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

1.1 Product identifier
Trade name: **SR Ivocron: Dentin, Schneide, Hals, Gingiva, Intensiv Pulver**

1.2 Relevant identified uses of the substance or mixture and uses advised against
No further relevant information available.

1.3 Details of the supplier of the safety data sheet
Manufacturer/Supplier:
Ivoclar Vivadent AG
Bendererstrasse 2
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, 9494 Schaan, Liechtenstein)

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

Hazard pictograms

GHS07

Signal word Warning

Hazard-determining components of labelling:
dibenzoyl peroxide

Hazard statements
H317 May cause an allergic skin reaction.

Precautionary statements
P261 Avoid breathing dust/fume/gas/mist/vapours/spray.
P262 Do not get in eyes, on skin, or on clothing.
P280 Wear protective gloves/protective clothing/eye protection/face protection.
P501 Dispose of contents/container in accordance with local/regional/national/international regulations.

2.3 Other hazards
Dust generation
Particular danger of slipping on leaked/spilled product.

Results of PBT and vPvB assessment
PBT: Not applicable.

(Contd. on page 2)
SECTION 3: Composition/information on ingredients

- 3.2 Chemical characterisation: Mixtures
  - Description: Mixture of substances listed below with nonhazardous additions.
  - Dangerous components:
    - CAS: 94-36-0  dibenzoyl peroxide
    - EINECS: 202-327-6
    - Org. Perox. B, H241; Eye Irrit. 2, H319; Skin Sens. 1, H317
    - 1-<2.5%
  - 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
  - After inhalation: Supply fresh air; consult doctor in case of complaints.
    In case of unconsciousness place patient stably in side position for transportation.
  - After skin contact: Rinse with water.
    If skin irritation continues, consult a doctor.
  - After eye contact: Rinse opened eye for several minutes under running water. Then consult a doctor.
  - After swallowing: Rinse out mouth and then drink plenty of water.
    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
  - Avoid formation of dust.
  - Particular danger of slipping on leaked/spilled product.
- 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
  - 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.

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 heat and direct sunlight.

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

SECTION 8: Exposure controls/personal protection

8.1 Control parameters

8.2 Exposure controls
- Personal protective equipment:
  - General protective and hygienic measures:
    - Usual hygienic measures for dental practice and dental laboratories.
    - Immediately remove all soiled and contaminated clothing
    - Wash hands before breaks and at the end of work.
    - Avoid contact with the skin.
  - Respiratory protection: Use respiratory protective device against the effects of dust.
  - 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.
  - Eye protection: Safety glasses

SECTION 9: Physical and chemical properties

9.1 Information on basic physical and chemical properties
- General Information
- Appearance:
  - Form: Powder
**SECTION 10: Stability and reactivity**

- **10.1 Reactivity** No further relevant information available.
- **10.2 Chemical stability** Stable under normal handling and storage conditions.
- **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** 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** May cause an allergic skin reaction.
  - **Additional toxicological information:** No further relevant information available.
  - **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: Not hazardous for water.

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:
Take to an approved landfill or a waste incineration plant, under conditions approved by the local authority.

European waste catalogue
20 01 39 plastics

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

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 classes
ADR/RID/ADN, ADN, IMDG, IATA: Void

14.4 Packing group
ADR/RID/ADN, 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.

· Relevant phrases
  H241 Heating may cause a fire or explosion.
  H317 May cause an allergic skin reaction.
  H319 Causes serious eye irritation.

· 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
  Org. Perox. B: Organic peroxides – Type B
  Eye Irrit. 2: Serious eye damage/eye irritation – Category 2
  Skin Sens. 1: Skin sensitisation – Category 1

· * Data compared to the previous version altered.