

SAFETY DATA SHEET

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

1.1 PRODUCT IDENTIFIER

Product name: Voriconazole for Injection
REACH reg.# : medicinal product, the mixture does not legally require an SDS and REACH pre-registration

1.2 RELEVANT IDENTIFIED USES OF THE SUBSTANCE OR MIXTURE AND USES ADVISED AGAINST

Antibiotic for Injection

Product Formulation Name: Voriconazole for Injection
Chemical Family: Voriconazole
Generic Name: Pharmaceutical product

1.3 DETAILS OF THE SUPPLIER OF THE SAFETY DATA SHEET

Xellia Pharmaceuticals ApS
Dalslandsgade 11
2300 Copenhagen S
Denmark
Responsible person for the safety data sheet (e-mail): sales@xellia.com

1.4 EMERGENCY TELEPHONE NUMBER

Xellia: 32 64 5500 in Denmark
Xellia: + 45 32 64 5500 outside of Denmark
Poison Control Center (USA): 877 800 5553
CANUTEC (Canadian Transportation): 613 996 6666
CHEMTREC (USA Transportation): 800 424 9300
UN #: No applicable information found

COMMENTS: To the best of our knowledge, this MSDS conforms to the requirements of USA OSHA 29 CFR 1910.1200, 1907/2006/EC, 453/2010/EC and Canadian Hazardous Products Act. You are urged to consider laws and regulations applicable to your state and country.

SECTION 2: HAZARDS IDENTIFICATION

2.1 CLASSIFICATION OF THE SUBSTANCE OR MIXTURE

This is a medicinal product that may affect body functions. When inside vials the hazard is considered negligible.

CLP:

H401: Toxic to aquatic life.

P201: Obtain special instructions before use.

P202: Do not handle until all safety precautions have been read and understood.

P273: Avoid release to the environment.

P281: Use personal protective equipment as required.

P308+P313: If exposed or concerned: Get medical advice/attention.

P405: Store locked up.

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

2.2 LABEL ELEMENTS:

Contents: Voriconazole vials



WARNING

2.3 OTHER HAZARDS:

None known.

PBT/vPvB: The substance is not considered PBT/vPvB according to criteria in Annex XIII.

SECTION 3: Composition/information on ingredients

3.1 SUBSTANCES:

Active substance	CAS#	EINECS#	INDEX#	Hazards	Quantity per unit (mg/vial)
Voriconazole	137234-62-9	None	None	H401 Toxic to aquatic life.	200

Comments: Product composition ranges shown are typical values for health, safety and environmental use and are not intended as specifications.

SECTION 4: First aid measures

4.1 DESCRIPTION OF FIRST AID MEASURES:

Eye contact: In case of contact with eyes, hold eyelids apart and flush eyes with plenty of water. After initial flushing, remove any contact lenses and continue flushing for at least 15 minutes. Have eyes examined and tested by medical personnel.

Skin contact: In case of skin contact, immediately wash skin with soap and plenty of water. Remove contaminated clothing. Get medical attention if symptoms occur.

Remove and wash / dispose of contaminated clothing promptly.

Ingestion: If swallowed, wash out mouth with water provided person is conscious. Never give anything by mouth to an unconscious person. Get medical attention. Do NOT induce vomiting unless directed to do so by medical personnel.

Inhalation: If inhaled remove to fresh air. If not breathing, give artificial respiration or give oxygen by trained personnel. Get immediate medical attention.

Medical Attention: Seek emergency medical attention if you think you have used too much of this medicine.

SECTION 5: Firefighting measures

5.1 EXTINGUISHING MEDIA:

Use water spray, dry chemical powder or appropriate foam, carbon dioxide.

5.2 SPECIAL HAZARDS ARISING FROM THE SUBSTANCE OR MIXTURE:

General hazards: No applicable information found.

Hazardous combustion products: Emits toxic fumes under fire conditions.

Flash point and method: No applicable information found.

Flammable limits: No applicable information found.

Auto ignition temperature: No applicable information found.

Flammable class: No applicable information found.

Sensitivity to static charge: No applicable information found.

