

5-FLUOROURACIL EBEWE (EBEFLUORO)

Safety Data Sheet

according to Regulation (EC) No. 1907/2006 (REACH) with its amendment Regulation (EU) 2020/878

Issue date: 01/04/2021

Revision date: 01/04/2021

Supersedes: 26/02/2016

Version: 2.0

SDS No: 11470-16

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

1.1. Product identifier

Product form : Mixture
Product name : 5-FLUOROURACIL EBEWE (EBEFLUORO)

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

1.2.1. Relevant identified uses

Use of the substance/mixture : Pharmaceutical
Function or use category : The product is considered a medicinal product according to AMG paragraph 2, section 2, no. 4 b.

1.2.2. Uses advised against

No additional information available

1.3. Details of the supplier of the safety data sheet

FAREVA Unterach GmbH

Mondseestraße 11

4866 Unterach - A

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office.unterach@fareva.com

E-mail address of competent person responsible for the SDS: sds@gbk-ingelheim.de

1.4. Emergency telephone number

Emergency number : Deutschland: 06132 - 84463 (GBK GmbH; 24 Stunden - 7 Tage/Woche - 365 Tage/Jahr)
Emergency CONTACT (24-Hour-Number)
GBK/Infotrac ID 103736: (USA domestic) 1 800 535 5053 or international (001)
352 323 3500

SECTION 2: Hazards identification

2.1. Classification of the substance or mixture

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

Acute toxicity (oral), Category 4	H302
Germ cell mutagenicity, Category 1A	H340
Reproductive toxicity, Category 1B	H360

Full text of H statements : see section 16

Adverse physicochemical, human health and environmental effects

May cause genetic defects. May damage fertility or the unborn child. Harmful if swallowed.

2.2. Label elements

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

Hazard pictograms (CLP) :



GHS07

GHS08

Signal word (CLP) : Danger
Contains : 5-Fluorouracil
Hazard statements (CLP) : H302 - Harmful if swallowed.
H340 - May cause genetic defects.
H360 - May damage fertility or the unborn child.

5-FLUOROURACIL EBEWE (EBEFLUORO)

Safety Data Sheet

according to Regulation (EC) No. 1907/2006 (REACH) with its amendment Regulation (EU) 2020/878
SDS No: 11470-16

FAREVA
UNTERACH

Precautionary statements (CLP)

- : P201 - Obtain special instructions before use.
- P202 - Do not handle until all safety precautions have been read and understood.
- P264 - Wash hands, forearms and face thoroughly after handling.
- P270 - Do not eat, drink or smoke when using this product.
- P280 - Wear protective gloves, eye protection.
- P301+P312 - IF SWALLOWED: Call a doctor, a POISON CENTER if you feel unwell.
- P308+P313 - IF exposed or concerned: Get medical advice/attention.
- P330 - Rinse mouth.
- P405 - Store locked up.
- P501 - Dispose of contents and container to in accordance with local and national regulations.

2.3. Other hazards

Other information

- : According to EC directives and the Ordinance on Hazardous Substances, the product is not subject to compulsory labelling.

The mixture does not contain substance(s) included in the list established in accordance with Article 59(1) of REACH for having endocrine disrupting properties, or is not identified as having endocrine disrupting properties in accordance with the criteria set out in Commission Delegated Regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605

SECTION 3: Composition/information on ingredients

3.1. Substances

Not applicable

3.2. Mixtures

Comments

- : Cytostatic drug. Active ingredient: 5-fluoro-1H-pyrimidine-2,4-dione

Name	Product identifier	%	Classification according to Regulation (EC) No. 1272/2008 [CLP]
5-Fluorouracil	CAS-No.: 51-21-8 EC-No.: 200-085-6	< 10	Acute Tox. 3 (Oral), H301 Acute Tox. 4 (Dermal), H312 Muta. 1A, H340 Repr. 1B, H360

Full text of H-statements: see section 16

SECTION 4: First aid measures

4.1. Description of first aid measures

- First-aid measures general : IF exposed or concerned: Get medical advice/attention. Call a poison center or a doctor if you feel unwell.
- First-aid measures after inhalation : Remove person to fresh air and keep comfortable for breathing.
- First-aid measures after skin contact : Wash skin with plenty of water.
- First-aid measures after eye contact : Rinse eyes with water as a precaution.
- First-aid measures after ingestion : Rinse mouth. Call a poison center or a doctor if you feel unwell.

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

No additional information available

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

Treat symptomatically.

