# SAFETY DATA SHEET
according to the OSHA Hazard Communication Standard

Public

ORGANON

# Mianserin Formulation

| Version | Revision Date: | SDS Number: | Date of last issue: 04/04/2023 |
|---|---|---|---|
| 3.8 | 09/30/2023 | 1601083-00012 | Date of first issue: 05/01/2017 |

## SECTION 1. IDENTIFICATION

Product name : Mianserin Formulation

**Manufacturer or supplier's details**

Company name of supplier : Organon & Co.
Address : 30 Hudson Street, 33nd floor
Jersey City, New Jersey, U.S.A 07302
Telephone : 1-551-430-6000
Emergency telephone : 1-215-631-6999
E-mail address : EHSSTEWARD@organon.com

**Recommended use of the chemical and restrictions on use**

Recommended use : Pharmaceutical
Restrictions on use : Not applicable

## SECTION 2. HAZARDS IDENTIFICATION

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

Reproductive toxicity : Category 2

Specific target organ toxicity - single exposure : Category 1 (Central nervous system)

**GHS label elements**

Hazard pictograms :

Signal Word : Danger

Hazard Statements : H361fd Suspected of damaging fertility. Suspected of damaging the unborn child.
H370 Causes damage to organs (Central nervous system).

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 dust, fume, gas, mist, vapors or spray.
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:**

P307 + P311 IF exposed: Call a doctor.

**Storage:**

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) |
|---|---|---|
| mianserin hydrochloride | 21535-47-7 | >= 10 - < 20 |
| Starch | 9005-25-8 | >= 10 - < 20 |
| Silica | 71187-19-4 | >= 1 - < 5 |

Actual concentration is withheld as a trade secret

## 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.
Never give anything by mouth to an unconscious person.

Most important symptoms and effects, both acute and delayed : Suspected of damaging fertility. Suspected of damaging the unborn child.
Causes damage to organs.

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 (CO2)<br>Dry chemical |
| Unsuitable extinguishing media | : | None known. |
| Specific hazards during fire fighting | : | Exposure to combustion products may be a hazard to health. |
| Hazardous combustion products | : | Carbon oxides<br>Metal oxides<br>Oxides of phosphorus<br>Silicon oxides |
| Specific extinguishing methods | : | Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.<br>Use water spray to cool unopened containers.<br>Remove undamaged containers from fire area if it is safe to do so.<br>Evacuate area. |
| Special protective equipment for fire-fighters | : | In the event of fire, wear self-contained breathing apparatus.<br>Use personal protective equipment. |

## SECTION 6. ACCIDENTAL RELEASE MEASURES

| | | |
|---|---|---|
| Personal precautions, protective equipment and emergency procedures | : | Use personal protective equipment.<br>Follow safe handling advice (see section 7) and personal protective equipment recommendations (see section 8). |
| Environmental precautions | : | Avoid release to the environment.<br>Prevent further leakage or spillage if safe to do so.<br>Retain and dispose of contaminated wash water.<br>Local authorities should be advised if significant spillages cannot be contained. |
| Methods and materials for containment and cleaning up | : | Surround spill with absorbents and place a damp covering over the area to minimize entry of the material into the air.<br>Add excess liquid to allow the material to enter into solution.<br>Soak up with inert absorbent material.<br>Clean up remaining materials from spill with suitable absorbent.<br>Local or national regulations may apply to releases and disposal of this material, as well as those materials and items employed in the cleanup of releases. You will need to determine which regulations are applicable.<br>Sections 13 and 15 of this SDS provide information regarding certain local or national requirements. |

## SECTION 7. HANDLING AND STORAGE

| | | |
|---|---|---|
| Technical measures | : | See Engineering measures under EXPOSURE CONTROLS/PERSONAL PROTECTION section. |
| Local/Total ventilation | : | Use only with adequate ventilation. |
| Advice on safe handling | : | Do not breathe dust, fume, gas, mist, vapors or spray.<br>Do not swallow.<br>Avoid contact with eyes. |

