# SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006, as amended by Commission Regulation (EU) 2020/878

Public

ORGANON

# Losartan / Hydrochlorothiazide Formulation

| Version | Revision Date: | SDS Number: | Date of last issue: 26.09.2023 |
|---|---|---|---|
| 5.2 | 06.04.2024 | 17076-00023 | Date of first issue: 30.09.2014 |

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

### 1.1 Product identifier

Trade name : Losartan / Hydrochlorothiazide Formulation

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

Use of the Substance/Mixture : Pharmaceutical

Recommended restrictions on use : Not applicable

### 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 : +1-551-430-6000

E-mail address of person responsible for the SDS : EHSSTEWARD@organon.com

### 1.4 Emergency telephone number

+1-215-631-6999

## SECTION 2: Hazards identification

### 2.1 Classification of the substance or mixture

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

| | |
|---|---|
| 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 : 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.

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
Hydrochlorothiazide

### 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.

Ecological information: 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.

Toxicological information: 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.

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.<br>EC-No.<br>Index-No.<br>Registration number | Classification | Concentration (% w/w) |
|---|---|---|---|

| | | | |
|---|---|---|---|
| Losartan | 124750-99-8 | Acute Tox. 4; H302<br>Eye Dam. 1; H318<br>Skin Sens. 1; H317<br>Repr. 1B; H360D Lact.H362<br>STOT RE 2; H373 (Blood, Cardio-vascular system, Stomach, Kidney) | >= 20 - < 30 |
| Hydrochlorothiazide | 58-93-5<br>200-403-3 | STOT RE 1; H372 (Kidney, Parathy-roid gland) | >= 1 - < 10 |

For explanation of abbreviations see section 16.

## SECTION 4: First aid measures

### 4.1 Description of first aid measures

General advice : In the case of accident or if you feel unwell, seek medical advice immediately.
When symptoms persist or in all cases of doubt seek medical advice.

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

If inhaled : If inhaled, remove to fresh air.
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.

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

Risks : 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

Unsuitable extinguishing media : None known.

### 5.2 Special hazards arising from the substance or mixture

Specific hazards during fire-fighting : 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)
Chlorine compounds
Sulphur oxides

### 5.3 Advice for firefighters

Special protective equipment for firefighters : In the event of fire, wear self-contained breathing apparatus.
Use personal protective equipment.

Specific extinguishing methods : Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.
Use water spray to cool unopened containers.
Remove undamaged containers from fire area if it is safe to do so.
Evacuate area.

## 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 pro-

tective 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.
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.

## 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 : Avoid contact during pregnancy and while nursing.
Do not get on skin or clothing.
Do not breathe dust.
Do not swallow.
Do not get in eyes.
Wash skin thoroughly after handling.
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.

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. Contaminated work clothing should not be allowed out of the workplace. 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. 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
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**

Dust

5 mg/m3
Value type (Form of exposure): TWA (respirable dust)
Basis: FOR-2011-12-06-1358

10 mg/m3
Value type (Form of exposure): TWA (total dust)
Basis: FOR-2011-12-06-1358

| Components | CAS-No. | Value type (Form of exposure) | Control parameters | Basis |
|---|---|---|---|---|
| Losartan | 124750-99-8 | TWA | 100 µg/m3 (OEB 2) | Internal |
| Hydrochlorothia-zide | 58-93-5 | TWA | 100 µg/m3 (OEB 2) | Internal |

### 8.2 Exposure controls

**Engineering measures**

Use feasible engineering controls to minimize exposure to compound.
All engineering controls should be implemented by facility design and operated in accordance with GMP principles to protect products, workers, and the environment.

