SAFETY DATA SHEET
according to Regulation (EC) No. 1907/2006

Losartan / Amlodipine Besylate Formulation

Version 3.2  Revision Date: 09/13/2019  SDS Number: 51861-00014  Date of last issue: 24.04.2019

3.2  Date of first issue: 26.01.2015

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

1.1 Product identifier
   Trade name : Losartan / Amlodipine Besylate 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
   Shotton Lane
   NE23 3JU Crailmington NU - Great Britain
   Telephone : 44 1 670 59 30 00
   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 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

<table>
<thead>
<tr>
<th>Components</th>
<th>CAS-No.</th>
<th>Classification</th>
<th>Concentration (% w/w)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>EC-No.</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Index-No.</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Registration number</td>
<td></td>
<td></td>
</tr>
<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 RE 2; H373</td>
<td>&gt;= 10 - &lt; 20</td>
</tr>
<tr>
<td>Amlodipine Besylate</td>
<td>652969-01-2</td>
<td>Acute Tox. 4; H302 Eye Irrit. 2; H319 Aquatic Chronic 2; H411</td>
<td>&gt;= 1 - &lt; 2.5</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), Metal 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.
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

<table>
<thead>
<tr>
<th>Components</th>
<th>CAS-No.</th>
<th>Value type (Form)</th>
<th>Control parameters</th>
<th>Basis</th>
</tr>
</thead>
</table>

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Further information

For the purposes of these limits, respirable dust and inhalable dust are those fractions of airborne dust which will be collected when sampling is undertaken in accordance with the methods described in MDHS14/4 General methods for sampling and gravimetric analysis or respirable, thoracic and inhalable aerosols. The COSHH definition of a substance hazardous to health includes dust of any kind when present at a concentration in air equal to or greater than 10 mg.m\(^{-3}\) 8-hour TWA of inhalable dust or 4 mg.m\(^{-3}\) 8-hour TWA of respirable dust. This means that any dust will be subject to COSHH if people are exposed to dust above these levels. Some dusts have been assigned specific WELs and exposure to these must comply with the appropriate limits. Most industrial dusts contain particles of a wide range of sizes. The behaviour, deposition and fate of any particular particle after entry into the human respiratory system, and the body response that it elicits, depend on the nature and size of the particle. HSE distinguishes two size fractions for limit-setting purposes termed 'inhalable' and 'respirable'. Inhalable dust approximates to the fraction of airborne material that enters the nose and mouth during breathing and is therefore available for deposition in the respiratory tract. Respirable dust approximates to the fraction that penetrates to the gas exchange region of the lung. Fuller definitions and explanatory material are given in MDHS14/4. Where dusts contain components that have their own assigned WEL, all the relevant limits should be complied with.

<table>
<thead>
<tr>
<th>Substance</th>
<th>TWA (Respirable dust)</th>
<th>STEL (inhalable dust)</th>
<th>Category</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cellulose</td>
<td>10 mg/m(^3)</td>
<td>20 mg/m(^3)</td>
<td>GB EH40</td>
</tr>
<tr>
<td>Losartan</td>
<td>100 µg/m(^3) (OEB 2)</td>
<td>Internal</td>
<td>Internal</td>
</tr>
<tr>
<td>Amlodipine Besylate</td>
<td>20 µg/m(^3) (OEB 3)</td>
<td>Internal</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 BS 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.

Filter type: Particulates type (P)

### SECTION 9: Physical and chemical properties

#### 9.1 Information on basic physical and chemical properties

<table>
<thead>
<tr>
<th>Property</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Appearance</td>
<td>powder</td>
</tr>
<tr>
<td>Colour</td>
<td>No data available</td>
</tr>
<tr>
<td>Odour</td>
<td>No data available</td>
</tr>
<tr>
<td>Odour Threshold</td>
<td>No data available</td>
</tr>
<tr>
<td>pH</td>
<td>No data available</td>
</tr>
<tr>
<td>Melting point/freezing point</td>
<td>No data available</td>
</tr>
<tr>
<td>Initial boiling point and boiling range</td>
<td>No data available</td>
</tr>
<tr>
<td>Flash point</td>
<td>Not applicable</td>
</tr>
<tr>
<td>Evaporation rate</td>
<td>No data available</td>
</tr>
<tr>
<td>Flammability (solid, gas)</td>
<td>May form explosive dust-air mixture during processing, handling or other means.</td>
</tr>
<tr>
<td>Upper explosion limit / Upper flammability limit</td>
<td>No data available</td>
</tr>
<tr>
<td>Lower explosion limit / Lower flammability limit</td>
<td>No data available</td>
</tr>
<tr>
<td>Vapour pressure</td>
<td>No data available</td>
</tr>
<tr>
<td>Relative vapour density</td>
<td>No data available</td>
</tr>
</tbody>
</table>
Relative density : No data available
Density : No data available
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
  Particle size : No data available

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
Not classified based on available information.

Product:
Acute oral toxicity: Acute toxicity estimate: > 5,000 mg/kg
Method: Expert judgement

Components:
Losartan:
Acute oral toxicity: LD50 (Mouse): 1,257 - 1,590 mg/kg
LDLo (Rat): 200 mg/kg
LDLo (Mouse): 400 mg/kg

Amlodipine Besylate:
Acute oral toxicity: LD50 (Rat): 393 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

Amlodipine Besylate:
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

Amlodipine Besylate:
- Genotoxicity in vitro: Test Type: Bacterial reverse mutation assay (AMES)
  Result: negative
  Test Type: Chromosome aberration test in vitro
  Result: negative

Carcinogenicity
Not classified based on available information.

