

## Amoxicillin Trihydrate Liquid Formulation

Version            Revision Date:            SDS Number:            Date of last issue: 04/09/2022  
3.5                10/01/2022                1198851-00016            Date of first issue: 01/05/2017

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### SECTION 1. IDENTIFICATION

Product name                                : Amoxicillin Trihydrate Liquid Formulation  
Other means of identification            : No data available

#### 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 Hazardous Products Regulations

Respiratory sensitization                : Sub-category 1A

#### GHS label elements

Hazard pictograms                        : 

Signal Word                                : Danger

Hazard Statements                        : H334 May cause allergy or asthma symptoms or breathing difficulties if inhaled.

Precautionary Statements                : **Prevention:**  
P261 Avoid breathing mist or vapors.  
P284 Wear respiratory protection.  
**Response:**  
P304 + P340 IF INHALED: Remove person to fresh air and keep comfortable for breathing.  
P342 + P311 If experiencing respiratory symptoms: Call a doctor.  
**Disposal:**  
P501 Dispose of contents and container to an approved waste disposal plant.

#### Other hazards

None known.

## Amoxicillin Trihydrate Liquid Formulation

Version 3.5      Revision Date: 10/01/2022      SDS Number: 1198851-00016      Date of last issue: 04/09/2022  
 Date of first issue: 01/05/2017

### SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture : Mixture

#### Components

Chemical name	Common Name/Synonym	CAS-No.	Concentration (% w/w)
Coconut Oil	Cococ nucifera (coconut) oil	8001-31-8	78.32
Amoxicillin Trihydrate	No data available	61336-70-7	17
Fatty acids, C14-26, aluminum salts	Aluminum Stearate	97404-28-9	1.32

### 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.  
 If not breathing, give artificial respiration.  
 If breathing is difficult, give oxygen.  
 Get medical attention.

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 delayed : May cause allergy or asthma symptoms or breathing difficulties if inhaled.  
 Excessive exposure may aggravate preexisting asthma and other respiratory disorders (e.g. emphysema, bronchitis, reactive airways dysfunction syndrome).

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 fighting : Exposure to combustion products may be a hazard to health.

Hazardous combustion products : Carbon oxides  
 Metal oxides

## Amoxicillin Trihydrate Liquid Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 04/09/2022
3.5	10/01/2022	1198851-00016	Date of first issue: 01/05/2017

---

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 : Use only with adequate ventilation.

Advice on safe handling : Avoid breathing mist or vapors.  
Do not swallow.  
Avoid contact with eyes.  
Avoid prolonged or repeated contact with skin.  
Handle in accordance with good industrial hygiene and safety practice, based on the results of the workplace exposure assessment  
Keep container tightly closed.  
Already sensitized individuals, and those susceptible to asthma, allergies, chronic or recurrent respiratory disease, should consult their physician regarding working with

## Amoxicillin Trihydrate Liquid Formulation

Version 3.5      Revision Date: 10/01/2022      SDS Number: 1198851-00016      Date of last issue: 04/09/2022  
 Date of first issue: 01/05/2017

- respiratory irritants or sensitizers.  
 Take care to prevent spills, waste and minimize release to the environment.
- Conditions for safe storage : Keep in properly labeled containers.  
 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  
 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
Coconut Oil	8001-31-8	TWAEV (Mist)	10 mg/m <sup>3</sup>	CA QC OEL
Amoxicillin Trihydrate	61336-70-7	TWA	1 mg/m <sup>3</sup> (OEB 1)	Internal
Further information: RSEN				
Fatty acids, C14-26, aluminum salts	97404-28-9	TWA (Respirable)	1 mg/m <sup>3</sup> (Aluminum)	CA BC OEL
		TWA (Respirable particulate matter)	1 mg/m <sup>3</sup> (Aluminum)	ACGIH

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

#### Personal protective equipment

- 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
- 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:  
 Safety glasses
- Skin and body protection : Skin should be washed after contact.
- 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.



