

Safety data sheet

according to 1907/2006/EC, Article 31

Printing date 26.10.2015

Version number 3

Revision: 26.10.2015

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

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



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
dibenzoyl peroxide
dicyclohexyl phthalate

(Contd. on page 2)

GB

Safety data sheet

according to 1907/2006/EC, Article 31

Printing date 26.10.2015

Version number 3

Revision: 26.10.2015

Trade name: VITA ENAMIC® STAIN

(Contd. of page 1)

- **Hazard statements**

H317 May cause an allergic skin reaction.

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

- **Precautionary statements**

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

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

P264 Wash thoroughly after handling.

P270 Do not eat, drink or smoke when using this product.

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

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	cristobalite	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. 2, H361; ⚠ Skin Sens. 1, H317; Aquatic Chronic 3, H412	

- **Additional information:** For the wording of the listed risk 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.

Do not induce vomiting.

Call a doctor immediately.

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

No further relevant information available.

(Contd. on page 3)

Safety data sheet

according to 1907/2006/EC, Article 31

Printing date 26.10.2015

Version number 3

Revision: 26.10.2015

Trade name: VITA ENAMIC® STAIN

(Contd. of page 2)

- **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**
No further relevant information available.
- **5.3 Advice for firefighters**
- **Protective equipment:** No special measures required.
- **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 contact with skin and eyes.
Avoid formation of dust.
- **6.2 Environmental precautions:** No special measures required.
- **6.3 Methods and material for containment and cleaning up:**
Dispose contaminated material as waste according to item 13.
- **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.
- **Information about fire - and explosion protection:** Protect against electrostatic charges.
- **7.2 Conditions for safe storage, including any incompatibilities**
- **Storage:**
- **Requirements to be met by storerooms and receptacles:** Store at max. 30 °C.
- **Information about storage in one common storage facility:** Not required.
- **Further information about storage conditions:** Store in dry conditions.
- **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

(Contd. on page 4)

Safety data sheet

according to 1907/2006/EC, Article 31

Printing date 26.10.2015

Version number 3

Revision: 26.10.2015

Trade name: VITA ENAMIC® STAIN

(Contd. of page 3)

94-36-0 dibenzoyl peroxideWEL Long-term value: 5 mg/m³**84-61-7 dicyclohexyl phthalate**WEL Long-term value: 5 mg/m³

- **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.

- **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.

- **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:** Safety glasses

- **Body protection:** Protective work clothing

GB

(Contd. on page 5)

Safety data sheet

according to 1907/2006/EC, Article 31

Printing date 26.10.2015

Version number 3

Revision: 26.10.2015

Trade name: VITA ENAMIC® STAIN

(Contd. of page 4)

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/Melting range:	Undetermined.
Boiling point/Boiling range:	Undetermined.
· Flash point:	Not applicable.
· Flammability (solid, gaseous):	Not determined.
· Ignition temperature:	> 370 °C
· Decomposition temperature:	Not determined.
· Self-igniting:	Product is not selfigniting.
· Danger of explosion:	Product does not present an explosion hazard.
· Explosion limits:	
Lower:	Not determined.
Upper:	Not determined.
· Oxidising properties	Not determined
· Vapour pressure:	Not applicable.
· Density at 20 °C:	2.3 g/cm ³
· 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.
· Viscosity:	
Dynamic:	Not applicable.
Kinematic:	Not applicable.
· Solvent content:	
Organic solvents:	0.0 %
· 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.

(Contd. on page 6)

Safety data sheet

according to 1907/2006/EC, Article 31

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Version number 3

Revision: 26.10.2015

Trade name: VITA ENAMIC® STAIN

(Contd. of page 5)

- **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**
- **LD/LC50 values relevant for classification:**
Dibenzoyl peroxide 78 % LD-50 oral > 5000 mg/kg rat (Lit.)
- **Primary irritant effect:**
- **Skin corrosion/irritation** No irritant effect.
- **Serious eye damage/irritation** No irritant effect.
- **Respiratory or skin sensitisation** Sensitisation possible through skin contact.
- **Additional toxicological information:**
Max. 2,5 % Dibenzoyl peroxide.
The product shows the following dangers according to the calculation method of the General EU Classification Guidelines for Preparations as issued in the latest version:
Irritant

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.
- **Additional ecological information:**
- **General notes:** Not known to be hazardous to water.
- **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** 060899
- **Uncleaned packaging:**
- **Recommendation:** Disposal must be made according to official regulations.

GB

(Contd. on page 7)

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

Printing date 26.10.2015

Version number 3

Revision: 26.10.2015

Trade name: VITA ENAMIC® STAIN

(Contd. of page 6)

SECTION 14: Transport information

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

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.
- 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.
H361 Suspected of damaging fertility or the unborn child.
H372 Causes damage to the lung through prolonged or repeated exposure. Route of exposure: Inhalative.
H412 Harmful to aquatic life with long lasting effects.
- **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
Org. Perox. B: Organic Peroxides, Type B

(Contd. on page 8)

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

Printing date 26.10.2015

Version number 3

Revision: 26.10.2015

Trade name: VITA ENAMIC® STAIN

(Contd. of page 7)

Eye Irrit. 2: Serious eye damage/eye irritation, Hazard Category 2

Skin Sens. 1: Sensitisation - Skin, Hazard Category 1

Repr. 2: Reproductive toxicity, Hazard Category 2

STOT RE 1: Specific target organ toxicity - Repeated exposure, Hazard Category 1

Aquatic Chronic 3: Hazardous to the aquatic environment - Chronic Hazard, Category 3

GB