# Summary of Studies Supporting USDA Product Licensure

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| Establishment Name | Intervet Inc. |
| USDA Vet Biologics Establishment Number | 165A |
| Product Code | 7890.01 |
| True Name | Clostridium Perfringens Type C-Escherichia Coli Bacterin-Toxoid |
| Tradename(s) / Distributor or Subsidiary (if different from manufacturer) | ProSystem CE - Intervet, Inc.<br>ProSystem CE - Merck Animal Health |
| Date of Compilation Summary | October 25, 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.**

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| **Study Type** | Efficacy |
| **Pertaining to** | *Clostridium perfringens Type C toxoid* |
| **Study Purpose** | To demonstrate the efficacy against *C. perfringens* type C fraction in nursing piglets when administered to pregnant swine |
| **Product Administration** | |
| **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 requires publication of data submitted after that date. |
| **USDA Approval Date** | June 10, 1988 |

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|---|---|
| **Study Type** | Efficacy |
| **Pertaining to** | Clostridium perfringens |
| **Study Purpose** | Establish efficacy of *Clostridium perfringens* fraction in nursing piglets when administered to pregnant swine |
| **Product Administration** | |
| **Study Animals** | Pregnant Gilts and Sows |
| **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. Study data, however, are no longer available. |
| **USDA Approval Date** | June 10, 1988 |

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|---|---|
| **Study Type** | Efficacy |
| **Pertaining to** | *Escherichia coli* 987P |
| **Study Purpose** | Establish efficacy of *E. coli* 987P fraction in nursing piglets when administered to pregnant swine |
| **Product Administration** | |
| **Study Animals** | Pregnant Gilts and Sow |
| **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. Study data, however, are no longer available. |
| **USDA Approval Date** | June 10, 1988 |

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|---|---|
| **Study Type** | Efficacy |
| **Pertaining to** | *Escherichia coli* F41 |
| **Study Purpose** | Establish efficacy of *E. coli* F41 fraction in nursing piglets when administered to pregnant swine |
| **Product Administration** | |
| **Study Animals** | Pregnant Gilts and Sows |
| **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. Study data, however, are no longer available. |
| **USDA Approval Date** | June 10, 1988 |

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|---|---|
| **Study Type** | Efficacy |
| **Pertaining to** | *Escherichia coli* K88 |
| **Study Purpose** | Establish efficacy of *E. coli* K88 fraction in nursing piglets when administered to pregnant swine |
| **Product Administration** | |
| **Study Animals** | Pregnant Gilts and Sows |
| **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. Study data, however, are no longer available. |
| **USDA Approval Date** | June 10, 1988 |

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|---|---|
| **Study Type** | Efficacy |
| **Pertaining to** | *Escherichia coli* K99 |
| **Study Purpose** | Establish efficacy of *E. coli* K99 fraction in nursing piglets when administered to pregnant swine |
| **Product Administration** | |
| **Study Animals** | Pregnant Gilts and Sows |
| **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. Study data, however, are no longer available. |
| **USDA Approval Date** | June 10, 1988 |

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|---|---|
| **Study Type** | Efficacy |
| **Pertaining to** | *Escherichia coli 987P* |
| **Study Purpose** | Establish efficacy of the vaccine against colibacillosis including effect on mortality and clinical disease caused by *E. coli* 987P in nursing piglets |
| **Product Administration** | |
| **Study Animals** | Nursing piglets farrowed from pregnant swine administered product |
| **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. |
| **USDA Approval Date** | June 10, 1988 |

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| **Study Type** | Safety |
| **Pertaining to** | All |
| **Study Purpose** | Demonstrate safety under typical field conditions |
| **Product Administration** | |
| **Study Animals** | Pregnant sows and gilts |
| **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. |
| **USDA Approval Date** | June 10, 1988 |