

SAFETY DATA SHEETS

This SDS packet was issued with item:

078915493

The safety data sheets (SDS) in this packet apply to the individual products listed below. Please refer to invoice for specific item number(s).

078915494



SAFETY DATA SHEET

1. Identification

Product identifier	Losartan Potassium	
Other means of identification		
Catalog number	1370462	
Chemical name	2-Butyl-4-chloro-1-[p-(o-1H-tetrazol-5-ylphenyl)benzyl]imidazole-5-methanol, monopotassium salt	
Recommended use	Specified quality tests and assay use only.	
Recommended restrictions	Not for use as a drug. Not for administration to humans or animals.	
Manufacturer/Importer/Supplier/Distributor information		
Company name	U. S. Pharmacopeia	
Address	12601 Twinbrook Parkway Rockville MD 20852-1790 US	
Telephone	RS Technical Services	301-816-8129
Website	www.usp.org	
E-mail	RSTECH@usp.org	
Emergency phone number	CHEMTREC within US & Canada	1-800-424-9300
	CHEMTREC outside US & Canada	+1 703-527-3887

2. Hazard(s) identification

Physical hazards	Not classified.	
Health hazards	Acute toxicity, oral	Category 4
	Serious eye damage/eye irritation	Category 2A
	Sensitization, skin	Category 1B
	Reproductive toxicity	Category 1B
OSHA hazard(s)	Not classified.	

Label elements



Signal word	Danger	
Hazard statement	Harmful if swallowed. May cause an allergic skin reaction. Causes serious eye irritation. May damage fertility or the unborn child.	
Precautionary statement		
Prevention	Obtain special instructions before use. Do not handle until all safety precautions have been read and understood. Avoid breathing dust. Wash thoroughly after handling. Do not eat, drink or smoke when using this product. Contaminated work clothing must not be allowed out of the workplace. Wear protective gloves/protective clothing/eye protection/face protection.	
Response	If exposed or concerned: Get medical advice/attention. Rinse mouth. If swallowed: Call a poison center/doctor/medical professional/ if you feel unwell. If on skin: Wash with plenty of water/soap. If skin irritation or rash occurs: Get medical advice/attention. Wash contaminated clothing before reuse. If in eyes: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. If eye irritation persists: Get medical advice/attention.	
Storage	Store locked up.	
Disposal	Dispose of contents/container to an approved disposal site.	
Hazard(s) not otherwise classified (HNOC)	Not classified.	

3. Composition/information on ingredients

Substance

Hazardous components

Chemical name	Common name and synonyms	CAS number	%
Losartan Potassium		124750-99-8	100

4. First-aid measures

Inhalation	Move to fresh air. Call a physician if symptoms develop or persist.
Skin contact	Rinse skin with water/shower. Get medical attention if irritation develops and persists.
Eye contact	Rinse cautiously with water for several minutes. Get medical attention if irritation develops and persists.
Ingestion	Rinse mouth. Get medical attention if symptoms occur.
Most important symptoms/effects, acute and delayed	Irritation of eyes and mucous membranes. May cause allergic skin reaction.
Indication of immediate medical attention and special treatment needed	Provide general supportive measures and treat symptomatically. In patients with a potentially toxic ingestion, consider pre-hospital administration of activated charcoal in an aqueous slurry. Consider gastric lavage if it can be performed soon after ingestion. In the event of hypotension, infuse isotonic fluid. If hypotension persists, administer dopamine or norepinephrine. This material is not removed by hemodialysis. [Meditext]
General information	Remove from exposure. Remove contaminated clothing. For treatment advice, seek guidance from an occupational health physician or other licensed health-care provider familiar with workplace chemical exposures. In the United States, the national poison control center phone number is 1-800-222-1222. If person is not breathing, give artificial respiration. If breathing is difficult, give oxygen if available. Persons developing serious hypersensitivity (anaphylactic) reactions must receive immediate medical attention.

