HYALURONIC ACID DERMAL FILLER

lēfilleo

PRODUCT INFORMATION

FILLERS FOR AESTHETIC COSMETOLOGY

A line of fifth generation hyaluronic fillers.
The products are safe and comfortable to use.
The gels have a uniform consistency and density.

The products combine the best properties of monophasic and biphasic drugs: ease of administration and distribution, resistance to deformation and lack of displacement from the injection zone.

1. Biodegradable gels, which decompose without harm in the body and are excreted naturally without a trace within 6-12, 12-18 months.

2.Based on High quality Hyaluronic acid. 24mg / ml

3. Contains the anesthetic lidocaine, which ensures almost painless injection. 3 mg / ml

FILLERS FOR AESTHETIC COSMETOLOGY

lefilleo are produced according to the patented technologies of maximizing purification of the final product which is almost free from BDDE and a unique technique of double cross-linking of hyaluronic acid molecules.
As a result, the final product is an incredibly stable monophasic gel with a permanently dense reticular three-dimensional structure of the molecule.

LINE

lefilleo™ Fine

Recommended for the correction of fine expression lines on the skin surface (in the areas around the eyes, lips, neck and forehead).
Injected into the upper layers of the dermis.
The duration of the effect after the procedure is 8-12 months.
The most smooth and uniform injection exactly to the target area.

lefilleo™ Deep

Recommended for the correction of deep and medium depth defects in the skin.
It is possible to fill in nasolabial folds, wrinkles around the corners of the mouth, etc.
It is also used to enlarge or correct certain areas of the face (contour reinforcement, lip modeling / augmentation, chin shape).
Injected into the subcutaneous layer.
The duration of the effect after the procedure is 12-18 months.

lefilleo™ Shape

High viscoelasticity.
Used to remove deep wrinkles and folds of the skin, as well as contour face plastics.
Volumetric modeling of the cheeks, cheekbones, chin, rhinoplasty, etc. is possible.
It is inserted deep into the hypodermis.
The duration of the effect after the procedure is 12-18 months.

Deatailed Technology

Thanks to the **Grinding Irregular technology** of the filler gel particles, smooth injection and stability of the entire procedure are achieved, which allows the product to be injected into the target area as evenly as possible.

Excellent Quality

lefilleo filler is created by the **best research and development professionals**.
lefilleo filler is a high-quality product qualified by a quality assurance system with the introduction of the latest test equipment. lefilleo filler maximizes wrinkle improvement and volume recovery effect after the procedure..

Strength of lefilleo

Superior Duration

In the cross-linking procedure
Hyaluronic acid uses a special **Hyaluronic Acid Moisture Correction technology**. It slows down the internal degradation of the filler in the skin, resulting in a long-lasting effect after injection.

High Safety

lefilleo is made from high quality **Hyaluronic Acid (Shiseido.Co., Ltd**, Japan). All possible risk factors such as BDDE, endotoxin, heavy metals or contamination have been eliminated in the production of lefilleo through continuous real-time monitoring during production. This guarantees real safety of the final product.