5.3 ADVICE FOR FIREFIGHTERS:

As in any fire, wear self-contained breathing apparatus pressure-demand, MSHA/NIOSH (approved or equivalent) and full protective gear to prevent contact with eye and skin.

SECTION 6: Accidental release measures

6.1 PERSONAL PRECAUTIONS, PROTECTIVE EQUIPMENT AND EMERGENCY RESPONSE:

Wear self-contained breathing apparatus and rubber boots, heavy rubber gloves. Splash goggles.

6.2 ENVIRONMENTAL PRECAUTIONS:

Water spill: Do not empty into drains.

Land spill: Vacuum material with appropriate dust collection in place. If a vacuum is not available, lightly mist material and remove by sweeping or wet wiping. Wear appropriate equipment including eye protection, to avoid exposure.

Release notes: If the spill could potentially enter any waterway, including intermittent dry creeks, contact the local authorities. In the USA, contact the USA Coast Guard National Response Center toll free 800 424 8802. In case of accident or spill, notify:

- CHEMTREC (USA): 800 424 9300
- CHEMTREC (outside USA): +1 703 527 3887
- CANUTEC (Canada): 613 996 6666

6.3 METHODS AND MATERIALS FOR CONTAINMENT AND CLEANING UP:

Ventilate area and wash spill site after pick-up complete.

6.4 REFERENCES TO OTHER SECTIONS:

See section 1 for emergency contact information, section 8 for personal protective equipment details, and section 13 for disposal information.

SECTION 7: Handling and storage

7.1 PRECAUTIONS FOR SAFE HANDLING:

Wash thoroughly after handling. Wash hands before eating. Use with adequate ventilation. Avoid breath dust, vapor, mist or gas. Avoid contact with skin, eyes. Avoid ingestion and inhalation.

7.2 CONDITIONS FOR SAFE STORAGE, INCLUDING ANY INCOMPATIBILITIES:

Keep vials tightly closed.

7.3 SPECIFIC END USES:

See section 1. Use original container.

SECTION 8: Exposure controls/personal protection

8.1 CONTROL PARAMETERS:

Not listed.

8.2 EXPOSURE CONTROLS:

When inside vials the hazard is considered negligible. If opened for some purpose then follow below advices.

Respiratory Protection: Use NIOH/MSHA or European Standards approved respirator if exposure limits are exceeded or when dust generated.

Eye Protection: Wear appropriate safety glasses or goggles when splash potential exists.

Ventilation: Good ventilation should be sufficient to control airborne levels.

Protective Clothing and Hand Protection: Wear appropriate gloves and clothing to prevent contact with skin.

Comments: This product is not specifically listed by OSHA as hazardous. However, this material may cause sensitization or an allergic response with minimal exposure. Under conditions of overexposure, the material may be hazardous.

SECTION 9: Physical and chemical properties

9.1 INFORMATION ON BASIC PHYSICAL AND CHEMICAL PROPERTIES:

Physical state:	Vials
Appearance:	White to off white powder or cake
Color:	White to off-white.
Odor:	Odorless.
Odor threshold:	Not relevant.
pH:	No applicable information found.
Vapour pressure:	No applicable information found.
Vapour density:	No applicable information found.
Evaporation rate:	No applicable information found.
Freezing point:	Not applicable.
Melting point:	Decomposes when heated.
Boiling point:	No applicable information found as this is a powder.
Flash point:	No applicable information found.
Decomposition temperature:	No applicable information found.
Flammability:	No applicable information found.
Upper/lower flammability or explosive limits (vol-%):	No applicable information found.
Auto-ignition temperature:	No applicable information found.
Soluble in water:	Soluble.
Density:	No applicable information found.
Specific gravity:	No applicable information found as this is a powder.
Viscosity:	No applicable information found.
Explosive properties:	No applicable information found.
Oxidising properties:	No applicable information found.
Molecular formula:	No applicable information found.
Molecular weight:	No applicable information found.
Coefficient of oil and water:	No applicable information found.

9.2 OTHER INFORMATION:

None relevant.

SECTION 10: Stability and reactivity

When inside vials the hazard is considered negligible. If opened for some purpose then follow below advices.

