

# SAFETY DATA SHEET



## Alendronate Liquid Formulation



Version 2.14      Revision Date: 09.04.2021      SDS Number: 28221-00017      Date of last issue: 16.10.2020  
Date of first issue: 05.11.2014

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### SECTION 1: Identification of the substance/mixture and of the company/undertaking

#### 1.1 Product identifier

Trade name : Alendronate Liquid Formulation

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

Use of the Substance/Mixture : Pharmaceutical

#### 1.3 Details of the supplier of the safety data sheet

Company : Organon & Co.  
30 Hudson Street, 33rd floor  
07302 Jersey City, New Jersey, U.S.A

Telephone : 551-430-6000

E-mail address of person responsible for the SDS : EHSSTEWARD@organon.com

#### 1.4 Emergency telephone number

215-631-6999

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### SECTION 2: Hazards identification

#### 2.1 Classification of the substance or mixture

##### Classification (REGULATION (EC) No 1272/2008)

Not a hazardous substance or mixture.

#### 2.2 Label elements

##### Labelling (REGULATION (EC) No 1272/2008)

Not a hazardous substance or mixture.

##### Additional Labelling

EUH210      Safety data sheet available on request.

#### 2.3 Other hazards

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

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### SECTION 3: Composition/information on ingredients

#### 3.2 Mixtures

##### Components

Chemical name	CAS-No.	Classification	Concentration
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## Alendronate Liquid Formulation

Version 2.14      Revision Date: 09.04.2021      SDS Number: 28221-00017      Date of last issue: 16.10.2020  
Date of first issue: 05.11.2014

	EC-No. Index-No. Registration number		(% w/w)
Alendronate	121268-17-5	Acute Tox. 4; H302 Skin Irrit. 2; H315 Eye Dam. 1; H318 Repr. 2; H361d STOT SE 3; H335 STOT RE 2; H373 (Bone, Stomach, Kidney)	>= 0,1 - < 1

For explanation of abbreviations see section 16.

## SECTION 4: First aid measures

### 4.1 Description of first aid measures

- General advice : In the case of accident or if you feel unwell, seek medical advice immediately.  
When symptoms persist or in all cases of doubt seek medical advice.
- Protection of first-aiders : First Aid responders should pay attention to self-protection, and use the recommended personal protective equipment when the potential for exposure exists (see section 8).
- If inhaled : If inhaled, remove to fresh air.  
Get medical attention.
- In case of skin contact : In case of contact, immediately flush skin with soap and plenty of water.  
Remove contaminated clothing and shoes.  
Get medical attention.  
Wash clothing before reuse.  
Thoroughly clean shoes before reuse.
- In case of eye contact : 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.

### 4.2 Most important symptoms and effects, both acute and delayed

None known.

### 4.3 Indication of any immediate medical attention and special treatment needed

- Treatment : Treat symptomatically and supportively.

**Alendronate Liquid Formulation**

Version	Revision Date:	SDS Number:	Date of last issue: 16.10.2020
2.14	09.04.2021	28221-00017	Date of first issue: 05.11.2014

---

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

Suitable extinguishing media : Water spray  
Alcohol-resistant foam  
Carbon dioxide (CO<sub>2</sub>)  
Dry chemical

Unsuitable extinguishing media : None known.

**5.2 Special hazards arising from the substance or mixture**

Specific hazards during fire-fighting : Exposure to combustion products may be a hazard to health.

Hazardous combustion products : Carbon oxides  
Metal oxides

**5.3 Advice for firefighters**

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

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

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

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

**6.2 Environmental precautions**

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

**6.3 Methods and material for containment and cleaning up**

Methods for cleaning up : Soak up with inert absorbent material.  
For large spills, provide dyking or other appropriate containment to keep material from spreading. If dyked material can be pumped, store recovered material in appropriate container.

## Alendronate Liquid Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 16.10.2020
2.14	09.04.2021	28221-00017	Date of first issue: 05.11.2014

---

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.

