

SAFETY DATA SHEET



Losartan / Amlodipine Besylate Formulation



Version 4.1 Revision Date: 30.09.2023 SDS Number: 49946-00023 Date of last issue: 04.04.2023
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

Recommended restrictions on use : Not applicable

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 : +1-551-430-6000

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

1.4 Emergency telephone number

+1-215-631-6999

SECTION 2: Hazards identification

2.1 Classification of the substance or mixture

Classification (REGULATION (EC) No 1272/2008)

Serious eye damage, Category 1	H318: Causes serious eye damage.
Skin sensitisation, Category 1	H317: May cause an allergic skin reaction.
Reproductive toxicity, Category 1B	H360D: May damage the unborn child.
Effects on or via lactation	H362: May cause harm to breast-fed children.
Specific target organ toxicity - repeated exposure, Category 2	H373: May cause damage to organs through prolonged or repeated exposure.

2.2 Label elements

Labelling (REGULATION (EC) No 1272/2008)

Hazard pictograms :

Signal word : Danger

Hazard statements : H317 May cause an allergic skin reaction.
H318 Causes serious eye damage.

Losartan / Amlodipine Besylate Formulation

Version 4.1 Revision Date: 30.09.2023 SDS Number: 49946-00023 Date of last issue: 04.04.2023
Date of first issue: 26.01.2015

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

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.

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
Amlodipine Besylate	652969-01-2	Acute Tox. 4; H302 Eye Irrit. 2; H319 Aquatic Chronic 2; H411	>= 1 - < 2,5

Losartan / Amlodipine Besylate Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 04.04.2023
4.1	30.09.2023	49946-00023	Date of first issue: 26.01.2015

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.

Losartan / Amlodipine Besylate Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 04.04.2023
4.1	30.09.2023	49946-00023	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 container for disposal.

Losartan / Amlodipine Besylate Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 04.04.2023
4.1	30.09.2023	49946-00023	Date of first issue: 26.01.2015

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. |
| Advice on common storage | : | Do not store with the following product types:
Strong oxidizing agents |

Losartan / Amlodipine Besylate Formulation

Version 4.1 Revision Date: 30.09.2023 SDS Number: 49946-00023 Date of last issue: 04.04.2023
Date of first issue: 26.01.2015

Self-reactive substances and mixtures
Organic peroxides
Explosives
Gases

7.3 Specific end use(s)

Specific use(s) : No data available

SECTION 8: Exposure controls/personal protection**8.1 Control parameters****Occupational Exposure Limits**

Components	CAS-No.	Value type (Form of exposure)	Control parameters	Basis
Cellulose	9004-34-6	OEL-RL	10 mg/m ³	ZA OEL
Further information: Occupational Exposure Limits - Restricted Limits For Hazardous Chemical Agents				
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/face protection : Wear the following personal protective equipment:
Chemical resistant goggles must be worn.
If splashes are likely to occur, wear:
Face-shield

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 re-

Losartan / Amlodipine Besylate Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 04.04.2023
4.1	30.09.2023	49946-00023	Date of first issue: 26.01.2015

sistance 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**

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 range	:	No data available
Flash point	:	Not applicable
Evaporation rate	:	No data available
Flammability (solid, gas)	:	May form explosive dust-air mixture during processing, handling or other means.
Upper explosion limit / Upper flammability limit	:	No data available
Lower explosion limit / Lower flammability limit	:	No data available
Vapour pressure	:	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

Losartan / Amlodipine Besylate Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 04.04.2023
4.1	30.09.2023	49946-00023	Date of first issue: 26.01.2015

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

Losartan / Amlodipine Besylate Formulation

Version 4.1 Revision Date: 30.09.2023 SDS Number: 49946-00023 Date of last issue: 04.04.2023
Date of first issue: 26.01.2015

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

Losartan / Amlodipine Besylate Formulation

Version 4.1 Revision Date: 30.09.2023 SDS Number: 49946-00023 Date of last issue: 04.04.2023
Date of first issue: 26.01.2015

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
Dose : 270 mg/kg body weight
Result : negative

Amlodipine Besylate:

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

Losartan / Amlodipine Besylate Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 04.04.2023
4.1	30.09.2023	49946-00023	Date of first issue: 26.01.2015

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 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

Losartan / Amlodipine Besylate Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 04.04.2023
4.1	30.09.2023	49946-00023	Date of first issue: 26.01.2015

ment

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

Losartan / Amlodipine Besylate Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 04.04.2023
4.1	30.09.2023	49946-00023	Date of first issue: 26.01.2015

