Effective date: 2023-04-29 01:00

Effective

Version: 8.0

SAFETY DATA SHEET

Date: 2023-04-27

1. IDENTIFICATION OF THE PRODUCT AND THE MANUFACTURE

Trade name: Restylane Refyne
Restylane Defyne
Restylane Kysse
Restylane Volyme
Restylane Contour

Chemical/technical name: Crosslinked Hyaluronic Acid gel with 0.3% Lidocaine Hydrochloride

Use of the substance/preparation Used as a medical device

Manufacturer: Q-Med AB, Seminariegatan 21,
SE-752 28 Uppsala, Sweden
Telephone +46 18 474 9000

2. HAZARDS IDENTIFICATION

2.1 Classification of the substance or mixture

Not classified as a dangerous substance or mixture according to regulation (EC) No 1272/2008 (CLP).

2.2 Labelling

No marking required according to EC directives or corresponding national laws. Not classified as a dangerous substance.

3. COMPOSITION

Components	Conc	EC No	CAS No	Hazard pictogram	Hazard Statement[1]
Lidocaine Hydrochloride	< 1%	200-803-8	73-78-9	GHS07	H302
Hyaluronic Acid (Sodium Salt)	1-5%	232-678-0	9067-32-7		
Water for Injection	95-100%	231-791-2	7732-18-5		

4. FIRST AID MEASURES

4.1 General Information

Lidocaine Hydrochloride is a local anaesthesia.

[1] The explanations of the hazard statement in section 16

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Effective date: 2023-04-29 01:00

Effective

Version: 8.0

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4.2 Eye contact

Restylane products with Lidocaine is a gel and can be removed with water. If necessary, seek medical advice.

4.3 Skin contact

Wash with water.

4.4 Inhalation

No particular precautions necessary.

4.5 Ingestion

If swallowed: Rinse mouth. Immediately contact a poison control centre or a physician.

5. FIRE-FIGHTING MEASURES

5.1 Special risks

Not combustible.

5.2 Suitable extinguishing media

All available products can be used.

6. ACCIDENTAL RELEASE MEASURES

Remove with any conventional methods.

7. HANDLING AND STORAGE

Store at up to 25°C. Protect from sunlight and freezing

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1 Exposure limit values

None assigned

8.2 Personal protective equipment

No specific measures necessary.

9. PHYSICAL AND CHEMICAL PROPERTIES

9.1 General information

Form:	Gel
Colour:	Transparent gel

9.2 Health, safety and environmental information

Melting temperature	0°C

Effective date: 2023-04-29 01:00

Boiling temperature	100°C
Density(g/ml)	1
pH value	6.0 – 7.5
Flash point	Not applicable
Flammability:	Not combustible**.**

10. STABILITY AND REACTIVITY

Stable

11. TOXICOLOGICAL INFORMATION

This product has been tested according to ISO 10993-1, Biological Evaluation of Medical Devices. The biological evaluation is a part of the risk management process based on data from scientific literature and relevant tests. These programs have been judged as relevant when assessing the toxicity, dermal irritation, delayed hypersensitivity, mutagenicity and carcinogenicity of the product. The conclusion from the biological evaluation is that the product is biocompatible, not toxic or irritant when used as intended.

12. ECOLOGICAL INFORMATION

To our knowledge, the amounts of Lidocaine Hydrochloride in one syringe do not cause any ecologic toxic property.

13. DISPOSAL CONSIDERATIONS

Disposal of the product according to local legislation.

14. TRANSPORT INFORMATION

Not dangerous goods according to the transport regulations ADR/RID/ICAO/IMDG.

15. REGULATORY INFORMATION

Classification
Not classified as a fire, health or environment hazard according to regulation (EC) No 1272/2008 (CLP).

16. OTHER INFORMATION

H302 Harmful if swallowed, GHS07, Warning. Acute Toxicity 4.

Effective

Version: 8.0

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Effective date: 2023-04-29 01:00

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SIGNATURES PAGE

Date	Signed by
2023-04-27 14:29	CABO GALINDO Mikael
Justification	Compiled by

2023-04-28 06:24	STENKLO Urban
Justification	Approved by Owner

2023-04-28 13:41	WINLOF Per
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