

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

### 1.1 Product identifier:

Trade name: **Mastrelle® Flora Plus vaginal capsules**

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

Identified uses	Adjuvant therapy in the treatment of bacterial vaginitis and vaginal candidiasis
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### 1.3 Details of the supplier of the safety data sheet:

Company identification	<b>LOOK AHEAD Ltd.</b> Sos. Pacurari no. 127, Iasi, 700544, Romania
Telephone	+40 232252800
E-mail	regulatory@lookahead.ro

#### 1.4 Emergency telephone number:

Emergency telephone number: +40752 226776

## SECTION 2: Hazards identification

## 2.1 Classification of the substance or mixture

## Regulation (EC) No. 1272/2008 (CLP)

The mixture is not classified as hazardous

## 2.2 Label elements:

In case of eye contact, please rinse with plenty of water.

### 2.3 Other hazards:

None

### SECTION 3: Composition/information on ingredients

### 3.1 Substances:

Not applicable.

### 3.2 Mixtures:

According to Regulation (EC) No. 1907/2006 (REACH), with its amendments (Regulation (EU) 2015/830 and Regulation (EU) 2020/878)

Description	CAS number	EC /EINECS / ECHA list number	REACH registration number	Conc. (%)	Classification according to Regulation (EC) No 1272/2008 (CLP)		
					Pictogram, signal word code(s)	Hazard class and category code(s)	Hazard statement code(s)
Capsule content							
Oligosaccharides	9074-78-6	Not listed	Not listed	*	Not listed	Not listed	Not listed
Vitamin C (ascorbic acid)	50-81-7	200-066-2	Not listed	*	Not listed	Not listed	Not listed
Vitamin E ( <i>α</i> -tocopherol)	59-02-9	200-412-2	Not listed	*	Not listed	Not listed	Not listed
Sodium hyaluronate	9067-32-7	Not listed	Not listed	*	Not listed	Not listed	Not listed
Xylitol	87-99-0	201-788-0	Not listed	*	Not listed	Not listed	Not listed
Lactose	63-42-3	200-559-2	Not listed	*	Not listed	Not listed	Not listed
Capsule shell							
Hydroxypropyl methylcellulose	9004-65-3	618-389-6	Pre-registered under REACH. No number available	*	Not listed	Not listed	Not listed
Purified water	7732-18-5	Not listed	Not listed	*	Not listed	Not listed	Not listed
Carrageenan	9000-07-1	232-524-2	Pre-registered under REACH. No number available.	*	Not listed	Not listed	Not listed
Potassium acetate	127-08-2	204-822-2	Not available	*	Not listed	Not listed	Not listed
Calcium carbonate)	471-34-1	207-439-9	Not available	*	Not listed	Not listed	Not listed
Starch Sodium Octenyl Succinate	Not available	Not listed	Not listed	*	Not listed	Not listed	Not listed

\*Proprietary

## SECTION 4: First aid measures

### 4.1 Description of first aid measures:

First-aid measures after inhalation	Remove person to fresh air and keep comfortable for breathing.
First-aid measures after skin contact	Wash off with soap and plenty of water
First-aid measures after eye contact	Rinse eyes with water as a precaution. If eye irritation persists, consult a specialist.
First-aid measures after ingestion	Rinse mouth with water. Call a poison center or a doctor if you feel unwell.

### 4.2 Most important symptoms and effects, both acute and delayed:

Symptoms/effects after skin contact                      May cause local irritation.

### 4.3 Indication of any immediate medical attention and special treatment needed:

Treat symptomatically.

## SECTION 5: Firefighting measures

According to Regulation (EC) No. 1907/2006 (REACH), with its amendments (Regulation (EU) 2015/830 and Regulation (EU) 2020/878)

### 5.1 Extinguishing media:

**5.1.1 Suitable extinguishing media:** Use water spray, alcohol-resistant foam, dry chemical or carbon dioxide.

**5.1.2 Unsuitable extinguishing media:** No further relevant information.

### 5.2 Special hazards arising from the substance or mixture:

No further relevant information.

### 5.3 Advice for firefighters:

Do not attempt to take action without suitable protective equipment. Self-contained breathing apparatus. Complete protective clothing.

## SECTION 6: Accidental release measures

### 6.1 Personal precautions, protective equipment and emergency procedures:

**6.1.1 For non-emergency personnel:** No additional information available.

**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".

### 6.2 Environmental precautions:

Avoid release to the environment.

### 6.3 Methods and material for containment and cleaning up:

Methods for cleaning up: Sweep up and shovel. Keep in suitable, closed containers for disposal.  
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.