Strength of lefilleo

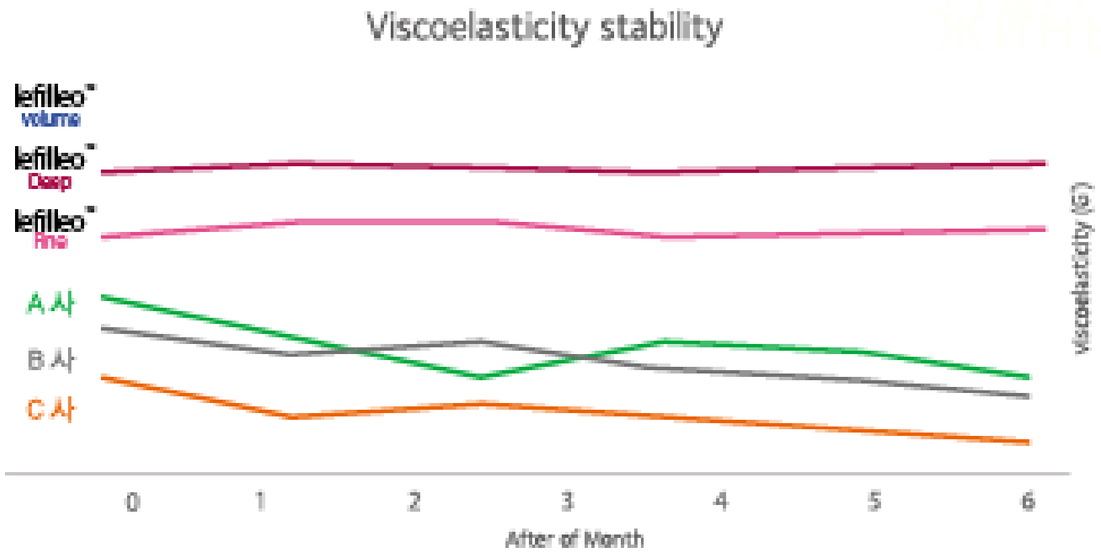
Pain-free treatment

The composition includes lidocaine - 0.3%. It makes the injection procedure painless and comfortable for the patient and is completely eliminated from the body in a few hours.

Economic benefit

The kit includes an ultra-thin UTW (Ultra Thin Wall) needle. It has a large inner diameter, which, in addition to comfortable administration and precise distribution, ensures optimal consumption.

DISTINCTIVE QUALITIES

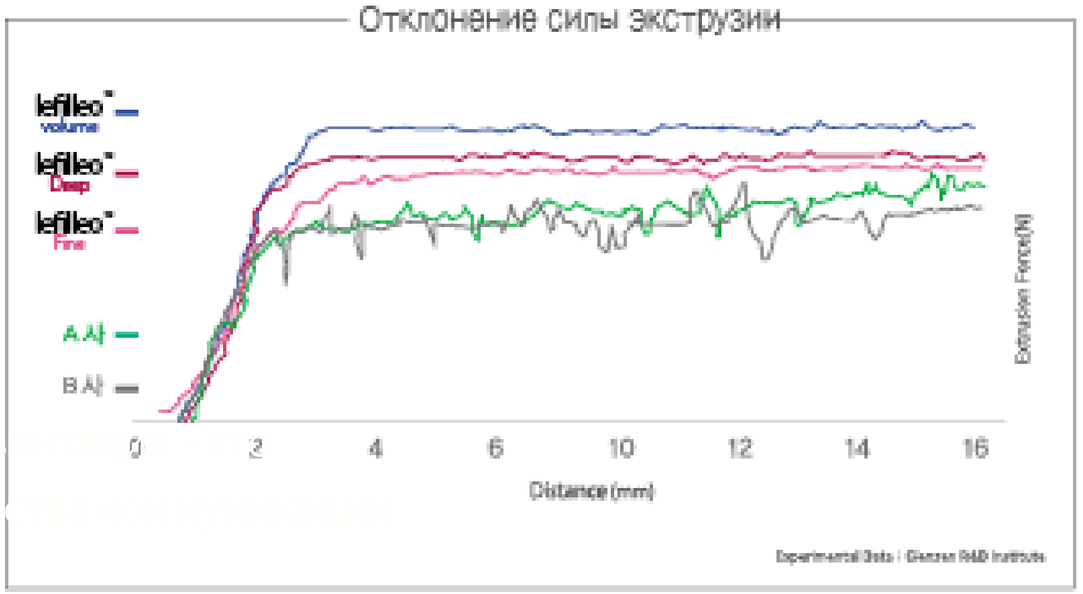


Stable level of viscoelasticity

Compared to other fillers, which quickly lose their viscoelasticity, lefileo retains a stable 3% viscoelasticity even over time, which always provides a satisfying result regardless of the period after production.

Stable level of extrusion force

Compared to other fillers with a high degree of risk due to its high extrusion force, lefilleo delivers uniform injection pressure, ensuring customer comfort and accident prevention.



