

## Material Safety Data Sheet

1. CHEMICAL PRODUCT AND COMPANY IDENTIFICATION		
<b>Common/Trade Name:</b> Topiramate Tablets USP		
<b>Chemical Name:</b> 2,3:4,5-Di-O-isopropylidene-β-D-fructopyranose sulfamate		
<b>Synonyms:</b> Topiramate		
<b>Molecular Formula:</b> C <sub>12</sub> H <sub>21</sub> NO <sub>8</sub> S		
<b>Molecular Weight:</b> 339.36		
<b>CAS No:</b> 97240-79-4		
<b>Product Group:</b> Topiramate is a sulfamate-substituted monosaccharide		
<b>Product Use:</b> Monotherapy of epilepsy and adjunctive therapy of Epilepsy		
<b>Manufacturer's Name</b>	Unichem Laboratories Limited	
<b>Address</b>	Unichem Laboratories Limited, C-31&32, Industrial Area, Meerut Road, Ghaziabad, INDIA	
<b>Marketed by</b>	Unichem Pharmaceuticals (USA), Inc. Rochelle Park, NJ 07662 Tel. : 201-226-0240 Fax : 201-226-0241	
2. COMPOSITION / INFORMATION ON INGREDIENTS		
Composition	CAS #	Quantity
Topiramate (active ingredient)	97240-79-4	25 mg, 50 mg, 100 mg and 200 mg.
REFER to PHYSICIAN'S DESK REFERENCE for common components		
3. HAZARDS IDENTIFICATION		
<b>Emergency Overview</b>	<b>Physical State:</b> <b>25 mg :</b> Light yellow, round, biconvex, film-coated tablets with 'U' debossed on one side and '115' debossed on other side <b>50 mg:</b> White to off-white, round, bevel edged, biconvex, film-coated tablets with 'U' debossed on one side and '116' debossed on other side. <b>100 mg:</b> Salmon, round, bevel edged, biconvex, film-coated tablets with 'U' debossed on one side and '117' debossed on other side. <b>200 mg:</b> Yellow, round, bevel edged, biconvex, film-coated tablets with 'U' debossed on one side and '118' debossed on other side.  <b>Odor:</b> Not available. <b>WARNING!</b> May be harmful if swallowed. Accidental ingestion of large amounts may be harmful.	
<b>Primary Route(s) of Entry</b>	Ingestion	
<b>Potential Health Effects:</b>	<b>Eyes</b> May Cause eye irritation <b>Skin</b> Slightly hazardous in case of skin contact (irritant) <b>Inhalation</b> Not expected to be an inhalation hazard in final pharmaceutical form. <b>Ingestion</b> Ingestion of this material may cause effects such as paresthesia, anorexia, weight decrease, speech disorder related speech problem, fatigue, dizziness, somnolence, nervousness, psychomotor slowing, abnormal vision and fever.  Please see Patient Package Insert for further information	
<b>Toxicity Data:</b>	See Section 11	

<b>Effects of Overexposure:</b>	Overdose may cause convulsions, drowsiness, speech disturbance, blurred vision, diplopia, mentation impaired, lethargy, abnormal coordination, stupor, hypotension, abdominal pain, agitation, dizziness and depression.
<b>Target Organs:</b>	Central Nervous System
<b>4. FIRST AID MEASURES</b>	
<b>Eye Contact</b>	In the case of contact with eyes, rinse immediately with plenty of water for 15 minutes and seek medical advice.
<b>Skin Exposure</b>	Take off contaminated clothing and shoes immediately. Wash off immediately with soap and plenty of water. If skin irritation persists, call a physician.
<b>Ingestion</b>	If symptoms persist, call a physician. Do not induce vomiting without medical advice. Never give anything by mouth to an unconscious person.
<b>Inhalation</b>	Physical form suggests that risk of inhalation exposure is negligible.
<b>5. FIRE AND EXPLOSION HAZARDS</b>	
<b>Flammability</b>	Presumed to be a combustible particulate solid.
<b>Flash Point</b>	Not available.
<b>Extinguishing Media</b>	Use carbon dioxide, dry chemical, or water spray.
<b>Special Fire Fighting Procedures</b>	In the event of fire, wear self-contained breathing apparatus and special protective equipment for fire fighters. Evacuate area and fight fire from a safe distance. Cool closed containers exposed to fire with water spray. Do NOT use water jet. In the event of fire and/or explosion do not breathe fumes.
<b>Unusual Fire/Explosion Hazards</b>	Not Applicable.
<b>Hazardous Combustion Products</b>	Hazardous combustion or decomposition products are expected when the product is exposed to fire.
<b>6. ACCIDENTAL RELEASE INFORMATION</b>	
STEPS TO BE TAKEN IF SIGNIFICANT QUANTITIES ARE SPILLED: Use appropriate personal protective equipment (see Section 8). Prevent product from entering drains. Local authorities should be advised if a significant spill cannot be contained. Take up mechanically and collect in suitable container for disposal. Clean contaminated surface thoroughly. Avoid formation of dust and aerosols.	
<b>7. PRECAUTIONS FOR SAFE HANDLING AND USE</b>	
<b>Precautions General Handling:</b>	Handle in accordance with good industrial hygiene and safety practice. Skin should be washed after contact. Avoid formation of dust and aerosols.
<b>Storage</b>	Store at 20 <sup>0</sup> to 25 <sup>0</sup> C (68 <sup>0</sup> to 77 <sup>0</sup> F) [See USP Controlled Room Temperature].
<b>8. CONTROL MEASURES AND PERSONAL PROTECTIVE EQUIPMENT</b>	
<b>Engineering Controls</b>	Apply technical measures to comply with the occupational exposure guideline. Local exhaust ventilation is needed for limited open handling or where aerosols may be generated
<b>Respiratory Protection</b>	Base respirator selection on a risk assessment.
<b>Personal Protection</b>	<b>Eye/face Protection</b> Provide eye protection based on risk assessment.
	<b>Skin Protection</b> Wear nitrile or latex gloves. Wear protective garment
	<b>General Hygiene Considerations</b> When using, do not eat, drink or smoke. General industrial hygiene practice. Wash hands before breaks and at the end of workday.
	<b>Other</b> Limit access to only personnel trained in the safe handling of this material Consult a health and safety professional for specific PPE, respirator, and risk assessment guidance
<b>Recommended Facilities</b>	Eye wash, washing facilities

