

Losartan Formulation

Version Revision Date: SDS Number: Date of last issue: 03/27/2017 5.2 05/02/2017 19367-00009 Date of first issue: 10/07/2014

SECTION 1. IDENTIFICATION

Product name : Losartan Formulation

Manufacturer or supplier's details

Company name of supplier : Merck & Co., Inc

Address : 2000 Galloping Hill Road

Kenilworth - New Jersey - USA 1685

Telephone : 908-740-4000

Telefax : 908-735-1496

Emergency telephone : 1-908-423-6000

E-mail address : EHSDATASTEWARD@merck.com

Recommended use of the chemical and restrictions on use

Recommended use : Pharmaceutical

SECTION 2. HAZARDS IDENTIFICATION

GHS classification in accordance with 29 CFR 1910.1200

Combustible dust

Acute toxicity (Oral) : Category 4

Serious eye damage : Category 1

Skin sensitization : Category 1

Reproductive toxicity : Category 1B

Effects on or via lactation

Specific target organ systemic toxicity - repeated

exposure (Oral)

Category 2 (Blood, Cardio-vascular system, Stomach, Kidney)

GHS label elements

Hazard pictograms





Signal Word : Danger

Hazard Statements : If small particles are generated during further processing,

handling or by other means, may form combustible dust



Losartan Formulation

Version **Revision Date:** SDS Number: Date of last issue: 03/27/2017 05/02/2017 19367-00009 Date of first issue: 10/07/2014 5.2

concentrations in air.

H302 Harmful if swallowed.

H317 May cause an allergic skin reaction. H318 Causes serious eye damage. H360D May damage the unborn child.

H362 May cause harm to breast-fed children.

H373 May cause damage to organs (Blood, Cardio-vascular system, Stomach, Kidney) through prolonged or repeated

exposure if swallowed.

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 must not be allowed out of the workplace.

P280 Wear protective gloves/ protective clothing/ eye protection/ face protection.

Response:

P301 + P312 + P330 IF SWALLOWED: Call a POISON

CENTER/doctor if you feel unwell. Rinse mouth.

P302 + P352 IF ON SKIN: Wash with plenty of soap and 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.

P363 Wash contaminated clothing before reuse.

Storage:

P405 Store locked up.

Disposal:

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

Other hazards

Contact with dust can cause mechanical irritation or drying of the skin.

SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture Mixture

Hazardous ingredients

Chaminal name	CAC No	Composite tion (0//)
Chemical name	CAS-No.	Concentration (% w/w)



Losartan Formulation

Version Revision Date: SDS Number: Date of last issue: 03/27/2017 5.2 05/02/2017 19367-00009 Date of first issue: 10/07/2014

Cellulose	9004-34-6	>= 30 -< 50
Losartan	124750-99-8	>= 30 -< 50
Starch	9005-25-8	>= 10 -< 20

SECTION 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.

Never give anything by mouth to an unconscious person.

Most important symptoms and effects, both acute and

delayed

Contact with dust can cause mechanical irritation or drying of

the skin.

Harmful if swallowed.

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 if swallowed.

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.

Notes to physician : Treat symptomatically and supportively.

SECTION 5. FIRE-FIGHTING MEASURES

Suitable extinguishing media : Water spray

Alcohol-resistant foam Carbon dioxide (CO2)

Dry chemical



Losartan Formulation

Version Revision Date: SDS Number: Date of last issue: 03/27/2017 5.2 05/02/2017 19367-00009 Date of first issue: 10/07/2014

Unsuitable extinguishing

media

None known.

Specific hazards during fire

fighting

Exposure to combustion products may be a hazard to health.

Hazardous combustion prod-

ucts

Carbon oxides
Chlorine compounds

Nitrogen oxides (NOx)

Specific extinguishing meth-

ods

Use extinguishing measures that are appropriate to local cir-

cumstances 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 fire-fighters

In the event of fire, wear self-contained breathing apparatus.

Use personal protective equipment.

SECTION 6. ACCIDENTAL RELEASE MEASURES

Personal precautions, protec- :

tive equipment and emer-

gency procedures

Use personal protective equipment.

