

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; Part I".



Posaconazole Suspension Formulation

| | | | |
|---------|----------------|---------------|---------------------------------|
| Version | Revision Date: | SDS Number: | Date of last issue: 13.09.2019 |
| 2.3 | 23.03.2020 | 2541008-00007 | Date of first issue: 23.02.2018 |

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

1.1 Product identifier

Trade name : Posaconazole Suspension 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

Reproductive toxicity, Category 2
Specific target organ toxicity - repeated exposure, Category 2
Long-term (chronic) aquatic hazard, Category 2

H361d: Suspected of damaging the unborn child.
H373: May cause damage to organs through prolonged or repeated exposure.
H411: Toxic to aquatic life with long lasting effects.

2.2 Label elements

Labelling T.R. SEA No 28848

Hazard pictograms :



Signal word : Warning

Hazard statements : H361d Suspected of damaging the unborn child.
H373 May cause damage to organs through prolonged or repeated exposure.
H411 Toxic to aquatic life with long lasting effects.

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| 2.3 | 23.03.2020 | 2541008-00007 | Date of first issue: 23.02.2018 |

Precautionary statements :

Prevention:

P201 Obtain special instructions before use.
P273 Avoid release to the environment.
P280 Wear protective gloves/ protective clothing/ eye protection/ face protection.

Response:

P308 + P313 IF exposed or concerned: Get medical advice/ attention.
P391 Collect spillage.

Storage:

P405 Store locked up.

Hazardous components which must be listed on the label:

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) |
|------------------|---|---|--------------------------|
| 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 | >= 3 - < 10 |
| Titanium dioxide | 13463-67-7 236-675-5 | Carc.2; H351 | >= 0,1 - < 1 |

For explanation of abbreviations see section 16.

SECTION 4: First aid measures

4.1 Description of first aid measures

General advice : In the case of accident or if you feel unwell, seek medical advice immediately.

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| 2.3 | 23.03.2020 | 2541008-00007 | Date of first issue: 23.02.2018 |

- 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
Nausea
Headache
Vomiting
- Risks : Suspected of damaging the unborn child.
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.

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|---------|----------------|---------------|---------------------------------|
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| 2.3 | 23.03.2020 | 2541008-00007 | Date of first issue: 23.02.2018 |

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

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.

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.

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| 2.3 | 23.03.2020 | 2541008-00007 | Date of first issue: 23.02.2018 |

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 | : | Avoid inhalation of vapour or mist. Do not swallow. Avoid contact with eyes. Avoid prolonged or repeated contact with skin. Handle in accordance with good industrial hygiene and safety practice, based on the results of the workplace exposure assessment 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. 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. 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 Organic peroxides Explosives Gases |

7.3 Specific end use(s)

- | | | |
|-----------------|---|-------------------|
| Specific use(s) | : | No data available |
|-----------------|---|-------------------|

SECTION 8: Exposure controls/personal protection

8.1 Control parameters

Occupational Exposure Limits

| Components | CAS-No. | Value type (Form of exposure) | Control parameters | Basis |
|--------------|------------|-------------------------------|--------------------|----------|
| Posaconazole | 171228-49- | TWA | 300 µg/m3 (OEB 2) | Internal |

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Version 2.3 Revision Date: 23.03.2020 SDS Number: 2541008-00007 Date of last issue: 13.09.2019
Date of first issue: 23.02.2018

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|--|---|--|--|--|
| | 2 | | | |
|--|---|--|--|--|

Derived No Effect Level (DNEL) :

| Substance name | End Use | Exposure routes | Potential health effects | Value |
|----------------|-----------|-----------------|----------------------------|----------------------|
| Glycerine | Workers | Inhalation | Long-term local effects | 56 mg/m ³ |
| | Consumers | Ingestion | Long-term systemic effects | 229 mg/kg bw/day |
| | Consumers | Inhalation | Long-term local effects | 33 mg/m ³ |

Predicted No Effect Concentration (PNEC) :

| Substance name | Environmental Compartment | Value |
|----------------|---------------------------|-------------------------------|
| Glycerine | Fresh water | 0,885 mg/l |
| | Marine water | 0,0885 mg/l |
| | Intermittent use/release | 8,85 mg/l |
| | Sewage treatment plant | 1000 mg/l |
| | Fresh water sediment | 3,3 mg/kg dry weight (d.w.) |
| | Marine sediment | 0,33 mg/kg dry weight (d.w.) |
| | Soil | 0,141 mg/kg dry weight (d.w.) |

