

SAFETY DATA SHEET

according to the OSHA Hazard Communication Standard



Posaconazole Suspension Formulation

Version 8.0 Revision Date: 12/06/2025 SDS Number: 28777-00025 Date of last issue: 04/14/2025
Date of first issue: 11/06/2014

SECTION 1. IDENTIFICATION

Product name : Posaconazole Suspension Formulation

Manufacturer or supplier's details

Company name of supplier : Merck & Co., Inc
Address : 126 E. Lincoln Avenue
Rahway, New Jersey U.S.A. 07065
Telephone : 908-740-4000
Emergency telephone : 1-908-423-6000
E-mail address : EHSDATASTEWARD@merck.com

Recommended use of the chemical and restrictions on use

Recommended use : Pharmaceutical
Restrictions on use : Not applicable

SECTION 2. HAZARDS IDENTIFICATION

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

Hazards for the product as supplied

Reproductive toxicity : Category 2
Specific target organ toxicity - repeated exposure (Oral) : Category 1 (Adrenal gland, Bone marrow, Kidney, Liver, Nervous system, Reproductive organs)

Other hazards

None known.

GHS label elements

Hazard pictograms : 

Signal Word : Danger

Hazard Statements : H361d Suspected of damaging the unborn child.
H372 Causes damage to organs (Adrenal gland, Bone marrow, Kidney, Liver, Nervous system, Reproductive organs) through prolonged or repeated exposure if swallowed.

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 mist or vapors.
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

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and face protection.

Response:

P308 + P313 IF exposed or concerned: Get medical attention.

Storage:

P405 Store locked up.

Disposal:

P501 Dispose of contents and container to an approved waste disposal plant.

SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture : Mixture

Components

Chemical name	CAS No./Unique ID	Concentration (% w/w)	Trade secret
Glycerine	56-81-5*	>= 7 - <= 13	TSC
Posaconazole	171228-49-2*	>= 3 - <= 7	TSC
Titanium dioxide	13463-67-7*	>= 0.1 - <= 1	TSC

* Indicates that the identifier is a CAS No.

TSC- the actual concentration or concentration range is withheld as a trade secret

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 : Flush eyes with water as a precaution.
Get medical attention if irritation develops and persists.
- If swallowed : If swallowed, DO NOT induce vomiting.
Get medical attention.
Rinse mouth thoroughly with water.
- Most important symptoms and effects, both acute and delayed : Diarrhea
Fever
Nausea
Headache
Vomiting

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- || Suspected of damaging the unborn child.
Causes damage to organs through prolonged or repeated exposure if swallowed.
No information available.
 - || 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 (see section 8).
 - || 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.
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SECTION 6. ACCIDENTAL RELEASE MEASURES

- Personal precautions, protective equipment and emergency procedures : Use personal protective equipment.
Follow safe handling advice (see section 7) and personal protective equipment recommendations (see section 8).
- Environmental precautions : Avoid release to the environment.
Prevent further leakage or spillage if safe to do so.
Prevent spreading over a wide area (e.g., by containment or oil barriers).
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 : Soak up with inert absorbent material.
For large spills, provide diking or other appropriate containment to keep material from spreading. If diked material

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can be pumped, store recovered material in appropriate container.
Clean up remaining materials from spill with suitable absorbent.
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 : See Engineering measures under EXPOSURE CONTROLS/PERSONAL PROTECTION section.
- Local/Total ventilation : Use only with adequate ventilation.
- Advice on safe handling : Do not breathe mist or vapors.
Do not swallow.
Avoid contact with eyes.
Avoid prolonged or repeated contact with skin.
Wash skin thoroughly after handling.
Handle in accordance with good industrial hygiene and safety practice, based on the results of the workplace exposure assessment
Do not eat, drink or smoke when using this product.
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
Self-reactive substances and mixtures
Organic peroxides
Explosives
Gases

SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Ingredients with workplace control parameters

Components	CAS-No.	Value type (Form of exposure)	Control parameters / Permissible concentration	Basis
Posaconazole	171228-49-2	TWA	300 µg/m ³ (OEB 2)	Internal
Titanium dioxide	13463-67-7	TWA (total dust)	15 mg/m ³	OSHA Z-1

- Engineering measures** : Use appropriate engineering controls and manufacturing technologies to control airborne concentrations (e.g., drip-less quick connections).

