

Version	Revision Date:	SDS Number:	Date of last issue: 2022/09/25
2.15	2022/10/21	10000014489	Date of first issue: 2018/04/12

#### **SECTION 1. IDENTIFICATION**

Product name	: TOPAMAX
Substance name	: TOPAMAX 100 mg tablets
	Topiramate
	Tablets 100 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



			or younnon-younnon
TOPAN	ЛАХ		
Version 2.15	Revision Date: 2022/10/21	SDS Number: 100000014489	Date of last issue: 2022/09/25 Date of first issue: 2018/04/12
Haza	rd pictograms		
Signa	al word	: Warning	
Haza	rd statements	: H361 Suspected of	f damaging fertility or the unborn child.
Precautionary statements		P202 Do not handle and understood.	al instructions before use. e until all safety precautions have been read ive gloves/ protective clothing.
		<b>Response:</b> P308 + P313 IF ex attention.	posed or concerned: Get medical advice/
		<b>Storage:</b> P405 Store locked	up.
		<b>Disposal:</b> P501 Dispose of co	ontents/ container to an approved waste

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 accidently 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
TOPIRAMATE	97240-79-4	>= 50 - < 70
Cellulose	9004-34-6	>= 10 - < 20
Octadecanoic acid, magnesium salt	557-04-0	>= 0.1 - < 1



	/ // \		
Version	Revision Date:	SDS Number:	Date of last issue: 2022/09/25
2.15	2022/10/21	10000014489	Date of first issue: 2018/04/12

Actual concentration is withheld as a trade secret

#### **SECTION 4. FIRST AID MEASURES** 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. 2 Wash off with soap and water. If symptoms persist, call a physician. Rinse immediately with plenty of water, also under the eyelids, In case of eye contact 1 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. Consult the patient packaging insert for more information Most important symptoms : about this Finished Pharmaceutical Product. and effects, both acute and delayed Abdominal pain anorexia insomnia Disorientation Dizziness Tremors Blurred vision nausea Diarrhoea constipation stomach discomfort dry mouth Spasm Fatigue nasopharyngitis Cough weight decrease Notes to physician Treat symptomatically. 1 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.
Hazardous combustion products	:	No information available.



				or younon-younnen
TOPAN	IAX			
Version 2.15	Revision Date: 2022/10/21		0S Number: 0000014489	Date of last issue: 2022/09/25 Date of first issue: 2018/04/12
Furthe	er information	:	No information available	9.
•	al protective equipment efighters	:	In the event of fire, wear self-contained breathing apparatus.	
SECTION	6. ACCIDENTAL RELE	AS	EMEASURES	
protec	Personal precautions, protective equipment and emergency procedures			ental release the emergency response ed on a risk assessment and use ipment as appropriate.
Enviro	Environmental precautions		Should not be released Do not flush into surface	into the environment. e water or sanitary sewer system.
	Methods and materials for containment and cleaning up		Large spills + Small spills: Keep in suitable, closed contain 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 creatin 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

### SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

#### Components with workplace control parameters



rsion 5	Revision Date: 2022/10/21	SDS Number: 100000014489		Date of last issu Date of first issu	
Com	ponents	CAS-No.	Value type (Form of exposure)	Control parameters / Permissible concentration	Basis
TOPIRAMATE		97240-79-4	TWA	0.120 mg/m3	J&J OEL/PBOEL HHC
			PBOEL-HHC	1 B	J&J OEL/PBOEL HHC
		HHC. This sub 1B., Notation F	stance is classif	hazard banding no ied by J&J as being potential to have a lopment	g PBOEL HHC
Cellu	lose	9004-34-6	TWA	10 mg/m3	ACGIH
			TWA (Respirable)	5 mg/m3	NIOSH REL
			TWA (total)	10 mg/m3	NIOSH REL
			TWA (total dust)	15 mg/m3	OSHA Z-1
			TWA (respirable fraction)	5 mg/m3	OSHA Z-1
			TWA (Total dust)	15 mg/m3	OSHA P0
			TWÁ (respirable dust fraction)	5 mg/m3	OSHA P0
	Octadecanoic acid, magnesium salt	557-04-0	TWA (Inhalable particulate matter)	10 mg/m3	ACGIH
			TWA (Respirable particulate	3 mg/m3	ACGIH

**Engineering measures** 

: All personal protective equipment should be based on a risk assessment. Consult a Environment Health Safety expert if necessary.

matter)

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).



