

SAFETY DATA SHEET

Cefepime

According to Regulation (EC) No 1907/2006, Annex II, as amended. Commission Regulation (EU) No 2015/830 of 28 May 2015.

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

1.1. Product identifier

Product name Cefepime

Chemical name 1-[[(6R,7R)-7-[[(2Z)-2-(2-amino-4-thiazolyl)-2-(methoxyimino)acetyl]amino]-2-carboxy-8-oxo-5-

thia-1-azabicyclo[4.2.0]oct-2-en-3-yl]methyl]-1-methyl-pyrrolidinium

 Product number
 12850730

 CAS number
 88040-23-7

 EC number
 643-019-5

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

Uses advised againstNo specific uses advised against are identified.

1.3. Details of the supplier of the safety data sheet

Supplier Molekula Ltd.

Lingfield Way, Darlington, DL1 4XX, United Kingdom +44 (0) 3302000333 info@molekula.com

1.4. Emergency telephone number

+44 (0) 7769276927

SECTION 2: Hazards identification

2.1. Classification of the substance or mixture

Classification (EC 1272/2008)

Physical hazards Not Classified

Health hazards Skin Irrit. 2 - H315 Eye Irrit. 2 - H319 Resp. Sens. 1 - H334 Skin Sens. 1 - H317

Environmental hazards Not Classified

2.2. Label elements

EC number 643-019-5

Hazard pictograms



Signal word Danger

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Hazard statements H315 Causes skin irritation.

H317 May cause an allergic skin reaction. H319 Causes serious eye irritation.

H334 May cause allergy or asthma symptoms or breathing difficulties if inhaled.

H335 May cause respiratory irritation.

Precautionary statements P261 Avoid breathing dust.

P264 Wash contaminated skin thoroughly after handling.

P272 Contaminated work clothing should not be allowed out of the workplace. P280 Wear protective gloves/ protective clothing/ eye protection/ face protection.

P284 [In case of inadequate ventilation] wear respiratory protection.

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

P304+P340 IF INHALED: Remove person to fresh air and keep comfortable for breathing. P305+P351+P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove

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

P333+P313 If skin irritation or rash occurs: Get medical advice/ attention. P337+P313 If eye irritation persists: Get medical advice/ attention.

P342+P311 If experiencing respiratory symptoms: Call a POISON CENTER/ doctor.

P501 Dispose of contents/ container in accordance with national regulations.

2.3. Other hazards

This substance is not classified as PBT or vPvB according to current EU criteria.

SECTION 3: Composition/information on ingredients

3.1. Substances

Product name Cefepime

Chemical name 1-[[(6R,7R)-7-[[(2Z)-2-(2-amino-4-thiazolyl)-2-(methoxyimino)acetyl]amino]-2-carboxy-8-oxo-5-

thia-1-azabicyclo[4.2.0]oct-2-en-3-yl]methyl]-1-methyl-pyrrolidinium

CAS number 88040-23-7 **EC number** 643-019-5

Chemical formula C19H24N6O5S2

SECTION 4: First aid measures

4.1. Description of first aid measures

General information Get medical attention if any discomfort continues. Show this Safety Data Sheet to the medical

personnel.

Inhalation Move affected person to fresh air and keep warm and at rest in a position comfortable for

breathing. Maintain an open airway. Loosen tight clothing such as collar, tie or belt. Rinse nose and mouth with water. Never give anything by mouth to an unconscious person. Get medical attention if symptoms are severe or persist. In the event of any sensitisation

 $symptoms\ developing,\ ensure\ further\ exposure\ is\ avoided.$

Ingestion Rinse mouth thoroughly with water. Get medical advice/attention if you feel unwell. Do not

induce vomiting unless under the direction of medical personnel.

Skin contact It is important to remove the substance from the skin immediately. In the event of any

sensitisation symptoms developing, ensure further exposure is avoided. Remove

contamination with soap and water or recognised skin cleansing agent. Get medical attention

if symptoms are severe or persist after washing.

Eye contact Rinse with water. Do not rub eye. Remove any contact lenses and open eyelids wide apart.

Get medical attention if any discomfort continues.

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Protection of first aiders First aid personnel should wear appropriate protective equipment during any rescue.

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

General information The severity of the symptoms described will vary dependent on the concentration and the

length of exposure.

