

Safety Data Sheet

MEROPENEM FOR INJECTION USP AND SODIUM CHLORIDE INJECTION USP

SDS Revision Date:

05/13/2015

1. Identification

1.1. Product identifier

Product Identity MEROPENEM FOR INJECTION USP AND SODIUM CHLORIDE INJECTION USP
Alternate Names Catalog No: 3183-11, 3185-11

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

Intended use Carbapenem antibiotic for parenteral use
Application Method See prescribing information

1.3. Details of the supplier of the safety data sheet

Company Name B. Braun Medical Inc.
(Product Manufactured by Facta-See below) 824 Twelfth Ave
Bethlehem, PA 18018-3524, USA
Emergency (800) 854-6851
Customer Service: B. Braun Medical Inc. (800) 854-6851
Manufactured By (Company Name) Facta Farmaceutici SpA
Nucleo Industriale Sant'Atto
San Nicolo a Tordino, 64100 Teramo (TE), Italy
Emergency Dr. Alessandro Tagliaboschi, Plant Managing Director
+39- 331 6755373

2. Hazard(s) identification

2.1. Classification of the substance or mixture

Eye Irritation, 2;H319	Causes serious eye irritation.
Skin sensitization, 1B, H317	May cause an allergic skin reaction.
Respiratory sensitization, 1B, H334	May cause allergy or asthma symptoms or breathing difficulties in inhaled.
Acute aquatic toxicity, 1, H400	Very toxic to aquatic life.
chronic Aquatic Toxicity, 1, H410	Very toxic to aquatic life with long lasting effects.

Refer to Section 16 for 'Other Information'

2.2. Label elements

Using the Toxicity Data listed in Section 11 and 12 the product is labeled as follows.

Signal Word: Danger

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[Prevention]:

P261: Avoid breathing dust / fume / gas / mist / vapors / spray.

P273: Avoid release to the environment.

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

P285: In case of inadequate ventilation wear respiratory protection.

P391: Collect spillage.

P501: Dispose of contents/container to an approved incineration plant.

[Response]:

P302+352: IF ON SKIN: Wash with plenty of soap and water.

P304+341: IF INHALED: If breathing is difficult, remove victim to fresh air and keep at rest in a position comfortable for breathing.

P313: Get medical advice / attention.

P321: Specific treatment (see information on this label).

P333+313: If skin irritation or a rash occurs: Get medical advice / attention.

P342+311: If experiencing respiratory symptoms: Call a POISON CENTER or doctor / physician.

P363: Wash contaminated clothing before reuse.

[Storage]:

No GHS storage statements

[Disposal]:

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

3. Composition/information on ingredients

This product contains the following substances that present a hazard within the meaning of the relevant State and Federal Hazardous Substances regulations.

Ingredient/Chemical Designations	Weight %	GHS Classification	Notes
Meropenem Trihydrate CAS Number: 119478-56-7	~ 85%	Skin Sensitization, 1;H317 Respiratory Sensitization, 1;H334 Acute Aquatic Toxicity, 1; H400 Chronic Aquatic Toxicity, 1; H410	[1]
Sodium Carbonate CAS Number: 497-19-8	~ 15%	Eye irritation, 2; H319	[1]

In accordance with paragraph (i) of §1910.1200, the specific chemical identity and/or exact percentage (concentration) of composition has been withheld as a trade secret.

[1] Substance classified with a health or environmental hazard.

[2] Substance with a workplace exposure limit.

[3] PBT-substance or vPvB-substance.

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*The full texts of the phrases are shown in Section 16.

This SDS and its hazards pertain to the drug component only - the diluent is a nonhazardous mixture of sodium chloride and water.

4. First aid measures

4.1. Description of first aid measures

General	Remove from exposure. Remove contaminated clothing. Persons developing serious hypersensitivity (anaphylactic) reactions must receive immediate medical attention. If person is not breathing give artificial respiration. If breathing is difficult give oxygen. Obtain medical attention.
Inhalation	Remove patient from exposure, keep warm and at rest. Obtain medical attention for symptoms of difficulty in breathing and wheeziness, however minor.
Eyes	Irrigate with eyewash solution or clean water, holding the eyelids apart, for at least 10 minutes. Obtain medical attention.
Skin	Take off all contaminated clothing immediately. After contact with skin, wash immediately with plenty of water. Obtain medical attention.
Ingestion	Wash out mouth with water and give 200-300ml of water to drink. Do NOT induce vomiting as a First-Aid measure. Obtain medical attention.

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

Overview	Refer to Section 2 and Section 11.
Indication of any immediate medical attention and special treatment needed	Symptomatic treatment and supportive therapy as indicated. For further detail, consult the prescribing information.

5. Fire-fighting measures

5.1. Extinguishing media

Water spray, foam, dry powder or CO₂. Avoid high pressure media which could cause the formation of a potentially explosive dust-air mixture.

5.2. Special hazards arising from the substance or mixture

If involved in a fire, it may burn and emit noxious and toxic fumes.

Avoid breathing dust / fume / gas / mist / vapors / spray.