**Amoxicillin Trihydrate Liquid Formulation**

Version            Revision Date:            SDS Number:            Date of last issue: 04/09/2022  
3.5                10/01/2022                1198851-00016            Date of first issue: 01/05/2017

---

Oxidizing properties            :    The substance or mixture is not classified as oxidizing.  
Molecular weight                :    No data available  
Particle size                      :    Not applicable

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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 reac- :    Can react with strong oxidizing agents.  
tions  
Conditions to avoid               :    None known.  
Incompatible materials            :    Oxidizing agents  
Hazardous decomposition        :    No hazardous decomposition products are known.  
products

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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:****Coconut Oil:**

Acute oral toxicity                :    LD50 (Rat): > 5,000 mg/kg  
Acute dermal toxicity              :    LD50 (Guinea pig): > 3,000 mg/kg  
Remarks: Based on data from similar materials

**Amoxicillin Trihydrate:**

Acute oral toxicity                :    LD50 (Rat): > 8,000 mg/kg  
LD50 (Mouse): > 10,000 mg/kg  
LD50 (Dog): > 3,000 mg/kg

**Fatty acids, C14-26, aluminum salts:**

Acute oral toxicity                :    LD50 (Rat, female): > 2,000 mg/kg  
Method: OECD Test Guideline 423  
Remarks: Based on data from similar materials  
Acute inhalation toxicity        :    LC50 (Rat): > 5.15 mg/l  
Exposure time: 4 h  
Test atmosphere: dust/mist  
Method: OECD Test Guideline 403

**Amoxicillin Trihydrate Liquid Formulation**

Version            Revision Date:            SDS Number:            Date of last issue: 04/09/2022  
3.5                10/01/2022                1198851-00016            Date of first issue: 01/05/2017

---

Remarks: Based on data from similar materials

**Skin corrosion/irritation**

Not classified based on available information.

**Components:****Coconut Oil:**

Species                                : Rabbit  
Result                                 : No skin irritation

**Fatty acids, C14-26, aluminum salts:**

Species                                : reconstructed human epidermis (RhE)  
Method                                 : OECD Test Guideline 431  
Remarks                                : Based on data from similar materials

Species                                : reconstructed human epidermis (RhE)  
Method                                 : OECD Test Guideline 439  
Remarks                                : Based on data from similar materials

Result                                 : No skin irritation

**Serious eye damage/eye irritation**

Not classified based on available information.

**Components:****Coconut Oil:**

Species                                : Rabbit  
Result                                 : No eye irritation

**Fatty acids, C14-26, aluminum salts:**

Species                                : Rabbit  
Result                                 : No eye irritation  
Method                                 : OECD Test Guideline 405  
Remarks                                : Based on data from similar materials

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

Not classified based on available information.

**Respiratory sensitization**

May cause allergy or asthma symptoms or breathing difficulties if inhaled.

**Components:****Coconut Oil:**

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

**Amoxicillin Trihydrate Liquid Formulation**

Version 3.5      Revision Date: 10/01/2022      SDS Number: 1198851-00016      Date of last issue: 04/09/2022  
Date of first issue: 01/05/2017

---

**Amoxicillin Trihydrate:**

Result : Sensitizer  
Remarks : May cause sensitization by inhalation.  
largely based on human evidence

**Fatty acids, C14-26, aluminum salts:**

Test Type : Local lymph node assay (LLNA)  
Routes of exposure : Skin contact  
Species : Mouse  
Method : OECD Test Guideline 429  
Result : negative  
Remarks : Based on data from similar materials

**Germ cell mutagenicity**

Not classified based on available information.

**Components:****Coconut Oil:**

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

**Amoxicillin Trihydrate:**

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

Genotoxicity in vivo : Test Type: Micronucleus test  
Species: Mouse  
Result: negative

Test Type: Rodent dominant lethal test (germ cell) (in vivo)  
Species: Mouse  
Result: negative

**Fatty acids, C14-26, aluminum salts:**

Genotoxicity in vitro : Test Type: Bacterial reverse mutation assay (AMES)  
Method: OECD Test Guideline 471  
Result: negative  
Remarks: Based on data from similar materials

Test Type: In vitro mammalian cell gene mutation test  
Method: OECD Test Guideline 476  
Result: negative  
Remarks: Based on data from similar materials

**Carcinogenicity**

Not classified based on available information.

**Reproductive toxicity**

Not classified based on available information.



