Tigecycline

Version number:

Issued: 2023-10-13



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

1.1. Product identifier

Trade name

Tigecycline

CAS number

220620-09-7

EC number

685-736-6

Synonyms

4S,4aS,5aR,12aS)-9- [2-(tert-butylamino)acetamido] -4,7-bis (dimethylamino) -1,4,4a,5,5a,6,11, 12a-octahydro-3,10,12, 2a-tetrahydroxy-1, 11-dioxo-2-naphthacenecarboxamide (hydrochloride)

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

Research and development.

Not suitable for use in

Not suitable for human consumption or veterinary purposes.

1.3. Details of the supplier of the safety data sheet

Supplier

Molekula Group

Street address

Molekula Ltd, Lingfield Way, Darlington,

DL1 4XX Darlington

United Kingdom

Telephone

+44 (0) 3302 000 333

Email

info@molekula.com

Web site

www.molekula.com

Contact person

Kevin Banks

Email address

+44 (0) 7769276927

1.4. Emergency telephone number

Poison center/Additional emergency number

0344 892 0111 - National Poisons Information Service (Newcastle Centre)

Tigecycline

Version number:

Issued: 2023-10-13



SECTION 2: Hazards identification

2.1. Classification of the substance or mixture

Classification according to Regulation (EC) No 1272/2008

Classification

Serious eye damage, hazard category 1
Hazardous to the aquatic environment — Chronic hazard category 2
Skin sensitisation, hazard category 1
Reproductive toxicity, hazard category 1B

Hazard statements

H317, H318, H360, H411

2.2. Label elements

Labelling according to Regulation (EC) No 1272/2008

Hazard pictograms









Signal word

Danger

Hazard statements

H317 May cause an allergic skin reaction.

H318 Causes serious eye damage.

H360 May damage fertility or the unborn child.

H411 Toxic to aquatic life with long lasting effects.

Tigecycline

Version number:

Issued: 2023-10-13



Precautionary statements

P201 Obtain special instructions before use.

P202 Do not handle until all safety precautions have been read and understood.

P260 Do not breathe dust/fumes/gas/mist/vapours/spray.

P262 Do not get in eyes, on skin, or on clothing.

P264 Wash skin thoroughly after handling.

P270 Do not eat, drink or smoke when using this product.

P271 Use only outdoors or in a well-ventilated area.

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.

P302 + P352 IF ON SKIN: Wash with plenty of water/.

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

lenses, if present and easy to do. Continue rinsing.

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

P310 Immediately call a POISON CENTER/doctor.

P314 Get medical advice/attention if you feel unwell.

P333 +P313 If skin irritation or rash occurs: Get medical advice/attention.

P362 + P364 Take off contaminated clothing and wash it before reuse.

P391 Collect spillage.

P403 Store in a well-ventilated place.

P405 Store locked up.

P501 Dispose of contents/container to local regulations.

2.3. Other hazards

No data available

SECTION 3: Composition/information on ingredients

3.2. Mixtures

| Chemical name | CAS No. EC No. REACH No. Index No. | Concentration | Classification | H-phrase M factor acute M factor chronic | Note |
|---------------|---|---------------|---|--|------|
| Tigecycline | 220620-09-7 685-736-6 - | 100% | Skin Sens. 1, Eye Dam. 1, Repr. 1B, Aquatic Chronic 2 | H360, H411 | - |

Molecular weight

585.65

Substance additional information

For the complete text of H- / EUH-statements mentioned in this section, see section 16.

Tigecycline

Version number:

Issued: 2023-10-13



SECTION 4: First aid measures

4.1. Description of first aid measures

IF exposed or concerned: Get medical advice/attention. First aiders/ medical personnel need to protect themselves. Show this Safety Data Sheet (SDS) to medical personnel.

Inhalation

IF INHALED: Remove person to fresh air and keep comfortable for breathing. Immediately call a POISON CENTER/doctor. If breathing stops, provide artificial respiration. For breathing difficulties oxygen may be necessary.

