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



# **Posaconazole Injection Formulation**

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### 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** 

Piercetown

A86 HD21 Dunboyne, Ireland

Telephone 908-740-4000

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

H317: May cause an allergic skin reaction.

H373: May cause damage to organs through pro-

exposure, Category 2

longed or repeated exposure.

Long-term (chronic) aquatic hazard, Cat-

H412: Harmful to aquatic life with long lasting ef-

egory 3

fects.

#### 2.2 Label elements

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

Hazard pictograms

Signal word

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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. EC-No. Index-No. Registration number	Classification	Concentration (% w/w)
.betaCyclodextrin, 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	>= 1 - < 2.5

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			marrow, Kidney, Liver, Nervous system, Reproductive organs) Aquatic Acute 1; H400 Aquatic Chronic 1; H410		
			M-Factor (Acute aquatic toxicity): 1 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 ad-

vice immediately.

When symptoms persist or in all cases of doubt seek medical

advice.

Protection of first-aiders : First Aid responders should pay attention to self-protection,

and use the recommended personal protective equipment when the potential for exposure exists (see section 8).

If inhaled : If inhaled, remove to fresh air.

Get medical attention.

In case of skin contact : In case of contact, immediately flush skin with soap and plenty

of water.

Remove contaminated clothing and shoes.

Get medical attention. Wash clothing before reuse.

Thoroughly clean shoes before reuse.

In case of eye contact : Flush eyes with water as a precaution.

Get medical attention if irritation develops and persists.

If swallowed : If swallowed, DO NOT induce vomiting.

Get medical attention.

Rinse mouth thoroughly with water.

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

Symptoms : Diarrhoea

Fever Headache Nausea Vomiting

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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 (CO2)

Dry chemical

Unsuitable extinguishing

media

None known.

5.2 Special hazards arising from the substance or mixture

Specific hazards during fire-

fighting

Exposure to combustion products may be a hazard to health.

Hazardous combustion prod: :

ucts

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 meth-

ods

Use extinguishing measures that are appropriate to local cir-

cumstances 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 pro-

tective 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

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



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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 absor-

bent.

Local or national regulations may apply to releases and disposal of this material, as well as those materials and items employed in the cleanup of releases. You will need to deter-

mine 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.

Do not breathe mist or vapours.

Do not swallow.

Avoid contact with eyes.

Wash skin thoroughly after handling.

Handle in accordance with good industrial hygiene and safety practice, based on the results of the workplace exposure as-

sessment

Do not eat, drink or smoke when using this product.

Take care to prevent spills, waste and minimize release to the

environment.

Hygiene measures : If exposure to chemical is likely during typical use, provide eye

flushing systems and safety showers close to the working place. When using do not eat, drink or smoke. Contaminated work clothing should not be allowed out of the workplace.

Wash contaminated clothing before re-use.

The effective operation of a facility should include review of engineering controls, proper personal protective equipment, appropriate degowning and decontamination procedures, industrial hygiene monitoring, medical surveillance and the

use of administrative controls.

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



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#### 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	Control parameters	Basis
		of exposure)		
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 rec-

ommended guidelines, use respiratory protection.

Equipment should conform to I.S. EN 143

Filter type : Particulates type (P)

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### **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

Density : 1.15 g/cm<sup>3</sup>

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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 : Inhalation exposure 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): > 8,800 mg/kg

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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:** 

Posaconazole:

Species : Rabbit

Result : No skin irritation

Serious eye damage/eye irritation

Not classified based on available information.

**Components:** 

Posaconazole:

Species : Rabbit

Result : Mild eye irritation

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:** 

Posaconazole:

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Genotoxicity in vitro : Test Type: Bacterial reverse mutation assay (AMES)

Result: negative

Test Type: Chromosomal aberration

Result: negative

Genotoxicity in vivo : Test Type: Micronucleus test

Species: Mouse

Cell type: Bone marrow

Application Route: Intravenous

Result: negative

### 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:**

#### .beta.-Cyclodextrin, sulfobutyl ethers, sodium salts:

Effects on fertility : Test Type: Fertility

Species: Rat

Application Route: Intravenous injection

Result: negative

Effects on foetal develop-

Test Type: Embryo-foetal development

Species: Rat

Application Route: Intravenous injection

Result: negative

Posaconazole:

ment

Effects on fertility : Test Type: Fertility/early embryonic development

Species: Rat, male

General Toxicity - Parent: NOAEL: 180 mg/kg body weight

Symptoms: No effects on mating performance

Result: negative

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Test Type: Fertility/early embryonic development

Species: Rat, female

General Toxicity - Parent: NOAEL: 45 mg/kg body weight

Symptoms: No effects on mating performance

Result: negative

Effects on foetal develop-

ment

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 - As-

sessment

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.

#### Repeated dose toxicity

### **Components:**

### Posaconazole:

Species : Rat, female LOAEL : 5 mg/kg
Application Route : Oral : 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

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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**

#### **Product:**

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

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

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### **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

aquatic invertebrates

Toxicity to daphnia and other : EC50 (Daphnia magna (Water flea)): > 96 mg/l

Exposure time: 48 h

Toxicity to algae/aquatic

plants

EC50 (Selenastrum capricornutum (green algae)): > 100 mg/l

Exposure time: 72 h

Posaconazole:

LC50 (Oncorhynchus mykiss (rainbow trout)): > 0.95 mg/l Toxicity to fish

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 ma/l

Exposure time: 72 h

Method: OECD Test Guideline 201

NOEC (Pseudokirchneriella subcapitata (green algae)): 0.041

mg/l

Exposure time: 72 h

Method: OECD Test Guideline 201

M-Factor (Acute aquatic tox- :

icity)

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 tox-

icity)

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 (Chron-

ic toxicity)

NOEC: 0.244 mg/l Exposure time: 21 d

Species: Daphnia magna (Water flea)

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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:

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:**

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 environ-

mental 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 Endocrine disrupting properties

#### **Product:**

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

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

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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.

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 han-

dling site for recycling or disposal.

If not otherwise specified: Dispose of as unused product.

### **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

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**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.

#### **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.

Not applicable

Not applicable

Not applicable

Not applicable

REACH - Candidate List of Substances of Very High Concern for Authorisation (Article 59).

laver

Regulation (EC) on substances that deplete the ozone

Regulation (EU) 2019/1021 on persistent organic pollutants (recast)

Regulation (EU) No 649/2012 of the European Parliament and the Council concerning the export and import of dangerous chemicals

REACH - List of substances subject to authorisation

Not applicable (Annex XIV)

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:

16 / 18

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



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Take note of Directive 94/33/EC on the protection of young people at work or stricter national regulations, where applicable.

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

AICS : not determined

DSL : not determined

IECSC : not determined

### 15.2 Chemical safety assessment

A Chemical Safety Assessment has not been carried out.

#### **SECTION 16: Other information**

Other information : Items where changes have been made to the previous version

are highlighted in the body of this document by two vertical

lines.

### **Full text of H-Statements**

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;

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: 06.04.2024 6.12 28.09.2024 22504-00027 Date of first issue: 16.10.2014

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; TRGS - Technical Rule for Hazardous Substances; TSCA - Toxic Substances Control Act (United States); UN - United Nations; 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 Agen-

cy, http://echa.europa.eu/

#### Classification of the mixture: Classification procedure:

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

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