



ACCORDING TO EC-REGULATIONS 1907/2006 (REACH), 1272/2008 (CLP) & 2015/830

SECTION 1: IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND OF THE COMPANY/UNDERTAKING

1.1 Product identifier

Product Name	OptiLube Sterile Lubricating Jelly
Trade Name	OptiLube
Product code	1123, 11233, 1129, 1129USB, 1129US, 1120, 11200, 1120E, 1120N, 1120SA, 1120US, 1119(A), 1119DW 1119S, 1124, 1114, 1140, 1141, 1141SA, 1121, 1121UK, 1121E, 1121N, 1110, 1110US 1122, 1122UK, 1122E, 1122N, 1127, 1127SA, 1127US
CAS No.	Mixture
EC No.	Mixture
REACH Registration No.	Not applicable

1.2 Relevant identified uses of the substance or mixture and uses advised against

Identified Use(s)	For use as a medical lubricant
Uses Advised Against	Not for use as a contraceptive

1.3 Details of the supplier of the safety data sheet

Manufacturer	
Company Identification	Optimum Medical Solutions Limited
Address of Manufacturer	Tennant Hall, Blenheim Grove Leeds
Postal code	LS2 9ET
Telephone:	+44 (0) 8456 435 579
Fax	+44 (0) 114 238 3826
E-mail	enquiries@optimummedical.co.uk
Office hours	Mon - Fri 09:00 - 17:00
Supplier	
Company Identification	Optimum Medical Solutions Limited
Address of Supplier	Tennant Hall, Blenheim Grove Leeds
Postal code	LS2 9ET
Telephone:	+44 (0) 8456 435 579
Fax	+44 (0) 114 238 3826
E-mail	enquiries@optimummedical.co.uk
Office hours	Mon - Fri 09:00 - 17:00

1.4 Emergency telephone number

Emergency Phone No.	08456435579
Contact	enquiries@optimummedical.co.uk

SECTION 2: HAZARDS IDENTIFICATION

2.1 Classification of the substance or mixture

Regulation (EC) No. 1272/2008 (CLP)	Not classified as dangerous for supply/use.
-------------------------------------	---

2.2 Label elements

Product Name	According to Regulation (EC) No. 1272/2008 (CLP) OptiLube
Hazard Pictogram(s)	None.
Signal Word(s)	None.
Hazard Statement(s)	None.
Precautionary Statement(s)	None.
2.3 Other hazards	None known.
2.4 Additional Information	None.

SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

**3.1 Substances**

Not applicable.

3.2 Mixtures

Not applicable.

SECTION 4: FIRST AID MEASURES**4.1 Description of first aid measures**

Inhalation If breathing is difficult, remove victim to fresh air and keep at rest in a position comfortable for breathing.

Skin Contact Wash skin with water.

Eye Contact Flush eyes with water for at least 15 minutes.

Ingestion Wash out mouth with water.

4.2 Most important symptoms and effects, both acute and delayed

None anticipated. Treat symptomatically.

4.3 Indication of any immediate medical attention and special treatment needed

Unlikely to be required but if necessary, treat symptomatically.

SECTION 5: FIREFIGHTING MEASURES**5.1 Extinguishing media**

Suitable Extinguishing media As appropriate for surrounding fire.

Unsuitable extinguishing media None.

5.2 Special hazards arising from the substance or mixture

None anticipated. Heating may cause decomposition.

5.3 Advice for firefighters

As appropriate for surrounding fire.

SECTION 6: ACCIDENTAL RELEASE MEASURES**6.1 Personal precautions, protective equipment and emergency procedures**

Provide adequate ventilation. Wear suitable gloves if prolonged skin contact is likely.

6.2 Environmental precautions

Do not release large quantities into the surface water or into drains.

6.3 Methods and material for containment and cleaning up

Adsorb spillages onto sand, earth or any suitable adsorbent material.

6.4 Reference to other sections

See Also Section 8, 13.

SECTION 7: HANDLING AND STORAGE**7.1 Precautions for safe handling**

Not known.

7.2 Conditions for safe storage, including any incompatibilities

Storage temperature

Ambient.

Storage life

Stable under normal conditions.

Incompatible materials

None known.

7.3 Specific end use(s)

For use as a medical lubricant

SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION**8.1 Control parameters**

8.1.1 Occupational Exposure Limits

Occupational Exposure Limits						
SUBSTANCE.	CAS No.	LTEL (8 hr TWA ppm)	LTEL (8 hr TWA mg/m ³)	STEL (ppm)	STEL (mg/m ³)	Note



Glycerol, mist	56-81-5		10			
Sodium hydroxide	1310-73-2				2	

Region Source
 EU EU Occupational Exposure Limits
 United Kingdom UK Workplace Exposure Limits EH40/2005 (Third edition, published 2018)

Remark Notes

8.2 Exposure controls

8.2.1. Appropriate engineering controls Ensure adequate ventilation.

8.2.2. Personal protection equipment



Eye Protection Wear eye protection with side protection (EN166).



Skin protection Not normally required.



Respiratory protection Normally no personal respiratory protection is necessary.



Thermal hazards None known.

