SAFETY DATA SHEET

According to 13 December 2014, No:29204, “Ministry of Environment and Urbanization; Regulation on Safety data sheets regarding hazardous substances and mixtures; Part I”.

Losartan Formulation

Version 2.3 Revision Date: 23.03.2020 SDS Number: 1942018-00007 Date of last issue: 13.09.2019 Date of first issue: 12.09.2017

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 Substance/Mixture: Pharmaceutical

1.3 Details of the supplier of the safety data sheet
   Company: Organon & Co.
   30 Hudson Street, 33nd 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

SECTION 2: Hazards identification

2.1 Classification of the substance or mixture

   Classification T.R. SEA No 28848
   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 T.R. SEA No 28848
   Hazard pictograms: 
   Signal word: Danger
   Hazard statements: 
   H302 Harmful if swallowed.
   H317 May cause an allergic skin reaction.
   H318 Causes serious eye damage.
Losartan Formulation

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.

Precautionary statements:

Prevention:
P201 Obtain special instructions before use.
P260 Do not breathe dust.
P263 Avoid contact during pregnancy/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 or doctor/physician.
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

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

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.
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<td>12.09.2017</td>
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</tbody>
</table>

When symptoms persist or in all cases of doubt seek medical advice.

**Protection of first-aiders**

- First Aid responders should pay attention to self-protection, and use the recommended personal protective equipment when the potential for exposure exists (see section 8).

**If inhaled**

- If inhaled, remove to fresh air.
- Get medical attention.

**In case of skin contact**

- In case of contact, immediately flush skin with soap and plenty of water.
- Remove contaminated clothing and shoes.
- Get medical attention.
- Wash clothing before reuse.
- Thoroughly clean shoes before reuse.

**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.

### SECTION 5: Firefighting measures

#### 5.1 Extinguishing media

- Suitable extinguishing media: Water spray
- Alcohol-resistant foam
- Carbon dioxide (CO2)
- Dry chemical
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Unsuitable extinguishing media: None known.

5.2 Special hazards arising from the substance or mixture

Specific hazards during firefighting: Avoid generating dust; fine dust dispersed in air in sufficient 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.

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 dis-
Losartan Formulation

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: 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
**Losartan Formulation**

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### SECTION 8: Exposure controls/personal protection

#### 8.1 Control parameters

**Occupational Exposure Limits**

<table>
<thead>
<tr>
<th>Components</th>
<th>CAS-No.</th>
<th>Value type (Form of exposure)</th>
<th>Control parameters</th>
<th>Basis</th>
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<tbody>
<tr>
<td>Losartan</td>
<td>124750-99-8</td>
<td>TWA</td>
<td>100 µg/m³ (OEB 2)</td>
<td>Internal</td>
</tr>
</tbody>
</table>

#### 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 TS EN 166.
- **Hand protection**: Choose gloves to protect hands against chemicals depending on the concentration and quantity of the hazardous substance and specific to place of work. 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 TS EN 143.
- **Filter type**: Particulates type (P)
Losartan Formulation

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 range**: No data available
- **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/cm³
- **Solubility(ies)**: No data available
  - **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**: No data available
  - **Viscosity, kinematic**: No data available
- **Explosive properties**: Not explosive
- **Oxidizing properties**: The substance or mixture is not classified as oxidizing.
9.2 Other information

<table>
<thead>
<tr>
<th>Property</th>
<th>Value</th>
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</thead>
<tbody>
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<td>Flammability (liquids)</td>
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<tr>
<td>Minimum ignition energy</td>
<td>&gt; 300 mJ</td>
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<tr>
<td>Particle size</td>
<td>No data available</td>
</tr>
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</table>

**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: 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.

**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
Losartan Formulation

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

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
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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.

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
Losartan Formulation

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.

STOT - single exposure
Not classified based on available information.

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
Losartan Formulation

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

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)
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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

12.6 Other adverse effects
No data available

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.

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
SAFETY DATA SHEET
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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.

SECTION 15: Regulatory information

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

- KKDIK (30105 (Bis)) - Restrictions on the manufacture, placing on the market and use of certain dangerous substances, mixtures and articles (Annex 17) : Not applicable
- Regulation on Persistent Organic Pollutants (Number 30595) : Not applicable
- Regulation on prevention of major industrial accidents. Reg number 30702 Not applicable

Other regulations:
According to 13 December 2014, No:29204, “Ministry of Environment and Urbanization; Regulation on Safety data sheets regarding hazardous substances and mixtures; Part I”.

Regulation on Classification, Labelling and Packaging of Substances and Mixtures. Dated 11 December 2013, Numbered 28848 (Bis) Ministry of Environment and Forestry.

Regulation on Health and Safety Measures Of Working with Chemicals Substances Dated 12.08.13, numbered 28733 Ministry of Labour and Social Security.

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

- AICS : not determined
- DSL : not determined
- IECSC : not determined

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

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SAFETY DATA SHEET
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</table>

The Turkish SDS has been prepared according to the Regulation on Safety Data Sheets for Hazardous Substances and Mixtures No. 29204.

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 - 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


Classification of the mixture:

Classification procedure:
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<table>
<thead>
<tr>
<th>Property</th>
<th>Code</th>
<th>Calculation method</th>
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</thead>
<tbody>
<tr>
<td>Acute Tox. 4</td>
<td>H302</td>
<td>Calculation method</td>
</tr>
<tr>
<td>Eye Dam. 1</td>
<td>H318</td>
<td>Calculation method</td>
</tr>
<tr>
<td>Skin Sens. 1</td>
<td>H317</td>
<td>Calculation method</td>
</tr>
<tr>
<td>Repr. 1B</td>
<td>H360D</td>
<td>Calculation method</td>
</tr>
<tr>
<td>Lact.</td>
<td>H362</td>
<td>Calculation method</td>
</tr>
<tr>
<td>STOT RE 2</td>
<td>H373</td>
<td>Calculation method</td>
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</tbody>
</table>

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.

TR / EN