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



## Posaconazole Solid Formulation

Version Revision Date: SDS Number: Date of last issue: 06.04.2024 6.3 28.09.2024 23530-00025 Date of first issue: 21.10.2014

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

1.1 Product identifier

Trade name : Posaconazole Solid 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)

Eye irritation, Category 2 H31

Reproductive toxicity, Category 2 Specific target organ toxicity - repeated

exposure, Category 1

Long-term (chronic) aquatic hazard, Category 2

H319: Causes serious eye irritation.

H361d: Suspected of damaging the unborn child. H372: Causes damage to organs through pro-

longed or repeated exposure.

H411: Toxic to aquatic life with long lasting effects.

#### 2.2 Label elements

Labelling (REGULATION (EC) No 1272/2008)

Hazard pictograms





Signal word : Danger

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



## Posaconazole Solid Formulation

Version Revision Date: SDS Number: Date of last issue: 06.04.2024 6.3 28.09.2024 23530-00025 Date of first issue: 21.10.2014

Hazard statements : H319 Causes serious eye irritation.

H361d Suspected of damaging the unborn child.

H372 Causes damage to organs through prolonged or re-

peated exposure.

H411 Toxic to aquatic life with long lasting effects.

Precautionary statements : Prevention:

P201 Obtain special instructions before use.

P260 Do not breathe dust.

P273 Avoid release to the environment.

P280 Wear protective gloves/ protective clothing/ eye protec-

tion/ face protection.

Response:

P308 + P313 IF exposed or concerned: Get medical advice/

attention.

P391 Collect spillage.

Hazardous components which must be listed on the label:

Posaconazole

#### 2.3 Other hazards

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

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.

Contact with dust can cause mechanical irritation or drying of the skin.

May form explosive dust-air mixture during processing, handling or other means.

## **SECTION 3: Composition/information on ingredients**

### 3.2 Mixtures

#### Components

Chemical name	CAS-No. EC-No. Index-No. Registration number	Classification	Concentration (% w/w)
Posaconazole	171228-49-2	Eye Irrit. 2; H319 Repr. 2; H361d STOT RE 1; H372 (Adrenal gland, Bone marrow, Kid-	>= 10 - < 20

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



## Posaconazole Solid Formulation

Version 6.3	Revision Date: 28.09.2024	SDS Number: 23530-00025	Date of last issue: 06.04.2024 Date of first issue: 21.10.2014	
			ney, 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 : In case of contact, immediately flush eyes with plenty of water

for at least 15 minutes.

If easy to do, remove contact lens, if worn.

Get medical attention.

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

Headache Vomiting Nausea

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



## Posaconazole Solid Formulation

Version Revision Date: SDS Number: Date of last issue: 06.04.2024 6.3 28.09.2024 23530-00025 Date of first issue: 21.10.2014

Fever

Risks : Causes serious eye irritation.

Suspected of damaging the unborn child.

Causes damage to organs through prolonged or repeated

exposure.

Contact with dust can cause mechanical irritation or drying of

the skin.

### 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

Avoid generating dust; fine dust dispersed in air in sufficient concentrations, and in the presence of an ignition source is a

potential dust explosion hazard.

Exposure to combustion products may be a hazard to health.

Hazardous combustion prod: :

ucts

Carbon 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.

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



## Posaconazole Solid Formulation

Version Revision Date: SDS Number: Date of last issue: 06.04.2024 6.3 28.09.2024 23530-00025 Date of first issue: 21.10.2014

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. 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 Sweep up or vacuum up spillage and collect in suitable con-

tainer for disposal.

Avoid dispersal of dust in the air (i.e., clearing dust surfaces

with compressed air).

Dust deposits should not be allowed to accumulate on surfaces, as these may form an explosive mixture if they are released into the atmosphere in sufficient concentration. 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 Static electricity may accumulate and ignite suspended dust

causing an explosion.

Provide adequate precautions, such as electrical grounding

and bonding, or inert atmospheres.

Local/Total ventilation

Use only with adequate ventilation. Do not breathe dust. Advice on safe handling

> Do not swallow. Do not get in eyes.

Avoid prolonged or repeated contact with skin.

Wash skin thoroughly after handling.

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

sessment

Minimize dust generation and accumulation. Keep container closed when not in use. Keep away from heat and sources of ignition.

Take precautionary measures against static discharges. Do not eat, drink or smoke when using this product.

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

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



### Posaconazole Solid Formulation

Version Revision Date: SDS Number: Date of last issue: 06.04.2024 6.3 28.09.2024 23530-00025 Date of first issue: 21.10.2014

environment.

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

flushing systems and safety showers close to the working place. When using do not eat, drink or smoke. Wash contami-

nated clothing before re-use.

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

use of administrative controls.

#### 7.2 Conditions for safe storage, including any incompatibilities

Requirements for storage areas and containers

Keep in properly labelled containers. Store locked up. Store in

accordance with the particular national regulations.

