

# SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006, as amended by  
Commission Regulation (EU) 2020/878



## Posaconazole Injection Formulation

|         |                |             |                                 |
|---------|----------------|-------------|---------------------------------|
| Version | Revision Date: | SDS Number: | Date of last issue: 28.09.2024  |
| 6.12    | 14.04.2025     | 22513-00027 | 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  
Kilsheelan  
Clonmel Tipperary, IE

Telephone : 353-51-601000

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

Specific target organ toxicity - repeated  
exposure, Category 2

Long-term (chronic) aquatic hazard, Cat-  
egory 3

H317: May cause an allergic skin reaction.

H373: May cause damage to organs through pro-  
longed or repeated exposure.

H412: Harmful to aquatic life with long lasting ef-  
fects.

#### 2.2 Label elements

##### Labelling (REGULATION (EC) No 1272/2008)

Hazard pictograms :



Signal word : Warning

# SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006, as amended by  
Commission Regulation (EU) 2020/878



## Posaconazole Injection Formulation

|         |                |             |                                 |
|---------|----------------|-------------|---------------------------------|
| Version | Revision Date: | SDS Number: | Date of last issue: 28.09.2024  |
| 6.12    | 14.04.2025     | 22513-00027 | Date of first issue: 16.10.2014 |

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

Ecological information: 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.

Toxicological information: 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 3: Composition/information on ingredients

### 3.2 Mixtures

#### Components

| Chemical name                                        | CAS-No.<br>EC-No.<br>Index-No.<br>Registration number | Classification                       | Concentration<br>(% w/w) |
|------------------------------------------------------|-------------------------------------------------------|--------------------------------------|--------------------------|
| .beta.-Cyclodextrin, sulfobutyl ethers, sodium salts | 182410-00-0<br>417-710-5                              | Skin Sens. 1; H317                   | >= 30 - < 50             |
| Posaconazole                                         | 171228-49-2                                           | Eye Irrit. 2; H319<br>Repr. 2; H361d | >= 1 - < 2,5             |

# SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006, as amended by  
Commission Regulation (EU) 2020/878



## Posaconazole Injection Formulation

|         |                |             |                                 |
|---------|----------------|-------------|---------------------------------|
| Version | Revision Date: | SDS Number: | Date of last issue: 28.09.2024  |
| 6.12    | 14.04.2025     | 22513-00027 | Date of first issue: 16.10.2014 |

|  |  |                                                                                                                                                                                                                                                                             |  |
|--|--|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--|
|  |  | STOT RE 1; H372<br>(Adrenal gland,<br>Bone marrow, Kid-<br>ney, Liver, Nervous<br>system, Reproduc-<br>tive organs)<br>Aquatic Acute 1;<br>H400<br>Aquatic Chronic 1;<br>H410<br><hr/> M-Factor (Acute<br>aquatic toxicity): 1<br>M-Factor (Chronic<br>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 |
|----------|---|--------------------------------|

# SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006, as amended by  
Commission Regulation (EU) 2020/878



## Posaconazole Injection Formulation

|         |                |             |                                 |
|---------|----------------|-------------|---------------------------------|
| Version | Revision Date: | SDS Number: | Date of last issue: 28.09.2024  |
| 6.12    | 14.04.2025     | 22513-00027 | Date of first issue: 16.10.2014 |

Nausea  
Vomiting

Risks : May cause an allergic skin reaction.  
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 (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).

# SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006, as amended by  
Commission Regulation (EU) 2020/878



## Posaconazole Injection Formulation

|         |                |             |                                 |
|---------|----------------|-------------|---------------------------------|
| Version | Revision Date: | SDS Number: | Date of last issue: 28.09.2024  |
| 6.12    | 14.04.2025     | 22513-00027 | Date of first issue: 16.10.2014 |

---

### 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 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, |

# SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006, as amended by  
Commission Regulation (EU) 2020/878



## Posaconazole Injection Formulation

|         |                |             |                                 |
|---------|----------------|-------------|---------------------------------|
| Version | Revision Date: | SDS Number: | Date of last issue: 28.09.2024  |
| 6.12    | 14.04.2025     | 22513-00027 | Date of first issue: 16.10.2014 |

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:  
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    |
|--------------|-------------|-------------------------------|--------------------|----------|
| Posaconazole | 171228-49-2 | TWA                           | 300 µg/m3 (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.  
Equipment should conform to NS EN 143

# SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006, as amended by  
Commission Regulation (EU) 2020/878



## Posaconazole Injection Formulation

|         |                |             |                                 |
|---------|----------------|-------------|---------------------------------|
| Version | Revision Date: | SDS Number: | Date of last issue: 28.09.2024  |
| 6.12    | 14.04.2025     | 22513-00027 | Date of first issue: 16.10.2014 |

Filter type : Particulates type (P)

### SECTION 9: Physical and chemical properties

#### 9.1 Information on basic physical and chemical properties

|                                                  |                            |
|--------------------------------------------------|----------------------------|
| Physical state                                   | : Aqueous solution         |
| Colour                                           | : Colorless to pale yellow |
| Odour                                            | : odourless                |
| Odour Threshold                                  | : No data available        |
| Melting point/freezing point                     | : No data available        |
| Initial boiling point and boiling range          | : 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        |
| Flash point                                      | : No data available        |
| Auto-ignition temperature                        | : No data available        |
| Decomposition temperature                        | : No data available        |
| pH                                               | : 2,6                      |
| Viscosity                                        |                            |
| Viscosity, kinematic                             | : No data available        |
| Solubility(ies)                                  |                            |
| Water solubility                                 | : No data available        |
| Partition coefficient: n-octanol/water           | : Not applicable           |
| Vapour pressure                                  | : No data available        |
| Relative density                                 | : No data available        |

# SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006, as amended by  
Commission Regulation (EU) 2020/878



## Posaconazole Injection Formulation

|         |                |             |                                 |
|---------|----------------|-------------|---------------------------------|
| Version | Revision Date: | SDS Number: | Date of last issue: 28.09.2024  |
| 6.12    | 14.04.2025     | 22513-00027 | Date of first issue: 16.10.2014 |

|                          |   |                        |
|--------------------------|---|------------------------|
| Density                  | : | 1,15 g/cm <sup>3</sup> |
| Relative vapour density  | : | No data available      |
| Particle characteristics | : |                        |
| Particle size            | : | Not applicable         |

### 9.2 Other information

|                      |   |                                                          |
|----------------------|---|----------------------------------------------------------|
| Explosives           | : | Not explosive                                            |
| Oxidizing properties | : | The substance or mixture is not classified as oxidizing. |
| Evaporation rate     | : | No data available                                        |
| Molecular weight     | : | No data available                                        |

## 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. |
|---------------------|---|-----------------------------------------|

### 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 hazard classes as defined in Regulation (EC) No 1272/2008

|                                          |   |                                                        |
|------------------------------------------|---|--------------------------------------------------------|
| Information on likely routes of exposure | : | Inhalation<br>Skin contact<br>Ingestion<br>Eye contact |
|------------------------------------------|---|--------------------------------------------------------|

#### Acute toxicity

Not classified based on available information.



# SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006, as amended by  
Commission Regulation (EU) 2020/878



## Posaconazole Injection Formulation

|         |                |             |                                 |
|---------|----------------|-------------|---------------------------------|
| Version | Revision Date: | SDS Number: | Date of last issue: 28.09.2024  |
| 6.12    | 14.04.2025     | 22513-00027 | Date of first issue: 16.10.2014 |

---

### 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.

### 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 |
|------------|---|---------------------------------------------------------|

# SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006, as amended by  
Commission Regulation (EU) 2020/878



## Posaconazole Injection Formulation

|         |                |             |                                 |
|---------|----------------|-------------|---------------------------------|
| Version | Revision Date: | SDS Number: | Date of last issue: 28.09.2024  |
| 6.12    | 14.04.2025     | 22513-00027 | Date of first issue: 16.10.2014 |

---

### 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)<br>Result: negative                                                                                               |
|                       | Test Type: In vitro mammalian cell gene mutation test<br>Method: OECD Test Guideline 476<br>Result: negative<br>Remarks: The test was conducted according to guideline |
|                       | Test Type: Chromosome aberration test in vitro<br>Result: negative                                                                                                     |

### Posaconazole:

|                       |                                                                                                                                  |
|-----------------------|----------------------------------------------------------------------------------------------------------------------------------|
| Genotoxicity in vitro | : Test Type: Bacterial reverse mutation assay (AMES)<br>Result: negative                                                         |
|                       | Test Type: Chromosomal aberration<br>Result: negative                                                                            |
| Genotoxicity in vivo  | : Test Type: Micronucleus test<br>Species: Mouse<br>Cell type: Bone marrow<br>Application Route: Intravenous<br>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                                                       |

# SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006, as amended by  
Commission Regulation (EU) 2020/878



## Posaconazole Injection Formulation

|         |                |             |                                 |
|---------|----------------|-------------|---------------------------------|
| Version | Revision Date: | SDS Number: | Date of last issue: 28.09.2024  |
| 6.12    | 14.04.2025     | 22513-00027 | Date of first issue: 16.10.2014 |

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.

