

## 1. Identification

Product identifier	Topiramate
Other means of identification	
Catalog number	1672206
CAS number	97240-79-4
Chemical name	Beta-D-fructopyranose, 2,3:4,5-bis-O-(1-methylethylidene)-, sulfamate
Recommended use	Specified quality tests and assay use only.
Recommended restrictions	Not for use as a drug. Not for administration to humans or animals.

## Manufacturer/Importer/Supplier/Distributor information

### Manufacturer

Company name	U. S. Pharmacopeia
Address	12601 Twinbrook Parkway Rockville MD 20852-1790 United States
Telephone	RS Technical Services      301-816-8129
Website	<a href="http://www.usp.org">www.usp.org</a>
E-mail	RSTECH@usp.org
Emergency phone number	CHEMTRAC within US &      1-800-424-9300 Canada CHEMTRAC outside US &      +1 703-527-3887 Canada

## 2. Hazard(s) identification

Physical hazards	Not classified.
Health hazards	Reproductive toxicity
Environmental hazards	Not classified.
OSHA defined hazards	Not classified.

### Label elements



Signal word	Warning
Hazard statement	Suspected of damaging fertility or the unborn child.
Precautionary statement	
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.
Hazard(s) not otherwise classified (HNOC)	This product is supplied in a small quantity which does not constitute a combustible dust hazard. The physical properties of this material indicate that in large quantities accumulated dust may be hazardous.
Supplemental information	Pharmacologically active material.

## 3. Composition/information on ingredients

### Substance

Chemical name	Common name and synonyms	CAS number	%
Topiramate		97240-79-4	100
<b>4. First-aid measures</b>			
<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>Most important symptoms/effects, acute and delayed</b>	Central nervous system effects. Mood or mental changes. Metabolic acidosis. Pharmacologically active material. Occupational exposure may cause physiological effects.		
<b>Indication of immediate medical attention and special treatment needed</b>	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.		
<b>General information</b>	Remove from exposure. Remove contaminated clothing. For treatment advice, seek guidance from an occupational health physician or other licensed health-care provider familiar with workplace chemical exposures. In the United States, the national poison control center phone number is 1-800-222-1222. If person is not breathing, give artificial respiration. If breathing is difficult, give oxygen if available. Persons developing serious hypersensitivity (anaphylactic) reactions must receive immediate medical attention.		
<b>5. Fire-fighting measures</b>			
<b>Suitable extinguishing media</b>	Water. Foam. Dry chemical or CO <sub>2</sub> . Use fire-extinguishing media appropriate for surrounding materials.		
<b>Unsuitable extinguishing media</b>	None known.		
<b>Specific hazards arising from the chemical</b>	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.		
<b>Special protective equipment and precautions for firefighters</b>	Wear suitable protective equipment.		
<b>Fire fighting equipment/instructions</b>	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.		
<b>Specific methods</b>	Use standard firefighting procedures and consider the hazards of other involved materials.		
<b>General fire hazards</b>	No unusual fire or explosion hazards noted.		
<b>6. Accidental release measures</b>			
<b>Personal precautions, protective equipment and emergency procedures</b>	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.		
<b>Methods and materials for containment and cleaning up</b>	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.		
<b>Environmental precautions</b>	Avoid discharge into drains, water courses or onto the ground.		
<b>7. Handling and storage</b>			
<b>Precautions for safe handling</b>	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.		

**Conditions for safe storage, including any incompatibilities** Store in tight container as defined in the USP-NF. This material should be handled and stored per label instructions to ensure product integrity.