Avoid prolonged or repeated contact with skin.
Wash skin thoroughly after handling.
Handle in accordance with good industrial hygiene and safety practice, based on the results of the workplace exposure assessment
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.
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 |
|---|---|---|---|---|
| mianserin hydrochloride | 21535-47-7 | TWA | 20 µg/m3 (OEB 3) | Internal |
| | Further information: Skin | | | |
| | | Wipe limit | 200 µg/100 cm² | Internal |
| Starch | 9005-25-8 | TWA | 10 mg/m³ | ACGIH |
| | | TWA (Respirable) | 5 mg/m³ | NIOSH REL |
| | | TWA (total) | 10 mg/m³ | NIOSH REL |
| | | TWA (total dust) | 15 mg/m³ | OSHA Z-1 |
| | | TWA (respirable fraction) | 5 mg/m³ | OSHA Z-1 |
| Silica | 71187-19-4 | TWA (Dust) | 20 Million particles per cubic foot (Silica) | OSHA Z-3 |
| | | TWA (Dust) | 80 mg/m3 / %SiO2 (Silica) | OSHA Z-3 |
| | | TWA | 6 mg/m³ (Silica) | NIOSH REL |

**Engineering measures** : Ensure adequate ventilation, especially in confined areas.
Minimize workplace exposure concentrations.

**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 |
| Remarks | : | Choose gloves to protect hands against chemicals depending on the concentration specific to place of work. Breakthrough time is not determined for the product. Change gloves often! For special applications, we recommend clarifying the resistance to chemicals of the aforementioned protective gloves with the glove manufacturer. Wash hands before breaks and at the end of workday. |
| Eye protection | : | Wear the following personal protective equipment:<br>Safety glasses |
| Skin and body protection | : | Select appropriate protective clothing based on chemical resistance data and an assessment of the local exposure potential.<br>Skin contact must be avoided by using impervious protective clothing (gloves, aprons, boots, etc). |
| Hygiene measures | : | If exposure to chemical is likely during typical use, provide eye flushing systems and safety showers close to the working place.<br>When using do not eat, drink or smoke.<br>Wash contaminated clothing before re-use. |

## SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

| | | |
|---|---|---|
| Appearance | : | Crystalline solid |
| Color | : | white to off-white |
| 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 | : | No data available |

| | | |
|---|---|---|
| Flammability (solid, gas) | : | Not classified as a flammability hazard |
| 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) | | |
| Water solubility | : | No data available |
| 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 | : | Not applicable |
| 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 | : | Can react with strong oxidizing agents. |
| Conditions to avoid | : | None known. |
| Incompatible materials | : | Oxidizing agents |
| Hazardous decomposition products | : | No hazardous decomposition products are known. |

## SECTION 11. TOXICOLOGICAL INFORMATION

**Information on likely routes of exposure**

Skin contact
Ingestion
Eye contact

**Acute toxicity**

Not classified based on available information.

**Product:**

| | | |
|---|---|---|
| Acute oral toxicity | : | Acute toxicity estimate: > 5,000 mg/kg<br>Method: Calculation method |

**Components:**

**mianserin hydrochloride:**

| | | |
|---|---|---|
| Acute oral toxicity | : | LD50 (Rat): 780 mg/kg<br><br>LD50 (Mouse): 224 mg/kg |
| Acute toxicity (other routes of administration) | : | LD50 (Mouse): 32 mg/kg<br>Application Route: Intravenous |

**Starch:**

| | | |
|---|---|---|
| Acute oral toxicity | : | LD50 (Rat): > 5,000 mg/kg |
| Acute dermal toxicity | : | LD50 (Rabbit): > 2,000 mg/kg |

**Silica:**

| | | |
|---|---|---|
| Acute oral toxicity | : | LD50 (Rat): > 5,000 mg/kg<br>Remarks: Based on data from similar materials |

**Skin corrosion/irritation**

Not classified based on available information.

**Components:**

**mianserin hydrochloride:**

| | | |
|---|---|---|
| Remarks | : | Not classified due to lack of data. |

**Silica:**

| | | |
|---|---|---|
| Result | : | No skin irritation |
| Remarks | : | Based on data from similar materials |

**Serious eye damage/eye irritation**

Not classified based on available information.

