

Safety Data Sheet

according to Regulation (EC) No 1907/2006

Revision date: 11.06.2019

OpSil Artificial Eye Lubricant

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SECTION 1: Identification of the substance/mixture and of the company

1.1. Product identifier

Product Name:

OpSil Standard & OpSil Thick

Product Code(s):

M901 & M902

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

Lubricant for artificial eye

1.3. Details of the supplier of the safety data sheet

Company name: Technovent Ltd
Street: Unit 5 York Park
Bridgend CF31 3TB
Place: UK
Telephone: +44 1656 768566
e-mail: info@technovent.com
Internet: www.technovent.com

Emergency number: +44 1656768566

This number is only obtainable during office hours
(Monday - Thursday 9.00 am - 5.00 pm, Friday 9.00 am - 4.00 pm)

1.4. Emergency telephone number

+4401656 768566

This number is only obtainable during office hours
(Monday - Thursday 8.00 am - 5.00 pm, Friday 8.00 am - 4.00 pm)

SECTION 2: Hazards Identification

2.1. Classification of the substance or mixture

Regulation (EC) No. 1272/2008

This mixture is not classified as hazardous in accordance with Regulation (EC) No. 1272/2008.

2.2. Label elements

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Additional advice on labelling
According to Regulation (EC) 1272/2008

2.3. Other hazards

None known

SECTION 3: Composition/information on ingredients

3.2. Mixtures

Chemical characterization

Silicone fluid

Hazardous components

CAS No	Chemical Name			Quantity
	EC no	Index no	REACH no	
	Classification according to Regulation (EC) no: 1272/2008 [CLP]			
63148-62-9	Dimethyl siloxane, trimethylsiloxy-terminated			100

Full text of H and EUH statements: see section 16.

SECTION 4: First Aid Measures

4.1. Description of first aid measures

General information

First aider: Pay attention to self-protection! Remove affected person from the danger area and lay down.

After inhalation

Provide fresh air. Medical treatment necessary.

After contact with skin

Wash with plenty of water. Immediately remove any contaminated clothing, shoes or stockings. Medical treatment necessary.

After contact with eyes

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After eye contact: Rinse immediately carefully and thoroughly with eye-bath or water. Consult an ophthalmologist.

After ingestion

Let water be drunken in little sips (dilution effect).

Do not induce vomiting. If you feel unwell, seek medical advice.

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

No information available.

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

Treat symptomatically.

SECTION 5: Firefighting Measures

5.1. Extinguishing media

Suitable extinguishing media

Co-ordinate fire-fighting measures to the fire surroundings.

5.2. Special hazards arising from the substance or mixture

May form carbon oxides, silicone oxides, formaldehyde on combustion

5.3. Advice for firefighters

In case of fire: Wear self-contained breathing apparatus.

Additional information

Use water spray jet to protect personnel and to cool endangered containers. Suppress gases/vapours/mists

with water spray jet. Collect contaminated fire extinguishing water separately. Do not allow entering drains or surface water.

SECTION 6: Accidental Release Measures

6.1. Personal precautions, protective equipment and emergency procedures

Provide adequate ventilation. Do not breathe gas/fumes/vapour/spray. Avoid contact with skin, eyes and clothes. Use personal protection equipment.

6.2. Environmental precautions

Do not allow to enter into surface water or drains.

6.3. Methods and material for containment and cleaning up

Absorb with liquid-binding material (e.g. sand, diatomaceous earth, acid- or universal binding agents). Treat the recovered material as prescribed in the section on waste disposal.

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6.4. Reference to other sections

Safe handling: see section 7

Personal protection equipment: see section 8

Disposal: see section 13

SECTION 7: Handling & Storage

7.1. Precautions for safe handling

Advice on safe handling

If handled uncovered, arrangements with local exhaust ventilation have to be used. Do not breathe gas/fumes/vapour/spray.

Advice on protection against fire and explosion

No special fire protection measures are necessary.

7.2. Conditions for safe storage, including any incompatibilities

Requirements for storage rooms and vessels

Keep container tightly closed. Keep locked up. Store in a place accessible by authorized persons only. Provide adequate ventilation as well as local exhaustion at critical locations.

Advice on storage compatibility

Do not store with acids, lyes, alcohols, metallic powders and metallic oxides (release of hydrogen is favoured).

Further information on storage conditions

Keep only in the original container in a cool, dry and well-ventilated place, away from foodstuffs.

7.3. Specific end use(s)

Silicone for oral impression taking.

For use by trained specialist staff.

