



Summary of Studies Supporting USDA Product Licensure

| | |
|---|---|
| Establishment Name | Epitopix, LLC |
| USDA Vet Biologics Establishment Number | 365 |
| Product Code | 2707.02 |
| True Name | Pasteurella Multocida Bacterial Extract |
| Tradename(s) / Distributor or Subsidiary (if different from manufacturer) | Vaxxon SRP Pasteurella - No distributor specified |
| Date of Compilation Summary | January 12, 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.

| Study Type | Efficacy | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
|--|---|-------------------|-----------------|-------------|-------------------|------------|-------------|------------|--------------|-----------|------------|-------|-------------------|--------------|-------|-------------------|-----|-----|-----|-----|----|----|-----|-----|-----|-----|----|----|-----|-----|-----|-----|----|----|-----|-----|-----|-----|----|----|-----|-----|-----|-----|----|----|-----|-----|-----|-----|----|----|-----|-----|-----|-----|----|----|-----|-----|-----|-----|----|----|-----|-----|-----|-----|----|----|-----|-----|-----|-----|----|----|-----|-----|-----|-----|----|----|-----|-----|-----|-----|----|----|-----|----|----|-----|----|----|-----|-----|-----|-----|----|----|-----|----|----|-----|----|----|-----|----|----|-----|----|----|-----|-----|-----|-----|----|----|-----|-----|-----|-----|----|----|-----|-----|-----|-----|----|----|-----|----|----|-----|----|----|
| Pertaining to | <i>Pasteurella multocida</i> | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Study Purpose | To demonstrate effectiveness against <i>Pasteurella multocida</i> serotype 1 | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Product Administration | Two doses administered at an 3-week interval by subcutaneous injection. | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Study Animals | Twelve week old chickens were randomly assigned to one of two treatments, vaccinates (20 birds) or placebo (20 birds). | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Challenge Description | Twenty chickens in each group were challenged with <i>Pasteurella multocida</i> 14 days following second vaccination. | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Interval observed after challenge | The chickens were monitored for 14 days after challenge for mortality. | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Results | <p>The primary outcome was mortality as per 9 CFR 113.117.</p> <p>Summary</p> <table border="1"> <thead> <tr> <th></th> <th>Survived</th> <th>Died</th> </tr> </thead> <tbody> <tr> <td>Placebo</td> <td>4/20 (20%)</td> <td>16/20 (80%)</td> </tr> <tr> <td>Vaccinates</td> <td>20/20 (100%)</td> <td>0/20 (0%)</td> </tr> </tbody> </table> <p>Raw Data Mortality due to <i>Pasteurella multocida</i>, as confirmed by culture</p> <table border="1"> <thead> <tr> <th>Placebo ID</th> <th>Death</th> <th>Culture confirmed</th> <th>Vaccinate ID</th> <th>Death</th> <th>Culture confirmed</th> </tr> </thead> <tbody> <tr><td>421</td><td>Yes</td><td>Yes</td><td>423</td><td>No</td><td>No</td></tr> <tr><td>422</td><td>Yes</td><td>Yes</td><td>427</td><td>No</td><td>No</td></tr> <tr><td>424</td><td>Yes</td><td>Yes</td><td>428</td><td>No</td><td>No</td></tr> <tr><td>425</td><td>Yes</td><td>Yes</td><td>429</td><td>No</td><td>No</td></tr> <tr><td>426</td><td>Yes</td><td>Yes</td><td>430</td><td>No</td><td>No</td></tr> <tr><td>432</td><td>Yes</td><td>Yes</td><td>431</td><td>No</td><td>No</td></tr> <tr><td>434</td><td>Yes</td><td>Yes</td><td>433</td><td>No</td><td>No</td></tr> <tr><td>440</td><td>Yes</td><td>Yes</td><td>435</td><td>No</td><td>No</td></tr> <tr><td>444</td><td>Yes</td><td>Yes</td><td>436</td><td>No</td><td>No</td></tr> <tr><td>445</td><td>Yes</td><td>Yes</td><td>437</td><td>No</td><td>No</td></tr> <tr><td>447</td><td>Yes</td><td>Yes</td><td>438</td><td>No</td><td>No</td></tr> <tr><td