**Components:**

**mianserin hydrochloride:**

Remarks : Not classified due to lack of data.

**Starch:**

Species : Rabbit
Result : No eye irritation

**Silica:**

Species : Rabbit
Result : No eye irritation
Method : Draize Test
Remarks : Based on data from similar materials

**Respiratory or skin sensitization**

**Skin sensitization**

Not classified based on available information.

**Respiratory sensitization**

Not classified based on available information.

**Components:**

**mianserin hydrochloride:**

Remarks : Not classified due to lack of data.

**Starch:**

Test Type : Maximization Test
Routes of exposure : Skin contact
Species : Guinea pig
Result : negative

**Germ cell mutagenicity**

Not classified based on available information.

**Components:**

**mianserin hydrochloride:**

Genotoxicity in vitro : Test Type: gene mutation test
Result: positive

Test Type: Bacterial reverse mutation assay (AMES)
Result: negative
Remarks: Based on data from similar materials

Test Type: sister chromatid exchange assay
Result: negative
Remarks: Based on data from similar materials

Test Type: In vitro mammalian cell gene mutation test
Result: negative
Remarks: Based on data from similar materials

Test Type: unscheduled DNA synthesis assay
Result: negative
Remarks: Based on data from similar materials

Genotoxicity in vivo : Test Type: Micronucleus test
Species: Rat
Cell type: Bone marrow
Application Route: Oral
Result: negative
Remarks: Based on data from similar materials

**Starch:**

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

**Silica:**

Genotoxicity in vitro : Test Type: Bacterial reverse mutation assay (AMES)
Result: negative
Remarks: Based on data from similar materials

**Carcinogenicity**

Not classified based on available information.

**Components:**

**mianserin hydrochloride:**

Remarks : Not classified due to lack of data.

**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**

Suspected of damaging fertility. Suspected of damaging the unborn child.

**Components:**

**mianserin hydrochloride:**

Effects on fertility : Test Type: Fertility
Species: Rat, male
Fertility: NOAEL: 100 mg/kg body weight
Result: No effects on fertility., No effects on mating performance.

Test Type: Fertility
Species: Rat, female
Fertility: LOAEL: 30 mg/kg body weight
Result: Preimplantation loss., ovarian dysfunction, Effect on estrous cycle

Effects on fetal development : Test Type: Development
Species: Rat
Application Route: Subcutaneous
Developmental Toxicity: LOAEL: 10 mg/kg body weight
Result: Effects on postnatal development.

Test Type: Development
Species: Rat
Developmental Toxicity: LOAEL: 3 mg/kg body weight
Result: Embryolethal effects., No teratogenic effects.

Test Type: Development
Species: Rabbit
Result: Reduced fetal weight., No teratogenic effects.

Test Type: Development
Species: Mouse
Developmental Toxicity: NOAEL: 30 mg/kg body weight
Result: No effects on fetal development.

Reproductive toxicity - Assessment : Suspected of damaging fertility. Suspected of damaging the unborn child.

**STOT-single exposure**

Causes damage to organs (Central nervous system).

**Components:**

**mianserin hydrochloride:**

Target Organs : Central nervous system
Assessment : Causes damage to organs.

**STOT-repeated exposure**

Not classified based on available information.

**Repeated dose toxicity**

**Components:**

**mianserin hydrochloride:**

Species : Rat
NOAEL : 30 mg/kg
Application Route : Oral
Exposure time : 6 Months
Remarks : No significant adverse effects were reported

Species : Dog

| | | |
|---|---|---|
| LOAEL | : | 3 - 30 mg/kg |
| Application Route | : | Oral |
| Exposure time | : | 6 Months |
| Symptoms | : | Reduced body weight |

**Starch:**

| | | |
|---|---|---|
| Species | : | Rat |
| NOAEL | : | >= 2,000 mg/kg |
| Application Route | : | Skin contact |
| Exposure time | : | 28 Days |
| Method | : | OECD Test Guideline 410 |

**Aspiration toxicity**

Not classified based on available information.

