

Safety Data Sheet

acc. to OSHA HCS

Printing date 06/28/2019

Reviewed on 06/28/2019

1 Identification

- **Product identifier**
- **Trade name: VITA ENAMIC® STAIN**
- **Article number:** EENST012, EENST022, EENST032, EENST042, EENST052, EENST062
- **Application of the substance / the mixture** Colours to paint resins and gingiva parts
- **Details of the supplier of the safety data sheet**
- **Manufacturer/Supplier:**
VITA Zahnfabrik
H. Rauter GmbH & Co. KG
PO Box 1338
D 79704 Bad Säckingen
Tel.: +49 7761/562-0
Fax: +49 7761/562 299
- **Information department:**
VITA Zahnfabrik
Tel.: +49 7761 562-0
Fax: +49 7761 562 299
e-mail: info@vita-zahnfabrik.com
- **Emergency telephone number:** Tel.: +49 761 19240

2 Hazard(s) identification

- **Classification of the substance or mixture**



GHS08 Health hazard

Carc. 2 H351 Suspected of causing cancer.

Repr. 1B H360 May damage fertility or the unborn child.

STOT RE 1 H372 Causes damage to the lung through prolonged or repeated exposure. Route of exposure: Inhalation.



GHS07

Skin Sens. 1 H317 May cause an allergic skin reaction.

- **Label elements**
- **GHS label elements**
The product is classified and labeled according to the Globally Harmonized System (GHS).
- **Hazard pictograms**



GHS07 GHS08

- **Signal word** Danger
- **Hazard-determining components of labeling:**
titanium dioxide
cristobalite
dicyclohexyl phthalate
dibenzoyl peroxide

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- **Hazard statements**

May cause an allergic skin reaction.

Suspected of causing cancer.

May damage fertility or the unborn child.

Causes damage to the lung through prolonged or repeated exposure. Route of exposure: Inhalation.

- **Precautionary statements**

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

Wear protective gloves/protective clothing/eye protection/face protection.

IF exposed or concerned: Get medical advice/attention.

Wash contaminated clothing before reuse.

Store locked up.

Dispose of contents/container in accordance with local/regional/national/international regulations.

- **Classification system:**

- **NFPA ratings (scale 0 - 4)**



Health = 1

Fire = 0

Reactivity = 0

- **HMIS-ratings (scale 0 - 4)**



Health = *0

Fire = 0

Reactivity = 0

- **Other hazards**

- **Results of PBT and vPvB assessment**

• **PBT:** Not applicable.

• **vPvB:** Not applicable.

3 Composition/information on ingredients

- **Chemical characterization: Mixtures**

• **Description:** Mixture of the substances listed below with nonhazardous additions.

- **Dangerous components:**

| | | |
|------------|------------------------|---------|
| 14464-46-1 | cristobalite | 2.5-10% |
| 13463-67-7 | titanium dioxide | 2.5-10% |
| 94-36-0 | dibenzoyl peroxide | ≤2.5% |
| 84-61-7 | dicyclohexyl phthalate | ≤2.5% |

• **Additional information:** For the wording of the listed hazard phrases refer to section 16.

4 First-aid measures

- **Description of first aid measures**

• **General information:** Immediately remove any clothing soiled by the product.

- **After inhalation:**

Supply fresh air and to be sure call for a doctor.

In case of unconsciousness place patient stably in side position for transportation.

- **After skin contact:**

Immediately wash with water and soap and rinse thoroughly.

If skin irritation continues, consult a doctor.

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- **After eye contact:**
Rinse opened eye for several minutes under running water. Then consult a doctor.
- **After swallowing:**
Rinse out mouth and then drink plenty of water.
Do not induce vomiting.
Call a doctor immediately.
- **Information for doctor:**
- **Most important symptoms and effects, both acute and delayed**
No further relevant information available.
- **Indication of any immediate medical attention and special treatment needed**
No further relevant information available.

5 Fire-fighting measures

- **Extinguishing media**
- **Suitable extinguishing agents:**
CO₂, extinguishing powder or water spray. Fight larger fires with water spray or alcohol resistant foam.
- **For safety reasons unsuitable extinguishing agents:** Water with full jet
- **Special hazards arising from the substance or mixture**
During heating or in case of fire poisonous gases are produced.
- **Advice for firefighters**
- **Protective equipment:** Mount respiratory protective device.
- **Additional information**
Collect contaminated fire fighting water separately. It must not enter the sewage system.

