

### **Safety Data Sheet**

SDS Title: Tigecycline for Injection Safety Data Sheet	SDS Number: SDS-000054	Page Number: Page 1 of 16
Function: Regulatory Affairs	Effective Date: March 01, 2024	Version number: 2.0

### **Section 1. Identification**

GHS product identifier : Tigecycline for Injection

Other means of identification: Not available.

Product type: Powder.

Relevant identified uses of the substance or mixture and uses advised against

Product use : Pharmaceuticals. (For intended use only.)

Observe technical data sheet/instructions for use.

Specific Treatments: Complicated skin infections, intra-abdominal infections and

pneumonia.

Area of application : Professional applications.

**Supplier's details**: Meitheal Pharmaceuticals, Inc.

8700 W. Bryn Mawr, Suite 600S

Chicago, IL 60631

Telephone: 224-443-4617 www.meithealpharma.com

e-mail address of person responsible for this SDS

: info@meithealpharma.com

Emergency telephone number (with hours of

operation)

: 844-824-8426 (Monday - Friday, 08:00 - 18:00 CST)

### Section 2. Hazards identification

OSHA/HCS status : This material is considered hazardous by the OSHA Hazard Communication Standard

(29 CFR 1910.1200).

Classification of the : COMBUSTIBLE DUSTS

**substance or mixture** H319 EYE IRRITATION - Category 2A

H360 TOXIC TO REPRODUCTION - Category 1B

**GHS label elements** 

Hazard pictograms :





Signal word : Danger

**Hazard statements**: H319 - Causes serious eye irritation.

H360 - May damage fertility or the unborn child. May form combustible dust concentrations in air.



#### Meitheal Pharmaceuticals, Inc. Safety Data Sheet

SDS Title: Tigecycline for Injection Safety Data Sheet	Page Number: Page 2 of 16
Function: Regulatory Affairs	Version number: 2.0

## Section 2. Hazards identification

**Precautionary statements** 

**Prevention** : P201 - Obtain special instructions before use.

> P202 - Do not handle until all safety precautions have been read and understood. P280 - Wear protective gloves, protective clothing and eye or face protection.

P264 - Wash thoroughly after handling.

P308 + P313 - IF exposed or concerned: Get medical advice or attention. Response

P305 + P351 + P338 - IF IN EYES: Rinse cautiously with water for several minutes.

Remove contact lenses, if present and easy to do. Continue rinsing. P337 + P313 - If eye irritation persists: Get medical advice or attention.

: P405 - Store locked up. **Storage** 

**Disposal** : P501 - Dispose of contents and container in accordance with all local, regional, national

and international regulations.

Supplemental label

: Keep container tightly closed. Keep away from heat, hot surfaces, sparks, open flames elements and other ignition sources. No smoking. Prevent dust accumulation.

Hazards not otherwise

classified

: None known.

# Section 3. Composition/information on ingredients

Substance/mixture : Mixture

Other means of identification

: Not available.

Ingredient name	Other names	%	CAS number
D-Glucose, 4-O-β-D-galactopyranosyl-, hydrate (1:1)	Lactose monohydrate	≥50 - ≤75	64044-51-5
tigecycline	-	≥25 - ≤50	220620-09-7
Hydrochloric acid	-	≤0.1	7647-01-0
sodium hydroxide	-	≤0.1	1310-73-2

Any concentration shown as a range is to protect confidentiality or is due to batch variation.

There are no additional ingredients present which, within the current knowledge of the supplier and in the concentrations applicable, are classified and hence require reporting in this section.

### Section 4. First aid measures

### **Description of necessary first aid measures**

Eye contact

: Immediately flush eyes with plenty of water, occasionally lifting the upper and lower eyelids. Check for and remove any contact lenses. Continue to rinse for at least 10 minutes. Get medical attention.



