

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

1.1. Product identifier

5-FLUOROURACIL EBEWE (EBEFLUORO)

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

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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, Harmful

R-phrases:

May cause heritable genetic damage.

Harmful by inhalation, in contact with skin and if swallowed.

GHS classification

Hazard categories:

Acute toxicity: Acute Tox. 4

Germ cell mutagenicity: Muta. 1A

Specific target organ toxicity - single exposure: STOT SE 2

Hazard Statements:

Harmful if swallowed.

May cause genetic defects.

May cause damage to organs.

2.2. Label elements

Pictograms:

GHS07-GHS08



Signal word:

Danger

Hazardous components which must be listed on the label

5-Fluorouracil

Hazard statements

H302 Harmful if swallowed.

H340 May cause genetic defects.

H371 May cause damage to organs.

Precautionary statements

P201 Obtain special instructions before use.

P202 Do not handle until all safety precautions have been read and understood.

P260 Do not breathe dust/fume/gas/mist/vapours/spray.

P281 Use personal protective equipment as required.
P301+P312 IF SWALLOWED: Call a POISON CENTER or doctor/physician if you feel unwell.
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: 5-fluoro-1H-pyrimidine-2,4-dione

Sum formula: C₄H₃FN₂O₂

Hazardous components

EC No	Chemical name	Quantity
CAS No	Classification	
Index No	GHS classification	
REACH No		
200-085-6	5-Fluorouracil	
51-21-8	Muta. Cat. 1, T R46-23/24/25-39-48	5 - 10 %
	Acute Tox. 3, Acute Tox. 3, Acute Tox. 3, STOT SE 1, Muta. 1A, STOT RE 2; H331 H311 H301 H370 H340 H373	

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.

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

Harmful by inhalation, in contact with skin and if swallowed.

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.

In case of breathing difficulties give oxygen.

Treat symptoms.

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 (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/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

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

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.

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Physical state: Liquid
Colour: Colourless - yellowish, clear

pH-Value: 8.5 - 9.5

Changes in the physical state

Boiling point: 100,3 °C OECD 103
Flash point: > 101 °C
Vapour pressure: 24,24 hPa OECD 104
(at 20 °C)
Density (at 20 °C): 1,031 g/cm³
Water solubility: Soluble
(at 20 °C)

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

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 genetic defects. May cause damage to organs.

Harmful if swallowed.

Acute toxicity

5-Fluorouracil, CAS-No. 51-21-8

LD50/oral/rat: 230 mg/kg

LD50/oral/mouse: 115 mg/kg

LD50/oral/Dog: 30 mg/kg

LD50/intraperitoneal /Rat: 70 mg/kg

LD50/intraperitoneal /mouse: 100 mg/kg

LD50/intravenous/mouse: 245 mg/kg

LD50/intravenous/Rat: 81 mg/kg

LD50/intravenous/Guinea pig 25 mg/kg

LD50/subcutaneous/mouse: 169 mg/kg

LD50/subcutaneous/Rat: 217 mg/kg

Irritation and corrosivity

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

Not classified as skin sensitiser.

Possible sensitization in case of persons suffering from hypersensitivity.

Severe effects after repeated or prolonged exposure

STOT - Single exposure: 2

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: Not classified.

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

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.

12.6. Other adverse effects

No information available.

Further information

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

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)

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.

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

20/21/22	Harmful by inhalation, in contact with skin and if swallowed.
23/24/25	Toxic by inhalation, in contact with skin and if swallowed.
39	Danger of very serious irreversible effects.
46	May cause heritable genetic damage.
48	Danger of serious damage to health by prolonged exposure.

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

H301	Toxic if swallowed.
H302	Harmful if swallowed.
H311	Toxic in contact with skin.
H331	Toxic if inhaled.
H340	May cause genetic defects.
H370	Causes damage to organs.
H371	May cause damage to organs.
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.)