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All engineering controls should be implemented by facility design and operated in accordance with GMP principles to protect products, workers, and the environment. Laboratory operations do not require special containment.

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
- Eye protection : Wear safety glasses with side shields or goggles. If the work environment or activity involves dusty conditions, mists or aerosols, wear the appropriate goggles. Wear a faceshield or other full face protection if there is a potential for direct contact to the face with dusts, mists, or aerosols.
- Skin and body protection : Work uniform or laboratory coat.
Hygiene measures : If exposure to chemical is likely during typical use, provide eye flushing systems and safety showers close to the working place.
When using do not eat, drink or smoke.
Wash contaminated clothing before re-use.
The effective operation of a facility should include review of engineering controls, proper personal protective equipment, appropriate degowning and decontamination procedures, industrial hygiene monitoring, medical surveillance and the use of administrative controls.
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SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

- Appearance : suspension
- Color : white
- Odor : No data available
- Odor Threshold : No data available
- pH : 4.2 - 4.8
- Melting point/freezing point : No data available
- Initial boiling point and boiling : No data available

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range

Flash point : No data available

Evaporation rate : No data available

Flammability (solid, gas) : Not applicable

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

Relative vapor density : No data available

Relative density : No data available

Density : 1 g/cm³

Solubility(ies)
Water solubility : soluble

Partition coefficient: n-octanol/water : Not applicable

Autoignition temperature : No data available

Decomposition temperature : No data available

Viscosity
Viscosity, kinematic : No data available

Explosive properties : Not explosive

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

Molecular weight : No data available

Particle characteristics
Particle size : Not applicable

SECTION 10. STABILITY AND REACTIVITY

Reactivity : Not classified as a reactivity hazard.

Chemical stability : Stable under normal conditions.

Possibility of hazardous reactions : Can react with strong oxidizing agents.

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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:

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

Components:

Glycerine:

|| Acute oral toxicity : LD50 (Rat): > 5,000 mg/kg
|| Acute dermal toxicity : LD50 (Guinea pig): > 5,000 mg/kg

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

Titanium dioxide:

|| Acute oral toxicity : LD50 (Rat): > 5,000 mg/kg
Method: OECD Test Guideline 425
Remarks: The test was conducted according to guideline
|| Acute inhalation toxicity : LC50 (Rat): > 5.09 mg/l
Exposure time: 4 h
Test atmosphere: dust/mist
Method: OECD Test Guideline 403
Assessment: The substance or mixture has no acute inhalation toxicity
Remarks: The test was conducted according to guideline

Skin corrosion/irritation

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Components:

Glycerine:

Species : Rabbit
Result : No skin irritation

Posaconazole:

Species : Rabbit
Result : No skin irritation

Titanium dioxide:

Species : Rabbit
Method : OECD Test Guideline 404
Result : No skin irritation
Remarks : The test was conducted equivalent or similar to guideline

Serious eye damage/eye irritation

Not classified based on available information.

Components:

Glycerine:

Species : Rabbit
Result : No eye irritation

Posaconazole:

Species : Rabbit
Result : Mild eye irritation

Titanium dioxide:

Species : Rabbit
Result : No eye irritation
Method : OECD Test Guideline 405
Remarks : The test was conducted according to guideline

Respiratory or skin sensitization

Skin sensitization

Not classified based on available information.

Respiratory sensitization

Not classified based on available information.

Components:

Posaconazole:

Test Type : Magnusson-Kligman-Test
Routes of exposure : Skin contact
Species : Guinea pig
Result : negative

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Titanium dioxide:

Test Type : Buehler Test
Routes of exposure : Skin contact
Species : Guinea pig
Method : OECD Test Guideline 406
Result : negative
Remarks : The test was conducted according to guideline

Germ cell mutagenicity

|| Not classified based on available information.