Follow safe handling advice and personal protective

equipment recommendations.

Environmental precautions : Discharge into the environment must be avoided.

Prevent further leakage or spillage if safe to do so. Retain and dispose of contaminated wash water.

Local authorities should be advised if significant spillages

cannot be contained.

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.

SECTION 7. HANDLING AND STORAGE

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.



Losartan Formulation

Version Revision Date: SDS Number: Date of last issue: 03/27/2017 5.2 05/02/2017 19367-00009 Date of first issue: 10/07/2014

Local/Total ventilation : Use with local exhaust ventilation.

Advice on safe handling : Do not get on skin or clothing.

Do not breathe dust. Do not swallow. Do not get in eyes.

Handle in accordance with good industrial hygiene and safety

practice.

Keep container tightly closed.

Minimize dust generation and accumulation. Keep container closed when not in use. Keep away from heat and sources of ignition.

Take precautionary measures against static discharges.

Take care to prevent spills, waste and minimize release to the

environment.

Conditions for safe storage : Keep in properly labeled 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 Organic peroxides

Explosives Gases

SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Ingredients with workplace control parameters

Ingredients	CAS-No.	Value type (Form of exposure)	Control parameters / Permissible concentration	Basis
Cellulose	9004-34-6	TWA	10 mg/m ³	ACGIH
		TWA (Respirable)	5 mg/m³	NIOSH REL
		TWA (total)	10 mg/m ³	NIOSH REL
		TWA (total dust)	15 mg/m³	OSHA Z-1
		TWA (respirable fraction)	5 mg/m³	OSHA Z-1
Losartan	124750-99-8	TWA	100 μg/m3 (OEB 2)	Merck
Starch	9005-25-8	TWA	10 mg/m ³	ACGIH
		TWA (Res- pirable)	5 mg/m³	NIOSH REL
		TWA (total)	10 mg/m ³	NIOSH REL
		TWA (total dust)	15 mg/m³	OSHA Z-1
		TWA (respirable fraction)	5 mg/m³	OSHA Z-1



Losartan Formulation

Version Revision Date: SDS Number: Date of last issue: 03/27/2017 5.2 05/02/2017 19367-00009 Date of first issue: 10/07/2014

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).

Use with local exhaust ventilation.

Dust formation may be relevant in the processing of this product. In addition to substance-specific OELs, general limitations of concentrations of particulates in the air at workplaces have to be considered in workplace risk assessment. Relevant limits include: OSHA PEL for Particulates Not Otherwise Regulated of 15 mg/m3 - total dust, 5 mg/m3 - respirable fraction; and ACGIH TWA for Particles (insoluble or poorly soluble) Not Otherwise Specified of 3 mg/m3 - respirable particles, 10 mg/m3 - inhalable particles.

Personal protective equipment

Respiratory protection : General and local exhaust ventilation is recommended to

maintain vapor exposures below recommended limits. Where concentrations are above recommended limits or are unknown, appropriate respiratory protection should be worn. Follow OSHA respirator regulations (29 CFR 1910.134) and use NIOSH/MSHA approved respirators. Protection provided

by air purifying respirators against exposure to any hazardous chemical is limited. Use a positive pressure air supplied respirator if there is any potential for uncontrolled

release, exposure levels are unknown, or any other

circumstance where air purifying respirators may not provide

adequate protection.

Hand protection

Material : Chemical-resistant gloves

Remarks : Choose gloves to protect hands against chemicals depending

on the concentration 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.

Eye 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).



Losartan Formulation

Version Revision Date: SDS Number: Date of last issue: 03/27/2017 5.2 05/02/2017 19367-00009 Date of first issue: 10/07/2014

Hygiene measures : Ensure that eye flushing systems and safety showers are

located close to the working place. When using do not eat, drink or smoke. Wash contaminated clothing before re-use.

SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance : powder

Color : White to light yellow

Odor : No information available.

