



Trade name: Regofix opaque Comp. A

Substance number: 15401

Version: 1 / GB

Date revised: 10.02.2023

Replaces Version: - / GB

Print date: 24.03.2023

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

1.1. Product identifier

Regofix opaque 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

59423 Unna

Telephone no.

+49 2303 8807-0

Fax no.

+49 2303 8807-29

Information provided

Department Research & Development: Fax: +49 2303 8807-562

by / telephone

E-mail address of

sicherheitsdatenblatt@dreve.com

person responsible

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

3.2. Mixtures

Chemical characterization

Addition-vulcanising 2-component silicone

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Hazardous ingredients**Cristobalite**

| | | | | | |
|--|------------|---|------|---|--|
| CAS No. | 14464-46-1 | | | | |
| EINECS no. | 238-455-4 | | | | |
| Concentration | >= 25 | < | 50 | % | |
| Classification (Regulation (EC) No. 1272/2008) | STOT RE 1 | | H372 | | |

Quartz

| | | | | | |
|--|------------------|---|------|---|--|
| CAS No. | 14808-60-7 | | | | |
| EINECS no. | 238-878-4 | | | | |
| Registration no. | 01-2120770509-45 | | | | |
| Concentration | >= 10 | < | 45 | % | |
| Classification (Regulation (EC) No. 1272/2008) | STOT RE 1 | | H372 | | |

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****Suitable extinguishing media**

Recommended: alcohol resistant foam, CO₂, powders, water spray/mist, Extinguishing measures to suit surroundings



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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.

SECTION 8: Exposure controls/personal protection**8.1. Control parameters**

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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

| | | |
|---|-----------------|----|
| Physical state | liquid, viscous | |
| Colour | white | |
| Odour | characteristic | |
| Melting point | | |
| Remarks | not determined | |
| Freezing point | | |
| Remarks | not determined | |
| Boiling point or initial boiling point and boiling range | | |
| Value | > 300 | °C |
| Flammability | | |
| not determined | | |
| Upper and lower explosive limits | | |
| Remarks | not determined | |
| Flash point | | |
| Value | > 110 | °C |
| Method | closed cup | |
| Ignition temperature | | |
| Remarks | not determined | |
| Decomposition temperature | | |
| Remarks | not determined | |
| pH value | | |
| Remarks | not determined | |
| Viscosity | | |
| Remarks | not determined | |
| Solubility(ies) | | |
| Remarks | not determined | |

Trade name: Regofix opaque Comp. A

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Print date: 24.03.2023

Partition coefficient n-octanol/water (log value)

Remarks not determined

Vapour pressure

Remarks not determined

Density and/or relative densityValue 1,45 g/cm³
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.

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



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

Acute dermal toxicity

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

Acute inhalational toxicity

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

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

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

Specific Target Organ Toxicity (STOT) (Components)**Quartz****Repeated exposure**

evaluation Causes damage to organs through prolonged or repeated exposure
Route of exposure inhalative

Species

Human

Cristobalite**Repeated exposure**

evaluation Causes damage to organs through prolonged or repeated exposure
Route of exposure inhalative

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

Trade name: Regofix opaque Comp. A

Substance number: 15401

Version: 1 / GB

Date revised: 10.02.2023

Replaces Version: - / GB

Print date: 24.03.2023

12.1. Toxicity

General information

not determined

12.2. Persistence and degradability

General information

not determined

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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Version: 1 / GB

Date revised: 10.02.2023

Replaces Version: - / GB

Print date: 24.03.2023

| | Land transport ADR/RID | Marine transport IMDG/GGVSee | Air transport ICAO/IATA |
|---|--|---|---|
| 14.1. UN 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 | | - | - |
| 14.5. Environmental hazards | | no | - |

SECTION 15: Regulatory information

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 3

H372 Causes damage to organs through prolonged or repeated exposure.

CLP categories listed in Chapter 3

STOT RE 1 Specific target organ toxicity - repeated exposure, Category 1

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.



Trade name: Regofix opaque Comp. B

Substance number: 15402

Version: 1 / GB

Date revised: 10.02.2023

Replaces Version: - / GB

Print date: 24.03.2023

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

1.1. Product identifier

Regofix opaque Comp. B

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

59423 Unna

Telephone no.

