

Safety Data Sheet

Meropenem for Injection 1g

Savior Lifetec Corporation

Version: 1

page number: 1 of 11

Issued date: 2016/03/28

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

1.1 Product identifier

Substance name: Meropenem for Injection, USP (I.V.) 1g per vial

EC No: N/A

REACH Registration No.: N/D

CAS No.: N/A

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

Recommended use : Treatment of infections caused by Meropenem susceptible bacteria

Restrictions on use : Prescribed by the physician

1.3 Details of the supplier of the safety data sheet

Manufacturer: Savior Lifetec Corporation

Address: 29, Kejhong Road, Chu-Nan Chen, Hsinchu Science-Based Industrial Park, Miao-Li County, Taiwan 35053, R.O.C.

Telephone No.: 886-37-580-100

E-mail address of competent person responsible for the SDS: info@saviorlifetec.com.tw

1.4 Emergency telephone number

Opening hours: Only available during the following office hours: 8.30am to 5.30pm

Other comments: Available languages: Chinese and English

Telephone number: 886-37-580-100

SECTION 2: Hazards identification

2.1 Classification of the substance or mixture

Classification according CLP regulation (Regulation (EC) No. 1272/2008, as amended)

Hazard class	Hazard Category	H-phrases
Acute toxicity	Category 4	Harmful if inhaled

S-phrases(s)

S3 : Keep in a cool place.

S7 : Keep container tightly closed.

2.2. Label elements

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Labeling in accordance with EC-Directives (67/548/EEC or 1999/45/EC, as amended)

This product contains no hazardous constituents, or the concentration of all chemical constituents are below the regulatory threshold limits described by Occupational Safety Health Administration Hazard Communication standard 29 CFR 1910.1200 and the European Directive 91/155/EEC, and 93/112/EC.

Classification system :

The classification was made according to the latest editions of international substances lists, and expanded upon from company and literature data.

Symbols/Indication of danger



Hazard statement(s)

Category	Causes
H315	Causes skin irritation
H317	May cause an allergic skin reaction.
H319	Causes serious eye irritation
H335	May cause respiratory irritation

Precautionary statement(s)

P301+P310 : If swallowed, immediately call a poison center or doctor/physician.

P302+P334 : If on skin, immerse in cool water/wrap in wet bandages.

P302+P350 : If on skin, gently wash with plenty of soap and water.

P304+P340 : If inhaled, move the victim to the fresh air and let the victim take rest in a position comfortable for breathing.

P305+P351 : If in eye, rinse with water continuously for several minutes. Remove contact lenses, if you wear which would be easier for rinsing water.

P280 : Wear protective gloves/protective clothing/eye protection/face protection.

P281 : Use personal protective equipment as required.

Supplemental Hazard information (EU): Not applicable

2.3. Other hazards

Causes hypersensitivity due to the exposure

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SECTION 3: Composition/information on ingredients

3.1 Substances.

Chemical Name: (4R,5S,6S)-3-[[[(3S,5S)-5-(Dimethylcarbamoyl)-3-pyrrolidinyl]thio]-6-[(1R)-1-hydroxyethyl]-4-methyl-7-oxo-1-azabicyclo[3.2.0]hept-2-ene-2-carboxylic acid trihydrate

Formula: $C_{17}H_{25}N_3O_5S \cdot 3H_2O$

CAS No: N/A

3.2 Mixtures

Chemical characterization

Meropenem and Sodium Carbonate (Sterile Bulk)

Hazardous ingredients

Component : Meropenem trihydrate

CAS No : 119478-56-7

EC number: N/A

Index number: N/A

Therapeutic Category : Antibacterial

Classification hazard substance EC

Xn	Harmful	R42
Acute toxicity	Category 4	H302

SECTION 4: First aid measures

4.1 Description of first aid measures

Due to the composition and type of the substances present in the product, no particular warnings are necessary.

Inhalation:

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Take the victim into open air; keep them warm and calm. If breathing is irregular or stops, perform artificial respiration. Do not administer anything orally. If unconscious, place them in a suitable position and seek medical assistance.

Eye contact:

If wearing contact lenses, remove them. Wash eyes with plenty of clean and cool water for at least 10 minutes while pulling eyelids up, and seek medical assistance.

Skin contact:

Remove contaminated clothing. Wash skin vigorously with water and soap or a suitable skin cleaner. NEVER use solvents or thinners.

Ingestion:

If accidentally ingested, seek immediate medical attention. Keep calm. NEVER induce vomiting.

