Safety Data Sheet

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

PROGESTERONE 100-200MG

Date of issue: 30/04/2020 Revision date: 30/04/2023 Supersedes: 05/10/2015 Version: 1.1

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

1.1. Product identifier

Product form : Mixture

Product name : PROGESTERONE 100-200MG

Product code : 702721

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

León Farma, S.A.
Pol. Ind. Navatejera - C/La Vallina, s/n
24008 Navatejera. León - SPAIN
T + 34 987 878 000 - F +34 987 278 524
jairo.pelaez@chemogroup.net

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]

Carc. 1B	H350
Repr. 1B	H360

Full text of classification categories and H statements : see section 16

Adverse physicochemical, human health and environmental effects

No additional information available

2.2. Label elements

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

Hazard pictograms (CLP) :



GHS08

Signal word (CLP) : Danger

Hazardous ingredients : PROGESTERONE

Hazard statements (CLP) : H350 - May cause cancer
H360 - May damage fertility or the unborn child

Precautionary statements (CLP) : P280 - Wear eye protection, protective gloves, face shield
P201 - Obtain special instructions before use
P202 - Do not handle until all safety precautions have been read and understood
P308+P313 - IF exposed or concerned: Get medical advice/attention
P405 - Store locked up
P501 - Dispose of contents/container to hazardous or special waste collection point, in accordance with local, regional, national and/or international regulation

2.3. Other hazards

No additional information available

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]
PROGESTERONE	(CAS No) 57-83-0 (EC no) 200-350-6	10 - 20	Carc. 1B, H350 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 : 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.

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.

6.3. Methods and material for containment and cleaning up

Methods for cleaning up : On land, sweep or shovel into suitable containers. Minimize generation of dust. Store away from other materials.

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

Precautions for safe handling : 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.

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

Personal protective equipment : 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.

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Physical state	:	Solid
Colour	:	Colourless.
Odour	:	characteristic.
Odour threshold	:	No data available
pH	:	No data available
Relative evaporation rate (butylacetate=1)	:	No data available
Melting point	:	No data available
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	:	No data available
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

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

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	:	Not classified
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	:	May cause cancer.
Reproductive toxicity	:	May damage fertility or the unborn child.
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

No additional information available

12.2. Persistence and degradability

PROGESTERONE 100-200MG	
Persistence and degradability	Not established.

PROGESTERONE (57-83-0)	
Persistence and degradability	Not established.

12.3. Bioaccumulative potential

PROGESTERONE 100-200MG	
Bioaccumulative potential	Not established.

PROGESTERONE (57-83-0)	
Bioaccumulative potential	Not established.

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

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

Germany

Water hazard class (WGK) : 3 - severe hazard to waters

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:

Carc. 1B	Carcinogenicity, Category 1B
Repr. 1B	Reproductive toxicity, Category 1B
H350	May cause cancer
H360	May damage fertility or the unborn child

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