5. Fire-fighting measures

Suitable extinguishing media	Water spray, dry chemical, carbon dioxide, or foam as appropriate for surrounding fire and materials.
Unsuitable extinguishing media	None known.
Specific hazards arising from the chemical	No unusual fire or explosion hazards noted.
Special protective equipment and precautions for firefighters	Wear suitable protective equipment.
Fire-fighting equipment/instructions	As with all fires, evacuate personnel to a safe area. Firefighters should use self-contained breathing equipment and protective clothing.
Specific methods	Cool containers exposed to flames with water until well after the fire is out.

6. Accidental release measures

Personal precautions, protective equipment and emergency procedures	Keep unnecessary personnel away. Do not touch damaged containers or spilled material unless wearing appropriate protective clothing. Ensure adequate ventilation. Avoid inhalation of dust from the spilled material. Wear appropriate personal protective equipment.
Methods and materials for containment and cleaning up	Sweep up or vacuum up spillage and collect in suitable container for disposal. Avoid the generation of dusts during clean-up. For waste disposal, see section 13 of the SDS. Wash spill site.

7. Handling and storage

Precautions for safe handling	As a general rule, when handling USP Reference Standards, avoid all contact and inhalation of dust, mists, and/or vapors associated with the material. Clean equipment and work surfaces with suitable detergent or solvent after use. After removing gloves, wash hands and other exposed skin thoroughly.
Conditions for safe storage, including any incompatibilities	Store in tight container as defined in the USP-NF. This material should be handled and stored per label instructions to ensure product integrity.

8. Exposure controls/personal protection

Exposure limit values

Industrial Use

Material	Type	Value
Losartan Potassium (CAS 124750-99-8)	TWA	0.1 micrograms/m3

Biological limit values	No biological exposure limits noted for the ingredient(s).
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Appropriate engineering controls	<p>Airborne exposure should be controlled primarily by engineering controls such as general dilution ventilation, local exhaust ventilation, or process enclosure. Local exhaust ventilation is generally preferred to general exhaust because it can control the contaminant at its source, preventing dispersion into the work area. An industrial hygiene survey involving air monitoring may be used to determine the effectiveness of engineering controls. Effectiveness of engineering controls intended for use with highly potent materials should be assessed by use of nontoxic surrogate materials.</p> <p>Avoid any open handling of this material, particularly for grinding, crushing, weighing or other dust-generating or aerosol-generating procedures. Use a laboratory fume hood, vented enclosure, glovebox, or other effective containment.</p>
Individual protection measures, such as personal protective equipment	
Eye/face protection	Safety glasses with sideshields are recommended. Face shields or goggles may be required if splash potential exists or if corrosive materials are present. Approved eye protection (e.g., bearing the ANSI Z87 or CSA stamp) is preferred. Maintain eyewash facilities in the work area.
Skin protection	
Hand protection	Chemically compatible gloves. For handling solutions, ensure that the glove material is protective against the solvent being used. Use handling practices that minimize direct hand contact. Employees who are sensitive to natural rubber (latex) should use nitrile or other synthetic nonlatex gloves. Use of powdered latex gloves should be avoided due to the risk of latex allergy. This material is extremely irritating. To reduce the risk of contamination of skin and surfaces, wear two pairs of gloves. Remove the outer gloves after handling and cleanup of the material, and remove the inner gloves only after removing other personal protective equipment.
Other	For handling of laboratory scale quantities, a cloth lab coat is recommended. Where significant quantities are handled, work clothing may be necessary to prevent take-home contamination.
Respiratory protection	Where respirators are deemed necessary to reduce or control occupational exposures, use NIOSH-approved respiratory protection and have an effective respirator program in place (applicable U.S. regulation OSHA 29 CFR 1910.134).
Thermal hazards	Not available.
General hygiene considerations	Handle in accordance with good industrial hygiene and safety practice.