**6.4 Reference to other sections**

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

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**SECTION 7: Handling and storage****7.1 Precautions for safe handling**

- |                         |   |  |
|-------------------------|---|--|
| Technical measures      | : | See Engineering measures under EXPOSURE CONTROLS/PERSONAL PROTECTION section.  |
| Local/Total ventilation | : | Use only with adequate ventilation.  |
| Advice on safe handling | : | Avoid inhalation of vapour or mist.<br>Do not swallow.<br>Avoid contact with eyes.<br>Avoid prolonged or repeated contact with skin.<br>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.  |
| Hygiene measures        | : | If exposure to chemical is likely during typical use, provide eye flushing systems and safety showers close to the working place. When using do not eat, drink or smoke. Wash contaminated clothing before re-use.<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. |

**7.2 Conditions for safe storage, including any incompatibilities**

- |   |   |   |
|---|---|---|
| Requirements for storage areas and containers | : | Keep in properly labelled containers. Store in accordance with the particular national regulations. |
| Advice on common storage                      | : | Do not store with the following product types:<br>Strong oxidizing agents                           |

**7.3 Specific end use(s)**

- |                 |   |                   |
|-----------------|---|-------------------|
| Specific use(s) | : | No data available |
|-----------------|---|-------------------|
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**SECTION 8: Exposure controls/personal protection****8.1 Control parameters****Occupational Exposure Limits**

## Alendronate Liquid Formulation

Version 2.14      Revision Date: 09.04.2021      SDS Number: 28221-00017      Date of last issue: 16.10.2020  
 Date of first issue: 05.11.2014

Components	CAS-No.	Value type (Form of exposure)	Control parameters	Basis
Alendronate	121268-17-5	TWA	20 µg/m <sup>3</sup> (OEB 3)	Internal
		Wipe limit	200 µg/100 cm <sup>2</sup>	Internal

## 8.2 Exposure controls

### 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.

Containment technologies suitable for controlling compounds are required to control at source and to prevent migration of the compound to uncontrolled areas (e.g., open-face containment devices).

Minimize open handling.

### Personal protective equipment

- 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.  
 Wear a faceshield or other full face protection if there is a potential for direct contact to the face with dusts, mists, or aerosols.
- Hand protection
- Material : Chemical-resistant gloves
- Remarks : Consider double gloving.
- Skin and body protection : Work uniform or laboratory coat.  
 Additional body garments should be used based upon the task being performed (e.g., sleevelets, apron, gauntlets, disposable suits) to avoid exposed skin surfaces.  
 Use appropriate degowning techniques to remove potentially contaminated clothing.
- Respiratory protection : If adequate local exhaust ventilation is not available or exposure assessment demonstrates exposures outside the recommended guidelines, use respiratory protection.
- Filter type : Particulates type (P)

## SECTION 9: Physical and chemical properties

### 9.1 Information on basic physical and chemical properties

- Appearance : liquid
- Colour : clear
- Odour : No data available
- Odour Threshold : No data available
- pH : 6,4 - 7,2
- Melting point/freezing point : No data available
- Initial boiling point and boiling : 100 °C

## Alendronate Liquid Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 16.10.2020
2.14	09.04.2021	28221-00017	Date of first issue: 05.11.2014

---

range		
Flash point	:	No data available
Evaporation rate	:	No data available
Flammability (solid, gas)	:	Not applicable
Upper explosion limit / Upper flammability limit	:	No data available
Lower explosion limit / Lower flammability limit	:	No data available
Vapour pressure	:	No data available
Relative vapour density	:	No data available
Relative density	:	No data available
Density	:	No data available
Solubility(ies)		
Water solubility	:	soluble
Partition coefficient: n-octanol/water	:	Not applicable
Auto-ignition 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.

**9.2 Other information**

Flammability (liquids)	:	No data available
Particle size	:	Not applicable

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

Not classified as a reactivity hazard.

**10.2 Chemical stability**

Stable under normal conditions.

**10.3 Possibility of hazardous reactions**

Hazardous reactions : Can react with strong oxidizing agents.

