

# SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006



## Amoxicillin Trihydrate Paste Formulation

Version 2.4      Revision Date: 09/13/2019      SDS Number: 2373605-00007      Date of last issue: 24.04.2019  
Date of first issue: 16.01.2018

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

#### 1.1 Product identifier

Trade name : Amoxicillin Trihydrate Paste Formulation

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

Use of the Sub-stance/Mixture : Veterinary product

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

Company : MSD  
Shotton Lane  
NE23 3JU Cramlington NU - Great Britain

Telephone : 44 1 670 59 30 00

Telefax : 908-735-1496

E-mail address of person responsible for the SDS : EHSDATASTEWARD@msd.com

#### 1.4 Emergency telephone number

1-908-423-6000

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### SECTION 2: Hazards identification

#### 2.1 Classification of the substance or mixture

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

Respiratory sensitisation, Category 1      H334: May cause allergy or asthma symptoms or breathing difficulties if inhaled.

Short-term (acute) aquatic hazard, Category 1      H400: Very toxic to aquatic life.

#### 2.2 Label elements

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

Hazard pictograms :

Signal word : Danger

Hazard statements : H334 May cause allergy or asthma symptoms or breathing difficulties if inhaled.  
H400 Very toxic to aquatic life.

Precautionary statements : **Prevention:**

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P273    Avoid release to the environment.

**Response:**

P304 + P340    IF INHALED: Remove person to fresh air and keep comfortable for breathing.

P342 + P311    If experiencing respiratory symptoms: Call a POISON CENTER/doctor.

P391    Collect spillage.

Hazardous components which must be listed on the label:  
Amoxicillin Trihydrate

### 2.3 Other hazards

None known.

## SECTION 3: Composition/information on ingredients

### 3.2 Mixtures

#### Components

Chemical name	CAS-No. EC-No. Index-No. Registration number	Classification	Concentration (% w/w)
Amoxicillin Trihydrate	61336-70-7	Resp. Sens. 1A; H334 Aquatic Acute 1; H400 <hr/> M-Factor (Acute aquatic toxicity): 100	>= 0.25 - < 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.  
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.

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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.

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

Risks : 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).

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

Treatment : Treat symptomatically and supportively.

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## 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

### 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.

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### SECTION 6: Accidental release measures

#### 6.1 Personal precautions, protective equipment and emergency procedures

Personal precautions : Use personal protective equipment.  
Follow safe handling advice and personal protective equipment recommendations.

#### 6.2 Environmental precautions

Environmental precautions : Discharge into the environment must be avoided.  
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.  
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.  
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 sensitised individuals should consult their physician regarding working with respiratory irritants or sensitisers.  
Take care to prevent spills, waste and minimize release to the

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Hygiene measures : environment.  
: If exposure to chemical is likely during typical use, provide eye flushing systems and safety showers close to the working place. When using do not eat, drink or smoke. Wash contaminated clothing before re-use.  
The effective operation of a facility should include review of engineering controls, proper personal protective equipment, appropriate degowning and decontamination procedures, industrial hygiene monitoring, medical surveillance and the use of administrative controls.

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

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

### 7.3 Specific end use(s)

Specific use(s) : No data available  
No data available

## SECTION 8: Exposure controls/personal protection

### 8.1 Control parameters

#### Occupational Exposure Limits

Components	CAS-No.	Value type (Form of exposure)	Control parameters	Basis
Amoxicillin Trihydrate	61336-70-7	TWA	1 mg/m <sup>3</sup> (OEB 1)	Internal
Further information	RSEN			

#### Derived No Effect Level (DNEL) according to Regulation (EC) No. 1907/2006:

Substance name	End Use	Exposure routes	Potential health effects	Value
Glycerides, mixed decanoyl and octanoyl	Workers	Inhalation	Long-term systemic effects	177.79 mg/m <sup>3</sup>
	Workers	Skin contact	Long-term systemic effects	25.21 mg/kg bw/day
	Consumers	Inhalation	Long-term systemic effects	43.84 mg/m <sup>3</sup>
	Consumers	Skin contact	Long-term systemic effects	12.61 mg/kg bw/day
	Consumers	Ingestion	Long-term systemic effects	12.61 mg/kg bw/day

#### Predicted No Effect Concentration (PNEC) according to Regulation (EC) No. 1907/2006:

Substance name	Environmental Compartment	Value
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Glycerides, mixed decanoyl and octanoyl	Oral (Secondary Poisoning)	0.03 mg/kg food
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### 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.

Laboratory operations do not require special containment.

#### 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
- Skin and body protection : Work uniform or laboratory coat.
- Respiratory protection : If adequate local exhaust ventilation is not available or exposure assessment demonstrates exposures outside the recommended guidelines, use respiratory protection.
- Filter type : Combined particulates and organic vapour type (A-P)

## SECTION 9: Physical and chemical properties

### 9.1 Information on basic physical and chemical properties

- Appearance : paste
- Colour : colourless, to, white
- Odour : characteristic
- Odour 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 : No data available
- Evaporation rate : No data available
- Flammability (solid, gas) : Not classified as a flammability hazard
- Upper explosion limit / Upper flammability limit : No data available
- Lower explosion limit / Lower flammability limit : No data available

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Vapour pressure	:	No data available
Relative vapour density	:	No data available
Relative density	:	No data available
Density	:	No data available
Solubility(ies)		
Water solubility	:	slightly 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
Molecular weight	:	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.
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### 10.4 Conditions to avoid

Conditions to avoid	:	None known.
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### 10.5 Incompatible materials

Materials to avoid	:	Oxidizing agents
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### 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:

##### Amoxicillin Trihydrate:

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

##### Skin corrosion/irritation

Not classified based on available information.

