



Trade name: Regofix transparent Comp. A

Substance number: 15301

Version: 2 / GB

Date revised: 01.07.2024

Replaces Version: 1 / GB

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

### 1.1. Product identifier

Regofix transparent Comp. A

### 1.2. Relevant identified uses of the substance or mixture and uses advised against

#### Use of the substance/preparation

Bite registration material based on vinyl polysiloxane

### 1.3. Details of the supplier of the safety data sheet

#### Address/Manufacturer

Dreve Dentamid GmbH

Max-Planck-Straße 31

DE-59423 Unna

Telephone no. +49 2303 8807-0

Fax no. +49 2303 8807-29

Information provided by / telephone Department Research &amp; Development: Fax: +49 2303 8807-562

E-mail address of person responsible sicherheitsdatenblatt@dreve.com

for this SDS

### 1.4. Emergency telephone number

Henkel Fire Department / 24h-Emergency-Contact-No.: +49 211 797-3350

## SECTION 2: Hazards identification \*\*\*

### 2.1. Classification of the substance or mixture

This product is not classified hazardous in accordance with Regulation (EC) No 1272/2008.

### 2.2. Label elements

#### Labelling according to regulation (EC) No 1272/2008

#### Supplemental information

EUH210

Safety data sheet available on request.

### 2.3. Other hazards

No special hazards have to be mentioned.

The product contains no PBT substances. The product contains no vPvB substances. This product does not contain a substance that has endocrine disrupting properties with respect to human. The product does not contain a substance that has endocrine disrupting properties with respect to non-target organisms.

## SECTION 3: Composition/information on ingredients \*\*\*



Trade name: Regofix transparent Comp. A

Substance number: 15301

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Replaces Version: 1 / GB

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### 3.2. Mixtures

#### Chemical characterization

Addition-vulcanising 2-component silicone

#### Hazardous ingredients \*\*\*

##### Silanamine, 1,1,1-trimethyl-N-(trimethylsilyl)

CAS No. 68909-20-6

EINECS no. 272-697-1

Registration no. 01-2119379499-16

Concentration  $\geq 1$  < 10 %

Classification (Regulation (EC) No. 1272/2008)

STOT RE 2 H373

Name of set of nanoform

Nanoaggregate

Particle size distribution

d50 60-300 nm

Method

Transmission Electron Microscopy (TEM)

Shape and aspect ratio of particles

amorphous

40 to 350 m<sup>2</sup>/g

## SECTION 4: First aid measures

### 4.1. Description of first aid measures

#### General information

No special measures required

#### After inhalation

Ensure supply of fresh air. In the event of symptoms take medical treatment.

#### After skin contact

In case of contact with skin wash off with warm water. Consult a doctor if skin irritation persists.

#### After eye contact

Separate eyelids, wash the eyes thoroughly with water (15 min.). In case of irritation consult an oculist.

#### After ingestion

Do not induce vomiting - aspiration hazard. Summon a doctor immediately.

#### Adhere to personal protective measures when giving first aid

First aider: Pay attention to self-protection!

### 4.2. Most important symptoms and effects, both acute and delayed

Until now no symptoms known so far.

### 4.3. Indication of any immediate medical attention and special treatment needed

#### Hints for the physician / hazards

In the case of swallowing with subsequent vomiting, aspiration of the lungs can occur which can lead to chemical pneumonia or asphyxiation.

## SECTION 5: Firefighting measures

### 5.1. Extinguishing media



Trade name: Regofix transparent Comp. A

Substance number: 15301

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Date revised: 01.07.2024

Replaces Version: 1 / GB

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**Suitable extinguishing media**

Recommended: alcohol resistant foam, CO<sub>2</sub>, powders, water spray/mist, Extinguishing measures to suit surroundings

**Non suitable extinguishing media**

Full water jet

**5.2. Special hazards arising from the substance or mixture**

In case of combustion evolution of dangerous gases possible.

**5.3. Advice for firefighters****Special protective equipment for fire-fighting**

In case of combustion use a suitable breathing apparatus.

**Other information**

Fire residues and contaminated fire-fighting water must be disposed of in accordance with the local regulations.

**SECTION 6: Accidental release measures****6.1. Personal precautions, protective equipment and emergency procedures**

Avoid contact with skin, eyes and clothing.

**6.2. Environmental precautions**

Do not allow to enter drains or waterways.

