

SAFETY DATA SHEET(SDS)

1. PRODUCT INFORMATION/IDENTIFICATION OF THE SUBSTANCE

Product Name	Calcium Folate
Common Name	Leucovorin Calcium
Chemical Name	N-[4-[[[(2-amino-5-formyl-1,4,5,6,7,8-hexahydro-4-oxo-6-pteridiny]methyl]amino]benzoyl]-L-glutamic acid, monocalcium salt;
Molecular Formula	C ₂₀ H ₂₁ N ₇ O ₇ • Ca
Molecular weight	511.5
Synonyms	Leucovorin calcium as per USP
CAS NO	1492-18-8
Recommended use	Drug substance
Recommended restrictions	No information is available
Manufacturer/Importer/Supplier/Distributor information	
Company name	Anthem Biosciences Pvt Ltd
Address	Plot No 276-P & 277-P SYNO 20, Bannikuppe Road, Harohalli Industrial Area 2nd Phase Harohalli Hobli, Kanakapura Taluk, Ramanagar District, Karnataka, India-562112
Telephone	+91 80 66724000
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2. HAZARDS IDENTIFICATION

Physical hazards	Not classified
Health hazards	Skin Corrosion/Irritation, Category 2 Serious Eye Damage/Eye Irritation, Category 2 Respiratory Sensitization, Category 1 Skin Sensitization, Category 1 Specific Target Organ Toxicity (single exposure), Category 3
OSHA hazard(s)	Not classified
Label elements	No information is available
Hazard symbol	
Signal word	GHS Signal word : Danger
Hazard statement	H315: Causes skin irritation. H317: May cause an allergic skin reaction. H319: Causes serious eye irritation. H334: May cause allergy or asthma symptoms or breathing difficulties if inhaled. H335: May cause respiratory irritation
Precautionary statement	P261: Avoid breathing {dust/fume/gas/mist/vapors/spray}. P264: Wash {hands} thoroughly after handling. P272: Contaminated work clothing should not be allowed out of the workplace. P280: Wear {protective gloves/protective clothing/eye protection/face protection}. P285: In case of inadequate ventilation wear respiratory protection.
Prevention	Wash thoroughly after handling. Wear eye/face protection
Response	P302+352: IF ON SKIN: Wash with plenty of soap and water. P304+340: IF INHALED: Remove victim to fresh air and keep at rest in a position comfortable for breathing P305+351+338: IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. P312: Call a POISON CENTER or doctor/physician if you feel unwell. P332+313: If skin irritation occurs, get medical advice/attention.

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P333+313: If skin irritation or rash occurs, seek medical advice/attention.
P337+313: If eye irritation persists, get medical advice/attention.
P342+311: If experiencing respiratory symptoms call a POISON CENTER or doctor/physician.
P362+364: Take off contaminated clothing and wash it before reuse.

Storage
Disposal
Hazard(s) not otherwise classified (HNOC)

Store locked up.
Dispose of contents/container in accordance with local/regional/national/international regulations.
Not classified.

3. COMPOSITION/INFORMATION ON INGREDIENTS

Chemical name	CAS NO	Molecular formula	Percent(%)
Calcium Folate	1492-18-8	C ₂₀ H ₂₁ N ₇ O ₇ • Ca	95.0 % to 105.0 % w/w% (anhydrous basis)

4. FIRST AID MEASURES

Inhalation If breathing is difficult, remove to fresh air and keep at rest in a position comfortable for breathing.

Skin contact Immediately wash skin with copious amounts of water for at least 15 minutes while removing contaminated clothing and shoes. If irritation persists, seek medical attention.

Eye contact Immediately wash skin with copious amounts of water for at least 15 minutes. Assure adequate flushing of the eyes by separating the eyelids with fingers. If irritation persists, seek medical attention.

Ingestion Wash out mouth with copious amounts of water for at least 15 minutes. Seek medical attention

Most important symptoms/effects, acute and delayed No information is available

Indication of immediate medical attention and special treatment needed Treatment of overdose should be symptomatic and supportive.

