



## Safety Data Sheet

For Compliance with OSHA 29 CFR 1910.1200 and ANSI Z400.1-1998

Topiramate USP

30-4671

### Section 1: Identification

**Product Name** Topiramate USP  
**Commercial Name** Topiramate  
**Product Use** Pharmaceutical ingredient  
**Restrictions On Use** Not available

**Product Code** 30-4671

**Company** PCCA  
9901 South Wilcrest  
Houston, TX 77099  
Phone: 1-800-331-2498  
Fax: 1-800-874-5760

In case of emergency contact:  
**CHEMTREC (24hr) 1-800-424-9300**

### Section 2: Hazard(s) Identification

**OSHA Haz Com:** Skin Irrit. 2 - skin irritation (hazard category 2) Eye Irrit. 2 – eye irritation (hazard category 2) STOT SE -  
**CFR 1910.1200** specific target organ toxicity - single exposure (hazard category 3)

**Signal Word** WARNING

**Hazard Statement(s)** Causes skin irritation. Causes serious eye irritation. May cause respiratory irritation.

**Pictogram(s) or Symbol(s)**



#### Precautionary Statement(s):

<b>Prevention</b>	Obtain special instructions before use. Do not handle until all safety precautions have been read and understood. Wear protective gloves/protective clothing/eye protection/face protection.
<b>Response</b>	If exposed or concerned: Get medical advice/attention.
<b>Storage</b>	Store locked up.
<b>Disposal</b>	Dispose of contents/container in accordance with local/regional/national/international regulations

### Section 3: Composition/Information on Ingredients

**Substance/Mixture** Substance  
**Components** Topiramate  
**% By Weight** 100  
**CAS#** 97240-79-4  
**Molecular Weight** 339.36  
**Chemical Formula** C12H21NO8S  
**Synonym(s)** 2,3:4,5 - Bis-(7-(1-Metlaylethylidene),-beta-D-fructopyranose sulfamate

#### Mixtures

Name	CAS#	% by Weight	TLV/PEL	LC50/LD50
Topiramate	97240-79-4	100	N/A	N/A

**Section 4: First-Aid Measures**

<b>Inhalation</b>	Move to fresh air. Call a physician if symptoms develop or persist.
<b>Skin Contact</b>	Wash off with soap and water. Get medical attention if irritation develops and persists
<b>Eye Contact</b>	Rinse with water. Get medical attention if irritation develops and persists
<b>Ingestion</b>	Rinse mouth. Get medical attention if symptoms occur. If ingestion of a large amount does occur, call a poison control center immediately.
<b>Symptoms/Effects</b>	
<b>Acute</b>	Central nervous system effects. Mood or mental changes. Metabolic acidosis. Pharmacologically active material. Occupational exposure may cause physiological effects
<b>Delayed</b>	Central nervous system effects. Mood or mental changes. Metabolic acidosis. Pharmacologically active material. Occupational exposure may cause physiological effects

**Immediate Medical Attention**

Provide general supportive measures and treat symptomatically. Treatment of overdose may include: Do not induce vomiting. Administer activated charcoal as a slurry. For acidosis, administer sodium bicarbonate. For hypotension, infuse 10- 20 mL/kg isotonic fluid. Administer dopamine or norepinephrine if hypotension persists. For seizures, administer a benzodiazepine intravenously, followed by phenobarbital or propofol if the seizures recur. Monitor for hypotension, dysrhythmias, respiratory depression, and need for endotracheal intubation. Evaluate for hypoglycemia, electrolyte disturbances, hypoxia. Hemodialysis may be of benefit.

**Section 5: Fire-Fighting Measures****Suitable Extinguishing Media**

Water. Foam. Dry chemical or CO<sub>2</sub>. Use fire-extinguishing media appropriate for surrounding materials.

**Unsuitable Extinguishing Media**

Not available.

**Products of Combustion**

Explosion hazard: Avoid generating dust; fine dust dispersed in air in sufficient concentrations and in the presence of an ignition source is a potential dust explosion hazard.

**Firefighters Special Equipment and Precautions**

Wear suitable protective equipment. Use water spray to cool unopened containers. As with all fires, evacuate personnel to a safe area. Firefighters should use self-contained breathing equipment and protective clothing. Use standard firefighting procedures and consider the hazards of other involved materials.

