



SAFETY DATA SHEET

Revision date 15-Jun-2025

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Section 1: IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND OF THE COMPANY/UNDERTAKING

1.1. Product identifier

Product Name	Tigecycline for Injection
Product Code(s)	WP00030
Synonyms	Tigecycline For Injection for intravenous use
Trade Name:	TYGACIL; TYZEL
Compound Number	WAY-156936; GAR-936
Chemical Family:	Tetracycline derivative

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

Recommended Use	Pharmaceutical product used as antibiotic agent
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1.3. Details of the supplier of the safety data sheet

Pfizer Inc 66 Hudson Boulevard East New York, New York 10001 1-800-879-3477	Pfizer Ireland Pharmaceuticals OSG Building Ringaskiddy, Co. Cork. Ireland +353 21 4378701
E-mail address	pfizer-MSDS@pfizer.com

1.4. Emergency telephone number

Emergency Telephone	Chemtrec 1-800-424-9300 International Chemtrec (24 hours):+1-703-527-3887
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Section 2: HAZARDS IDENTIFICATION

2.1. Classification of the substance or mixture

GHS - Classification.

Serious eye damage/eye irritation	Category 1 - (H318)
Skin sensitization	Category 1 - (H317)
Reproductive toxicity	Category 1A - (H360D)
Hazardous to the aquatic environment - acute	Category 1 - (H400)
Hazardous to the aquatic environment - chronic	Category 1 - (H410)

OSHA Classification

Hazards not otherwise classified (HNOC)

Not applicable

Hazards classified under paragraph (d)(1)(ii) of 1910.1200

Not applicable

2.2. Label elements

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Signal word

Danger

Hazard statements

H317 - May cause an allergic skin reaction
H318 - Causes serious eye damage
H360D - May damage the unborn child
H410 - Very toxic to aquatic life with long lasting effects

Precautionary Statements - EU (§28, 1272/2008)

P201 - Obtain special instructions before use
P202 - Do not handle until all safety precautions have been read and understood
P261 - Avoid breathing dust/fume/gas/mist/vapors/spray
P272 - Contaminated work clothing should not be allowed out of the workplace
P273 - Avoid release to the environment
P280 - Wear protective gloves/protective clothing/eye protection/face protection
P305 + P351 + P338 - IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing
P310 - Immediately call a POISON CENTER or doctor/physician
P333 + P313 - If skin irritation or rash occurs: Get medical advice/attention
P362 + P364 - Take off contaminated clothing and wash it before reuse
P308 + P313 - IF exposed or concerned: Get medical advice/attention
P391 - Collect spillage
P405 - Store locked up
P501 - Dispose of contents/container in accordance with local, regional, national, and international regulations as applicable
P302 + P352 - IF ON SKIN: Wash with plenty of soap and water

2.3. Other hazards

Other hazards

An Occupational Exposure Value has been established for one or more of the ingredients (see Section 8).

PBT & vPvB

The product does not contain any substance(s) classified as PBT or vPvB.

Endocrine Disruptor Information

This product does not contain any known or suspected endocrine disruptors.

Note:

This document has been prepared in accordance with standards for workplace safety, which require the inclusion of all known hazards of the product or its ingredients regardless of the potential risk. The precautionary statements and warnings included may not apply in all cases. Your needs may vary depending upon the potential for exposure in your workplace.

