

**Posaconazole Injection Formulation**

Version	Revision Date:	SDS Number:	Date of last issue: 26.09.2023
6.9	14.04.2025	22520-00024	Date of first issue: 16.10.2014

---

**SECTION 1: Identification of the substance/mixture and of the company/undertaking****1.1 Product identifier**

Trade name : Posaconazole Injection 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  
117 16th Road  
1685 Halfway house, Midrand, South Africa

Telephone : +27 11 655 3000

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)**

Skin sensitisation, Category 1	H317: May cause an allergic skin reaction.
Specific target organ toxicity - repeated exposure, Category 2	H373: May cause damage to organs through prolonged or repeated exposure.
Long-term (chronic) aquatic hazard, Category 3	H412: Harmful to aquatic life with long lasting effects.

**2.2 Label elements****Labelling (REGULATION (EC) No 1272/2008)**

Hazard pictograms :



Signal word : Warning

Hazard statements : H317 May cause an allergic skin reaction.  
H373 May cause damage to organs through prolonged or

## Posaconazole Injection Formulation

Version 6.9      Revision Date: 14.04.2025      SDS Number: 22520-00024      Date of last issue: 26.09.2023  
 Date of first issue: 16.10.2014

repeated exposure.  
 H412 Harmful to aquatic life with long lasting effects.

Precautionary statements :

**Prevention:**

P272 Contaminated work clothing should not be allowed out of the workplace.  
 P273 Avoid release to the environment.  
 P280 Wear protective gloves.

**Response:**

P314 Get medical advice/ attention if you feel unwell.  
 P333 + P313 If skin irritation or rash occurs: Get medical advice/ attention.  
 P362 + P364 Take off contaminated clothing and wash it before reuse.

Hazardous components which must be listed on the label:

.beta.-Cyclodextrin, sulfobutyl ethers, sodium salts  
 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)
.beta.-Cyclodextrin, sulfobutyl ethers, sodium salts	182410-00-0 417-710-5	Skin Sens. 1; H317	>= 30 - < 50
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) Aquatic Acute 1; H400 Aquatic Chronic 1; H410  M-Factor (Acute aquatic toxicity): 1	>= 1 - < 2,5

**Posaconazole Injection Formulation**

Version 6.9	Revision Date: 14.04.2025	SDS Number: 22520-00024	Date of last issue: 26.09.2023 Date of first issue: 16.10.2014
----------------	------------------------------	----------------------------	-------------------------------------------------------------------

		M-Factor (Chronic aquatic toxicity): 1	
--	--	----------------------------------------	--

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.<br>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.<br>Get medical attention.                                                                                                                                                            |
| In case of skin contact    | : | In case of contact, immediately flush skin with soap and plenty of water.<br>Remove contaminated clothing and shoes.<br>Get medical attention.<br>Wash clothing before reuse.<br>Thoroughly clean shoes before reuse. |
| In case of eye contact     | : | Flush eyes with water as a precaution.<br>Get medical attention if irritation develops and persists.                                                                                                                  |
| If swallowed               | : | If swallowed, DO NOT induce vomiting.<br>Get medical attention.<br>Rinse mouth thoroughly with water.                                                                                                                 |

**4.2 Most important symptoms and effects, both acute and delayed**

- |          |   |                                                                                                            |
|----------|---|------------------------------------------------------------------------------------------------------------|
| Symptoms | : | Diarrhoea<br>Fever<br>Headache<br>Nausea<br>Vomiting                                                       |
| Risks    | : | May cause an allergic skin reaction.<br>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. |
|-----------|---|-----------------------------------------|

**Posaconazole Injection Formulation**

Version	Revision Date:	SDS Number:	Date of last issue: 26.09.2023
6.9	14.04.2025	22520-00024	Date of first issue: 16.10.2014

---

**SECTION 5: Firefighting measures****5.1 Extinguishing media**

Suitable extinguishing media : Water spray  
Alcohol-resistant foam  
Carbon dioxide (CO<sub>2</sub>)  
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  
Sulphur oxides  
Metal 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).  
Retain and dispose of contaminated wash water.  
Local authorities should be advised if significant spillages cannot be contained.

