



Summary of Studies Supporting USDA Product Licensure

Establishment Name	Diamond Animal Health, Inc.
USDA Vet Biologics Establishment Number	213
Product Code	2915.00
True Name	Paenibacillus Larvae Bacterin
Tradename(s) / Distributor or Subsidiary (if different from manufacturer)	Dalan Animal Health, Inc. - Diamond Animal Health, Inc. Diamond Animal Health, Inc.
Date of Compilation Summary	January 26, 2023

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	Paenibacillus Larvae Bacterin																									
Study Purpose	Demonstrate safety																									
Product Administration	Queen feed mixed with Paenibacillus Larvae Bacterin administered to cage with queen honeybee eight days before introduction into a new hive																									
Study Animals	Queen honeybee																									
Challenge Description	NA																									
Interval observed after challenge	Observation of queen daily until placed into a hive on Study Day 8 then monitor of the 7-frame nucleus size hive for at least 18 days.																									
Results	<p>Data is presented in the table below.</p> <p><i>Queen and Hive survival</i></p> <table border="1"> <thead> <tr> <th><i>Site - Event</i></th> <th><i>Vaccinates Survived</i></th> <th><i>Vaccinates Total</i></th> <th><i>Controls Survived</i></th> <th><i>Controls Total</i></th> </tr> </thead> <tbody> <tr> <td>Site 1 – Queens survival (Vaccination phase)</td> <td>32</td> <td>32</td> <td>16</td> <td>16</td> </tr> <tr> <td>Site 1 – Hive survival</td> <td>15</td> <td>20</td> <td>7</td> <td>10</td> </tr> <tr> <td>Site 2 – Queens survival (Vaccination phase)</td> <td>15</td> <td>15</td> <td>15</td> <td>15</td> </tr> <tr> <td>Site 2– Hive survival</td> <td>11</td> <td>15</td> <td>10</td> <td>15</td> </tr> </tbody> </table> <p>Honeybee hives are located in natural conditions. Queen bees lay eggs at different rates dependent upon factors such as weather and food-source.</p>	<i>Site - Event</i>	<i>Vaccinates Survived</i>	<i>Vaccinates Total</i>	<i>Controls Survived</i>	<i>Controls Total</i>	Site 1 – Queens survival (Vaccination phase)	32	32	16	16	Site 1 – Hive survival	15	20	7	10	Site 2 – Queens survival (Vaccination phase)	15	15	15	15	Site 2– Hive survival	11	15	10	15
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USDA Approval Date	April 14, 2022																									