## SECTION 7: Handling and storage

### 7.1 Precautions for safe handling:

Precautions for safe handling: Ensure good ventilation of the work station. Avoid contact with eyes. Avoid breathing dust. Wear personal protective equipment.  
Hygiene measures: Contaminated work clothing should not be allowed out of the workplace. Wash contaminated clothing before reuse. Do not eat, drink or smoke when using this product.

### 7.2 Conditions for safe storage, including any incompatibilities:

**Storage Conditions:** Store as directed by product packaging.

According to Regulation (EC) No. 1907/2006 (REACH), with its amendments (Regulation (EU) 2015/830 and Regulation (EU) 2020/878)

### 7.3 Specific end use(s):

No additional information available.

## SECTION 8: Exposure controls/personal protection

### 8.1 Control parameters:

**8.1.1 National occupational exposure and biological limit values:** No additional information available

**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.

#### 8.2.2 Individual protection measures, such as personal protective equipment:

##### 8.2.2.1 Eye and face protection

##### Eye protection:

Not expected to present a significant hazard under anticipated conditions of normal use.

Wear safety glasses with side-shields in circumstances where there is a risk of dust generation which could lead to mechanical irritation of the eye.

##### 8.2.2.2 Skin protection

##### Skin and body protection:

It has no negative effects when used in accordance with the instructions.

##### Hand protection:

When used in accordance with the instructions, no adverse effects are seen.

##### Other skin protection

##### Materials for protective clothing:

No special clothing/skin protection equipment is recommended under normal conditions of use.

##### 8.2.2.3 Respiratory protection

##### Respiratory protection:

According to Regulation (EC) No. 1907/2006 (REACH), with its amendments (Regulation (EU) 2015/830 and Regulation (EU) 2020/878)

No respiratory protection needed under normal use conditions.

#### 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:

Parameter	Value / Test method / Remarks
Physical state	white capsules
Colour	white
Odour, odour threshold	no data
pH	no data
Melting point/freezing point	no data
Boiling point or initial boiling point and boiling range	no data
Flammability	no data
Lower and upper explosion limit	no data
Flash point	no data
Auto-ignition temperature	no data
Kinematic viscosity	no data
Solubility in water in other solvents	no data
Partition coefficient n-octanol/water (log value)	no data
Vapour pressure	no data
Density and/or relative density	no data
Relative vapour density	no data
Particle characteristics	no data

#### 9.2 Other information:

No additional information available

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:

The product is non-reactive under normal conditions of use, storage and transport.

#### 10.2 Chemical stability:

Stable under normal conditions.

#### 10.3 Possibility of hazardous reactions:

No dangerous reactions known under normal conditions of use.

According to Regulation (EC) No. 1907/2006 (REACH), with its amendments (Regulation (EU) 2015/830 and Regulation (EU) 2020/878)

**10.4 Conditions to avoid:**

None under recommended storage and handling conditions (see section 7).

**10.5 Incompatible materials:**

Strong oxidizing agents

**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):

**Oligosaccharides**

LD50 > 2000 mg/kg

**Vitamin C**

LD50 oral rat: = >11900 mg / kg

LD50 oral mouse: = >3367 mg / kg

LD50 intraperitoneal mouse: = >643 mg / kg

Subacute to chronic toxicity: Not carcinogenic in tests on animals.

**Vitamin E (D-alpha-Tocopherol)**

LD50 oral rat: = > 5000 mg/kg

LD50 dermal rat: No data available.

LC50 inhalation rat: No data available.

**Sodium hyaluronate**

LD50 oral, mouse: = >2400 mg/kg;

LD50 oral, rabbit: = >1000 mg/kg;

LD50 oral, rat: = >800 mg/kg;

**Xylitol**

LD50 - Oral rat >5000 mg/kg

LD50 intraperitoneal-mouse = > 22.100 mg/kg.;

LD50 intravenous-mouse = > 3770 mg/kg;

LD50 intravenous-rabbit = > 4000 mg/kg.

**Lactose**

LD50 oral, rat >10000 mg/kg

LD50 Dermal: Not determined

Inhalation LC50: Not determined

**Hydroxypropyl methylcellulose**

LD50 oral rat: >10000 mg/kg

**Carrageenan, potassium acetate, calcium carbonate, starch sodium octenyl succinate:** No information available

According to Regulation (EC) No. 1907/2006 (REACH), with its amendments (Regulation (EU) 2015/830 and Regulation (EU) 2020/878)

Acute toxicity (dermal):

Not classified

Acute toxicity (inhalation):

Not classified

Skin corrosion/irritation:

### **Oligosacharides**

Primary cutaneous tolerance - nonirritant (product diluted at 5%)

Ocular tolerance - nonirritant (product diluted at 5%)

Repeat insult patch test nonirritant (product diluted at 5%)

Sensitizing potential - non sensitizing (product diluted at 5%)

Phototoxicity non phototoxic (product diluted at 5%)

### **Vitamin C**

Irritation: No information available

Sensitization: No information available

### **Vitamin E (D-alpha-Tocopherol)**

Dermal irritation (rabbit): Not irritant.

