

# SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006



ORGANON

## Losartan Formulation

Version 3.3      Revision Date: 23.03.2020      SDS Number: 19361-00016      Date of last issue: 13.09.2019  
Date of first issue: 07.10.2014

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

#### 1.1 Product identifier

Trade name : Losartan Formulation

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

Use of the Sub-stance/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)

Acute toxicity, Category 4	H302: Harmful if swallowed.
Serious eye damage, Category 1	H318: Causes serious eye damage.
Skin sensitisation, Category 1	H317: May cause an allergic skin reaction.
Reproductive toxicity, Category 1B	H360D: May damage the unborn child.
Effects on or via lactation	H362: May cause harm to breast-fed children.
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 : Danger

Hazard statements : H302 Harmful if swallowed.  
H317 May cause an allergic skin reaction.  
H318 Causes serious eye damage.  
H360D May damage the unborn child.  
H362 May cause harm to breast-fed children.

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H373 May cause damage to organs through prolonged or repeated exposure.

Precautionary statements :

### Prevention:

P201 Obtain special instructions before use.  
P260 Do not breathe dust.  
P263 Avoid contact during pregnancy and while nursing.  
P280 Wear protective gloves/ protective clothing/ eye protection/ face protection.

### Response:

P305 + P351 + P338 + P310 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. Immediately call a POISON CENTER/ doctor.  
P308 + P313 IF exposed or concerned: Get medical advice/ attention.

Hazardous components which must be listed on the label:

Losartan

### 2.3 Other hazards

Contact with dust can cause mechanical irritation or drying of the skin.  
May form explosive dust-air mixture during processing, handling or other means.

## SECTION 3: Composition/information on ingredients

### 3.2 Mixtures

#### Components

Chemical name	CAS-No. EC-No. Index-No. Registration number	Classification	Concentration (% w/w)
Losartan	124750-99-8	Acute Tox.4; H302 Eye Dam.1; H318 Skin Sens.1; H317 Repr.1B; H360D Lact.H362 STOT RE2; H373	>= 30 - < 50

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

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- 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 : In case of contact, immediately flush eyes with plenty of water for at least 15 minutes.  
If easy to do, remove contact lens, if worn.  
Get medical attention immediately.
- 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 : Harmful if swallowed.  
May cause an allergic skin reaction.  
Causes serious eye damage.  
May damage the unborn child.  
May cause harm to breast-fed children.  
May cause damage to organs through prolonged or repeated exposure.
- Contact with dust can cause mechanical irritation or drying of the skin.

### 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- : Avoid generating dust; fine dust dispersed in air in sufficient

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fighting concentrations, and in the presence of an ignition source is a potential dust explosion hazard. Exposure to combustion products may be a hazard to health.

Hazardous combustion products : Carbon oxides  
Chlorine compounds  
Nitrogen oxides (NOx)

### 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. 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 : Sweep up or vacuum up spillage and collect in suitable container for disposal. Avoid dispersal of dust in the air (i.e., clearing dust surfaces with compressed air). Dust deposits should not be allowed to accumulate on surfaces, as these may form an explosive mixture if they are released into the atmosphere in sufficient concentration. 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 : Static electricity may accumulate and ignite suspended dust causing an explosion.  
Provide adequate precautions, such as electrical grounding and bonding, or inert atmospheres.
- Local/Total ventilation : If sufficient ventilation is unavailable, use with local exhaust ventilation.
- Advice on safe handling : Do not get on skin or clothing.  
Do not breathe dust.  
Do not swallow.  
Do not get in eyes.  
Handle in accordance with good industrial hygiene and safety practice, based on the results of the workplace exposure assessment  
Keep container tightly closed.  
Minimize dust generation and accumulation.  
Keep container closed when not in use.  
Keep away from heat and sources of ignition.  
Take precautionary measures against static discharges.  
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.

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

- Requirements for storage areas and containers : Keep in properly labelled containers. Store locked up. 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  
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
Losartan	124750-99-8	TWA	100 µg/m <sup>3</sup> (OEB 2)	Internal

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### 8.2 Exposure controls

#### Engineering measures

Minimize workplace exposure concentrations.

Apply measures to prevent dust explosions.

Ensure that dust-handling systems (such as exhaust ducts, dust collectors, vessels, and processing equipment) are designed in a manner to prevent the escape of dust into the work area (i.e., there is no leakage from the equipment).

If sufficient ventilation is unavailable, use with local exhaust ventilation.

