SAFETY DATA SHEET

1. Identification

Product identifier **Chlorhexidine Acetate**

Other means of identification

Catalog number 1111103

CAS number 56-95-1

Synonyms Chlorhexidine diacetate * Biguanide, 1,1'-hexamethylenebis(5-p-chlorophenyl)-, diacetate

Chemical name 2,4,11,13-Tetraazatetradecanediimidamide, N,N''-bis(4-chlorophenyl)-3,12-diimino-, diacetate

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

Manufacturer

Company name U. S. Pharmacopeia

Address 12601 Twinbrook Parkway
Rockville
MD
20852-1790
United States

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
Acute toxicity, inhalation	Category 2
Skin corrosion/irritation	Category 2
Serious eye damage/eye irritation	Category 1
Sensitization, respiratory	Category 1
Sensitization, skin	Category 1

Environmental hazards Not classified.

OSHA defined hazards Not classified.

Label elements

Signal word Danger

Hazard statement Harmful if swallowed. Fatal if inhaled. Causes skin irritation. Causes serious eye damage. May cause an allergic skin reaction. May cause allergy or asthma symptoms or breathing difficulties if inhaled.

Precautionary statement

Prevention Do not breathe dust/fume. Wash thoroughly after handling. Wear protective gloves/protective clothing/eye protection/face protection. Use only outdoors or in a well-ventilated area. In case of inadequate ventilation wear respiratory protection.

Response	If swallowed: Call a poison center/doctor if you feel unwell. Rinse mouth. If on skin: Wash with plenty of water. If skin irritation or rash occurs: Get medical advice/attention. Take off contaminated clothing and wash before reuse. If inhaled: Remove person to fresh air and keep comfortable for breathing. Immediately call a poison center/doctor. 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.
Storage	Store in a well-ventilated place. Keep container tightly closed. Store locked up.
Disposal	Dispose of contents/container in accordance with local/regional/national/international regulations.
Hazard(s) not otherwise classified (HNOC)	None known.
Supplemental information	None.

3. Composition/information on ingredients

Substance

Chemical name	Common name and synonyms	CAS number	%
Chlorhexidine Acetate	Chlorhexidine diacetate Biguanide, 1,1'-hexamethylenebis(5-p-chlorophenyl)-, diacetate	56-95-1	100

4. First-aid measures

Inhalation	If breathing is difficult, remove to fresh air and keep at rest in a position comfortable for breathing. Oxygen or artificial respiration if needed. Do not use mouth-to-mouth method if the substance is inhaled. Induce artificial respiration with the aid of a pocket mask equipped with a one-way valve or other proper respiratory medical device. Call a physician or poison control center immediately.
Skin contact	If skin irritation or rash occurs: Get medical advice/attention. In case of eczema or other skin disorders: Seek medical attention and take along these instructions. Wash contaminated clothing before reuse. Remove contaminated clothing immediately and wash skin with soap and water.
Eye contact	Immediately flush eyes with plenty of water for at least 15 minutes. Remove contact lenses, if present and easy to do. Continue rinsing. Call a physician or poison control center immediately.
Ingestion	Rinse mouth thoroughly. If ingestion of a large amount does occur, call a poison control center immediately. Do not induce vomiting without advice from poison control center. If vomiting occurs, keep head low so that stomach content doesn't get into the lungs.
Most important symptoms/effects, acute and delayed	Irritant effects.
Indication of immediate medical attention and special treatment needed	Provide general supportive measures and treat symptomatically. Treatment of chlorhexidine overdose may include: Following ingestion without vomiting or respiratory distress in patients who are able to swallow, dilute with 4 to 8 oz. of water or milk. Do not induce vomiting. Perform gastric lavage cautiously. Activated charcoal and cathartics are not effective. Perform gastrointestinal endoscopy to evaluate for burns. Aggressive airway management in patients with any indication of upper airway injury. Treat hypotension with fluids, vasopressors if needed. Monitor vital signs and serum electrolytes, renal function and liver enzymes in symptomatic patients. Monitor arterial blood gasses, pulse oximetry, and pulmonary function tests.
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. Foam. Dry chemical or CO2. Use fire-extinguishing media appropriate for surrounding 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	Use water spray to cool unopened containers. As with all fires, evacuate personnel to a safe area. Firefighters should use self-contained breathing equipment and protective clothing.