10.1 REACTIVITY: No applicable information found.

10.2 CHEMICAL STABILITY: Stable at normal temperatures and pressures.

10.3 POSSIBILITY OF HAZARDOUS REACTIONS: No applicable information found.

10.4 CONDITIONS TO AVOID: Avoid heat, moisture.

10.5 INCOMPATIBLE MATERIALS: May react with strong oxidizing agents (e.g., peroxides, permanganates, nitric acid, etc.)

10.6 HAZARDOUS DECOMPOSITION PRODUCTS: If heated to very high temperatures, the product may form hazardous decomposition products such as oxides of carbon and nitrogen and corrosive hydrogen chloride.

SECTION 11: Toxicological information

11.1 INFORMATION ON TOXICOLOGICAL EFFECTS:

p.o. No applicable information found.

i.v. No applicable information found.

i.p. No applicable information found.

s.c. No applicable information found.

i.m. No applicable information found.

Skin: No applicable information found.

Inhalation: No applicable information found.

Eyes: No applicable information found.

OSHA Not Listed

ACGIH Not Listed

NOISH Not Listed

SECTION 12: Ecological information

12.1 TOXICITY: No applicable information found.

12.2 PERSISTENCE AND DEGRADABILITY: No applicable information found.

12.3 BIOACCUMULATIVE POTENTIAL: No applicable information found.

12.4 MOBILITY IN SOIL: No applicable information found.

12.5 RESULTS OF PBT AND vPvB ASSESSMENT: The substance is not considered PBT/vPvB according to criteria in Annex XIII.

12.6 OTHER ADVERSE EFFECTS: The substance is possibly harmful for the aquatic environment, due to its antibiotic properties.

SECTION 13: Disposal considerations

13.1 WASTE TREATMENT METHODS:

Dissolve or mix material with a suitable combustible solvent and incinerate in a chemical incinerator equipped with an afterburner and scrubber. Material should be disposed of in accordance with all local and national legislation. Packaging should be disposed of in line with all local and national legislation. Handle contaminated vials as product.

SECTION 14: Transport information

14.1 UN NUMBER: Not regulated.

14.2 UN PROPER SHIPPING NAME: Not relevant.

14.3 TRANSPORT HAZARD CLASS(ES): Not relevant.

14.4 PACKING GROUP: Not relevant.

14.5 ENVIRONMENTAL HAZARDS: None.

14.6 SPECIAL PRECAUTIONS FOR USER: None.

14.7 TRANSPORT IN BULK ACCORDING TO ANNEX II MARPOL 73/78 AND THE IBC CODE: Not relevant.

USA DOT (DEPARTMENT OF TRANSPORTATION)

Proper Shipping Name: Not regulated

CANADA TRANSPORT OF DANGEROUS GOODS

Proper Shipping Name: Not regulated.

AIR (ICAO/IATA)

Proper Shipping Name: Not regulated.

VESSEL (IMO/IMDG)

Proper Shipping Name: Not regulated.
EUROPEAN TRANSPORTATION:
ADR/RID HAZARD CLASSIFICATION: Not regulated.
U.S. CUSTOMS HARMONIZATION NUMBER: Not regulated.

SECTION 15: Regulatory information

15.1 SAFETY, HEALTH AND ENVIRONMENTAL REGULATION/LEGISLATION SPECIFIC FOR THE SUBSTANCE OR MIXTURE:

This section contains selected regulatory information for possible use by Xellia Pharmaceuticals ApS. This section is not intended to be a complete listing of all applicable regulations. You are urged to consider laws and regulations applicable to your state and country.

EUROPEAN COMMUNITY

Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH),

Council Directive 94/33/EC of 22 June 1994 on the protection of young people at work:

Must not be used by persons under 18 years of age.

Council Directive 92/85/EEC of 19 October 1992 on the introduction of measures to encourage improvements in the safety and health at work of pregnant workers and workers who have recently given birth or are breastfeeding:

Not regulated. However, it is recommended, that the employer assess the working conditions and, if there is any risk to the safety or health and any effects on the pregnancy or breastfeeding of workers, take the necessary measures to adjust the working conditions.