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 tox- : NOEC: 10 mg/l

Losartan / Amlodipine Besylate Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 04.04.2023
4.1	30.09.2023	49946-00023	Date of first issue: 26.01.2015

icity) 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**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 Other adverse effects**Product:**

Endocrine disrupting poten- : The substance/mixture does not contain components consid-

Losartan / Amlodipine Besylate Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 04.04.2023
4.1	30.09.2023	49946-00023	Date of first issue: 26.01.2015

tial	ered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.
------	-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------

SECTION 13: Disposal considerations**13.1 Waste treatment methods**

Product	: Dispose of in accordance with local regulations. 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. Do not dispose of waste into sewer.
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**

ADN	: Not regulated as a dangerous good
ADR	: Not regulated as a dangerous good
RID	: Not regulated as a dangerous good
IMDG	: Not regulated as a dangerous good
IATA	: Not regulated as a dangerous good

14.2 UN proper shipping name

ADN	: Not regulated as a dangerous good
ADR	: Not regulated as a dangerous good
RID	: Not regulated as a dangerous good
IMDG	: Not regulated as a dangerous good
IATA	: Not regulated as a dangerous good

14.3 Transport hazard class(es)

ADN	: Not regulated as a dangerous good
ADR	: Not regulated as a dangerous good
RID	: Not regulated as a dangerous good
IMDG	: Not regulated as a dangerous good
IATA	: Not regulated as a dangerous good

14.4 Packing group

ADN	: Not regulated as a dangerous good
ADR	: Not regulated as a dangerous good

Losartan / Amlodipine Besylate Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 04.04.2023
4.1	30.09.2023	49946-00023	Date of first issue: 26.01.2015

RID : Not regulated as a dangerous good
IMDG : Not regulated as a dangerous good
IATA (Cargo) : Not regulated as a dangerous good
IATA (Passenger) : Not regulated as a dangerous good

14.5 Environmental hazards

Not regulated as a dangerous good

14.6 Special precautions for user

Not applicable

14.7 Transport in bulk according to Annex II of Marpol and the IBC Code

Remarks : Not applicable for product as supplied.

SECTION 15: Regulatory information**15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture**

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

AICS : not determined
DSL : not determined
IECSC : not determined

15.2 Chemical safety assessment

A Chemical Safety Assessment has not been carried out.

SECTION 16: Other information

Other information : Items where changes have been made to the previous version are highlighted in the body of this document by two vertical lines.

Full text of H-Statements

H302 : Harmful if swallowed.
H317 : May cause an allergic skin reaction.
H318 : Causes serious eye damage.
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

Losartan / Amlodipine Besylate Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 04.04.2023
4.1	30.09.2023	49946-00023	Date of first issue: 26.01.2015

Lact.	:	Effects on or via lactation
Repr.	:	Reproductive toxicity
Skin Sens.	:	Skin sensitisation
STOT RE	:	Specific target organ toxicity - repeated exposure
ZA OEL	:	South Africa. The Regulations for Hazardous Chemical Agents, Occupational Exposure Limits
ZA OEL / OEL-RL	:	Occupational Exposure Limit Restricted limit - 8- hour exposure or equivalent (12 hour shifts)

ADN - European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways; ADR - 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) Effect Level; NOELR - No Observable Effect Loading Rate; NZIoC - New Zealand Inventory of Chemicals; OECD - Organization for Economic Co-operation and Development; OPPTS - Office of Chemical Safety and Pollution Prevention; PBT - Persistent, Bioaccumulative and Toxic substance; PICCS - Philippines Inventory of Chemicals and Chemical Substances; (Q)SAR - (Quantitative) Structure Activity Relationship; REACH - Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals; RID - Regulations concerning the International Carriage of Dangerous Goods by Rail; SADT - Self-Accelerating Decomposition Temperature; SDS - Safety Data Sheet; SVHC - Substance of very high concern; TCSI - Taiwan Chemical Substance Inventory; TECI - Thailand Existing Chemicals Inventory; TSCA - Toxic Substances Control Act (United States); UN - United Nations; UNRTDG - United Nations Recommendations on the Transport of Dangerous Goods; vPvB - Very Persistent and Very Bioaccumulative

Further information

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

Classification of the mixture:

Eye Dam. 1	H318
Skin Sens. 1	H317
Repr. 1B	H360D
Lact.	H362

Classification procedure:

Calculation method
Calculation method
Calculation method
Calculation method

SAFETY DATA SHEET



Losartan / Amlodipine Besylate Formulation



Version	Revision Date:	SDS Number:	Date of last issue: 04.04.2023
4.1	30.09.2023	49946-00023	Date of first issue: 26.01.2015

STOT RE 2

H373

Calculation method

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

ZA / EN