

SAFETY DATA SHEET



TOPAMAX

Version	Revision Date:	SDS Number:	Date of last issue: 2022/05/18
3.9	2022/09/24	100000010227	Date of first issue: 2014/06/27

SECTION 1. IDENTIFICATION

Product name : TOPAMAX
Substance name : TOPAMAX 25 mg tablets
Topiramate
Tablets 25 mg

Manufacturer or supplier's details

Company name of supplier : Janssen Pharmaceuticals, Inc.
Address : 1125 Trenton-Harbourton Rd
Titusville NJ 08560
USA
Telephone : +16097302000
E-mail address of person responsible for the SDS : SDSJanssen@its.jnj.com
Emergency telephone number : **CHEMTREC US: 1-800-424-9300**
CHEMTREC International: +1 703-741-5970

Recommended use of the chemical and restrictions on use

Recommended use : Finished Pharmaceutical Product
Pharmacotherapeutic group: Antiepileptics
This SDS is only intended for occupational use and not for consumer use (see patient packaging insert for consumer use). This SDS is written to provide environmental, health and safety information for personnel that will be handling this finished pharmaceutical product. For health and safety information during manufacturing of this product we refer to the appropriate SDS for each component.
This dosage form is exempt from the requirements of the OSHA Hazard Communication Standard (US OSHA Standard 29 CFR Part 1910.1200).

SECTION 2. HAZARDS IDENTIFICATION

GHS classification in accordance with the OSHA Hazard Communication Standard (29 CFR 1910.1200)

Reproductive toxicity : Category 2


GHS label elements

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- Hazard pictograms : 
- Signal word : Warning
- Hazard statements : H361 Suspected of damaging fertility or the unborn child.
- Precautionary statements : **Prevention:**
P201 Obtain special instructions before use.
P202 Do not handle until all safety precautions have been read and understood.
P280 Wear protective gloves/ protective clothing.
Response:
P308 + P313 IF exposed or concerned: Get medical advice/ attention.
Storage:
P405 Store locked up.
Disposal:
P501 Dispose of contents/ container to an approved waste disposal plant.

Additional Labelling

The following percentage of the mixture consists of ingredient(s) with unknown acute toxicity:
15.43 %

Other hazards

Refer to the pharmacotherapeutic group (section 1.2) and the patient packaging insert to evaluate the possible workplace hazards when this Finished Pharmaceutical Product is accidentally leaking, broken or crushed.

SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

- Substance / Mixture : Mixture
- Chemical nature : Solid

Components

Chemical name	CAS-No.	Concentration (% w/w)
TOPIRAMATE	97240-79-4	>= 50 - < 70
Cellulose	9004-34-6	>= 10 - < 20
Octadecanoic acid, magnesium salt	557-04-0	>= 0.1 - < 1

Actual concentration is withheld as a trade secret

SECTION 4. FIRST AID MEASURES

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- If inhaled : Health injuries are not known or expected under normal use.
If breathed in, move person into fresh air.
Consult a physician.
- In case of skin contact : Take off all contaminated clothing immediately.
Wash off with soap and water.
If symptoms persist, call a physician.
- In case of eye contact : Rinse immediately with plenty of water, also under the eyelids,
for at least 5 minutes.
Remove contact lenses.
If eye irritation persists, consult a specialist.
- If swallowed : If swallowed, rinse mouth with water (only if the person is
conscious).
Call a physician immediately.
- Most important symptoms and effects, both acute and delayed : Consult the patient packaging insert for more information
about this Finished Pharmaceutical Product.
Abdominal pain
anorexia
insomnia
Disorientation
Dizziness
Tremors
Blurred vision
nausea
Diarrhoea
constipation
stomach discomfort
dry mouth
Spasm
Fatigue
nasopharyngitis
Cough
weight decrease
anemia
hypertension
depression
aggression
Rash
Vertigo
tinnitus
- Notes to physician : Treat symptomatically.
Consult the patient packaging insert for more information
about this Finished Pharmaceutical Product.

SECTION 5. FIREFIGHTING MEASURES

- Suitable extinguishing media : Use extinguishing measures that are appropriate to local
circumstances and the surrounding environment.

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- Hazardous combustion products : No information available.
- Further information : No information available.
- Special protective equipment for firefighters : In the event of fire, wear self-contained breathing apparatus.

