



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 | Ultrasound gel, sterile |
| Trade Name | Vue |
| Product code | 1156 |
| 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) | Gel for diagnostic and therapeutic medical ultrasound |
| 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 |
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| 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) Ultrasound gel, ultrasound gel sterile |
|--------------|--|

| | |
|---------------------|-------|
| 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

SAFETY DATA SHEET



| HAZARDOUS INGREDIENT(S) | CAS No. | EC No. / REACH Registration No. | Hazard Statement(s) | Hazard Pictogram(s) |
|--------------------------|------------|---------------------------------|---------------------|---------------------|
| Glycerine | 56-81-5 | 200-289-5 | Not classified. | None |
| PEG-300 | 25322-68-3 | 500-038-2 | Not classified. | None |
| PEG-1450 | 25322-68-3 | 500-038-2 | Not classified. | None |
| Carbomer | 9007-20-9 | 618-435-5 | Not classified. | None |
| Methyl 4-hydroxybenzoate | 99-76-3 | 202-785-7 | Not classified. | None |
| Propyl 4-hydroxybenzoate | 94-13-3 | 202-307-7 | Not classified. | None |
| Sodium hydroxide | 1310-73-2 | 215-185-5 | Not classified. | None |
| Injection water | 7732-18-5 | 231-791-2 | Not classified. | None |

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)

Gel for diagnostic and therapeutic medical ultrasound

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 Liquid.
 Colour : Colourless.
 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) | 1.037 g/cm ³ |
| Relative density | Not known. |
| Solubility(ies) | Solubility (Water) : Not known. Solubility (Other) : Not known. |
| Partition coefficient: n-octanol/water | Not known. |
| Auto-ignition temperature | Not known. |
| Decomposition Temperature (°C) | Not known. |
| Viscosity | Not known. |
| Explosive properties | Not known. |
| Oxidising properties | Not known. |
| 9.2 Other information | |
| pH | 5.5 - 7.5 |

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) methyl 4-hydroxybenzoate (99-76-3), propyl 4-hydroxybenzoate (94-13-3)

Regulation (EC) N° 850/2004 of the European Parliament and of the Council on persistent organic pollutants 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

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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) None.

Acronyms

CAS : Chemical Abstracts Service

CLP : Regulation (EC) No 1272/2008 on classification, labelling and packaging of substances and mixtures

SAFETY DATA SHEET



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

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