

Safety Data Sheet

according to Regulation (EC) No. 1907/2006 (REACH) with its amendment Regulation (EU) 2015/830

ESTRADIOL VALERATE 20MG_ML INYECTION

Date of issue: 05/08/2020

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Version: 0.1

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

1.1. Product identifier

Product form : Mixture
Trade name : ESTRADIOL VALERATE 20MG_ML INYECTION
EC no : 213-559-2
CAS No : 979-32-8
Product code : FL ESTRA_VALE INYECT

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 industry

1.2.2. Uses advised against

No additional information available

1.3. Details of the supplier of the safety data sheet

FARMALAN
Pol. Ind. Navatejera - C/La Vallina, s/n
24008 Navatejera. León - SPAIN
T + 34 987 878 000 - F +34 987 278 524
leonfarma@chemogroup.com

1.4. Emergency telephone number

Emergency number : + 34 987 878 000
Office hours

SECTION 2: Hazards identification

2.1. Classification of the substance or mixture

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

Not classified

Adverse physicochemical, human health and environmental effects

No additional information available

2.2. Label elements

2.3. Other hazards

Other hazards not contributing to the classification : According to Article 1, item 5 (a) of CLP Regulation (EC) 1272/2008, medicinal products in the finished state for human use, as defined in 2001/83/EC, are excepted from classification and other criteria of 1272/2008.

SECTION 3: Composition/information on ingredients

3.1. Substance

Not applicable

3.2. Mixture

Name	Product identifier	%	Classification according to Regulation (EC) No. 1272/2008 [CLP]
Aceite de ricino	(CAS No) 8001-79-4	50 - 80	Not classified
Benzoato de bencilo	(CAS No) 120-51-4	20 - 50	Acute Tox. 4 (Oral), H302 Aquatic Acute 1, H400 Aquatic Chronic 2, H411
Benzyl alcohol.	(CAS No) 100-51-6 (EC no) 202-859-9 (EC index no) 603-057-00-5	1 - 2,5	Acute Tox. 4 (Inhalation), H332 Acute Tox. 4 (Oral), H302

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Name	Product identifier	%	Classification according to Regulation (EC) No. 1272/2008 [CLP]
ESTRADIOL VALERATE		1 - 2,5	Carc. 1B, H350 Repr. 1A, H360Fd Aquatic Chronic 4, H413

Full text of H-statements: see section 16

SECTION 4: First aid measures

4.1. Description of first aid measures

First-aid measures general	: Never give anything by mouth to an unconscious person. IF exposed or concerned: Get medical advice/attention.
First-aid measures after inhalation	: Allow breathing of fresh air. Allow the victim to rest.
First-aid measures after skin contact	: Remove affected clothing and wash all exposed skin area with mild soap and water, followed by warm water rinse.
First-aid measures after eye contact	: Rinse immediately with plenty of water. Obtain medical attention if pain, blinking or redness persist.
First-aid measures after ingestion	: Rinse mouth. Do NOT induce vomiting. Obtain emergency medical attention.

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

No additional information available

SECTION 5: Firefighting measures

5.1. Extinguishing media

Suitable extinguishing media	: Foam. Dry powder. Carbon dioxide. Water spray. Sand.
Unsuitable extinguishing media	: Do not use a heavy water stream.

5.2. Special hazards arising from the substance or mixture

No additional information available

5.3. Advice for firefighters

Firefighting instructions	: Use water spray or fog for cooling exposed containers. Exercise caution when fighting any chemical fire. Prevent fire-fighting water from entering environment.
Protection during firefighting	: Do not enter fire area without proper protective equipment, including respiratory protection.

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

6.1.1. For non-emergency personnel

Emergency procedures	: Evacuate unnecessary personnel.
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6.1.2. For emergency responders

Protective equipment	: Equip cleanup crew with proper protection.
Emergency procedures	: Ventilate area.

