

# SAFETY DATA SHEET

according to the Hazardous Products Regulations



## Nobivac Puppy DP Plus Formulation

Version 2.2      Revision Date: 04/22/2024      SDS Number: 7776476-00008      Date of last issue: 09/30/2023  
Date of first issue: 02/05/2021

### SECTION 1. IDENTIFICATION

Product name : Nobivac Puppy DP Plus Formulation  
Product code : Nobivac Puppy DP Formulation  
Other means of identification : Nobivac Puppy DP (A006018)

#### Manufacturer or supplier's details

Company name of supplier : Merck & Co., Inc  
Address : 126 E. Lincoln Avenue  
Rahway, New Jersey U.S.A. 07065  
Telephone : 908-740-4000  
Emergency telephone : 1-908-423-6000  
E-mail address : EHSDATASTEWARD@merck.com

#### Recommended use of the chemical and restrictions on use

Recommended use : Veterinary product  
Restrictions on use : Not applicable

### SECTION 2. HAZARDS IDENTIFICATION

#### GHS classification in accordance with the Hazardous Products Regulations

Not a hazardous substance or mixture.

#### GHS label elements

No hazard pictogram, no signal word, no hazard statement(s), no precautionary statement(s) required

#### Other hazards

Dust contact with the eyes can lead to mechanical irritation.  
Contact with dust can cause mechanical irritation or drying of the skin.  
May form explosive dust-air mixture during processing, handling or other means.

### SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture : Mixture

#### Components

Chemical name	Common Name/Synonym	CAS-No.	Concentration (% w/w)
Antigen	No data available	Not Assigned	$\geq 8.9235 - \leq 13.6343$
Neomycin, sulfate (salt)	No data available	1405-10-3	$\geq 0.0457 - \leq 0.0482$

### SECTION 4. FIRST AID MEASURES

General advice : In the case of accident or if you feel unwell, seek medical advice immediately.  
When symptoms persist or in all cases of doubt seek medical advice.  
If inhaled : If inhaled, remove to fresh air.

# SAFETY DATA SHEET

according to the Hazardous Products Regulations



## Nobivac Puppy DP Plus Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 09/30/2023
2.2	04/22/2024	7776476-00008	Date of first issue: 02/05/2021

---

In case of skin contact	:	Get medical attention if symptoms occur. Wash with water and soap.
In case of eye contact	:	Get medical attention if symptoms occur. If in eyes, rinse well with water.
If swallowed	:	Get medical attention if irritation develops and persists. If swallowed, DO NOT induce vomiting. Get medical attention if symptoms occur. Rinse mouth thoroughly with water.
Most important symptoms and effects, both acute and delayed	:	Contact with dust can cause mechanical irritation or drying of the skin. Dust contact with the eyes can lead to mechanical irritation.
Protection of first-aiders	:	No special precautions are necessary for first aid responders.
Notes to physician	:	Treat symptomatically and supportively.

---

### SECTION 5. FIRE-FIGHTING MEASURES

Suitable extinguishing media	:	Water spray Alcohol-resistant foam Carbon dioxide (CO <sub>2</sub> ) Dry chemical
Unsuitable extinguishing media	:	None known.
Specific hazards during fire fighting	:	Avoid generating dust; fine dust dispersed in air in sufficient concentrations, and in the presence of an ignition source is a potential dust explosion hazard. Exposure to combustion products may be a hazard to health.
Hazardous combustion products	:	Carbon oxides Nitrogen oxides (NO <sub>x</sub> )
Specific extinguishing methods	:	Use extinguishing measures that are appropriate to local circumstances and the surrounding environment. Use water spray to cool unopened containers. Remove undamaged containers from fire area if it is safe to do so. Evacuate area.
Special protective equipment for fire-fighters	:	Wear self-contained breathing apparatus for firefighting if necessary. Use personal protective equipment.