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 : If adequate local exhaust ventilation is not available or exposure assessment demonstrates exposures outside the recommended guidelines, use respiratory protection.
Equipment should conform to TS EN 14387

Filter type : Combined particulates and organic vapour type (A-P)

SAFETY DATA SHEET

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| | | | |
|---------|----------------|---------------|---------------------------------|
| Version | Revision Date: | SDS Number: | Date of last issue: 13.09.2019 |
| 2.3 | 23.03.2020 | 2541008-00007 | Date of first issue: 23.02.2018 |

SECTION 9: Physical and chemical properties

9.1 Information on basic physical and chemical properties

| | | |
|--|---|--|
| Appearance | : | suspension |
| Colour | : | white |
| Odour | : | No data available |
| Odour Threshold | : | No data available |
| pH | : | 4,2 - 4,8 |
| 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 g/cm3 |
| Solubility(ies) | | |
| Water solubility | : | soluble |
| Partition coefficient: n-octanol/water | : | Not applicable |
| Auto-ignition temperature | : | No data available |
| Decomposition temperature | : | No data available |
| Viscosity | | |
| Viscosity, kinematic | : | No data available |
| Explosive properties | : | Not explosive |
| Oxidizing properties | : | The substance or mixture is not classified as oxidizing. |

9.2 Other information

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| | | | |
|---------|----------------|---------------|---------------------------------|
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| 2.3 | 23.03.2020 | 2541008-00007 | Date of first issue: 23.02.2018 |

| | | |
|------------------------|---|-------------------|
| 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:

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

Titanium dioxide:

Acute oral toxicity : LD50 (Rat): > 5.000 mg/kg

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| | | | |
|---------|----------------|---------------|---------------------------------|
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| 2.3 | 23.03.2020 | 2541008-00007 | Date of first issue: 23.02.2018 |

Acute inhalation toxicity : LC50 (Rat): > 6,82 mg/l
Exposure time: 4 h
Test atmosphere: dust/mist
Assessment: The substance or mixture has no acute inhalation toxicity

Skin corrosion/irritation

Not classified based on available information.

Components:

Posaconazole:

Species : Rabbit
Result : No skin irritation

Titanium dioxide:

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

Titanium dioxide:

Species : Rabbit
Result : No eye irritation

Respiratory or skin sensitisation

Skin sensitisation

Not classified based on available information.

Respiratory sensitisation

Not classified based on available information.

Components:

Posaconazole:

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

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| | | | |
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| Version | Revision Date: | SDS Number: | Date of last issue: 13.09.2019 |
| 2.3 | 23.03.2020 | 2541008-00007 | Date of first issue: 23.02.2018 |

Titanium dioxide:

| | |
|-----------------|---------------------------------|
| Test Type | : Local lymph node assay (LLNA) |
| Exposure routes | : Skin contact |
| Species | : Mouse |
| 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 |
|----------------------|--|

Titanium dioxide:

| | |
|-----------------------|--|
| Genotoxicity in vitro | : Test Type: Bacterial reverse mutation assay (AMES) Result: negative |
|-----------------------|--|

| | |
|----------------------|--|
| Genotoxicity in vivo | : Test Type: In vivo micronucleus test Species: Mouse 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. |

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| | | | |
|---------|----------------|---------------|---------------------------------|
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| 2.3 | 23.03.2020 | 2541008-00007 | Date of first issue: 23.02.2018 |

Titanium dioxide:

| | | |
|-------------------|---|--|
| Species | : | Rat |
| Application Route | : | inhalation (dust/mist/fume) |
| Exposure time | : | 2 Years |
| Method | : | OECD Test Guideline 453 |
| Result | : | positive |
| Remarks | : | The mechanism or mode of action may not be relevant in humans. |

| | | |
|------------------------------|---|---|
| Carcinogenicity - Assessment | : | Limited evidence of carcinogenicity in inhalation studies with animals. |
|------------------------------|---|---|

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 |
|----------------------|---|---|

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

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

STOT - single exposure

Not classified based on available information.

