

Posaconazole Solid Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 04/23/2015
4.1	02/04/2016	23536-00004	Date of first issue: 10/21/2014

SECTION 1. IDENTIFICATION

Product name : Posaconazole Solid 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**

Combustible dust

Reproductive toxicity : Category 2

Specific target organ systemic toxicity - repeated exposure (Oral) : Category 1 (Adrenal gland, Bone marrow, Kidney, Nervous system, Reproductive organs)

GHS label elements

Hazard pictograms :



Signal Word : Danger

Hazard Statements : If small particles are generated during further processing, handling or by other means, may form combustible dust concentrations in air.
H361 Suspected of damaging fertility or the unborn child.
H372 Causes damage to organs (Adrenal gland, Bone marrow, Kidney, Nervous system, Reproductive organs) through prolonged or repeated exposure if swallowed.

Precautionary Statements : **Prevention:**
P201 Obtain special instructions before use.

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P202 Do not handle until all safety precautions have been read and understood.
P260 Do not breathe dust/ fume/ gas/ mist/ vapors/ spray.
P264 Wash skin thoroughly after handling.
P270 Do not eat, drink or smoke when using this product.
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 disposal 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)
Posaconazole	171228-49-2	>= 10 - < 20
Cellulose	9004-34-6	>= 10 - < 20

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.
Get medical attention if irritation develops and persists.

If swallowed : If swallowed, DO NOT induce vomiting.
Get medical attention.
Rinse mouth thoroughly with water.

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Most important symptoms and effects, both acute and delayed : Suspected of damaging fertility or the unborn child.
Causes damage to organs through prolonged or repeated exposure if swallowed.
Contact with dust can cause mechanical irritation or drying of the skin.
Dust contact with the eyes can lead to mechanical irritation.

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 products : Carbon oxides

Specific extinguishing methods : Use extinguishing measures that are appropriate to local circumstances 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 emergency procedures : Use personal protective equipment.
Follow safe handling advice and personal protective equipment recommendations.

Environmental precautions : Discharge into the environment must be avoided.
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 : Sweep up or vacuum up spillage and collect in suitable con-

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containment and cleaning up tainer 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 care to prevent spills, waste and minimize release to the environment.
Conditions for safe storage	: Keep in properly labeled containers. Store locked up. Store in accordance with the particular national regulations.
Materials to avoid	: Do not store with the following product types: Strong oxidizing agents Organic peroxides Explosives Gases

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

Ingredients	CAS-No.	Value type (Form of exposure)	Control parameters / Permissible concentration	Basis
Posaconazole	171228-49-2	TWA	1,000 µg/m3	Merck
Cellulose	9004-34-6	TWA	10 mg/m3	ACGIH

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		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

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

: Impervious gloves

Remarks

: Choose gloves to protect hands against chemicals depending 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

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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	: No data available
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
Upper explosion limit	: No data available
Lower explosion limit	: No data available
Vapor pressure	: No data available
Relative vapor density	: No data available
Relative density	: No data available
Density	: 1 g/cm3
Solubility(ies)	
Water solubility	: No data available
Partition coefficient: n-octanol/water	: No data available
Autoignition temperature	: No data available

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Decomposition temperature	: No data available
Viscosity	
Viscosity, dynamic	: No data available
Explosive properties	: Not explosive
Oxidizing properties	: The substance or mixture is not classified as oxidizing.
Molecular weight	: No data available

SECTION 10. STABILITY AND REACTIVITY

Reactivity	: Not classified as a reactivity hazard.
Chemical stability	: Stable under normal conditions.
Possibility of hazardous reactions	: 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.

Ingredients:**Posaconazole:**

Acute oral toxicity	: LD50 (Rat): > 5,000 mg/kg
	LD50 (Mouse): > 3,000 mg/kg

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

Acute oral toxicity	: LD50 (Rat): > 5,000 mg/kg
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Acute inhalation toxicity	: LC50 (Rat): > 5.8 mg/l Exposure time: 4 h Test atmosphere: dust/mist
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Acute dermal toxicity	: LD50 (Rabbit): > 2,000 mg/kg
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Assessment: The substance or mixture has no acute dermal toxicity

Skin corrosion/irritation

|| Not classified based on available information.

Ingredients:**Posaconazole:**

Species: Rabbit

Result: No skin irritation

Cellulose:

Result: No skin irritation

Remarks: Based on data from similar materials

Serious eye damage/eye irritation

|| Not classified based on available information.

Ingredients:**Posaconazole:**

Species: Rabbit

Result: Mild eye irritation

Cellulose:

Result: No eye irritation

Remarks: Based on data from similar materials

Respiratory or skin sensitization

|| Skin sensitization: Not classified based on available information.

|| Respiratory sensitization: Not classified based on available information.

Ingredients:**Posaconazole:**

Test Type: Magnusson-Kligman-Test

Routes of exposure: Skin contact

Species: Guinea pig

Result: negative

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

Germ cell mutagenicity

|| Not classified based on available information.