**Section 6: Accidental Release Measures**

Dust deposits should not be allowed to accumulate on surfaces, as these may form an explosive mixture if they are released into the atmosphere in sufficient concentration. 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. For personal protection, see section 8 of the SDS. 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, see section 13 of the SDS. Environmental precautions: Avoid discharge into drains, water courses or onto the ground.

**Section 7: Handling and Storage**

Handling: As a general rule, when handling USP Reference Standards, avoid all contact and inhalation of dust, mists, and/or vapors 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. Avoid significant deposits of material, especially on horizontal surfaces, which may become airborne and form combustible dust clouds and may contribute to secondary explosions. Combustible dust clouds may be created where operations produce fine material (dust). Select and use containment devices and personal protective equipment based on a risk assessment of material potency and exposure potential. Storage: Store in tight container as defined in the USP-NF. This material should be handled and stored per label instructions to ensure product integrity.

**Section 8: Exposure Controls/Personal Protection**

<b>Exposure Limits</b>	TWA 0.01 mg/m <sup>3</sup>
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**Engineering Controls**

For laboratory operations, use local exhaust ventilation or a ventilated enclosure for high energy operations such as particle sizing. Control exposures to below the occupational exposure level (if available). Select and use containment devices and personal protective equipment based on a risk assessment of exposure potential. Cover all containers for solutions and slurries while being transferred.

**Personal Protection**

Eye/face protection: Wear safety glasses with side shields, chemical splash goggles, or full face shield, if necessary. Base the choice of protection on the job activity and potential for contact with eyes or face. An emergency eye wash station should be available. Skin protection Hand protection: Wear nitrile or other impervious gloves if skin contact is possible. When the material is dissolved or suspended in an organic solvent, wear gloves that provide protection against the solvent. Other: Train employees in proper gowning and degowning practices. Wear lab coat. Base the choice of skin protection on the job activity, potential for skin contact and solvents and reagents in use. Do not wear protective garments in common areas (e.g., cafeterias) or out-of-doors. Respiratory protection: Respirators are generally not required for laboratory operations. Use a tight-fitting full-face respirator with HEPA filters for spill cleanup. Choose respiratory protection appropriate to the task and the level of existing engineering controls. Thermal hazards: Wear appropriate thermal protective clothing, when necessary. General hygiene considerations: Handling practices in this SDS are recommendations for laboratory use of reference standards. Procedures for any other uses or quantities should be determined after an appropriate assessment.

**Section 9: Physical and Chemical Properties**

<b>Appearance</b>	White to off-white Crystalline powder. Solid.		
<b>Odor</b>	Odorless		
<b>Odor Threshold</b>	Not available		
<b>Melting Point</b>	251.6 - 262.4 °F (122 - 128 °	<b>pH</b>	in aqueous solution 6.3 (saturated
<b>Freezing Point</b>	Not available	<b>Vapor Pressure</b>	N/A
<b>Boiling Point/Range</b>	Not available.	<b>Vapor Density</b>	N/A
<b>Decomposition temperature</b>	Not available	<b>Viscosity</b>	N/A
<b>Partition Coefficient: n-octanol/water</b>	Not available	<b>Evaporation Rate</b>	Not available
<b>Flash Point</b>	N/A	<b>Autoignition temperature</b>	Not applicable
<b>Flammability</b>	Not available	<b>Flammability or Explosive Limits:</b>	
		<b>Lower</b>	Not available
		<b>Upper</b>	Not available
<b>Solubility(ies)</b>	Sparingly soluble in water. Most soluble in alkaline solutions with sodium hydroxide or sodium phosphate (pH 9 to 10)		
<b>Other</b>	Ethanol: Freely soluble. Dichloromethane: Freely soluble. Dimethylsulfoxide: Freely soluble. Chloroform: Freely soluble. Acetone: Freely soluble. Chemical family Sulfamate-substituted monosaccharide. Dust explosion properties Kst 214 bar.m/s Molecular formula C12H21NO8S Molecular weight 339.36		

**Section 10: Stability and Reactivity**

<b>Reactivity</b>	The product is stable and non-reactive under normal conditions of use, storage and transport.
<b>Chemical Stability</b>	Material is stable under normal conditions.
<b>Hazardous Polymerization</b>	No dangerous reaction known under conditions of normal use.
<b>Conditions to Avoid</b>	Contact with incompatible materials
<b>Incompatible Materials</b>	Acids.
<b>Hazardous Decomposition Products</b>	NOx, SOx. Irritating and/or toxic fumes or gases. Emits toxic fumes under fire conditions.