5.3. Advice for fire-fighters

A self contained breathing apparatus and suitable protective clothing should be worn in fire conditions. Prevent fire extinguishing water from contaminating surface water or the ground water system.

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6. Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

Ensure suitable personal protection during removal of spillages. See Section 8. Ensure adequate ventilation. In case of accident, avoid breathing dust from damaged or crushed container.

6.2. Environmental precautions

Prevent entry into drains, sewers or watercourses. Collect spillage.

6.3. Methods and material for containment and cleaning up

Avoid dust generation. Wash the spillage area with water. Transfer spilled vials to a suitable container for disposal. Avoid release to the environment. See section 13.

7. Handling and storage

7.1. Precautions for safe handling

No special precautions are necessary when handling packed product. In case of accident, avoid contact with skin and eyes. Do not breathe dust. Minimize dust generation and accumulation. Procedures for handling should be in accordance with the AstraZeneca Code of Practice for Handling beta-Lactam Antibiotics.

7.2. Conditions for safe storage, including any incompatibilities

Keep container tightly closed. Do not freeze bag. See product label for additional information.

7.3. Specific end use(s)

See prescribing information.

8. Exposure controls and personal protection

8.1. Control parameters

CAS No.	Ingredient	Value	Control Parameters
119478-56-7	Meropenem Trihydrate	0.1 mg/m ³	LTEL 8Hr TWA This value is not a health base OEL. The exposure should be kept as low as possible below this level to protect against respiratory sensitization.

Carcinogen Data

CAS No.	Ingredient	Source	Value
119478-56-7	Meropenem Trihydrate	N/A	Carcinogen: No information available

8.2. Exposure controls

Respiratory

Use a self-contained breathing apparatus if the risk assessment does not support the selection of other protection

Eyes

Use goggles to protect against direct contact with the substance if the risk assessment does not support the selection of other protection.

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Skin Use impervious clothing to protect against direct contact with the product if the risk assessment does not support the selection of other protection. Use impervious protective gloves to protect against direct contact with the product. If the product is dissolved or wetted use a glove material that is resistant to the solvent/liquid.

Engineering Controls The specific controls will depend on local circumstances and should be based on the risk assessment. Appropriate controls to reduce exposure may include engineering controls, for example ventilation, procedural controls and the use of personal protection equipment. Prevent entry into drains, sewers or water courses. See Section 6 for environmental precautions.

Other Work Practices The recommended personal protective equipment (PPE) is based on preventing the potential adverse health effects from exposure to the active pharmaceutical ingredient (API). The risk of exposure to the API in the formulation/product needs to be taken into consideration.

Decisions about whether the use of personal protective equipment (PPE) is appropriate as part of the control strategy should be based on the workplace risk assessment and should take account of local legislative requirements for selection and use. There are multiple factors that will affect the specific requirements such as amount and concentration of the material, duration of exposure, frequency of exposure, external environmental conditions, the task, the user etc. The information below should not be used in isolation and should be considered in the context of the workplace risk assessment on a case by case basis.

9. Physical and chemical properties

Appearance	White to off-white Powder
Odor	Not Measured
Odor threshold	Not Measured
pH	Not Measured
Melting point / freezing point	Not Measured
Initial boiling point and boiling range	Not Measured
Flash Point	Not Measured
Evaporation rate (Ether = 1)	Not Measured
Flammability (solid, gas)	Not Applicable
Upper/lower flammability or explosive limits	Lower Explosive Limit: Not Measured Upper Explosive Limit: Not Measured
Vapor pressure (Pa)	Not Measured
Vapor Density	Not Measured
Specific Gravity	Not Measured
Solubility in Water	Not Measured
Partition coefficient n-octanol/water (Log Kow)	Not Measured
Auto-ignition temperature	Not Measured
Decomposition temperature	Not Measured
Viscosity (cSt)	Not Measured

9.2. Other information

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No other relevant information.

10. Stability and reactivity

10.1. Reactivity

No known reactivity hazard under normal conditions.

10.2. Chemical stability

Stable under normal circumstances.

10.3. Possibility of hazardous reactions

No data available.

10.4. Conditions to avoid

No conditions producing hazardous situations known.

10.5. Incompatible materials

No data available.

10.6. Hazardous decomposition products

No hazardous decomposition products are known.

11. Toxicological information

Acute toxicity

Ingredient	Oral LD50, mg/kg	Skin LD50, mg/kg	Inhalation Vapor LC50, mg/L/4hr	Inhalation Dust/Mist LC50, mg/L/4hr	Inhalation Gas LC50, ppm
Meropenem Trihydrate, CAS# 119478-56-7	No data available	No data available	No data available	No data available	No data available

Note: As a result of the physical presentation of the product, the risk to health is expected to be very low under normal conditions of handling and use. The following health hazard assessment is based on a consideration of the composition of this product.

