

Vorapaxar Formulation

 Version
 Revision Date:
 SDS Number:
 Date of last issue: 02/07/2017

 3.1
 05/02/2017
 86302-00005
 Date of first issue: 04/01/2015

SECTION 1. IDENTIFICATION

Product name : Vorapaxar Formulation

Manufacturer or supplier's details

Company name of supplier : Merck & Co., Inc

Address : 2000 Galloping Hill Road

Kenilworth - New Jersey - USA 1685

Telephone : 908-740-4000

Telefax : 908-735-1496

Emergency telephone : 1-908-423-6000

E-mail address : EHSDATASTEWARD@merck.com

Recommended use of the chemical and restrictions on use

Recommended use : Pharmaceutical

SECTION 2. HAZARDS IDENTIFICATION

GHS classification in accordance with 29 CFR 1910.1200

Combustible dust

Carcinogenicity (Inhalation) : Category 2

Reproductive toxicity : Category 2

Specific target organ

systemic toxicity - repeated

exposure

Category 2 (Liver, Blood, thymus, Kidney, Skeletal muscle, Tes-

tes, eye - retina)

GHS label elements

Hazard pictograms :



Signal Word : Warning

Hazard Statements : If small particles are generated during further processing,

handling or by other means, may form combustible dust

concentrations in air.

H351 Suspected of causing cancer if inhaled. H361d Suspected of damaging the unborn child.

H373 May cause damage to organs (Liver, Blood, thymus, Kidney, Skeletal muscle, Testes, eye - retina) through prolonged

or repeated exposure.



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Precautionary Statements : Prevention:

P201 Obtain special instructions before use.

P202 Do not handle until all safety precautions have been read

and understood.

P260 Do not breathe dust.

P280 Wear protective gloves/ protective clothing/ eye protection/

face protection.

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 dis-

posal plant.

Other hazards

Dust contact with the eyes can lead to mechanical irritation.

Contact with dust can cause mechanical irritation or drying of the skin.

SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture : Mixture

Hazardous ingredients

Chemical name	CAS-No.	Concentration (% w/w)
Cellulose	9004-34-6	>= 10 -< 20
Vorapaxar	705260-08-8	>= 1 -< 5
Titanium dioxide	13463-67-7	>= 0.1 -< 1

SECTION 4. FIRST AID MEASURES

General advice : In the case of accident or if you feel unwell, seek medical

advice immediately.

When symptoms persist or in all cases of doubt seek medical

advice.

If inhaled : If inhaled, remove to fresh air.

Get medical attention.

In case of skin contact : In case of contact, immediately flush skin with soap and plenty

of water.

Remove contaminated clothing and shoes.

Get medical attention. Wash clothing before reuse.

Thoroughly clean shoes before reuse.

In case of eye contact : If in eyes, rinse well with water.



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Get medical attention if irritation develops and persists.

If swallowed, DO NOT induce vomiting.

Get medical attention.

Rinse mouth thoroughly with water.

Most important symptoms and effects, both acute and

delayed

Contact with dust can cause mechanical irritation or drying of

the skin.

Dust contact with the eyes can lead to mechanical irritation.

Suspected of causing cancer if inhaled. Suspected of damaging the unborn child.

May cause damage to organs through prolonged or repeated

exposure.

Protection of first-aiders : First Aid responders should pay attention to self-protection,

and use the recommended personal protective equipment

when the potential for exposure exists.

Notes to physician : Treat symptomatically and supportively.

SECTION 5. FIRE-FIGHTING MEASURES

Suitable extinguishing media : Water spray

Alcohol-resistant foam Carbon dioxide (CO2)

Dry chemical

Unsuitable extinguishing

media

None known.

Specific hazards during fire

fighting

Exposure to combustion products may be a hazard to health.

Hazardous combustion prod- :

ucts

Carbon oxides

Nitrogen oxides (NOx)

Specific extinguishing meth-

ods

Use extinguishing measures that are appropriate to local cir-

cumstances and the surrounding environment. Use water spray to cool unopened containers.

