

SAFETY DATA SHEET

according to GB/T 16483 and GB/T 17519



ORGANON

Losartan / Amlodipine Besylate Formulation

Version 4.10 Revision Date: 2020/10/10 SDS Number: 49933-00016 Date of last issue: 2020/03/23
Date of first issue: 2015/01/26

1. PRODUCT AND COMPANY IDENTIFICATION

Product name : Losartan / Amlodipine Besylate Formulation

Manufacturer or supplier's details

Company : Organon & Co.

Address : 30 Hudson Street, 33rd floor
Jersey City, New Jersey, U.S.A 07302

Telephone : 551-430-6000

Emergency telephone number : 215-631-6999

E-mail address : EHSSTEWARD@organon.com

Recommended use of the chemical and restrictions on use

Recommended use : Pharmaceutical

2. HAZARDS IDENTIFICATION

Emergency Overview

Appearance : powder
Colour : No data available
Odour : No data available

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.

GHS Classification

Serious eye damage/eye irritation : Category 1
Skin sensitisation : Category 1
Reproductive toxicity : Category 1B
Effects on or via lactation
Specific target organ toxicity - repeated exposure : Category 2

GHS label elements

Hazard pictograms : 

Signal word : Danger

SAFETY DATA SHEET

according to GB/T 16483 and GB/T 17519



ORGANON

Losartan / Amlodipine Besylate Formulation

| | | | |
|---------|----------------|-------------|---------------------------------|
| Version | Revision Date: | SDS Number: | Date of last issue: 2020/03/23 |
| 4.10 | 2020/10/10 | 49933-00016 | Date of first issue: 2015/01/26 |

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.
P202 Do not handle until all safety precautions have been read and understood.
P260 Do not breathe dust.
P263 Avoid contact during pregnancy/ while nursing.
P264 Wash skin thoroughly after handling.
P270 Do not eat, drink or smoke when using this product.
P272 Contaminated work clothing should not be allowed out of the workplace.
P280 Wear protective gloves/ protective clothing/ eye protection/ face protection.

Response:
P302 + P352 IF ON SKIN: Wash with plenty of water.
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.
P333 + P313 If skin irritation or rash occurs: Get medical advice/ attention.
P362 + P364 Take off contaminated clothing and wash it before reuse.

Storage:
P405 Store locked up.

Disposal:
P501 Dispose of contents/ container to an approved waste disposal plant.

Physical and chemical hazards

Not classified based on available information.

Health hazards

Causes serious eye damage. May cause an allergic skin reaction. May damage the unborn child. May cause harm to breast-fed children. May cause damage to organs through prolonged or repeated exposure.

Environmental hazards

Not classified based on available information.

Other hazards which do not result in classification

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

SAFETY DATA SHEET

according to GB/T 16483 and GB/T 17519



Losartan / Amlodipine Besylate Formulation

Version 4.10 Revision Date: 2020/10/10 SDS Number: 49933-00016 Date of last issue: 2020/03/23
Date of first issue: 2015/01/26

3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture : Mixture

Components

| Chemical name | CAS-No. | Concentration (% w/w) |
|---------------------|-------------|-----------------------|
| Cellulose | 9004-34-6 | >= 50 -< 70 |
| Losartan | 124750-99-8 | >= 10 -< 20 |
| Amlodipine Besylate | 652969-01-2 | >= 1 -< 2.5 |
| Titanium dioxide | 13463-67-7 | >= 0.1 -< 1 |

4. 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.
- 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.
- Most important symptoms and effects, both acute and delayed : 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.
- 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).
- Notes to physician : Treat symptomatically and supportively.

5. FIREFIGHTING MEASURES

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

SAFETY DATA SHEET

according to GB/T 16483 and GB/T 17519



Losartan / Amlodipine Besylate Formulation

| | | | |
|---------|----------------|-------------|---------------------------------|
| Version | Revision Date: | SDS Number: | Date of last issue: 2020/03/23 |
| 4.10 | 2020/10/10 | 49933-00016 | Date of first issue: 2015/01/26 |

- media
- 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 (NO_x)
Metal oxides
- 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.
- Special protective equipment for firefighters : In the event of fire, wear self-contained breathing apparatus. Use personal protective equipment.

6. ACCIDENTAL RELEASE MEASURES

- Personal precautions, protective equipment and emergency procedures : Use personal protective equipment. Follow safe handling advice (see section 7) and personal protective equipment recommendations (see section 8).
- 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.
- Methods and materials for containment and 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.

7. HANDLING AND STORAGE

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.