### Meitheal Pharmaceuticals, Inc. Safety Data Sheet

SDS Title: Tigecycline for Injection Safety Data Sheet	SDS Number: SDS-000054	Page Number: Page 3 of 16
Function: Regulatory Affairs	Effective Date: March 01, 2024	Version number: 2.0

### Section 4. First aid measures

#### Inhalation

: Remove victim to fresh air and keep at rest in a position comfortable for breathing. If not breathing, if breathing is irregular or if respiratory arrest occurs, provide artificial respiration or oxygen by trained personnel. It may be dangerous to the person providing aid to give mouth-to-mouth resuscitation. Get medical attention. If unconscious, place in recovery position and get medical attention immediately. Maintain an open airway. Loosen tight clothing such as a collar, tie, belt or waistband. In case of inhalation of decomposition products in a fire, symptoms may be delayed. The exposed person may need to be kept under medical surveillance for 48 hours.

### Skin contact

Flush contaminated skin with plenty of water. Remove contaminated clothing and shoes. Wash contaminated clothing thoroughly with water before removing it, or wear gloves. Continue to rinse for at least 10 minutes. Get medical attention. Wash clothing before reuse. Clean shoes thoroughly before reuse.

### Ingestion

: Wash out mouth with water. Remove dentures if any. If material has been swallowed and the exposed person is conscious, give small quantities of water to drink. Stop if the exposed person feels sick as vomiting may be dangerous. Do not induce vomiting unless directed to do so by medical personnel. If vomiting occurs, the head should be kept low so that vomit does not enter the lungs. Get medical attention. Never give anything by mouth to an unconscious person. If unconscious, place in recovery position and get medical attention immediately. Maintain an open airway. Loosen tight clothing such as a collar, tie, belt or waistband.

### Most important symptoms/effects, acute and delayed

### Potential acute health effects

**Eye contact** : Causes serious eye irritation.

Inhalation : Exposure to airborne concentrations above statutory or recommended exposure limits

may cause irritation of the nose, throat and lungs.

Skin contactIngestionNo known significant effects or critical hazards.No known significant effects or critical hazards.

### Over-exposure signs/symptoms

**Eye contact**: Adverse symptoms may include the following:

pain or irritation watering redness

**Inhalation** : Adverse symptoms may include the following:

respiratory tract irritation

coughing

reduced fetal weight increase in fetal deaths skeletal malformations

**Skin contact** : Adverse symptoms may include the following:

reduced fetal weight increase in fetal deaths skeletal malformations



Safety Data Sheet

	SDS Number: SDS-000054	Page Number: Page 4 of 16
Function: Regulatory Affairs	Effective Date: March 01, 2024	Version number: 2.0

### Section 4. First aid measures

Ingestion

: Adverse symptoms may include the following: reduced fetal weight

increase in fetal deaths skeletal malformations

### Indication of immediate medical attention and special treatment needed, if necessary

Notes to physician

: In case of inhalation of decomposition products in a fire, symptoms may be delayed. The exposed person may need to be kept under medical surveillance for 48 hours.

Specific treatments

: No specific treatment.

Protection of first-aiders

: No action shall be taken involving any personal risk or without suitable training. If it is suspected that fumes are still present, the rescuer should wear an appropriate mask or self-contained breathing apparatus. It may be dangerous to the person providing aid to give mouth-to-mouth resuscitation. Wash contaminated clothing thoroughly with water before removing it, or wear gloves.

### See toxicological information (Section 11)

### Section 5. Fire-fighting measures

### **Extinguishing media**

Suitable extinguishing media

: Use dry chemical powder.

Unsuitable extinguishing

media

: Do not use water jet.

Specific hazards arising from the chemical

: May form explosible dust-air mixture if dispersed.

Hazardous thermal decomposition products

: Decomposition products may include the following materials: carbon dioxide

carbon dioxide carbon monoxide nitrogen oxides

Special protective actions for fire-fighters

: Promptly isolate the scene by removing all persons from the vicinity of the incident if there is a fire. No action shall be taken involving any personal risk or without suitable training. Move containers from fire area if this can be done without risk. Use water spray to keep fire-exposed containers cool.

