



SAFETY DATA SHEET
for
TOPIRAMATE IMMEDIATE RELEASE TABLETS

1. Identification

Product Name: TOPIRAMATE IMMEDIATE RELEASE TABLETS
Synonyms: Topamax
CAS Number: Mixture
Product Use: Epilepsy
Manufacturer/Supplier: Upsher-Smith Laboratories, Inc.
Address: 6701 Evenstad Drive, Maple Grove, MN 55369
General Information: 1 - (763)-315-2000; 1-(800)-654-2299
Emergency Contacts: INFOTRAC 1-(800)-535-5053

2. Hazards Identification

GHS Classification:

Health	Environmental	Physical
Acute Toxicity: Category 4 Skin Corrosion: Category 3 Eye Corrosion: Category 2B Skin Sensitization: Not available Carcinogenicity: N/A Reproductive/Developmental: 2 Target Organ Toxicity (Repeated): Liver & Central Nervous System	Not classified	Not classified

GHS Label:

Symbols:	
<p style="text-align: center;"><u>Hazard Statements</u></p> May cause slight skin irritation. May cause slight eye irritation. Suspected of damaging fertility or the unknown child. Overexposure may cause convulsions, drowsiness, speech disturbance, blurred vision, diplopia, mentation impaired, lethargy, abnormal coordination, stupor, hypotension, abdominal pain, agitation, dizziness and depression. Overdose has also resulted in severe metabolic acidosis.	<p style="text-align: center;"><u>Precautionary Statements</u></p> Do not eat or drink in areas where Topiramate or a solution containing Topiramate is handled, processed, or stored.

3. Composition / Information on Ingredients

Component	CAS Number	Weight %
Topiramate	97240-79-4	< 40
Silicified Microcrystalline Cellulose	NA	< 30
Lactose Monohydrate	63-42-3	< 40
Sodium Starch Glycolate	9063-38-1	< 10
Magnesium Stearate	557-04-0	< 1
Cosmetic Film Coating	NA	< 5

4. First Aid Measures

Eye:	In case of eye contact, flush with copious amounts of water for at least 15 minutes. Hold eyelids away from eyeball to ensure thorough rinsing. Seek medical attention immediately.
Skin:	If redness, dryness or other signs of irritation develop, wash the affected area with plenty of warm water and soap. If irritation persists, seek medical attention immediately.
Inhalation:	In the final form not a likely route of exposure. However, in case of inhalation, remove to fresh air. If not breathing, give artificial respiration. If breathing is difficult administer oxygen. Seek medical attention immediately.
Ingestion:	In case of accidental ingestion, give the victim several glasses of water to drink. Do not induce vomiting unless directed to do so by medical personnel. Do not force an unconscious or convulsing person to drink liquids or to vomit. Seek medical attention immediately.

5. Fire Fighting Measures

Suitable Extinguishing Media:	Use an appropriate media including water spray, dry powder, foam, carbon dioxide.
Firefighting Procedures:	Wear self-contained breathing apparatus and personal protective equipment to prevent contact with skin and eyes.
Unusual Fire and Explosion Hazards	Not applicable

Combustion Products When heated to decomposition it emits toxic gases (such as carbon monoxide) and fumes may be released in a fire involving Topiramate.

6. Accidental Release Measures

Spill Response

Instructions:

The following spill response instructions only apply to bulk quantities of the material. Report emergency situations immediately. Non-essential personnel should be evacuated from the affected area. Spills should be cleaned up in a manner that minimizes exposure to personnel. Personnel involved in the clean up of spills should wear the appropriate respiratory protection, gloves, eye protection, and protective coveralls. Remove all sources of heat and ignition. Cover spill with absorbent material and collect for disposal. Ventilate the area and clean spill area thoroughly with soap and water. Collect wash with absorbent material and transfer all waste to a labeled container for disposal. Observe all applicable regulations when disposing of this substance.

7. Handling and Storage

General Handling

In a manufacturing setting or other situation where exposure to aerosols may occur appropriate personal protective equipment, including respiratory protection, must be worn. Use good personal hygiene – wash hands and exposed skin thoroughly with soap and water after use. Remove any contaminated clothing and clean before reuse. Destroy contaminated belts and shoes and other items that cannot be decontaminated.

Keep away from heat and flame. Keep operating temperatures below ignition temperatures at all times. Use non-sparking tools.

Storage

When not in use, store in a cool, dry, well-ventilated area, in tightly sealed containers that are labeled in accordance with OSHA's Hazard Communication Standard [29 CFR 1910.1200]. Keep away from ignition sources including electrostatic charge, heat, sparks, open flame, and strong oxidizers. In case of insufficient ventilation, wear suitable respiratory protection. Keep this drug out of the reach of children. Protect from physical damage. Do not cut, grind, or weld on or near containers unless precautions are taken against these hazards.

8. Exposure Controls / Personal Protection

Exposure Limits

Component Name	WEEL (TWA)	OSHA PEL (TWA)	ACGIH TLV (TWA)	NIOSH REL
Magnesium Stearate	N.E.	N.E.	10 mg/m ³	N.E.

