



Summary of Studies Supporting USDA Product Licensure

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| Establishment Name | Zoetis Inc. |
| USDA Vet Biologics Establishment Number | 190 |
| Product Code | 7410.00 |
| True Name | Clostridium Chauvoei-Septicum-Novyi-Sordellii-Perfringens Types C & D Bacterin-Toxoid |
| Tradename(s) / Distributor or Subsidiary (if different from manufacturer) | Ultrabac 7 - No distributor specified Ultrabac 7 - Zoetis Mexico |
| Date of Compilation Summary | September 02, 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 | <i>Clostridium chauvoei</i> |
| Study Purpose | Demonstrate effectiveness against <i>Clostridium chauvoei</i> |
| Product Administration | |
| Study Animals | Bovine |
| 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 | July 1, 1997 |

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| Study Type | Efficacy |
| Pertaining to | <i>Clostridium chauvoei</i> |
| Study Purpose | Demonstrate effectiveness against <i>Clostridium chauvoei</i> |
| Product Administration | |
| Study Animals | Ovine |
| 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 | July 1, 1997 |

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| Study Type | Efficacy |
| Pertaining to | <i>Clostridium novyi</i> |
| Study Purpose | Demonstrate effectiveness against <i>Clostridium novyi</i> |
| Product Administration | |
| Study Animals | Bovine |
| 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 | July 1, 1997 |

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|--|---|
| Study Type | Efficacy |
| Pertaining to | <i>Clostridium novyi</i> |
| Study Purpose | Demonstrate effectiveness against <i>Clostridium novyi</i> |
| Product Administration | |
| Study Animals | Ovine |
| 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 | July 1, 1997 |

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|--|---|
| Study Type | Efficacy |
| Pertaining to | <i>Clostridium perfringens</i> Type C |
| Study Purpose | Demonstrate effectiveness against <i>Clostridium perfringens</i> Type C |
| Product Administration | |
| Study Animals | Bovine |
| 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 | July 1, 1997 |

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|--|---|
| Study Type | Efficacy |
| Pertaining to | <i>Clostridium perfringens</i> Type C |
| Study Purpose | Demonstrate effectiveness against <i>Clostridium perfringens</i> Type C |
| Product Administration | |
| Study Animals | Ovine |
| 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 | July 1, 1997 |

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|--|---|
| Study Type | Efficacy |
| Pertaining to | <i>Clostridium perfringens</i> Type D |
| Study Purpose | Demonstrate effectiveness against <i>Clostridium perfringens</i> Type D |
| Product Administration | |
| Study Animals | Bovine |
| 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 | July 1, 1997 |

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|--|---|
| Study Type | Efficacy |
| Pertaining to | <i>Clostridium perfringens</i> Type D |
| Study Purpose | Demonstrate effectiveness against <i>Clostridium perfringens</i> Type D |
| Product Administration | |
| Study Animals | Ovine |
| 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 | July 1, 1997 |

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|--|---|
| Study Type | Efficacy |
| Pertaining to | <i>Clostridium septicum</i> |
| Study Purpose | Demonstrate effectiveness against <i>Clostridium septicum</i> |
| Product Administration | |
| Study Animals | Bovine |
| 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 | July 1, 1997 |

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|--|---|
| Study Type | Efficacy |
| Pertaining to | <i>Clostridium septicum</i> |
| Study Purpose | Demonstrate effectiveness against <i>Clostridium septicum</i> |
| Product Administration | |
| Study Animals | Ovine |
| 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 | July 1, 1997 |

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| Study Type | Efficacy |
| Pertaining to | <i>Clostridium sordelli</i> |
| Study Purpose | Demonstrate effectiveness against <i>Clostridium sordelli</i> |
| Product Administration | |
| Study Animals | Bovine |
| 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 | July 1, 1997 |

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|--|---|
| Study Type | Efficacy |
| Pertaining to | <i>Clostridium sordelli</i> |
| Study Purpose | Demonstrate effectiveness against <i>Clostridium sordelli</i> |
| Product Administration | |
| Study Animals | Ovine |
| 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 | July 1, 1997 |

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| Study Type | Safety |
| Pertaining to | ALL |
| Study Purpose | Demonstrate safety under typical field conditions |
| Product Administration | Subcutaneous |
| Study Animals | Bovine |
| 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 | August 01, 1984 |

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|--|---|
| Study Type | Safety |
| Pertaining to | ALL |
| Study Purpose | Demonstrate safety under typical field conditions |
| Product Administration | Subcutaneous |
| Study Animals | Bovine |
| 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 | July 1, 1997 |

| | |
|--|---|
| Study Type | Safety |
| Pertaining to | ALL |
| Study Purpose | Demonstrate safety under typical field conditions |
| Product Administration | |
| Study Animals | Ovine |
| 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 | August 6, 1984 |