SAFETY DATA SHEET
according to Regulation (EC) No. 1907/2006

Posaconazole Solid Formulation

Version 4.2 Revision Date: 09/13/2019 SDS Number: 23518-00013 Date of last issue: 24.04.2019
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 Substance/Mixture: Pharmaceutical

1.3 Details of the supplier of the safety data sheet
Company: MSD
Shotton Lane
NE23 3JU Cramlington NU - Great Britain
Telephone: 44 1 670 59 30 00
Telefax: 908-735-1496
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)
Reproductive toxicity, Category 2: H361d: Suspected of damaging the unborn child.
Specific target organ toxicity - repeated exposure, Category 1: H372: Causes damage to organs through prolonged or repeated exposure.
Long-term (chronic) aquatic hazard, Category 2: H411: Toxic to aquatic life with long lasting effects.

2.2 Label elements
Labelling (REGULATION (EC) No 1272/2008)
Hazard pictograms: 
Signal word: Danger
Hazard statements: H361d Suspected of damaging the unborn child.
H372 Causes damage to organs through prolonged or repeated 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 protection/ 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
Dust contact with the eyes can lead to mechanical irritation.
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

<table>
<thead>
<tr>
<th>Components</th>
<th>Chemical name</th>
<th>CAS-No.</th>
<th>EC-No.</th>
<th>Index-No.</th>
<th>Registration number</th>
<th>Classification</th>
<th>Concentration (% w/w)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Posaconazole</td>
<td>171228-49-2</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Repr. 2; H361d</td>
<td>&gt;= 10 - &lt; 20</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Classification</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>STOT RE 1; H372 Aquatic Acute 1; H400 Aquatic Chronic 1; H410</td>
</tr>
<tr>
<td>M-Factor (Acute aquatic toxicity): 1</td>
<td></td>
</tr>
<tr>
<td>M-Factor (Chronic aquatic toxicity): 1</td>
<td></td>
</tr>
</tbody>
</table>

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.
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
: If in eyes, rinse well with water.
    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
    Headache
    Vomiting
    Nausea
    Fever

Risks
: 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.
    Dust contact with the eyes can lead to mechanical irritation.

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.
SAFETY DATA SHEET
according to Regulation (EC) No. 1907/2006

Posaconazole Solid Formulation

Version 4.2  Revision Date: 09/13/2019  SDS Number: 23518-00013  Date of last issue: 24.04.2019

5.2 Special hazards arising from the substance or mixture
Specific hazards during firefighting: 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 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. 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 container 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 determine which regulations are applicable. Sections 13 and 15 of this SDS provide information regarding certain local or national requirements.
SAFETY DATA SHEET
according to Regulation (EC) No. 1907/2006

Posaconazole Solid Formulation

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.

Advice on safe handling:
- Do not breathe dust.
- 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
- 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.
- 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
8.1 Control parameters

<table>
<thead>
<tr>
<th>Components</th>
<th>CAS-No.</th>
<th>Value type (Form of exposure)</th>
<th>Control parameters</th>
<th>Basis</th>
</tr>
</thead>
<tbody>
<tr>
<td>Posaconazole</td>
<td>171228-49-2</td>
<td>TWA</td>
<td>300 µg/m³ (OEB 2)</td>
<td>Internal</td>
</tr>
<tr>
<td>Cellulose</td>
<td>9004-34-6</td>
<td>TWA (inhalable dust)</td>
<td>10 mg/m³</td>
<td>GB EH40</td>
</tr>
</tbody>
</table>

Further information: For the purposes of these limits, respirable dust and inhalable dust are those fractions of airborne dust which will be collected when sampling is undertaken in accordance with the methods described in MDHS14/4 General methods for sampling and gravimetric analysis or respirable, thoracic and inhalable aerosols. The COSHH definition of a substance hazardous to health includes dust of any kind when present at a concentration in air equal to or greater than 10 mg/m³ 8-hour TWA of inhalable dust or 4 mg/m³ 8-hour TWA of respirable dust. This means that any dust will be subject to COSHH if people are exposed to dust above these levels. Some dusts have been assigned specific WELs and exposure to these must comply with the appropriate limits. Most industrial dusts contain particles of a wide range of sizes. The behaviour, deposition and fate of any particular particle after entry into the human respiratory system, and the body response that it elicits, depend on the nature and size of the particle. HSE distinguishes two size fractions for limit-setting purposes termed ‘inhalable’ and ‘respirable’. Inhalable dust approximates to the fraction of airborne material that enters the nose and mouth during breathing and is therefore available for deposition in the respiratory tract. Respirable dust approximates to the fraction that penetrates to the gas exchange region of the lung. Fuller definitions and explanatory material are given in MDHS14/4. Where dusts contain components that have their own assigned WEL, all the relevant limits should be complied with.