**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

## Posaconazole Injection Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 26.09.2023
6.9	14.04.2025	22520-00024	Date of first issue: 16.10.2014

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 get on skin or clothing.<br>Do not breathe mist or vapours.<br>Do not swallow.<br>Avoid contact with eyes.<br>Wash skin thoroughly after handling.<br>Handle in accordance with good industrial hygiene and safety practice, based on the results of the workplace exposure assessment<br>Do not eat, drink or smoke when using this product.<br>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. Contaminated work clothing should not be allowed out of the workplace.<br>Wash contaminated clothing before re-use.<br>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 in accordance with the particular national regulations.                                                            |
| Advice on common storage                      | : | Do not store with the following product types:<br>Strong oxidizing agents<br>Self-reactive substances and mixtures<br>Organic peroxides<br>Explosives<br>Gases |

### 7.3 Specific end use(s)

**Posaconazole Injection Formulation**

Version	Revision Date:	SDS Number:	Date of last issue: 26.09.2023
6.9	14.04.2025	22520-00024	Date of first issue: 16.10.2014

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
Posaconazole	171228-49-2	TWA	300 µg/m <sup>3</sup> (OEB 2)	Internal

**8.2 Exposure controls****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**

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 type	:	Particulates type (P)

**SECTION 9: Physical and chemical properties****9.1 Information on basic physical and chemical properties**

Appearance	:	Aqueous solution
Colour	:	Colorless to pale yellow
Odour	:	odourless
Odour Threshold	:	No data available
pH	:	2,6
Melting point/freezing point	:	No data available
Initial boiling point and boiling range	:	No data available
Flash point	:	No data available

**Posaconazole Injection Formulation**

Version	Revision Date:	SDS Number:	Date of last issue: 26.09.2023
6.9	14.04.2025	22520-00024	Date of first issue: 16.10.2014

---

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
Relative density	:	No data available
Density	:	1,15 g/cm <sup>3</sup>
Solubility(ies)		
Water solubility	:	No data available
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.
---------------------	---	-----------------------------------------

**Posaconazole Injection Formulation**

Version	Revision Date:	SDS Number:	Date of last issue: 26.09.2023
6.9	14.04.2025	22520-00024	Date of first issue: 16.10.2014

---

**10.4 Conditions to avoid**

Conditions to avoid : None known.

**10.5 Incompatible materials**

Materials to avoid : Oxidizing agents

**10.6 Hazardous decomposition products**

No hazardous decomposition products are known.

---

**SECTION 11: Toxicological information****11.1 Information on toxicological effects**

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

**Acute toxicity**

Not classified based on available information.

**Components:****.beta.-Cyclodextrin, sulfobutyl ethers, sodium salts:**

Acute oral toxicity : LD50 (Rat): > 2.000 mg/kg

Acute dermal toxicity : LD50 (Rabbit): > 2.000 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

**Skin corrosion/irritation**

Not classified based on available information.

**Components:****.beta.-Cyclodextrin, sulfobutyl ethers, sodium salts:**

Result : No skin irritation

**Posaconazole:**

Species : Rabbit

Result : No skin irritation

**Serious eye damage/eye irritation**

Not classified based on available information.



## Posaconazole Injection Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 26.09.2023
6.9	14.04.2025	22520-00024	Date of first issue: 16.10.2014

---

**Components:****.beta.-Cyclodextrin, sulfobutyl ethers, sodium salts:**

Result : No eye irritation

**Posaconazole:**

Species : Rabbit

Result : Mild eye irritation

**Respiratory or skin sensitisation****Skin sensitisation**

May cause an allergic skin reaction.

**Respiratory sensitisation**

Not classified based on available information.

**Components:****.beta.-Cyclodextrin, sulfobutyl ethers, sodium salts:**

Assessment : Probability or evidence of skin sensitisation in humans

**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:****.beta.-Cyclodextrin, sulfobutyl ethers, sodium salts:**Genotoxicity in vitro : Test Type: Bacterial reverse mutation assay (AMES)  
Result: negative

Test Type: In vitro mammalian cell gene mutation test

Method: OECD Test Guideline 476

Result: negative

Remarks: The test was conducted according to guideline

Test Type: Chromosome aberration test in vitro

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

## Posaconazole Injection Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 26.09.2023
6.9	14.04.2025	22520-00024	Date of first issue: 16.10.2014

Species: Mouse  
Cell type: Bone marrow  
Application Route: Intravenous  
Result: negative

**Carcinogenicity**

Not classified based on available information.

**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.

**Reproductive toxicity**

Not classified based on available information.

