

# Soft Paraffins BP/EP, Liquid & Light Liquid Paraffins BP/EP (White Oils)

LUBRICANTS. TECHNOLOGY. PEOPLE.





FUCHS has over 40 years' experience in the production of White & Yellow Soft Paraffins BP/EP which are used by many pharmaceutical and cosmetics companies worldwide. We are in the unique position of being the only European manufacturer of White & Yellow Soft Paraffins BP/EP with a Manufacturing Licence ML02021/01 granted by the UK Medicines & Healthcare products Regulatory Agency (MHRA).

Our manufacturing plant is routinely audited by the UK MHRA in order to satisfy the requirements of Good Manufacturing Practices (GMP).

Our quality controls and quality systems enable us to manufacture stable, consistent and pure products.



#### THE FUCHS GROUP

FUCHS is the world's largest independent lubricant manufacturer. The Group comprises 55 operating companies with 34 production plants worldwide.

In addition to products developed for industry in the UK, we have access to over 2,500 industrial FUCHS products from within the Group. Customers have available FUCHS technical expertise and experience, providing access to international fluid technology.



#### FUCHS LUBRICANTS (UK) PLC **PROFILE**

The headquarters are located in Stoke-on-Trent which is also the location of our MHRA licensed manufacturing plant. Our modern, highly automated production plant ensures we can offer exceptional levels of service and delivery. FUCHS UK has over 100 years' experience of supplying lubricants within the UK. We have demonstrated excellent performance in all aspects of lubricant supply including lubricant quality, timely supply and health and safety compliance. Our UK manufacturing site is routinely audited to the highest levels in order to ensure compliance to a wide range of quality standards including BS OHSAS 18001, AS9100 C, ISO 14001, ISO 9001, ISO/TS 16949, and we hold the MHRA Medicines Manufacturing & Marketing Authorisation Licence ML 02021/01.



#### MANUFACTURING **EXCELLENCE**

Our production facilities are modern and efficient with state of the art process control and quality management systems. The site has an overall production capacity in excess of 100,000 tonnes per annum, 5,000 pallet storage locations and bulk fluid handling capabilities. The FUCHS production team undertakes a continuous improvement programme to maximise and improve production efficiency even further.

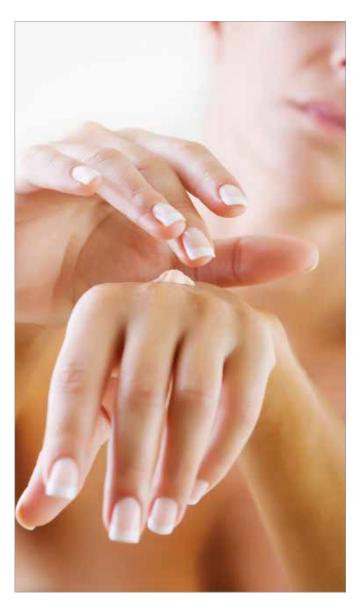


#### **EXPERIENCE** YOU CAN TRUST

Lubricant suppliers are common, but the number of lubricant suppliers with the expertise, service support and experience of FUCHS in the pharmaceutical industry are limited. In choosing a partner, you need confidence in their ability to understand the requirements of the pharmaceutical industry, and have the technology, intellect and support services to deliver. FUCHS is that partner. We have over 40 years' experience in manufacturing and supplying White and Yellow Soft Paraffins BP/EP, specialist products and technical services to the pharmaceutical and cosmetics industries.

# LIQUID & LIGHT LIQUID PARAFFINS BP/EP (WHITE OILS)





FUCHS White Oils are highly refined mineral hydrocarbons, consisting of saturated aliphatic hydrocarbons. These products are safe, highly hydrophobic, colourless and odourless or almost odourless, making them ideal for pharmaceutical and cosmetic uses.

They are highly resistant to microbiological spoilage, FUCHS White oils lead the market in purity and safety.

#### Uses

FUCHS Liquid & Light Liquid Paraffins (White Oils) are the ideal choice for both cosmetic and pharmaceutical bases. They are widely used in cosmetic and pharmaceutical applications which gives their natural lubricating and soothing nature full reign in uses ranging from baby oils and lotions to cleansing tissues and cosmetics.

FUCHS White Oils are also used extensively in food applications. They comply with the requirements of Stat. Inst. 1073 (1966) Liquid Mineral Hydrocarbon in food Regulations. Whether they are used for lubricating food machinery or as dividing dough oils in bakeries, our products show the highest performance and cleanliness attributes associated with these important industries.

