

Posaconazole Suspension Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 06.04.2024
7.0	06.07.2024	28743-00022	Date of first issue: 06.11.2014

SECTION 1: IDENTIFICATION

Product name : Posaconazole Suspension Formulation

Manufacturer or supplier's details

Company : MSD

Address : Building A - Level 1/26 Talavera Rd
Macquarie Park NSW, Australia 2113

Telephone : 1 800 033 461

Emergency telephone number : Poisons Information Centre: Phone 13 11 26

E-mail address : EHSDATASTEWARD@msd.com

Recommended use of the chemical and restrictions on use

Recommended use : Pharmaceutical


Restrictions on use : Not applicable

SECTION 2. HAZARDS IDENTIFICATION**GHS Classification**

Reproductive toxicity : Category 2

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

GHS label elements

Hazard pictograms : 

Signal word : Warning

Hazard statements : H361d Suspected of damaging the unborn child.
H373 May cause 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 vapours.
P280 Wear protective gloves/ protective clothing/ eye protec-

Posaconazole Suspension Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 06.04.2024
7.0	06.07.2024	28743-00022	Date of first issue: 06.11.2014

tion/ 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 which do not result in classification

None known.

SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture : Mixture

Components

Chemical name	CAS-No.	Concentration (% w/w)
Glycerine	56-81-5	≥ 10 -< 30
Posaconazole	171228-49-2	≥ 3 -< 10
Titanium dioxide	13463-67-7	< 1

SECTION 4. FIRST AID MEASURES

General advice	: In the case of accident or if you feel unwell, seek medical advice immediately. When symptoms persist or in all cases of doubt seek medical advice.
If inhaled	: If inhaled, remove to fresh air. Get medical attention.
In case of skin contact	: In case of contact, immediately flush skin with soap and plenty of water. Remove contaminated clothing and shoes. Get medical attention. Wash clothing before reuse. Thoroughly clean shoes before reuse.
In case of eye contact	: 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	: Diarrhoea Fever Nausea Headache Vomiting Suspected of damaging the unborn child. May cause damage to organs through prolonged or repeated

Posaconazole Suspension Formulation

Version	Revision Date:	SDS Number:	Date of last issue:
7.0	06.07.2024	28743-00022	06.04.2024
			Date of first issue: 06.11.2014

exposure if swallowed.

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. FIREFIGHTING 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 firefighters : In the event of fire, wear self-contained breathing apparatus.
Use personal protective equipment.

Hazchem Code : •3Z

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 dyking or other appropriate containment to keep material from spreading. If dyked 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 deter-

Posaconazole Suspension Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 06.04.2024
7.0	06.07.2024	28743-00022	Date of first issue: 06.11.2014

mine 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 vapours.
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.
- 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.
- Conditions for safe storage : Keep in properly labelled 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

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

Components	CAS-No.	Value type (Form of exposure)	Control parameters / Permissible concentration	Basis
Glycerine	56-81-5	TWA (Mist)	10 mg/m ³	AU OEL
Posaconazole	171228-49-2	TWA	300 µg/m ³ (OEB 2)	Internal
Titanium dioxide	13463-67-7	TWA	10 mg/m ³	AU OEL

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

Posaconazole Suspension Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 06.04.2024
7.0	06.07.2024	28743-00022	Date of first issue: 06.11.2014

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	:	If adequate local exhaust ventilation is not available or exposure assessment demonstrates exposures outside the recommended guidelines, use respiratory protection.
Filter type	:	Combined particulates and organic vapour type
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.

SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance	:	suspension
Colour	:	white
Odour	:	No data available
Odour 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
Upper explosion limit / Upper flammability limit	:	No data available
Lower explosion limit / Lower flammability limit	:	No data available

Posaconazole Suspension Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 06.04.2024
7.0	06.07.2024	28743-00022	Date of first issue: 06.11.2014

Vapour pressure	:	No data available
Relative vapour density	:	No data available
Relative density	:	No data available
Density	:	1 g/cm ³
Solubility(ies)	:	
Water solubility	:	soluble
Partition coefficient: n-octanol/water	:	Not applicable
Auto-ignition 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.

SECTION 11. TOXICOLOGICAL INFORMATION

Exposure routes	:	Inhalation Skin contact Ingestion Eye contact
-----------------	---	--

Acute toxicity

Not classified based on available information.

Posaconazole Suspension Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 06.04.2024
7.0	06.07.2024	28743-00022	Date of first issue: 06.11.2014

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

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 Suspension Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 06.04.2024
7.0	06.07.2024	28743-00022	Date of first issue: 06.11.2014

Posaconazole:

Species	: Rabbit
Result	: Mild eye irritation

Titanium dioxide:

Species	: Rabbit
Result	: No eye irritation

Respiratory or skin sensitisation**Skin sensitisation**

Not classified based on available information.