**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

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 Injection Formulation**

Version	Revision Date:	SDS Number:	Date of last issue: 26.09.2023
6.9	14.04.2025	22520-00024	Date of first issue: 16.10.2014

---

**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
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

**Posaconazole Injection Formulation**

Version	Revision Date:	SDS Number:	Date of last issue: 26.09.2023
6.9	14.04.2025	22520-00024	Date of first issue: 16.10.2014

Application Route	:	Intravenous
Exposure time	:	1 Months
Target Organs	:	Cardio-vascular system, Lungs, Adrenal gland, Blood

**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
-----------	---	------------------------------------------------------------------------------------------------------------------------------------------------

**SECTION 12: Ecological information****12.1 Toxicity****Components:****.beta.-Cyclodextrin, sulfobutyl ethers, sodium salts:**

Toxicity to fish	:	LC50 (Oncorhynchus mykiss (rainbow trout)): > 220 mg/l Exposure time: 96 h
Toxicity to daphnia and other aquatic invertebrates	:	EC50 (Daphnia magna (Water flea)): > 96 mg/l Exposure time: 48 h
Toxicity to algae/aquatic plants	:	ErC50 (Selenastrum capricornutum (green algae)): > 100 mg/l Exposure time: 72 h
Toxicity to microorganisms	:	NOEC : 100 mg/l Exposure time: 3 h
Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity)	:	NOEC: 100 mg/l Exposure time: 21 d Species: Daphnia magna (Water flea) Method: OECD Test Guideline 211 Remarks: The test was conducted according to guideline

**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

## Posaconazole Injection Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 26.09.2023
6.9	14.04.2025	22520-00024	Date of first issue: 16.10.2014

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

## 12.2 Persistence and degradability

Components:**.beta.-Cyclodextrin, sulfobutyl ethers, sodium salts:**

Biodegradability : Result: Not readily biodegradable.  
Biodegradation: 2 %  
Exposure time: 28 d

**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

## 12.3 Bioaccumulative potential

Components:**.beta.-Cyclodextrin, sulfobutyl ethers, sodium salts:**

Partition coefficient: n-octanol/water : log Pow: < -2

**Posaconazole Injection Formulation**

Version	Revision Date:	SDS Number:	Date of last issue: 26.09.2023
6.9	14.04.2025	22520-00024	Date of first issue: 16.10.2014

**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

**12.4 Mobility in soil****Components:****Posaconazole:**

Distribution among environmental compartments : log Koc: 5,52

**12.5 Results of PBT and vPvB assessment****Product:**

Assessment : 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.

**12.6 Other adverse effects****Product:**

Endocrine disrupting potential : The substance/mixture does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.

---

**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 : Not regulated as a dangerous good  
ADR : Not regulated as a dangerous good

**Posaconazole Injection Formulation**

Version 6.9	Revision Date: 14.04.2025	SDS Number: 22520-00024	Date of last issue: 26.09.2023 Date of first issue: 16.10.2014
----------------	------------------------------	----------------------------	-------------------------------------------------------------------

---

<b>RID</b>	: Not regulated as a dangerous good
<b>IMDG</b>	: Not regulated as a dangerous good
<b>IATA</b>	: Not regulated as a dangerous good

**14.2 UN proper shipping name**

<b>ADN</b>	: Not regulated as a dangerous good
<b>ADR</b>	: Not regulated as a dangerous good
<b>RID</b>	: Not regulated as a dangerous good
<b>IMDG</b>	: Not regulated as a dangerous good
<b>IATA</b>	: Not regulated as a dangerous good

**14.3 Transport hazard class(es)**

<b>ADN</b>	: Not regulated as a dangerous good
<b>ADR</b>	: Not regulated as a dangerous good
<b>RID</b>	: Not regulated as a dangerous good
<b>IMDG</b>	: Not regulated as a dangerous good
<b>IATA</b>	: Not regulated as a dangerous good

**14.4 Packing group**

<b>ADN</b>	: Not regulated as a dangerous good
<b>ADR</b>	: Not regulated as a dangerous good
<b>RID</b>	: Not regulated as a dangerous good
<b>IMDG</b>	: Not regulated as a dangerous good
<b>IATA (Cargo)</b>	: Not regulated as a dangerous good
<b>IATA (Passenger)</b>	: Not regulated as a dangerous good

**14.5 Environmental hazards**

Not regulated as a dangerous good

**14.6 Special precautions for user**

Not applicable

**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**

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

AICS	: not determined
DSL	: not determined

## Posaconazole Injection Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 26.09.2023
6.9	14.04.2025	22520-00024	Date of first issue: 16.10.2014

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**

H317	: May cause an allergic skin reaction.
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
Skin Sens.	: Skin sensitisation
STOT RE	: Specific target organ toxicity - repeated exposure

ADN - European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways; ADR - Agreement concerning the International Carriage of Dangerous Goods by Road; AIIC - 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 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 Re-



## Posaconazole Injection Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 26.09.2023
6.9	14.04.2025	22520-00024	Date of first issue: 16.10.2014

---

striction 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:**

Skin Sens. 1	H317
STOT RE 2	H373
Aquatic Chronic 3	H412

**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.

ZA / EN