ophtha futur®

gas

- High purity
- Improved convenience
- Adjustable gas concentration
- Environmental friendly
- Enhanced safety

ophthafutur® gas

technical data-sheet

Product Name	ophthafutur® SF6	ophthafutur® C2F6	ophthafutur® C3F8
Active compound	sulfur hexafluoride	hexafluoroethane	octafluoropropane
Composition			
Sum Formula	SF_6	C_2F_6	C_3F_8
Purity	> 4.5	> 5.0	> 4.0
Mass fraction	> 99.995%	> 99.999%	> 99.99%
Non expansive gas concentration	20%	16%	12%
Potential tamponade time	6 days	15 days	30 days
Retention time	10-14 days	30-35 days	55-65 days
Properties			
Pure Gas Volume	15 ml	12 ml	9 ml
Total Syringe Volume - Mixing Device	60 ml	60 ml	60 ml
Shelf life	24 months	24 months	24 months
Presentation			
Container	Glass Syringe	Glass Syringe	Glass Syringe
Mixing Device	Plastic Syringe with Filter	Plastic Syringe with Filter	Plastic Syringe with Filter

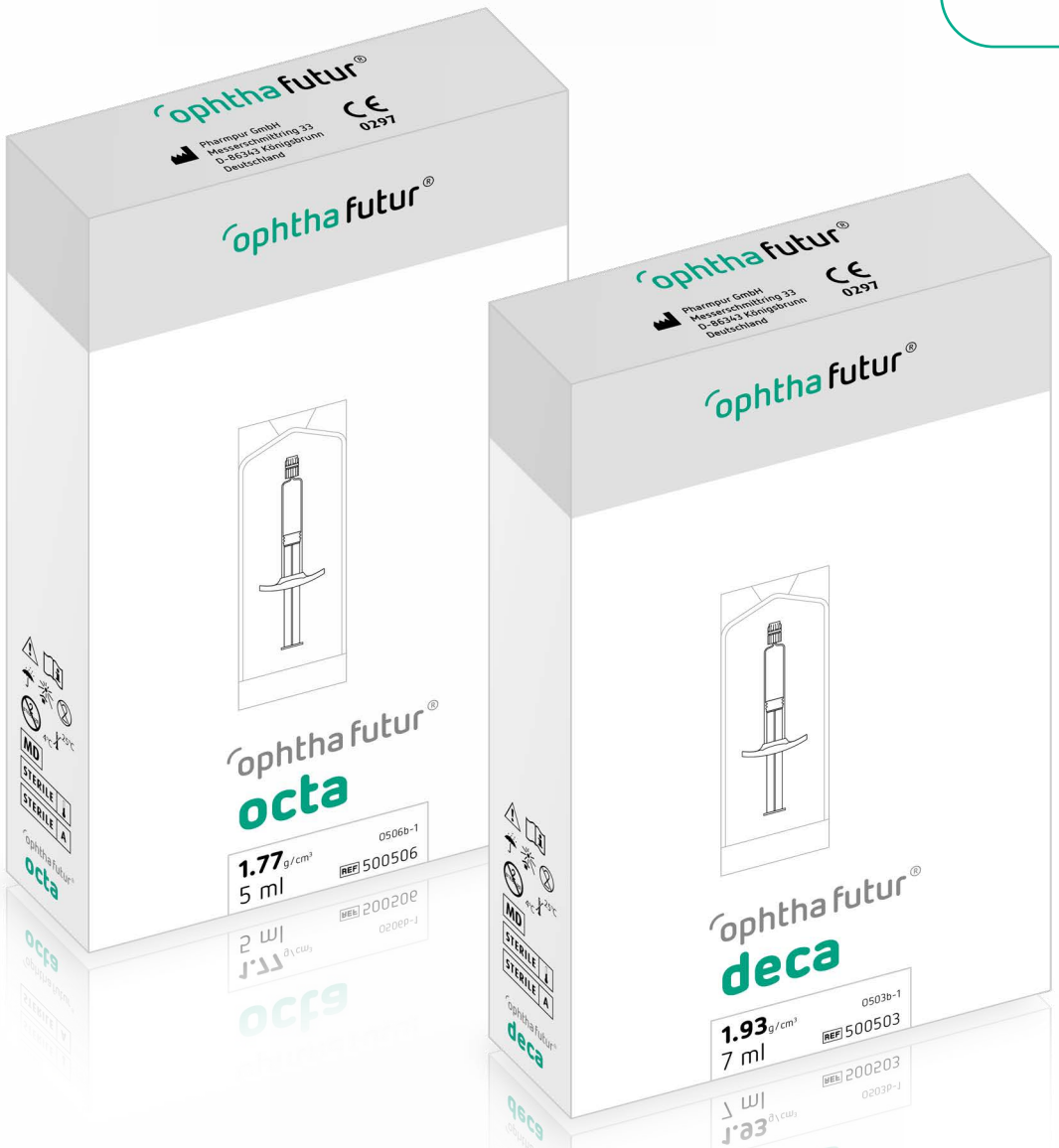
Accessories

Injection needle
Illustrated IFUs
Patient's safety card
Patient's wristband
Stickers

ophtha futur®

octa & deca

- High patient and product safety
- Multi-step proven & tested ultra-purification process
- Safe, biocompatible, sterile, endotoxin-free products
