

according to Regulation (EC) No 1907/2006

**sta-seal f**

Revision date: 15.08.2016

Product code: 10310

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

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**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**

Hazard categories:

Hazardous to the aquatic environment: Aquatic Chronic 3

Hazard Statements:

Harmful to aquatic life with long lasting effects.

**2.2. Label elements****Regulation (EC) No. 1272/2008****Hazard statements**

H412 Harmful to aquatic life with long lasting effects.

**Precautionary statements**

P273 Avoid release to the environment.

P501 Dispose of contents/ container in accordance with legal and national regulations.

**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

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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]			
1314-13-2	zinc oxide			< 1 %
	215-222-5	030-013-00-7		
	Aquatic Acute 1 (M-Factor = 1), Aquatic Chronic 1; H400 H410			

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

#### 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.

###### After contact with eyes

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

###### After ingestion

Rinse mouth immediately and drink plenty 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. 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.

##### 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 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**

No special measures are necessary.

**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)**

Component B of a silicone based dental impression material.  
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.

**SECTION 9: Physical and chemical properties****9.1. Information on basic physical and chemical properties**

Physical state:	Paste
Colour:	green
Odour:	like peppermint

**Test method**

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pH-Value:	not determined
<b>Changes in the physical state</b>	
Melting point:	not determined
Initial boiling point and boiling range:	not determined
Flash point:	>100 °C DIN 51755
<b>Flammability</b>	
Solid:	not applicable
Gas:	not applicable
Lower explosion limits:	not determined
Upper explosion limits:	not determined
Ignition temperature:	>200 °C DIN 51794
<b>Auto-ignition temperature</b>	
Solid:	not applicable
Gas:	not applicable
Decomposition temperature:	>250 °C
<b>Oxidizing properties</b>	
Not oxidizing.	
Vapour pressure: (at 20 °C)	<1 hPa
Density (at 20 °C):	1,38 g/cm <sup>3</sup> DIN 51757
Water solubility:	practically insoluble
<b>Solubility in other solvents</b>	
not determined	
Partition coefficient:	not determined
Viscosity / dynamic: (at 23 °C)	3000000 mPa·s BROOKFIELD
Vapour density:	not determined
Evaporation rate:	not determined
<b><u>9.2. Other information</u></b>	
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**

No known hazardous reactions.

### **10.4. Conditions to avoid**

Temperatures > 150°C/ 302 °F.

### **10.5. Incompatible materials**

No information available.

### **10.6. Hazardous decomposition products**

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

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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 &gt; 5000 mg/kg has been found.

CAS No	Chemical name			
	Exposure route	Dose	Species	Source
1314-13-2	zinc oxide			
	oral	LD50 > 5000 mg/kg	Rat	IUCLID

#### 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.

#### Aspiration hazard

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

## SECTION 12: Ecological information

### 12.1. Toxicity

Harmful to aquatic organisms, may cause long-term adverse effects in the aquatic environment.

CAS No	Chemical name				
	Aquatic toxicity	Dose	[h]   [d]	Species	Source
1314-13-2	zinc oxide				
	Acute fish toxicity	LC50 1120 mg/l	96 h		GESTIS
	Acute algae toxicity	ErC50 0,21 mg/l	72 h	Selenastrum capricornutum	CSR
	Acute crustacea toxicity	EC50 0,67 mg/l	48 h	Ceriodaphnia spec	CSR

### 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

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.

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## 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)

<b>14.1. UN number:</b>	No dangerous good in sense of this transport regulation.
<b>14.2. UN proper shipping name:</b>	No dangerous good in sense of this transport regulation.
<b>14.3. Transport hazard class(es):</b>	No dangerous good in sense of this transport regulation.
<b>14.4. Packing group:</b>	No dangerous good in sense of this transport regulation.

### Inland waterways transport (ADN)

<b>14.1. UN number:</b>	No dangerous good in sense of this transport regulation.
<b>14.2. UN proper shipping name:</b>	No dangerous good in sense of this transport regulation.
<b>14.3. Transport hazard class(es):</b>	No dangerous good in sense of this transport regulation.
<b>14.4. Packing group:</b>	No dangerous good in sense of this transport regulation.

### Marine transport (IMDG)

<b>14.1. UN number:</b>	No dangerous good in sense of this transport regulation.
<b>14.2. UN proper shipping name:</b>	No dangerous good in sense of this transport regulation.
<b>14.3. Transport hazard class(es):</b>	No dangerous good in sense of this transport regulation.
<b>14.4. Packing group:</b>	No dangerous good in sense of this transport regulation.

### Air transport (ICAO-TI/IATA-DGR)

<b>14.1. UN number:</b>	No dangerous good in sense of this transport regulation.
<b>14.2. UN proper shipping name:</b>	No dangerous good in sense of this transport regulation.
<b>14.3. Transport hazard class(es):</b>	No dangerous good in sense of this transport regulation.
<b>14.4. Packing group:</b>	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

#### EU regulatory information

2010/75/EU (VOC):	0,002 % (0,026 g/l)
2004/42/EC (VOC):	0,002 % (0,026 g/l)

#### 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):	1 - slightly water contaminating

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**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)**

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 above information describes exclusively the safety requirements of the product and is based on our present-day knowledge. The information is intended to give you advice about the safe handling of the product named in this safety data sheet, for storage, processing, transport and disposal. The information cannot be transferred to other products. In the case of mixing the product with other products or in the case of processing, the information on this safety data sheet is not necessarily valid for the new made-up material.

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