

Summary of Studies Supporting USDA Product Licensure

| Establishment Name | Boehringer Ingelheim Animal Health USA Inc. |
|---|---|
| USDA Vet Biologics Establishment Number | 124 |
| Product Code | 8201.01 |
| True Name | Clostridium Perfringens Types C & D Toxoid |
| Tradename(s) / Distributor or Subsidiary (if different from manufacturer) | Bar Vac CD - No distributor specified |
| Date of Compilation Summary | September 04, 2019 |

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 |
| Study Purpose | Demonstration of efficacy against Clostridium perfringens Type C |
| 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 requires publication of data submitted after that date. |
| USDA Approval Date | December 16, 1977 |

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| Study Type | Efficacy |
|-------------------------------|---|
| Pertaining to | Clostridium perfringens Type D |
| Study Purpose | Demonstration of efficacy against Clostridium perfringens Type D |
| 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 requires publication of data submitted after that date. |
| USDA Approval Date | December 16, 1977 |

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| Study Type | Safety |
|-------------------------------|---|
| Pertaining to | All fractions |
| Study Purpose | To demonstrate safety under field conditions |
| 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. Study data, however, are no longer available. |
| USDA Approval Date | December 16, 1977 |

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| Study Type | Safety |
|-------------------------------|---|
| Pertaining to | All fractions |
| Study Purpose | To demonstrate safety under field conditions |
| Product Administration | |
| Study Animals | Bovine (cattle) including pregnant cattle |
| 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 | February 10, 1998 |

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