TOPAN	IAX				
Version	Revision Date:	SE	DS Number:	Date of last issue: 2022/09/25	
2.15	2022/10/21	10	0000014489	Date of first issue: 2018/04/12	
Perso	onal protective equip	ment			
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.		
Hygie	ne measures	:	Handle in accordance w practice.	vith good industrial hygiene and safety	

#### SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance	:	tablet, Coated
Colour	:	No data available
Odour	:	No data available
Odour Threshold	:	No data available
рН	:	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
Vapour pressure	:	No data available
Relative density	:	No data available



TOPAMAX					
Version 2.15	Revision Date: 2022/10/21	SDS Number:Date of last issue: 2022/0100000014489Date of first issue: 2018/0			
	2022, 10, 21				
Den	sity	: No data available			
Solubility(ies) Water solubility		: No data available			
Partition coefficient: n- octanol/water		: No data available			
Dec	omposition temperature	: No data available			
	osity /iscosity, dynamic	: Not applicable			
١	iscosity, kinematic	: Not applicable			
Exp	losive properties	: No data available			
Oxic	dizing 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
Components:	
<b>TOPIRAMATE:</b> Acute oral toxicity	: LD50 (Rat): 2,436 mg/kg



		of golu	ион-ускинск
TOPAN	/IAX		
Version 2.15	Revision Date: 2022/10/21		e of last issue: 2022/09/25 e of first issue: 2018/04/12
Acute	e inhalation toxicity	: Remarks: May be harmful if inhaled.	
Acute	e dermal toxicity	: Remarks: No data available	
Cellu			
Acute	e oral toxicity	: LD50 (Rat): > 5,000 mg/kg	
ΤΟΡΙ	RAMATE:		
Acute	e oral toxicity	: LD50 (Rat): 2,436 mg/kg	
Acute	e inhalation toxicity	: Remarks: May be harmful if inhaled.	
Acute	e dermal toxicity	: Remarks: No data available	
Cellu	lose:		
Acute	e oral toxicity	: LD50 (Rat): > 5,000 mg/kg	
Skin	corrosion/irritation		
Com	ponents:		
TOPI	RAMATE:		
Speci Resu		: Rabbit : No skin irritation	
Cellu			
Speci Rema		: Rabbit : No skin irritation	
ΤΟΡΙ	RAMATE:		
Speci Resu		: Rabbit : No skin irritation	
Cellu			
Speci Rema		: Rabbit : No skin irritation	
Serio	ous eye damage/eye i	ritation	
Com	ponents:		
ΤΟΡΙ	RAMATE:		
Speci Resu	ies	: Rabbit : No eye irritation	
Cellu			
Spec	ies	: Rabbit	



TOPAN	IAX		0
Version 2.15	Revision Date: 2022/10/21	SDS Number: 100000014489	Date of last issue: 2022/09/25 Date of first issue: 2018/04/12
Rema	arks	: No eye irritation	
ΤΟΡΙ	RAMATE:		
Speci Resul		: Rabbit : No eye irritation	
Cellu	lose:		
Speci Rema		: Rabbit : No eye irritation	
Resp	iratory or skin sensi	tisation	
<u>Com</u>	oonents:		
	RAMATE:		
Resu	t	: Not a sensitizer	
Cellu	lose:		
Speci Rema		: Guinea pig : Did not cause sensitisa	tion on laboratory animals.
ΤΟΡΙ	RAMATE:		
Resu	t	: Not a sensitizer	
Cellu	lose:		
Speci	es	: Guinea pig	
Rema	arks	: Did not cause sensitisa	tion on laboratory animals.
Germ	cell mutagenicity		
<u>Com</u>	oonents:		
ТОРІ	RAMATE:		
Geno	toxicity in vitro	: Test Type: Ames test Result: negative	
		Test Type: Chromosom Test system: Human ly Result: negative	ne aberration test in vitro mphocytes
		Test Type: A mouse lyr Result: negative	mphoma test
Geno	toxicity in vivo	: Test Type: In vivo micro Species: Rat Result: negative	onucleus test

