

Tetracycline Hydrochloride

Version	Revision Date:	SDS Number:	Date of last issue: 30.09.2023
3.0	14.04.2025	5479502-00012	Date of first issue: 05.03.2020

SECTION 1: Identification of the substance/mixture and of the company/undertaking**1.1 Product identifier**

Trade name	:	Tetracycline Hydrochloride
Product code	:	tetracycline hydrochloride, Tetracycline hydrochloride
Substance name	:	tetracycline hydrochloride
EC-No.	:	200-593-8

1.2 Relevant identified uses of the substance or mixture and uses advised against

Use of the Sub- stance/Mixture	:	Pharmaceutical
Recommended restrictions on use	:	Not applicable

1.3 Details of the supplier of the safety data sheet

Company	:	MSD 20 Spartan Road 1619 Spartan, South Africa
Telephone	:	+27119239300
E-mail address of person responsible for the SDS	:	EHSDATASTEWARD@msd.com

1.4 Emergency telephone number

+1-908-423-6000

SECTION 2: Hazards identification**2.1 Classification of the substance or mixture****Classification (REGULATION (EC) No 1272/2008)**

Reproductive toxicity, Category 1A	H360D: May damage the unborn child.
Effects on or via lactation	H362: May cause harm to breast-fed children.
Specific target organ toxicity - repeated exposure, Category 2, Gastrointestinal tract, Nervous system, Skin, Teeth	H373: May cause damage to organs through prolonged or repeated exposure if swallowed.
Short-term (acute) aquatic hazard, Category 1	H400: Very toxic to aquatic life.
Long-term (chronic) aquatic hazard, Category 1	H410: Very toxic to aquatic life with long lasting effects.

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2.2 Label elements

Labelling (REGULATION (EC) No 1272/2008)

Hazard pictograms :



Signal word : Danger

Hazard statements : H360D May damage the unborn child.
H362 May cause harm to breast-fed children.
H373 May cause damage to organs (Gastrointestinal tract, Nervous system, Skin, Teeth) through prolonged or repeated exposure if swallowed.
H410 Very toxic to aquatic life with long lasting effects.

Precautionary statements :

Prevention:

P201 Obtain special instructions before use.
P260 Do not breathe dust.
P263 Avoid contact during pregnancy and while nursing.
P273 Avoid release to the environment.
P280 Wear protective gloves/ protective clothing/ eye protection/ face protection.

Response:

P391 Collect spillage.

2.3 Other hazards

This substance/mixture contains no components considered to be either persistent, bioaccumulative and toxic (PBT), or very persistent and very bioaccumulative (vPvB) at levels of 0.1% or higher.

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

3.1 Substances

Substance name : tetracycline hydrochloride

EC-No. : 200-593-8

Components

Chemical name	CAS-No. EC-No.	Concentration (% w/w)
tetracycline hydrochloride	64-75-5 200-593-8	>= 90 - <= 100

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SECTION 4: First aid measures**4.1 Description of 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. |
| Protection of first-aiders | : | 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). |
| 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 | : | If swallowed, DO NOT induce vomiting.
Get medical attention.
Rinse mouth thoroughly with water. |

4.2 Most important symptoms and effects, both acute and delayed

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

May damage the unborn child.
May cause harm to breast-fed children.
May cause damage to organs through prolonged or repeated exposure if swallowed. |
|-------|---|--|

4.3 Indication of any immediate medical attention and special treatment needed

- | | | |
|-----------|---|---|
| Treatment | : | Treat symptomatically and supportively. |
|-----------|---|---|
-

SECTION 5: Firefighting measures**5.1 Extinguishing media**

- | | | |
|------------------------------|---|--|
| Suitable extinguishing media | : | Water spray
Alcohol-resistant foam
Carbon dioxide (CO ₂)
Dry chemical |
| Unsuitable extinguishing | : | None known. |
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media

5.2 Special hazards arising from the substance or mixture

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 (NOx)
Chlorine compounds

5.3 Advice for firefighters

Special protective equipment for firefighters : In the event of fire, wear self-contained breathing apparatus.
Use personal protective equipment.