#### Personal protective equipment

Eye protection	:	Wear the following personal protective equipment: Chemical resistant goggles must be worn. If splashes are likely to occur, wear: Face-shield Equipment should conform to NS EN 166
Hand protection	:	
Material	:	Chemical-resistant gloves
Remarks	:	Choose gloves to protect hands against chemicals depending on the concentration and quantity of the hazardous substance and specific to place of work. Breakthrough time is not determined for the product. Change gloves often! For special applications, we recommend clarifying the resistance to chemicals of the aforementioned protective gloves with the glove manufacturer. Wash hands before breaks and at the end of workday.
Skin and body protection	:	Select appropriate protective clothing based on chemical resistance data and an assessment of the local exposure potential. Skin contact must be avoided by using impervious protective clothing (gloves, aprons, boots, etc).
Respiratory protection	:	If adequate local exhaust ventilation is not available or exposure assessment demonstrates exposures outside the recommended guidelines, use respiratory protection. Equipment should conform to NS EN 143
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	:	powder
Colour	:	White to light yellow
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	:	No data available

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range	
Flash point	: No data available
Evaporation rate	: No data available
Flammability (solid, gas)	: May form explosive dust-air mixture during processing, handling or other means.
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	: 1 g/cm <sup>3</sup>
Solubility(ies)	
Water solubility	: No data available
Partition coefficient: n-octanol/water	: No data available
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
Minimum ignition energy	: > 300 mJ
Particle size	: No data available

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## SECTION 10: Stability and reactivity

### 10.1 Reactivity

Not classified as a reactivity hazard.

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### 10.2 Chemical stability

Stable under normal conditions.

### 10.3 Possibility of hazardous reactions

Hazardous reactions : May form explosive dust-air mixture during processing, handling or other means.  
Can react with strong oxidizing agents.

### 10.4 Conditions to avoid

Conditions to avoid : Heat, flames and sparks.  
Avoid dust formation.

### 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

Harmful if swallowed.

#### Product:

Acute oral toxicity : Acute toxicity estimate: 1.502 mg/kg  
Method: Calculation method

#### Components:

##### Losartan:

Acute oral toxicity : LD50 (Mouse): 1.257 - 1.590 mg/kg  
LDLo (Rat): 200 mg/kg  
LDLo (Mouse): 400 mg/kg

#### Skin corrosion/irritation

Not classified based on available information.

#### Components:

##### Losartan:

Species : Rabbit  
Result : Mild skin irritation



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### Serious eye damage/eye irritation

Causes serious eye damage.

#### Components:

##### Losartan:

Species	:	Rabbit
Result	:	Severe irritation

### Respiratory or skin sensitisation

#### Skin sensitisation

May cause an allergic skin reaction.

#### Respiratory sensitisation

Not classified based on available information.

#### Components:

##### Losartan:

Test Type	:	Maximisation Test
Exposure routes	:	Skin contact
Species	:	Guinea pig
Assessment	:	Probability or evidence of skin sensitisation in humans
Result	:	positive

### Germ cell mutagenicity

Not classified based on available information.

#### Components:

##### Losartan:

Genotoxicity in vitro	:	Test Type: in vitro assay
		Result: negative
		Test Type: In vitro mammalian cell gene mutation test
		Test system: Chinese hamster ovary cells
		Result: negative
		Test Type: Alkaline elution assay
		Result: negative
		Test Type: Chromosomal aberration
		Result: negative
Genotoxicity in vivo	:	Test Type: Chromosomal aberration
		Result: negative

### Carcinogenicity

Not classified based on available information.

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### Components:

#### **Losartan:**

Species : Mouse  
Application Route : Oral  
Exposure time : 92 weeks  
Dose : 200 mg/kg body weight  
Result : negative

Species : Rat  
Application Route : Oral  
Exposure time : 105 weeks  
Dose : 270 mg/kg body weight  
Result : negative

#### **Reproductive toxicity**

May damage the unborn child.  
May cause harm to breast-fed children.

### Components:

#### **Losartan:**

Effects on fertility : Test Type: Fertility  
Species: Rat, female  
Application Route: Oral  
Fertility: LOAEL: 200 mg/kg body weight  
Result: female reproductive effects  
Remarks: Maternal toxicity observed.

Effects on foetal development : Test Type: Development  
Species: Rabbit  
Application Route: Oral  
General Toxicity Maternal: NOAEL: 10 mg/kg body weight  
Developmental Toxicity: NOAEL F1: 20 mg/kg body weight  
Result: Embryotoxic effects and adverse effects on the offspring were detected only at high maternally toxic doses, No teratogenic effects

Test Type: Development  
Species: Rat  
Application Route: Oral  
Developmental Toxicity: LOAEL: 10 mg/kg body weight  
Result: Fetotoxicity, No teratogenic effects

Reproductive toxicity - Assessment : Clear evidence of adverse effects on development, based on animal experiments.