Engineering Controls: In a manufacturing setting, local exhaust ventilation may be necessary to control air contaminants to their exposure limits. The use of local ventilation is recommended to control emissions near the source. Provide mechanical ventilation for confined spaces.

Personal Protective Equipment (PPE)

In a manufacturing setting, the following personal protective equipment requirements apply:

Eye Protection: Wear appropriate chemical safety goggles, safety glasses or face shield as described by OSHA's eye and face protection regulations in 29 CFR 1910.133. Have eyewash stations available where eye contact can occur.

Skin Protection: Avoid skin contact. Wear gloves impervious to conditions of use. Additional protection may be necessary to prevent skin contact including the use of an apron, face shield, boots, or full body protection. A safety shower should be located in the work area.

Respiratory Protection: If exposure limits are exceeded, approved respiratory protection should be worn. Seek professional assistance for proper selection of respiratory protection.

9. Physical and Chemical Properties

Flash Point: N/A	Lower Flammability Limit: N/A
Autoignition Temperature: N/A	Upper Flammability Limit: N/A
Boiling Point: N/A	Specific Gravity: N/A
Melting Point: 88°C	% Volatile: N/A
Vapor Pressure: N/A	Evaporation Rate (Water=1): N/A
Vapor Density: N/A	Viscosity: N/A
% Solubility in Water: N/A	Octanol/Water Partition Coefficient: N/A
Pour Point: N/A	pH: N/A
Molecular Formula: Mixture	Molecular Weight: Mixture
Odor/Appearance: White odorless solid	

10. Stability and Reactivity

Stability/Incompatibility: The mixture is stable under normal conditions of use.

11. Toxicology Information

Signs and Symptoms of Overexposure: In its final form overexposure is unlikely. Signs and symptoms of reported overexposures include convulsions, drowsiness, speech disturbance, blurred vision, diplopia, mentation impaired, lethargy, abnormal coordination, stupor, hypotension, abdominal pain, agitation, dizziness and depression. Overdose has also resulted in severe metabolic acidosis.

Eye Contact: May cause slight irritation. Avoid contact with eyes.

Skin Contact: May cause slight irritation. Avoid contact with skin.

Inhalation: In the final form, not a likely route of exposure. However, in case of inhalation, respiratory tract irritation may occur.

Ingestion: May result in slight irritation of the mouth and throat and abdominal pain.

Target Organ Effects: Reproductive, Liver, and Central Nervous System.

Chronic Effects: Topiramate is a suspected human teratogen. It has been shown to cause teratogenic effects and embryo fetal toxicity in rabbits, rats, and mice. FDA Pregnancy Category D

Acute Toxicity Values:

LD50 (rat oral) = >1500 mg/kg (for Topiramate)

12. Ecological Information

Ecological impact data has not been determined for this mixture.

13. Disposal Considerations

Disposal Procedure: Must dispose of in accordance with all local, state, and federal regulations.

14. Transportation Information

U. S. Department of Transportation (DOT)

Proper Shipping Name: N/A

Hazard Class: N/A

UN/NA Number: N/A

Packing Group: N/A

Labels Required: N/A

International Maritime Organization (MDG)

Proper Shipping Name: N/A

Hazard Class: N/A

UN/NA: N/A

Packing Group: N/A

Labels Required: N/A

15. Regulatory Information

U. S. Federal Regulations

Not regulated.

Toxic Substance Control Act (TSCA): Magnesium Stearate is included on the TSCA inventory.

Clean Water Act (CWA): There are no ingredients in this mixture listed in the Clean Water Act.

Clean Air Act (CAA): There are no ingredients in this mixture listed under the Clean Air Act.

Superfund Amendments and Reauthorization Act (SARA) Title III Information: There are no ingredients in this mixture listed under SARA.

State Regulations

California: This product contains chemical(s) known to the State of California to cause cancer, birth defects or reproductive harm, which would require a warning under the statute: Magnesium Stearate, Sodium Starch Glycolate (heavy metals)

Canadian Environmental Protection Act: Lactose Monohydrate, Sodium Starch Glycolate and Magnesium Stearate are listed on the Canadian Domestic Substances list (DSL).

Canadian Workplace Hazardous Materials Information System (WHMIS): Lactose Monohydrate and Magnesium Stearate are controlled by the WHMIS.

European Inventory of Existing Chemicals (EINECS): Two components contained in this product (Lactose Monohydrate and Magnesium Stearate) are included on the European Inventory of Existing Commercial Chemical Substances.

EU Classification: European labeling in accordance with EC directives.

EU Risk (R) and Safety (S) Phrases:

R36/37/38: Irritating to eyes, respiratory system and skin.

R22: Harmful if swallowed.

R61: May cause harm to the unborn child.

S26: In case of contact with eyes, rinse immediately with plenty of water and seek medical advice.

S36: Wear suitable protective clothing.

16. Other Information

National Fire Protection Association (NFPA) Warnings

Health: 1 Flammability: 1 Reactivity: 0 Other: 0

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