

SAFETY DATA SHEET

According to 13 December 2014, No:29204, "Ministry of Environment and Urbanization; Regulation on Safety data sheets regarding hazardous substances and mixtures".



Posaconazole Injection Formulation

Version 3.0	Revision Date: 24.04.2019	SDS Number: 2568059-00005	Date of last issue: 15.10.2018 Date of first issue: 26.02.2018
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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 Substance/Mixture : Pharmaceutical

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

National Poison Control Center (UZEM): 114
Emergency: 1-908-423-6000

SECTION 2: Hazards identification

2.1 Classification of the substance or mixture

Classification T.R. SEA No 28848

Skin sensitisation, Category 1
Specific target organ toxicity - repeated exposure, Category 2
Long-term (chronic) aquatic hazard, Category 3

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.

2.2 Label elements

Labelling T.R. SEA No 28848

Hazard pictograms :  

Signal word : Warning

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.

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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.
P363 Wash contaminated clothing before reuse.

Hazardous components which must be listed on the label:

.beta.-Cyclodextrin, sulfobutyl ethers, sodium salts

Posaconazole

2.3 Other hazards

None known.

SECTION 3: Composition/information on ingredients

3.2 Mixtures

Components

Chemical name	CAS-No. EC-No. Index-No. Registration number	Classification	Concentration (% w/w)
.beta.-Cyclodextrin, sulfobutyl ethers, sodium salts	182410-00-0 417-710-5	Skin Sens.1; H317	>= 30 - < 50
Hydrochloric acid	7647-01-0 231-595-7 017-002-01-X	Met. Corr.1; H290 Skin Corr.1A; H314 Eye Dam.1; H318 STOT SE3; H335	>= 3 - < 5
Posaconazole	171228-49-2	Repr.2; H361d STOT RE1; H372 Aquatic Acute1; H400 Aquatic Chronic1; H410 M-Factor (Acute aquatic toxicity): 1 M-Factor (Chronic aquatic toxicity): 1	>= 1 - < 2,5

For explanation of abbreviations see section 16.

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SECTION 4: First aid measures

4.1 Description of first aid measures

General advice : In the case of accident or if you feel unwell, seek medical advice immediately.
When symptoms persist or in all cases of doubt seek medical advice.

Protection of first-aiders : First Aid responders should pay attention to self-protection, and use the recommended personal protective equipment when the potential for exposure exists.

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 immediately.

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

Risks : May cause an allergic skin reaction.
Causes serious eye damage.
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.

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SECTION 5: Firefighting measures

5.1 Extinguishing media

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

Unsuitable extinguishing media : None known.

5.2 Special hazards arising from the substance or mixture

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

Hazardous combustion products : Carbon oxides
Chlorine compounds
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 and personal protective equipment recommendations.

6.2 Environmental precautions

Environmental precautions : Discharge into the environment must be avoided.
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.

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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. Avoid inhalation of vapour or mist. Do not swallow. Do not get in eyes. Handle in accordance with good industrial hygiene and safety practice, based on the results of the workplace exposure assessment. Keep container tightly closed. Take care to prevent spills, waste and minimize release to the environment.

Hygiene measures : Ensure that eye flushing systems and safety showers are located close to the working place. When using do not eat, drink or smoke. Wash contaminated clothing before re-use. The effective operation of a facility should include review of engineering controls, proper personal protective equipment, appropriate degowning and decontamination procedures, industrial hygiene monitoring, medical surveillance and the use of administrative controls.

7.2 Conditions for safe storage, including any incompatibilities

Requirements for storage areas and containers : Keep in properly labelled containers. Keep tightly closed. Store in accordance with the particular national regulations.