9. Physical and chemical properties

Appearance	White to off-white crystalline powder.
Physical state	Solid.
Form	Powder.
Odor	Not available.
Odor threshold	Not available.
pH	8.2 (1% aqueous solution)
Melting point/freezing point	509 °F (265 °C) / 362.3 - 364.1 °F (183.5 - 184.5 °C)
Initial boiling point and boiling range	Not available.
Flash point	Not available.
Evaporation rate	Not available.
Flammability (solid, gas)	Not applicable.
Upper/lower flammability or explosive limits	
Flammability limit - lower (%)	Not available.
Flammability limit - upper (%)	Not available.
Explosive limit - lower (%)	Not available.
Explosive limit - upper (%)	Not available.
Vapor pressure	< 0.0000001 kPa at 25 °C
Vapor density	Not available.
Relative density	Not available.
Solubility in water	Freely soluble.
Partition coefficient (n-octanol/water)	1.3
Auto-ignition temperature	Not available.
Decomposition temperature	Not available.
Viscosity	Not available.

Other information

Molecular formula	C22H22ClN6O
Molecular weight	461
Solubility (other)	Soluble in isopropyl alcohol and in methanol; slightly soluble in acetonitrile; practically insoluble in chloroform.

10. Stability and reactivity

Reactivity	No reactivity hazards known.
Chemical stability	Stable at normal conditions.
Possibility of hazardous reactions	No dangerous reaction known under conditions of normal use.
Conditions to avoid	None known.
Incompatible materials	None known.
Hazardous decomposition products	NOx. Phosgene, a highly toxic material. Irritating and/or toxic fumes or gases. Emits toxic fumes under fire conditions.

11. Toxicological information

Information on likely routes of exposure

Ingestion	Harmful if swallowed.
Inhalation	Due to lack of data the classification is not possible.
Skin contact	May cause an allergic skin reaction.
Eye contact	Causes serious eye irritation.

Symptoms related to the physical, chemical, and toxicological characteristics Headache. Diarrhea. Fatigue. Dizziness. Bone pain. Muscle pain. Nausea. Vomiting. Heartburn. Fast heartbeat. Slow heartbeat. Lightheadedness. Fainting.

Medical conditions aggravated by exposure Psoriasis. Kidney disease. Liver impairment.

Acute toxicity Harmful if swallowed.

Skin corrosion/irritation Based on available data, the classification criteria are not met.

Serious eye damage/eye irritation Causes serious eye irritation.

Local effects

Irritancy test
Result: Irritant.
Species: Rabbit
Organ: Eye.
Severity: Severe.
Irritancy test
Result: Irritant.
Species: Rabbit
Organ: Skin.
Severity: Mild.

Respiratory sensitization Due to lack of data the classification is not possible.

Skin sensitization May cause an allergic skin reaction.

Sensitization

Sensitization test
Result: Sensitizer.
Species: Guinea pig
Organ: Skin.
Severity: Mild.

Germ cell mutagenicity Based on available data, the classification criteria are not met. Negative in a battery of tests.

Carcinogenicity Based on available data, the classification criteria are not met. This product is not considered to be a carcinogen by IARC, ACGIH, NTP, or OSHA.

200 mg/kg/day Carcinogenicity test
Result: Not carcinogenic.
Species: Mouse
Test Duration: 92 weeks
270 mg/kg/day Carcinogenicity test
Result: Not carcinogenic.
Species: Rat
Test Duration: 150 weeks

Reproductive toxicity	May damage fertility or the unborn child. Maternal use during the second and third trimesters of pregnancy of drugs that act on the renin-angiotensin system has been associated with fetal and newborn injury and death. Adverse effects include growth retardation, incomplete lung development, skeletal deformities, and kidney damage.
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Reproductivity