DISTINCTIVE QUALITIES

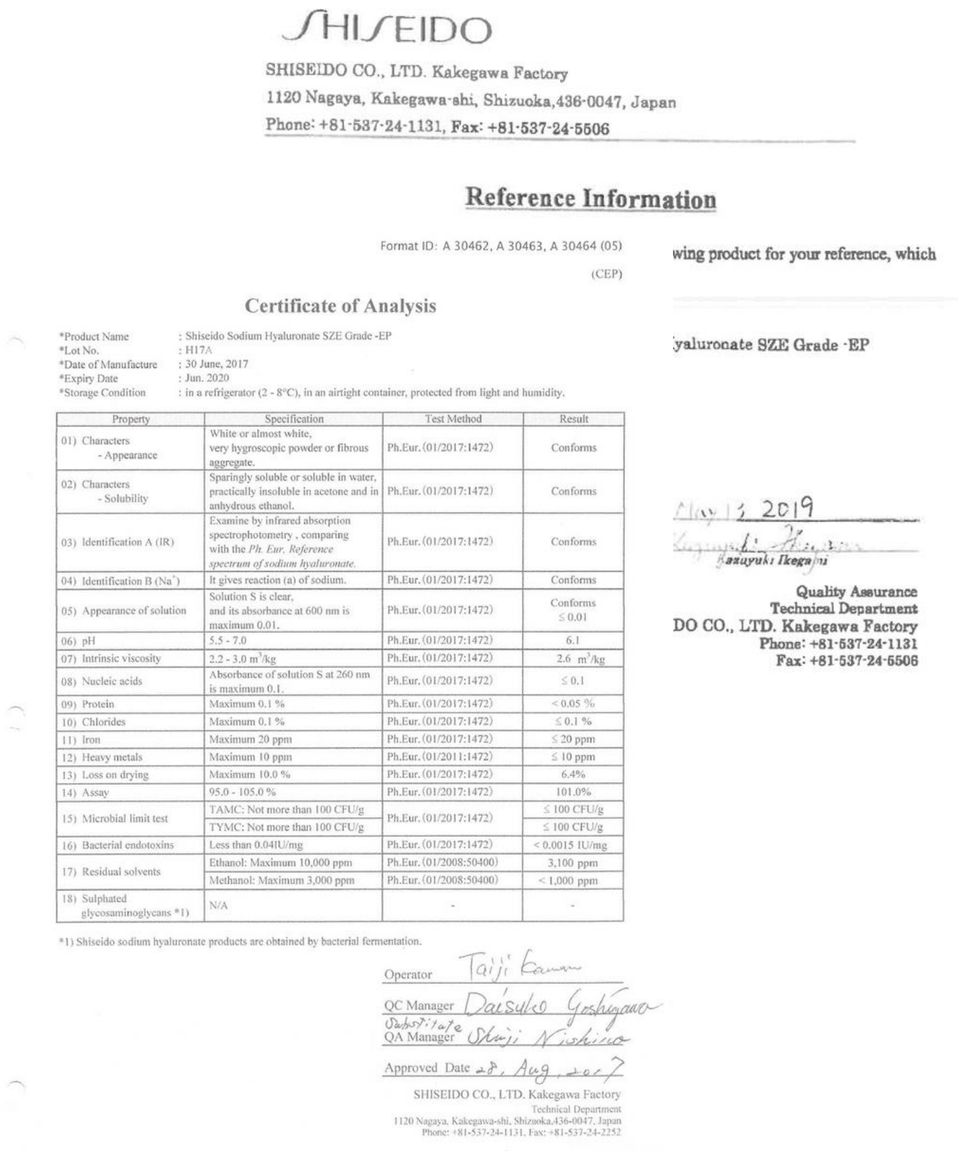
SHISEIDO

To create fillers, modern scientific developments were taken and only high-quality materials were used.

The original hyaluronic acid polymer is supplied as a dry powder by the Japanese manufacturer Shiseido.