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.

SECTION 6: Accidental release measures**6.1 Personal precautions, protective equipment and emergency procedures**

Personal precautions : Use personal protective equipment.
Follow safe handling advice (see section 7) and personal protective equipment recommendations (see section 8).

6.2 Environmental precautions

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.

6.3 Methods and material for containment and cleaning up

Methods for 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.

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6.4 Reference to other sections

See sections: 7, 8, 11, 12 and 13.

SECTION 7: Handling and storage

7.1 Precautions for safe handling

- | | | |
|-------------------------|---|---|
| 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 | : | If sufficient ventilation is unavailable, use with local exhaust ventilation. |
| Advice on safe handling | : | Avoid contact during pregnancy and while nursing.
Do not get on skin or clothing.
Do not breathe dust.
Do not swallow.
Avoid contact with eyes.
Wash skin thoroughly after handling.
Handle in accordance with good industrial hygiene and safety practice, based on the results of the workplace exposure assessment
Keep container tightly closed.
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.
Do not eat, drink or smoke when using this product.
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. 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. |

7.2 Conditions for safe storage, including any incompatibilities

- | | | |
|---|---|--|
| Requirements for storage areas and containers | : | Keep in properly labelled containers. Store locked up. Keep tightly closed. Store in accordance with the particular national regulations. |
| Advice on common storage | : | Do not store with the following product types:
Strong oxidizing agents
Self-reactive substances and mixtures
Organic peroxides
Explosives
Gases |

7.3 Specific end use(s)

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Specific use(s) : No data available

SECTION 8: Exposure controls/personal protection**8.1 Control parameters****Occupational Exposure Limits**

Components	CAS-No.	Value type (Form of exposure)	Control parameters	Basis
tetracycline hydrochloride	64-75-5	TWA	0.9 mg/m3 (OEB 2)	Internal

8.2 Exposure controls**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

Eye/face 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.
Hand protection	:	
Material	:	Chemical-resistant gloves
Skin and body protection	:	Work uniform or laboratory coat.
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 (P)

SECTION 9: Physical and chemical properties**9.1 Information on basic physical and chemical properties**

Appearance	:	Crystalline powder
Colour	:	No data available
Odour	:	No data available
Odour Threshold	:	No data available
pH	:	No data available
Melting point/freezing point	:	214 °C
Initial boiling point and boiling range	:	No data available
Flash point	:	No data available
Evaporation rate	:	Not applicable

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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
Vapour pressure	:	Not applicable
Relative vapour density	:	Not applicable
Relative density	:	No data available
Density	:	No data available
Solubility(ies)		
Water solubility	:	0,231 g/l
Partition coefficient: n-octanol/water	:	log Pow: -1,37 pH: 7
Auto-ignition 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.

9.2 Other information

Molecular weight	:	480,9 g/mol
Particle size	:	No data available

SECTION 10: Stability and reactivity**10.1 Reactivity**

Not classified as a reactivity hazard.

10.2 Chemical stability

Stable under normal conditions.

10.3 Possibility of hazardous reactions

Hazardous reactions	:	May form explosive dust-air mixture during processing, handling or other means.
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Can react with strong oxidizing agents.

10.4 Conditions to avoid

Conditions to avoid : Heat, flames and sparks.
Avoid dust formation.

10.5 Incompatible materials

Materials to avoid : Oxidizing agents

10.6 Hazardous decomposition products

No hazardous decomposition products are known.

SECTION 11: Toxicological information**11.1 Information on toxicological effects**

Information on likely routes of exposure : Inhalation
Skin contact
Ingestion
Eye contact

Acute toxicity

|| Not classified based on available information.

Components:**tetracycline hydrochloride:**

|| Acute oral toxicity : LD50 (Rat): 6.443 mg/kg
LD50 (Mouse): 2.759 mg/kg
Acute toxicity (other routes of administration) : LD50 (Rat): 128 mg/kg
Application Route: Intravenous
LD50 (Mouse): 157 mg/kg
Application Route: Intravenous

Skin corrosion/irritation

|| Not classified based on available information.