- 36 months shelf life
- Novel high performance polymer syringes (HPPS)



ophthafutur® octa & deca
technical data-sheet

Product Name	ophthafutur® octa	ophthafutur® deca
Active compound	perfluorooctane	perfluorodecalin
Physical and Chemical Parameters		
Sum Formula	C_8F_{18}	$C_{10}F_{18}$
Refractive Index n_D^{20}	1.27	1.31
Density (20 °C)	1.77 g/ml	1.93 g/ml
Vapor pressure (at 37°C)	8.8 kPa	3.4 kPa
Compound Surface Tension	14 mN/m	19 mN/m
Interfacial Tension against Water	54 mN/m	53 mN/m
Chemical Control		
Fluorination level	100 %	100 %
H-value	≤ 10 ppm	≤ 10 ppm
Additionally controlled Impurities (GC/MS)		
• concentration of C-H components	< 10 ppm	< 10 ppm
• 1H-PFO content	< 1 ppm	n.a.
• Perfluorofurane content	< 0.4%	n.a.
Microbial control		
Product Sterility ensured by	Sterile Filtration	Sterile Filtration
Outer Surface Sterility ensured by	Steam Sterilization	Steam Sterilization
Bacterial Endotoxins[1]	≤ 0.2 EU/ml	≤ 0.2 EU/ml

[1] LAL test acc. to EP 2.6.14/USP <85>

Biocompatibility acc. to DIN EN ISO 10993		
Cytotoxicity[2]	Non cytotoxic	Non cytotoxic
Sensitization[3]	Non sensitizing	Non sensitizing
Irritation[4]	Non irritating	Non irritating

