

# SAFETY DATA SHEET

according to the OSHA Hazard Communication Standard



## Posaconazole Suspension Formulation

Version 6.0      Revision Date: 07/06/2024      SDS Number: 28777-00023      Date of last issue: 04/06/2024  
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)

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

#### GHS label elements

Hazard pictograms : 

Signal Word : Danger

Hazard Statements : H351 Suspected of causing cancer if inhaled.  
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 and face protection.

# SAFETY DATA SHEET

according to the OSHA Hazard Communication Standard



## Posaconazole Suspension Formulation

Version 6.0      Revision Date: 07/06/2024      SDS Number: 28777-00023      Date of last issue: 04/06/2024  
Date of first issue: 11/06/2014

**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.

**Other hazards**

None known.

### SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture : Mixture

**Components**

Chemical name	CAS-No.	Concentration (% w/w)
Glycerine	56-81-5	$\geq 10 - < 20$
Posaconazole	171228-49-2	$\geq 1 - < 5$
Titanium dioxide	13463-67-7	$\geq 0.1 - < 1$

Actual concentration 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  
Suspected of causing cancer if inhaled.  
Suspected of damaging the unborn child.  
Causes damage to organs through prolonged or repeated exposure if swallowed.

# SAFETY DATA SHEET

according to the OSHA Hazard Communication Standard



## Posaconazole Suspension Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 04/06/2024
6.0	07/06/2024	28777-00023	Date of first issue: 11/06/2014

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 (CO<sub>2</sub>)  
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 (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 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

# SAFETY DATA SHEET

according to the OSHA Hazard Communication Standard



## Posaconazole Suspension Formulation

Version 6.0      Revision Date: 07/06/2024      SDS Number: 28777-00023      Date of last issue: 04/06/2024  
Date of first issue: 11/06/2014

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 <sup>3</sup> (OEB 2)	Internal
Titanium dioxide	13463-67-7	TWA (total dust)	15 mg/m <sup>3</sup>	OSHA Z-1

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

# SAFETY DATA SHEET

according to the OSHA Hazard Communication Standard



## Posaconazole Suspension Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 04/06/2024
6.0	07/06/2024	28777-00023	Date of first issue: 11/06/2014

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  
Hygiene measures : Work uniform or laboratory coat.  
: 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.

### 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 range : No data available

Flash point : No data available

Evaporation rate : No data available

Flammability (solid, gas) : Not applicable

Flammability (liquids) : No data available

# SAFETY DATA SHEET

according to the OSHA Hazard Communication Standard



## Posaconazole Suspension Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 04/06/2024
6.0	07/06/2024	28777-00023	Date of first issue: 11/06/2014

---

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/cm <sup>3</sup>
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.
Conditions to avoid	:	None known.
Incompatible materials	:	Oxidizing agents
Hazardous decomposition products	:	No hazardous decomposition products are known.

# SAFETY DATA SHEET

according to the OSHA Hazard Communication Standard



## Posaconazole Suspension Formulation

Version: 6.0      Revision Date: 07/06/2024      SDS Number: 28777-00023      Date of last issue: 04/06/2024  
Date of first issue: 11/06/2014

---

### 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  
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 inhalation toxicity

#### Skin corrosion/irritation

Not classified based on available information.

#### Components:

##### Glycerine:

Species : Rabbit  
Result : No skin irritation

##### Posaconazole:

Species : Rabbit  
Result : No skin irritation

# SAFETY DATA SHEET

according to the OSHA Hazard Communication Standard



## Posaconazole Suspension Formulation

Version 6.0      Revision Date: 07/06/2024      SDS Number: 28777-00023      Date of last issue: 04/06/2024  
Date of first issue: 11/06/2014

---

### Titanium dioxide:

Species : Rabbit  
Result : No skin irritation

### 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

### 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

#### 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.

### Components:

#### Glycerine:

# SAFETY DATA SHEET

according to the OSHA Hazard Communication Standard



## Posaconazole Suspension Formulation

Version 6.0      Revision Date: 07/06/2024      SDS Number: 28777-00023      Date of last issue: 04/06/2024  
Date of first issue: 11/06/2014

---

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

### Carcinogenicity

Suspected of causing cancer if inhaled.

### 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.

# SAFETY DATA SHEET

according to the OSHA Hazard Communication Standard



## Posaconazole Suspension Formulation

Version 6.0      Revision Date: 07/06/2024      SDS Number: 28777-00023      Date of last issue: 04/06/2024  
Date of first issue: 11/06/2014

---

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

### 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 - Assessment : 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.