Section 3: COMPOSITION/INFORMATION ON INGREDIENTS

3.1 Substances

Substances

Not applicable

3.2 Mixtures

Hazardous

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Chemical name	Weight-%	REACH registration number	EC No (EU Index No)	Classification according to Regulation (EC) No. 1272/2008 [CLP]	Specific concentration limit (SCL)	M-Factor	M-Factor (long-term)
Tigecycline (CAS #: 220620-09-7)	30 - 33		Not Listed	Repr. 1A(H360D) Skin Sens.1(H317) Eye Dam.1(H318) Aquatic Acute 1 (H400) Aquatic Chronic 1 (H410)	Not classified	1	1
Sodium hydroxide (CAS #: 1310-73-2)	**	-	215-185-5 (011-002-00-6)	Skin Corr.1A (H314)	Eye Irrit. 2 :: 0.5%<=C<2% Skin Corr. 1A :: C>=5% Skin Corr. 1B :: 2%<=C<5% Skin Irrit. 2 :: 0.5%<=C<2%	No data available	No data available
+ Hydrochloric Acid (CAS #: 7647-01-0)	**	-	231-595-7 (017-002-00-2) (017-002-01-X)	Press. Gas Skin Corr. 1A (H314) Acute Tox. 3 (H331)	Eye Irrit. 2 :: 10%<=C<25% Skin Corr. 1B :: C>=25% Skin Irrit. 2 :: 10%<=C<25% STOT SE 3 :: C>=10%	No data available	No data available

NonHazardous

Chemical name	Weight-%	REACH registration number	EC No (EU Index No)	Classification according to Regulation (EC) No. 1272/2008 [CLP]	Specific concentration limit (SCL)	M-Factor	M-Factor (long-term)
Lactose NF, monohydrate (CAS #: 64044-51-5)	*	-	Not Listed	Not classified	Not classified	No data available	No data available

Full text of H- and EUH-phrases: see section 16

Acute Toxicity Estimate

Chemical name	Oral LD50 mg/kg	Dermal LD50 mg/kg	Inhalation LC50 - 4 hour - dust/mist - mg/L	Inhalation LC50 - 4 hour - vapor - mg/L	Inhalation LC50 - 4 hour - gas - ppm
Sodium hydroxide 1310-73-2	325	1350	No data available	No data available	No data available
+ Hydrochloric Acid 7647-01-0	238	5010	No data available	No data available	563.3022

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This product does not contain candidate substances of very high concern at a concentration $\geq 0.1\%$ (Regulation (EC) No. 1907/2006 (REACH), Article 59).

Additional information

+ Substance with a Union workplace exposure limit

* Proprietary

** to adjust pH

Non-hazardous ingredients provided for completeness. Ingredient(s) indicated as hazardous have been assessed under standards for workplace safety. In accordance with 29 CFR 1910.1200, the exact percentage composition of this mixture has been withheld as a trade secret.

Section 4: FIRST AID MEASURES

4.1. Description of first aid measures

Inhalation	Remove to fresh air. Seek immediate medical attention/advice.
Eye contact	Rinse thoroughly with plenty of water for at least 15 minutes, lifting lower and upper eyelids. Consult a physician.
Skin contact	Remove contaminated clothing. Flush area with large amounts of water. Use soap. Seek medical attention.
Ingestion	Never give anything by mouth to an unconscious person. Wash out mouth with water. Do not induce vomiting unless directed by medical personnel. Seek medical attention immediately.

4.2. Most important symptoms and effects, both acute and delayed

Most important symptoms and effects	For information on potential signs and symptoms of exposure, See Section 2 - Hazards Identification and/or Section 11 - Toxicological Information.
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4.3. Indication of any immediate medical attention and special treatment needed

Note to physicians	None.
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Section 5: FIRE-FIGHTING MEASURES

5.1. Extinguishing media

Suitable Extinguishing Media	Dry chemical, CO2 or water spray.
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5.2. Special hazards arising from the substance or mixture

Specific hazards arising from the chemical	Fine particles (such as dust and mists) may fuel fires/explosions.
Hazardous combustion products	Emits toxic fumes of carbon monoxide, carbon dioxide, and nitrogen oxides.
Explosion data	
Sensitivity to mechanical impact	No information available.
Sensitivity to static discharge	No information available.

5.3. Advice for firefighters

Special protective equipment and	Firefighters should wear self-contained breathing apparatus and full firefighting turnout gear.
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precautions for fire-fighters Use personal protection equipment.

Section 6: ACCIDENTAL RELEASE MEASURES

6.1. Personal precautions, protective equipment and emergency procedures

Personal precautions Personnel involved in clean-up should wear appropriate personal protective equipment (see Section 8). Minimize exposure.
For emergency responders Use personal protection recommended in Section 8.