SECTION 6. ACCIDENTAL RELEASE MEASURES

- Personal precautions, protective equipment and emergency procedures : In the event of an accidental release the emergency response team must respond based on a risk assessment and use personal protective equipment as appropriate.
- Environmental precautions : Should not be released into the environment.
Do not flush into surface water or sanitary sewer system.
- Methods and materials for containment and cleaning up : Large spills + Small spills: Keep in suitable, closed containers for disposal. Treat recovered material as described in the section "Disposal considerations".
Large spills: Sweep up (intact) or vacuum with HEPA filter (broken or crushed) or via wet cleaning into suitable containers for disposal. Pick up and arrange without creating dust. Keep in properly labelled containers.
Small spills: Moisten a towel, cover the spill, pick up the spill or use HEPA vacuum.

SECTION 7. HANDLING AND STORAGE

- Advice on protection against fire and explosion : No data available
- Advice on safe handling : To avoid thermal decomposition, do not overheat.
Avoid inhalation, ingestion and contact with skin and eyes.
Do not break, crush or spill this Finished Pharmaceutical Product.
Use personal protective equipment as required.
- Conditions for safe storage : To maintain product quality, do not store in heat or direct sunlight.
Store in original container.
Keep containers tightly closed in a dry, cool and well-ventilated place.
Keep away from heat and sources of ignition.
Keep locked up.
- Recommended storage temperature : < 77 °F / < 25 °C

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SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION**Components with workplace control parameters**

Components	CAS-No.	Value type (Form of exposure)	Control parameters / Permissible concentration	Basis
TOPIRAMATE	97240-79-4	TWA	0.120 mg/m ³	J&J OEL/PBOEL HHC
		PBOEL-HHC	1 B	J&J OEL/PBOEL HHC
	Further information: J&J has a hazard banding notation: PBOEL HHC. This substance is classified by J&J as being PBOEL HHC 1B., Notation REPRO: has the potential to have adverse effects on reproduction and fetal development			
Cellulose	9004-34-6	TWA	10 mg/m ³	ACGIH
		TWA (Respirable)	5 mg/m ³	NIOSH REL
		TWA (total)	10 mg/m ³	NIOSH REL
		TWA (total dust)	15 mg/m ³	OSHA Z-1
		TWA (respirable fraction)	5 mg/m ³	OSHA Z-1
		TWA (Total dust)	15 mg/m ³	OSHA P0
		TWA (respirable dust fraction)	5 mg/m ³	OSHA P0
Octadecanoic acid, magnesium salt	557-04-0	TWA (Inhalable particulate matter)	10 mg/m ³	ACGIH
		TWA (Respirable particulate matter)	3 mg/m ³	ACGIH

Engineering measures : All personal protective equipment should be based on a risk assessment. Consult a Environment Health Safety expert if necessary.
If this product is processed not in accordance with the prescribed use, contact the Industrial Hygiene / Environment Health Safety Expert to assess the situation.
Validated Industrial Hygiene Analytical methods are developed to monitor and quantify inhalable exposure to the Active Pharmaceutical Ingredient. For more information contact Maxxam Analytics (www.maxxamlabs.com) or the Laboratory of Occupational and Environmental Hygiene (www.lamh.be).

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Personal protective equipment

Respiratory protection : No personal respiratory protective equipment normally required.

Hand protection
Remarks : Disposable gloves

Eye protection : No special precautions required.

Skin and body protection : closed work clothing

Protective measures : The type of protective equipment must be selected based on the Environmental Health and Safety risk assessment. Consult a Environmental Health and Safety expert if necessary.

Hygiene measures : Handle in accordance with good industrial hygiene and safety practice.

SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance : tablet, Coated

Colour : No data available

Odour : No data available

Odour Threshold : No data available

pH : No data available

Melting point/range : No data available

Boiling point/boiling range : No data available

Flash point : No data available

Evaporation rate : No data available

Flammability (solid, gas) : No information available.