Special protective equipment for fire-fighters

: Fire-fighters should wear appropriate protective equipment and self-contained breathing apparatus (SCBA) with a full face-piece operated in positive pressure mode.



### Meitheal Pharmaceuticals, Inc. Safety Data Sheet

SDS Title: Tigecycline for Injection Safety Data Sheet	Page Number: Page 5 of 16
Function: Regulatory Affairs	Version number: 2.0

### Section 6. Accidental release measures

### Personal precautions, protective equipment and emergency procedures

For non-emergency personnel

: No action shall be taken involving any personal risk or without suitable training. Evacuate surrounding areas. Keep unnecessary and unprotected personnel from entering. Do not touch or walk through spilled material. Shut off all ignition sources. No flares, smoking or flames in hazard area. Avoid breathing dust. Provide adequate ventilation. Wear appropriate respirator when ventilation is inadequate. Put on appropriate personal protective equipment.

For emergency responders

If specialized clothing is required to deal with the spillage, take note of any information in Section 8 on suitable and unsuitable materials. See also the information in "For non-emergency personnel".

**Environmental precautions** 

: Avoid dispersal of spilled material and runoff and contact with soil, waterways, drains and sewers. Inform the relevant authorities if the product has caused environmental pollution (sewers, waterways, soil or air).

### Methods and materials for containment and cleaning up

Small spill

: Move containers from spill area. Use spark-proof tools and explosion-proof equipment. Avoid dust generation. Do not dry sweep. Vacuum dust with equipment fitted with a HEPA filter and place in a closed, labeled waste container. Place spilled material in a designated, labeled waste container. Dispose of via a licensed waste disposal contractor.

Large spill

Move containers from spill area. Use spark-proof tools and explosion-proof equipment. Approach release from upwind. Prevent entry into sewers, water courses, basements or confined areas. Avoid dust generation. Do not dry sweep. Vacuum dust with equipment fitted with a HEPA filter and place in a closed, labeled waste container. Avoid creating dusty conditions and prevent wind dispersal. Dispose of via a licensed waste disposal contractor. Note: see Section 1 for emergency contact information and Section 13 for waste disposal.

### Section 7. Handling and storage

### Precautions for safe handling

**Protective measures** 

Put on appropriate personal protective equipment (see Section 8). Avoid exposure obtain special instructions before use. Avoid exposure during pregnancy. Do not handle until all safety precautions have been read and understood. Do not get in eyes or on skin or clothing. Do not ingest. Avoid breathing dust. Avoid the creation of dust when handling and avoid all possible sources of ignition (spark or flame). Prevent dust accumulation. Use only with adequate ventilation. Wear appropriate respirator when ventilation is inadequate. Keep in the original container or an approved alternative made from a compatible material, kept tightly closed when not in use. Electrical equipment and lighting should be protected to appropriate standards to prevent dust coming into contact with hot surfaces, sparks or other ignition sources. Take precautionary measures against electrostatic discharges. To avoid fire or explosion, dissipate static electricity during transfer by grounding and bonding containers and equipment before transferring material. Empty containers retain product residue and can be hazardous. Do not reuse container.



**Safety Data Sheet** 

SDS Title: Tigecycline for Injection Safety Data Sheet	SDS Number: SDS-000054	Page Number: Page 6 of 16
Function:	Effective Date:	Version number:
Regulatory Affairs	March 01, 2024	2.0

### Section 7. Handling and storage

**Advice on general** occupational hygiene : Eating, drinking and smoking should be prohibited in areas where this material is handled, stored and processed. Workers should wash hands and face before eating, drinking and smoking. Remove contaminated clothing and protective equipment before entering eating areas. See also Section 8 for additional information on hygiene measures.

including any incompatibilities

Conditions for safe storage, : Store in accordance with local regulations. Store in a segregated and approved area. Store in original container protected from direct sunlight in a dry, cool and well-ventilated area, away from incompatible materials (see Section 10) and food and drink. Store locked up. Eliminate all ignition sources. Separate from oxidizing materials. Keep container tightly closed and sealed until ready for use. Containers that have been opened must be carefully resealed and kept upright to prevent leakage. Do not store in unlabeled containers. Use appropriate containment to avoid environmental contamination. See Section 10 for incompatible materials before handling or use.