## 8. Exposure controls/personal protection

### Occupational exposure limits

#### Exposure limit values

Industrial Use Material	Type	Value
Topiramate (CAS 97240-79-4)	TWA	0.01 mg/m <sup>3</sup>

#### Biological limit values

**Appropriate 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.

#### Individual protection measures, such as personal protective equipment

**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.

## 9. Physical and chemical properties

**Appearance** Appearance descriptions are general information and not specific to any USP lot.

**Physical state** Solid.

**Form** Crystalline powder.

**Color** White. Off-white.

**Odor** Odorless.

**Odor threshold** Not available.

**pH** Not available.

**Melting point/freezing point** 251.6 - 262.4 °F (122 - 128 °C)

**Initial boiling point and boiling range** Not available.

**Flash point** Not available.

**Evaporation rate** Not available.

**Flammability (solid, gas)** Not available.

#### Upper/lower flammability or explosive limits

**Flammability limit - lower (%)** Not available.

**Flammability limit - upper (%)** Not available.

**Explosive limit - lower (%)** Not available.

**Explosive limit - upper (%)** Not available.

**Vapor pressure** Not available.

<b>Vapor density</b>	Not available.
<b>Relative density</b>	Not available.
<b>Solubility(ies)</b>	
<b>Solubility (water)</b>	Sparingly soluble.
<b>Solubility (other)</b>	Ethanol: Freely soluble. Dichloromethane: Freely soluble. Dimethylsulfoxide: Freely soluble. Chloroform: Freely soluble. Acetone: Freely soluble. Most soluble in alkaline solutions with sodium hydroxide or sodium phosphate (pH 9 to 10).
<b>Auto-ignition temperature</b>	Not available.
<b>Decomposition temperature</b>	Not available.
<b>Viscosity</b>	Not available.
<b>Other information</b>	
<b>Chemical family</b>	Sulfamate-substituted monosaccharide.
<b>Dust explosion properties</b>	
<b>Kst</b>	214 bar.m/s
<b>Molecular formula</b>	C12H21NO8S
<b>Molecular weight</b>	339.36
<b>pH in aqueous solution</b>	6.3 (saturated solution)

## 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>Possibility of hazardous reactions</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.

## 11. Toxicological information

### Information on likely routes of exposure

<b>Inhalation</b>	Knowledge about health hazard is incomplete.
<b>Skin contact</b>	Knowledge about health hazard is incomplete.
<b>Eye contact</b>	Knowledge about health hazard is incomplete.
<b>Ingestion</b>	Based on information from therapeutic use, this material may cause: Central nervous system effects.
<b>Symptoms related to the physical, chemical, and toxicological characteristics</b>	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.

### Information on toxicological effects

#### Acute toxicity

Product	Species	Test Results
Topiramate (CAS 97240-79-4)		
<b>Oral</b>		
LD50	Mouse	2915 mg/kg (female) 2338 mg/kg (male)
	Rat	3745 mg/kg (male) 2436 mg/kg (female)
<b>Skin corrosion/irritation</b>		Based on available data, the classification criteria are not met.
<b>Serious eye damage/eye irritation</b>		Based on available data, the classification criteria are not met.

**Local effects**

Eye irritation test  
Result: Non-irritating.  
Species: Rabbit  
Skin irritation test  
Result: Non-irritating.  
Species: Rabbit

**Respiratory or skin sensitization**

**Respiratory sensitization** Knowledge about health hazard is incomplete.  
**Skin sensitization** Knowledge about health hazard is incomplete.  
**Germ cell mutagenicity** Knowledge about mutagenicity is incomplete.

**Mutagenicity**

Ames test (Salmonella typhimurium): with and without activation.  
Result: Negative  
DNA repair test: rat hepatocyte.  
Result: Negative  
In vitro chromosome aberration test: human lymphocyte.  
Result: Negative  
In vitro gene mutation study in mammalian cells: mouse lymphoma.  
Result: Negative  
In vivo chromosome aberration: rat bone marrow.  
Result: Negative

**Carcinogenicity**

Based on available data, the classification criteria are not met.  
120 mg/kg/day Two-year carcinogenicity study, administered orally.  
Result: Negative.  
Species: Rat  
Test Duration: 2 years  
300 mg/kg/day Carcinogenicity, administered orally.  
Result: Increase in bladder tumors unique to species  
Species: Mouse  
Test Duration: 21 months

**IARC Monographs. Overall Evaluation of Carcinogenicity**

Not listed.

