

SAFETY DATA SHEET

According to REACH Regulation (EC) No 1907/2006, as amended by
UK REACH Regulations SI 2019/758



Posaconazole Suspension Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 28.09.2024
6.2	14.04.2025	9371481-00010	Date of first issue: 27.08.2021

SECTION 1: Identification of the substance/mixture and of the company/undertaking

1.1 Product identifier

Trade name : Posaconazole Suspension Formulation

1.2 Relevant identified uses of the substance or mixture and uses advised against

Use of the Sub-
stance/Mixture : Pharmaceutical

Recommended restrictions
on use : Not applicable

1.3 Details of the supplier of the safety data sheet

Company : MSD
120 Moorgate
EC2M 6UR London, United Kingdom

Telephone : +44 (0) 2081548000

E-mail address of person
responsible for the SDS : EHSDATASTEWARD@msd.com

1.4 Emergency telephone number

+1-908-423-6000

SECTION 2: Hazards identification

2.1 Classification of the substance or mixture

Classification (REGULATION (EC) No 1272/2008) as amended by GB-CLP Regulation, UK SI 2019/720, and UK SI 2020/1567)

Reproductive toxicity, Category 2 H361d: Suspected of damaging the unborn child.

Specific target organ toxicity - repeated
exposure, Category 2 H373: May cause damage to organs through pro-
longed or repeated exposure.

Long-term (chronic) aquatic hazard, Cat-
egory 2 H411: Toxic to aquatic life with long lasting effects.

2.2 Label elements

Labelling (REGULATION (EC) No 1272/2008) as amended by GB-CLP Regulation, UK SI 2019/720, and UK SI 2020/1567)

SAFETY DATA SHEET

According to REACH Regulation (EC) No 1907/2006, as amended by
UK REACH Regulations SI 2019/758



Posaconazole Suspension Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 28.09.2024
6.2	14.04.2025	9371481-00010	Date of first issue: 27.08.2021

Hazard pictograms :

Signal word : Warning

Hazard statements : H361d Suspected of damaging the unborn child.
H373 May cause damage to organs through prolonged or repeated exposure.
H411 Toxic to aquatic life with long lasting effects.

Precautionary statements : **Prevention:**
P201 Obtain special instructions before use.
P273 Avoid release to the environment.
P280 Wear protective gloves/ protective clothing/ eye protection/ face protection.

Response:
P308 + P313 IF exposed or concerned: Get medical advice/ attention.
P391 Collect spillage.

Storage:
P405 Store locked up.

Hazardous components which must be listed on the label:
Posaconazole

2.3 Other hazards

This substance/mixture contains no components considered to be either persistent, bioaccumulative and toxic (PBT), or very persistent and very bioaccumulative (vPvB) at levels of 0.1% or higher.

SECTION 3: Composition/information on ingredients

3.2 Mixtures

Components

Chemical name	CAS-No. EC-No. Index-No. Registration number	Classification	Concentration (% w/w)
Posaconazole	171228-49-2	Eye Irrit. 2; H319 Repr. 2; H361d STOT RE 1; H372 (Adrenal gland, Bone marrow, Kid- ney, Liver, Nervous system, Reproduc- tive organs)	>= 3 - < 10

SAFETY DATA SHEET

According to REACH Regulation (EC) No 1907/2006, as amended by
UK REACH Regulations SI 2019/758



Posaconazole Suspension Formulation

Version 6.2 Revision Date: 14.04.2025 SDS Number: 9371481-00010 Date of last issue: 28.09.2024
Date of first issue: 27.08.2021

		Aquatic Acute 1; H400 Aquatic Chronic 1; H410	
		M-Factor (Acute aquatic toxicity): 1 M-Factor (Chronic aquatic toxicity): 1	
Substances with a workplace exposure limit :			
Glycerine	56-81-5 200-289-5		>= 10 - < 20

For explanation of abbreviations see section 16.

SECTION 4: First aid measures

4.1 Description of 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.
- 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).
- 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.

4.2 Most important symptoms and effects, both acute and delayed

- Symptoms : Diarrhoea
Fever
Nausea
Headache
Vomiting

SAFETY DATA SHEET

According to REACH Regulation (EC) No 1907/2006, as amended by
UK REACH Regulations SI 2019/758



Posaconazole Suspension Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 28.09.2024
6.2	14.04.2025	9371481-00010	Date of first issue: 27.08.2021

Risks : Suspected of damaging the unborn child.
May cause damage to organs through prolonged or repeated exposure.

