CALCIUM CHLORIDE INJECTION, USP

Safety Data Sheet

According to 29 CFR 1910.1200 (g) [Federal Register Vol. 77, No. 58 Dated March 26, 2012]

MEDEFIL, INC.

Date of Issue: 09/08/2020 Revision: 001

1. IDENTIFICATION

(a) **Product Identifier**:

Product Name: Calcium Chloride Injection, USP
Trade Name: Calcium Chloride Injection, USP

(b) **Intended Use of the Product**: 10% Calcium Chloride Injection, USP is indicated for the treatment of hypocalcemia in those conditions requiring a prompt increase in plasma calcium levels.

(c) **Name, Address, Telephone of the Manufacturer**:

Medefil, Inc.
405 Windy Point Drive
Glendale Heights, IL. 60139
(630) 682 – 4600
www.medefilinc.com

(d) **Emergency Telephone Number**: 1-630-682-4600

2. HAZARDS IDENTIFICATION

(a) **Classification of the Substance of Mixture**

GHS-US Classification: Eye Irritation: Category 2A

(b) **Label Elements**

Signal Word (GHS-US): Warning
Hazard Statements (GHS-US): H319 - Causes serious eye irritation
Precautionary Statements (GHS-US): P264 - Wash hands thoroughly after handling
P280 - Wear protective gloves/protective clothing/eye protection/face protection
P305 + P351 + P338 - IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing
P337 + P313 - If eye irritation persists: Get medical advice/attention

Hazard Pictograms (GHS-US):



(c) **Other Hazards:** Exposure may aggravate pre-existing eye, skin or respiratory conditions.

(d) **Unknown Acute Toxicity (GHS-US):** No data available

3. COMPOSITION/INFORMATION ON INGREDIENTS

3.2 **Mixture**

Name	CAS Number	%	GHS-US Classification
Calcium Chloride	10035-04-8	10	Eye Irritant 2A, H319
Water for Injection	7732-18-5	90	Not classified
Hydrochloric Acid*	7647-01-0	-	Skin Corr. 1B, H314
Sodium Hydroxide*	1310-73-2	-	Skin Corr. 1A, H314

***** to adjust pH
For full text of H-phrases, see Section 16

4. FIRST AID MEASURES

4.1 **Description of First-aid Measures**

General: Never give anything by mouth to an unconscious person. If you feel unwell, seek medical advice (show the label where possible).

Skin Contact: Remove contaminated clothing. Rinse affected area with plenty of water. Obtain medical attention if irritation develops or persists.

Eye Contact: Rinse cautiously with plenty of water. Remove contact lenses, if present and easy to do. Continue rinsing. Obtain medical attention if irritation develops or persists.

Ingestion: Wash mouth with water. Do NOT induce vomiting. Obtain medical attention.

Inhalation: Move to fresh air and ventilate suspected area. If discomfort occurs, obtain medical attention.

4.2 **Most Important Symptoms and Effects Both Acute and Delayed**

After Inhalation: Prolonged exposure may cause irritation.
After Skin Contact: Prolonged exposure may cause skin irritation.
After Eye Contact: Contact causes severe irritation with redness and swelling of the conjunctiva.
Ingestion: Ingestion may cause adverse effects.
Chronic Symptoms: None expected under normal conditions of use.

4.3 **Indication of Any Immediate Medical Attention and Special Treatment Needed**

If exposed or concerned, get medical advice and attention. If medical advice is needed, have product container or label at hand.

5. FIRE-FIGHTING MEASURES

5.1. **Extinguishing Media**: As for primary cause of fire.

5.2. **Special Hazards Arising From the Substance or Mixture:**
Fire Hazard: Not flammable.
Explosion Hazard: Product is not explosive.
Reactivity: Hazardous reactions will not occur under normal conditions.

5.3. **Advice for Firefighters:** During all fire-fighting activities, wear appropriate protective

equipment, including self-contained breathing apparatus.

6. ACCIDENTAL RELEASE MEASURES

6.1. Personal Precautions, Protective Equipment and Emergency Procedures

Personnel involved in clean-up should wear appropriate personal protective equipment. Minimize exposure.

