

This safety data sheet was created pursuant to the requirements of: Regulation (EC) No. 1907/2006 and Regulation (EC) No. 1272/2008

Revision Date 15-Feb-2024
Revision Number 1

100-1649 - Fulvestrant

Section 1: IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND OF THE COMPANY/UNDERTAKING

1.1. Product identifier

Document Number 10000027345

Product Name Fulvestrant

Synonym ICI-182780, ZD-9238,

 7α , 17β -[9-[(4,4,5,5,5-Pentafluoropentyl)sulfinyl]nonyl]estra-1,3,5(10)-triene-3,17-diol

Pure substance/mixture Substance

Contains (17β)-7-{ 9-[(4,4,5,5,5-pentafluoropentyl)sulfinyl]nonyl} estra-1,3,5(10)-triene-3,17-diol

Molecular weight 606.8

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

Recommended Use Laboratory chemical

Uses advised against No information available

1.3. Details of the supplier of the safety data sheet

Manufacturer

STEMCELL Technologies SARL

40 Rue des Berges, Miniparc Polytec, Bâtiment Sirocco, 38000 Grenoble, France

+33 (0) 4 76 04 75 30

STEMCELL Technologies Germany GmbH

Stolberger Str. 200, 50933, Köln, Germany

+33 (0) 4 76 04 75 30

STEMCELL Technologies UK Ltd.

Building 7100, Cambridge Research Park, Beach Drive, Waterbeach, Cambridge, UK, CB25 9TL

+33 (0) 4 76 04 75 30

For further information, please contact

1.4. Emergency telephone number

Emergency Telephone No information available

Emergency Telephone - §45 - (EC)1272/2008

Europe 112

Section 2: HAZARDS IDENTIFICATION



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2.1. Classification of the substance or mixture

Regulation (EC) No 1272/2008

| Reproductive toxicity | Category 1B - (H360) |
|-----------------------------|----------------------|
| Effects on or via lactation | Yes - (H362) |
| Acute aquatic toxicity | Category 1 - (H400) |
| Chronic aquatic toxicity | Category 1 - (H410) |

2.2. Label elements

Contains (17β)-7-{ 9-[(4,4,5,5,5-pentafluoropentyl)sulfinyl]nonyl} estra-1,3,5(10)-triene-3,17-diol



Signal word Danger

Hazard statements

Hazard statements

H360 - May damage fertility or the unborn child

H362 - May cause harm to breast-fed children

H410 - Very toxic to aquatic life with long lasting effects

Precautionary Statements - EU (§28, 1272/2008)

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

P260 - Do not breathe dust/fume/gas/mist/vapors/spray

P263 - Avoid contact during pregnancy/while nursing

2.3. Other hazards

No information available

Section 3: COMPOSITION/INFORMATION ON INGREDIENTS

3.1 Synonym

| Chemical name | EC No. | CAS No. | Weight-% | Classification according to | REACH |
|---|--------|-------------|----------|-----------------------------|-------------------|
| | | | | Regulation (EC) No. | Registration |
| | | | | 1272/2008 [CLP] | Number |
| (17β)-7-{ | - | 129453-61-8 | 100 | Repr. 1 (H360) | No data available |
| 9-[(4,4,5,5,5-pentafluoropentyl)sulfiny | | | | Lact. (H362) | |



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| l]nonyl} | | Aquatic Acute 1 (H400) | |
|----------------------------------|--|--------------------------|--|
| estra-1,3,5(10)-triene-3,17-diol | | Aquatic Chronic 1 (H410) | |

Full text of H- and EUH-phrases: see section 16

Section 4: FIRST AID MEASURES

4.1. Description of first aid measures

General advice Show this safety data sheet to the doctor in attendance.

Inhalation Remove to fresh air.

Eye contact Rinse thoroughly with plenty of water for at least 15 minutes, lifting lower and upper eyelids.

Consult a physician.

Skin contactWash skin with soap and water. In the case of skin irritation or allergic reactions see a

physician.

Ingestion Clean mouth with water and drink afterwards plenty of water.

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

Symptoms No information available.

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

Note to physicians Treat symptomatically.

Section 5: FIRE-FIGHTING MEASURES

5.1. Extinguishing media

surrounding environment.

Unsuitable Extinguishing Media No information available.

5.2. Special hazards arising from the substance or mixture

Specific hazards arising from the

homical

No information available.

chemical

5.3. Advice for firefighters



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Special protective equipment for

fire-fighters

Firefighters should wear self-contained breathing apparatus and full firefighting turnout gear. Use personal protection equipment.

Section 6: ACCIDENTAL RELEASE MEASURES

6.1. Personal precautions, protective equipment and emergency procedures

Personal precautions Ensure adequate ventilation.

