

SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006



ORGANON

Losartan / Amlodipine Besylate Formulation

Version 3.5 Revision Date: 09.04.2021 SDS Number: 51862-00017 Date of last issue: 10.10.2020
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 : Organon & Co.
30 Hudson Street, 33rd floor
07302 Jersey City, New Jersey, U.S.A

Telephone : 551-430-6000

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

1.4 Emergency telephone number

215-631-6999

SECTION 2: Hazards identification

2.1 Classification of the substance or mixture

Classification (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.

SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006



Losartan / Amlodipine Besylate Formulation

Version 3.5 Revision Date: 09.04.2021 SDS Number: 51862-00017 Date of last issue: 10.10.2020
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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

This substance/mixture contains no components considered to be either persistent, bioaccumulative and toxic (PBT), or very persistent and very bioaccumulative (vPvB) at levels of 0.1% or higher.

Ecological information: The substance/mixture does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.

Toxicological information: The substance/mixture does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.

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

SECTION 3: Composition/information on ingredients

3.2 Mixtures

Components

Chemical name	CAS-No. EC-No. Index-No. Registration number	Classification	Concentration (% w/w)
Losartan	124750-99-8	Acute Tox. 4; H302 Eye Dam. 1; H318 Skin Sens. 1; H317 Repr. 1B; H360D Lact.H362 STOT RE 2; H373 (Blood, Cardio-vascular system, Stomach, Kidney)	>= 10 - < 20

SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006



ORGANON

Losartan / Amlodipine Besylate Formulation

Version 3.5 Revision Date: 09.04.2021 SDS Number: 51862-00017 Date of last issue: 10.10.2020
Date of first issue: 26.01.2015

Amlodipine Besylate	652969-01-2	Acute Tox. 4; H302 Eye Irrit. 2; H319 Aquatic Chronic 2; H411	>= 1 - < 2.5
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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.

SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006



ORGANON

Losartan / Amlodipine Besylate Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 10.10.2020
3.5	09.04.2021	51862-00017	Date of first issue: 26.01.2015

SECTION 5: Firefighting measures

5.1 Extinguishing media

Suitable extinguishing media : Water spray
Alcohol-resistant foam
Carbon dioxide (CO₂)
Dry chemical

Unsuitable extinguishing media : None known.

5.2 Special hazards arising from the substance or mixture

Specific hazards during fire-fighting : Avoid generating dust; fine dust dispersed in air in sufficient concentrations, and in the presence of an ignition source is a potential dust explosion hazard.
Exposure to combustion products may be a hazard to health.

Hazardous combustion products : Carbon oxides
Chlorine compounds
Nitrogen oxides (NO_x)
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 (see section 7) and personal protective equipment recommendations (see section 8).

6.2 Environmental precautions

Environmental precautions : Avoid release to the environment.
Prevent further leakage or spillage if safe to do so.
Retain and dispose of contaminated wash water.
Local authorities should be advised if significant spillages cannot be contained.

6.3 Methods and material for containment and cleaning up

Methods for cleaning up : Sweep up or vacuum up spillage and collect in suitable con-

SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006



Losartan / Amlodipine Besylate Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 10.10.2020
3.5	09.04.2021	51862-00017	Date of first issue: 26.01.2015

tainer for disposal.
Avoid dispersal of dust in the air (i.e., clearing dust surfaces with compressed air).
Dust deposits should not be allowed to accumulate on surfaces, as these may form an explosive mixture if they are released into the atmosphere in sufficient concentration.
Local or national regulations may apply to releases and disposal of this material, as well as those materials and items employed in the cleanup of releases. You will need to determine which regulations are applicable.
Sections 13 and 15 of this SDS provide information regarding certain local or national requirements.

6.4 Reference to other sections

See sections: 7, 8, 11, 12 and 13.

SECTION 7: Handling and storage

7.1 Precautions for safe handling

- | | | |
|-------------------------|---|--|
| Technical measures | : | Static electricity may accumulate and ignite suspended dust causing an explosion.
Provide adequate precautions, such as electrical grounding and bonding, or inert atmospheres. |
| Local/Total ventilation | : | If sufficient ventilation is unavailable, use with local exhaust ventilation. |
| Advice on safe handling | : | Avoid contact during pregnancy and while nursing.
Do not get on skin or clothing.
Do not breathe dust.
Do not swallow.
Do not get in eyes.
Wash skin thoroughly after handling.
Handle in accordance with good industrial hygiene and safety practice, based on the results of the workplace exposure assessment
Keep container tightly closed.
Minimize dust generation and accumulation.
Keep container closed when not in use.
Keep away from heat and sources of ignition.
Take precautionary measures against static discharges.
Do not eat, drink or smoke when using this product.
Take care to prevent spills, waste and minimize release to the environment. |
| Hygiene measures | : | If exposure to chemical is likely during typical use, provide eye flushing systems and safety showers close to the working place. When using do not eat, drink or smoke. Contaminated work clothing should not be allowed out of the workplace.
Wash contaminated clothing before re-use. |