**Experience with human exposure**

**Components:**

**mianserin hydrochloride:**

| | | |
|---|---|---|
| Inhalation | : | Remarks: May be harmful if inhaled.<br>May cause irritation of respiratory tract. |
| Skin contact | : | Remarks: Can be absorbed through skin.<br>May irritate skin. |
| Eye contact | : | Remarks: May irritate eyes. |
| Ingestion | : | Symptoms: central nervous system effects, dry mouth, constipation, Headache, Tremors |

## SECTION 12. ECOLOGICAL INFORMATION

**Ecotoxicity**

**Components:**

**Silica:**

| | | |
|---|---|---|
| Toxicity to fish | : | LC50 (Brachydanio rerio (zebrafish)): > 10,000 mg/l<br>Exposure time: 96 h<br>Method: OECD Test Guideline 203<br>Remarks: Based on data from similar materials |
| Toxicity to algae/aquatic plants | : | EC50: > 10,000 mg/l<br>Exposure time: 72 h<br>Method: OECD Test Guideline 201<br>Remarks: Based on data from similar materials |

**Persistence and degradability**

No data available

**Bioaccumulative potential**

**Components:**

**mianserin hydrochloride:**

Partition coefficient: n-octanol/water : log Pow: 3.36

**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.

## SECTION 14. TRANSPORT INFORMATION

**International Regulations**

**UNRTDG**
Not regulated as a dangerous good

**IATA-DGR**
Not regulated as a dangerous good

**IMDG-Code**
Not regulated as a dangerous good

**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**
Not regulated as a dangerous good

**Special precautions for user**

Not applicable

## SECTION 15. REGULATORY INFORMATION

**CERCLA Reportable Quantity**

This material does not contain any components with a CERCLA 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)

**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**

| | |
|---|---|
| Calcium hydrogenorthophosphate dihydrate | 7789-77-7 |
| Starch | 9005-25-8 |
| mianserin hydrochloride | 21535-47-7 |

**California Permissible Exposure Limits for Chemical Contaminants**

| | |
|---|---|
| Starch | 9005-25-8 |
| Silica | 71187-19-4 |

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

AICS : not determined

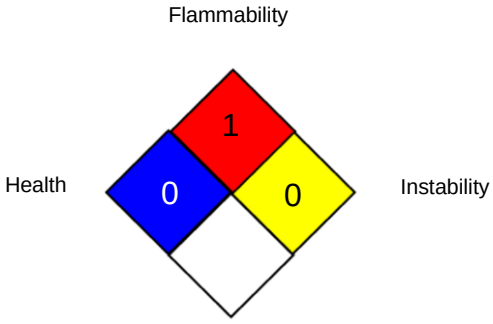
DSL : not determined

IECSC : not determined

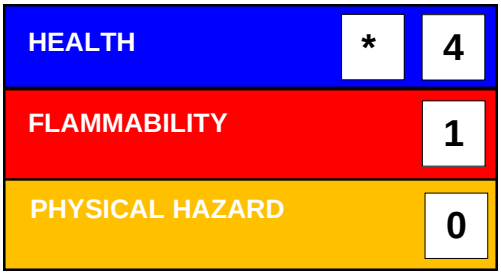
## SECTION 16. OTHER INFORMATION

**Further information**

**NFPA 704:**




**HMIS® IV:**




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**

| | | |
|---|---|---|
| ACGIH | : | USA. ACGIH Threshold Limit Values (TLV) |
| NIOSH REL | : | USA. NIOSH Recommended Exposure Limits |
| OSHA Z-1 | : | USA. Occupational Exposure Limits (OSHA) - Table Z-1 Limits for Air Contaminants |

| | | |
|---|---|---|
| OSHA Z-3 | : | USA. Occupational Exposure Limits (OSHA) - Table Z-3 Mineral Dusts |
| ACGIH / TWA | : | 8-hour, time-weighted average |
| NIOSH REL / TWA | : | Time-weighted average concentration for up to a 10-hour workday during a 40-hour workweek |
| OSHA Z-1 / TWA | : | 8-hour time weighted average |
| 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; 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 | : | 09/30/2023 |

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