[2] Growth inhibition test of serum extract acc. to DIN EN ISO 10993-5:2009

[3] Murine Local Lymph Node Assay (LLNA) acc. to DIN EN ISO 10993-10:2010

[4] Acute eye-irritation on rabbits acc. to DIN EN ISO 10993-10:2010 Appendix B

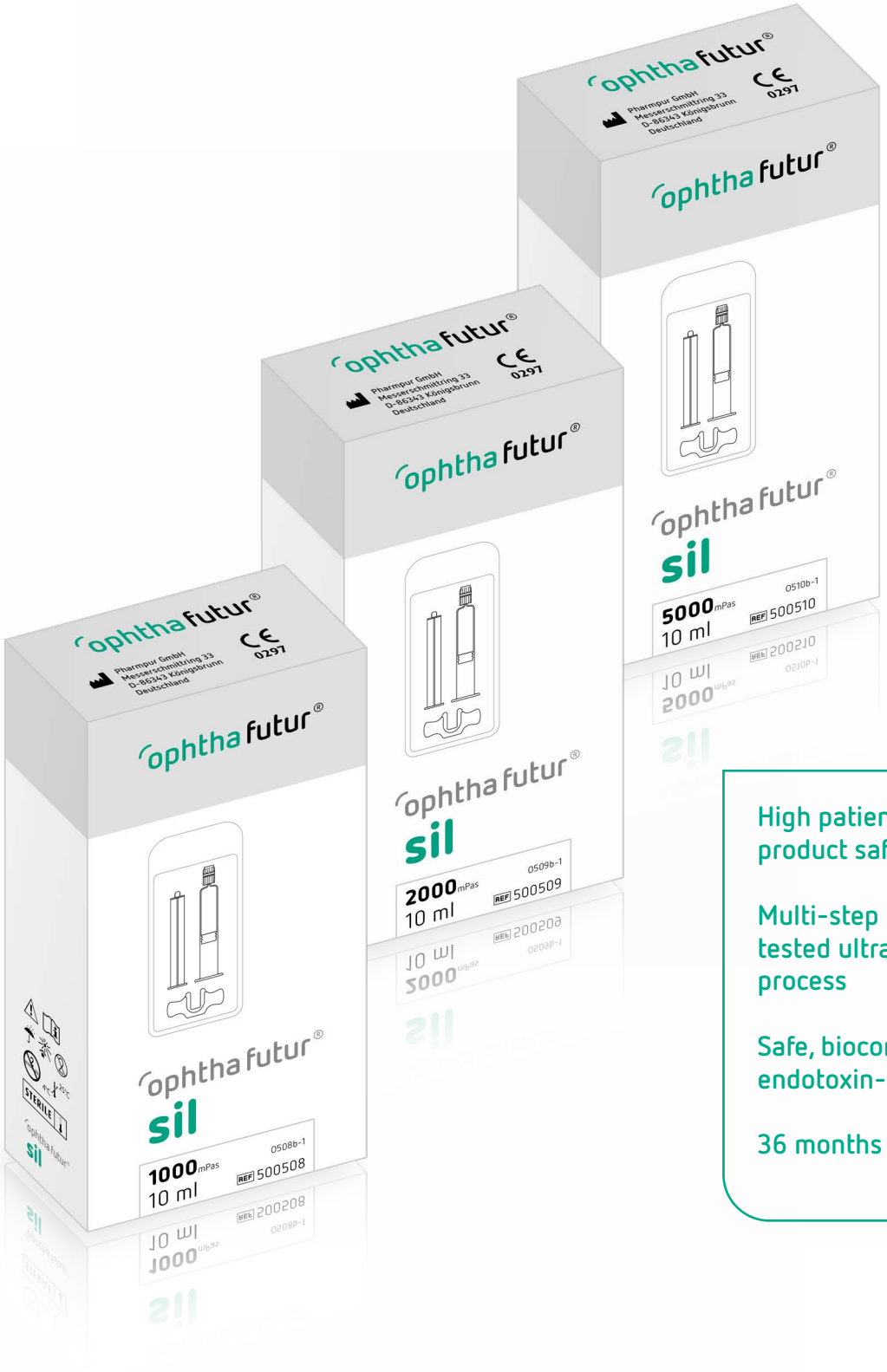
Cell Toxicity (%)	0	8	14	36	72	87	92
H-value (ppm)	≤ 10	175	350	700	1,400	2,100	2,800

Menz D-H, Feltgen N, Menz H, et al. How to ward off retinal toxicity of perfluorooctane and other perfluorocarbon liquids? *Invest Ophthalmol Vis. Sci.* 2018; 59: 4841-4846.

