



Summary of Studies Supporting USDA Product Licensure

Establishment Name	Biomune Company
USDA Vet Biologics Establishment Number	368
Product Code	1045.21
True Name	Avian Reovirus Vaccine, Killed Virus
Tradename(s) / Distributor or Subsidiary (if different from manufacturer)	
Date of Compilation Summary	September 13, 2019

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	Demonstrate safety of product under typical use conditions.																																																																																									
Product Administration	One dose administered via the intramuscular route.																																																																																									
Study Animals	Commercial broiler breeder chickens at 12 weeks of age via the intramuscular route. 72,129 chickens were vaccinated with Product and 68,801 chickens were kept as controls.																																																																																									
Challenge Description	Not applicable																																																																																									
Interval observed after challenge	Animals were observed daily for mortality through no less than 21 days after vaccination.																																																																																									
Results	<table border="1"> <thead> <tr> <th rowspan="2">Location</th> <th rowspan="2">Vaccine Serial No./ Treatment Group</th> <th rowspan="2">House No.</th> <th rowspan="2">No. of Chickens Placed</th> <th rowspan="2">No. Days observed</th> <th colspan="2">Mortality</th> <th rowspan="2">Observations</th> </tr> <tr> <th>Total</th> <th>Percent</th> </tr> </thead> <tbody> <tr> <td rowspan="2">KY</td> <td>Product</td> <td>2</td> <td>24,914</td> <td>23</td> <td>142</td> <td>0.57</td> <td>No adverse reactions</td> </tr> <tr> <td>Control</td> <td>1</td> <td>23,762</td> <td>38¹</td> <td>330</td> <td>1.39</td> <td>No adverse reactions</td> </tr> <tr> <td rowspan="2">AL</td> <td>Product</td> <td>2</td> <td>27,633</td> <td>22</td> <td>93</td> <td>0.34</td> <td>No adverse reactions</td> </tr> <tr> <td>Control</td> <td>1</td> <td>27,482</td> <td>44¹</td> <td>178</td> <td>0.65</td> <td>No adverse reactions</td> </tr> <tr> <td rowspan="6">PA</td> <td>Product</td> <td>Bottom</td> <td>8,431</td> <td>21</td> <td>37</td> <td>0.44</td> <td>No adverse reactions</td> </tr> <tr> <td>Product</td> <td>1</td> <td>11,151</td> <td>24</td> <td>34</td> <td>0.30</td> <td>No adverse reactions</td> </tr> <tr> <td>Total</td> <td>NA</td> <td>19,582</td> <td>NA</td> <td>71</td> <td>0.36</td> <td>NA</td> </tr> <tr> <td>Control</td> <td>Top</td> <td>8,690</td> <td>21</td> <td>73</td> <td>0.84</td> <td>No adverse reactions</td> </tr> <tr> <td>Control</td> <td>2</td> <td>8,867</td> <td>24</td> <td>27</td> <td>0.30</td> <td>No adverse reactions</td> </tr> <tr> <td>Total</td> <td>NA</td> <td>17,557</td> <td>NA</td> <td>100</td> <td>0.57</td> <td>NA</td> </tr> </tbody> </table> <p>¹ Observation period is longer due to the older age of the control group (14-18 weeks of age) at time of vaccination with the product.</p> <p>No adverse reactions attributable to the vaccine were recorded.</p>							Location	Vaccine Serial No./ Treatment Group	House No.	No. of Chickens Placed	No. Days observed	Mortality		Observations	Total	Percent	KY	Product	2	24,914	23	142	0.57	No adverse reactions	Control	1	23,762	38 ¹	330	1.39	No adverse reactions	AL	Product	2	27,633	22	93	0.34	No adverse reactions	Control	1	27,482	44 ¹	178	0.65	No adverse reactions	PA	Product	Bottom	8,431	21	37	0.44	No adverse reactions	Product	1	11,151	24	34	0.30	No adverse reactions	Total	NA	19,582	NA	71	0.36	NA	Control	Top	8,690	21	73	0.84	No adverse reactions	Control	2	8,867	24	27	0.30	No adverse reactions	Total	NA	17,557	NA	100	0.57	NA
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