SAFETY DATA SHEET

according to GB/T 16483 and GB/T 17519



Losartan / Amlodipine Besylate Formulation

Version 4.10 Revision Date: 2020/10/10 SDS Number: 49933-00016 Date of last issue: 2020/03/23
Date of first issue: 2015/01/26

- 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.
- Avoidance of contact : Oxidizing agents
- Storage**
- Conditions for safe storage : Keep in properly labelled containers.
Store locked up.
Keep tightly closed.
Store in accordance with the particular national regulations.
- Materials to avoid : Do not store with the following product types:
Strong oxidizing agents
- Packaging material : Unsuitable material: None known.

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Components with workplace control parameters

| Components | CAS-No. | Value type (Form of exposure) | Control parameters / Permissible concentration | Basis |
|------------------------------------------------------------|-------------|-------------------------------|------------------------------------------------|----------|
| Cellulose | 9004-34-6 | PC-TWA | 10 mg/m ³ | CN OEL |
| | | TWA | 10 mg/m ³ | ACGIH |
| Losartan | 124750-99-8 | TWA | 100 µg/m ³ (OEB 2) | Internal |
| Amlodipine Besylate | 652969-01-2 | TWA | 20 µg/m ³ (OEB 3) | Internal |
| | | Wipe limit | 100 µg/100 cm ² | Internal |
| Titanium dioxide | 13463-67-7 | PC-TWA | 8 mg/m ³ | CN OEL |
| | | (Total dust) | | |
| Further information: G2B - Possibly carcinogenic to humans | | | | |
| | | TWA | 10 mg/m ³ (Titanium dioxide) | ACGIH |

- 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 de-

SAFETY DATA SHEET

according to GB/T 16483 and GB/T 17519



ORGANON

Losartan / Amlodipine Besylate Formulation

| | | | |
|---------|----------------|-------------|---------------------------------|
| Version | Revision Date: | SDS Number: | Date of last issue: 2020/03/23 |
| 4.10 | 2020/10/10 | 49933-00016 | Date of first issue: 2015/01/26 |

signed 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

- 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
- Eye/face protection : Wear the following personal protective equipment:
Chemical resistant goggles must be worn.
If splashes are likely to occur, wear:
Face-shield
- 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).
- 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.
- 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.

9. PHYSICAL AND CHEMICAL PROPERTIES

- Appearance : powder
- Colour : No data available
- Odour : No data available
- Odour Threshold : No data available
- pH : No data available
- Melting point/freezing point : No data available
- Initial boiling point and boiling : No data available

SAFETY DATA SHEET

according to GB/T 16483 and GB/T 17519



ORGANON

Losartan / Amlodipine Besylate Formulation

Version 4.10 Revision Date: 2020/10/10 SDS Number: 49933-00016 Date of last issue: 2020/03/23
Date of first issue: 2015/01/26

range

Flash point : Not applicable

Evaporation rate : 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

Vapour pressure : No data available

Relative vapour density : No data available

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.

Molecular weight : No data available

Particle size : No data available

10. STABILITY AND REACTIVITY

Reactivity : Not classified as a reactivity hazard.

Chemical stability : Stable under normal conditions.

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

SAFETY DATA SHEET

according to GB/T 16483 and GB/T 17519



Losartan / Amlodipine Besylate Formulation

| | | | |
|---------|----------------|-------------|---------------------------------|
| Version | Revision Date: | SDS Number: | Date of last issue: 2020/03/23 |
| 4.10 | 2020/10/10 | 49933-00016 | Date of first issue: 2015/01/26 |

| | | |
|----------------------------------|---|---------------------------------------------------|
| Conditions to avoid | : | Heat, flames and sparks. Avoid dust formation. |
| Incompatible materials | : | Oxidizing agents |
| Hazardous decomposition products | : | No hazardous decomposition products are known. |

11. TOXICOLOGICAL INFORMATION

| | | |
|-----------------|---|--------------------------------------------------------|
| Exposure routes | : | 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:

Cellulose:

| | | |
|---------------------|---|---------------------------|
| Acute oral toxicity | : | LD50 (Rat): > 5,000 mg/kg |
|---------------------|---|---------------------------|

| | | |
|---------------------------|---|----------------------------------------------------------------------------|
| Acute inhalation toxicity | : | LC50 (Rat): > 5.8 mg/l Exposure time: 4 h Test atmosphere: dust/mist |
|---------------------------|---|----------------------------------------------------------------------------|

| | | |
|-----------------------|---|------------------------------|
| Acute dermal toxicity | : | LD50 (Rabbit): > 2,000 mg/kg |
|-----------------------|---|------------------------------|

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 |
|---------------------|---|-----------------------|

Titanium dioxide:

| | | |
|---------------------|---|---------------------------|
| Acute oral toxicity | : | LD50 (Rat): > 5,000 mg/kg |
|---------------------|---|---------------------------|

| | | |
|---------------------------|---|------------------------------------------------------------------------------------------------------------------------------------------------------|
| Acute inhalation toxicity | : | LC50 (Rat): > 6.82 mg/l Exposure time: 4 h Test atmosphere: dust/mist Assessment: The substance or mixture has no acute inhalation toxicity |
|---------------------------|---|------------------------------------------------------------------------------------------------------------------------------------------------------|

SAFETY DATA SHEET

according to GB/T 16483 and GB/T 17519



ORGANON

Losartan / Amlodipine Besylate Formulation

Version 4.10 Revision Date: 2020/10/10 SDS Number: 49933-00016 Date of last issue: 2020/03/23
Date of first issue: 2015/01/26

Skin corrosion/irritation

Not classified based on available information.