Self-ignition : No data available

Upper explosion limit / Upper flammability limit : No data available

Lower explosion limit / Lower flammability limit : No data available

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Vapour pressure : No data available

Relative density : No data available

Density : No data available

Solubility(ies)
Water solubility : No data available

Partition coefficient: n-octanol/water : No data available

Decomposition temperature : No data available

Viscosity
Viscosity, dynamic : Not applicable

Viscosity, kinematic : Not applicable

Explosive properties : No data available

Oxidizing properties : No data available

SECTION 10. STABILITY AND REACTIVITY

Reactivity : None reasonably foreseeable.

Chemical stability : Stable under normal conditions.

Possibility of hazardous reactions : No dangerous reaction known under conditions of normal use.

Conditions to avoid : To avoid thermal decomposition, do not overheat.
Heat, flames and sparks.
Exposure to moisture

Incompatible materials : None known.

Hazardous decomposition products : None known.

SECTION 11. TOXICOLOGICAL INFORMATION

Acute toxicity

Product:

Acute oral toxicity : Acute toxicity estimate: 4,418 mg/kg
Method: Calculation method

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Components:

TOPIRAMATE:

Acute oral toxicity : LD50 (Rat): 2,436 mg/kg

Acute inhalation toxicity : Remarks: May be harmful if inhaled.

Acute dermal toxicity : Remarks: No data available

Cellulose:

Acute oral toxicity : LD50 (Rat): > 5,000 mg/kg

Skin corrosion/irritation

Components:

TOPIRAMATE:

Species : Rabbit

Result : No skin irritation

Cellulose:

Species : Rabbit

Remarks : No skin irritation

Serious eye damage/eye irritation

Components:

TOPIRAMATE:

Species : Rabbit

Result : No eye irritation

Cellulose:

Species : Rabbit

Remarks : No eye irritation

Respiratory or skin sensitisation

Components:

TOPIRAMATE:

Result : Not a sensitizer

Cellulose:

Species : Guinea pig

Remarks : Did not cause sensitisation on laboratory animals.

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Germ cell mutagenicity**Components:****TOPIRAMATE:**

Genotoxicity in vitro : Test Type: Ames test
Result: negative

Test Type: Chromosome aberration test in vitro
Test system: Human lymphocytes
Result: negative

Test Type: A mouse lymphoma test
Result: negative

Genotoxicity in vivo : Test Type: In vivo micronucleus test
Species: Rat
Result: negative

Carcinogenicity**Components:****TOPIRAMATE:**

Species : Rat
Application Route : Oral
Exposure time : 2 years
Dose : 120 mg/kg/day
Remarks : no
carcinogenic effects

IARC No component of this product present at levels greater than or equal to 0.1% is identified as probable, possible or confirmed human carcinogen by IARC.

OSHA No component of this product present at levels greater than or equal to 0.1% is on OSHA's list of regulated carcinogens.

NTP No component of this product present at levels greater than or equal to 0.1% is identified as a known or anticipated carcinogen by NTP.

Reproductive toxicity**Components:****TOPIRAMATE:**

Effects on foetal development : Species: Rabbit
Remarks: positive

Species: Rat
Remarks: positive

Species: Mouse
Remarks: positive

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Reproductive toxicity - Assessment : Some evidence of adverse effects on development, based on animal experiments.

Teratogenicity - Assessment : Limited evidence of adverse effects on development in animal studies and/ or human studies.

STOT - single exposure

Components:

TOPIRAMATE:

Remarks : No data available

STOT - repeated exposure

No data available

Repeated dose toxicity

Components:

TOPIRAMATE:

Species : Rat
NOAEL : 10 mg/kg
Exposure time : 3 months

Species : Dog
NOAEL : 10 mg/kg
Exposure time : 3 months

Species : Dog
NOAEL : 10 mg/kg
Exposure time : 12 months

Aspiration toxicity

No data available

Experience with human exposure

No data available

Toxicology, Metabolism, Distribution

No data available

Neurological effects

No data available

Further information

No data available

Other health hazards

No data available

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SECTION 12. ECOLOGICAL INFORMATION**Ecotoxicity****Components:****TOPIRAMATE:**

