Safety data sheet

According to 1907/2006/EC, Article 31

Revision: Not Applicable

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

· 1.1 Product identifier

· Product name: Voriconazole

· Part number: MM1094.00

• CAS Number: 137234-62-9 • EC number: 629-701-5

· 1.2 Relevant identified uses of the substance or mixture and uses advised against No further relevant information available.

- · Application of the substance / the mixture Reference material for laboratory use only
- · 1.3 Details of the supplier of the safety data sheet
- · Manufacturer/Supplier:

Will be updated as per company.

· 1.4 Emergency telephone number:

Will be updated as per company.

SECTION 2: Hazards identification

- · 2.1 Classification of the substance or mixture
- · Classification according to Regulation (EC) No 1272/2008



skull and crossbones

Acute Tox. 3 H301 Toxic if swallowed.



health hazard

Carc. 2 H351 Suspected of causing cancer.

Repr. 1B H360Df May damage the unborn child. Suspected of damaging fertility.

STOT RE 2 H373 May cause damage to organs through prolonged or repeated exposure.

(Contd. on page 2)

Safety data sheet

According to 1907/2006/EC, Article 31

Revision: Not Applicable

Product name: Voriconazole

(Contd. from page 1)

- · 2.2 Label elements
- · Labelling according to Regulation (EC) No 1272/2008

The substance is classified and labelled according to the CLP regulation.

· Hazard pictograms





GHS06

- · Signal word Danger · Hazard statements
- H301 Toxic if swallowed.
- H351 Suspected of causing cancer.

H360Df May damage the unborn child. Suspected of damaging fertility.

H373 May cause damage to organs through prolonged or repeated exposure.

· Precautionary statements

P260 Do not breathe dust/fume/gas/mist/vapours/spray.

P280 Wear protective gloves/protective clothing/eye protection/face protection/hearing protection.

P301+P310 IF SWALLOWED: Immediately call a POISON CENTER/doctor.

P321 Specific treatment (see on this label).

P405 Store locked up.

P501 Dispose of contents/container in accordance with local/regional/national/international

regulations.

· Additional information:

Restricted to professional users.

- · 2.3 Other hazards
- · Results of PBT and vPvB assessment
- · **PBT**: Not applicable.
- · vPvB: Not applicable.

SECTION 3: Composition/information on ingredients

- · 3.1 Substances
- · CAS No. Description
- 137234-62-9 Voriconazole
- · Identification number(s) None
- · EC number: 629-701-5
- · RTECS: UV9145000
- · Additional information: For the wording of the listed hazard phrases refer to section 16.

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SECTION 4: First aid measures

- · 4.1 Description of first aid measures
- · General information:

Immediately remove any clothing soiled by the product.

Symptoms of poisoning may occur even after several hours; therefore medical observation for at least 48 hours after the accident is recommended.

In case of irregular breathing or respiratory arrest provide artificial respiration.

- · After inhalation: Supply fresh air; consult doctor in case of complaints.
- · After skin contact: Immediately wash with water and soap and rinse thoroughly.
- · After eye contact: Rinse opened eye for several minutes under running water. Then consult a doctor.
- · After swallowing:

Rinse mouth. Do not induce vomiting.

Call for a doctor immediately.

- · 4.2 Most important symptoms and effects, both acute and delayed No further relevant information available.
- · 4.3 Indication of any immediate medical attention and special treatment needed

No further relevant information available.

SECTION 5: Firefighting measures

- · 5.1 Extinguishing media
- · Suitable extinguishing agents: Use fire extinguishing methods suitable for surrounding conditions.
- · 5.2 Special hazards arising from the substance or mixture

Formation of toxic gases is possible during heating or in case of fire.

- · 5.3 Advice for firefighters
- · Protective equipment: Wear self-contained respiratory protective device.

SECTION 6: Accidental release measures

- 6.1 Personal precautions, protective equipment and emergency procedures Avoid formation of dust.
- 6.2 Environmental precautions: Do not allow to enter sewers/ surface or ground water.
- · 6.3 Methods and material for containment and cleaning up:

Dispose of contaminated material as waste according to item 13.

· 6.4 Reference to other sections

See Section 7 for information on safe handling.

See Section 8 for information on personal protection equipment.

See Section 13 for disposal information.

SECTION 7: Handling and storage

· 7.1 Precautions for safe handling

Remove dust thoroughly.

Store in cool, dry place in tightly closed receptacles.

• Information about fire - and explosion protection: No special measures required.

(Contd. on page 4)

(Contd. from page 3)

- 7.2 Conditions for safe storage, including any incompatibilities
- · Storage#:
- · Requirements to be met by storerooms and receptacles:

Please refer to the manufacturer's certificate for specific storage and transport temperature conditions.

Store only in the original receptacle unless other advice is given on the CoA.

Keep container in a well-ventilated place. Keep away from sources of ignition and heat.

