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

1.1. Product identifier

Detaseal® hydroflow lite (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	
Street:	Carl-Zeiss-Straße 4	
Place:	D-76275 Ettlingen	
Telephone:	+49 7243/510-0	Telefax: +49 7243/510-100
e-mail:	post@detax.com	
Internet:	www.detax.com	
Responsible Department:	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:

+1-800-424-9300 (CHEMTREC worldwide)

SECTION 2: Hazards identification

2.1. Classification of the substance or mixture

Regulation (EC) No. 1907/2006

Aquatic Chronic 3; H412

Full text of hazard statements: see SECTION 16.

2.2. Label elements

Regulation (EC) No. 1907/2006

Hazard statements

H412 Harmful to aquatic life with long lasting effects.

Precautionary statements

P273 Avoid release to the environment.

P501 Dispose of contents/container to according to local and applicable legislation of dispose of waste.

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

The mixture contains the following substances fulfilling the PBT criteria according to UK REACH:
Octamethylcyclotetrasiloxane.
The mixture contains the following substances fulfilling the vPvB criteria according to UK REACH:
Octamethylcyclotetrasiloxane.

SECTION 3: Composition/information on ingredients

3.2. Mixtures

Chemical characterization

Contains polydimethylsiloxane with functional groups. + fillers and pigment
catalyst: additionally platinum complex compound.

Hazardous components

CAS No	Chemical name			Quantity
	EC No	Index No	REACH No	
	Classification (Regulation (EC) No. 1907/2006)			
14464-46-1	cristobalite flour			20 - < 40 %
	238-455-4			
	STOT RE 1; H372			
27306-78-1	poly(oxy-1,2-ethanediyl),.alpha.-methyl-.omega.-[3-[1,3,3,3-tetramethyl-1-[(trimethylsilyl)oxy] -1-disiloxanyl]propoxy]-			0.1 - < 5 %
	Acute Tox. 4, Eye Irrit. 2, Aquatic Chronic 3; H332 H319 H412			
556-67-2	Octamethylcyclotetrasiloxane			< 0.1 %
	209-136-7	014-018-00-1	01-2119529238-36	
	Flam. Liq. 3, Repr. 2, Aquatic Chronic 1; H226 H361f H410			
2390-63-8	3,6-bis(diethylamino)-9-[2-(ethoxycarbonyl)phenyl]xanthylium chloride			< 0.1 %
	219-233-6			
	Acute Tox. 3, Acute Tox. 4, Eye Dam. 1, Aquatic Acute 1, Aquatic Chronic 1; H301 H332 H318 H400 H410			

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

Specific Conc. Limits, M-factors and ATE

CAS No	EC No	Chemical name	Quantity
	Specific Conc. Limits, M-factors and ATE		
27306-78-1		poly(oxy-1,2-ethanediyl),.alpha.-methyl-.omega.-[3-[1,3,3,3-tetramethyl-1-[(trimethylsilyl)oxy]-1-disiloxanyl]propoxy]-	0.1 - < 5 %
	inhalation: ATE = 11 mg/l (vapours); inhalation: ATE = 1,5 mg/l (dusts or mists)		
556-67-2	209-136-7	Octamethylcyclotetrasiloxane	< 0.1 %
	inhalation: LC50 = 36 mg/l (vapours); dermal: LD50 = >2400 mg/kg; oral: LD50 = 4800 mg/kg M chron.; H410: M=10		
2390-63-8	219-233-6	3,6-bis(diethylamino)-9-[2-(ethoxycarbonyl)phenyl]xanthylium chloride	< 0.1 %
	inhalation: ATE = 11 mg/l (vapours); inhalation: ATE = 1,5 mg/l (dusts or mists); oral: ATE = 100 mg/kg M acute; H400: M=100 M chron.; H410: M=10		

SECTION 4: First aid measures

4.1. Description of first aid measures

After inhalation

Provide fresh air.

After contact with skin

Wash with plenty of water. Take off contaminated clothing and wash it before reuse. Remove product mechanically with cloth or paper. Wash with plenty of water and soap. In case of visible changes on the skin or complaints, seek medical advice (if possible have label or safety data sheet with you).

After contact with eyes

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

After ingestion

Rinse mouth immediately and drink 1 glass of of 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.

5.3. Advice for firefighters

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

Additional information

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

General advice

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

For cleaning up

Take up mechanically. 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.

Advice on general occupational hygiene

Take off contaminated clothing. Wash hands before breaks and after work. When using do not eat, drink, smoke, sniff. Take off contaminated clothing. Wash hands before breaks and after work.

7.2. Conditions for safe storage, including any incompatibilities

Requirements for storage rooms and vessels

Keep container tightly closed.

Hints on joint storage

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

Individual protection measures, such as personal protective equipment

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

Use of protective clothing.

Respiratory protection

In case of inadequate ventilation wear respiratory protection.

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

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

		Test method
Melting point/freezing point:	not determined	
Boiling point or initial boiling point and boiling range:	>200 °C	
Flammability		
Solid/liquid:	not determined	
Gas:	not applicable	
Lower explosion limits:	not determined	
Upper explosion limits:	not determined	
Flash point:	>150 °C	DIN 51755
Auto-ignition temperature:	365 °C	DIN 51794
Decomposition temperature:	>180 °C	
pH-Value:	not determined	
Water solubility:	practically insoluble	
Solubility in other solvents		
not determined		
Partition coefficient n-octanol/water:	not determined	
Vapour pressure: (at 20 °C)	<10 hPa	
Density (at 20 °C):	1,28 g/cm³	DIN 51757
Relative vapour density:	not determined	

9.2. Other information

Information with regard to physical hazard classes

Explosive properties

The product is not: Explosive.