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**

Dust 5 mg/m3

Value type (Form of exposure): TWA (respirable dust)

Basis: FOR-2011-12-06-1358

10 mg/m3

Value type (Form of exposure): TWA (total dust)

Basis: FOR-2011-12-06-1358

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 feasible engineering controls to minimize exposure to compound.

All engineering controls should be implemented by facility design and operated in accordance with GMP principles to protect products, workers, and the environment.

#### Personal protective equipment

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



## Posaconazole Solid Formulation

Version Revision Date: SDS Number: Date of last issue: 06.04.2024 6.3 28.09.2024 23530-00025 Date of first issue: 21.10.2014

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

Filter type

Material : Chemical-resistant gloves

Skin and body protection

: Work uniform or laboratory coat.

Respiratory protection : If adequate local exhaust ventilation is not available or expo-

sure assessment demonstrates exposures outside the rec-

ommended guidelines, use respiratory protection. Equipment should conform to NS EN 143

: Particulates type (P)

## **SECTION 9: Physical and chemical properties**

### 9.1 Information on basic physical and chemical properties

Physical state : powder

Colour : No data available

Odour : No data available

Odour Threshold : No data available

Melting point/freezing point : No data available

Initial boiling point and boiling

range

No data available

Flammability (solid, gas) : May form explosive dust-air mixture during processing, han-

dling or other means.

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 : Not applicable

Auto-ignition temperature : No data available

Decomposition temperature : No data available

pH : No data available

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



## Posaconazole Solid Formulation

Version Revision Date: SDS Number: Date of last issue: 06.04.2024 6.3 28.09.2024 23530-00025 Date of first issue: 21.10.2014

Viscosity

Viscosity, kinematic : Not applicable

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 : No data available

Relative vapour density : Not applicable

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 : Not applicable

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 : May form explosive dust-air mixture during processing, han-

dling or other means.

Can react with strong oxidizing agents.

10.4 Conditions to avoid

Conditions to avoid : Heat, flames and sparks.

Avoid dust formation.

10.5 Incompatible materials

Materials to avoid : Oxidizing agents

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



## Posaconazole Solid Formulation

Version Revision Date: SDS Number: Date of last issue: 06.04.2024 6.3 28.09.2024 23530-00025 Date of first issue: 21.10.2014

### 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:** 

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

Causes serious eye irritation.

**Components:** 

Posaconazole:

Species : Rabbit

Result : Mild eye irritation

Respiratory or skin sensitisation

Skin sensitisation

Not classified based on available information.

Respiratory sensitisation

Not classified based on available information.

**Components:** 

Posaconazole:

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



## Posaconazole Solid Formulation

Version Revision Date: SDS Number: Date of last issue: 06.04.2024 6.3 28.09.2024 23530-00025 Date of first issue: 21.10.2014

Test Type : Magnusson-Kligman-Test

Exposure routes : Skin contact
Species : Guinea pig
Result : negative

### Germ cell mutagenicity

Not classified based on available information.

### **Components:**

#### Posaconazole:

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

Result: negative

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

Suspected of damaging the unborn child.

#### **Components:**

### Posaconazole:

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

Species: Rat, male

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

Symptoms: No effects on mating performance

Result: negative

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



### Posaconazole Solid Formulation

Version Revision Date: SDS Number: Date of last issue: 06.04.2024 6.3 28.09.2024 23530-00025 Date of first issue: 21.10.2014

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

Causes 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

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



## Posaconazole Solid Formulation

Version Revision Date: SDS Number: Date of last issue: 06.04.2024 6.3 28.09.2024 23530-00025 Date of first issue: 21.10.2014

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

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



## Posaconazole Solid Formulation

Version Revision Date: SDS Number: Date of last issue: 06.04.2024 6.3 28.09.2024 23530-00025 Date of first issue: 21.10.2014

### **SECTION 12: Ecological information**

### 12.1 Toxicity

**Components:** 

Posaconazole:

Toxicity to fish : LC50 (Oncorhynchus mykiss (rainbow trout)): > 0,95 mg/l

Exposure time: 96 h

Method: OECD Test Guideline 203

Remarks: No toxicity at the limit of solubility

Toxicity to daphnia and other :

aquatic invertebrates

EC50 (Daphnia magna (Water flea)): 0,276 mg/l

Exposure time: 48 h

Method: OECD Test Guideline 202

Toxicity to algae/aquatic

plants

EC50 (Pseudokirchneriella subcapitata (green algae)): >

0,509 mg/l

Exposure time: 72 h

Method: OECD Test Guideline 201

NOEC (Pseudokirchneriella subcapitata (green algae)): 0,041

mg/l

Exposure time: 72 h

Method: OECD Test Guideline 201

M-Factor (Acute aquatic tox-

icity)

: 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 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) 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:

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



## Posaconazole Solid Formulation

Version Revision Date: SDS Number: Date of last issue: 06.04.2024 6.3 28.09.2024 23530-00025 Date of first issue: 21.10.2014

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 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 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.