- Information about storage in one common storage facility: Store away from foodstuffs.
- · Further information about storage conditions: None.
- · 7.3 Specific end use(s) No further relevant information available.

SECTION 8: Exposure controls/personal protection

- · 8.1 Control parameters
- · Ingredients with limit values that require monitoring at the workplace: Not required.
- · Additional information: Lists used were valid at the time of SDS preparation.
- · 8.2 Exposure controls
- · Appropriate engineering controls No further data; see item 7.
- · Individual protection measures, such as personal protective equipment
- · General protective and hygienic measures:

Keep away from foodstuffs, beverages and feed.

Immediately remove all soiled and contaminated clothing

Wash hands before breaks and at the end of work.

Store protective clothing separately.

· Respiratory protection:

In case of brief exposure or low pollution use respiratory filter device. In case of intensive or longer exposure use self-contained respiratory protective device.

· Hand protection

The glove material has to be impermeable and resistant to the product/ the substance/ the preparation.

Selection of the glove material on consideration of the penetration times, rates of diffusion and the degradation

The protective gloves to be used must comply with the specifications of EC Directive 89/686/EEC and the related standard EN374



Protective gloves

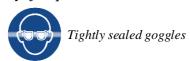
- · Material of gloves Fluorocarbon rubber (Viton)
- · Penetration time of glove material

The exact break through time has to be found out by the manufacturer of the protective gloves and has to be observed.

(Contd. on page 5)

(Contd. from page 4)

· Eye/face protection



SECTION 9: Physical and chemical properties

· 9.1 Information on basic physical and chemical properties

· General Information

Physical state
Colour:
Odour:
Odourless
Odour threshold:
Melting point/freezing point:
129 °C

· Boiling point or initial boiling point and boiling

range Not determined.
Flammability Not determined.

· Lower and upper explosion limit

Lower: Not determined.
Upper: Not determined.
Flash point: Not applicable.
Auto-ignition temperature: Not determined.
Decomposition temperature: Not determined.
pH Not applicable.

· Viscosity:

Kinematic viscosity
Dynamic:
Not applicable.
Not applicable.

· Soluble in Chloroform, Methanol, Acetonitrile

water:
Partition coefficient n-octanol/water (log value)
Vapour pressure:
Not determined.
1.69 Log P
Not applicable.

Density and/or relative density

Density: Not determined.
Relative density Not determined.
Vapour density Not applicable.

· 9.2 Other information

· Appearance:

· Form: Crystalline powder

· Important information on protection of health and environment, and on safety.

Ignition temperature: Not determined
 Explosive properties: Not determined.

(Contd. on page 6)

(Contd. from page 5)

•	Change	in	condition
	_	_	

· Evaporation rate Not applicable.

· Information with regard to physical hazard classes

· Explosives Not applicable · Flammable gases Not applicable · Aerosols Not applicable · Oxidising gases Not applicable · Gases under pressure Not applicable · Flammable liquids Not applicable · Flammable solids Not applicable · Self-reactive substances and mixtures Not applicable · Pyrophoric liquids Not applicable · Pyrophoric solids Not applicable

· Substances and mixtures, which emit flammable

· Self-heating substances and mixtures

gases in contact with water

Oxidising liquids

Oxidising solids

Organic peroxides

Corrosive to metals

Desensitised explosives

Not applicable

Not applicable

Not applicable

Not applicable

Not applicable

SECTION 10: Stability and reactivity

· 10.1 Reactivity

Stable under normal conditions.

No further relevant information available.

- · 10.2 Chemical stability Stable under normal conditions.
- Thermal decomposition / conditions to be avoided:
- Formation of toxic gases is possible during heating or in case of fire.
- · 10.3 Possibility of hazardous reactions No dangerous reactions known.
- · 10.4 Conditions to avoid Heat.
- · 10.5 Incompatible materials: Strong oxidizing agents.
- · 10.6 Hazardous decomposition products:

Formation of toxic gases is possible during heating or in case of fire.

SECTION 11: Toxicological information

- · 11.1 Information on hazard classes as defined in Regulation (EC) No 1272/2008
- · Acute toxicity Toxic if swallowed.
- · Skin corrosion/irritation

Based on available data, the classification criteria are not met.

Based on available data, the classification criteria are not met.

- · Serious eye damage/irritation Based on available data, the classification criteria are not met.
- · Respiratory or skin sensitisation Based on available data, the classification criteria are not met.

(Contd. on page 7)

(Contd. from page 6)

- · Carcinogenicity Suspected of causing cancer.
- · Reproductive toxicity May damage the unborn child. Suspected of damaging fertility.
- · STOT-repeated exposure May cause damage to organs through prolonged or repeated exposure.
- Additional toxicological information:
- · CMR effects (carcinogenity, mutagenicity and toxicity for reproduction) Carc. 2, Repr. 1B
- · 11.2 Information on other hazards
- · Endocrine disrupting properties Substance is not listed.