**6.3. Methods and material for containment and cleaning up**

Pick up mechanically. Clean contaminated floors and objects thoroughly, observing environmental regulations.

**6.4. Reference to other sections**

Refer to protective measures listed in Sections 7 and 8.

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

Observe the usual precautions for handling chemicals. For personal protection see Section 8.

**Advice on protection against fire and explosion**

No special measures required.

**7.2. Conditions for safe storage, including any incompatibilities****Requirements for storage rooms and vessels**

Store product in closed containers.

**Hints on storage assembly**

Do not store together with foodstuffs.

**Further information on storage conditions**

Keep container tightly closed and dry.



Trade name: Regofix transparent Comp. A

Substance number: 15301

Version: 2 / GB

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Replaces Version: 1 / GB

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## SECTION 8: Exposure controls/personal protection

### 8.1. Control parameters

#### Other information

Contains no substances with occupational exposure limit values.

### 8.2. Exposure controls

#### General protective and hygiene measures

Observe the usual precautions for handling chemicals. Do not eat, drink or smoke during work time. Wash hands before breaks and after work. Avoid contact with eyes.

#### Respiratory protection

Not necessary.

#### Hand protection

Not necessary.

#### Eye protection

Not necessary.

#### Body protection

Clothing as usual in the chemical industry.

## SECTION 9: Physical and chemical properties

### 9.1. Information on basic physical and chemical properties

<b>Physical state</b>	liquid, viscous	
<b>Colour</b>	transparent	
<b>Odour</b>	characteristic	
<b>Melting point</b>		
Remarks	not determined	
<b>Freezing point</b>		
Remarks	not determined	
<b>Boiling point or initial boiling point and boiling range</b>		
Value	> 300	°C
<b>Flammability</b>		
evaluation	not determined	
<b>Upper and lower explosive limits</b>		
Remarks	not determined	
<b>Flash point</b>		
Value	> 130	°C
Method	closed cup	
<b>Auto-ignition temperature</b>		
Remarks	not determined	
<b>Decomposition temperature</b>		
Remarks	not determined	
<b>pH value</b>		
Remarks	not determined	



Trade name: Regofix transparent Comp. A

Substance number: 15301

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**Viscosity**

Remarks not determined

**Solubility(ies)**

Remarks not determined

**Partition coefficient n-octanol/water (log value)**

Remarks not determined

**Vapour pressure**

Remarks not determined

**Density and/or relative density**

Value	1,10		g/cm <sup>3</sup>
Temperature	20	°C	

**Relative vapour density**

Remarks not determined

**9.2. Other information****Odour threshold**

Remarks not determined

**Evaporation rate (ether = 1) :**

Remarks not determined

**Solubility in water**

Remarks virtually insoluble

**Explosive properties**

evaluation not determined

**Oxidising properties**

Remarks not determined

**Other information**

None known

**SECTION 10: Stability and reactivity****10.1. Reactivity**

No hazardous reactions when stored and handled according to prescribed instructions.

**10.2. Chemical stability**

No hazardous reactions known.

**10.3. Possibility of hazardous reactions**

No hazardous reactions known.

**10.4. Conditions to avoid**

No hazardous reactions known.

**10.5. Incompatible materials**

None known

**10.6. Hazardous decomposition products**

No hazardous decomposition products known.



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**SECTION 11: Toxicological information****11.1. Information on hazard classes as defined in Regulation (EC) No 1272/2008****Acute oral toxicity**

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

**Acute oral toxicity (Components)****Silanamine, 1,1,1-trimethyl-N-(trimethylsilyl)**

Species	rat	
LD50	> 5000	mg/kg
Method	OECD 401	
Remarks	Test conducted with a similar formulation.	

**Acute dermal toxicity**

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

**Acute dermal toxicity (Components)****Silanamine, 1,1,1-trimethyl-N-(trimethylsilyl)**

Species	rabbit	
LD50	> 5000	mg/kg
Source	Analogous	

**Acute inhalational toxicity**

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

**Acute inhalative toxicity (Components)****Silanamine, 1,1,1-trimethyl-N-(trimethylsilyl)**

Species	rat	
LC50	> 5,01	mg/l
Duration of exposure	4	h
Administration/Form	Dust/Mist	
Source	Analogous	

**Skin corrosion/irritation**

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

**Serious eye damage/irritation**

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

**Sensitization**

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

**Subacute, subchronic, chronic toxicity**

Remarks not determined

**Mutagenicity**

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

**Reproductive toxicity**

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

**Carcinogenicity**

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

**Specific Target Organ Toxicity (STOT)****Single exposure**

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

**Repeated exposure**



Trade name: Regofix transparent Comp. A

Substance number: 15301

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Replaces Version: 1 / GB

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

**Aspiration hazard**

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

**11.2. Information on other hazards****Endocrine disrupting properties with respect to humans**

The product does not contain a substance that has endocrine disrupting properties with respect to humans.