Implementation of directive 2001/82/EC of the European Parliament and of the council of 6 November 2001 in the Community code relating to veterinary medical products:

Denmark: The Danish Medicines Agency (Lægemiddelstyrelsen) must be notified that this substance is produced, imported, exported, stored, sold, delivered, packed, possessed or in other ways handled in Denmark (Bekendtgørelse nr. 1226 af 7. December 2005 om omgang med visse stoffer og produkter hvis indhold kan anvendes som lægemidler til dyr.).
For other countries: Please contact national authorities regarding notification of the substance.

UNITED STATES FEDERAL REGULATIONS

Superfund Amendments and Reauthorization Act (SARA) Title III 311/312 hazard categories:

Fire: No **Pressure generating:** No **Reactivity:** No **Acute:** Yes **Chronic:** No

313 Reportable Ingredients: Not listed.

Title III notes:

Comprehensive Response, Compensation, and Liability Act (CERCLA)

CERCLA RQ: Not listed

Toxic Substances Control Act (TSCA)

TSCA Regulatory: Not listed.

National Response Center: US Coast Guard National Center Response Telephone number is 800 424 8802.

UNITED STATES STATE REGULATIONS

California Proposition 65: Not listed.

CANADA

Workplace Hazardous Material Information System (WHMIS) hazard symbol and classification

WHMIS Controlled: Not regulated.

Canadian Environmental Protection Act: Not listed.

15.2 CHEMICAL SAFETY ASSESSMENT:

No CSR.

SECTION 16: Other information'

Reason for issue: EC regulation, REACH and CLP

Contact Information: See Section 1

Revision summary: 1-16

	HMIS RATING	NFPA RATING
Health	ND	ND
Flammability	ND	ND
Physical hazard	ND	ND
Personal protection	ND	ND
Incompatibilities	ND	ND

Data sources: Martindale 33 edition; www.lmk.dk; Chemindex.

Disclaimer: Information given herein is offered in good faith as accurate, but without guarantee. Conditions of use and suitability of the product for particular uses are beyond our control; all risks of use of the product are therefore assumed by the user. Nothing is intended as a recommendation for uses that infringe valid patents or as extending license under valid patents. Appropriate warnings and safe handling procedures should be provided to handlers and users.

Glossary:

ACGIH – American Conference of Governmental Hygienists
 AIHA – American Industrial Hygiene Association
 BEI – Biological Exposure Index
 CAS – Chemical Abstract Service Registry Number
 CSR – Chemical Safety Report
 CERCLA – Comprehensive Environmental Response Compensation and Liability Act of 1989
 CHEMTREC – Chemical Transportation Emergency Center
 DOT – Department of Transportation (USA)
 EC – European Community
 EINECS – European Inventory of Existing Chemical Substances
 ELINCS - European List of New Chemical Substances
 EPA – Environmental Protection Agency
 FDA – United States Food and Drug Administration
 HEPA- High Efficiency Particulate Air (Filter)
 HMIS – Hazardous Material Information System
 IARC- International Agency on Research for Cancer
 ICAO/IATA – International Civil Aviation Organization/International Air Transport Association
 IMO – International Maritime Organization
 LEL – Lower Explosive Limit
 MSDS – Material Safety Data Sheet
 MSHA – Mine Safety and Health Administration
 NA – Not Applicable
 NADA – New Animal Drug Application
 NAIF – No Applicable Information Found
 NCI – National Cancer Institute
 ND – Not Determined
 NFPA – National Fire Protection Association
 NIOSH – National Institute for Occupational Health and Safety
 NL – Not Listed
 NOS – Not Otherwise Specified
 NTP – National Toxicology Program
 OEL – Occupational Exposure Limit
 OSHA – Occupational Safety and Health Administration
 PEL – Permissible Exposure Limit (USA)
 RCRA – Resource Conservation and Recovery Act
 RQ – Reportable Quantity
 RTECS – Registry of Toxic Effects of Chemical Substances
 SARA – Superfund Amendments and Reauthorization Act
 STEL – Short Term Exposure Limit
 TLV – Threshold Limit Value
 TPQ – Threshold Planning Quantity
 TSCA – Toxic Substances Control Act
 TWA – Time Weighted Average
 UEL – Upper Explosive Limit
 UN – United Nations
 WEEL – Workplace Environmental Exposure Level (USA - AIHA)