

**Nobivac Puppy DP Plus Formulation**

Version	Revision Date:	SDS Number:	Date of last issue: 04.04.2023
2.1	30.09.2023	9672381-00006	Date of first issue: 21.09.2021

**SECTION 1. IDENTIFICATION**

Product name : Nobivac Puppy DP Plus Formulation

Product code : Nobivac Puppy DP Formulation

**Manufacturer or supplier's details**

Company : MSD

Address : Calle 127A #53A-45 Torre 3 – Piso 8  
Bogotá D.C., Colombia Complejo Empresarial Colpatría

Telephone : (+57) 1 2886012

Emergency telephone : 01 8000 916012

E-mail address : EHSDATASTEWARD@msd.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**

Short-term (acute) aquatic hazard : Category 1

Long-term (chronic) aquatic hazard : Category 3

**GHS label elements**

Hazard pictograms :



Signal Word : Warning

Hazard Statements : H400 Very toxic to aquatic life.  
H412 Harmful to aquatic life with long lasting effects.

Precautionary Statements : **Prevention:**  
P273 Avoid release to the environment.

**Response:**  
P391 Collect spillage.

**Nobivac Puppy DP Plus Formulation**

Version	Revision Date:	SDS Number:	Date of last issue: 04.04.2023
2.1	30.09.2023	9672381-00006	Date of first issue: 21.09.2021

**Disposal:**

P501 Dispose of contents/ container to an approved waste disposal plant.

**Other hazards which do not result in classification**

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	CAS-No.	Concentration (% w/w)
Antigen	Not Assigned	$\geq 10$ -< 20
Neomycin, sulfate (salt)	1405-10-3	$\geq 0,025$ -< 0,1

**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.  
Get medical attention if symptoms occur.

In case of skin contact : Wash with water and soap.  
Get medical attention if symptoms occur.

In case of eye contact : If in eyes, rinse well with water.  
Get medical attention if irritation develops and persists.

If swallowed : 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.

**Nobivac Puppy DP Plus Formulation**

Version	Revision Date:	SDS Number:	Date of last issue: 04.04.2023
2.1	30.09.2023	9672381-00006	Date of first issue: 21.09.2021

- 
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|--|---|---|
| Hazardous combustion products                  | : | Carbon oxides<br>Nitrogen oxides (NO <sub>x</sub> )   |
| Specific extinguishing methods                 | : | Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.<br>Use water spray to cool unopened containers.<br>Remove undamaged containers from fire area if it is safe to do so.<br>Evacuate area. |
| Special protective equipment for fire-fighters | : | Wear self-contained breathing apparatus for firefighting if necessary.<br>Use personal protective equipment.  |
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**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.<br>Prevent further leakage or spillage if safe to do so.<br>Retain and dispose of contaminated wash water.<br>Local authorities should be advised if significant spillages cannot be contained.  |
| Methods and materials for containment and cleaning up               | : | Sweep up or vacuum up spillage and collect in suitable container for disposal.<br>Avoid dispersal of dust in the air (i.e., clearing dust surfaces with compressed air).<br>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.<br>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.<br>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.<br>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.<br>Handle in accordance with good industrial hygiene and safety practice, based on the results of the workplace exposure assessment<br>Minimize dust generation and accumulation.<br>Keep container closed when not in use.<br>Keep away from heat and sources of ignition.<br>Take precautionary measures against static discharges. |

## Nobivac Puppy DP Plus Formulation

Version 2.1      Revision Date: 30.09.2023      SDS Number: 9672381-00006      Date of last issue: 04.04.2023  
 Date of first issue: 21.09.2021

- 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.

## 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 : 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

**Nobivac Puppy DP Plus Formulation**

Version 2.1	Revision Date: 30.09.2023	SDS Number: 9672381-00006	Date of last issue: 04.04.2023 Date of first issue: 21.09.2021
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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
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.

**Nobivac Puppy DP Plus Formulation**

Version	Revision Date:	SDS Number:	Date of last issue: 04.04.2023
2.1	30.09.2023	9672381-00006	Date of first issue: 21.09.2021

Molecular weight : No data available

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.

