



Saugella Poligyn 50+ moisture intense vaginal ovules

Safety data sheet for Medical Devices

This data sheet should not be considered a safety data sheet for the purposes of art. 31 of Regulation (EC) no. 1907/2006 (REACH)

First compilation date: 05/12/2025

Revision date: 05/12/2025

Rev. 0

Page

1/8

Safety data sheet for medical devices

SECTION 1. Identification of the substance/mixture and the company/company

1.1. Product identifier

Denomination Saugella Poligyn 50+ moisture intense vaginal ovules

1.2. Relevant identified uses of the substance or mixture and discouraged uses

Description/Use Medical device designed for women with vaginal atrophy.
The product is considered "a medical device" under Directive 93/42 EU.

1.3. Information on the Info Sheet Provider

Name Ekuberg Pharma S.r.l.
Address Via Tito Schipa, 6
Location and State 73020 – Carpignano Salentino (LE)-Italy
Tel: +39 0836 574512

e-mail address of the person responsible for the information sheet info@ekubergpharma.com

1.4. Emergency telephone number

For urgent information, please contact Tel: +39 0836 574512 - Ekuberg Pharma S.r.l.

SECTION 2. Hazard identification

2.1. Classification of the substance or mixture

Medical devices do not have to be classified and labelled in accordance with the provisions of Regulation (EC) 1272/2008 (CLP) (as subsequently amended and adapted).

Hazard identification:

No particular hazards known.

2.2. Label elements

Medical devices do not have to be labelled in accordance with the provisions of EC Regulation 1272/2008 (CLP) and subsequent amendments and adaptations. This information sheet has only been drawn up as an annex to the Multimodal Dangerous Goods Form in the case of shipments of dangerous goods by sea.

2.3. Other hazards

Based on the available data, the product does not contain more than 0.1% of PBT or vPvB substances.

SECTION 3. Composition/ingredient information

3.2. Mixtures

The product does not contain substances classified as hazardous to health or the environment pursuant to the provisions of Regulation (EU) 1272/2008 (CLP) (as subsequently amended and adapted) in quantities that require declaration.

SECTION 4. First aid measures



Saugella Poligyn 50+ moisture intense vaginal ovules

Safety data sheet for Medical Devices

This data sheet should not be considered a safety data sheet for the purposes of art. 31 of Regulation (EC) no. 1907/2006 (REACH)

First compilation date: 05/12/2025

Revision date: 05/12/2025

Rev. 0

Page

2/8

4.1. Description of first aid measures

Not specifically necessary. In any case, compliance with the rules of good industrial hygiene is recommended.

4.2. Main symptoms and effects, both acute and delayed

No specific information is known about the symptoms and effects caused by the product.

4.3. Indication of the need for immediate medical advice and special treatment

Information not available

SECTION 5. Fire protection measures

5.1. Extinguishing means

SUITABLE EXTINGUISHING MEANS

The means of extinguishing are the traditional ones: carbon dioxide, foam, dust and water spray.

UNSUITABLE MEANS OF EXTINGUISHING

Water jets.

5.2. Special hazards arising from the substance or mixture

Product is not combustible or explosive.

5.3. Recommendations for firefighters

Special protective equipment:

No specific firefighting procedure or equipment given.

Further information:

Dispose of fire debris and contaminated extinguishing water in accordance with official regulations.

SECTION 6. Measures in the event of accidental release

6.1. Personal Precautions, Protective Equipment and Emergency Procedures

Stop the leak if there is no danger.

Wear appropriate protective equipment (including personal protective equipment referred to in section 8 of the Safety Data Sheet) to prevent contamination of the skin, eyes and personal clothing. These indications are valid both for workers and for emergency interventions.

6.2. Environmental precautions

Prevent the product from entering sewers, surface water, groundwater.

6.3. Methods and materials for containment and remediation

Vacuum the spilled product into a suitable container. Evaluate the compatibility of the container to be used with the product, checking section 10. Absorb the remainder with inert absorbent material.

Provide sufficient ventilation of the place affected by the leak. Disposal of contaminated material shall be carried out in accordance with the provisions of point 13.

6.4. Reference to other sections



Saugella Poligyn 50+ moisture intense vaginal ovules

Safety data sheet for Medical Devices

This data sheet should not be considered a safety data sheet for the purposes of art. 31 of Regulation (EC) no. 1907/2006 (REACH)

First compilation date: 05/12/2025

Revision date: 05/12/2025

Rev. 0

Page

3/8

Any information regarding personal protection and disposal can be found in sections 8 and 13.