**Amoxicillin Trihydrate Liquid Formulation**

Version 3.5      Revision Date: 10/01/2022      SDS Number: 1198851-00016      Date of last issue: 04/09/2022  
Date of first issue: 01/05/2017

---

**Components:****Amoxicillin Trihydrate:**

- Effects on fertility : Test Type: Fertility  
Species: Rat  
Application Route: Oral  
Fertility: NOAEL: 200 mg/kg body weight  
Result: Reduced fertility  
Remarks: Not classified due to inconclusive data.
- Test Type: Fertility  
Species: Rat  
Application Route: Oral  
Fertility: LOAEL: 500 mg/kg body weight  
Result: Reduced fertility  
Remarks: Not classified due to inconclusive data.
- Effects on fetal development : Test Type: Development  
Species: Rat  
Application Route: Oral  
Developmental Toxicity: NOAEL:  $\geq$  1,000 mg/kg body weight  
Result: No embryo-fetal toxicity.
- Test Type: Development  
Species: Mouse  
Application Route: Oral  
Developmental Toxicity: LOAEL: 200 mg/kg body weight  
Result: Some evidence of adverse effects on development, based on animal experiments.  
Remarks: Not classified due to inconclusive data.
- Test Type: Development  
Species: Rat  
Application Route: Oral  
Developmental Toxicity: LOAEL: 200 mg/kg body weight  
Result: Reduced embryonic survival, Reduced offspring weight gain.  
Remarks: Not classified due to inconclusive data.

**Fatty acids, C14-26, aluminum salts:**

- Effects on fertility : Test Type: Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test  
Species: Rat  
Application Route: Ingestion  
Method: OECD Test Guideline 422  
Result: negative  
Remarks: Based on data from similar materials
- Effects on fetal development : Test Type: Reproduction/Developmental toxicity screening test  
Species: Rat  
Application Route: Ingestion  
Method: OECD Test Guideline 414  
Result: negative

**Amoxicillin Trihydrate Liquid Formulation**

Version 3.5      Revision Date: 10/01/2022      SDS Number: 1198851-00016      Date of last issue: 04/09/2022  
Date of first issue: 01/05/2017

---

Remarks: Based on data from similar materials

**STOT-single exposure**

Not classified based on available information.

**STOT-repeated exposure**

Not classified based on available information.

**Components:****Amoxicillin Trihydrate:**

Remarks : Not classified due to inconclusive data.

**Repeated dose toxicity****Components:****Amoxicillin Trihydrate:**

Species : Rat  
Application Route : Oral  
Exposure time : 6 Months  
Remarks : No significant adverse effects were reported

Species : Dog  
Application Route : Oral  
Exposure time : 6 Months  
Remarks : No significant adverse effects were reported

**Fatty acids, C14-26, aluminum salts:**

Species : Rat  
: >= 1000 mg/kg  
Application Route : Ingestion  
Exposure time : 42 Days  
Remarks : Based on data from similar materials

**Aspiration toxicity**

Not classified based on available information.

**Experience with human exposure****Components:****Amoxicillin Trihydrate:**

Ingestion : Symptoms: Nausea, Vomiting, Abdominal pain, Diarrhea, flatulence, skin rash, Breathing difficulties  
Remarks: May produce an allergic reaction.

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**SECTION 12. ECOLOGICAL INFORMATION****Ecotoxicity****Components:****Amoxicillin Trihydrate:**

**Amoxicillin Trihydrate Liquid Formulation**

Version	Revision Date:	SDS Number:	Date of last issue: 04/09/2022
3.5	10/01/2022	1198851-00016	Date of first issue: 01/05/2017

---

Toxicity to fish : LC50 (Carassius auratus (goldfish)): 0.035 mg/l  
Exposure time: 96 h  
Method: OECD Test Guideline 203

Toxicity to algae/aquatic plants : NOEC (green algae): 530 mg/l  
Exposure time: 72 h

EC50 (Synechococcus leopoliensis (blue-green algae)):  
0.0022 mg/l  
Exposure time: 96 h

NOEC (blue-green algae): 0.0057 mg/l  
Exposure time: 72 h

**Persistence and degradability****Components:****Amoxicillin Trihydrate:**

Biodegradability : Result: Readily biodegradable.  
Biodegradation: 88 %  
Exposure time: 28 d  
Method: OECD Test Guideline 301B

**Fatty acids, C14-26, aluminum salts:**

Biodegradability : Result: Readily biodegradable.  
Biodegradation: 81.2 %  
Exposure time: 28 d  
Method: OECD Test Guideline 301B  
Remarks: Based on data from similar materials

**Bioaccumulative potential****Components:****Amoxicillin Trihydrate:**

Bioaccumulation : Remarks: Bioaccumulation is unlikely.