Advice on common storage : Do not store with the following product types:
Strong oxidizing agents
Organic peroxides
Explosives
Gases

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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
Hydrochloric acid	7647-01-0	STEL	10 ppm 15 mg/m ³	2000/39/EC
Further information	Indicative			
		TWA	5 ppm 8 mg/m ³	2000/39/EC
Further information	Indicative			
Posaconazole	171228-49-2	TWA	300 µg/m ³ (OEB 2)	Internal

Derived No Effect Level (DNEL) :

Substance name	End Use	Exposure routes	Potential health effects	Value
Hydrochloric acid	Workers	Inhalation	Long-term local effects	8 mg/m ³
	Workers	Inhalation	Acute local effects	15 mg/m ³

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 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 : Use respiratory protection unless adequate local exhaust ventilation is provided or exposure assessment demonstrates that

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Filter type : exposures are within recommended exposure guidelines.
Combined particulates and acidic gas/vapour type (E-P)

SECTION 9: Physical and chemical properties

9.1 Information on basic physical and chemical properties

Appearance	: Aqueous solution
Colour	: Colorless to pale yellow
Odour	: odourless
Odour Threshold	: No data available
pH	: 2,6
Melting point/freezing point	: No data available
Initial boiling point and boiling range	: No data available
Flash point	: No data available
Evaporation rate	: No data available
Flammability (solid, gas)	: Not applicable
Upper explosion limit / Upper flammability limit	: No data available
Lower explosion limit / Lower flammability limit	: No data available
Vapour pressure	: No data available
Relative vapour density	: No data available
Relative density	: No data available
Density	: 1,15 g/cm ³
Solubility(ies)	
Water solubility	: No data available
Partition coefficient: n-octanol/water	: Not applicable
Auto-ignition temperature	: No data available
Decomposition temperature	: No data available
Viscosity	
Viscosity, kinematic	: No data available
Explosive properties	: Not explosive
Oxidizing properties	: The substance or mixture is not classified as oxidizing.

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9.2 Other information

Flammability (liquids)	:	No data available
Molecular weight	:	No data available
Particle size	:	Not applicable

SECTION 10: Stability and reactivity

10.1 Reactivity

Not classified as a reactivity hazard.

10.2 Chemical stability

Stable under normal conditions.

10.3 Possibility of hazardous reactions

Hazardous reactions : Can react with strong oxidizing agents.

10.4 Conditions to avoid

Conditions to avoid : None known.

10.5 Incompatible materials

Materials to avoid : Oxidizing agents

10.6 Hazardous decomposition products

No hazardous decomposition products are known.

SECTION 11: Toxicological information

11.1 Information on toxicological effects

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

Acute toxicity

Not classified based on available information.

Components:

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

Acute oral toxicity : LD50 (Rat): > 8.800 mg/kg

Hydrochloric acid:

Acute inhalation toxicity : LC50 (Rat): 8,3 mg/l
Exposure time: 30 min

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Test atmosphere: dust/mist

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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:

Hydrochloric acid:

Method	: EPISKIN Human Skin Model Test
Result	: Corrosive after 3 minutes or less of exposure

Posaconazole:

Species	: Rabbit
Result	: No skin irritation

Serious eye damage/eye irritation

Not classified based on available information.

Components:

Hydrochloric acid:

Method	: OECD Test Guideline 437
Result	: Irreversible effects on the eye

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
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Hydrochloric acid:

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Test Type	:	Maximisation Test
Exposure routes	:	Skin contact
Species	:	Guinea pig
Method	:	OECD Test Guideline 406
Result	:	negative

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Test Type	:	Magnusson-Kligman-Test
Exposure routes	:	Skin contact
Species	:	Guinea pig
Result	:	negative

Germ cell mutagenicity

Not classified based on available information.