6.2. Environmental precautions

Environmental precautions Place waste in an appropriately labeled, sealed container for disposal. Care should be taken to avoid environmental release.

6.3. Methods and material for containment and cleaning up

Methods for containment Prevent further leakage or spillage if safe to do so.
Methods for cleaning up Contain the source of the spill or leak. Collect spilled material by a method that controls dust generation. Avoid use of a filtered vacuum to clean spills of dry solids. Clean contaminated surface thoroughly.
Prevention of secondary hazards Clean contaminated objects and areas thoroughly observing environmental regulations.

6.4. Reference to other sections

Reference to other sections See section 8 for more information. See section 13 for more information.

Section 7: HANDLING AND STORAGE

7.1. Precautions for safe handling

Advice on safe handling Minimize dust generation and accumulation. Avoid breathing dust/fume/gas/mist/vapors/spray. Avoid contact with skin, eyes or clothing. When handling, use appropriate personal protective equipment (see Section 8). Wash thoroughly after handling. Releases to the environment should be avoided. Review and implement appropriate technical and procedural waste water and waste disposal measures to prevent occupational exposure or environmental releases. Potential points of process emissions of this material to the atmosphere should be controlled with dust collectors, HEPA filtration systems or other equivalent controls.
General hygiene considerations Handle in accordance with good industrial hygiene and safety practice.

7.2. Conditions for safe storage, including any incompatibilities

Storage Conditions Store as directed by product packaging.

7.3. Specific end use(s)

Specific use(s) Pharmaceutical drug product.

Section 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1. Control parameters

Exposure Limits

Refer to available public information for specific member state Occupational Exposure Limits.

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Pfizer OEL TWA-8 Hr: 100 µg/m³, Sensitizer,, Severe Eye Irritant

Tigecycline

Germany TRGS

DS

RS

Sodium hydroxide

ACGIH OEL (Ceiling)

2 mg/m³

ACGIH TLV

Ceiling: 2 mg/m³

Austria

TWA-TMW: 2 mg/m³; inhalable fraction

STEL-KZGW: 4 mg/m³ (8 X 5 min); inhalable fraction

Bulgaria

TWA: 2.0 mg/m³; alkaline aerosols

Czech Republic

1 mg/m³

Ceiling: 2 mg/m³

Denmark

Ceiling: 2 mg/m³;

Estonia

TWA: 1 mg/m³;

STEL: 2 mg/m³;

Finland

Ceiling: 2 mg/m³;

France

2 mg/m³

Hungary

TWA-AK: 1 mg/m³;

STEL-CK: 2 mg/m³;

Ireland

STEL: 2 mg/m³;

Ceiling Limit Value

2 mg/m³

Latvia

TWA: 0.5 mg/m³;

Poland

TWA-NDS: 0.5 mg/m³;

STEL-NDSch: 1 mg/m³;

Romania

TWA: 1 mg/m³;

STEL: 3 mg/m³;

Slovakia

TWA: 2 mg/m³;

Spain

STEL (VLA-EC): 2 mg/m³;

Switzerland

TWA-MAK: 2 mg/m³; inhalable dust

STEL-KZGW: 2 mg/m³; inhalable dust

OSHA PEL

TWA: 2 mg/m³

(vacated) Ceiling: 2 mg/m³

STEL: 2 mg/m³;

United Kingdom

+ Hydrochloric Acid

ACGIH OEL (Ceiling)

2 ppm

ACGIH TLV

Ceiling: 2 ppm

Austria

TWA-TMW: 5 ppm;

TWA-TMW: 8 mg/m³;

STEL-KZGW: 10 ppm (8 X 5 min);

STEL-KZGW: 15 mg/m³ (8 X 5 min);

Bulgaria

TWA: 5 ppm;

TWA: 8.0 mg/m³;

STEL: 10 ppm;

STEL: 15.0 mg/m³;

Czech Republic

8 mg/m³

Ceiling: 15 mg/m³

Denmark

STEL: 5 ppm;

STEL: 8 mg/m³;

Estonia

TWA: 5 ppm;