Components:

Glycerine:

Genotoxicity in vitro : Test Type: In vitro mammalian cell gene mutation test
Result: negative

Test Type: Bacterial reverse mutation assay (AMES)
Result: negative

Test Type: Chromosome aberration test in vitro
Result: negative

Test Type: DNA damage and repair, unscheduled DNA synthesis in mammalian cells (in vitro)
Result: negative

Posaconazole:

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

Test Type: Chromosomal aberration
Result: negative

Genotoxicity in vivo : Test Type: Micronucleus test
Species: Mouse
Cell type: Bone marrow
Application Route: Intravenous
Result: negative

Titanium dioxide:

Genotoxicity in vitro : Test Type: Bacterial reverse mutation assay (AMES)
Method: OECD Test Guideline 471
Result: negative
Remarks: The test was conducted according to guideline

Test Type: In vitro mammalian cell gene mutation test
Method: OECD Test Guideline 476
Result: negative
Remarks: The test was conducted according to guideline

Test Type: Chromosome aberration test in vitro

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Genotoxicity in vivo : Method: OECD Test Guideline 473
Result: negative
Remarks: The test was conducted according to guideline
: Test Type: Transgenic rodent somatic cell gene mutation assay
Species: Mouse (male)
Application Route: Intravenous injection
Method: OECD Test Guideline 488
Result: negative
Remarks: The test was conducted equivalent or similar to guideline

Carcinogenicity

Not classified based on available information.

Components:

Glycerine:

Species : Rat
Application Route : Ingestion
Exposure time : 2 Years
Result : negative

Posaconazole:

Species : Rat
Application Route : oral (feed)
Exposure time : 2 Years
Result : positive
Remarks : The mechanism or mode of action is not relevant in humans.

Species : Mouse
Application Route : Oral
Exposure time : 2 Years
Result : positive
Remarks : The mechanism or mode of action is not relevant in humans.

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.

Components:

Glycerine:

Effects on fertility : Test Type: Two-generation reproduction toxicity study

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Species: Rat
Application Route: Ingestion
Result: negative

Effects on fetal development : Test Type: Embryo-fetal development
Species: Rat
Application Route: Ingestion
Result: negative

Posaconazole:

Effects on fertility : Test Type: Fertility/early embryonic development
Species: Rat, male
General Toxicity Parent: NOAEL: 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: 45 mg/kg body weight
Symptoms: No effects on mating performance.
Result: negative

Effects on fetal development : Test Type: Embryo-fetal development
Species: Rat, female
Application Route: Oral
Developmental Toxicity: LOAEL: 29 mg/kg body weight
Result: Fetotoxicity., Malformations were observed.

Test Type: Embryo-fetal development
Species: Rabbit, female
Developmental Toxicity: LOAEL: 40 mg/kg body weight
Result: Fetotoxicity.

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

Titanium dioxide:

Effects on fertility : Test Type: Extended one-generation reproduction toxicity study
Species: Rat
Application Route: Ingestion
Method: OECD Test Guideline 443
Result: negative
Remarks: The test was conducted according to guideline

Effects on fetal development : Test Type: Embryo-fetal development
Species: Rat
Application Route: Ingestion
Method: OECD Test Guideline 414
Result: negative
Remarks: The test was conducted according to guideline

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STOT-single exposure

|| Not classified based on available information.

STOT-repeated exposure

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

Components:

Posaconazole:

|| Routes of exposure : Ingestion
|| Target Organs : Adrenal gland, Bone marrow, Kidney, Liver, Reproductive organs, Nervous system
|| Assessment : Causes damage to organs through prolonged or repeated exposure.

Repeated dose toxicity

Components:

Glycerine:

|| Species : Rat
|| NOAEL : 0.167 mg/l
|| LOAEL : 0.622 mg/l
|| Application Route : inhalation (dust/mist/fume)
|| Exposure time : 13 Weeks

|| Species : Rat
|| NOAEL : 8,000 - 10,000 mg/kg
|| Application Route : Ingestion
|| Exposure time : 2 y

|| Species : Rabbit
|| NOAEL : 5,040 mg/kg
|| Application Route : Skin contact
|| Exposure time : 45 Weeks

Posaconazole:

|| Species : Rat, female
|| LOAEL : 5 mg/kg
|| Application Route : Oral
|| Exposure time : 6 Months
|| Target Organs : Adrenal gland, Lungs, Heart, Liver, spleen, Kidney, Ovary

|| Species : Dog
|| LOAEL : 3 mg/kg
|| Application Route : Oral
|| Exposure time : 392 Days
|| Target Organs : Lungs, Liver, Brain, small intestine, Adrenal gland, Spinal cord, lymphoid tissue

|| Species : Monkey
|| LOAEL : 15 mg/kg

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Application Route : Oral
Exposure time : 1 Months
Target Organs : Bone marrow, Adrenal gland, Lymph nodes, Blood

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

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

Titanium dioxide:

Species : Rat
NOAEL : $\geq 1,000$ mg/kg
Application Route : Ingestion
Exposure time : 90 Days
Method : OECD Test Guideline 408
Remarks : The test was conducted according to guideline

Aspiration toxicity

Not classified based on available information.

