

according to Regulation (EC) No 1907/2006

silasoft direct (base + catalyst 10:1 cartridge)

Revision date: 23.07.2015

Product code: 10760

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

1.1. Product identifier

silasoft direct (base + catalyst 10:1 cartridge)

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 a.m. - 4.00 p.m.)

SECTION 2: Hazards identification

2.1. Classification of the substance or mixture

Regulation (EC) No. 1272/2008

Hazard categories:

Serious eye damage/eye irritation: Eye Irrit. 2

Germ cell mutagenicity: Muta. 2

Specific target organ toxicity - repeated exposure: STOT RE 2

Hazard Statements:

Causes serious eye irritation.

Suspected of causing genetic defects.

May cause damage to organs through prolonged or repeated exposure.

2.2. Label elements

Regulation (EC) No. 1272/2008

Hazard components for labelling

alkylstannonic siloxanes

Signal word: Danger

Pictograms:



Hazard statements

H319

Causes serious eye irritation.

H341

Suspected of causing genetic defects.

H373

May cause damage to organs through prolonged or repeated exposure.

Precautionary statements

P201

Obtain special instructions before use.

P260

Do not breathe dust/fume/gas/mist/vapours/spray.

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P280	Wear protective gloves/protective clothing/eye protection/face protection.
P305+P351+P338	IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
P308+P313	IF exposed or concerned: Get medical advice/attention.
P310	Immediately call a POISON CENTER/doctor.
P501	Dispose of contents/container to SECTION 13: Disposal considerations.

Special labelling of certain mixtures

EUH208	Contains (R)-p-mentha-1,8-diene, d-limonene. May produce an allergic reaction. Restricted to professional users.
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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 + fillers.

Hazardous components

CAS No	Chemical name			Quantity
	EC No	Index No	REACH No	
	Classification according to Regulation (EC) No. 1272/2008 [CLP]			
93925-42-9	alkylstannonic siloxanes			1 - <10 %
	300-344-4		01-2119560586-30	
	Flam. Liq. 3, Muta. 2, Repr. 1, Acute Tox. 4, Acute Tox. 4, Eye Dam. 1, STOT RE 1, Aquatic Chronic 3; H226 H341 H360F H332 H302 H318 H372 H412			
556-67-2	octamethylcyclotetrasiloxane			1 - < 5 %
	209-136-7	014-018-00-1		
	Repr. 2, Aquatic Chronic 4; H361f H413			
5989-27-5	(R)-p-mentha-1,8-diene, d-limonene			< 1 %
	227-813-5	601-029-00-7		
	Flam. Liq. 3, Skin Irrit. 2, Skin Sens. 1, Aquatic Acute 1, Aquatic Chronic 1; H226 H315 H317 H400 H410			

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. If breathing is irregular or stopped, administer artificial respiration. Medical treatment necessary.

After contact with skin

After contact with skin, wash immediately with polyethylene glycol, followed by plenty of water. Take off immediately all contaminated clothing and wash it before reuse. If skin irritation occurs: Get medical advice/attention.

After contact with eyes

In case of contact with eyes flush immediately with plenty of flowing water for 10 to 15 minutes holding eyelids

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apart and consult an ophthalmologist.

After ingestion

Rinse mouth immediately and drink plenty of water. Let water be drunken in little sips (dilution effect).
Seek immediately medical advice. Do not induce vomiting. In case of spontaneous vomiting take care of an unhindered flow out of the vomit (danger of suffocation).

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

Wear a self-contained breathing apparatus and chemical protective clothing. Full protection suit.

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.

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

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 exhaust at critical locations.

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Advice on storage compatibility

Do not store with strong oxidising materials.

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

Appropriate engineering controls

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

Protective and hygiene measures

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

Suitable eye protection: goggles.