<table>
<thead>
<tr>
<th></th>
<th>4 mg/m³</th>
<th>GB EH40</th>
</tr>
</thead>
<tbody>
<tr>
<td>TWA (Respirable dust)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>STEL (inhalable dust)</td>
<td>20 mg/m³</td>
<td>GB EH40</td>
</tr>
</tbody>
</table>

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
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
SAFETY DATA SHEET
according to Regulation (EC) No. 1907/2006

Posaconazole Solid Formulation

Version 4.2  Revision Date: 09/13/2019  SDS Number: 23518-00013  Date of last issue: 24.04.2019
Date of first issue: 21.10.2014

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.
Filter type: Particulates type (P)

SECTION 9: Physical and chemical properties

9.1 Information on basic physical and chemical properties

Appearance: powder
Colour: No data available
Odour: No data available
Odour Threshold: No data available
pH: No data available
Melting point/freezing point: No data available
Initial boiling point and boiling range: No data available
Flash point: Not applicable
Evaporation rate: Not applicable
Flammability (solid, gas): May form explosive dust-air mixture during processing, handling or other means.
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: Not applicable
Relative density: No data available
Density: No data available
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 : Not applicable

Explosive properties : Not explosive

Oxidizing properties : The substance or mixture is not classified as oxidizing.

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

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

<table>
<thead>
<tr>
<th>Species</th>
<th>LD50 (Rat)</th>
<th>LD50 (Mouse)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>&gt; 5,000 mg/kg</td>
<td>&gt; 3,000 mg/kg</td>
</tr>
</tbody>
</table>

### Acute dermal toxicity

<table>
<thead>
<tr>
<th>Species</th>
<th>LD50 (Rat)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>&gt; 2,000 mg/kg</td>
</tr>
</tbody>
</table>

### Skin corrosion/irritation
Not classified based on available information.

#### Components:

**Posaconazole:**

<table>
<thead>
<tr>
<th>Species</th>
<th>Result</th>
</tr>
</thead>
<tbody>
<tr>
<td>Rabbit</td>
<td>No skin irritation</td>
</tr>
</tbody>
</table>

### Serious eye damage/eye irritation
Not classified based on available information.

#### Components:

**Posaconazole:**

<table>
<thead>
<tr>
<th>Species</th>
<th>Result</th>
</tr>
</thead>
<tbody>
<tr>
<td>Rabbit</td>
<td>Mild eye irritation</td>
</tr>
</tbody>
</table>

### Respiratory or skin sensitisation

#### Skin sensitisation
Not classified based on available information.

#### Respiratory sensitisation
Not classified based on available information.

#### Components:

**Posaconazole:**

<table>
<thead>
<tr>
<th>Test Type</th>
<th>Exposure routes</th>
<th>Species</th>
<th>Result</th>
</tr>
</thead>
<tbody>
<tr>
<td>Magnusson-Kligman-Test</td>
<td>Skin contact</td>
<td>Guinea pig</td>
<td>negative</td>
</tr>
</tbody>
</table>

### Germ cell mutagenicity
Not classified based on available information.

#### Components:

**Posaconazole:**

<table>
<thead>
<tr>
<th>Genotoxicity in vitro</th>
<th>Test Type</th>
<th>Result</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Bacterial reverse mutation assay (AMES)</td>
<td>negative</td>
</tr>
<tr>
<td></td>
<td>Chromosomal aberration</td>
<td>negative</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Genotoxicity in vivo</th>
<th>Test Type</th>
<th>Result</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Micronucleus test</td>
<td></td>
</tr>
</tbody>
</table>
Species: Mouse  
Cell type: Bone marrow  
Application Route: Intravenous  
Result: negative

**Carcinogenicity**  
Not classified based on available information.

**Components:**

**Posaconazole:**

<table>
<thead>
<tr>
<th>Species</th>
<th>Application Route</th>
<th>Exposure time</th>
<th>Result</th>
<th>Remarks</th>
</tr>
</thead>
<tbody>
<tr>
<td>Rat</td>
<td>Oral (feed)</td>
<td>2 Years</td>
<td>positive</td>
<td>The mechanism or mode of action is not relevant in humans.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Species</th>
<th>Application Route</th>
<th>Exposure time</th>
<th>Result</th>
<th>Remarks</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mouse</td>
<td>Oral</td>
<td>2 Years</td>
<td>positive</td>
<td>The mechanism or mode of action is not relevant in humans.</td>
</tr>
</tbody>
</table>

