# MATERIAL SAFETY DATA SHEETS

# **CEFPROZIL MONOHYDRATE EP IMPURITY H**

# **1.IDENTIFICATION**

## **1.1 GHS PRODUCT IDENTIFIER**

Product Name Cefprozil Monohydrate EP Impurity H
--

#### **1.2 OTHER MEANS OF IDENTIFICATION**

Product Name	Cefprozil Monohydrate EP Impurity H
Other names	6R,7R)-7-[[(2R)-2-[[(2R)-2-Amino-2-(4-hydroxyphenyl)acetyl]amino]-2-(4-hydroxyphenyl)acetyl]amino]-8-oxo-3-[(1Z)-prop-1-enyl]-5-thia-1- azabicyclo[4.2.0]oct-2-ene-2-carboxylic acid ; (6R,7R)-7-{(R)-2-{(R)-2-Amino-2-(4-hydroxyphenyl)acetamido]-2-(4-hydroxyphenyl)acetamido}-8-oxo-3- [(Z)-prop-1-enyl]-5-thia-1-azabicyclo[4.2.0]oct-2-ene-2-carboxylic acid (as per USP)

## **1.3 RECOMMENDED USE OF THE CHEMICAL AND RESTRICTIONS ON USE**

Identified uses	Industrial and scientific research uses
Uses advised against	No data available

## **1.4 SUPPLIER'S DETAILS**

Company	Cleanchem Laboratories LLP
Address	Plot No.R-80, 2nd Floor, Prama Instruments,TTC Industrial area, Rabale, Navi Mumbai, Maharashtra- 400 701
Telephone	022-27601987

#### 2. HAZARD IDENTIFICATION

# **2.1 CLASSIFICATION OF THE SUBSTANCE OR MIXTURE**

## NO DATA AVAILABLE

#### 2.2 GHS LABEL ELEMENTS, INCLUDING PRECAUTIONARY STATEMENTS

Pictogram(s)	No data available
Signal word	No data available
Hazard statement(s)	No data available
Precautionary statement(s)	
Prevention	No data available
Response	No data available
Storage	No data available
Disposal	No data available
Hazard(s) not otherwise	None known
classified (HNOC)	Pharmaceutical related compound of unknown potency.
Supplemental information	

# **3. COMPOSITION/INFORMATION ON INGREDIENTS**

# **3.1 SUBSTANCES**

NO DATA AVAILABLE

## MOLECULAR FORMULA: C26H26N4O7S MOLECULAR WEIGHT: 538.6

Chemical name	Common names and synonyms	CAS number
6R,7R)-7-[[(2R)-2-[[(2R)-2-Amino-2-(4- hydroxyphenyl)acetyl]amino]-2-(4- hydroxyphenyl)acetyl]amino]-8-oxo-3-[(1Z)-prop-1- enyl]-5-thia-1-azabicyclo[4.2.0]oct-2-ene-2-carboxylic acid ; (6R,7R)-7-{(R)-2-{(Mino-2-(4- hydroxyphenyl)acetamido]-2-(4- hydroxyphenyl)acetamido]-8-oxo-3-[(Z)-prop-1-enyl]-5- thia-1-azabicyclo[4.2.0]oct-2-ene-2-carboxylic acid (as per USP)	NA	NA

#### 4. FIRST-AID MEASURES

#### 4.1 DESCRIPTION OF NECESSARY FIRST-AID MEASURES

#### **General advice**

Medical attention is required. Consult a doctor. Show this safety data sheet (SDS) to the doctor in attendance

#### Inhalation

If breathing is difficult, remove to fresh air and keep at rest in a position comfortable for breathing. Call a physician if symptoms develop or persist.

#### Following skin contact

Take off contaminated clothing immediately. Wash off with soap and plenty of water. Consult a doctor.

#### **Following eye contact**

Rinse with pure water for at least 15 minutes. Consult a doctor.

#### **Following ingestion**

Rinse mouth with water. Do not induce vomiting. Never give anything by mouth to an unconscious person. Call a doctor or Poison Control Center immediately.

#### 4.2 MOST IMPORTANT SYMPTOMS/EFFECTS, ACUTE AND DELAYED

may cause physiological effects

# **4.3 INDICATION OF IMMEDIATE MEDICAL ATTENTION AND SPECIAL TREATMENT NEEDED, IF NECESSARY**

Treat symptomatically

#### **5. FIRE-FIGHTING MEASURES**

#### **5.1 EXTINGUISHING MEDIA**

#### Suitable extinguishing media

Water, use dry chemical, carbon dioxide or alcohol-resistant foam.

## 5.2 SPECIFIC HAZARDS ARISING FROM THE CHEMICAL

Carbon oxides, Nitrogen oxides, Hydrogen fluoride, Sulphur oxides

## **5.3 SPECIAL PROTECTIVE ACTIONS FOR FIRE-FIGHTERS**

Wear self-contained breathing apparatus for fire fighting if necessary.

## 6. ACCIDENTAL RELEASE MEASURES

6.1 Personal precautions, protective equipment and emergency procedures

Keep unnecessary personnel away. Wear appropriate personal protective equipment. Avoid

Inhalation of dust from the spilled material. Do not touch damaged containers or spilled material

Unless wearing appropriate protective clothing. Ensure adequate ventilation.

## **6.2 ENVIRONMENTAL PRECAUTIONS**

Avoid discharge into drains, water courses or onto the ground.