Components:**tetracycline hydrochloride:**

|| Remarks : No data available

Serious eye damage/eye irritation

|| Not classified based on available information.

Components:**tetracycline hydrochloride:**

|| Remarks : No data available

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Respiratory or skin sensitisation**Skin sensitisation**

|| Not classified based on available information.

Respiratory sensitisation

|| Not classified based on available information.

Components:**tetracycline hydrochloride:**

|| Remarks : No data available

Germ cell mutagenicity

|| Not classified based on available information.

Components:**tetracycline hydrochloride:**

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

Test Type: Cytogenetic assay
Test system: Chinese hamster ovary cells
Result: negative

Test Type: sister chromatid exchange assay
Result: negative

Test Type: Mouse Lymphoma
Result: negative

Carcinogenicity

|| Not classified based on available information.

Components:**tetracycline hydrochloride:**

|| Species : Rat
Application Route : Oral
Exposure time : 103 W
Result : negative

|| Species : Mouse
Application Route : Oral
Exposure time : 103 W
Result : negative

Reproductive toxicity

|| May damage the unborn child.
|| May cause harm to breast-fed children.

Components:**tetracycline hydrochloride:**

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Effects on fertility	: Test Type: Fertility Species: Rat Application Route: Oral Fertility: NOAEL: 400 mg/kg body weight Result: No effects on fertility
Effects on foetal development	: Test Type: Development Result: Embryo-foetal toxicity, Specific developmental abnormalities, Skeletal malformations
Reproductive toxicity - Assessment	: Studies indicating a hazard to babies during the lactation period, May damage the unborn child.

STOT - single exposure

Not classified based on available information.

STOT - repeated exposure

May cause damage to organs (Gastrointestinal tract, Nervous system, Skin, Teeth) through prolonged or repeated exposure if swallowed.

Components:**tetracycline hydrochloride:**

Exposure routes	: Oral
Target Organs	: Gastrointestinal tract, Nervous system, Skin, Teeth
Assessment	: May cause damage to organs through prolonged or repeated exposure.

Repeated dose toxicity**Components:****tetracycline hydrochloride:**

Species	: Rat
NOAEL	: 625 mg/kg
LOAEL	: 1.250 mg/kg
Application Route	: oral (feed)
Exposure time	: 13 W
Target Organs	: Liver
Symptoms	: Reduced body weight

Species	: Mouse
NOAEL	: 3.750 mg/kg
LOAEL	: 7.500 mg/kg
Application Route	: oral (feed)
Exposure time	: 13 W
Symptoms	: Reduced body weight

Aspiration toxicity

Not classified based on available information.

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Components:**tetracycline hydrochloride:****||** Not applicable**Experience with human exposure****Components:****tetracycline hydrochloride:**

Ingestion	:	Target Organs: Teeth Symptoms: Gastrointestinal disturbance, Nausea, Vomiting, Diarrhoea, Liver effects, skin rash, central nervous system effects Remarks: May cause sensitisation of susceptible persons. May cause photosensitisation. Based on Human Evidence
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SECTION 12: Ecological information**12.1 Toxicity****Components:****tetracycline hydrochloride:**

Toxicity to algae/aquatic plants	:	EC50 (Anabaena flos-aquae (cyanobacterium)): 6,2 mg/l Exposure time: 72 h NOEC (Anabaena flos-aquae (cyanobacterium)): 2,5 mg/l Exposure time: 72 h EC50 (Pseudokirchneriella subcapitata (green algae)): 3,31 mg/l Exposure time: 72 h NOEC (Pseudokirchneriella subcapitata (green algae)): 0,032 mg/l Exposure time: 72 h EC50 (Microcystis aeruginosa (blue-green algae)): 0,09 mg/l Exposure time: 7 d
M-Factor (Acute aquatic toxicity)	:	10
Toxicity to microorganisms	:	EC50 : 0,08 mg/l Exposure time: 3 h Test Type: Respiration inhibition Method: OECD Test Guideline 209
M-Factor (Chronic aquatic toxicity)	:	1