4.3 Indication of any immediate medical attention and special treatment needed

Treatment : Treat symptomatically and supportively.

SECTION 5: Firefighting measures

5.1 Extinguishing media

Suitable extinguishing media : Water spray
Alcohol-resistant foam
Carbon dioxide (CO₂)
Dry chemical

Unsuitable extinguishing media : None known.

5.2 Special hazards arising from the substance or mixture

Specific hazards during fire-fighting : Exposure to combustion products may be a hazard to health.

Hazardous combustion products : Carbon oxides

5.3 Advice for firefighters

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

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.

SECTION 6: Accidental release measures

6.1 Personal precautions, protective equipment and emergency procedures

Personal precautions : Use personal protective equipment.
Follow safe handling advice (see section 7) and personal protective equipment recommendations (see section 8).

6.2 Environmental precautions

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).

SAFETY DATA SHEET

According to REACH Regulation (EC) No 1907/2006, as amended by
UK REACH Regulations SI 2019/758



Posaconazole Suspension Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 28.09.2024
6.2	14.04.2025	9371481-00010	Date of first issue: 27.08.2021

Retain and dispose of contaminated wash water.
If spillage enters rivers or watercourses, inform the Environment Agency (emergency telephone number 0800 807060).

6.3 Methods and material for containment and cleaning up

Methods for 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 determine which regulations are applicable.
Sections 13 and 15 of this SDS provide information regarding certain local or national requirements.

6.4 Reference to other sections

See sections: 7, 8, 11, 12 and 13.

SECTION 7: Handling and storage

7.1 Precautions for safe handling

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.

7.2 Conditions for safe storage, including any incompatibilities

Requirements for storage areas and containers	:	Keep in properly labelled containers. Store locked up. Store in accordance with the particular national regulations.
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SAFETY DATA SHEET

According to REACH Regulation (EC) No 1907/2006, as amended by
UK REACH Regulations SI 2019/758



Posaconazole Suspension Formulation

Version 6.2 Revision Date: 14.04.2025 SDS Number: 9371481-00010 Date of last issue: 28.09.2024
Date of first issue: 27.08.2021

Advice on common storage : Do not store with the following product types:
Strong oxidizing agents
Self-reactive substances and mixtures
Organic peroxides
Explosives
Gases

7.3 Specific end use(s)

Specific use(s) : No data available

SECTION 8: Exposure controls/personal protection

8.1 Control parameters

Occupational Exposure Limits

Components	CAS-No.	Value type (Form of exposure)	Control parameters	Basis
Glycerine	56-81-5	TWA (Mist)	10 mg/m ³	GB EH40
Posaconazole	171228-49-2	TWA	300 µg/m ³ (OEB 2)	Internal

Derived No Effect Level (DNEL)

Substance name	End Use	Exposure routes	Potential health effects	Value
Glycerine	Workers	Inhalation	Long-term local effects	56 mg/m ³
	Consumers	Ingestion	Long-term systemic effects	229 mg/kg bw/day
	Consumers	Inhalation	Long-term local effects	33 mg/m ³

Predicted No Effect Concentration (PNEC)

Substance name	Environmental Compartment	Value
Glycerine	Fresh water	0.885 mg/l
	Marine water	0.0885 mg/l
	Intermittent use/release	8.85 mg/l
	Sewage treatment plant	1000 mg/l
	Fresh water sediment	3.3 mg/kg dry weight (d.w.)
	Marine sediment	0.33 mg/kg dry weight (d.w.)
	Soil	0.141 mg/kg dry weight (d.w.)

8.2 Exposure controls

Engineering measures

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

SAFETY DATA SHEET

According to REACH Regulation (EC) No 1907/2006, as amended by
UK REACH Regulations SI 2019/758



Posaconazole Suspension Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 28.09.2024
6.2	14.04.2025	9371481-00010	Date of first issue: 27.08.2021

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

Eye/face 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.
Hand protection	:	
Material	:	Chemical-resistant gloves
Skin and body protection	:	Work uniform or laboratory coat.
Respiratory protection	:	If adequate local exhaust ventilation is not available or exposure assessment demonstrates exposures outside the recommended guidelines, use respiratory protection. Filter should conform to BS EN 14387
Filter type	:	Combined particulates and organic vapour type (A-P)

SECTION 9: Physical and chemical properties

9.1 Information on basic 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
Vapour pressure	:	No data available
Relative vapour density	:	No data available

SAFETY DATA SHEET

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UK REACH Regulations SI 2019/758



Posaconazole Suspension Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 28.09.2024
6.2	14.04.2025	9371481-00010	Date of first issue: 27.08.2021

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.