---

### SECTION 6. ACCIDENTAL RELEASE MEASURES

Personal precautions, protective equipment and emergency procedures	:	Follow safe handling advice (see section 7) and personal protective equipment recommendations (see section 8).
Environmental precautions	:	Avoid release to the environment. Prevent further leakage or spillage if safe to do so. Retain and dispose of contaminated wash water. Local authorities should be advised if significant spillages cannot be contained.
Methods and materials for	:	Sweep up or vacuum up spillage and collect in suitable

# SAFETY DATA SHEET

according to the Hazardous Products Regulations



## Nobivac Puppy DP Plus Formulation

Version 2.2      Revision Date: 04/22/2024      SDS Number: 7776476-00008      Date of last issue: 09/30/2023  
Date of first issue: 02/05/2021

containment and cleaning up      container for disposal.  
Avoid dispersal of dust in the air (i.e., clearing dust surfaces with compressed air).  
Dust deposits should not be allowed to accumulate on surfaces, as these may form an explosive mixture if they are released into the atmosphere in sufficient concentration.  
Local or national regulations may apply to releases and disposal of this material, as well as those materials and items employed in the cleanup of releases. You will need to determine which regulations are applicable.  
Sections 13 and 15 of this SDS provide information regarding certain local or national requirements.

### SECTION 7. HANDLING AND STORAGE

Technical measures      :      Static electricity may accumulate and ignite suspended dust causing an explosion.  
Provide adequate precautions, such as electrical grounding and bonding, or inert atmospheres.

Local/Total ventilation      :      Use only with adequate ventilation.

Advice on safe handling      :      Do not breathe dust.  
Handle in accordance with good industrial hygiene and safety practice, based on the results of the workplace exposure assessment  
Minimize dust generation and accumulation.  
Keep container closed when not in use.  
Keep away from heat and sources of ignition.  
Take precautionary measures against static discharges.  
Take care to prevent spills, waste and minimize release to the environment.

Conditions for safe storage      :      Keep in properly labeled containers.  
Store in accordance with the particular national regulations.

Materials to avoid      :      Do not store with the following product types:  
Strong oxidizing agents

### SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

#### Ingredients with workplace control parameters

Components	CAS-No.	Value type (Form of exposure)	Control parameters / Permissible concentration	Basis
Neomycin, sulfate (salt)	1405-10-3	TWA	1 mg/m <sup>3</sup> (OEB 1)	Internal
Further information: DSEN, OTO				
		Wipe limit	0.1 mg/100 cm <sup>2</sup>	Internal

**Engineering measures**      :      Use feasible engineering controls to minimize exposure to compound.  
All engineering controls should be implemented by facility design and operated in accordance with GMP principles to protect products, workers, and the environment.

# SAFETY DATA SHEET

according to the Hazardous Products Regulations



## Nobivac Puppy DP Plus Formulation

Version 2.2      Revision Date: 04/22/2024      SDS Number: 7776476-00008      Date of last issue: 09/30/2023  
Date of first issue: 02/05/2021

---

### Personal protective equipment

- Respiratory protection : If adequate local exhaust ventilation is not available or exposure assessment demonstrates exposures outside the recommended guidelines, use respiratory protection.
- Filter type : Particulates type
- Hand protection  
Material : Chemical-resistant gloves
- Eye protection : Wear safety glasses with side shields or goggles.  
If the work environment or activity involves dusty conditions, mists or aerosols, wear the appropriate goggles.  
Wear a faceshield or other full face protection if there is a potential for direct contact to the face with dusts, mists, or aerosols.
- Skin and body protection : Work uniform or laboratory coat.
- Hygiene measures : If exposure to chemical is likely during typical use, provide eye flushing systems and safety showers close to the working place.  
When using do not eat, drink or smoke.  
Wash contaminated clothing before re-use.  
The effective operation of a facility should include review of engineering controls, proper personal protective equipment, appropriate degowning and decontamination procedures, industrial hygiene monitoring, medical surveillance and the use of administrative controls.
- 

### SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

- Appearance : lyophilized cake
- Color : off-white  
light yellow
- Odor : No data available
- Odor Threshold : No data available
- pH : No data available
- Melting point/freezing point : No data available
- Initial boiling point and boiling range : No data available
- Flash point : Not applicable
- Evaporation rate : Not applicable
- Flammability (solid, gas) : May form explosive dust-air mixture during processing, handling or other means.
- Flammability (liquids) : Not applicable