6.2. Environmental precautions

Environmental precautions See Section 12 for additional Ecological Information.

6.3. Methods and material for containment and cleaning up

Methods for containment Prevent further leakage or spillage if safe to do so.

Methods for cleaning up Take up mechanically, placing in appropriate containers for disposal.

Prevention of secondary hazards Clean contaminated objects and areas thoroughly observing environmental regulations.

6.4. Reference to other sections

Reference to other sections See section 8 for more information. See section 13 for more information.

Section 7: HANDLING AND STORAGE

7.1. Precautions for safe handling

Advice on safe handling Handle in accordance with good industrial hygiene and safety practice. Avoid contact with

skin, eyes or clothing. Do not eat, drink or smoke when using this product. Remove

contaminated clothing and shoes.

General hygiene considerations Do not eat, drink or smoke when using this product. Wash hands before breaks and

immediately after handling the product.

7.2. Conditions for safe storage, including any incompatibilities

Storage Conditions Store in accordance with information listed on the Product Information Sheet (PIS).

7.3. Specific end use(s)



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Identified Uses

Risk Management Methods (RMM) The information required is contained in this Material Safety Data Sheet.

Section 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1. Control parameters

Exposure Limits This product, as supplied, does not contain any hazardous materials with occupational

exposure limits established by the region specific regulatory bodies.

Derived No Effect Level (DNEL) No information available.

Predicted No Effect Concentration

(PNEC)

No information available.

8.2. Exposure controls

Personal protective equipment

Eye/face protection No special protective equipment required.

Hand protection Wear suitable gloves.

Skin and body protection Wear suitable protective clothing.

Respiratory protection No protective equipment is needed under normal use conditions. If exposure limits are

exceeded or irritation is experienced, ventilation and evacuation may be required.

General hygiene considerations Do not eat, drink or smoke when using this product. Wash hands before breaks and

immediately after handling the product.

Environmental exposure controls No information available.

Section 9: PHYSICAL AND CHEMICAL PROPERTIES

9.1. Information on basic physical and chemical properties

Physical state Solid Appearance Powder

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Color white

Odor No data available.
Odor threshold No data available

 Property
 Values
 Remarks • Method

 pH
 No data available
 None known

рΗ Melting point / freezing point No data available None known Boiling point / boiling range No data available None known Flash point No data available None known **Evaporation rate** No data available None known Flammability (solid, gas) No data available None known Flammability Limit in Air None known

Upper flammability limit: No data available

Lower flammability limit: No data available

Vapor pressure No data available None known None known Vapor density No data available Relative density No data available None known No data available Water solubility None known Solubility(ies) No data available None known **Partition coefficient** No data available None known **Autoignition temperature** No data available None known **Decomposition temperature** No data available None known Kinematic viscosity No data available None known Dynamic viscosity No data available None known

Explosive propertiesNo information available

Oxidizing properties No information available

9.2. Other information

Softening point No information available

Molecular weight 606.8

Molecular formula C32H47F5O3S

VOC Content (%)No information availableLiquid DensityNo information availableBulk densityNo information available

Section 10: STABILITY AND REACTIVITY

10.1. Reactivity

Reactivity No information available.

10.2. Chemical stability

Stability Stable under recommended transport or storage conditions.

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Explosion data

Sensitivity to Mechanical Impact None.

Sensitivity to Static Discharge None. 10.3. Possibility of hazardous reactions

Possibility of hazardous reactions
None under normal processing.

10.4. Conditions to avoid

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Conditions to avoid None known based on information supplied.

10.5. Incompatible materials

Incompatible materials Strong oxidizing agents.

10.6. Hazardous decomposition products

Hazardous decomposition products Carbon oxides. Carbon monoxide. Hydrogen fluoride. Sulfur oxides.

Section 11: TOXICOLOGICAL INFORMATION

11.1. Information on toxicological effects

Information on likely routes of exposure

Product Information

Inhalation Specific test data for the substance or mixture is not available.

Eye contact Specific test data for the substance or mixture is not available.

Skin contact Specific test data for the substance or mixture is not available.

Ingestion Specific test data for the substance or mixture is not available.

Symptoms related to the physical, chemical and toxicological characteristics

Symptoms No information available.

Numerical measures of toxicity

Acute toxicity

Unknown acute toxicity 100 % of the mixture consists of ingredient(s) of unknown toxicity.



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100 % of the mixture consists of ingredient(s) of unknown acute oral toxicity.

100 % of the mixture consists of ingredient(s) of unknown acute dermal toxicity.

100 % of the mixture consists of ingredient(s) of unknown acute inhalation toxicity (gas).

100 % of the mixture consists of ingredient(s) of unknown acute inhalation toxicity (vapor).