## 6.3 METHODS AND MATERIALS FOR CONTAINMENT AND CLEANING UP

Avoid the generation of dusts during clean-up. Sweep up or vacuum up spillage and collect in Suitable container for disposal. Clean surface thoroughly to remove residual contamination. For Waste disposal

## 7. HANDLING AND STORAGE

## 7.1 Precautions for safe handling

Avoid contact with skin and eyes. Avoid formation of dust and aerosols. Provide appropriate exhaust ventilation at places where dust is formed

# 7.2 CONDITIONS FOR SAFE STORAGE, INCLUDING ANY INCOMPATIBILITIES

Keep container tightly closed in a dry and well-ventilated place

Keep in a dry place.

Storage conditions: Refrigernator

# 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

# 8.1 Control parametersg

# **Occupational Exposure limit values**

No exposure limits noted for ingredient

# 8.2 Appropriate engineering controls

A laboratory fume hood or other appropriate form of local exhaust ventilations

# 8.3 Individual protection measures, such as personal protective equipment (PPE)

## **Eye/face protection**

Wear tightly fitting safety goggles with side-shields conforming to EN 166(EU) or NIOSH (US).

## **Skin protection**

Wear fire/flame resistant and impervious clothing. Handle with gloves. Gloves must be inspected prior to use. Wash and dry hands. The selected protective gloves have to satisfy the specifications of EU Directive 89/686/EEC and the standard EN 374 derived from it.

## **Respiratory protection**

Recommended respirators are NIOSH-approved N100 or CEN-approved FFP3 particulate respirators. These are to be only used as

a backup to local exhaust ventilation or other engineering controls. If the respirator is the only means of protection, a full-face

supplied air respirator must be used

## Thermal hazards

Wear appropriate thermal protective clothing, when necessary

# 9. PHYSICAL AND CHEMICAL PROPERTIES

Physical state Colour

Odour	
Melting point/ freezing point	
Boiling point or initial boiling point and boiling range	
Flammability	
Lower and upper explosion limit / flammability limit	
Flash point	NA
Auto-ignition temperature	NA
Decomposition temperature	NA
рН	
Kinematic viscosity	
Solubility	
Partition coefficient n- octanol/water	
Vapour pressure	NA
Density and/or relative density	NA
Relative vapour density	NA
Particle characteristics	NA

# **10. STABILITY AND REACTIVITY**

#### **10.1 Reactivity**

The product is stable and non-reactive under normal conditions of use, storage and transport

## **10.2 Chemical stability**

Material is stable under normal conditions

## **10.3 Possibility of hazardous reactions**

No dangerous reaction known under conditions of normal use

#### **10.4 Conditions to avoid**

Contact with incompatible materials

# **10.5 Incompatible materials**

Strong oxidizing agents

# **10.6 Hazardous decomposition products**

Irritating and/or toxic fumes or gases. Emits toxic fumes under fire conditions.

# **11. TOXICOLOGICAL INFORMATION**

# Acute toxicity

- ORAL LD50: NO DATA AVAILABLE
- INHALATION: NO DATA AVAILABLE
- DERMAL: NO DATA AVAILABLE

## Skin corrosion/irritation

No data available

## Serious eye damage/irritation

No data available

## **Respiratory or skin sensitization**

No data available

## Germ cell mutagenicity

No data available

# Carcinogenicity

No data available

## **Reproductive toxicity**

No data available

#### **STOT-single exposure**

No data available

## **STOT-repeated exposure**

No data available

## **Aspiration hazard**

Based on available data, the classification criteria are not met

# **12. ECOLOGICAL INFORMATION**

# **12.1 Ecotoxicity**

There are no data on the ecotoxicity of this product.

# **12.2 Persistence and degradability**

No data available

#### **12.3 Bioaccumulative potential**

No data available

#### **12.4 Mobility in soil**

No data available

## 12.5 Other adverse effects

No data available

# **13. DISPOSAL CONSIDERATIONS**

#### 13.1 Disposal methods Product

Product may be burned in an incinerator equipped with afterburner and scrubber. Excess and expired materials are to be offered to a licensed hazardous material disposal company. Ensure that all Federal and Local regulations regarding the disposal and destruction of this material are followed.

Contaminated packaging Dispose of as above.

## **14. TRANSPORT INFORMATION**

14.1 DOT: Not regulated as dangerous goods

IATA: Not regulated as dangerous goods

#### **14.2 UN Proper Shipping Name**

ADR/RID: No data available	IMDG: No data available	IATA: No data available
14.2 UN Proper Shipping Name		
ADR/RID: No data available	IMDG: No data available	IATA: No data available
14.3 Transport hazard class(es)		
ADR/RID: No data available	IMDG: No data available	IATA: No data available

# 14.4 Packing group, if applicable

ADR/RID: No data available	IMDG: No data available	IATA: No data available
14.5 Environmental hazards		
ADR/RID: No	IMDG: No	IATA: No
14.6 Special precautions for user		
No data available		
14.7 Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code		

It is the shipper's responsibility to determine the correct transport classification at the time of shipment

## **15. Regulatory information**

US federal regulations	This product is not known to be a "Hazardous Chemical" as defined by the OSHA Hazard
	Communication Standard, 29 CFR 1910.1200.

## TSCA Section 12(b) Export Notification (40 CFR 707, Subpt. D)

Not regulated.

**European Union** 

Not regulated.

## **OSHA Specifically Regulated Substances (29 CFR 1910.1001-1052)**

Not regulated.

## **16. OTHER INFORMATION**

## Abbreviations and acronyms

- CAS: CHEMICAL ABSTRACTS SERVICE
- IATA: INTERNATIONAL AIR TRANSPORTATION ASSOCIATION
- LD50: LETHAL DOSE 50%

Disclaimer: The above information is believed to be correct but does not purport to be all inclusive and shall be used only as a guide. The information in this document is based on the present state of our knowledge and is applicable to the product with regard to appropriate safety precautions. It does not represent any guarantee of the properties of the product. We as supplier shall not be held liable for any damage resulting from handling or from contact with the above product