

**Butorphanol Formulation**

Version 3.2      Revision Date: 04.12.2023      SDS Number: 918672-00017      Date of last issue: 30.09.2023  
Date of first issue: 03.10.2016

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**SECTION 1: Identification of the substance/mixture and of the company/undertaking****1.1 Product identifier**

Trade name : Butorphanol Formulation  
Other means of identification : Dolorex® (A006877)

**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)**

Specific target organ toxicity - single exposure, Category 2      H371: May cause damage to organs.  
Specific target organ toxicity - repeated exposure, Category 2      H373: May cause damage to organs through prolonged or repeated exposure.

**2.2 Label elements****Labelling (REGULATION (EC) No 1272/2008)**

Hazard pictograms :   
Signal word : Warning  
Hazard statements : H371 May cause damage to organs.  
H373 May cause damage to organs through prolonged or

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repeated exposure.

Precautionary statements :

**Prevention:**

P264 Wash skin thoroughly after handling.

P270 Do not eat, drink or smoke when using this product.

**Response:**

P308 + P311 IF exposed or concerned: Call a POISON CENTER/ doctor.

**Storage:**

P405 Store locked up.

Hazardous components which must be listed on the label:

17-(Cyclobutylmethyl)morphinan-3,14-diyl [S-(R\*,R\*)]-2,3-dihydroxysuccinate

**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)
17-(Cyclobutylmethyl)morphinan-3,14-diyl [S-(R*,R*)]-2,3-dihydroxysuccinate	58786-99-5 261-443-5	Acute Tox. 4; H302 Repr. 2; H361fd STOT SE 1; H370 (Central nervous system) STOT RE 1; H372 (Blood, Central nervous system) Aquatic Chronic 3; H412	>= 1 - < 2,5

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,

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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.  
Never give anything by mouth to an unconscious person.

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

- Risks : May cause damage to organs.  
May cause damage to organs through prolonged or repeated exposure.

### 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.

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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 (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.

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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 : Do not breathe mist or vapours.  
Do not swallow.  
Avoid contact with eyes.  
Avoid prolonged or repeated contact with skin.

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Wash skin thoroughly after handling.  
 Handle in accordance with good industrial hygiene and safety practice, based on the results of the workplace exposure assessment  
 Do not eat, drink or smoke when using this product.  
 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. Store locked up. Store in accordance with the particular national regulations.

Advice on common storage : Do not store with the following product types:  
 Strong oxidizing agents  
 Self-reactive substances and mixtures  
 Organic peroxides  
 Explosives  
 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
17-(Cyclobutylmethyl)morphinan-3,14-diyl [S-(R*,R*)]-2,3-dihydroxysuccinate	58786-99-5	TWA	3 µg/m <sup>3</sup> (OEB 4)	Internal
		Wipe limit	30 µg/100 cm <sup>2</sup>	Internal

### 8.2 Exposure controls

#### Engineering measures

All engineering controls should be implemented by facility design and operated in accordance with GMP principles to protect products, workers, and the environment.  
 Essentially no open handling permitted.

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Use closed processing systems or containment technologies.

If handled in a laboratory, use a properly designed biosafety cabinet, fume hood, or other containment device if the potential exists for aerosolization. If this potential does not exist, handle over lined trays or benchtops.

**Personal protective equipment**

- 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
- 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)
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**SECTION 9: Physical and chemical properties****9.1 Information on basic physical and chemical properties**

- Appearance : liquid
- Colour : colourless
- 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 : 100 °C
- 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

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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**

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.
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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.

**Product:**

Acute oral toxicity : Acute toxicity estimate: > 2.000 mg/kg  
Method: Calculation method

**Components:****17-(Cyclobutylmethyl)morphinan-3,14-diyl [S-(R\*,R\*)]-2,3-dihydroxysuccinate:**

Acute oral toxicity : LD50 (Mouse): 395 mg/kg  
LD50 (Dog): > 50 mg/kg  
LD50 (Monkey): > 50 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:****17-(Cyclobutylmethyl)morphinan-3,14-diyl [S-(R\*,R\*)]-2,3-dihydroxysuccinate:**

Remarks : No data available

**Serious eye damage/eye irritation**

Not classified based on available information.

**Components:****17-(Cyclobutylmethyl)morphinan-3,14-diyl [S-(R\*,R\*)]-2,3-dihydroxysuccinate:**

Species : Rat  
Result : No eye irritation

**Respiratory or skin sensitisation****Skin sensitisation**

Not classified based on available information.

**Respiratory sensitisation**

Not classified based on available information.



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**Components:****17-(Cyclobutylmethyl)morphinan-3,14-diyl [S-(R\*,R\*)]-2,3-dihydroxysuccinate:**

Exposure routes : Dermal  
Assessment : Does not cause skin sensitisation.  
Result : negative

**Germ cell mutagenicity**

Not classified based on available information.

