

SAFETY DATA SHEETS

This SDS packet was issued with item:

077076789

The safety data sheets (SDS) in this packet apply to one or more components included in the items listed below. Items listed below may require one or more SDS. Please refer to invoice for specific item number(s).

077062409 077062417 077062425 077062433 077062441 077062458 077062466 077062474 077062482 077062490

077062508 077069784 077071988 077076896 273045119 273045685

Material Safety Data Sheet

acc. to ISO/DIS 11014

Printing date 06/14/2012

Reviewed on 06/14/2012

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

- **Product identifier**
- **Trade name: VITA ENAMIC® STAINS LIQUID**
- **Article number: EENSTL20**
- **Relevant identified uses of the substance or mixture and uses advised against**
- **Application of the substance / the preparation** Light-curing mixing liquid
- **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 Hazards identification

- **Classification of the substance or mixture**



GHS02 Flame

Flam. Liq. 2 H225 Highly flammable liquid and vapour.



GHS07

Skin Irrit. 2 H315 Causes skin irritation.

H319 Causes serious eye irritation.

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

STOT SE 3 H335 May cause respiratory irritation.

- **Classification according to Directive 67/548/EEC or Directive 1999/45/EC**



Xi; Irritant

R36/37/38-43: Irritating to eyes, respiratory system and skin. May cause sensitization by skin contact.



F; Highly flammable

R11: Highly flammable.

- **Information concerning particular hazards for human and environment:**

The product has to be labelled due to the calculation procedure of the "General Classification guideline for preparations of the EU" in the latest valid version.

- **Classification system:**

The classification was made according to the latest editions of international substances lists, and expanded upon from company and literature data.

(Contd. on page 2)

USA

Material Safety Data Sheet

acc. to ISO/DIS 11014

Printing date 06/14/2012

Reviewed on 06/14/2012

Trade name: VITA ENAMIC® STAINS LIQUID

(Contd. of page 1)

- **Label elements**

- **Labelling according to EU guidelines:**

The product has been classified and marked in accordance with directives on hazardous materials.

- **Code letter and hazard designation of product:**



Xi Irritant
F Highly flammable

- **Hazard-determining components of labelling:**

methyl methacrylate
aromatic urethanmethacrylate

- **Risk phrases:**

11 Highly flammable.
36/37/38 Irritating to eyes, respiratory system and skin.
43 May cause sensitization by skin contact.

- **Safety phrases:**

9 Keep container in a well-ventilated place.
16 Keep away from sources of ignition - No smoking.
23 Do not breathe gas/fumes/vapour/spray.
24 Avoid contact with skin.
37 Wear suitable gloves.
60 This material and its container must be disposed of as hazardous waste.

- **Classification system:**

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



Health = 1
Fire = 3
Reactivity = 0

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



Health = 1
Fire = 3
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:** Activating liquid of Methacrylate acid ester

- **Dangerous components:**

80-62-6	methyl methacrylate	25-50%
	Flam. Liq. 2, H225; Skin Irrit. 2, H315; Skin Sens. 1, H317; STOT SE 3, H335	
	aromatic urethanmethacrylate	25-50%
	Skin Irrit. 2, H315; H319; Skin Sens. 1, H317	

(Contd. on page 3)

USA

Material Safety Data Sheet

acc. to ISO/DIS 11014

Printing date 06/14/2012

Reviewed on 06/14/2012

Trade name: VITA ENAMIC® STAINS LIQUID

(Contd. of page 2)

- **Additional information:** For the wording of the listed risk phrases refer to section 16.

4 First aid measures

- **Description of first aid measures**
- **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.
- **After eye contact:**
Rinse opened eye for several minutes under running water. If symptoms persist, consult a doctor.
- **After swallowing:** If symptoms persist consult doctor.
- **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 Firefighting measures

- **Extinguishing media**
- **Suitable extinguishing agents:** CO₂, sand, extinguishing powder. Do not use water.
- **For safety reasons unsuitable extinguishing agents:**
Water
Water with full jet
- **Special hazards arising from the substance or mixture**
No further relevant information available.
- **Advice for firefighters**
- **Protective equipment:** No special measures required.

6 Accidental release measures

- **Personal precautions, protective equipment and emergency procedures**
Keep away from ignition sources
Wear protective equipment. Keep unprotected persons away.
- **Environmental precautions:**
Prevent seepage into sewage system, workpits and cellars.
Do not allow to enter sewers/ surface or ground water.
- **Methods and material for containment and cleaning up:**
Absorb with liquid-binding material (sand, diatomite, acid binders, universal binders, sawdust).
Ensure adequate ventilation.
Do not flush with water or aqueous cleansing agents
- **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.

7 Handling and storage

- **Handling:**
- **Precautions for safe handling**
Ensure good ventilation/exhaustion at the workplace.

(Contd. on page 4)

—USA—

Material Safety Data Sheet

acc. to ISO/DIS 11014

Printing date 06/14/2012

Reviewed on 06/14/2012

Trade name: VITA ENAMIC® STAINS LIQUID

(Contd. of page 3)

- Prevent formation of aerosols.
- **Information about protection against explosions and fires:**
Keep ignition sources away - Do not smoke.
Protect against electrostatic charges.
- **Conditions for safe storage, including any incompatibilities**
- **Storage:**
- **Requirements to be met by storerooms and receptacles:**
Store between 15 °C and 30 °C in a dry and well ventilated place. Avoid temperatures exceeding 50 °C or falling below 5 °C.
Protect against sunlight.
Store in a cool location.
- **Information about storage in one common storage facility:** Not required.
- **Further information about storage conditions:**
Keep receptacle tightly sealed.
Store in cool, dry conditions in well sealed receptacles.
- **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:**

80-62-6 methyl methacrylate

PEL	410 mg/m ³ , 100 ppm
REL	410 mg/m ³ , 100 ppm
TLV	Short-term value: 410 mg/m ³ , 100 ppm Long-term value: 205 mg/m ³ , 50 ppm
SEN	

- **Additional information:** The lists that were valid during the creation were used as basis.
- **Exposure controls**
- **Personal protective equipment:**
- **General protective and hygienic measures:**
Keep away from foodstuffs, beverages and feed.
Immediately remove all soiled and contaminated clothing.
Wash hands before breaks and at the end of work.
Avoid contact with the eyes and skin.
- **Breathing equipment:**
In case of brief exposure or low pollution use respiratory filter device. In case of intensive or longer exposure use respiratory protective device that is independent of circulating air.
- **Protection of hands:**



Protective gloves

The glove material has to be impermeable and resistant to the product/ the substance/ the preparation.
Due to missing tests no recommendation to the glove material can be given for the product/ the preparation/ the chemical mixture.
Selection of the glove material on consideration of the penetration times, rates of diffusion and the degradation

(Contd. on page 5)

USA

Material Safety Data Sheet

acc. to ISO/DIS 11014

Printing date 06/14/2012

Reviewed on 06/14/2012

Trade name: VITA ENAMIC® STAINS LIQUID

(Contd. of page 4)

- **Material of gloves**

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.