# Section 8. Exposure controls/personal protection

#### **Control parameters**

Occupational exposure limits

Ingredient name	Exposure limits
D-Glucose, 4-O-β-D-galactopyranosyl-, hydrate (1:1) tigecycline Hydrochloric acid	None. None. ACGIH TLV (United States, 1/2023). C: 2 ppm NIOSH REL (United States, 10/2020). CEIL: 5 ppm CEIL: 7 mg/m³
sodium hydroxide	OSHA PEL (United States, 5/2018).  CEIL: 5 ppm CEIL: 7 mg/m³ CAL OSHA PEL (United States, 5/2018).  C: 2 ppm TWA: 0.45 mg/m³ 8 hours. TWA: 0.3 ppm 8 hours.  ACGIH TLV (United States, 1/2023).  C: 2 mg/m³ NIOSH REL (United States, 10/2020).  CEIL: 2 mg/m³ OSHA PEL (United States, 5/2018).  TWA: 2 mg/m³ 8 hours.  CAL OSHA PEL (United States, 5/2018).  C: 2 mg/m³



### Meitheal Pharmaceuticals, Inc. Safety Data Sheet

SDS Title: Tigecycline for Injection Safety Data Sheet	Page Number: Page 7 of 16	
Function: Regulatory Affairs	Version number: 2.0	

### Section 8. Exposure controls/personal protection

# Appropriate engineering controls

: Use only with adequate ventilation. If user operations generate dust, fumes, gas, vapor or mist, use process enclosures, local exhaust ventilation or other engineering controls to keep worker exposure to airborne contaminants below any recommended or statutory limits. The engineering controls also need to keep gas, vapor or dust concentrations below any lower explosive limits. Use explosion-proof ventilation equipment.

# **Environmental exposure** controls

: Emissions from ventilation or work process equipment should be checked to ensure they comply with the requirements of environmental protection legislation. In some cases, fume scrubbers, filters or engineering modifications to the process equipment will be necessary to reduce emissions to acceptable levels.

#### **Individual protection measures**

### **Hygiene measures**

: Wash hands, forearms and face thoroughly after handling chemical products, before eating, smoking and using the lavatory and at the end of the working period. Appropriate techniques should be used to remove potentially contaminated clothing. Wash contaminated clothing before reusing. Ensure that eyewash stations and safety showers are close to the workstation location.

### Eye/face protection

: Safety eyewear complying with an approved standard should be used when a risk assessment indicates this is necessary to avoid exposure to liquid splashes, mists, gases or dusts. If contact is possible, the following protection should be worn, unless the assessment indicates a higher degree of protection: chemical splash goggles. If operating conditions cause high dust concentrations to be produced, use dust goggles.

# Skin protection Hand protection

: Chemical-resistant, impervious gloves complying with an approved standard should be worn at all times when handling chemical products if a risk assessment indicates this is necessary. Considering the parameters specified by the glove manufacturer, check during use that the gloves are still retaining their protective properties. It should be noted that the time to breakthrough for any glove material may be different for different glove manufacturers. In the case of mixtures, consisting of several substances, the protection time of the gloves cannot be accurately estimated.

### **Body protection**

: Personal protective equipment for the body should be selected based on the task being performed and the risks involved and should be approved by a specialist before handling this product.