100 mg/kg/day Reproductivity test
Result: Decreased pup weight, fetal heart and kidney abnormalities, and increased pup mortality.
Species: Rat
20 mg/kg Reproductivity test
Result: Decreased bone hardening and fetal weight.
Species: Rabbit
40 mg/kg Reproductivity test
Result: Maternal death and miscarriage but no treatment-related fetal malformations.
Species: Rabbit

Specific target organ toxicity - single exposure	Based on available data, the classification criteria are not met.
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Specific target organ toxicity - repeated exposure	Based on available data, the classification criteria are not met.
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Aspiration hazard	Based on available data, the classification criteria are not met.
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12. Ecological information

Ecotoxicity	No ecotoxicity data noted for the ingredient(s).
Persistence and degradability	No data is available on the degradability of this product.
Bioaccumulative potential	Not available.
Mobility in soil	Not available.
Other adverse effects	Not available.

13. Disposal considerations

Disposal instructions	This product, in its present state, when discarded or disposed of, is not a hazardous waste according to Federal regulations (40 CFR 261.4 (b)(4)). Under RCRA, it is the responsibility of the user of the product to determine, at the time of disposal, whether the product meets RCRA criteria for hazardous waste. Dispose in accordance with all applicable regulations.
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Local disposal regulations	Not available.
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Hazardous waste code	Not regulated.
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Waste from residues / unused products	Empty containers or liners may retain some product residues. This material and its container must be disposed of in a safe manner (see: Disposal instructions).
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Contaminated packaging	Empty containers should be taken to an approved waste handling site for recycling or disposal. Since emptied containers may retain product residue, follow label warnings even after container is emptied.
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14. Transport information

DOT

Not regulated as a hazardous material by DOT.

IATA

Not regulated as a dangerous good.

Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code	No information available.
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15. Regulatory information

US federal regulations	CERCLA/SARA Hazardous Substances - Not applicable.
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One or more components are not listed on TSCA.

Superfund Amendments and Reauthorization Act of 1986 (SARA)

Hazard categories	Immediate Hazard - Yes Delayed Hazard - No Fire Hazard - No Pressure Hazard - No Reactivity Hazard - No
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SARA 302 Extremely hazardous substance	No
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SARA 311/312 Hazardous chemical	No	
Other federal regulations		
Safe Drinking Water Act (SDWA)	Not regulated.	
Food and Drug Administration (FDA)	Not regulated.	
US state regulations	This product does not contain a chemical known to the State of California to cause cancer, birth defects or other reproductive harm.	
International Inventories		
Country(s) or region	Inventory name	On inventory (yes/no)*
Australia	Australian Inventory of Chemical Substances (AICS)	No
Canada	Domestic Substances List (DSL)	No
Canada	Non-Domestic Substances List (NDSL)	No
China	Inventory of Existing Chemical Substances in China (IECSC)	No
Europe	European Inventory of Existing Commercial Chemical Substances (EINECS)	No
Europe	European List of Notified Chemical Substances (ELINCS)	No
Japan	Inventory of Existing and New Chemical Substances (ENCS)	No
Korea	Existing Chemicals List (ECL)	No
New Zealand	New Zealand Inventory	No
Philippines	Philippine Inventory of Chemicals and Chemical Substances (PICCS)	No
United States & Puerto Rico	Toxic Substances Control Act (TSCA) Inventory	No

* A "Yes" indicates that all components of this product comply with the inventory requirements administered by the governing country(s)

*A "Yes" indicates that all components of this product comply with the inventory requirements administered by the governing country(s)