Components:

Losartan:

Species : Rabbit
Result : Mild skin irritation

Titanium dioxide:

Species : Rabbit
Result : No 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

Titanium dioxide:

Species : Rabbit
Result : No 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

Titanium dioxide:

Test Type : Local lymph node assay (LLNA)
Exposure routes : Skin contact
Species : Mouse

SAFETY DATA SHEET

according to GB/T 16483 and GB/T 17519



Losartan / Amlodipine Besylate Formulation

| | | | |
|---------|----------------|-------------|---------------------------------|
| Version | Revision Date: | SDS Number: | Date of last issue: 2020/03/23 |
| 4.10 | 2020/10/10 | 49933-00016 | Date of first issue: 2015/01/26 |

Result : negative

Germ cell mutagenicity

Not classified based on available information.

Components:

Cellulose:

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

Test Type: In vitro mammalian cell gene mutation test
Result: negative

Genotoxicity in vivo : Test Type: Mammalian erythrocyte micronucleus test (in vivo cytogenetic assay)
Species: Mouse
Application Route: Ingestion
Result: negative

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

Amlodipine Besylate:

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

Test Type: Chromosome aberration test in vitro
Result: negative

Titanium dioxide:

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

Genotoxicity in vivo : Test Type: In vivo micronucleus test
Species: Mouse
Result: negative

SAFETY DATA SHEET

according to GB/T 16483 and GB/T 17519



Losartan / Amlodipine Besylate Formulation

Version 4.10 Revision Date: 2020/10/10 SDS Number: 49933-00016 Date of last issue: 2020/03/23
Date of first issue: 2015/01/26

Carcinogenicity

Not classified based on available information.

Components:

Cellulose:

Species : Rat
Application Route : Ingestion
Exposure time : 72 weeks
Result : negative

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

Amlodipine Besylate:

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

Species : Rat
Application Route : Oral
Exposure time : 2 Years
Result : negative

Titanium dioxide:

Species : Rat
Application Route : inhalation (dust/mist/fume)
Exposure time : 2 Years
Method : OECD Test Guideline 453
Result : positive
Remarks : The mechanism or mode of action may not be relevant in humans.

Carcinogenicity - Assessment : Limited evidence of carcinogenicity in inhalation studies with animals.

Reproductive toxicity

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

SAFETY DATA SHEET

according to GB/T 16483 and GB/T 17519



ORGANON

Losartan / Amlodipine Besylate Formulation

Version 4.10 Revision Date: 2020/10/10 SDS Number: 49933-00016 Date of last issue: 2020/03/23
Date of first issue: 2015/01/26

Components:

Cellulose:

Effects on fertility : Test Type: One-generation reproduction toxicity study
Species: Rat
Application Route: Ingestion
Result: negative

Effects on foetal development : Test Type: Fertility/early embryonic development
Species: Rat
Application Route: Ingestion
Result: negative

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

SAFETY DATA SHEET

according to GB/T 16483 and GB/T 17519



Losartan / Amlodipine Besylate Formulation

| | | | |
|---------|----------------|-------------|---------------------------------|
| Version | Revision Date: | SDS Number: | Date of last issue: 2020/03/23 |
| 4.10 | 2020/10/10 | 49933-00016 | Date of first issue: 2015/01/26 |

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:

Cellulose:

Species : Rat
NOAEL : $\geq 9,000$ mg/kg
Application Route : Ingestion
Exposure time : 90 Days

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

SAFETY DATA SHEET

according to GB/T 16483 and GB/T 17519



ORGANON

Losartan / Amlodipine Besylate Formulation

Version 4.10 Revision Date: 2020/10/10 SDS Number: 49933-00016 Date of last issue: 2020/03/23
Date of first issue: 2015/01/26

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

Titanium dioxide:

Species : Rat
NOAEL : 24,000 mg/kg
Application Route : Ingestion
Exposure time : 28 Days

Species : Rat
NOAEL : 10 mg/m³
Application Route : inhalation (dust/mist/fume)
Exposure time : 2 yr

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

SAFETY DATA SHEET

according to GB/T 16483 and GB/T 17519



ORGANON

Losartan / Amlodipine Besylate Formulation

Version 4.10 Revision Date: 2020/10/10 SDS Number: 49933-00016 Date of last issue: 2020/03/23
Date of first issue: 2015/01/26