6.2. Environmental Precautions

Place waste in appropriately labeled, sealed container for disposal. Prevent entry to sewers and public waters.

6.3. Methods and Materials for Containment and Cleaning Up

Contain the source of spill, if it is safe to do so. Collect spill with absorbent material. Clean spill area thoroughly.

7. HANDLING AND STORAGE

7.1. **Precautions for Safe Handling**

Wash hands and other exposed areas with mild soap and water before eating, drinking or smoking and when leaving work. Avoid breathing vapors, mist, and spray. Avoid contact with skin, eyes and clothing. Hygiene Measures: Handle in accordance with good industrial hygiene and safety procedures.

7.2. **Conditions for Safe Storage, Including Any Incompatibilities**

Storage Conditions: Store as directed by product packaging. Do not refrigerate.
Incompatible Products: None Known.

7.3 **Specific End Use(s):**

10% Calcium Chloride Injection, USP is indicated for the treatment of hypocalcemia in those conditions requiring a prompt increase in plasma calcium levels.

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1 **Control Parameters:** Refer to available public information for specific member state Occupational Exposure Limits.

Hydrochloric Acid:	ACGIH Ceiling Threshold Limit:	2 ppm.
Sodium Hydroxide:	ACGIH Ceiling Threshold Limit:	2 mg/m^3.

8.2 **Exposure Controls:**

Appropriate Engineering Controls: Engineering controls should be used as the primary means to control exposure. General room ventilation is adequate unless the process generates dust, mist or fumes. Ensure all national/local regulations are observed.

Personal Protective Equipment: Gloves, Protective clothing, Protective goggles.
Materials for Protective Clothing: Chemically resistant materials and fabrics.
Hand Protection: Wear protective gloves.
Eye Protection: Chemical safety goggles.
Skin and Body Protection: Wear suitable protective clothing.

Respiratory Protection:	If exposure limits are exceeded or irritation is experienced, approved respiratory protection should be worn. In case of inadequate ventilation, oxygen deficient atmosphere, or where exposure levels are not known wear approved respiratory protection.
Other Information:	When using, do not eat, drink or smoke.

9. PHYSICAL AND CHEMICAL PROPERTIES

9.1. Information on Basic Physical and Chemical Properties

Physical State:	Liquid
Appearance:	Clear, colorless solution
Odor:	Odorless
Odor Threshold:	No data available
pH:	5.5 - 7.5
Evaporation Rate:	No data available
Melting Point:	No data available
Freezing Point:	No data available
Boiling Point:	No data available
Flash Point:	No data available
Auto-ignition Temperature:	No data available
Decomposition Temperature:	No data available
Flammability (solid, gas):	No data available
Vapor Pressure:	No data available
Relative Vapor Density at 20°C:	No data available
Specific Gravity:	≈ 1.1
Solubility:	Water: Freely soluble in water
Partition Coefficient:	N-Octanol/Water: No data available
Viscosity:	No data available
Calcium Chloride, USP:	No data available
Hydrochloric Acid:	No data available
Sodium Hydroxide:	No data available
Water for Injection, USP:	No data available

9.2. **Other Information** No additional information available.

10. STABILITY AND REACTIVITY

10.1.	**Reactivity:**	Hazardous reactions will not occur under normal conditions.
10.2.	**Chemical Stability:**	Stable under recommended handling and storage conditions.
10.3.	**Possibility of Hazardous Reactions:**	Hazardous polymerization will not occur.
10.4.	**Conditions to Avoid:**	Direct sunlight, extremely high or low temperatures, and incompatible materials.
10.5.	**Incompatible Materials:**	Strong acids, strong bases, strong oxidizers. Zinc. Bromine trifluoride.
10.6.	**Hazardous Decomposition Products:**	Thermal decomposition products may include Hydrogen chloride gas, chlorine.

11 TOXICOLOGICAL INFORMATION

11.1. Information on Toxicological Effects:

General Information: The information included in this section describes the potential hazards of the individual ingredients.

Short Term: May cause eye irritation (based on components).