- **Eye protection:**



Tightly sealed goggles

- **Body protection:** Protective work clothing

9 Physical and chemical properties

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

- **General Information**

- **Appearance:**

Form:	Fluid
Color:	Yellow tint
Odor:	Characteristic
Odour threshold:	Not determined.

pH-value:	Not determined.
-----------	-----------------

- **Change in condition**

Melting point/Melting range:	Undetermined.
Boiling point/Boiling range:	101°C (214 °F)

Flash point:	10°C (50 °F)
--------------	--------------

Flammability (solid, gaseous):	Not applicable.
--------------------------------	-----------------

Ignition temperature:	430°C (806 °F)
-----------------------	----------------

Decomposition temperature:	Not determined.
----------------------------	-----------------

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

Danger of explosion:	Product is not explosive. However, formation of explosive air/vapor mixtures are possible.
----------------------	--

- **Explosion limits:**

Lower:	2.1 Vol %
Upper:	12.5 Vol %

Vapor pressure at 20°C (68 °F):	47 hPa (35 mm Hg)
---------------------------------	-------------------

Density:	Not determined.
Relative density	Not determined.
Vapour density	Not determined.
Evaporation rate	Not determined.

- **Solubility in / Miscibility with**

Water:	Not miscible or difficult to mix.
--------	-----------------------------------

(Contd. on page 6)

USA

Material Safety Data Sheet

acc. to ISO/DIS 11014

Printing date 06/14/2012

Reviewed on 06/14/2012

Trade name: VITA ENAMIC® STAINS LIQUID

(Contd. of page 5)

- | | |
|---|-----------------|
| · Segregation coefficient (n-octanol/water): Not determined. | |
| · Viscosity: | |
| Dynamic: | Not determined. |
| Kinematic: | Not determined. |
| · Solvent content: | |
| Organic solvents: | 0.0 % |
| · Other information No further relevant information available. | |

10 Stability and reactivity

- **Reactivity**
- **Chemical stability**
- **Thermal decomposition / conditions to be avoided:**
No decomposition if used according to specifications.
- **Possibility of hazardous reactions** No dangerous reactions known.
- **Conditions to avoid** No further relevant information available.
- **Incompatible materials:** No further relevant information available.
- **Hazardous decomposition products:** No dangerous decomposition products known.

11 Toxicological information

- **Information on toxicological effects**
- **Acute toxicity:**
- **Primary irritant effect:**
- **on the skin:** Irritant to skin and mucous membranes.
- **on the eye:** Irritating effect.
- **Sensitization:** Sensitization possible through skin contact.
- **Additional toxicological information:**
The product shows the following dangers according to internally approved calculation methods for preparations:
Irritant

- **Carcinogenic categories**

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

80-62-6 | methyl methacrylate

3

- **NTP (National Toxicology Program)**

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.

(Contd. on page 7)

—USA—

Material Safety Data Sheet

acc. to ISO/DIS 11014

Printing date 06/14/2012

Reviewed on 06/14/2012

Trade name: VITA ENAMIC® STAINS LIQUID

(Contd. of page 6)

- **Additional ecological information:**

- **General notes:**

Water hazard class 1 (Self-assessment): slightly hazardous for water

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:**

Disposal must be made according to official regulations.

Must not be disposed of together with household garbage. Do not allow product to reach sewage system.

- **Uncleaned packagings:**

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

14 Transport information

- **UN-Number**

- **DOT, ADR, IMDG, IATA**

UN1247

- **UN proper shipping name**

- **DOT, IMDG, IATA**

METHYL METHACRYLATE MONOMER, STABILIZED

- **ADR**

1247 METHYLMETHACRYLAT, MONOMER, STABILISIERT

- **Transport hazard class(es)**

- **DOT**



- **Class**

3 Flammable liquids.

- **Label**

3

- **ADR, IMDG, IATA**



- **Class**

3 Flammable liquids

- **Label**

3

- **Packing group**

- **DOT, ADR, IMDG, IATA**

II

(Contd. on page 8)

—USA—

Material Safety Data Sheet

acc. to ISO/DIS 11014

Printing date 06/14/2012

Reviewed on 06/14/2012

Trade name: VITA ENAMIC® STAINS LIQUID

(Contd. of page 7)

· Environmental hazards:	
· Marine pollutant:	No
· Special precautions for user	Warning: Flammable liquids
· Danger code (Kemler):	339
· EMS Number:	F-E,S-D
· Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code	Not applicable.
· UN "Model Regulation":	UN1247, METHYL METHACRYLATE MONOMER, STABILIZED, 3, II

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):**

80-62-6 | methyl methacrylate

- **TSCA (Toxic Substances Control Act):**

All ingredients are listed.

- **Proposition 65**

- **Chemicals known to cause cancer:**

None of the ingredients is listed.

- **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.

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

None of the ingredients is listed.

- **Carcinogenicity categories**

- **EPA (Environmental Protection Agency)**

80-62-6 | methyl methacrylate

NL

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

80-62-6 | methyl methacrylate

A4

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

None of the ingredients is listed.

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

None of the ingredients is listed.

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

None of the ingredients is listed.

- **Product related hazard informations:**

The product has been classified and marked in accordance with directives on hazardous materials.

(Contd. on page 9)

USA

Material Safety Data Sheet

acc. to ISO/DIS 11014

Printing date 06/14/2012

Reviewed on 06/14/2012

Trade name: VITA ENAMIC® STAINS LIQUID

(Contd. of page 8)

· **Hazard symbols:**



Xi Irritant
F Highly flammable

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

methyl methacrylate
aromatic urethanmethacrylate

· **Risk phrases:**

11 Highly flammable.
36/37/38 Irritating to eyes, respiratory system and skin.
43 May cause sensitization by skin contact.

· **Safety phrases:**

9 Keep container in a well-ventilated place.
16 Keep away from sources of ignition - No smoking.
23 Do not breathe gas/fumes/vapour/spray.
24 Avoid contact with skin.
37 Wear suitable gloves.
60 This material and its container must be disposed of as hazardous waste.

· **National regulations:**

· **Technical instructions (air):**

Class	Share in %
NK	25-50

- **Water hazard class:** Water hazard class 1 (Self-assessment): slightly hazardous for water.
- **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.

