

Safety data sheet according to 1907/2006/EC, Article 31

Printing date 28.06.2019

Version number 4

Revision: 28.06.2019

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

- **1.1 Product identifier**
- **Trade name: VITA ENAMIC® STAIN**
- **Article number:** EENST012, EENST022, EENST032, EENST042, EENST052, EENST062
- **1.2 Relevant identified uses of the substance or mixture and uses advised against**
No further relevant information available.
- **Application of the substance / the mixture** Colours to paint resins and gingiva parts
- **1.3 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
- **Further information obtainable from:**
VITA Zahnfabrik
Tel.: +49 7761 562-0
Fax: +49 7761 562 299
e-mail: info@vita-zahnfabrik.com
- **1.4 Emergency telephone number:** Tel.: +49 761 19240

SECTION 2: Hazards identification

- **2.1 Classification of the substance or mixture**
- **Classification according to Regulation (EC) No 1272/2008**



GHS08 health hazard

Repr. 1B H360D May damage 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.

- **2.2 Label elements**
- **Labelling according to Regulation (EC) No 1272/2008**
The product is classified and labelled according to the CLP regulation.
- **Hazard pictograms**



GHS07 GHS08

- **Signal word** Danger
- **Hazard-determining components of labelling:**
cristobalite
dicyclohexyl phthalate

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dibenzoyl peroxide

- **Hazard statements**

H317 May cause an allergic skin reaction.

H360D May damage the unborn child.

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

- **Precautionary statements**

P260 Do not breathe dust/fume/gas/mist/vapours/spray.

P264 Wash thoroughly after handling.

P280 Wear protective gloves/protective clothing/eye protection/face protection.

P333+P313 If skin irritation or rash occurs: Get medical advice/attention.

P405 Store locked up.

P501 Dispose of contents/container in accordance with local/regional/national/international regulations.

- **2.3 Other hazards**

- **Results of PBT and vPvB assessment**

- **PBT:** Not applicable.

- **vPvB:** Not applicable.

SECTION 3: Composition/information on ingredients

- **3.2 Chemical characterisation: Mixtures**

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

- **Dangerous components:**

CAS: 14464-46-1	crystalite	2.5-10%
EINECS: 238-455-4	☠ STOT RE 1, H372	
CAS: 13463-67-7	titanium dioxide	2.5-10%
EINECS: 236-675-5	substance with a Community workplace exposure limit	
CAS: 94-36-0	dibenzoyl peroxide	≤2.5%
EINECS: 202-327-6	☠☠ Org. Perox. B, H241; ⚠ Eye Irrit. 2, H319; Skin Sens. 1, H317	
CAS: 84-61-7	dicyclohexyl phthalate	≤2.5%
EINECS: 201-545-9	☠ Repr. 1B, H360D; ⚠ Skin Sens. 1, H317	

- **SVHC**

84-61-7	dicyclohexyl phthalate
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- **Additional information:** For the wording of the listed hazard phrases refer to section 16.

SECTION 4: First aid measures

- **4.1 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.

- **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.

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Do not induce vomiting.

Call a doctor immediately.

- **4.2 Most important symptoms and effects, both acute and delayed**

No further relevant information available.

- **4.3 Indication of any immediate medical attention and special treatment needed**

No further relevant information available.

SECTION 5: Firefighting measures

- **5.1 Extinguishing media**

- **Suitable extinguishing agents:**

CO₂, powder or water spray. Fight larger fires with water spray or alcohol resistant foam.

- **For safety reasons unsuitable extinguishing agents:** Water with full jet

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

During heating or in case of fire poisonous gases are produced.

- **5.3 Advice for firefighters**

- **Protective equipment:** Mount respiratory protective device.

- **Additional information**

Collect contaminated fire fighting water separately. It must not enter the sewage system.

SECTION 6: Accidental release measures

- **6.1 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.

- **6.2 Environmental precautions:** Do not allow to enter sewers/ surface or ground water.

- **6.3 Methods and material for containment and cleaning up:**

Dispose contaminated material as waste according to item 13.

Ensure adequate ventilation.

- **6.4 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.

SECTION 7: Handling and storage

- **7.1 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 fire - and explosion protection:** Keep respiratory protective device available.

- **7.2 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 container tightly sealed.

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- **7.3 Specific end use(s)** No further relevant information available.

SECTION 8: Exposure controls/personal protection

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

- **8.1 Control parameters**

- **Ingredients with limit values that require monitoring at the workplace:**

13463-67-7 titanium dioxide

WEL	Long-term value: 10* 4** mg/m ³ *total inhalable **respirable
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94-36-0 dibenzoyl peroxide

WEL	Long-term value: 5 mg/m ³
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84-61-7 dicyclohexyl phthalate

WEL	Long-term value: 5 mg/m ³
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- **Additional information:** The lists valid during the making were used as basis.

- **8.2 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.

- **Respiratory protection:**

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.

These recommendations only apply to the product mentioned in the safety data sheet. When mixing with other substances or under conditions deviant from norm EN 374 a manufacturer of CE-approved gloves should be referred to.

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.

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- **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

SECTION 9: Physical and chemical properties

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

- **General Information**

- **Appearance:**

Form: Powder
Colour: Different according to colouring

- **Odour:** Characteristic

- **Odour threshold:** Not determined.

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

- **Change in condition**

Melting point/freezing point: Undetermined.

Initial boiling point and boiling range: Undetermined.

- **Flash point:** Not applicable.

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

- **Ignition temperature:** >370 °C

- **Decomposition temperature:** Not determined.

- **Auto-ignition temperature:** Product is not selfigniting.

- **Explosive properties:** Product does not present an explosion hazard.

- **Explosion limits:**

Lower: Not determined.

