



SAFETY DATA SHEET

SECTION 1: IDENTIFICATION OF THE PRODUCT & THE COMPANY

a) Product Name	: Levoleucovorin Injection
b) Common/ trade Name	: Levoleucovorin Injection
c) Chemical Name	: calcium (6S)-N-{4-[[[(2-amino-5-formyl-1,4,5,6,7,8-hexahydro-4-oxo-6-pteridiny]methyl]amino]benzoyl]-L-glutamate pentahydrate.
d) Product Use	: Pharmaceutical, injectable
Product type	: Regulated prescription drug
Container Information	: Vial
e) Manufacture Name	: Gland pharma Limited
Address	: Survey No.: 143-148, 150 & 151 Industrial Park, pashamylaram Patancheru Mandal Sanga Reddy District Hyderabad- 502307 Telangana, India
Telephone Number for Info	: +91-0845-5222000

SECTION 2: HAZARDS IDENTIFICATION

Primary physical and Health Hazard:	The primary health effects anticipated in an occupational setting include irritation of eyes and skin as well as redness and local swelling after: accidental injection. In case of over-exposure by injection, effects such as headache, fatigue, vomiting, nausea, diarrhea, limb pain, hypotension and allergy may occur.
Routes of Entry:	Inhalation, eye/skin contact or ingestion
Signs and symptoms of Exposure:	Potential adverse reactions from prescribed doses and overdoses are described in the package insert. Adverse reactions from therapeutic dose include: headache, fatigue, nausea, diarrhea, limb pain, hypotension, and vomiting. Allergic reaction may also occur. Occupational exposure has not been fully investigated.
Chemical listed as carcinogen:	NTP: No IARC: No OSHA: No
Medical condition	Individuals with known hypersensitivity to Levoleucovorin



SAFETY DATA SHEET

generally aggravated by exposure	compounds or pre-existing skin and respiratory conditions.
---	--

SECTION 3 – COMPOSITION AND INGREDIENTS

Chemical Name	CAS number	mg/mL
Levoleucovorin	74050-97-8	10
Sodium Chloride	7647-14-5	8.3 mg
Sodium hydroxide	1310-73-2	q.s to pH

SECTION 4 - FIRST AID MEASURES

EYE EXPOSURE : If easy to do, remove contact lenses, if worn. Immediately flush eyes with copious quantities of water for at least 15 minutes. If irritation occurs or persists, notify medical personnel and supervisor.

Skin Contact : Wash exposed area with soap and water and remove contaminated clothing/shoes. If irritation occurs or persists, notify medical personnel and supervisor.

Ingestion : Do not induce vomiting unless directed by medical personnel. Do not give anything to drink unless directed by medical personnel. Never give anything by mouth to an unconscious person. Notify medical personnel and supervisor.

Inhalation : Immediately move exposed subject to fresh air. If not breathing, give artificial respiration. If breathing is labored, administer oxygen. Immediately notify medical personnel and supervisor.

SECTION 5: FIRE-FIGHTING MEASURES

Flash Point : Not established

Auto Ignition Temperature : Not established.

Flammable Limits : Not established

Extinguishing media : Use water spray, alcohol-resistant foam, dry chemical or carbon dioxide.

Specific hazards arising from the substance : No information identified. May emit toxic fumes of carbon monoxide, carbon dioxide, and oxides of nitrogen.

Flammability/ Explosivity : Not considered to be a fire hazard. No explosivity data available. High concentrations of finely divided airborne organic particles can potentially explode if ignited.

Advice for firefighters : Wear full protective clothing and a self-contained breathing apparatus with a



SAFETY DATA SHEET

full face piece operated in the pressure demand or other positive pressure mode.
Decontaminate all equipment after use.

SECTION 6: ACCIDENTAL RELEASE MEASURES

Personal precautions:

If product is released or spilled, take proper precautions to minimize exposure by using appropriate personal protective equipment area should be adequately ventilated. Do not breathe dust.

Environmental precautions:

Do not empty into drains. Avoid release to the environment.

Methods and material for containment and cleaning up:

DO NOT RAISE DUST. Surround spill or powder with absorbents and place a damp cloth or towel over the area to minimize entry of powder into the air. Add excess liquid to allow the material to enter solution. Capture remaining liquid onto spill absorbents. Place spill materials into a leak-proof container suitable for disposal in accordance with applicable waste disposal regulations. Decontaminate the area twice.

SECTION 7: HANDLING AND STORAGE

Precautions for safe handling: Follow recommendations for handling potent cytotoxic pharmaceutical agents (i.e., use of engineering controls and/or other personal protective equipment if needed). Avoid breathing dust. Wash thoroughly after handling.

Waste disposal Methods : Incineration in an approved incinerator is recommended refer to local, state and federal rules.

Conditions for safe storage : Store vials as directed in pack insert. Keep vials closed when not in use. Store away from incompatible materials. Protect from light. Store in refrigerator at 2°C-8°C (36°F- 46°C).

SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

Personal protective equipment

Exposure/Engineering controls:

Open handling should not be performed when handling potent substances or substances of unknown toxicity. Control exposures to below the OEL (if available). Otherwise, selection and use of containment devices and personal protective equipment should be based on a risk assessment of exposure potential. Material should be handled inside a closed process, ventilated enclosure, isolator or device of equivalent or better control that is suitable for dusts and/or aerosols.

