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.

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.

2.3 Hazard pictograms

GHS07  GHS08

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

(Contd. on page 2)
Safety data sheet  
according to 1907/2006/EC, Article 31  

Trade name: VITA ENAMIC® STAIN

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

  - **SVHC**
    - 84-61-7 dicyclohexyl phthalate

  - **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.

(Contd. on page 3)
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.
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

<table>
<thead>
<tr>
<th>Ingredient</th>
<th>WEL</th>
<th>Long-term value:</th>
</tr>
</thead>
<tbody>
<tr>
<td>13463-67-7 titanium dioxide</td>
<td></td>
<td>10* 4** mg/m³</td>
</tr>
<tr>
<td></td>
<td></td>
<td>total inhalable</td>
</tr>
<tr>
<td></td>
<td></td>
<td>**respirable</td>
</tr>
<tr>
<td>94-36-0 dibenzoyl peroxide</td>
<td></td>
<td>5 mg/m³</td>
</tr>
<tr>
<td>84-61-7 dicyclohexyl phthalate</td>
<td></td>
<td>5 mg/m³</td>
</tr>
</tbody>
</table>

- 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.
**Trade name:** VITA ENAMIC® STAIN

- **Penetration time of glove material**
  The exact breakthrough 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.
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.
Trade name: **VITA ENAMIC® STAIN**

- 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.

<table>
<thead>
<tr>
<th>European waste catalogue</th>
</tr>
</thead>
<tbody>
<tr>
<td>HP5</td>
</tr>
<tr>
<td>HP10</td>
</tr>
</tbody>
</table>

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

### 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: Void
  - 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 Marpol and the IBC Code
  - Not applicable.
- 14.8 UN "Model Regulation": Void

(Contd. on page 8)
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

<table>
<thead>
<tr>
<th>Substances of very high concern (SVHC) according to REACH, Article 57</th>
</tr>
</thead>
<tbody>
<tr>
<td>84-61-7 dicyclohexyl phthalate</td>
</tr>
</tbody>
</table>

- 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