### Other skin protection

: Appropriate footwear and any additional skin protection measures should be selected based on the task being performed and the risks involved and should be approved by a specialist before handling this product.

### **Respiratory protection**

: Based on the hazard and potential for exposure, select a respirator that meets the appropriate standard or certification. Respirators must be used according to a respiratory protection program to ensure proper fitting, training, and other important aspects of use.



Safety Data Sheet

SDS Title: Tigecycline for Injection Safety Data Sheet	SDS Number: SDS-000054	Page Number: Page 8 of 16
Function:	Effective Date:	Version number:
Regulatory Affairs	March 01, 2024	2.0

# Section 9. Physical and chemical properties

The conditions of measurement of all properties are at standard temperature and pressure unless otherwise indicated.

**Appearance** 

Physical state : Solid. [Lyophilized/Powder.]

Color : Orange.

Odor : Not available.

Odor threshold : Not available.

pH : 4.5 to 5.5 [Conc. (% w/w): 1%] [Reconstitution solution]

Melting point: Not available.Boiling point, initial boiling: Not available.

Boiling point, initial boiling point, and boiling range

Flash point : Not applicable.
Evaporation rate : Not available.
Flammability : Not available.
Lower and upper explosion : Not applicable.

limit/flammability limit

Vapor pressure : Not available.

Relative vapor density : Not applicable.

Relative density : Not available.

Density : Not available.

Solubility(ies) : Media Result
water Very slightly soluble

Miscible with water : No.

Partition coefficient: n-

octanol/water

: Not applicable.

Auto-ignition temperature : Not applicable.

Decomposition temperature : Not available.

SADT : Not available.

Viscosity : Not applicable.

Flow time (ISO 2431) : Not available.

**Particle characteristics** 

**Median particle size** : Not available.

**Other information** 

Physical/chemical : No additional information.

properties comments



**Safety Data Sheet** 

SDS Title: Tigecycline for Injection Safety Data Sheet	SDS Number: SDS-000054	Page Number: Page 9 of 16
Function: Regulatory Affairs	Effective Date: March 01, 2024	Version number: 2.0

## Section 10. Stability and reactivity

Reactivity

: No specific test data related to reactivity available for this product or its ingredients.

**Chemical stability** 

: The product is stable.

Possibility of hazardous reactions

: Under normal conditions of storage and use, hazardous reactions will not occur.

Under normal conditions of storage and use, hazardous polymerization will not occur.

**Conditions to avoid** 

: Avoid the creation of dust when handling and avoid all possible sources of ignition (spark or flame). Take precautionary measures against electrostatic discharges. To avoid fire or explosion, dissipate static electricity during transfer by grounding and bonding containers and equipment before transferring material. Prevent dust accumulation.

**Incompatible materials** 

: Reactive or incompatible with the following materials: oxidizing materials

Hazardous decomposition products

: Under normal conditions of storage and use, hazardous decomposition products should not be produced.

# Section 11. Toxicological information

### Information on toxicological effects

### **Acute toxicity**

Product/ingredient name	Result	Species	Dose	Exposure
Hydrochloric acid	LC50 Inhalation Gas.	Rat	3124 ppm	1 hours

### **Irritation/Corrosion**

Product/ingredient name	Result	Species	Score	Exposure	Observation
Hydrochloric acid	Eyes - Mild irritant	Rabbit	-	0.5 minutes 5	-
•				mg	
sodium hydroxide	Eyes - Mild irritant	Rabbit	_	400 ug	-
•	Eyes - Severe irritant	Rabbit	-	1 %	-
	Eyes - Severe irritant	Rabbit	_	0.5 minutes 1	-
				mg	
	Eyes - Severe irritant	Rabbit	-	24 hours 50	-
	-			ug	
	Skin - Severe irritant	Rabbit	-	24 hours 500	-
				mg	

### **Sensitization**

Not available.