· **Abbreviations and acronyms:**

RID: Règlement international concernant le transport des marchandises dangereuses par chemin de fer (Regulations Concerning the International Transport of Dangerous Goods by Rail)
ICAO: International Civil Aviation Organization
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
NFPA: National Fire Protection Association (USA)
HMIS: Hazardous Materials Identification System (USA)

—USA—

Material Safety Data Sheet

acc. to ISO/DIS 11014

Printing date 06/14/2012

Reviewed on 06/14/2012

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

- **Product identifier**
- **Trade name:** VITA ENAMIC® STAIN
- **Article number:** EENST012, EENST022, EENST032, EENST042, EENST052, EENST062
- **Relevant identified uses of the substance or mixture and uses advised against**
- **Application of the substance / the preparation** Colours to paint resin, 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 Hazards identification

- **Classification of the substance or mixture**

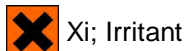


GHS07

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

Acute Tox. 5 H333 May be harmful if inhaled.

- **Classification according to Directive 67/548/EEC or Directive 1999/45/EC**



Xi; Irritant

R43: May cause sensitization by skin contact.

- **Information concerning particular hazards for human and environment:**

The product has to be labelled due to the calculation procedure of the "General Classification guideline for preparations of the EU" in the latest valid version.

- **Classification system:**

The classification was made according to the latest editions of international substances lists, and expanded upon from company and literature data.

- **Label elements**

- **Labelling according to EU guidelines:**

The product has been classified and marked in accordance with directives on hazardous materials.

- **Code letter and hazard designation of product:**



Xi Irritant

- **Hazard-determining components of labelling:**

dibenzoyl peroxide

(Contd. on page 2)

—USA—

Material Safety Data Sheet

acc. to ISO/DIS 11014

Printing date 06/14/2012

Reviewed on 06/14/2012

Trade name: VITA ENAMIC® STAIN

(Contd. of page 1)

- **Risk phrases:**

43 May cause sensitization by skin contact.

- **Safety phrases:**

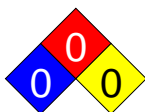
24 Avoid contact with skin.

37 Wear suitable gloves.

60 This material and its container must be disposed of as hazardous waste.

- **Classification system:**

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



Health = 0

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	50-100%
13463-67-7	titanium dioxide	2.5-10%
	Acute Tox. 5, H333	
94-36-0	dibenzoyl peroxide	≤ 2.5%
	Org. Perox. B, H241; Eye Irrit. 2, H319; Skin Sens. 1, H317	

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

4 First aid measures

- **Description of first aid measures**

- **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:**

If skin irritation continues, consult a doctor.

Immediately wash with water and soap and rinse thoroughly.

• **After eye contact:** Rinse opened eye for several minutes under running water.

• **After swallowing:** If symptoms persist consult doctor.

- **Information for doctor:**

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

No further relevant information available.

(Contd. on page 3)

—USA—

Material Safety Data Sheet

acc. to ISO/DIS 11014

Printing date 06/14/2012

Reviewed on 06/14/2012

Trade name: VITA ENAMIC® STAIN

(Contd. of page 2)

- **Indication of any immediate medical attention and special treatment needed**
No further relevant information available.

5 Firefighting measures

- **Extinguishing media**
- **Suitable extinguishing agents:**
CO₂, extinguishing powder or water spray. Fight larger fires with water spray or alcohol resistant foam.
- **Special hazards arising from the substance or mixture**
No further relevant information available.
- **Advice for firefighters**
- **Protective equipment:** No special measures required.

6 Accidental release measures

- **Personal precautions, protective equipment and emergency procedures**
Avoid formation of dust.
- **Environmental precautions:** No special measures required.
- **Methods and material for containment and cleaning up:** Pick up mechanically.
- **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.

7 Handling and storage

- **Handling:**
- **Precautions for safe handling** Avoid contact with skin and eyes.
- **Information about protection against explosions and fires:** No special measures required.
- **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.
- **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	½ value from respirable dust formulae for Quartz
REL	0.05* mg/m ³
	*respirable dust; See Pocket Guide App. A
TLV	0.025* mg/m ³
	*as respirable fraction

(Contd. on page 4)

—USA—

Material Safety Data Sheet

acc. to ISO/DIS 11014

Printing date 06/14/2012

Reviewed on 06/14/2012

Trade name: VITA ENAMIC® STAIN

(Contd. of page 3)

13463-67-7 titanium dioxide

PEL	15* mg/m ³ *total dust
REL	See Pocket Guide App. A
TLV	10 mg/m ³

94-36-0 dibenzoyl peroxide

PEL	5 mg/m ³
REL	5 mg/m ³
TLV	5 mg/m ³

- **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.
Immediately remove all soiled and contaminated clothing.
Wash hands before breaks and at the end of work.
- **Breathing equipment:** Filter P2
- **Protection of hands:**



Protective gloves

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

Due to missing tests no recommendation to the glove material can be given for the product/ the preparation/ the chemical mixture.

Selection of the glove material on consideration of the penetration times, rates of diffusion and the degradation

- **Material of gloves**

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.

- **Eye protection:** Not required.
- **Body protection:** Protective work clothing

9 Physical and chemical properties

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

- **General Information**

- **Appearance:**

Form:	Powder
Color:	Different according to coloring

- **Odor:** Characteristic
- **Odour threshold:** Not determined.

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

(Contd. on page 5)

USA

Material Safety Data Sheet

acc. to ISO/DIS 11014

Printing date 06/14/2012

Reviewed on 06/14/2012

Trade name: VITA ENAMIC® STAIN

(Contd. of page 4)

· Change in condition Melting point/Melting range:	Undetermined.
Boiling point/Boiling range:	Undetermined.
· Flash point:	Not applicable.
· Flammability (solid, gaseous):	Not determined.
· Ignition temperature:	
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.
· Vapor pressure:	Not applicable.
· Density at 20°C (68 °F):	2.3 g/cm ³ (19.194 lbs/gal)
· Relative density	Not determined.
· Vapour density	Not applicable.
· Evaporation rate	Not applicable.
· Solubility in / Miscibility with Water:	Insoluble.
· Segregation coefficient (n-octanol/water):	Not determined.
· Viscosity: Dynamic:	Not applicable.
Kinematic:	Not applicable.
· Solvent content: Organic solvents:	0.0 %
· Other information	No further relevant information available.

10 Stability and reactivity

- **Reactivity**
- **Chemical stability**
- **Thermal decomposition / conditions to be avoided:**
Heating above 30°C, decomposition of dibenzoyl peroxide
- **Possibility of hazardous reactions** No dangerous reactions known.
- **Conditions to avoid** No further relevant information available.
- **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.)

