



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

**Product identifier**

DOCETAXEL EBEWE (EBEDOCE)

**Chemical characterization ( Mixture )**

Cytotoxic agent:

Active substance: 1,7 $\beta$ ,10 $\beta$ -trihydroxy-9-oxo-5 $\beta$ ,20-epoxytax-11-ene-2a,4,13a-triyl 4-acetate 2-benzoate 13-((2R,3S)-3-[(tert-butoxycarbonyl)amino]-2-hydroxy-3-phenylpropanoate)

**Use of the substance/mixture**

Finished medicinal product

**Details of the supplier of the safety data sheet**

SANDOZ Oncology Injectables

EBEWE Pharma Ges.m.b.H. Nfg.KG

Mondseestrasse 11

A-4866 Unterach

Telephone: +43 7665 8123 0

Telefax: +43 7665 8123 11

ask.oncology@sandoz.com

Responsible for the safety data sheet: sds@gbk-ingelheim.de

Emergency CONTACT (24-Hour-Number)

GBK/Infotrac ID 103736: (USA domestic) 1 800 535 5053 or international (001) 352 323 3500

**Further Information**

As a drug, the product does not need to be labelled.

**SECTION 2: Hazards identification**

**Route(s) of Entry**

Skin and eye contact, inhalation and ingestion.

**Signs and Symptoms of Exposure**

WARNING !

Highly flammable

May impair fertility.

May cause harm to the unborn child.

May cause harm to breastfed babies

OSHA Hazard Communication: This material is considered hazardous by the OSHA Hazard Communication Standard 29CFR 1910.1200.

Carcinogenicity (NTP): Not listed

Carcinogenicity (IARC): Not listed

Carcinogenicity (OSHA): Not listed

**Other hazards**

Not known.

**SECTION 3: Composition/information on ingredients**

**Mixtures**

Sum formula: C43H53NO1

**Hazardous components**

CAS No	Components	Quantity
64-17-5	ethanol, ethyl alcohol	45 - 50 %
114977-28-5	Docetaxel	1 - 5 %

**SECTION 4: First aid measures**

**Description of first aid measures**



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### General information

Remove contaminated soaked clothing immediately and dispose of safely. Take away from danger area and lay down affected person. If you feel unwell, seek medical advice.

#### After inhalation

In case of inhalation of mist seek medical advice. Information on label instructions. Remove the casualty into fresh air and keep him immobile. Medical treatment.

#### After contact with skin

Wash off immediately with soap and plenty of water. Consult a doctor if skin irritation persists.

#### After contact with eyes

Rinse immediately with plenty of water, also under the eyelids, for at least 15 minutes. Seek medical treatment by eye specialist. Administer physiological saline i.v..

#### After ingestion

If swallowed seek medical advice immediately and show the doctor packing or label. Rinse out mouth and give plenty of water to drink. Do not induce vomiting. Never give anything by mouth to an unconscious person.

#### Indication of any immediate medical attention and special treatment needed

This product is a cytostatic. (Heart rhythm disturbances, Vomiting, Nausea) Treat symptoms. Continue to monitor for pneumonia and pulmonary oedema. Immediate medical treatment necessary, as untreated burns can result in slow-healing wounds.

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## SECTION 5: Firefighting measures

### Extinguishing media

#### Suitable extinguishing media

Alcohol-resistant foam, dry chemical, carbon dioxide (CO<sub>2</sub>), water-spray. Fire-extinguishing activities according to surrounding.

#### Unsuitable extinguishing media

Full water jet

#### Special hazards arising from the substance or mixture

In case of fire formation of dangerous gases possible. Fire may produce: Carbon monoxide (CO), carbon dioxide (CO<sub>2</sub>) and nitrogen oxides (NO<sub>x</sub>).

#### Advice for firefighters

Wear self-contained breathing apparatus and protective suit.

#### Additional information

Cool containers at risk with water spray jet. Collect contaminated firefighting water separately, must not be discharged into the drains. Fire residues and contaminated firefighting water must be disposed of in accordance with the local regulations.

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## SECTION 6: Accidental release measures

### Personal precautions, protective equipment and emergency procedures

Get unprotected persons to safety. Do not breathe vapours. Use personal protective clothing. Avoid contact with skin, eyes and clothing. Ensure adequate ventilation. Keep away sources of ignition.

### Environmental precautions

Do not discharge into the drains/surface waters/groundwater.

### Methods and material for containment and cleaning up

Soak up with inert absorbent material (e.g. sand, silica gel, acid binder, universal binder). Contaminated objects and floor clean thoroughly by consideration of environment regulations. Wear complete protection equipment (P3-mask, safety goggles, protective gloves) when cleaning the area.

### Reference to other sections

Observe protective instructions (see Sections 7 and 8). Information for disposal look up chapter 13.

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## SECTION 7: Handling and storage

### Precautions for safe handling

#### Advice on safe handling

Avoid formation of aerosols. Allow for sucking off. Handle and open container with care. Use personal protective clothing.



