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

1.1 Product identifier

Trade name: SR Orthosit PE, SR Orthosit S PE

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: Manufacture of dental prothesis

1.3 Details of the supplier of the safety data sheet

Manufacturer/Supplier:
Ivoclar Vivadent AG
Bendererstrasse 2
FL-9494 Schaan
PRINCIPALITY OF LIECHTENSTEIN

Tel: +423 235 35 35
Fax: +423 235 33 60

Further information obtainable from:
Regulatory Affairs
sds@ivoclarvivadent.com

1.4 Emergency telephone number: +423 / 235 33 13 (Ivoclar Vivadent AG, FL-9494 Schaan, Liechtenstein)

SECTION 2: Hazards identification

2.1 Classification of the substance or mixture

Classification according to Regulation (EC) No 1272/2008
The product is not classified according to the CLP regulation.

2.2 Label elements

Labelling according to Regulation (EC) No 1272/2008 Void

Hazard pictograms Void
Signal word Void
Hazard statements Void

2.3 Other hazards
Avoid breathing sanding dust /swarf.

Results of PBT and vPvB assessment
PBT: Not applicable.
vPvB: Not applicable.

SECTION 3: Composition/information on ingredients

3.2 Chemical characterisation: Mixtures

Description: Resin teeth based on methacrylates

Dangerous components: Void

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: No special measures required.

After skin contact: Generally the product does not irritate the skin.

After eye contact:
Rinse opened eye for several minutes under running water. If symptoms persist, consult a doctor.
Mechanical effects only.

After swallowing: Seek medical treatment.
Safety data sheet
according to 1907/2006/EC, Article 31

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Revision: 16.01.2018

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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.

5.2 Special hazards arising from the substance or mixture
No further relevant information available.

5.3 Advice for firefighters
Protective equipment: No special measures required.

SECTION 6: Accidental release measures

6.1 Personal precautions, protective equipment and emergency procedures
Not required.

6.2 Environmental precautions:
No special measures required.

6.3 Methods and material for containment and cleaning up:
Pick up mechanically.

6.4 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.

SECTION 7: Handling and storage

7.1 Precautions for safe handling
Only adequately trained personnel should handle this product.
For use in dentistry only.

Information about fire - and explosion protection:
No special measures required.

7.2 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.

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:
Usual hygienic measures for dental practice and dental laboratories.
Respiratory protection: Use respiratory protective device against the effects of dust.
Protection of hands:
The glove material has to be impermeable and resistant to the product, the substance, and the preparation. Due to missing tests no recommendation to the glove material can be given for the product, the preparation, and 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:
Always wear safety goggles during mechanical processing (grinding, sawing, cutting, drilling, milling).

SECTION 9: Physical and chemical properties

9.1 Information on basic physical and chemical properties

General Information

Appearance:
Form: Solid
Colour: According to product specification

Odour:
Odour: Odourless
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.

Auto-ignition temperature:
Product is not selfigniting.

Explosive properties:
Product does not present an explosion hazard.

Explosion limits:
Lower: Not determined.
Upper: Not determined.

Vapour pressure:
Not applicable.

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

Solubility in / Miscibility with water:
Insoluble.

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

Viscosity:
Dynamic:
Not applicable.
Trade name: SR Orthosit PE, SR Orthosit S PE

SECTION 10: Stability and reactivity

10.1 Reactivity
No further relevant information available.

10.2 Chemical stability
Stable under normal handling and storage conditions.

10.3 Thermal decomposition / conditions to be avoided
No decomposition if used according to specifications.

10.4 Conditions to avoid
No further relevant information available.

10.5 Incompatible materials
No further relevant information available.

10.6 Hazardous decomposition products
None under normal conditions of storage and use.

SECTION 11: Toxicological information

11.1 Information on toxicological effects

- Acute toxicity Based on available data, the classification criteria are not met.
- 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 Based on available data, the classification criteria are not met.
- 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 Toxicty

- Aquatic toxicity: No further relevant information available.
- Persistence and degradability: No further relevant information available.
- 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
  - 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
Take to an approved landfill or a waste incineration plant, under conditions approved by the local authority.

(Contd. on page 5)
SECTION 14: Transport information

- **14.1 UN-Number**
  - **ADR/RID/ADN, ADN, IMDG, IATA** Void

- **14.2 UN proper shipping name**
  - **ADR/RID/ADN, ADN, IMDG, IATA** Void

- **14.3 Transport hazard class(es)**
  - **ADR/RID/ADN, ADN, IMDG, IATA** Void
  - **Class** Void

- **14.4 Packing group**
  - **ADR/RID/ADN, 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.

- **Transport/Additional information:**
  - Product is not classified as a dangerous good for transport (ADR, IMDG, IATA).

- **UN "Model Regulation":** Void

SECTION 15: Regulatory information

- **15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture**
  - National regulations:
  - Other regulations, limitations and prohibitive regulations
    - The product is a medical device according to the Directive 93/42/EEC.

- **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.

- **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
  - **CAS**: Chemical Abstracts Service (division of the American Chemical Society)
  - **PBT**: Persistent, Bioaccumulative and Toxic
  - **vPvB**: very Persistent and very Bioaccumulative

* Data compared to the previous version altered.