SAFETY DATA SHEET

MOISTURE GEL

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

Product name: **Moisture Gel**

This product is also marketed under the following name:
Balance Active Moisture Gel
Menopause Moisture Gel

Moisture Gel has a CE Marking of Conformity Certificate (EC Certificate) according to Directive (EEC) No 93/42. Reference number 2115297CE03, issued 2019-03-28.

Product description: Vaginal lubricant, medical product

Manufacturer/supplier:
Rolf Kullgren AB (BBI Healthcare Sweden)
Ågatan 4
646 30 Gnesta
Sweden
Tel: +46(0)158- 130 30
E-mail: info@bbihealthcare.com

2. Hazard identification

Product definition: Medical product that is invasive or used in direct physical contact with the human body.

This product does **not** require classification and labelling according to Regulation (EC) No 1272/2008 regarding classification, labelling and packaging (CLP/GHS). This product falls under the exception in Article 1.5 (d) of Regulation (EC) No 1272/2008.

This product does **not** require a safety data sheet according to Regulation (EU) No 1907/2006 concerning the registration, evaluation, authorization and restriction of chemical substances (REACH). A safety data sheet can be provided on request.

This product should be kept out of reach from children.

3. Product composition

Clear gel consisting of the following ingredients:

Substance	CAS number
Sodium Phosphate Monobasic Dihydrate	13472-35-0
Sodium Phosphate Dibasic Dihydrate	10028-24-7
Sodium Chloride	7647-14-5
HyActive, (LMW) Sodium Hyaluronate	9067-32-7
HySilk, (HMW) Sodium Hyaluronate	9067-32-7
2-Phenoxyethanol	122-99-6
Methylparaben	99-76-3
Purified water	7732-18-5

4. First aid measures

Eyes:	If irritation occurs, seek medical attention.
Skin:	If irritation occurs, seek medical attention.
Inhalation:	Not applicable due to the physical form of the product.
Ingestion:	If any symptoms of sickness appear, consult a physician.
Notes to physician:	No special information available. Treat symptomatically.

5. Fire-fighting measures

The product is not flammable. No special measures need to be taken into consideration.

6. Accidental release measures

No special measures need to be taken into consideration. Can be flushed off with water and released into drains.

7. Handling and storage

Store at 4-25 °C.

8. Exposure controls/Personal protection

There are no controls necessary concerning normal handling. No need for personal protection.

9. Physical and chemical properties

Viscous gel suspension consisting of sodium hyaluronate (1.0 %).

Appearance	Homogeneous
Colour	Colourless
Odour	Characteristic Odour
pH	4.5– 5.6
Viscosity at 20°	120 – 340 mPas
Osmolality	250 – 350 mOsm/kg

10. Stability and reactivity

This product is stable in a tight container at normal room temperature.

11. Toxicology information

Irritation to skin or eyes is not expected.

This product is not labelled as hazardous.

12. Ecology information

This product can be released to the environment without special treatment.

Sodium hyaluronate has no influence on the environment and is degraded by oxidation and hydrolysis.

13. Disposal considerations

There are no special disposal considerations. This product is not labelled as hazardous.

14. Transport information

This product is not hazardous for transportation.

Product packaging is made out of Polyethylene (PE) plastic. Product packaging is fragile. Avoid crushing or dropping. Avoid extreme pressures.

15. Regulatory information

This product does not require classification and labelling according to Regulation (EC) No 1272/2008 regarding classification, labelling and packaging (CLP/GHS). This product falls under the exception in Article 1.5 (d) of Regulation (EC) No 1272/2008, since it is a medical product that is invasive or used in direct physical contact with the human body.

This product is regulated under the Directive (EEC) No 93/42 concerning medical devices.

16. Other information

Not applicable.