General information Remove from exposure. Remove contaminated clothing. For treatment advice, seek guidance from an occupational health physician or other licensed health-care provider familiar with workplace chemical exposures. Call a physician if symptoms develop or persist

5. FIRE FIGHTING MEASURES

Suitable extinguishing media In the event of a fire involving this material, alone or in combination with other materials, use alcohol resistant foam, carbon dioxide, water, or dry chemical spray . Protective clothing and self-contained breathing apparatus should be worn

Unsuitable extinguishing media A solid water stream may be inefficient

Specific hazards arising from the chemical No unusual fire or explosion hazards noted

Special protective equipment and precautions for firefighters Wear suitable protective equipment.

Fire-fighting equipment/instructions As with all fires, evacuate personnel to a safe area. Firefighters should use self-contained breathing equipment and protective clothing.

Specific methods Use standard firefighting procedures and consider the hazards of other involved materials.

6. ACCIDENTAL RELEASE MEASURES

Personal precautions, protective equipment and emergency procedure Keep unnecessary personnel away. Do not touch damaged containers or spilled material unless wearing appropriate protective clothing. Avoid raising and breathing dust, and provide adequate ventilation. Wear appropriate personal protective equipment.

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Methods and materials for containment and cleaning up Mix with sand or similar inert absorbent material, sweep up and keep in a tightly closed container for disposal. Avoid the generation of dusts during clean-up. Clean surface thoroughly to remove residual contamination for waste disposal, see section 13 of the SDS.

7. HANDLING AND STORAGE

Precautions for safe handling While handling avoid all contact and inhalation of dust/vapours associated with the material. Clean equipment and work surfaces with suitable detergent or solvent after use. After removing gloves, wash hands and other exposed skin thoroughly.

Packaging details(if any) Container closure system to be followed is detailed below. Check the LLDPE bags and HDPE container for cleanliness.

Pack the material in double LLDPE bags placed in black LDPE bags keep under Argon atmosphere and then Place it in triple laminated aluminum bags bent and heat seal the aluminum bags placed in a HDPE container. Place the product label on outer side of the HDPE container.

Conditions for safe storage, including any incompatibilities Store between 20°C to 25°C under inert atmosphere. Preserve in well closed, light and moisture resistant container

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Exposure limit values

Material	Type	Value
Calcium Folate	No information is available	

Biological limit values No biological exposure limits noted for the ingredient(s).

Appropriate engineering controls Airborne exposure should be controlled primarily by engineering controls such as general dilution ventilation, local exhaust ventilation, or process enclosure. Local exhaust ventilation is generally preferred to general exhaust because it can control the contaminant at its source, preventing dispersion into the work area. Local exhaust ventilation such as a laboratory fume hood or other vented enclosure is recommended, particularly for grinding, crushing, weighing, or other dust-generating procedures.

Individual protection measures, such as personal protective equipment

Eye/face protection Safety glasses with side shields. Use of goggles or full face protection may be required based on hazard, potential for contact, or level of exposure. Maintain eyewash facilities in the work area.

Skin protection Wear appropriate protective gloves to prevent skin exposure

Hand protection Wear Chemically compatible gloves. Use handling practices that minimize direct hand contact.

Other For handling of laboratory scale quantities, wear lab coat where significant quantities are handled, work clothing and shoes may be necessary to prevent take-home contamination.

Respiratory protection Wear respirators to reduce or control occupational exposures

Thermal hazards Not available.

General hygiene considerations Handle in accordance with good industrial hygiene and safety practice

9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance White to off white to Pale yellow solid

Physical State Solid

Molecular weight 511.5

Form Crystalline

Odor Odourless

Odor Threshold No information is available

pH No information is available

Specific Gravity No information is available

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Solubility in water	~ 0.3 mg/ml
Solubility(other)	Practically insoluble in Ethanol (95%)
Evaporation Rate	No information is available
Partition Coefficient (n-octane/water)	No information is available
Vapour Pressure	No information is available
Vapour density	No information is available
Relative density	No information is available
Initial Boiling Point	No information is available
And Boiling range	No information is available
Autoignition Temperature	No information is available
Decomposition temperature	No information is available
Viscosity	No information is available
Flash Point	No information is available
Melting Point/Freezing point	Melting Point Range: 240 - 250 °C
Flammability Limits in Air	Upper No information is available Lower
Explosion Limits	Upper No information is available Lower

