <table border="1"> <thead> <tr> <th>Geographical Location</th> <th>Total Doses</th> <th>Approximate Doses to Kits</th> <th>Approximate Doses to Adults</th> </tr> </thead> <tbody> <tr> <td>Midwest</td> <td>1,955,927</td> <td>1,639,147</td> <td>316,780</td> </tr> <tr> <td>West</td> <td>502,000</td> <td>443,150</td> <td>58,850</td> </tr> <tr> <td>Northwest</td> <td>214,850</td> <td>187,625</td> <td>27,225</td> </tr> <tr> <td>East</td> <td>417,200</td> <td>289,465</td> <td>57,235</td> </tr> <tr> <td>Total</td> <td>3,089,977</td> <td>2,559,387</td> <td>460,090</td> </tr> </tbody> </table> <p>The only reported abnormal health events recorded were deaths, which were within numbers expected at each farm site. The numbers and rates reported were comparable to those observed for animals vaccinated in previous years with different veterinary biologics products.</p>	Geographical Location	Total Doses	Approximate Doses to Kits	Approximate Doses to Adults	Midwest	1,955,927	1,639,147	316,780	West	502,000	443,150	58,850	Northwest	214,850	187,625	27,225	East	417,200	289,465	57,235	Total	3,089,977	2,559,387	460,090
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