Specific methods	Use standard firefighting procedures and consider the hazards of other involved materials.
General fire hazards	No unusual fire or explosion hazards noted.

6. Accidental release measures

Personal precautions, protective equipment and emergency procedures	Keep unnecessary personnel away. Wear appropriate personal protective equipment. Avoid inhalation of dust from the spilled material. Do not touch damaged containers or spilled material unless wearing appropriate protective clothing. Ensure adequate ventilation. For personal protection, see section 8 of the SDS.
Methods and materials for containment and cleaning up	Avoid the generation of dusts during clean-up. Sweep up or vacuum up spillage and collect in suitable container for disposal. Clean surface thoroughly to remove residual contamination. For waste disposal, see section 13 of the SDS.
Environmental precautions	Avoid discharge into drains, water courses or onto the ground.

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. Select and use containment devices and personal protective equipment based on a risk assessment of material potency and exposure potential.
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

Occupational exposure limits	No exposure limits noted for ingredient(s).
Biological limit values	No biological exposure limits noted for the ingredient(s).
Appropriate engineering controls	For laboratory operations, use good technique and limit open handling. Control exposures to below the occupational exposure level (if available). Select and use containment devices and personal protective equipment based on a risk assessment of exposure potential. Cover all containers for solutions and slurries while being transferred.

Individual protection measures, such as personal protective equipment

Eye/face protection	Wear safety glasses with side shields, chemical splash goggles, or full face shield, if necessary. Base the choice of protection on the job activity and potential for contact with eyes or face. An emergency eye wash station should be available.
Skin protection	
Hand protection	Wear nitrile or other impervious gloves if skin contact is possible. When the material is dissolved or suspended in an organic solvent, wear gloves that provide protection against the solvent.
Other	Wear lab coat. Base the choice of skin protection on the job activity, potential for skin contact and solvents and reagents in use. Do not wear protective garments in common areas (e.g., cafeterias) or out-of-doors.
Respiratory protection	Respirators are generally not required for laboratory operations. Choose respiratory protection appropriate to the task and the level of existing engineering controls.
Thermal hazards	Wear appropriate thermal protective clothing, when necessary.
General hygiene considerations	Handling practices in this SDS are recommendations for laboratory use of reference standards. Procedures for any other uses or quantities should be determined after an appropriate assessment.

9. Physical and chemical properties

Appearance	Appearance descriptions are general information and not specific to any USP lot.
Physical state	Solid.
Form	Powder.
Color	White. Off-white.
Odor	Odorless. Practically odorless.
Odor threshold	Not available.
pH	Not available.
Melting point/freezing point	307.4 - 312.8 °F (153 - 156 °C)
Initial boiling point and boiling range	Not available.
Flash point	Not available.
Evaporation rate	Not available.

Flammability (solid, gas)	Not available.
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 (77 °F (25 °C))
Vapor density	Not available.
Relative density	Not available.
Solubility(ies)	
Solubility (water)	Soluble.
Solubility (other)	Propylene glycol: Slightly soluble. Glycerol: Slightly soluble. Alcohol: Soluble.
Partition coefficient (n-octanol/water)	-1.23
Auto-ignition temperature	Not available.
Decomposition temperature	Not available.
Viscosity	Not available.
Other information	
Chemical family	Biguanide salt.
Molecular formula	C22H30Cl2N10 . 2(C2H4O2)
Molecular weight	625.56
pH in aqueous solution	6.8 Solution: 1%

10. Stability and reactivity

Reactivity	The product is stable and non-reactive under normal conditions of use, storage and transport.
Chemical stability	Stable at normal conditions.
Possibility of hazardous reactions	No dangerous reaction known under conditions of normal use.
Conditions to avoid	Contact with incompatible materials.
Incompatible materials	Strong bases. Strong acids. Potassium iodide. Oxidizing agents.
Hazardous decomposition products	Cl-. NOx. Ammonia. Irritating and/or toxic fumes or gases. Emits toxic fumes under fire conditions.

