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

· 1.1 Product identifier

· Trade name: ReVeneer Composite

· Article number: 232231, 232232, 232233, 232236

· 1.2 Relevant identified uses of the substance or mixture and uses advised against

No further relevant information available.

· Application of the substance / the mixture Dental filling material

· 1.3 Details of the supplier of the safety data sheet

· Manufacturer/Supplier:

Schütz Dental GmbH, Dieselstrasse 5-6, D-61191 Rosbach v.d.H. (Germany)

Tel.: +49 (0)6003/814-0 Fax: +49 (0)6003/814-900 www.schuetz-dental.de; e-mail: info@schuetz-dental.de

· Further information obtainable from: F&E, Tel. +49 (0)6003/814-100

· 1.4 Emergency telephone number:

+49 (0) 6003 8140 Schütz Dental (8:00 - 17:00 Uhr) or

+49 (0) 6131 19240 Poison Information Center, University Mainz (24 h)

#### SECTION 2: Hazards identification

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

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

- · 2.2 Label elements
- · Labelling according to Regulation (EC) No 1272/2008

The product is classified and labelled according to the CLP regulation.

· Hazard pictograms



· Signal word Warning

· Hazard-determining components of labelling:

tetramethylene dimethacrylate

· Hazard statements

H317 May cause an allergic skin reaction.

· Precautionary statements

P261 Avoid breathing dust/fume/gas/mist/vapours/spray.

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

P321 Specific treatment (see on this label). P363 Wash contaminated clothing before reuse.

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

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

regulations.

- · Labelling of packages where the contents do not exceed 125 ml
- · Hazard pictograms



- · Signal word Warning
- · Hazard-determining components of labelling:

tetramethylene dimethacrylate

(Contd. on page 2)

Trade name: ReVeneer Composite

(Contd. of page 1)

· Hazard statements

H317 May cause an allergic skin reaction.

· Precautionary statements

P261 Avoid breathing dust/fume/gas/mist/vapours/spray.

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

P321 Specific treatment (see on this label).

*P363* Wash contaminated clothing before reuse.

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

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

regulations.

· 2.3 Other hazards

· Results of PBT and vPvB assessment

· **PBT**: Not applicable. · **vPvB**: Not applicable.

## SECTION 3: Composition/information on ingredients

- · 3.2 Chemical characterisation: Mixtures
- · Description:

1,4-Butandioldimethacrylate

Urethandimethacrylate

Bis-GMA

· Dangerous	components:
-------------	-------------

CAS: 2082-81-7 tetramethylene dimethacrylate \$\ \frac{\( \Dagger)}{\( \Dagger)} \) Skin Sens. 1B, H317 2,5-10%

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

## SECTION 4: First aid measures

- · 4.1 Description of first aid measures
- · General information No special measures required.
- · After inhalation Supply fresh air; consult doctor in case of complaints.
- · After skin contact

Immediately wash with water and soap and rinse thoroughly.

If skin irritation continues, consult a doctor.

· After eve contact

Rinse opened eye for several minutes under running water. If symptoms persist, consult a doctor.

· After swallowing

Rinse out mouth and then drink plenty of water.

Do not induce vomiting; call for medical help immediately.

- · 4.2 Most important symptoms and effects, both acute and delayed No further relevant information available.
- · 4.3 Indication of any immediate medical attention and special treatment needed

No further relevant information available.

## **SECTION 5: Firefighting measures**

- · 5.1 Extinguishing media
- · Suitable extinguishing agents

Foam

Fire-extinguishing powder

Water haze

Carbon dioxide

- · For safety reasons unsuitable extinguishing agents Water with full jet.
- 5.2 Special hazards arising from the substance or mixture No further relevant information available.

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(Contd. of page 2)

- · 5.3 Advice for firefighters
- · Protective equipment:

Wear self-contained respiratory protective device.

Wear fully protective suit.

## SECTION 6: Accidental release measures

- · 6.1 Personal precautions, protective equipment and emergency procedures Not required.
- 6.2 Environmental precautions: Do not allow to enter sewers/ surface or ground water.
- · 6.3 Methods and material for containment and cleaning up:

Absorb with liquid-binding material (sand, diatomite, acid binders, universal binders, sawdust).

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 Keep receptacles tightly sealed.
- · Information about fire and explosion protection: Keep ignition sources away Do not smoke.
- · 7.2 Conditions for safe storage, including any incompatibilities
- · Storage
- · Requirements to be met by storerooms and receptacles:

Close container immediately after use and protect product from light incidence.

Storage between 10 °C and 25 °C.

- · Information about storage in one common storage facility: Store away from foodstuffs.
- · Further information about storage conditions:

Keep receptacle tightly sealed.

Protect from heat and direct sunlight.

