

## **Neomycin Formulation**

**Revision Date:** SDS Number: Date of last issue: 30.09.2023 Version 9404866-00008 3.2 06.04.2024 Date of first issue: 02.09.2021

**SECTION 1: IDENTIFICATION** 

Product name **Neomycin Formulation** 

Manufacturer or supplier's details

Intervet Australia Pty Limited (trading as MSD Animal Health) Company

Address 91-105 Harpin Street

Bendigo 3550, Victoria Austrailia

Telephone 1 800 033 461

Emergency telephone number : Poisons Information Centre: Phone 13 11 26

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** 

Skin sensitisation Category 1

Reproductive toxicity Category 2

repeated exposure

Specific target organ toxicity - : Category 2 (Kidney, inner ear)

**GHS** label elements

Hazard pictograms

Signal word Warning

Hazard statements H317 May cause an allergic skin reaction.

H361d Suspected of damaging the unborn child.

H373 May cause damage to organs (Kidney, inner ear) through

prolonged or repeated exposure.

Precautionary statements Prevention:

P201 Obtain special instructions before use.

P202 Do not handle until all safety precautions have been read

and understood.



## **Neomycin Formulation**

Version Revision Date: SDS Number: Date of last issue: 30.09.2023 3.2 06.04.2024 9404866-00008 Date of first issue: 02.09.2021

P260 Do not breathe dust.

P272 Contaminated work clothing should not be allowed out of

the workplace.

P280 Wear protective gloves/ protective clothing/ eye protec-

tion/ face protection.

Response:

P302 + P352 IF ON SKIN: Wash with plenty of water.

P308 + P313 IF exposed or concerned: Get medical advice/

attention.

P333 + P313 If skin irritation or rash occurs: Get medical ad-

vice/ attention.

Storage:

P405 Store locked up.

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 combustible dust concentrations in air during processing, handling or other means.

#### **SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS**

Substance / Mixture : Mixture

Components

Chemical name	CAS-No.	Concentration (% w/w)	
Neomycin, sulfate (salt)	1405-10-3	>= 30 -< 60	

#### **SECTION 4. FIRST AID MEASURES**

General advice : In the case of accident or if you feel unwell, seek medical ad-

vice immediately.

When symptoms persist or in all cases of doubt seek medical

advice.

If inhaled : If inhaled, remove to fresh air.

Get medical attention.

In case of skin contact : In case of contact, immediately flush skin with soap and plenty

of water.

Remove contaminated clothing and shoes.

Get medical attention. Wash clothing before reuse.

Thoroughly clean shoes before reuse.

In case of eye contact : If in eyes, rinse well with water.

Get medical attention if irritation develops and persists.

If swallowed, DO NOT induce vomiting.

Get medical attention.

Rinse mouth thoroughly with water.



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## **Neomycin Formulation**

Version Revision Date: SDS Number: Date of last issue: 30.09.2023 3.2 06.04.2024 9404866-00008 Date of first issue: 02.09.2021

Most important symptoms and effects, both acute and

Protection of first-aiders

delaved

May cause an allergic skin reaction.

Suspected of damaging the unborn child.

May cause damage to organs through prolonged or repeated

exposure.

Contact with dust can cause mechanical irritation or drying of

the skin.

Dust contact with the eyes can lead to mechanical irritation. First Aid responders should pay attention to self-protection, and use the recommended personal protective equipment

when the potential for exposure exists (see section 8).

Notes to physician : Treat symptomatically and supportively.

#### **SECTION 5. FIREFIGHTING MEASURES**

Suitable extinguishing media : Water spray

Alcohol-resistant foam Carbon dioxide (CO2)

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 prod-

ucts

Carbon oxides

Specific extinguishing meth-

ods

Use extinguishing measures that are appropriate to local cir-

cumstances 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 firefighters

In the event of fire, wear self-contained breathing apparatus.

Use personal protective equipment.