**Personal protective equipment**

| | | |
|---|---|---|
| Eye/face protection | : | Wear safety glasses with side shields or goggles.<br>If the work environment or activity involves dusty conditions, mists or aerosols, wear the appropriate goggles.<br>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.<br>Equipment should conform to NS EN 143 |
| Filter type | : | Particulates type (P) |

## SECTION 9: Physical and chemical properties

### 9.1 Information on basic physical and chemical properties

| | | |
|---|---|---|
| Physical state | : | powder |
| Colour | : | yellow |
| Odour | : | odourless |
| Odour Threshold | : | No data available |
| Melting point/freezing point | : | No data available |
| Initial boiling point and boiling range | : | No data available |
| Flammability (solid, gas) | : | May form explosive dust-air mixture during processing, handling or other means. |
| Flammability (liquids) | : | No data available |
| Upper explosion limit / Upper flammability limit | : | No data available |
| Lower explosion limit / Lower flammability limit | : | No data available |

| | | |
|---|---|---|
| Flash point | : | Not applicable |
| Auto-ignition temperature | : | No data available |
| Decomposition temperature | : | No data available |
| pH | : | No data available |
| Viscosity | | |
| Viscosity, kinematic | : | Not applicable |
| Solubility(ies) | | |
| Water solubility | : | No data available |
| Partition coefficient: n-octanol/water | : | Not applicable |
| Vapour pressure | : | Not applicable |
| Relative density | : | No data available |
| Density | : | No data available |
| Relative vapour density | : | Not applicable |
| Particle characteristics | | |
| Particle size | : | No data available |

### 9.2 Other information

| | | |
|---|---|---|
| Explosives | : | Not explosive |
| Oxidizing properties | : | The substance or mixture is not classified as oxidizing. |
| Evaporation rate | : | Not applicable |

## 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.<br>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 hazard classes as defined in Regulation (EC) No 1272/2008

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:**

**Losartan:**

Acute oral toxicity : LD50 (Mouse): 1.257 - 1.590 mg/kg

LDLo (Rat): 200 mg/kg

LDLo (Mouse): 400 mg/kg

**Hydrochlorothiazide:**

Acute oral toxicity : LD50 (Rat): > 2.750 mg/kg

LD50 (Mouse): > 2.830 mg/kg

Acute toxicity (other routes of administration) : LD50 (Rat): 990 mg/kg
Application Route: Intravenous

LD50 (Mouse): 590 mg/kg
Application Route: Intravenous

**Skin corrosion/irritation**

Not classified based on available information.

**Components:**

**Losartan:**

Species : Rabbit

Result : Mild skin irritation

**Hydrochlorothiazide:**

Species : Rabbit
Result : No skin irritation

**Serious eye damage/eye irritation**

Causes serious eye damage.

**Components:**

**Losartan:**

Species : Rabbit
Result : Severe irritation

**Hydrochlorothiazide:**

Species : Rabbit
Result : Mild eye 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

**Hydrochlorothiazide:**

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

Test Type: Chromosomal aberration
Test system: Chinese hamster ovary cells
Result: negative

Test Type: sister chromatid exchange assay
Test system: Chinese hamster ovary cells
Result: positive

Test Type: in vitro assay
Test system: mouse lymphoma cells
Result: positive

Genotoxicity in vivo : Test Type: Chromosomal aberration
Species: Chinese hamster
Cell type: Bone marrow
Result: negative

Test Type: in vivo assay
Species: Mouse
Cell type: Bone marrow
Result: negative

Germ cell mutagenicity- Assessment : Weight of evidence does not support classification as a germ cell mutagen.

**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

**Hydrochlorothiazide:**

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

Species : Mouse, male
Application Route : Oral
Exposure time : 2 Years
Result : equivocal

Species : Rat, male and female
Application Route : Oral
Exposure time : 2 Years
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

**Hydrochlorothiazide:**

Effects on fertility : Test Type: Fertility
Species: Rat, male and female
Application Route: oral (feed)
Fertility: NOAEL: 4 mg/kg body weight
Result: Effects on fertility

Test Type: Fertility
Species: Mouse, male and female
Application Route: oral (feed)
Fertility: NOAEL: 100 mg/kg body weight
Result: Effects on fertility

Effects on foetal development : Test Type: Development
Species: Mouse
Application Route: Oral
Developmental Toxicity: NOAEL: 3.000 mg/kg body weight
Result: No teratogenic effects

Test Type: Development
Species: Rat
Application Route: Oral
Developmental Toxicity: NOAEL: 1.000 mg/kg body weight
Result: No teratogenic effects

