

1. Identification

Product identifier	Quinidine Gluconate		
Other means of identification			
Catalog number	1595000		
Chemical name	Cinchonan-9-ol, 6'-methoxy-, (9S)-, mono-D-gluconate (salt)		
Synonym(s)	Quinidine mono-D-gluconate		
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 3
	Sensitization, skin	Category 1
OSHA hazard(s)	Not classified.	
Label elements		



Signal word	Danger		
Hazard statement	Toxic if swallowed. May cause an allergic skin reaction.		
Precautionary statement			
Prevention	Wash thoroughly after handling. Avoid breathing dust. Contaminated work clothing must not be allowed out of the workplace. Wear protective gloves.		
Response	If swallowed: Immediately call a poison center/doctor. Rinse mouth. If on skin: Wash with plenty of water. If skin irritation or rash occurs: Get medical advice/attention. Wash contaminated clothing before reuse.		
Storage	Store locked up.		
Disposal	Dispose of contents/container in accordance with local/regional/national/international regulations.		
Hazard(s) not otherwise classified (HNOC)	Not classified.		

3. Composition/information on ingredients

Substance

Hazardous components

Chemical name	Common name and synonyms	CAS number	%
Quinidine Gluconate	Quinidine mono-D-gluconate	7054-25-3	100

4. First-aid measures

Inhalation	Move to fresh air. Call a physician if symptoms develop or persist.
Skin contact	Wash off with soap and plenty of water. For minor skin contact, avoid spreading material on unaffected skin. If skin irritation or rash occurs: Get medical advice/attention.
Eye contact	Rinse with water. Get medical attention if irritation develops and persists.
Ingestion	Call a physician or poison control center immediately. Rinse mouth. 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. Do not use mouth-to-mouth method if victim ingested the substance. Induce artificial respiration with the aid of a pocket mask equipped with a one-way valve or other proper respiratory medical device.
Most important symptoms/effects, acute and delayed	May cause allergic skin reaction. Irregular heart rate.
Indication of immediate medical attention and special treatment needed	Treatment of quinidine overdose should be symptomatic and supportive and may include the following: Do NOT induce vomiting. Administer activated charcoal as a slurry. Perform gastric lavage soon after ingestion (within one hour). Protect airway by placement in Trendelenburg and left lateral decubitus position or by endotracheal intubation. Control any seizures first. Monitor plasma and serum potassium levels. In refractory dysrhythmia develops, assess calcium and magnesium. To decrease toxicity, administer sodium bicarbonate. For torsades de pointes in hemodynamically unstable patients, treat with electrical conversion. In stable patients, treat with magnesium, isoproterenol, and/or atrial overdrive pacing. Correct abnormalities (hypermagnesemia, hypokalemia, hypocalcemia). To control some types of dysrhythmias, administer phenytoin or lidocaine (type I antiarrhythmics). Phenytoin is preferred. Do NOT use procainamide or disopyramide. For initial treatment of bradycardia or heartblock, administer atropine and isoproterenol. For hypotension, infuse isotonic fluid. If hypotension persists, administer dopamine, norepinephrine, or metaraminol. For seizures, administer intravenous diazepam or lorazepam. If seizures recur, consider phenobarbital. Monitor for hypotension, dysrhythmias, respiratory depression, and need for endotracheal intubation. Evaluate for hypoglycemia, electrolytes disturbances, and hypoxia. [Meditext 2006]
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	Use fire-extinguishing media appropriate for surrounding materials. Water. Foam. Dry chemical or CO ₂ .
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.

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. Clean surface thoroughly to remove residual contamination.

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
Quinidine Gluconate (CAS 7054-25-3)	STEL	3600 micrograms/m3
	TWA	450 micrograms/m3

Biological limit values

No biological exposure limits noted for the ingredient(s).

Appropriate engineering controls

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. Local exhaust ventilation such as a laboratory fume hood or other vented enclosure is recommended, particularly for grinding, crushing, weighing, or other dust-generating procedures.

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.

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 powder.

Physical state

Solid.

Form

Powder.

Odor

Odorless.

Odor threshold

Not available.

pH

6.4 (1% aqueous solution)

Melting point/freezing point

345.2 - 350.6 °F (174 - 177 °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 density

Not available.

Relative density

Not available.