Remove undamaged containers from fire area if it is safe to do

SO.

Evacuate area.

Special protective equipment:

for fire-fighters

In the event of fire, wear self-contained breathing apparatus.

Use personal protective equipment.

SECTION 6. ACCIDENTAL RELEASE MEASURES

Personal precautions, protective equipment and emer-

are equipment and emer-

gency procedures

Use personal protective equipment.

Follow safe handling advice and personal protective

equipment recommendations.

Environmental precautions : Discharge into the environment must be avoided.



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Prevent further leakage or spillage if safe to do so. Retain and dispose of contaminated wash water.

Local authorities should be advised if significant spillages

cannot be contained.

Methods and materials for containment and cleaning up

Sweep up or vacuum up spillage and collect in suitable

container for disposal.

Avoid dispersal of dust in the air (i.e., clearing dust surfaces

with compressed air).

Dust deposits should not be allowed to accumulate on surfaces, as these may form an explosive mixture if they are released into the atmosphere in sufficient concentration. Local or national regulations may apply to releases and disposal of this material, as well as those materials and items employed in the cleanup of releases. You will need to

determine which regulations are applicable.

Sections 13 and 15 of this SDS provide information regarding

certain local or national requirements.

SECTION 7. HANDLING AND STORAGE

Technical measures : Static electricity may accumulate and ignite suspended dust

causing an explosion.

Provide adequate precautions, such as electrical grounding

and bonding, or inert atmospheres.

Local/Total ventilation : Use only with adequate ventilation.

Advice on safe handling : Do not breathe dust.

Do not swallow.

Avoid contact with eyes.

Avoid prolonged or repeated contact with skin.

Handle in accordance with good industrial hygiene and safety

practice.

Minimize dust generation and accumulation. Keep container closed when not in use. Keep away from heat and sources of ignition.

Take precautionary measures against static discharges.

Take care to prevent spills, waste and minimize release to the

environment.

Conditions for safe storage : Keep in properly labeled containers.

Store in accordance with the particular national regulations.

Materials to avoid : Do not store with the following product types:

Strong oxidizing agents

SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Ingredients with workplace control parameters

Ingredients	CAS-No.	Value type (Form of	Control parame- ters / Permissible	Basis
		exposure)	concentration	



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Cellulose	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
Vorapaxar	705260-08-8	TWA	5 μg/m3 (OEB 4)	Merck
		Wipe limit	50 μg/100 cm ²	Merck
Titanium dioxide	13463-67-7	TWA (total dust)	15 mg/m³	OSHA Z-1
		TWA	10 mg/m³ (Titanium dioxide)	ACGIH

Engineering measures

: Ensure adequate ventilation, especially in confined areas. Minimize workplace exposure concentrations.

Apply measures to prevent dust explosions.

Ensure that dust-handling systems (such as exhaust ducts, dust collectors, vessels, and processing equipment) are designed in a manner to prevent the escape of dust into the work area (i.e., there is no leakage from the equipment). Dust formation may be relevant in the processing of this product. In addition to substance-specific OELs, general limitations of concentrations of particulates in the air at workplaces have to be considered in workplace risk assessment. Relevant limits include: OSHA PEL for Particulates Not Otherwise Regulated of 15 mg/m3 - total dust, 5 mg/m3 - respirable fraction; and ACGIH TWA for Particles (insoluble or poorly soluble) Not Otherwise Specified of 3 mg/m3 - respirable particles, 10 mg/m3 - inhalable particles.

Personal protective equipment

Respiratory protection

General and local exhaust ventilation is recommended to maintain vapor exposures below recommended limits. Where concentrations are above recommended limits or are unknown, appropriate respiratory protection should be worn. Follow OSHA respirator regulations (29 CFR 1910.134) and use NIOSH/MSHA approved respirators. Protection provided by air purifying respirators against exposure to any hazardous chemical is limited. Use a positive pressure air supplied respirator if there is any potential for uncontrolled release, exposure levels are unknown, or any other circumstance where air purifying respirators may not provide

adequate protection.

