

Safety Data Sheet for Drug Products (EU)



Date of issue: 15-MAY-2018

Replaces version of:

MEROP PWU 1000MG 22GLW 1350MG.001 7008275.001 (BASIS)

1. Identification of the substance/preparation and of the company

Product name MEROP PWU 1000MG 22GLW 1350MG.001
Generic Name Meropenem trihydrate
Pharmacological Action Antibiotic
Usage Drug product (pharmaceutical bulk, primary packed, finished product, pharmaceutical intermediate)
Company name Novartis Pharma AG
4002 Basel
Switzerland
Tel: +41 61 324 11 11, email: sds.support@novartis.com
Emergency phone number CHEMTEL (International) +1 813 676 1670 (365/24/7)

2. Hazards identification

For side effects, which could also have impact for people working with this substance, please refer to the Patient Information Leaflet.

3. Composition / information on ingredients

For classification of declared components, see section 15, "Regulatory Information"

Chemical Name	Contains:	CAS Number
Meropenem trihydrate	80 - 90 %	119478-56-7

Remaining components are inert ingredients.

For TLV values of declared components, see Section 8, Exposure controls / Personal

4. First aid measures

Eye Contact Immediately rinse eyes thoroughly with running water as long as possible (approx. 15 min). Take injured quickly to factory medical center or call an ambulance (code word: eye accident).
Skin Contact Remove contaminated clothing. Rinse contaminated skin immediately with plenty of water and soap and seek medical advice.
Inhalation Remove the victim from danger zone, avoid further exposure.
Ingestion If swallowed, seek medical advice immediately and show this container or label.
Notes to Physician General measures to eliminate the substance and to reduce absorption.

5. Fire fighting measures

Suitable Extinguishing Media Water spray or fog, foam, dry chemical powder, CO2, dry sand
Unsuitable Extinguishing Media No restrictions
Protective equipment for firefighters Wear self-contained breathing apparatus and fire protective suite.

6. Accidental release measures

Personal precautions Avoid contact with skin, eyes and clothing.
Environmental precautions Must not be released into sewers, drains or wells.
Methods for cleaning Transfer large quantities into a container. Clean up the rest with absorbent material and discharge properly.

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7. Handling and storage

No special handling requirements for normal use of this material.

Store in a dry and cool place and observe special instructions from supplier.

8. Exposure controls / Personal protection

Occupational Exposure Limit (OEL)

no data available

TLV values of declared components

Contains:

Meropenem trihydrate

no data available

Personal protection for open handling

Health care personnel



Safety glasses (EN166) Lab coat Disposable gloves (EN374)

9. Physical and chemical properties

Formulation powder

Flash Point not applicable

10. Stability and reactivity

Under the normal conditions of use, the product is stable.

11. Toxicological information

Acute Toxicity Data of Meropenem trihydrate
no data available

Irritation, Corrosion Data of Meropenem trihydrate
Skin (Species: rabbit) non irritant
Data of Meropenem trihydrate
Eyes (Species: rabbit) non irritant

Sensitisation Data of Meropenem trihydrate
Respiratory system Suspicion
Data of Meropenem trihydrate
Skin Suspicion

Mutagenicity Data of Meropenem trihydrate
Negative (Mammalian Cytogenetic Test in Vitro)
Method: OECD 473 * 1997 * In vitro Mammalian Chromosome Aberration Test
2000/32/EC B.10
Data of Meropenem trihydrate
Negative (AMES-Test (reverse mutation assay))
Method: 2000/32/EC B.13/14

12. Ecological information

Biological Elimination Data of Meropenem trihydrate
not degradable in biol. waste water treatment plant

Fish acute toxicity no data available

Aquatic invertebrate acute toxicity Data of Meropenem trihydrate
EC50: > 900 mg/l

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	Species: daphnia magna (water flea)
Algae Toxicity	no data available
Bacterial Respiration Inhibition	no data available
Chemical Oxygen Demand	Data of Meropenem trihydrate 1.03 mg O ₂ /g

13. Disposal considerations

Disposal Requirements Fill into suitable waste receptacles, seal and label them properly. Incineration in an approved, controlled furnace with combustion gas scrubbing and emission gas control. Local regulations should be adhered to.

14. Transport information


Regulation	Class	UN No.	PG	Label	LQ
RID/ADR:	Not restricted	0			N.A.
IMDG-Code:	Not restricted	0			
ICAO/IATA-DGR:	Not restricted	0			

ICAO/IATA-DGR: no dangerous good

Proper shipping name: -

15. Regulatory information

Classifications of components:

Chemical Name	Contains:	CAS Number	Picto	Signal Word	Classification
Meropenem trihydrate	80 - 90 %	119478-56-7		D	H334, H317

Remaining components are inert ingredients.

16. Other information

Abbreviations used

H317: May cause an allergic skin reaction.

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

Recipient Sandoz , Inc
Sandoz

Product should be stored, handled and used in accordance with good industrial hygiene practices and in conformity with legal regulations. The information contained herein is based on the present state of our knowledge and is intended to describe our products from the point of view of safety requirements. It should therefore not be construed as guaranteeing specific properties.