It is the oldest existing cosmetic company and the fourth largest player in the global market.

Non-animal hyaluronic acid.



SHISEIDO

SHISEIDO CO., LTD. Kakegawa Factory
1120 Nagaya, Kakegawa-shi, Shizuoka,436-0047, Japan
Phone: +81-537-24-1131, Fax: +81-537-24-5506

Reference Information

Format ID: A 30462, A 30463, A 30464 (05)

(CEP)

wing product for your reference, which

yaluronate SZE Grade -EP

Certificate of Analysis

*Product Name : Shiseido Sodium Hyaluronate SZE Grade -EP
*Lot No. : H17A
*Date of Manufacture : 30 June, 2017
*Expiry Date : Jun. 2020
*Storage Condition : in a refrigerator (2 - 8°C), in an airtight container, protected from light and humidity.

Property	Specification	Test Method	Result
01) Characters - Appearance	White or almost white, very hygroscopic powder or fibrous aggregate.	Ph.Eur.(01/2017:1472)	Conforms
02) Characters - Solubility	Sparingly soluble or soluble in water, practically insoluble in acetone and in anhydrous ethanol.	Ph.Eur.(01/2017:1472)	Conforms
03) Identification A (IR)	Examine by infrared absorption spectrophotometry , comparing with the *Ph. Eur. Reference spectrum of sodium hyaluronate.*	Ph.Eur.(01/2017:1472)	Conforms
04) Identification B (Na^+)	It gives reaction (a) of sodium.	Ph.Eur.(01/2017:1472)	Conforms
05) Appearance of solution	Solution S is clear, and its absorbance at 600 nm is maximum 0.01.	Ph.Eur.(01/2017:1472)	Conforms ≤ 0.01
06) pH	5.5 - 7.0	Ph.Eur.(01/2017:1472)	6.1
07) Intrinsic viscosity	2.2 - 3.0 m^3/kg	Ph.Eur.(01/2017:1472)	2.6 m^3/kg
08) Nucleic acids	Absorbance of solution S at 260 nm is maximum 0.1.	Ph.Eur.(01/2017:1472)	≤ 0.1
09) Protein	Maximum 0.1 %	Ph.Eur.(01/2017:1472)	< 0.05 %
10) Chlorides	Maximum 0.1 %	Ph.Eur.(01/2017:1472)	≤ 0.1 %
11) Iron	Maximum 20 ppm	Ph.Eur.(01/2017:1472)	≤ 20 ppm
12) Heavy metals	Maximum 10 ppm	Ph.Eur.(01/2011:1472)	≤ 10 ppm
13) Loss on drying	Maximum 10.0 %	Ph.Eur.(01/2017:1472)	6.4%
14) Assay	95.0 - 105.0 %	Ph.Eur.(01/2017:1472)	101.0%
15) Microbial limit test	TAMC: Not more than 100 CFU/g	Ph.Eur.(01/2017:1472)	≤ 100 CFU/g
	TYMC: Not more than 100 CFU/g		≤ 100 CFU/g
16) Bacterial endotoxins	Less than 0.04IU/mg	Ph.Eur.(01/2017:1472)	< 0.0015 IU/mg
17) Residual solvents	Ethanol: Maximum 10,000 ppm	Ph.Eur.(01/2008:50400)	3,100 ppm
	Methanol: Maximum 3,000 ppm	Ph.Eur.(01/2008:50400)	< 1,000 ppm
18) Sulphated glycosaminoglycans *1)	N/A	-	-

*1) Shiseido sodium hyaluronate products are obtained by bacterial fermentation.

