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

1.1. Product identifier

DOCETAXEL EBEWE (EBEDOCE)

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

Use of the substance/mixture

Finished medicinal product

1.3. 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

1.4. Emergency telephone: +49 (0) 6132 / 84463 (GBK Gefahrgut Büro GmbH)

Further Information

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

SECTION 2: Hazards identification

2.1. Classification of the substance or mixture

Indications of danger : Highly flammable, Toxic, Harmful
R-phrases:
May impair fertility.
May cause harm to the unborn child.
Highly flammable.
May cause harm to breastfed babies.

GHS classification

Hazard categories:
Flammable liquid: Flam. Liq. 2
Germ cell mutagenicity: Muta. 2
Reproductive toxicity: Repr. 1A
Specific target organ toxicity - repeated exposure: STOT RE 2
Hazard Statements:
Highly flammable liquid and vapour.
Suspected of causing genetic defects.
May damage fertility. May damage the unborn child.
May cause damage to organs through prolonged or repeated exposure.

2.2. Label elements

Pictograms: GHS02-GHS08



Signal word: Danger

Hazardous components which must be listed on the label

Docetaxel

Hazard statements

H225	Highly flammable liquid and vapour.
H341	Suspected of causing genetic defects.
H360FD	May damage fertility. May damage the unborn child.

H373	May cause damage to organs through prolonged or repeated exposure.

Precautionary statements

P201	Obtain special instructions before use.
P202	Do not handle until all safety precautions have been read and understood.
P210	Keep away from heat/sparks/open flames/hot surfaces. - No smoking.
P308+P313	IF exposed or concerned: Get medical advice/attention.
P403+P235	Store in a well-ventilated place. Keep cool.
P405	Store locked up.

Additional advice on labelling

According to EC-rules and correspondent national legislation, this product, being a ready medicine, is not subject to mandatory identification.

2.3. Other hazards

Not known.

SECTION 3: Composition/information on ingredients

3.2. Mixtures

Chemical characterization

Cytotoxic agent:
Active substance: 1,7ß,10ß-trihydroxy-9-oxo-5ß,20-epoxytax-11-ene-2a,4,13a-triyl 4-acetate 2-benzoate 13-{(2R,3S)-3-[(tert-butoxycarbonyl)amino]-2-hydroxy-3-phenylpropanoate}
Sum formula: C43H53NO1

Hazardous components

EC No	Chemical name	Quantity
CAS No	Classification	
Index No	GHS classification	
REACH No		
200-578-6	ethanol, ethyl alcohol	25 - 50 %
64-17-5	F R11	
603-002-00-5	Flam. Liq. 2; H225	
	Docetaxel	1 - 5 %
114977-28-5	Muta. Cat. 3, Repr. Cat. 1, T, Xi R60-61-36-48/23/24/25-64-68	
	Eye Irrit. 2, STOT RE 1, Repr. 1A, Lact., Muta. 2; H319 H372 H360FD H362 H341	

Full text of R- and H-phrases: see section 16.

SECTION 4: First aid measures

4.1. Description of first aid measures

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

Do not use emetics. 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.

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

May cause harm to breastfed babies

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

This product is a cytostatic. In case of therapeutical use of the product, typical side effects are: Heart rhythm

disturbances, Vomiting, Nausea. Treat symptoms. Continue to monitor for pneumonia and pulmonary oedema. Do not use emetics. Immediate medical treatment necessary, as untreated burns can result in slow-healing wounds.

SECTION 5: Firefighting measures

5.1. Extinguishing media

Suitable extinguishing media

Alcohol-resistant foam, dry chemical, carbon dioxide (CO2), water-spray. Fire-extinguishing activities according to surrounding.

Extinguishing media which must not be used for safety reasons

Full water jet.

5.2. 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 (CO2) and nitrogen oxides (NOx).

5.3. 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.

SECTION 6: Accidental release measures

6.1. 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.

6.2. Environmental precautions

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

6.3. 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.

6.4. Reference to other sections

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

SECTION 7: Handling and storage

7.1. 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.

7.2. 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.

7.3. Specific end use(s)

Finished medicinal product

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

Exposure limits (EH40)

CAS No	Chemical name	ml/m³	mg/m³	F/ml	Category	Origin
64-17-5	Ethanol	1000	1920		TWA (8 h)	WEL
		-	-		STEL (15 min)	WEL

Additional advice on limit values

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

8.2. 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

9.1. Information on basic physical and chemical properties

Physical state:	Liquid	
Colour:	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.	
Upper explosion limits:		
Ignition temperature:	n.a.	
Vapour pressure: (at 20 °C)	42.79 hPa	OECD 104
Vapour pressure: (at 25 °C)	54.35 hPa	OECD 104
Density (at 20 °C):	1.021 g/cm³	

9.2. Other information

No data available.

