

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 - specific target organ toxicity - single exposure (hazard category 3)

CFR 1910.1200

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):

Prevention	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.
Response	If exposed or concerned: Get medical advice/attention.
Storage	Store locked up.
Disposal	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-Metylallylidene),-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

Inhalation	Move to fresh air. Call a physician if symptoms develop or persist.
Skin Contact	Wash off with soap and water. Get medical attention if irritation develops and persists
Eye Contact	Rinse with water. Get medical attention if irritation develops and persists
Ingestion	Rinse mouth. Get medical attention if symptoms occur. If ingestion of a large amount does occur, call a poison control center immediately.
Symptoms/Effects	
Acute	Central nervous system effects. Mood or mental changes. Metabolic acidosis. Pharmacologically active material. Occupational exposure may cause physiological effects
Delayed	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 CO₂. 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**Exposure Limits**TWA 0.01 mg/m³

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

Appearance	White to off-white Crystalline powder. Solid.		
Odor	Odorless		
Odor Threshold	Not available		
Melting Point	251.6 - 262.4 °F (122 - 128 °	pH	in aqueous solution 6.3 (saturated
Freezing Point	Not available	Vapor Pressure	N/A
Boiling Point/Range	Not available.	Vapor Density	N/A
Decomposition temperature	Not available	Viscosity	N/A
Partition Coefficient: n-octanol/water	Not available	Evaporation Rate	Not available
Flash Point	N/A	Autoignition temperature	Not applicable
Flammability	Not available	Flammability or Explosive Limits:	
		Lower	Not available
		Upper	Not available
Solubility(ies)	Sparingly soluble in water. Most soluble in alkaline solutions with sodium hydroxide or sodium phosphate (pH 9 to 10)		
Other	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

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

Section 11: Toxicological Information

RTECS	N/A
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Acute Toxicity

Oral LD50 Mouse 2915 mg/kg (female), 2338 mg/kg (male) Rat 3745 mg/kg (male), 2436 mg/kg (female)

Skin Corrosion/Irritation

Not available

Serious Eye Damage/Irritation

Not available

Respiratory or Skin Sensitization

Not available

Germ Cell Mutagenicity

Not available

Carcinogenicity

Not available

Reproductive Toxicity

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. WARNING: California Proposition 65 - CRT: Listed date/Developmental toxin Topiramate (CAS 97240-79-4) Listed: November 27, 2015



Safety Data Sheet

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

Topiramate USP

30-4671

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.