(Contd. on page 6)

USA

Material Safety Data Sheet

acc. to ISO/DIS 11014

Printing date 06/14/2012

Reviewed on 06/14/2012

Trade name: VITA ENAMIC® STAIN

(Contd. of page 5)

- **Primary irritant effect:**
- **on the skin:** No irritant effect.
- **on the eye:** No irritant effect.
- **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
------------	--------------	---

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:** Generally not hazardous for water
- **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:**
Disposal must be made according to official regulations.
Must not be disposed of together with household garbage. Do not allow product to reach sewage system.
- **Waste disposal key:** 31443
- **Uncleaned packagings:**
- **Recommendation:** Disposal must be made according to official regulations.

14 Transport information

- **UN-Number**
- **DOT, ADN, IMDG, IATA** Void

(Contd. on page 7)

USA

Material Safety Data Sheet

acc. to ISO/DIS 11014

Printing date 06/14/2012

Reviewed on 06/14/2012

Trade name: VITA ENAMIC® STAIN

(Contd. of page 6)

· UN proper shipping name	
· DOT, ADN, IMDG, IATA	Void
· Transport hazard class(es)	
· DOT, ADN, IMDG, IATA	
· Class	Void
· Packing group	
· DOT, IMDG, IATA	Void
· Environmental hazards:	
· 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":	-

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):

All ingredients are listed.

· Proposition 65

· Chemicals known to cause cancer:

None of the ingredients is listed.

· 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.

· Chemicals known to cause developmental toxicity:

None of the ingredients is listed.

· Cancerogenity 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

(Contd. on page 8)

USA

Material Safety Data Sheet

acc. to ISO/DIS 11014

Printing date 06/14/2012

Reviewed on 06/14/2012

Trade name: VITA ENAMIC® STAIN

(Contd. of page 7)

• **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

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

None of the ingredients is listed.

• **Product related hazard informations:**

The product has been classified and marked in accordance with directives on hazardous materials.

• **Hazard symbols:**



Xi Irritant

• **Hazard-determining components of labelling:**

dibenzoyl peroxide

• **Risk phrases:**

43 May cause sensitization by skin contact.

• **Safety phrases:**

24 Avoid contact with skin.

37 Wear suitable gloves.

60 This material and its container must be disposed of as hazardous waste.

• **National regulations:**

• **Water hazard class:** Generally not hazardous for water.

• **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.

• **Abbreviations and acronyms:**

ICAO: International Civil Aviation Organization

IMDG: International Maritime Code for Dangerous Goods

DOT: US Department of Transportation

IATA: International Air Transport Association

ACGIH: American Conference of Governmental Industrial Hygienists

NFPA: National Fire Protection Association (USA)

HMIS: Hazardous Materials Identification System (USA)

LC50: Lethal concentration, 50 percent

LD50: Lethal dose, 50 percent

USA

Safety data sheet

according to 1907/2006/EC, Article 31

Printing date 30.07.2012

Version number 1

Revision: 30.07.2012

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

- **Product identifier**
- **Trade name:** VITA ENAMIC
- **Article number:** EC4...
- **Relevant identified uses of the substance or mixture and uses advised against** Not determined
- **Article category** AC4 Stone, plaster, cement, glass and ceramic articles
- **Application of the substance / product** Auxiliary for manufacture of dental prothesis
- **Details of the supplier of the safety data sheet**
- **Manufacturer/Supplier:**
VITA Zahnfabrik
H. Rauter GmbH & Co. KG
- Postfach 1338
D 79704 Bad Säckingen
e-mail: info@vita-zahnfabrik.com
- **Emergency telephone number:** Tel.: ++49-(0)7761-562-0

Tel.: 07761/562-0
Fax: 07761/562299

2 Hazards identification

- **Classification of the substance or mixture**
- **Classification according to Regulation (EC) No 1272/2008**
The product is not classified according to the CLP regulation.
- **Classification according to Directive 67/548/EEC or Directive 1999/45/EC** Void
- **Information concerning particular hazards for human and environment:**
The product does not have to be labelled due to the calculation procedure of the "General Classification guideline for preparations of the EU" in the latest valid version.
- **Classification system:**
The classification is according to the latest editions of the EU-lists, and extended by company and literature data.
- **Label elements** None
- **Labelling according to EU guidelines:**
Observe the general safety regulations when handling chemicals
The product is not subject to identification regulations under EU Directives and the Ordinance on Hazardous Materials (German GefStoffV).
- **Safety phrases:**
29 Do not empty into drains.
- **Other hazards**
- **Results of PBT and vPvB assessment**
- **PBT:** Not applicable.
- **vPvB:** Not applicable.

3 Composition/information on ingredients

- **Chemical characterization: Mixtures**
AC4 Stone, plaster, cement, glass and ceramic articles
article
- **Description:** Porous sintered ceramic network whose pores are filled with plastic.
- **Dangerous components:** Void
- **Additional information** For the wording of the listed risk phrases refer to section 16.

GB

(Contd. on page 2)

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

Printing date 30.07.2012

Version number 1

Revision: 30.07.2012

Trade name: VITA ENAMIC

(Contd. of page 1)

4 First aid measures

- **Description of first aid measures**
- **General information** No special measures required.
- **After inhalation** Supply fresh air.
- **After skin contact** Generally the product does not irritate the skin.
- **After eye contact** Rinse opened eye for several minutes under running water.
- **After swallowing** If symptoms persist consult doctor.
- **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 Firefighting measures

- **Extinguishing media**
- **Suitable extinguishing agents**
CO₂, powder or water spray. Fight larger fires with water spray or alcohol resistant foam.
- **Special hazards arising from the substance or mixture** No further relevant information available.
- **Advice for firefighters**
- **Protective equipment:** No special measures required.

6 Accidental release measures

- **Personal precautions, protective equipment and emergency procedures** Not required.
- **Environmental precautions:** Do not allow product to reach sewage system or any water course.
- **Methods and material for containment and cleaning up:** No special measures required.
- **Reference to other sections**
No dangerous substances are released.
See Section 7 for information on safe handling
See Section 8 for information on personal protection equipment.
See Section 13 for disposal information.

7 Handling and storage

- **Handling**
- **Precautions for safe handling** No special measures required.
- **Information about fire - and explosion protection:** No special measures required.
- **Conditions for safe storage, including any incompatibilities**
- **Storage**
- **Requirements to be met by storerooms and receptacles:** No special requirements.
- **Information about storage in one common storage facility:** Not required.
- **Further information about storage conditions:** None.
- **Storage class 10**
- **Specific end use(s)** No further relevant information available.