# SAFETY DATA SHEET

according to the Hazardous Products Regulations



## Nobivac Puppy DP Plus Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 09/30/2023
2.2	04/22/2024	7776476-00008	Date of first issue: 02/05/2021

---

Upper explosion limit / Upper flammability limit	:	No data available
Lower explosion limit / Lower flammability limit	:	No data available
Vapor pressure	:	Not applicable
Relative vapor density	:	Not applicable
Relative density	:	No data available
Density	:	No data available
Solubility(ies)	:	
Water solubility	:	soluble
Partition coefficient: n-octanol/water	:	Not applicable
Autoignition temperature	:	No data available
Decomposition temperature	:	No data available
Viscosity	:	
Viscosity, kinematic	:	Not applicable
Explosive properties	:	Not explosive
Oxidizing properties	:	The substance or mixture is not classified as oxidizing.
Molecular weight	:	No data available
Particle characteristics	:	
Particle size	:	No data available

---

### SECTION 10. STABILITY AND REACTIVITY

Reactivity	:	Not classified as a reactivity hazard.
Chemical stability	:	Stable under normal conditions.
Possibility of hazardous reactions	:	May form explosive dust-air mixture during processing, handling or other means. Can react with strong oxidizing agents.
Conditions to avoid	:	Heat, flames and sparks. Avoid dust formation.
Incompatible materials	:	Oxidizing agents
Hazardous decomposition products	:	No hazardous decomposition products are known.

# SAFETY DATA SHEET

according to the Hazardous Products Regulations



## Nobivac Puppy DP Plus Formulation

Version 2.2      Revision Date: 04/22/2024      SDS Number: 7776476-00008      Date of last issue: 09/30/2023  
Date of first issue: 02/05/2021

---

### SECTION 11. TOXICOLOGICAL INFORMATION

#### Information on likely routes of exposure

Inhalation  
Skin contact  
Ingestion  
Eye contact

#### Acute toxicity

Not classified based on available information.

#### Components:

##### Neomycin, sulfate (salt):

Acute oral toxicity : LD50 (Mouse): 2,880 mg/kg  
LD50 (Rat): 2,750 mg/kg

Acute toxicity (other routes of administration) : LD50 (Rat): 633 mg/kg  
Application Route: Subcutaneous

LD50 (Mouse): 116 mg/kg  
Application Route: Intraperitoneal

LD50 (Mouse): 27.6 mg/kg  
Application Route: Intravenous

LD50 (Mouse): 275 mg/kg  
Application Route: Subcutaneous

#### Skin corrosion/irritation

Not classified based on available information.

#### Components:

##### Neomycin, sulfate (salt):

Species : Rabbit  
Result : Mild skin irritation

#### Serious eye damage/eye irritation

Not classified based on available information.

#### Components:

##### Neomycin, sulfate (salt):

Species : Rabbit  
Result : No eye irritation

#### Respiratory or skin sensitization

##### Skin sensitization

Not classified based on available information.

# SAFETY DATA SHEET

according to the Hazardous Products Regulations



## Nobivac Puppy DP Plus Formulation

Version 2.2      Revision Date: 04/22/2024      SDS Number: 7776476-00008      Date of last issue: 09/30/2023  
Date of first issue: 02/05/2021

---

### Respiratory sensitization

Not classified based on available information.

#### Components:

##### Neomycin, sulfate (salt):

Routes of exposure : Dermal  
Species : Humans  
Result : positive

### Germ cell mutagenicity

Not classified based on available information.

#### Components:

##### Neomycin, sulfate (salt):

Genotoxicity in vitro : Test Type: Bacterial reverse mutation assay (AMES)  
Result: negative

Test Type: In vitro mammalian cell gene mutation test  
Test system: Chinese hamster ovary cells  
Result: negative

Test Type: Chromosomal aberration  
Test system: Human lymphocytes  
Result: positive

Test Type: in vitro micronucleus test  
Result: negative

Genotoxicity in vivo : Test Type: Cytogenetic assay  
Species: Mouse  
Cell type: Bone marrow  
Application Route: Intravenous injection  
Result: negative

### Carcinogenicity

Not classified based on available information.