### 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.

# SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006, as amended by  
Commission Regulation (EU) 2020/878



## Posaconazole Injection Formulation

|         |                |             |                                 |
|---------|----------------|-------------|---------------------------------|
| Version | Revision Date: | SDS Number: | Date of last issue: 28.09.2024  |
| 6.12    | 14.04.2025     | 22513-00027 | Date of first issue: 16.10.2014 |

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

### Aspiration toxicity

Not classified based on available information.

### 11.2 Information on other hazards

#### **Endocrine disrupting properties**

Not classified based on available information.

#### Product:

|            |                                                             |
|------------|-------------------------------------------------------------|
| Assessment | : The substance/mixture does not contain components consid- |
|------------|-------------------------------------------------------------|

# SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006, as amended by  
Commission Regulation (EU) 2020/878



## Posaconazole Injection Formulation

|         |                |             |                                 |
|---------|----------------|-------------|---------------------------------|
| Version | Revision Date: | SDS Number: | Date of last issue: 28.09.2024  |
| 6.12    | 14.04.2025     | 22513-00027 | Date of first issue: 16.10.2014 |

ered 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.

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

##### **Posaconazole:**

|                                                     |                                                                                                                                                                        |
|-----------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Toxicity to fish                                    | : LC50 (Oncorhynchus mykiss (rainbow trout)): > 0,95 mg/l<br>Exposure time: 96 h<br>Method: OECD Test Guideline 203<br>Remarks: No toxicity at the limit of solubility |
| Toxicity to daphnia and other aquatic invertebrates | : EC50 (Daphnia magna (Water flea)): 0,276 mg/l<br>Exposure time: 48 h<br>Method: OECD Test Guideline 202                                                              |
| Toxicity to algae/aquatic plants                    | : EC50 (Pseudokirchneriella subcapitata (green algae)): > 0,509 mg/l<br>Exposure time: 72 h                                                                            |

# SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006, as amended by  
Commission Regulation (EU) 2020/878



## Posaconazole Injection Formulation

|         |                |             |                                 |
|---------|----------------|-------------|---------------------------------|
| Version | Revision Date: | SDS Number: | Date of last issue: 28.09.2024  |
| 6.12    | 14.04.2025     | 22513-00027 | 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- : log Pow: < -2

# SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006, as amended by  
Commission Regulation (EU) 2020/878



## Posaconazole Injection Formulation

|         |                |             |                                 |
|---------|----------------|-------------|---------------------------------|
| Version | Revision Date: | SDS Number: | Date of last issue: 28.09.2024  |
| 6.12    | 14.04.2025     | 22513-00027 | Date of first issue: 16.10.2014 |

---

octanol/water

### **Posaconazole:**

Bioaccumulation : Species: *Lepomis macrochirus* (Bluegill sunfish)  
Bioconcentration factor (BCF): 20  
Method: OECD Test Guideline 305

Partition coefficient: n- : log Pow: 4,15  
octanol/water

### 12.4 Mobility in soil

#### **Components:**

### **Posaconazole:**

Distribution among environ- : log Koc: 5,52  
mental compartments

### 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 Endocrine disrupting properties

#### **Product:**

Assessment : 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.