SECTION 7. Handling and storage

7.1. Precautions for safe handling

Handle in accordance with good industrial hygiene and safety practice.

Protection against fire and explosion:

No special precautions necessary.

7.2. Conditions for safe storage, including any incompatibilities

Store in a cool, dry place away from heat sources (below 25 °C).

7.3. Special end-uses

No use other than as set out in section 1.2 of this information sheet.

SECTION 8. Exposure control/personal protection

8.1. Control parameters

Information not available

8.2. Exposure Controls

Considering that the use of appropriate technical measures should always take priority over personal protective equipment, ensure good ventilation in the workplace by means of effective local suction.

HAND PROTECTION

Not necessary.

SKIN PROTECTION

Not necessary.

EYE PROTECTION

Not necessary.

RESPIRATORY PROTECTION

Not necessary.

ENVIRONMENTAL EXPOSURE CONTROLS

Emissions from production processes, including those from ventilation equipment, should be controlled for compliance with environmental protection legislation.

SECTION 9. Physical and chemical properties

9.1. Information on fundamental physical and chemical properties

Appearance	Solid ovule
Color	Ivory
Odour	Characteristic
Olfactory threshold	Unavailable



Saugella Poligyn 50+ moisture intense vaginal ovules

Safety data sheet for Medical Devices

This data sheet should not be considered a safety data sheet for the purposes of art. 31 of Regulation (EC) no. 1907/2006 (REACH)

First compilation date: 05/12/2025

Revision date: 05/12/2025

Rev. 0

Page

4/8

Melting or freezing point	35-37°C (melting point)
Initial boiling point	Not applicable
Boiling range	Unavailable
Flash point	Not applicable
Evaporation rate	Unavailable
Flammability of solids and gases	Unavailable
Lower flammability limit	Unavailable
Upper flammability limit	Unavailable
Lower explosive limit	Unavailable
Upper explosive limit	Unavailable
Vapour pressure	Unavailable
Vapour density	Unavailable
Relative Density	Unavailable
Solubility	Unavailable
Partition coefficient: n-octanol/water:	Unavailable
Auto-ignition temperature	Unavailable
Decomposition Temperature	Unavailable
Viscosity	Unavailable
Explosive properties	Unavailable
Oxidizing properties	Unavailable

9.2. Other information

Information not available

SECTION 10. Stability and responsiveness

10.1. Responsiveness

There is no particular danger of reaction with other substances under normal conditions of use.

10.2. Chemical Stability

The product is stable under normal conditions of use and storage.

10.3. Possibility of dangerous reactions

Under normal use and storage, no hazardous reactions are to be expected.

10.4. Conditions to be avoided

No special precautions other than good housekeeping of chemicals.

10.5. Incompatible Materials

Substances to avoid: metal alloys.



Saugella Poligyn 50+ moisture intense vaginal ovules

Safety data sheet for Medical Devices

This data sheet should not be considered a safety data sheet for the purposes of art. 31 of Regulation (EC) no. 1907/2006 (REACH)

First compilation date: 05/12/2025

Revision date: 05/12/2025

Rev. 0

Page

5/8

10.6. Hazardous decomposition products

Hazardous decomposition products:

No hazardous decomposition products if stored and handled as prescribed/indicated.

SECTION 11. Toxicological information

There are no known episodes of damage to health due to exposure to the product.

11.1. Information on toxicological effects

ACUTE TOXICITY

LC50 (Inhalation) Mixture: Not Classified

Mixture LD50 (Oral): Not Classified

LD50 (Cutaneous) Mixture: Not Classified

SKIN CORROSION / SKIN IRRITATION

Does not meet the classification criteria for this hazard class according to UNI EN ISO 10993-10 – Not irritant

SEVERE EYE DAMAGE/EYE IRRITATION

Does not meet the classification criteria for this hazard class

RESPIRATORY OR SKIN SENSITIZATION

Does not meet the classification criteria for this hazard class according to UNI EN ISO 10993-10 – Not sensitizer