Safety Data Sheet

SDS Title: Tigecycline for Injection Safety Data Sheet	Page Number: Page 10 of 16
Function: Regulatory Affairs	Version number: 2.0

### **Section 11. Toxicological information**

**Mutagenicity** 

**Conclusion/Summary**: Not available.

**Carcinogenicity** 

**Conclusion/Summary**: Not available.

**Classification** 

Product/ingredient name	OSHA	IARC	NTP
Hydrochloric acid	-	3	-

Reproductive toxicity

**Conclusion/Summary**: Not available.

**Teratogenicity** 

Conclusion/Summary : Not available.

Specific target organ toxicity (single exposure)

Name	Category	Route of exposure	Target organs
Hydrochloric acid	Category	3 -	Respiratory tract irritation
sodium hydroxide	Category	3 -	Respiratory tract irritation

Specific target organ toxicity (repeated exposure)

Not available.

**Aspiration hazard** 

Not available.

Information on the likely routes of exposure

: Routes of entry anticipated: Oral, Dermal, Inhalation, Eyes.

Potential acute health effects

**Eye contact** : Causes serious eye irritation.

Inhalation : Exposure to airborne concentrations above statutory or recommended exposure limits

may cause irritation of the nose, throat and lungs.

Skin contactIngestionNo known significant effects or critical hazards.No known significant effects or critical hazards.

Symptoms related to the physical, chemical and toxicological characteristics

**Eye contact** : Adverse symptoms may include the following:

pain or irritation watering

redness



### Meitheal Pharmaceuticals, Inc. Safety Data Sheet

	SDS Number: SDS-000054	Page Number: Page 11 of 16
Function:	Effective Date:	Version number:
Regulatory Affairs	March 01, 2024	2.0

# **Section 11. Toxicological information**

**Inhalation** : Adverse symptoms may include the following:

respiratory tract irritation

coughing

reduced fetal weight increase in fetal deaths skeletal malformations

**Skin contact**: Adverse symptoms may include the following:

reduced fetal weight increase in fetal deaths skeletal malformations

**Ingestion**: Adverse symptoms may include the following:

reduced fetal weight increase in fetal deaths skeletal malformations

### Delayed and immediate effects and also chronic effects from short and long term exposure

**Short term exposure** 

**Potential immediate** 

: Not available.

effects

Potential delayed effects

: Not available.

Long term exposure

Potential immediate : Not available.

effects

Potential delayed effects: Not available.

Potential chronic health effects

**General** : Repeated or prolonged inhalation of dust may lead to chronic respiratory irritation.

Carcinogenicity : No known significant effects or critical hazards.

Mutagenicity : No known significant effects or critical hazards.

**Reproductive toxicity**: May damage fertility or the unborn child.

### **Numerical measures of toxicity**

### **Acute toxicity estimates**

	Oral (mg/ kg)	(mg/kg)	Inhalation (gases) (ppm)	(vapors)	Inhalation (dusts and mists) (mg/ I)
Hydrochloric acid	N/A	N/A	1562	N/A	N/A



**Safety Data Sheet** 

SDS Title: Tigecycline for Injection Safety Data Sheet	SDS Number: SDS-000054	Page Number: Page 12 of 16
Function:	Effective Date:	Version number:
Regulatory Affairs	March 01, 2024	2.0

# Section 12. Ecological information

### **Toxicity**

Product/ingredient name	Result	Species	Exposure
Hydrochloric acid	Acute LC50 240000 μg/l Marine water	Crustaceans - Carcinus maenas - Adult	48 hours
sodium hydroxide	Acute LC50 282 ppm Fresh water Acute EC50 40.38 mg/l Fresh water	Fish - Gambusia affinis - Adult Crustaceans - Ceriodaphnia dubia - Neonate	96 hours 48 hours
	Acute LC50 125 ppm Fresh water	Fish - <i>Gambusia affinis</i> - Adult	96 hours

Conclusion/Summary : Not available.

### Persistence and degradability

Not available.