**Section 11: Toxicological Information**

<b>RTECS</b>	N/A
<b>Acute Toxicity</b>	Oral LD50 Mouse 2915 mg/kg (female), 2338 mg/kg (male) Rat 3745 mg/kg (male), 2436 mg/kg (female)
<b>Skin Corrosion/Irritation</b>	Not available
<b>Serious Eye Damage/Irritation</b>	Not available
<b>Respiratory or Skin Sensitization</b>	Not available
<b>Germ Cell Mutagenicity</b>	Not available
<b>Carcinogenicity</b>	Not available
<b>Reproductive Toxicity</b>	Suspected of damaging fertility or the unborn child. Data from registries indicate that therapeutic use of this material during pregnancy increases the risk for oral clefts in offspring.

**Routes of Entry**

Ingestion.

**Symptoms Related to Exposure**

Headache. Dizziness. Drowsiness. Stupor. Anxiety. Confusion. Depression. Tremor. Unsteadiness. Slowed reaction times. Numbness, pain, tingling, or weakness in hands or feet. Memory loss. Speech or language disturbances. Visual disturbances. Loss of appetite. Weight loss. Unpleasant taste. Rapid breathing. Fever. Gastrointestinal disturbances.

**Potential Health Effects**

Not available

**Target Organ(s)**

Not available

**Section 12: Ecological Information****Ecotoxicity**

The product is not classified as environmentally hazardous. However, this does not exclude the possibility that large or frequent spills can have a harmful or damaging effect on the environment.

**Persistence and Degradability**

Not available

**Bioaccumulative Potential**

Not available

**Mobility in Soil**

Not available

**Other Adverse Effects**

Not available

**Section 13: Disposal Considerations****Waste Disposal**

Dispose in accordance with all applicable regulations. Under RCRA, it is the responsibility of the user of the product to determine, at the time of disposal, whether the product meets RCRA criteria for hazardous waste. The waste code should be assigned in discussion between the user, the producer and the waste disposal company. 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)

**Disposal of Container**

Since emptied containers may retain product residue, follow label warnings even after container is emptied. Empty containers should be taken to an approved waste handling site for recycling or disposal

**Other Considerations**

Not available

**Section 14: Transport Information****DOT Classification**

DOT Not regulated as dangerous goods.

**Section 15: Regulatory Information****Regulations**

US federal regulations: This product is 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. CERCLA Hazardous Substance List (40 CFR 302.4) Not listed. SARA 304 Emergency release notification Not regulated. OSHA Specifically Regulated Substances (29 CFR 1910.1001-1052) Not regulated. SARA 302 Extremely hazardous substance Superfund Amendments and Reauthorization Act of 1986 (SARA) Not listed. YesSARA 311/312 Hazardous chemical Combustible dust Reproductive toxicity Classified hazard categories SARA 313 (TRI reporting) Not regulated. Other federal regulations Clean Air Act (CAA) Section 112 Hazardous Air Pollutants (HAPs) List Not regulated. Clean Air Act (CAA) Section 112(r) Accidental Release Prevention (40 CFR 68.130) Not regulated. Not regulated. Safe Drinking Water Act (SDWA) US state regulations California Proposition 65 This product can expose you to Topiramate, which is known to the State of California to cause birth defects or other reproductive harm. For more information go to [www.P65Warnings.ca.gov](http://www.P65Warnings.ca.gov). WARNING: California Proposition 65 - CRT: Listed date/Developmental toxin Topiramate (CAS 97240-79-4) Listed: November 27, 2015



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Other  
N/A

### Section 16: Other Information

USE AND RESTRICTIONS: Pharmaceutical uses. APPLICATIONS: Anticonvulsant The above mentioned data correspond to our present state of knowledge and experience. They serve as a description of the products in regard to necessary safety measures and do not guarantee the described chemical properties.