6 Accidental release measures

- **Personal precautions, protective equipment and emergency procedures**
Avoid formation of dust.
Avoid contact with skin and eyes.
Use respiratory protective device against the effects of fumes/dust/aerosol.
- **Environmental precautions:** Do not allow to enter sewers/ surface or ground water.
- **Methods and material for containment and cleaning up:**
Dispose contaminated material as waste according to item 13.
Ensure adequate ventilation.
- **Reference to other sections**
See Section 7 for information on safe handling.
See Section 8 for information on personal protection equipment.
See Section 13 for disposal information.
- **Protective Action Criteria for Chemicals**

- **PAC-1:**

| | | |
|------------|--------------------------------------|-------------------------|
| 7631-86-9 | silicon dioxide, chemically prepared | 18 mg/m ³ |
| 14464-46-1 | cristobalite | 0.075 mg/m ³ |
| 13463-67-7 | titanium dioxide | 30 mg/m ³ |
| 94-36-0 | dibenzoyl peroxide | 15 mg/m ³ |

- **PAC-2:**

| | | |
|------------|--------------------------------------|-----------------------|
| 7631-86-9 | silicon dioxide, chemically prepared | 740 mg/m ³ |
| 14464-46-1 | cristobalite | 33 mg/m ³ |
| 13463-67-7 | titanium dioxide | 330 mg/m ³ |

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| | | |
|-----------------|--------------------------------------|-------------------------|
| 94-36-0 | dibenzoyl peroxide | 1,200 mg/m ³ |
| · PAC-3: | | |
| 7631-86-9 | silicon dioxide, chemically prepared | 4,500 mg/m ³ |
| 14464-46-1 | cristobalite | 200 mg/m ³ |
| 13463-67-7 | titanium dioxide | 2,000 mg/m ³ |
| 94-36-0 | dibenzoyl peroxide | 7,000 mg/m ³ |

7 Handling and storage

- **Handling:**
- **Precautions for safe handling**
Avoid contact with skin and eyes.
Ensure good ventilation/exhaustion at the workplace.
Open and handle receptacle with care.
- **Information about protection against explosions and fires:**
Keep respiratory protective device available.
- **Conditions for safe storage, including any incompatibilities**
- **Storage:**
- **Requirements to be met by storerooms and receptacles:**
Store between 10 °C and 25°C at a well ventilated place.
- **Information about storage in one common storage facility:** Not required.
- **Further information about storage conditions:**
Store in dry conditions.
Keep receptacle tightly sealed.
- **Specific end use(s)** No further relevant information available.

8 Exposure controls/personal protection

- **Additional information about design of technical systems:** No further data; see item 7.
- **Control parameters**

· **Components with limit values that require monitoring at the workplace:**

14464-46-1 cristobalite

| | |
|-----|---|
| PEL | Long-term value: 0.05* mg/m ³ *resp. dust; ½ value from resp.dust formulae Quartz |
| REL | Long-term value: 0.05* mg/m ³ *respirable dust; See Pocket Guide App. A |
| TLV | Long-term value: 0.025* mg/m ³ *as respirable fraction |

13463-67-7 titanium dioxide

| | |
|-----|---|
| PEL | Long-term value: 15* mg/m ³ *total dust |
| REL | See Pocket Guide App. A |
| TLV | Long-term value: 10 mg/m ³ |

94-36-0 dibenzoyl peroxide

| | |
|-----|--------------------------------------|
| PEL | Long-term value: 5 mg/m ³ |
| REL | Long-term value: 5 mg/m ³ |
| TLV | Long-term value: 5 mg/m ³ |

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- **Additional information:** The lists that were valid during the creation were used as basis.

- **Exposure controls**

- **Personal protective equipment:**

- **General protective and hygienic measures:**

Do not eat, drink, smoke or sniff while working.
Keep away from foodstuffs, beverages and feed.
Immediately remove all soiled and contaminated clothing.
Wash hands before breaks and at the end of work.
Store protective clothing separately.

- **Breathing equipment:**

Not necessary if room is well-ventilated.
Short term filter device:
Filter P2

- **Protection of hands:**



Protective gloves

Protective gloves should be changed regularly, especially after intensive contact with the product. For every workplace a suitable type of protective gloves must be selected.

The glove material has to be impermeable and resistant to the product/ the substance/ the preparation.

- **Material of gloves**

Butyl rubber (0,7 mm) EN 374

As there are many different conditions in every day work these indications can only serve as an aid to orientation for the selection of suitable gloves for the handling of chemical products. By no means they can replace qualifying examinations by the end-user.

Diese Empfehlung gilt nur für das im Sicherheitsdatenblatt genannte Produkt. Bei Vermischung mit anderen Substanzen und bei von der EN 374 abweichenden Bedingungen müssen Sie sich an den Hersteller von CE-genehmigten Handschuhen wenden.

The selection of the suitable gloves does not only depend on the material, but also on further marks of quality and varies from manufacturer to manufacturer. As the product is a preparation of several substances, the resistance of the glove material can not be calculated in advance and has therefore to be checked prior to the application.