Partition coefficient: n-octanol/water : log Pow: -0.124  
Method: OECD Test Guideline 107

**Fatty acids, C14-26, aluminum salts:**

Partition coefficient: n-octanol/water : log Pow: > 7  
Remarks: Calculation

**Mobility in soil**

No data available

**Other adverse effects****Components:****Amoxicillin Trihydrate:**

## Amoxicillin Trihydrate Liquid Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 04/09/2022
3.5	10/01/2022	1198851-00016	Date of first issue: 01/05/2017

Results of PBT and vPvB assessment : This substance is not considered to be persistent, bioaccumulating and toxic (PBT). This mixture contains no substance considered to be very persistent and very bioaccumulating (vPvB).

### 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.

### SECTION 14. TRANSPORT INFORMATION

#### International Regulations

##### UNRTDG

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

##### IATA-DGR

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

##### IMDG-Code

UN number : UN 3082  
 Proper shipping name : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S.  
 (Amoxicillin Trihydrate)  
 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

## Amoxicillin Trihydrate Liquid Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 04/09/2022
3.5	10/01/2022	1198851-00016	Date of first issue: 01/05/2017

---

### TDG

UN number	:	UN 3082
Proper shipping name	:	ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S. (Amoxicillin Trihydrate)
Class	:	9
Packing group	:	III
Labels	:	9
ERG Code	:	171
Marine pollutant	:	yes(Amoxicillin Trihydrate)

### 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

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

AICS	:	not determined
DSL	:	not determined
IECSC	:	not determined

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## SECTION 16. OTHER INFORMATION

### Full text of other abbreviations

ACGIH	:	USA. ACGIH Threshold Limit Values (TLV)
CA BC OEL	:	Canada. British Columbia OEL
CA QC OEL	:	Québec. Regulation respecting occupational health and safety, Schedule 1, Part 1: Permissible exposure values for airborne contaminants
ACGIH / TWA	:	8-hour, time-weighted average
CA BC OEL / TWA	:	8-hour time weighted average
CA QC OEL / TWAEV	:	Time-weighted average exposure value

AIIC - Australian Inventory of Industrial Chemicals; ANTT - National Agency for Transport by Land of Brazil; ASTM - American Society for the Testing of Materials; bw - Body weight; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DSL - Domestic Substances List (Canada); ECx - Concentration associated with x% response; ELx - Loading rate associated with x% response; EmS - Emergency Schedule; ENCS - Existing and New Chemical Substances (Japan); ErCx - Concentration associated with x% growth rate response; ERG - Emergency Response Guide; GHS - Globally Harmonized System; GLP - Good Laboratory Practice; IARC - International Agency for Research on Cancer; IATA - International Air Transport Association; IBC - International Code for the Construction and Equipment of Ships carrying Dangerous Chemicals in Bulk; IC50 - Half maximal inhibitory concentration; ICAO - International Civil Aviation Organization; IECSC - Inventory of Existing Chemical Substances in China; IMDG - International Maritime Dangerous Goods; IMO - International Maritime Organization; ISHL - Industrial Safety and Health Law (Japan); ISO - International Organisation for Standardization; KECI - Korea Existing Chemicals Inventory; LC50 - Lethal Con-

**Amoxicillin Trihydrate Liquid Formulation**

Version	Revision Date:	SDS Number:	Date of last issue: 04/09/2022
3.5	10/01/2022	1198851-00016	Date of first issue: 01/05/2017

---

centration to 50 % of a test population; LD50 - Lethal Dose to 50% of a test population (Median Lethal Dose); MARPOL - International Convention for the Prevention of Pollution from Ships; n.o.s. - Not Otherwise Specified; Nch - Chilean Norm; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; NOM - Official Mexican Norm; NTP - National Toxicology Program; NZIoC - New Zealand Inventory of Chemicals; OECD - Organization for Economic Co-operation and Development; OPPTS - Office of Chemical Safety and Pollution Prevention; PBT - Persistent, Bioaccumulative and Toxic substance; PICCS - Philippines Inventory of Chemicals and Chemical Substances; (Q)SAR - (Quantitative) Structure Activity Relationship; REACH - Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals; SADT - Self-Accelerating Decomposition Temperature; SDS - Safety Data Sheet; TCSI - Taiwan Chemical Substance Inventory; TDG - Transportation of Dangerous Goods; TECI - Thailand Existing Chemicals Inventory; TSCA - Toxic Substances Control Act (United States); UN - United Nations; UNRTDG - United Nations Recommendations on the Transport of Dangerous Goods; vPvB - Very Persistent and Very Bioaccumulative; WHMIS - Workplace Hazardous Materials Information System

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  
Date format : mm/dd/yyyy

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.

CA / Z8