16. Other information, including date of preparation or last revision

Issue date	01-25-2011
Revision date	03-08-2013
Version #	02
Further information	Not available.
Disclaimer	USP Reference Standards are sold for chemical test and assay purposes only, and NOT for human consumption. The information contained herein is applicable solely to the chemical substance when used as a USP Reference Standard and does not necessarily relate to any other use of the substance described, (i.e. at different concentrations, in drug dosage forms, or in bulk quantities). USP Reference Standards are intended for use by persons having technical skill and at their own discretion and risk. This information has been developed by USP staff from sources considered reliable but has not been independently verified by the USP. Therefore, the USP Convention cannot guarantee the accuracy of the information in these sources nor should the statements contained herein be considered an official expression. NO REPRESENTATION OR WARRANTY, EXPRESS OR IMPLIED, INCLUDING THE WARRANTIES OF MERCHANTABILITY AND FITNESS FOR A PARTICULAR PURPOSE is made with respect to the information contained herein.
Revision Information	This document has undergone significant changes and should be reviewed in its entirety.



SAFETY DATA SHEET

1. Identification

Product identifier	Losartan Potassium	
Other means of identification		
Catalog number	1370462	
Chemical name	2-Butyl-4-chloro-1-[p-(o-1H-tetrazol-5-ylphenyl)benzyl]imidazole-5-methanol, monopotassium salt	
Recommended use	Specified quality tests and assay use only.	
Recommended restrictions	Not for use as a drug. Not for administration to humans or animals.	
Manufacturer/Importer/Supplier/Distributor information		
Company name	U. S. Pharmacopeia	
Address	12601 Twinbrook Parkway Rockville MD 20852-1790 US	
Telephone	RS Technical Services	301-816-8129
Website	www.usp.org	
E-mail	RSTECH@usp.org	
Emergency phone number	CHEMTREC within US & Canada	1-800-424-9300
	CHEMTREC outside US & Canada	+1 703-527-3887

2. Hazard(s) identification

Physical hazards	Not classified.	
Health hazards	Acute toxicity, oral	Category 4
	Serious eye damage/eye irritation	Category 2A
	Sensitization, skin	Category 1B
	Reproductive toxicity	Category 1B
OSHA hazard(s)	Not classified.	

Label elements



Signal word	Danger
Hazard statement	Harmful if swallowed. May cause an allergic skin reaction. Causes serious eye irritation. May damage fertility or the unborn child.
Precautionary statement	
Prevention	Obtain special instructions before use. Do not handle until all safety precautions have been read and understood. Avoid breathing dust. Wash thoroughly after handling. Do not eat, drink or smoke when using this product. Contaminated work clothing must not be allowed out of the workplace. Wear protective gloves/protective clothing/eye protection/face protection.
Response	If exposed or concerned: Get medical advice/attention. Rinse mouth. If swallowed: Call a poison center/doctor/medical professional/ if you feel unwell. If on skin: Wash with plenty of water/soap. If skin irritation or rash occurs: Get medical advice/attention. Wash contaminated clothing before reuse. If in eyes: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. If eye irritation persists: Get medical advice/attention.
Storage	Store locked up.
Disposal	Dispose of contents/container to an approved disposal site.
Hazard(s) not otherwise classified (HNOC)	Not classified.

3. Composition/information on ingredients

Substance

Hazardous components

Chemical name	Common name and synonyms	CAS number	%
Losartan Potassium		124750-99-8	100

4. First-aid measures

Inhalation	Move to fresh air. Call a physician if symptoms develop or persist.
Skin contact	Rinse skin with water/shower. Get medical attention if irritation develops and persists.
Eye contact	Rinse cautiously with water for several minutes. Get medical attention if irritation develops and persists.
Ingestion	Rinse mouth. Get medical attention if symptoms occur.
Most important symptoms/effects, acute and delayed	Irritation of eyes and mucous membranes. May cause allergic skin reaction.
Indication of immediate medical attention and special treatment needed	Provide general supportive measures and treat symptomatically. In patients with a potentially toxic ingestion, consider pre-hospital administration of activated charcoal in an aqueous slurry. Consider gastric lavage if it can be performed soon after ingestion. In the event of hypotension, infuse isotonic fluid. If hypotension persists, administer dopamine or norepinephrine. This material is not removed by hemodialysis. [Meditext]
General information	Remove from exposure. Remove contaminated clothing. For treatment advice, seek guidance from an occupational health physician or other licensed health-care provider familiar with workplace chemical exposures. In the United States, the national poison control center phone number is 1-800-222-1222. If person is not breathing, give artificial respiration. If breathing is difficult, give oxygen if available. Persons developing serious hypersensitivity (anaphylactic) reactions must receive immediate medical attention.