SECTION 12: Ecological information

· 12.1 Toxicity

· Aquatic toxicity:

EC50/72h >97 mg/l (Algae) LC50/96 h 110 mg/l (fish)

- · 12.2 Persistence and degradability No further relevant information available.
- · 12.3 Bioaccumulative potential No further relevant information available.
- · 12.4 Mobility in soil No further relevant information available.
- · 12.5 Results of PBT and vPvB assessment
- · PBT: Not applicable.
- · vPvB: Not applicable.
- · 12.6 Endocrine disrupting properties

The product does not contain substances with endocrine disrupting properties.

- · 12.7 Other adverse effects
- · Additional ecological information:
- · General notes:

Water hazard class 3 (German Regulation) (Self-assessment): extremely hazardous for water

Do not allow product to reach ground water, water course or sewage system, even in small quantities.

Danger to drinking water if even extremely small quantities leak into the ground.

SECTION 13: Disposal considerations

- · 13.1 Waste treatment methods
- · Recommendation

Must not be disposed of together with household garbage. Do not allow product to reach sewage system.

- Uncleaned packaging:
- · Recommendation: Dispose of in accordance with national regulations.

SECTION 14: Transport information

- · 14.1 UN number or ID number
- · ADR, IMDG, IATA

UN2811

 \cdot ADR

2811 TOXIC SOLID, ORGANIC, N.O.S. (Voriconazole)

(Contd. on page 8)

(Contd. from page 7) · IMDG, IATA TOXIC SOLID, ORGANIC, N.O.S. (Voriconazole) · 14.3 Transport hazard class(es) · ADR, IMDG, IATA · Class 6.1 Toxic substances. · Label 6.1 · 14.4 Packing group · ADR, IMDG, IATA III · 14.5 Environmental hazards: Not applicable. · 14.6 Special precautions for user Warning: Toxic substances. · Hazard identification number (Kemler code): 60 · EMS Number: F-A,S-A· Stowage Category · 14.7 Maritime transport in bulk according to IM O instruments Not applicable. · Transport/Additional information: $\cdot ADR$ · Limited quantities (LQ) 5 kg· Excepted quantities (EQ) Code: E1 Maximum net quantity per inner packaging: 30 g Maximum net quantity per outer packaging: 1000 g · Transport category · Tunnel restriction code \boldsymbol{E} UN "Model Regulation": UN 2811 TOXIC SOLID, ORGANIC, N.O.S. (VORICONAZOLE), 6.1, III

SECTION 15: Regulatory information

- · 15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture
- · Directive 2012/18/EU
- · Named dangerous substances ANNEX I Substance is not listed.
- · Seveso category H2 ACUTE TOXIC
- Qualifying quantity (tonnes) for the application of lower-tier requirements 50 t
- · Qualifying quantity (tonnes) for the application of upper-tier requirements 200 t
- · 15.2 Chemical safety assessment: A Chemical Safety Assessment has not been carried out.

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SECTION 16: Other information

The information in this safety data sheet (SDS) has been prepared with due care and is true and accurate to the best of our knowledge. The user must determine the suitability of the information for its particular purpose, ensure compliance with existing laws and regulations, and be aware that other or additional safety or performance considerations may arise when using, handling and/or storing the material. The information in this SDS does not purport to be all inclusive or a guarantee as to the properties of the material supplied, and should be used only as a guide. Company makes no warranties or representations as to the accuracy and completeness of the information contained herein, shall not be held responsible for the suitability of this information for the user's intended purposes or the consequences of such use, and shall not be liable for any damage or loss, howsoever arising, direct or otherwise.

· Abbreviations and acronyms:

ADR: Accord relatif au transport international des marchandises dangereuses par route (European Agreement Concerning the International Carriage of Dangerous Goods by Road)

IMDG: International Maritime Code for Dangerous Goods

IATA: International Air Transport Association

GHS: Globally Harmonised System of Classification and Labelling of Chemicals

EINECS: European Inventory of Existing Commercial Chemical Substances

CAS: Chemical Abstracts Service (division of the American Chemical Society)

PBT: Persistent, Bioaccumulative and Toxic

vPvB: very Persistent and very Bioaccumulative

Acute Tox. 3: Acute toxicity - Category 3

Carc. 2: Carcinogenicity - Category 2

Repr. 1B: Reproductive toxicity – Category 1B

STOT RE 2: Specific target organ toxicity (repeated exposure) – Category 2

· Sources

Tables 3.1 and 3.2 from Annex 6 of EC 1272/2008, EC 1907/2006, EH40/2005 as amended 2011, Registry of Toxic Effects of Chemical Substances (RTECS), The Dictionary of Substances and their Effects, 1st Edition, IUCLID.

· Data compared to the previous version altered. All sections have been updated.

Disclaimer

The Final Document will be available at the time of consignment. # Can vary as per company.

End of Safety Data Sheet