SAFET DATA SHEET (SDS)

CALCIUM GLUCONATE INJECTION USP,100mg/mL

- **SECTION – 1: IDENTIFICATION**

Product Name	Calcium Gluconate Injection USP, 100 mg/mL
Name of the organization	Amneal Pharmaceuticals Pvt. Ltd. Amneal Parenteral Unit, Pipan, Taluka –Sanand, District - Ahmedabad, Gujarat, India
Use of the Substance/Mixture	Pharmaceuticals
Emergency contact numbers	Phone: +91 2717 684300

- **SECTION - 2: HAZARDS IDENTIFICATION**

Principal Hazards of the product	Not classified as hazardous.
Harmful Effect of the drug on Health	**Eye:** Causes eye irritation. **Skin:** Causes skin irritation. May be harmful if absorbed through the skin. **Ingestion:** Harmful if swallowed. May cause irritation of the digestive tract. **Inhalation:** Causes respiratory tract irritation. May be harmful if inhaled. **Chronic:** No data available
Effects on the Environment	Environmental properties have not been thoroughly investigated. Releases to the environment should be avoided
Physical & Chemical Hazards	None under normal processing.

- **SECTION – 3: COMPOSITION/INFORMATION ON INGREDIENTS**

Ingredients	CAS Number
Calcium Gluconate	66905-23-5
Calcium Saccharate tetrahydrate	5793-89-5
Sodium Chloride	7440-23-5
Sodium hydroxide	1310-73-2
Water for Injection	7732-18-5

Note: The exact percentage composition of this mixture has been withheld as a trade secret

- **SECTION - 4: FIRST-AID MEASURES**

Contact With Skin	Remove contaminated clothing. Flush area with large amounts of water. Use soap. Seek medical attention.
Contact With Eyes	Flush with water while holding eyelids open for at least 15 minutes. Seek medical attention immediately
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.
Instruction for the physician	Treat symptomatically
Protection for first aiders	Use a mask, safety glasses and gloves. Wash the hand with plenty of water.

- **SECTION - 5: FIRE-FIGHTING MEASURES**

Specific hazards	Fire Hazard: Not flammable. Explosion Hazard Product is not explosive. Reactivity: Hazardous reactions will not occur under normal conditions.
Fire extinguishing media	As for primary cause of fire. Do not use a heavy water stream. Use of heavy stream of water may spread fire.
Protection equipment	As in any fire, wear self-contained breathing apparatus.
Other advice	Keep product and empty container away from heat and sources of ignition.

- **SECTION – 6: ACCIDENTAL RELEASE MEASURES**

Personal precautions	Avoid prolonged contact with eyes, skin and clothing. Avoid breathing (vapor, mist, spray).
Precautions for environmental Protection	Place waste in appropriately labelled, sealed container for disposal. Prevent entry to sewers and public waters.
Cleaning methods	For Containment: Contain any spills with dikes or absorbents to prevent migration and entry into sewers or streams. Methods for Cleaning Up: Use plastic tools to scoop up, sweep or containerize. spilled material. Use plastic drums to contain spilled materials. Wipe working surfaces to dryness, and then wash with soap and water. If spilled directly onto the ground, remove sufficient soil to ensure material is fully recovered. container for disposal

- **SECTION -7: HANDLING AND STORAGE**

Handling Appropriate technical measures	Additional Hazards When Processed: Practice good housekeeping – spillage can be slippery on smooth surface either wet or dry. 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 prolonged contact with eyes, skin and clothing. Avoid breathing vapors, mist,
Storage Recommended storage conditions	Comply with applicable regulations. Storage Conditions: Store in a dry, well-ventilated place at 20 - 25 °C (68 - 77 °F). Store away from direct sunlight and incompatible materials. Incompatible Products: Strong acids, strong bases, strong oxidizers. Do not mix with other drugKeep refrigerated. Incompatible Materials Strong oxidizing agents. Strong acids.
Recommended packaging materials	Injection/Vials in Carton in Corrugated boxes (As per label instructions)
Precautions	Do not ingest. Do not breathe dust. Wear suitable protective clothing If ingested, seek medical advice immediately and show the container or the label. Avoid contact with skin and eyes.