May 13, 2019

Kazuyuki Ikegami

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Operator Taiji Kawai

QC Manager Daisuke Yoshigawa

Substitute QA Manager Shinji Nishino

Approved Date 28, Aug. 2017

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Technical Department
1120 Nagaya, Kakegawa-shi, Shizuoka,436-0047, Japan
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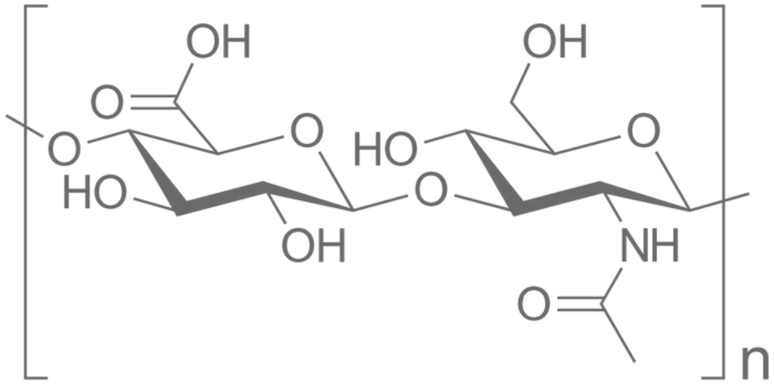
THE DEGREE OF PURIFICATION

According to US standards, the BDDE level must not exceed 2 ppm (parts per million). The most famous fillers on the world market have a level of 0.3-0.4 ppm.



Lefilleo dermal fillers are some of the most refined on the market with no BDDE residues. This is confirmed by the certificates of analysis.

The product is suitable for almost all patients. The high degree of purification makes it harmless and hypoallergenic, and also allows you to work comfortably even after injecting this lefilleo