**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

**Nobivac Puppy DP Plus Formulation**

Version	Revision Date:	SDS Number:	Date of last issue: 04.04.2023
2.1	30.09.2023	9672381-00006	Date of first issue: 21.09.2021

---

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.

**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.

**Nobivac Puppy DP Plus Formulation**

Version	Revision Date:	SDS Number:	Date of last issue: 04.04.2023
2.1	30.09.2023	9672381-00006	Date of first issue: 21.09.2021

---

**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 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.
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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.
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	:	Test Type: Development Species: Rat Application Route: Subcutaneous Developmental Toxicity: LOAEL: 6 mg/kg body weight Result: positive
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Reproductive toxicity - Assessment	:	Some evidence of adverse effects on development, based on animal experiments.
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**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):**



## Nobivac Puppy DP Plus Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 04.04.2023
2.1	30.09.2023	9672381-00006	Date of first issue: 21.09.2021

---

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  
 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.

**Nobivac Puppy DP Plus Formulation**

Version	Revision Date:	SDS Number:	Date of last issue: 04.04.2023
2.1	30.09.2023	9672381-00006	Date of first issue: 21.09.2021

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

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

M-Factor (Acute aquatic toxicity) : 1.000

M-Factor (Chronic aquatic toxicity) : 10

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):**

## Nobivac Puppy DP Plus Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 04.04.2023
2.1	30.09.2023	9672381-00006	Date of first issue: 21.09.2021

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- : log Pow: < -2  
octanol/water

**Mobility in soil**

No data available

**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 : 956  
aircraft)  
Packing instruction (passen- : 956  
ger aircraft)  
Environmentally hazardous : yes

## Nobivac Puppy DP Plus Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 04.04.2023
2.1	30.09.2023	9672381-00006	Date of first issue: 21.09.2021

**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 IMO instruments**

Not applicable for product as supplied.

**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****Safety, health and environmental regulations/legislation specific for the substance or mixture**

Substances and chemicals controlled by the Ministry of Justice : Not applicable

List of substances included for special control and subject to supervision by the Ministry of Health and Social Protection : Not applicable

Resolution 2715/2014, which establishes the substances subject to registration of retail sales, based on defined classification criteria. : Not applicable

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

DSL : not determined

AICS : not determined

IECSC : not determined

**SECTION 16. OTHER INFORMATION**

Revision Date	: 30.09.2023
Date format	: dd.mm.yyyy

**Further information**

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/>

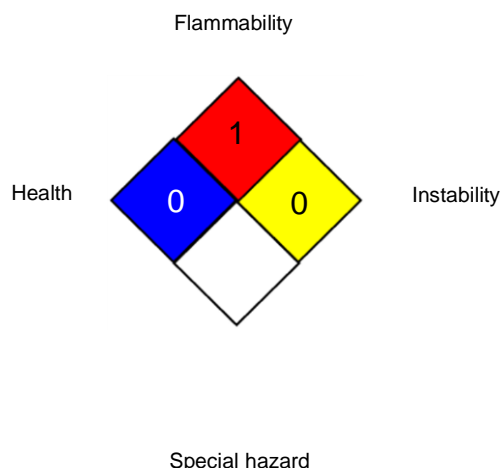
# SAFETY DATA SHEET



## Nobivac Puppy DP Plus Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 04.04.2023
2.1	30.09.2023	9672381-00006	Date of first issue: 21.09.2021

### NFPA:



### HMIS® IV:

HEALTH	/	0
FLAMMABILITY		3
PHYSICAL HAZARD		0

HMIS® ratings are based on a 0-4 rating scale, with 0 representing minimal hazards or risks, and 4 representing significant hazards or risks. The "\*" represents a chronic hazard, while the "/" represents the absence of a chronic hazard.

### 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 Development; 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; TECI - 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

**Nobivac Puppy DP Plus Formulation**

Version	Revision Date:	SDS Number:	Date of last issue: 04.04.2023
2.1	30.09.2023	9672381-00006	Date of first issue: 21.09.2021

---

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.

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