

---

## SAFETY DATA SHEET

**Date of Original Issue:** August, 21, 2012  
**Revision Number:** 4  
**Revision Date:** November 19, 2021

---

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

#### 1.1 PRODUCT IDENTIFIER

**Product name:** Tigecycline 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:** Tigecycline for Injection  
**Chemical Family:** Tetracycline derivative  
**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

#### EMERGENCY OVERVIEW

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

#### 2.1 CLASSIFICATION OF THE SUBSTANCE OR MIXTURE

CLP:

**H Statements:** H361: Suspected of damaging fertility or the unborn child. H401: Toxic to aquatic life.

**P Statements:** 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:** Tigecycline for Injection



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 Ingredient Name: Tigecycline

Sr. No.	Ingredients	Function	CAS#	Hazards	Quantity per unit (mg/vial)
1.	Tigecycline	Active substance	220620-09-7	<b>H361:</b> Suspected of damaging fertility or the unborn child. <b>H401:</b> Toxic to aquatic life.	50
2.	Lactose monohydrate	Bulking agent	10039-26-6	<b>None</b>	100
3.	Hydrochloric acid	pH adjusting agent	7647-01-0	<b>Neglectible</b>	q.s.
4.	Sodium hydroxide	pH adjusting agent	1310-73-2	<b>Neglectible</b>	q.s.

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 20 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. Wash clothing before reuse.

**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. Overdose symptoms may include nausea and vomiting.

### MOST IMPORTANT SYMPTOMS AND EFFECTS, BOTH ACUTE AND DELAYED:

ACUTE TOXICITY:

**Eyes, Skin and Inhalation:** Irritating to eye/skin/respiratory tract. Asthenia, headache, abdominal pain, phlebitis, diarrhea, dyspepsia, nausea, vomiting.

**Ingestion Exposure:** May cause mechanical eye irritation. May cause respiratory tract irritation. May cause skin irritation. May cause eye irritation. May be harmful if swallowed.

CHRONIC TOXICITY:

**Delayed Effects:** May result in oral thrush or a new vaginal yeast infection. May cause a very serious allergic reaction: rash, itching, swelling, severe dizziness, trouble breathing.

**Carcinogenicity:** No applicable information identified.

**Mutagenicity:** No applicable information identified.

REPRODUCTIVE TOXICITY:

**Pregnancy Comments:** Tigecycline may cause fetal harm when administered to a pregnant woman. There are no adequate and well-controlled studies of tigecycline in pregnant women. It should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus.

**Medical Conditions Aggravated by Exposure:** Anaphylaxis/ anaphylactoid reactions have been reported and may be life-threatening. Tigecycline is structurally similar to tetracycline-class antibiotics and should be administered with caution in patients with known hypersensitivity to tetracycline-class antibiotics.

SENSITIZATION:

No applicable information identified.

MEDICAL CONDITIONS AGGRAVATED:

No applicable information identified.

### INDICATIONS OF ANY IMMEDIATE MEDICAL ATTENTION AND SPECIAL TREATMENT NEEDED:

In case of discomfort or unconsciousness: Show this safety data sheet to a physician or emergency ward.

ANTIDOTE INFORMATION: No specific antidote available.

---

## SECTION 5: Firefighting measures

### 5.1 EXTINGUISHING MEDIA:

Water, carbon dioxide, dry chemical, foam, or other alternatives.

### 5.2 SPECIAL HAZARDS ARISING FROM THE SUBSTANCE OR MIXTURE:

<b>General hazards:</b>	May be combustible at high temperature.
<b>Hazardous combustion products:</b>	Emits toxic fumes under fire conditions.
<b>Flash point and method:</b>	No applicable information identified.
<b>Flammable limits:</b>	No applicable information identified.
<b>Autoignition temperature:</b>	No applicable information identified.
<b>Flammable class:</b>	No applicable information identified.
<b>Sensitivity to static charge:</b>	No applicable information identified.

### 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.

---

## SECTION 6: Accidental release measures

### 6.1 PERSONAL PRECAUTIONS, PROTECTIVE EQUIPMENT AND EMERGENCY RESPONSE:

Wear personal protective equipment to avoid exposure – see section 8. Avoid generation of dust.