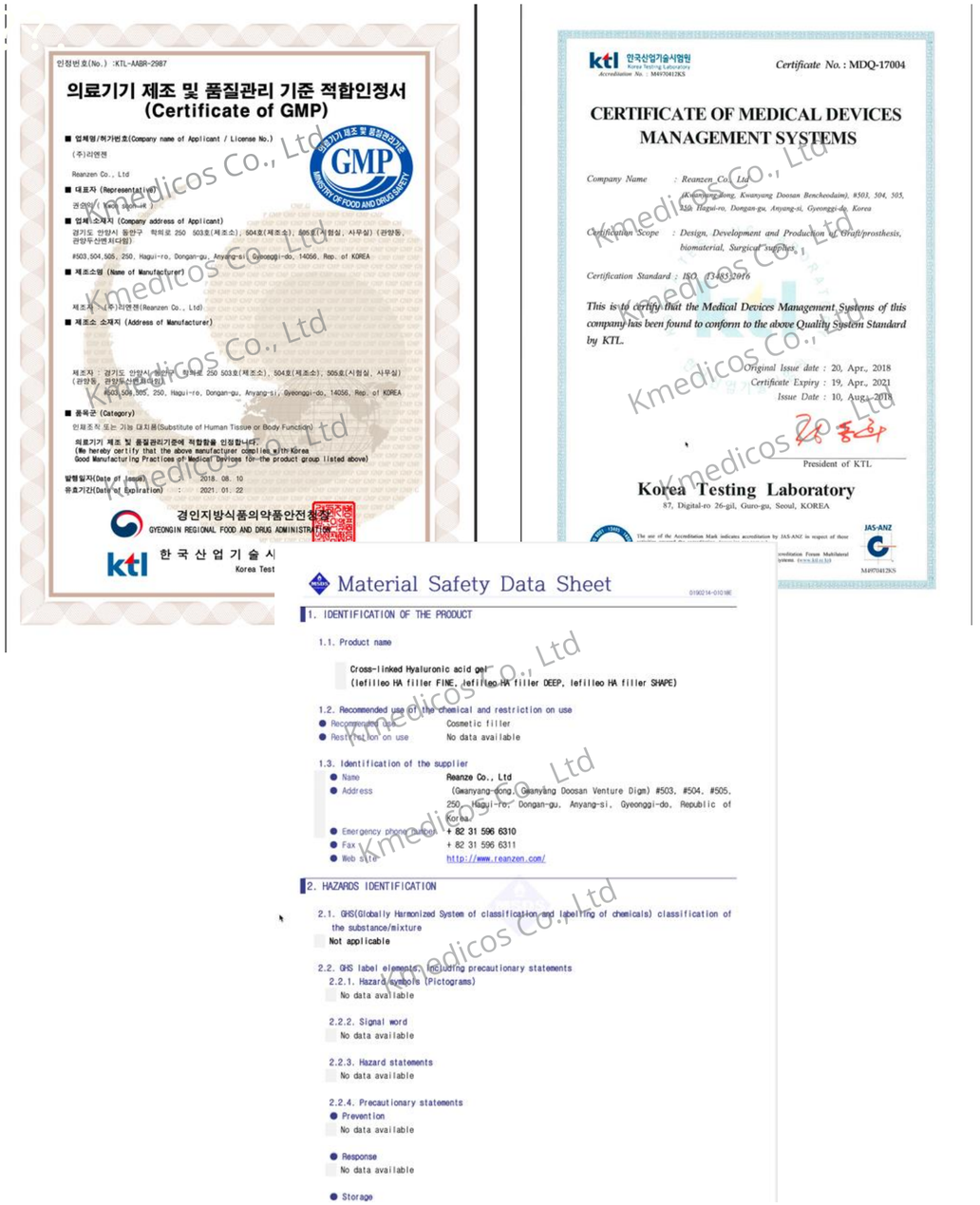
DISTINCTIVE QUALITIES

PRODUCTION CONTROL

Lefilleo fillers are manufactured in one of the best R&D centers in South Korea, which is specialized in the products of aesthetic cosmetology and biotechnology for many years. The production has all the necessary certifications for the production of medical devices, such as

-ISO 13485 is an international industry standard developed by the International Organization for Standardization. The standard contains requirements for a quality management system for medical device manufacturers.

-Certificate GMP - an official document indicating that the production process of a particular enterprise meets all the requirements of the international standard of the same name. Therefore, the medicines (or other goods) produced by this company are safe and of high quality. etc



인정번호(No.) :KTL-AABR-2987

의료기기 제조 및 품질관리 기준 적합인정서
(Certificate of GMP)

■ 업체명/허가번호(Company name of Applicant / License No.)
(주)리엔젠
Reanzen Co., Ltd

■ 대표자 (Representative)

■ 업체소재지 (Company address of Applicant)
경기도 안양시 동안구 학의로 250 503호(제조소), 504호(제조소), 505호(시험실, 사무실) (관양동, 관양두산벤처타워)
#503,504,505, 250, Hagui-ro, Dongan-gu, Anyang-si, Gyeonggi-do, 14056, Rep. of KOREA

■ 제조소명 (Name of Manufacturer)
제조자 (주)리엔젠(Reanzen Co., Ltd)

■ 제조소 소재지 (Address of Manufacturer)
제조자 : 경기도 안양시 동안구 학의로 250 503호(제조소), 504호(제조소), 505호(시험실, 사무실) (관양동, 관양두산벤처타워)
#503,504,505, 250, Hagui-ro, Dongan-gu, Anyang-si, Gyeonggi-do, 14056, Rep. of KOREA

■ 품목군 (Category)
인체조직 또는 기능 대치품(Substitute of Human Tissue or Body Function)

의료기기 제조 및 품질관리기준에 적합함을 인정합니다.
(We hereby certify that the above manufacturer complies with Korea Good Manufacturing Practices of Medical Devices for the product group listed above)

발행일자(Date of issue) : 2018. 08. 10
유효기간(Date of Expiration) : 2021. 01. 22

경인지방식품의약품안전청장
GYEONGIN REGIONAL FOOD AND DRUG ADMINISTRATION

ktl 한국산업기술시험원
Korea Testing Laboratory
Accreditation No. : M497041KS

Certificate No. : MDQ-17004

CERTIFICATE OF MEDICAL DEVICES MANAGEMENT SYSTEMS

Company Name : Reanzen Co., Ltd
(Gwanyang-dong, Gwanyang Doosan Bencheodaim), #503, 504, 505, 250, Hagui-ro, Dongan-gu, Anyang-si, Gyeonggi-do, Korea

Certification Scope : Design, Development and Production of, Graft/prosthesis, biomaterial, Surgical supplies,

Certification Standard : ISO 13485:2016

This is to certify that the Medical Devices Management Systems of this company has been found to conform to the above Quality System Standard by KTL.

