

**Ampicillin Formulation**

Version	Revision Date:	SDS Number:	Date of last issue: 28.09.2024
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**SECTION 1: Identification of the substance/mixture and of the company/undertaking****1.1 Product identifier**

Trade name : Ampicillin Formulation

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

Use of the Sub-  
stance/Mixture : Veterinary product

Recommended restrictions  
on use : Not applicable

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

Company : MSD  
20 Spartan Road  
1619 Spartan, South Africa

Telephone : +27119239300

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.
Long-term (chronic) aquatic hazard, Category 3	H412: Harmful to aquatic life with long lasting effects.

**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.  
H412 Harmful to aquatic life with long lasting effects.

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Precautionary statements :

**Prevention:**

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.

Hazardous components which must be listed on the label:  
ampicillin

**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.

**SECTION 3: Composition/information on ingredients****3.2 Mixtures****Components**

Chemical name	CAS-No. EC-No. Index-No. Registration number	Classification	Concentration (% w/w)
ampicillin	69-53-4 200-709-7	Resp. Sens. 1; H334 Aquatic Acute 1; H400 Aquatic Chronic 2; H411  M-Factor (Acute aquatic toxicity): 1	>= 10 - < 20

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).

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- |                         |   |   |
|-------------------------|---|---|
| If inhaled              | : | If inhaled, remove to fresh air.<br>If not breathing, give artificial respiration.<br>If breathing is difficult, give oxygen.<br>Get medical attention. |
| In case of skin contact | : | Wash with water and soap as a precaution.<br>Get medical attention if symptoms occur.   |
| In case of eye contact  | : | Flush eyes with water as a precaution.<br>Get medical attention if irritation develops and persists.  |
| If swallowed            | : | If swallowed, DO NOT induce vomiting.<br>Get medical attention if symptoms occur.<br>Rinse mouth thoroughly with water.                                 |

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

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

**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<br>Alcohol-resistant foam<br>Carbon dioxide (CO <sub>2</sub> )<br>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         | : | Nitrogen oxides (NO <sub>x</sub> )<br>Carbon oxides<br>Sulphur oxides |

**5.3 Advice for firefighters**

- |   |   |  |
|---|---|--|
| Special protective equipment for firefighters | : | In the event of fire, wear self-contained breathing apparatus.<br>Use personal protective equipment. |
| Specific extinguishing method                 | : | Use extinguishing measures that are appropriate to local cir-  |

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cumstances 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.  
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.

**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	:	If sufficient ventilation is unavailable, use with local exhaust ventilation.
Advice on safe handling	:	Do not breathe mist or vapours. Do not swallow. Avoid contact with eyes. Avoid prolonged or repeated contact with skin. Handle in accordance with good industrial hygiene and safety

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practice, based on the results of the workplace exposure assessment  
 Keep container tightly closed.  
 Already sensitised individuals, and those susceptible to asthma, allergies, chronic or recurrent respiratory disease, should consult their physician regarding working with respiratory irritants or sensitisers.  
 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.  
 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.  
 Keep in a cool, well-ventilated place. Store in accordance with the particular national regulations.

Advice on common storage : Do not store with the following product types:  
 Strong oxidizing agents  
 Gases

## 7.3 Specific end use(s)

Specific use(s) : 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
ampicillin	69-53-4	TWA	0.6 mg/m3 (OEB 2)	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/m3
	Workers	Skin contact	Long-term systemic effects	25,21 mg/kg bw/day
	Consumers	Inhalation	Long-term systemic effects	43,84 mg/m3
	Consumers	Skin contact	Long-term systemic	12,61 mg/kg

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			effects	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
Glycerides, mixed decanoyl and octanoyl	Oral (Secondary Poisoning)	0,03 mg/kg food

**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/face 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	:	suspension
Colour	:	white to off-white
Odour	:	No data available
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 applicable
Flammability (liquids)	:	No data available

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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	:	No data available
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**

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.

## 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:

##### ampicillin:

Acute oral toxicity	: LD50 (Rat): 10.000 mg/kg
	LD50 (Mouse): 15.200 mg/kg
Acute toxicity (other routes of administration)	: LD50 (Rat): 6.200 mg/kg
	Application Route: Intravenous
	LD50 (Mouse): 4.600 mg/kg
	Application Route: Intravenous

#### 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:

##### ampicillin:

Exposure routes	: Inhalation
Result	: Sensitiser

#### Germ cell mutagenicity

|| Not classified based on available information.

#### Components:

##### ampicillin:



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Genotoxicity in vitro	: Test Type: Bacterial reverse mutation assay (AMES) Result: negative  Test Type: In vitro mammalian cell gene mutation test Test system: mouse lymphoma cells Result: negative  Test Type: sister chromatid exchange assay Test system: Chinese hamster ovary cells Result: negative  Test Type: Chromosomal aberration Test system: Chinese hamster ovary cells Result: negative  Test Type: Chromosomal aberration Test system: Human lymphocytes Result: negative
Genotoxicity in vivo	: Test Type: Micronucleus test Species: Rat Application Route: Oral Result: negative

**Carcinogenicity**

Not classified based on available information.

**Components:****ampicillin:**

Species	: Rat
Application Route	: Oral
Exposure time	: 2 Years
	: 750 mg/kg body weight
Tumor Type	: adrenal, Leukaemia, breast tumors

Species	: Mouse
Application Route	: Oral
Exposure time	: 2 Years
	: 3.000 mg/kg body weight
Tumor Type	: Lungs
Remarks	: Benign tumor(s)

Carcinogenicity - Assessment	: Weight of evidence does not support classification as a carcinogen
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**Reproductive toxicity**

Not classified based on available information.