Classification	Category	Hazard Description
Acute toxicity (Ingestion)	---	May produce headache, diarrhoea, drowsiness, skin rashes or cough.
Acute toxicity (skin)	---	Unlikely to cause skin irritation.
Acute toxicity (inhalation)	---	May cause effects as described under repeated exposure (STOT).
Skin corrosion/irritation	---	Unlikely to cause skin irritation.
Serious eye damage/irritation	---	Causes serious eye irritation.
Respiratory sensitization	1	May cause effects as described under repeated exposure (STOT).
Skin sensitization	1	May cause sensitisation by inhalation and skin

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		contact. Symptoms may include wheeziness and difficulty in breathing.
Germ cell mutagenicity	---	Not considered to be a genotoxic.
Carcinogenicity	---	No information available.
Reproductive toxicity	---	There is no evidence of a teratogenic potential or any other adverse effects on reproductive function. The substance may be excreted in breast milk at low concentrations.
STOT-single exposure	---	May cause effects as described under repeated exposure.(STOT).
STOT-repeated exposure	---	Repeated exposure by inhalation may produce hypersensitivity reactions as described above.
Aspiration hazard	---	No information available.

12. Ecological information

12.1. Toxicity

Aquatic Ecotoxicity

Very toxic to aquatic life with long lasting effects. No information on this formulation. The following information refers to active ingredient.

Ingredient	48 hr EC50 Daphnia Magna, mg/l	72 hr EC50 Blue-Green Algae, mg/l	ErC50 algae, mg/l
Meropenem Trihydrate	> 900 (Tested at concentration above water solubility)	0.026	Not Available
Effect on Effluent Treatment	There is no evidence of inhibition to the aerobic treatment process at a concentration of > 100 mg/l.		

12.2. Persistence and degradability

Not rapidly degradable.

12.3. Bioaccumulative potential

The substance has low potential for bioaccumulation

12.4. Mobility in soil

The substance has low mobility in soil (pH 7.7, Koc 220). The substance has moderate mobility in soil (pH 5.8, Koc 1121). The substance has high mobility in soil (pH 5.0, Koc 21724).

12.5. Results of PBT and vPvB assessment

This product contains no PBT/vPvB chemicals.

12.6. Other adverse effects

No data available.

13. Disposal considerations

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13.1. Waste treatment methods

Disposal should be in accordance with local, state or national legislation. Waste, even small quantities, should never be poured down drains, sewers or water courses. Dispose of contents/ container to an approved incineration plant.

13.2. Contaminated Packaging

Empty container will retain product residue. Observe all hazard precautions.

14. Transport information

RESTRICTED FOR TANSPORT

	DOT (Domestic Surface Transportation)	IMO / IMDG (Ocean Transportation)	ICAO/IATA
14.1. UN number	Not Applicable	3077	3077
14.2. UN proper shipping name	Not Regulated	ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (MEROPENEM TRIHYDRATE)	Environmentally hazardous substance, solid, n.o.s. (MEROPENEM TRIHYDRATE)
14.3. Transport hazard class(es)	DOT Hazard Class: Not Applicable	9	9
14.4. Packing group	Not Applicable	Not Applicable	Not Applicable
14.5. Environmental hazards			
IMDG	Marine Pollutant		
14.6. Special precautions for user	No further information		

15. Regulatory information

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

This material and its container must be disposed of as hazardous waste. In order to comply with legal duties it is necessary to consult local and national legislation.

Regulatory Overview	The regulatory data in Section 15 is not intended to be all-inclusive, only selected regulations are represented.
Toxic Substance Control Act (TSCA)	All components of this material are either listed or exempt from listing on the TSCA Inventory.
WHMIS Classification	D2A
US EPA Tier II Hazards	

Fire: No

Sudden Release of Pressure: No

Reactive: No

Immediate (Acute): Yes

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Delayed (Chronic): No

EPCRA 311/312 Chemicals and RQs:

No information available

EPCRA 302 Extremely Hazardous:

No information available

EPCRA 313 Toxic Chemicals:

No information available

Proposition 65 - Carcinogens (>0.0%):

No information available

Proposition 65 - Developmental Toxins (>0.0%):

No information available

Proposition 65 - Female Repro Toxins (>0.0%):

No information available

Proposition 65 - Male Repro Toxins (>0.0%):

No information available

New Jersey RTK Substances (>1%) :

No information available

Pennsylvania RTK Substances (>1%) :

No information available

16. Other information

The information provided in this SDS is intended to be used in the handling of this material in the work place. This SDS is not a substitute for the direction for use of product literature that may accompany the finished product. All information contained in this SDS has been assembled from other published documents and are assumed to be accurate. In the event of an adverse incident associated with this material, this SDS is not intended to be a substitute for consultation with appropriately qualified personnel.

The full text of the phrases appearing in Section 3 is:

H317 May cause an allergic skin reaction.

H334 May cause allergic or asthmatic symptoms or breathing difficulties if inhaled.

H319 Causes serious eye irritation.

H319 Causes serious eye irritation.

H400 Very toxic to aquatic life

H410 Very toxic to aquatic life with long lasting effects

H319 Causes serious eye irritation.

This is the first version in the GHS SDS format for Meropenem for Injection and Sodium Chloride Injection in DUPLEX®. Listings of changes from previous versions in other formats are not applicable.

References:

Safety Data Sheet: Meronem, Revision 15.07.2013, Version 2.0-AstraZeneca

Customer Service: B. Braun Medical Inc.

(949) 660-2000

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