

MATERIAL SAFETY AND DATA SHEET (MSDS)

1. CHEMICAL PRODUCT AND COMPANY IDENTIFICATION	
Common/Trade Name: Trokendi XR™	
Chemical Name: 2,3:4,5-Di-O-isopropylidene-β-D-fructopyranose sulfamate	
Synonyms: Topiramate extended-release capsules	
Molecular Formula: C ₁₂ H ₂₁ NO ₈ S	
Molecular Weight: 339.4 g/mol	
CAS No.: 97240-79-4	
Chemical Family: Antiepileptic	
Product Use: Antiepileptic	
Manufacturer's Name: Catalent Pharma Solutions	
Address: 1100 Enterprise Drive Winchester KY 40391 USA	
2. COMPOSITION / INFORMATION ON INGREDIENTS	
Composition	Exposure Limit
Topiramate (active ingredient)	Contains no substances with occupational exposure limit values
<p>REFER to Label for components that are present. Quantitative composition is proprietary information.</p> <p>Inactive ingredients are: Sugar Spheres, NF; Hypromellose (Type 2910), USP; Mannitol, USP; Docusate Sodium, USP; Sodium Benzoate, NF; Ethylcellulose, NF; Oleic Acid, NF; Medium Chain Triglycerides, NF; Polyethylene Glycol, NF; Polyvinyl Alcohol, USP; Titanium Dioxide, USP; Talc, USP; Lecithin, NF; Xanthan Gum, NF.</p> <p>The capsule shells contain gelatin, USP; Titanium Dioxide, USP; and Colorants.</p> <p>The colorants are: FD&C Blue #1 (all strength capsules); Yellow Iron Oxide, USP (25 mg and 50 mg capsules); FD&C Red #3 (50 mg, 100 mg and 200 mg capsules); FD&C Yellow #6 (50 mg, 100 mg and 200 mg capsules); Riboflavin, USP (25 mg capsules).</p> <p>All capsule shells are imprinted with black print that contains shellac, NF, and black iron oxide, NF.</p>	
3. HAZARDS IDENTIFICATION	
Emergency Overview	<p>Physical State: Hard gelatin capsules</p> <p>The 25 mg capsule has a light green opaque body/yellow opaque cap (printed "SPN" on the cap, "25" on the body)</p> <p>The 50 mg capsule has a light green opaque body/orange opaque cap (printed "SPN" on the cap, "50" on the body)</p> <p>The 100 mg capsule has a green opaque body/blue opaque cap (printed "SPN" on the cap, "100" on the body)</p>

Unusual Fire/Explosion Hazards	Not applicable		
Hazardous Combustion Products	During combustion, product may emit but not limited to carbon dioxide, carbon monoxide, low molecular weight hydrocarbons, sulfur oxides, and nitrogen oxides.		
6. ACCIDENTAL RELEASE INFORMATION			
Personal precautions Use personal protective equipment. Avoid dust formation. Avoid breathing vapors, mist or gas. Ensure adequate ventilation. Avoid ignition sources. Evacuate personnel to safe areas. Avoid breathing dust.			
Environmental precautions Do not let product enter drains.			
Methods and materials for containment and cleaning up Pick up and arrange disposal without creating dust. Sweep up and shovel. Keep in suitable, closed containers for disposal.			
7. PRECAUTIONS FOR SAFE HANDLING AND USE			
Precautions Handling Significant Quantities of Product	Observe good industrial hygiene practices.		
Storage	Trokendi XR™ (topiramate) extended-release capsules should be stored in well closed containers at controlled room temperature [25°C (77°F); excursions 15°C-30°C (59°F-86°F)]. Protect from moisture and light.		
8. CONTROL MEASURES AND PERSONAL PROTECTIVE EQUIPMENT			
Exposure Limits	Contains no substances with occupational exposure limit values.		
Engineering Controls	Not required when handling capsules or containers. Ventilation should be matched to conditions.		
Respiratory Protection	Not required when handling capsules or containers. NIOSH/MSHA approved respirators for protection should be used if respirators are found to be necessary. Ventilation should be matched to conditions.		
Personal Protection	Not required when handling capsules. If containers are compromised or exposure is likely, then wear: goggles, protective clothing and gloves		
Recommended Facilities	Eye wash, washing facilities		
9. PHYSICAL / CHEMICAL CHARACTERISTICS			
Appearance	Odor	Taste	pH
Capsules	No data available	No data available	Not applicable
Melting point	Boiling point	Vapor Pressure	Density
Mixture	Mixture	Not applicable	No data available
Solubility in Water	Specific Gravity	Flash Point	Flammability Limits
Some residuals remain undissolved in water	No data available	No data available	No data available
10. STABILITY AND REACTIVITY DATA			
Stability	Stable		
Incompatibility	Oxidizing agents, strong acids, strong bases.		
Hazardous	Upon decomposition, this product may emit but not limited to carbon dioxide,		

Decomposition	carbon monoxide, low molecular weight hydrocarbons, sulfur oxides, and nitrogen oxides
Conditions to Avoid	Avoid creation of dust. May be explosive or flammable if dispersed in air and in the presence of ignition sources.
Hazardous Polymerization	Under normal conditions of storage and use, hazardous polymerization will not occur
11. TOXICOLOGICAL INFORMATION FOR TOPIRAMATE	
Acute Toxicity	50% Lethal dose (LD ₅₀) in mice: 1000-3400mg/kg; in rats: 1500-4200mg/kg
Carcinogenicity	Was not carcinogenic in rats; bladder tumors in mice were considered "unique" to this species
Reproductive Toxicity	No effects on animal fertility, and perinatal and postnatal development; however teratogenicity in rats, mice, and rabbits was observed resulting in an assignment of Pregnancy Category C
Mutagenicity	Was not mutagenic in a battery of genotoxicity assays
12. ENVIRONMENTAL IMPACT INFORMATION	
An assessment of the environmental impact, as included in the NDA, showed this to be minimal because the estimated concentration of the substance at the point of entry into the aquatic environment will be below 1 part per billion.	
13. DISPOSAL INFORMATION	
Waste Disposal Considerations: Dispose of material according to federal, state and local disposal regulations or company operating procedures. Disposal by incineration is recommended. At home: Discard away from children's reach.	
14. TRANSPORTATION INFORMATION	
This product is not subject to the regulations for the safe transport of hazardous chemicals. DOT : Not regulated TDG: Not regulated IATA: Not regulated IMDG: Not regulated	
15. REGULATORY INFORMATION	
OSHA Hazards Irritant	
16. OTHER INFORMATION	
ABBREVIATIONS: DOT: Department of Transportation; TDG: Transportation of Dangerous Goods; IATA: International Air Transport Association; IMDG: International Maritime Dangerous Goods; OSHA: Occupational Safety and Health Administration; RTECS: Registry of Toxic Effects of Chemical Substances; FDA: Food and Drug Agency; NDA: New Drug Application	
References: 1. Trokendi XR™ (topiramate) extended-release capsules FDA NDA 201635 Approved Labeling 2. RTECS No. LS7083000 3. Topamax® NDA 020505, NDA 020844 Summary Basis of Approval	