8 Exposure controls/personal protection

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

(Contd. on page 3)

GB

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

Printing date 30.07.2012

Version number 1

Revision: 30.07.2012

Trade name: VITA ENAMIC

(Contd. of page 2)

- **Control parameters**
- **Ingredients with limit values that require monitoring at the workplace:**
The product does not contain any relevant quantities of materials with critical values that have to be monitored at the workplace.
- **Additional information:** The lists valid during the making were used as basis.
- **Exposure controls**
- **Personal protective equipment**
- **General protective and hygienic measures**
The usual precautionary measures are to be adhered to when handling chemicals.
- **Respiratory protection:** Not required.
- **Protection of hands:** Not required.
- **Material of gloves -**
- **Penetration time of glove material -**
- **Eye protection:** Not required.

*

9 Physical and chemical properties

- **Information on basic physical and chemical properties**
- **General Information**
- **Appearance:**

Form:	Solid.
Colour:	According to product specification
- **Odour:** Odourless
- **Odour threshold:** Not determined.
- **pH-value:** Not determined.
- **Change in condition**

Melting point/Melting range:	undetermined
Boiling point/Boiling range:	undetermined
- **Flash point:** Not applicable
- **Flammability (solid, gaseous)** Not applicable.
- **Ignition temperature:**
- **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.
- **Oxidizing properties** Not applicable
- **Vapour pressure:** Not determined.
- **Density at 20°C:** 2 g/cm³
- **Relative density** Not determined.
- **Vapour density** Not determined.
- **Evaporation rate** Not determined.
- **Solubility in / Miscibility with**

Water:	Not miscible or difficult to mix
--------	----------------------------------
- **Segregation coefficient (n-octanol/water):** Not determined.
- **Viscosity:**

dynamic:	Not determined.
----------	-----------------

(Contd. on page 4)

GB

Safety data sheet

according to 1907/2006/EC, Article 31

Printing date 30.07.2012

Version number 1

Revision: 30.07.2012

Trade name: VITA ENAMIC

(Contd. of page 3)

kinematic:	Not determined.
-------------------	-----------------

· Solvent content:	
---------------------------	--

· Organic solvents:	0.0 %
----------------------------	-------

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

10 Stability and reactivity

- **Reactivity** No decomposition if used and stored according to specifications.
- **Chemical stability** No decomposition if used and stored according to specifications.
- **Thermal decomposition / conditions to be avoided:** No decomposition if used according to specifications.
- **Possibility of hazardous reactions** No dangerous reactions known
- **Conditions to avoid** No further relevant information available.
- **Incompatible materials:** No further relevant information available.
- **Hazardous decomposition products:** No dangerous decomposition products known

11 Toxicological information

- **Information on toxicological effects**
- **Acute toxicity:**
- **Primary irritant effect:**
- **on the skin:** No irritant effect.
- **on the eye:** No irritating effect.
- **Sensitization:** No sensitizing effects known.
- **Additional toxicological information:**

The product is not subject to classification according to the calculation method of the General EU Classification Guidelines for Preparations as issued in the latest version.

When used and handled according to specifications, the product does not have any harmful effects to our experience and the information provided to us.

12 Ecological information

- **Toxicity**
- **Aquatic toxicity:** No further relevant information available.
- **Persistence and degradability** No further relevant information available.
- **Behaviour in environmental systems:**
- **Bioaccumulative potential** No further relevant information available.
- **Mobility in soil** No further relevant information available.
- **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** Disposal must be made according to official regulations.
- **Uncleaned packaging:**
- **Recommendation:** Disposal must be made according to official regulations.

GB

(Contd. on page 5)

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

Printing date 30.07.2012

Version number 1

Revision: 30.07.2012

Trade name: VITA ENAMIC

(Contd. of page 4)

*

14 Transport information

· UN-Number	
· ADR, ADN, IMDG, IATA	Void
· UN proper shipping name	
· ADR, ADN, IMDG, IATA	Void
· Transport hazard class(es)	
· ADR, ADN, IMDG, IATA	
· Class	Void
· Packing group	
· ADR, IMDG, IATA	Void
· Environmental hazards:	
· 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.
· Transport/Additional information:	Not dangerous according to the above specifications.
· UN "Model Regulation":	-

15 Regulatory information

- **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.

- *** Data compared to the previous version altered.**

GB

Safety Data Sheet

acc. to OSHA HCS

Printing date 06/03/2014

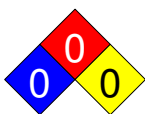
Reviewed on 06/03/2014

1 Identification

- **Product identifier**
- **Trade name:** VITA ENAMIC
- **Article number:** EC4...
- **Relevant identified uses of the substance or mixture and uses advised against** Not determined
- **Article category** AC4 Stone, plaster, cement, glass and ceramic articles
- **Application of the substance / the mixture** Auxiliary for manufacture of dental prothesis
- **Details of the supplier of the safety data sheet**
- **Manufacturer/Supplier:**
VITA Zahnfabrik
H. Rauter GmbH & Co. KG
- Postfach 1338
D 79704 Bad Säckingen
e-mail: info@vita-zahnfabrik.com
- **Emergency telephone number:** Tel.: ++49-(0)7761-562-0

Tel.: 07761/562-0
Fax: 07761/562299

2 Hazard(s) identification

- **Classification of the substance or mixture**
The product is not classified according to the Globally Harmonized System (GHS).
 - **Classification according to Directive 67/548/EEC or Directive 1999/45/EC** not applicable
 - **Information concerning particular hazards for human and environment:**
The product does not have to be labelled due to the calculation procedure of the "General Classification guideline for preparations of the EU" in the latest valid version.
 - **Classification system:**
The classification was made according to the latest editions of international substances lists, and expanded upon from company and literature data.
 - **Label elements** None
 - **GHS label elements** Void
 - **Hazard pictograms** Void
 - **Signal word** Void
 - **Hazard statements** Void
 - **Classification system**
 - **NFPA 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 article
- **Description:** Porous sintered ceramic network whose pores are filled with plastic.
- **Dangerous components:** Void

(Contd. on page 2)

USA

Safety Data Sheet

acc. to OSHA HCS

Printing date 06/03/2014

Reviewed on 06/03/2014

Trade name: VITA ENAMIC

(Contd. of page 1)

· **Additional information** For the wording of the listed risk phrases refer to section 16.

4 First-aid measures

- **Description of first aid measures**
- **General information** No special measures required.
- **After inhalation** Supply fresh air.
- **After skin contact** Generally the product does not irritate the skin.
- **After eye contact** Rinse opened eye for several minutes under running water.
- **After swallowing** If symptoms persist consult doctor.
- **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.
- **Special hazards arising from the substance or mixture** No further relevant information available.
- **Advice for firefighters**
- **Protective equipment:** No special measures required.