TWA: 8 mg/m³;

STEL: 10 ppm;

STEL: 15 mg/m³;

European Union

TWA: 5 ppm;

TWA: 8 mg/m³;

STEL: 10 ppm;

STEL: 15 mg/m³;

Finland

STEL: 5 ppm;

STEL: 7.6 mg/m³;

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Germany DFG	TWA-MAK: 2 ppm; I(2); TWA-MAK: 3.0 mg/m ³ ; I(2); Peak: 4 ppm; Peak: 6 mg/m ³ ;
Germany TRGS	TWA-AGW: 2 ppm (exposure factor 2); TWA-AGW: 3 mg/m ³ (exposure factor 2);
Hungary	TWA-AK: 8 mg/m ³ ; TWA-AK: 5 ppm; STEL-CK: 165 mg/m ³ ; STEL-CK: 10 ppm;
Ireland	TWA: 8 mg/m ³ ; TWA: 5 ppm; STEL: 10 ppm; STEL: 15 mg/m ³ ;
Italy MDLPS	TWA: 5 ppm; TWA: 8 mg/m ³ ; STEL: 10 ppm; STEL: 15 mg/m ³ ;
Ceiling Limit Value	2 ppm 3.0 mg/m ³
Latvia	TWA: 5 ppm; TWA: 8 mg/m ³ ; STEL: 10 ppm; STEL: 15 mg/m ³ ;
Netherlands	TWA: 5 ppm; TWA: 8 mg/m ³ ; STEL: 10 ppm; STEL: 15 mg/m ³ ;
Poland	TWA-NDS: 5 mg/m ³ ; STEL-NDSch: 10 mg/m ³ ;
Romania	TWA: 5 ppm; TWA: 8 mg/m ³ ; STEL: 10 ppm; STEL: 15 mg/m ³ ;
Russia	MAC: 5 mg/m ³
Slovakia	TWA: 5 ppm; TWA: 8.0 mg/m ³ ; Ceiling: 15 mg/m ³ ;
Spain	TWA-(VLA-ED): 5 ppm; TWA-(VLA-ED): 7.6 mg/m ³ ; STEL (VLA-EC): 10 ppm; STEL (VLA-EC): 15 mg/m ³ ;
Switzerland	TWA-MAK: 2 ppm; TWA-MAK: 3 mg/m ³ ; STEL-KZGW: 4 ppm; STEL-KZGW: 6 mg/m ³ ;
U.S. - OSHA - Final PELs - Ceiling Limits	5 ppm 7 mg/m ³
OSHA PEL	Ceiling: 5 ppm Ceiling: 7 mg/m ³ (vacated) Ceiling: 5 ppm (vacated) Ceiling: 7 mg/m ³
United Kingdom	TWA: 1 ppm; gas and aerosol mist TWA: 2 mg/m ³ ; gas and aerosol mist STEL: 5 ppm; gas and aerosol mist STEL: 8 mg/m ³ ; gas and aerosol mist

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8.2. Exposure controls

Engineering controls	Engineering controls should be used as the primary means to control exposures. General room ventilation is adequate unless the process generates dust, mist or aerosols. Keep airborne contamination levels below the exposure limits listed above in this section.
Personal protective equipment	Refer to applicable national standards and regulations in the selection and use of personal protective equipment (PPE). Contact your safety and health professional or safety equipment supplier for assistance in selecting the correct protective clothing/equipment based on an assessment of the workplace conditions, other chemicals used or present in the workplace and specific operational processes.
Eye/face protection	Wear safety goggles if eye contact is possible. (Eye protection must meet the standards in accordance with EN166, ANSI Z87.1 or international equivalent.).
Hand protection	Impervious gloves (e.g. Nitrile, etc.) are recommended if skin contact with drug product is possible and for bulk processing operations. (Protective gloves must meet the standards in accordance with EN374, ASTM F1001 or international equivalent.).
Skin and body protection	Impervious protective clothing is recommended if skin contact with drug product is possible and for bulk processing operations. (Protective clothing must meet the standards in accordance with EN13982, ANSI 103 or international equivalent.).
Respiratory protection	Under normal conditions of use, if the applicable Occupational Exposure Limit (OEL) is exceeded, wear an appropriate respirator with a protection factor sufficient to control exposures to below the OEL (e.g. particulate respirator with a full mask, P3 filter). (Respirators must meet the standards in accordance with EN136, EN143, ASTM F2704-10 or international equivalent.).
Thermal hazards	No information available.
Environmental exposure controls	No information available.