#### **Our Products**

Can be supplied in bulk and barrels to the highest European Good Manufacturing Practice Standards in our custom built, computer controlled facility. A wide viscosity range can be catered for providing blends suitable for all our customers needs. FUCHS White Oils are produced to meet both the British & European Pharmacopoeia standards for Liquid & Light Liquid Paraffins (White Oils). They also meet the requirements for the USP / NF Mineral and Light Mineral Oil USP. In addition to this FUCHS White Oils meet FDA21 CFR172.878 and 178.3620(a) for direct food contact. FUCHS Lubricants (UK) Plc maintains a Medicines Licence for the blending, storage and filling of all medicinal and cosmetic grade white oil which is confirmed by audit by the UK's Department of Health via the MHRA.

## **PRODUCT SUMMARY**

The following table illustrates a selection of FUCHS Liquid & Light Liquid Paraffins, please enquire for further details.

Additionally we have other grades available and we are able to blend to customer requirements should the quantity justify.

WHITE OILS	RELATIVE DENSITY AT 20°C	DYNAMIC VISCOSITY AT 20°C – mm²/S (TYPICAL)	KINEMATIC VISCOSITY AT 40°C – mm²/S	VISCOSITY AT 37.8°C SUS (TYPICAL)
Test Method	BP/EP	ASTM D445	ASTM D445/IP71	ASTM D445
LMH SILKOLENE SIRIUS M40 - STAT. INST. 1073 (1966)	0.810 - 0.825	4.8	3.0 - 5.0	40
LMH SILKOLENE SIRIUS M55 - STAT. INST. 1073 (1966)	0.830 - 0.846	14.3	7.0 - 10.0	55
LMH SILKOLENE SIRIUS M70 - STAT. INST. 1073 (1966)	0.830 - 0.855	21	10.0 - 13.0	70
LMH USP SILKOLENE SIRIUS M180 - STAT. INST. 1073 (1966)	0.850 - 0.877	90	34.5 - 43.0	180
LLP BP/EP SILKOLENE SIRIUS M85	0.835 - 0.861	31	14.0 - 17.0	85
LLP BP/EP SILKOLENE SIRIUS M125	0.845 - 0.870	52	22.0 - 25.0	125
LP BP/EP/USP SILKOLENE SIRIUS M350	0.850 - 0.890	190	63.0 - 83.0	350
TECH WO SIRIUS T85	0.830 - 0.865		10.0 - 18.0	85



### SOFT **PARAFFINS** BP/EP



FUCHS Soft Paraffins (Petrolatum) comply with both British and European Pharmacopoeia Monographs. They are a semisolid purified mixture of hydrocarbons containing waxes and oil. FUCHS Soft Paraffins are odourless and range in colour from pure white to yellow and range in consistency (degree of softness) depending on the desired end product application. FUCHS Soft Paraffins are occlusive by nature. The melting range and consistency dictate overall performance which is designed to retain structure but can still be easily spread on the skin.

#### Uses

FUCHS Soft Paraffins BP/EP are used extensively in the cosmetic, personal care and pharmaceutical industries. They are used as base components in creams, lotions and ointments meeting the requirements of the British and European Pharmacopeias, United States Pharmacopeia and Japanese Pharmacopeias making them ideal for use in medicinal products. A fact confirmed by The Medicines & Healthcare products Regulatory Agency who audit the FUCHS Soft Paraffins' manufacturing facility in order to ensure compliance with Medicines and European Good Manufacturing Practices.

#### **Our Products**

FUCHS holds Europe's only Medicines Licence for the manufacturing and marketing of Soft Paraffins as well as Liquid & Light Liquid Paraffins (White Oils) and as such, has a leading position within the market. All our grades meet the British and European Pharmacopoeia Monographs as a minimum, and our quality régime enables us to manufacture some of the world's most stable, consistent and pure products.



## **PRODUCT** SUMMARY

The following table illustrates a selection of FUCHS White & Yellow Soft Paraffins, please enquire for further details.

Additionally we have other grades available and we are able to blend to customer requirements should the quantity justify.

WHITE SOFT PARAFFINS	DROP POINT	CONSISTENCY (CONE PENETRATION NO. AT 25°C - mmx10 <sup>-1</sup> )	APPEARANCE COLOUR (2" CELL)
Test Method	IP 371	IP 179	IP 17
WSP BP/EP SILKOLENE 783L	49 - 59	150 - 180	1.0Y max
WSP BP/EP/USP SILKOLENE 783LP	42 - 55	150 - 165	0.5Y max
WSP BP/EP SILKOLENE 944	49 - 59	195 - 225	1.0Y max
WSP BP/EP SILKOLENE 895	49 - 59	170 - 210	0.5Y max (in 6" cell)
YELLOW SOFT PARAFFINS			
YSP BP/EP SILKOLENE 775	49 - 59	145 - 175	16Y + 2R max
YSP BP/EP SILKOLENE 775P	42 - 52	180 - 210	16Y + 2R max
YSP BP/EP SILKOLENE 902H	50 - 60	185 - 215	16Y + 2R max
TECHNICAL YELLOW SOFT PARAFFINS			
TECHNICAL YSP 495	49 - 59	145 - 175	YELLOW/BROWN