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. |
|---|---|---|

SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006



ORGANON

Losartan / Amlodipine Besylate Formulation

Version 3.5 Revision Date: 09.04.2021 SDS Number: 51862-00017 Date of last issue: 10.10.2020
Date of first issue: 26.01.2015

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	OELV - 8 hrs (TWA)	10 mg/m ³	IE OEL
	Further information: Where no specific short-term exposure limit is listed, a figure three times the long-term exposure limit value should be used			
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

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 I.S. 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

SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006



Losartan / Amlodipine Besylate Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 10.10.2020
3.5	09.04.2021	51862-00017	Date of first issue: 26.01.2015

Skin and body protection	:	chemicals of the aforementioned protective gloves with the glove manufacturer. Wash hands before breaks and at the end of workday. Select appropriate protective clothing based on chemical resistance data and an assessment of the local exposure potential. Skin contact must be avoided by using impervious protective clothing (gloves, aprons, boots, etc).
Respiratory protection	:	If adequate local exhaust ventilation is not available or exposure assessment demonstrates exposures outside the recommended guidelines, use respiratory protection. Equipment should conform to I.S. EN 143
Filter type	:	Particulates type (P)

SECTION 9: Physical and chemical properties

9.1 Information on basic physical and chemical properties

Physical state	:	powder
Colour	:	No data available
Odour	:	No data available
Odour Threshold	:	No data available
Melting point/freezing point	:	No data available
Initial boiling point and boiling range	:	No data available
Flammability (solid, gas)	:	May form explosive dust-air mixture during processing, handling or other means.
Flammability (liquids)	:	No data available
Upper explosion limit / Upper flammability limit	:	No data available
Lower explosion limit / Lower flammability limit	:	No data available
Flash point	:	Not applicable
Auto-ignition temperature	:	No data available
Decomposition temperature	:	No data available
Decomposition temperature	:	No data available
pH	:	No data available
Viscosity	:	No data available
Viscosity, kinematic	:	No data available
Solubility(ies)	:	No data available
Water solubility	:	No data available
Partition coefficient: n-	:	No data available

SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006



ORGANON

Losartan / Amlodipine Besylate Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 10.10.2020
3.5	09.04.2021	51862-00017	Date of first issue: 26.01.2015

octanol/water	
Vapour pressure	: No data available
Relative density	: No data available
Density	: No data available
Relative vapour density	: No data available
Particle characteristics	
Particle size	: No data available

9.2 Other information

Explosives	: Not explosive
Oxidizing properties	: The substance or mixture is not classified as oxidizing.
Evaporation rate	: No data available
Molecular weight	: 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.
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10.4 Conditions to avoid

Conditions to avoid	: Heat, flames and sparks. Avoid dust formation.
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10.5 Incompatible materials

Materials to avoid	: Oxidizing agents
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10.6 Hazardous decomposition products

No hazardous decomposition products are known.

SECTION 11: Toxicological information

11.1 Information on hazard classes as defined in Regulation (EC) No 1272/2008

Information on likely routes of exposure	: Inhalation Skin contact Ingestion
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SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006



ORGANON

Losartan / Amlodipine Besylate Formulation

Version 3.5 Revision Date: 09.04.2021 SDS Number: 51862-00017 Date of last issue: 10.10.2020
Date of first issue: 26.01.2015

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.

SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006



ORGANON

Losartan / Amlodipine Besylate Formulation

Version 3.5 Revision Date: 09.04.2021 SDS Number: 51862-00017 Date of last issue: 10.10.2020
Date of first issue: 26.01.2015

Components:

Losartan:

Test Type : Maximisation Test
Exposure routes : Skin contact
Species : Guinea pig
Assessment : Probability or evidence of skin sensitisation in humans
Result : positive

Germ cell mutagenicity

Not classified based on available information.

Components:

Losartan:

Genotoxicity in vitro : Test Type: in vitro assay
Result: negative

Test Type: In vitro mammalian cell gene mutation test
Test system: Chinese hamster ovary cells
Result: negative

Test Type: Alkaline elution assay
Result: negative

Test Type: Chromosomal aberration
Result: negative

Genotoxicity in vivo : Test Type: Chromosomal aberration
Result: negative

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

Species : Rat
Application Route : Oral
Exposure time : 105 weeks

SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006



ORGANON

Losartan / Amlodipine Besylate Formulation

Version 3.5 Revision Date: 09.04.2021 SDS Number: 51862-00017 Date of last issue: 10.10.2020
Date of first issue: 26.01.2015

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

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

SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006



ORGANON

Losartan / Amlodipine Besylate Formulation

Version 3.5 Revision Date: 09.04.2021 SDS Number: 51862-00017 Date of last issue: 10.10.2020
Date of first issue: 26.01.2015

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

SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006



Losartan / Amlodipine Besylate Formulation

Version 3.5 Revision Date: 09.04.2021 SDS Number: 51862-00017 Date of last issue: 10.10.2020
Date of first issue: 26.01.2015

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

11.2 Information on other hazards

Endocrine disrupting properties

Product:

Assessment : The substance/mixture does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.