- **SECTION - 8: EXPOSURE CONTROL/PERSONAL PROTECTION**

Technical measures	Ensure that eyewash stations and safety showers are close to the workstation location.
Respiratory protection	Follow the OSHA respirator regulations found in 29 CFR 1910.134 or European Standard EN 149. Use a NIOSH/MSHA or European Standard EN 149 approved respirators if exposure limits are exceeded or if irritation or other symptoms are experienced.
Hand protection	Gloves.
Eye protection	Wear appropriate protective eyeglasses or chemical safety goggles as described by OSHA's eye and face protection regulations in 29 CFR 1910.133 or European Standard EN166.
Body and skin protection	Wear appropriate protective gloves and clothing to prevent skin exposure.
Specific safety protection	Do not drink or eat during handling.

- **SECTION - 9: PHYSICAL AND CHEMICAL PROPERTIES**

colour description of the vials or Appearance	Clear solution
Form	Liquid
Odor	Odorless
Water Solubility	Soluble in water
Boiling Point	No data available
Melting Point	No data available
Specific gravity	No data available
Percent Volite	No data available

- **SECTION - 10: STABILITY AND REACTIVITY**

Stability	Stable under recommended handling and storage conditions (see section 7).
Conditions to avoid	Incompatible products.
Materials to avoid	Incompatible products.
Hazardous decomposition Products	No data Available
Incompatibility	Strong acids, strong bases, strong oxidizers. Zinc. Bromine trifluoride
Hazardous Polymerization	No data Available

- **SECTION - 11: TOXICOLOGICAL INFORMATION**

Calcium Gluconate Injection USP, 100 mg/mL	Dermal contact. Eye contact. Ingestion.

Toxicity to Animals: Acute	Sodium Hydroxide ((1310-73-2) LD50 Dermal Rabbit 1350 mg/kg Hydrochloric acid (7647-01-0) LD50 Dermal Rabbit > 5010 mg/kg
OEL	Not known
Chronic Effects on Humans:	No data available.
Other Toxic Effects on Humans (Clinically)	No data available.
Special Remarks on Toxicity to animals:	Not available.
Special Remarks on Chronic Effects on Humans:	No known significant effects or critical hazards.
Special Remarks on other Toxic Effects on Humans:	No known significant effects or critical hazards.

- **SECTION - 12: ECOLOGICAL INFORMATION**

Persistence / degradation of the	Not established.
Bioaccumulation	Not established.
Aquatic Toxicity	Not established

- **SECTION - 13: DISPOSAL CONSIDERATIONS**

Product disposal	Disposed of in accordance with state and local environmental control regulations.

- **SECTION - 14: TRANSPORT INFORMATION**

IATA/ICAO – Not Regulated	**IMDG - Not Regulated**
IATA Proper shipping Name: N/A IATA UN/ID No: N/A IATA Hazard Class: N/A IATA Packaging Group: N/A IATA Label: N/A	IMDG Proper shipping Name: N/A IMDG UN/ID No: N/A IMDG Hazard Class: N/A IMDG Flash Point: N/A IMDG Label: N/A

DOT - Not Regulated
DOT Proper shipping Name: N/A
DOT UN/ID No: N/A
DOT Hazard Class: N/A
DOT Flash Point: N/A
DOT Packing Group: N/A
DOT Label: N/A

- **SECTION - 15: REGULATORY INFORMATION**

This Section Contains Information relevant to compliance with other Federal and/or state laws.

- **SECTION - 16: OTHER INFORMATION**

The above information is believed to be correct but does not purport to be all-inclusive and shall be used only as a guide. Nothing herein shall be deemed to create any warranty, express or implied. It is the responsibility of the user to determine the applicability of this information and the suitability of the material or product for any particular purpose.

- **Revision History: -**

Issue date	22-May-2024
Revision date	NA
Version #	000
Further information if any,	No

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