

**MATERIAL SAFETY DATA SHEET**

<b>Product</b> : TOPIRAMATE	<b>Revision No</b> : 04
<b>Date of Issue</b> : 10.03.2014	

**1. IDENTIFICATION OF SUBSTANCE**

**Trade Name** : TOPIRAMATE  
**Company** : Cipla Limited  
Head Office - 289, Bellasis Road, Mumbai Central,  
Mumbai, Maharashtra, India (Pin Code - 400 008)  
Manufacturing division -  
Cipla Limited, Virgonagar,  
Old Madras road Bangalore-560049

**Telephone** : (+91 80) 28471180      **Fax** : (+91 80) 28472795

**E-mail** : [ckkulkarni@cipla.com](mailto:ckkulkarni@cipla.com)      **Web Site** : [www.cipla.com](http://www.cipla.com)  
**Emergency Contact No** : 022-23082891 / 022-23095521 / 022-23070160  
**Note** : Active pharmaceutical ingredient for Human consumption

**2. HAZARD IDENTIFICATION****Classification as per EC-**

**Physical** : Not Classified  
**Health** : Acute Toxicity, Category - 4  
**Environmental** : Not Classified

**Label in accordance with EC-**

**Hazard Symbols** :  
**Single Word** : Warning  
**Contains** : Topiramate Pure Material  
**Hazard Statement** - H302: Harmful if swallowed  
**Precautionary Statement** - P264: wash ...thoroughly after handling.  
P270: Do not eat, Drink or smoke when using this product.  
P301 + P312: IF SWALLOWED: Call a POISON CENTER or doctor/physician. if you feel unwell  
P330: Rinse mouth.  
P501: Dispose of contents/container

**3. COMPOSITION / INFORMATION ON INGREDIENTS**

**Chemical Name** :  $\beta$ -D-Fructopyranose, 2, 3:4, 5-bis-O-(1-methyl ethylidene) - sulfamate.  
**Molecular Formula** :  $C_{12}H_{21}NO_8S$   
**Molecular Weight** : 339.36      **EC No** : ----  
**CAS No** : 97240-79-4      **UN No** : ----

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### 4. FIRST AID MEASURES

**General Advice** : Minimize dust generation and accumulation. avoid breathing dust and avoid contact with eyes, skin, and clothing. when handling, use appropriate personal protective equipment.

**Inhalation** : If inhaled, remove to fresh air. If not breathing, give artificial respiration... if breathing is difficult, give oxygen. get medical attention

**Skin Contact** : Wash with soap and water. get medical attention if irritation develops.

**Eye Contact** : Check for and remove any contact lenses. In case of contact, immediately flush eyes with plenty of water for at least 15 minutes. get medical attention if irritation develops.

**Ingestion** : Rinse mouth, if ingestion of a large amount does occur, call a poison control center immediately.

#### **NOTES TO HEALTH PROFESSIONALS**

**Medical Treatment** : Treat symptomatically. Consult the physicians' desk reference for additional details.

**Medical conditions caused** : Data not available.

**or aggravated by exposure**

**Antidote** : Data not available

### 5. FIRE FIGHTING MEASURES

**Fire and Explosion hazard** : No unusual fire or explosion noted.

**Extinguishing media** : Water spray, dry chemical, carbon dioxide or foam as appropriate for surrounding fire and materials.

**Special fire fighting Procedure & protective Measures**: As with all fires, evacuate personnel to a safe area. Fire-fighters should use self-contained breathing apparatus and protective clothing

**Hazardous Combustion Products** : Incomplete combustion will generate poisonous carbon dioxide and other toxic gases.

### 6. ACCIDENTAL RELEASE MEASURES

**Personal Precautions** : Wear self-contained breathing apparatus, rubber boots & heavy rubber gloves.

**Environmental Precaution** : For large spills, take precautions to prevent entry into waterways, sewers, or surface drainage systems.

**Clean - up procedure** : Collect and place it in a suitable, properly labeled container for recovery or disposal. avoid the generation dust during clean-up.

**Decontamination Procedure**: Material should be disposed of in keeping with all local and national legislation. Packaging should be disposed of in keeping with all local and national legislation. Handle contaminated containers as product.

### 7. HANDLING AND STORAGE

**Handling** : Handle and open container with care. avoid all contact and inhalation of dust, mists, and/ or vapors associated with the material. after removing glove wash hands and other exposed skin thoroughly.

#### **Storage:**

1. **Bulk Storage** – Store at controlled room temperature 15 - 30 °C in tightly closed containers protected from light.
2. **Department storage** – Store at controlled room temperature 15 - 30 °C in tightly closed containers protected from light.