Hand protection

Material : Chemical-resistant gloves

Remarks : For prolonged or repeated contact use protective gloves.

Choose gloves to protect hands against chemicals depending



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on the concentration specific to place of work. Breakthrough time is not determined for the product. Change gloves often! For special applications, we recommend clarifying the resistance to chemicals of the aforementioned protective gloves with the glove manufacturer. Wash hands before

breaks and at the end of workday.

Eye protection : Wear the following personal protective equipment:

Safety goggles

Skin and body protection : Select appropriate protective clothing based on chemical

resistance data and an assessment of the local exposure

potential.

Skin contact must be avoided by using impervious protective

clothing (gloves, aprons, boots, etc).

Hygiene measures : Ensure that eye flushing systems and safety showers are

located close to the working place. When using do not eat, drink or smoke. Wash contaminated clothing before re-use.

SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance : powder

Color : yellow

Odor : No information available.

Odor Threshold : No data available

pH : No data available

Melting point/freezing point : No data available

Initial boiling point and boiling

range

No data available

Flash point : No data available

Evaporation rate : No data available

Flammability (solid, gas) : May form explosive dust-air mixture during processing,

handling or other means

Flammability (liquids) : No data available

Upper explosion limit / Upper

flammability limit

No data available

Lower explosion limit / Lower

flammability limit

No data available

Vapor pressure : No data available



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Relative vapor density : No data available

Density No data available

Solubility(ies)

Water solubility No data available

Partition coefficient: n-

octanol/water

No data available

Autoignition temperature No data available

Decomposition temperature No data available

Viscosity

No data available Viscosity, kinematic

Explosive properties Not explosive

Oxidizing properties The substance or mixture is not classified as oxidizing.

Molecular weight No data available

Particle size No data available

SECTION 10. STABILITY AND REACTIVITY

Reactivity : Not classified as a reactivity hazard.

Chemical stability Stable under normal conditions.

tions

Possibility of hazardous reac- : Dust can form an explosive mixture in air. Can react with strong oxidizing agents.

Conditions to avoid None known.

Incompatible materials Oxidizing agents

Hazardous decomposition

products

No hazardous decomposition products are known.

SECTION 11. TOXICOLOGICAL INFORMATION

Information on likely routes of exposure

Inhalation Skin contact Ingestion

Eye contact

Acute toxicity

Not classified based on available information.

Product:



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Acute oral toxicity : Acute toxicity estimate: > 5,000 mg/kg

Method: Calculation method

Ingredients:

Cellulose:

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

Acute inhalation toxicity : LC50 (Rat): > 5.8 mg/l

Exposure time: 4 h

Test atmosphere: dust/mist

Acute dermal toxicity : LD50 (Rabbit): > 2,000 mg/kg

Assessment: The substance or mixture has no acute dermal

toxicity

Vorapaxar:

Acute oral toxicity : LD50 (Rat): > 2,000 mg/kg

Titanium dioxide:

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

Acute inhalation toxicity : LC50 (Rat): > 6.82 mg/l

Exposure time: 4 h

Test atmosphere: dust/mist

Assessment: The substance or mixture has no acute inhala-

tion toxicity

Skin corrosion/irritation

Not classified based on available information.

Ingredients:

Cellulose:

Result: No skin irritation

Remarks: Based on data from similar materials

Vorapaxar:

Species: Rabbit

Result: No skin irritation

Titanium dioxide:

Species: Rabbit

Result: No skin irritation

Serious eye damage/eye irritation

Not classified based on available information.



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Ingredients:

Cellulose:

Result: No eye irritation

Remarks: Based on data from similar materials

Vorapaxar:

Species: Rabbit

Result: Mild eye irritation Remarks: slight irritation

Titanium dioxide:

Species: Rabbit

Result: No eye irritation

Respiratory or skin sensitization

Skin sensitization

Not classified based on available information.