6 Accidental release measures

- **Personal precautions, protective equipment and emergency procedures** Not required.
- **Environmental precautions:** Do not allow product to reach sewage system or any water course.
- **Methods and material for containment and cleaning up:**
Absorb with liquid-binding material (sand, diatomite, acid binders, universal binders, sawdust).
- **Reference to other sections**
No dangerous substances are released.
See Section 7 for information on safe handling
See Section 8 for information on personal protection equipment.
See Section 13 for disposal information.

7 Handling and storage

- **Handling**
- **Precautions for safe handling** No special measures required.
- **Information about protection against explosions and fires:** No special measures required.
- **Conditions for safe storage, including any incompatibilities**
- **Storage**
- **Requirements to be met by storerooms and receptacles:** No special requirements.
- **Information about storage in one common storage facility:** Not required.
- **Further information about storage conditions:** None.
- **Storage class** 10
- **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.

(Contd. on page 3)

USA

Safety Data Sheet

acc. to OSHA HCS

Printing date 06/03/2014

Reviewed on 06/03/2014

Trade name: VITA ENAMIC

(Contd. of page 2)

- **Control parameters**
- **Components with limit values that require monitoring at the workplace:**
The product does not contain any relevant quantities of materials with critical values that have to be monitored at the workplace.
- **Additional information:** The lists that were valid during the creation were used as basis.
- **Exposure controls**
- **Personal protective equipment**
- **General protective and hygienic measures**
The usual precautionary measures for handling chemicals should be followed.
- **Breathing equipment:** Not required.
- **Protection of hands:**
Protective gloves and protective skin cream.
The glove material has to be impermeable and resistant to the product/ the substance/ the preparation.
Due to missing tests no recommendation to the glove material can be given for the product/ the preparation/ the chemical mixture.
Selection of the glove material on consideration of the penetration times, rates of diffusion and the degradation
- **Material of gloves**
Nitrile rubber, NBR
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.
- **Eye protection:** Not required.

9 Physical and chemical properties

- **Information on basic physical and chemical properties**
- **General Information**
- **Appearance:**

Form:	Solid.
Color:	According to product specification
- **Odor:** Odorless
- **Odour threshold:** Not determined.
- **pH-value:** Not determined.
- **Change in condition**

Melting point/Melting range:	undetermined
Boiling point/Boiling range:	undetermined
- **Flash point:** Not applicable
- **Flammability (solid, gaseous)** Not applicable.
- **Ignition temperature:**
- **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.
--------	-----------------

(Contd. on page 4)

USA

Safety Data Sheet

acc. to OSHA HCS

Printing date 06/03/2014

Reviewed on 06/03/2014

Trade name: VITA ENAMIC

(Contd. of page 3)

Upper:	Not determined.
· Oxidizing properties	Not applicable
· Vapor pressure:	Not determined.
· Density at 20 °C (68 °F):	2 g/cm ³ (16.69 lbs/gal)
· Relative density	Not determined.
· Vapour density	Not determined.
· Evaporation rate	Not determined.
· Solubility in / Miscibility with Water:	Not miscible or difficult to mix
· Partition coefficient (n-octanol/water):	Not determined.
· Viscosity:	
dynamic:	Not determined.
kinematic:	Not determined.
· Solvent content:	
Organic solvents:	0.0 %
· Other information	No further relevant information available.

10 Stability and reactivity

- **Reactivity** No decomposition if used and stored according to specifications.
- **Chemical stability** No decomposition if used and stored according to specifications.
- **Thermal decomposition / conditions to be avoided:** No decomposition if used according to specifications.
- **Possibility of hazardous reactions** No dangerous reactions known
- **Conditions to avoid** No further relevant information available.
- **Incompatible materials:** No further relevant information available.
- **Hazardous decomposition products:** No dangerous decomposition products known

11 Toxicological information

- **Information on toxicological effects**
- **Acute toxicity:**
- **Primary irritant effect:**
- **on the skin:** No irritant effect.
- **on the eye:** No irritating effect.
- **Sensitization:** No sensitizing effects known.
- **Additional toxicological information:**
The product is not subject to classification according to internally approved calculation methods for preparations:
When used and handled according to specifications, the product does not have any harmful effects according to our experience and the information provided to us.
- **Carcinogenic categories**
- **IARC (International Agency for Research on Cancer)**
None of the ingredients is listed.
- **NTP (National Toxicology Program)**
None of the ingredients is listed.

USA

(Contd. on page 5)

Safety Data Sheet

acc. to OSHA HCS

Printing date 06/03/2014

Reviewed on 06/03/2014

Trade name: VITA ENAMIC

(Contd. of page 4)

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:**
Water hazard class 1 (Self-assessment): slightly hazardous for water.
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** Disposal must be made according to official regulations.
- **Uncleaned packagings:**
- **Recommendation:** Disposal must be made according to official regulations.

14 Transport information

- | | |
|--|--|
| · UN-Number | |
| · DOT, ADR, ADN, IMDG, IATA | Void |
| · UN proper shipping name | |
| · DOT, ADN, IMDG, IATA | Void |
| · ADR | Void |
| · Transport hazard class(es) | |
| · DOT, ADR, ADN, IMDG, IATA | |
| · Class | Void |
| · Packing group | |
| · DOT, ADR, IMDG, IATA | Void |
| · Environmental hazards: | |
| · 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. |
| · Transport/Additional information: | Not dangerous according to the above specifications. |
| · UN "Model Regulation": | - |

USA

(Contd. on page 6)

Safety Data Sheet

acc. to OSHA HCS

Printing date 06/03/2014

Reviewed on 06/03/2014

Trade name: VITA ENAMIC

(Contd. of page 5)

15 Regulatory information

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

· **SARA Section 355 (extremely hazardous substances)**

None of the ingredients is listed.

· **SARA Section 313 (specific toxic chemical listings)**

None of the ingredients is listed.

· **TSCA (Toxic Substances Control Act)**

Ceramic frits, chemicals

· **Prop 65 - Chemicals known to cause cancer**

None of the ingredients is listed.

· **Cancerogenity categories**

· **EPA (Environmental Protection Agency)**

None of the ingredients is listed.

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

None of the ingredients is listed.

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

None of the ingredients is listed.

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

None of the ingredients is listed.

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

None of the ingredients is listed.

· **National regulations**

· **Water hazard class:** Water hazard class 1 (Self-assessment): slightly hazardous for water.

· **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.

