# SAFETY DATA SHEET
according to the OSHA Hazard Communication Standard

## Insulin Porcine (with Metacresol) Formulation

| Version | Revision Date: | SDS Number: | Date of last issue: 09/20/2023 |
|---|---|---|---|
| 2.1 | 09/28/2024 | 11259069-00004 | Date of first issue: 08/11/2023 |

### SECTION 1. IDENTIFICATION

Product name : Insulin Porcine (with Metacresol) 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

### SECTION 2. HAZARDS IDENTIFICATION

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

Not a hazardous substance or mixture.

**GHS label elements**

No hazard pictogram, no signal word, no hazard statement(s), no precautionary statement(s) required.

**Other hazards**

None known.

### SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture : Mixture

**Components**

| Chemical name | CAS-No. | Concentration (% w/w) |
|---|---|---|
| m-Cresol | 108-39-4 | 0.23 |
| Insulin (ox), 8A-l-threonine-10A-l-isoleucine- | 12584-58-6 | 0.15 |

### SECTION 4. FIRST AID MEASURES

If inhaled : If inhaled, remove to fresh air.
Get medical attention if symptoms occur.
In case of skin contact : Wash with water and soap as a precaution.
Get medical attention if symptoms occur.
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 if symptoms occur.
Rinse mouth thoroughly with water.
Most important symptoms and effects, both acute and : None known.

delayed
Protection of first-aiders : No special precautions are necessary for first aid responders.
Notes to physician : Treat symptomatically and supportively.

### SECTION 5. FIRE-FIGHTING MEASURES

Suitable extinguishing media : Water spray
Alcohol-resistant foam
Carbon dioxide (CO2)
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 : No hazardous combustion products are known

Specific extinguishing methods : Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.
Use water spray to cool unopened containers.
Remove undamaged containers from fire area if it is safe to do so.
Evacuate area.

Special protective equipment for fire-fighters : Wear self-contained breathing apparatus for firefighting if necessary.
Use personal protective equipment.

### SECTION 6. ACCIDENTAL RELEASE MEASURES

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

Environmental precautions : Avoid release to the environment.
Prevent further leakage or spillage if safe to do so.
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.

## 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 | : | Handle in accordance with good industrial hygiene and safety practice, based on the results of the workplace exposure assessment<br>Take care to prevent spills, waste and minimize release to the environment. |
| Conditions for safe storage | : | Keep in properly labeled containers.<br>Store in accordance with the particular national regulations. |
| Materials to avoid | : | Do not store with the following product types:<br>Strong oxidizing agents<br>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 |
|---|---|---|---|---|
| m-Cresol | 108-39-4 | TWA | 2.3 ppm<br>10 mg/m³ | NIOSH REL |
| | | TWA | 5 ppm<br>22 mg/m³ | OSHA Z-1 |
| | | TWA (Inhalable fraction and vapor) | 20 mg/m³ | ACGIH |
| Insulin (ox), 8A-l-threonine-10A-l-isoleucine- | 12584-58-6 | TWA | 3 µg/m3 (OEB 4) | Internal |

**Engineering measures** : All engineering controls should be implemented by facility design and operated in accordance with GMP principles to protect products, workers, and the environment.
Essentially no open handling permitted.
Use closed processing systems or containment technologies.
If handled in a laboratory, use a properly designed biosafety cabinet, fume hood, or other containment device if the potential exists for aerosolization. If this potential does not exist, handle over lined trays or benchtops.

**Personal protective equipment**

Respiratory protection : No personal respiratory protective equipment normally

required.