Respiratory sensitization

Not classified based on available information.

Ingredients:

Cellulose:

Test Type: Local lymph node assay (LLNA)

Routes of exposure: Skin contact

Species: Mouse

Method: OECD Test Guideline 429

Result: negative

Remarks: Based on data from similar materials

Vorapaxar:

Test Type: Local lymph node assay (LLNA)

Routes of exposure: Dermal

Species: Mouse

Assessment: Does not cause skin sensitization.

Result: negative

Titanium dioxide:

Test Type: Local lymph node assay (LLNA)

Routes of exposure: Skin contact

Species: Mouse Result: negative

Germ cell mutagenicity

Not classified based on available information.

Ingredients:

Cellulose:



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Genotoxicity in vitro Test Type: Bacterial reverse mutation assay (AMES)

Result: negative

Remarks: Based on data from similar materials

Genotoxicity in vivo Test Type: Mammalian erythrocyte micronucleus test (in vivo

> cytogenetic assay) Species: Mouse

Application Route: Ingestion

Result: negative

Remarks: Based on data from similar materials

Vorapaxar:

Genotoxicity in vitro Test Type: Bacterial reverse mutation assay (AMES)

Result: negative

Test Type: Chromosome aberration test in vitro

Result: negative

Genotoxicity in vivo Test Type: Mammalian erythrocyte micronucleus test (in vivo

cytogenetic assay) Species: Mouse Application Route: Oral Result: negative

Germ cell mutagenicity -

Assessment

Weight of evidence does not support classification as a germ

cell mutagen.

Titanium dioxide:

Genotoxicity in vitro Test Type: Bacterial reverse mutation assay (AMES)

Result: negative

Genotoxicity in vivo Test Type: In vivo micronucleus test

> Species: Mouse Result: negative

Carcinogenicity

Suspected of causing cancer if inhaled.

Ingredients:

Vorapaxar:

Species: Rat

Application Route: Oral Exposure time: 2 Years

Result: negative

Species: Mouse

Application Route: Oral Exposure time: 2 Years

Result: negative



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Titanium dioxide:

Species: Rat

Application Route: inhalation (dust/mist/fume)

Exposure time: 2 Years

Method: OECD Test Guideline 453

Result: positive

Remarks: The mechanism or mode of action may not be relevant in humans.

Carcinogenicity - Assess-

ment

Limited evidence of carcinogenicity in inhalation studies with

animals.

IARC Group 2B: Possibly carcinogenic to humans

Titanium dioxide 13463-67-7

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 ingredient 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

Suspected of damaging the unborn child.

Ingredients:

Vorapaxar:

Effects on fertility : Species: Rat, male and female

Application Route: Oral

Fertility: NOAEL: >= 50 mg/kg body weight

Effects on fetal development : Test Type: Embryo-fetal development

Species: Rat

Application Route: Oral

Developmental Toxicity: LOAEL: 75 mg/kg body weight

Result: negative

Remarks: The effects were seen only at maternally toxic dos-

es.

Test Type: Embryo-fetal development

Species: Rat

Application Route: Oral

Developmental Toxicity: NOAEL: 25 mg/kg body weight

Result: negative

Remarks: The effects were seen only at maternally toxic dos-

es.

Test Type: Embryo-fetal development

Species: Rabbit Application Route: Oral

Developmental Toxicity: LOAEL: 20 mg/kg body weight

Symptoms: Malformations were observed.

Result: positive



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Test Type: Embryo-fetal development

Species: Rabbit Application Route: Oral

Developmental Toxicity: NOAEL: 10 mg/kg body weight

Symptoms: Malformations were observed.

Result: positive

Test Type: Embryo-fetal development

Species: Rat

Application Route: Oral

Developmental Toxicity: LOAEL: 25 mg/kg body weight

Result: positive

Test Type: Embryo-fetal development

Species: Rat

Application Route: Oral

Developmental Toxicity: NOAEL: 5 mg/kg body weight

Result: positive

Reproductive toxicity - As-

sessment

Some evidence of adverse effects on development, based on

animal experiments.

