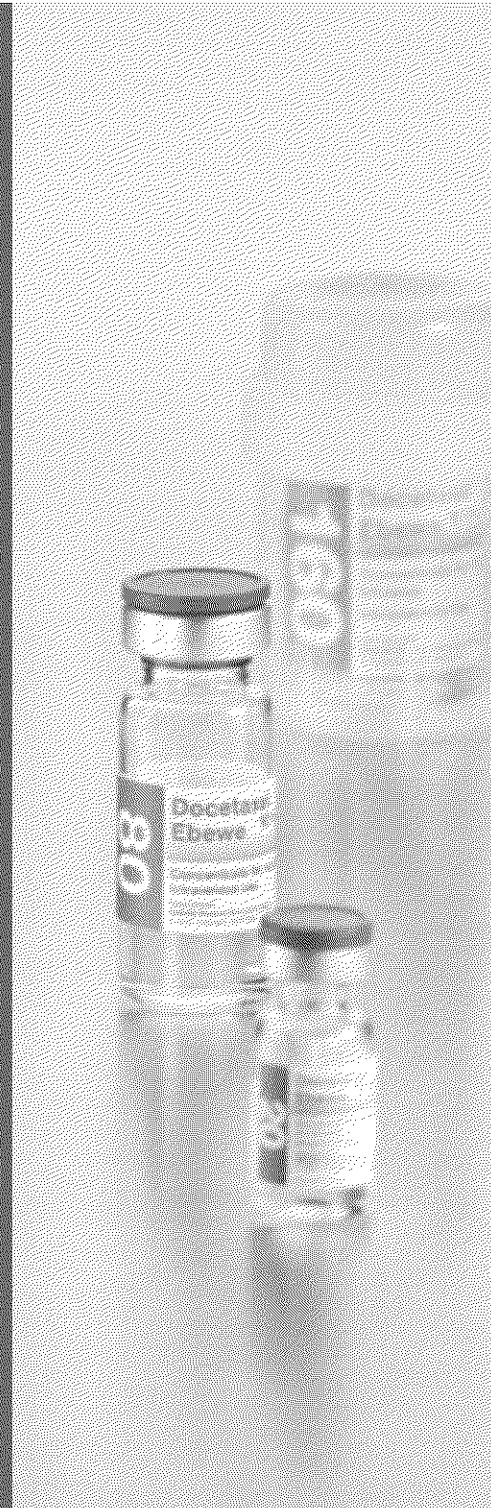


# Docetaxel Ebewe

## Ebedoce

### Safety Data Sheet

According to REACH Directive (EU) No. 1907/2006



# Safety-Data-Sheet

According to REACH Directive (EU) No. 1907/2006

Brand name: Docetaxel Ebewe (Ebedoce)

Last modification: January 2010 version: 2

## This safety data sheet refers to the finished pharmaceutical product

### 1. Product and Company Identification

**Brand name:** Docetaxel Ebewe (Ebedoce)

**Active ingredient: Docetaxel**

**Chemical name:**

(2R,3S)-N-carboxy-3-phenylisoserine,N-*tert*-butyl ester, 13-ester with 5β-20-epoxy-1,2α,4,7β,10β,13α-hexahydroxytax-11-en-9-one 4-acetate 2-benzoate

Formula: C<sub>43</sub>H<sub>53</sub>NO<sub>1</sub>

**Pharmacotherapeutic category:**

Antineoplastic agent for treating cancer

**Manufacturer and Marketing Authorisation Holder:**

EBEWE Pharma Ges.m.b.H.Nfg

Mondseestr. 11

4866 Unterach

Austria

e-mail: oncology@ebewe.com

In cases of emergency: +43 664 30 83 234

### 2. Potential hazards

**Hazard designation:**

Cytotoxic agent

**Classification system:**

Pharmaceuticals, which are subject to an approval procedure or registration process in keeping with the pharmacopoeia, are exempt from the provisions of the Chemicals Act.

- Toxic by inhalation, if swallowed and after contact with skin
- may cause hereditary damage
- can affect fertility
- may irritate the respiratory organs and the skin.
- may cause serious eye damage

### 3. Composition

|                  | Symbol       | R-phrases                        | Concentration<br>per ml |
|------------------|--------------|----------------------------------|-------------------------|
| <b>Docetaxel</b> | T: toxic     | 60-61-R36-<br>48/23/24/25-64-R68 | 10 mg                   |
| <b>Ethanol</b>   | F: flammable | R11                              | 258,9 mg                |

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#### 4. First-aid measures

**After skin contact:**

- Wash with copious amounts of soap and water.
- Immediately remove any contaminated clothing and dispose of safely (hazardous waste).
- Seek medical advice

**After eye contact:**

- Remove contact lenses.
- Immediately rinse eyes with plenty of water for fifteen minutes
- Seek medical advice

**After swallowing:**

- Rinse mouth with water
- Do not induce vomiting
- Seek medical attention

#### 5. Fire-fighting measures

**Extinguishing media:**

- Choose fire-extinguishing agents according to the environment
- Packaging material fires may be extinguished with water, carbon dioxide, or dry chemical.