Studies indicating a hazard to babies during the lactation period

#### **STOT - single exposure**

Not classified based on available information.

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### STOT - repeated exposure

May cause damage to organs through prolonged or repeated exposure.

#### Components:

##### Losartan:

Exposure routes : Ingestion  
Target Organs : Blood, Cardio-vascular system, Stomach, Kidney  
Assessment : May cause damage to organs through prolonged or repeated exposure.

### Repeated dose toxicity

#### Components:

##### Losartan:

Species : Rat  
LOAEL : 15 mg/kg  
Application Route : Oral  
Exposure time : 309 d  
Number of exposures : daily  
Target Organs : Blood, Kidney, Cardio-vascular system, Stomach

Species : Dog  
NOAEL : 5 mg/kg  
Application Route : Oral  
Exposure time : 1 Months  
Symptoms : Salivation, Vomiting

Species : Dog  
LOAEL : 25 mg/kg  
Application Route : Oral  
Exposure time : 53 Weeks  
Number of exposures : daily  
Symptoms : Salivation, Vomiting

### Aspiration toxicity

Not classified based on available information.

#### Components:

##### Losartan:

No aspiration toxicity classification

### Experience with human exposure

#### Components:

##### Losartan:

Eye contact : Symptoms: Eye irritation  
Ingestion : Symptoms: hypotension, tachycardia

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### SECTION 12: Ecological information

#### 12.1 Toxicity

##### Components:

##### Losartan:

- Toxicity to fish : LC50 (Oncorhynchus mykiss (rainbow trout)): > 929 mg/l  
Exposure time: 96 h  
Method: FDA 4.11
- Toxicity to daphnia and other aquatic invertebrates : EC50 (Daphnia magna (Water flea)): 331 mg/l  
Exposure time: 48 h  
Method: OECD Test Guideline 202
- Toxicity to algae/aquatic plants : NOEC (Microcystis aeruginosa (blue-green algae)): 949 mg/l  
Exposure time: 10 d  
Method: FDA 4.01
- NOEC (Selenastrum capricornutum (green algae)): 143 mg/l  
Exposure time: 10 d  
Method: FDA 4.01
- Toxicity to fish (Chronic toxicity) : NOEC: 10 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: 100 mg/l  
Exposure time: 21 d  
Species: Daphnia magna (Water flea)  
Method: OECD Test Guideline 211

#### 12.2 Persistence and degradability

##### Components:

##### Losartan:

- Stability in water : Hydrolysis: < 10 %(5 d)

#### 12.3 Bioaccumulative potential

##### Components:

##### Losartan:

- Partition coefficient: n-octanol/water : log Pow: 1,2

#### 12.4 Mobility in soil

No data available

#### 12.5 Results of PBT and vPvB assessment

Not relevant

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### 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

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

REACH - Restrictions on the manufacture, placing on the market and use of certain dangerous substances, preparations and articles (Annex XVII)	:	Not applicable
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 (EU) 2019/1021 on persistent organic pollutants (recast)	:	Not applicable

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Regulation (EC) No 649/2012 of the European Parliament and the Council concerning the export and import of dangerous chemicals : Not applicable

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

Not applicable

### Other regulations:

Take note of Directive 92/85/EEC regarding maternity protection or stricter national regulations, where applicable.

Young people under the age of 18 are not allowed to use or be exposed to the product professionally. Young people above the age of 15 are, however, except from this rule if the product is a necessary part of their education.

### 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

H302 : Harmful if swallowed.  
H317 : May cause an allergic skin reaction.  
H318 : Causes serious eye damage.  
H360D : May damage the unborn child.  
H362 : May cause harm to breast-fed children.  
H373 : May cause damage to organs through prolonged or repeated exposure if swallowed.

### Full text of other abbreviations

Acute Tox. : Acute toxicity  
Eye Dam. : Serious eye damage  
Lact. : Effects on or via lactation  
Repr. : Reproductive toxicity  
Skin Sens. : Skin sensitisation  
STOT RE : Specific target organ toxicity - repeated 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; 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 -

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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; 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:

Acute Tox. 4	H302
Eye Dam. 1	H318
Skin Sens. 1	H317
Repr. 1B	H360D
Lact.	H362
STOT RE 2	H373

### Classification procedure:

Calculation method
Calculation method
Calculation method
Calculation method
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.

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