- Toxicity to fish : NOEC (Lepomis macrochirus (Bluegill sunfish)): < 75 mg/l
Method: FDA 4.11
- LC50 (Lepomis macrochirus (Bluegill sunfish)): > 2,400 mg/l
Exposure time: 96 h
Method: FDA 4.11
- Toxicity to daphnia and other aquatic invertebrates : NOEC (Daphnia (water flea)): 1,000 mg/l
Method: FDA 4.08
- EC50 (Daphnia (water flea)): 1,000 mg/l
Method: FDA 4.08
- Toxicity to algae/aquatic plants : EbC50 (Pseudokirchneriella subcapitata (green algae)): > 93 mg/l
Test Type: Cell multiplication inhibition test
Method: OECD Test Guideline 201
- NOECb (Pseudokirchneriella subcapitata (green algae)): 93 mg/l
Test Type: Cell multiplication inhibition test
Method: OECD Test Guideline 201
- ErC50 (Pseudokirchneriella subcapitata (green algae)): > 93 mg/l
Test Type: Growth inhibition
Method: OECD Test Guideline 201
- NOECr (Pseudokirchneriella subcapitata (green algae)): 93 mg/l
Test Type: Growth inhibition
Method: OECD Test Guideline 201
- Toxicity to microorganisms : NOEC (activated sludge): \geq 1,000 mg/l
Exposure time: 3 h
Method: OECD Test Guideline 209
- EC50 (activated sludge): > 1,000 mg/l
Exposure time: 3 h
Method: OECD Test Guideline 209
- EC50: > 100 mg/l
Test Type: Growth inhibition
Method: similar to OECD Test Guideline 209
- MIC: > 10 mg/l

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Test Type: Growth inhibition
Method: similar to OECD Test Guideline 209

Cellulose:

Toxicity to fish : Remarks: No data available

Persistence and degradability**Components:****TOPIRAMATE:**

Biodegradability : Remarks: No data available

Bioaccumulative potential**Components:****TOPIRAMATE:**

Bioaccumulation : Remarks: No data available

Partition coefficient: n-octanol/water : Remarks: No data available

Octadecanoic acid, magnesium salt:

Partition coefficient: n-octanol/water : Remarks: No data available

Mobility in soil**Components:****TOPIRAMATE:**

Distribution among environmental compartments : log Koc: 2.1
Method: OECD Test Guideline 121
Remarks: high mobility

Other adverse effects**Components:****TOPIRAMATE:**

Results of PBT and vPvB assessment : No information available.

Additional ecological information : No data available
No data available

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SECTION 13. DISPOSAL CONSIDERATIONS**Disposal methods**

- Waste from residues : In accordance with National, Federal, State and Local regulations.
- Contaminated packaging : Empty containers should be taken to an approved waste handling site for recycling or disposal.

SECTION 14. TRANSPORT INFORMATION**International Regulations****UNRTDG**

Not regulated as a dangerous good

IATA-DGR

Not regulated as a dangerous good

IMDG-Code

Not regulated as a dangerous good

Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code

Not applicable for product as supplied.

National Regulations**49 CFR**

Not regulated as a dangerous good

SECTION 15. REGULATORY INFORMATION**SARA 302 Extremely Hazardous Substances Threshold Planning Quantity**

This material does not contain any components with a section 302 EHS TPQ.

- SARA 313** : This material does not contain any chemical components with known CAS numbers that exceed the threshold (De Minimis) reporting levels established by SARA Title III, Section 313.

US State Regulations**Massachusetts Right To Know**

Cellulose	9004-34-6
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Pennsylvania Right To Know

TOPIRAMATE	97240-79-4
Cellulose	9004-34-6
alpha-D-Glucopyranose, 4-O-beta-D-galactopyranosyl-, hydrate (1:1)	5989-81-1
NATRIUM ZETMEELGLYCOLAAT	9063-38-1

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Maine Chemicals of High Concern

Product does not contain any listed chemicals

Vermont Chemicals of High Concern

Product does not contain any listed chemicals

Washington Chemicals of High Concern

Product does not contain any listed chemicals

New York City Hazardous Substances

Carnauba wax 8015-86-9

California Prop. 65

WARNING: This product can expose you to chemicals including TOPIRAMATE, which is/are known to the State of California to cause birth defects or other reproductive harm. For more information go to www.P65Warnings.ca.gov.

California Permissible Exposure Limits for Chemical Contaminants

Cellulose 9004-34-6

The components of this product are reported in the following inventories:

- : This product is not subject to TSCA and TSCA 12(b) Export notification because Food, Drugs and cosmetic products are exempt.