- **Penetration time of glove material**

The exact break through time has to be found out by the manufacturer of the protective gloves and has to be observed.

The determined penetration times according to EN 374 part III are not performed under practical conditions. Therefore a maximum wearing time, which corresponds to 50% of the penetration time, is recommended.

- **Eye protection:**



Tightly sealed goggles

- **Body protection:** Protective work clothing

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9 Physical and chemical properties

- **Information on basic physical and chemical properties**

- **General Information**

- **Appearance:**

| | |
|--------|---------------------------------|
| Form: | Powder |
| Color: | Different according to coloring |

- **Odor:** Characteristic

- **Odor threshold:** Not determined.

- **pH-value:** Not applicable.

- **Change in condition**

| | |
|------------------------------|---------------|
| Melting point/Melting range: | Undetermined. |
| Boiling point/Boiling range: | Undetermined. |

- **Flash point:** Not applicable.

- **Flammability (solid, gaseous):** Not determined.

- **Ignition temperature:** >370 °C (>698 °F)

- **Decomposition temperature:** Not determined.

- **Auto igniting:** Product is not selfigniting.

- **Danger of explosion:** Product does not present an explosion hazard.

- **Explosion limits:**

| | |
|--------|-----------------|
| Lower: | Not determined. |
| Upper: | Not determined. |

- **Oxidizing properties** Not determined

- Not applicable.

- **Vapor pressure:** Not applicable.

- **Density at 20 °C (68 °F):** 2.3 g/cm³ (19.1935 lbs/gal)

- **Relative density** Not determined.

- **Vapor density** Not applicable.

- **Evaporation rate** Not applicable.

- **Solubility in / Miscibility with**

| | |
|--------|------------|
| Water: | Insoluble. |
|--------|------------|

- **Partition coefficient (n-octanol/water):** Not determined.

- **Viscosity:**

| | |
|------------|-----------------|
| Dynamic: | Not applicable. |
| Kinematic: | Not applicable. |

- **Other information** No further relevant information available.

10 Stability and reactivity

- **Reactivity** No dangerous reactions if used according to specifications

- **Chemical stability** Stable if used according to specifications

- **Thermal decomposition / conditions to be avoided:**

Heating above 30°C, decomposition of dibenzoyl peroxide

No decomposition if used according to specifications.

- **Possibility of hazardous reactions** No dangerous reactions known.

- **Conditions to avoid** No further relevant information available.

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- **Incompatible materials:** No further relevant information available.
- **Hazardous decomposition products:** No dangerous decomposition products known.

11 Toxicological information

- **Information on toxicological effects**
- **Acute toxicity:**
- **LD/LC50 values that are relevant for classification:**
Dibenzoyl peroxide 78 % LD-50 oral > 5000 mg/kg rat (Lit.)
- **Sensitization:** Sensitization possible through skin contact.
- **Additional toxicological information:**
Max. 2,5 % Dibenzoyl peroxide.
The product shows the following dangers according to internally approved calculation methods for preparations:
Irritant

- **Carcinogenic categories**

- **IARC (International Agency for Research on Cancer)**

| | | |
|------------|--------------------|----|
| 14464-46-1 | cristobalite | 1 |
| 13463-67-7 | titanium dioxide | 2B |
| 94-36-0 | dibenzoyl peroxide | 3 |

- **NTP (National Toxicology Program)**

| | | |
|------------|--------------|---|
| 14464-46-1 | cristobalite | K |
|------------|--------------|---|

- **OSHA-Ca (Occupational Safety & Health Administration)**

None of the ingredients is listed.

12 Ecological information

- **Toxicity**
- **Aquatic toxicity:** No further relevant information available.
- **Persistence and degradability** No further relevant information available.
- **Behavior in environmental systems:**
- **Bioaccumulative potential** No further relevant information available.
- **Mobility in soil** No further relevant information available.
- **Additional ecological information:**
- **General notes:**
Do not allow undiluted product or large quantities of it to reach ground water, water course or sewage system.
- **Results of PBT and vPvB assessment**
- **PBT:** Not applicable.
- **vPvB:** Not applicable.
- **Other adverse effects** No further relevant information available.

13 Disposal considerations

- **Waste treatment methods**
- **Recommendation:**
Must not be disposed of together with household garbage. Do not allow product to reach sewage system.
Disposal must be made according to official regulations.

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- **Uncleaned packagings:**
- **Recommendation:** Disposal must be made according to official regulations.