**Components:****17-(Cyclobutylmethyl)morphinan-3,14-diyl [S-(R\*,R\*)]-2,3-dihydroxysuccinate:**

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

Test Type: DNA damage and repair, unscheduled DNA synthesis in mammalian cells (in vitro)  
Result: negative

**Carcinogenicity**

Not classified based on available information.

**Components:****17-(Cyclobutylmethyl)morphinan-3,14-diyl [S-(R\*,R\*)]-2,3-dihydroxysuccinate:**

Species : Rat  
Application Route : Oral  
Exposure time : 2 Years  
Result : negative

Species : Mouse  
Application Route : Oral  
Exposure time : 2 Years  
Result : negative

**Reproductive toxicity**

Not classified based on available information.

**Components:****17-(Cyclobutylmethyl)morphinan-3,14-diyl [S-(R\*,R\*)]-2,3-dihydroxysuccinate:**

Effects on fertility : Test Type: Fertility/early embryonic development  
Species: Rat  
Application Route: Oral  
Fertility: LOAEL: 160 mg/kg body weight  
Result: Effects on fertility

Effects on foetal development : Test Type: Embryo-foetal development  
Species: Rat  
Application Route: Subcutaneous  
Developmental Toxicity: LOAEL: 1 mg/kg body weight  
Result: No teratogenic effects, Increased stillbirths

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Test Type: Embryo-foetal development  
 Species: Rabbit  
 Application Route: Oral  
 Developmental Toxicity: LOAEL: 30 mg/kg body weight  
 Result: No teratogenic effects, Maternal toxicity observed.,  
 Postimplantation loss.

Test Type: Embryo-foetal development  
 Species: Rat  
 Application Route: Subcutaneous  
 Developmental Toxicity: LOAEL: 0,5 mg/kg body weight  
 Result: Maternal toxicity observed.

Reproductive toxicity - Assessment : Some evidence of adverse effects on sexual function and fertility, based on animal experiments., Some evidence of adverse effects on development, based on animal experiments.

**STOT - single exposure**

May cause damage to organs.

**Components:****17-(Cyclobutylmethyl)morphinan-3,14-diyl [S-(R\*,R\*)]-2,3-dihydroxysuccinate:**

Target Organs : Central nervous system  
 Assessment : Causes damage to organs.

**STOT - repeated exposure**

May cause damage to organs through prolonged or repeated exposure.

**Components:****17-(Cyclobutylmethyl)morphinan-3,14-diyl [S-(R\*,R\*)]-2,3-dihydroxysuccinate:**

Target Organs : Blood, Central nervous system  
 Assessment : Causes damage to organs through prolonged or repeated exposure.

**Repeated dose toxicity****Components:****17-(Cyclobutylmethyl)morphinan-3,14-diyl [S-(R\*,R\*)]-2,3-dihydroxysuccinate:**

Species : Rat  
 LOAEL : 0,4 mg/kg  
 Application Route : Subcutaneous  
 Exposure time : 6 Months  
 Target Organs : Blood, Central nervous system

Species : Monkey  
 LOAEL : 0,15 mg/kg  
 Application Route : Intramuscular  
 Exposure time : 6 Months  
 Target Organs : Central nervous system

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Species : Dog  
LOAEL : 0,1 mg/kg  
Application Route : Intramuscular  
Exposure time : 3 Months  
Symptoms : reduced body weight gain

### Aspiration toxicity

Not classified based on available information.

### Experience with human exposure

#### Components:

#### **17-(Cyclobutylmethyl)morphinan-3,14-diyl [S-(R\*,R\*)]-2,3-dihydroxysuccinate:**

Ingestion : Symptoms: Drowsiness, Sweating, Nausea, Dizziness, Vertigo, Palpitation, respiratory depression

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## SECTION 12: Ecological information

### 12.1 Toxicity

#### Components:

#### **17-(Cyclobutylmethyl)morphinan-3,14-diyl [S-(R\*,R\*)]-2,3-dihydroxysuccinate:**

Toxicity to daphnia and other aquatic invertebrates : EC50 (Daphnia magna (Water flea)): 38,1 mg/l  
Exposure time: 48 h  
Method: OECD Test Guideline 202

### 12.2 Persistence and degradability

No data available

### 12.3 Bioaccumulative potential

No data available

### 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.

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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.  
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.
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### SECTION 14: Transport information

#### 14.1 UN number

- 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

#### 14.2 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

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### 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

DSL : not determined

IECSC : not determined

### 15.2 Chemical safety assessment

A Chemical Safety Assessment has not been carried out.

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## 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.

H361fd : Suspected of damaging fertility. Suspected of damaging the unborn child.

H370 : Causes damage to organs if swallowed.

H372 : Causes damage to organs through prolonged or repeated exposure if swallowed.

H412 : Harmful to aquatic life with long lasting effects.

### Full text of other abbreviations

Acute Tox. : Acute toxicity

Aquatic Chronic : Long-term (chronic) aquatic hazard

Repr. : Reproductive toxicity

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 - 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

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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 - 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:**

STOT SE 2	H371
STOT RE 2	H373

**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.

ZA / EN