



Summary of Studies Supporting USDA Product Licensure

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| Establishment Name | Elanco US Inc. |
| USDA Vet Biologics Establishment Number | 196 |
| Product Code | 2674.00 |
| True Name | Actinobacillus Pleuropneumoniae-Glaesserella Parasuis-Pasteurella Multocida Bacterin |
| Tradename(s) / Distributor or Subsidiary (if different from manufacturer) | Elanco US Inc. Parapleuro Shield P - CONG TY CO PHAN THU ONG MAI VA SAN XUAT THUOC THU Y THINH A - Elanco US Inc. Parapleuro Shield P - Elanco Philippines, Inc - Elanco US Inc. Parapleuro Shield P - Elanco Saude Animal Ltda. (Brazil) Parapleuro Shield P - Elanco Saude Animal Ltda. (Brazil) - Elanco US Inc. Parapleuro Shield P - Elanco US Inc. Parapleuro Shield P - No distributor specified |
| Date of Compilation Summary | September 21, 2022 |

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.

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| Study Type | Efficacy |
| Pertaining to | Actinobacillus Pleuropneumoniae serotype 5 & 7 |
| Study Purpose | To demonstrate effectiveness against <i>Actinobacillus pleuropneumoniae</i> |
| Product Administration | 2 doses 2 weeks apart |
| Study Animals | Swine |
| Challenge Description | |
| Interval observed after challenge | |
| Results | 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 require publication of data submitted after that date. |
| USDA Approval Date | December 17, 1985 |

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| Study Type | Efficacy |
| Pertaining to | <i>Haemophilus parasuis</i> |
| Study Purpose | To demonstrate effectiveness against <i>Haemophilus parasuis</i> |
| Product Administration | |
| Study Animals | Porcine |
| Challenge Description | |
| Interval observed after challenge | |
| Results | 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 require publication of data submitted after that date. |
| USDA Approval Date | October 27, 1986 |

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| Study Type | Efficacy |
| Pertaining to | <i>Pasteurella multocida</i> |
| Study Purpose | To demonstrate effectiveness against <i>Pasteurella multocida</i> |
| Product Administration | |
| Study Animals | |
| Challenge Description | |
| Interval observed after challenge | |
| Results | 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 require publication of data submitted after that date. |
| USDA Approval Date | April 23, 1984 |

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| Study Type | Efficacy |
| Pertaining to | Actinobacillus Pleuropneumoniae serotype 1 |
| Study Purpose | To demonstrate effectiveness against <i>Actinobacillus pleuropneumoniae</i> |
| Product Administration | 2 doses 2 weeks apart |
| Study Animals | Swine |
| Challenge Description | |
| Interval observed after challenge | |
| Results | 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 require publication of data submitted after that date. |
| USDA Approval Date | December 17, 1985 |

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| Study Type | Safety |
| Pertaining to | All |
| Study Purpose | To demonstrate safety under typical field conditions |
| Product Administration | |
| Study Animals | Porcine |
| Challenge Description | |
| Interval observed after challenge | |
| Results | 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 require publication of data submitted after that date. |
| USDA Approval Date | October 27, 1986 |