9.2 Other information

Molecular weight	:	No data available
Particle size	:	Not applicable

SECTION 10: Stability and reactivity

10.1 Reactivity

Not classified as a reactivity hazard.

10.2 Chemical stability

Stable under normal conditions.

10.3 Possibility of hazardous reactions

Hazardous reactions	:	Can react with strong oxidizing agents.
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10.4 Conditions to avoid

Conditions to avoid	:	None known.
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10.5 Incompatible materials

Materials to avoid	:	Oxidizing agents
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10.6 Hazardous decomposition products

No hazardous decomposition products are known.

SECTION 11: Toxicological information

11.1 Information on toxicological effects

SAFETY DATA SHEET

According to REACH Regulation (EC) No 1907/2006, as amended by
UK REACH Regulations SI 2019/758



Posaconazole Suspension Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 28.09.2024
6.2	14.04.2025	9371481-00010	Date of first issue: 27.08.2021

Information on likely routes of exposure :
Inhalation
Skin contact
Ingestion
Eye contact

Acute toxicity

Not classified based on available information.

Components:

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

Glycerine:

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

Skin corrosion/irritation

Not classified based on available information.

Components:

Posaconazole:

Species : Rabbit
Result : No skin irritation

Glycerine:

Species : Rabbit
Result : No skin irritation

Serious eye damage/eye irritation

Not classified based on available information.

Components:

Posaconazole:

Species : Rabbit
Result : Mild eye irritation

Glycerine:

Species : Rabbit
Result : No eye irritation

SAFETY DATA SHEET

According to REACH Regulation (EC) No 1907/2006, as amended by
UK REACH Regulations SI 2019/758



Posaconazole Suspension Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 28.09.2024
6.2	14.04.2025	9371481-00010	Date of first issue: 27.08.2021

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

Germ cell mutagenicity

Not classified based on available information.

Components:

Posaconazole:

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

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

Not classified based on available information.

SAFETY DATA SHEET

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UK REACH Regulations SI 2019/758



Posaconazole Suspension Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 28.09.2024
6.2	14.04.2025	9371481-00010	Date of first issue: 27.08.2021

Components:

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.

Glycerine:

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

Reproductive toxicity

Suspected of damaging the unborn child.

Components:

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
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	:	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.
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SAFETY DATA SHEET

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UK REACH Regulations SI 2019/758



Posaconazole Suspension Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 28.09.2024
6.2	14.04.2025	9371481-00010	Date of first issue: 27.08.2021

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

STOT - single exposure

Not classified based on available information.

STOT - repeated exposure

May cause damage to organs through prolonged or repeated exposure.

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:

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

SAFETY DATA SHEET

According to REACH Regulation (EC) No 1907/2006, as amended by
UK REACH Regulations SI 2019/758



Posaconazole Suspension Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 28.09.2024
6.2	14.04.2025	9371481-00010	Date of first issue: 27.08.2021

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

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

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

SAFETY DATA SHEET

According to REACH Regulation (EC) No 1907/2006, as amended by
UK REACH Regulations SI 2019/758



Posaconazole Suspension Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 28.09.2024
6.2	14.04.2025	9371481-00010	Date of first issue: 27.08.2021

SECTION 12: Ecological information

12.1 Toxicity

Components:

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 |
| M-Factor (Acute aquatic toxicity) | : | 1 |
| Toxicity to microorganisms | : | EC50 (Natural microorganism): > 1,000 mg/l
Exposure time: 3 h
Test Type: Respiration inhibition
Method: OECD Test Guideline 209 |
| Toxicity to fish (Chronic toxicity) | : | NOEC: 0.206 mg/l
Exposure time: 33 d
Species: Pimephales promelas (fathead minnow)
Method: OECD Test Guideline 210 |
| Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity) | : | NOEC: 0.244 mg/l
Exposure time: 21 d
Species: Daphnia magna (Water flea)
Method: OECD Test Guideline 211
Remarks: No toxicity at the limit of solubility |
| M-Factor (Chronic aquatic toxicity) | : | 1 |