5. Fire-fighting measures

Suitable extinguishing media	Water spray, dry chemical, carbon dioxide, or foam as appropriate for surrounding fire and materials.
Unsuitable extinguishing media	None known.
Specific hazards arising from the chemical	No unusual fire or explosion hazards noted.
Special protective equipment and precautions for firefighters	Wear suitable protective equipment.
Fire-fighting equipment/instructions	As with all fires, evacuate personnel to a safe area. Firefighters should use self-contained breathing equipment and protective clothing.
Specific methods	Cool containers exposed to flames with water until well after the fire is out.

6. Accidental release measures

Personal precautions, protective equipment and emergency procedures	Keep unnecessary personnel away. Do not touch damaged containers or spilled material unless wearing appropriate protective clothing. Ensure adequate ventilation. Avoid inhalation of dust from the spilled material. Wear appropriate personal protective equipment.
Methods and materials for containment and cleaning up	Sweep up or vacuum up spillage and collect in suitable container for disposal. Avoid the generation of dusts during clean-up. For waste disposal, see section 13 of the SDS. Wash spill site.

7. Handling and storage

Precautions for safe handling	As a general rule, when handling USP Reference Standards, avoid all contact and inhalation of dust, mists, and/or vapors associated with the material. Clean equipment and work surfaces with suitable detergent or solvent after use. After removing gloves, wash hands and other exposed skin thoroughly.
Conditions for safe storage, including any incompatibilities	Store in tight container as defined in the USP-NF. This material should be handled and stored per label instructions to ensure product integrity.

8. Exposure controls/personal protection

Exposure limit values

Industrial Use

Material	Type	Value
Losartan Potassium (CAS 124750-99-8)	TWA	0.1 micrograms/m3

Biological limit values	No biological exposure limits noted for the ingredient(s).
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Appropriate engineering controls	<p>Airborne exposure should be controlled primarily by engineering controls such as general dilution ventilation, local exhaust ventilation, or process enclosure. Local exhaust ventilation is generally preferred to general exhaust because it can control the contaminant at its source, preventing dispersion into the work area. An industrial hygiene survey involving air monitoring may be used to determine the effectiveness of engineering controls. Effectiveness of engineering controls intended for use with highly potent materials should be assessed by use of nontoxic surrogate materials.</p> <p>Avoid any open handling of this material, particularly for grinding, crushing, weighing or other dust-generating or aerosol-generating procedures. Use a laboratory fume hood, vented enclosure, glovebox, or other effective containment.</p>
Individual protection measures, such as personal protective equipment	
Eye/face protection	Safety glasses with sideshields are recommended. Face shields or goggles may be required if splash potential exists or if corrosive materials are present. Approved eye protection (e.g., bearing the ANSI Z87 or CSA stamp) is preferred. Maintain eyewash facilities in the work area.
Skin protection	
Hand protection	Chemically compatible gloves. For handling solutions, ensure that the glove material is protective against the solvent being used. Use handling practices that minimize direct hand contact. Employees who are sensitive to natural rubber (latex) should use nitrile or other synthetic nonlatex gloves. Use of powdered latex gloves should be avoided due to the risk of latex allergy. This material is extremely irritating. To reduce the risk of contamination of skin and surfaces, wear two pairs of gloves. Remove the outer gloves after handling and cleanup of the material, and remove the inner gloves only after removing other personal protective equipment.
Other	For handling of laboratory scale quantities, a cloth lab coat is recommended. Where significant quantities are handled, work clothing may be necessary to prevent take-home contamination.
Respiratory protection	Where respirators are deemed necessary to reduce or control occupational exposures, use NIOSH-approved respiratory protection and have an effective respirator program in place (applicable U.S. regulation OSHA 29 CFR 1910.134).
Thermal hazards	Not available.
General hygiene considerations	Handle in accordance with good industrial hygiene and safety practice.