#### Components:

##### Neomycin, sulfate (salt):

Species : Rat  
Exposure time : 2 Years  
Result : negative

### Reproductive toxicity

Not classified based on available information.

#### Components:

##### Neomycin, sulfate (salt):

Effects on fertility : Test Type: Three-generation reproduction toxicity study

# SAFETY DATA SHEET

according to the Hazardous Products Regulations



## Nobivac Puppy DP Plus Formulation

Version 2.2      Revision Date: 04/22/2024      SDS Number: 7776476-00008      Date of last issue: 09/30/2023  
Date of first issue: 02/05/2021

---

Species: Rat  
Application Route: Oral  
General Toxicity Parent: NOAEL: 25 mg/kg body weight  
Result: No effects on fertility and early embryonic development were detected.

Effects on fetal development : Test Type: Embryo-fetal development  
Species: Rat  
Application Route: Oral  
Embryo-fetal toxicity.: NOAEL: 275 mg/kg body weight  
Result: No adverse effects., No teratogenic effects.

Test Type: Development  
Species: Rat  
Application Route: Subcutaneous  
Developmental Toxicity: LOAEL: 6 mg/kg body weight  
Result: positive

Reproductive toxicity - Assessment : Some evidence of adverse effects on development, based on animal experiments.

### **STOT-single exposure**

Not classified based on available information.

### **STOT-repeated exposure**

Not classified based on available information.

### **Components:**

#### **Neomycin, sulfate (salt):**

Target Organs : Kidney, inner ear  
Assessment : May cause damage to organs through prolonged or repeated exposure.  
Remarks : Based on human experience.

### **Repeated dose toxicity**

#### **Components:**

#### **Neomycin, sulfate (salt):**

Species : Mouse  
LOAEL : 30 mg/kg  
Application Route : Subcutaneous  
Exposure time : 14 d  
Target Organs : Kidney

Species : Guinea pig  
NOAEL : 50 mg/kg  
LOAEL : 100 mg/kg  
Application Route : Intramuscular  
Exposure time : 30 - 60 Weeks  
Target Organs : ear

Species : Guinea pig



# SAFETY DATA SHEET

according to the Hazardous Products Regulations



## Nobivac Puppy DP Plus Formulation

Version 2.2      Revision Date: 04/22/2024      SDS Number: 7776476-00008      Date of last issue: 09/30/2023  
Date of first issue: 02/05/2021

---

NOAEL : 10 mg/kg  
Application Route : Oral  
Exposure time : 90 d  
Remarks : No significant adverse effects were reported

Species : Guinea pig  
LOAEL : 100 mg/kg  
Application Route : Subcutaneous  
Exposure time : 34 d

Species : Dog  
LOAEL : 24 mg/kg  
Application Route : Intramuscular  
Exposure time : 30 d  
Target Organs : Kidney

Species : Rat  
LOAEL : 25 mg/kg  
Application Route : oral (feed)  
Exposure time : 84 Weeks  
Target Organs : ear  
Symptoms : hearing loss  
Remarks : mortality observed

Species : Dog  
LOAEL : 20 mg/kg  
Application Route : Subcutaneous  
Exposure time : 90 d  
Target Organs : Kidney

### Aspiration toxicity

Not classified based on available information.

