

SDS Title: Tigecycline for Injection Safety Data Sheet	SDS Number: SDS-000054	Page Number: Page 1 of 17
Function: Regulatory Affairs	Effective Date: February 19, 2026	Version number: 3.0

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 substance or mixture :
H319 COMBUSTIBLE DUSTS
H360 EYE IRRITATION - Category 2A
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.

SDS Title: Tigecycline for Injection Safety Data Sheet	SDS Number: SDS-000054	Page Number: Page 2 of 17
Function: Regulatory Affairs	Effective Date: February 19, 2026	Version number: 3.0

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.
Response	: P308 + P313 - IF exposed or concerned: Get medical advice or attention. 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.
Storage	: P405 - Store locked up.
Disposal	: P501 - Dispose of contents and container in accordance with all local, regional, national and international regulations.
Supplemental label elements	: Keep container tightly closed. Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking. Prevent dust accumulation.
Hazards not otherwise classified	: None known.
Hazards identified when used	: No known significant effects or critical hazards.

Section 3. Composition/information on ingredients

Substance/mixture	: Mixture
Other means of identification	: Not available.

Ingredient name	Synonyms	%	Identifiers
D-Glucose, 4-O-β-D-galactopyranosyl-, hydrate (1:1)	Lactose monohydrate	≥60 - ≤80	CAS: 64044-51-5
tigecycline	-	≥15 - ≤40	CAS: 220620-09-7
Hydrochloric acid	-	≤0.1	CAS: 7647-01-0
sodium hydroxide	-	≤0.1	CAS: 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.
--------------------	---

SDS Title: Tigecycline for Injection Safety Data Sheet	SDS Number: SDS-000054	Page Number: Page 3 of 17
Function: Regulatory Affairs	Effective Date: February 19, 2026	Version number: 3.0

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 contact** : No known significant effects or critical hazards.
- Ingestion** : 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

SDS Title: Tigecycline for Injection Safety Data Sheet	SDS Number: SDS-000054	Page Number: Page 4 of 17
Function: Regulatory Affairs	Effective Date: February 19, 2026	Version number: 3.0

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 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.

SDS Title: Tigecycline for Injection Safety Data Sheet	SDS Number: SDS-000054	Page Number: Page 5 of 17
Function: Regulatory Affairs	Effective Date: February 19, 2026	Version number: 3.0

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.

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.

SDS Title: Tigecycline for Injection Safety Data Sheet	SDS Number: SDS-000054	Page Number: Page 6 of 17
Function: Regulatory Affairs	Effective Date: February 19, 2026	Version number: 3.0

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.

Conditions for safe storage, including any incompatibilities : 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, 1/2025) A4. C: 2 ppm. NIOSH REL (United States, 10/2020) CEIL: 5 ppm. CEIL: 7 mg/m ³ . OSHA PEL (United States, 5/2018) CEIL: 5 ppm. CEIL: 7 mg/m ³ . CAL OSHA PEL (United States, 1/2025) C: 2 ppm. TWA 8 hours: 0.45 mg/m ³ . TWA 8 hours: 0.3 ppm.
sodium hydroxide	ACGIH TLV (United States, 1/2025) C: 2 mg/m ³ . NIOSH REL (United States, 10/2020) CEIL: 2 mg/m ³ . OSHA PEL (United States, 5/2018) TWA 8 hours: 2 mg/m ³ . CAL OSHA PEL (United States, 1/2025) C: 2 mg/m ³ .

Biological exposure indices

None known.

SDS Title: Tigecycline for Injection Safety Data Sheet	SDS Number: SDS-000054	Page Number: Page 7 of 17
Function: Regulatory Affairs	Effective Date: February 19, 2026	Version number: 3.0

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.

SDS Title: Tigecycline for Injection Safety Data Sheet	SDS Number: SDS-000054	Page Number: Page 8 of 17
Function: Regulatory Affairs	Effective Date: February 19, 2026	Version number: 3.0

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 or initial boiling point and boiling range** : Not available.
- Flash point** : Not applicable.
- Evaporation rate** : Not available.
- Flammability** : Not available.
- Lower and upper explosion limit/flammability limit** : Not applicable.
- 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** : Dynamic (room temperature): Not available.
Kinematic (room temperature): Not available.
Kinematic (40°C (104°F)): Not available.

