



Summary of Studies Supporting USDA Product Licensure

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| Establishment Name | Intervet Inc. |
| USDA Vet Biologics Establishment Number | 165A |
| Product Code | 46J7.20 |
| True Name | Canine Distemper-Adenovirus Type 2-Coronavirus-Parainfluenza-Parvovirus Vaccine, Modified Live & Killed Virus, Leptospira Canicola-Icterohaemorrhagiae Bacterin |
| Tradename(s) / Distributor or Subsidiary (if different from manufacturer) | Intervet Argentina S.A. Nobivac Canine 1 DAPPv + L2 - Merck Sharp & Dohme Saude Animal Ltda. Nobivac Canine 1 DAPPvL2 +Cv - No distributor specified Nobivac Canine 1-DAPPvL2 +Cv - Merck Animal Health Nobivac DAPPvL2 + CV - Intervet Veterinaria Chile Ltda Procyon Dog DA2PPvL +Cv - MSD Salud Animal Columbia S.A.S. Quantum Dog DA2PPvL+Cv - Intervet Argentina S.A. Quantum Dog DA2PPvL+Cv - No distributor specified |
| Date of Compilation Summary | March 14, 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 | Canine Adenovirus Type-2 (CAV-2) |
| Study Purpose | To demonstrate efficacy against Canine Adenovirus Type 1 (hepatitis) and Canine Adenovirus Type 2 (respiratory disease). |
| Product Administration | |
| Study Animals | Canine |
| 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 | May 24, 1999 |

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| Study Type | Safety |
| Pertaining to | Canine Adenovirus Type-2 (CAV-2) |
| Study Purpose | To demonstrate the development of corneal opacity is not associated with the use of this product. |
| 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 | 1980 |

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|--|---|
| Study Type | Efficacy |
| Pertaining to | Canine Coronavirus (CCV) |
| Study Purpose | To demonstrate efficacy against CCV |
| Product Administration | |
| Study Animals | Canine |
| 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 17, 1993 |

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|--|---|
| Study Type | Efficacy |
| Pertaining to | <i>Leptospira interrogans</i> serovar canicola |
| Study Purpose | To demonstrate efficacy against <i>L. canicola</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 requires publication of data submitted after that date. |
| USDA Approval Date | May 24, 1999 |

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|--|---|
| Study Type | Efficacy |
| Pertaining to | <i>Leptospira interrogans</i> serovar <i>icterohaemorrhagiae</i> |
| Study Purpose | To demonstrate efficacy against <i>L. icterohaemorrhagiae</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 requires publication of data submitted after that date. |
| USDA Approval Date | May 24, 1999 |

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|--|---|
| Study Type | Efficacy |
| Pertaining to | Canine Parainfluenza (CPI) |
| Study Purpose | To demonstrate efficacy against CPI |
| Product Administration | |
| Study Animals | Canine |
| 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 9, 1999 |

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|--|---|
| Study Type | Efficacy |
| Pertaining to | Canine Distemper Virus (CDV) |
| Study Purpose | To demonstrate efficacy against CDV. |
| Product Administration | |
| Study Animals | Canine |
| 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 8, 1999 |

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|--|---|
| Study Type | Efficacy |
| Pertaining to | Canine Parvovirus (CPV) |
| Study Purpose | To demonstrate efficacy against CPV |
| Product Administration | |
| Study Animals | Canine |
| 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 | May 21, 1999 |

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|--|---|
| Study Type | Safety |
| Pertaining to | ALL |
| Study Purpose | To demonstrate safety under field conditions. |
| Product Administration | |
| Study Animals | Canine |
| 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 16, 1994 |