### Experience with human exposure

#### Components:

#### **Neomycin, sulfate (salt):**

Skin contact : Symptoms: Sensitization  
Remarks: May irritate skin.  
Eye contact : Remarks: May cause eye irritation.  
Ingestion : Symptoms: Nausea, Vomiting, Diarrhea, tinnitus, hearing loss,  
Loss of balance

---

## SECTION 12. ECOLOGICAL INFORMATION

### Ecotoxicity

#### Components:

#### **Neomycin, sulfate (salt):**

Toxicity to daphnia and other aquatic invertebrates : EC50 (Daphnia magna (Water flea)): > 72 mg/l  
Exposure time: 48 h  
Method: OECD Test Guideline 202

# SAFETY DATA SHEET

according to the Hazardous Products Regulations



## Nobivac Puppy DP Plus Formulation

Version 2.2      Revision Date: 04/22/2024      SDS Number: 7776476-00008      Date of last issue: 09/30/2023  
Date of first issue: 02/05/2021

---

LC50 (Americamysis): 39 mg/l  
Exposure time: 96 h  
Method: US-EPA OPPTS 850.1035

Toxicity to algae/aquatic plants : EC50 (Anabaena flos-aquae (cyanobacterium)): 0.00075 mg/l  
Exposure time: 72 h  
Method: OECD Test Guideline 201

NOEC (Anabaena flos-aquae (cyanobacterium)): 0.0003 mg/l  
Exposure time: 72 h  
Method: OECD Test Guideline 201

EC50 (Pseudokirchneriella subcapitata (green algae)): 0.0099 mg/l  
Exposure time: 72 h  
Method: OECD Test Guideline 201

NOEC (Pseudokirchneriella subcapitata (green algae)): 0.0022 mg/l  
Exposure time: 72 h  
Method: OECD Test Guideline 201

Toxicity to microorganisms : EC50 (Natural microorganism): 107.6 mg/l  
Exposure time: 3 h  
Test Type: Respiration inhibition  
Method: OECD Test Guideline 209

EC10 (Natural microorganism): 2.8 mg/l  
Exposure time: 3 h  
Test Type: Respiration inhibition  
Method: OECD Test Guideline 209

### Persistence and degradability

#### Components:

##### **Neomycin, sulfate (salt):**

Biodegradability : Result: rapidly degradable  
Biodegradation: 50 %  
Exposure time: 1.2 d  
Method: OECD Test Guideline 314

### Bioaccumulative potential

#### Components:

##### **Neomycin, sulfate (salt):**

Partition coefficient: n-octanol/water : log Pow: < -2

##### **Mobility in soil**

No data available

# SAFETY DATA SHEET

according to the Hazardous Products Regulations



## Nobivac Puppy DP Plus Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 09/30/2023
2.2	04/22/2024	7776476-00008	Date of first issue: 02/05/2021

### Other adverse effects

No data available

## SECTION 13. DISPOSAL CONSIDERATIONS

### Disposal methods

Waste from residues : Do not dispose of waste into sewer.  
Dispose of in accordance with local regulations.

Contaminated packaging : Empty containers should be taken to an approved waste handling site for recycling or disposal.  
If not otherwise specified: Dispose of as unused product.

## SECTION 14. TRANSPORT INFORMATION

### International Regulations

#### UNRTDG

UN number : UN 3077

Proper shipping name : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID,  
N.O.S.  
(Neomycin, sulfate (salt))

Class : 9

Packing group : III

Labels : 9

Environmentally hazardous : yes

#### IATA-DGR

UN/ID No. : UN 3077

Proper shipping name : Environmentally hazardous substance, solid, n.o.s.  
(Neomycin, sulfate (salt))

Class : 9

Packing group : III

Labels : Miscellaneous

Packing instruction (cargo aircraft) : 956

Packing instruction (passenger aircraft) : 956

Environmentally hazardous : yes

#### IMDG-Code

UN number : UN 3077

Proper shipping name : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID,  
N.O.S.  
(Neomycin, sulfate (salt))

Class : 9

Packing group : III

Labels : 9

EmS Code : F-A, S-F

Marine pollutant : yes

### Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code

Not applicable for product as supplied.

### Domestic regulation

# SAFETY DATA SHEET

according to the Hazardous Products Regulations



## Nobivac Puppy DP Plus Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 09/30/2023
2.2	04/22/2024	7776476-00008	Date of first issue: 02/05/2021

---

### **TDG**

UN number	:	UN 3077
Proper shipping name	:	ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (Neomycin, sulfate (salt))
Class	:	9
Packing group	:	III
Labels	:	9
ERG Code	:	171
Marine pollutant	:	yes(Neomycin, sulfate (salt))

### **Special precautions for user**

The transport classification(s) provided herein are for informational purposes only, and solely based upon the properties of the unpackaged material as it is described within this Safety Data Sheet. Transportation classifications may vary by mode of transportation, package sizes, and variations in regional or country regulations.