**Reproductive toxicity**  
Suspected of damaging the unborn child.

**Components:**

**Posaconazole:**

**Effects on fertility**

<table>
<thead>
<tr>
<th>Species</th>
<th>Application Route</th>
<th>Frequency of Treatment</th>
<th>Result</th>
<th>Remarks</th>
</tr>
</thead>
<tbody>
<tr>
<td>Rat, male</td>
<td>Oral</td>
<td>6 - 15 days</td>
<td>negative</td>
<td></td>
</tr>
</tbody>
</table>

**General Toxicity - Parent**:  
NOAEL: 180 mg/kg body weight  
Symptoms: No effects on mating performance  

**Test Type**:  
Fertility/embryonic development

<table>
<thead>
<tr>
<th>Species</th>
<th>Application Route</th>
<th>Frequency of Treatment</th>
<th>Developmental Toxicity</th>
<th>Result</th>
<th>Remarks</th>
</tr>
</thead>
<tbody>
<tr>
<td>Rat, female</td>
<td>Oral</td>
<td>6 - 15 days</td>
<td>LOAEL: 29 mg/kg body weight</td>
<td>Fetotoxicity, Malformations were observed.</td>
<td></td>
</tr>
</tbody>
</table>

**Effects on foetal development**

<table>
<thead>
<tr>
<th>Species</th>
<th>Application Route</th>
<th>Frequency of Treatment</th>
<th>Developmental Toxicity</th>
<th>Result</th>
<th>Remarks</th>
</tr>
</thead>
<tbody>
<tr>
<td>Rat, female</td>
<td>Oral</td>
<td>7 - 19 days</td>
<td>LOAEL: 40 mg/kg body weight</td>
<td>Fetotoxicity</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Species</th>
<th>Application Route</th>
<th>Frequency of Treatment</th>
<th>Developmental Toxicity</th>
<th>Result</th>
<th>Remarks</th>
</tr>
</thead>
<tbody>
<tr>
<td>Rabbit, female</td>
<td>Oral</td>
<td>7 - 19 days</td>
<td>LOAEL: 40 mg/kg body weight</td>
<td>Fetotoxicity</td>
<td></td>
</tr>
</tbody>
</table>
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
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

**Exposure time**
6 Months

**Target Organs**
Adrenal gland, Lungs, Heart, Liver, spleen, Kidney, Ovary

**Species**
Dog

**LOAEL**
3 mg/kg

**Application Route**
Oral

**Exposure time**
392 Days

**Target Organs**
Lungs, Liver, Brain, small intestine, Adrenal gland, Spinal cord, lymphoid tissue

**Species**
Monkey

**LOAEL**
15 mg/kg

**Application Route**
Oral

**Exposure time**
1 Months

**Target Organs**
Bone marrow, Adrenal gland, Lymph nodes, Blood

**Species**
Dog

**LOAEL**
3 mg/kg

**Application Route**
Oral

**Exposure time**
56 Weeks

**Target Organs**
Adrenal gland, Bone marrow, Kidney, Nervous system, spleen, thymus gland, Testis, lymphoid tissue

**Species**
Monkey

**LOAEL**
180 mg/kg

**Application Route**
Oral

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

Aspiration toxicity
Not classified based on available information.

Experience with human exposure

Components:

Posaconazole:
Ingestion: Symptoms: Cough, Headache, Nausea, Vomiting, Fever, Liver effects, Rash, pruritus, 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

Toxicity to microorganisms: EC50 (Natural microorganism): > 1,000 mg/l
Exposure time: 3 h
Test Type: Respiration inhibition
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

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

<p>| | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
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</thead>
<tbody>
<tr>
<td>ADN</td>
<td>UN 3077</td>
</tr>
<tr>
<td>ADR</td>
<td>UN 3077</td>
</tr>
<tr>
<td>RID</td>
<td>UN 3077</td>
</tr>
<tr>
<td>IMDG</td>
<td>UN 3077</td>
</tr>
<tr>
<td>IATA</td>
<td>UN 3077</td>
</tr>
</tbody>
</table>

14.2 UN proper shipping name

<p>| | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>ADN</td>
<td>ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (Posaconazole)</td>
</tr>
<tr>
<td>ADR</td>
<td>ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (Posaconazole)</td>
</tr>
<tr>
<td>RID</td>
<td>ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (Posaconazole)</td>
</tr>
<tr>
<td>IMDG</td>
<td>ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (Posaconazole)</td>
</tr>
<tr>
<td>IATA</td>
<td>Environmentally hazardous substance, solid, n.o.s. (Posaconazole)</td>
</tr>
</tbody>
</table>

