

according to Regulation (EC) No 1907/2006

Detaseal® hydroflow Xlite (base + catalyst)

Revision date: 20.07.2018

Product code: 10758

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SECTION 1: Identification of the substance/mixture and of the company/undertaking**1.1. Product identifier**

Detaseal® hydroflow Xlite (base + catalyst)

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

Impression material for use in dental technology.

1.3. Details of the supplier of the safety data sheet

| | | |
|-------------------------|---------------------|---------------------------|
| Company name: | DETAX GmbH & Co. KG | |
| Street: | Carl-Zeiss-Strasse | |
| Place: | D-76275 Ettlingen | |
| Telephone: | +49 7243/510-0 | Telefax: +49 7243/510-100 |
| e-mail: | post@detax.de | |
| Internet: | www.detax.de | |
| Responsible Department: | Emergency number: | |

+49 7243/510-0

This number is only obtainable during office hours (Monday - Thursday 8.00 a.m. - 5.00 p.m., Friday 8.00 a.m. - 4.00 p.m.)

1.4. Emergency telephone number:

+49 7243/510-0

This number is only obtainable during office hours (Monday - Thursday 8.00 a.m. - 5.00 p.m., Friday 8.00 - 4.00 p.m.)

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**Regulation (EC) No. 1272/2008****Special labelling of certain mixtures**

EUH210 Safety data sheet available on request.

Additional advice on labelling

According to Regulation (EC) 1272/2008, art.1 No. 5 (d) this product as a medical product must not be labelled!

2.3. Other hazards

No information available.

SECTION 3: Composition/information on ingredients**3.2. Mixtures****Chemical characterization**Contains polydimethylsiloxane with functional groups. + fillers and pigment
catalyst: additionally platinum complex compound.

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Hazardous components

| CAS No | Chemical name | | | Quantity |
|------------|---|----------|----------|-------------|
| | EC No | Index No | REACH No | |
| | Classification according to Regulation (EC) No. 1272/2008 [CLP] | | | |
| 14464-46-1 | cristobalite | | | 40 - < 50 % |
| | 238-455-4 | | | |
| | STOT RE 1; H372 | | | |
| | silicone polyalkylene oxide copolymer | | | 1 - < 5 % |
| | | | | |
| | Acute Tox. 4, Eye Irrit. 2, Aquatic Chronic 2; H332 H319 H411 | | | |

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.

After contact with skin

Wash with plenty of water. Take off contaminated clothing and wash it before reuse.

After contact with eyes

Rinse immediately carefully and thoroughly with eye-bath or water.

After ingestion

Rinse mouth thoroughly with water. 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

Non-flammable. Vapours can form explosive mixtures with air.

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. 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

Use personal protection equipment.

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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.

6.4. Reference to other sections

Safe handling: see section 7

Personal protection equipment: see section 8

Disposal: see section 13

SECTION 7: Handling and storage**7.1. Precautions for safe handling****Advice on safe handling**

No special measures are necessary.

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.

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)

Impression material for use in dentistry.

For use by trained specialist staff.

SECTION 8: Exposure controls/personal protection**8.1. Control parameters****8.2. Exposure controls****Protective and hygiene measures**

Take off contaminated clothing. Wash hands before breaks and after work. 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.

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SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Physical state: Paste
 Colour: base: blue , catalyst: white
 Odour: like peppermint

Test method

pH-Value: not determined

Changes in the physical state

Melting point: not determined

Initial boiling point and boiling range: not determined

Flash point: >100 °C DIN 51755

Flammability

Solid: not applicable

Gas: not applicable

Lower explosion limits: not determined

Upper explosion limits: not determined

Ignition temperature: >400 °C DIN 51794

Auto-ignition temperature

Solid: not applicable

Gas: not applicable

Decomposition temperature: >180 °C

Oxidizing properties

Not oxidizing.

Vapour pressure: <10 hPa
 (at 20 °C)

Density (at 20 °C): 1,28 g/cm³ DIN 51757

Water solubility: practically insoluble

Solubility in other solvents

not determined

Partition coefficient: not determined

Viscosity / dynamic: 14000 mPa·s BROOKFIELD
 (at 23 °C)

Vapour density: not determined

Evaporation rate: not determined

9.2. Other information

Solid content: not determined

SECTION 10: Stability and 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.

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10.4. Conditions to avoid

Temperatures > 150°C/ 302 °F.

10.5. Incompatible materials

No information available.

10.6. Hazardous decomposition products

In case of thermic decomposition hydrogen is released.

At a temperature of approx. 150°C/ 302°F a small amount of formaldehyde can be released by oxidative degradation.

SECTION 11: Toxicological information

11.1. Information on toxicological effects

Acute toxicity

Based on available data, the classification criteria are not met.

For the product itself no toxicological data are available. In products with a comparable composition, a LD50 (orally, species rat) of > 5000 mg/kg has been found.

| CAS No | Chemical name | | | | |
|--------|---------------------------------------|------------------|---------|--------|--------|
| | Exposure route | Dose | Species | Source | Method |
| | silicone polyalkylene oxide copolymer | | | | |
| | oral | LD50 >2000 mg/kg | Rat | | |
| | dermal | LD50 >2000 mg/kg | Rat | | |
| | inhalation vapour | ATE 11 mg/l | | | |
| | inhalation aerosol | ATE 1,5 mg/l | | | |

Irritation and corrosivity

Based on available data, the classification criteria are not met.

Sensitising effects

Based on available data, the classification criteria are not met.

Carcinogenic/mutagenic/toxic effects for reproduction

Based on available data, the classification criteria are not met.

STOT-single exposure

Based on available data, the classification criteria are not met.

STOT-repeated exposure

Based on available data, the classification criteria are not met.

Due to physical form (paste) classification with H372 is not appropriate. An inhalation of the product is not possible.

EC regulation 1272/2008 annex 1, section 1.1.1.5: "For the purpose of classification of health hazards (part 3), the route of exposure, information on mechanisms and metabolism studies are useful for determining the relevance of effects in humans. If this information raises doubts as to their relevance in humans, in spite of the indisputable data legitimacy and quality, a lower classification may be justified. When there is scientific evidence that the mechanism or mode of action is not relevant to humans, the substance or mixture should not be classified."

Aspiration hazard

Based on available data, the classification criteria are not met.

Additional information on tests

This mixture is classified as not hazardous according to regulation (EC) 1272/2008 [CLP].

SECTION 12: Ecological information

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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.

Partition coefficient n-octanol/water

| CAS No | Chemical name | Log Pow |
|--------|---------------------------------------|---------|
| | silicone polyalkylene oxide copolymer | 1,951 |

12.4. Mobility in soil

The product has not been tested.

12.5. Results of PBT and vPvB assessment

Not identified as PBT/ vPvB substances

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

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

Non-contaminated packages may be recycled. Handle contaminated packages in the same way as the substance itself.

SECTION 14: Transport information

Land transport (ADR/RID)

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)

14.2. UN proper shipping name:

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.

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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

EU regulatory information

Additional information

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

National regulatory information

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.
EUH210 Safety data sheet available on request.

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.

(The data for the hazardous ingredients were taken respectively from the last version of the sub-contractor's safety data sheet.)