6.2. Environmental precautions

Prevent entry to sewers and public waters. Notify authorities if liquid enters sewers or public waters. Avoid release to the environment.

6.3. Methods and material for containment and cleaning up

Methods for cleaning up	: Soak up spills with inert solids, such as clay or diatomaceous earth as soon as possible. Collect spillage. Store away from other materials.
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6.4. Reference to other sections

See Heading 8. Exposure controls and personal protection.

SECTION 7: Handling and storage

7.1. Precautions for safe handling

Additional hazards when processed	: Keep away from heat/sparks/open flames/hot surfaces. - No smoking.
Precautions for safe handling	: Avoid dust formation. Avoid breathing dust/fume/gas/mist/vapours/spray. Wear personal protective equipment. Provide local exhaust or general room ventilation. Wash hands and other exposed areas with mild soap and water before eating, drinking or smoking and when leaving work. Provide good ventilation in process area to prevent formation of vapour. Obtain special instructions before use. Do not handle until all safety precautions have been read and understood.

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7.2. Conditions for safe storage, including any incompatibilities

Storage conditions	: Keep only in the original container in a well ventilated place. Keep container closed when not in use.
Incompatible products	: Strong bases. Strong acids.
Incompatible materials	: Sources of ignition. Direct sunlight.

7.3. Specific end use(s)

No additional information available

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

No additional information available

8.2. Exposure controls

Appropriate engineering controls	: Ensure good ventilation of the work station.
Personal protective equipment	: EN 374. In case of dust production: protective goggles. EN 143. Dust production: dust mask with filter type P3. Wear suitable protective clothing. Remove contaminated clothes. Avoid all unnecessary exposure.
Hand protection	: Wear protective gloves
Eye protection	: Chemical goggles or safety glasses
Respiratory protection	: Wear appropriate mask



Other information	: Do not eat, drink or smoke during use.
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SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Physical state	: Liquid
Colour	: white.
Odour	: characteristic.
Odour threshold	: No data available
pH	: No data available
Relative evaporation rate (butylacetate=1)	: No data available
Melting point	: 144 (≥ 150) °C
Freezing point	: No data available
Boiling point	: No data available
Flash point	: No data available
Auto-ignition temperature	: No data available
Decomposition temperature	: No data available
Flammability (solid, gas)	: Non flammable
Vapour pressure	: No data available
Relative vapour density at 20 °C	: No data available
Relative density	: No data available
Solubility	: Alcohol.
Log Pow	: No data available
Viscosity, kinematic	: No data available
Viscosity, dynamic	: No data available
Explosive properties	: No data available
Oxidising properties	: No data available
Explosive limits	: No data available

9.2. Other information

No additional information available

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SECTION 10: Stability and reactivity

10.1. Reactivity

No additional information available

10.2. Chemical stability

Not established.

10.3. Possibility of hazardous reactions

Not established.

10.4. Conditions to avoid

Protect from light. Overheating. Direct sunlight. Extremely high or low temperatures.

10.5. Incompatible materials

Strong acids. Strong bases.

10.6. Hazardous decomposition products

fume. Carbon monoxide. Carbon dioxide.

SECTION 11: Toxicological information

11.1. Information on toxicological effects

Acute toxicity	: LD50 oral mouse
Skin corrosion/irritation	: Not classified Based on available data, the classification criteria are not met
Serious eye damage/irritation	: Not classified Based on available data, the classification criteria are not met
Respiratory or skin sensitisation	: Not classified Based on available data, the classification criteria are not met
Germ cell mutagenicity	: Not classified Based on available data, the classification criteria are not met
Carcinogenicity	: Not classified
Reproductive toxicity	: Not classified
Specific target organ toxicity (single exposure)	: Not classified Based on available data, the classification criteria are not met
Specific target organ toxicity (repeated exposure)	: Not classified Based on available data, the classification criteria are not met
Aspiration hazard	: Not classified Based on available data, the classification criteria are not met
Potential adverse human health effects and symptoms	: Based on available data, the classification criteria are not met.