Skin contact

IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water [or shower]. Immediately call a POISON CENTER/doctor.

Eye contact

Remove contact lenses if present. Rinse eyes with water. Continue to rinse for at least 15 minutes and seek medical attention.

Ingestion

IF SWALLOWED: give water to drink (two glasses at most). Seek medical advice immediately. In exceptional cases only, if medical care is not available within one hour, induce vomiting (only if the persons are fully conscious and awake). Administer activated charcoal (20 - 40g in a 10% slurry) and consult a doctor as quickly as possible. Do not attempt to neutralise.

Information for doctors

No data available.

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

The severity of the symptoms described will vary dependant of the concentration and the length of exposure. Causes burns by all exposure routes.

See section 11 for more detailed information on health effects and symptoms.

<u>Inhalation</u>

Single exposure may cause the following adverse effects: Causes severe burns. Difficulty in breathing.

Skin contact

Single exposure may cause the following adverse effects: Causes severe burns. Blistering may occur. May be absorbed in the body and cause dizziness, nausea and vomiting.

Eye contact

Single exposure may cause the following adverse effects: Causes serious eye damage.

Ingestion

Single exposure may cause the following adverse effects: Severe abdominal pain. May cause severe internal injury.

4.3. Indication of any immediate medical attention and special treatment needed

Treat symptomatically. Immediately call a POISON CENTER/doctor.

Tigecycline

Version number:

Issued: 2023-10-13



SECTION 5: Firefighting measures

5.1. Extinguishing media

Suitable extinguishing media

In case of fire: Use foam, carbon dioxide, dry powder or water fog to extinguish.

Unsuitable extinguishing media

No specific fire fighting procedure given.

5.2. Special hazards arising from the substance or mixture

Specific hazards: Corrosive.

Thermal decomposition or combustion may liberate carbon oxides and other toxic gases or

Carbon monoxide (CO). Carbon dioxide (CO2).

Nitrous gases (NOx).

Combustible.

Development of hazardous combustion gases or vapours possible in the event of fire.

5.3. Advice for firefighters

Special protective equipment for fire-fighters

Evacuate area. Avoid breathing gas, fume, vapours or spray. Prevent skin contact by maintaining a safe distance and by wearing suitable protective equipment/ clothing. Cool containers exposed to heat with water spray and remove container, if no risk is involved.

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

Do not breathe vapour/spray. Avoid contact with skin and eyes. For personal protection, see section 8.

In case of fire: Evacuate area. Fight fire remotely due to the risk of explosion.

6.2. Environmental precautions

Avoid discharge into drains, water courses or onto the ground.

6.3. Methods and material for containment and cleaning up

Collect with absorbent, non-combustible material into suitable containers.

6.4. Reference to other sections

For personal protection, see section 8. For waste disposal, see section 13.

Tigecycline

Version number:

Issued: 2023-10-13



SECTION 7: Handling and storage

7.1. Precautions for safe handling

Preventive handling precautions

For precautions see section 2.2. Wear protective clothing, gloves, eye and face protection. Work under hood Do not breathe dust/fume/gas/mist/vapours/spray. Keep away from food, drink and animal feeding stuffs. Keep container tightly closed. May damage fertility. May damage the unborn child. Avoid discharge to the aquatic environment. Do not handle until all safety precautions have been read and understood. Do not handle broken packages without protective equipment. Do not reuse empty containers.

General hygiene

Observe good chemical hygiene practices. IF ON SKIN: Wash skin thoroughly with soap and water for several minutes. Do not eat, drink or smoke when using this product. Remove contaminated clothing and launder thoroughly before re-use.

7.2. Conditions for safe storage, including any incompatibilities

Store in a dry place. Store in a closed container. Recommended storage temperature: -20 to -15 $^{\circ}$ C (-4 to 5 $^{\circ}$ F)

Hygroscopic.

7.3. Specific end use(s)

No specific usage precautions noted.

