

FULVESTRANT

Safety Data Sheet

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

Issue date: 01/04/2021

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Supersedes: 18/04/2016

Version: 2.0

SDS No: 11470-41

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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 : FULVESTRANT

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

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

T +43 7665 8123 0

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 - 365Tage/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]

Flammable liquids, Category 3	H226
Reproductive toxicity, Category 1A	H360FD
Reproductive toxicity, Additional category, Effects on or via lactation	H362
Hazardous to the aquatic environment — Chronic Hazard, Category 3	H412

Full text of H statements : see section 16

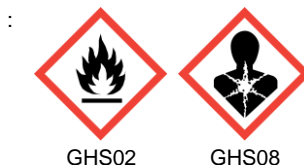
Adverse physicochemical, human health and environmental effects

Flammable liquid and vapour. May cause harm to breast-fed children. Harmful to aquatic life with long lasting effects.

2.2. Label elements

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

Hazard pictograms (CLP)



GHS02

GHS08

Signal word (CLP)

: Danger

Contains

: Fulvestrant / (1S,9R,10R,11S,14S,15S)-15-methyl-9-[(4,4,5,5,5-pentafluoropentane)sulfinyl]nonyl)tetracyclo[8.7.0.0.0^{2,7}.0^{11,15}]heptadeca-2(7),3,5-triene-5,14-diol

Hazard statements (CLP)

: H226 - Flammable liquid and vapour.
H360FD - May damage fertility. May damage the unborn child.

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Precautionary statements (CLP)

H362 - May cause harm to breast-fed children.
H412 - Harmful to aquatic life with long lasting effects.
: P210 - Keep away from heat, hot surfaces, sparks, open flames and other ignition sources.
No smoking.
P260 - Do not breathe gas, mist, spray, vapours.
P263 - Avoid contact during pregnancy and while nursing.
P273 - Avoid release to the environment.
P308+P313 - IF exposed or concerned: Get medical advice.
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

: Complex mixture based on:
Castor oil

Name	Product identifier	%	Classification according to Regulation (EC) No. 1272/2008 [CLP]
benzyl benzoate	CAS-No.: 120-51-4 EC-No.: 204-402-9 EC Index-No.: 607-085-00-9	≥ 15 – < 20	Acute Tox. 4 (Oral), H302 Aquatic Chronic 2, H411
Ethanol	CAS-No.: 64-17-5 EC-No.: 200-578-6 EC Index-No.: 603-002-00-5 REACH-no: 01-2119457610-43	≥ 10 – < 15	Flam. Liq. 2, H225 Eye Irrit. 2, H319
benzyl alcohol	CAS-No.: 100-51-6 EC-No.: 202-859-9 EC Index-No.: 603-057-00-5 REACH-no: 01-2119492630-38	≥ 10 – < 15	Acute Tox. 4 (Oral), H302 Acute Tox. 4 (Inhalation), H332
Fulvestrant / (1S,9R,10R,11S,14S,15S)-15-methyl-9- {9- [(4,4,5,5,5- pentafluoropentane)sulfinyl]nonyl}tetracyclo[8.7.0.0 [^] {7}.0 [^] {11,15}]heptadeca-2(7),3,5-triene-5,14-diol	CAS-No.: 129453-61-8	≥ 5 – < 10	Repr. 1A, H360FD Lact., H362 Aquatic Chronic 4, H413

Specific concentration limits

Name	Product identifier	Specific concentration limits
Ethanol	CAS-No.: 64-17-5 EC-No.: 200-578-6 EC Index-No.: 603-002-00-5 REACH-no: 01-2119457610-43	(50 ≤C ≤ 100) Eye Irrit. 2, H319

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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.
First-aid measures after inhalation	: Remove person to fresh air and keep comfortable for breathing.
First-aid measures after skin contact	: Rinse skin with water/shower. Take off immediately all contaminated clothing.
First-aid measures after eye contact	: Rinse eyes with water as a precaution.
First-aid measures after ingestion	: 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.

SECTION 5: Firefighting measures

5.1. Extinguishing media

Suitable extinguishing media	: Water spray. Dry powder. Foam. Carbon dioxide.
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5.2. Special hazards arising from the substance or mixture

Fire hazard	: Flammable liquid and vapour.
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.
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SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

6.1.1. For non-emergency personnel

Emergency procedures	: Ventilate spillage area. No open flames, no sparks, and no smoking. Do not breathe Vapours, gas, spray, mist.
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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".
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6.2. Environmental precautions

Avoid release to the environment.