Section 9: PHYSICAL AND CHEMICAL PROPERTIES

9.1. Information on basic physical and chemical properties

Physical state	Powder
Color	Orange
Odor	No information available.
Odor threshold	No information available
Property	Values
Melting point / freezing point	No data available
Boiling point or initial boiling point and boiling range	No data available
Flammability (solid, gas)	No data available
Lower and upper explosion limit/flammability limit	
Lower explosion limit	No data available
Upper explosion limit	No data available
Flash point	No data available
Autoignition temperature	No data available
Decomposition temperature	

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SADT (°C)	No data available
pH	No data available
pH (as aqueous solution)	No data available
Kinematic viscosity	No data available
Dynamic viscosity	No data available
Solubility	No data available
Vapor pressure	No data available
Density and/or relative density	No data available
Bulk density	No data available
Liquid Density	No data available
Vapor density	No data available
Particle characteristics	
Particle Size	No information available
Particle Size Distribution	No information available

Partition Coefficient: (Method, pH, Endpoint, Value)

Tigecycline

Predicted Log P 6.7

9.2. Other information

Molecular formula	Mixture
Molecular weight	Mixture

9.2.1. Information with regard to physical hazard classes

No information available

9.2.2. Other safety characteristics

No information available

Section 10: STABILITY AND REACTIVITY

10.1. Reactivity

Reactivity No information available.

10.2. Chemical stability

Stability Stable under normal conditions.

Explosion data

Sensitivity to mechanical impact No information available.

Sensitivity to static discharge No information available.

10.3. Possibility of hazardous reactions

Possibility of hazardous reactions No information available.

10.4. Conditions to avoid

Conditions to avoid Fine particles (such as dust and mists) may fuel fires/explosions.

10.5. Incompatible materials

Incompatible materials As a precautionary measure, keep away from strong oxidizers.

10.6. Hazardous decomposition products

Hazardous decomposition products No data available.

Section 11: TOXICOLOGICAL INFORMATION

11.1. Information on hazard classes as defined in Regulation (EC) No 1272/2008

General Information: The information included in this section describes the potential hazards of the individual ingredients

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Long Term:

Repeat-dose studies in animals have shown a potential to cause adverse effects on the developing fetus. High doses of tetracyclines can cause a liver condition known as fatty liver. Individuals who suffer from high cholesterol, high triglycerides, or have alcoholic liver disease may be more susceptible. May produce kidney toxicity if kidney damage already exists (based on animal data).

Known Clinical Effects:

May cause effects similar to those seen in clinical use including transient diarrhea, nausea and abdominal pain. Symptoms of chronic exposure to tetracyclines include redness and swelling of the skin, rash, chills, tooth discoloration, yellowing of the skin and eyes, nausea, vomiting, diarrhea, stomach pain, and chest pain. Individuals sensitive to this material or other materials in its chemical class may develop allergic reactions. Wheezing, asthma, low or high blood pressure, dizziness, lung congestion, blood changes (leukocytosis, atypical lymphocytes, toxic granulation of granulocytes and thrombocytopenia purpura), convulsion or shock may also occur. Clinical use of this drug has caused inflammation of the pancreas (pancreatitis) liver effects increased mortality Photosensitivity has been reported in some individuals taking tetracyclines.

Acute toxicity

Based on available data, the classification criteria are not met.

Serious eye damage/eye irritation

Causes serious eye damage. Classification is based on mixture calculation methods based on component data.

Skin corrosion/irritation

Based on available data, the classification criteria are not met.

Respiratory or skin sensitization

May cause an allergic skin reaction. Classification is based on mixture calculation methods based on component data.

