



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

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

### 1.1 Product identifier

Product Name	Sterile lubricating jelly with lidocaine
Trade Name	Optilube Active, CHG Free
Product code	1167, 1168
CAS No.	Mixture.
EC No.	Mixture.
REACH Registration No.	Mixture.

### 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 oral use.

### 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)

### 2.2 Label elements

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



Product Name Sterile lubricating jelly with lidocaine and antiseptic

Hazard Pictogram(s)

Signal Word(s) None.

Hazard Statement(s)

Precautionary Statement(s) P264: Wash hands and exposed skin thoroughly after handling.  
 P302+P352: IF ON SKIN: Wash with plenty of water.  
 P305+P351+P338: IF IN EYES: Rinse cautiously with water for several minutes.  
 Remove contact lenses, if present and easy to do. Continue rinsing.  
 P332+P313: If skin irritation occurs: Get medical advice/attention.  
 P337+P313: If eye irritation persists: Get medical advice/attention.

2.3 Other hazards

None known.

2.4 Additional Information

For full text of H/P Statements see section 16.

### 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)
propane-1,2-diol	57-55-6	200-338-0	20 - 30%	Not classified	
lidocaine hydrochloride	73-78-9	200-803-8	2	Not classified.	
Hydroxyethylcellulose,			1 - 2%	Not classified.	
Sodium metabisulphite	7681-57-4	231-673-0	0.1%	Not classified.	



#### 4. SECTION 4: FIRST AID MEASURES

##### 4.1 Description of first aid measures

Inhalation	Treat symptomatically.
Skin Contact	IF ON SKIN: Wash with plenty of water. If skin irritation occurs: Get medical advice/attention.
Eye Contact	Treat symptomatically.
Ingestion	Treat symptomatically.

##### 4.2 Most important symptoms and effects, both acute and delayed

Causes irritation to eyes and skin.

##### 4.3 Indication of any immediate medical attention and special treatment needed

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

Heating may cause decomposition.

##### 5.3 Advice for firefighters

Fire fighters should wear complete protective clothing including self-contained breathing apparatus. Dike fire control water for later disposal.

#### 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. Wash hands and exposed skin thoroughly after handling.

##### 6.2 Environmental precautions

Avoid release to the environment.

##### 6.3 Methods and material for containment and cleaning up

Adsorb large spillages onto sand, earth or any suitable adsorbent material. Contain spillages with sand, earth or any suitable adsorbent material. Earth may be shovelled to contain spillage and to avoid contamination of sewers and watercourses.

##### 6.4 Reference to other sections

See Also Section 8, 13.

#### 7. SECTION 7: HANDLING AND STORAGE

##### 7.1 Precautions for safe handling

Take off contaminated clothing and wash it before reuse.

##### 7.2 Conditions for safe storage, including any incompatibilities



Keep container in a well-ventilated place.

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/m <sup>3</sup> )	STEL (ppm)	STEL (mg/m <sup>3</sup> )	Note
Propane-1,2-diol total vapour and particulates	57-55-6	50	474			
Propane-1,2-diol particulates	57-55-6		10			

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 Avoid release to the environment.

## 9. SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

### 9.1 Information on basic physical and chemical properties

Appearance Liquid.  
Colour : Colourless



Odour	Not known.
Odour threshold	Not known.
pH	pH 5.20 - 6.20
Melting point/freezing point	Not known.
Initial boiling point and boiling range	Not known.
Flash Point	Not known.
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)	1.0 +/- 0.1 g/mL
Relative density	Not known.
Solubility(ies)	Solubility (Water) : Completely miscible with water. Solubility (Other) : Not known.
Partition coefficient: n-octanol/water	Not known.
Auto-ignition temperature	Not known.
Decomposition Temperature (°C)	Not known.
Viscosity	950 – 3700 mPa.s
Explosive properties	Not known.
Oxidising properties	Not known.
9.2 Other information	Not known.

## 10. SECTION 10: STABILITY AND REACTIVITY

10.1 Reactivity	Stable under normal conditions.
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	None 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	Not classified.
Acute toxicity - Skin Contact	Not classified.
Acute toxicity - Inhalation	Not classified.
Skin corrosion/irritation	Not classified.
Serious eye damage/irritation	Not classified.
Skin sensitization data	Not classified.
Respiratory sensitization data	Not classified.



Germ cell mutagenicity	Not classified.
Carcinogenicity	Not classified.
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.

## 12. SECTION 12: ECOLOGICAL INFORMATION

12.1 Toxicity	
Toxicity - Aquatic invertebrates	Not known.
Toxicity - Fish	Not known.
Toxicity - Algae	Not known.
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.

## 13. SECTION 13: DISPOSAL CONSIDERATIONS

13.1 Waste treatment methods	Dispose of contents/container to: approved waste disposal facility.
13.2 Additional Information	Disposal should be in accordance with local, state or national legislation.

## 14. SECTION 14: TRANSPORT INFORMATION

NOT CLASSED AS DANGEROUS FOR TRANSPORT.

## 15. SECTION 15: REGULATORY INFORMATION

15.1 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	Not listed



use of certain dangerous substances,  
 mixtures and articles  
 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  
 15.2 National regulations  
 Other Not known.

## 16. SECTION 16: OTHER INFORMATION

The following sections contain revisions  
 or new statements:

### LEGEND

Hazard Pictogram(s)

None.

Hazard Statement(s) H412: Harmful to aquatic life with long lasting effects.

Precautionary Statement(s) P273: Avoid release to the environment.  
 P501: Dispose of contents/container to: .

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