#### TOPIRAMATE:



TOPAMA	AX		v v
Version 2.15	Revision Date: 2022/10/21	SDS Number: 100000014489	Date of last issue: 2022/09/25 Date of first issue: 2018/04/12
Genoto	xicity in vitro	: Test Type: Ames test Result: negative	
		Test Type: Chromoso Test system: Human Result: negative	me aberration test in vitro lymphocytes
		Test Type: A mouse ly Result: negative	ymphoma test
Genoto	xicity in vivo	: Test Type: In vivo mic Species: Rat Result: negative	cronucleus test
Carcino	ogenicity		
<u>Compo</u>	<u>nents:</u>		
TOPIRA	MATE:		
Species Applicat Exposu Dose Remark	tion Route re time	<ul> <li>Rat</li> <li>Oral</li> <li>2 years</li> <li>120 mg/kg/day</li> <li>no carcinogenic effects</li> </ul>	
		Ū	
Species	tion Route re time	<ul> <li>Rat</li> <li>Oral</li> <li>2 years</li> <li>120 mg/kg/day</li> <li>no carcinogenic effects</li> </ul>	
IARC			levels greater than or equal to 0.1% is med human carcinogen by IARC.
			levels greater than or equal to 0.1% is med human carcinogen by IARC.
OSHA		ent of this product present at list of regulated carcinogens	levels greater than or equal to 0.1% is
		ent of this product present at list of regulated carcinogens	levels greater than or equal to 0.1% is
NTP		ent of this product present at a known or anticipated carc	levels greater than or equal to 0.1% is inogen by NTP.
		ent of this product present at a known or anticipated carc	levels greater than or equal to 0.1% is inogen by NTP.



		ог устистустист
PAMAX		
sion Revision Date: 5 2022/10/21	SDS Number: 100000014489	Date of last issue: 2022/09/25 Date of first issue: 2018/04/12
Reproductive toxicity		
Components:		
TOPIRAMATE:		
Effects on foetal development	: Species: Rabbit Remarks: positive	
	Species: Rat Remarks: positive	
	Species: Mouse Remarks: positive	
Reproductive toxicity - Assessment	: Some evidence of advanimal experiments.	verse effects on development, based on
Teratogenicity - Assessment	: Limited evidence of a studies and/ or humar	dverse effects on development in animal n studies.
TOPIRAMATE:		
Effects on foetal development	: Species: Rabbit Remarks: positive	
	Species: Rat Remarks: positive	
	Species: Mouse Remarks: positive	
Reproductive toxicity - Assessment	: Some evidence of advantage animal experiments.	verse effects on development, based on
Teratogenicity - Assessment	: Limited evidence of a studies and/ or humar	dverse effects on development in animal n studies.
STOT - single exposure		
Components:		
TOPIRAMATE:		
Remarks	: No data available	
TOPIRAMATE:		

No data available



# TOPAMAXVersionRevision Date:SDS Number:Date of last issue: 2022/09/252.152022/10/21100000014489Date of first issue: 2018/04/12

#### Repeated dose toxicity

#### Components:

#### TOPIRAMATE:

Species NOAEL	:	Rat 10 mg/kg
Exposure time	:	3 months
Species NOAEL	:	Dog 10 mg/kg
Exposure time Species	:	3 months Dog
NOAEL Exposure time	:	10 mg/kg 12 months
	-	12 11011015

#### **TOPIRAMATE:**

'nβ
hs

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



Version 2.15

Revision Date: 2022/10/21

SDS Number: 100000014489

Date of last issue: 2022/09/25 Date of first issue: 2018/04/12

#### **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
plants		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): >= 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



TOPAN	IAX			
Version 2.15	Revision Date: 2022/10/21		0S Number: 0000014489	Date of last issue: 2022/09/25 Date of first issue: 2018/04/12
			Test Type: Growth inhibition Method: similar to OECD Test	Guideline 209
Cellu	lose:			
Toxic	ity to fish	:	Remarks: No data available	
TOPI	RAMATE:			
Toxic	ity to fish	:	NOEC (Lepomis macrochirus ( Method: FDA 4.11	(Bluegill sunfish)): < 75 mg/l
			LC50 (Lepomis macrochirus (E Exposure time: 96 h Method: FDA 4.11	Bluegill sunfish)): > 2,400 mg/l
	ity to daphnia and other ic invertebrates	:	NOEC (Daphnia (water flea)): Method: FDA 4.08	1,000 mg/l
			EC50 (Daphnia (water flea)): 1 Method: FDA 4.08	,000 mg/l
Toxic plants	ity to algae/aquatic	:	EbC50 (Pseudokirchneriella su mg/l Test Type: Cell multiplication ir Method: OECD Test Guideline	nhibition test
			NOECb (Pseudokirchneriella s mg/l Test Type: Cell multiplication ir Method: OECD Test Guideline	nhibition test
			ErC50 (Pseudokirchneriella su mg/l Test Type: Growth inhibition Method: OECD Test Guideline	
			NOECr (Pseudokirchneriella su mg/l Test Type: Growth inhibition Method: OECD Test Guideline	
Toxic	ity to microorganisms	:	NOEC (activated sludge): >= 1 Exposure time: 3 h Method: OECD Test Guideline	-
			EC50 (activated sludge): > 1,0 Exposure time: 3 h Method: OECD Test Guideline	
			EC50: > 100 mg/l Test Type: Growth inhibition Method: similar to OECD Test	Guideline 209