· **Abbreviations and acronyms:**

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)

· *** Data compared to the previous version altered.**

USA

Safety Data Sheet

acc. to OSHA HCS

Printing date 08/12/2015

Reviewed on 08/12/2015

1 Identification

- **Product identifier**
- **Trade name: VITA ENAMIC® GLAZE**
- **Article number:** EENSTG20
- **Relevant identified uses of the substance or mixture and uses advised against**
No further relevant information available.
- **Application of the substance / the mixture** Light-polymerising lacquer
- **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**



GHS02 Flame

Flam. Liq. 2 H225 Highly flammable liquid and vapor.



GHS08 Health hazard

Repr. 2 H361 Suspected of damaging fertility or the unborn child.



GHS05 Corrosion

Eye Dam. 1 H318 Causes serious eye damage.



GHS07

Skin Irrit. 2 H315 Causes skin irritation.

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

STOT SE 3 H335 May cause respiratory irritation.

- **Label elements**

- **GHS label elements**

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

(Contd. on page 2)

—US—

Safety Data Sheet

acc. to OSHA HCS

Printing date 08/12/2015

Reviewed on 08/12/2015

Trade name: VITA ENAMIC® GLAZE

(Contd. of page 1)

· Hazard pictograms



GHS02 GHS05 GHS07 GHS08

· Signal word Danger

· Hazard-determining components of labeling:

methyl methacrylate
2-Propenoic acid, reaction product with Pentaerythrite
Diphenyl(2,4,6-trimethylbenzoyl)phosphine oxide

· Hazard statements

Highly flammable liquid and vapor.
Causes skin irritation.
Causes serious eye damage.
May cause an allergic skin reaction.
Suspected of damaging fertility or the unborn child.
May cause respiratory irritation.

· Precautionary statements

Keep away from heat/sparks/open flames/hot surfaces. - No smoking.
IF ON SKIN (or hair): Remove/Take off immediately all contaminated clothing. Rinse skin with water/shower.
If in eyes: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
Immediately call a poison center/doctor.
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 = 3
Reactivity = 0

· HMIS-ratings (scale 0 - 4)



Health = *1
Fire = 3
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: Preparation of methacrylates and amorphous silica.

· Dangerous components:

80-62-6	methyl methacrylate	25-50%
	Acrylic resin	10-25%

(Contd. on page 3)

US

Safety Data Sheet

acc. to OSHA HCS

Printing date 08/12/2015

Reviewed on 08/12/2015

Trade name: VITA ENAMIC® GLAZE

(Contd. of page 2)

1245638-61-2	2-Propenoic acid, reaction product with Pentaerythrite	2.5-10%
75980-60-8	Diphenyl(2,4,6-trimethylbenzoyl)phosphinoxide	2.5-10%
	BYK-UV 3570	≤ 2.5%

- **Additional information:** For the wording of the listed risk 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.
- **After eye contact:**
Rinse opened eye for several minutes under running water. Then consult a doctor.
- **After swallowing:**
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, sand, extinguishing powder. Do not use water.
- **For safety reasons unsuitable extinguishing agents:**
Water
Water with full jet
- **Special hazards arising from the substance or mixture**
No further relevant information available.
- **Advice for firefighters**
- **Protective equipment:** No special measures required.
- **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 contact with skin and eyes.
Wear protective equipment. Keep unprotected persons away.
- **Environmental precautions:**
Prevent seepage into sewage system, workpits and cellars.
Inform respective authorities in case of seepage into water course or sewage system.
Do not allow to enter sewers/ surface or ground water.
- **Methods and material for containment and cleaning up:**
Absorb with liquid-binding material (sand, diatomite, acid binders, universal binders, sawdust).
Ensure adequate ventilation.

(Contd. on page 4)

US

Safety Data Sheet

acc. to OSHA HCS

Printing date 08/12/2015

Reviewed on 08/12/2015

Trade name: VITA ENAMIC® GLAZE

(Contd. of page 3)

Do not flush with water or aqueous cleansing agents

- **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.

7 Handling and storage

- **Handling:**

- **Precautions for safe handling**

Avoid contact with skin and eyes.

Ensure good ventilation/exhaustion at the workplace.

Prevent formation of aerosols.

- **Information about protection against explosions and fires:**

Keep ignition sources away - Do not smoke.

Protect against electrostatic charges.

- **Conditions for safe storage, including any incompatibilities**

- **Storage:**

- **Requirements to be met by storerooms and receptacles:**

Protect from heat and direct sunlight.

Store in a cool location.

- **Information about storage in one common storage facility:** Not required.

- **Further information about storage conditions:**

Keep receptacle tightly sealed.

Store in cool, dry conditions in well sealed receptacles.

- **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:**

80-62-6 methyl methacrylate

PEL	Long-term value: 410 mg/m ³ , 100 ppm
REL	Long-term value: 410 mg/m ³ , 100 ppm
TLV	Short-term value: 410 mg/m ³ , 100 ppm
	Long-term value: 205 mg/m ³ , 50 ppm
	(SEN) NIC-DSEN

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

- **Exposure controls**

- **Personal protective equipment:**

- **General protective and hygienic measures:**

Keep away from foodstuffs, beverages and feed.

Immediately remove all soiled and contaminated clothing.

Wash hands before breaks and at the end of work.

Avoid contact with the eyes and skin.

- **Breathing equipment:**

In case of brief exposure or low pollution use respiratory filter device. In case of intensive or longer exposure use respiratory protective device that is independent of circulating air.

(Contd. on page 5)

US

Safety Data Sheet

acc. to OSHA HCS

Printing date 08/12/2015

Reviewed on 08/12/2015

Trade name: **VITA ENAMIC® GLAZE**

(Contd. of page 4)

• **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**

Penetration time: 60 min

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

9 Physical and chemical properties

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

• **General Information**

• **Appearance:**

Form:	Fluid
Color:	Colorless
• Odor:	Characteristic
• Odour threshold:	Not determined.

• **pH-value:** Not determined.

• **Change in condition**

Melting point/Melting range:	Undetermined.
Boiling point/Boiling range:	101 °C (214 °F)

• **Flash point:** 10 °C (50 °F)

• **Flammability (solid, gaseous):** Not applicable.