Experience with human exposure

Components:

Losartan:

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

Amlodipine Besylate:

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

SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006



ORGANON

Losartan / Amlodipine Besylate Formulation

Version 3.5 Revision Date: 09.04.2021 SDS Number: 51862-00017 Date of last issue: 10.10.2020
Date of first issue: 26.01.2015

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)

SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006



Losartan / Amlodipine Besylate Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 10.10.2020
3.5	09.04.2021	51862-00017	Date of first issue: 26.01.2015

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

Product:

Assessment : This substance/mixture contains no components considered to be either persistent, bioaccumulative and toxic (PBT), or very persistent and very bioaccumulative (vPvB) at levels of 0.1% or higher.

12.6 Endocrine disrupting properties

Product:

Assessment : The substance/mixture does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.

12.7 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 or ID number

Not regulated as a dangerous good

SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006



ORGANON

Losartan / Amlodipine Besylate Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 10.10.2020
3.5	09.04.2021	51862-00017	Date of first issue: 26.01.2015

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 Maritime transport in bulk according to IMO instruments

Remarks : Not applicable for product as supplied.

SECTION 15: Regulatory information

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

REACH - Restrictions on the manufacture, placing on the market and use of certain dangerous substances, preparations and articles (Annex XVII) : Not applicable

REACH - Candidate List of Substances of Very High Concern for Authorisation (Article 59). : Not applicable

REACH - List of substances subject to authorisation (Annex XIV) : Not applicable

Regulation (EC) No 1005/2009 on substances that deplete the ozone layer : Not applicable

Regulation (EU) 2019/1021 on persistent organic pollutants (recast) : Not applicable

Regulation (EC) No 649/2012 of the European Parliament and the Council concerning the export and import of dangerous chemicals : Not applicable

Seveso III: Directive 2012/18/EU of the European Parliament and of the Council on the control of major-accident hazards involving dangerous substances.
Not applicable

Other regulations:

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

SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006



ORGANON

Losartan / Amlodipine Besylate Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 10.10.2020
3.5	09.04.2021	51862-00017	Date of first issue: 26.01.2015

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 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
IE OEL : Ireland. List of Chemical Agents and Occupational Exposure Limit Values - Schedule 1
IE OEL / OELV - 8 hrs (TWA) : Occupational exposure limit value (8-hour 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; AIIIC - Australian Inventory of Industrial Chemicals; ASTM - American Society for the Testing of Materials; bw - Body weight; CLP - Classification Labelling Packaging Regulation; Regulation (EC) No 1272/2008; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DSL - Domestic Substances List (Canada); ECHA - European Chemicals Agency; EC-Number - European Community number; ECx - Concentration associated with x% response; ELx - Loading rate associated with x% response; EmS - Emergency Schedule; ENCS - Existing and New Chemical Substances (Japan); ErCx - Concentration associated with x% growth rate response; GHS - Globally Harmonized System; GLP - Good Laboratory Practice; IARC - International Agency for Research on Cancer; IATA - International Air Transport Association; IBC - International Code for the Construction and Equipment of Ships carrying Dangerous Chemicals in Bulk; IC50 - Half maximal inhibitory concentration; ICAO - International Civil Aviation Organization; IECSC - Inventory of Existing Chemical Substances in China; IMDG - International Maritime Dangerous Goods; IMO - International Maritime Organization; ISHL - Industrial Safety and Health Law (Japan); ISO - International Organisation for Standardization; KECI - Korea Existing Chemicals Inventory; LC50 - Lethal Concentration to 50 % of a test population; LD50 - Lethal Dose to 50% of a test population (Median Lethal Dose); MARPOL - International Convention for the Prevention of Pollution from Ships; n.o.s. - Not Otherwise Specified; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse)

SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006



ORGANON

Losartan / Amlodipine Besylate Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 10.10.2020
3.5	09.04.2021	51862-00017	Date of first issue: 26.01.2015

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; TRGS - Technical Rule for Hazardous Substances; TSCA - Toxic Substances Control Act (United States); UN - United Nations; vPvB - Very Persistent and Very Bioaccumulative

Further information

Sources of key data used to compile the Safety Data Sheet : Internal technical data, data from raw material SDSs, OECD eChem Portal search results and European Chemicals Agency, <http://echa.europa.eu/>

Classification of the mixture:

Eye Dam. 1	H318
Skin Sens. 1	H317
Repr. 1B	H360D
Lact.	H362
STOT RE 2	H373

Classification procedure:

Calculation method
Calculation method
Calculation method
Calculation method
Calculation method

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IE / EN