

## Gentamicin (10%) Injection Formulation

Version            Revision Date:            SDS Number:            Date of last issue: 07/22/2022  
6.3                10/01/2022                804052-00017            Date of first issue: 07/15/2016

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### SECTION 1. IDENTIFICATION

Product name                                : Gentamicin (10%) Injection Formulation

#### 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


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### SECTION 2. HAZARDS IDENTIFICATION

#### GHS classification in accordance with the OSHA Hazard Communication Standard (29 CFR 1910.1200)

Reproductive toxicity                      : Category 1A  
Specific target organ toxicity             : Category 1 (Kidney, inner ear)  
- repeated exposure (Oral)

#### GHS label elements

Hazard pictograms                         : 

Signal Word                                 : Danger

Hazard Statements                         : H360D May damage the unborn child.  
    : H372 Causes damage to organs (Kidney, inner ear) through  
    : prolonged or repeated exposure if swallowed.

Precautionary Statements                : **Prevention:**  
    : P201 Obtain special instructions before use.  
    : P202 Do not handle until all safety precautions have been read  
    : and understood.  
    : P260 Do not breathe mist or vapors.  
    : P264 Wash skin thoroughly after handling.  
    : P270 Do not eat, drink or smoke when using this product.  
    : P280 Wear protective gloves, protective clothing, eye protection  
    : and face protection.

#### Response:

P308 + P313 IF exposed or concerned: Get medical attention.

#### Storage:

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P405 Store locked up.

**Disposal:**

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

**Other hazards**

None known.

### SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture : Mixture

**Components**

Chemical name	CAS-No.	Concentration (% w/w)
Gentamicin	1403-66-3	10

### 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.
- 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 : Flush eyes with water as a precaution.  
 Get medical attention if irritation develops and persists.
- If swallowed : If swallowed, DO NOT induce vomiting.  
 Get medical attention.  
 Rinse mouth thoroughly with water.
- Most important symptoms and effects, both acute and delayed : May damage the unborn child.  
 Causes damage to organs through prolonged or repeated exposure if swallowed.
- 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).
- 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 : Exposure to combustion products may be a hazard to health.

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fighting  
Hazardous combustion products : Carbon oxides

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

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### SECTION 6. ACCIDENTAL RELEASE MEASURES

Personal precautions, protective equipment and emergency procedures : Use personal protective equipment.  
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.  
Prevent spreading over a wide area (e.g., by containment or oil barriers).  
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 : Soak up with inert absorbent material.  
For large spills, provide diking or other appropriate containment to keep material from spreading. If diked material can be pumped, store recovered material in appropriate container.  
Clean up remaining materials from spill with suitable absorbent.  
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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### SECTION 7. HANDLING AND STORAGE

Technical measures : See Engineering measures under EXPOSURE CONTROLS/PERSONAL PROTECTION section.

Local/Total ventilation : If sufficient ventilation is unavailable, use with local exhaust ventilation.

Advice on safe handling : Do not get on skin or clothing.  
Do not breathe mist or vapors.  
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

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- assessment  
 Keep container tightly closed.  
 Do not eat, drink or smoke when using this product.  
 Take care to prevent spills, waste and minimize release to the environment.
- Conditions for safe storage : Keep in properly labeled containers.  
 Store locked up.  
 Keep tightly closed.  
 Store in accordance with the particular national regulations.
- Materials to avoid : Do not store with the following product types:  
 Strong oxidizing agents  
 Self-reactive substances and mixtures  
 Organic peroxides  
 Explosives  
 Gases

### SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

#### Ingredients with workplace control parameters

Components	CAS-No.	Value type (Form of exposure)	Control parameters / Permissible concentration	Basis
Gentamicin	1403-66-3	TWA	0.1 mg/m <sup>3</sup> (OEB 2)	Internal
Further information: OTO				

- Engineering measures** : Use appropriate engineering controls and manufacturing technologies to control airborne concentrations (e.g., drip-less quick connections).  
 All engineering controls should be implemented by facility design and operated in accordance with GMP principles to protect products, workers, and the environment.  
 Laboratory operations do not require special containment.

#### 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.

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Skin and body protection Hygiene measures	: Wear a faceshield or other full face protection if there is a potential for direct contact to the face with dusts, mists, or aerosols. : 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. 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.
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### SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance	: liquid
Color	: clear
Odor	: odorless
Odor Threshold	: No data available
pH	: 3.0 - 5.5
Melting point/freezing point	: No data available
Initial boiling point and boiling range	: > 212 °F / > 100 °C
Flash point	: No data available
Evaporation rate	: 1
Flammability (solid, gas)	: Not applicable
Flammability (liquids)	: No data available
Upper explosion limit / Upper flammability limit	: No data available
Lower explosion limit / Lower flammability limit	: No data available
Vapor pressure	: No data available
Relative vapor density	: No data available
Relative density	: No data available
Density	: No data available
Solubility(ies)	

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Water solubility : soluble

Partition coefficient: n-octanol/water : No data available

Autoignition temperature : No data available

Decomposition temperature : No data available

Viscosity

    Viscosity, kinematic : No data available

Explosive properties : Not explosive

Oxidizing properties : The substance or mixture is not classified as oxidizing.

