

according to Regulation (EC) No 1907/2006

Lustrol (Catalyst)

Revision date: 07.02.2020

Product code: 10534

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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**

Lacquer for denture relinings for use in dentistry.

1.3. Details of the supplier of the safety data sheet**Manufacturer**

Company name: DETAX GmbH & Co. KG
Street: Carl-Zeiss-Strasse
Place: D-76275 Ettlingen
Telephone: +49 7243/510-0
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.)
Telefax: +49 7243/510-100

Importer / Distributer

Company name: Ivoclar Vivadent Pty Ltd
Place: 1-5 Overseas Drive Noble Park North VIC 3174
Telephone: +61 3 9795 9599
e-mail: info@ivoclarvivadent.com
Telefax: Fax: +61 3 9795 9645

1.4. Emergency telephone number:

13 11 26
Poisons Hotline (24 hours / 7 days)

SECTION 2: Hazards identification**2.1. Classification of the substance or mixture****Regulation (EC) No. 1272/2008**

Hazard categories:
Acute toxicity: Acute Tox. 4
Acute toxicity: Acute Tox. 4
Serious eye damage/eye irritation: Eye Irrit. 2
Germ cell mutagenicity: Muta. 2
Reproductive toxicity: Repr. 1A
Specific target organ toxicity - repeated exposure: STOT RE 1
Hazardous to the aquatic environment: Aquatic Chronic 3
Hazard Statements:
Harmful if swallowed.
Harmful if inhaled.
Causes serious eye irritation.
Suspected of causing genetic defects.
May damage fertility.
Causes damage to organs through prolonged or repeated exposure.
Harmful to aquatic life with long lasting effects.

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

Hazard components for labelling
alkylstannonic siloxanes

according to Regulation (EC) No 1907/2006

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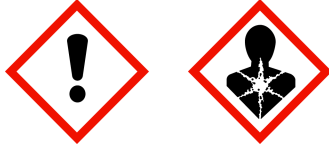
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Signal word: Danger

Pictograms:



Hazard statements

H302+H332 Harmful if swallowed or if inhaled.
 H319 Causes serious eye irritation.
 H341 Suspected of causing genetic defects.
 H360F May damage fertility.
 H372 Causes damage to organs (Thymus) through prolonged or repeated exposure if swallowed.
 H412 Harmful to aquatic life with long lasting effects.

Precautionary statements

P201 Obtain special instructions before use.
 P260 Do not breathe dust/fume/gas/mist/vapours/spray.
 P280 Wear protective gloves/protective clothing/eye protection/face protection/hearing 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.

Special labelling of certain mixtures

Restricted to professional users.

2.3. Other hazards

No information available.

SECTION 3: Composition/information on ingredients

3.2. Mixtures

Chemical characterization

Silicon-tin-compound with auxilliary matters.

Hazardous components

CAS No	Chemical name			Quantity
	EC No	Index No	REACH No	
	GHS Classification			
93925-42-9	alkylstannonic siloxanes			45 - < 50 %
	300-344-4		01-2119560586-30	
	Flam. Liq. 3, Muta. 2, Repr. 1A, Acute Tox. 4, Acute Tox. 4, Eye Dam. 1, STOT RE 1, Aquatic Chronic 3; H226 H341 H360F H332 H302 H318 H372 H412			
540-97-6	Dodecaemthylcyclohexasiloxane			< 0,5 %
	208-762-8		01-2119517435-42	

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

SECTION 4: First aid measures

4.1. Description of first aid measures

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General information

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

After inhalation

Provide fresh air. When in doubt or if symptoms are observed, get medical advice.

After contact with skin

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

After contact with eyes

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

5.3. Advice for firefighters

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

Additional information

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

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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.

Hints on joint storage

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)

Component A of a silicone lacquer 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: Butyl caoutchouc (butyl rubber), FKM (fluoro rubber), CR (polychloroprene, chloroprene 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:	liquid:
Colour:	colourless
Odour:	characteristic

Test method

pH-Value: not determined

Changes in the physical state

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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
Upper explosion limits:	not determined
Ignition temperature:	>300 °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):	0,97 g/cm ³ DIN 51757
Water solubility:	insoluble
Solubility in other solvents	
not determined	
Partition coefficient:	not determined
Viscosity / dynamic: (at 23 °C)	<80 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

No known hazardous decomposition products.

SECTION 11: Toxicological information

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11.1. Information on toxicological effects

Acute toxicity

Harmful if swallowed.

Harmful if inhaled.

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.

ATEmix calculated

ATE (oral) 1095,2 mg/kg; ATE (inhalation aerosol) 3,286 mg/l

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			
540-97-6	Dodecaemthylcyclohexasiloxane				
	oral	LD50 2000 mg/kg	Rat		
	dermal	LD50 2000 mg/kg	Rat		

Irritation and corrosivity

Causes serious eye irritation.

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

Based on a Bovine Corneal Permeability Study conducted in accordance with OECD Guideline No. 437 (July 2013), H318 is not shown.

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."

Sensitising effects

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

Carcinogenic/mutagenic/toxic effects for reproduction

Suspected of causing genetic defects. (alkylstannonic siloxanes)

May damage fertility. (alkylstannonic siloxanes)

Carcinogenicity: 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

Causes 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

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

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

Dodecamethylcyclohexasiloxane (D6) fulfills the current criteria set forth under Annex XIII of the EU REACH Regulation for very persistent and very bioaccumulative substances (vPvB) and was included in the candidate list of substances of very high concern (SVHC). According to our knowledge of the state of the art, however, D6 cannot be compared with known persistent, bioaccumulative and toxic (PBT) and/or vPvB substances. The interpretation of the available data by the silicone industry reveals that scientific evidence obtained from field tests essentially points out that D6 does not lead to biomagnification in aquatic and terrestrial food chains. In air, D6 is decomposed by naturally occurring processes in the atmosphere. D-residues which do not decompose in this way in the air are not expected to accumulate from the air in water, the soil or living organisms.

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

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

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.

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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

EU regulatory information

Additional information

The mixture contains substances of very high concern (SVHC candidates):
Dodecamethylcyclohexasiloxane (D6), CAS no. 540-97-6

National regulatory information

Employment restrictions: Observe restrictions to employment for juveniles 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 hazard class (D): 3 - strongly 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%

Classification for mixtures and used evaluation method according to Regulation (EC) No. 1272/2008 [CLP]

Classification	Classification procedure
Acute Tox. 4; H302	Calculation method
Acute Tox. 4; H332	Calculation method
Eye Irrit. 2; H319	
Muta. 2; H341	Calculation method
Repr. 1A; H360F	Calculation method
STOT RE 1; H372	Calculation method
Aquatic Chronic 3; H412	Calculation method

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Relevant H and EUH statements (number and full text)

H226	Flammable liquid and vapour.
H302	Harmful if swallowed.
H302+H332	Harmful if swallowed or if inhaled.
H318	Causes serious eye damage.
H319	Causes serious eye irritation.
H332	Harmful if inhaled.
H341	Suspected of causing genetic defects.
H360F	May damage fertility.
H372	Causes damage to organs (Thymus) through prolonged or repeated exposure if swallowed.
H372	Causes damage to organs through prolonged or repeated exposure.
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.

Identified uses

No	Short title	LCS	SU	PC	PROC	ERC	AC	TF	Specification
1	Gewerblich	-	-	-	-	-	-	-	2

LCS: Life cycle stages

SU: Sectors of use

PC: Product categories

PROC: Process categories

ERC: Environmental release categories

AC: Article categories

TF: Technical functions

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