#### 12.7 Other adverse effects

No data available

#### **SECTION 13: Disposal considerations**

## 13.1 Waste treatment methods

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



## Posaconazole Solid Formulation

Version Revision Date: SDS Number: Date of last issue: 06.04.2024 6.3 28.09.2024 23530-00025 Date of first issue: 21.10.2014

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 : UN 3077
ADR : UN 3077
RID : UN 3077
IMDG : UN 3077
IATA : UN 3077

### 14.2 UN proper shipping name

ADN : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID,

N.O.S.

(Posaconazole)

ADR : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID,

N.O.S.

(Posaconazole)

RID : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID,

N.O.S.

(Posaconazole)

IMDG : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID,

N.O.S.

(Posaconazole)

IATA : Environmentally hazardous substance, solid, n.o.s.

(Posaconazole)

### 14.3 Transport hazard class(es)

Class Subsidiary risks

 ADN
 : 9

 ADR
 : 9

 RID
 : 9

 IMDG
 : 9

 IATA
 : 9

#### 14.4 Packing group

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



## Posaconazole Solid Formulation

Version Revision Date: SDS Number: Date of last issue: 06.04.2024 6.3 28.09.2024 23530-00025 Date of first issue: 21.10.2014

ADN

Packing group : III
Classification Code : M7
Hazard Identification Number : 90
Labels : 9

**ADR** 

Packing group : III
Classification Code : M7
Hazard Identification Number : 90
Labels : 9
Tunnel restriction code : (-)

**RID** 

Packing group : III
Classification Code : M7
Hazard Identification Number : 90
Labels : 9

**IMDG** 

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

IATA (Cargo)

Packing instruction (cargo : 956

aircraft)

Packing instruction (LQ) : Y956
Packing group : III

Labels : Miscellaneous

IATA (Passenger)

Packing instruction (passen: 956

ger aircraft)

Packing instruction (LQ) : Y956 Packing group : III

Labels : Miscellaneous

14.5 Environmental hazards

ADN

Environmentally hazardous : yes

ADR

Environmentally hazardous : yes

RID

Environmentally hazardous : yes

**IMDG** 

Marine pollutant : yes

IATA (Passenger)

Environmentally hazardous : yes

IATA (Cargo)

Environmentally hazardous : yes

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



### Posaconazole Solid Formulation

Version Revision Date: SDS Number: Date of last issue: 06.04.2024 6.3 28.09.2024 23530-00025 Date of first issue: 21.10.2014

### 14.6 Special precautions for user

The transport classification(s) provided herein are for informational purposes only, and solely based upon the properties of the unpackaged material as it is described within this Safety Data Sheet. Transportation classifications may vary by mode of transportation, package sizes, and variations in regional or country regulations.

#### 14.7 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

: Not applicable

REACH - Restrictions on the manufacture, placing on

the market and use of certain dangerous substances,

mixtures and articles (Annex XVII)

REACH - Candidate List of Substances of Very High : Not applicable

Concern for Authorisation (Article 59).

REACH - List of substances subject to authorisation : Not applicable

(Annex XIV)

Regulation (EC) on substances that deplete the ozone : Not applicable

aver

Regulation (EU) 2019/1021 on persistent organic pollu- : Not applicable

tants (recast)

Regulation (EU) No 649/2012 of the European Parlia: Not applicable

ment and the Council concerning the export and import

of dangerous chemicals

Seveso III: Directive 2012/18/EU of the European Parliament and of the Council on the control of

major-accident hazards involving dangerous substances.

Quantity 1 Quantity 2

E2 ENVIRONMENTAL 200 t 500 t

HAZARDS

### Other regulations:

Note the Working Environment Act § 4-1 and § 4-2 on requirements for the employer to protect pregnant employees against discomfort and injury as a result of the work situation and the working environment.

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**

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



### Posaconazole Solid Formulation

Version Revision Date: SDS Number: Date of last issue: 06.04.2024 6.3 28.09.2024 23530-00025 Date of first issue: 21.10.2014

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

are highlighted in the body of this document by two vertical

lines.

**Full text of H-Statements** 

H319 : Causes serious eye irritation.

H361d : Suspected of damaging the unborn child.

H372 : Causes damage to organs through prolonged or repeated

exposure if swallowed.

H400 : Very toxic to aquatic life.

H410 : Very toxic to aquatic life with long lasting effects.

Full text of other abbreviations

Aquatic Acute : Short-term (acute) aquatic hazard
Aquatic Chronic : Long-term (chronic) aquatic hazard

Eye Irrit. : Eye irritation

Repr. : Reproductive toxicity

STOT RE : Specific target organ toxicity - repeated exposure

FOR-2011-12-06-1358 : Norway. Occupational Exposure limits

FOR-2011-12-06-1358 / : Long term exposure limit

TWA

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 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

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- 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 Agen-

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

### Classification of the mixture: Classification procedure:

Eye Irrit. 2 H319 Calculation method
Repr. 2 H361d Calculation method
STOT RE 1 H372 Calculation method
Aquatic Chronic 2 H411 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.

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