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

No data available

8.2. Exposure controls

Personal Protective Equipment Symbols











Eye / face protection

Wear eye protection.

Hand protection

Wear protective gloves. Recommended gloves: Nitrile.

Glove Thickness: 0.11mm Breakthrough time: 8 hours

Always inspect gloves before use. If signs of wear and tear are noticed then the gloves should be replaced.

No specific hygiene procedures noted, but good personal hygiene practices are always advisable, especially when working with chemicals. Wash contaminated skin thoroughly after handling.

Tigecycline

Version number:

Issued: 2023-10-13



Other skin protection

Wash skin thoroughly after handling.

Respiratory protection

Provide adequate ventilation. If ventilation is insufficient, suitable respiratory protection must be provided.

Environmental exposure controls

Avoid discharge into drains.

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Physical state

Solid

Colour

Orange.

<u>Odour</u>

Odourless.

Melting point / freezing point

180 - 185 °C

Boiling point or initial boiling point and boiling range

No data available

Flammability

No data available

Lower and upper explosion limit

No data available

Flash point

No data available

Auto-ignition temperature

No data available

Decomposition temperature

No data available

<u>рН</u>

7 - 8.5

Kinematic viscosity

No data available

Solubility

soluble

Tigecycline

Version number:

2023-10-13 Issued:



Partition coefficient n-octanol/water

No data available

Vapour pressure

No data available

Density and/or relative density

No data available

Relative vapour density

No data available

Particle characteristics

No data available

9.2. Other information

No data available

SECTION 10: Stability and reactivity

10.1. Reactivity

The following applies in general to flammable organic substances and mixtures: when finely distributed, the risk of a dust explosion may be assumed.

10.2. Chemical stability

Stable under the prescribed storage conditions.

10.3. Possibility of hazardous reactions

Violent reactions possible with:

Strong oxidising agents.

10.4. Conditions to avoid

No data available

10.5. Incompatible materials

Strong oxidising agents.

10.6. Hazardous decomposition products

See section 5.

SECTION 11: Toxicological information

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

| Product / Substance name CAS / EC no. | Result | Species |
|--|--------------------|---------|
| Tigecycline | Severe irritation. | Rabbit |

Tigecycline

Version number:

Issued: 2023-10-13



| Product / Substance name CAS / EC no. | Result | Species |
|---------------------------------------|--------|---------|
| 220620-09-7 / 685-736-6 | | |

Respiratory or skin sensitisation

| Product / Substance name CAS / EC no. | Result | Species | Method / Guideline | Other |
|---|-----------|---------|---------------------------|--------------------------------------|
| Tigecycline 220620-09-7 / 685-736- 6 | Positive. | Mouse | Local Lymph Node Assay | May cause an allergic skin reaction. |

Germ cell mutagenicity

| Product / Substance name CAS / EC no. | Result | Species | Method / Guideline |
|--|-----------|------------------------------|---|
| Tigecycline 220620-09-7 / 685-736-6 | Negative. | Chinese Hamster cells: Ovary | Mutagenicity (mammal cell test): Chromosome aberration: |
| Tigecycline 220620-09-7 / 685-736-6 | Negative. | Mouse lymphoma test | In vitro mammalian cell gene mutation test. |
| Tigecycline 220620-09-7 / 685-736-6 | Negative. | Mouse | in vivo Micronucleus test |

Reproductive toxicity

| Product / Substance name CAS / EC no. | Result |
|--|--|
| Tigecycline 220620-09-7 / 685-736-6 | May damage fertility. May damage the unborn child. |

Aspiration hazard

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

11.2. Information on other hazards

Endocrine disrupting properties

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

SECTION 12: Ecological information

12.1. Toxicity

Acute fish toxicity

Tigecycline

Version number:

Issued: 2023-10-13



| Product / Substance name CAS / EC no. | Measurement type | Value / Result | Duration of exposure | Species |
|---|------------------|----------------|----------------------|--|
| Tigecycline 220620-09-7 / 685-736- 6 | LC50 | 0.26 mg/l | 72 hours | Pimephales promelas (Fat-head Minnow) |