Eyes irritation (rabbit): Not irritant.

Other toxicological information: No data available

### **Sodium hyaluronate**

Skin irritation(human): not irritant

Skin irritation(rabbit): not irritant

Eye irritation: no irritation effect on the mucosa of conjunctiva

no irritation of the corneal epithelium

Sensitization: human repeat insult patch test : no sensitization

Photosensitization: no sensitization

### **Xylitol**

Skin irritation: No data available.

Serious eye irritation: No data available.

Sensitization: No data available.

### **Lactose**

Skin corrosion/irritation: no data available

Serious eye damage/eye irritation: no data available

Respiratory or skin sensitization: no data available

### **Hydroxypropyl methylcellulose**

Eye damage/eye irritation: Solid or dust may cause irritation or corneal injury due to mechanical action.

Skin corrosion/irritation: Essentially nonirritating to skin.

Sensitization: A similar material did not cause allergic skin reactions when tested in humans.

**Carrageenan, potassium acetate, calcium carbonate, starch sodium octenyl succinate:** No information

According to Regulation (EC) No. 1907/2006 (REACH), with its amendments (Regulation (EU) 2015/830 and Regulation (EU) 2020/878)

available

Serious eye damage/irritation:	Not classified
Respiratory or skin sensitisation:	Not classified
Germ cell mutagenicity:	Not classified
Carcinogenicity:	Not classified
Reproductive toxicity:	Not classified
STOT-single exposure:	Not classified
STOT-repeated exposure:	Not classified
Aspiration hazard:	Not classified

#### **11.2. Information on other hazards:**

No additional information available

### **SECTION 12: Ecological information**

#### **12.1. Toxicity**

Ecology – general:	The product is not considered harmful to aquatic organisms nor to cause long-term adverse effects in the environment.
Hazardous to the aquatic environment, short-term (acute):	Not classified
Hazardous to the aquatic environment, long-term (chronic):	Not classified
Not readily degradable	

#### **12.2 Persistence and degradability:**

No additional information available

#### **12.3. Bioaccumulative potential:**

No additional information available

#### **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:**



According to Regulation (EC) No. 1907/2006 (REACH), with its amendments (Regulation (EU) 2015/830 and Regulation (EU) 2020/878)

Dispose of contents/container in accordance with licensed collector's sorting instructions. Member State specific and Community specific provisions must be considered.

## SECTION 14: Transport information

ADR	IMDG	IATA	AND	RID
<b>14.1. UN number or ID number</b>				
Not regulated	Not regulated	Not regulated	Not regulated	Not regulated
<b>14.2. UN proper shipping name</b>				
Not regulated	Not regulated	Not regulated	Not regulated	Not regulated
<b>14.3. Transport hazard class(es)</b>				
Not regulated	Not regulated	Not regulated	Not regulated	Not regulated
<b>14.4. Packing group</b>				
Not regulated	Not regulated	Not regulated	Not regulated	Not regulated
<b>14.5. Environmental hazards</b>				
Not regulated	Not regulated	Not regulated	Not regulated	Not regulated

## 14.6. Special precautions for user:

**Overland transport:** Not regulated  
**Transport by sea:** Not regulated  
**Air transport:** Not regulated  
**Inland waterway transport:** Not regulated  
**Rail transport:** Not regulated

## 14.7. Transport in bulk according to Annex II of Marpol 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  
 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.

#### 15.2. Chemical safety assessment:

No chemical safety assessment has been carried out.

## SECTION 16: Other information

**Data Sources:** Publicly available toxicity information. Safety data sheets for individual ingredients.  
 Look Ahead proprietary medical device development information.

## Safety Data Sheet

Date of issue: 04.04.2018

Date of revision: 06.10.2025

2<sup>nd</sup> Edition

**Mastrelle® Flora Plus vaginal capsules**

**Class I medical device**

According to Regulation (EC) No. 1907/2006 (REACH), with its amendments (Regulation (EU) 2015/830 and Regulation (EU) 2020/878)

**Prepared by:** Look Ahead, Regulatory Affairs and Vigilance Department  
**Creation Date:** 04.04.2018  
**Revision Date:** 06.10.2025  
**Revision Summary:** Minor changes concerning MSDS format  
Change in the type of capsule (capsules without titanium dioxide)

Safety data sheet was prepared by:  
Look Ahead, Romania

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