5-FLUOROURACIL EBEWE (EBEFLUORO)

Safety Data Sheet

according to Regulation (EC) No. 1907/2006 (REACH) with its amendment Regulation (EU) 2020/878
SDS No: 11470-16

FAREVA
UNTERACH

SECTION 5: Firefighting measures

5.1. Extinguishing media

Suitable extinguishing media : Water spray. Dry powder. Foam. Carbon dioxide.

5.2. Special hazards arising from the substance or mixture

Hazardous decomposition products in case of fire : Toxic fumes may be released.

5.3. Advice for firefighters

Protection during firefighting : Do not attempt to take action without suitable protective equipment. Self-contained breathing apparatus. Complete protective clothing.

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

6.1.1. For non-emergency personnel

Emergency procedures : Only qualified personnel equipped with suitable protective equipment may intervene.

6.1.2. For emergency responders

Protective equipment : Do not attempt to take action without suitable protective equipment. For further information refer to section 8: "Exposure controls/personal protection".

6.2. Environmental precautions

Avoid release to the environment. Notify authorities if product enters sewers or public waters.

6.3. Methods and material for containment and cleaning up

Methods for cleaning up : Take up liquid spill into absorbent material. Notify authorities if product enters sewers or public waters.

Other information : Dispose of materials or solid residues at an authorized site.

6.4. Reference to other sections

For further information refer to section 13.

SECTION 7: Handling and storage

7.1. Precautions for safe handling

Precautions for safe handling : Ensure good ventilation of the work station. Obtain special instructions before use. Do not handle until all safety precautions have been read and understood. Take all necessary technical measures to avoid or minimize the release of the product on the workplace. Limit quantities of product at the minimum necessary for handling and limit the number of exposed workers. Provide local exhaust or general room ventilation. Wear personal protective equipment. Floors, walls and other surfaces in the hazard area must be cleaned regularly.
Hygiene measures : Separate working clothes from town clothes. Launder separately. Do not eat, drink or smoke when using this product. Always wash hands after handling the product.

7.2. Conditions for safe storage, including any incompatibilities

Storage conditions : Store locked up. Store in a well-ventilated place. Keep cool.

7.3. Specific end use(s)

No additional information available

5-FLUOROURACIL EBEWE (EBEFLUORO)

Safety Data Sheet

according to Regulation (EC) No. 1907/2006 (REACH) with its amendment Regulation (EU) 2020/878
SDS No: 11470-16

FAREVA
UNTERACH

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

8.1.1. National occupational exposure and biological limit values

No additional information available

8.1.2. Recommended monitoring procedures

No additional information available

8.1.3. Air contaminants formed

No additional information available

8.1.4. DNEL and PNEC

No additional information available

8.1.5. Control banding

No additional information available

8.2. Exposure controls

8.2.1. Appropriate engineering controls

Appropriate engineering controls:

Ensure good ventilation of the work station.

8.2.2. Personal protection equipment

Personal protective equipment symbol(s):



8.2.2.1. Eye and face protection

Eye protection:

Safety glasses

8.2.2.2. Skin protection

Skin and body protection:

Wear suitable protective clothing

Hand protection:

Protective gloves

8.2.2.3. Respiratory protection

Respiratory protection:

[In case of inadequate ventilation] wear respiratory protection.

8.2.2.4. Thermal hazards

No additional information available

8.2.3. Environmental exposure controls

Environmental exposure controls:

Avoid release to the environment.

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Physical state	: Liquid
Colour	: colourless to yellowish.
Appearance	: Clear.
Odour	: characteristic.

5-FLUOROURACIL EBEWE (EBEFLUORO)

Safety Data Sheet

according to Regulation (EC) No. 1907/2006 (REACH) with its amendment Regulation (EU) 2020/878
SDS No: 11470-16

FAREVA
UNTERACH

Odour threshold	: Not available
Melting point	: Not available
Freezing point	: Not available
Boiling point	: 100.3 °C
Flammability	: Not applicable
Explosive limits	: Not available
Lower explosive limit (LEL)	: Not available
Upper explosive limit (UEL)	: Not available
Flash point	: > 101 °C
Auto-ignition temperature	: Not available
Decomposition temperature	: Not available
pH	: 8.5 – 9.1
Viscosity, kinematic	: Not available
Solubility	: soluble in water.
Partition coefficient n-octanol/water (Log Kow)	: Not available
Vapour pressure	: 24.24 hPa
Vapour pressure at 50 °C	: Not available
Density	: 1.031 g/cm³
Relative density	: Not available
Relative vapour density at 20 °C	: Not available
Particle size	: Not applicable
Particle size distribution	: Not applicable
Particle shape	: Not applicable
Particle aspect ratio	: Not applicable
Particle aggregation state	: Not applicable
Particle agglomeration state	: Not applicable
Particle specific surface area	: Not applicable
Particle dustiness	: Not applicable

9.2. Other information

9.2.1. Information with regard to physical hazard classes

No additional information available

9.2.2. Other safety characteristics

No additional information available

SECTION 10: Stability and reactivity

10.1. Reactivity

The product is non-reactive under normal conditions of use, storage and transport.

