



## Summary of Studies Supporting USDA Product Licensure

Establishment Name	Zoetis Inc.
USDA Vet Biologics Establishment Number	190
Product Code	16D1.20
True Name	Feline Rhinotracheitis-Calici-Panleukopenia Vaccine, Modified Live Virus
Tradename(s) / Distributor or Subsidiary (if different from manufacturer)	Feline Guard 3 - Zoetis Australia Pty Ltd Felocell 3 - No distributor specified Felocell 3 - Zoetis Argentina Felocell 3 - Zoetis Mexico Felocell 3 - Zoetis New Zealand Ltd Felocell 3 - Zoetis South Africa Ltd Felocell CVR - No distributor specified Felocell CVR - Zoetis (Thailand) Limited Felocell CVR - Zoetis Inc. Felocell CVR - Zoetis Industria Produtos Veterinarios Ltda. Felocell CVR - Zoetis Japan Inc. Felocell CVR - Zoetis Russia Vanguard Feline RCP - No distributor specified Zoetis Mexico
Date of Compilation Summary	July 20, 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>	Feline Calicivirus																				
<b>Study Purpose</b>	Demonstrate efficacy against feline calicivirus																				
<b>Product Administration</b>	Two 1ml doses, administered subcutaneously, 3 weeks apart.																				
<b>Study Animals</b>	Study involved 20 vaccinates cats for vaccination and 10 controls. Cats at initial vaccination were 9-12 weeks of age.																				
<b>Challenge Description</b>	Feline Calicivirus challenge was administered into the nose, eyes and mouth 6 weeks after the initial vaccination.																				
<b>Interval observed after challenge</b>	During the 13-day post-challenge, all vaccinate and controls were observed for temperatures and clinical symptoms.																				
<b>Results</b>	<p>A numerical value key was prepared for evaluating clinical symptoms and is as follows:</p> <table border="1" data-bbox="486 884 1484 1332"> <thead> <tr> <th>Clinical Observations</th> <th>Numerical Value</th> </tr> </thead> <tbody> <tr> <td>Normal</td> <td>1</td> </tr> <tr> <td>Mouth ulcer &lt;3 mm</td> <td>2</td> </tr> <tr> <td>Mouth ulcers 2-3 &lt;3 mm, or 1 ulcer &gt;3mm</td> <td>3</td> </tr> <tr> <td>More than 3 distinct ulcers, or ulcers with early erosion</td> <td>4</td> </tr> <tr> <td>Mouth ulcers with excessive erosion</td> <td>5</td> </tr> <tr> <td>Eroded mouth ulcers with bleeding and/or salivation</td> <td>6</td> </tr> <tr> <td>Mouth and/or nasal erosions with anorexia and depression</td> <td>7</td> </tr> <tr> <td>Labored breathing and/or pneumonia</td> <td>9</td> </tr> <tr> <td>Death</td> <td>10</td> </tr> </tbody> </table> <p>Data table is appended to end of this summary.</p>	Clinical Observations	Numerical Value	Normal	1	Mouth ulcer <3 mm	2	Mouth ulcers 2-3 <3 mm, or 1 ulcer >3mm	3	More than 3 distinct ulcers, or ulcers with early erosion	4	Mouth ulcers with excessive erosion	5	Eroded mouth ulcers with bleeding and/or salivation	6	Mouth and/or nasal erosions with anorexia and depression	7	Labored breathing and/or pneumonia	9	Death	10
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Death	10																				
<b>USDA Approval Date</b>	9/22/1978																				

Clinical Score By Post-Challenge Day														
	Day 0	Day 1	Day 2	Day 3	Day 4	Day 5	Day 6	Day 7	Day 8	Day 9	Day 10	Day 11	Day 12	Day 13
Vacc 1	1	1	1	1	1	1	1	1	1	1	1	1	1	1
Vacc 2	1	1	1	1	1	1	1	1	1	1	1	1	1	1
Vacc 3	1	1	1	1	1	2	2	2	3	3	2	1	1	1
Vacc 4	1	1	1	1	1	1	1	1	1	1	1	1	1	1
Vacc 5	1	1	1	1	1	1	1	1	1	1	1	1	1	1
Vacc 6	1	1	1	1	1	1	1	1	1	1	1	1	1	1
Vacc 7	1	1	1	1	1	1	1	1	1	1	1	1	1	1
Vacc 8	1	1	1	1	1	1	1	1	1	1	1	1	1	1
Vacc 9	1	1	1	1	3	3	3	3	3	3	3	3	2	2
Vacc 10	1	1	1	1	1	1	1	1	1	1	1	1	1	1
Vacc 11	1	1	1	1	1	1	1	1	1	1	1	1	1	1
Vacc 12	1	1	1	1	1	1	1	1	1	1	1	1	1	1
Vacc 13	1	1	1	1	1	1	1	1	1	1	1	1	1	1
Vacc 14	1	1	1	1	1	1	1	1	1	1	1	1	1	1
Vacc 15	1	1	1	1	1	1	1	1	1	1	1	1	1	1
Vacc 16	1	1	1	1	1	1	1	1	1	1	1	1	1	1
Vacc 17	1	1	1	1	1	1	1	1	1	1	1	1	1	1
Vacc 18	1	1	1	1	1	1	1	1	1	1	1	1	1	1
Vacc 19	1	1	1	1	1	1	1	1	1	1	1	1	1	1
Vacc 20	1	1	1	1	1	1	1	1	1	1	1	1	1	1
Control 1	1	1	4	6	6	8	8	6	5	4	4	4	3	3
Control 2	1	1	1	2	3	3	3	3	3	3	3	2	2	2
Control 3	1	1	1	3	3	4	3	3	3	2	2	2	1	1
Control 4	1	1	1	2	2	3	3	3	3	3	3	3	3	1
Control 5	1	1	1	3	6	6	5	5	5	5	5	4	3	4
Control 6	1	1	1	2	2	2	2	2	2	2	2	2	1	1
Control 7	1	1	1	1	1	2	4	4	4	4	4	4	3	2
Control 8	1	1	1	1	6	4	4	4	4	4	3	2	1	1
Control 9	1	1	1	1	1	1	1	1	1	1	1	1	3	2
Control 10	1	1	1	3	3	3	3	3	3	3	2	2	2	2

<b>Study Type</b>	Efficacy
<b>Pertaining to</b>	Feline Rhinotracheitis Virus
<b>Study Purpose</b>	To demonstrate efficacy against Feline Rhinotracheitis Virus
<b>Product Administration</b>	Subcutaneous
<b>Study Animals</b>	Cats
<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 20, 1981

<b>Study Type</b>	Efficacy
<b>Pertaining to</b>	Feline Panleukopenia virus
<b>Study Purpose</b>	To demonstrate efficacy against Feline Panleukopenia virus
<b>Product Administration</b>	Subcutaneous and intramuscular
<b>Study Animals</b>	Cats
<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>	November 21, 1979

<b>Study Type</b>	Efficacy
<b>Pertaining to</b>	Feline Panleukopenia Virus
<b>Study Purpose</b>	To demonstrate efficacy against Feline Panleukopenia Virus
<b>Product Administration</b>	
<b>Study Animals</b>	Cats
<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>	17 February, 1972

<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>	
<b>Study Animals</b>	Cats
<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>	12 December 1978