Odor 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 : No data available

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

Vapor pressure : No data available

Relative vapor density : No data available

Density : 1 g/cm³

Solubility(ies)

Water solubility : No data available

Partition coefficient: n-

octanol/water

No data available

Autoignition temperature : No data available

Decomposition temperature : No data available



Losartan Formulation

Version Revision Date: SDS Number: Date of last issue: 03/27/2017 5.2 05/02/2017 19367-00009 Date of first issue: 10/07/2014

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

Minimum ignition energy : > 300 mJ

Particle size : No data available

SECTION 10. STABILITY AND REACTIVITY

Reactivity : Not classified as a reactivity hazard.

Chemical stability : Stable under normal conditions.

Possibility of hazardous reac-

tions

Dust can form an explosive mixture in air.

Can react with strong oxidizing agents.

Conditions to avoid : None known.

Incompatible materials : Oxidizing agents

Hazardous decomposition

products

No hazardous decomposition products are known.

SECTION 11. TOXICOLOGICAL INFORMATION

Information on likely routes of exposure

Inhalation Skin contact Ingestion Eye contact

Acute toxicity

Harmful if swallowed.

Product:

Acute oral toxicity : Acute toxicity estimate: 1,502 mg/kg

Method: Calculation method

Ingredients:

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 Formulation

Version Revision Date: SDS Number: Date of last issue: 03/27/2017 5.2 05/02/2017 19367-00009 Date of first issue: 10/07/2014

Assessment: The substance or mixture has no acute dermal

toxicity

Losartan:

Acute oral toxicity : LD50 (Mouse): 1,257 - 1,590 mg/kg

LDLo (Rat): 200 mg/kg

LDLo (Mouse): 400 mg/kg

Starch:

Acute oral toxicity : LD50 (Mouse): > 5,000 mg/kg

Skin corrosion/irritation

Not classified based on available information.

Ingredients:

Cellulose:

Result: No skin irritation

Remarks: Based on data from similar materials

Losartan:

Species: Rabbit

Result: Mild skin irritation

Serious eye damage/eye irritation

Causes serious eye damage.

Ingredients:

Cellulose:

Result: No eye irritation

Remarks: Based on data from similar materials

Losartan:

Species: Rabbit

Result: Severe irritation

Respiratory or skin sensitization

Skin sensitization

May cause an allergic skin reaction.

Respiratory sensitization

Not classified based on available information.

Ingredients:

Cellulose:

Test Type: Local lymph node assay (LLNA)



Losartan Formulation

Version Revision Date: SDS Number: Date of last issue: 03/27/2017 5.2 05/02/2017 19367-00009 Date of first issue: 10/07/2014

Routes of exposure: Skin contact

Species: Mouse

Method: OECD Test Guideline 429

Result: negative

Remarks: Based on data from similar materials

Losartan:

Test Type: Maximization Test Routes of exposure: Skin contact

Species: Guinea pig

Assessment: Probability or evidence of skin sensitization in humans

Result: positive

Germ cell mutagenicity

Not classified based on available information.

Ingredients:

Cellulose:

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

Result: negative

Remarks: Based on data from similar materials

Genotoxicity in vivo : Test Type: Mammalian erythrocyte micronucleus test (in vivo

cytogenetic assay) Species: Mouse

Application Route: Ingestion

Result: negative

Remarks: Based on data from similar materials

Losartan:

Genotoxicity in vitro : Test Type: in vitro test

Result: negative

: Test Type: In vitro mammalian cell gene mutation test

Species: 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

Carcinogenicity

Not classified based on available information.



Losartan Formulation

Version Revision Date: SDS Number: Date of last issue: 03/27/2017 5.2 05/02/2017 19367-00009 Date of first issue: 10/07/2014

Ingredients:

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

IARC No ingredient of this product present at levels greater than or

equal to 0.1% is identified as probable, possible or confirmed

human carcinogen by IARC.

OSHANo component of this product present at levels greater than or

equal to 0.1% is on OSHA's list of regulated carcinogens.

NTP No ingredient of this product present at levels greater than or

equal to 0.1% is identified as a known or anticipated carcinogen

by NTP.

Reproductive toxicity

May damage the unborn child.

May cause harm to breast-fed children.

Ingredients:

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 fetal 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.