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:	base: violet , catalyst: liigth blue
Odour:	characteristic

Test method

pH-Value:	not determined
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Changes in the physical state

Melting point:	not determined
Initial boiling point and boiling range:	>200 °C DIN 51356
Flash point:	>100 °C DIN 51755

Flammability

Solid:	not applicable
Gas:	not applicable
Lower explosion limits:	not determined

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Upper explosion limits:	not determined
Ignition temperature:	>200 °C DIN 51794
Auto-ignition temperature	
Solid:	not applicable
Gas:	not applicable
Decomposition temperature:	>250 °C
Oxidizing properties	
Not oxidizing.	
Vapour pressure: (at 20 °C)	<1 hPa
Density (at 20 °C):	1,1 g/cm³ DIN 51757
Water solubility:	insoluble
Solubility in other solvents	
not determined	
Partition coefficient:	not determined
Viscosity / dynamic: (at 23 °C)	12000 mPa·s BROOKFIELD
Vapour density:	not determined
Evaporation rate:	not determined

9.2. Other information

Solid content:	not determined
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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 : strong oxidising agents.

10.4. Conditions to avoid

Higher temperatures advance the formation of flammable vapours, therefore don't expose the product to increased temperatures.

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 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 >2000 mg/kg has been found.

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CAS No	Chemical name				
	Exposure route	Dose	Species	Source	Method
93925-42-9	alkylstannonic siloxanes				
	oral	ATE 500 mg/kg			
	inhalation vapour	ATE 11 mg/l			
	inhalation aerosol	ATE 1,5 mg/l			
556-67-2	octamethylcyclotetrasiloxane				
	oral	LD50 1540 mg/kg	Rat	GESTIS	
	dermal	LD50 759 mg/kg	Rabbit	GESTIS	
	inhalation (4 h) vapour	LC50 36 mg/l	Rat	GESTIS	
5989-27-5	(R)-p-mentha-1,8-diene, d-limonene				
	oral	LD50 > 2000 mg/kg	Rat		
	dermal	LD50 > 2000 mg/kg	Rabbit	IUCLID	

Irritation and corrosivity

Causes serious eye irritation.

Skin corrosion/irritation: Based on available data, the classification criteria are not met.

Sensitising effects

Contains (R)-p-mentha-1,8-diene, d-limonene. May produce an allergic reaction.

Carcinogenic/mutagenic/toxic effects for reproduction

Suspected of causing genetic defects. (alkylstannonic siloxanes)

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

Reproductive toxicity: 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

May cause damage to organs through prolonged or repeated exposure. (alkylstannonic siloxanes)

Aspiration hazard

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

Additional information on tests

This mixture is classified as hazardous according to regulation (EC) No. 1272/2008 [CLP]. Special hazards arising from the substance or mixture!

SECTION 12: Ecological information

12.1. Toxicity

The product is not: Ecotoxic.

CAS No	Chemical name					
	Aquatic toxicity	Dose	[h] [d]	Species	Source	Method
5989-27-5	(R)-p-mentha-1,8-diene, d-limonene					
	Acute fish toxicity	LC50 0,7 mg/l	96 h	Pimephales promelas		
	Acute crustacea toxicity	EC50 0,42 mg/l	48 h	Daphnia magna		

12.2. Persistence and degradability

The product has not been tested.

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12.3. Bioaccumulative potential

The product has not been tested.

Partition coefficient n-octanol/water

CAS No	Chemical name	Log Pow
5989-27-5	(R)-p-mentha-1,8-diene, d-limonene	4,23

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

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)

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.

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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

2010/75/EU (VOC): 0,126 % (1,382 g/l)

2004/42/EC (VOC): 0,126 % (1,382 g/l)

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). Observe employment restrictions under the Maternity Protection Directive (92/85/EEC) for expectant or nursing mothers.

Water contaminating class (D): 3 - highly water contaminating

Skin resorption/Sensitization: Causes allergic hypersensitivity reactions.

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)

H226	Flammable liquid and vapour.
H302	Harmful if swallowed.
H315	Causes skin irritation.
H317	May cause an allergic skin reaction.
H318	Causes serious eye damage.
H319	Causes serious eye irritation.
H332	Harmful if inhaled.
H341	Suspected of causing genetic defects.
H360F	May damage fertility.
H361f	Suspected of damaging fertility.
H372	Causes damage to organs (Thymus) through prolonged or repeated exposure if swallowed.
H373	May cause damage to organs through prolonged or repeated exposure.
H400	Very toxic to aquatic life.

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H410	Very toxic to aquatic life with long lasting effects.
H412	Harmful to aquatic life with long lasting effects.
H413	May cause long lasting harmful effects to aquatic life.
EUH208	Contains (R)-p-mentha-1,8-diene, d-limonene. May produce an allergic reaction.

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.

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