Hand protection

| | | |
|---|---|---|
| Material | : | Chemical-resistant gloves |
| Remarks | : | Consider double gloving. |
| Eye protection | : | Wear safety glasses with side shields or goggles.<br>If the work environment or activity involves dusty conditions, mists or aerosols, wear the appropriate goggles.<br>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.<br>Additional body garments should be used based upon the task being performed (e.g., sleevelets, apron, gauntlets, disposable suits) to avoid exposed skin surfaces.<br>Use appropriate degowning techniques to remove potentially contaminated clothing. |
| 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.<br>The effective operation of a facility should include review of engineering controls, proper personal protective equipment, appropriate degowning and decontamination procedures, industrial hygiene monitoring, medical surveillance and the use of administrative controls. |

## SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

| | | |
|---|---|---|
| Appearance | : | suspension |
| Color | : | white to off-white |
| Odor | : | No data available |
| Odor Threshold | : | No data available |
| pH | : | 6.9 - 7.8 |
| Melting point/freezing point | : | No data available |
| Initial boiling point and boiling range | : | No data available |
| Flash point | : | No data available |
| Evaporation rate | : | No data available |
| 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 | : | 1.003 g/cm³ |
| Solubility(ies) | | |
| Water solubility | : | No data available |
| Partition coefficient: n-octanol/water | : | Not applicable |
| 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 characteristics | | |
| Particle size | : | Not applicable |

## 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**

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

**Components:**

**m-Cresol:**

| | | |
|---|---|---|
| Acute oral toxicity | : | LD50 (Rat): 121 mg/kg<br>Remarks: Based on data from similar materials |
| Acute inhalation toxicity | : | Assessment: Corrosive to the respiratory tract. |
| Acute dermal toxicity | : | LD50 (Rabbit): 301 mg/kg<br>Remarks: Based on data from similar materials |

**Insulin (ox), 8A-l-threonine-10A-l-isoleucine-:**

| | | |
|---|---|---|
| Acute toxicity (other routes of administration) | : | LD50 (Rat): > 36 mg/kg |

**Skin corrosion/irritation**

Not classified based on available information.

**Components:**

**m-Cresol:**

| | | |
|---|---|---|
| Species | : | Rabbit |
| Result | : | Corrosive after 3 minutes to 1 hour of exposure |

**Insulin (ox), 8A-l-threonine-10A-l-isoleucine-:**

| | | |
|---|---|---|
| Remarks | : | No data available |

**Serious eye damage/eye irritation**

Not classified based on available information.

**Components:**

**m-Cresol:**

| | | |
|---|---|---|
| Species | : | Rabbit |
| Result | : | Irreversible effects on the eye |

**Insulin (ox), 8A-l-threonine-10A-l-isoleucine-:**

| | | |
|---|---|---|
| Remarks | : | No data available |

**Respiratory or skin sensitization**

**Skin sensitization**

Not classified based on available information.

**Respiratory sensitization**

Not classified based on available information.

**Germ cell mutagenicity**

Not classified based on available information.

**Components:**

**m-Cresol:**

| | | |
|---|---|---|
| Genotoxicity in vitro | : | Test Type: Chromosome aberration test in vitro<br>Method: OECD Test Guideline 473<br>Result: positive<br><br>Test Type: Bacterial reverse mutation assay (AMES)<br>Method: OECD Test Guideline 471<br>Result: negative |
| Genotoxicity in vivo | : | Test Type: Mutagenicity (in vivo mammalian bone-marrow cytogenetic test, chromosomal analysis)<br>Species: Mouse<br>Application Route: Ingestion<br>Method: OECD Test Guideline 475<br>Result: negative |

**Insulin (ox), 8A-l-threonine-10A-l-isoleucine-:**

| | | |
|---|---|---|
| Genotoxicity in vitro | : | Test Type: Bacterial reverse mutation assay (AMES)<br>Test system: Salmonella typhimurium<br>Method: OECD Test Guideline 471<br>Result: negative<br><br>Test Type: Chromosome aberration test in vitro<br>Test system: Chinese hamster lung cells<br>Method: OECD Test Guideline 473<br>Result: negative |
| Genotoxicity in vivo | : | Test Type: In vivo micronucleus test<br>Cell type: Bone marrow<br>Method: OECD Test Guideline 475<br>Result: negative |
| Germ cell mutagenicity - Assessment | : | Weight of evidence does not support classification as a germ cell mutagen. |

**Carcinogenicity**

Not classified based on available information.

