Supernus Pharmaceuticals, Inc. 1550 East Gude Drive, Rockville, MD 20850, USA IN CASE OF EMERGENCY

Emergency Phone: 1-866-398-0833

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: C₁₂H₂₁NO₈S 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	

REFER to Label for components that are present. Quantitative composition is proprietary information.

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.

The capsule shells contain gelatin, USP; Titanium Dioxide, USP; and Colorants.

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).

All capsule shells are imprinted with black print that contains shellac, NF, and black iron oxide, NF.

3. HAZARDS IDENTIFICATION

Emergency	Physical State: Hard gelatin capsules
Overview	The 25 mg capsule has a light green opaque body/yellow opaque cap (printed "SPN" on the cap, "25" on the body)
	The 50 mg capsule has a light green opaque body/orange opaque cap (printed "SPN" on the cap, "50" on the body)
	The 100 mg capsule has a green opaque body/blue opaque cap (printed "SPN" on the cap, "100" on the body)



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	The 200 mg capsule has a pink opaque body/blue opaque cap (printed "SPN" on the cap, "200" on the body)
	Odor: No data available
	WARNING! 1. In case of accident or the situation is uncomfortable, seek medical help immediately (show the label where possible) 2. Wear suitable protective clothing 3. Do not inhale the powder
Primary Route(s)	Ingestion
of Entry Potential Health Effects	Inhalation: May be harmful if inhaled. May cause respiratory irritation Eye Contact: Causes serious eye irritation Skin Contact: May be harmful if absorbed through skin. Causes skin irritation Ingestion: This is the therapeutic route, but, see label for other health effects. May be harmful if swallowed in excess. Others: No data available
Toxicity Data	See Section 11
Effects of Overexposure	Overdoses of topiramate resulted in signs and symptoms which included convulsions, drowsiness, speech disturbance, blurred vision, diplopia, mentation impaired, lethargy, abnormal coordination, stupor, hypotension, abdominal pain, agitation, dizziness and depression. Topiramate overdose has resulted in severe metabolic acidosis. Similar signs, symptoms, and clinical consequences are
T	expected to occur with overdosage of Trokendi XR™.
Target Organs	Brain
4. FIRST AID MEAS	
General Advice: Cor dangerous area	nsult physician. Show the safety data sheet to the doctor in attendance. Move out of
Eye Exposure	Rinse cautiously with plenty of water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. Consult a physician.
Skin Exposure	Wash off with soap and copious amounts of water. Consult a physician.
Ingestion	Never give anything by mouth to an unconscious person. Rinse mouth with water. If the ingestion is recent, the stomach should be emptied immediately by lavage or by induction of emesis. Consult a physician.
Inhalation	Avoid breathing dust/ fume/ gas/ mist/ vapors/ spray. If breathed in, move person into fresh air. If not breathing, give artificial respiration. Consult a physician.
5. FIRE EXPLOSION	
Flammability	Lower: No data available Upper: No data available
Flash Point	No data available
Extinguishing Media	Use water (but do not generate a dust cloud), carbon dioxide or dry chemical
Special Fire/ Explosion Hazards	May be explosive or flammable if dispersed in air and in the presence of ignition sources



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1550 East Gade Brive, Rockvine, WB 20050, COA		
Unusual Fire/	Not applicable	
Explosion Hazards		
Hazardous	During combustion, product may emit but not limited to carbon dioxide, carbon	
Combustion	monoxide, low molecular weight hydrocarbons, sulfur oxides, and nitrogen oxides.	
Products		

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.

containers for dispos	sal.		containers for disposal.			
7. PRECAUTIONS FOR SAFE HANDLING AND USE						
Precautions	Observe good industrial hygiene practices.					
Handling						
Significant						
Quantities of						
Product						
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 MEAS	8. CONTROL MEASURES AND PERSONAL PROTECTIVE EQUIPMENT					
Exposure Limits	Contains no substances with occupational exposure limit values.					
Engineering	Not required when handling capsules or containers. Ventilation should be matched					
Controls	to conditions.					
Respiratory	Not required when handling capsules or containers. NIOSH/MSHA approved					
Protection	respirators for protection should be used if respirators are found to be necessary.					
	Ventilation should be matched to conditions.					
Personal	Not required when handling capsules. If containers are compromised or exposure					
Protection	is likely, then wear: goggles, protective clothing and gloves					
Recommended	Eye wash, washing facilities					
Facilities						
•	MICA	L 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 rema	nin	No data available	No data available	No data available		
undissolved in water						
10. STABILITY AND I	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,					



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Decomposition	carbon monoxide, low molecular weight hydrocarbons, sulfur oxides, and nitrogen	
	oxides	
Conditions to	Avoid creation of dust. May be explosive or flammable if dispersed in air and in	
Avoid	the presence of ignition sources.	
Hazardous	Under normal conditions of storage and use, hazardous polymerization will not	
Polymerization	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	No effects on animal fertility, and perinatal and postnatal development; however	
Toxicity	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

ABBEVIATIONS:

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