STOT - single exposure

Based on available data, the classification criteria are not met.

STOT - repeated exposure

Based on available data, the classification criteria are not met.

Reproductive toxicity

May damage the unborn child. Classification is based on mixture calculation methods based on component data.

Germ cell mutagenicity

Based on available data, the classification criteria are not met.

Carcinogenicity

Based on available data, the classification criteria are not met.

Aspiration hazard

Based on available data, the classification criteria are not met.

Acute Toxicity: (Species, Route, End Point, Dose)

Tigecycline

Mouse (M) IV LD50 124 mg/kg

Mouse (F) IV LD50 98 mg/kg

Rat IV LD50 106 mg/kg

Sodium hydroxide

Mouse IP LD50 40 mg/kg

Chemical name	Oral LD50	Dermal LD50	Inhalation LC50
Sodium hydroxide	= 325 mg/kg (Rat)	= 1350 mg/kg (Rabbit)	-
+ Hydrochloric Acid	238 - 277 mg/kg (Rat)	> 5010 mg/kg (Rabbit)	= 1.68 mg/L (Rat) 1 h

Irritation / Sensitization: (Study Type, Species, Severity)

Tigecycline

Antigenicity- Passive cutaneous anaphylaxis Rat Negative

Antigenicity- Passive cutaneous anaphylaxis Mouse Negative

Skin Corrosivity (*In vitro* , RHE) Not applicable Negative

Eye Irritation (*In vitro* , BCOP) Not applicable Negative

Eye Irritation Rabbit Severe

Skin Sensitization - LLNA Mouse Positive

Sodium hydroxide

Eye Irritation Rabbit Severe

Skin Irritation Rabbit Severe

+ Hydrochloric Acid

Skin irritation Severe

Eye irritation Severe

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Repeated Dose Toxicity: (Duration, Species, Route, Dose, End Point, Target Organ)

Tigecycline

13 Week(s) Dog Intravenous 1.5 mg/kg/day NOAEL Lymphoid tissue
26 Week(s) Rat Intravenous 6 mg/kg/day NOAEL No effects at maximum dose
13 Week(s) Rat Intravenous 2 mg/kg/day NOAEL Lymphoid tissue

Reproduction & Development Toxicity: (Duration, Species, Route, Dose, End Point, Effect(s))

Tigecycline

Embryo / Fetal Development Rabbit Intravenous 4 mg/kg/day NOAEL No effects at maximum dose
Embryo / Fetal Development Rat Intravenous 4 mg/kg/day NOAEL Maternal Toxicity, Fetotoxicity
Embryo / Fetal Development Rabbit Intravenous 4 mg/kg/day NOAEL No effects at maximum dose
Peri-/Postnatal Development Rat Intravenous 12 mg/kg/day NOAEL No effects at maximum dose

Genetic Toxicity: (Study Type, Cell Type/Organism, Result)

Tigecycline

In Vitro Chromosome Aberration Chinese Hamster Ovary (CHO) cells Negative
In Vivo Micronucleus Mouse liver Negative
In Vitro Forward Mutation Assay Mouse Lymphoma Negative

+ Hydrochloric Acid

Bacterial Mutagenicity (Ames) *Salmonella* Negative
In Vivo Micronucleus Rat Negative

Carcinogenicity

None of the components of this formulation are listed as a carcinogen by IARC, NTP or OSHA.

+ Hydrochloric Acid

IARC

Group 3

11.2. Information on other hazards

11.2.1. Endocrine disrupting properties

Endocrine disrupting properties Based on available data, the classification criteria are not met.

11.2.2. Other information

Other adverse effects

No information available.

Section 12: ECOLOGICAL INFORMATION

Environmental Overview:

Very toxic to aquatic life with long lasting effects.

12.1. Toxicity

Aquatic Toxicity: (Species, Method, End Point, Duration, Result)

Tigecycline

Daphnia magna (Water Flea) OECD EC50 48 hours 2 mg/L
Pseudokirchneriella subcapitata (Green Alga) OECD EC50 72 hours 1.65 mg/L

Aquatic Toxicity Comments:

A greater than (>) symbol indicates that acute ecotoxicity was not observed at the maximum solubility. Since the substance is insoluble in aqueous solutions above this concentration, an acute ecotoxicity value (i.e. LC/EC50) is not achievable.