SECTION 8: Exposure Control/Personal Protection

8.1. Control parameters

Contains no substances with occupational exposure limit values

8.2. Exposure controls

Appropriate engineering controls

If handled uncovered, arrangements with local exhaust ventilation have to be used. Do not breathe gas/fumes/vapour/spray. Processing may form hazardous compounds (see Section 10)

Protective and hygiene measures

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Remove contaminated, saturated clothing immediately. Draw up and observe skin protection programme. Wash hands and face before breaks and after work and take a shower if necessary. When using do not eat or drink.

Eye/face protection

Wear eye/face protection.

Hand protection

When handling with chemical substances, protective gloves must be worn with the CE-label including the four control digits. The quality of the protective gloves resistant to chemicals must be chosen as a function of the specific working place concentration and quantity of hazardous substances. For special purposes, it is recommended to check the resistance to chemicals of the protective gloves mentioned above together with the supplier of these gloves.

Suitable are gloves of the following material: NBR (Nitrile rubber)

Skin protection

Wear suitable protective clothing.

Respiratory protection

In case of inadequate ventilation wear respiratory protection.

SECTION 9: Physical/Chemical Properties

9.1. Information on basic physical and chemical properties

Physical state: Liquid
Colour: Colourless
Odour: None

pH-Value: not determined

Test method

Changes in the physical state

Melting point: not determined
Initial boiling point and boiling range: >65 deg C

Flash point: >121.1 °C Closed cup

Flammability

Solid: not applicable
Gas: not applicable

Lower explosion limits: not determined
Upper explosion limits: not determined

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Ignition temperature: not determined

Auto-ignition temperature

Solid: not applicable

Gas: not applicable

Decomposition temperature: no data available

Oxidizing properties

Not oxidizing.

Vapour pressure: no data available

Density (at 20 °C): 0.97 g/cm³

Water solubility: practically insoluble

Solubility in other solvents: not determined

Partition coefficient: not determined

Viscosity / dynamic:
(at 23 °C) 100cSt (M901), 350 cSt (M902)

Vapour density: not determined

Evaporation rate: not determined

9.2. Other information

Solid content: not determined

SECTION 10: Stability & Reactivity

10.1. Reactivity

No hazardous reaction when handled and stored according to provisions.

10.2. Chemical stability

The product is stable under storage at normal ambient temperatures.

10.3. Possibility of hazardous reactions

Reacts with : Acids, alkalis, alcohols, powdered metals or metal oxides with release of hydrogen.

10.4. Conditions to avoid

Temperatures > 120°C

10.5. Incompatible materials

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No information available.

10.6. Hazardous decomposition products

In case of thermic decomposition hydrogen is released.

At a temperature in excess of approx. 121°C a small amount of formaldehyde may be released by oxidative degradation.

SECTION 11: Toxicological Information

Likely routes of exposure

Inhalation
Skin Contact
Ingestion
Eye Contact

Acute toxicity

Not classified based on available information

Product

Acute oral toxicity LD50 (Rat): > 15400 mg/kg
Assessment: The substance or mixture has no acute oral toxicity
Remarks: Based on data from similar materials

Acute dermal toxicity LD50 (Rat): > 2000 mg/kg
Assessment: The substance or mixture has no acute oral toxicity
Remarks: Based on data from similar materials

Skin corrosion/irritation

Not classified based on available information

Product:

Species: Rabbit
Result: No skin irritation
Remarks : Based on data from similar materials

Serious eye damage/eye irritation

Not classified based on available information.

Product:

Species: Rabbit
Result: No eye irritation

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Remarks : Based on data from similar materials

Respiratory or skin sensitization

Skin sensitization

Not classified based on available information

Respiratory sensitization

Not classified based on available information.

Germ cell mutagenicity

Not classified based on available information

Product:

Genotoxicity in vitro

Test Type: Bacterial reverse mutation assay (AMES)

Result: negative

Remarks: Based on data from similar materials

Carcinogenicity

Not classified based on available information

Species: Rat

Application Route: Ingestion Result:

negative

Remarks : Based on data from similar materials

IARC

No ingredient of this product present at levels greater than or equal to 0.1% is identified as probable, possible or confirmed human carcinogen by IARC.

OSHA

No ingredient of this product present at levels greater than or equal to 0.1% is identified as a carcinogen or potential carcinogen by OSHA

NPT

No ingredient of this product present at levels greater than or equal to 0.1% is identified as a known or anticipated carcinogen by **NTP**

Reproductive toxicity

Not classified based on available information

Effects on fertility

Species: Rabbit, male Application Route: Ingestion Symptoms: No effects on fertility. Remarks: On basis of test data

Effects on fetal development

Test Type: Prenatal development toxicity study (teratogenicity) Species: Rabbit, female

Application Route: Skin contact

Symptoms: No effects on fetal development. Remarks: On basis of test data

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Reproductive toxicity - Assessment

No evidence of adverse effects on sexual function and fertility, or on development, based on animal experiments.