12. ECOLOGICAL INFORMATION

Ecotoxicity

Components:

Cellulose:

Toxicity to fish : LC50 (*Oryzias latipes* (Japanese medaka)): > 100 mg/l
Exposure time: 48 h
Remarks: Based on data from similar materials

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 (*Pimephales promelas* (fathead minnow)): 10 mg/l
Exposure time: 32 d
Method: OECD Test Guideline 210

Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity) : NOEC (*Daphnia magna* (Water flea)): 100 mg/l
Exposure time: 21 d
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

Titanium dioxide:

Toxicity to fish : LC50 (*Oncorhynchus mykiss* (rainbow trout)): > 100 mg/l
Exposure time: 96 h
Method: OECD Test Guideline 203

SAFETY DATA SHEET

according to GB/T 16483 and GB/T 17519



Losartan / Amlodipine Besylate Formulation

| | | | |
|---------|----------------|-------------|---------------------------------|
| Version | Revision Date: | SDS Number: | Date of last issue: 2020/03/23 |
| 4.10 | 2020/10/10 | 49933-00016 | Date of first issue: 2015/01/26 |

Toxicity to daphnia and other aquatic invertebrates : EC50 (Daphnia magna (Water flea)): > 100 mg/l
Exposure time: 48 h

Toxicity to algae/aquatic plants : EC50 (Skeletonema costatum (marine diatom)): > 10,000 mg/l
Exposure time: 72 h

Toxicity to microorganisms : EC50: > 1,000 mg/l
Exposure time: 3 h
Method: OECD Test Guideline 209

Persistence and degradability

Components:

Cellulose:

Biodegradability : Result: Readily biodegradable.

Losartan:

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

Bioaccumulative potential

Components:

Losartan:

Partition coefficient: n-octanol/water : log Pow: 1.2

Amlodipine Besylate:

Partition coefficient: n-octanol/water : log Pow: 3

Mobility in soil

No data available

Other adverse effects

No data available

13. DISPOSAL CONSIDERATIONS

Disposal methods

Waste from residues : Dispose of in accordance with local regulations.
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.

14. TRANSPORT INFORMATION

International Regulations

UNRTDG

Not regulated as a dangerous good

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Losartan / Amlodipine Besylate Formulation

| | | | |
|---------|----------------|-------------|---------------------------------|
| Version | Revision Date: | SDS Number: | Date of last issue: 2020/03/23 |
| 4.10 | 2020/10/10 | 49933-00016 | Date of first issue: 2015/01/26 |

IATA-DGR

Not regulated as a dangerous good

IMDG-Code

Not regulated as a dangerous good

Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code

Not applicable for product as supplied.

National Regulations

GB 6944/12268

Not regulated as a dangerous good

Special precautions for user

Not applicable

15. REGULATORY INFORMATION

National regulatory information

Law on the Prevention and Control of Occupational Diseases

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

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

16. OTHER INFORMATION

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/>

Date format : yyyy/mm/dd

Full text of other abbreviations

ACGIH : USA. ACGIH Threshold Limit Values (TLV)
CN OEL : Occupational exposure limits for hazardous agents in the workplace - Chemical hazardous agents.

ACGIH / TWA : 8-hour, time-weighted average
CN OEL / PC-TWA : Permissible concentration - time weighted average

AllC - Australian Inventory of Industrial Chemicals; ANTT - National Agency for Transport by Land of Brazil; ASTM - American Society for the Testing of Materials; bw - Body weight; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DSL - Domestic Substances List (Canada); ECx - Concentration associated with x% response; ELx - Loading rate associated with x% response; EmS - Emergency Schedule;

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ORGANON

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ENCS - Existing and New Chemical Substances (Japan); ErCx - Concentration associated with x% growth rate response; ERG - Emergency Response Guide; 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; Nch - Chilean Norm; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; NOM - Official Mexican Norm; NTP - National Toxicology Program; 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; SADT - Self-Accelerating Decomposition Temperature; SDS - Safety Data Sheet; TCSI - Taiwan Chemical Substance Inventory; TDG - Transportation of Dangerous Goods; 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; WHMIS - Workplace Hazardous Materials Information System

Disclaimer

The information provided in this Safety Data Sheet is correct to the best of our knowledge, information and belief at the date of its publication. The information is designed only as a guidance for safe handling, use, processing, storage, transportation, disposal and release and shall not be considered a warranty or quality specification of any type. The information provided relates only to the specific material identified at the top of this SDS and may not be valid when the SDS material is used in combination with any other materials or in any process, unless specified in the text. Material users should review the information and recommendations in the specific context of their intended manner of handling, use, processing and storage, including an assessment of the appropriateness of the SDS material in the user's end product, if applicable.

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