Bacterial Inhibition: (Inoculum, Method, End Point, Result)

Tigecycline

Activated sludge OECD EC50 140 mg/L (hydrolyzed tigecycline)
Activated sludge OECD EC50 58 mg/L (unhydrolyzed tigecycline)

Chronic Aquatic Toxicity: (Species, Method, Duration, Endpoint, Result, Adverse Endpoint)

Tigecycline

Daphnia magna (Water Flea) OECD 21 Day(s) NOEC 2.1 mg/L Reproduction

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Pimephales promelas (Fathead Minnow) OECD 32 Day(s) NOEC 0.022 mg/L Survival
Chironomus riparius (Sediment-Dwelling Midges) OECD 28 Day(s) NOEC > 94 mg/kg

12.2. Persistence and degradability

Persistence and degradability

Biodegradation: (Method, Inoculum, Biodeg Study, Result, Endpoint, Duration, Classification)

Tigecycline

OECD Activated sludge Ultimate (CO2 Evolution) 36 % in 46 Day(s) Inherently biodegradable
OECD Water - Sediment (various) Total System DT50 0.9-1.1 Day(s)

12.3. Bioaccumulative potential

Bioaccumulation

Partition Coefficient: (Method, pH, Endpoint, Value)

Tigecycline

Predicted Log P 6.7

12.4. Mobility in soil

Mobility in soil

Sorption:

Tigecycline (220620-09-7)

Method

OECD

Inoculum

Activated sludge

End Point

Koc

Result

4570

Sorption: (Method, Inoculum, Sorption Endpoint, Endpoint, Results)

12.5. Results of PBT and vPvB assessment

PBT and vPvB assessment

Chemical name	PBT and vPvB assessment
Sodium hydroxide	Not PBT/vPvB PBT assessment does not apply
+ Hydrochloric Acid	Not PBT/vPvB PBT assessment does not apply

12.6. Endocrine disrupting properties

Endocrine disrupting properties Based on available data, the classification criteria are not met.

12.7. Other adverse effects

Other adverse effects

No information available.

PMT or vPvM properties

Based on available data, the classification criteria are not met.

Section 13: DISPOSAL CONSIDERATIONS

13.1. Waste treatment methods

Waste from residues/unused products

Dispose of waste in accordance with all applicable laws and regulations. Member State specific and Community specific provisions must be considered. Considering the relevant known environmental and human health hazards of the material, review

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and implement appropriate technical and procedural wastewater and waste disposal measures to prevent occupational exposure and environmental release. It is recommended that waste minimization be practiced. The best available technology should be utilized to prevent environmental releases. This may include destructive techniques for waste and wastewater.

Section 14: TRANSPORT INFORMATION

The following refers to all modes of transportation unless specified below.

This material is regulated for transportation as a hazardous material/dangerous good.

UN number: UN 3077
UN proper shipping name: Environmentally Hazardous Substance, Solid, n.o.s (Tigecycline)
Transport hazard class(es): 9
Packing group: III
Environmental Hazard(s): Marine Pollutant

5 kg/5L Exception:

UN3082 and UN3077 materials contained in good quality packaging in the quantities listed below are not subject to the dangerous goods transportation regulations by any mode:

* Single packagings containing a net quantity of 5 liters or less for liquids or a net mass of 5 kg or less for solids.

* Combination packagings containing a net quantity per inner packaging of 5 liters or less for liquids or a net mass of 5 kg or less for solids.