 $\cdot$  7.3 Specific end use(s) No further relevant information available.

## SECTION 8: Exposure controls/personal protection

- · Additional information about design of technical facilities: No further data; see item 7.
- · 8.1 Control parameters
- · Ingredients with limit values that require monitoring at the workplace:

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.
- · 8.2 Exposure controls
- · Personal protective equipment
- · General protective and hygienic measures

Keep away from foodstuffs, beverages and feed.

Avoid contact with the eyes and skin.

Wash hands before breaks and at the end of work.

- · Respiratory protection: Not required.
- · Protection of hands: Protective gloves.
- · Material of gloves Butyl rubber, BR
- $\cdot \textit{Penetration time of glove material}$

0,1 - 0,2 mm

Penetration time: 5 min.

(Contd. on page 4)

Trade name: ReVeneer Composite

· Eye protection: Goggles recommended during refilling.

(Contd. of page 3)

## SECTION 9: Physical and chemical properties

· 9.1 Information on basic physical and chemical properties

· General Information

· Appearance:

Form: Pasty

Colour: Different according to colouring

Odour: Characteristic
 Odour threshold: Not determined.
 pH-value: Not determined.

· Change in condition

Melting point/Melting range:undeterminedBoiling point/Boiling range:251 °C

· Flash point: 101 °C

· Flammability (solid, gaseous) Not applicable.

• Ignition temperature:  $> 370 \, ^{\circ}C$ 

· Decomposition temperature: Not determined.

· Self-igniting: Product is not selfigniting.

· Danger of explosion: Product does not present an explosion hazard.

· Explosion limits:

Lower:Not determined.Upper:Not determined.· Vapour pressure:Not determined.

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

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

· Viscosity:

dynamic: Not determined. kinematic: Not determined.

· Solvent content:

Organic solvents: 0,0 %

• 9.2 Other information No further relevant information available.

## SECTION 10: Stability and reactivity

- · 10.1 Reactivity No further relevant information available.
- · 10.2 Chemical stability
- · Thermal decomposition / conditions to be avoided: No decomposition if used according to specifications.
- · 10.3 Possibility of hazardous reactions

Photoreactive

Danger of polymerization

· 10.4 Conditions to avoid No further relevant information available.

(Contd. on page 5)

Trade name: ReVeneer Composite

(Contd. of page 4)

· 10.5 Incompatible materials:

In presence of radical formers (e. g. peroxides), deoxidizing substances, and/or heavy metal ions, polymerization with heat release is possible.

 $\cdot \textbf{10.6 Hazardous decomposition products:} \ \textit{No dangerous decomposition products known}$ 

## 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:

tetramethylene dimethacrylate LD-50 oral > 5000 mg/kg (rat)

- · 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.

- · CMR effects (carcinogenity, 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 Based on available data, the classification criteria are not met.
- · STOT-single exposure Based on available data, the classification criteria are not met.
- · STOT-repeated exposure Based on available data, the classification criteria are not met.
- · 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.
- · Additional ecological information:
- · General notes:

Water hazard class 2 (German Regulation) (Self-assessment): hazardous for water.

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.

- · 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 be specially treated adhering to official regulations.

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

· European waste catalogue

08 01 12 waste paint and varnish other than those mentioned in 08 01 11

- · Uncleaned packaging:
- · Recommendation:

Packagings that may not be cleansed are to be disposed of in the same manner as the product.

(Contd. on page 6)

Trade name: ReVeneer Composite

· Recommended cleansing agents: Alcohol

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SECTION 14: Transport informat	ion
· 14.1 UN-Number · ADR, ADN, IMDG, IATA	Void
14.2 UN proper shipping name ADR, ADN, IMDG, IATA	Void
14.3 Transport hazard class(es)	
ADR, ADN, IMDG, IATA Class	Void
14.4 Packing group ADR, IMDG, IATA	Void
14.5 Environmental hazards: Marine pollutant:	No
14.6 Special precautions for user	Not applicable.
14.7 Transport in bulk according to Anne Marpol and the IBC Code	e <b>x II of</b> Not applicable.
Transport/Additional information:	Not dangerous according to the above specifications.
UN ''Model Regulation'':	Void

## **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.
- · National regulations
- · Technical instructions (air):

Class	Share in %
III	2,5-10

- · Waterhazard class: Water hazard class 2 (Self-assessment): hazardous for water.
- · 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

H317 May cause an allergic skin reaction.

- · Department issuing MSDS: F & E
- · Contact: Dr. U. Krichbaum
- · 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

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

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

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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 vPvB: very Persistent and very Bioaccumulative Skin Sens. 1: Sensitisation - Skin, Hazard Category 1 Skin Sens. 1B: Sensitisation - Skin, Hazard Category 1B

\* Data compared to the previous version altered.

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