	<small>Title</small> SDS Restylane products with Lidocaine	<small>Document template</small> Material Safety Data Sheet
		<small>Doc id</small> QMS-6556

SAFETY DATA SHEET

Date: 2018-09-27

1. IDENTIFICATION OF THE PRODUCT AND THE MANUFACTURE

Trade name:	Restylane Lidocaine, Restylane Perlane Lidocaine, Restylane Lyft Lidocaine, Restylane SubQ Lidocaine, Restylane Skinboosters Vital Lidocaine, Restylane Skinboosters Vital Light Lidocaine, Restylane Lip Volume, Restylane Lyps Lidocaine, Restylane Silk, Restylane Fine Lines, Restylane Vital Lidocaine, Restylane Vital Light Lidocaine, Perlane-L, Restylane Lyft
Chemical/technical name:	NASHA 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		

¹ The explanations of the hazard statement in section 16

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4. FIRST AID MEASURES

4.1 General Information

Lidocaine Hydrochloride is a local anaesthesia.

4.2 Eye contact

Restylane 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.

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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
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).

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16. OTHER INFORMATION

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

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SIGNATURES PAGE

Date	Signed by
2018-09-27 14:02	CABO GALINDO Mikael
Justification	Compiled by
2018-09-27 14:18	NORDQVIST Ola
Justification	Approved by Owner
2018-09-27 15:28	WINLOF Per
Justification	Approved by Chief Design Expert

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