Losartan Formulation

Version Revision Date: SDS Number: Date of last issue: 03/27/2017 5.2 05/02/2017 19367-00009 Date of first issue: 10/07/2014

Reproductive toxicity - As-

sessment

Clear evidence of adverse effects on development, based on

animal experiments.

Studies indicating a hazard to babies during the lactation

period

STOT-single exposure

Not classified based on available information.

STOT-repeated exposure

May cause damage to organs (Blood, Cardio-vascular system, Stomach, Kidney) through prolonged or repeated exposure if swallowed.

Ingredients:

Losartan:

Routes of exposure: Ingestion

Target Organs: Blood, Cardio-vascular system, Stomach, Kidney

Assessment: May cause damage to organs through prolonged or repeated exposure.

Repeated dose toxicity

Ingredients:

Cellulose:

Species: Rat

NOAEL: > 5,000 mg/kg Application Route: Ingestion Exposure time: 90 Days

Remarks: Based on data from similar materials

Losartan:

Species: Rat LOAEL: 15 mg/kg Application Route: Oral Exposure time: 309 d Number of exposures: daily

Target Organs: Blood, Kidney, Cardio-vascular system, Stomach

Species: Dog NOAEL: 5 mg/kg Application Route: Oral Exposure time: 1 Months Symptoms: Salivation, Vomiting

Species: Dog LOAEL: 25 mg/kg Application Route: Oral Exposure time: 53 Weeks Number of exposures: daily Symptoms: Salivation, Vomiting



Losartan Formulation

Version Revision Date: SDS Number: Date of last issue: 03/27/2017 5.2 05/02/2017 19367-00009 Date of first issue: 10/07/2014

Aspiration toxicity

Not classified based on available information.

Ingredients:

Losartan:

No aspiration toxicity classification

Experience with human exposure

Ingredients:

Losartan:

Eye contact : Symptoms: Eye irritation

Ingestion : Symptoms: hypotension, tachycardia

SECTION 12. ECOLOGICAL INFORMATION

Ecotoxicity

Ingredients:

Cellulose:

Toxicity to fish : LC50 (Cyprinus carpio (Carp)): > 100 mg/l

Exposure time: 96 h

Method: OECD Test Guideline 203

Remarks: Based on data from similar materials

Toxicity to daphnia and other :

aquatic invertebrates

EC50 (Daphnia magna (Water flea)): > 100 mg/l Exposure time: 48 h

Method: OECD Test Guideline 202

Remarks: Based on data from similar materials

Toxicity to algae : EC50 (Pseudokirchneriella subcapitata (green algae)): > 100

mg/l

Exposure time: 72 h

Method: OECD Test Guideline 201

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 : NOEC (Microcystis aeruginosa (blue-green algae)): 949 mg/l

Exposure time: 10 d Method: FDA 4.01



Losartan Formulation

Version Revision Date: SDS Number: Date of last issue: 03/27/2017 5.2 05/02/2017 19367-00009 Date of first issue: 10/07/2014

NOEC (Selenastrum capricornutum (green algae)): 143 mg/l

Exposure time: 10 d Method: FDA 4.01

Toxicity to fish (Chronic tox-

icity)

NOEC (Pimephales promelas (fathead minnow)): 10 mg/l

Exposure time: 32 d

Method: OECD Test Guideline 210

Toxicity to daphnia and other : aquatic invertebrates (Chron-

ic toxicity)

NOEC (Daphnia magna (Water flea)): 100 mg/l

Exposure time: 21 d

Method: OECD Test Guideline 211

Persistence and degradability

Ingredients:

Cellulose:

Biodegradability : Result: Readily biodegradable.

Losartan:

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

Bioaccumulative potential

Ingredients:

Losartan:

Partition coefficient: n-

octanol/water

log Pow: 1.2

Mobility in soil

No data available

Other adverse effects

No data available

SECTION 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.

SECTION 14. TRANSPORT INFORMATION

International Regulations

UNRTDG

Not regulated as a dangerous good



Losartan Formulation

Version Revision Date: SDS Number: Date of last issue: 03/27/2017 5.2 05/02/2017 19367-00009 Date of first issue: 10/07/2014

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.

