



## Summary of Studies Supporting USDA Product Licensure

|                                                                            |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             |
|----------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Establishment Name                                                         | Boehringer Ingelheim Animal Health USA Inc.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 |
| USDA Vet Biologics Establishment Number                                    | 124                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         |
| Product Code                                                               | 10L1.01                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     |
| True Name                                                                  | Lawsonia Intracellularis Vaccine, Avirulent Live Culture                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    |
| Tradenname(s) / Distributor or Subsidiary (if different from manufacturer) | <p>Enterisol Iletis - Boehringer Ingelheim (Canada) Ltd.<br/> Enterisol Iletis - Boehringer Ingelheim (Schweiz) GmbH, Switzerland<br/> Enterisol Iletis - Boehringer Ingelheim (Tha) Ltd.<br/> Enterisol Iletis - Boehringer Ingelheim Animal Health Argentina S.A.<br/> Enterisol Iletis - Boehringer Ingelheim Animal Health Australia Pty. Ltd.<br/> Enterisol Iletis - Boehringer Ingelheim Animal Health Korea, Ltd.<br/> Enterisol Iletis - Boehringer Ingelheim Animal Health Mexico<br/> Enterisol Iletis - Boehringer Ingelheim Animal Health Philippines, Inc.<br/> Enterisol Iletis - Boehringer Ingelheim Animal Health Portugal<br/> Enterisol Iletis - Boehringer Ingelheim Animal Health South Africa (Pty) Ltd/ (Edms) Bpk<br/> Enterisol Iletis - Boehringer Ingelheim Animal Health do Brasil Ltda<br/> Enterisol Iletis - Boehringer Ingelheim Russia<br/> Enterisol Iletis - Boehringer Ingelheim Vetmedica GmbH<br/> Enterisol Iletis - Boehringer Ingelheim Vetmedica Korea, Ltd.<br/> Enterisol Iletis - No distributor specified<br/> Enterisol Iletis vet - Boehringer Ingelheim Vetmedica GmbH<br/> Enterisol Iletis vet - No distributor specified<br/> Oralisol - Boehringer Ingelheim Ltda</p> |
| Date of Compilation Summary                                                | February 13, 2020                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |

**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>                     | Lawsonia Intracellularis                                                                                                                                                                                                                                                                                        |
| <b>Study Purpose</b>                     | Demonstration of Efficacy against <i>Lawsonia intracellularis</i> including gross and microscopic lesions in the ileum/colon                                                                                                                                                                                    |
| <b>Product Administration</b>            | Administered orally by oral drench                                                                                                                                                                                                                                                                              |
| <b>Study Animals</b>                     | Twenty-five pigs, 3 weeks of age or older, divided into 15 vaccinates and 10 controls                                                                                                                                                                                                                           |
| <b>Challenge Description</b>             | Pigs were challenged with live <i>Lawsonia intracellularis</i> 3 weeks after vaccination.                                                                                                                                                                                                                       |
| <b>Interval observed after challenge</b> | Pigs were observed daily for clinical signs of <i>Lawsonia intracellularis</i> for 21 days after challenge, and then tissues were examined grossly and microscopically.                                                                                                                                         |
| <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>                | July 11, 2003                                                                                                                                                                                                                                                                                                   |

|                                          |                                                                                                                                                                                                                                                                                                                 |
|------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Study Type</b>                        | Efficacy                                                                                                                                                                                                                                                                                                        |
| <b>Pertaining to</b>                     | Lawsonia Intracellularis                                                                                                                                                                                                                                                                                        |
| <b>Study Purpose</b>                     | Demonstration of 3 week onset of immunity against <i>Lawsonia intracellularis</i>                                                                                                                                                                                                                               |
| <b>Product Administration</b>            | Administered orally in drinking water                                                                                                                                                                                                                                                                           |
| <b>Study Animals</b>                     | Pigs                                                                                                                                                                                                                                                                                                            |
| <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>                | June 7, 2004                                                                                                                                                                                                                                                                                                    |

|                                          |                                                                                                                                                                                                                                                                                                                 |
|------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Study Type</b>                        | Safety                                                                                                                                                                                                                                                                                                          |
| <b>Pertaining to</b>                     | Lawsonia Intracellularis                                                                                                                                                                                                                                                                                        |
| <b>Study Purpose</b>                     | To demonstrate safety under field conditions                                                                                                                                                                                                                                                                    |
| <b>Product Administration</b>            | Administered orally in drinking water                                                                                                                                                                                                                                                                           |
| <b>Study Animals</b>                     | 1279 pigs 3-4 weeks of age, divided into 640 vaccinates and 639 controls                                                                                                                                                                                                                                        |
| <b>Challenge Description</b>             | N/A                                                                                                                                                                                                                                                                                                             |
| <b>Interval observed after challenge</b> | N/A                                                                                                                                                                                                                                                                                                             |
| <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>                | June 25, 2003                                                                                                                                                                                                                                                                                                   |