**Advice on protection against fire and explosion**

Keep away from heat and sources of ignition. Do not smoke. Take precautionary measures against static discharges.

**Further information on handling**

Take the usual precautions when handling with chemicals. At work do not eat, drink and smoke.

**Conditions for safe storage, including any incompatibilities**

**Requirements for storage rooms and vessels**

Keep only in original container. Keep container tightly closed in a dry, cool and well-ventilated place. Store in a cool and shaded area.

**Advice on storage compatibility**

Do not store together with oxidizing agents. Do not store with acids or alkalies. Keep away from food, drink and animal feeding stuffs.

**Further information on storage conditions**

Protect against direct sun radiation. Keep away from heat.

**SECTION 8: Exposure controls/personal protection**

**Control parameters**

**Exposure limits**

CAS No	Components	ppm	mg/m <sup>3</sup>	fib/cc	Category	Origin
64-17-5	Ethyl alcohol (Ethanol)	1000	1900		TWA (8 h)	PEL
	Ethyl alcohol	1000	1900		TWA (8 h)	REL

**Additional advice on limit values**

Avoid explosion - before application obtain special instructions. Handling should only be allowed by trained Personnel.

**Exposure controls**

**Occupational exposure controls**

Ensure adequate ventilation, especially in confined areas. Avoid formation of Aerosols. Provide emergency shower. Provide eye bath.

**Protective and hygiene measures**

Wash hands before breaks and immediately after handling the product. When using, do not eat, drink or smoke. Avoid contact with skin, eyes and clothing. Take off immediately all contaminated clothing.

**Respiratory protection**

No special protection is necessary when the product is handled inside a safety cabinet or an isolator. "Not required; except in case of aerosol formation." Short term: filter apparatus, Filter P3

**Hand protection**

Chemical-resistant gloves (EN 374) (Latex gloves.)

Follow the recommendations of the glove manufacturer for breakthrough properties especially for workplace conditions involving mechanical stress and contact duration.

**Eye protection**

Tightly fitting goggles

**Skin protection**

Protective suit.

**SECTION 9: Physical and chemical properties**

**Information on basic physical and chemical properties**

Physical state: Liquid  
 Color: Colourless - yellowish

pH-Value: 3.0 - 4.5

**Changes in the physical state**

Boiling point: 88.1 °C OECD 103  
 Flash point: 19.5 °C DIN EN ISO 13736  
 Lower explosion limits: n.d.

**DOCETAXEL EBEWE (EBEDOCE)**

Upper explosion limits:

Ignition temperature:

n.a.

Vapour pressure:

42.79 hPa OECD 104

(at 20 °C)

Vapour pressure:

54.35 hPa OECD 104

(at 25 °C)

Density (at 20 °C):

1.021 g/cm<sup>3</sup>

**Other information**

No data available.

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**SECTION 10: Stability and reactivity**

Stability: Stable

Possibility of Hazardous Reactions: Will not occur

**Conditions to avoid**

To avoid thermal decomposition, do not overheat.

**Incompatible materials**

Polyvinyl chloride - PVC

**Hazardous decomposition products**

No decomposition if stored and applied as directed.

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**SECTION 11: Toxicological information**

**Information on toxicological effects**

**Toxicokinetics, metabolism and distribution**

Cytotoxic agent

Suspected of causing genetic defects. May damage fertility. May cause harm to the unborn child. May cause damage to organs through prolonged or repeated exposure.

**Acute toxicity**

Docetaxel (Solution)

LD50/oral/rat: > 2000 mg/kg

Docetaxel (100%), CAS-No.: 114977-28-5

LD50/ intravenous / mouse: 156 mg/kg

LD50/ intravenous / Dog: 2.5 mg/kg

LD0/ intravenous / Rat: > 20 mg/kg

ethanol, ethyl alcohol, CAS-No.: 64-17-5

LD50/oral/rat: 6200 mg/kg

LC50/inhalativ/rat: 95,6 mg//4h

**Specific effects in experiment on an animal**

Docetaxel (100%), CAS-No.: 114977-28-5

Eye irritation (rabbit): Irritant

Skin irritation (rabbit): Non-irritant

Sensitization skin: Negative

**Irritation and corrosivity**

Skin: No information on irritating effect if properly used and handled. Frequent persistent contact with the skin may cause skin irritation. (Ethanol)

Eye: No information on irritating effect if properly used and handled. Splashes may cause eye irritation and reversible damage. Spray/mist may have a low irritating effect on eyes. (Ethanol)

**Sensitizing effects**

Not classified as skin sensitiser.

Possible sensitization in case of persons suffering from hypersensitivity.

**Severe effects after repeated or prolonged exposure**

STOT - Single exposure: Not classified.

STOT - Repeated exposure: 2

Aspiration hazard: Not classified. Inadvertent inhalation of the product aerosol may produce respiratory irritation.

**Carcinogenic/mutagenic/toxic effects for reproduction**

Carcinogenicity: Not classified.

