



ACCORDING . . . .008 (CLP) & 2015/830

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

### 1.1 Product identifier

Product Name	Optilube
CAS No.	Not applicable.
EC No.	Not applicable.
REACH Registration No.	Exempt

### 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	Unit 5, First Floor, Armley Road Armley
Postal code	LS12 2LB
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	Unit 5, First Floor, Armley Road Armley
Postal code	LS12 2LB
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

## 2. SECTION 2: HAZARDS IDENTIFICATION

### 2.1 Classification of the substance or mixture

2.1.1 Regulation (EC) No. 1272/2008 (CLP)	Not classified as dangerous for supply/use.
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### 2.2 Label elements

	According to Regulation (EC) No. 1272/2008 (CLP)
Product Name	Optilube



Signal Word(s) None.

Hazard Statement(s) None.

Precautionary Statement(s) None.

### 2.3 Other hazards

None known.

### 2.4 Additional Information

None.

## 3. SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

### 3.1 Substances

Not applicable.

### 3.2 Mixtures

HAZARDOUS INGREDIENT(S)	CAS No.	EC No. / REACH Registration No.	%W/W	Hazard Statement(s)	Hazard Pictogram(s)
Polyethylene glycol-300	25422-68-3		7-10%	Not classified.	
Polyethylene glycol-1450	25322-68-3		7-10%	Not classified.	
methyl 4-hydroxybenzoate	99-76-3	202-785-7	< 0.2%	Not classified.	
propyl 4-hydroxybenzoate	94-13-3	202-307-7	<0.2%	Not classified.	
sodium hydroxide caustic soda	1310-73-2	215-185-5	0.24 %	Not classified.	

## 4. 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.



## 5. 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.

## 6. 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.

## 7. 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

## 8. 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/m³)	STEL (ppm)	STEL (mg/m³)	Note
Sodium hydroxide	1310-73-2				2	

Remark

Footnote



## 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.

## 9. SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

## 9.1 Information on basic physical and chemical properties

Appearance	Liquid.
	Colour : Colourless.
Odour	Characteristic.
Odour threshold	No data
pH	6.00 - 7.00
Melting point/freezing point	No data
Initial boiling point and boiling range	No data
Flash Point	Not known.
Evaporation rate	No data
Flammability (solid, gas)	Not known.
Upper/lower flammability or explosive limits	No data
Vapour pressure	No data
Vapour density	No data
Density (g/ml)	No data
Relative density	1 approx.
Solubility(ies)	Solubility (Water) : Completely miscible with water.
	Solubility (Other) : No data
Partition coefficient: n-octanol/water	No data
Auto-ignition temperature	No data
Decomposition Temperature (°C)	No data
Viscosity	13,000 - 18,000 mPa
Explosive properties	Not explosive.
Oxidising properties	Not oxidising.



## 9.2 Other information

None.

## 10. 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.

## 11. SECTION 11: TOXICOLOGICAL INFORMATION

## 11.1 Information on toxicological effects

Acute toxicity - Ingestion	Self classification: Low oral toxicity. LD50, rat > 10,000 mg/kg
Acute toxicity - Skin Contact	Self classification: LD50, rabbit > 20,000 mg/kg
Acute toxicity - Inhalation	Self classification: Unlikely route of exposure. LC50, 6h, . . . . No deaths occurred.
Skin corrosion/irritation	Not classified. Prolonged . . . .n with local redness
Serious eye damage/irritation	Self classification: May cause . . . .ransient irritation.
Skin sensitization data	Self classification: It is not a skin sensitiser.
Respiratory sensitization data	Not classified
Germ cell mutagenicity	Self classification: No evidence of genotoxicity.
Carcinogenicity	Self classification: No evidenc. . . . of carcinogenicity.
Reproductive toxicity	Self classification: Studies in. . . .teratogenic effects.
Lactation	Not classified
STOT - single exposure	Not classified
STOT - repeated exposure	Not classified
Aspiration hazard	Not classified
11.2 Other information	Not known.

## 12. SECTION 12: ECOLOGICAL INFORMATION

## 12.1 Toxicity



Toxicity - Aquatic invertebrates	A study in . . . the concentration of
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	The produc. . . gh mobility in soil.
12.5. Results of. . . and vPvB assessment	Not known.
12.6 Other adverse effects	Not known.

### 13. SECTION 13: DISPOSAL CONSIDERATIONS

#### 13.1 Waste treatment methods

No special precautions are required for this product.

#### 13.2 Additional Information

No special precautions are required for this product.

### 14. SECTION 14: TRANSPORT INFORMATION

NOT CLASSED AS DANGEROUS FOR TRANSPORT.

### 15. 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) methyl 4-hydroxybenzoate (99-76-3)

Regulation (EC) N° 850/2004 of the European Parliament and of the Council on persistent organic pollutants Not listed

Regulation (EC) N° 2037/2000 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.

## 16. SECTION 16: OTHER INFORMATION

The following sections contain revisions  
or new statements:

LEGEND

Hazard Pictogram(s)

None.

Hazard Statement(s)

None.

Precautionary Statement(s)

None.

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