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

1.1 Product identifier

Trade name: SR Spectrasit Dentin, Incisal

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: Crowns- and bridges material

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

Eye Irrit. 2 H319 Causes serious eye irritation.
Skin Sens. 1 H317 May cause an allergic skin reaction.
Aquatic Chronic 3 H412 Harmful to aquatic life with long lasting effects.

2.2 Label elements

Labelling according to Regulation (EC) No 1272/2008

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

Hazard pictograms

GHS07

Signal word: Warning

Hazard-determining components of labelling:
urethane dimethacrylate
1,10-decanediol dimethacrylate

Hazard statements

H319 Causes serious eye irritation.
H317 May cause an allergic skin reaction.
H412 Harmful to aquatic life with long lasting effects.

Precautionary statements

P280 Wear protective gloves/protective clothing/eye protection/face protection.
P363 Wash contaminated clothing before reuse.
P333+P313 If skin irritation or rash occurs: Get medical advice/attention.
P337+P313 If eye irritation persists: Get medical advice/attention.

(Contd. on page 2)
2.3 Other hazards
Results of PBT and vPvB assessment
- PBT: Not applicable.
- vPvB: Not applicable.

SECTION 3: Composition/information on ingredients

3.2 Chemical characterisation: Mixtures
Description: Mixture of substances listed below with nonhazardous additions.

- Dangerous components:
  - CAS: 72869-86-4 EINECS: 276-957-5
    - urethane dimethacrylate
    - Eye Irrit. 2, H319; Skin Sens. 1, H317; Aquatic Chronic 3, H412 ≤25%
  - CAS: 6701-13-9 EINECS: 229-745-1
    - 1,10-decandiol dimethacrylate
    - Eye Irrit. 2, H319; Skin Sens. 1, H317 3-<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
- 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: Rinse with water.
- After eye contact: Rinse opened eye for several minutes under running water. Then consult a doctor.
- After swallowing:
  - Rinse out mouth and then drink plenty of water.
  - If symptoms persist consult doctor.
- 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: Do not allow to enter sewers/surface or ground water.
- 6.3 Methods and material for containment and cleaning up: Pick up mechanically.
- 6.4 Reference to other sections
  - See Section 7 for information on safe handling.
  - See Section 8 for information on personal protection equipment.
SECTION 7: Handling and storage

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

7.2 Conditions for safe storage, including any incompatibilities

Storage:
Requirements to be met by storerooms and receptacles: Store only in the original receptacle.
Information about storage in one common storage facility: Not required.
Further information about storage conditions:
- Protect from exposure to the light.
- Protect from heat and direct sunlight.
- Keep container tightly sealed.

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

SECTION 8: Exposure controls/personal protection

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

8.1 Control parameters
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.
Wash hands before breaks and at the end of work.
Keep away from foodstuffs, beverages and feed.
Avoid contact with the eyes and skin.
Respiratory protection: Not required.
Protection of hands:

Protective gloves

After use of gloves apply skin-cleaning agents and skin cosmetics.

Material of gloves
Selection of the glove material on consideration of the penetration times, rates of diffusion and the degradation
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.
Not suitable are gloves made of the following materials:
Commercial medical gloves do not provide protection against the sensitizing effect of methacrylates.
SECTION 9: Physical and chemical properties

9.1 Information on basic physical and chemical properties

General Information

Appearance:
Form: Pasty
Colour: Cream coloured
Odour: Characteristic
Odour threshold: Not determined.

pH-value: Not applicable.

Change in condition
Melting point/Melting range: Undetermined.
Boiling point/Boiling range: Undetermined.

Flash point: Not applicable.

Flammability (solid, gaseous): Not applicable.

Self-igniting: Product is not self-igniting.

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: Nearly insoluble.

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

Viscosity:
Dynamic: Not determined.
Kinematic: Not determined.

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
Stable under normal handling and storage conditions.
Photoreactive (Danger of polymerization).

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

10.3 Possibility of hazardous reactions
No dangerous reactions known.

10.4 Conditions to avoid
Protect from exposure to the light.
Keep away from heat and direct sunlight.

10.5 Incompatible materials
No further relevant information available.
SECTION 11: Toxicological information

11.1 Information on toxicological effects
  - Acute toxicity:
  - Primary irritant effect:
    - on the skin: No irritant effect.
    - on the eye: Irritating effect.
  - Sensitisation: Sensitisation possible through skin contact.
  - Additional toxicological information: No further relevant information available.

SECTION 12: Ecological information

12.1 Toxicity
  - 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:
      - 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.
    - Results of PBT and vPvB assessment
      - PBT: Not applicable.
      - vPvB: Not applicable.
    - 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.
  - Uncleaned packaging:
    - Recommendation: Disposal must be made according to official regulations.

SECTION 14: Transport information

14.1 UN-Number
  - ADR, ADN, IMDG, IATA: Void

14.2 UN proper shipping name
  - ADR, ADN, IMDG, IATA: Void

14.3 Transport hazard class(es)
  - ADR, ADN, IMDG, IATA: Void
  - Class: Void

14.4 Packing group
  - ADR, IMDG, IATA: Void
Trade name: SR Spectrasit Dentin, Incisal

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 73/78 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": -

SECTION 15: Regulatory information

15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture
- National regulations:

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.
  - H319 Causes serious eye irritation.
  - H412 Harmful to aquatic life with long lasting effects.

- 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)
  - Skin Sens. 1: Sensitisation - Skin, Hazard Category 1
  - Aquatic Chronic 3: Hazardous to the aquatic environment - Chronic Hazard, Category 3
  - * Data compared to the previous version altered.