9. Physical and chemical properties

Appearance	White to off-white crystalline powder.
Physical state	Solid.
Form	Powder.
Odor	Not available.
Odor threshold	Not available.
pH	8.2 (1% aqueous solution)
Melting point/freezing point	509 °F (265 °C) / 362.3 - 364.1 °F (183.5 - 184.5 °C)
Initial boiling point and boiling range	Not available.
Flash point	Not available.
Evaporation rate	Not available.
Flammability (solid, gas)	Not applicable.
Upper/lower flammability or explosive limits	
Flammability limit - lower (%)	Not available.
Flammability limit - upper (%)	Not available.
Explosive limit - lower (%)	Not available.
Explosive limit - upper (%)	Not available.
Vapor pressure	< 0.0000001 kPa at 25 °C
Vapor density	Not available.
Relative density	Not available.
Solubility in water	Freely soluble.
Partition coefficient (n-octanol/water)	1.3
Auto-ignition temperature	Not available.
Decomposition temperature	Not available.
Viscosity	Not available.

Other information

Molecular formula	C22H22ClN6O
Molecular weight	461
Solubility (other)	Soluble in isopropyl alcohol and in methanol; slightly soluble in acetonitrile; practically insoluble in chloroform.

10. Stability and reactivity

Reactivity	No reactivity hazards known.
Chemical stability	Stable at normal conditions.
Possibility of hazardous reactions	No dangerous reaction known under conditions of normal use.
Conditions to avoid	None known.
Incompatible materials	None known.
Hazardous decomposition products	NOx. Phosgene, a highly toxic material. Irritating and/or toxic fumes or gases. Emits toxic fumes under fire conditions.

11. Toxicological information

Information on likely routes of exposure

Ingestion	Harmful if swallowed.
Inhalation	Due to lack of data the classification is not possible.
Skin contact	May cause an allergic skin reaction.
Eye contact	Causes serious eye irritation.

Symptoms related to the physical, chemical, and toxicological characteristics Headache. Diarrhea. Fatigue. Dizziness. Bone pain. Muscle pain. Nausea. Vomiting. Heartburn. Fast heartbeat. Slow heartbeat. Lightheadedness. Fainting.

Medical conditions aggravated by exposure Psoriasis. Kidney disease. Liver impairment.

Acute toxicity Harmful if swallowed.

Skin corrosion/irritation Based on available data, the classification criteria are not met.

Serious eye damage/eye irritation Causes serious eye irritation.

Local effects

Irritancy test
Result: Irritant.
Species: Rabbit
Organ: Eye.
Severity: Severe.
Irritancy test
Result: Irritant.
Species: Rabbit
Organ: Skin.
Severity: Mild.

Respiratory sensitization Due to lack of data the classification is not possible.

Skin sensitization May cause an allergic skin reaction.

Sensitization

Sensitization test
Result: Sensitizer.
Species: Guinea pig
Organ: Skin.
Severity: Mild.

Germ cell mutagenicity Based on available data, the classification criteria are not met. Negative in a battery of tests.

Carcinogenicity Based on available data, the classification criteria are not met. This product is not considered to be a carcinogen by IARC, ACGIH, NTP, or OSHA.