Domestic regulation

49 CFR

Not regulated as a dangerous good

SECTION 15. REGULATORY INFORMATION

EPCRA - Emergency Planning and Community Right-to-Know

CERCLA Reportable Quantity

This material does not contain any components with a CERCLA RQ.

SARA 304 Extremely Hazardous Substances Reportable Quantity

This material does not contain any components with a section 304 EHS RQ.

SARA 302 Extremely Hazardous Substances Threshold Planning Quantity

This material does not contain any components with a section 302 EHS TPQ.

SARA 311/312 Hazards : Fire Hazard

Acute Health Hazard Chronic Health Hazard

SARA 313 : This material does not contain any chemical components with

known CAS numbers that exceed the threshold (De Minimis) reporting levels established by SARA Title III, Section 313.

US State Regulations

Pennsylvania Right To Know

 Cellulose
 9004-34-6

 Losartan
 124750-99-8

 D-Glucose, 4-O-.beta.-D-galactopyranosyl-, monohydrate
 64044-51-5

 Starch
 9005-25-8

California Prop. 65

This product does not contain any chemicals known to the State of California to cause cancer, birth, or any other reproductive defects.

California Permissible Exposure Limits for Chemical Contaminants

 Cellulose
 9004-34-6

 Starch
 9005-25-8

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

AICS : not determined

DSL : not determined



Losartan Formulation

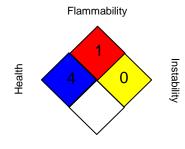
Version Revision Date: SDS Number: Date of last issue: 03/27/2017 5.2 05/02/2017 19367-00009 Date of first issue: 10/07/2014

IECSC : not determined

SECTION 16. OTHER INFORMATION

Further information

NFPA:



Special hazard.

HMIS® IV:



HMIS® ratings are based on a 0-4 rating scale, with 0 representing minimal hazards or risks, and 4 representing significant hazards or risks. The "*" represents a chronic hazard, while the "/" represents the absence of a chronic hazard.

Full text of other abbreviations

ACGIH : USA. ACGIH Threshold Limit Values (TLV)
NIOSH REL : USA. NIOSH Recommended Exposure Limits

OSHA Z-1 : USA. Occupational Exposure Limits (OSHA) - Table Z-1 Lim-

its for Air Contaminants

ACGIH / TWA : 8-hour, time-weighted average

NIOSH REL / TWA : Time-weighted average concentration for up to a 10-hour

workday during a 40-hour workweek

OSHA Z-1 / TWA : 8-hour time weighted average

AICS - Australian Inventory of Chemical Substances; ASTM - American Society for the Testing of Materials; bw - Body weight; CERCLA - Comprehensive Environmental Response, Compensation, and Liability Act; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DOT - Department of Transportation; DSL - Domestic Substances List (Canada); ECx - Concentration associated with x% response; EHS - Extremely Hazardous Substance; 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; ERG - Emergency Response Guide; GHS - Globally Harmonized System; GLP - Good Laboratory Practice; HMIS - Hazardous Materials Identification System; 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; MSHA - Mine Safety and Health Administration; n.o.s. - Not Otherwise Specified; NFPA - National Fire Protection Association; NO(A)EC - No Observed (Adverse)



Losartan Formulation

Version Revision Date: SDS Number: Date of last issue: 03/27/2017 5.2 05/02/2017 19367-00009 Date of first issue: 10/07/2014

Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; 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; RCRA - Resource Conservation and Recovery Act; REACH - Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals; RQ - Reportable Quantity; SADT - Self-Accelerating Decomposition Temperature; SARA - Superfund Amendments and Reauthorization Act; SDS - Safety Data Sheet; TCSI - Taiwan Chemical Substance Inventory; TSCA - Toxic Substances Control Act (United States); UN - United Nations; UNRTDG - United Nations Recommendations on the Transport of Dangerous Goods; vPvB - Very Persistent and Very Bioaccumulative

Sources of key data used to compile the Material Safety

Data Sheet

Internal technical data, data from raw material SDSs, OECD eChem Portal search results and European Chemicals Agen-

cy, http://echa.europa.eu/

Revision Date : 05/02/2017

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

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.

US / Z8