Acute Toxicity: (Species, Route, End Point, Dose)

Calcium Chloride, USP (10035-04-8)			
Rat	Oral	LD50	1000 mg/Kg
Mouse	Oral	LD50	1940 mg/Kg

Hydrochloric Acid (7647-01-0)			
Rat	Oral	LD50	238 – 277 mg/Kg

Irritation / Sensitization: (Study Type, Species, Severity)

Calcium Chloride, USP (10035-04-8)		
Eye Irritation	Rabbit	Moderate

Skin Corrosion / Irritation: Not Classified pH: 5.5 – 7.5
Serious Eye Damage / Irritation: Not Classified pH: 5.5 – 7.5
Respiratory or Skin Sensitization: Not Classified
Germ Cell Mutagenicity: Not classified
Carcinogenicity: None of the components of this formulation are listed as a carcinogen by IARC, NTP or OSHA classified
Reproductive Toxicity: Not classified
Specific Target Organ Toxicity (Single Exposure): Not classified
Specific Target Organ Toxicity (Repeated Exposure): Not classified
Aspiration Hazard: Not classified
Symptoms/Injuries after Inhalation: Prolonged exposure may cause irritation.
Symptoms/Injuries after Skin Contact: Prolonged exposure may cause skin irritation.
Symptoms/Injuries after Eye Contact: Contact causes severe irritation with redness and swelling of the conjunctiva.
Symptoms/Injuries after Ingestion: Ingestion may cause adverse effects.
Chronic Symptoms: None expected under normal conditions of use.

12 ECOLOGICAL INFORMATION

Environmental Overview: Environmental properties have not been investigated. Releases to the environment should be avoided.

12.1 Toxicity: No data available.

12.2 Persistence and Degradability: No data available.

12.3 Bio-accumulative Potential: No data available **.**

12.4 Mobility in Soil: No data available.

13 DISPOSAL CONSIDERATIONS

13.1 Waste Treatment Methods: Dispose of contents/container in accordance with local, regional, national, and international regulations.

13.2 Ecology – Waste Materials: Avoid release to the environment.

14 TRANSPORT INFORMATION

The following refers to all modes of transportation unless specified below

14.1 In Accordance with DOT: Not regulated for transport.

14.2 In Accordance with IMDG: Not regulated for transport.

14.3 In Accordance with IATA: Not regulated for transport.

15 REGULATORY INFORMATION

Calcium Chloride, USP

CERCLA/SARA313 Emission reporting	Not listed
California Proposition 65	Not listed

Water for Injection, USP

CERCLA/SARA313 Emission reporting	Not listed
California Proposition 65	Not listed
Inventory – United States TSCA – Sec. 8(b)	Present

Hydrochloric Acid

CERCLA/SARA313 Emission reporting	1.0%
CERCLA/SARA Hazardous substances	5000 lbs
And their reportable quantities:	2270 Kg
CERCLA/SARA – Section 302 Extremely Hazardous TPQs	500 lbs
CERCLA/SARA – Section 302 Extremely Hazardous EPCRA RQs	5000 lbs
California Proposition 65	Not listed
Inventory – United States TSCA – Sec. 8(b)	Present

Sodium Hydroxide

CERCLA/SARA313 Emission reporting	Not listed
CERCLA/SARA Hazardous substances	1000 lbs
And their reportable quantities:	454 Kg
California Proposition 65	Not listed
Inventory – United States TSCA – Sec. 8(b)	Present

16 OTHER INFORMATION

Date of Preparation of Latest Information: September 08, 2020

Other Information: This document has been prepared in accordance with the SDS requirements of the OSHA Hazard Communication Standard 29 CFR 1910.1200.

GHS Full Text Phrases:

Acute Toxicity 4 (Oral)	Acute toxicity (oral) Category 4
Eye Irritation 2A	Serious eye damage/eye irritation Category 2A
Skin Corrosion / Irritation Category 1A	H314 – Causes severe skin burns
Skin Corrosion / Irritation Category 1B	
Respiratory Tract Irritation Category 3	H335 – May cause respiratory irritation
H302	Harmful if swallowed
H319	Causes serious eye irritation

Refer to Prescribing Information for further information at www.medefilinc.com

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