Respiratory protection:

Choice of respiratory protection should be appropriate to the task and the level of existing engineering controls. For routine powder handling tasks, an approved and properly worn powered air-purifying respirator equipped with HEPA filters or combination filters should provide ancillary protection based on the known or



SAFETY DATA SHEET

foreseeable limitations of existing engineering controls. Use a positive-pressure air supplied respirator if there is any potential for an uncontrolled release, when exposure levels are not known or in any other circumstances where air purifying respirators may not provide adequate protection.

Hand protection:

Wear nitrile or other impervious gloves if skin contact is possible. Double gloves should be considered. When the material is dissolved or suspended in an organic solvent, wear gloves that provide protection against the solvent.

Skin protection:

Wear appropriate gloves, lab coat, or other protective over garment if skin contact is likely. Base the choice of skin protection on the job activity, potential for skin contact and solvents and reagents in use.

Eye/face protection:

Wear safety glasses with side shields, chemical splash goggles, or full face shield, if necessary. Base the choice of protection on the job activity and potential for contact with eyes or face. An emergency eye wash station should be available.

Environmental Exposure Controls:

Avoid release to the environment and operate within closed systems wherever practicable. Air and liquid emissions should be directed to appropriate pollution control devices. In case of spill, do not release to drains. Implement appropriate and effective emergency response procedures to prevent release or spread of contamination and to prevent inadvertent contact by personnel.

Other protective measures:

Wash hands in the event of contact with this substance, especially before eating, drinking or smoking. Protective equipment is not to be worn outside the work area (e.g., in common areas or out-of-doors).

Precautions:

Exposure Limits

<u>Compound</u>	<u>OEL</u>
Levoleucovorin	25 $\mu\text{g}/\text{m}^3$
Sodium chloride	5 $\mu\text{g}/\text{m}^3$
Sodium Hydroxide	2 $\mu\text{g}/\text{m}^3$



SAFETY DATA SHEET

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

Property	Levoleucovorin injection
Description:	Clear, pale yellow color solution
pH:	6.5 to 8.5
Water Solubility:	Soluble in water
Solvent Solubility:	Soluble in most organic solvents
Specific Gravity (g/ml):	No data available
Boiling Point (°C):	No data available
Melting Point (°C):	No data available
Molecular weight	No data available
Ignition Temperature (°C):	No data available
Density	No data available
Evaporation rate	No data available

SECTION 10: STABILITY AND REACTIVITY

Property	Levoleucovorin
Chemical stability	Stable under normal conditions and temperature
Conditions to avoid:	Extreme heat, any conditions that are incompatibility with water, mixing this product with incompatible chemicals
Conditions to avoid:	Avoid from strong oxidizer and Cisplatin
Hazardous decomposition products:	Carbon oxides, nitrogen oxides
Possibility of Hazardous Reactions	Hazardous polymerization will not occur

SECTION 11: TOXICOLOGICAL INFORMATION

Acute Toxicity

Component	Type	Route	Species	Dosage
Levoleucovorin	LD ₅₀	Oral	Rat	>8000 mg/kg
Levoleucovorin	LD ₅₀	Oral	Mouse	>7000 mg/kg
Levoleucovorin	LD ₅₀	Intravenous	Mouse	732 mg/kg
Levoleucovorin	LD ₅₀	Intraperitoneal	Rat	1063 mg/kg
Sodium chloride	LD ₅₀	Oral	Rat	3000 mg/kg
Sodium chloride	LD ₅₀	Oral	Rat	4000 mg/kg
Sodium hydroxide	LD ₅₀	Intraperitoneal	Mouse	40 mg/kg



SAFETY DATA SHEET

SECTION 12: ECOLOGICAL CONSIDERATIONS

Ecotoxicity: No Ecotoxicity was found for this product.

Environmental toxicity: No Environmental information was found for this product.

SECTION 13: DISPOSAL CONSIDERATIONS

Waste Disposal: - Dispose of wastes in accordance to prescribed federal, state, and local guidelines, e.g. appropriately permitted chemical waste incinerator.

SECTION 14: TRANSPORT INFORMATION

Regulatory Organizations:

USDOT: Not Regulated

ICAO/IATA: Not Regulated

IMDG: Not Regulated

SECTION 15: REGULATORY INFORMATION

Below is selected regulatory information. 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

TSCA - *No*

CERCLA - *Not on this list*

SARA 302 - *Not on this list*

SARA 313 - *Not on this list*

OSHA Substance Specific - *No*

SECTION 16: OTHER INFORMATION:

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 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.



SAFETY DATA SHEET

Glossary: This glossary contains definitions of general terms used in SDSs. Not all of these Glossary terms will apply to this SDS.

AIHA	American Industrial Hygiene Association
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
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
IMO	International Maritime Organization
KOW	Octanol/Water Partition Coefficient
LEL	Lower Explosive Limit
MSDS	Material Safety Data Sheet
MSHA	Mine Safety and Health Administration
NA	Not Applicable,
NE	Not Established
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
OEL	Occupational Exposure Limit
PEL	Permissible Exposure Limit (OSHA)
IOEL	International Occupational Exposure Limit
RCRA	Resource Conservation and Recovery Act
RQ	Reportable Quantity
RTECS	Registry of Toxic Effects of Chemical Substances
SARA	Superfund Amendments and Reauthorization Act
SDS	Safety Data Sheet
STEL	Short Term Exposure Limit
TLV	Threshold Limit Value (ACGIH)
TPQ	Threshold Planning Quantity
TSCA	Toxic Substances Control Act



SAFETY DATA SHEET

TWA	Time Weighted Average/8 Hours Unless Otherwise Noted
UEL	Upper Explosive Limit
UN	United Nations