**Components:****ampicillin:**

Effects on fertility	: Test Type: Fertility Species: Guinea pig
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Effects on foetal development	: Target Organs: Uterus (including cervix)
	: Test Type: Development
	: Species: Rat
	: Developmental Toxicity: NOAEL: 250 mg/kg body weight
	: Result: No effects on foetal development

**STOT - single exposure**

Not classified based on available information.

**STOT - repeated exposure**

Not classified based on available information.

**Repeated dose toxicity****Components:****ampicillin:**

Species	: Rat
LOAEL	: 3.000 mg/kg
Application Route	: Oral
Exposure time	: 13 Weeks
Symptoms	: Diarrhoea

Species	: Mouse
LOAEL	: 2.000 mg/kg
Application Route	: Oral
Exposure time	: 13 Weeks
Symptoms	: Diarrhoea

Species	: Rat
LOAEL	: 750 mg/kg
Application Route	: Oral
Exposure time	: 2 yr
Target Organs	: Thyroid, forestomach
Symptoms	: Diarrhoea, Salivation, decreased activity

Species	: Mouse
LOAEL	: 2.000 mg/kg
Application Route	: Oral
Exposure time	: 2 yr
Target Organs	: forestomach
Symptoms	: Ulceration, Inflammation, fungal infections

**Aspiration toxicity**

Not classified based on available information.

**Experience with human exposure****Components:****ampicillin:**

Inhalation	: Symptoms: Asthma, Hay fever
	: Remarks: May cause allergy or asthma symptoms or breathing difficulties if inhaled.

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Ingestion	: Symptoms: skin rash, Nausea, Diarrhoea, Vomiting, colitis, urticaria
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**SECTION 12: Ecological information****12.1 Toxicity****Components:****ampicillin:**

Toxicity to fish	: LC50 ( <i>Oryzias latipes</i> (Japanese medaka)): > 1.000 mg/l Exposure time: 96 h  LC50 ( <i>Oncorhynchus mykiss</i> (rainbow trout)): > 100 mg/l Exposure time: 96 h
Toxicity to daphnia and other aquatic invertebrates	: EC50 ( <i>Daphnia magna</i> (Water flea)): > 100 mg/l Exposure time: 48 h
Toxicity to algae/aquatic plants	: EC50 ( <i>Anabaena flos-aquae</i> ): 190 µg/l Exposure time: 72 h Method: OECD Test Guideline 201  NOEC ( <i>Anabaena flos-aquae</i> ): 13 µg/l Exposure time: 72 h Method: OECD Test Guideline 201  EC50 ( <i>Pseudokirchneriella subcapitata</i> (green algae)): > 100 mg/l Exposure time: 72 h Method: OECD Test Guideline 201  NOEC ( <i>Pseudokirchneriella subcapitata</i> (green algae)): 100 mg/l Exposure time: 72 h Method: OECD Test Guideline 201
M-Factor (Acute aquatic toxicity)	: 1
Toxicity to microorganisms	: EC50 : > 1.000 mg/l Exposure time: 3 h Test Type: Respiration inhibition Method: OECD Test Guideline 209  NOEC : 9 mg/l Exposure time: 3 h Test Type: Respiration inhibition Method: OECD Test Guideline 209

**12.2 Persistence and degradability****Components:****ampicillin:**

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Biodegradability : Result: rapidly degradable  
Biodegradation: 35 %  
Exposure time: 28 d  
Method: OECD Test Guideline 301B

## 12.3 Bioaccumulative potential

Components:

## ampicillin:

Partition coefficient: n-octanol/water : log Pow: -2,0  
pH: 7

## 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 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.

## 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.  
Do not dispose of waste into sewer.

Contaminated packaging : Empty containers should be taken to an approved waste handling site for recycling or disposal.  
If not otherwise specified: Dispose of as unused product.

## SECTION 14: Transport information

## 14.1 UN number

ADN : Not regulated as a dangerous good

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ADR	:	Not regulated as a dangerous good
RID	:	Not regulated as a dangerous good
IMDG	:	Not regulated as a dangerous good
IATA	:	Not regulated as a dangerous good

## 14.2 UN proper shipping name

ADN	:	Not regulated as a dangerous good
ADR	:	Not regulated as a dangerous good
RID	:	Not regulated as a dangerous good
IMDG	:	Not regulated as a dangerous good
IATA	:	Not regulated as a dangerous good

## 14.3 Transport hazard class(es)

ADN	:	Not regulated as a dangerous good
ADR	:	Not regulated as a dangerous good
RID	:	Not regulated as a dangerous good
IMDG	:	Not regulated as a dangerous good
IATA	:	Not regulated as a dangerous good

## 14.4 Packing group

ADN	:	Not regulated as a dangerous good
ADR	:	Not regulated as a dangerous good
RID	:	Not regulated as a dangerous good
IMDG	:	Not regulated as a dangerous good
IATA (Cargo)	:	Not regulated as a dangerous good
IATA (Passenger)	:	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.

## 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

DSL : not determined

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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.
H411	: Toxic to aquatic life with long lasting effects.

**Full text of other abbreviations**

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

ADN - European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways; ADR - Agreement concerning the International Carriage of Dangerous Goods by Road; AIIIC - 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 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; TECI - Thailand Existing Chemicals Inventory; TSCA - Toxic Substances Control Act (United States); UN

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- United Nations; UNRTDG - United Nations Recommendations on the Transport of Dangerous Goods; 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 Chronic 3	H412

**Classification procedure:**

Calculation method
Calculation method

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

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.

ZA / EN