Molecular weight : No data available

Particle size : No data available

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**SECTION 10. STABILITY AND REACTIVITY**

Reactivity : Not classified as a reactivity hazard.

Chemical stability : Stable under normal conditions.

Possibility of hazardous reactions : Can react with strong oxidizing agents.

Conditions to avoid : None known.

Incompatible materials : Oxidizing agents

Hazardous decomposition products : No hazardous decomposition products are known.

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**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:****Gentamicin:**

Acute oral toxicity : LD50 (Rat): 8,000 - 10,000 mg/kg  
LD50 (Mouse): 10,000 mg/kg

Acute inhalation toxicity : LC50 (Rat): > 0.2 mg/l  
Exposure time: 4 h  
Test atmosphere: dust/mist  
Remarks: No mortality observed at this dose.

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Acute toxicity (other routes of administration) : LD50 (Rat): 67 - 96 mg/kg  
Application Route: Intravenous

LD50 (Rat): 371 - 384 mg/kg  
Application Route: Intramuscular

LDLo (Monkey): 30 mg/kg  
Application Route: Intravenous

**Skin corrosion/irritation**

Not classified based on available information.

**Components:****Gentamicin:**

Species : Rabbit  
Result : Mild skin irritation

**Serious eye damage/eye irritation**

Not classified based on available information.

**Components:****Gentamicin:**

Species : Rabbit  
Result : Mild eye irritation

**Respiratory or skin sensitization****Skin sensitization**

Not classified based on available information.

**Respiratory sensitization**

Not classified based on available information.

**Components:****Gentamicin:**

Remarks : No data available

**Germ cell mutagenicity**

Not classified based on available information.

**Components:****Gentamicin:**

Genotoxicity in vitro : Test Type: In vitro mammalian cell gene mutation test  
Result: negative

Test Type: Chromosome aberration test in vitro  
Result: equivocal

Genotoxicity in vivo : Test Type: Mammalian erythrocyte micronucleus test (in vivo cytogenetic assay)

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Species: Mouse  
Application Route: Intravenous injection  
Result: negative

**Carcinogenicity**

Not classified based on available information.

**Components:****Gentamicin:**

Carcinogenicity - Assessment : No data available

**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**

May damage the unborn child.

**Components:****Gentamicin:**

Effects on fertility : Test Type: Two-generation reproduction toxicity study  
Species: Rat  
Fertility: NOAEL: 20 mg/kg body weight  
Result: No significant adverse effects were reported

Effects on fetal development : Test Type: Embryo-fetal development  
Species: Rabbit  
Developmental Toxicity: NOAEL: 3.6 mg/kg body weight  
Result: No embryo-fetal toxicity.

Test Type: Embryo-fetal development  
Species: Rat  
Application Route: Intraperitoneal  
Developmental Toxicity: LOAEL: 75 mg/kg body weight  
Result: Embryo-fetal toxicity.

Test Type: Embryo-fetal development  
Species: Mouse  
Application Route: Intraperitoneal  
Developmental Toxicity: LOAEL: 10 mg/kg body weight  
Result: Fetal mortality., No malformations were observed.

Test Type: Embryo-fetal development  
Species: Rat  
Application Route: Intraperitoneal  
Developmental Toxicity: LOAEL: 50 mg/kg body weight  
Result: Fetal mortality., No malformations were observed.



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Reproductive toxicity - Assessment : Positive evidence of adverse effects on development from human epidemiological studies.

### STOT-single exposure

Not classified based on available information.

### STOT-repeated exposure

Causes damage to organs (Kidney, inner ear) through prolonged or repeated exposure if swallowed.

### Components:

#### Gentamicin:

Target Organs : Kidney, inner ear  
 Assessment : Causes damage to organs through prolonged or repeated exposure.

### Repeated dose toxicity

### Components:

#### Gentamicin:

Species : Dog  
 LOAEL : 3 mg/kg  
 Application Route : Intramuscular  
 Exposure time : 12 Months  
 Target Organs : Kidney  
 Symptoms : Vomiting, Salivation

Species : Monkey  
 LOAEL : 50 mg/kg  
 Application Route : Subcutaneous  
 Exposure time : 3 Weeks  
 Target Organs : Kidney, inner ear

Species : Monkey  
 LOAEL : 6 mg/kg  
 Application Route : Intramuscular  
 Exposure time : 3 Weeks  
 Target Organs : Blood, Kidney, inner ear, Liver

Species : Rat  
 NOAEL : 5 mg/kg  
 LOAEL : 10 mg/kg  
 Application Route : Intramuscular  
 Exposure time : 52 Weeks  
 Target Organs : Kidney, Blood

Species : Rat  
 NOAEL : 12.5 mg/kg  
 LOAEL : 50 mg/kg  
 Application Route : Intramuscular  
 Exposure time : 13 Weeks  
 Target Organs : Kidney

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**Aspiration toxicity**

Not classified based on available information.