14.3 Transport hazard class(es)

<p>| | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>ADN</td>
<td>9</td>
</tr>
<tr>
<td>ADR</td>
<td>9</td>
</tr>
<tr>
<td>RID</td>
<td>9</td>
</tr>
<tr>
<td>IMDG</td>
<td>9</td>
</tr>
<tr>
<td>IATA</td>
<td>9</td>
</tr>
</tbody>
</table>

14.4 Packing group
## 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 aircraft): 956
- Packing instruction (LQ): Y956
- Packing group: III
- Labels: Miscellaneous

## IATA (Passenger)
- Packing instruction (passenger aircraft): 956
- 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
SAFETY DATA SHEET
according to Regulation (EC) No. 1907/2006

Posaconazole Solid Formulation

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

REACH - Candidate List of Substances of Very High Concern for Authorisation (Article 59): Not applicable
REACH - List of substances subject to authorisation (Annex XIV): Not applicable
Regulation (EC) No 1005/2009 on substances that deplete the ozone layer: Not applicable
Regulation (EC) No 850/2004 on persistent organic pollutants: Not applicable
Regulation (EC) No 649/2012 of the European Parliament and the Council concerning the export and import of dangerous chemicals: Not applicable
REACH - Restrictions on the manufacture, placing on the market and use of certain dangerous substances, preparations and articles (Annex XVII): Not applicable

<table>
<thead>
<tr>
<th>E2</th>
<th>ENVIRONMENTAL HAZARDS</th>
<th>Quantity 1</th>
<th>Quantity 2</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>200 t</td>
<td>500 t</td>
</tr>
</tbody>
</table>

Other regulations:
Take note of Directive 92/85/EEC regarding maternity protection or stricter national regulations, where applicable.
Take note of Directive 94/33/EC on the protection of young people at work or stricter national regulations, where applicable.

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

AICS: not determined
DSL: not determined
IECSC: not determined

15.2 Chemical safety assessment
A Chemical Safety Assessment has not been carried out.

SECTION 16: Other information

Other information: Items where changes have been made to the previous version are highlighted in the body of this document by two vertical
### SAFETY DATA SHEET
according to Regulation (EC) No. 1907/2006

### Posaconazole Solid Formulation

<table>
<thead>
<tr>
<th>Version</th>
<th>Revision Date:</th>
<th>SDS Number:</th>
<th>Date of last issue:</th>
<th>Date of first issue:</th>
</tr>
</thead>
</table>

**Full text of H-Statements**

<table>
<thead>
<tr>
<th>H-Statement</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>H361d</td>
<td>Suspected of damaging the unborn child.</td>
</tr>
<tr>
<td>H372</td>
<td>Causes damage to organs through prolonged or repeated exposure if swallowed.</td>
</tr>
<tr>
<td>H400</td>
<td>Very toxic to aquatic life.</td>
</tr>
<tr>
<td>H410</td>
<td>Very toxic to aquatic life with long lasting effects.</td>
</tr>
</tbody>
</table>

**Full text of other abbreviations**

<table>
<thead>
<tr>
<th>Abbreviation</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Aquatic Acute</td>
<td>Short-term (acute) aquatic hazard</td>
</tr>
<tr>
<td>Aquatic Chronic</td>
<td>Long-term (chronic) aquatic hazard</td>
</tr>
<tr>
<td>Repr.</td>
<td>Reproductive toxicity</td>
</tr>
<tr>
<td>STOT RE</td>
<td>Specific target organ toxicity - repeated exposure</td>
</tr>
<tr>
<td>GB EH40 Lethal</td>
<td>UK. EH40 WEL - Workplace Exposure Limits</td>
</tr>
<tr>
<td>GB EH40 / TWA Lethal</td>
<td>Long-term exposure limit (8-hour TWA reference period)</td>
</tr>
<tr>
<td>GB EH40 / STEL Lethal</td>
<td>Short-term exposure limit (15-minute reference period)</td>
</tr>
</tbody>
</table>

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); Erix - 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; TRGS - Technical Rule for Hazardous Substances; TSCA - Toxic Substances Control Act (United States); UN - United Nations; vPvB - Very Persistent and Very Bioaccumulative

**Further information**

Sources of key data used to : Internal technical data, data from raw material SDSs, OECD

Classification of the mixture: Classification procedure:
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.

GB / EN