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.

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SECTION 7: Handling and storage

7.1. Precautions for safe handling

- Precautions for safe handling : Ensure good ventilation of the work station. Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking. Ground/bond container and receiving equipment. Use only non-sparking tools. Take precautionary measures against static discharge. Flammable vapours may accumulate in the container. Use explosion-proof equipment. Wear personal protective equipment. Obtain special instructions before use. Avoid contact during pregnancy/while nursing. Do not breathe spray, Vapours, gas, mist.
- Hygiene measures : 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

- Technical measures : Ground/bond container and receiving equipment.
- Storage conditions : Store in a well-ventilated place. Keep cool. Keep container tightly closed.

7.3. Specific end use(s)

See Heading 1.

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

8.1.1. National occupational exposure and biological limit values

Ethanol (64-17-5)	
United Kingdom - Occupational Exposure Limits	
Local name	Ethanol
WEL TWA (OEL TWA) [1]	1920 mg/m ³
WEL TWA (OEL TWA) [2]	1000 ppm
WEL STEL (OEL STEL)	5760 mg/m ³ (calculated)
WEL STEL (OEL STEL) [ppm]	3000 ppm (calculated)
Regulatory reference	EH40/2005 (Fourth edition, 2020). HSE

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.

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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 insufficient ventilation, wear suitable respiratory equipment

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.
Appearance	: Clear.
Odour	: ether-like odour.
Odour threshold	: Not available
Melting point	: Not available
Freezing point	: Not available
Boiling point	: Not available
Flammability	: Not applicable
Explosive limits	: Not available
Lower explosive limit (LEL)	: 3.5 vol %
Upper explosive limit (UEL)	: 19 vol %
Flash point	: 33 °C
Auto-ignition temperature	: 365 °C
Decomposition temperature	: Not available
pH	: Not available
Viscosity, kinematic	: Not available
Solubility	: Not available
Partition coefficient n-octanol/water (Log Kow)	: Not available
Vapour pressure	: Not available
Vapour pressure at 50 °C	: Not available
Density	: Not available
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

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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

Flammable liquid and vapour.

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

Avoid contact with hot surfaces. Heat. No flames, no sparks. Eliminate all sources of ignition.

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.

SECTION 11: Toxicological information

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

Acute toxicity (oral)	: Not classified
Acute toxicity (dermal)	: Not classified
Acute toxicity (inhalation)	: Not classified

benzyl alcohol (100-51-6)	
LD50 oral rat	1620 mg/kg
LD50 dermal rat	> 2000 mg/kg
LC50 Inhalation - Rat	> 4178 mg/l/4h

Skin corrosion/irritation	: Not classified
Serious eye damage/irritation	: Not classified
Respiratory or skin sensitisation	: Not classified
Germ cell mutagenicity	: Not classified
Carcinogenicity	: Not classified

Ethanol (64-17-5)	
IARC group	1 - Carcinogenic to humans

Reproductive toxicity	: May damage fertility. May damage the unborn child. May cause harm to breast-fed children.
STOT-single exposure	: Not classified
STOT-repeated exposure	: Not classified

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Aspiration hazard : Not classified

11.2. Information on other hazards

No additional information available

SECTION 12: Ecological information

12.1. Toxicity

Ecology - general : Harmful to aquatic life with long lasting effects.
Hazardous to the aquatic environment, short-term (acute) : Not classified
Hazardous to the aquatic environment, long-term (chronic) : Harmful to aquatic life with long lasting effects.

benzyl alcohol (100-51-6)	
LC50 fish 1	460 mg/l
EC50 Daphnia 1	230 mg/l

12.2. Persistence and degradability

No additional information available

12.3. Bioaccumulative potential

benzyl alcohol (100-51-6)	
Log Pow	1.1

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

SECTION 13: Disposal considerations

13.1. Waste treatment methods

Waste treatment methods : Dispose of contents/container in accordance with licensed collector's sorting instructions.
Additional information : Flammable vapours may accumulate in the container.
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				
UN 1170	Not regulated	UN 1170	UN 1170	UN 1170