14 Transport information

- | | |
|--|-----------------|
| · UN-Number | Void |
| · DOT, ADR, ADN, IMDG, IATA | Void |
| · UN proper shipping name | Void |
| · DOT, ADR, ADN, IMDG, IATA | Void |
| · Transport hazard class(es) | Void |
| · DOT, ADR, ADN, IMDG, IATA | Void |
| · Class | Void |
| · Packing group | Void |
| · DOT, ADR, IMDG, IATA | Void |
| · Environmental hazards: | No |
| · Marine pollutant: | No |
| · Special precautions for user | Not applicable. |
| · Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code | Not applicable. |
| · UN "Model Regulation": | Void |

15 Regulatory information

- **Safety, health and environmental regulations/legislation specific for the substance or mixture**
- **Sara**

| |
|--|
| · Section 355 (extremely hazardous substances): |
|--|

None of the ingredient is listed.

| |
|--|
| · Section 313 (Specific toxic chemical listings): |
|--|

94-36-0 | dibenzoyl peroxide

| |
|---|
| · TSCA (Toxic Substances Control Act): |
|---|

14464-46-1 | cristobalite

13463-67-7 | titanium dioxide

94-36-0 | dibenzoyl peroxide

| |
|-----------------------------------|
| · Hazardous Air Pollutants |
|-----------------------------------|

None of the ingredients is listed.

| |
|-------------------------|
| · Proposition 65 |
|-------------------------|

| |
|---|
| · Chemicals known to cause cancer: |
|---|

14464-46-1 | cristobalite

| |
|--|
| · Chemicals known to cause reproductive toxicity for females: |
|--|

None of the ingredients is listed.

| |
|--|
| · Chemicals known to cause reproductive toxicity for males: |
|--|

None of the ingredients is listed.

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· **Chemicals known to cause developmental toxicity:**

None of the ingredients is listed.

· **Carcinogenicity categories**

· **EPA (Environmental Protection Agency)**

None of the ingredients is listed.

· **TLV (Threshold Limit Value established by ACGIH)**

| | | |
|------------|--------------------|----|
| 14464-46-1 | cristobalite | A2 |
| 13463-67-7 | titanium dioxide | A4 |
| 94-36-0 | dibenzoyl peroxide | A4 |

· **MAK (German Maximum Workplace Concentration)**

| | | |
|------------|------------------|----|
| 14464-46-1 | cristobalite | 1 |
| 13463-67-7 | titanium dioxide | 3A |

· **NIOSH-Ca (National Institute for Occupational Safety and Health)**

| | |
|------------|------------------|
| 14464-46-1 | cristobalite |
| 13463-67-7 | titanium dioxide |

· **GHS label elements**

The product is classified and labeled according to the Globally Harmonized System (GHS).

· **Hazard pictograms**



GHS07 GHS08

· **Signal word** Danger

· **Hazard-determining components of labeling:**

titanium dioxide
cristobalite
dicyclohexyl phthalate
dibenzoyl peroxide

· **Hazard statements**

May cause an allergic skin reaction.
Suspected of causing cancer.
May damage fertility or the unborn child.
Causes damage to the lung through prolonged or repeated exposure. Route of exposure:
Inhalation.

· **Precautionary statements**

Do not breathe dust/fume/gas/mist/vapors/spray.
Wear protective gloves/protective clothing/eye protection/face protection.
IF exposed or concerned: Get medical advice/attention.
Wash contaminated clothing before reuse.
Store locked up.
Dispose of contents/container in accordance with local/regional/national/international regulations.

· **Chemical safety assessment:** A Chemical Safety Assessment has not been carried out.

16 Other information

This information is based on our present knowledge. However, this shall not constitute a guarantee for any specific product features and shall not establish a legally valid contractual relationship.

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· **Date of preparation / last revision** 06/28/2019 / 3

· **Abbreviations and acronyms:**

ICAO: International Civil Aviation Organisation

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

DOT: US Department of Transportation

IATA: International Air Transport Association

ACGIH: American Conference of Governmental Industrial Hygienists

EINECS: European Inventory of Existing Commercial Chemical Substances

ELINCS: European List of Notified Chemical Substances

CAS: Chemical Abstracts Service (division of the American Chemical Society)

NFPA: National Fire Protection Association (USA)

HMIS: Hazardous Materials Identification System (USA)

LC50: Lethal concentration, 50 percent

LD50: Lethal dose, 50 percent

PBT: Persistent, Bioaccumulative and Toxic

vPvB: very Persistent and very Bioaccumulative

NIOSH: National Institute for Occupational Safety

OSHA: Occupational Safety & Health

TLV: Threshold Limit Value

PEL: Permissible Exposure Limit

REL: Recommended Exposure Limit

Skin Sens. 1: Skin sensitisation – Category 1

Carc. 2: Carcinogenicity – Category 2

Repr. 1B: Reproductive toxicity – Category 1B

STOT RE 1: Specific target organ toxicity (repeated exposure) – Category 1

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