100 % of the mixture consists of ingredient(s) of unknown acute inhalation toxicity (dust/mist).

Product Information

Delayed and immediate effects as well as chronic effects from short and long-term exposure

Skin corrosion/irritation
Product Information

Serious eye damage/eye irritation

No information available.

Product Information

No information available.

Respiratory or skin sensitization No information available.

Product Information

Germ cell mutagenicity

No information available.

Product Information

 Carcinogenicity
 No information available.

 Product Information

Reproductive toxicity Classification based on data available for ingredients. May cause harm to breastfed babies.

Product Information

STOT - single exposure

No information available.

Product Information

STOT - repeated exposure No information available.

Product Information

Aspiration hazard No information available.

Section 12: ECOLOGICAL INFORMATION

12.1. Toxicity

Ecotoxicity Very toxic to aquatic life with long lasting effects.

Unknown aquatic toxicityContains 0 % of components with unknown hazards to the aquatic environment.

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Product Information

12.2. Persistence and degradability

Persistence and degradability No information available.

12.3. Bioaccumulative potential

Bioaccumulation No information available.

12.4. Mobility in soil

Mobility in soil No information available.

12.5. Results of PBT and vPvB assessment

PBT and vPvB assessment No information available.

12.6. Other adverse effects

Other adverse effects No information available.

Section 13: DISPOSAL CONSIDERATIONS

13.1. Waste treatment methods

Waste from residues/unused

products

Dispose of in accordance with local regulations. Dispose of waste in accordance with

environmental legislation.

Contaminated packaging Do not reuse empty containers.

Section 14: TRANSPORT INFORMATION

IMDG

14.1 UN NumberNot regulated14.2 UN proper shipping nameNot regulated14.3 Transport hazard class(es)Not regulated14.4 Packing GroupNot regulated14.5 Marine pollutantNot applicable

14.6 Special Provisions None

14.7. Transport in bulk according to No information available

Annex II of MARPOL and the IBC

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Code

14.1 UN NumberNot regulated14.2 UN proper shipping nameNot regulated14.3 Transport hazard class(es)Not regulated14.4 Packing GroupNot regulated14.5 Environmental hazardNot applicable

14.6 Special Provisions None

ADR

14.1 UN Number
Not regulated
Not applicable

14.6 Special Provisions None

IATANot regulated14.1 UN NumberNot regulated14.2 UN proper shipping nameNot regulated14.3 Transport hazard class(es)Not regulated14.4 Packing GroupNot regulated14.5 Environmental hazardNot applicable

14.6 Special Provisions None

Section 15: REGULATORY INFORMATION

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

European Union

Take note of Directive 98/24/EC on the protection of the health and safety of workers from the risks related to chemical agents at work

Authorizations and/or restrictions on use:

This product does not contain substances subject to authorization (Regulation (EC) No. 1907/2006 (REACH), Annex XIV) This product does not contain substances subject to restriction (Regulation (EC) No. 1907/2006 (REACH), Annex XVII)

Persistent Organic Pollutants

Not applicable

Dangerous substance category per Seveso Directive (2012/18/EU)



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E1 - Hazardous to the Aquatic Environment in Category Acute 1 or Chronic 1

Ozone-depleting substances (ODS) regulation (EC) 1005/2009 Not applicable

International Inventories

TSCA Does not comply **DSL/NDSL** Does not comply **EINECS/ELINCS** Does not comply **ENCS** Does not comply **IECSC** Does not comply **KECL** Does not comply **PICCS** Does not comply **AICS** Does not comply

Legend:

TSCA - United States Toxic Substances Control Act Section 8(b) Inventory

DSL/NDSL - Canadian Domestic Substances List/Non-Domestic Substances List

EINECS/ELINCS - European Inventory of Existing Chemical Substances/European List of Notified Chemical Substances

ENCS - Japan Existing and New Chemical Substances

IECSC - China Inventory of Existing Chemical Substances

KECL - Korean Existing and Evaluated Chemical Substances

PICCS - Philippines Inventory of Chemicals and Chemical Substances

AICS - Australian Inventory of Chemical Substances

15.2. Chemical safety assessment

Chemical Safety Report No information available

Section 16: OTHER INFORMATION

Key or legend to abbreviations and acronyms used in the safety data sheet

Full text of H-Statements referred to under section 3

H360 - May damage fertility or the unborn child

H362 - May cause harm to breast-fed children

H400 - Very toxic to aquatic life

H410 - Very toxic to aquatic life with long lasting effects

Legend

SVHC: Substances of Very High Concern for Authorization:

Legend Section 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

TWA TWA (time-weighted average) STEL STEL (Short Term Exposure Limit)

Ceiling Maximum limit value * Skin designation

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This material safety data sheet complies with the requirements of Regulation (EC) No. 1907/2006

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