12.2 Persistence and degradability

No data available

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12.3 Bioaccumulative potential

Components:

tetracycline hydrochloride:

Partition coefficient: n-octanol/water	: log Pow: -1,37 pH: 7
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12.4 Mobility in soil

No data available

12.5 Results of PBT and vPvB assessment

Product:

Assessment	: This substance/mixture contains no components considered to be either persistent, bioaccumulative and toxic (PBT), or very persistent and very bioaccumulative (vPvB) at levels of 0.1% or higher.
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12.6 Other adverse effects

Product:

Endocrine disrupting potential	: The substance/mixture does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.
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SECTION 13: Disposal considerations

13.1 Waste treatment methods

Product	: Dispose of in accordance with local regulations. According to the European Waste Catalogue, Waste Codes are not product specific, but application specific. Waste codes should be assigned by the user, preferably in discussion with the waste disposal authorities. 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.

SECTION 14: Transport information

14.1 UN number

ADN	: UN 3077
ADR	: UN 3077
RID	: UN 3077
IMDG	: UN 3077
IATA	: UN 3077

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14.2 UN proper shipping name

ADN	:	ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (tetracycline hydrochloride)
ADR	:	ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (tetracycline hydrochloride)
RID	:	ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (tetracycline hydrochloride)
IMDG	:	ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (tetracycline hydrochloride)
IATA	:	Environmentally hazardous substance, solid, n.o.s. (tetracycline hydrochloride)

14.3 Transport hazard class(es)

	Class	Subsidiary risks
ADN	:	9
ADR	:	9
RID	:	9
IMDG	:	9
IATA	:	9

14.4 Packing group

ADN	
Packing group	: III
Classification Code	: M7
Hazard Identification Number	: 90
Labels	: 9
ADR	
Packing group	: III
Classification Code	: M7
Hazard Identification Number	: 90
Labels	: 9
Tunnel restriction code	: (-)
RID	
Packing group	: III
Classification Code	: M7
Hazard Identification Number	: 90
Labels	: 9
IMDG	
Packing group	: III
Labels	: 9
EmS Code	: F-A, S-F
IATA (Cargo)	
Packing instruction (cargo)	: 956

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aircraft)
Packing instruction (LQ) : Y956
Packing group : III
Labels : Miscellaneous

IATA (Passenger)

Packing instruction (passenger aircraft) : 956
Packing instruction (LQ) : Y956
Packing group : III
Labels : Miscellaneous

14.5 Environmental hazards**ADN**

Environmentally hazardous : yes

ADR

Environmentally hazardous : yes

RID

Environmentally hazardous : yes

IMDG

Marine pollutant : yes

IATA (Passenger)

Environmentally hazardous : yes

IATA (Cargo)

Environmentally hazardous : yes

14.6 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.

14.7 Transport in bulk according to Annex II of Marpol and the IBC Code

Remarks : Not applicable for product as supplied.

SECTION 15: Regulatory information**15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture**

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

AICS : not determined

DSL : not determined

IECSC : not determined

15.2 Chemical safety assessment

A Chemical Safety Assessment has not been carried out.

SECTION 16: Other information

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

Full text of other abbreviations

ADN - European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways; ADR - Agreement concerning the International Carriage of Dangerous Goods by Road; AIIC - Australian Inventory of Industrial Chemicals; ASTM - American Society for the Testing of Materials; bw - Body weight; CLP - Classification Labelling Packaging Regulation; Regulation (EC) No 1272/2008; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DSL - Domestic Substances List (Canada); ECHA - European Chemicals Agency; EC-Number - European Community number; 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; 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; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; 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; RID - Regulations concerning the International Carriage of Dangerous Goods by Rail; SADT - Self-Accelerating Decomposition Temperature; SDS - Safety Data Sheet; SVHC - Substance of very high concern; 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

Further information

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

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

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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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