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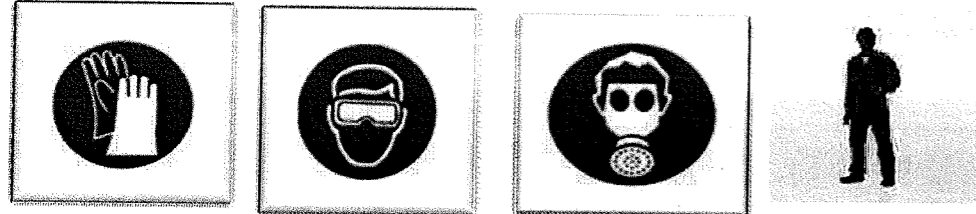
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### 8. EXPOSURE CONTROLS / PERSONAL PROTECTION

**Exposure Limits:** No data available.

**Personal protective equipments ensure before use –**

**Pictograms**



**Respiratory protection** : Be sure to use an approved/certified respirator or equivalent tested and approved under appropriate government standards such as NIOSH (US) or CEN (EU). self contained breathing apparatus should be used to avoid inhalation of the product.

**Hand protection** : Chemical resistant gloves.

**Eye protection** : Splash goggles

**Skin protection** : Protective clothing including apron / suit, shoes

**Exposure control Ventilation:** Use process enclosures, local exhaust ventilation, or other engineering controls to keep airborne levels below recommended exposure limits. if user operations generate dust, fume or mist, use ventilation to keep exposure to below the exposure limit.

**Hygiene Measure** : Immediately change contaminated clothing. Wash hands and face after working with substance

### 9. PHYSICAL AND CHEMICAL PROPERTIES

**Appearance and odour** : White to off-white powder and odorless

**Vapour pressure** : Data not available

**Flash point** : Data not available

**Melting range** : 120-130 °C

**Specific gravity** : Data not available

**Relative density** : Data not available

**Vapor density** : Data not available

**Viscosity** : Data not available

**Boiling Point** : Data not available

**Auto-ignition** : Data not available

**Flammability** : Data not available

### 10. STABILITY AND REACTIVITY

**Stability** : Stable under recommended storage conditions.

**Incompatibilities / Condition to avoid** : Incompatible with strong oxidizing agents. / No data available.

**Hazardous decomposition products** : Carbon oxides, nitrogen oxides, sulphur oxides.

**Hazardous reactions** : No data available.

**Hazardous polymerization** : Will not occur.

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### 11. TOXICOLOGICAL INFORMATION

**Oral Toxicity** : No data available.  
**Sensitization** : No data available.  
**Inhalation Toxicity** : No data available.  
**Genetic Toxicity** : No data available.  
**Skin effects** : Irritation might occur following direct contact.  
**Carcinogenicity** : No data available.  
**Eye Effects** : Irritation might occur following direct contact with eyes.  
**Reproductive Effects** : No data available.  
**Target Organ Effects** : No data available.

**Toxicity data**  
ORL-RAT LD 50 Intraperitoneal : >1500 mg/kg      SCU-RAT LD 50 : No data available.  
ORL- MICE LD 50 : No data available.              SCU-MUS LD 50 : No data available.

### 12. ENVIRONMENTAL / ECOLOGICAL INFORMATION

**Summary** : The environmental characteristics of this mixture have not been fully evaluated. releases to the environment should be avoided.  
**Ecotoxicity** : No data available.  
**Degradability** : No data available.

### 13. DISPOSAL CONSIDERATION

**Disposal Recommendations** : Dispose material as Hazardous Waste and as per applicable local, state and federal regulatory procedures and laws.

**Regulatory Requirements** : Dispose material as Hazardous Waste and as per applicable local, state and federal regulatory procedures and laws.

### 14. TRANSPORT INFORMATION (UN Classifications and Labeling)

ADR Packing group ---

ADR Class ---

Additional Pictograms -

ADR

IATA

GHS



Not dangerous goods

Not dangerous goods

**Other information** : Not regulated as a dangerous goods.

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**15. REGULATORY INFORMATION**

**Labeling according to EEC directives** : As mentioned in section 14 of this document.

**National legislation regulation  
any other regulatory information** : No data available.

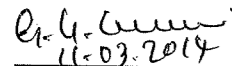
**16. OTHER INFORMATION**


**Therapeutic category of material** : Anticonvulsant

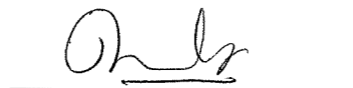
**Reference:**

1. Globally Harmonized System Of Classification And Labelling Of Chemicals (GHS)
2. Material safety data sheet from SIGMA-ALDRICH (Date 26.02.2010 version 4.0)

*The information contained herein is based on the present state of our knowledge and does not therefore guarantee certain properties. The information given was obtained from sources which we believe are reliable. The information and recommendation given are to be the best of our knowledge, accurate as of the date of issue. Nothing herein shall be deemed to create any warranty, express or implied. Recipients of material must take responsibility for observing existing laws, regulation and suitability of material for handling, transport and any particular purpose. We do not assume responsibility and expressly disclaim liability for loss, damage and expenses arising out of or in any way connected with handling, storage, use and disposal of the product. Information mentioned in this document relates only to the specific material designated and may not be valid for such material used in combination with other material or in any process.*

  
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**Prepared by  
Safety**

  
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11.03.2014

  
**Noted by 11-03-2014  
Unit Head**