<b>9. PHYSICAL / CHEMICAL CHARACTERISTICS</b>					
Appearance	Round, biconvex film-coated tablets	Melting point	Not available	Solubility in water	Not available
Odor	odorless	Boiling point	Not available	Specific Gravity	Not available
Taste	Not available	Vapor Pressure	Not available	Flashpoint	Not available
pH	Not available	Density	Not available	Flammability Limits	Not available
<b>10. STABILITY AND REACTIVITY DATA</b>					
<b>Stability</b>		Stable at normal conditions.			
<b>Incompatibility</b>		Acids			
<b>Hazardous Decomposition</b>		NO <sub>x</sub> , SO <sub>x</sub> . Irritating and/or toxic fumes or gases. Emits toxic fumes under fire conditions.			
<b>Conditions to Avoid</b>		None known.			
<b>Hazardous Polymerization</b>		None under normal use.			
<b>11. TOXICOLOGICAL INFORMATION</b>					
<b>The following effects are based on the Active Pharmaceutical Ingredient.</b>					
<b>Topiramate</b>					
Rat : LD50 – 3745 mg/kg (male); 2436 mg/kg (female)					
Mouse : LD50 – 2915 mg/kg, (female); 2338 mg/kg (male)					
<b><u>Maximum Tolerated Dose (MTD), Oral</u></b>					
<b>Topiramate:</b>					
<b>Carcinogenicity</b>	An increase in urinary bladder tumors was observed in mice given topiramate (20, 75, and 300 mg/kg) in the diet for 21 months. The elevated bladder tumor incidence, which was statistically significant in males and females receiving 300 mg/kg, was primarily due to the increased occurrence of a smooth muscle tumor considered histomorphologically unique to mice. Plasma exposures in mice receiving 300 mg/kg were approximately 0.5 to 1 times steady-state exposures measured in patients receiving topiramate monotherapy at the recommended human dose (RHD) of 400 mg, and 1.5 to 2 times steady-state topiramate exposures in patients receiving 400 mg of topiramate plus phenytoin. The relevance of this finding to human carcinogenic risk is uncertain. No evidence of carcinogenicity was seen in rats following oral administration of topiramate for 2 years at doses up to 120 mg/kg (approximately 3 times the RHD on a mg/m <sup>2</sup> basis).				
<b>Genetic Toxicity</b>	Topiramate did not demonstrate genotoxic potential when tested in a battery of in vitro and in vivo assays. Topiramate was not mutagenic in the Ames test or the in vitro mouse lymphoma assay; it did not increase unscheduled DNA synthesis in rat hepatocytes in vitro; and it did not increase chromosomal aberrations in human lymphocytes in vitro or in rat bone marrow in vivo.				
<b>Reproductive Toxicity &amp; Developmental Toxicity</b>	No adverse effects on male or female fertility were observed in rats at doses up to 100 mg/kg (2.5 times the RHD on a mg/m <sup>2</sup> basis).				
<b>12. ENVIRONMENTAL IMPACT INFORMATION</b>					
The environmental characteristics of this mixture have not been fully evaluated. The active ingredient in this formulation may be harmful to aquatic organisms. Releases to the environment should be avoided.					
<b>13. DISPOSAL INFORMATION</b>					
<b>Waste Disposal Method</b>	Dispose of in accordance with local and national regulations				

<b>14. TRANSPORTATION INFORMATION</b>
The Material Safety Data Sheet (MSDS) should accompany all shipments for reference in the event of spillage or accidental release. Transportation and shipping of this product is not restricted. It has no known significant hazards requiring special packaging or labeling for air, maritime or ground transport purpose.
<b>15. REGULATORY INFORMATION</b>
Not regulated for transport under USDOT, EUADR, IATA, or IMDG regulations. FDA: Topiramate Tablets USP is an approved prescription medication.
<b>16. OTHER DATA</b>
ABBREVIATIONS: N/A – not applicable
Prepared by: Unichem Laboratories Limited
References: 1. Drug Bank 2. PDR – Physicians Desk Reference 3. Topiramate Tablets USP, Package Insert, Unichem Laboratories Limited
Date: June 08, 2015 - New MSDS
SEE CURRENT PACKAGE INSERT FOR FURTHER INFORMATION

Notice to Reader: To the best of our knowledge, the information contained herein is accurate. However, neither the above named supplier nor any of its subsidiaries assumes any liability whatsoever for the accuracy or completeness of the information contained herein. Final determination of suitability of any material is the sole responsibility of the user. All materials may present unknown hazards and should be used with caution. Although certain hazards are described herein, we cannot guarantee that these are the only hazards that exist.