11. Toxicological information

Information on likely routes of exposure

Inhalation	Fatal if inhaled. May cause allergy or asthma symptoms or breathing difficulties if inhaled.
Skin contact	Causes skin irritation. May cause an allergic skin reaction.
Eye contact	Causes serious eye damage.
Ingestion	Harmful if swallowed.
Symptoms related to the physical, chemical and toxicological characteristics	Headache. Vertigo. Fatigue. Nausea. Vomiting. Cough. Wheezing. Sore throat. Mouth ulcers. Sore mouth or tongue. Blindness. Irritant effects.

Information on toxicological effects

Acute toxicity Fatal if inhaled. Harmful if swallowed.

Product	Species	Test Results
Chlorhexidine Acetate (CAS 56-95-1)		
Dermal		
LD50	Rabbit	> 2000 mg/kg

Product	Species	Test Results
Inhalation		
LC50	Rat	0.3 mg/l (male)
Oral		
LD50	Mouse	1.8 g/kg
	Rat	1710 mg/kg (male)
		1180 mg/kg (female)

Skin corrosion/irritation Causes skin irritation.

Serious eye damage/eye irritation Causes serious eye damage.

Local effects

Eye irritation (0.1 g, 99.5% purity)
Result: Irritant.
Species: New Zealand white rabbit
Severity: Severe.
Skin irritation
Result: Non-irritant.
Species: New Zealand white rabbit
Test Duration: 4 hours

Respiratory or skin sensitization

Respiratory sensitization May cause allergy or asthma symptoms or breathing difficulties if inhaled. Anaphylactic reactions following therapeutic use have been reported.

Skin sensitization May cause an allergic skin reaction. Individuals with eczema, leg ulcers, or leg eczema are more prone to chlorhexidine allergies.

1 % Patch test
Result: Sensitizing in 5.4% of participants.
Species: Human
Organ: Skin.
Test Duration: 42 hours
Sensitization test
Result: Non-sensitizing.
Species: Guinea pig
Organ: Skin.

Germ cell mutagenicity Knowledge about mutagenicity is incomplete.

Mutagenicity

DNA damage (rat hepatocyte)
Result: Negative.
Gene mutation assay (mouse lymphoma)
Result: Negative (with and without activation).
In vitro cytogenic assay (Chinese hamster ovary)
Result: Negative (with and without activation).

Carcinogenicity Knowledge about carcinogenicity is incomplete.

38 mg/kg/day Carcinogenicity: Drinking water, (Chlorhexidine)
Result: Negative.
Species: Rat

IARC Monographs. Overall Evaluation of Carcinogenicity

Not listed.

OSHA Specifically Regulated Substances (29 CFR 1910.1001-1053)

Not listed.

US. National Toxicology Program (NTP) Report on Carcinogens

Not listed.

Reproductive toxicity Knowledge about health hazard is incomplete.

Reproductivity

62.5 mg/kg/day Reproductivity test
Result: Adverse maternal effects; no developmental effects.
Species: Rat

Specific target organ toxicity - single exposure Knowledge about health hazard is incomplete.

Specific target organ toxicity - repeated exposure Knowledge about health hazard is incomplete.

Aspiration hazard Based on available data, the classification criteria are not met.

12. Ecological information

Ecotoxicity

Product		Species	Test Results
Chlorhexidine Acetate (CAS 56-95-1)			
Aquatic			
Crustacea	EC50	Daphnia	< 1 mg/l, 96 h
Fish	LC50	Bluegill (Lepomis macrochirus)	0.6 ppm, 96 h
		Rainbow Trout	1.9 ppm, 96 h

Persistence and degradability The product is expected to be slowly biodegradable.