Components:

Hydrochloric acid:

Genotoxicity in vitro	:	Test Type: Saacharomyces cerevisiae, mitotic recombination assay (in vitro) Result: negative
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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:

Hydrochloric acid:

Species	:	Rat
Application Route	:	Inhalation
Exposure time	:	128 weeks
Result	:	negative

Posaconazole:

Species	:	Rat
Application Route	:	oral (feed)

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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 development	:	Test Type: Embryo-foetal development Species: Rat Application Route: Intravenous injection Result: negative

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 Frequency of Treatment: 6 - 15 days Developmental Toxicity: LOAEL: 29 mg/kg body weight Result: Fetotoxicity, Malformations were observed.
		Test Type: Embryo-foetal development Species: Rabbit, female Frequency of Treatment: 7 - 19 days Developmental Toxicity: LOAEL: 40 mg/kg body weight Result: Fetotoxicity

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Reproductive toxicity - Assessment : Some evidence of adverse effects on development, based on animal experiments.

STOT - single exposure

Not classified based on available information.

Components:

Hydrochloric acid:

Assessment : May cause respiratory irritation.

STOT - repeated exposure

May cause damage to organs through prolonged or repeated exposure.

Components:

Posaconazole:

Exposure routes : Ingestion
Target Organs : Adrenal gland, Bone marrow, Kidney, Liver, Reproductive organs, Nervous system
Assessment : Causes damage to organs through prolonged or repeated exposure.

Repeated dose toxicity

Components:

Posaconazole:

Species : Rat, female
LOAEL : 5 mg/kg
Application Route : Oral
Exposure time : 6 Months
Target Organs : Adrenal gland, Lungs, Heart, Liver, spleen, Kidney, Ovary

Species : Dog
LOAEL : 3 mg/kg
Application Route : Oral
Exposure time : 392 Days
Target Organs : Lungs, Liver, Brain, small intestine, Adrenal gland, Spinal cord, lymphoid tissue

Species : Monkey
LOAEL : 15 mg/kg
Application Route : Oral
Exposure time : 1 Months
Target Organs : Bone marrow, Adrenal gland, Lymph nodes, Blood

Species : Dog
LOAEL : 3 mg/kg
Application Route : Oral

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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.

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
Toxicity to daphnia and other aquatic invertebrates	:	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:

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

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aquatic invertebrates	Exposure time: 48 h Method: OECD Test Guideline 202
Toxicity to algae/aquatic plants	: EC50 (Pseudokirchneriella subcapitata (green algae)): > 0,509 mg/l Exposure time: 72 h Method: OECD Test Guideline 201
	NOEC (Pseudokirchneriella subcapitata (green algae)): 0,041 mg/l Exposure time: 72 h Method: OECD Test Guideline 201
M-Factor (Acute aquatic toxicity)	: 1
Toxicity to microorganisms	: EC50 (Natural microorganism): > 1.000 mg/l Exposure time: 3 h Test Type: Respiration inhibition Method: OECD Test Guideline 209
Toxicity to fish (Chronic toxicity)	: NOEC: 0,206 mg/l Exposure time: 33 d Species: Pimephales promelas (fathead minnow) Method: OECD Test Guideline 210
Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity)	: NOEC: 0,244 mg/l Exposure time: 21 d Species: Daphnia magna (Water flea) Method: OECD Test Guideline 211 Remarks: No toxicity at the limit of solubility
M-Factor (Chronic aquatic toxicity)	: 1

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:

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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
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12.5 Results of PBT and vPvB assessment

Not relevant

12.6 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.
Contaminated packaging	: Empty containers should be taken to an approved waste handling site for recycling or disposal. If not otherwise specified: Dispose of as unused product.

SECTION 14: Transport information

14.1 UN number

ADR	: UN 3265
RID	: UN 3265
IMDG	: UN 3265
IATA	: UN 3265

14.2 UN proper shipping name

ADR	: CORROSIVE LIQUID, ACIDIC, ORGANIC, N.O.S. (Hydrochloric acid)
RID	: CORROSIVE LIQUID, ACIDIC, ORGANIC, N.O.S. (Hydrochloric acid)
	: CORROSIVE LIQUID, ACIDIC, ORGANIC, N.O.S.

