# Summary of Studies Supporting USDA Product Licensure

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| Establishment Name | Neogen Corporation |
| USDA Vet Biologics Establishment Number | 302 |
| Product Code | 8010.00 |
| True Name | Clostridium Botulinum Type B Toxoid |
| Tradename(s) / Distributor or Subsidiary (if different from manufacturer) | BotVax B - No distributor specified |
| Date of Compilation Summary | November 17, 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.**

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| **Study Type** | Efficacy |
| **Pertaining to** | Clostridium botulinum |
| **Study Purpose** | To demonstrate efficacy against botulism caused by C. botulinum Type B toxoid |
| **Product Administration** | Three doses given intramuscularly at monthly intervals. |
| **Study Animals** | Equine |
| **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** | November 16, 1984 |

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|---|---|
| **Study Type** | Efficacy |
| **Pertaining to** | Clostridium botulinum |
| **Study Purpose** | To demonstrate passive immunity efficacy against botulism caused by C. botulinum Type B toxoid in foals |
| **Product Administration** | Three doses given intramuscularly at monthly intervals in pregnant mares |
| **Study Animals** | Equine |
| **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** | November 16, 1984 |

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|---|---|
| **Study Type** | Safety |
| **Pertaining to** | All fractions |
| **Study Purpose** | To demonstrate safety of product under typical field conditions in pregnant mares |
| **Product Administration** | Pregnant mares |
| **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** | November 16, 1984 |

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|---|---|
| **Study Type** | Safety |
| **Pertaining to** | All fractions |
| **Study Purpose** | To demonstrate safety of product under typical field conditions |
| **Product Administration** | |
| **Study Animals** | Equine |
| **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. |
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