**10.4 Conditions to avoid**

# SAFETY DATA SHEET



## Alendronate Liquid Formulation



Version 2.14      Revision Date: 09.04.2021      SDS Number: 28221-00017      Date of last issue: 16.10.2020  
Date of first issue: 05.11.2014

---

Conditions to avoid : None known.

### 10.5 Incompatible materials

Materials to avoid : Oxidizing agents

### 10.6 Hazardous decomposition products

No hazardous decomposition products are known.

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## SECTION 11: Toxicological information

### 11.1 Information on toxicological effects

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

#### Acute toxicity

Not classified based on available information.

#### Components:

##### Alendronate:

Acute oral toxicity : LD50 (Rat): 552 - 626 mg/kg  
LD50 (Mouse): 966 - 1.280 mg/kg

Acute inhalation toxicity : Remarks: No data available

Acute dermal toxicity : Remarks: No data available

#### Skin corrosion/irritation

Not classified based on available information.

#### Components:

##### Alendronate:

Species : Rabbit  
Remarks : Severe skin irritation

#### Serious eye damage/eye irritation

Not classified based on available information.

#### Components:

##### Alendronate:

Species : Rabbit  
Result : Severe irritation

#### Respiratory or skin sensitisation

##### Skin sensitisation

Not classified based on available information.

## Alendronate Liquid Formulation

Version 2.14      Revision Date: 09.04.2021      SDS Number: 28221-00017      Date of last issue: 16.10.2020  
Date of first issue: 05.11.2014

---

**Respiratory sensitisation**

Not classified based on available information.

**Components:****Alendronate:**

Remarks : No data available

**Germ cell mutagenicity**

Not classified based on available information.

**Components:****Alendronate:**

Genotoxicity in vitro : Test Type: Alkaline elution assay  
Test system: rat hepatocytes  
Result: negative

Test Type: Bacterial reverse mutation assay (AMES)  
Metabolic activation: with and without metabolic activation  
Result: negative

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

Test Type: Chromosomal aberration  
Test system: Chinese hamster ovary cells  
Result: equivocal

Genotoxicity in vivo : Test Type: Chromosomal aberration  
Species: Mouse  
Result: negative

**Carcinogenicity**

Not classified based on available information.

**Components:****Alendronate:**

Species : Rat, male  
Application Route : Oral  
Exposure time : 2 Years  
: 1 mg/kg body weight  
: 3,75 mg/kg body weight  
Target Organs : Thyroid  
Remarks : The mechanism or mode of action may not be relevant in humans.

**Reproductive toxicity**

Not classified based on available information.

**Components:****Alendronate:**



## Alendronate Liquid Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 16.10.2020
2.14	09.04.2021	28221-00017	Date of first issue: 05.11.2014

---

- Effects on fertility : Test Type: Fertility  
Species: Rat, male and female  
Application Route: Oral  
Fertility: NOAEL: 5 mg/kg body weight  
Result: Animal testing did not show any effects on fertility.
- Effects on foetal development : Test Type: Development  
Species: Rat, female  
Application Route: Oral  
Developmental Toxicity: LOAEL: 1 - 15 mg/kg body weight  
Symptoms: Reduced number of viable fetuses, Reduced body weight, Skeletal malformations  
Result: Embryotoxic effects and adverse effects on the offspring were detected.
- Test Type: Development  
Species: Rabbit, female  
Application Route: Oral  
Developmental Toxicity: NOAEL: 40 mg/kg body weight  
Result: No adverse effects
- Reproductive toxicity - Assessment : Some evidence of adverse effects on development, based on animal experiments.

**STOT - single exposure**

Not classified based on available information.

**Components:****Alendronate:**

Assessment : May cause respiratory irritation.

**STOT - repeated exposure**

Not classified based on available information.

**Components:****Alendronate:**

Target Organs : Bone, Stomach, Kidney  
Assessment : May cause damage to organs through prolonged or repeated exposure.