				or Johnson-Johnson
OPAN	IAX			
ersion	Revision Date:	S	DS Number:	Date of last issue: 2022/09/2
15	2022/10/21	10	0000014489	Date of first issue: 2018/04/12
			MIC: > 10 mg/l	
			Test Type: Growth inhibition	
			Method: similar to OECD Tes	t Guideline 209
Cellul	i <b>ose:</b> ity to fish		Remarks: No data available	
TOXICI		•	Remarks. NO dala available	
Persi	stence and degradabil	ity		
Comp	oonents:			
TOPI	RAMATE:			
Biode	gradability	:	Remarks: No data available	
-	RAMATE:			
Biode	gradability	:	Remarks: No data available	
Bioac	cumulative potential			
<u>Comp</u>	oonents:			
TOPI	RAMATE:			
Bioac	cumulation	:	Remarks: No data available	
Partiti	on coefficient: n-	:	Remarks: No data available	
octano	ol/water			
Octac	lecanoic acid, magnes	iun	n salt:	
	on coefficient: n-	:	Remarks: No data available	
	ol/water			
тори	RAMATE:			
	cumulation	•	Remarks: No data available	
		-		
	on coefficient: n- ol/water	:	Remarks: No data available	
•				
	decanoic acid, magnes on coefficient: n-	un.		
	ol/water	•		
Mobil	ity in soil			
	oonents:			
	RAMATE:			
	oution among	:	log Koc: 2.1	
	onmental compartments		Method: OECD Test Guideline	e 121



TOPAN				or gennen gennen
Version 2.15	Revision Date: 2022/10/21	-	DS Number: 0000014489	Date of last issue: 2022/09/25 Date of first issue: 2018/04/12
			Remarks: high mobility	
Distri	RAMATE: bution among onmental compartments	:	log Koc: 2.1 Method: OECD Test Guideline Remarks: high mobility	121
Othe	r adverse effects			
Com	oonents:			
Resu	RAMATE: Its of PBT and vPvB ssment	:	No information available.	
	onal ecological nation	:	No data available No data available	
Resu	RAMATE: Its of PBT and vPvB ssment	:	No information available.	
	onal ecological nation	:	No data available No data available	

#### 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.



Version	Revision Date:	SDS Number:	Date of last issue: 2022/09/25
2.15	2022/10/21	10000014489	Date of first issue: 2018/04/12

#### 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
Massachusetts Right To Know	
Cellulose	9004-34-6
Pennsylvania Right To Know	
TOPIRAMATE Cellulose alpha-D-Glucopyranose, 4-O-beta-D-galactopyranosyl-, hydrate (1:1) NATRIUM ZETMEELGLYCOLAAT	97240-79-4 9004-34-6 5989-81-1 9063-38-1
Pennsylvania Right To Know	
TOPIRAMATE Cellulose alpha-D-Glucopyranose, 4-O-beta-D-galactopyranosyl-, hydrate (1:1)	97240-79-4 9004-34-6 5989-81-1
NATRIUM ZETMEELGLYCOLAAT	9063-38-1
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 Jersey Right To Know TOPIRAMATE Cellulose alpha-D-Glucopyranose, 4-O-beta-D-galactopyranosyl-, hydrate (1:1) NATRIUM ZETMEELGLYCOLAAT	97240-79-4 9004-34-6 5989-81-1 9063-38-1
New York City Hazardous Substances	

#### New York City Hazardous Substances

#### TOPAMAX Version Revision Date: SDS Number: Date of last issue: 2022/09/25 Date of first issue: 2018/04/12 2022/10/21 100000014489 2.15

No components listed on the New York City Hazardous Substances List

#### **New York City Hazardous Substances**

Carnauba wax

#### California Prop. 65

WARNING: This product contains a chemical known to the State of California to cause birth defects or other reproductive harm.

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

**California Permissible Exposure Limits for Chemical Contaminants** Cellulose

## 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 J&J OEL/PBOEL HHC NIOSH REL OSHA P0	:	USA. ACGIH Threshold Limit Values (TLV) J&J OEL/PBOEL HHC USA. NIOSH Recommended Exposure Limits 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, Compensation, and Liability Act; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN -



8015-86-9

9004-34-6

9004-34-6

. . . . . . . .



IOPAMAX						
Version	Revision Date:	SDS Number:	Date of last issue: 2022/09/25			
2.15	2022/10/21	10000014489	Date of first issue: 2018/04/12			

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 : 2022/10/21

#### 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.

US / EN