GERM CELL MUTAGENICITY

Does not meet the classification criteria for this hazard class

CARCINOGENICITY

Does not meet the classification criteria for this hazard class

REPRODUCTIVE TOXICITY

Does not meet the classification criteria for this hazard class

SPECIFIC TARGET ORGAN TOXICITY (STOT) - SINGLE EXPOSURE

Does not meet the classification criteria for this hazard class

SPECIFIC TARGET ORGAN TOXICITY (STOT) - REPEATED EXPOSURE

Does not meet the classification criteria for this hazard class

DANGER IN CASE OF SUCTION

Does not meet the classification criteria for this hazard class

SECTION 12. Ecological information

Use according to good working practices, avoiding dispersing the product into the environment. Notify the competent authorities if the product has reached watercourses or if it has contaminated soil or vegetation.

12.1. Toxicity

Information not available

12.2. Persistence and degradability

Information not available

12.3. Bioaccumulation potential



Saugella Poligyn 50+ moisture intense vaginal ovules

Safety data sheet for Medical Devices

This data sheet should not be considered a safety data sheet for the purposes of art. 31 of Regulation (EC) no. 1907/2006 (REACH)

First compilation date: 05/12/2025

Revision date: 05/12/2025

Rev. 0

Page

6/8

Information not available

12.4. Mobility in soil

Information not available

12.5. Results of the PBT and vPvB assessment

Based on the available data, the product does not contain more than 0.1% of PBT or vPvB substances.

12.6. Other adverse effects

Information not available

SECTION 13. Disposal considerations

13.1. Waste treatment methods

The residues of the product as they are to be considered special non-hazardous waste.

Disposal must be entrusted to a company authorized to manage waste, in compliance with national and possibly local legislation.

The transport of waste may be subject to ADR.

CONTAMINATED PACKAGING

Contaminated packaging must be sent for recovery or disposal in compliance with national waste management regulations.

SECTION 14. Transportation Information

14.1. UN Number

ADR / RID, IMDG, IATA: Not classified as a dangerous good under transport regulations

14.2. UN Shipping Name

ADR/RID: Not applicable

IMDG: Not applicable

IATA: Not applicable

14.3. Transport hazard classes

ADR/RID: Class: Not applicable

IMDG: Class: Not applicable

IATA: Class: Not applicable

14.4. Packaging Assembly

ADR / RID, IMDG, IATA: Not applicable

14.5. Hazards to the environment

ADR/RID: Not applicable

IMDG: Not applicable

IATA: Not applicable

14.6. Special precautions for users

ADR/RID: None known



Saugella Poligyn 50+ moisture intense vaginal ovules

Safety data sheet for Medical Devices

This data sheet should not be considered a safety data sheet for the purposes of art. 31 of Regulation (EC) no. 1907/2006 (REACH)

First compilation date: 05/12/2025

Revision date: 05/12/2025

Rev. 0

Page

7/8

IMDG: None known

IATA: None known

14.7. Transport of bulk according to MARPOL Annex II and the IBC Code

Information not applicable

SECTION 15. Regulatory Information

15.1. Laws and regulations on health, safety and the environment specific to the substance or mixture

Seveso Category - Directive 2012/18/EC:

None

Restrictions on the product or substances contained in Annex XVII Regulation (EC) 1907/2006

None

Substances on the Candidate List (Art. 59 REACH)

Based on the available data, the product does not contain SVHC substances in a percentage greater than 0.1%.

Substances subject to authorisation (Annex XIV REACH)

None

Substances subject to export notification Reg. (EC) 649/2012:

None

Substances subject to the Rotterdam Convention:

None

Substances subject to the Stockholm Convention:

None

Health Checks

Information not available

15.2. Chemical Safety Assessment

Not applicable.

SECTION 16. Other information

LEGEND:

- ADR: European Agreement for the Carriage of Dangerous Goods by Road
- CAS NUMBER: Number of the Chemical Abstract Service
- EC50: Concentration that affects 50% of the population being tested
- CE NUMBER: Identification number in ESIS (European repository of existing substances)
- CLP: EC Regulation 1272/2008
- DNEL: Derived level with no effect
- EmS: Emergency Schedule
- GHS: Global Harmonized System for the Classification and Labelling of Chemicals
- IATA DGR: Regulations for the Carriage of Dangerous Goods of the International Air Transport Association
- IC50: Immobilization concentration of 50% of the test population
- IMDG: International Maritime Code for the Transport of Dangerous Goods
- IMO: International Maritime Organization