Hazchem Code : 2

#### **SECTION 6. ACCIDENTAL RELEASE MEASURES**

Personal precautions, protective equipment and emer-

gency procedures

Use personal protective equipment.

Follow safe handling advice (see section 7) and personal pro-

tective 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 containment and cleaning up

Sweep up or vacuum up spillage and collect in suitable con-

tainer for disposal.





## **Neomycin Formulation**

 Version
 Revision Date:
 SDS Number:
 Date of last issue: 30.09.2023

 3.2
 06.04.2024
 9404866-00008
 Date of first issue: 02.09.2021

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 Advice on safe handling Use only with adequate ventilation.

Do not get on skin or clothing.

Do not breathe dust.

Do not swallow.

Avoid contact with eyes.

Handle in accordance with good industrial hygiene and safety practice, based on the results of the workplace exposure as-

sessment

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.

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.

Contaminated work clothing should not be allowed out of the

workplace.

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.

Conditions for safe storage : Keep in properly labelled containers.

Store locked up.

Store in accordance with the particular national regulations.

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

Strong oxidizing agents





## **Neomycin Formulation**

SDS Number: Date of last issue: 30.09.2023 Version Revision Date: 3.2 06.04.2024 9404866-00008 Date of first issue: 02.09.2021

#### SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

### Components with workplace control parameters

Components	CAS-No.	Value type	Control parame-	Basis	
		(Form of	ters / Permissible		
		exposure)	concentration		
Neomycin, sulfate (salt)	1405-10-3	TWA	1 mg/m3 (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 expo-

sure assessment demonstrates exposures outside the rec-

ommended guidelines, use respiratory protection.

Filter type

Hand protection

Particulates type

Material Chemical-resistant gloves

Wear safety glasses with side shields or goggles. Eye protection

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.

## **SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES**

Appearance powder

Colour White to light yellow

Odour No data available

Odour Threshold No data available

No data available pΗ

Melting point/freezing point No data available

Initial boiling point and boiling

range

No data available

Flash point Not applicable



## **Neomycin Formulation**

SDS Number: Date of last issue: 30.09.2023 Version **Revision Date:** 3.2 06.04.2024 9404866-00008 Date of first issue: 02.09.2021

**Evaporation rate** Not applicable

Flammability (solid, gas) May form combustible dust concentrations in air during pro-

cessing, 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

Vapour pressure Not applicable

Relative vapour density Not applicable

Relative density No data available

No data available Density

Solubility(ies)

Water solubility No data available

Partition coefficient: n-

octanol/water

Not applicable

Auto-ignition temperature No data available

No data available Decomposition temperature

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**

Not classified as a reactivity hazard. Reactivity Chemical stability Stable under normal conditions.

Possibility of hazardous reac-

tions

May form combustible dust concentrations in air during pro-

cessing, handling or other means.

Can react with strong oxidizing agents.



## **Neomycin Formulation**

Version Revision Date: SDS Number: Date of last issue: 30.09.2023 3.2 06.04.2024 9404866-00008 Date of first issue: 02.09.2021

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**

Exposure routes : 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



## **Neomycin Formulation**

Version Revision Date: SDS Number: Date of last issue: 30.09.2023 3.2 06.04.2024 9404866-00008 Date of first issue: 02.09.2021

### Respiratory or skin sensitisation

#### Skin sensitisation

May cause an allergic skin reaction.

### Respiratory sensitisation

Not classified based on available information.

#### **Components:**

## Neomycin, sulfate (salt):

Exposure routes : Dermal Species : Humans Result : positive

#### **Chronic toxicity**

#### 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



## **Neomycin Formulation**

Version Revision Date: SDS Number: Date of last issue: 30.09.2023 3.2 06.04.2024 9404866-00008 Date of first issue: 02.09.2021

#### Reproductive toxicity

Suspected of damaging the unborn child.

#### 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 develop-

ment were detected.

Effects on foetal develop-

ment

Test Type: Embryo-foetal development

Species: Rat

Application Route: Oral

Embryo-foetal 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 - As-

sessment

Some evidence of adverse effects on development, based on

animal experiments.

