

FLUDARABIN EBEWE (EBERABIN)

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

1.1. Product identifier

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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

Company name: SANDOZ Oncology Injectables
EBEWE Pharma Ges.m.b.H. Nfg.KG

Street: Mondseestrasse 11

Place: A-4866 Unterach

Telephone: +43 7665 8123 0

Telefax: +43 7665 8123 11

e-mail: 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 number: +49 (0) 6132 / 84463 (GBK 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: T - Toxic

R phrases:

May cause cancer.

May cause heritable genetic damage.

May impair fertility.

May cause harm to the unborn child.

Classification according to Regulation (EC) No. 1272/2008 [CLP]

Hazard categories:

Germ cell mutagenicity: Muta. 1A

Carcinogenicity: Carc. 1A

Reproductive toxicity: Repr. 1A

Hazard Statements:

May cause genetic defects.

May cause cancer.

May damage fertility. May damage the unborn child.

2.2. Label elements

Signal word: Danger

Pictograms: GHS08



Hazard statements

H340 May cause genetic defects.

H350 May cause cancer.

H360FD May damage fertility. May damage the unborn child.

Precautionary statements

P201 Obtain special instructions before use.

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P202	Do not handle until all safety precautions have been read and understood.
P281	Use personal protective equipment as required.
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: [(2R,3R,4S,5R)-5-(6-amino-2-fluoro-purin-9-yl)- 3,4-dihydroxy-oxolan-2-yl]methoxyphosphonic acid

Sum formula: C₁₀H₁₃FN₅O₇P

Hazardous components

EC No	Chemical name	Quantity
CAS No	Classification according to Directive 67/548/EEC	
Index No	Classification according to Regulation (EC) No. 1272/2008 [CLP]	
REACH No		
	Fludarabine phosphate	1 - < 5 %
75607-67-9	Carc. Cat. 1, Muta. Cat. 1, Repr. Cat. 1, Xn - Harmful R45-46-60-61-20/21/22-48	
	Carc. 1A, Muta. 1A, Repr. 1A, Acute Tox. 4, Acute Tox. 4, Acute Tox. 4, STOT RE 2; H350 H340 H360FD H302 H312 H332 H373	

Full text of R-, H- and EUH-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 this container 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 cancer.

May cause heritable genetic damage

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.

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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.

Unsuitable extinguishing media

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 (NO_x).

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/ground water.

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 see section 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

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

8.2. Exposure controls

Appropriate engineering 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.

Eye/face protection

Tightly fitting goggles (EN 166).

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.

Skin protection

Protective suit.

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

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Physical state:	Liquid
Colour:	Colourless, clear
pH-Value:	6.0 - 7.1
Initial boiling point and boiling range:	~ 100 °C
Flash point:	> 101 °C
Density (at 20 °C):	1.023 g/cm ³
Water solubility: (at 20 °C)	Soluble

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.

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10.5. Incompatible materials

Not known.

10.6. Hazardous decomposition products

No decomposition if stored and applied as directed.

SECTION 11: Toxicological information

11.1. Information on toxicological effects

Toxicokinetics, metabolism and distribution

Cytotoxic agent.

May cause cancer. May cause heritable genetic damage. May impair fertility. May cause harm to the unborn child.

Acute toxicity

Based on available data, the classification criteria are not met.

Fludarabine phosphate, CAS-No. 75607-67-9

LD50/oral/rat: 230 mg/kg

LD50/intraperitoneal /Rat: 70 mg/kg

LD50/intravenous/mouse: 1236 mg/kg

LD50/intravenous/Rat (male) : 910 mg/kg

LD50/intravenous/Rat (female) : 1050 mg/kg

LD50/intravenous/Mouse (male) : 1404 mg/kg

LD50/intravenous/Mouse (female) : 1235 mg/kg

Irritation and corrosivity

Based on available data, the classification criteria are not met.

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

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.

Sensitising effects

Based on available data, the classification criteria are not met.

Possible sensitization in case of persons suffering from hypersensitivity.

STOT-single exposure

Based on available data, the classification criteria are not met.

Severe effects after repeated or prolonged exposure

Based on available data, the classification criteria are not met.

Carcinogenic/mutagenic/toxic effects for reproduction

May cause genetic defects. (Fludarabine phosphate)

May cause cancer. (Fludarabine phosphate)

May damage fertility. May damage the unborn child. (Fludarabine phosphate)

Aspiration hazard

Based on available data, the classification criteria are not met.

Inadvertent inhalation of the product aerosol may produce respiratory irritation.

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/ground water.

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.

12.6. Other adverse effects

No information available.

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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.

SECTION 14: Transport information

Land transport (ADR/RID); Marine transport (IMDG); Air transport (ICAO); Inland waterways transport (ADN)

14.1. UN number:

Not applicable. No hazardous material as defined by the transport regulations.

14.2. UN proper shipping name:

Not applicable. No hazardous material as defined by the transport regulations.

14.3. Transport hazard class(es):

Not applicable. No hazardous material as defined by the transport regulations.

14.4. Packing group:

Not applicable. No hazardous material as defined by the transport regulations.

14.5. Environmental hazards

Not applicable. No hazardous material as defined by the transport regulations.

14.6. Special precautions for user

Not applicable. No hazardous material as defined by the transport regulations.

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

Not applicable. No hazardous material as defined by the transport regulations.

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

Changes

Section: 1 - 16

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Abbreviations and acronyms

ADR = Accord européen relatif au transport international des marchandises Dangereuses par Route

RID = Règlement concernant le transport international ferroviaire de marchandises dangereuses

ADN = Accord européen relatif au transport international des marchandises dangereuses par voie de navigation intérieure

IMDG = International Maritime Code for Dangerous Goods

IATA/ICAO = International Air Transport Association / International Civil Aviation Organization

MARPOL = International Convention for the Prevention of Pollution from Ships

IBC-Code = International Code for the Construction and Equipment of Ships Carrying Dangerous Chemicals in Bulk

GHS = Globally Harmonized System of Classification and Labelling of Chemicals

REACH = Registration, Evaluation, Authorization and Restriction of Chemicals

CAS = Chemical Abstract Service

EN = European norm

ISO = International Organization for Standardization

DIN = Deutsche Industrie Norm

PBT = Persistent Bioaccumulative and Toxic

LD = Lethal dose

LC = Lethal concentration

EC = Effect concentration

IC = Median immobilisation concentration or median inhibitory concentration

Relevant R-phrases (Number and full text)

20/21/22 Harmful by inhalation, in contact with skin and if swallowed.

45 May cause cancer.

46 May cause heritable genetic damage.

48 Danger of serious damage to health by prolonged exposure.

60 May impair fertility.

61 May cause harm to the unborn child.

Relevant H- and EUH-phrases (Number and full text)

H302 Harmful if swallowed.

H312 Harmful in contact with skin.

H332 Harmful if inhaled.

H340 May cause genetic defects.

H350 May cause cancer.

H360FD May damage fertility. May damage the unborn child.

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.)