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

Not regulated.

**US. National Toxicology Program (NTP) Report on Carcinogens**

Not listed.

**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.

**Reproductivity**

100 mg/kg Fertility study  
Result: No adverse effects on fertility.  
Species: Rat  
120 mg/kg Reproductivity and development study  
Result: Increased incidence of rib and vertebral malformations.  
Species: Rabbit  
20 - 500 mg/kg Reproductivity and development study  
Result: Increased incidence of craniofacial malformations.  
Species: Mouse  
400 mg/kg Reproductivity and development study  
Result: Increased incidence of limb malformations.  
Species: Rat

**Specific target organ toxicity - single exposure** Knowledge about health hazard is incomplete.

**Specific target organ toxicity - repeated exposure** Knowledge about health hazard is incomplete.

**Aspiration hazard** Based on available data, the classification criteria are not met.

**Further information** Pharmacologically active material. Occupational exposure may cause physiological effects.

## 12. Ecological information

<b>Ecotoxicity</b>	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.
<b>Persistence and degradability</b>	No data is available on the degradability of this substance.
<b>Bioaccumulative potential</b>	No data available.
<b>Mobility in soil</b>	No data available.

**Other adverse effects** No other adverse environmental effects (e.g. ozone depletion, photochemical ozone creation potential, endocrine disruption, global warming potential) are expected from this component.

## 13. Disposal considerations

<b>Disposal instructions</b>	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.
<b>Local disposal regulations</b>	Dispose in accordance with all applicable regulations.
<b>Hazardous waste code</b>	The waste code should be assigned in discussion between the user, the producer and the waste disposal company.
<b>Waste from residues / unused products</b>	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).
<b>Contaminated packaging</b>	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.

## 14. Transport information

<b>DOT</b>	Not regulated as dangerous goods.
<b>IATA</b>	Not regulated as dangerous goods.
<b>Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code</b>	Not applicable.
<b>General information</b>	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 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.

### Superfund Amendments and Reauthorization Act of 1986 (SARA)

#### SARA 302 Extremely hazardous substance

Not listed.

#### SARA 311/312 Hazardous chemical

Yes  
Combustible dust  
Reproductive toxicity

#### 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.

**Safe Drinking Water Act (SDWA)** Not regulated.**US state regulations****California Proposition 65**

**WARNING:** 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).

**California Proposition 65 - CRT: Listed date/Developmental toxin**

Topiramate (CAS 97240-79-4)

Listed: November 27, 2015

**International Inventories**

Country(s) or region	Inventory name	On inventory (yes/no)*
Australia	Australian Inventory of Chemical Substances (AICS)	No
Canada	Domestic Substances List (DSL)	No
Canada	Non-Domestic Substances List (NDSL)	No
China	Inventory of Existing Chemical Substances in China (IECSC)	No
Europe	European Inventory of Existing Commercial Chemical Substances (EINECS)	No
Europe	European List of Notified Chemical Substances (ELINCS)	No
Japan	Inventory of Existing and New Chemical Substances (ENCS)	No
Korea	Existing Chemicals List (ECL)	No
New Zealand	New Zealand Inventory	Yes
Philippines	Philippine Inventory of Chemicals and Chemical Substances (PICCS)	No
Taiwan	Taiwan Chemical Substance Inventory (TCSI)	Yes
United States & Puerto Rico	Toxic Substances Control Act (TSCA) Inventory	No

\*A "Yes" indicates that all components of this product comply with the inventory requirements administered by the governing country(s). A "No" indicates that one or more components of the product are not listed or exempt from listing on the inventory administered by the governing country(s).

**16. Other information, including date of preparation or last revision**

<b>Issue date</b>	03-15-2011
<b>Revision date</b>	08-20-2019
<b>Version #</b>	03
<b>Further information</b>	Refer to NFPA 654, Standard for the Prevention of Fire and Dust Explosions from the Manufacturing, Processing, and Handling of Combustible Particulate Solids, for safe handling.
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