

SAFETY DATA SHEET

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1. IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND OF THE COMPANY/UNDERTAKING

PRODUCT IDENTIFIER:

Product name: Micafungin sodium for injection, 50mg and 100mg
CAS# : 208538-73-2
REACH reg.# : medicinal product, the mixture does not legally require an SDS and REACH pre-registration

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

Product Formulation Name: Antibiotic for Injection
Chemical Family: Micafungin sodium for Injection
Generic Name: Echinocandines
Pharmaceutical product, Antifungal

DETAILS OF THE SUPPLIER OF THE SAFETY DATA SHEET:

Xellia Pharmaceuticals ApS
Dalslandsgade 11
2300 Copenhagen S
Denmark

EMERGENCY TELEPHONE NUMBER

Xellia: +45 32 64 5500 in Denmark
Xellia: +011 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

Responsible person for the safety data sheet (e-mail): sales@xellia.com

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

2. HAZARDS IDENTIFICATION

Emergency Overview

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

Physical Appearance: Pharmaceutical white to off white powder in vials

Hazards (if the vial is broken): Adverse developmental effects in rats and rabbits.

CLASSIFICATION OF THE SUBSTANCE OR MIXTURE:

CLP: GHS09 (Environment); Aquatic Acute 1; H400 (Very toxic to aquatic life).

HAZARD SIGN: WARNING!

Contents: Micafungin sodium



AQUATIC TOXICITY

H400: Very toxic to aquatic life.

P273: Avoid release to the environment.

OTHER HAZARDS:

None known.

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

3. COMPOSITION/INFORMATION ON INGREDIENTS

SUBSTANCES:

Ingredients	Quantity per unit (mg/vial)	Function	CAS#	Hazards	Quantity per unit (mg/vial)
50 mg					
Micafungin Sodium	50.91	Active substance	208539-73-2	H400	
Lactose monohydrate	200.00	Bulking agent	63-42-3	-	
Citric acid, anhydrous	q.s.	pH adjusting agent	77-92-9	H317	
Sodium Hydroxide	q.s.	pH adjusting agent	1310.73-2	H290, H314	Sodium hydroxide is considered an eye irritant
100 mg					
Micafungin Sodium	101.81	Active substance	208539-73-2	H400	
Lactose monohydrate	200.00	Bulking agent	63-42-3	-	
Citric acid, anhydrous	q.s.	pH adjusting agent	77-92-9	H317	
Sodium Hydroxide	q.s.	pH adjusting agent	1310.73-2	H290, H314	Sodium hydroxide is considered an eye irritant

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

4. FIRST AID MEASURES

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.

5. FIREFIGHTING MEASURES

EXTINGUISHING MEDIA:

Use water

SPECIAL HAZARDS ARISING FROM THE SUBSTANCE OR MIXTURE:

General hazards: No applicable information found.
Hazardous combustion products: No applicable information found she works in
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.

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.

6. ACCIDENTAL RELEASE MEASURES

PERSONAL PRECAUTIONS, PROTECTIVE EQUIPMENT AND EMERGENCY RESPONSE:

Material intended clinical uses only. Handle all pharmaceutical products in a way that will avoid contact with and inhalation of dust, fumes, mists, and / or vapors associated with the product.

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.

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

METHODS AND MATERIALS FOR CONTAINMENT AND CLEANING UP:

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

REFERENCES TO OTHER SECTIONS:

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

7. HANDLING AND STORAGE

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

Storage: Keep vials tightly closed.

SPECIFIC END USES:

See section 1. Use original container.

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1 CONTROL PARAMETERS:

OSHA'S hazardous components (29 CFR 1910.1020)

EXPOSURE LIMITS AND GUIDELINES

	<u>OSHA PEL</u>		<u>ACGIH TLV</u>		<u>OTHER OEL (TWA)</u>	
	<u>ppm</u>	<u>mg/m³</u>	<u>ppm</u>	<u>mg/m³</u>	<u>ppm</u>	<u>mg/m³</u>
Micafungin Sodium (CAS#: 208538-73-2)	NL	NL	NL	NL	NL	0.03

This value is not a health base OEL. The exposure should be kept as low as possible below this level to protect against respiratory sensitization.

Other country exposure limits: Not listed.

Other country exposure limits: Not listed.

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. Wash hands with soap and water whenever gloves are removed.

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.

9. PHYSICAL AND CHEMICAL PROPERTIES

INFORMATION ON BASIC PHYSICAL AND CHEMICAL PROPERTIES:

Appearance: White to off white powder or cake

Solubility of active ingredient in water by weight: More than 200 mg/mL Odor: No applicable information found.

Odor: No applicable information found.

Molecular Weight of active ingredient: 1292.26

Boiling Point: No applicable information found.

Melting Point/Range: No applicable information found.

pH: No applicable information found.

10. STABILITY AND REACTIVITY

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

Reactivity: No applicable information found.

Chemical stability: Stable at normal temperatures and pressures.
Possibility of hazardous reactions: No applicable information found.
Conditions to avoid: Moisture, heat.

11. TOXICOLOGICAL INFORMATION

Toxicity Data Single Exposure

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

12. ECOLOGICAL INFORMATION

TOXICITY: No applicable information found.
PERSISTENCE AND DEGRADABILITY: No applicable information found.
BIOACCUMULATIVE POTENTIAL: No applicable information found.
MOBILITY IN SOIL: No applicable information found.
RESULTS OF PBT AND vPvB ASSESSMENT: The substance is not considered PBT/vPvB according to criteria in Annex XIII.
OTHER ADVERSE EFFECTS: The substance is possibly harmful for the aquatic environment, due to its antibiotic properties.

13. DISPOSAL CONSIDERATIONS

WASTE TREATMENT METHODS:

Disposal (includes medicine, Empty vials): 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.

14. TRANSPORT INFORMATION

UN NUMBER: Not regulated.
UN PROPER SHIPPING NAME: Not relevant.
TRANSPORT HAZARD CLASS(ES): Not relevant.
PACKING GROUP: Not relevant.
ENVIRONMENTAL HAZARDS: None.
SPECIAL PRECAUTIONS FOR USER: None.
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.

15. REGULATORY INFORMATION

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.

CHEMICAL SAFETY ASSESSMENT:

No CSR.

16. OTHER INFORMATION

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)