SECTION 10: Stability and reactivity

10.1. Reactivity

No decomposition if stored and applied as directed.

10.2. Chemical stability

Stable under normal conditions.

10.3. Possibility of hazardous reactions
Stable under normal conditions.

10.4. Conditions to avoid
To avoid thermal decomposition, do not overheat.

10.5. Incompatible materials
Polyvinyl chloride - PVC

10.6. Hazardous decomposition products
No decomposition if stored and applied as directed.

SECTION 11: Toxicological information

11.1. Information on toxicological effects

Toxicocinetics, 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/inhalation/rat: 95,6 mg/l/4h

Specific effects in experiment on an animal

Docetaxel (100%), CAS-No.: 114977-28-5
Eyes irritation (rabbit): Irritant
Skin irritation (rabbit): Non-irritant
Skin sensitization: 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)

Sensitising 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

12.1. 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)

12.2. Persistence and degradability
Not readily biodegradable. (0%, 28 d)

12.3. Bioaccumulative potential
No information available.

12.4. Mobility in soil
No information available.

12.5. Results of PBT and vPvB assessment
No information available.

12.6. Other adverse effects
No information available.

SECTION 13: Disposal considerations

13.1. 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.

Waste disposal number of waste from residues/unused products

180108	WASTES FROM HUMAN OR ANIMAL HEALTH CARE AND/OR RELATED RESEARCH (except kitchen and restaurant wastes not arising from immediate health care); wastes from natal care, diagnosis, treatment or prevention of disease in humans; cytotoxic and cytostatic medicines Classified as hazardous waste.

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

Land transport (ADR/RID)

14.1. UN number:	UN1170
14.2. UN proper shipping name:	ETHANOL SOLUTION (ETHYL ALCOHOL SOLUTION)
14.3. Transport hazard class(es):	3
14.4. Packing group:	II
Hazard label:	3



Classification code:	F1
Special Provisions:	144 601
Limited quantity:	1 L
Transport category:	2
Hazard No:	33
Tunnel restriction code:	D/E

Other applicable information (land transport)
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

14.1. UN number:	UN1170
14.2. UN proper shipping name:	ETHANOL SOLUTION (ETHYL ALCOHOL SOLUTION)
14.3. Transport hazard class(es):	3
14.4. Packing group:	II
Hazard label:	3



Classification code: F1
Special Provisions: 144 601
Limited quantity: 1 L

Other applicable information (inland waterways transport)

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

14.1. UN number: UN1170

14.2. UN proper shipping name: ETHANOL SOLUTION (ETHYL ALCOHOL SOLUTION)

14.3. Transport hazard class(es): 3

14.4. Packing group: II

Hazard label: 3



Special Provisions: 144
Limited quantity: 1 L
EmS: F-E, S-D

Air transport

UN/ID number: ID8000

14.2. UN proper shipping name: CONSUMER COMMODITY

14.3. Transport hazard class(es): 9

Hazard label: 9



Special Provisions: A112
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

14.5. Environmental hazards

Dangerous for the environment: no

14.6. Special precautions for user

Handle in accordance with good industrial hygiene and safety practice.

14.7. Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code

The transport takes place only in approved and appropriate packaging.

SECTION 15: Regulatory information

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

EU regulatory information

Additional information

According to EC-rules and correspondent national legislation, this product, being a ready medicine, is not subject to mandatory identification.

National regulatory information

Employment restrictions: Observe employment restrictions for young people. Observe employment restrictions for child bearing mothers and nursing.

15.2. Chemical Safety Assessment

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

SECTION 16: Other information

Full text of R-phrases referred to under sections 2 and 3

11	Highly flammable.
36	Irritating to eyes.
48/23/24/25	Toxic: danger of serious damage to health by prolonged exposure through inhalation, in contact with skin and if swallowed.
60	May impair fertility.
61	May cause harm to the unborn child.
64	May cause harm to breastfed babies.
68	Possible risks of irreversible effects.

Full text of H-Statements referred to under sections 2 and 3

H225	Highly flammable liquid and vapour.
H319	Causes serious eye irritation.
H341	Suspected of causing genetic defects.
H360FD	May damage fertility. May damage the unborn child.
H362	May cause harm to breast-fed children.
H372	Causes damage to organs through prolonged or repeated exposure.
H373	May cause damage to organs through prolonged or repeated exposure.

Further Information

Data of items 4 to 8, as well as 10 to 12, do partly not refer to the use and the regular employing of the product (in this sense consult information on use and on product), but to liberation 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)

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