SAFETY DATA SHEET

Losartan / Hydrochlorothiazide Formulation

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

1.3 Details of the supplier of the safety data sheet
   Company : MSD
   117 16th Road
   07033 Halfway house, Midrand, South Africa
   Telephone : +27 11 655 3000
   Telefax : 908-735-1496
   E-mail address of person responsible for the SDS : EHSDATASTEWARD@msd.com

1.4 Emergency telephone number
   1-908-423-6000

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...
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

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

<table>
<thead>
<tr>
<th>Components</th>
<th>CAS-No. EC-No.</th>
<th>Classification</th>
<th>Concentration (% w/w)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Losartan</td>
<td>124750-99-8</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;= 20 - &lt; 30</td>
</tr>
<tr>
<td>Hydrochlorothiazide</td>
<td>58-93-5 200-403-3</td>
<td>STOT RE1; H372</td>
<td>&gt;= 1 - &lt; 10</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.
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 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)
- 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 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.
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.
- 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
  - 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 |
--- | --- | --- | --- | --- |
Cellulose | 9004-34-6 | TWA OEL-RL (Respirable dust) | 5 mg/m3 | ZA OEL |
Further information | Recommended Limit | TWA OEL-RL (inhalable dust) | 10 mg/m3 | ZA OEL |
Further information | Recommended Limit | STEL OEL-RL (Dust) | 20 mg/m3 | ZA OEL |
Further information | Recommended Limit | Losartan | 124750-99-8 | TWA | 100 µg/m3 (OEB 2) | Internal |
Further information | Recommended Limit | Starch | 9005-25-8 | TWA OEL-RL (Respirable dust) | 5 mg/m3 | ZA OEL |
Further information | Recommended Limit | TWA OEL-RL (inhalable dust) | 10 mg/m3 | ZA OEL |
Further information | Recommended Limit | Hydrochlorothiazide | 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 protection
Wear safety glasses with side shields or goggles.
If the work environment or activity involves dusty conditions, mists or aerosols, wear the appropriate goggles.
Wear a faceshield or other full face protection if there is a potential for direct contact to the face with dusts, mists, or aerosols.

Hand protection
Material: Chemical-resistant gloves

Skin and body protection
Work uniform or laboratory coat.

Respiratory protection
If adequate local exhaust ventilation is not available or exposure assessment demonstrates exposures outside the recommended guidelines, use respiratory protection.
Filter type: Particulates type (P)

SECTION 9: Physical and chemical properties

9.1 Information on basic physical and chemical properties

Appearance: powder
Colour: yellow
Odour: odourless
Odour Threshold: No data available
SAFETY DATA SHEET
Losartan / Hydrochlorothiazide Formulation

Version 4.2 Revision Date: 09/13/2019 SDS Number: 17083-00014 Date of last issue: 24.04.2019 Date of first issue: 30.09.2014

pH : No data available
Melting point/freezing point : No data available
Initial boiling point and boiling range : No data available
Flash point : Not applicable
Evaporation rate : Not applicable
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 : Not applicable
Relative vapour density : Not applicable
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 : Not applicable
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 : No data available

SECTION 10: Stability and reactivity

10.1 Reactivity
Not classified as a reactivity hazard.
SAFETY DATA SHEET

Losartan / Hydrochlorothiazide Formulation

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
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): 10.000 mg/kg
LD50 (Mouse): 10.000 mg/kg

Acute toxicity (other routes of administration): LD50 (Rat): 990 mg/kg
Application Route: Intravenous
LD50 (Dog): 250 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  
Result: negative

Hydrochlorothiazide:
Genotoxicity in vitro  
Result: negative

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  
Result: negative

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

<table>
<thead>
<tr>
<th>Species</th>
<th>Application Route</th>
<th>Exposure time</th>
<th>Dose</th>
<th>Result</th>
</tr>
</thead>
<tbody>
<tr>
<td>Rat</td>
<td>Oral</td>
<td>105 weeks</td>
<td>270 mg/kg body weight</td>
<td>negative</td>
</tr>
</tbody>
</table>

### Hydrochlorothiazide

<table>
<thead>
<tr>
<th>Species</th>
<th>Application Route</th>
<th>Exposure time</th>
<th>Result</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mouse, female</td>
<td>Oral</td>
<td>2 Years</td>
<td>negative</td>
</tr>
<tr>
<td>Mouse, male</td>
<td>Oral</td>
<td>2 Years</td>
<td>equivocal</td>
</tr>
<tr>
<td>Rat, male and female</td>
<td>Oral</td>
<td>2 Years</td>
<td>negative</td>
</tr>
</tbody>
</table>

### 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
- **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
### SAFETY DATA SHEET

**Losartan / Hydrochlorothiazide Formulation**

<table>
<thead>
<tr>
<th>Version</th>
<th>Revision Date:</th>
<th>SDS Number:</th>
<th>Date of last issue:</th>
<th>Date of first issue:</th>
</tr>
</thead>
</table>

**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  

**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  
**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
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
  Exposure time: 21 d
  Species: Daphnia magna (Water flea)
  Method: OECD Test Guideline 211

**Hydrochlorothiazide:**
- **Toxicity to fish**: LC50 (Pimephales promelas (fathead minnow)): > 500 mg/l
  Exposure time: 96 h

- **Toxicity to daphnia and other aquatic invertebrates**: EC50 (Daphnia magna (Water flea)): > 500 mg/l
  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
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
14.5 Environmental hazards
Not regulated as a dangerous good

14.6 Special precautions for user
Not applicable

14.7 Transport in bulk according to Annex II of Marpol and the IBC Code
Remarks : Not applicable for product as supplied.

SECTION 15: Regulatory information

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

The components of this product are reported in the following inventories:
AICS : not determined
DSL : not determined
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
ZA OEL : South Africa. Hazardous Chemical Substances Regulations, Occupational Exposure Limits
ZA OEL / TWA OEL-RL : Long term occupational exposure limits - recommended limit
ZA OEL / STEL OEL-RL : Short term occupational exposure limits - recommended limit
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:

<table>
<thead>
<tr>
<th>Classification procedure:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Calculation method</td>
</tr>
</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.

ZA / EN