>448</td><td>Yes</td><td>Yes</td><td>439</td><td>No</td><td>No</td></tr> <tr><td>450</td><td>No</td><td>No</td><td>441</td><td>No</td><td>No</td></tr> <tr><td>451</td><td>Yes</td><td>Yes</td><td>442</td><td>No</td><td>No</td></tr> <tr><td>452</td><td>No</td><td>No</td><td>443</td><td>No</td><td>No</td></tr> <tr><td>454</td><td>No</td><td>No</td><td>449</td><td>No</td><td>No</td></tr> <tr><td>455</td><td>Yes</td><td>Yes</td><td>453</td><td>No</td><td>No</td></tr> <tr><td>456</td><td>Yes</td><td>Yes</td><td>457</td><td>No</td><td>No</td></tr> <tr><td>459</td><td>Yes</td><td>Yes</td><td>458</td><td>No</td><td>No</td></tr> <tr><td>462</td><td>No</td><td>No</td><td>460</td><td>No</td><td>No</td></tr> </tbody> </table> <p>All vaccinates survived challenge with <i>Pasteurella multocida</i>, Type 1.</p> | | Survived | Died | Placebo | 4/20 (20%) | 16/20 (80%) | Vaccinates | 20/20 (100%) | 0/20 (0%) | Placebo ID | Death | Culture confirmed | Vaccinate ID | Death | Culture confirmed | 421 | Yes | Yes | 423 | No | No | 422 | Yes | Yes | 427 | No | No | 424 | Yes | Yes | 428 | No | No | 425 | Yes | Yes | 429 | No | No | 426 | Yes | Yes | 430 | No | No | 432 | Yes | Yes | 431 | No | No | 434 | Yes | Yes | 433 | No | No | 440 | Yes | Yes | 435 | No | No | 444 | Yes | Yes | 436 | No | No | 445 | Yes | Yes | 437 | No | No | 447 | Yes | Yes | 438 | No | No | 448 | Yes | Yes | 439 | No | No | 450 | No | No | 441 | No | No | 451 | Yes | Yes | 442 | No | No | 452 | No | No | 443 | No | No | 454 | No | No | 449 | No | No | 455 | Yes | Yes | 453 | No | No | 456 | Yes | Yes | 457 | No | No | 459 | Yes | Yes | 458 | No | No | 462 | No | No | 460 | No | No |
| | Survived | Died | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Placebo | 4/20 (20%) | 16/20 (80%) | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Vaccinates | 20/20 (100%) | 0/20 (0%) | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Placebo ID | Death | Culture confirmed | Vaccinate ID | Death | Culture confirmed | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| 421 | Yes | Yes | 423 | No | No | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| 422 | Yes | Yes | 427 | No | No | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| 424 | Yes | Yes | 428 | No | No | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| 425 | Yes | Yes | 429 | No | No | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| 426 | Yes | Yes | 430 | No | No | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| 432 | Yes | Yes | 431 | No | No | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| 434 | Yes | Yes | 433 | No | No | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| 440 | Yes | Yes | 435 | No | No | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| 444 | Yes | Yes | 436 | No | No | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| 445 | Yes | Yes | 437 | No | No | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| 447 | Yes | Yes | 438 | No | No | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| 448 | Yes | Yes | 439 | No | No | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| 450 | No | No | 441 | No | No | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| 451 | Yes | Yes | 442 | No | No | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| 452 | No | No | 443 | No | No | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| 454 | No | No | 449 | No | No | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| 455 | Yes | Yes | 453 | No | No | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| 456 | Yes | Yes | 457 | No | No | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| 459 | Yes | Yes | 458 | No | No | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| 462 | No | No | 460 | No | No | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| USDA Approval Date | August 22, 2019 | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |

| Study Type | Safety | | | | | | | | | | | | | | | | | | | | | | | | | | | |
|--|--|--|--|--------------------|--------------------|--------------|--------|-----|------|----------------|--------|-----|------|-----------|---------------------|--|--|--------------------|----------------|--------|----|----|------|---------|--------|----|----|------|
| Pertaining to | ALL | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Study Purpose | To demonstrate safety of the product under field conditions. | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Product Administration | Two doses administered at a 6-9 week interval by a subcutaneous route of injection. | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Study Animals | A total of 115,575 chickens, 12 weeks of age, were enrolled in the study and housed at commercial egg or layer operations in three geographically distinct regions of the United States. | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Challenge Description | Not applicable | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Interval observed after challenge | No challenge. Chickens were observed for adverse events and mortality for 21 days after each of two vaccinations given 6-9 weeks apart. | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Results | <p>Summary No adverse events were observed in any chickens after vaccination. Mortality rates were higher in controls than vaccinates in all regions.</p> <table border="1"> <thead> <tr> <th>Treatment</th> <th>Number of Birds Tested</th> <th>Total Mortality</th> <th>Mortality Rate (%)</th> </tr> </thead> <tbody> <tr> <td>Test Vaccine</td> <td>59,033</td> <td>286</td> <td>0.48</td> </tr> <tr> <td>Control houses</td> <td>56,542</td> <td>354</td> <td>0.63</td> </tr> </tbody> </table> <p>Mortality by Region</p> <p>Region 1:</p> <table border="1"> <thead> <tr> <th>Treatment</th> <th>Starting Population</th> <th>Mortality post 1st Vaccination</th> <th>Mortality Post 2nd Vaccination</th> <th>Mortality Rate (%)</th> </tr> </thead> <tbody> <tr> <td>Vaccine Serial</td> <td>32,177</td> <td>59</td> <td>29</td> <td>0.27</td> </tr> <tr> <td>Control</td> <td>29,516</td> <td>90</td> <td>23</td> <td>0.38</td> </tr> </tbody> </table> | Treatment | Number of Birds Tested | Total Mortality | Mortality Rate (%) | Test Vaccine | 59,033 | 286 | 0.48 | Control houses | 56,542 | 354 | 0.63 | Treatment | Starting Population | Mortality post 1 st Vaccination | Mortality Post 2 nd Vaccination | Mortality Rate (%) | Vaccine Serial | 32,177 | 59 | 29 | 0.27 | Control | 29,516 | 90 | 23 | 0.38 |
| Treatment | Number of Birds Tested | Total Mortality | Mortality Rate (%) | | | | | | | | | | | | | | | | | | | | | | | | | |
| Test Vaccine | 59,033 | 286 | 0.48 | | | | | | | | | | | | | | | | | | | | | | | | | |
| Control houses | 56,542 | 354 | 0.63 | | | | | | | | | | | | | | | | | | | | | | | | | |
| Treatment | Starting Population | Mortality post 1 st Vaccination | Mortality Post 2 nd Vaccination | Mortality Rate (%) | | | | | | | | | | | | | | | | | | | | | | | | |
| Vaccine Serial | 32,177 | 59 | 29 | 0.27 | | | | | | | | | | | | | | | | | | | | | | | | |
| Control | 29,516 | 90 | 23 | 0.38 | | | | | | | | | | | | | | | | | | | | | | | | |

Region 2:

| Treatment | Starting Population | Mortality post 1st Vaccination | Mortality Post 2nd Vaccination | Mortality Rate (%) |
|-----------------------|----------------------------|--|--|---------------------------|
| Vaccine Serial | 11,595 | 31 | 35 | 0.57 |
| Control | 11,758 | 28 | 49 | 0.65 |

Region 3:

| Treatment | Starting Population | Mortality post 1st Vaccination | Mortality Post 2nd Vaccination | Mortality Rate (%) |
|-----------------------|----------------------------|--|--|---------------------------|
| Vaccine Serial | 15,261 | 45 | 87 | 0.86 |
| Control | 15,268 | 59 | 105 | 1.07 |

**USDA
Approval Date**

December 2, 2020