STOT-single exposure

Not classified based on available information.

STOT-repeated exposure

Not classified based on available information.

Product:

Routes of exposure: Ingestion

Assessment: No significant health effects observed in animals at concentrations of 100 mg/kg bw or less.

Routes of exposure: Skin contact

Assessment: No significant health effects observed in animals at concentrations of 200 mg/kg bw or less.

Repeated dose toxicity Product:

Species: Rat

Application Route: Ingestion

Remarks: On basis of test data.

Species: Rabbit

Application Route: Skin contact

Remarks: On basis of test data.

Aspiration toxicity

Not classified based on available information.

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SECTION 12: Ecological Information

12.1. Toxicity

The product is not: Ecotoxic.

12.2. Persistence and degradability

The product has not been tested.

12.3. Bioaccumulative potential

The product has not been tested.

12.4. Mobility in soil

The product has not been tested.

12.5. Results of PBT and vPvB assessment

No information available

12.6. Other adverse effects

No information available.

Further information

Do not allow to enter into surface water or drains. Do not allow to enter into soil/subsoil.

SECTION 13: Disposal Considerations

Further information

Do not allow to enter into surface water or drains. Do not allow to enter into soil/subsoil.

13.1. Waste treatment methods

Advice on disposal

Do not allow to enter into surface water or drains. Do not allow to enter into soil/subsoil. Dispose of waste according to applicable legislation.

Contaminated packaging

This material and its container must be disposed of as hazardous waste. Handle contaminated packages in the same way as the substance itself.

SECTION 14: Transport Information

Land transport (ADR/RID)

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14.1. UN number: No dangerous good in sense of this transport regulation.

14.2. UN proper shipping name: No dangerous good in sense of this transport regulation.

14.3. Transport hazard class(es): No dangerous good in sense of this transport regulation.

14.4. Packing group: No dangerous good in sense of this transport regulation.

Inland waterways transport (ADN)

14.1. UN number: No dangerous good in sense of this transport regulation.

14.2. UN proper shipping name: No dangerous good in sense of this transport regulation.

14.3. Transport hazard class(es): No dangerous good in sense of this transport regulation.

14.4. Packing group: No dangerous good in sense of this transport regulation.

Marine transport (IMDG)

14.1. UN number: No dangerous good in sense of this transport regulation.

14.2. UN proper shipping name: No dangerous good in sense of this transport regulation.

14.3. Transport hazard class(es): No dangerous good in sense of this transport regulation.

14.4. Packing group: No dangerous good in sense of this transport regulation.

Air transport (ICAO-TI/IATA-DGR)

14.1. UN number: No dangerous good in sense of this transport regulation.

14.2. UN proper shipping name: No dangerous good in sense of this transport regulation.

14.3. Transport hazard class(es): No dangerous good in sense of this transport regulation.

14.4. Packing group: No dangerous good in sense of this transport regulation.

14.6. Special precautions for user

No dangerous good in sense of this transport regulation.

14.7. Transport in bulk according to Annex II of Marpol and the IBC Code

No dangerous good in sense of this transport regulation.

SECTION 15: Regulatory Information

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

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EU regulatory information

Additional information

To follow: 850/2004/EC, 79/117/EEC, 689/2008/EC

National regulatory information

Employment restrictions:

Observe restrictions to employment for juvenils according to the ' juvenile work protection guideline' (94/33/EC).

Water contaminating class (D):

2 - clearly water contaminating

15.2. Chemical safety assessment

Chemical safety assessments for substances in this mixture were not carried out.

SECTION 16: Other Information

Abbreviations and acronyms

ADR: Accord européen sur le transport des marchandises dangereuses par Route (European Agreement concerning the International Carriage of Dangerous Goods by Road)

IMDG: International Maritime Code for Dangerous Goods

IATA: International Air Transport Association

GHS: Globally Harmonized System of Classification and Labelling of Chemicals

EINECS: European Inventory of Existing Commercial Chemical Substances

ELINCS: European List of Notified Chemical Substances

CAS: Chemical Abstracts Service

LC50: Lethal concentration, 50%

LD50: Lethal dose, 50%

Relevant H and EUH statements (number and full text)

H372 Causes damage to organs (lung) through prolonged or repeated exposure if inhaled.

Further Information

The information is based on present level of our knowledge. It does not, however, give assurances of product properties and establishes no contract legal rights. The receiver of our product is singularly responsible for adhering to existing laws and regulations.