**Special hazards caused by the agent, its combustion product or gases produced:**

CO, CO<sub>2</sub> and oxides of nitrogen may be generated in a fire.

**Special protective equipment for fire fighting:**

Firefighting in confined spaces requires full protective gear and supplied air respiratory protection.

#### 6. Measures in case of unintentional release

**Personal precautionary measures:**

In case of spills:

- evacuate the area - keep unprotected persons away
- avoid inhalation and contact with skin and eyes
- wear complete protection equipment (P3-mask, safety goggles, protective gloves) when cleaning the area

**Environmental protection measures:**

- the product or contaminated firewater must not get into the sewage system / upper water / ground-water.

**Method of cleaning**

- Soak up any spilled fluid with copious amounts of cotton wool or similar
- soil: collect carefully and place in a closable container
- thoroughly clean the affected area after complete removal of the material
- dispose all materials used in the cleaning process including the personal protection equipment as hazardous waste

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## 7. Handling and storage

### Notes on safe handling:

- Take appropriate measures to prevent any contact with skin or inhalation of aerosols
- Only open and withdraw fluid from vials or ampoules in safety cabinets for cytotoxic handling or isolators
- wear personal protective clothing (gloves designated for handling cytotoxic drugs)
- ensure correct and clean method of working
- Do not keep, eat or drink any food or beverages in the work area.

### Notes on protection against fire and explosion:

- In case of a fire in the vicinity, protect the product against heat or cool the container.

### Requirements on storage areas and containers:

- Store in original primary packaging only.
- Store separated from food
- Do not store together with lyes
- Do not store together with acids
- Do not store together with oxidizing agents

**Further information on storage conditions:** Please refer to the local SPC and PIL.

## 8. Exposure limitation and personal protection equipment

- Use suitable safety cabinets or isolators for preparation – please refer to your local regulations and laws.  
According to the ISOPP Standards of Practice of 2007 biological safety cabinets (BSC) of at least class 2 (EN 12469 2000) which are designed and constructed for the preparation of sterile products should be used.
- Keep the development of aerosols to a minimum via correct working technique.
- Provide emergency shower.
- Provide eye bath.

### Limitation of exposure:

Due to the absence of conclusive scientific examinations so far, it is still not possible to define work protection values (TLV values, PEL values, TRC values) for finished cytotoxic pharmaceuticals.

### Personal protection equipment:

#### General protection and hygiene measures

- Do not eat, drink or smoke during work
- Avoid contact with skin, eyes and mucous membranes
- Immediately change contaminated, saturated clothing; only wear again after cleaning
- Wear fresh clothing every day
- Do not wear used work clothing outside of the working area.
- Use water and soap to thoroughly wash hands before breaks and after work
- The product must be handled by trained personnel only

#### Breathing protection

- no special protection is necessary when the product is handled inside a safety cabinet or an isolator
- use filter type with filter class P3 when cleaning up spills

#### Protective clothing

- Wear protective gloves designated for handling of cytotoxics, e.g. made of latex (wearing duration - 20 minutes maximum).
- Protect exposed skin (e.g. gown, safety goggles if applicable)

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### 9. Physical and chemical characteristics

**Appearance:** Clear, colorless to light yellow solution  
**pH:** 3.0 – 4.5  
**Density:** 1.021 g/ml

### 10. Stability and reactivity

**Stability:** Stable under recommended storage conditions.

**Materials / conditions to be avoided:**

PVC.

Only use PVC-free containers and infusion sets.

### 11. Information on toxicology

Cytotoxic substance; cancerogenic, mutagenic and teratogenic properties.  
For further information please refer to the local SPC and PIL

### 12. Environment-related information

**General instructions:**

This product must not be released into the environment.

**Water hazard classification (WHC):**

The substance potentially constitutes a water hazard and must not get into the sewage system undiluted.

### 13. Information on disposal

Waste must be segregated, packaged, and disposed of in a way that personnel and the environment are not contaminated according to local regulatory laws and regulations for cytotoxic drugs.

### 14. Information on transport

Transportation must be in accordance with all local, state, provincial or federal legislation concerning the transport of hazardous agents.

**Note:** Final pharmaceutical products are no hazardous freight in keeping with the ADR/GGVSE (special regulation 601) applicable for road and rail traffic.

**UN-No.:** UN 1851  
**ADR/GGVSE-Class:** 6.1  
**Name:** Drug, liquid, toxic, no further remarks

IATA: NF  
IMDG: NF  
ADR: NF  
RID: NF  
ADNR: NF

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### 15. Legal regulations

The final pharmaceutical product is not subject to labeling requirement according to EU guidelines.

### 16. Miscellaneous information

#### Miscellaneous notes:

These data describe the safety requirements of the product exclusively and are based on today's state of knowledge. They are no assurance of characteristic features of the product described in the sense of the legal warranty provisions.

The safety data sheet is used to describe the product with respect to handling and safety requirements.

For more information please refer to the local SPC and PIL.

#### Data sheet issuing department:

EBEWE Pharma, Dr. Manfred Nussbaumer, site manager.