STOT - repeated exposure

May cause damage to organs through prolonged or repeated exposure.

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| | | | |
|---------|----------------|---------------|---------------------------------|
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| 2.3 | 23.03.2020 | 2541008-00007 | Date of first issue: 23.02.2018 |

Components:

Posaconazole:

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

Repeated dose toxicity

Components:

Posaconazole:

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

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

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

| | | |
|-------------------|---|---|
| Species | : | Dog |
| LOAEL | : | 3 mg/kg |
| Application Route | : | Oral |
| Exposure time | : | 56 Weeks |
| Target Organs | : | Adrenal gland, Bone marrow, Kidney, Nervous system, spleen, thymus gland, Testis, lymphoid tissue |

| | | |
|-------------------|---|---------------------------------------|
| Species | : | Monkey |
| LOAEL | : | 180 mg/kg |
| Application Route | : | Oral |
| Exposure time | : | 12 Months |
| Target Organs | : | Blood, Gastrointestinal tract, spleen |

| | | |
|-------------------|---|---|
| Species | : | Monkey |
| LOAEL | : | 8 mg/kg |
| Application Route | : | Intravenous |
| Exposure time | : | 1 Months |
| Target Organs | : | Cardio-vascular system, Lungs, Adrenal gland, Blood |

SAFETY DATA SHEET

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| | | | |
|---------|----------------|---------------|---------------------------------|
| Version | Revision Date: | SDS Number: | Date of last issue: 13.09.2019 |
| 2.3 | 23.03.2020 | 2541008-00007 | Date of first issue: 23.02.2018 |

Titanium dioxide:

| | | |
|-------------------|---|-----------------------------|
| Species | : | Rat |
| NOAEL | : | 24.000 mg/kg |
| Application Route | : | Ingestion |
| Exposure time | : | 28 Days |
| Species | : | Rat |
| NOAEL | : | 10 mg/m3 |
| Application Route | : | inhalation (dust/mist/fume) |
| Exposure time | : | 2 yr |

Aspiration toxicity

Not classified based on available information.

Experience with human exposure

Components:

Posaconazole:

| | | |
|-----------|---|--|
| Ingestion | : | Symptoms: Cough, Headache, Nausea, Vomiting, Fever, Liver effects, Rash, pruritis, Diarrhoea, hypertension, neutropenia, electrolyte imbalance |
|-----------|---|--|

SECTION 12: Ecological information

12.1 Toxicity

Components:

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 toxicity) | : | 1 |

SAFETY DATA SHEET

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| | | | |
|---------|----------------|---------------|---------------------------------|
| Version | Revision Date: | SDS Number: | Date of last issue: 13.09.2019 |
| 2.3 | 23.03.2020 | 2541008-00007 | Date of first issue: 23.02.2018 |

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|--|---|--|
| 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 |
| Titanium dioxide: | | |
| Toxicity to fish | : | LC50 (Oncorhynchus mykiss (rainbow trout)): > 100 mg/l Exposure time: 96 h Method: OECD Test Guideline 203 |
| Toxicity to daphnia and other aquatic invertebrates | : | EC50 (Daphnia magna (Water flea)): > 100 mg/l Exposure time: 48 h |
| Toxicity to algae/aquatic plants | : | EC50 (Skeletonema costatum (marine diatom)): > 10.000 mg/l Exposure time: 72 h |
| Toxicity to microorganisms | : | EC50 : > 1.000 mg/l Exposure time: 3 h Method: OECD Test Guideline 209 |

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 |

SAFETY DATA SHEET

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| | | | |
|---------|----------------|---------------|---------------------------------|
| Version | Revision Date: | SDS Number: | Date of last issue: 13.09.2019 |
| 2.3 | 23.03.2020 | 2541008-00007 | Date of first issue: 23.02.2018 |