200 mg/kg/day Carcinogenicity test
Result: Not carcinogenic.
Species: Mouse
Test Duration: 92 weeks
270 mg/kg/day Carcinogenicity test
Result: Not carcinogenic.
Species: Rat
Test Duration: 150 weeks

Reproductive toxicity	May damage fertility or the unborn child. Maternal use during the second and third trimesters of pregnancy of drugs that act on the renin-angiotensin system has been associated with fetal and newborn injury and death. Adverse effects include growth retardation, incomplete lung development, skeletal deformities, and kidney damage.
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Reproductivity

100 mg/kg/day Reproductivity test
Result: Decreased pup weight, fetal heart and kidney abnormalities, and increased pup mortality.
Species: Rat
20 mg/kg Reproductivity test
Result: Decreased bone hardening and fetal weight.
Species: Rabbit
40 mg/kg Reproductivity test
Result: Maternal death and miscarriage but no treatment-related fetal malformations.
Species: Rabbit

Specific target organ toxicity - single exposure	Based on available data, the classification criteria are not met.
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Specific target organ toxicity - repeated exposure	Based on available data, the classification criteria are not met.
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Aspiration hazard	Based on available data, the classification criteria are not met.
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12. Ecological information

Ecotoxicity	No ecotoxicity data noted for the ingredient(s).
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Persistence and degradability	No data is available on the degradability of this product.
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Bioaccumulative potential	Not available.
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Mobility in soil	Not available.
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Other adverse effects	Not available.
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13. Disposal considerations

Disposal instructions	This product, in its present state, when discarded or disposed of, is not a hazardous waste according to Federal regulations (40 CFR 261.4 (b)(4)). Under RCRA, it is the responsibility of the user of the product to determine, at the time of disposal, whether the product meets RCRA criteria for hazardous waste. Dispose in accordance with all applicable regulations.
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Local disposal regulations	Not available.
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Hazardous waste code	Not regulated.
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Waste from residues / unused products	Empty containers or liners may retain some product residues. This material and its container must be disposed of in a safe manner (see: Disposal instructions).
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Contaminated packaging	Empty containers should be taken to an approved waste handling site for recycling or disposal. Since emptied containers may retain product residue, follow label warnings even after container is emptied.
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14. Transport information

DOT

Not regulated as a hazardous material by DOT.

IATA

Not regulated as a dangerous good.

Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code	No information available.
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15. Regulatory information

US federal regulations	CERCLA/SARA Hazardous Substances - Not applicable.
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One or more components are not listed on TSCA.

Superfund Amendments and Reauthorization Act of 1986 (SARA)

Hazard categories	Immediate Hazard - Yes Delayed Hazard - No Fire Hazard - No Pressure Hazard - No Reactivity Hazard - No
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SARA 302 Extremely hazardous substance	No
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SARA 311/312 Hazardous chemical	No	
Other federal regulations		
Safe Drinking Water Act (SDWA)	Not regulated.	
Food and Drug Administration (FDA)	Not regulated.	
US state regulations	This product does not contain a chemical known to the State of California to cause cancer, birth defects or other reproductive harm.	
International Inventories		
Country(s) or region	Inventory name	On inventory (yes/no)*
Australia	Australian Inventory of Chemical Substances (AICS)	No
Canada	Domestic Substances List (DSL)	No
Canada	Non-Domestic Substances List (NDSL)	No
China	Inventory of Existing Chemical Substances in China (IECSC)	No
Europe	European Inventory of Existing Commercial Chemical Substances (EINECS)	No
Europe	European List of Notified Chemical Substances (ELINCS)	No
Japan	Inventory of Existing and New Chemical Substances (ENCS)	No
Korea	Existing Chemicals List (ECL)	No
New Zealand	New Zealand Inventory	No
Philippines	Philippine Inventory of Chemicals and Chemical Substances (PICCS)	No
United States & Puerto Rico	Toxic Substances Control Act (TSCA) Inventory	No

* A "Yes" indicates that all components of this product comply with the inventory requirements administered by the governing country(s)

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16. Other information, including date of preparation or last revision

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Further information	Not available.
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Revision Information	This document has undergone significant changes and should be reviewed in its entirety.