**Components:**

**m-Cresol:**

| | | |
|---|---|---|
| Species | : | Mouse, males |
| Application Route | : | Ingestion |
| Exposure time | : | 105 weeks |
| Result | : | equivocal |
| Remarks | : | Based on data from similar materials |

| | | |
|---|---|---|
| Species | : | Mouse, female |
| Application Route | : | Ingestion |
| Exposure time | : | 106 - 107 weeks |
| Result | : | positive |
| Remarks | : | Based on data from similar materials |

| | | |
|---|---|---|
| Carcinogenicity - Assessment | : | Weight of evidence does not support classification as a carcinogen |

**Insulin (ox), 8A-l-threonine-10A-l-isoleucine-:**

| | | |
|---|---|---|
| Species | : | Rat |
| Application Route | : | Subcutaneous |
| Exposure time | : | 2 Years |
| LOAEL | : | 180 µg/kg |

| | | |
|---|---|---|
| Carcinogenicity - Assessment | : | Weight of evidence does not support classification as a carcinogen |

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

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

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

**Reproductive toxicity**

Not classified based on available information.

**Components:**

**m-Cresol:**

| | | |
|---|---|---|
| Effects on fertility | : | Test Type: Two-generation reproduction toxicity study<br>Species: Rat<br>Application Route: Ingestion<br>Result: negative |
| Effects on fetal development | : | Test Type: Prenatal development toxicity study (teratogenicity)<br>Species: Rat<br>Application Route: Ingestion<br>Result: negative |

**Insulin (ox), 8A-l-threonine-10A-l-isoleucine-:**

| | | |
|---|---|---|
| Effects on fertility | : | Test Type: Fertility/early embryonic development<br>Species: Rat<br>Application Route: Intraperitoneal<br>Fertility: NOAEL Mating/Fertility: 360 µg/kg<br>Symptoms: No effects on fertility.<br>Result: No effects on fertility and early embryonic development were detected. |

**STOT-single exposure**

Not classified based on available information.

**STOT-repeated exposure**

Not classified based on available information.

**Repeated dose toxicity**

**Components:**

**m-Cresol:**

| | | |
|---|---|---|
| Species | : | Rat |
| NOAEL | : | 150 mg/kg |
| Application Route | : | Ingestion |
| Exposure time | : | 13 Weeks |
| Method | : | OECD Test Guideline 408 |

**Insulin (ox), 8A-l-threonine-10A-l-isoleucine-:**

| | | |
|---|---|---|
| Species | : | Rat |
| | : | 5.8 mg/kg |
| Application Route | : | Inhalation |
| Exposure time | : | 6 Months |
| Symptoms | : | Hypoglycemia |
| | | |
| Species | : | Monkey |
| | : | 0.64 mg/kg |
| Application Route | : | Inhalation |
| Exposure time | : | 6 Months |
| Symptoms | : | Hypoglycemia |
| | | |
| Species | : | Rat |
| NOAEL | : | 0.085 mg/kg |
| Application Route | : | Subcutaneous |
| Exposure time | : | 1 Months |
| | | |
| Species | : | Dog |
| NOAEL | : | 0.07 mg/kg |
| Application Route | : | Subcutaneous |
| Exposure time | : | 1 Months |

**Aspiration toxicity**

Not classified based on available information.

**Experience with human exposure**

**Components:**

**Insulin (ox), 8A-l-threonine-10A-l-isoleucine-:**

Inhalation : Symptoms: Hypoglycemia, Fatigue, Drowsiness, Sweating, Headache, Nausea, Palpitation, tingling, numbness, altered mental status, Breathing difficulties

## SECTION 12. ECOLOGICAL INFORMATION

**Ecotoxicity**

**Components:**

**m-Cresol:**

Toxicity to fish : LC50 (Oncorhynchus mykiss (rainbow trout)): 8.6 mg/l
Exposure time: 96 h

Toxicity to daphnia and other aquatic invertebrates : EC50 (Daphnia pulex (Water flea)): > 99.5 mg/l
Exposure time: 48 h