Inhalation May cause sensitisation or allergic reactions in sensitive individuals.

Ingestion May cause sensitisation or allergic reactions in sensitive individuals. May cause irritation.

Skin contact May cause skin sensitisation or allergic reactions in sensitive individuals. Redness. Irritating to

skin.

Eye contact Irritating to eyes.

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

Notes for the doctor

Treat symptomatically. May cause sensitisation or allergic reactions in sensitive individuals.

SECTION 5: Firefighting measures

5.1. Extinguishing media

Suitable extinguishing media Extinguish with alcohol-resistant foam, carbon dioxide, dry powder or water fog. Use fire-

extinguishing media suitable for the surrounding fire.

Unsuitable extinguishing

media

Do not use water jet as an extinguisher, as this will spread the fire.

5.2. Special hazards arising from the substance or mixture

Specific hazards None known.

Hazardous combustion

products

Thermal decomposition or combustion products may include the following substances: Harmful gases or vapours. Carbon monoxide (CO). Carbon dioxide (CO2). Nitrous gases

(NOx). Sulphurous gases (SOx).

5.3. Advice for firefighters

Protective actions during

firefighting

Avoid breathing fire gases or vapours. Evacuate area. Cool containers exposed to heat with water spray and remove them from the fire area if it can be done without risk. Cool containers exposed to flames with water until well after the fire is out. Control run-off water by containing and keeping it out of sewers and watercourses. If risk of water pollution occurs, notify

appropriate authorities.

Special protective equipment

for firefighters

Wear positive-pressure self-contained breathing apparatus (SCBA) and appropriate protective clothing. Firefighter's clothing conforming to European standard EN469 (including helmets, protective boots and gloves) will provide a basic level of protection for chemical incidents.

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

Personal precautions Wear protective clothing as described in Section 8 of this safety data sheet. No action shall be

taken without appropriate training or involving any personal risk. Do not touch or walk into spilled material. Avoid inhalation of dust. Use suitable respiratory protection if ventilation is

inadequate. Avoid contact with skin and eyes.

6.2. Environmental precautions

Environmental precautions Avoid discharge into drains or watercourses or onto the ground.

6.3. Methods and material for containment and cleaning up

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Methods for cleaning up

Wear protective clothing as described in Section 8 of this safety data sheet. Clear up spills immediately and dispose of waste safely. Collect spillage with a shovel and broom, or similar and reuse, if possible. Collect and place in suitable waste disposal containers and seal securely. Flush contaminated area with plenty of water. Wash thoroughly after dealing with a spillage. For waste disposal, see Section 13.

6.4. Reference to other sections

Reference to other sections For personal protection, see Section 8. See Section 11 for additional information on health

hazards. See Section 12 for additional information on ecological hazards. For waste disposal,

see Section 13.

SECTION 7: Handling and storage

7.1. Precautions for safe handling

Usage precautions Read and follow manufacturer's recommendations. Wear protective clothing as described in

Section 8 of this safety data sheet. Keep away from food, drink and animal feeding stuffs. Keep container tightly sealed when not in use. 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.

Advice on general occupational hygiene

Wash promptly if skin becomes contaminated. Take off contaminated clothing. Wash

contaminated clothing before reuse.

7.2. Conditions for safe storage, including any incompatibilities

Storage precautions Store away from incompatible materials (see Section 10). Keep only in the original container.

Keep container tightly closed, in a cool, well ventilated place. Keep containers upright. Protect

containers from damage.

Store at temperatures between 2°C and 8°C.

Storage class Chemical storage.

7.3. Specific end use(s)

Specific end use(s) The identified uses for this product are detailed in Section 1.2.

SECTION 8: Exposure controls/Personal protection

8.1. Control parameters

8.2. Exposure controls

Protective equipment







Appropriate engineering controls

Provide adequate ventilation. Observe any occupational exposure limits for the product or ingredients.

Eye/face protection

Wear tight-fitting, chemical splash goggles or face shield. If inhalation hazards exist, a full-face respirator may be required instead.

Hand protection

Wear protective gloves. The most suitable glove should be chosen in consultation with the glove supplier/manufacturer, who can provide information about the breakthrough time of the glove material. To protect hands from chemicals, gloves should comply with European Standard EN374. Considering the data specified by the glove manufacturer, check during use that the gloves are retaining their protective properties and change them as soon as any deterioration is detected. Frequent changes are recommended.