Ingredients:**Cellulose:**

Genotoxicity in vitro

: Test Type: Bacterial reverse mutation assay (AMES)

Result: negative

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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

Carcinogenicity**||** Not classified based on available information.**Ingredients:****Posaconazole:**

Species: Rat
Application Route: oral (feed)
Exposure time: 2 Years
Result: negative

Species: Mouse
Application Route: Oral
Exposure time: 2 Years
Result: negative

IARC

No ingredient 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 ingredient of this product present at levels greater than or equal to 0.1% is identified as a carcinogen or potential carcinogen by OSHA.

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 fertility or the unborn child.**Ingredients:****Posaconazole:**

Effects on fertility : Test Type: Fertility/early embryonic development
Species: Rat, male
General Toxicity Parent: NOAEL (No observed adverse effect level): 180 mg/kg body weight
Symptoms: No effects on mating performance.
Result: negative

Test Type: Fertility/early embryonic development
Species: Rat, female
General Toxicity Parent: NOAEL (No observed adverse effect level): 45 mg/kg body weight
Symptoms: No effects on mating performance.
Result: negative

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Effects on fetal development : Test Type: Embryo-fetal development
Species: Rat, female
Application Route: Oral
Frequency of Treatment: 6 - 15 days
Developmental Toxicity: LOAEL (Lowest observed adverse effect level): 29 mg/kg body weight
Result: Fetotoxicity., Malformations were observed.

Test Type: Embryo-fetal development
Species: Rabbit, female
Frequency of Treatment: 7 - 19 days
Developmental Toxicity: LOAEL (Lowest observed adverse effect level): 40 mg/kg body weight
Result: Fetotoxicity.

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

STOT-single exposure

|| Not classified based on available information.

STOT-repeated exposure

|| Causes damage to organs (Adrenal gland, Bone marrow, Kidney, Nervous system, Reproductive organs) through prolonged or repeated exposure if swallowed.

Ingredients:**Posaconazole:**

Routes of exposure: Ingestion

Target Organs: Adrenal gland, Bone marrow, Kidney, Reproductive organs, Nervous system

Assessment: Causes damage to organs through prolonged or repeated exposure.

Repeated dose toxicity**Ingredients:****Posaconazole:**

Species: Rat, female

LOAEL: 5 mg/kg

Application Route: Oral

Exposure time: 6 Months

Target Organs: Adrenal gland, Lungs, Heart, Liver, spleen, Kidney, ovaries

Species: Dog

LOAEL: 3 mg/kg

Application Route: Oral

Exposure time: 392 Days

Target Organs: Lungs, Liver, brain, small intestine, Adrenal gland

Species: Monkey

LOAEL: 15 mg/kg

Application Route: Oral

Exposure time: 1 Months

Target Organs: Bone marrow, Adrenal gland, lymph node, Blood

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Species: Dog
LOAEL: 3 mg/kg
Application Route: Oral
Exposure time: 56 Weeks
Target Organs: Adrenal gland, Bone marrow, Kidney, Nervous system, spleen, thymus, Testes

Species: Monkey
LOAEL: 180 mg/kg
Application Route: Oral
Exposure time: 12 Months
Target Organs: Blood, Gastrointestinal tract, spleen

Species: Monkey
LOAEL: 8 mg/kg
Application Route: Intravenous
Exposure time: 1 Months
Target Organs: Cardio-vascular system, Lungs, Adrenal gland, Blood

Cellulose:

Species: Rat
NOAEL: > 5,000 mg/kg
Application Route: Ingestion
Exposure time: 90 Days
Remarks: Based on data from similar materials

Aspiration toxicity

|| Not classified based on available information.

Experience with human exposure**Ingredients:****Posaconazole:**

Ingestion : Symptoms: Cough, Headache, Nausea, Vomiting, Diarrhea, Fever

SECTION 12. ECOLOGICAL INFORMATION**Ecotoxicity****Ingredients:****Posaconazole:**

Toxicity to fish	: LC50 (Oncorhynchus mykiss (rainbow trout)): > 0.95 mg/l Exposure time: 96 h Method: OECD Test Guideline 203 Remarks: No toxicity at the limit of solubility.
Toxicity to daphnia and other aquatic invertebrates	: EC50 (Daphnia magna (Water flea)): 0.276 mg/l Exposure time: 48 h Method: OECD Test Guideline 202
Toxicity to algae	: EC50 (Pseudokirchneriella subcapitata (green algae)): > 0.509 mg/l Exposure time: 72 h

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Method: OECD Test Guideline 201

NOEC (*Pseudokirchneriella subcapitata* (green algae)): 0.041 mg/l

Exposure time: 72 h

Method: OECD Test Guideline 201

M-Factor (Acute aquatic toxicity) : 1

Toxicity to fish (Chronic toxicity) : NOEC (*Pimephales promelas* (fathead minnow)): 0.206 mg/l
Exposure time: 33 d
Method: OECD Test Guideline 210Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity) : NOEC (*Daphnia magna* (Water flea)): 0.244 mg/l
Exposure time: 21 d
Method: OECD Test Guideline 211
Remarks: No toxicity at the limit of solubility.