Experience with human exposure

Components:

Posaconazole:

Ingestion : Symptoms: Cough, Headache, Nausea, Vomiting, Fever, Liver effects, Rash, pruritis, Diarrhea, hypertension, neutropenia, electrolyte imbalance

SECTION 12. ECOLOGICAL INFORMATION

Ecotoxicity

Components:

Glycerine:

Toxicity to fish : LC50 (Oncorhynchus mykiss (rainbow trout)): 54,000 mg/l
Exposure time: 96 h

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Toxicity to daphnia and other aquatic invertebrates : EC50 (Daphnia magna (Water flea)): 1,955 mg/l
Exposure time: 48 h

Toxicity to microorganisms : NOEC (Pseudomonas putida): > 10,000 mg/l
Exposure time: 16 h
Method: DIN 38 412 Part 8

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/aquatic plants : EC50 (Pseudokirchneriella subcapitata (green algae)): > 0.509 mg/l
Exposure time: 72 h
Method: OECD Test Guideline 201

NOEC (Pseudokirchneriella subcapitata (green algae)): 0.041 mg/l
Exposure time: 72 h
Method: OECD Test Guideline 201

Toxicity to fish (Chronic toxicity) : NOEC (Pimephales promelas (fathead minnow)): 0.206 mg/l
Exposure time: 33 d
Method: OECD Test Guideline 210

Toxicity 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.

Toxicity to microorganisms : EC50 (Natural microorganism): > 1,000 mg/l
Exposure time: 3 h
Test Type: Respiration inhibition
Method: OECD Test Guideline 209

Titanium dioxide:

Toxicity to fish : LL50 (Oncorhynchus mykiss (rainbow trout)): > 100 mg/l
Exposure time: 96 h
Test substance: Water Accommodated Fraction
Method: OECD Test Guideline 203
Remarks: The test was conducted according to guideline Based on transformation/dissolution testing and data from soluble metal compounds

Toxicity to daphnia and other : EC50 (Daphnia magna (Water flea)): > 100 mg/l

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aquatic invertebrates	:	Exposure time: 48 h Method: OECD Test Guideline 202 Remarks: The test was conducted according to guideline
Toxicity to algae/aquatic plants	:	EL50 (Raphidocelis subcapitata (freshwater green alga)): > 100 mg/l Exposure time: 72 h Test substance: Water Accommodated Fraction Method: OECD Test Guideline 201 Remarks: The test was conducted according to guideline NOELR (Raphidocelis subcapitata (freshwater green alga)): >= 100 mg/l Exposure time: 72 h Test substance: Water Accommodated Fraction Method: OECD Test Guideline 201 Remarks: The test was conducted according to guideline
Toxicity to microorganisms	:	NOEC (activated sludge): >= 1,000 mg/l Exposure time: 3 h Method: OECD Test Guideline 209 Remarks: The test was conducted according to guideline

Persistence and degradability

Components:

Glycerine:

Biodegradability	:	Result: Readily biodegradable. Biodegradation: 92 % Exposure time: 30 d Method: OECD Test Guideline 301D
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Posaconazole:

Biodegradability	:	Result: Not readily biodegradable. Biodegradation: 50 % Exposure time: 28 h Method: OECD Test Guideline 314
Stability in water	:	Degradation half life (DT50): > 30 d Method: OECD Test Guideline 111

Bioaccumulative potential

Components:

Glycerine:

Partition coefficient: n-octanol/water	:	log Pow: -1.75
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Posaconazole:

Bioaccumulation	:	Species: Lepomis macrochirus (Bluegill sunfish) Bioconcentration factor (BCF): 20
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Method: OECD Test Guideline 305
Partition coefficient: n-octanol/water : log Pow: 4.15