Other regulations

Medicinal products in the finished state, intended for the final user, are not subject to GHS labeling.

Restricted to professional users.

SECTION 16. OTHER INFORMATION**Full text of other abbreviations**

ACGIH	:	USA. ACGIH Threshold Limit Values (TLV)
J&J OEL/PBOEL HHC	:	J&J OEL/PBOEL HHC
NIOSH REL	:	USA. NIOSH Recommended Exposure Limits
OSHA P0	:	USA. Table Z-1-A Limits for Air Contaminants (1989 vacated values)
OSHA Z-1	:	USA. Occupational Exposure Limits (OSHA) - Table Z-1 Limits for Air Contaminants
ACGIH / TWA	:	8-hour, time-weighted average
J&J OEL/PBOEL HHC / TWA	:	Time weighted average
J&J OEL/PBOEL HHC / PBOEL-HHC	:	PBOEL-HHC
NIOSH REL / TWA	:	Time-weighted average concentration for up to a 10-hour workday during a 40-hour workweek
OSHA P0 / TWA	:	8-hour time weighted average
OSHA Z-1 / TWA	:	8-hour time weighted average

AIIC - Australian Inventory of Industrial Chemicals; ASTM - American Society for the Testing of Materials; bw - Body weight; CERCLA - Comprehensive Environmental Response,

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Compensation, and Liability Act; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DOT - Department of Transportation; DSL - Domestic Substances List (Canada); ECx - Concentration associated with x% response; EHS - Extremely Hazardous Substance; ELx - Loading rate associated with x% response; EmS - Emergency Schedule; ENCS - Existing and New Chemical Substances (Japan); ErCx - Concentration associated with x% growth rate response; ERG - Emergency Response Guide; GHS - Globally Harmonized System; GLP - Good Laboratory Practice; HMIS - Hazardous Materials Identification System; IARC - International Agency for Research on Cancer; IATA - International Air Transport Association; IBC - International Code for the Construction and Equipment of Ships carrying Dangerous Chemicals in Bulk; IC50 - Half maximal inhibitory concentration; ICAO - International Civil Aviation Organization; IECSC - Inventory of Existing Chemical Substances in China; IMDG - International Maritime Dangerous Goods; IMO - International Maritime Organization; ISHL - Industrial Safety and Health Law (Japan); ISO - International Organisation for Standardization; KECI - Korea Existing Chemicals Inventory; LC50 - Lethal Concentration to 50 % of a test population; LD50 - Lethal Dose to 50% of a test population (Median Lethal Dose); MARPOL - International Convention for the Prevention of Pollution from Ships; MSHA - Mine Safety and Health Administration; n.o.s. - Not Otherwise Specified; NFPA - National Fire Protection Association; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; NTP - National Toxicology Program; NZIoC - New Zealand Inventory of Chemicals; OECD - Organization for Economic Co-operation and Development; OPPTS - Office of Chemical Safety and Pollution Prevention; PBT - Persistent, Bioaccumulative and Toxic substance; PICCS - Philippines Inventory of Chemicals and Chemical Substances; (Q)SAR - (Quantitative) Structure Activity Relationship; RCRA - Resource Conservation and Recovery Act; REACH - Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals; RQ - Reportable Quantity; SADT - Self-Accelerating Decomposition Temperature; SARA - Superfund Amendments and Reauthorization Act; SDS - Safety Data Sheet; TCSI - Taiwan Chemical Substance Inventory; TECI - Thailand Existing Chemicals Inventory; TSCA - Toxic Substances Control Act (United States); UN - United Nations; UNRTDG - United Nations Recommendations on the Transport of Dangerous Goods; vPvB - Very Persistent and Very Bioaccumulative

Revision Date : 2022/09/24

Date and Number Formats

This document uses the following notation for printing dates and numbers:

Date:	Dec 31th, 2012	as	2012/12/31
Numbers:	123456,78	as	123,456.78

The information provided in this Safety Data Sheet is correct to the best of our knowledge, information and belief at the date of its publication. The information given is designed only as a guidance for safe handling, use, processing, storage, transportation, disposal and release and is not to be considered a warranty or quality specification. The information relates only to the specific material designated and may not be valid for such material used in combination with any other materials or in any process, unless specified in the text.

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