Saugella Poligyn 50+ moisture intense vaginal ovules

Safety data sheet for Medical Devices

This data sheet should not be considered a safety data sheet for the purposes of art. 31 of Regulation (EC) no. 1907/2006 (REACH)

First compilation date: 05/12/2025

Revision date: 05/12/2025

Rev. 0

Page

8/8

- INDEX NUMBER: Identification number in Annex VI of the CLP
- LC50: Lethal concentration 50%
- LD50: Lethal dose 50%
- OEL: Occupational exposure level
- PBT: Persistent, bioaccumulative and toxic according to REACH
- PEC: Predictable environmental concentration
- PEL: Predictable level of exposure
- PNEC: Predictable no-effect concentration
- REACH: EC Regulation 1907/2006
- RID: Regulations for the International Carriage of Dangerous Goods by Train
- TLV: Threshold Limit Value
- TLV CEILING: Concentration that must not be exceeded during any time of occupational exposure.
- TWA STEL: Short-Term Exposure Limit
- TWA: Weighted Average Exposure Limit
- VOC: Volatile Organic Compound
- vPvB: Very persistent and very bioaccumulative according to REACH
- WGK: Aquatic hazard class (Germany).

GENERAL BIBLIOGRAPHY:

1. Regulation (EC) 1907/2006 of the European Parliament (REACH)
 2. Regulation (EC) 1272/2008 of the European Parliament (CLP)
 3. Regulation (EU) 790/2009 of the European Parliament (I Atp. CLP)
 4. Regulation (EU) 2015/830 of the European Parliament
 5. Regulation (EU) 286/2011 of the European Parliament (II Atp. CLP)
 6. Regulation (EU) 618/2012 of the European Parliament (III Atp. CLP)
 7. Regulation (EU) 487/2013 of the European Parliament (IV Atp. CLP)
 8. Regulation (EU) 944/2013 of the European Parliament (V Atp. CLP)
 9. Regulation (EU) 605/2014 of the European Parliament (VI Atp. CLP)
 10. Regulation (EU) 2015/1221 of the European Parliament (VII Atp. CLP)
 11. Regulation (EU) 2016/918 of the European Parliament (VIII Atp. CLP)
 12. Regulation (EU) 2016/1179 (IX Atp. CLP)
 13. Regulation (EU) 2017/776 (X Atp. CLP)
 14. Regulation (EU) 2018/669 (XI Atp. CLP)
 15. Regulation (EU) 2018/1480 (XIII Atp. CLP)
 16. Regulation (EU) 2019/521 (XII Atp. CLP)
- The Merck Index. - 10th Edition
 - Handling Chemical Safety
 - INRS - Fiche Toxicologique (toxicological sheet)
 - Patty - Industrial Hygiene and Toxicology
 - N.I. Sax - Dangerous properties of Industrial Materials-7, 1989 Edition
 - IFA GESTIS website
 - ECHA Agency website
 - Database of SDS models of chemical substances - Ministry of Health and Istituto Superiore di Sanità

Note to the recipient of the Information Sheet (SI):

It is the addressee of this SI who must ensure that the information contained therein is read and understood by all persons who handle, store, use, or otherwise come into contact in any way with the substance or mixture to which this sheet refers. In particular, the recipient must provide adequate training to personnel involved in the use of hazardous substances or mixtures.

The recipient must ensure that the information is appropriate and complete in relation to the specific use of the substance or mixture. The substance or mixture to which this SI relates shall not, however, be used for any use other than those specified in Section 1. They do not accept responsibility for improper use. Since the use of the product does not fall under the direct control of the Supplier, it is the user's obligation to comply with the laws and regulations in force on national and EU hygiene and safety under his or her own responsibility.

The information contained in this SI is provided in good faith and is based on the current state of scientific and technical knowledge, as of the revision date indicated, available from the Supplier indicated in section 1 of this sheet. SI should not be interpreted as a guarantee of any specific properties of the substance or mixture. The information relates only to the substance or mixture specifically designated in Section 1 and may not apply to the substance or mixture used in combination with other materials or in other processes not specifically specified in the text.

This version of the SI replaces all previous versions.

Changes from the previous version

The following sections have been modified:

01/ 02 / 03 / 04 / 05 / 06 / 07 / 08 / 09 / 10 / 11 / 12 / 13 / 14 / 15 / 16