**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.

**Hydrochlorothiazide:**

Target Organs : Kidney, Parathyroid gland
Assessment : Causes 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 |

**Hydrochlorothiazide:**

| | | |
|---|---|---|
| Species | : | Rat, male and female |
| LOAEL | : | 10 mg/kg |
| Application Route | : | Oral |
| Exposure time | : | 2 yr |
| Target Organs | : | Kidney, Parathyroid gland |

| | | |
|---|---|---|
| Species | : | Mouse, male and female |
| NOAEL | : | 300 - 550 mg/kg |
| Application Route | : | Oral |
| Exposure time | : | 2 yr |
| Remarks | : | No significant adverse effects were reported |

| | | |
|---|---|---|
| Species | : | Dog |
| | : | 50 - 200 mg/kg |
| Application Route | : | Oral |
| Exposure time | : | 9 Months |
| Target Organs | : | Parathyroid gland |

**Aspiration toxicity**

Not classified based on available information.

**Components:**

**Losartan:**

No aspiration toxicity classification

**Hydrochlorothiazide:**

No aspiration toxicity classification

### 11.2 Information on other hazards

**Endocrine disrupting properties**

**Product:**

Assessment : 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.

**Experience with human exposure**

**Components:**

**Losartan:**

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

**Hydrochlorothiazide:**

Eye contact : Symptoms: Eye irritation
Ingestion : Symptoms: Dizziness, Headache, Fatigue, Nausea, Abdominal pain, hypotension, dry mouth, electrolyte imbalance, eye pain

## 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<br>Exposure time: 21 d<br>Species: Daphnia magna (Water flea)<br>Method: OECD Test Guideline 211 |

**Hydrochlorothiazide:**

| | | |
|---|---|---|
| Toxicity to fish | : | LC50 (Pimephales promelas (fathead minnow)): > 500 mg/l<br>Exposure time: 96 h |
| Toxicity to daphnia and other aquatic invertebrates | : | EC50 (Daphnia magna (Water flea)): > 500 mg/l<br>Exposure time: 48 h |

### 12.2 Persistence and degradability

**Components:**

**Losartan:**

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

**Hydrochlorothiazide:**

| | | |
|---|---|---|
| Stability in water | : | Hydrolysis: 46,2 %(96 h) |

### 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

**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 Endocrine disrupting properties

**Product:**

| | | |
|---|---|---|
| Assessment | : | 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.<br>According to the European Waste Catalogue, Waste Codes are not product specific, but application specific.<br>Waste codes should be assigned by the user, preferably in discussion with the waste disposal authorities.<br>Do not dispose of waste into sewer. |
| Contaminated packaging | : | Empty containers should be taken to an approved waste handling site for recycling or disposal.<br>If not otherwise specified: Dispose of as unused product. |

## SECTION 14: Transport information

### 14.1 UN number or ID 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

**14.5 Environmental hazards**

Not regulated as a dangerous good

**14.6 Special precautions for user**

Not applicable

**14.7 Maritime transport in bulk according to IMO instruments**

Remarks : Not applicable for product as supplied.

## SECTION 15: Regulatory information

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

REACH - Restrictions on the manufacture, placing on the market and use of certain dangerous substances, mixtures 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

Regulation (EU) 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:**

Note the Working Environment Act § 4-1 and § 4-2 on requirements for the employer to protect pregnant employees against discomfort and injury as a result of the work situation and the working environment.
Note the regulation on organization, leadership and participation, chapter 12 on the work of children and young people.

**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. |
| H372 | : | Causes damage to organs through prolonged or repeated exposure. |
| 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 |
| FOR-2011-12-06-1358 | : | Norway. Occupational Exposure limits |
| FOR-2011-12-06-1358 / TWA | : | Long term exposure limit |

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 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:** | | **Classification procedure:** |
|---|---|---|
| Eye Dam. 1 | H318 | Calculation method |
| Skin Sens. 1 | H317 | Calculation method |
| Repr. 1B | H360D | Calculation method |
| Lact. | H362 | Calculation method |
| STOT RE 2 | H373 | 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.

NO / EN