Section 15: REGULATORY INFORMATION

15.1. Safety, health and environmental regulations/legislation specific for the substance or mixture

Lactose NF, monohydrate

CERCLA/SARA Section 313 de minimus %	Not Listed
California Proposition 65	Not Listed
EINECS	Not Listed
AICS	Present

Tigecycline

CERCLA/SARA Section 313 de minimus %	Not Listed
California Proposition 65	Not Listed
EINECS	Not Listed
Standard for Uniform Scheduling of Medicines and Poisons (SUSMP)	Schedule 4

Sodium hydroxide

CERCLA/SARA Section 313 de minimus %	Not Listed
Hazardous Substances RQs	1000 lb
California Proposition 65	Not Listed
TSCA	Present
EINECS	215-185-5
AICS	Present
Standard for Uniform Scheduling of Medicines and Poisons (SUSMP)	Schedule 5
	Schedule 6

+ Hydrochloric Acid

CERCLA/SARA Section 313 de minimus %	1.0 %
Hazardous Substances RQs	5000 lb
California Proposition 65	Not Listed

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TSCA
EINECS
AICS
Standard for Uniform Scheduling of Medicines and Poisons (SUSMP)

Present
231-595-7
Present
Schedule 5
Schedule 6

National regulations

Germany

Chemical Prohibition Ordinance (ChemVerbotsV)
Not applicable

TRGS 905

Not applicable

Switzerland

Ordinance on the Incentive Tax on Volatile Organic Compounds (OVOC) SR 814.018 Not applicable
Storage of Hazardous Material Not applicable
WPO (GSchV) SR 814.201; WPA (GSchG) SR 814.20 Not applicable
Major Accidents Ordinance SR 814.012 Not applicable

European Union

Take note of Directive 98/24/EC on the protection of the health and safety of workers from the risks related to chemical agents at work.

Authorizations and/or restrictions on use:

This product contains one or more substance(s) subject to restriction (Regulation (EC) No. 1907/2006 (REACH), Annex XVII)

Chemical name	Restricted substance per REACH Annex XVII	Substance subject to authorization per REACH Annex XIV
Sodium hydroxide 1310-73-2	75	-
+ Hydrochloric Acid 7647-01-0	75	-

Persistent Organic Pollutants

Not applicable

Named dangerous substances per Seveso Directive (2012/18/EU)

Chemical name	Lower-tier requirements (tons)	Upper-tier requirements (tons)
+ Hydrochloric Acid 7647-01-0	25	250

Ozone-depleting substances (ODS) Regulation (EU) 2024/590

Not applicable.

Biocidal Products Regulation (EU) No 528/2012 (BPR)

Chemical name	Biocidal Products Regulation (EU) No 528/2012 (BPR)
+ Hydrochloric Acid 7647-01-0	Product-type 2: Disinfectants and algacides not intended for direct application to humans or animals

Explosives Precursors Marketing and Use (2019/1148)

Not applicable

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Legend:

TSCA - United States Toxic Substances Control Act Section 8(b) Inventory
DSL/NDSL - Canadian Domestic Substances List/Non-Domestic Substances List
EINECS/ELINCS - European Inventory of Existing Chemical Substances/European List of Notified Chemical Substances
ENCS - Japan Existing and New Chemical Substances
IECSC - China Inventory of Existing Chemical Substances
KECL - Korean Existing Chemicals Inventory
PICCS - Philippines Inventory of Chemicals and Chemical Substances
AICS - Australian Inventory of Chemical Substances
NZIoC - New Zealand Inventory of Chemicals
TCSI - Taiwan Chemical Substance Inventory

15.2. Chemical safety assessment

Chemical Safety Report No information available

Section 16: OTHER INFORMATION

Key or legend to abbreviations and acronyms used in the safety data sheet

Full text of any hazard and/or precautionary statements referred to under Sections 2-15

H317 - May cause an allergic skin reaction. H318 - Causes serious eye damage. H360D - May damage the unborn child. H400 - Very toxic to aquatic life. H410 - Very toxic to aquatic life with long lasting effects.

Data Sources: Pfizer proprietary drug development information. Publicly available toxicity information.

Reason for revision Updated Section 2 - Hazard Identification. Updated Section 8 - Exposure Controls / Personal Protection. Updated Section 11 - Toxicology Information. Updated Section 12 - Ecological Information.

Revision date 15-Jun-2025

Prepared By Pfizer Global Environment, Health, and Safety

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