Presentation	Filling Volume	Container	Sterile Barrier	Shelf Life
ophthafutur® deca	5 ml / 7 ml	Vial	Pouch	36 months
ophthafutur® deca	5 ml / 7 ml	Syringe	Pouch	36 months
ophthafutur® octa	5 ml / 7 ml	Vial	Pouch	36 months
ophthafutur® octa	5 ml / 7 ml	Syringe	Pouch	36 months

ophtha futur®

sil



High patient and product safety

Multi-step proven and tested ultra-purification process

Safe, biocompatible, sterile, endotoxin-free products

36 months shelf life

ophthafutur® sil

technical data-sheet

Product Name	ophthafutur® sil 5000	ophthafutur® sil 2000	ophthafutur® sil 1000
Active compound	silicone oil	silicone oil	silicone oil
Physical and Chemical Parameters			
Viscosity (25 °C)	5,000 mPas	2,000 mPas	1,000 mPas
Density (25 °C)	0.97 g/cm³	0.97 g/cm³	0.97 g/cm³
Refractive Index n_D25	1.404	1.404	1.404
Chemical Control			
Polydispersity (GPC)			
Specified Range	1.0 – 2.3	1.0 – 2.3	1.0 – 2.3
Typical Range	1.6 – 1.7	1.6 – 1.7	1.6 – 1.7
Content of Volatile Oligosiloxanes (HS-GC/MS)			
HMCTS/D3	≤ 10 ppm	≤ 10 ppm	≤ 10 ppm
OMCTS/D4	≤ 10 ppm	≤ 10 ppm	≤ 10 ppm
DMCPS/D5	≤ 10 ppm	≤ 10 ppm	≤ 10 ppm
DMCPS/D6	≤ 10 ppm	≤ 10 ppm	≤ 10 ppm
MM/L2	≤ 10 ppm	≤ 10 ppm	≤ 10 ppm
MDM/L3	≤ 10 ppm	≤ 10 ppm	≤ 10 ppm
MD2M/L4	≤ 10 ppm	≤ 10 ppm	≤ 10 ppm
∑	≤ 25 ppm	≤ 25 ppm	≤ 25 ppm
Microbial control			
Product Sterility ensured by	Heat Sterilization	Heat Sterilization	Heat Sterilization
Outer Surface Sterility ensured by	Steam Sterilization	Steam Sterilization	Steam Sterilization
Bacterial Endotoxins[1]	≤ 0.2 EU/ml	≤ 0.2 EU/ml	≤ 0.2 EU/ml

[1] LAL test acc. to EP 2.6.14/USP <85>

Biocompatibility acc. to DIN EN ISO 10993			
Cytotoxicity[2]	Non cytotoxic	Non cytotoxic	Non cytotoxic
Sensitization[3]	Non sensitizing	Non sensitizing	Non sensitizing
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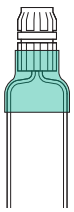
[2] Growth inhibition test of serum extract acc. to DIN EN ISO 10993-5:2009

[3] Murine Local Lymph Node Assay (LLNA) acc. to DIN EN ISO 10993-10:2010

[4] Acute eye-irritation on rabbits acc. to DIN EN ISO 10993-10:2010 Appendix B

Presentation	Filling Volume	Container	Sterile Barrier	Shelf Life
ophthafutur® sil5000	10 ml	Glass Syringe	Pouch	36 months
ophthafutur® sil2000	10 ml	Glass Syringe	Pouch	36 months
ophthafutur® sil1000	10 ml	Glass Syringe	Pouch	36 months



EU Declaration of Conformity
According to EU 2017/745

Name of the manufacturer:	Pharmpur GmbH
Address and place of issue:	Messerschmittring 33, 86343 Königsbrunn, Germany
SRN:	DE-MF-000008337

Herewith we declare, that the **Ocular endotamponades (Perfluorocarbons)** described below comply (complies) to the recognised requirements of EU 2017/745, Annex IX and Article 120 (Legacy devices) and, where applicable, with other relevant union legislation providing for the issue of an EU declaration of conformity.

Trade name	Specification number	Article number	Basic UDI-DI	Classification	Nomenclature (EMDN/CND)	
ophthafutur® deca	0500, 0501, 0502, 0503	500500, 500501, 500502, 500503	426026005000 TF-01-03FM	II a	Q020302	„Liquid fluids in ophthalmology"
ophthafutur® octa	0504, 0505, 0506, 0507	500504, 500505, 500506, 500507				

Our Quality Management System fulfils the requirements of the standard EN ISO 13485.