10.2. Chemical stability

Stable under normal conditions.

10.3. Possibility of hazardous reactions

No dangerous reactions known under normal conditions of use.

10.4. Conditions to avoid

None under recommended storage and handling conditions (see section 7).

10.5. Incompatible materials

No additional information available

10.6. Hazardous decomposition products

Under normal conditions of storage and use, hazardous decomposition products should not be produced.

5-FLUOROURACIL EBEWE (EBEFLUORO)

Safety Data Sheet

according to Regulation (EC) No. 1907/2006 (REACH) with its amendment Regulation (EU) 2020/878
SDS No: 11470-16

FAREVA
UNTERACH

SECTION 11: Toxicological information

11.1. Information on hazard classes as defined in Regulation (EC) No 1272/2008

Acute toxicity (oral)	: Harmful if swallowed.
Acute toxicity (dermal)	: Not classified
Acute toxicity (inhalation)	: Not classified

5-FLUOROURACIL EBEWE (EBEFLUORO)

ATE CLP (oral)	2000 mg/kg bodyweight
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5-Fluorouracil (51-21-8)

LD50 oral rat	230 mg/kg
LD50 oral	115 mg/kg
Skin corrosion/irritation	: Not classified pH: 8.5 – 9.1
Serious eye damage/irritation	: Not classified pH: 8.5 – 9.1
Respiratory or skin sensitisation	: Not classified
Germ cell mutagenicity	: May cause genetic defects.
Carcinogenicity	: Not classified
Reproductive toxicity	: May damage fertility or the unborn child.
STOT-single exposure	: Not classified
STOT-repeated exposure	: Not classified
Aspiration hazard	: Not classified

11.2. Information on other hazards

No additional information available

SECTION 12: Ecological information

12.1. Toxicity

Ecology - general	: The product is not considered harmful to aquatic organisms nor to cause long-term adverse effects in the environment.
Hazardous to the aquatic environment, short-term (acute)	: Not classified
Hazardous to the aquatic environment, long-term (chronic)	: Not classified

12.2. Persistence and degradability

No additional information available

12.3. Bioaccumulative potential

No additional information available

12.4. Mobility in soil

No additional information available

12.5. Results of PBT and vPvB assessment

No additional information available

12.6. Endocrine disrupting properties

No additional information available

12.7. Other adverse effects

No additional information available

5-FLUOROURACIL EBEWE (EBEFLUORO)

Safety Data Sheet

according to Regulation (EC) No. 1907/2006 (REACH) with its amendment Regulation (EU) 2020/878
SDS No: 11470-16

FAREVA
UNTERACH

SECTION 13: Disposal considerations

13.1. Waste treatment methods

Waste treatment methods : Dispose of contents/container in accordance with licensed collector's sorting instructions.
European List of Waste (LoW) code : 18 01 08* - cytotoxic and cytostatic medicines

SECTION 14: Transport information

In accordance with ADR / IMDG / IATA / ADN / RID

ADR	IMDG	IATA	ADN	RID
14.1. UN number or ID number				
Not regulated	Not regulated	Not regulated	Not regulated	Not regulated
14.2. UN proper shipping name				
Not regulated	Not regulated	Not regulated	Not regulated	Not regulated
14.3. Transport hazard class(es)				
Not regulated	Not regulated	Not regulated	Not regulated	Not regulated
14.4. Packing group				
Not regulated	Not regulated	Not regulated	Not regulated	Not regulated
14.5. Environmental hazards				
Not regulated	Not regulated	Not regulated	Not regulated	Not regulated
No supplementary information available				

14.6. Special precautions for user

Overland transport

Not regulated

Transport by sea

Not regulated

Air transport

Not regulated

Inland waterway transport

Not regulated

Rail transport

Not regulated

14.7. Maritime transport in bulk according to IMO instruments

Not applicable

SECTION 15: Regulatory information

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

15.1.1. EU-Regulations

Contains no REACH substances with Annex XVII restrictions

Contains no substance on the REACH candidate list

Contains no REACH Annex XIV substances

Contains no substance subject to Regulation (EU) No 649/2012 of the European Parliament and of the Council of 4 July 2012 concerning the export and import of hazardous chemicals.