Original Issue date : 20, Apr., 2018
Certificate Expiry : 19, Apr., 2021
Issue Date : 10, Aug., 2018

President of KTL

Korea Testing Laboratory
87, Digital-ro 26-gil, Guro-gu, Seoul, KOREA

JAS-ANZ
M497041KS

Material Safety Data Sheet

1. IDENTIFICATION OF THE PRODUCT

1.1. Product name
Cross-linked Hyaluronic acid gel
(lefilleo HA filler FINE, lefilleo HA filler DEEP, lefilleo HA filler SHAPE)

1.2. Recommended use of the chemical and restriction on use
- Recommended use: Cosmetic filler
- Restriction on use: No data available

1.3. Identification of the supplier
- Name: Reanze Co., Ltd
- Address: (Gwanyang-dong, Gwanyang Doosan Venture Digm) #503, #504, #505, 250, Hagui-ro, Dongan-gu, Anyang-si, Gyeonggi-do, Republic of Korea
- Emergency phone number: + 82 31 596 6310
- Fax: + 82 31 596 6311
- Web site: http://www.reanzen.com/

2. HAZARDS IDENTIFICATION

2.1. GHS(Globally Harmonized System of classification and labelling of chemicals) classification of the substance/mixture
Not applicable

2.2. GHS label elements, including precautionary statements
2.2.1. Hazard symbols (Pictograms)
No data available

2.2.2. Signal word
No data available

2.2.3. Hazard statements
No data available

2.2.4. Precautionary statements
- Prevention
No data available

- Response
No data available

- Storage

Summary table of lefilleo properties, analysis correspondence

test Item		CRITERIA	RESULT
		1.1mL	1.1mL
Appearance		Colorless transparent, Viscous liquid with no foreign material	Conformity
Actual Capacity		More than 1,1 mL	1.1 mL
pH		6.8 ~ 7.5	7.01
BDDE residue		< 2.0 ppm	0 ppm
Heavy metal		< 10.0 ppm	0 ppm
Osmotic pressure		200 ~ 400 mOsm/kg	302 mOsm/kg
Extrusion Force		10 ~ 25 N	14 ~ 19 N
Endotoxin		< 12.5 EU / mL	< 0.05 EU / mL
Stenrility test		Sterile	Conformity
Assay	Sodium Hyaluronate	Sodium Hyaluronate 90.0 ~ 110.0 %	101.1 %
	Lidocaine HCl	Lidocaine HCl 0.27 ~ 0.33 %	0.31 %
Viscoelasticity		60 ~ 300 Pa	60 ~ 300 Pa

Product Specification

Product Name	lefilleo™ - Fine -	lefilleo™ - Deep -	lefilleo™
Gel Type	Monophasic		
Crosslinked HA	24mg/mL		
Lidocaine HCl	3mg/mL		
Volume	1.1mL		
Viscoelasticty (Pa)	60 ~ 100 Pa	160 ~ 200Pa	260 ~ 300 Pa
Extrusion Force(N)	17 ~ 19N	14 ~ 16N	14 ~ 16N
Needle Size	30G	27G	25G
		T.S.K Premium Needle(Made in Japan)	
Duration	6 ~ 12 months	12 ~ 18 months	
Crosslinking Agent	BDDE(1,4-ButaneDiol Diglycidyl Ether)		
Injection area	Shallow wrinkles	Deep wrinkles	Deep wrinkles and facial contouring
Injection Depth	Dermis	Subcutaneous	Deep subcutaneous
Packing	1 syringe, 2 Needle / carton	1 syringe, 1 Needle, 1 cannula needle / carton	

"Lefilleo are manufactured , using only high quality raw materials with specialized production processing"

lēfilleo

KMEDICOS
Health& Beauty Care Products

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