Notified Body which approved the full quality assurance system:	DQS Medizinprodukte GmbH August-Schanz-Straße 21, 60433 Frankfurt am Main, Germany
Identification number of the notified body:	0297
Certificate registration number and unique ID:	058646 MR2, 170775522

This declaration is applicable in combination with batch individually issued certificates of conformity.

This declaration is issued under the sole responsibility of Pharmpur GmbH.

Effective date (date of issue):	2021-06-25	
Expiry date:	2024-05-26	Equates to expiry date of manufacturer's EU certificate according to 93/42/EEC
Supersedes declaration of:	2021-05-26	Reason: SRN Issued by CA

Kristian Fürst
Head of Quality Assurance, Management Representative,
Person Responsible for Regulatory Compliance
Pharmpur GmbH

Dr. Andreas Hofmann
Head of Regulatory Affairs,
Person Responsible for Regulatory Compliance
Pharmpur GmbH

EU Declaration of Conformity
According to EU 2017/745

Name of the manufacturer:	Pharmpur GmbH
Address and place of issue:	Messerschmittring 33, 86343 Königsbrunn, Germany
SRN:	DE-MF-000008337

Herewith we declare, that the **Ocular endotamponades (Silicone oils)** described below comply (complies) to the recognised requirements of EU 2017/745, Annex IX and Article 120 (Legacy devices) and, where applicable, with other relevant union legislation providing for the issue of an EU declaration of conformity.

Trade name	Specification number	Article number	Basic UDI-DI	Classification	Nomenclature (EMDN/CND)	
ophthafutur® sil 1000	0508	500508	426026005000 TF-02-03FU	II b	Q020302	„Liquid fluids in ophthalmology"
ophthafutur® sil 2000	0509	500509				
ophthafutur® sil 5000	0510	500510				

Our Quality Management System fulfils the requirements of the standard EN ISO 13485.

Notified Body which approved the full quality assurance system:	DQS Medizinprodukte GmbH August-Schanz-Straße 21, 60433 Frankfurt am Main, Germany
Identification number of the notified body:	0297
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Kristian Fürst
Head of Quality Assurance, Management Representative,
Person Responsible for Regulatory Compliance
Pharmpur GmbH

Dr. Andreas Hofmann
Head of Regulatory Affairs,
Person Responsible for Regulatory Compliance
Pharmpur GmbH

EU Declaration of Conformity
According to EU 2017/745

Name of the manufacturer:	Pharmpur GmbH
Address and place of issue:	Messerschmittring 33, 86343 Königsbrunn, Germany
SRN:	DE-MF-000008337

Herewith we declare, that the **Ocular endotamponades (gas)** described below comply (complies) to the recognised requirements of EU 2017/745, Annex IX and Article 120 (Legacy devices) and, where applicable, with other relevant union legislation providing for the issue of an EU declaration of conformity.

Trade name	Specification number	Article number	Basic UDI-DI	Classification	Nomenclature (EMDN/CND)	
ophthafutur® sf6	0512	500512	426026005000 TF-01-16FW	II b	Q020301	"Gas fluids in ophthalmic surgery"
ophthafutur® c2f6	0513	500513				
ophthafutur® c3f8	0514	500514				

Our Quality Management System fulfils the requirements of the standard EN ISO 13485.

Notified Body which approved the full quality assurance system:	DQS Medizinprodukte GmbH August-Schanz-Straße 21, 60433 Frankfurt am Main, Germany
Identification number of the notified body:	0297
Certificate registration number and unique ID:	058646 MR2, 170775522

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Supersedes declaration of:	2021-05-26	Reason: SRN Issued by CA

Kristian Fürst
Head of Quality Assurance, Management Representative,
Person Responsible for Regulatory Compliance
Pharmpur GmbH

Dr. Andreas Hofmann
Head of Regulatory Affairs,
Person Responsible for Regulatory Compliance
Pharmpur GmbH

CERTIFICATE

This is to certify that the company

Pharmpur GmbH

Messerschmittring 33
86343 Königsbrunn
Germany

has implemented and maintains a **Quality Management System**.

