

SAFETY DATA SHEET (SDS)

Folic acid Tablets, USP 1 mg

Revision Date: 24-November-2023

Version 1.0

1. IDENTIFICATION OF THE SUBSTANCE / PREPARATION AND COMPANY UNDERTAKING

Product Name: Folic acid Tablets, USP 1 mg

Product Information: Folic acid Tablets, USP

Company Name: Cadila Pharmaceuticals Limited

Address: 1389, Dholka – 382225, District: Ahmedabad, Gujarat State, India.

Phone No.: 02714/221481

Fax No.: 02714/220315

2. HAZARD(S) IDENTIFICATION:

Appearance: Yellow tablets

Statement of Hazard: Non-hazardous in accordance with international standards for workplace safety.

Additional Hazard Information:

Short Term: Not acutely toxic (based on components)

Known Clinical Effects: Ingestion of this material may cause effects similar to those seen in clinical use including effects on gastrointestinal disturbances and abdominal pain.

EU Indication of danger: Not classified

Australian Hazard Classification Non-Hazardous Substance. Non-Dangerous Goods.

(NOHSC):

Note: This document has been prepared in accordance with standards for workplace safety, which require the inclusion of all known hazards of the active substance or its intermediates regardless of the potential risk. The precautionary statements and warnings included may not apply in all cases. Your needs may vary depending upon the potential for exposure in your workplace.

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3. COMPOSITION / INFORMATION ON INGREDIENTS

Chemical Name: N-[p-[[[2-Amino-4-hydroxy-6-pteridiny]methyl]amino]-benzoyl]-Lglutamic acid

Hazardous Ingredients / Components: Not Applicable

CAS No.: 59-30-3

Other Components:

Inactive Ingredients	CAS No.
Lactose Monohydrate	10039-26-6
Microcrystalline Cellulose	9004-34-6
Sodium Starch Glycolate	9063-38-1
Lactose Monohydrate	10039-26-6
Stearic Acid	57-11-4

4. FIRST – AID MEASURES

Eye Contact Flush with water while holding eyelids open for at least 15 minutes. Seek medical attention immediately.

Skin Contact Remove contaminated clothing. Flush area with large amounts of water. Use soap. Seek medical attention.

Ingestion: Never give anything by mouth to an unconscious person. Wash out mouth with water. Do not induce vomiting unless directed by medical personnel. Seek medical attention immediately.

Inhalation: Remove to fresh air and keep patient at rest. Seek medical attention immediately.

Symptoms and Effects of Exposure: For information on potential signs and symptoms of exposure, See Section 2 – Hazards Identification and/or Section 11 - Toxicological Information.

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5. FIRE FIGHTING MEASURES

Extinguishing Media: Use carbon dioxide, dry chemical, or water spray.

Hazardous Combustion Products: Formation of toxic gases is possible during heating or fire.

Products:

Fire Fighting Procedures: During all fire fighting activities, wear appropriate protective equipment, including self contained breathing apparatus.

Fire / Explosion Hazards: Fine particles (such as dust and mists) may fuel fires/explosions.

6. ACCIDENTAL RELEASE MEASURES

Health and Safety Precautions: Personnel involved in clean-up should wear appropriate personal protective equipment (see Section 8). Minimize exposure.

Measures for Cleaning / Collecting: Contain the source of spill if it is safe to do so. Collect spilled material by a method that controls dust generation. A damp cloth or a filtered vacuum should be used to clean spills of dry solids. Clean spill area thoroughly.

Measures for Environmental Protections: Place waste in an appropriately labeled, sealed container for disposal. Care should be taken to avoid environmental release.

Additional Consideration for Large Spills: Non-essential personnel should be evacuated from affected area. Report emergency situations immediately. Clean up operations should only be undertaken by trained personnel.

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7. HANDLING AND STORAGE

General Handling: Minimize dust generation and accumulation. If tablets or capsules are crushed and/or broken, avoid breathing dust and avoid contact with eyes, skin, and clothing. When handling, use appropriate personal protective equipment (see Section 8). Wash thoroughly after handling. Releases to the environment should be avoided. Review and implement appropriate technical and procedural waste water and waste disposal measures to prevent occupational exposure or environmental releases. Potential points of process emissions of this material to the atmosphere should be controlled with dust collectors, HEPA filtration systems or other equivalent controls.

Storage: Store as directed by product packaging.

8. EXPOSURE CONTROL / PERSONAL PROTECTION

Folic Acid

Occupational Exposure Band (OEB): OEB 3 (control exposure to the range of >10ug/m³ to < 100ug/m³)

Engineering Controls: Engineering controls should be used as the primary means to control exposures. General room ventilation is adequate unless the process generates dust, mist or fumes. Keep airborne contamination levels below the exposure limits listed above in this section.

Environmental Exposure Controls: Refer to specific Member State legislation for requirements under Community environmental legislation.

Personal Protective Equipment: Refer to applicable national standards and regulations in the selection and use of personal.

Hands: Impervious gloves are recommended if skin contact with drug product is possible and for bulk processing operations.

Eyes: Wear safety glasses or goggles if eye contact is possible.

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Skin: Impervious protective clothing is recommended if skin contact with drug product is possible and for bulk processing operations.

Respiratory protection: If the applicable Occupational Exposure Limit (OEL) is exceeded, wear an appropriate respirator with a protection factor sufficient to control exposures to below the OEL.

9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance:

Folic Acid Tablets, USP 1 mg

Yellow, round, biconvex uncoated tablets, debossed with "C3" on one side and break line on other side.

Molecular formula: Mixture

Molecular weight: Mixture

10. STABILITY AND REACTIVITY

Chemical Stability: Stable under normal conditions of use.

Conditions to Avoid: Fine particles (such as dust and mists) may fuel fires/explosions.

Incompatible Materials: As a precautionary measure, keep away from strong oxidizers

11. TOXICOLOGY INFORMATION

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

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

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Mouse Oral LD 50 10 g/kg

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12. ECOLOGICAL INFORMATION

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

13. DISPOSAL CONSIDERATIONS

Waste Treatment Methods: Dispose of waste in accordance with all applicable laws and regulations. Member State specific and Community specific provisions must be considered. Considering the relevant known environmental and human health hazards of the material, review and implement appropriate technical and procedural waste water and waste disposal measures to prevent occupational exposure and environmental release. It is recommended that waste minimization be practiced. The best available technology should be utilized to prevent environmental releases. This may include destructive techniques for waste and wastewater.

14. TRANSPORT INFORMATION

The following refers to all modes of transportation unless specified below.

Not regulated for transport under USDOT, EUADR, IATA, or IMDG regulations.

15. REGULATORY INFORMATION

EU Indication of danger: Not classified

OSHA Label: Non-hazardous in accordance with international standards for workplace safety.

Canada - WHMIS: Classifications

WHMIS hazard class: None required

Folic Acid

Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present

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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.

Cadila Pharmaceutical Limited shall not be held liable for any damage resulting from handling or from contact with the above product.

Cadila Pharmaceutical Limited reserves the right to revise this MSDS.