**Repeated dose toxicity****Components:****Alendronate:**

Species : Rat  
NOAEL : 2,5 mg/kg  
LOAEL : > 2,5 mg/kg  
Application Route : Intravenous  
Exposure time : 53 Weeks  
Target Organs : Stomach

## Alendronate Liquid Formulation

Version 2.14      Revision Date: 09.04.2021      SDS Number: 28221-00017      Date of last issue: 16.10.2020  
Date of first issue: 05.11.2014

Species : Dog  
LOAEL : 0,01 mg/kg  
Application Route : Intravenous  
Exposure time : 3 yr  
Target Organs : Stomach, Bone, Kidney

Species : Dog  
NOAEL : 2 mg/kg  
LOAEL : 4 mg/kg  
Application Route : Oral  
Exposure time : 53 Weeks  
Target Organs : Kidney

**Aspiration toxicity**

Not classified based on available information.

**Components:****Alendronate:**

Not applicable

**Experience with human exposure****Product:**

Inhalation : Symptoms: respiratory tract irritation  
Skin contact : Symptoms: May cause, Skin irritation  
Eye contact : Symptoms: May cause, Eye irritation  
Ingestion : Symptoms: Gastrointestinal disturbance, musculoskeletal pain

**Components:****Alendronate:**

Inhalation : Symptoms: respiratory tract irritation  
Skin contact : Symptoms: Severe irritation, skin blistering  
Eye contact : Symptoms: Severe irritation  
Ingestion : Symptoms: Gastrointestinal disturbance, musculoskeletal pain

**SECTION 12: Ecological information****12.1 Toxicity****Components:****Alendronate:**

Toxicity to fish : LC50 (Pimephales promelas (fathead minnow)): 27 mg/l  
Exposure time: 96 h  
Method: OECD Test Guideline 203  
  
LC50 (Oncorhynchus mykiss (rainbow trout)): > 1.000 mg/l  
Exposure time: 96 h  
Method: FDA 4.11

Toxicity to daphnia and other aquatic invertebrates : EC50 (Daphnia magna (Water flea)): 170 mg/l  
Exposure time: 48 h

## Alendronate Liquid Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 16.10.2020
2.14	09.04.2021	28221-00017	Date of first issue: 05.11.2014

---

Method: OECD Test Guideline 202

Toxicity to algae/aquatic plants : ErC50 (Pseudokirchneriella subcapitata (green algae)): > 10 mg/l  
Exposure time: 72 h  
Method: OECD Test Guideline 201

NOEC (Pseudokirchneriella subcapitata (green algae)): 4 mg/l  
Exposure time: 72 h  
Method: OECD Test Guideline 201

Toxicity to fish (Chronic toxicity) : NOEC: 1,1 mg/l  
Exposure time: 32 d  
Species: Pimephales promelas (fathead minnow)  
Method: OECD Test Guideline 210

LOEC: 1,9 mg/l  
Exposure time: 32 d  
Species: Pimephales promelas (fathead minnow)  
Method: OECD Test Guideline 210

Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity) : NOEC: 4,7 mg/l  
Exposure time: 21 d  
Species: Daphnia magna (Water flea)  
Method: OECD Test Guideline 211

**12.2 Persistence and degradability****Components:****Alendronate:**

Biodegradability : Result: Readily biodegradable.  
Biodegradation: 70,3 %  
Exposure time: 7 d

Stability in water : Degradation half life (DT50): 375 d  
Method: OECD Test Guideline 111

**12.3 Bioaccumulative potential****Components:****Alendronate:**

Partition coefficient: n-octanol/water : log Pow: -1,73

**12.4 Mobility in soil**

No data available

**12.5 Results of PBT and vPvB assessment****Product:**

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

# SAFETY DATA SHEET



## Alendronate Liquid Formulation



Version 2.14      Revision Date: 09.04.2021      SDS Number: 28221-00017      Date of last issue: 16.10.2020  
Date of first issue: 05.11.2014

---

0.1% or higher.