Glycerine:

- | | | |
|-------------------------------|---|--|
| Toxicity to fish | : | LC50 (Oncorhynchus mykiss (rainbow trout)): 54,000 mg/l
Exposure time: 96 h |
| Toxicity to daphnia and other | : | EC50 (Daphnia magna (Water flea)): 1,955 mg/l |

SAFETY DATA SHEET

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UK REACH Regulations SI 2019/758



Posaconazole Suspension Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 28.09.2024
6.2	14.04.2025	9371481-00010	Date of first issue: 27.08.2021

aquatic invertebrates	Exposure time: 48 h
Toxicity to microorganisms	: NOEC (Pseudomonas putida): > 10,000 mg/l Exposure time: 16 h Method: DIN 38 412 Part 8

12.2 Persistence and degradability

Components:

Posaconazole:

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

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

Components:

Posaconazole:

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

Glycerine:

Partition coefficient: n-octanol/water	: log Pow: -1.75
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12.4 Mobility in soil

Components:

Posaconazole:

Distribution among environmental compartments	: log Koc: 5.52
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12.5 Results of PBT and vPvB assessment

Product:

Assessment	: This substance/mixture contains no components considered
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Posaconazole Suspension Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 28.09.2024
6.2	14.04.2025	9371481-00010	Date of first issue: 27.08.2021

to be either persistent, bioaccumulative and toxic (PBT), or very persistent and very bioaccumulative (vPvB) at levels of 0.1% or higher.

12.6 Other adverse effects

Product:

Endocrine disrupting potential : This substance/mixture does not contain components considered to have endocrine disrupting properties for environment according to UK REACH Article 57(f).

SECTION 13: Disposal considerations

13.1 Waste treatment methods

Product : Dispose of in accordance with local regulations.
According to the European Waste Catalogue, Waste Codes are not product specific, but application specific.
Waste codes should be assigned by the user, preferably in discussion with the waste disposal authorities.
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

14.1 UN number

ADN	: UN 3082
ADR	: UN 3082
RID	: UN 3082
IMDG	: UN 3082
IATA	: UN 3082

14.2 UN proper shipping name

ADN	: ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S. (Posaconazole)
ADR	: ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S. (Posaconazole)
RID	: ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S. (Posaconazole)
IMDG	: ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S. (Posaconazole)

SAFETY DATA SHEET

According to REACH Regulation (EC) No 1907/2006, as amended by
UK REACH Regulations SI 2019/758



Posaconazole Suspension Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 28.09.2024
6.2	14.04.2025	9371481-00010	Date of first issue: 27.08.2021

IATA : Environmentally hazardous substance, liquid, n.o.s.
(Posaconazole)

14.3 Transport hazard class(es)

	Class	Subsidiary risks
ADN	: 9	
ADR	: 9	
RID	: 9	
IMDG	: 9	
IATA	: 9	

14.4 Packing group

ADN
Packing group : III
Classification Code : M6
Hazard Identification Number : 90
Labels : 9

ADR
Packing group : III
Classification Code : M6
Hazard Identification Number : 90
Labels : 9
Tunnel restriction code : (-)

RID
Packing group : III
Classification Code : M6
Hazard Identification Number : 90
Labels : 9

IMDG
Packing group : III
Labels : 9
EmS Code : F-A, S-F

IATA (Cargo)
Packing instruction (cargo aircraft) : 964
Packing instruction (LQ) : Y964
Packing group : III
Labels : Miscellaneous

IATA (Passenger)
Packing instruction (passenger aircraft) : 964
Packing instruction (LQ) : Y964
Packing group : III
Labels : Miscellaneous

14.5 Environmental hazards

ADN

SAFETY DATA SHEET

According to REACH Regulation (EC) No 1907/2006, as amended by
UK REACH Regulations SI 2019/758



Posaconazole Suspension Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 28.09.2024
6.2	14.04.2025	9371481-00010	Date of first issue: 27.08.2021

Environmentally hazardous : yes

ADR

Environmentally hazardous : yes

RID

Environmentally hazardous : yes

IMDG

Marine pollutant : yes

IATA (Passenger)

Environmentally hazardous : yes

IATA (Cargo)

Environmentally hazardous : yes

14.6 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.