5-FLUOROURACIL EBEWE (EBEFLUORO)

Safety Data Sheet

according to Regulation (EC) No. 1907/2006 (REACH) with its amendment Regulation (EU) 2020/878
SDS No: 11470-16

FAREVA
UNTERACH

Contains no substance subject to Regulation (EU) No 2019/1021 of the European Parliament and of the Council of 20 June 2019 on persistent organic pollutants

15.1.2. National regulations

No additional information available

15.2. Chemical safety assessment

No chemical safety assessment has been carried out

SECTION 16: Other information

Indication of changes			
Section	Changed item	Change	Comments
1.3		Modified	
2.1		Modified	
3.2		Modified	

Abbreviations and acronyms

ADN	European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways
ADR	European Agreement concerning the International Carriage of Dangerous Goods by Road
ATE	Acute Toxicity Estimate
BCF	Bioconcentration factor
BLV	Biological limit value
BOD	Biochemical oxygen demand (BOD)
COD	Chemical oxygen demand (COD)
DMEL	Derived Minimal Effect level
DNEL	Derived-No Effect Level
EC-No.	European Community number
EC50	Median effective concentration
EN	European Standard
IARC	International Agency for Research on Cancer
IATA	International Air Transport Association
IMDG	International Maritime Dangerous Goods
LC50	Median lethal concentration
LD50	Median lethal dose
LOAEL	Lowest Observed Adverse Effect Level
NOAEC	No-Observed Adverse Effect Concentration
NOAEL	No-Observed Adverse Effect Level
NOEC	No-Observed Effect Concentration
OECD	Organisation for Economic Co-operation and Development
OEL	Occupational Exposure Limit
PBT	Persistent Bioaccumulative Toxic
PNEC	Predicted No-Effect Concentration
RID	Regulations concerning the International Carriage of Dangerous Goods by Rail

5-FLUOROURACIL EBEWE (EBEFLUORO)

Safety Data Sheet

according to Regulation (EC) No. 1907/2006 (REACH) with its amendment Regulation (EU) 2020/878
SDS No: 11470-16

FAREVA
UNTERACH

Abbreviations and acronyms

SDS	Safety Data Sheet
STP	Sewage treatment plant
ThOD	Theoretical oxygen demand (ThOD)
TLM	Median Tolerance Limit
VOC	Volatile Organic Compounds
CAS-No.	Chemical Abstract Service number
N.O.S.	Not Otherwise Specified
vPvB	Very Persistent and Very Bioaccumulative
ED	Endocrine disrupting properties
DOT	Department of Transport
TDG	Transportation of Dangerous Goods
REACH	Registration, Evaluation, Authorisation and Restriction of Chemicals Regulation (EC) No 1907/2006
GHS	Globally Harmonized System of Classification, Labelling and Packaging of Chemicals
CAS	CAS (Chemical Abstracts Service) number
IBC-Code	International Code for the Construction and Equipment of Ships carrying Dangerous Chemicals in Bulk
CLP	Classification Labelling Packaging Regulation; Regulation (EC) No 1272/2008
MARPOL 73/78	MARPOL 73/78: International Convention for the Prevention of Pollution From Ships
ADG	Transport of Australian Dangerous Goods

Other information

: Data of sections 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.

Full text of H- and EUH-statements

Acute Tox. 3 (Oral)	Acute toxicity (oral), Category 3
Acute Tox. 4 (Dermal)	Acute toxicity (dermal), Category 4
Acute Tox. 4 (Oral)	Acute toxicity (oral), Category 4
Muta. 1A	Germ cell mutagenicity, Category 1A
Repr. 1B	Reproductive toxicity, Category 1B
H301	Toxic if swallowed.
H302	Harmful if swallowed.
H312	Harmful in contact with skin.
H340	May cause genetic defects.
H360	May damage fertility or the unborn child.

Classification and procedure used to derive the classification for mixtures according to Regulation (EC) 1272/2008 [CLP]

Acute Tox. 4 (Oral)	H302	Calculation method
Muta. 1A	H340	Calculation method
Repr. 1B	H360	Calculation method

5-FLUOROURACIL EBEWE (EBEFLUORO)

Safety Data Sheet

according to Regulation (EC) No. 1907/2006 (REACH) with its amendment Regulation (EU) 2020/878
SDS No: 11470-16

FAREVA
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This information is based on our current knowledge and is intended to describe the product for the purposes of health, safety and environmental requirements only. It should not therefore be construed as guaranteeing any specific property of the product.