Scope:
Development, manufacturing and distribution of ultra-purified Perfluorocarbons, Silicone oils, Ocular endotamponades, Viscoelastics and Aids in Ophthalmic surgery.
Contract development and Contract manufacturing of ultra-purified Perfluorocarbons, Silicone oils, Ocular endotamponades, Viscoelastics, Haemostatics, Dyes and Staining Solutions, Aids in Ophthalmic surgery and Orthopaedics.

Through an audit, documented in a report, performed by DQS Medizinprodukte GmbH, it was verified that the management system fulfills the requirements of the following standard:

DIN EN ISO 13485 : 2016 + AC : 2017-07
EN ISO 13485 : 2016 + AC : 2016
ISO 13485 : 2016

Certificate registration no.	058646 MP2016
Certificate unique ID	170779766
Effective date	2022-03-17
Expiry date	2024-07-15
Frankfurt am Main	2022-03-17

DAkkS
Deutsche
Akkreditierungsstelle
D-ZM-16021-01-00

DQS Medizinprodukte GmbH

Sigrid Uhlemann
Managing Director

Dr. Thomas Feldmann
Head of Certification Body

August-Schanz-Straße 21, 60433 Frankfurt am Main,
Tel. +49 (0) 69 95427-300, medical.devices@dqs-med.de

EC-CERTIFICATE

(Full quality assurance system)

This is to certify that the company

Pharmpur GmbH

Messerschmittring 33
86343 Königsbrunn
Germany

has implemented and maintains a full quality assurance system which applies to the products at every stage from design to final controls.

Through an audit, documented in a report, performed by DQS Medizinprodukte GmbH, it was verified that the management system fulfills the requirements of

Annex II – excluding Section 4 of Council Directive 93/42/EEC concerning medical devices

with respect to the following medical devices:

Ocular endotamponades, Viscoelastics and Ophthalmodiaphanoscope according annex.

The manufacturer is subject to surveillance according to Annex II, Section 5. The CE marking with the Notified Body Identification Number (0297) may be affixed on the devices listed in the certificate. An EC Design Examination Certificate according to Annex II, Section 4 is required for class III devices covered by this certificate. The certificate is in the case of class I(s) devices (I(s) = class I products placed on the market in sterile conditions) limited to the aspects of manufacture concerned with securing and maintaining sterile conditions. The certificate is in the case of class I(m) devices (I(m) = class I devices with a measuring function) limited to the aspects of manufacture concerned with the conformity of the products with the metrological requirements.

Certificate registration no.	058646 MR2
Certificate unique ID	170775522
Effective date	2021-04-16
Expiry date	2024-05-26
Frankfurt am Main	2021-04-16

DQS Medizinprodukte GmbH

Sigrid Uhlemann
Managing Director

Dr. Thomas Feldmann
Head of Certification Body

August-Schanz-Straße 21, 60433 Frankfurt am Main,
Tel. +49 (0) 69 95427-300, medical.devices@dqs-med.de

DQS Medizinprodukte GmbH is a Notified Body according to Council Directive 93/42/EEC concerning medical devices with the Identification Number 0297.

411.20 Version 1.0

Annex to certificate
Certificate registration No.: 058646 MR2
Certificate unique ID: 170775522
Effective date: 2021-04-16

Pharmpur GmbH

Messerschmittring 33
86343 Königsbrunn
Germany

Device family	Product		Class
MD 0105, Non-active ophthalmologic devices	Ocular endotamponades	Perfluorocarbons	IIa
		Silicone oils	IIb
		Gas C2F6 C3F8 SF6	IIb
	Viscoelastics	HPMC	IIa
MD1105 Active ophthalmologic devices	Ophthalmodiaphanoscope	safelight	Is