#### STOT - single exposure

Not classified based on available information.

#### STOT - repeated exposure

May cause damage to organs (Kidney, inner ear) through prolonged or repeated exposure.

#### **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



## **Neomycin Formulation**

Version Revision Date: SDS Number: Date of last issue: 30.09.2023 3.2 06.04.2024 9404866-00008 Date of first issue: 02.09.2021

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

Remarks : mortality observe

Species: DogLOAEL: 20 mg/kgApplication 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: Sensitisation

Remarks: May irritate skin.

Eye contact : Remarks: May cause eye irritation.

Ingestion : Symptoms: Nausea, Vomiting, Diarrhoea, tinnitus, hearing

loss, Loss of balance



## **Neomycin Formulation**

SDS Number: Date of last issue: 30.09.2023 Version **Revision Date:** 3.2 06.04.2024 9404866-00008 Date of first issue: 02.09.2021

#### **SECTION 12. ECOLOGICAL INFORMATION**

## **Ecotoxicity**

#### **Components:**

Neomycin, sulfate (salt):

aquatic invertebrates

Toxicity to daphnia and other : 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

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



## **Neomycin Formulation**

SDS Number: Date of last issue: 30.09.2023 Version **Revision Date:** 3.2 06.04.2024 9404866-00008 Date of first issue: 02.09.2021

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

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.

Empty containers should be taken to an approved waste han-Contaminated packaging

dling 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.

956

956

(Neomycin, sulfate (salt))

9 Class Packing group Ш 9 Labels Environmentally hazardous yes

**IATA-DGR** 

UN 3077 UN/ID No.

Environmentally hazardous substance, solid, n.o.s. Proper shipping name

(Neomycin, sulfate (salt))

Class 9 Ш Packing group

Miscellaneous Labels

Packing instruction (cargo

aircraft)

Packing instruction (passen-

ger aircraft)

Environmentally hazardous

yes

**IMDG-Code** 



## **Neomycin Formulation**

Date of last issue: 30.09.2023 Version Revision Date: SDS Number: 3.2 06.04.2024 9404866-00008 Date of first issue: 02.09.2021

**UN** number UN 3077

Proper shipping name ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID,

N.O.S.

(Neomycin, sulfate (salt))

Class 9 Packing group Ш 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.

## **National Regulations**

**ADG** 

**UN** number UN 3077

Proper shipping name ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID,

N.O.S.

(Neomycin, sulfate (salt))

Class 9 Packing group Ш Labels 9 Hazchem Code 27 Environmentally hazardous yes

#### 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

Therapeutic Goods (Poisons:

Standard) Instrument

No poison schedule number allocated (Please use the original publication to check for specific uses, specific conditions or

threshold limits that might apply for this chemical)

Prohibition/Licensing Requirements There is no applicable prohibition,

authorisation and restricted use requirements, including for carcinogens referred to in Schedule 10 of the model WHS Act and Regula-

tions.

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

**AICS** not determined

DSL not determined

**IECSC** not determined



## **Neomycin Formulation**

 Version
 Revision Date:
 SDS Number:
 Date of last issue: 30.09.2023

 3.2
 06.04.2024
 9404866-00008
 Date of first issue: 02.09.2021

#### **SECTION 16: ANY OTHER RELEVANT INFORMATION**

**Further information** 

Revision Date : 06.04.2024

Sources of key data used to : Internal technical data, data from raw material SDSs, OECD compile the Safety Data : Internal technical data, data from raw material SDSs, OECD eChem Portal search results and European Chemicals Agen-

Sheet cy, http://echa.europa.eu/

Date format : dd.mm.yyyy

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

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.



# **Neomycin Formulation**

Version Revision Date: SDS Number: Date of last issue: 30.09.2023 3.2 06.04.2024 9404866-00008 Date of first issue: 02.09.2021

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.

AU / EN