### **Bioaccumulative potential**

Not available.

### **Mobility in soil**

Soil/water partition coefficient (Koc)

: Not available.

Other adverse effects : No known significant effects or critical hazards.

### Section 13. Disposal considerations

### **Disposal methods**

: The generation of waste should be avoided or minimized wherever possible. Disposal of this product, solutions and any by-products should at all times comply with the requirements of environmental protection and waste disposal legislation and any regional local authority requirements. Dispose of surplus and non-recyclable products via a licensed waste disposal contractor. Waste should not be disposed of untreated to the sewer unless fully compliant with the requirements of all authorities with jurisdiction. Waste packaging should be recycled. Incineration or landfill should only be considered when recycling is not feasible. This material and its container must be disposed of in a safe way. Care should be taken when handling emptied containers that have not been cleaned or rinsed out. Empty containers or liners may retain some product residues. Avoid dispersal of spilled material and runoff and contact with soil, waterways, drains and sewers.



**Safety Data Sheet** 

	SDS-000054	Page Number: Page 13 of 16
Function:	Effective Date:	Version number:
Regulatory Affairs	March 01, 2024	2.0

# **Section 14. Transport information**

	DOT Classification	IMDG	IATA
UN number	Not regulated.	Not regulated.	Not regulated.
UN proper shipping name	-	-	-
Transport hazard class(es)	-	-	-
Packing group	-	- 0,	-
Environmental hazards	No.	No.	No.

### **Additional information**

Special precautions for user : Transport within user's premises: always transport in closed containers that are

upright and secure. Ensure that persons transporting the product know what to do in the

event of an accident or spillage.

Transport in bulk according : Not available.

to IMO instruments

# Section 15. Regulatory information

**U.S. Federal regulations** : TSCA 8(a) CDR Exempt/Partial exemption: Not determined

United States inventory (TSCA 8b): Not determined.

Clean Water Act (CWA) 311: Hydrochloric acid; sodium hydroxide

Clean Air Act Section 112

(b) Hazardous Air **Pollutants (HAPs)**  : Listed

Clean Air Act Section 602

Class I Substances

: Not listed

**Clean Air Act Section 602** 

Class II Substances

: Not listed

**DEA List I Chemicals** 

: Not listed

(Precursor Chemicals)

: Not listed

**DEA List II Chemicals** (Essential Chemicals)

**SARA 302/304** 

Composition/information on ingredients



**Safety Data Sheet** 

SDS Title:	SDS Number:	Page Number:
Tigecycline for Injection Safety Data Sheet	SDS-000054	Page 14 of 16
Function:	Effective Date:	Version number:
Regulatory Affairs	March 01, 2024	2.0

### **Section 15. Regulatory information**

	SARA 302 TPQ SARA 304 RQ		SARA 302 TPQ		Q	
Name	%	EHS	(lbs)	(gallons)	(lbs)	(gallons)
Hydrochloric acid	≤0.1	Yes.	500	-	5000	-

**SARA 304 RQ** : 5555555.6 lbs / 2522222.2 kg

**SARA 311/312** 

Classification : COMBUSTIBLE DUSTS

EYE IRRITATION - Category 2A

TOXIC TO REPRODUCTION - Category 1B

### Composition/information on ingredients

Name	%	Classification
tigecycline	≥25 - ≤50	EYE IRRITATION - Category 2A
		TOXIC TO REPRODUCTION - Category 1B
Hydrochloric acid	≤0.1	CORROSIVE TO METALS - Category 1
		ACUTE TOXICITY (inhalation) - Category 3
		SKIN CORROSION - Category 1B
		SERIOUS EYE DAMAGE - Category 1
		SPECIFIC TARGET ORGAN TOXICITY (SINGLE EXPOSURE)
		(Respiratory tract irritation) - Category 3
		HNOC - Corrosive to digestive tract
sodium hydroxide	≤0.1	CORROSIVE TO METALS - Category 1
		SKIN CORROSION - Category 1A
		SERIOUS EYE DAMAGE - Category 1
		SPECIFIC TARGET ORGAN TOXICITY (SINGLE EXPOSURE)
		(Respiratory tract irritation) - Category 3
		HNOC - Corrosive to digestive tract [severe]

### **SARA 313**

Not applicable.