Upper: Not determined.

- **Oxidising properties** Not determined
Not applicable.

- **Vapour pressure:** Not applicable.

- **Density at 20 °C:** 2.3 g/cm³

- **Relative density** Not determined.

- **Vapour density** Not applicable.

- **Evaporation rate** Not applicable.

- **Solubility in / Miscibility with water:**

Insoluble.

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

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- | | |
|--------------------------------|--|
| · Viscosity: | |
| Dynamic: | Not applicable. |
| Kinematic: | Not applicable. |
| · 9.2 Other information | No further relevant information available. |

SECTION 10: Stability and reactivity

- **10.1 Reactivity** No dangerous reactions if used according to specifications.
- **10.2 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.
- **10.3 Possibility of hazardous reactions** No dangerous reactions known.
- **10.4 Conditions to avoid** No further relevant information available.
- **10.5 Incompatible materials:** No further relevant information available.
- **10.6 Hazardous decomposition products:** No dangerous decomposition products known.

SECTION 11: Toxicological information

- **11.1 Information on toxicological effects**
- **Acute toxicity** Based on available data, the classification criteria are not met.
- **LD/LC50 values relevant for classification:**
Dibenzoyl peroxide 78 % LD-50 oral > 5000 mg/kg rat (Lit.)
- **Primary irritant effect:**
- **Skin corrosion/irritation** Based on available data, the classification criteria are not met.
- **Serious eye damage/irritation** Based on available data, the classification criteria are not met.
- **Respiratory or skin sensitisation**
May cause an allergic skin reaction.
- **Additional toxicological information:** Max. 2,5 % Dibenzoyl peroxide.
- **CMR effects (carcinogenicity, mutagenicity and toxicity for reproduction)**
- **Germ cell mutagenicity** Based on available data, the classification criteria are not met.
- **Carcinogenicity** Based on available data, the classification criteria are not met.
- **Reproductive toxicity**
May damage the unborn child.
- **STOT-single exposure** Based on available data, the classification criteria are not met.
- **STOT-repeated exposure**
Causes damage to the lung through prolonged or repeated exposure. Route of exposure: Inhalation.
- **Aspiration hazard** Based on available data, the classification criteria are not met.

SECTION 12: Ecological information

- **12.1 Toxicity**
- **Aquatic toxicity:** No further relevant information available.
- **12.2 Persistence and degradability** No further relevant information available.
- **12.3 Bioaccumulative potential** No further relevant information available.
- **12.4 Mobility in soil** No further relevant information available.

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- **Additional ecological information:**
- **General notes:**
Do not allow undiluted product or large quantities of it to reach ground water, water course or sewage system.
- **12.5 Results of PBT and vPvB assessment**
- **PBT:** Not applicable.
- **vPvB:** Not applicable.
- **12.6 Other adverse effects** No further relevant information available.

SECTION 13: Disposal considerations

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

- **European waste catalogue**

HP5	Specific Target Organ Toxicity (STOT)/Aspiration Toxicity
HP10	Toxic for reproduction

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

SECTION 14: Transport information

- | | |
|---|-----------------|
| <ul style="list-style-type: none"> · 14.1 UN-Number · ADR, ADN, IMDG, IATA | Void |
| <ul style="list-style-type: none"> · 14.2 UN proper shipping name · ADR, ADN, IMDG, IATA | Void |
| <ul style="list-style-type: none"> · 14.3 Transport hazard class(es) · ADR, ADN, IMDG, IATA · Class | Void |
| <ul style="list-style-type: none"> · 14.4 Packing group · ADR, IMDG, IATA | Void |
| <ul style="list-style-type: none"> · 14.5 Environmental hazards: · Marine pollutant: | No |
| <ul style="list-style-type: none"> · 14.6 Special precautions for user | Not applicable. |
| <ul style="list-style-type: none"> · 14.7 Transport in bulk according to Annex II of Marpol and the IBC Code | Not applicable. |
| <ul style="list-style-type: none"> · UN "Model Regulation": | Void |

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SECTION 15: Regulatory information

- **15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture**
 - **Directive 2012/18/EU**
 - **Named dangerous substances - ANNEX I** None of the ingredients is listed.
 - **REGULATION (EC) No 1907/2006 ANNEX XVII** Conditions of restriction: 30
 - **National regulations:**
 - **Other regulations, limitations and prohibitive regulations**
 - **Substances of very high concern (SVHC) according to REACH, Article 57**
- | | |
|---------|------------------------|
| 84-61-7 | dicyclohexyl phthalate |
|---------|------------------------|
- **15.2 Chemical safety assessment:** A Chemical Safety Assessment has not been carried out.

SECTION 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.

- **Relevant phrases**
 - H241 Heating may cause a fire or explosion.
 - H317 May cause an allergic skin reaction.
 - H319 Causes serious eye irritation.
 - H360D May damage the unborn child.
 - H372 Causes damage to the lung through prolonged or repeated exposure. Route of exposure: Inhalation.
- **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
 - IATA: International Air Transport Association
 - GHS: Globally Harmonised 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 (division of the American Chemical Society)
 - LC50: Lethal concentration, 50 percent
 - LD50: Lethal dose, 50 percent
 - PBT: Persistent, Bioaccumulative and Toxic
 - SVHC: Substances of Very High Concern
 - vPvB: very Persistent and very Bioaccumulative
 - Org. Perox. B: Organic peroxides – Type B
 - Eye Irrit. 2: Serious eye damage/eye irritation – Category 2
 - Skin Sens. 1: Skin sensitisation – Category 1
 - Repr. 1B: Reproductive toxicity – Category 1B
 - STOT RE 1: Specific target organ toxicity (repeated exposure) – Category 1

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