

SAFETY DATA SHEET

according to the OSHA Hazard Communication Standard



Nobivac Puppy DP Plus Formulation

Version 3.0 Revision Date: 07/06/2024 SDS Number: 7776451-00010 Date of last issue: 04/22/2024
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 OSHA Hazard Communication Standard (29 CFR 1910.1200)

Combustible dust

GHS label elements

Signal Word : Warning

Hazard Statements : If small particles are generated during further processing, handling or by other means, may form combustible dust concentrations in air.

Other hazards

Dust contact with the eyes can lead to mechanical irritation.
Contact with dust can cause mechanical irritation or drying of the skin.

SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture : Mixture

Components

Chemical name	CAS-No.	Concentration (% w/w)
Antigen	Not Assigned	$\geq 8.9235 - \leq 13.6343$
Neomycin, sulfate (salt)	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

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If inhaled	: advice. 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 ₂) 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 _x)
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.

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Methods and materials for containment and cleaning up : Sweep up or vacuum up spillage and collect in suitable 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

inert or nuisance dust	50 Million particles per cubic foot Value type (Form of exposure): TWA (total dust) Basis: OSHA Z-3
	15 mg/m ³ Value type (Form of exposure): TWA (total dust) Basis: OSHA Z-3
	5 mg/m ³ Value type (Form of exposure): TWA (respirable fraction) Basis: OSHA Z-3

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	15 Million particles per cubic foot Value type (Form of exposure): TWA (respirable fraction) Basis: OSHA Z-3
Dust, nuisance dust and particulates	10 mg/m ³ Value type (Form of exposure): PEL (Total dust) Basis: CAL PEL
	5 mg/m ³ Value type (Form of exposure): PEL (respirable dust fraction) Basis: CAL PEL

Components	CAS-No.	Value type (Form of exposure)	Control parameters / Permissible concentration	Basis
Neomycin, sulfate (salt)	1405-10-3	TWA	1 mg/m ³ (OEB 1)	Internal
	Further information: DSEN, OTO			
		Wipe limit	0.1 mg/100 cm ²	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 : General and local exhaust ventilation is recommended to maintain vapor exposures below recommended limits. Where concentrations are above recommended limits or are unknown, appropriate respiratory protection should be worn. Follow OSHA respirator regulations (29 CFR 1910.134) and use NIOSH/MSHA approved respirators. Protection provided by air purifying respirators against exposure to any hazardous chemical is limited. Use a positive pressure air supplied respirator if there is any potential for uncontrolled release, exposure levels are unknown, or any other circumstance where air purifying respirators may not provide adequate protection.

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
Hygiene measures

: Work uniform or laboratory coat.
: 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.

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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
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

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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.

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

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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.

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

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Genotoxicity in vivo	:	Result: negative
	:	Test Type: Chromosomal aberration
	:	Test system: Human lymphocytes
	:	Result: positive
	:	Test Type: in vitro micronucleus test
	:	Result: negative
	:	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

IARC No ingredient of this product present at levels greater than or equal to 0.1% is identified as probable, possible or confirmed human carcinogen by IARC.

OSHA No component of this product present at levels greater than or equal to 0.1% is on OSHA's list of regulated carcinogens.

NTP No ingredient of this product present at levels greater than or equal to 0.1% is identified as a known or anticipated carcinogen by NTP.

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.
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
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
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

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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 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

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	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
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Bioaccumulative potential

Components:

Neomycin, sulfate (salt):

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

No data available

Other adverse effects

No data available

SECTION 13. DISPOSAL CONSIDERATIONS

Disposal methods

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

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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

49 CFR

UN/ID/NA number	:	UN 3077
Proper shipping name	:	Environmentally hazardous substance, solid, n.o.s. (Neomycin, sulfate (salt))
Class	:	9
Packing group	:	III
Labels	:	CLASS 9
ERG Code	:	171
Marine pollutant	:	yes(Neomycin, sulfate (salt))
Remarks	:	Above applies only to containers over 119 gallons or 450 liters. Shipment by ground under DOT is non-regulated; however it

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may be shipped per the applicable hazard classification to facilitate multi-modal transport involving ICAO (IATA) or IMO.

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

CERCLA Reportable Quantity

Listed substances in the product are at low enough levels to not be expected to exceed the RQ

SARA 304 Extremely Hazardous Substances Reportable Quantity

This material does not contain any components with a section 304 EHS RQ.

SARA 302 Extremely Hazardous Substances Threshold Planning Quantity

This material does not contain any components with a section 302 EHS TPQ.

SARA 311/312 Hazards : Combustible dust

SARA 313 : This material does not contain any chemical components with known CAS numbers that exceed the threshold (De Minimis) reporting levels established by SARA Title III, Section 313.

US State Regulations

Pennsylvania Right To Know

D-Glucitol	50-70-4
Gelatins	9000-70-8
Peptones, casein	91079-40-2
Antigen	Not Assigned
Sodium phosphate, dihydrate	10028-24-7

California Prop. 65

WARNING: This product can expose you to chemicals including Neomycin, sulfate (salt), which is/are known to the State of California to cause birth defects or other reproductive harm. For more information go to www.P65Warnings.ca.gov.

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

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

SECTION 16. OTHER INFORMATION

Further information

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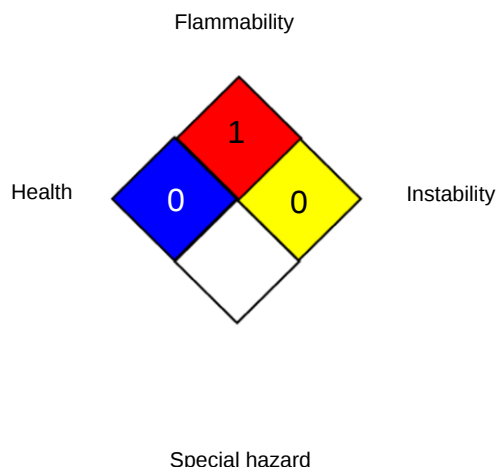
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NFPA 704:



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

CAL PEL	:	California permissible exposure limits for chemical contaminants (Title 8, Article 107)
OSHA Z-3	:	USA. Occupational Exposure Limits (OSHA) - Table Z-3 Mineral Dusts
CAL PEL / PEL	:	Permissible exposure limit
OSHA Z-3 / TWA	:	8-hour time weighted average

AIIC - Australian Inventory of Industrial Chemicals; ASTM - American Society for the Testing of Materials; bw - Body weight; CERCLA - Comprehensive Environmental Response, Compensation, and Liability Act; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DOT - Department of Transportation; DSL - Domestic Substances List (Canada); ECx - Concentration associated with x% response; EHS - Extremely Hazardous Substance; 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; HMIS - Hazardous Materials Identification System; 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; MSHA - Mine Safety and Health Administration; n.o.s. - Not Otherwise Specified; NFPA - National Fire Protection Association; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; 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; RCRA - Resource Conservation and Recovery Act;

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REACH - Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals; RQ - Reportable Quantity; SADT - Self-Accelerating Decomposition Temperature; SARA - Superfund Amendments and Reauthorization Act; SDS - Safety Data Sheet; TCSI - Taiwan Chemical Substance Inventory; 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

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 : 07/06/2024

Items where changes have been made to the previous version are highlighted in the body of this document by two vertical lines.

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.

US / Z8