Oxidizing properties

The product is not: oxidising.

Other safety characteristics

Evaporation rate:	not determined	
Solid content:	not determined	
Viscosity / dynamic: (at 23 °C)	17000 mPa·s	BROOKFIELD

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.

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 hazard classes as defined in Regulation (EC) No. 1907/2006

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.

ATEmix calculated

ATE (inhalation vapour) 733,95 mg/l; ATE (inhalation dust/mist) 102,978 mg/l

CAS No	Chemical name					
	Exposure route	Dose		Species	Source	Method
27306-78-1	poly(oxy-1,2-ethanediyl),.alpha.-methyl-.omega.-[3-[1,3,3,3-tetramethyl-1-[(trimethylsilyl)oxy]-1-disiloxanyl]propoxy]-					
	inhalation vapour	ATE	11 mg/l			
	inhalation dust/mist	ATE	1,5 mg/l			
556-67-2	Octamethylcyclotetrasiloxane					
	oral	LD50 mg/kg	4800	Rat		OECD 401
	dermal	LD50 mg/kg	>2400	Rabbit		OECD 402
	inhalation (4 h) vapour	LC50	36 mg/l	Rat	GESTIS	OECD 403
2390-63-8	3,6-bis(diethylamino)-9-[2-(ethoxycarbonyl)phenyl]xanthylium chloride					
	oral	ATE mg/kg	100			
	inhalation vapour	ATE	11 mg/l			
	inhalation dust/mist	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.

SECTION 12: Ecological information

12.1. Toxicity

Harmful to aquatic life with long lasting effects.

12.2. Persistence and degradability

The product has not been tested.

CAS No	Chemical name			
	Method	Value	d	Source
	Evaluation			
556-67-2	Octamethylcyclotetrasiloxane			
		3,7%	29	
	Not readily biodegradable (according to OECD criteria)			

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

The mixture contains the following substances fulfilling the PBT criteria according to UK REACH:
Octamethylcyclotetrasiloxane.
The mixture contains the following substances fulfilling the vPvB criteria according to UK REACH:
Octamethylcyclotetrasiloxane.
Not identivied as PBT/ vPvB substances

12.6. Endocrine disrupting properties

This product does not contain a substance that has endocrine disrupting properties with respect to non-target organisms as no components meets the criteria.

12.7. 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

Disposal recommendations

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 or ID 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 or ID 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 or ID 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 or ID 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.

14.5. Environmental hazards

ENVIRONMENTALLY HAZARDOUS: No

14.6. Special precautions for user

No dangerous good in sense of this transport regulation.

14.7. Maritime transport in bulk according to IMO instruments

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

Authorisations (REACH, annex XIV):

Substances of very high concern, SVHC (REACH, article 59):
Octamethylcyclotetrasiloxane

Restrictions on use (REACH, annex XVII):

Entry 70, Entry 75

2010/75/EU (VOC):	0,002 % (0,032 g/l)
2004/42/EC (VOC):	0,002 % (0,032 g/l)

Information according to 2012/18/EU (SEVESO III):	Not subject to 2012/18/EU (SEVESO III)

National regulatory information

Employment restrictions:	Observe restrictions to employment for juveniles according to the 'juvenile work protection guideline' (94/33/EC).
Water hazard class (D):	3 - highly hazardous to water

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%
CLP: Classification, labelling and Packaging
REACH: Registration, Evaluation and Authorization of Chemicals
GHS: Globally Harmonised System of Classification, Labelling and Packaging of Chemicals
UN: United Nations
DNEL: Derived No Effect Level
DMEL: Derived Minimal Effect Level
PNEC: Predicted No Effect Concentration
ATE: Acute toxicity estimate
LL50: Lethal loading, 50%
EL50: Effect loading, 50%
EC50: Effective Concentration 50%
ErC50: Effective Concentration 50%, growth rate
NOEC: No Observed Effect Concentration
BCF: Bio-concentration factor
PBT: persistent, bioaccumulative, toxic
vPvB: very persistent, very bioaccumulative
RID: Regulations concerning the international carriage of dangerous goods by rail
ADN: European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways
(Accord européen relatif au transport international des marchandises dangereuses par voies de navigation intérieures)
EmS: Emergency Schedules
MFAG: Medical First Aid Guide
ICAO: International Civil Aviation Organization
MARPOL: International Convention for the Prevention of Marine Pollution from Ships
IBC: Intermediate Bulk Container
VOC: Volatile Organic Compounds
SVHC: Substance of Very High Concern
For abbreviations and acronyms, see: ECHA Guidance on information requirements and chemical safety assessment, chapter R.20 (Table of terms and abbreviations).

Classification for mixtures and used evaluation method according to Regulation (EC) No. 1907/2006

Classification	Classification procedure
Aquatic Chronic 3; H412	Calculation method

Relevant H and EUH statements (number and full text)

H226	Flammable liquid and vapour.
H301	Toxic if swallowed.
H318	Causes serious eye damage.
H319	Causes serious eye irritation.
H332	Harmful if inhaled.
H361f	Suspected of damaging fertility.
H372	Causes damage to organs (lung) through prolonged or repeated exposure if inhaled.
H400	Very toxic to aquatic life.
H410	Very toxic to aquatic life with long lasting effects.
H412	Harmful to aquatic life with long lasting effects.

Further Information

The information is based on the present level of our knowledge. It does not, however, give assurance 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.)