STOT-single exposure

Not classified based on available information.

STOT-repeated exposure

May cause damage to organs (Liver, Blood, thymus, Kidney, Skeletal muscle, Testes, eye - retina) through prolonged or repeated exposure.

Ingredients:

Vorapaxar:

Target Organs: Liver, Blood, thymus, Kidney, Skeletal muscle, Testes, eye - retina Assessment: May cause damage to organs through prolonged or repeated exposure.

Repeated dose toxicity

Ingredients:

Cellulose:

Species: Rat

NOAEL: > 5,000 mg/kg Application Route: Ingestion Exposure time: 90 Days

Remarks: Based on data from similar materials

Vorapaxar:

Species: Monkey NOAEL: 20 mg/kg Application Route: Oral Exposure time: 12 Months

Species: Monkey LOAEL: 30 mg/kg



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Application Route: Oral Exposure time: 3 Months Target Organs: Liver, Blood

Species: Rat NOAEL: 3 mg/kg LOAEL: 10 mg/kg Application Route: Oral Exposure time: 6 Months Target Organs: Liver

Species: Mouse LOAEL: 25 mg/kg Application Route: Oral Exposure time: 3 Months

Target Organs: Liver, thymus, Kidney, Skeletal muscle

Titanium dioxide:

Species: Rat

NOAEL: 24,000 mg/kg Application Route: Ingestion Exposure time: 28 Days

Species: Rat NOAEL: 10 mg/m³

Application Route: inhalation (dust/mist/fume)

Exposure time: 2 y

Aspiration toxicity

Not classified based on available information.

Experience with human exposure

Ingredients:

Vorapaxar:

Ingestion : Symptoms: bleeding

SECTION 12. ECOLOGICAL INFORMATION

Ecotoxicity

Ingredients:

Cellulose:

Toxicity to fish : LC50 (Cyprinus carpio (Carp)): > 100 mg/l

Exposure time: 96 h

Method: OECD Test Guideline 203

Remarks: Based on data from similar materials

Toxicity to daphnia and other :

aquatic invertebrates

EC50 (Daphnia magna (Water flea)): > 100 mg/l

Exposure time: 48 h

Method: OECD Test Guideline 202



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Remarks: Based on data from similar materials

Toxicity to algae EC50 (Pseudokirchneriella subcapitata (green algae)): > 100

mg/l

Exposure time: 72 h

Method: OECD Test Guideline 201

Remarks: Based on data from similar materials

Vorapaxar:

Toxicity to algae EC50 (Pseudokirchneriella subcapitata (green algae)): > 6.8

mg/l

Exposure time: 72 h

Method: OECD Test Guideline 201

NOEC (Pseudokirchneriella subcapitata (green algae)): 0.13

mg/l

Exposure time: 72 h

Method: OECD Test Guideline 201

Toxicity to fish (Chronic tox-

icity)

NOEC (Pimephales promelas (fathead minnow)): 0.027 mg/l

Exposure time: 32 d

Method: OECD Test Guideline 210

Toxicity to daphnia and other

aquatic invertebrates (Chron-

ic toxicity)

NOEC (Daphnia magna (Water flea)): 0.055 mg/l

Exposure time: 21 d

Method: OECD Test Guideline 211

M-Factor (Chronic aquatic

toxicity)

1

EC50: > 1,000 mg/l Toxicity to microorganisms

Exposure time: 3 h

Test Type: Respiration inhibition Method: OECD Test Guideline 209

NOEC: 148 mg/l Exposure time: 3 h

Test Type: Respiration inhibition Method: OECD Test Guideline 209

Titanium dioxide:

LC50 (Oncorhynchus mykiss (rainbow trout)): > 100 mg/l Toxicity to fish

Exposure time: 96 h

Method: OECD Test Guideline 203

Toxicity to daphnia and other :

aquatic invertebrates

EC50 (Daphnia magna (Water flea)): > 100 mg/l

Exposure time: 48 h

Toxicity to algae EC50 (Skeletonema costatum (marine diatom)): > 10,000 mg/l

Exposure time: 72 h

Toxicity to microorganisms EC50: > 1,000 mg/l

Exposure time: 3 h

Method: OECD Test Guideline 209



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Persistence and degradability

Ingredients:

Cellulose:

Biodegradability : Result: Readily biodegradable.