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

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

ADN : UN 3082
ADR : UN 3082
RID : UN 3082
IMDG : UN 3082
IATA : UN 3082

14.2 UN proper shipping name

ADN : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID,

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



Posaconazole Suspension Formulation

| | | | |
|---------|----------------|---------------|---------------------------------|
| Version | Revision Date: | SDS Number: | Date of last issue: 13.09.2019 |
| 2.3 | 23.03.2020 | 2541008-00007 | Date of first issue: 23.02.2018 |

| | |
|-------------|---|
| | N.O.S. (Posaconazole) |
| ADR | : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S. (Posaconazole) |
| RID | : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S. (Posaconazole) |
| IMDG | : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S. (Posaconazole) |
| IATA | : Environmentally hazardous substance, liquid, n.o.s. (Posaconazole) |

14.3 Transport hazard class(es)

| | |
|-------------|-----|
| ADN | : 9 |
| ADR | : 9 |
| RID | : 9 |
| IMDG | : 9 |
| IATA | : 9 |

14.4 Packing group

| | |
|--------------------------------------|------------|
| ADN | |
| Packing group | : III |
| Classification Code | : M6 |
| Hazard Identification Number | : 90 |
| Labels | : 9 |
| ADR | |
| Packing group | : III |
| Classification Code | : M6 |
| Hazard Identification Number | : 90 |
| Labels | : 9 |
| Tunnel restriction code | : (-) |
| RID | |
| Packing group | : III |
| Classification Code | : M6 |
| Hazard Identification Number | : 90 |
| Labels | : 9 |
| IMDG | |
| Packing group | : III |
| Labels | : 9 |
| EmS Code | : F-A, S-F |
| IATA (Cargo) | |
| Packing instruction (cargo aircraft) | : 964 |

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; Part I".



Posaconazole Suspension Formulation

| | | | |
|----------------|------------------------------|------------------------------|---|
| Version 2.3 | Revision Date: 23.03.2020 | SDS Number: 2541008-00007 | Date of last issue: 13.09.2019 Date of first issue: 23.02.2018 |
|----------------|------------------------------|------------------------------|---|

Packing instruction (LQ) : Y964
Packing group : III
Labels : Miscellaneous

IATA (Passenger)

Packing instruction (passenger aircraft) : 964
Packing instruction (LQ) : Y964
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

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 Annex II of Marpol and the IBC Code

Remarks : Not applicable for product as supplied.

SECTION 15: Regulatory information

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

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:
Regulation on Persistent Organic Pollutants (Number 30595) : Not applicable

Regulation on prevention of major industrial accidents. Reg number 30702

| | | | |
|----|--------------------------|---------------------|---------------------|
| E2 | ENVIRONMENTAL HAZARDS | Quantity 1 200 t | Quantity 2 500 t |
|----|--------------------------|---------------------|---------------------|

Other regulations:

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; Part I".



Posaconazole Suspension Formulation

| | | | |
|---------|----------------|---------------|---------------------------------|
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| 2.3 | 23.03.2020 | 2541008-00007 | Date of first issue: 23.02.2018 |

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

Full text of H-Statements

| | |
|-------|--|
| H351 | : Suspected of causing cancer if inhaled. |
| 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. |

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

Full text of other abbreviations

| | |
|-----------------|--|
| Aquatic Acute | : Short-term (acute) aquatic hazard |
| Aquatic Chronic | : Long-term (chronic) aquatic hazard |
| Carc. | : Carcinogenicity |
| Repr. | : Reproductive toxicity |
| STOT RE | : Specific target organ toxicity - repeated exposure |

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

SAFETY DATA SHEET

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Posaconazole Suspension Formulation

| | | | |
|---------|----------------|---------------|---------------------------------|
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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; 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:

| | |
|-------------------|-------|
| Repr. 2 | H361d |
| STOT RE 2 | H373 |
| Aquatic Chronic 2 | H411 |

Classification procedure:

| |
|--------------------|
| Calculation method |
| Calculation method |
| Calculation method |

The information provided in this Safety Data Sheet is correct to the best of our knowledge, information and belief at the date of its publication. The information is designed only as a guidance for safe handling, use, processing, storage, transportation, disposal and release and shall not be considered a warranty or quality specification of any type. The information provided relates only to the specific material identified at the top of this SDS and may not be valid when the SDS material is used in combination with any other materials or in any process, unless specified in the text. Material users should review the information and recommendations in the specific context of their intended manner of handling, use, processing and storage, including an assessment of the appropriateness of the SDS material in the user's end product, if applicable.

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