Quinidine Gluconate Injection

Effective Date: 07-Mar-2006

Eli Lilly and Company
Material Safety Data Sheet

Section 1 - Chemical Product and Company

Manufacturer:
Eli Lilly and Company
Lilly Corporate Center
Indianapolis, IN 46285

Manufacturer's Emergency Phone:
1-317-276-2000
CHEMTREC:
1-800-424-9300 (North America)
1-703-527-3887 (International)

Common Name: Quinidine Gluconate Injection

Chemical Name: Cinchonan-9-ol, 6'-methoxy-, (9S)-, mono-D-gluconate (salt)
Synonym(s): 018716 Formulation; Quinidine mono-D-gluconate (salt) Injection; ; Vial No. 530 Quinidine Gluconate Injection, USP
Lilly Item Code(s): AM0530

See attached glossary for abbreviations.

Section 2 - Composition / Information on Ingredients

Ingredient	CAS	Concentration %
Quinidine Gluconate	7054-25-3	8.2
Phenol	108-95-2	0.25
Water for Injection	7732-18-5	91.5

Contains no hazardous components (one percent or greater) or carcinogens (one-tenth percent or greater) not listed above.

Exposure Guidelines:
Quinidine gluconate - LEG 300 micrograms/m3 TWA for 12 hours. LEG 450 micrograms/m3 TWA for 8 hours. 3600 micrograms/m3 for 15-minutes STEG.

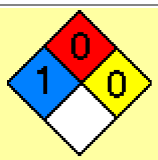
Phenol - PEL 5 ppm (19 mg/m3) TWA, TLV 5 ppm TWA (skin). BEI 250 mg total phenol per gram of creatinine in urine sampled at end of shift.
UK - Workplace Exposure Limit 2 ppm (skin).
Ireland - Occupational Exposure Limit 2 ppm (7.8 mg/m3) TWA (skin).
Italy - Occupational Exposure Limit 2 ppm (7.8 mg/m3) TWA (skin).
France - Occupational Exposure Limit 5 ppm (19 mg/m3) (VME) TWA (skin).
Spain - Occupational Exposure Limit 2 ppm (8 mg/m3) (VLA-ED) TWA (skin).
Germany - TRGS 900 Limit Value 5 ppm (19 mg/m3) TWA, 15-minute limit not to exceed MAK

(skin).

Section 3 - Hazards Identification

Appearance: Clear colorless aqueous solution
Physical State: Liquid
Odor: Odorless

Emergency Overview



Emergency Overview Effective Date: 13-Feb-2004

Lilly Laboratory Labeling Codes:
Health 1 **Fire** 0 **Reactivity** 0

Primary Physical and Health Hazards: Suspect Allergen. Nervous System and Heart Effects.

Caution Statement: Effects of exposure to Quinidine Gluconate Injection may include reduced activity, decreased heart rate, and change in heart rhythm.

Routes of Entry: Inhalation and skin contact.

Effects of Overexposure: None reported; however, skin, eye, and respiratory tract symptoms due to irritation have been reported for quinidine gluconate, including skin rashes, stuffy nose, eye redness, chest tightness, and wheezing. The most important ill effects of acute quinidine overdoses are ventricular arrhythmias and hypotension. Other signs and symptoms of overdose may include vomiting, diarrhea, tinnitus, high-frequency hearing loss, vertigo, blurred vision, diplopia, photophobia, headache, confusion, and delirium.

Medical Conditions Aggravated by Exposure: Hypersensitivity to quinidine, digitalis intoxication, heart block, and myasthenia gravis.

Carcinogenicity:
Quinidine gluconate - No carcinogenicity data found. Not listed by IARC, NTP, ACGIH, or OSHA. Phenol - IARC Group 3 (not classifiable as to human carcinogenicity). ACGIH A4 (not classifiable as a human carcinogen). Not listed by NTP or OSHA. Two-year carcinogenicity studies conducted by NTP in mice and rats demonstrated no evidence of carcinogenicity.

Section 4 - First Aid Measures

Eyes: Flush eyes with plenty of water. Get medical attention.

Skin: Remove contaminated clothing and clean before reuse. Wash all exposed areas of skin with plenty of soap and water. Get medical attention if irritation develops.

Inhalation: Move individual to fresh air. Get medical attention if breathing difficulty occurs. If not breathing, provide artificial respiration assistance (mouth-to-mouth) and call a physician immediately.

Ingestion: Do not induce vomiting. Call a physician or poison control center. If available, administer activated charcoal (6-8 heaping teaspoons) with two to three glasses of water. Do not give anything by mouth to an unconscious person. Immediately transport to a medical care facility and see a physician.

Section 5 - Fire Fighting Measures

Flash Point: No applicable information found
UEL: No applicable information found
LEL: No applicable information found

Extinguishing Media: Use water, carbon dioxide, dry chemical, foam, or Halon.

Unusual Fire and Explosion Hazards: None known.

Hazardous Combustion Products: May emit toxic fumes when exposed to heat or fire.

Section 6 - Accidental Release Measures

Spills: Prevent further migration into the environment. Use absorbent/adsorbent material to solidify liquids. Sweep up or vacuum. Wear protective equipment, including eye protection, to avoid exposure (see Section 8 for specific handling precautions).

Section 7 - Handling and Storage

Storage Conditions: Controlled Room Temperature: 15 to 30 C (59 to 86 F).

Section 8 - Exposure Controls / Personal Protection

See Section 2 for Exposure Guideline information. Under normal use and handling conditions, no protective equipment is required. The following is recommended for a production setting:

Respiratory Protection: Use an approved respirator.