10. STABILITY AND REACTIVITY

Reactivity	Stable under normal conditions.
Chemical stability	Stable under normal conditions
Possibility of hazardous reactions	No dangerous reactions known.
Conditions to avoid	Heat, Formation of toxic gases is possible during heating or in case of fire
Incompatible materials	Strong oxidizing agents.
Hazardous decomposition products	Formation of toxic gases is possible during heating or in case of fire

11. TOXICOLOGICAL INFORMATION

Information on likely routes of exposure

Ingestion	No information is available
Inhalation	May cause respiratory system irritation. May cause allergy or asthma symptoms or breathing difficulties if inhaled. Material may be irritating to the mucous membranes and upper respiratory tract
Skin contact	Causes skin irritation. May cause respiratory system irritation.
Eye contact	Causes serious eye irritation.
Delayed and immediate effects of exposure	No information is available.
Cross sensitivity	No information is available.
Medical conditions aggravated by exposure	No information is available.
Acute toxicity	Folinic Acid (calcium salt) - Toxicity Data: Oral LD50 (rat): >8 gm/kg; Intraperitoneal LD50 (rat):1063 mg/kg; Oral LD50 (mouse): >7 gm/kg; Intraperitoneal LD50 (mouse): 1036 mg/kg;
Skin corrosion/irritation	Due to lack of data the classification is not possible
Serious eye damage/eye irritation	No information is available.
Respiratory sensitization	No information is available.
Skin sensitization	No information is available.
Germ cell mutagenicity	Data from germ cell mutagenicity tests were not found
Mutagenicity	Based on available data, the classification criteria are not met.
Carcinogenicity	Based on available data, the classification criteria are not met. This material is not considered to be a carcinogen by IARC, NTP, or OSHA.
Reproductive toxicity	No information is available.

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Specific target organ toxicity - single exposure	No information is available.
Specific target organ toxicity - repeated exposure	No information is available.
Aspiration hazard	No information is available.
Additional Information	To the best of our knowledge, the chemical, physical and toxicological properties of this substance have not been thoroughly investigated.

12. ECOLOGICAL INFORMATION

Ecotoxicity	Avoid release into the environment. Runoff from fire control or dilution water may cause pollution
Persistence and degradability	No information is available.
Bio accumulative potential	No information is available.
Mobility in soil	No information is available.
Other adverse effects	No information is available.

13. DISPOSAL CONSIDERATION

Disposal instructions	Dispose in accordance with all applicable regulations.
Local disposal regulations	No information is available.
Hazardous waste code	No information is available.
Waste from residues / unused products	Dispose of in accordance with local regulations. Empty containers or liners may retain some product residues. This material and its container must be disposed of in a safe manner (see: Disposal instructions).
Contaminated packaging	Empty containers should be taken to an approved waste handling site for recycling or disposal. Since emptied containers may retain product residue, follow label warnings even after container is emptied.

14. TRANSPORT INFORMATION

DOT CLASSIFICATION	Not classified as hazardous for transport.
IATA	Not classified as hazardous for transport.
ADR CLASSIFICATION	Not classified as hazardous for transport.
IMDG/IMO CLASSIFICATION	Not classified as hazardous for transport.

15. REGULATORY INFORMATION

Local regulations should be consulted for product specific requirements.

16. OTHER INFORMATION

MSDS Created on	01-03-2021
Last revision date	NA
Current revision date	22-09-2022
Version	02

Disclaimer

The information provided in this Safety Data Sheet is correct to the best of our knowledge, information and belief at the date of its publication. The information given is designed only as a guidance for safe handling, use, processing, storage, transportation, disposal and release and is not to be considered a warranty or quality specification. The information relates only to the specific material designated and may not be valid for such material used in combination with any other materials or in any process unless specified in the text. This information has been developed by the staff of Anthem Biosciences from sources considered reliable. The user is responsible for determining the conditions of safe use of this product and for complying with all Federal, State and Local governmental laws and regulations.

If you have obtained this SDS other than in connection with the supply of this product from us, this SDS should be consulted for general information only, and should not be relied upon for any purpose.

References	1. British Pharmacopoeia SDS for Calcium folinate 2. Cayman Chemicals SDS for Folinic acid(Calcium salt)
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