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Other skin and body

protection

May cause skin sensitisation or allergic reactions in sensitive individuals. Wear appropriate

clothing to prevent repeated or prolonged skin contact.

Hygiene measures Wash after use and before eating, smoking and using the toilet. Do not eat, drink or smoke

when using this product.

Respiratory protection Ensure all respiratory protective equipment is suitable for its intended use and is 'CE'-marked.

> Check that the respirator fits tightly and the filter is changed regularly. Gas and combination filter cartridges should comply with European Standard EN14387. Full face mask respirators with replaceable filter cartridges should comply with European Standard EN136. Half mask and quarter mask respirators with replaceable filter cartridges should comply with European

Standard EN140.

Environmental exposure

controls

Keep container tightly sealed when not in use. 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.

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Appearance Crystalline powder.

Colour White/off-white.

Odour Not known.

Odour threshold No information available.

Hq No information available.

Melting point 150°C/302°F

Initial boiling point and range 894.93°C/1642.87°F

Flash point No information available. **Evaporation rate** No information available. Flammability (solid, gas) No information available. Upper/lower flammability or No information available.

explosive limits

Vapour pressure No information available. Vapour density No information available. Relative density No information available. Solubility(ies) No information available.

Partition coefficient -1.80

Auto-ignition temperature No information available. No information available. **Decomposition Temperature**

9.2. Other information

Molecular weight 480.56

SECTION 10: Stability and reactivity

10.1. Reactivity

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Reactivity See the other subsections of this section for further details.

10.2. Chemical stability

Stable under the prescribed storage conditions. Store at temperatures between 2°C/35.6°F

and 8°C/46.4°F.

10.3. Possibility of hazardous reactions

Possibility of hazardous

No potentially hazardous reactions known.

reactions

10.4. Conditions to avoid

Conditions to avoid Avoid exposure to high temperatures or direct sunlight.

10.5. Incompatible materials

Materials to avoid Avoid contact with strong oxidising agents.

10.6. Hazardous decomposition products

Hazardous decomposition

products

Does not decompose when used and stored as recommended. Thermal decomposition or combustion products may include the following substances: Harmful gases or vapours. Carbon monoxide (CO). Carbon dioxide (CO2). Nitrous gases (NOx). Sulphurous gases

(SOx).

SECTION 11: Toxicological information

11.1. Information on toxicological effects

Acute toxicity - oral

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

Acute toxicity - dermal

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

Acute toxicity - inhalation

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

Skin corrosion/irritation

Summary Causes skin irritation.

Serious eye damage/irritation

Summary Causes serious eye irritation.

Respiratory sensitisation

Summary May cause allergy or asthma symptoms or breathing difficulties if inhaled.

Skin sensitisation

Summary May cause an allergic skin reaction.

Germ cell mutagenicity

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

Carcinogenicity

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

IARC carcinogenicityNone of the ingredients are listed or exempt.

Reproductive toxicity

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

Specific target organ toxicity - single exposure

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

Specific target organ toxicity - repeated exposure

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

Aspiration hazard

Summary Not relevant. Solid.

General information The severity of the symptoms described will vary dependent on the concentration and the

length of exposure.

Inhalation May cause sensitisation or allergic reactions in sensitive individuals.

Ingestion May cause sensitisation or allergic reactions in sensitive individuals. May cause irritation.

Skin contact May cause skin sensitisation or allergic reactions in sensitive individuals. Redness. Irritating to

skin.

Eye contact Irritating to eyes.

Route of exposure Ingestion Inhalation Skin and/or eye contact

Target organs No specific target organs known.

Medical considerations Skin disorders and allergies.

SECTION 12: Ecological information

Ecotoxicity Not regarded as dangerous for the environment. However, large or frequent spills may have

hazardous effects on the environment.

12.1. Toxicity

Acute aquatic toxicity

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

Chronic aquatic toxicity

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

12.2. Persistence and degradability

Persistence and degradability The degradability of the product is not known.

12.3. Bioaccumulative potential

Bioaccumulative potential No data available on bioaccumulation.

Partition coefficient -1.80

12.4. Mobility in soil

Mobility No data available.