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

No known acute or delayed effects from exposure to the product.

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

In case of doubt or when symptoms of feeling unwell persist, get medical attention. Never administer anything orally to persons who are unconscious.

SECTION 5: Firefighting measures

5.1. Extinguishing Media

Suitable extinguishing media:

Water spray jet

Alcohol-resistant foam

Carbon dioxide

Dry powder

Unsuitable extinguishing media:

Do not use direct stream of water to extinguish

5.2. Special hazards arising from the substance or mixture

Special risks:

Fire can cause thick, black smoke. As a result of thermal decomposition, dangerous products can form: carbon monoxide, carbon dioxide. Exposure to combustion or decomposition products can be harmful to your health.

5.3. Advice for firefighters

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Special protective equipment during firefighting such as boots, overalls, gloves, eye and face protection and breathing apparatus

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

6.1.1. For non-emergency personnel

Ensure adequate ventilation

Wear suitable protective equipment

6.1.2. For emergency personnel

Evacuate the danger area or consult with an expert

6.2. Environmental precautions

Product not classified as hazardous for the environment, avoid spillage as much as possible.

6.3 Methods and material for containment and cleaning up

The contaminated area should be immediately cleaned with an appropriate de-contaminator. Pour the decontaminator on the remains in an opened container and let it act various days until no further reaction is produced.

SECTION 7: Handling and storage

7.1. Precautions for safe handling

Advice on safe handling

As a general rule, when handling the material avoid contact and inhalation of dusts, mists, and/vapors associated with the material. Wash thoroughly after handling.

Hygiene measures

Keep away from foodstuffs and beverages.

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Advice on protection against fire and explosion

Observe the general rules of industrial fire protection

7.2. Conditions for safe storage, including any incompatibilities

Advice on storage compatibility

This material should be handled and stored per label instruction to ensure product integrity. Store the dry powder in closed container at controlled room temperature.

Do not store with alkaline & strong oxidizing agents.

7.3. Specific end use(s)

Recommendations:

No further recommendations

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

Community occupational exposure limit	Directive 98/24/EC
Community limit	Directive 2004/37/EC
Community biological limit	Directive 98/24/EC

8.2. Exposure controls

General protective measures

Do not inhale vapors and avoid eye and skin contact

Eye/Face protection : The type of eye/face protection equipment required such as safety glasses, safety goggles, and face-shield

Skin & Hand protection: For long term exposure: Butyl rubber gloves, Minimum breakthrough time/Gloves: 480min. Minimum thickness/gloves 0.7mm, For short-term exposure (splash protection); Nitrile rubber gloves, Minimum breakthrough time/ Gloves: 30min, Minimum thickness/gloves 0.4mm, These types of protective gloves are offered by various manufacturers. Please note the manufacturers detailed statements, especially about the minimum thickness and the minimum breakthrough time. Consider also the particular working conditions under which the gloves are being used.

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Respiratory protection : For gases, vapors, mist or dust, the type of protective equipment to be used shall be specified based on the hazard and potential for exposure, including air-purifying respirators, specifying the proper purifying element (cartridge or canister), the adequate particulate filters and the adequate masks, or self-contained breathing apparatus.

Thermal hazards : When specifying protective equipment to be worn for materials that represent a thermal hazard, special consideration shall be given to the construction of the personal protective equipment.

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

- (a) Appearance : Crystalline powder
- (b) Odor : N/A
- (C) Odor threshold: N/A
- (d) pH: Between 7.3 ~ 8.3 for freshly constituted aqueous solutions
- (e) Melting point / freezing point: N/A
- (f) Initial boiling point and boiling range: N/A
- (g) Flash point: N/A
- (h) Evaporation rate: N/A
- (i) Flammability (solid, gas): N/A
- (j) Upper/lower flammability or explosive limits: N/A
- (k) Vapour pressure: N/A
- (l) Vapour density: N/A
- (m) Relative density: N/A
- (n) Solubility (ies): Soluble in water
- (o) Partition coefficient: n-octanol/water: N/A
- (p) Auto-ignition temperature: N/A
- (q) Decomposition temperature: N/A
- (r) Viscosity: N/A
- (s) Explosive properties: N/A

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(t) Oxidizing properties: N/A

SECTION 10: Stability and reactivity

10.1 Reactivity.

The product does not present hazards by their reactivity.

10.2 Chemical stability.

Stable under recommended storage conditions and decomposes at high temperature.