##### Serious eye damage/eye irritation

Not classified based on available information.

##### Respiratory or skin sensitisation

##### Skin sensitisation

Not classified based on available information.

##### Respiratory sensitisation

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

##### Components:

##### Amoxicillin Trihydrate:

Result : Sensitiser  
Remarks : May cause sensitisation by inhalation.  
largely based on human evidence

##### Germ cell mutagenicity

Not classified based on available information.

##### Components:

##### 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



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

### **Carcinogenicity**

Not classified based on available information.

### **Reproductive toxicity**

Not classified based on available information.

### **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 foetal development

: Test Type: Development  
Species: Rat  
Application Route: Oral  
Developmental Toxicity: NOAEL:  $\geq$  1,000 mg/kg body weight  
Result: No embryo-foetal 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.

### **STOT - single exposure**

Not classified based on available information.

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### 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

### Aspiration toxicity

Not classified based on available information.

### Experience with human exposure

#### Components:

##### Amoxicillin Trihydrate:

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

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## SECTION 12: Ecological information

### 12.1 Toxicity

#### Components:

##### Amoxicillin Trihydrate:

Toxicity to fish : LC50 (No species specified): 0.035 mg/l  
Exposure time: 96 h  
Method: OECD Test Guideline 203

Toxicity to algae/aquatic plants : EC50 (Selenastrum capricornutum (green algae)): 630 mg/l  
Exposure time: 72 h

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

M-Factor (Acute aquatic tox- : 100

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### 12.2 Persistence and degradability

#### Components:

##### **Amoxicillin Trihydrate:**

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

### 12.3 Bioaccumulative potential

#### Components:

##### **Amoxicillin Trihydrate:**

Partition coefficient: n-octanol/water : log Pow: -0.124

### 12.4 Mobility in soil

No data available

### 12.5 Results of PBT and vPvB assessment

Not relevant

### 12.6 Other adverse effects

No data available

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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

ADN : UN 3082  
ADR : UN 3082  
RID : UN 3082  
IMDG : UN 3082  
IATA : UN 3082

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### 14.2 UN proper shipping name

**ADN** : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S.  
(Amoxicillin Trihydrate)

**ADR** : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S.  
(Amoxicillin Trihydrate)

**RID** : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S.  
(Amoxicillin Trihydrate)

**IMDG** : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S.  
(Amoxicillin Trihydrate)

**IATA** : Environmentally hazardous substance, liquid, n.o.s.  
(Amoxicillin Trihydrate)

### 14.3 Transport hazard class(es)

**ADN** : 9

**ADR** : 9

**RID** : 9

**IMDG** : 9

**IATA** : 9

### 14.4 Packing group

**ADN**  
Packing group : III  
Classification Code : M6  
Hazard Identification Number : 90  
Labels : 9

**ADR**  
Packing group : III  
Classification Code : M6  
Hazard Identification Number : 90  
Labels : 9  
Tunnel restriction code : (-)

**RID**  
Packing group : III  
Classification Code : M6  
Hazard Identification Number : 90  
Labels : 9

**IMDG**  
Packing group : III  
Labels : 9  
EmS Code : F-A, S-F

**IATA (Cargo)**  
Packing instruction (cargo aircraft) : 964

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Packing instruction (LQ) : Y964  
Packing group : III  
Labels : Miscellaneous

### IATA (Passenger)

Packing instruction (passenger aircraft) : 964  
Packing instruction (LQ) : Y964  
Packing group : III  
Labels : Miscellaneous

### 14.5 Environmental hazards

#### ADN

Environmentally hazardous : yes

#### ADR

Environmentally hazardous : yes

#### RID

Environmentally hazardous : yes

#### IMDG

Marine pollutant : yes

### IATA (Passenger)

Environmentally hazardous : yes

### IATA (Cargo)

Environmentally hazardous : yes

### 14.6 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.

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

Remarks : Not applicable for product as supplied.

## SECTION 15: Regulatory information

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

REACH - Candidate List of Substances of Very High Concern for Authorisation (Article 59) : Not applicable  
REACH - List of substances subject to authorisation (Annex XIV) : Not applicable  
Regulation (EC) No 1005/2009 on substances that deplete the ozone layer : Not applicable  
Regulation (EC) No 850/2004 on persistent organic pollutants : Not applicable  
Regulation (EC) No 649/2012 of the European Parliament and the Council concerning the export and import of dangerous chemicals : Not applicable  
REACH - Restrictions on the manufacture, placing on the market and use of certain dangerous substances, : Conditions of restriction for the following entries should be considered:

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preparations and articles (Annex XVII)

Number on list 3

Seveso III: Directive 2012/18/EU of the European Parliament and of the Council on the control of major-accident hazards involving dangerous substances.

E1	ENVIRONMENTAL HAZARDS	Quantity 1 100 t	Quantity 2 200 t
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### Other regulations:

Take note of Directive 94/33/EC on the protection of young people at work or stricter national regulations, where applicable.

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

AICS	: not determined
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

H334	: May cause allergy or asthma symptoms or breathing difficulties if inhaled.
H400	: Very toxic to aquatic life.

### Full text of other abbreviations

Aquatic Acute	: Short-term (acute) aquatic hazard
Resp. Sens.	: Respiratory sensitisation

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; AICS - Australian Inventory of Chemical Substances; 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 Organisa-

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tion 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 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; 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; TRGS - Technical Rule for Hazardous Substances; TSCA - Toxic Substances Control Act (United States); UN - United Nations; vPvB - Very Persistent and Very Bioaccumulative

### 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/>

### Classification of the mixture:

Resp. Sens. 1	H334
Aquatic Acute 1	H400

### Classification procedure:

Calculation method
Calculation method

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.

IE / EN