---

## **SECTION 15. REGULATORY INFORMATION**

### **The ingredients of this product are reported in the following inventories:**

DSL	:	not determined
AICS	:	not determined
IECSC	:	not determined

---

## **SECTION 16. OTHER INFORMATION**

### **Full text of other abbreviations**

AIIC - Australian Inventory of Industrial Chemicals; ANTT - National Agency for Transport by Land of Brazil; ASTM - American Society for the Testing of Materials; bw - Body weight; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DSL - Domestic Substances List (Canada); ECx - Concentration associated with x% response; ELx - Loading rate associated with x% response; EmS - Emergency Schedule; ENCS - Existing and New Chemical Substances (Japan); ErCx - Concentration associated with x% growth rate response; ERG - Emergency Response Guide; GHS - Globally Harmonized System; GLP - Good Laboratory Practice; IARC - International Agency for Research on Cancer; IATA - International Air Transport Association; IBC - International Code for the Construction and Equipment of Ships carrying Dangerous Chemicals in Bulk; IC50 - Half maximal inhibitory concentration; ICAO - International Civil Aviation Organization; IECSC - Inventory of Existing Chemical Substances in China; IMDG - International Maritime Dangerous Goods; IMO - International Maritime Organization; ISHL - Industrial Safety and Health Law (Japan); ISO - International Organisation for Standardization; KECI - Korea Existing Chemicals Inventory; LC50 - Lethal Concentration to 50 % of a test population; LD50 - Lethal Dose to 50% of a test population (Median Lethal Dose); MARPOL - International Convention for the Prevention of Pollution from Ships; n.o.s. - Not Otherwise Specified; Nch - Chilean Norm; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; NOM - Official Mexican Norm; NTP - National Toxicology Program; NZIoC - New Zealand Inventory of Chemicals; OECD - Organization for Economic Co-operation and Develop-

# SAFETY DATA SHEET

according to the Hazardous Products Regulations



## Nobivac Puppy DP Plus Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 09/30/2023
2.2	04/22/2024	7776476-00008	Date of first issue: 02/05/2021

---

ment; OPPTS - Office of Chemical Safety and Pollution Prevention; PBT - Persistent, Bioaccumulative and Toxic substance; PICCS - Philippines Inventory of Chemicals and Chemical Substances; (Q)SAR - (Quantitative) Structure Activity Relationship; REACH - Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals; SADT - Self-Accelerating Decomposition Temperature; SDS - Safety Data Sheet; TCSI - Taiwan Chemical Substance Inventory; TDG - Transportation of Dangerous Goods; TECl - Thailand Existing Chemicals Inventory; TSCA - Toxic Substances Control Act (United States); UN - United Nations; UNRTDG - United Nations Recommendations on the Transport of Dangerous Goods; vPvB - Very Persistent and Very Bioaccumulative; WHMIS - Workplace Hazardous Materials Information System

Sources of key data used to compile the Material Safety Data Sheet : Internal technical data, data from raw material SDSs, OECD eChem Portal search results and European Chemicals Agency, <http://echa.europa.eu/>

Revision Date : 04/22/2024  
Date format : mm/dd/yyyy

The information provided in this Safety Data Sheet is correct to the best of our knowledge, information and belief at the date of its publication. The information is designed only as a guidance for safe handling, use, processing, storage, transportation, disposal and release and shall not be considered a warranty or quality specification of any type. The information provided relates only to the specific material identified at the top of this SDS and may not be valid when the SDS material is used in combination with any other materials or in any process, unless specified in the text. Material users should review the information and recommendations in the specific context of their intended manner of handling, use, processing and storage, including an assessment of the appropriateness of the SDS material in the user's end product, if applicable.

CA / Z8