12.5. Results of PBT and vPvB assessment

12.6. Other adverse effects

Other adverse effects None known.

SECTION 13: Disposal considerations

13.1. Waste treatment methods

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General information The generation of waste should be minimised or avoided wherever possible. Reuse or recycle

products wherever possible. This material and its container must be disposed of in a safe way. When handling waste, the safety precautions applying to handling of the product should be considered. Care should be taken when handling emptied containers that have not been thoroughly cleaned or rinsed out. Empty containers or liners may retain some product

residues and hence be potentially hazardous.

Disposal methods Do not empty into drains. Dispose of surplus products and those that cannot be recycled via a

licensed waste disposal contractor. Waste, residues, empty containers, discarded work clothes and contaminated cleaning materials should be collected in designated containers, labelled with their contents. Incineration or landfill should only be considered when recycling is

not feasible.

SECTION 14: Transport information

General The product is not covered by international regulations on the transport of dangerous goods

(IMDG, IATA, ADR/RID).

14.1. UN number

Not applicable.

14.2. UN proper shipping name

Not applicable.

14.3. Transport hazard class(es)

No transport warning sign required.

14.4. Packing group

Not applicable.

14.5. Environmental hazards

Environmentally hazardous substance/marine pollutant

No.

14.6. Special precautions for user

Not applicable.

14.7. Transport in bulk according to Annex II of MARPOL and the IBC Code

Transport in bulk according to Not applicable.

Annex II of MARPOL 73/78

and the IBC Code

SECTION 15: Regulatory information

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

National regulations Health and Safety at Work etc. Act 1974 (as amended).

The Carriage of Dangerous Goods and Use of Transportable Pressure Equipment

Regulations 2009 (SI 2009 No. 1348) (as amended) ["CDG 2009"].

EH40/2005 Workplace exposure limits.

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EU legislation Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18

December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of

Chemicals (REACH) (as amended).

Commission Regulation (EU) No 2015/830 of 28 May 2015.

Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures (as

amended).

15.2. Chemical safety assessment

No chemical safety assessment has been carried out.

Inventories

EU - EINECS/ELINCS

None of the ingredients are listed or exempt.

SECTION 16: Other information

Abbreviations and acronyms used in the safety data sheet

ADR: European Agreement concerning the International Carriage of Dangerous Goods by

Road.

ADN: European Agreement concerning the International Carriage of Dangerous Goods by

Inland Waterways.

RID: European Agreement concerning the International Carriage of Dangerous Goods by

Rail.

IATA: International Air Transport Association.

ICAO: Technical Instructions for the Safe Transport of Dangerous Goods by Air.

IMDG: International Maritime Dangerous Goods.

CAS: Chemical Abstracts Service.

ATE: Acute Toxicity Estimate.

 $LC_{50}{:}\;\;Lethal\;Concentration\;to\;50\;\%$ of a test population.

LD₅₀: Lethal Dose to 50% of a test population (Median Lethal Dose).

EC₅o: 50% of maximal Effective Concentration.

PBT: Persistent, Bioaccumulative and Toxic substance.

vPvB: Very Persistent and Very Bioaccumulative.

Classification abbreviations

and acronyms

Eye Irrit. = Eye irritation

Resp. Sens. = Respiratory sensitisation

Skin Irrit. = Skin irritation Skin Sens. = Skin sensitisation

Classification procedures according to Regulation (EC)

1272/2008

Skin Irrit. 2 - H315: Eye Irrit. 2 - H319: Resp. Sens. 1 - H334: Skin Sens. 1 - H317: : Expert

judgement.

Training advice Only trained personnel should use this material.

Revision date 08/03/2021

Revision 1
SDS number 44

Hazard statements in full H315 Causes skin irritation.

H317 May cause an allergic skin reaction.

H319 Causes serious eye irritation.

H334 May cause allergy or asthma symptoms or breathing difficulties if inhaled.

H335 May cause respiratory irritation.

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This information relates only to the specific material designated and may not be valid for such material used in combination with any other materials or in any process. Such information is, to the best of the company's knowledge and belief, accurate and reliable as of the date indicated. However, no warranty, guarantee or representation is made to its accuracy, reliability or completeness. It is the user's responsibility to satisfy himself as to the suitability of such information for his own particular use.