### **State regulations**

Massachusetts: None of the components are listed.New York: None of the components are listed.New Jersey: None of the components are listed.Pennsylvania: None of the components are listed.

California Prop. 65

This product does not require a Safe Harbor warning under California Prop. 65.

### **International regulations**

Chemical Weapon Convention List Schedules I, II & III Chemicals

Not listed.

### **Montreal Protocol**

Not listed.



**Safety Data Sheet** 

SDS Title: Tigecycline for Injection Safety Data Sheet	SDS Number: SDS-000054	Page Number: Page 15 of 16
Function:	Effective Date:	Version number:
Regulatory Affairs	March 01, 2024	2.0

### Section 15. Regulatory information

**Stockholm Convention on Persistent Organic Pollutants** 

Not listed.

Rotterdam Convention on Prior Informed Consent (PIC)

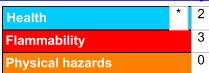
Not listed.

**UNECE Aarhus Protocol on POPs and Heavy Metals** 

Not listed.

### Section 16. Other information

**Hazardous Material Information System (U.S.A.)** 



Caution: HMIS® ratings are based on a 0-4 rating scale, with 0 representing minimal hazards or risks, and 4 representing significant hazards or risks. Although HMIS® ratings and the associated label are not required on SDSs or products leaving a facility under 29 CFR 1910.1200, the preparer may choose to provide them. HMIS® ratings are to be used with a fully implemented HMIS® program. HMIS® is a registered trademark and service mark of the American Coatings Association, Inc.

The customer is responsible for determining the PPE code for this material. For more information on HMIS® Personal Protective Equipment (PPE) codes, consult the HMIS® Implementation Manual.

### National Fire Protection Association (U.S.A.)



### Procedure used to derive the classification

Classification	Justification
COMBUSTIBLE DUSTS	On basis of test data
EYE IRRITATION - Category 2A	Calculation method
TOXIC TO REPRODUCTION - Category 1B	Calculation method

### **History**

Date of issue/Date of : 03/01/2024

revision

Date of previous issue : 03/03/2022

Version : 2.0

Prepared by : Sphera Solutions



Safety Data Sheet

	SDS Number: SDS-000054	Page Number: Page 16 of 16
Function: Regulatory Affairs	Effective Date: March 01, 2024	Version number: 2.0

### Section 16. Other information

Key to abbreviations

: ATE = Acute Toxicity Estimate

AMP = Acceptable maximum peak above the acceptable ceiling concentration for an

8-hr shift

BCF = Bioconcentration Factor

GHS = Globally Harmonized System of Classification and Labelling of Chemicals

IATA = International Air Transport Association

IBC = Intermediate Bulk Container

IMDG = International Maritime Dangerous Goods

LogPow = logarithm of the octanol/water partition coefficient

MARPOL = International Convention for the Prevention of Pollution From Ships, 1973 as

modified by the Protocol of 1978. ("Marpol" = marine pollution)

N/A = Not available UN = United Nations

References

HCS (U.S.A.)- Hazard Communication Standard

International transport regulations

Indicates information that has changed from previously issued version.

### **Notice to reader**

To the best of our knowledge, the information contained herein is accurate. However, neither the above-named supplier, nor any of its subsidiaries, assumes any liability whatsoever for the accuracy or completeness of the information contained herein.

Final determination of suitability of any material is the sole responsibility of the user. All materials may present unknown hazards and should be used with caution. Although certain hazards are described herein, we cannot guarantee that these are the only hazards that exist.