Acute algae toxicity

| Product / Substance name CAS / EC no. | Measurement type | Value / Result | Duration of exposure | Species |
|---|------------------|----------------|----------------------|---------|
| Tigecycline 220620-09-7 / 685-736- 6 | ErC50 | 1.65 mg/l | 72 hours | Algae |

Acute crustacean toxicity

| Product / Substance name CAS / EC no. | Measurement type | Value / Result | Duration of exposure | Species |
|---|------------------|----------------|----------------------|---------------|
| Tigecycline 220620-09-7 / 685-736- 6 | EC50 | 2 mg/l | 48 hours | Daphnia magna |

Chronical toxicity

| Product / Substance name CAS / EC no. | Measurement type | Value / Result | Duration of exposure | Species |
|---|------------------|----------------|----------------------|--|
| Tigecycline 220620-09-7 / 685-736- 6 | NOEC | 2.1 mg/l | 21 days | Daphnia magna |
| Tigecycline 220620-09-7 / 685-736- 6 | NOEC | 22 μg/l | 32 days | Pimephales promelas (Fat-head Minnow) |

12.2. Persistence and degradability <u>Persistence and degradability</u>

| Product / Substance name CAS / EC no. | Result |
|---------------------------------------|---|
| Tigecycline | The product is not readily biodegradable. |

Tigecycline

Version number:

Issued: 2023-10-13



| Product / Substance name CAS / EC no. | Result |
|---------------------------------------|--------|
| 220620-09-7 / 685-736-6 | |

12.3. Bioaccumulative potential

No data available

12.4. Mobility in soil

No data available

12.5. Results of PBT and vPvB assessment

No data available

12.6. Endocrine disrupting properties

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

12.7. Other adverse effects

No data available

SECTION 13: Disposal considerations

13.1. Waste treatment methods

Disposal considerations

Dispose of contents/container in accordance with local/regional/national/international regulations.

SECTION 14: Transport information

14.1. UN number

3077

14.2. UN proper shipping name

ADR / RID / ADN proper shipping name

ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (Tigecycline)

IMDG proper shipping name

ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (Tigecycline)

IATA proper shipping name

Environmentally hazardous substance, solid, n.o.s. (Tigecycline)

Tigecycline

Version number:

Issued: 2023-10-13



14.3. Transport hazard class(es)

<u>Label</u>

ADR/RID/ADN





9

Environmental hazard

IMDG



IATA





Environmental hazard

ADR / RID Class

ADR / RID Classification code

M7

ADR / RID hazard identification number

IMDG Class

IATA Class

ADN Class

ADN Class Code

M7

14.4. Packing group

ADR / RID / ADN: III

IMDG: III IATA: III

Tigecycline

Version number:

Issued: 2023-10-13



14.5. Environmental hazards

ADR/RID/ADN: Hazardous for the environment

IMDG EmS

F-A, S-F

14.6. Special precautions for user

Tunnel restriction code: - Transport category: 3

14.7. Maritime transport in bulk according to IMO instruments

IBC Instruction: IBC08

SECTION 15: Regulatory information

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

This material safety data sheet complies with the requirements of Regulation (EC) No. 1907/2006.

National regulations

Directive: 2012/18/EU: ENVIRONMENTAL HAZARDS

15.2. Chemical safety assessment

No chemical safety assessment has been carried out.

SECTION 16: Other information

Phrase meaning

Eye Dam. 1 - Serious eye damage, hazard category 1

Aquatic Chronic 2 - Hazardous to the aquatic environment — Chronic hazard category 2

Skin Sens. 1 - Skin sensitisation, hazard category 1

Repr. 1B - Reproductive toxicity, hazard category 1B

H317 May cause an allergic skin reaction.

H318 Causes serious eye damage.

H360 May damage fertility or the unborn child.

H411 Toxic to aquatic life with long lasting effects.