

SAFETY DATA SHEET

SECTION 1: IDENTIFICATION

Product Name: **Calcium Gluconate Injection, USP 10%**
 Supplier Name and Address: Somerset Therapeutics LLC, Hollywood, FL 33024

SECTION 2: HAZARD(S) IDENTIFICATION

GHS Pictograms



Signal Word: DANGER.

GHS Class: Serious Eye Damage, category 1.
 Skin corrosion, category 1.
 Reproductive toxicity, Effects on or via lactation.

Hazard Statements: Causes serious eye damage.
 Causes severe skin burns and eye damage.
 May cause harm to breast-fed children.

Precautionary Statements: Obtain special instructions before use.
 Do not breathe dust/fume/gas/mist/vapours/spray.
 Avoid contact during pregnancy and while nursing.
 Wash hands thoroughly after handling.
 Do not eat, drink or smoke when using this product.
 Wear protective gloves/protective clothing/eye protection/face protection.
 IF SWALLOWED: Rinse mouth. Do not induce vomiting.
 IF ON SKIN (or hair): Remove/Take off immediately all contaminated clothing. Rinse skin with water/shower.
 IF INHALED: Remove victim to fresh air and keep at rest in a position comfortable for breathing.
 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
 IF EXPOSED or CONCERNED: Get medical advice/attention.
 Immediately call a POISON CENTER or doctor/physician.
 Specific treatment (see ... on this label).
 Wash contaminated clothing before reuse.
 Store locked up.
 Dispose of contents/container in accordance with Local, State, Federal and Provincial regulations.

Emergency Overview: This product is intended for therapeutic use only when prescribed by a physician. Potential adverse reactions from prescribed doses and overdoses are described in the package insert.

Route of Exposure: Inhalation Ingestion Eye Contact Skin Absorption. Injection.

Potential Health Effects:

Eye: Contact with eyes may cause irritation.

Skin: May cause skin irritation.

Inhalation: May cause irritation of respiratory tract.

Ingestion: May cause irritation.

Signs/Symptoms: Adverse reactions from therapeutic doses include: tingling sensations, a sense of oppression or heat waves, calcium or chalky taste. Vasodilation, decreased blood pressure, bradycardia, cardiac arrhythmias, syncope, and cardiac arrest from rapid intravenous injection. Occupational exposure has not been fully investigated.

Aggravation of Pre-Existing Conditions: Individuals with ventricular fibrillation, hypercalcemia, or serum calcium levels above normal.

SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

Chemical Name	CAS#	Ingredient Percent
Calcium Gluconate	299-28-5	94 mg/mL
Calcium Saccharate, Tetrahydrate	5793-89-5	4.5 mg/mL
Water for Injection	7732-18-5	Quantity Sufficient

SECTION 4 : FIRST AID MEASURES

Eye Contact:	Immediately flush eyes with plenty of water for at least 15 to 20 minutes. Ensure adequate flushing of the eyes by separating the eyelids with fingers. Get immediate medical attention.
Skin Contact:	Immediately wash skin with plenty of soap and water for 15 to 20 minutes, while removing contaminated clothing and shoes. Get medical attention if irritation develops or persists.
Inhalation:	If inhaled, remove to fresh air. If not breathing, give artificial respiration or give oxygen by trained personnel. Seek immediate medical attention.
Ingestion:	If conscious, flush mouth out with water immediately. Call a physician or poison control center immediately. Do not induce vomiting unless directed to do so by medical personnel. Never give anything by mouth to an unconscious person.

SECTION 5 : FIRE FIGHTING MEASURES

Flash Point:	Not established.
Flash Point Method:	Not established.
Auto Ignition Temperature:	Not established.
Lower Flammable/Explosive Limit:	Not established.
Upper Flammable/Explosive Limit:	Not established.
Fire Fighting Instructions:	Evacuate area of unprotected personnel. Use cold water spray to cool fire exposed containers to minimize risk of rupture. Do not enter confined fire space without full protective gear. If possible, contain fire run-off water.
Extinguishing Media:	Use alcohol resistant foam, carbon dioxide, dry chemical, or water fog or spray when fighting fires involving this material. Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.
Protective Equipment:	As in any fire, wear Self-Contained Breathing Apparatus (SCBA), MSHA/NIOSH (approved or equivalent) and full protective gear.
Hazardous Combustion Byproducts:	Thermal decomposition products may include smoke and toxic fumes. Oxides of carbon, oxides of nitrogen and other organic substances may be formed. Other undetermined low molecular weight hydrocarbon compounds may be released in small quantities depending upon specific conditions of combustion.

SECTION 6: ACCIDENTAL RELEASE MEASURES

Personal Precautions:	Evacuate area and keep unnecessary and unprotected personnel from entering the spill area. Avoid personal contact and breathing vapors or mists. Use proper personal protective equipment as listed in Section 8.
Environmental Precautions:	Avoid runoff into storm sewers, ditches, and waterways.
Methods for containment:	Contain spills with an inert absorbent material such as soil, sand or oil dry.
Methods for cleanup:	Absorb spill with inert material (e.g., dry sand or earth), then place in a chemical waste container. After removal, flush spill area with soap and water to remove trace residue.