SECTION 12: Ecological information

12.1. Toxicity

Ecology - general	: Toxic to aquatic life. Harmful to aquatic life.
Ecology - water	: May cause long lasting harmful effects to aquatic life.

Benzoato de bencilo (120-51-4)

LC50 fish 1	0,29 mg/l
EC50 Daphnia 1	3,09 mg/l

12.2. Persistence and degradability

ESTRADIOL VALERATE 20MG_ML INYECTION (979-32-8)

Persistence and degradability	May cause long-term adverse effects in the environment.
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BenzyI alcohol. (100-51-6)

Persistence and degradability	Biodegradable. Not established.
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Benzoato de bencilo (120-51-4)

Persistence and degradability	May cause long-term adverse effects in the environment.
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ESTRADIOL VALERATE

Persistence and degradability	May cause long-term adverse effects in the environment.
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12.3. Bioaccumulative potential

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Bioaccumulative potential	Not established.
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Benzyl alcohol. (100-51-6)

Bioaccumulative potential	Not established.
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Benzoato de bencilo (120-51-4)

Bioaccumulative potential	Not established.
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Bioaccumulative potential	Not established.
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12.4. Mobility in soil

No additional information available

12.5. Results of PBT and vPvB assessment

No additional information available

12.6. Other adverse effects

Additional information : Avoid release to the environment

SECTION 13: Disposal considerations

13.1. Waste treatment methods

Waste disposal recommendations : Dispose in a safe manner in accordance with local/national regulations. Dispose of contents/container to ..

Ecology - waste materials : Avoid release to the environment.

SECTION 14: Transport information

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

14.1. UN number

Not regulated for transport

14.2. UN proper shipping name

Proper Shipping Name (ADR) : Not applicable

Proper Shipping Name (IMDG) : Not applicable

Proper Shipping Name (IATA) : Not applicable

Proper Shipping Name (RID) : Not applicable

14.3. Transport hazard class(es)

ADR

Transport hazard class(es) (ADR) : Not applicable

IMDG

Transport hazard class(es) (IMDG) : Not applicable

IATA

Transport hazard class(es) (IATA) : Not applicable

RID

Transport hazard class(es) (RID) : Not applicable

14.4. Packing group

Packing group (ADR) : Not applicable

Packing group (IMDG) : Not applicable

Packing group (IATA) : Not applicable

Packing group (RID) : Not applicable

14.5. Environmental hazards

Dangerous for the environment : No

Marine pollutant : No

Other information : No supplementary information available

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14.6. Special precautions for user

14.6.1. Overland transport

Not applicable

14.6.2. Transport by sea

Not applicable

14.6.3. Air transport

Not applicable

14.6.4. Inland waterway transport

Not applicable

14.6.5. Rail transport

Carriage prohibited (RID) : No

14.7. Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code

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

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

Data sources : REGULATION (EC) No 1272/2008 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006.

Other information : None.

Full text of R-, H- and EUH-statements:

Acute Tox. 4 (Inhalation)	Acute toxicity (inhal.), Category 4
Acute Tox. 4 (Oral)	Acute toxicity (oral), Category 4
Aquatic Acute 1	Hazardous to the aquatic environment — Acute Hazard, Category 1
Aquatic Chronic 2	Hazardous to the aquatic environment — Chronic Hazard, Category 2
Aquatic Chronic 4	Hazardous to the aquatic environment — Chronic Hazard, Category 4
Carc. 1B	Carcinogenicity, Category 1B
Repr. 1A	Reproductive toxicity, Category 1A
H302	Harmful if swallowed
H332	Harmful if inhaled
H350	May cause cancer
H360Fd	May damage fertility. Suspected of damaging the unborn child
H400	Very toxic to aquatic life
H411	Toxic to aquatic life with long lasting effects
H413	May cause long lasting harmful effects to aquatic life

FDS (Anexo II REACH)

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