(Contd. on page 6)

US

Safety Data Sheet

acc. to OSHA HCS

Printing date 08/12/2015

Reviewed on 08/12/2015

Trade name: **VITA ENAMIC® GLAZE**

(Contd. of page 5)

· Ignition temperature:	430 °C (806 °F)
· Decomposition temperature:	Not determined.
· Auto igniting:	Product is not selfigniting.
· Danger of explosion:	Product is not explosive. However, formation of explosive air/vapor mixtures are possible.
· Explosion limits:	
Lower:	2.1 Vol %
Upper:	12.5 Vol %
· Oxidizing properties	Not determined
· Vapor pressure at 20 °C (68 °F):	47 hPa (35 mm Hg)
· Density at 20 °C (68 °F):	1.03 g/cm ³ (8.595 lbs/gal)
· Relative density	Not determined.
· Vapour density	Not determined.
· Evaporation rate	Not determined.
· Solubility in / Miscibility with Water:	Not miscible or difficult to mix.
· Partition coefficient (n-octanol/water):	Not determined.
· Viscosity:	
Dynamic:	Not determined.
Kinematic:	Not determined.
· Solvent content:	
Organic solvents:	0.0 %
· 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:**
No decomposition if used according to specifications.
Protect from heat and direct sunlight.
- **Possibility of hazardous reactions** No dangerous reactions known.
- **Conditions to avoid** No further relevant information available.
- **Incompatible materials:** No further relevant information available.
- **Hazardous decomposition products:** No decomposition if used according to specifications.

11 Toxicological information

- **Information on toxicological effects**
- **Acute toxicity:**

- **LD/LC50 values that are relevant for classification:**

1245638-61-2 2-Propenoic acid, reaction product with Pentaerythrite

Oral	LD50	>2000 mg/kg (rat)
Dermal	LD50	>2000 mg/kg (rabbit)
Inhalative	LC50/4 h	>5 mg/l (rat)

(Contd. on page 7)

—US—

Safety Data Sheet

acc. to OSHA HCS

Printing date 08/12/2015

Reviewed on 08/12/2015

Trade name: VITA ENAMIC® GLAZE

(Contd. of page 6)

75980-60-8 Diphenyl(2,4,6-trimethylbenzoyl)phosphin oxide

Oral	LD50	>5000 mg/kg (rat)
Dermal	LD50	> 2000 mg/kg (rat) ((OECD 402))

- **Primary irritant effect:**

- **on the skin:** Irritant to skin and mucous membranes.

- **on the eye:** Irritating effect.

- **Sensitization:** Sensitization possible through skin contact.

- **Additional toxicological information:**

The product shows the following dangers according to internally approved calculation methods for preparations:

Irritant

- **Carcinogenic categories**

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

80-62-6	methyl methacrylate	3
1330-20-7	xylene (mix)	3

- **NTP (National Toxicology Program)**

None of the ingredients is listed.

- **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.

- **Ecotoxicological effects:**

- **Remark:** Harmful to fish

- **Additional ecological information:**

- **General notes:**

Do not allow product to reach ground water, water course or sewage system.

Danger to drinking water if even small quantities leak into the ground.

Harmful to aquatic organisms

- **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.

(Contd. on page 8)

—US—

Safety Data Sheet

acc. to OSHA HCS

Printing date 08/12/2015



Reviewed on 08/12/2015

Trade name: **VITA ENAMIC® GLAZE**

(Contd. of page 7)

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

14 Transport information

· UN-Number	
· DOT, ADR, IMDG, IATA	UN1247
· UN proper shipping name	
· DOT, IMDG, IATA	METHYL METHACRYLATE MONOMER, STABILIZED, SOLUTION
· ADR	1247 METHYLMETHACRYLAT, MONOMER, STABILISIERT, LÖSUNG
· Transport hazard class(es)	
· DOT	
	
· Class	3 Flammable liquids
· Label	3
· ADR, IMDG, IATA	
	
· Class	3 Flammable liquids
· Label	3
· Packing group	
· DOT, ADR, IMDG, IATA	II
· Environmental hazards:	
· Marine pollutant:	No
· Special precautions for user	Warning: Flammable liquids
· Danger code (Kemler):	339
· EMS Number:	F-E,S-D
· Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code	Not applicable.
· Transport/Additional information:	
· ADR	
· Excepted quantities (EQ)	Code: E2 Maximum net quantity per inner packaging: 30 ml Maximum net quantity per outer packaging: 500 ml
· IMDG	
· Limited quantities (LQ)	1L

(Contd. on page 9)

—US—

Safety Data Sheet

acc. to OSHA HCS

Printing date 08/12/2015

Reviewed on 08/12/2015

Trade name: **VITA ENAMIC® GLAZE**

(Contd. of page 8)

· Excepted quantities (EQ)	Code: E2 Maximum net quantity per inner packaging: 30 ml Maximum net quantity per outer packaging: 500 ml
· UN "Model Regulation":	UN1247, Methyl methacrylate monomer, stabilized, 3, II

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):**

80-62-6 methyl methacrylate

1330-20-7 xylene (mix)

- **TSCA (Toxic Substances Control Act):**

All ingredients are listed.

- **Proposition 65**

- **Chemicals known to cause cancer:**

None of the ingredients is listed.

- **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.

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

None of the ingredients is listed.

- **Carcinogen categories**

- **EPA (Environmental Protection Agency)**

80-62-6 methyl methacrylate

E, NL

1330-20-7 xylene (mix)

I

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

80-62-6 methyl methacrylate

A4

1330-20-7 xylene (mix)

A4

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

None of the ingredients is listed.

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

None of the ingredients is listed.

- **GHS label elements**

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

(Contd. on page 10)

US

Safety Data Sheet

acc. to OSHA HCS

Printing date 08/12/2015

Reviewed on 08/12/2015

Trade name: VITA ENAMIC® GLAZE

(Contd. of page 9)

· Hazard pictograms



GHS02 GHS05 GHS07 GHS08

· Signal word Danger

· Hazard-determining components of labeling:

methyl methacrylate
2-Propenoic acid, reaction product with Pentaerythrite
Diphenyl(2,4,6-trimethylbenzoyl)phosphin oxide

· Hazard statements

Highly flammable liquid and vapor.
Causes skin irritation.
Causes serious eye damage.
May cause an allergic skin reaction.
Suspected of damaging fertility or the unborn child.
May cause respiratory irritation.

· Precautionary statements

Keep away from heat/sparks/open flames/hot surfaces. - No smoking.
IF ON SKIN (or hair): Remove/Take off immediately all contaminated clothing. Rinse skin with water/shower.
If in eyes: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
Immediately call a poison center/doctor.
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.

· Date of preparation / last revision 08/12/2015 / 1

· Abbreviations and acronyms:

RID: Règlement international concernant le transport des marchandises dangereuses par chemin de fer (Regulations Concerning the International Transport of Dangerous Goods by Rail)
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
Flam. Liq. 2: Flammable liquids, Hazard Category 2
Skin Irrit. 2: Skin corrosion/irritation, Hazard Category 2
Eye Dam. 1: Serious eye damage/eye irritation, Hazard Category 1
Skin Sens. 1: Sensitisation - Skin, Hazard Category 1
Repr. 2: Reproductive toxicity, Hazard Category 2
STOT SE 3: Specific target organ toxicity - Single exposure, Hazard Category 3

— US —