SECTION 7: HANDLING and STORAGE

Handling:	When handling pharmaceutical products, avoid all contact and inhalation of vapor, mists and/or fumes. Use with adequate ventilation. Use only in accordance with directions.
Storage:	Store at controlled room temperature 15 to 30°C (59 to 86°F). Do not freeze.
Work Practices:	Facilities storing or utilizing this material should be equipped with an eyewash facility and a safety shower.
Hygiene Practices:	Wash thoroughly after handling. Avoid contact with eyes and skin. Avoid inhaling vapor or mist.

SECTION 8: EXPOSURE CONTROLS, PERSONAL PROTECTION

Engineering Controls:	General ventilation is sufficient if this product is being used in a controlled medical setting (clinic, hospital, medical office) for its sole intended parenteral (injection) purpose. Otherwise, use appropriate engineering control such as process enclosures, local exhaust ventilation, or other engineering controls including use of a biosafety cabinet / fume hood to control airborne levels below recommended exposure limits.
Eye/Face Protection:	Chemical splash goggles. Wear a face shield also when splash hazard exists.
Skin Protection Description:	Protective laboratory coat, apron, or disposable garment recommended.
Hand Protection Description:	Wear appropriate protective gloves. Consult glove manufacturer's data for permeability data. Nitrile rubber or natural rubber gloves are recommended.
Respiratory Protection:	No personal respiratory protective equipment is normally required when this product is being used/administered by a licensed healthcare practitioner (i.e. an end-user such as a clinician / doctor / nurse) for its sole intended parenteral (injection) purpose in a controlled medical setting. The need for

respiratory protection will vary according to the airborne concentrations and environmental conditions. A NIOSH approved air-purifying respirator with an organic vapor cartridge or canister may be permissible under certain circumstances. Consult the NIOSH web site (<http://www.cdc.gov/niosh/nppt/topics/respirators/>) for a list of respirator types and approved suppliers.

Other Protective: Consult with local procedures for selection, training, inspection and maintenance of the personal protective equipment.

EXPOSURE GUIDELINES

SECTION 9: PHYSICAL and CHEMICAL PROPERTIES

Physical State:	Liquid solution.
Color:	Colorless to slightly yellow.
Boiling Point:	Not established.
Melting Point:	120°C
Solubility:	Soluble. in water.
Vapor Density:	Not established.
Vapor Pressure:	Not established.
Percent Volatile:	Not established.
pH:	6.0 - 8.2
Molecular Formula:	Mixture
Molecular Weight:	430.38
Flash Point:	Not established.
Flash Point Method:	Not established.
Auto Ignition Temperature:	Not established.

SECTION 10 : STABILITY and REACTIVITY

Chemical Stability:	Stable under normal temperatures and pressures.
Hazardous Polymerization:	Not reported.
Conditions to Avoid:	Protect from freezing.

SECTION 11 : TOXICOLOGICAL INFORMATION

Acute Toxicity:	Eye, skin, and respiratory irritation may occur.
Acute Effects:	Eye, skin, and respiratory irritation may occur.
Chronic Effects:	None known.
Calcium Gluconate:	
RTECS Number:	EW2100000
Ingestion:	LD50 Oral Rat: 950 mg/kg
Other Toxicological Information:	Intravenous - Rat LD50 : 950 mg/kg [Details of toxic effects not reported other than lethal dose value] Intravenous - Mouse LD50 : 950 mg/kg [Details of toxic effects not reported other than lethal dose value] Intravenous - Guinea pig LDLo : 1810 mg/kg [Cardiac - other changes Lungs, Thorax, or Respiration - dyspnea Gastrointestinal - changes in structure or function of salivary glands] Subcutaneous - Mouse LD50: 2890 mg/kg [Details of toxic effects not reported other than lethal dose value] Intraperitoneal - Mouse LD50: 2200 mg/kg [Details of toxic effects not reported other than lethal dose value]

SECTION 12: ECOLOGICAL INFORMATION

Ecotoxicity:	No ecotoxicity data was found for the product.
Environmental Stability:	No environmental information found for this product.

SECTION 13: DISPOSAL CONSIDERATIONS

Waste Disposal:	Dispose of in accordance with Local, State, Federal and Provincial regulations.
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SECTION 14: TRANSPORT INFORMATION

DOT Shipping Name: Not Regulated.

DOT UN Number: Not Regulated.

IATA Shipping Name: Non regulated.

IATA UN Number: Non regulated.

IMDG UN Number: Non regulated.

IMDG Shipping Name: Non regulated.

SECTION 15: REGULATORY INFORMATION

Calcium Gluconate:

TSCA Inventory Status: Listed

EINECS Number: 206-075-8

Canada DSL: Listed

SECTION 16: ADDITIONAL INFORMATION

HMS Ratings:

HMS Health Hazard: 1

HMS Fire Hazard: 1

HMS Reactivity: 1

HMS Personal Protection: X

SDS Creation Date: January 08, 2009

SDS Revision Date: June 01, 2015

SDS Revision Notes: Changed the color in Section 9 from Colorless to Colorless to slightly yellow, due to an update to the visual color limit.

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