14.7 Transport in bulk according to Annex II of Marpol and the IBC Code

Remarks : Not applicable for product as supplied.

SECTION 15: Regulatory information

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

Relevant EU provisions transposed through retained EU law

UK REACH List of restrictions (Annex 17)	: Conditions of restriction for the following entries should be considered: Number on list 3
	Substance(s) or mixture(s) are listed here according to their appearance in the regulation, irrespective of their use/purpose or the conditions of the restriction. Please refer to the conditions in corresponding Regulation to determine whether an entry is applicable to the placing on the market or not.
UK REACH Candidate list of substances of very high concern (SVHC) for Authorisation	: Not applicable
The Persistent Organic Pollutants Regulations (retained Regulation (EU) 2019/1021 as amended for Great Britain)	: Not applicable
Regulation (EU) No 2024/590 on substances that deplete the ozone layer	: Not applicable
UK REACH List of substances subject to authorisation (Annex XIV)	: Not applicable
GB Export and import of hazardous chemicals - Prior	: Not applicable

SAFETY DATA SHEET

According to REACH Regulation (EC) No 1907/2006, as amended by
UK REACH Regulations SI 2019/758



Posaconazole Suspension Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 28.09.2024
6.2	14.04.2025	9371481-00010	Date of first issue: 27.08.2021

Informed Consent (PIC) Regulation
Control of Major Accident Hazards Regulations 2015 (COMAH)

E2	ENVIRONMENTAL HAZARDS	Quantity 1 200 t	Quantity 2 500 t
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Other regulations:

Take note of The Management of Health and Safety at Work Regulations 1999 (requirements relating to new and expectant mothers at work contained in Regulation 16 to 18) and of the Pregnant Workers Directive 92/85/EEC.

Take note of The Management of Health and Safety at Work Regulations 1999 (requirements relating to protection of young people at work contained in Regulation 19) and of Directive 94/33/EC on the protection of young people at work.

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

AICS : not determined

DSL : not determined

IECSC : not determined

15.2 Chemical safety assessment

A Chemical Safety Assessment has not been carried out.

SECTION 16: Other information

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

Full text of H-Statements

H319 : Causes serious eye irritation.
H361d : Suspected of damaging the unborn child.
H372 : Causes damage to organs through prolonged or repeated exposure if swallowed.
H400 : Very toxic to aquatic life.
H410 : Very toxic to aquatic life with long lasting effects.

Full text of other abbreviations

Aquatic Acute : Short-term (acute) aquatic hazard
Aquatic Chronic : Long-term (chronic) aquatic hazard
Eye Irrit. : Eye irritation
Repr. : Reproductive toxicity
STOT RE : Specific target organ toxicity - repeated exposure
GB EH40 : UK. EH40 WEL - Workplace Exposure Limits
GB EH40 / TWA : Long-term exposure limit (8-hour TWA reference period)

ADN - European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways; ADR - Agreement concerning the International Carriage of Dangerous Goods by Road; AIIIC - Australian Inventory of Industrial Chemicals; ASTM - American Society for the Testing of Materials; bw - Body weight; CLP - Classification Labelling Packaging Regulation; Regulation (EC) No 1272/2008; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard

SAFETY DATA SHEET

According to REACH Regulation (EC) No 1907/2006, as amended by
UK REACH Regulations SI 2019/758



Posaconazole Suspension Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 28.09.2024
6.2	14.04.2025	9371481-00010	Date of first issue: 27.08.2021

of the German Institute for Standardisation; DSL - Domestic Substances List (Canada); ECHA - European Chemicals Agency; EC-Number - European Community number; 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; 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; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; 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; RID - Regulations concerning the International Carriage of Dangerous Goods by Rail; SADT - Self-Accelerating Decomposition Temperature; SDS - Safety Data Sheet; SVHC - Substance of very high concern; 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

Further information

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/>

Classification of the mixture:

Repr. 2	H361d
STOT RE 2	H373
Aquatic Chronic 2	H411

Classification procedure:

Calculation method
Calculation method
Calculation method

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.

GB / EN

SAFETY DATA SHEET

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Posaconazole Suspension Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 28.09.2024
6.2	14.04.2025	9371481-00010	Date of first issue: 27.08.2021