Toxicity to fish (Chronic toxicity) : NOEC (Pimephales promelas (fathead minnow)): 1.35 mg/l
Exposure time: 32 d
Remarks: Based on data from similar materials

Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity) : NOEC (Daphnia magna (Water flea)): 1 mg/l
Exposure time: 21 d
Remarks: Based on data from similar materials

**Persistence and degradability**

**Components:**

**m-Cresol:**

Biodegradability : Result: Readily biodegradable.
Biodegradation: 90 %
Exposure time: 28 d
Method: OECD Test Guideline 301D

**Bioaccumulative potential**

**Components:**

**m-Cresol:**

Bioaccumulation : Species: Leuciscus idus (Golden orfe)
Bioconcentration factor (BCF): 17 - 20

Partition coefficient: n-octanol/water : log Pow: 1.96

**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.<br>Do not dispose of waste into sewer. |
| Contaminated packaging | : | Empty containers should be taken to an approved waste handling site for recycling or disposal.<br>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**

| | | |
|---|---|---|
| UN/ID/NA number | : | UN 3082 |
| Proper shipping name | : | Environmentally hazardous substance, liquid, n.o.s. (m-Cresol) |
| Class | : | 9 |
| Packing group | : | III |
| Labels | : | CLASS 9 |
| ERG Code | : | 171 |
| Marine pollutant | : | no |
| Remarks | : | THE ABOVE INFORMATION ONLY APPLIES TO PACKAGE SIZES WHERE THE HAZARDOUS SUBSTANCE MEETS THE REPORTABLE QUANTITY. |

**Special precautions for user**
The transport classification(s) provided herein are for informational purposes only, and solely based upon the properties of the unpackaged material as it is described within this Safety Data Sheet. Transportation classifications may vary by mode of transportation, package sizes, and variations in regional or country regulations.

## SECTION 15. REGULATORY INFORMATION

**CERCLA Reportable Quantity**

| Components | CAS-No. | Component RQ (lbs) | Calculated product RQ (lbs) |
|---|---|---|---|

| | | | |
|---|---|---|---|
| m-Cresol | 108-39-4 | 100 | 43478 |

**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** : No SARA Hazards

**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 |
| m-Cresol | 108-39-4 |
| Sodium hydroxide | 1310-73-2 |
| Hydrochloric acid | 7647-01-0 |

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

AICS : not determined

DSL : not determined

IECSC : not determined

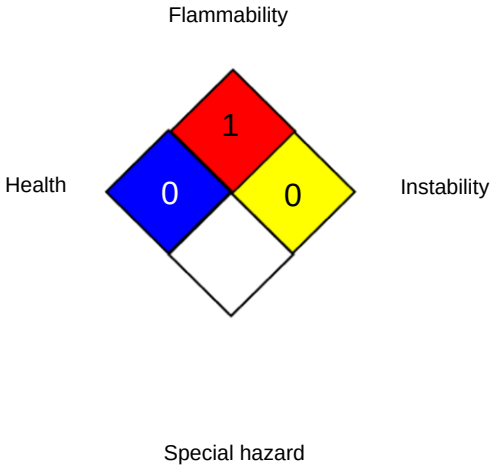
## SECTION 16. OTHER INFORMATION

**Further information**

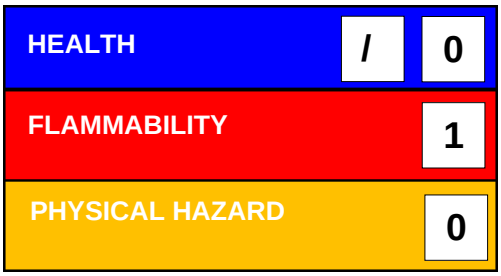
# Insulin Porcine (with Metacresol) Formulation

| Version | Revision Date: | SDS Number: | Date of last issue: 09/20/2023 |
|---|---|---|---|
| 2.1 | 09/28/2024 | 11259069-00004 | Date of first issue: 08/11/2023 |

**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 |
| 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 |

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 sub-

stance; 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 | : | 09/28/2024 |

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