Respiratory sensitisation

Not classified based on available information.

Components:**Posaconazole:**

Test Type	: Magnusson-Kligman-Test
Exposure routes	: Skin contact
Species	: Guinea pig
Result	: negative

Titanium dioxide:

Test Type	: Local lymph node assay (LLNA)
Exposure routes	: Skin contact
Species	: Mouse
Result	: negative

Chronic toxicity**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 Suspension Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 06.04.2024
7.0	06.07.2024	28743-00022	Date of first issue: 06.11.2014

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

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.

Titanium dioxide:

Species	: Rat
Application Route	: inhalation (dust/mist/fume)
Exposure time	: 2 Years
Method	: OECD Test Guideline 453

Posaconazole Suspension Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 06.04.2024
7.0	06.07.2024	28743-00022	Date of first issue: 06.11.2014

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.
------------------------------	---

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

	: Test Type: Embryo-foetal 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.
------------------------------------	---

Posaconazole Suspension Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 06.04.2024
7.0	06.07.2024	28743-00022	Date of first issue: 06.11.2014

STOT - single exposure

Not classified based on available information.

STOT - repeated exposure

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

Components:**Posaconazole:**

Exposure routes	: 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 yr

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
---------	----------

Posaconazole Suspension Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 06.04.2024
7.0	06.07.2024	28743-00022	Date of first issue: 06.11.2014

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 ³
Application Route	: inhalation (dust/mist/fume)
Exposure time	: 2 yr

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, Diarrhoea, hypertension, neutropenia, electrolyte imbalance
-----------	--

Posaconazole Suspension Formulation

Version	Revision Date:	SDS Number:	Date of last issue:
7.0	06.07.2024	28743-00022	06.04.2024
			Date of first issue: 06.11.2014

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
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

Posaconazole Suspension Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 06.04.2024
7.0	06.07.2024	28743-00022	Date of first issue: 06.11.2014

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
--	------------------

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

Posaconazole Suspension Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 06.04.2024
7.0	06.07.2024	28743-00022	Date of first issue: 06.11.2014

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

Contaminated packaging : Empty containers should be taken to an approved waste handling site for recycling or disposal.
If not otherwise specified: Dispose of as unused product.

SECTION 14. TRANSPORT INFORMATION**International Regulations****UNRTDG**

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, N.O.S.
(Posaconazole)

Class : 9

Posaconazole Suspension Formulation

Version	Revision Date:	SDS Number:	Date of last issue:
7.0	06.07.2024	28743-00022	06.04.2024
			Date of first issue: 06.11.2014

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.

National Regulations**ADG**

UN number : UN 3082
Proper shipping name : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID,
N.O.S.
(Posaconazole)
Class : 9
Packing group : III
Labels : 9
Hazchem Code : •3Z
Environmentally hazardous : yes

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**Safety, health and environmental regulations/legislation specific for the substance or mixture**

Therapeutic Goods (Poisons Standard) Instrument : No poison schedule number allocated (Please use the original publication to check for specific uses, specific conditions or threshold limits that might apply for this chemical)

Prohibition/Licensing Requirements : There is no applicable prohibition, authorisation and restricted use requirements, including for carcinogens referred to in Schedule 10 of the model WHS Act and Regulations.

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

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

SECTION 16: ANY OTHER RELEVANT INFORMATION**Further information**

Posaconazole Suspension Formulation

Version	Revision Date:	SDS Number:	Date of last issue:
7.0	06.07.2024	28743-00022	06.04.2024
			Date of first issue: 06.11.2014

Revision Date : 06.07.2024
Sources of key data used to compile the Safety Data Sheet : Internal technical data, data from raw material SDSs, OECD eChem Portal search results and European Chemicals Agency, <http://echa.europa.eu/>

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

Date format : dd.mm.yyyy

Full text of other abbreviations

AU OEL : Australia. Workplace Exposure Standards for Airborne Contaminants.

AU OEL / TWA : Exposure standard - time weighted average

AIIC - Australian Inventory of Industrial Chemicals; ANTT - National Agency for Transport by Land of Brazil; ASTM - American Society for the Testing of Materials; bw - Body weight; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DSL - Domestic Substances List (Canada); ECx - Concentration associated with x% response; 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; 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; n.o.s. - Not Otherwise Specified; Nch - Chilean Norm; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; NOM - Official Mexican Norm; 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; REACH - Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals; SADT - Self-Accelerating Decomposition Temperature; SDS - Safety Data Sheet; TCSI - Taiwan Chemical Substance Inventory; TDG - Transportation of Dangerous Goods; 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; WHMIS - Workplace Hazardous Materials Information System

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.

Posaconazole Suspension Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 06.04.2024
7.0	06.07.2024	28743-00022	Date of first issue: 06.11.2014

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.

AU / EN