Particle characteristics

- Median particle size** : Not available.

Other information

- Physical/chemical properties comments** : No additional information.

SDS Title: Tigecycline for Injection Safety Data Sheet	SDS Number: SDS-000054	Page Number: Page 9 of 17
Function: Regulatory Affairs	Effective Date: February 19, 2026	Version number: 3.0

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

Conclusion/Summary [Product] : Not available.

Skin corrosion/irritation

Product/ingredient name

sodium hydroxide

Result

Rabbit - Skin - Severe irritant

Duration of treatment/exposure: 24

hours

Amount/concentration applied: 500 mg

Conclusion/Summary [Product] : Not available.

Serious eye damage/eye irritation

Product/ingredient name

Result

SDS Title: Tigecycline for Injection Safety Data Sheet	SDS Number: SDS-000054	Page Number: Page 10 of 17
Function: Regulatory Affairs	Effective Date: February 19, 2026	Version number: 3.0

Section 11. Toxicological information

Hydrochloric acid

Rabbit - Eyes - Mild irritant

Duration of treatment/exposure: 0.5 minutes

Amount/concentration applied: 5 mg

sodium hydroxide

Rabbit - Eyes - Mild irritant

Amount/concentration applied: 400 ug

Rabbit - Eyes - Severe irritant

Duration of treatment/exposure: 24 hours

Amount/concentration applied: 50 ug

Rabbit - Eyes - Severe irritant

Amount/concentration applied: 1 %

Rabbit - Eyes - Severe irritant

Duration of treatment/exposure: 24 hours

Amount/concentration applied: 1 mg

Rabbit - Eyes - Severe irritant

Duration of treatment/exposure: 0.5 minutes

Amount/concentration applied: 1 mg

Conclusion/Summary [Product]

: Not available.

Respiratory corrosion/irritation

Conclusion/Summary [Product]

: Not available.

Respiratory or skin sensitization

Skin

Conclusion/Summary [Product]

: Not available.

Respiratory

Conclusion/Summary [Product]

: Not available.

Germ cell mutagenicity

Conclusion/Summary [Product]

: Not available.

Carcinogenicity

Conclusion/Summary [Product]

: Not available.

SDS Title: Tigecycline for Injection Safety Data Sheet	SDS Number: SDS-000054	Page Number: Page 11 of 17
Function: Regulatory Affairs	Effective Date: February 19, 2026	Version number: 3.0

Section 11. Toxicological information

Classification

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

Reproductive toxicity

Conclusion/Summary [Product] : Not available.

Specific target organ toxicity (single exposure)

Product/ingredient name	Result
Hydrochloric acid	SPECIFIC TARGET ORGAN TOXICITY (SINGLE EXPOSURE) (Respiratory tract irritation) - Category 3
sodium hydroxide	SPECIFIC TARGET ORGAN TOXICITY (SINGLE EXPOSURE) (Respiratory tract irritation) - Category 3

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 contact** : No known significant effects or critical hazards.
- Ingestion** : 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

SDS Title: Tigecycline for Injection Safety Data Sheet	SDS Number: SDS-000054	Page Number: Page 12 of 17
Function: Regulatory Affairs	Effective Date: February 19, 2026	Version number: 3.0

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 effects : Not available.

Potential delayed effects : Not available.

Long term exposure

Potential immediate effects : Not available.

Potential delayed effects : Not available.

Potential chronic health effects

Conclusion/Summary [Product] : Not available.