### 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:

**Handling:** Handle in accordance with good industrial hygiene and safety practice.

### 7.2 CONDITIONS FOR SAFE STORAGE, INCLUDING ANY INCOMPATIBILITIES:

**Storage:** Keep vials tightly closed.

### 7.3 SPECIFIC END USES:

See section 1.

---

## SECTION 8: Exposure controls/personal protection

### 8.1 CONTROL PARAMETERS:

**Other country exposure limits:** 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:** Base respirator selection on a risk assessment.

**Eye Protection:** Safety glasses or goggles when splash potential exists.

**Ventilation:** Use process enclosures, local exhaust ventilation, or other engineering controls to control airborne levels below recommended exposure limits.

**Hand Protection:** Wear nitrile or latex gloves.

**Protective Clothing:** Wear protective garment.

**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:

**Appearance:** Orange powder or cake  
**Solubility:** No applicable information found.  
**Odor:** No applicable information found.

**Molecular Weight:** No applicable information found.  
**Boiling Point:** No applicable information found.  
**Melting Point/Range:** No applicable information found.  
**pH:** 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.

<b>10.1 REACTIVITY:</b>	No applicable information found.
<b>10.2 CHEMICAL STABILITY:</b>	Stable at normal temperatures and pressures.
<b>10.3 POSSIBILITY OF HAZARDOUS REACTIONS:</b>	No applicable information found.
<b>10.4 CONDITIONS TO AVOID:</b>	Avoid heat, moisture, and sunlight.
<b>10.5 INCOMPATIBLE MATERIALS:</b>	Acids, strong oxidizer
<b>10.6 HAZARDOUS DECOMPOSITION PRODUCTS:</b>	COx, NOx and emits toxic fumes under fire conditions

---

## SECTION 11: Toxicological information

### 11.1 INFORMATION ON TOXICOLOGICAL EFFECTS:

<b>p.o.</b>	NAIF
<b>i.v.</b>	NAIF
<b>i.p.</b>	NAIF
<b>s.c.</b>	NAIF
<b>i.m.</b>	NAIF
<b>Skin:</b>	NAIF
<b>Inhalation:</b>	NAIF
<b>Eyes:</b>	NAIF

#### Toxicity Data Repeat Exposure

**Target Organs:** Cardiovascular system; Metabolic system; Skin; Urogenital system

**Carcinogenicity:** NTP

**IARC** Not Listed

**OSHA** Not Listed

**ACGIH** Not Listed

**NOISH** Not Listed

---

## SECTION 12: Ecological information

<b>12.1 TOXICITY:</b>	No applicable information found.
<b>12.2 PERSISTENCE AND DEGRADABILITY:</b>	No applicable information found.
<b>12.3 BIOACCUMULATIVE POTENTIAL:</b>	No applicable information found.
<b>12.4 MOBILITY IN SOIL:</b>	No applicable information found.
<b>12.5 RESULTS OF PBT AND vPvB ASSESSMENT:</b>	The substance is not considered PBT/vPvB according to criteria in Annex XIII.
<b>12.6 OTHER ADVERSE EFFECTS:</b>	The substance is possibly harmful for the aquatic environment, due to is antibiotic properties.

---

## SECTION 13: Disposal considerations

### 13.1 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.

---

## SECTION 14: Transport information

<b>14.1 UN NUMBER:</b>	Not regulated.
<b>14.2 UN PROPER SHIPPING NAME:</b>	Not relevant.
<b>14.3 TRANSPORT HAZARD CLASS(ES):</b>	Not relevant.
<b>14.4 PACKING GROUP:</b>	Not relevant.
<b>14.5 ENVIRONMENTAL HAZARDS:</b>	None.
<b>14.6 SPECIAL PRECAUTIONS FOR USER:</b>	None.
<b>14.7 TRANSPORT IN BULK ACCORDING TO ANNEX II MARPOL 73/78 AND THE IBC CODE:</b>	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. 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

	<b>HMIS RATING</b>	<b>NFPA RATING</b>
<b>Health</b>	ND	ND
<b>Flammability</b>	ND	ND
<b>Physical hazard</b>	ND	ND
<b>Personal protection</b>	ND	ND
<b>Incompatibilities</b>	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)