

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

### **1.1. Product identifier**

CYTARABIN EBEWE (ALEXAN)

### **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 : Toxic

R-phrases:

May cause heritable genetic damage.

May cause harm to the unborn child.

May cause sensitization by inhalation and skin contact.

#### **GHS classification**

Hazard categories:

Skin corrosion/irritation: Skin Irrit. 2

Serious eye damage/eye irritation: Eye Irrit. 2

Respiratory/skin sensitization: Resp. Sens. 1

Respiratory/skin sensitization: Skin Sens. 1

Germ cell mutagenicity: Muta. 1A

Reproductive toxicity: Repr. 1A

Hazard Statements:

Causes skin irritation.

Causes serious eye irritation.

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

May cause an allergic skin reaction.

May cause genetic defects.

May damage the unborn child.

### **2.2. Label elements**

Pictograms:

GHS08



Signal word:

Danger

**Hazardous components which must be listed on the label**

Cytarabine

#### Hazard statements

H315	Causes skin irritation.
H319	Causes serious eye irritation.
H334	May cause allergy or asthma symptoms or breathing difficulties if inhaled.
H317	May cause an allergic skin reaction.
H340	May cause genetic defects.
H360D	May damage the unborn child.

#### Precautionary statements

P201	Obtain special instructions before use.
P202	Do not handle until all safety precautions have been read and understood.
P280	Wear protective gloves/protective clothing/eye protection/face protection.
P308+P313	IF exposed or concerned: Get medical advice/attention.
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: 4-amino-1-[(2R,3S,4R,5R)-3,4-dihydroxy-5- (hydroxymethyl)oxolan-2-yl] pyrimidin-2-one

Sum formula: C<sub>9</sub>H<sub>13</sub>N<sub>3</sub>O<sub>5</sub>

##### Hazardous components

EC No	Chemical name	Quantity
CAS No	Classification	
Index No	GHS classification	
REACH No		
	Cytarabine	
147-94-4	Muta. Cat. 1, Repr. Cat. 1, Xi R46-61-36/37/38-42/43	2 / 5 / 10 %
	Eye Irrit. 2, STOT SE 3, Skin Irrit. 2, Resp. Sens. 1, Skin Sens. 1, Muta. 1A, Repr. 1A; H319 H335 H315 H334 H317 H340 H360D	

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.

##### 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.

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Never give anything by mouth to an unconscious person.

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

May cause heritable genetic damage

May cause sensitization by inhalation and skin contact.

**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.

Administration of activated charcoal.

Treat symptoms.

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**SECTION 5: Firefighting measures**

**5.1. Extinguishing media**

**Suitable extinguishing media**

Alcohol-resistant foam, dry chemical, carbon dioxide (CO<sub>2</sub>), 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 (CO<sub>2</sub>) and nitrogen oxides (NO<sub>x</sub>).

**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.

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**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.

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**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**

No specific precautions required.

**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

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

#### **8.1. Control parameters**

##### **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.

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### **SECTION 9: Physical and chemical properties**

#### **9.1. Information on basic physical and chemical properties**

Physical state:	Liquid
Colour:	Colourless, clear

pH-Value:	8.4 - 9.2
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##### **Changes in the physical state**

Boiling point:	102,3 °C	OECD 103
Flash point:	> 103 °C	EU A.9
Vapour pressure:	23,89 hPa	OECD 104
Water solubility: (at 20 °C)	Soluble	

#### **9.2. Other information**

Density: 1.012 g/ml (20 mg/ml), 1.022 g/ml (50 mg/ml), 1.041 g/ml (100 mg/ml).

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### **SECTION 10: Stability and reactivity**

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#### **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**

Not known.

#### **10.6. Hazardous decomposition products**

No decomposition if stored and applied as directed.

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### **SECTION 11: Toxicological information**

#### **11.1. Information on toxicological effects**

##### **Toxicokinetics, metabolism and distribution**

Cytotoxic agent

May cause harm to the unborn child. May cause genetic defects.

##### **Acute toxicity**

Cytarabine, CAS-No. 147-94-4

LD50/oral/rat: > 5000 mg/kg

LD50/oral/mouse: 3150 mg/kg

LD50/intraperitoneal /Rat: 1000 (> 5000) mg/kg

LD50/intraperitoneal /mouse: 1000 (3379) mg/kg

LD50/intravenous/mouse: > 7000 mg/kg

LD50/intravenous/Rat: > 5000 mg/kg

##### **Irritation and corrosivity**

Skin: Causes skin irritation.

Eye: Causes serious eye irritation.

##### **Sensitising effects**

May cause an allergic skin reaction. May cause allergy or asthma symptoms or breathing difficulties if inhaled.

##### **Severe effects after repeated or prolonged exposure**

STOT - Single exposure: Not classified.

STOT - Repeated exposure: Not classified.

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

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

Carcinogenicity: Not classified.

Mutagenicity: 1A

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.

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### **SECTION 12: Ecological information**

#### **12.1. Toxicity**

Ecological data are not available.

#### **12.2. Persistence and degradability**

No information available.

#### **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.

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#### **12.6. Other adverse effects**

No information available.

#### **Further information**

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

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### **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.

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### **SECTION 14: Transport information**

#### **Land transport (ADR/RID)**

##### **Other applicable information (land transport)**

No hazardous material as defined by the transport regulations.

#### **Inland waterways transport**

##### **Other applicable information (inland waterways transport)**

No hazardous material as defined by the transport regulations.

#### **Marine transport**

##### **Other applicable information (marine transport)**

No hazardous material as defined by the transport regulations.

#### **Air transport**

##### **Other applicable information (air transport)**

No hazardous material as defined by the transport regulations.

#### **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.

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### **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.

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### **SECTION 16: Other information**

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

36/37/38	Irritating to eyes, respiratory system and skin.
42/43	May cause sensitization by inhalation and skin contact.
46	May cause heritable genetic damage.
61	May cause harm to the unborn child.

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

H315	Causes skin irritation.
H317	May cause an allergic skin reaction.
H319	Causes serious eye irritation.
H334	May cause allergy or asthma symptoms or breathing difficulties if inhaled .
H335	May cause respiratory irritation.
H340	May cause genetic defects.
H360D	May damage the unborn child.

**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)

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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.)*