**Experience with human exposure****Components:****Gentamicin:**

Ingestion : Target Organs: Kidney  
Target Organs: inner ear  
Symptoms: Dizziness, Vertigo, hearing loss, tinnitus, fetal deafness

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**SECTION 12. ECOLOGICAL INFORMATION****Ecotoxicity****Components:****Gentamicin:**

Toxicity to daphnia and other aquatic invertebrates : EC50 (Daphnia magna (Water flea)): 86 mg/l  
Exposure time: 48 h  
Method: OECD Test Guideline 202  
  
LC50 (Americamysis): 30 mg/l  
Exposure time: 96 h  
Method: US-EPA OPPTS 850.1035

Toxicity to algae/aquatic plants : EC50 (Pseudokirchneriella subcapitata (green algae)): 10 µg/l  
Exposure time: 72 h  
Method: OECD Test Guideline 201  
  
NOEC (Pseudokirchneriella subcapitata (green algae)): 1.5 µg/l  
Exposure time: 72 h  
Method: OECD Test Guideline 201  
  
EC50 (Anabaena flos-aquae (cyanobacterium)): 4.7 µg/l  
Exposure time: 72 h  
Method: OECD Test Guideline 201  
  
NOEC (Anabaena flos-aquae (cyanobacterium)): 1.6 µg/l  
Exposure time: 72 h  
Method: OECD Test Guideline 201

Toxicity to microorganisms : EC50: 288.7 mg/l  
Exposure time: 3 h  
Test Type: Respiration inhibition  
Method: OECD Test Guideline 209

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**Persistence and degradability****Components:****Gentamicin:**

Biodegradability : Result: rapidly degradable  
Biodegradation: 100 %  
Exposure time: 28 d  
Method: OECD Test Guideline 314

**Bioaccumulative potential****Components:****Gentamicin:**

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

**Mobility in soil**

No data available

**Other adverse effects**

No data available

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**SECTION 13. DISPOSAL CONSIDERATIONS****Disposal methods**

Waste from residues : 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.

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**SECTION 14. TRANSPORT INFORMATION****International Regulations****UNRTDG**

UN number : UN 3082  
Proper shipping name : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S. (Gentamicin)  
Class : 9  
Packing group : III  
Labels : 9

**IATA-DGR**

UN/ID No. : UN 3082  
Proper shipping name : Environmentally hazardous substance, liquid, n.o.s. (Gentamicin)  
Class : 9  
Packing group : III  
Labels : Miscellaneous  
Packing instruction (cargo aircraft) : 964  
Packing instruction (passen- : 964

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ger aircraft)  
Environmentally hazardous : yes

### IMDG-Code

UN number : UN 3082  
Proper shipping name : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S. (Gentamicin)  
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 3082  
Proper shipping name : Environmentally hazardous substance, liquid, n.o.s. (Gentamicin)  
Class : 9  
Packing group : III  
Labels : CLASS 9  
ERG Code : 171  
Marine pollutant : yes(Gentamicin)  
Remarks : Above applies only to containers over 119 gallons or 450 liters.  
Shipment by ground under DOT is non-regulated; however it 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.

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## 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** : Reproductive toxicity  
Specific target organ toxicity (single or repeated exposure)

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**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

Water	7732-18-5
Gentamicin	1403-66-3
Sodium hydrogensulfite	7631-90-5
Acetic acid	64-19-7

#### California Prop. 65

WARNING: This product can expose you to chemicals including Gentamicin, 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](http://www.P65Warnings.ca.gov).

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

AICS : not determined

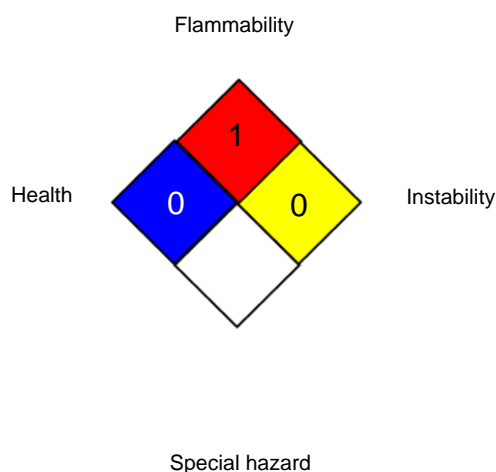
DSL : not determined

IECSC : not determined

## SECTION 16. OTHER INFORMATION

### Further information

#### NFPA 704:



#### HMIS® IV:

<b>HEALTH</b>	*	<b>3</b>
<b>FLAMMABILITY</b>		<b>1</b>
<b>PHYSICAL HAZARD</b>		<b>0</b>

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

AIC - Australian Inventory of Industrial Chemicals; ASTM - American Society for the Testing of Materials; bw - Body weight; CERCLA - Comprehensive Environmental Response, Compensation,

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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; 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 : 10/01/2022

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