Mobility in soil

Components:

Posaconazole:

Distribution among environmental compartments : log Koc: 5.52

Other adverse effects

No data available

SECTION 13. DISPOSAL CONSIDERATIONS

Disposal methods

Waste from residues : Dispose of in accordance with local regulations. Do not dispose of waste into sewer.
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

UN number : UN 3082
Proper shipping name : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S.
(Posaconazole)

Class : 9
Packing group : III
Labels : 9
Environmentally hazardous : yes

IATA-DGR

UN/ID No. : UN 3082
Proper shipping name : Environmentally hazardous substance, liquid, n.o.s.
(Posaconazole)

Class : 9
Packing group : III
Labels : Miscellaneous
Packing instruction (cargo aircraft) : 964
Packing instruction (passenger aircraft) : 964
Environmentally hazardous : yes

IMDG-Code

UN number : UN 3082
Proper shipping name : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID,

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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 IMO instruments

Not applicable for product as supplied.

Domestic regulation

49 CFR

UN/ID/NA number : UN 3082
Proper shipping name : Environmentally hazardous substance, liquid, 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 (450 liters) in case of liquids, or 882 lbs. (400 kg) in case of solids. 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.

Special precautions for user

The transport classification(s) provided herein are for informational purposes only, and solely based upon the properties of the unpackaged material as it is described within this Safety Data Sheet. Transportation classifications may vary by mode of transportation, package sizes, and variations in regional or country regulations.

SECTION 15. REGULATORY INFORMATION

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 : Reproductive toxicity
Specific target organ toxicity (single or repeated exposure)

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

SAFETY DATA SHEET

according to the OSHA Hazard Communication Standard



Posaconazole Suspension Formulation

Version 8.0 Revision Date: 12/06/2025 SDS Number: 28777-00025 Date of last issue: 04/14/2025
Date of first issue: 11/06/2014

Water	7732-18-5
Glucose	50-99-7
Glycerine	56-81-5
Posaconazole	171228-49-2

California Prop. 65

WARNING: This product can expose you to chemicals including Titanium dioxide, which is/are known to the State of California to cause cancer. For more information go to www.P65Warnings.ca.gov.

California Permissible Exposure Limits for Chemical Contaminants

Glycerine	56-81-5
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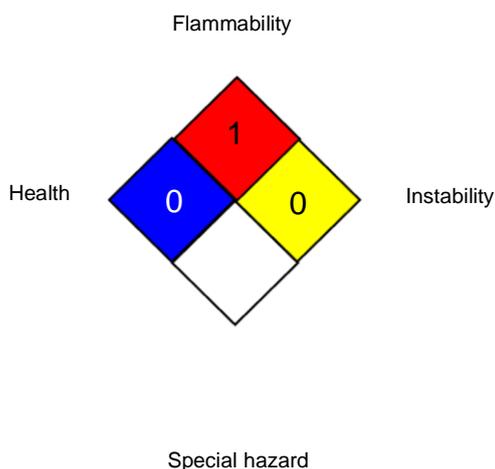
The ingredients of this product are reported in the following inventories:

AICS : not determined
CA. DSL : not determined
IECSC : not determined

SECTION 16. OTHER INFORMATION

Further information

NFPA 704:



HMIS® IV:

HEALTH	*	3
FLAMMABILITY		1
PHYSICAL HAZARD		0

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

OSHA Z-1 : USA. Occupational Exposure Limits (OSHA) - Table Z-1 Limits for Air Contaminants
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 - Standard of the

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Posaconazole Suspension Formulation

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8.0	12/06/2025	28777-00025	Date of first issue: 11/06/2014

German Institute for Standardization; 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 Organization 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, Authorization 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

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/>

Revision Date : 12/06/2025

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

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 is designed only as a guidance for safe handling, use, processing, storage, transportation, disposal and release and shall not be considered a warranty or quality specification of any type. The information provided relates only to the specific material identified at the top of this SDS and may not be valid when the SDS material is used in combination with any other materials or in any process, unless specified in the text. Material users should review the information and recommendations in the specific context of their intended manner of handling, use, processing and storage, including an assessment of the appropriateness of the SDS material in the user's end product, if applicable.

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