## **PACKAGING**

#### **WHITE OILS**

PRODUCT CODE	PRODUCT	PACK SIZE
600933081	LMH Silkolene Sirius M40 - Stat. Inst. 1073 (1966)	170KG
600933432	LMH Silkolene Sirius M55 - Stat. Inst. 1073 (1966)	17KG
600933098	LMH Silkolene Sirius M70 - Stat. Inst. 1073 (1966)	174KG
600933005	LMH USP Silkolene Sirius M180 - Stat. Inst. 1073 (1966)	17KG
600027216 600763107 600933241 600932985	LLP BP/EP Silkolene Sirius M85	BULK 850KG IBC 174KG 17KG
600933296 600933067	LLP BP/EP Silkolene Sirius M125	850KG IBC 174KG
600027322 600815059 600138448 600933012	LP BP/EP/USP Silkolene Sirius M350	BULK 862KG IBC 177KG 17KG
600027056 600933425 600933265 600932961	TECH WO Sirius T85	BULK 850KG IBC 174KG 17KG

#### **SOFT PARAFFINS**

PRODUCT CODE	PRODUCT	PACK SIZE
600026042 600026059 600715836 600128937	WSP BP/EP Silkolene 783L	BULK 190KG 48KG 12.5KG
600690311	WSP BP/EP/USP Silkolene 783LP	172KG
600026318	WSP BP/EP Silkolene 944	190KG
600026226 600904203	WSP BP/EP Silkolene 895	190KG 18KG
600026493	WSP BP/EP Silkolene 895/L	180KG
600026578 600026592 600713829 600128920	YSP BP/EP Silkolene 775	BULK 192KG 48KG 12.5KG
600016561	YSP BP/EP Silkolene 775P	192KG
600026837	YSP BP/EP Silkolene 902H	192KG
600147402	TECHNICAL YSP 495	192KG

## **QUALITY** & SUPPORT



# A LIST





#### **QUALITY STANDARDS**

The FUCHS Manufacturing Plant & procedures strictly comply with Good Manufacturing Practice (GMP) in accordance with The Orange Guide (Rules & Guidance for Pharmaceutical Manufacturers and Distributors) for Medicinal Products for Human Use in compliance with EC Directive 2003/94/EC. We have strict quality control procedures for the receipt of raw materials and packaging: all raw materials are tested before unloading into our bulk tanks and all packaging sourced from approved suppliers and is statistically sampled. Full Pharmacopoeia Monograph testing is carried out on products in all pack sizes.

#### **RESEARCH & DEVELOPMENT**

The FUCHS Group has a strong focus on R&D and technical support, having more than 400 chemists, engineers and specialists in over 40 laboratories worldwide. The UK labs are extremely well equipped and audited to the highest levels.

We have a wealth of experience at FUCHS and are committed to training up the chemists of the future. Our team comprises of highly trained individuals including employees with qualifications such as Chartered Chemist, BSc Hons Chemistry, PHD

#### **SPECIALIST PRODUCTION**

We have dedicated manufacturing vessels, filling equipment and pumping systems for our pharmaceutical products. Our filling room has positive air pressure and air filtered to EU7 standards. Our unique manufacturing technology utilises vacuum steam distillation resulting in smooth product of superior quality providing long term stability for manufacturing pharmaceutical and cosmetic end products. Operations and procedures for the production of White and Yellow Soft Paraffins as well as Liquid & Light Liquid Paraffins (White Oils) are under the control of Registered Qualified Persons. Products are released in accordance with Article 51 of EC Directive 2001/83/EC.

#### STORAGE & **DISTRIBUTION**

All of our finished products are stored in a GMP complying (Good Manufacturing Practices) certified warehouse which is clean, dry, and has active pest control measures. Bulk products are delivered in strictly controlled vehicles. Packaged products are protected from the elements during road transportation.

Logistical support is increased through active vehicle tracking and utilisation programmes, ensuring that the FUCHS delivery fleet is highly efficient.

# FOR ALL WHITE OILS AND SOFT PARAFFIN ENQUIRIES

Please get in touch with our speciality lubricants division:

#### FUCHS Lubricants (UK) plc Speciality Lubricants Division

New Century Street, Hanley, Stoke-on-Trent, ST1 5HU

Phone: +44 (0)1782 203700 Email: contact-uk@fuchs-oil.com Information contained in this brochure was correct at the time this publication was printed. Please be aware that this information may change due to continual product development within this field.

Always read the Safety Data Sheet before handling a product.

Website: www.fuchs.com/uk



# Innovative solutions need experienced advice

FUCHS Lubricants (UK) plc Special Products Team will be glad to advise on the right product for each application and offer the support services required.



#### Contact:

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