Mutagenicity: 2

Teratogenicity: Not classified.  
Reproductive toxicity: 1A  
**Additional information on tests**  
Classification in compliance with the assessment procedure specified in the Regulation (EC) no 1272/2008.

**SECTION 12: Ecological information**

**Toxicity**

Do not discharge into the drains/surface waters/groundwater.

ethanol, ethyl alcohol, CAS-No.: 64-17-5  
LC50/fish: 8140 mg/l (Golden orfe)  
EC50: 9268 - 14221 mg/l (Daphnia magna)

**Persistence and degradability**

Not readily biodegradable. (0%, 28 d)

**Bioaccumulative potential**

No information available

**Mobility in soil**

No information available

**Results of PBT and vPvB assessment**

No information available

**Other adverse effects**

No information available

**SECTION 13: Disposal considerations**

**Waste treatment methods**

**Advice on disposal**

ÖNORM S 2104 (BGBl II, Nr. 262, 21.07.2008): SN 53510 g 77  
Can be disposed of as a solid waste or burned in a suitable installation subject to local regulations.

**Contaminated packaging**

ÖNORM S 2100: SN 53502  
Empty containers should be taken for local recycling, recovery or waste disposal.  
Contaminated packaging should be emptied as far as possible and after appropriate cleansing may be taken for reuse.  
Packaging that cannot be cleaned should be disposed of like the product.

**SECTION 14: Transport information**

**US DOT 49 CFR 172.101**

**Proper shipping name**

ETHANOL SOLUTION (ETHYL ALCOHOL SOLUTION)

ID Number: UN1170  
Hazard Class or Division: 3  
Packing group: II  
Label:

**Land transport (ADR/RID)**

**UN number:** UN1170  
**UN proper shipping name:** ETHANOL SOLUTION (ETHYL ALCOHOL SOLUTION)  
**Transport hazard class(es):** 3  
**Packing group:** II  
Hazard label: 3



Classification Code: F1  
Limited quantity: 1 L  
Hazard No: 33

Tunnel restriction code: D/E

**Other applicable information**

SP 601: Pharmaceutical products (medicines) ready for use, which are substances manufactured and packaged for retail sale or distribution for personal or household consumption are not subject to the requirements of ADR/RID.

**Inland waterways transport**

**UN number:** UN1170  
**UN proper shipping name:** ETHANOL SOLUTION (ETHYL ALCOHOL SOLUTION)  
**Transport hazard class(es):** 3  
**Packing group:** II  
Hazard label: 3



Classification Code: F1  
Limited quantity: 1 L

**Other applicable information**

SP 601: Pharmaceutical products (medicines) ready for use, which are substances manufactured and packaged for retail sale or distribution for personal or household consumption are not subject to the requirements of ADR/RID.

**Marine transport**

**UN number:** UN1170  
**UN proper shipping name:** ETHANOL SOLUTION (ETHYL ALCOHOL SOLUTION)  
**Transport hazard class(es):** 3  
**Packing group:** II  
Hazard label: 3



Limited quantity: 1 L  
EmS: F-E, S-D

**Air transport**

**UN/ID number:** ID8000  
**UN proper shipping name:** CONSUMER COMMODITY  
**Transport hazard class(es):** 9  
Hazard label: 9



Limited quantity Passenger: 30 kg G  
IATA-packing instructions - Passenger: Y963  
IATA-max. quantity - Passenger: 30 kg G  
IATA-packing instructions - Cargo: Y963  
IATA-max. quantity - Cargo: 30 kg G

**Environmental hazards**

Dangerous for the environment: no

**SECTION 15: Regulatory information**

**U.S. Regulations**

**National Inventory TSCA**

The components of this product are not subject to TSCA.

**SARA**

To the best of our knowledge this product contains no toxic chemicals subject to the supplier notification requirements of Section 313 of the Superfund Amendments and Reauthorization Act (SARA/EPCRA) and the requirements of 40 CFR Part 372.



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**State Regulations**

This product contains max VOC: 48%

**Chemical Safety Assessment**

Chemical safety assessments for substances in this mixture were not carried out.

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**SECTION 16: Other information**

**Hazardous Materials Information Label (HMIS)**

Health:	*2
Flammability:	3
Physical Hazard:	0

**NFPA Hazard Ratings**

Health:	2
Flammability:	3
Reactivity:	0
Unique Hazard:	



**Other data**

Data of sections 4 to 8, as well as 10 to 12, do not necessarily refer to the use and the regular handling of the product (in this sense consult Prescribing Information and expert information), but to release of major amounts in case of accidents and irregularities.

The information describes exclusively the safety requirements for the product (s) and is based on the present level of our knowledge.

The delivery specifications are contained in the corresponding product sheet.

This data does not constitute a guarantee for the characteristics of the product(s) as defined by the legal warranty regulations.

(n.a. = not applicable; n.d. = not determined)

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*(The data for the hazardous ingredients were taken respectively from the last version of the sub-contractor's safety data sheet.)*