**Other information**

No toxicological data are available.

**SECTION 12: Ecological information****12.1. Toxicity****General information**

not determined

**Fish toxicity (Components)****Silanamine, 1,1,1-trimethyl-N-(trimethylsilyl)**

Species	zebra fish ( <i>Brachydanio rerio</i> )		
LC50	> 10000		mg/l
Duration of exposure	96	h	
Source	Analogous		

**Daphnia toxicity (Components)****Silanamine, 1,1,1-trimethyl-N-(trimethylsilyl)**

Species	<i>Daphnia magna</i>		
EC50	> 1000		mg/l
Duration of exposure	48	h	
Source	Analogous		

**Algae toxicity (Components)****Silanamine, 1,1,1-trimethyl-N-(trimethylsilyl)**

Species	<i>Desmodesmus subspicatus</i>		
EC50	> 173		mg/l
Duration of exposure	72	h	
Source	Analogous		

**Bacteria toxicity (Components)****Silanamine, 1,1,1-trimethyl-N-(trimethylsilyl)**

Species	activated sludge		
EC50	> 2500		mg/l
Duration of exposure	3	h	
Method	OECD 209		
Source	Analogous		

**12.2. Persistence and degradability****General information**

not determined

**Biodegradability (Components)****Silanamine, 1,1,1-trimethyl-N-(trimethylsilyl)**

Remarks Inorganic product, cannot be eliminated from the water by biological



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purification processes.

### 12.3. Bioaccumulative potential

#### General information

not determined

#### Partition coefficient n-octanol/water (log value)

Remarks not determined

### 12.4. Mobility in soil

#### General information

not determined

### 12.5. Results of PBT and vPvB assessment

#### General information

not determined

#### Results of PBT and vPvB assessment

The product contains no PBT substances

The product contains no vPvB substances.

### 12.6 Endocrine disrupting properties

#### Endocrine disrupting properties with respect to the environment

The product does not contain a substance that has endocrine disrupting properties with respect to non-target organisms.

### 12.7. Other adverse effects

#### General information

not determined

#### General information / ecology

Do not allow to enter soil, waterways or waste water canal. Avoid release into the atmosphere.

## SECTION 13: Disposal considerations

### 13.1. Waste treatment methods

#### Disposal recommendations for the product

Must not be disposed together with household garbage.

Dispose of waste according to applicable legislation.

#### Disposal recommendations for packaging

Packaging that cannot be cleaned should be disposed off in agreement with the regional waste disposal company.

## SECTION 14: Transport information \*\*\*





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	Land transport ADR/RID ***	Marine transport IMDG/GGVSee ***	Air transport ICAO/IATA ***
14.1. UN number or ID number	The product does not constitute a hazardous substance in land transport.	The product does not constitute a hazardous substance in sea transport.	The product does not constitute a hazardous substance in air transport.
14.2. UN proper shipping name	-	-	-
14.3. Transport hazard class(es)		-	-
Label			
14.4. Packing group		-	-

## SECTION 15: Regulatory information

### 15.1. Safety, health and environmental regulations/legislation specific for the substance or mixture

#### Other information

All components are contained in the TSCA inventory or exempted.

### 15.2. Chemical safety assessment

For this preparation a chemical safety assessment has not been carried out.

## SECTION 16: Other information

### Hazard statements listed in Chapter 2/3

H373 May cause damage to organs through prolonged or repeated exposure.

### CLP categories listed in Chapter 2/3

STOT RE 2 Specific target organ toxicity - repeated exposure, Category 2

### Supplemental information

Relevant changes compared with the previous version of the safety data sheet are marked with: \*\*\*  
This information is based on our present state of knowledge. However, it should not constitute a guarantee for any specific product properties and shall not establish a legally valid relationship.