

Safety Data Sheet

PRODUCT: Crosslinked Sodium Hyaluronate

Rome, 28.05.2019

1. IDENTIFICATION OF THE PRODUCT AND OF THE COMPANY

COMMERCIAL NAME: CrossYal

TYPE OF PRODUCT AND USE: Ophthalmic Solution (Medical Device)

SUPPLIER COMPANY: Bioitech srl – Via Chiana, 87 00198 Roma (Italy)

EMERGENCY REFERENCE: Contact the local emergency number

2. COMPOSITION / INFORMATION ON INGREDIENTS

Hyaluronic acid Sodium salt obtained from biological fermentation and chemically crosslinked

3. IDENTIFICATION OF DANGERS

HAZARDS FOR HEALTH AND PHYSICAL INTEGRITY: No danger to physical health.

HAZARDS FOR THE ENVIRONMENT: No danger to the environment.

4. FIRST AID MEASURES

SKIN CONTACT: No danger to human health.

EYE CONTACT: Rinse thoroughly with water or eyewash solution if dust gets in your eyes.

INGESTION: Do not induce vomiting. In case of complaints consult your doctor.

INHALATION: In case of complaints consult your doctor.

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5. FIRE-FIGHTING MEASURES

APPROPRIATE EXTINGUISHING MEANS: Water, CO₂, foam, powders.

EXTINGUISHING MEDIA NOT TO BE USED: None in particular

COMBUSTION RISKS: Data not available.

MEANS OF PROTECTION FOR THE ENDING PEOPLE: Usual for chemical products

6. MEASURES IN CASE OF ACCIDENTAL RELEASE

INDIVIDUAL PRECAUTIONS: Gloves and protective clothing.

ENVIRONMENTAL PRECAUTIONS: No special precautions for the environment.

CLEANING METHODS: Collect the material, place it in a waste container and wash with water; no special precaution for the environment.

7. HANDLING AND STORAGE

HANDLING PRECAUTIONS: None.

MANIPULATION TECHNICAL MEASURES: None in particular.

STORAGE CONDITIONS: Store at room temperature. The product is hygroscopic to store in a suitable environment in tightly closed containers.

INDICATIONS FOR LOCALS: Properly ventilated.

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8. EXPOSURE CONTROL / INDIVIDUAL PROTECTION

EXPOSURE LIMITS: N.D.

PRECAUTIONARY MEASURES: usual for chemical products.

RESPIRATORY PROTECTION: Dust mask.

HAND PROTECTION: Latex gloves.

EYE PROTECTION: Safety goggles.

PERSONAL PROTECTION: Tracksuit or shirts.

9. PHYSICAL AND CHEMICAL PROPERTIES

APPEARANCE: White powder.

ODOR: Odorless or very mild characteristic

pH: aqueous sol 0.1% (20 ° C) 5.0 - 8.50 pH unit

Viscosity: 6 - 12 cSt (0.15% in phosphate buffer)

Solubility: Soluble in water

Melting point: Not available

Decomposition temperature: Not available

Flash point: Not available

Self-ignition: Not available

Explosive properties: Not applicable

Oxidizing properties: Not applicable

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10. STABILITY AND REACTIVITY

The product is stable at room temperature.

Conditions to avoid: exposure to high temperatures, high humidity or light.

Hazardous decomposition products: None.

11. TOXICOLOGICAL INFORMATION

Skin contact: non-irritating.

Eye contact: may cause irritation if the powder comes into contact with the eyes.

Ingestion: no adverse reactions are known.

12. ECOLOGICAL INFORMATION

No harmful effects for the environment are known: the product is completely biodegradable.

Use correctly avoiding to disperse the packaging in the environment.

13. DISPOSAL CONSIDERATIONS

The product does not present any danger for disposal. The PE container must be disposed of according to the regulations in force.

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14. TRANSPORT INFORMATION

The product, if transported correctly and without risk of conditioning caused by impact or neglect, does not present risks. Avoid high temperatures.

15. REGULATORY INFORMATION

EU EINECS/ELINCS/NLP: not listed

16. OTHER INFORMATION

The information contained in this safety data sheet is based on our knowledge on the above date