Vorapaxar:

Biodegradability : Result: Not readily biodegradable.

Biodegradation: 0 % Exposure time: 28 d

Method: OECD Test Guideline 301

Bioaccumulative potential

Ingredients:

Vorapaxar:

Bioaccumulation : Species: Lepomis macrochirus (Bluegill sunfish)

Bioconcentration factor (BCF): 776 - 858

Partition coefficient: n-

octanol/water

log Pow: 5.11

Mobility in soil

Ingredients:

Vorapaxar:

Distribution among environ-

mental compartments

log Koc: 5.01

Method: OECD Test Guideline 106

Other adverse effects

No data available

SECTION 13. DISPOSAL CONSIDERATIONS

Disposal methods

Waste from residues : Dispose of in accordance with local regulations.

Contaminated packaging : Empty containers should be taken to an approved waste

handling site for recycling or disposal.

If not otherwise specified: Dispose of as unused product.

SECTION 14. TRANSPORT INFORMATION

International Regulations

UNRTDG

Not regulated as a dangerous good



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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.

Domestic regulation

49 CFR

Not regulated as a dangerous good

SECTION 15. REGULATORY INFORMATION

EPCRA - Emergency Planning and Community Right-to-Know

CERCLA Reportable Quantity

This material does not contain any components with a CERCLA RQ.

SARA 304 Extremely Hazardous Substances Reportable Quantity

This material does not contain any components with a section 304 EHS RQ.

SARA 302 Extremely Hazardous Substances Threshold Planning Quantity

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

SARA 311/312 Hazards : Fire Hazard

Chronic Health Hazard

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

Pennsylvania Right To Know

D-Glucose, 4-O-.beta.-D-galactopyranosyl-, monohydrate 64044-51-5 Cellulose 9004-34-6 Croscarmellose sodium 74811-65-7

California Prop. 65

WARNING! This product contains a chemical known in the State of California to cause cancer.

Titanium dioxide 13463-67-7

California List of Hazardous Substances

Polyvinyl pyrrolidone 9003-39-8

California Permissible Exposure Limits for Chemical Contaminants

Cellulose 9004-34-6

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

AICS : not determined

DSL : not determined



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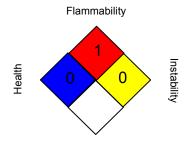
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IECSC : not determined

SECTION 16. OTHER INFORMATION

Further information

NFPA:



Special hazard.

HMIS® IV:



HMIS® ratings are based on a 0-4 rating scale, with 0 representing minimal hazards or risks, and 4 representing significant hazards or risks. The "*" represents a chronic hazard, while the "/" represents the absence of a chronic hazard.

Full text of other abbreviations

ACGIH : USA. ACGIH Threshold Limit Values (TLV)
NIOSH REL : USA. NIOSH Recommended Exposure Limits

OSHA Z-1 : USA. Occupational Exposure Limits (OSHA) - Table Z-1 Lim-

its for Air Contaminants

ACGIH / TWA : 8-hour, time-weighted average

NIOSH REL / TWA : Time-weighted average concentration for up to a 10-hour

workday during a 40-hour workweek

OSHA Z-1 / TWA : 8-hour time weighted average

AICS - Australian Inventory of Chemical Substances; 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 - 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)



Vorapaxar Formulation

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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; 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

Sources of key data used to compile the Material Safety Data Sheet

Internal technical data, data from raw material SDSs, OECD eChem Portal search results and European Chemicals Agen-

cy, http://echa.europa.eu/

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Items where changes have been made to the previous version are highlighted in the body of this document by two vertical lines.

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