- 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

N/A

SDS Title: Tigecycline for Injection Safety Data Sheet	SDS Number: SDS-000054	Page Number: Page 13 of 17
Function: Regulatory Affairs	Effective Date: February 19, 2026	Version number: 3.0

Section 12. Ecological information

Toxicity

Product/ingredient name

Result

Hydrochloric acid

Acute - LC50 - Marine water

Effect: Mortality

Crustaceans - Green crab - *Carcinus maenas* - Adult
240 mg/l [48 hours]

Acute - LC50 - Fresh water

Effect: Mortality

Fish - Western mosquitofish - *Gambusia affinis* - Adult
282 ppm [96 hours]

sodium hydroxide

Acute - LC50 - Fresh water

Effect: Mortality

Fish - Western mosquitofish - *Gambusia affinis* - Adult
125 ppm [96 hours]

Acute - EC50 - Fresh water

Effect: Intoxication

Crustaceans - Water flea - *Ceriodaphnia dubia* - Neonate
Age: <24 hours
40.38 mg/l [48 hours]

Conclusion/Summary [Product]

: Not available.

Persistence and degradability

Conclusion/Summary [Product]

: Not available.

Bioaccumulative potential

Product/ingredient name	LogP_{ow}	BCF	Potential
tigecycline	0.8	-	Low

Mobility in soil

Soil/Water partition coefficient

: Not available.

Other adverse effects

No known significant effects or critical hazards.

SDS Title: Tigecycline for Injection Safety Data Sheet	SDS Number: SDS-000054	Page Number: Page 14 of 17
Function: Regulatory Affairs	Effective Date: February 19, 2026	Version number: 3.0

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.

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	-	-	-
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 to IMO instruments : Not available.



SDS Title: Tigecycline for Injection Safety Data Sheet	SDS Number: SDS-000054	Page Number: Page 15 of 17
Function: Regulatory Affairs	Effective Date: February 19, 2026	Version number: 3.0

Section 15. Regulatory information

U.S. Federal regulations : TSCA 8(a) CDR Exempt/Partial exemption: Not determined
 United States inventory (TSCA 8b): All components are active or exempted.
 Clean Water Act (CWA) 311: Hydrochloric acid; sodium hydroxide

TSCA 12(b) - Chemical export notification

Not applicable.

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 (Precursor Chemicals) : Not listed
DEA List II Chemicals (Essential Chemicals) : Not listed

SARA 302/304

Composition/information on ingredients

Name	%	EHS	SARA 302 TPQ		SARA 304 RQ	
			(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	≥15 - ≤40	EYE IRRITATION - Category 2A TOXIC TO REPRODUCTION - Category 1B
Hydrochloric acid	≤0.1	CORROSIVE TO METALS - Category 1 SKIN CORROSION - Category 1B SERIOUS EYE DAMAGE - Category 1 SPECIFIC TARGET ORGAN TOXICITY (SINGLE EXPOSURE) (Respiratory tract irritation) - Category 3
sodium hydroxide	≤0.1	HNOC - Corrosive to digestive tract CORROSIVE TO METALS - Category 1 SKIN CORROSION - Category 1A SERIOUS EYE DAMAGE - Category 1



SDS Title: Tigecycline for Injection Safety Data Sheet	SDS Number: SDS-000054	Page Number: Page 16 of 17
Function: Regulatory Affairs	Effective Date: February 19, 2026	Version number: 3.0

Section 15. Regulatory information

		SPECIFIC TARGET ORGAN TOXICITY (SINGLE EXPOSURE) (Respiratory tract irritation) - Category 3 HNO3 - 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.

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.)

Health	*	2
Flammability		3
Physical hazards		0

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.)

This document contains proprietary information. It must not be reproduced or disclosed to others without prior written approval. The user is responsible for checking the current effective date before using this document.

SDS Title: Tigecycline for Injection Safety Data Sheet	SDS Number: SDS-000054	Page Number: Page 17 of 17
Function: Regulatory Affairs	Effective Date: February 19, 2026	Version number: 3.0

Section 16. Other information



Procedure used to derive the classification

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

History

- Date of issue/Date of revision** : 02/19/2026
- Date of previous issue** : 03/01/2024
- Version** : 3.0
- Prepared by** : Sphera Solutions
- Key to abbreviations** :
 - ATE = Acute Toxicity Estimate
 - 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
 - IMO = International Maritime Organization
 - 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
 - SGG = Segregation Group
 - TDG = Transportation of Dangerous Goods
 - 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.