10.3 Possibility of hazardous reactions.

The product does not present possibility of hazardous reactions.

10.4 Conditions to avoid.

Avoid any improper handling and High temperature

10.5 Incompatible materials.

Keep away from oxidizing agents and from highly alkaline or acidic materials in order to prevent exothermic reactions.

10.6 Hazardous decomposition products: When handled and stored appropriately, no dangerous decomposition products are known.

SECTION 11: Toxicological information

11.1. Information on toxicological effects

Repeated or prolonged contact with the product can cause the elimination of oil from the skin, giving rise to non-allergic contact dermatitis and absorption of the product through the skin. Splatters in the eyes can cause irritation and reversible damage.

Information related to product itself

Acute oral toxicity: Low order of acute toxicity.

Rat : LD50 : > 5 grams / kg

Mouse : LD50 : > 5 grams / kg

a) Eye irritation : The degree of irritation was insufficient to warrant labeling as an eye irritant.

b) Skin irritation : The degree of irritation was insufficient to warrant labeling as a skin irritant

c) Respiratory or skin sensitization: Not conclusive data for classification.

d) Germ cell mutagenicity: Not conclusive data for classification.

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e) Carcinogenicity; Not conclusive data for classification.

f) Reproductive toxicity: Not conclusive data for classification.

g) STOT-single exposure: Not conclusive data for classification.

h) STOT-repeated exposure: Not conclusive data for classification.

i) Aspiration hazard: Not conclusive data for classification

SECTION 12: Ecological information

12.1 Toxicity.

No information is available regarding the Eco toxicity.

12.2 Persistence and degradability.

No information is available about persistence and degradability of the product.

12.3 Bioaccumulative potencial.

No information is available regarding the bioaccumulation.

12.4 Mobility in soil.

No information is available about the mobility in soil.

The product must not be allowed to go into sewers or waterways.

Prevent penetration into the ground.

12.5 Results of PBT and vPvB assessment.

No information is available about the results of PBT and vPvB assessment of the product.

12.6 Other adverse effects.

No information is available about other adverse effects for the environment

SECTION 13: Disposal consideration

13.1. Waste treatment methods

13.1.1 Product/packaging disposal:

Dispose of according to all federal, state and local applicable regulations. Packaging that cannot be

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cleaned should be disposed of as product waste uncontaminated packaging may be reused.

Labels should not be removed from containers until they have been cleaned. Containers should be

cleaned by appropriate methods and then re-used or disposed of by landfill or incineration as appropriate.

13.1.2 Waste treatment-relevant information

Follow the provisions of Directive 2008/98/EC regarding waste management.

13.1.3 Sewage disposal-relevant information:

Do not dump into sewers or waterways. Waste and empty containers must be handled and eliminated according to current, local/national legislation.

SECTION 14: Transport information

Transportation is not dangerous. In case of road accident causing the product's spillage, proceed in accordance with point 6.

14.1 UN number.

Transportation is not dangerous.

14.2 UN proper shipping name.

Transportation is not dangerous.

14.3 Transport hazard class (es).

Transportation is not dangerous.

14.4 Packing group.

Transportation is not dangerous.

14.5 Environmental hazards.

Transportation is not dangerous.

SECTION 15: Regulatory information

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

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Savior Lifetec Corporation certified that all chemical substances in this shipment comply with all applicable rules or order under TSCA and that SLC are not offering a chemical substance for entry in violation of TSCA or any applicable rule or order thereunder.

The shipment being imported does not contain an "intergeneric microorganism" per 40 CFR 725.3, PCBs, asbestos, any of the chemical substances regulated by 40 CFR part 747 and any hexavalent chromium-based water treatment chemicals.

Moreover, this chemical substance is subject to neither a TSCA § 5 (e) Order to which you are a party nor to a Significant New Use Rule.

15.2 Chemical safety assessment.

There has been no evaluation a chemical safety assessment of the product.

SECTION 16: Other information

This sheet is issued on March 28th of year 2016 for the 1st version.

The information in this Safety Data Sheet on the Preparation is based on current knowledge and on current EC and national laws, as far as the working conditions of the users is beyond our knowledge and control. The product must not be used for purposes other than those that are specified without first having written instructions on how to handle. It is always the responsibility of the user to take the appropriate measures in order to comply with the requirements established by current legislation. The information contained in this Safety Sheet only states a description of the safety requirements for the preparation, and it must not be considered as a guarantee of its properties.