### 12.7 Other adverse effects

No data available

---

## SECTION 13: Disposal considerations

### 13.1 Waste treatment methods

|                        |                                                                                                                                                                                                                                                                                                                      |
|------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Product                | : Dispose of in accordance with local regulations.<br>According to the European Waste Catalogue, Waste Codes are not product specific, but application specific.<br>Waste codes should be assigned by the user, preferably in discussion with the waste disposal authorities.<br>Do not dispose of waste into sewer. |
| Contaminated packaging | : Empty containers should be taken to an approved waste handling site for recycling or disposal.<br>If not otherwise specified: Dispose of as unused product.                                                                                                                                                        |

# SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006, as amended by  
Commission Regulation (EU) 2020/878



## Posaconazole Injection Formulation

|         |                |             |                                 |
|---------|----------------|-------------|---------------------------------|
| Version | Revision Date: | SDS Number: | Date of last issue: 28.09.2024  |
| 6.12    | 14.04.2025     | 22513-00027 | Date of first issue: 16.10.2014 |

### SECTION 14: Transport information

#### 14.1 UN number or ID number

|      |   |                                   |
|------|---|-----------------------------------|
| ADN  | : | Not regulated as a dangerous good |
| ADR  | : | Not regulated as a dangerous good |
| RID  | : | Not regulated as a dangerous good |
| IMDG | : | Not regulated as a dangerous good |
| IATA | : | Not regulated as a dangerous good |

#### 14.2 UN proper shipping name

|      |   |                                   |
|------|---|-----------------------------------|
| ADN  | : | Not regulated as a dangerous good |
| ADR  | : | Not regulated as a dangerous good |
| RID  | : | Not regulated as a dangerous good |
| IMDG | : | Not regulated as a dangerous good |
| IATA | : | Not regulated as a dangerous good |

#### 14.3 Transport hazard class(es)

|      |   |                                   |
|------|---|-----------------------------------|
| ADN  | : | Not regulated as a dangerous good |
| ADR  | : | Not regulated as a dangerous good |
| RID  | : | Not regulated as a dangerous good |
| IMDG | : | Not regulated as a dangerous good |
| IATA | : | Not regulated as a dangerous good |

#### 14.4 Packing group

|                  |   |                                   |
|------------------|---|-----------------------------------|
| ADN              | : | Not regulated as a dangerous good |
| ADR              | : | Not regulated as a dangerous good |
| RID              | : | Not regulated as a dangerous good |
| IMDG             | : | Not regulated as a dangerous good |
| IATA (Cargo)     | : | Not regulated as a dangerous good |
| IATA (Passenger) | : | 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 Maritime transport in bulk according to IMO instruments

|         |   |                                         |
|---------|---|-----------------------------------------|
| Remarks | : | Not applicable for product as supplied. |
|---------|---|-----------------------------------------|



# SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006, as amended by  
Commission Regulation (EU) 2020/878



## Posaconazole Injection Formulation

|         |                |             |                                 |
|---------|----------------|-------------|---------------------------------|
| Version | Revision Date: | SDS Number: | Date of last issue: 28.09.2024  |
| 6.12    | 14.04.2025     | 22513-00027 | Date of first issue: 16.10.2014 |

### SECTION 15: Regulatory information

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

REACH - Restrictions on the manufacture, placing on the market and use of certain dangerous substances, mixtures and articles (Annex XVII) : 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.

REACH - Candidate List of Substances of Very High Concern for Authorisation (Article 59) : Not applicable

REACH - List of substances subject to authorisation (Annex XIV) : Not applicable

Regulation (EU) No 2024/590 on substances that deplete the ozone layer : Not applicable

Regulation (EU) 2019/1021 on persistent organic pollutants (recast) : Not applicable

Regulation (EU) No 649/2012 of the European Parliament and the Council concerning the export and import of dangerous chemicals : Not applicable

Seveso III: Directive 2012/18/EU of the European Parliament and of the Council on the control of major-accident hazards involving dangerous substances.  
Not applicable

#### Other regulations:

Note the regulation on organization, leadership and participation, chapter 12 on the work of children and young people.

#### 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

# SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006, as amended by  
Commission Regulation (EU) 2020/878



## Posaconazole Injection Formulation

|         |                |             |                                 |
|---------|----------------|-------------|---------------------------------|
| Version | Revision Date: | SDS Number: | Date of last issue: 28.09.2024  |
| 6.12    | 14.04.2025     | 22513-00027 | Date of first issue: 16.10.2014 |

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; 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 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

# SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006, as amended by  
Commission Regulation (EU) 2020/878



## Posaconazole Injection Formulation

|         |                |             |                                 |
|---------|----------------|-------------|---------------------------------|
| Version | Revision Date: | SDS Number: | Date of last issue: 28.09.2024  |
| 6.12    | 14.04.2025     | 22513-00027 | Date of first issue: 16.10.2014 |

---

### 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.

NO / EN