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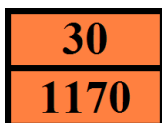
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ADR	IMDG	IATA	ADN	RID
14.2. UN proper shipping name				
ETHANOL SOLUTION (ETHYL ALCOHOL SOLUTION)	Not regulated	Ethanol solution	ETHANOL SOLUTION (ETHYL ALCOHOL SOLUTION)	ETHANOL SOLUTION (ETHYL ALCOHOL SOLUTION)
Transport document description				
UN 1170 ETHANOL SOLUTION (ETHYL ALCOHOL SOLUTION), 3, III, (D/E)	Not regulated	UN 1170 Ethanol solution, 3, III	UN 1170 ETHANOL SOLUTION (ETHYL ALCOHOL SOLUTION), 3, III	UN 1170 ETHANOL SOLUTION (ETHYL ALCOHOL SOLUTION), 3, III
14.3. Transport hazard class(es)				
3	Not regulated	3	3	3
	Not regulated			
14.4. Packing group				
III	Not regulated	III	III	III
14.5. Environmental hazards				
Dangerous for the environment: No	Not regulated	Dangerous for the environment: No	Dangerous for the environment: No	Dangerous for the environment: No
No supplementary information available				

14.6. Special precautions for user

Overland transport

Classification code (ADR) : F1
Special provisions (ADR) : 144, 601
Limited quantities (ADR) : 5I
Excepted quantities (ADR) : E1
Packing instructions (ADR) : P001, IBC03, LP01, R001
Mixed packing provisions (ADR) : MP19
Transport category (ADR) : 3
Hazard identification number (Kemler No.) : 30
Orange plates :



Tunnel restriction code (ADR) : D/E
EAC code : •2YE

Transport by sea

Not regulated

Air transport

PCA Excepted quantities (IATA) : E1
PCA Limited quantities (IATA) : Y344
PCA limited quantity max net quantity (IATA) : 10L
PCA packing instructions (IATA) : 355
PCA max net quantity (IATA) : 60L
CAO packing instructions (IATA) : 366
CAO max net quantity (IATA) : 220L
Special provisions (IATA) : A3, A58, A180
ERG code (IATA) : 3L

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Inland waterway transport

Classification code (ADN) : F1
Special provisions (ADN) : 144, 601
Limited quantities (ADN) : 5 L
Excepted quantities (ADN) : E1
Equipment required (ADN) : PP, EX, A
Ventilation (ADN) : VE01
Number of blue cones/lights (ADN) : 0

Rail transport

Classification code (RID) : F1
Special provisions (RID) : 144, 601
Limited quantities (RID) : 5L
Excepted quantities (RID) : E1
Packing instructions (RID) : P001, IBC03, LP01, R001
Transport category (RID) : 3
Hazard identification number (RID) : 30

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.

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	

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)

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Abbreviations and acronyms	
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
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

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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. 4 (Inhalation)	Acute toxicity (inhal.), Category 4
Acute Tox. 4 (Oral)	Acute toxicity (oral), Category 4
Aquatic Chronic 2	Hazardous to the aquatic environment — Chronic Hazard, Category 2
Aquatic Chronic 3	Hazardous to the aquatic environment — Chronic Hazard, Category 3
Aquatic Chronic 4	Hazardous to the aquatic environment — Chronic Hazard, Category 4
Eye Irrit. 2	Serious eye damage/eye irritation, Category 2
Flam. Liq. 2	Flammable liquids, Category 2
Flam. Liq. 3	Flammable liquids, Category 3
Lact.	Reproductive toxicity, Additional category, Effects on or via lactation
Repr. 1A	Reproductive toxicity, Category 1A
H225	Highly flammable liquid and vapour.
H226	Flammable liquid and vapour.
H302	Harmful if swallowed.
H319	Causes serious eye irritation.
H332	Harmful if inhaled.
H360FD	May damage fertility. May damage the unborn child.
H362	May cause harm to breast-fed children.
H411	Toxic to aquatic life with long lasting effects.
H412	Harmful to aquatic life with long lasting effects.
H413	May cause long lasting harmful effects to aquatic life.

Classification and procedure used to derive the classification for mixtures according to Regulation (EC) 1272/2008 [CLP]		
Flam. Liq. 3	H226	On basis of test data
Repr. 1A	H360FD	Calculation method
Lact.	H362	Calculation method
Aquatic Chronic 3	H412	Calculation method

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.