Components:

Losartan:
- Species: Mouse
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<table>
<thead>
<tr>
<th>Application Route</th>
<th>Oral</th>
</tr>
</thead>
<tbody>
<tr>
<td>Exposure time</td>
<td>92 weeks</td>
</tr>
<tr>
<td>Dose</td>
<td>200 mg/kg body weight</td>
</tr>
<tr>
<td>Result</td>
<td>negative</td>
</tr>
<tr>
<td>Species</td>
<td>Rat</td>
</tr>
</tbody>
</table>

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

**Amlodipine Besylate:**

<table>
<thead>
<tr>
<th>Species</th>
<th>Mouse</th>
</tr>
</thead>
<tbody>
<tr>
<td>Application Route</td>
<td>Oral</td>
</tr>
<tr>
<td>Exposure time</td>
<td>2 Years</td>
</tr>
<tr>
<td>Result</td>
<td>negative</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Species</th>
<th>Rat</th>
</tr>
</thead>
<tbody>
<tr>
<td>Application Route</td>
<td>Oral</td>
</tr>
<tr>
<td>Exposure time</td>
<td>2 Years</td>
</tr>
<tr>
<td>Result</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
- 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

**Amlodipine Besylate:**

**Effects on fertility**

- Test Type: Fertility/early embryonic development
- Species: Rat
- Application Route: Ingestion
- Fertility: NOAEL: 10 mg/kg body weight
- Result: No effects on fertility

- Test Type: Fertility/early embryonic development
- Species: Rabbit
- Application Route: Ingestion
- Fertility: NOAEL: 25 mg/kg body weight
- Result: No effects on fertility

**Effects on foetal development**

- Test Type: Embryo-foetal development
- Species: Rat
- Application Route: Ingestion
- Developmental Toxicity: LOAEL: 10 mg/kg body weight
- Result: Effects on foetal development

- Test Type: Embryo-foetal development
- Species: Rabbit
- Application Route: Ingestion
- Developmental Toxicity: NOAEL: 10 mg/kg body weight
- Result: No effects on foetal development

- Test Type: Embryo-foetal development
- Species: Mouse
- Application Route: Ingestion
- Developmental Toxicity: LOAEL: 1.6 mg/kg body weight
- Result: Effects on foetal development
- Remarks: Maternal toxicity observed.

**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
Exposure time: 53 Weeks
Number of exposures: daily
Symptoms: Salivation, Vomiting

Amlodipine Besylate:
Species: Rat
NOAEL: 15 mg/kg
Application Route: Oral
Exposure time: 90 d
Remarks: No significant adverse effects were reported

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

Amlodipine Besylate:
Eye contact: Symptoms: Severe irritation
Ingestion: Symptoms: Nausea, Abdominal pain, Fatigue, Headache, Oedema, Palpitation
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

Amlodipine Besylate:
Toxicity to fish:
LC50 (Pimephales promelas (fathead minnow)): 2.7 mg/l
Exposure time: 96 h

Toxicity to daphnia and other aquatic invertebrates:
EC50 (Daphnia magna (Water flea)): 3.2 mg/l
Exposure time: 48 h

Toxicity to algae/aquatic plants:
IC50 (Pseudokirchneriella subcapitata (green algae)): 5.6 mg/l
Exposure time: 72 h
Method: OECD Test Guideline 201

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

- **Amlodipine Besylate:**
  - Partition coefficient: n-octanol/water: log Pow: 3

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.
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SECTION 15: Regulatory information

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

- 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 (EC) No 850/2004 on persistent organic pollutants: Not applicable
- Regulation (EC) No 649/2012 of the European Parliament and the Council concerning the export and import of dangerous chemicals: Not applicable
- REACH - Restrictions on the manufacture, placing on the market and use of certain dangerous substances, preparations and articles (Annex XVII): Not applicable

Other regulations:
Take note of Directive 92/85/EEC regarding maternity protection or stricter national regulations, where applicable.
Take note of Directive 94/33/EC on the protection of young people at work or stricter national regulations, where applicable.

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.
- H319: Causes serious eye irritation.
- 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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Version: 3.2  Revision Date: 09/13/2019  SDS Number: 51861-00014  Date of last issue: 24.04.2019  Date of first issue: 26.01.2015

exposure if swallowed.

H411 : Toxic to aquatic life with long lasting effects.

**Full text of other abbreviations**

- **Acute Tox.**: Acute toxicity
- **Aquatic Chronic**: Long-term (chronic) aquatic hazard
- **Eye Dam.**: Serious eye damage
- **Eye Irrit.**: Eye irritation
- **Lact.**: Effects on or via lactation
- **Repr.**: Reproductive toxicity
- **Skin Sens.**: Skin sensitisation
- **STOT RE**: Specific target organ toxicity - repeated exposure
- **GB EH40**: UK. EH40 WEL - Workplace Exposure Limits
- **GB EH40 / TWA**: Long-term exposure limit (8-hour TWA reference period)
- **GB EH40 / STEL**: Short-term exposure limit (15-minute reference period)

- **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; **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; **IECS** - 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; **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 Road; **SADT** - Self-Accelerating Decomposition Temperature; **SDS** - Safety Data Sheet; **SVHC** - Substance of Very High Concern; **TCSI** - Taiwan Chemical Substance Inventory; **TRGS** - Technical Rule for Hazardous Substances; **TSCA** - Toxic Substances Control Act (United States); **UN** - United Nations; **vPvB** - Very Persistent and Very Bioaccumulative

**Further information**

Losartan / Amlodipine Besylate Formulation

Classification of the mixture:

<table>
<thead>
<tr>
<th>Effect</th>
<th>Classification</th>
<th>Calculation method</th>
</tr>
</thead>
<tbody>
<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>
</tr>
</tbody>
</table>

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GB / EN