8.2.3. Environmental Exposure Controls Do not release large quantities into the surface water or into drains.

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

9.1 Information on basic physical and chemical properties

Appearance	Gel/Jelly.
Colour	Colourless to pale yellow
Odour	Not known.
Odour threshold	Not known.
pH	Not known.
Melting point/freezing point	Not known.
Initial boiling point and boiling range	> 100 °C
Flash Point	Flash Point (°C) > 100
Evaporation rate	Not known.
Flammability (solid, gas)	Not known.
Upper/lower flammability or explosive limits	Not known.
Vapour pressure	Not known.
Vapour density	Not known.
Density (g/ml)	Not known.
Relative density	Not known.
Solubility(ies)	Solubility (Water) : Soluble. Solubility (Other) : Not known.
Partition coefficient: n-octanol/water	Not known.
Auto-ignition temperature	Not known.
Decomposition Temperature (°C)	Not known.
Viscosity	13000 – 18000 cP
Explosive properties	Not known.
Oxidising properties	Not known.

9.2 Other information

pH 5.0 - 7.0



SECTION 10: STABILITY AND REACTIVITY

10.1 Reactivity	None anticipated.
10.2 Chemical Stability	Stable under normal conditions.
10.3 Possibility of hazardous reactions	No hazardous reactions known if used for its intended purpose.
10.4 Conditions to avoid	None anticipated.
10.5 Incompatible materials	Not known.
10.6 Hazardous decomposition products	No hazardous decomposition products known.

SECTION 11: TOXICOLOGICAL INFORMATION

11.1 Information on toxicological effects	
Acute toxicity - Ingestion	Low acute toxicity
Acute toxicity - Skin Contact	Low acute toxicity
Acute toxicity - Inhalation	Low acute toxicity
Skin corrosion/irritation	Non-irritant
Serious eye damage/irritation	Non-irritant
Skin sensitization data	Not classified
Respiratory sensitization data	Not classified
Germ cell mutagenicity	There is no evidence of mutagenic potential.
Carcinogenicity	No evidence of carcinogenicity.
Reproductive toxicity	Not classified
Lactation	Not classified
STOT - single exposure	Not classified
STOT - repeated exposure	Not classified
Aspiration hazard	Not classified
11.2 Other information	Not known.

SECTION 12: ECOLOGICAL INFORMATION

12.1 Toxicity	
Toxicity - Aquatic invertebrates	Low toxicity to invertebrates.
Toxicity - Fish	Low toxicity to fish.
Toxicity - Algae	Low toxicity to algae.
Toxicity - Sediment Compartment	Not classified.
Toxicity - Terrestrial Compartment	Not classified.
12.2 Persistence and Degradation	Not known.
12.3 Bioaccumulative potential	Not known.
12.4 Mobility in soil	Not known.
12.5 Results of PBT and vPvB assessment	Not known.
12.6 Other adverse effects	Not known.

SECTION 13: DISPOSAL CONSIDERATIONS

13.1 Waste treatment methods	Dispose at suitable refuse site.
13.2 Additional Information	



No special precautions are required for this product.

SECTION 14: TRANSPORT INFORMATION

Not classified as hazardous for transport.

SECTION 15: REGULATORY INFORMATION

15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture

European Regulations - Authorisations and/or Restrictions On Use

Candidate List of Substances of Very High Concern for Authorisation Not listed

REACH: ANNEX XIV list of substances subject to authorisation Not listed

REACH: Annex XVII Restrictions on the manufacture, placing on the market and use of certain dangerous substances, mixtures and articles Not listed

Community Rolling Action Plan (CoRAP) Regulation (EC) N° 850/2004 of the European Parliament and of the Council on persistent organic pollutants methyl 4-hydroxybenzoate (99-76-3), propyl 4-hydroxybenzoate (94-13-3) Not listed

Regulation (EC) N° 1005/2009 on substances that deplete the ozone layer Not listed

Regulation (EU) N° 649/2012 of the European Parliament and of the Council concerning the export and import of hazardous chemicals Not listed

National regulations
Other Not known.

15.2 Chemical Safety Assessment

A REACH chemical safety assessment has not been carried out.

SECTION 16: OTHER INFORMATION

The following sections contain revisions or new statements:

LEGEND

Hazard Pictogram(s) None.

Hazard Statement(s) None.

Precautionary Statement(s)
Acronyms

None.
CAS : Chemical Abstracts Service
CLP : Regulation (EC) No 1272/2008 on classification, labelling and packaging of substances and mixtures
DNEL : Derived No Effect Level
EC : European Community
EINECS : European Inventory of Existing Commercial Chemical Substances
LTEL : Long term exposure limit
PBT : Persistent, Bioaccumulative and Toxic
PNEC : Predicted No Effect Concentration
REACH : Registration, Evaluation, Authorisation and Restriction of Chemicals
STEL : Short term exposure limit
STOT : Specific Target Organ Toxicity
vPvB : very Persistent and very Bioaccumulative

Disclaimers

Information contained in this publication or as otherwise supplied to Users is believed to be accurate and is given in good faith, but it is for the Users to satisfy themselves of the suitability of the product for their own particular purpose. Optimum Medical Solutions Limited gives no warranty as to the fitness of the product for any particular purpose and any implied warranty or condition (statutory or otherwise) is excluded

SAFETY DATA SHEET



except to the extent that exclusion is prevented by law. Optimum Medical Solutions Limited accepts no liability for loss or damage (other than that arising from death or personal injury caused by defective product, if proved), resulting from reliance on this information. Freedom under Patents, Copyright and Designs cannot be assumed.