Solubility in water

Freely soluble.

Partition coefficient (n-octanol/water)

Not available.

Auto-ignition temperature	Not available.
Decomposition temperature	Not available.
Viscosity	Not available.
Other information	
Chemical family	Quinoline.
Molecular formula	C20H24N2O2 . C6H12O7
Molecular weight	520.57
Solubility (other)	Slightly soluble in alcohol.
Specific gravity	0.52

10. Stability and reactivity

Reactivity	No reactivity hazards known.
Chemical stability	Material is stable under 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	Irritating and/or toxic fumes or gases. Emits toxic fumes under fire conditions. NOx.

11. Toxicological information

Information on likely routes of exposure

Ingestion	Toxic if swallowed.
Inhalation	Due to lack of data the classification is not possible.
Skin contact	May cause an allergic skin reaction.
Eye contact	Due to lack of data the classification is not possible.
Symptoms related to the physical, chemical, and toxicological characteristics	Very bitter taste. Skin rash. Stuffy nose. Eye redness. Chest tightness. Wheezing. Stomach pain or cramping. Nausea or vomiting. Diarrhea. Yellow eyes and/or skin. Fever. Visual disturbance or intolerance to light. Dizziness. Headache. Ringing or buzzing in ears. Loss of hearing. Fainting. Confusion. Delirium. Unusual tiredness. Muscle weakness.
Delayed and immediate effects of exposure	Change in or irregular heart rate. Low blood pressure. Respiratory depression or cessation of breath. Seizures. Coma. Cardiac arrest.
Cross sensitivity	Persons sensitive to quinine or other cinchona alkaloids may be sensitive to this material also.
Medical conditions aggravated by exposure	Heart problems. Long-QT syndrome. Quinidine or quinine-induced thrombocytopenic purpura. History of torsades de pointes. Asthma. Infections. Impaired kidney or liver function. Myasthenia gravis.
Acute toxicity	Toxic if swallowed.

Product	Species	Test Results
Quinidine Gluconate (CAS 7054-25-3)		
Oral LD50	Mouse	535 mg/kg, (quinidine)
	Rat	263 mg/kg, (quinidine)
Skin corrosion/irritation	Due to lack of data the classification is not possible.	
Serious eye damage/eye irritation	Due to lack of data the classification is not possible.	
Respiratory sensitization	Due to lack of data the classification is not possible.	
Skin sensitization	May cause an allergic skin reaction.	
Germ cell mutagenicity	Due to lack of data the classification is not possible. Data from germ cell mutagenicity tests were not found.	
Carcinogenicity	Due to lack of data the classification is not possible. This material is not considered to be a carcinogen by IARC, NTP, or OSHA.	
Reproductive toxicity	Due to lack of data the classification is not possible. Quinidine has been used during pregnancy for the treatment of cardiac arrhythmias. Adverse effects that have occurred during pregnancy are mild uterine contractions, premature labor, and neonatal thrombocytopenia. At toxic doses, quinidine has been reported to cause miscarriage and possible cranial nerve injury, but, in general, adverse effects are uncommon.	
Specific target organ toxicity - single exposure	Due to lack of data the classification is not possible.	

Specific target organ toxicity - repeated exposure	Due to lack of data the classification is not possible.
Aspiration hazard	Not classified.

12. Ecological information

Ecotoxicity	There are no data on the ecotoxicity of this product.
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	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	Not available.
Hazardous waste code	Not available.
Waste from residues / unused products	Dispose of in accordance with local regulations. 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	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.

14. Transport information

DOT

UN number	UN2811
UN proper shipping name	Toxic solids, organic, n.o.s. (Quinidine Gluconate)
Transport hazard class(es)	6.1
Subsidiary class(es)	Not available.
Packing group	III

IATA

UN number	UN2811
UN proper shipping name	Toxic solid, organic, n.o.s. (Quinidine Gluconate)
Transport hazard class(es)	6.1
Subsidiary class(es)	-
Packaging group	III

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

DOT; IATA



15. Regulatory information

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
SARA 302 Extremely hazardous substance	No
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

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.

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)	Yes
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)	Yes
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)

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

Issue date 10-05-2006

Revision date 04-21-2015

Version # 02

Further information Not available.

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Revision Information This document has undergone significant changes and should be reviewed in its entirety.