### Components:

#### Glycerine:

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

# SAFETY DATA SHEET

according to the OSHA Hazard Communication Standard



## Posaconazole Suspension Formulation

Version 6.0      Revision Date: 07/06/2024      SDS Number: 28777-00023      Date of last issue: 04/06/2024  
Date of first issue: 11/06/2014

---

	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.

### 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

# SAFETY DATA SHEET

according to the OSHA Hazard Communication Standard



## Posaconazole Suspension Formulation

Version 6.0      Revision Date: 07/06/2024      SDS Number: 28777-00023      Date of last issue: 04/06/2024  
Date of first issue: 11/06/2014

---

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

|| Species : Rat  
|| NOAEL : 10 mg/m<sup>3</sup>  
|| Application Route : inhalation (dust/mist/fume)  
|| Exposure time : 2 y

# SAFETY DATA SHEET

according to the OSHA Hazard Communication Standard



## Posaconazole Suspension Formulation

Version 6.0      Revision Date: 07/06/2024      SDS Number: 28777-00023      Date of last issue: 04/06/2024  
Date of first issue: 11/06/2014

### 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

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

# SAFETY DATA SHEET

according to the OSHA Hazard Communication Standard



## Posaconazole Suspension Formulation

Version 6.0      Revision Date: 07/06/2024      SDS Number: 28777-00023      Date of last issue: 04/06/2024  
Date of first issue: 11/06/2014

---

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 : LC50 (Oncorhynchus mykiss (rainbow trout)): > 100 mg/l  
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/aquatic plants : 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

### Persistence and degradability

#### Components:

##### Glycerine:

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

##### 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

# SAFETY DATA SHEET

according to the OSHA Hazard Communication Standard



## Posaconazole Suspension Formulation

Version 6.0      Revision Date: 07/06/2024      SDS Number: 28777-00023      Date of last issue: 04/06/2024  
Date of first issue: 11/06/2014

---

### 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

### 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

# SAFETY DATA SHEET

according to the OSHA Hazard Communication Standard



## Posaconazole Suspension Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 04/06/2024
6.0	07/06/2024	28777-00023	Date of first issue: 11/06/2014

---

### IMDG-Code

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

### 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.

<b>SARA 311/312 Hazards</b>	: Carcinogenicity Reproductive toxicity Specific target organ toxicity (single or repeated exposure)
-----------------------------	--

# SAFETY DATA SHEET

according to the OSHA Hazard Communication Standard



## Posaconazole Suspension Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 04/06/2024
6.0	07/06/2024	28777-00023	Date of first issue: 11/06/2014

---

**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

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](http://www.P65Warnings.ca.gov).

#### California Permissible Exposure Limits for Chemical Contaminants

Glycerine	56-81-5
-----------	---------

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

AICS	: not determined
DSL	: not determined
IECSC	: not determined

---

## SECTION 16. OTHER INFORMATION

### Further information

# SAFETY DATA SHEET

according to the OSHA Hazard Communication Standard



## Posaconazole Suspension Formulation

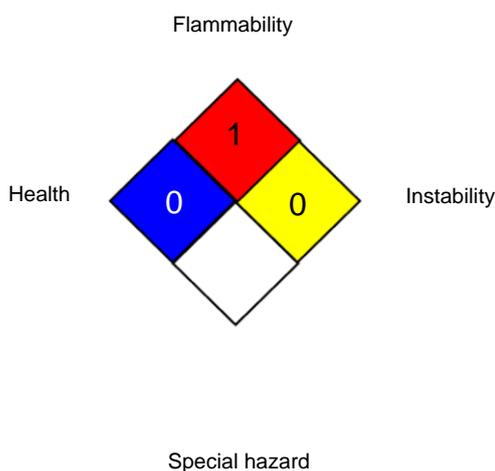
Version  
6.0

Revision Date:  
07/06/2024

SDS Number:  
28777-00023

Date of last issue: 04/06/2024  
Date of first issue: 11/06/2014

### 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 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 Amend-

# SAFETY DATA SHEET

according to the OSHA Hazard Communication Standard



## Posaconazole Suspension Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 04/06/2024
6.0	07/06/2024	28777-00023	Date of first issue: 11/06/2014

---

ments 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 : 07/06/2024

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.

US / Z8