Eye Protection: Safety glasses.

Ventilation: Laboratory fume hood or local exhaust ventilation.

Other Protective Equipment: Chemical-resistant gloves and body covering to minimize skin contact. If handled in a ventilated enclosure, as in a laboratory setting, respirator and goggles or face shield may not be required. Safety glasses are always required.

Section 9 - Physical and Chemical Properties

Appearance: Clear colorless aqueous solution
Odor: Odorless
Boiling Point: No applicable information found
Melting Point: Not applicable
Specific Gravity: No applicable information found
pH: 5.0-6.0
Evaporation Rate: No applicable information found
Water Solubility: Soluble
Vapor Density: No applicable information found
Vapor Pressure: No applicable information found

Section 10 - Stability and Reactivity

Stability: Stable at normal temperatures and pressures.

Incompatibility: May react with strong oxidizing agents (e.g., peroxides, permanganates, nitric acid, etc.).

Hazardous Decomposition: May emit toxic fumes when heated to decomposition.

Hazardous Polymerization: Will not occur.

Section 11 - Toxicological Information

Acute Exposure

Toxicity data for quinidine sulfate and quinidine gluconate injection (8%) solution are presented where indicated.

Oral:
Quinidine sulfate - Rat, median lethal dose 456 mg/kg.

Skin: No applicable information found.

Inhalation: No applicable information found.

Intravenous:
Quinidine gluconate injection (8% solution) - Rat, median lethal dose 72 to 77 mg/kg, immediate circulatory collapse, reduced activity.
Mouse, median lethal dose 81 mg/kg, tremors, convulsions preceding mortality.

Skin Contact: No applicable information found.

Eye Contact: No applicable information found.

Chronic Exposure

Target Organ Effects: No applicable information found.

Reproduction: No applicable information found.

Sensitization: No applicable information found.

Mutagenicity:
Quinidine - Negative in bacteria.

Section 12 - Ecological Information

No applicable ecological information found.

Section 13 - Disposal Considerations

Waste Disposal: Dispose of any cleanup materials and waste residue according to all applicable laws and regulations.

Section 14 - Transport Information

Regulatory Organizations:

DOT: Not Regulated

ICAO/IATA: Not Regulated

IMO: Not Regulated

Section 15 - Regulatory Information

Below is selected regulatory information chosen primarily for possible Eli Lilly and Company usage. This section is not a complete analysis or reference to all applicable regulatory information. Please consider all applicable laws and regulations for your country/state.

U.S. Regulations

Quinidine gluconate
TSCA - No
CERCLA - Not on this list
SARA 302 - Not on this list
SARA 313 - Not on this list
OSHA Substance Specific - No

EU Regulations

EC Classification
Not assigned an overall EC classification.

Section 16 - Other Information

MSDS Sections Revised: Section 2.

As of the date of issuance, we are providing available information relevant to the handling of this material in the workplace. All information contained herein is offered with the good faith belief that it is accurate. THIS MATERIAL SAFETY DATA SHEET SHALL NOT BE DEEMED TO CREATE ANY WARRANTY OF ANY KIND (INCLUDING WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE). In the event of an adverse incident associated with this material, this safety data sheet is not intended to be a substitute for consultation with appropriately trained personnel. Nor is this safety data sheet intended to be a substitute for product literature which may accompany the finished product.

For additional information contact:
Eli Lilly and Company
Hazard Communication
317-651-9533

For additional copies contact:
Eli Lilly and Company
1-800-LILLY-Rx (1-800-545-5979)

GLOSSARY:

ACGIH = American Conference of Governmental Industrial Hygienists
AIHA = American Industrial Hygiene Association
BEI = Biological Exposure Index
CAS Number = Chemical Abstract Service Registry Number
CERCLA = Comprehensive Environmental Response Compensation and Liability Act (of 1980)
CHAN = Chemical Hazard Alert Notice
CHEMTREC = Chemical Transportation Emergency Center
DOT = Department of Transportation
EC = European Community
EINECS = European Inventory of Existing Chemical Substances
ELINCS = European List of New Chemical Substances
EPA = Environmental Protection Agency
HEPA = High Efficiency Particulate Air (Filter)
IARC = International Agency for Research on Cancer
ICAO/IATA = International Civil Aviation Organization/International Air Transport Association
IEG = Lilly Interim Exposure Guideline
IMO = International Maritime Organization
Kow = Octanol/Water Partition Coefficient
LEG = Lilly Exposure Guideline
LEL = Lower Explosive Limit

MSDS = Material Safety Data Sheet
MSHA = Mine Safety and Health Administration
NA = Not Applicable, except in Section 14 where NA = North America
NADA = New Animal Drug Application
NAIF = No Applicable Information Found
NCI = National Cancer Institute
NIOSH = National Institute for Occupational Safety and Health
NOS = Not Otherwise Specified
NTP = National Toxicology Program
OSHA = Occupational Safety and Health Administration
PEL = Permissible Exposure Limit (OSHA)
RCRA = Resource Conservation and Recovery Act
RQ = Reportable Quantity
RTECS = Registry of Toxic Effects of Chemical Substances
SARA = Superfund Amendments and Reauthorization Act
STEG = Lilly Short Term Exposure Guideline
STEL = Short Term Exposure Limit
TLV = Threshold Limit Value (ACGIH)
TPQ = Threshold Planning Quantity
TSCA = Toxic Substances Control Act
TWA = Time Weighted Average/8 Hours Unless Otherwise Noted
UEL = Upper Explosive Limit
UN = United Nations
WEEL = Workplace Environmental Exposure Level (AIHA)