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IMDG	(Hydrochloric acid)
	: CORROSIVE LIQUID, ACIDIC, ORGANIC, N.O.S. (Hydrochloric acid)
IATA	Corrosive liquid, acidic, organic, n.o.s. (Hydrochloric acid)

14.3 Transport hazard class(es)

ADN	:	8
ADR	:	8
RID	:	8
IMDG	:	8
IATA	:	8

14.4 Packing group

ADN	
Packing group	: II
Classification Code	: C3
Hazard Identification Number	: 80
Labels	: 8
ADR	
Packing group	: II
Classification Code	: C3
Hazard Identification Number	: 80
Labels	: 8
Tunnel restriction code	: (E)
RID	
Packing group	: II
Classification Code	: C3
Hazard Identification Number	: 80
Labels	: 8
IMDG	
Packing group	: II
Labels	: 8
EmS Code	: F-A, S-B
IATA (Cargo)	
Packing instruction (cargo aircraft)	: 855
Packing instruction (LQ)	: Y840
Packing group	: II
Labels	: Corrosive
IATA (Passenger)	
Packing instruction (passenger aircraft)	: 851
Packing instruction (LQ)	: Y840
Packing group	: II
Labels	: Corrosive

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14.5 Environmental hazards

ADN

Environmentally hazardous : no

ADR

Environmentally hazardous : no

RID

Environmentally hazardous : no

IMDG

Marine pollutant : no

14.6 Special precautions for user

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

14.7 Transport in bulk according to 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

KKDIK (30105 (Bis)) - Restrictions on the manufacture, placing on the market and use of certain dangerous substances, mixtures and articles (Annex 17) : Conditions of restriction for the following entries should be considered: Number on list 3

Other regulations:

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Regulation on Classification, Labelling and Packaging of Substances and Mixtures. Dated 11 December 2013, Numbered 28848 (Bis) Ministry of Environment and Forestry.

Regulation on Health and Safety Measures Of Working with Chemicals Substances Dated 12.08.13, numbered 28733 Ministry of Labour and Social Security.

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

AICS : not determined

DSL : not determined

IECSC : not determined

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.

SAFETY DATA SHEET

According to 13 December 2014, No:29204, "Ministry of Environment and Urbanization; Regulation on Safety data sheets regarding hazardous substances and mixtures".



Posaconazole Injection Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 15.10.2018
3.0	24.04.2019	2568059-00005	Date of first issue: 26.02.2018

Full text of H-Statements

H290 : May be corrosive to metals.
H314 : Causes severe skin burns and eye damage.
H317 : May cause an allergic skin reaction.
H318 : Causes serious eye damage.
H335 : May cause respiratory 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 Dam. : Serious eye damage
Met. Corr. : Corrosive to metals
Repr. : Reproductive toxicity
Skin Corr. : Skin corrosion
Skin Sens. : Skin sensitisation
STOT RE : Specific target organ toxicity - repeated exposure
STOT SE : Specific target organ toxicity - single exposure
2000/39/EC : Europe. Commission Directive 2000/39/EC establishing a first list of indicative occupational exposure limit values
2000/39/EC / TWA : Limit Value - eight hours
2000/39/EC / STEL : Short term exposure limit

ADN - European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways; ADR - European Agreement concerning the International Carriage of Dangerous Goods by Road; AICS - Australian Inventory of Chemical Substances; 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,

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tion, 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; TSCA - Toxic Substances Control Act (United States); UN - United Nations; UNRTDG - United Nations Recommendations on the Transport of Dangerous Goods; vPvB - Very Persistent and Very Bioaccumulative

Further information

Sources of key data used to compile the Safety Data Sheet : Internal technical data, data from raw material SDSs, OECD eChem Portal search results and European Chemicals Agency, <http://echa.europa.eu/>

Classification of the mixture:

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

Classification procedure:

Calculation method
Calculation method
Calculation method

The Turkish SDS has been prepared according to the Regulation on Safety Data Sheets for Hazardous Substances and Mixtures No. 29204.

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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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