### 12.6 Other adverse effects

#### **Product:**

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

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## SECTION 13: Disposal considerations

### 13.1 Waste treatment methods

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

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

### 14.1 UN number

Not regulated as a dangerous good

### 14.2 UN proper shipping name

Not regulated as a dangerous good

### 14.3 Transport hazard class(es)

Not regulated as a dangerous good

### 14.4 Packing group

Not regulated as a dangerous good

### 14.5 Environmental hazards

Not regulated as a dangerous good

### 14.6 Special precautions for user

Not applicable

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

Remarks : Not applicable for product as supplied.

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## SECTION 15: Regulatory information

### 15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture

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

AICS : not determined

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## Alendronate Liquid Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 16.10.2020
2.14	09.04.2021	28221-00017	Date of first issue: 05.11.2014

---

DSL : not determined

IECSC : not determined

**15.2 Chemical safety assessment**

A Chemical Safety Assessment has not been carried out.

**SECTION 16: Other information**

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

**Full text of H-Statements**

H302 : Harmful if swallowed.  
 H315 : Causes skin irritation.  
 H318 : Causes serious eye damage.  
 H335 : May cause respiratory irritation.  
 H361d : Suspected of damaging the unborn child.  
 H373 : May cause damage to organs through prolonged or repeated exposure.

**Full text of other abbreviations**

Acute Tox. : Acute toxicity  
 Eye Dam. : Serious eye damage  
 Repr. : Reproductive toxicity  
 Skin Irrit. : Skin irritation  
 STOT RE : Specific target organ toxicity - repeated exposure  
 STOT SE : Specific target organ toxicity - single exposure

ADN - European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways; ADR - European Agreement concerning the International Carriage of Dangerous Goods by Road; AIIC - Australian Inventory of Industrial Chemicals; ASTM - American Society for the Testing of Materials; bw - Body weight; CLP - Classification Labelling Packaging Regulation; Regulation (EC) No 1272/2008; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DSL - Domestic Substances List (Canada); ECHA - European Chemicals Agency; EC-Number - European Community number; ECx - Concentration associated with x% response; ELx - Loading rate associated with x% response; EmS - Emergency Schedule; ENCS - Existing and New Chemical Substances (Japan); ErCx - Concentration associated with x% growth rate response; GHS - Globally Harmonized System; GLP - Good Laboratory Practice; IARC - International Agency for Research on Cancer; IATA - International Air Transport Association; IBC - International Code for the Construction and Equipment of Ships carrying Dangerous Chemicals in Bulk; IC50 - Half maximal inhibitory concentration; ICAO - International Civil Aviation Organization; IECSC - Inventory of Existing Chemical Substances in China; IMDG - International Maritime Dangerous Goods; IMO - International Maritime Organization; ISHL - Industrial Safety and Health Law (Japan); ISO - International Organisation for Standardization; KECI - Korea Existing Chemicals Inventory; LC50 - Lethal Concentration to 50 % of a test population; LD50 - Lethal Dose to 50% of a test population (Median Lethal Dose); MARPOL - International Convention for the Prevention of Pollution from Ships; n.o.s. - Not Otherwise Specified; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; NZIoC - New Zealand Inventory of Chemicals; OECD - Organization for Economic Co-operation and Development; OPPTS - Office of Chemical Safety and Pollution Prevention; PBT - Persistent, Bioaccumulative and Toxic sub-

# SAFETY DATA SHEET



## Alendronate Liquid Formulation



Version	Revision Date:	SDS Number:	Date of last issue: 16.10.2020
2.14	09.04.2021	28221-00017	Date of first issue: 05.11.2014

---

stance; PICCS - Philippines Inventory of Chemicals and Chemical Substances; (Q)SAR - (Quantitative) Structure Activity Relationship; REACH - Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals; RID - Regulations concerning the International Carriage of Dangerous Goods by Rail; SADT - Self-Accelerating Decomposition Temperature; SDS - Safety Data Sheet; SVHC - Substance of very high concern; TCSI - Taiwan Chemical Substance Inventory; 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 Bio-accumulative

### Further information

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

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.

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