M-Factor (Chronic aquatic toxicity) : 1

Toxicity to bacteria : EC50 (Natural microorganism): > 1,000 mg/l
Exposure time: 3 h
Test Type: Respiration inhibition
Method: OECD Test Guideline 209**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 materialsToxicity to daphnia and other aquatic invertebrates : EC50 (*Daphnia magna* (Water flea)): > 100 mg/l
Exposure time: 48 h
Method: OECD Test Guideline 202
Remarks: Based on data from similar materialsToxicity 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**Persistence and degradability****Ingredients:****Posaconazole:**Biodegradability : Result: Not readily biodegradable.
Biodegradation: 50 %
Exposure time: 28 h
Method: OECD Test Guideline 314Stability in water : Degradation half life (DT50): > 30 d
Method: OECD Test Guideline 111

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Cellulose:

Biodegradability : Result: Readily biodegradable.

Bioaccumulative potential**Ingredients:****Posaconazole:**

Bioaccumulation	:	Species: Lepomis macrochirus (Bluegill sunfish)
		Bioconcentration factor (BCF): 20
		Method: OECD Test Guideline 305

Partition coefficient: n-octanol/water	:	log Pow: 4.15
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Mobility in soil**Ingredients:****Posaconazole:**

Distribution among environmental compartments	:	log Koc: 5.52
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Other adverse effectsNo data available

SECTION 13. DISPOSAL CONSIDERATIONS**Disposal methods**

Waste from residues	:	Dispose of in accordance with local regulations.
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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.
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SECTION 14. TRANSPORT INFORMATION**International Regulation****UNRTDG**

UN number	:	UN 3077
Proper shipping name	:	ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (Posaconazole)
Class	:	9
Packing group	:	III
Labels	:	9

IATA-DGR

UN/ID No.	:	UN 3077
Proper shipping name	:	Environmentally hazardous substance, solid, n.o.s.

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Class : 9
Packing group : III
Labels : Miscellaneous
Packing instruction (cargo aircraft) : 956
Packing instruction (passenger aircraft) : 956

IMDG-Code
UN number : UN 3077
Proper shipping name : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S.
(Posaconazole)

Class : 9
Packing group : III
Labels : 9
EmS Code : F-A, S-F
Marine pollutant : yes

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**

UN/ID/NA number : UN 3077
Proper shipping name : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S.
(Posaconazole)

Class : 9
Packing group : III
Labels : CLASS 9
ERG Code : 171
Marine pollutant : yes (Posaconazole)

Remarks : Above applies only to containers over 119 gallons or 450 liters., Shipment by ground under DOT is non-regulated; however it may be shipped per the applicable hazard classification to facilitate multi-modal transport involving ICAO (IATA) or IMO.

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 311/312 Hazards : Fire Hazard

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Chronic Health Hazard

- SARA 302** : No chemicals in this material are subject to the reporting requirements of SARA Title III, Section 302.
- 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**

Cellulose, 2-hydroxypropyl methyl ether, acetate hydrogen butanedioate	71138-97-1	50 - 70 %
Posaconazole	171228-49-2	10 - 20 %
Hydroxypropyl cellulose	9004-64-2	10 - 20 %
Cellulose	9004-34-6	10 - 20 %
Croscarmellose sodium	74811-65-7	1 - 5 %

New Jersey Right To Know

Cellulose, 2-hydroxypropyl methyl ether, acetate hydrogen butanedioate	71138-97-1	50 - 70 %
Posaconazole	171228-49-2	10 - 20 %
Hydroxypropyl cellulose	9004-64-2	10 - 20 %
Cellulose	9004-34-6	10 - 20 %
Croscarmellose sodium	74811-65-7	1 - 5 %

California Prop. 65 This product does not contain any chemicals known to the State of California to cause cancer, birth, or any other reproductive defects.

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

AICS : not determined

DSL : not determined

IECSC : not determined

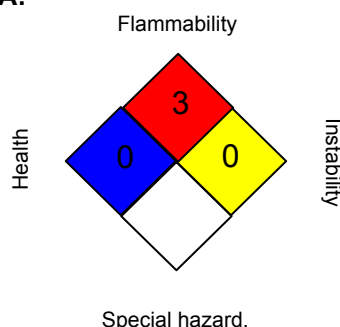
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SECTION 16. OTHER INFORMATION

Further information

NFPA:



HMIS III:

HEALTH	0*
FLAMMABILITY	3
PHYSICAL HAZARD	0

0 = not significant, 1 = Slight,
2 = Moderate, 3 = High
4 = Extreme, * = Chronic

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 Limits 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) 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

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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 Agency, <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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