+49 2303 8807-0

Fax no.

+49 2303 8807-29

Information provided

Department Research & Development: Fax: +49 2303 8807-562

by / telephone

E-mail address of

sicherheitsdatenblatt@dreve.com

person responsible

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

3.2. Mixtures

Chemical characterization

Addition-vulcanising 2-component silicone

Trade name: Regofix opaque Comp. B

Substance number: 15402

Version: 1 / GB

Date revised: 10.02.2023

Replaces Version: - / GB

Print date: 24.03.2023

Hazardous ingredients

Cristobalite

| | | | | | |
|--|------------|---|------|---|--|
| CAS No. | 14464-46-1 | | | | |
| EINECS no. | 238-455-4 | | | | |
| Concentration | >= 25 | < | 50 | % | |
| Classification (Regulation (EC) No. 1272/2008) | STOT RE 1 | | H372 | | |

Quartz

| | | | | | |
|--|------------------|---|------|---|--|
| CAS No. | 14808-60-7 | | | | |
| EINECS no. | 238-878-4 | | | | |
| Registration no. | 01-2120770509-45 | | | | |
| Concentration | >= 10 | < | 25 | % | |
| Classification (Regulation (EC) No. 1272/2008) | STOT RE 1 | | H372 | | |

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

Suitable extinguishing media

Recommended: alcohol resistant foam, CO₂, powders, water spray/mist, Extinguishing measures to suit surroundings



Trade name: Regofix opaque Comp. B

Substance number: 15402

Version: 1 / GB

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Print date: 24.03.2023

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.

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

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Date revised: 10.02.2023

Replaces Version: - / GB

Print date: 24.03.2023

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

| | | |
|---|-----------------|----|
| Physical state | liquid, viscous | |
| Colour | blue | |
| Odour | characteristic | |
| Melting point | | |
| Remarks | not determined | |
| Freezing point | | |
| Remarks | not determined | |
| Boiling point or initial boiling point and boiling range | | |
| Value | > 300 | °C |
| Flammability | | |
| not determined | | |
| Upper and lower explosive limits | | |
| Remarks | not determined | |
| Flash point | | |
| Value | > 110 | °C |
| Method | closed cup | |
| Ignition temperature | | |
| Remarks | not determined | |
| Decomposition temperature | | |
| Remarks | not determined | |
| pH value | | |
| Remarks | not determined | |
| Viscosity | | |
| Remarks | not determined | |
| Solubility(ies) | | |
| Remarks | not determined | |

Trade name: Regofix opaque Comp. B

Substance number: 15402

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Print date: 24.03.2023

Partition coefficient n-octanol/water (log value)

Remarks not determined

Vapour pressure

Remarks not determined

Density and/or relative densityValue 1,44 g/cm³
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.

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

Trade name: Regofix opaque Comp. B

Substance number: 15402

Version: 1 / GB

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Replaces Version: - / GB

Print date: 24.03.2023

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

Acute dermal toxicity

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

Acute inhalational toxicity

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

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

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

Specific Target Organ Toxicity (STOT) (Components)**Quartz****Repeated exposure**

evaluation Causes damage to organs through prolonged or repeated exposure
Route of exposure inhalative

Species Human

Cristobalite**Repeated exposure**

evaluation Causes damage to organs through prolonged or repeated exposure
Route of exposure inhalative

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

Trade name: Regofix opaque Comp. B

Substance number: 15402

Version: 1 / GB

Date revised: 10.02.2023

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Print date: 24.03.2023

12.1. Toxicity

General information

not determined

12.2. Persistence and degradability

General information

not determined

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

Trade name: Regofix opaque Comp. B

Substance number: 15402

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Replaces Version: - / GB

Print date: 24.03.2023

| | Land transport ADR/RID | Marine transport IMDG/GGVSee | Air transport ICAO/IATA |
|---|--|---|---|
| 14.1. UN 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 | | - | - |
| 14.5. Environmental hazards | | no | - |

SECTION 15: Regulatory information

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 3

H372 Causes damage to organs through prolonged or repeated exposure.

CLP categories listed in Chapter 3

STOT RE 1 Specific target organ toxicity - repeated exposure, Category 1

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.