Bioaccumulative potential

Octanol/water partition coefficient log Kow
-1.23

Mobility in soil No data available.

Other adverse effects No other adverse environmental effects (e.g. ozone depletion, photochemical ozone creation potential, endocrine disruption, global warming potential) are expected from this component.

13. Disposal considerations

Disposal instructions Dispose in accordance with all applicable regulations. 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.

Local disposal regulations Dispose in accordance with all applicable regulations.

Hazardous waste code The waste code should be assigned in discussion between the user, the producer and the waste disposal company.

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).

Contaminated packaging Since emptied containers may retain product residue, follow label warnings even after container is emptied.

14. Transport information

DOT

UN number UN2811
UN proper shipping name Toxic solid, organic, n.o.s. (Chlorhexidine Acetate)
Transport hazard class(es)
Class 6.1
Subsidiary risk -
Packing group II
Packaging exceptions 153
Packaging non bulk 212
Packaging bulk 242

IATA

UN number UN2811
UN proper shipping name Toxic solid, organic, n.o.s. (Chlorhexidine Acetate)
Transport hazard class(es)
Class 6.1
Subsidiary risk -
Packing group II
Other information
Passenger and cargo aircraft Allowed with restrictions.
Cargo aircraft only Allowed with restrictions.

Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code Not applicable.

DOT; IATA

General information It is the shipper's responsibility to determine the correct transport classification at the time of shipment.

15. Regulatory information

US federal regulations This product is a "Hazardous Chemical" as defined by the OSHA Hazard Communication Standard, 29 CFR 1910.1200.

Toxic Substances Control Act (TSCA)

TSCA Section 12(b) Export Notification (40 CFR 707, Subpt. D)

Not regulated.

CERCLA Hazardous Substance List (40 CFR 302.4)

Not listed.

SARA 304 Emergency release notification

Not regulated.

OSHA Specifically Regulated Substances (29 CFR 1910.1001-1053)

Not listed.

Superfund Amendments and Reauthorization Act of 1986 (SARA)

SARA 302 Extremely hazardous substance

Not listed.

SARA 311/312 Hazardous chemical Yes

Classified hazard categories
Acute toxicity (any route of exposure)
Skin corrosion or irritation
Serious eye damage or eye irritation
Respiratory or skin sensitization

SARA 313 (TRI reporting)

Not regulated.

Other federal regulations

Clean Air Act (CAA) Section 112 Hazardous Air Pollutants (HAPs) List

Not regulated.

Clean Air Act (CAA) Section 112(r) Accidental Release Prevention (40 CFR 68.130)

Not regulated.

Safe Drinking Water Act (SDWA) Not regulated.

US state regulations

California Proposition 65

California Safe Drinking Water and Toxic Enforcement Act of 1986 (Proposition 65): This material is not known to contain any chemicals currently listed as carcinogens or reproductive toxins. For more information go to www.P65Warnings.ca.gov.

International Inventories

Country(s) or region	Inventory name	On inventory (yes/no)*
Australia	Australian Inventory of Chemical Substances (AICS)	Yes
Canada	Domestic Substances List (DSL)	Yes
Canada	Non-Domestic Substances List (NDSL)	No
China	Inventory of Existing Chemical Substances in China (IECSC)	Yes
Europe	European Inventory of Existing Commercial Chemical Substances (EINECS)	Yes

Country(s) or region	Inventory name	On inventory (yes/no)*
Europe	European List of Notified Chemical Substances (ELINCS)	No
Japan	Inventory of Existing and New Chemical Substances (ENCS)	Yes
Korea	Existing Chemicals List (ECL)	No
New Zealand	New Zealand Inventory	Yes
Philippines	Philippine Inventory of Chemicals and Chemical Substances (PICCS)	No
Taiwan	Taiwan Chemical Substance Inventory (TCSI)	Yes
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 "No" indicates that one or more components of the product are not listed or exempt from listing on the inventory administered by the governing country(s).

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

Issue date 06-12-2009

Revision date 11-12-2020

Version # 04

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