

Printing date 29.04.2015 Version number 3 Revision: 18.04.2015

## 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
- $\cdot \textbf{1.2 Relevant identified uses of the substance or \textit{mixture and uses advised against}}$

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

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



GHS07

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

dibenzovl peroxide

· Hazard statements

H317 May cause an allergic skin reaction.

· Precautionary statements

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

P363 Wash contaminated clothing before reuse.

P302+P352 IF ON SKIN: Wash with plenty of water.

· 2.3 Other hazards

Dust generation

Particular danger of slipping on leaked/spilled product.

- · Results of PBT and vPvB assessment
- · **PBT**: Not applicable.
- · vPvB: Not applicable.

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#### 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

1-<2.5%

EINECS: 202-327-6 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.

#### 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. If symptoms persist, 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.

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#### **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: 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

- · 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:

94-36-0 dibenzoyl peroxide

WEL Long-term value: 5 mg/m<sup>3</sup>

- · 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.

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

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Colour:	According to product specification	
· Odour:	Characteristic	
· Odour threshold:	Not determined.	
pH-value:	Not applicable.	
Change in condition		
Melting point/Melting range:	150 °C	
Boiling point/Boiling range:	Undetermined.	
Flash point:	250 °C	
Flammability (solid, gaseous):	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 applicable.	
Density at 20 °C:	$1.2 \text{ g/cm}^3$	
Relative density	Not determined.	
Vapour density	Not applicable.	
Evaporation rate	Not applicable.	
Solubility in / Miscibility with		
water:	Nearly insoluble.	
Partition coefficient (n-octanol/wat	ter): Not determined.	
· Viscosity:		
Dynamic:	Not applicable.	
Kinematic:	Not applicable.	
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.
- · 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.
- $\cdot \textbf{ 10.5 Incompatible materials:} \ No \ further \ relevant \ information \ available.$
- · 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:
- · Primary irritant effect:
- · on the skin: No irritant effect.
- · on the eye: No irritating effect.
- · Sensitisation: Sensitisation possible through skin contact.

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· Additional toxicological information: No further relevant information available.

### 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: Generally 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.

Void Void
Void
Void
Void
No
Not applicable.
<b>f</b> Not applicable.
Product is not classified as a dangerous good for transpo (ADR, IMDG, IATA).

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· UN "Model Regulation":

# SECTION 15: Regulatory information

- $\cdot$  15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture
- · National regulations:
- $\cdot \textit{Other regulations, limitations and prohibitive regulations}$

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)

Org. Perox. B: Organic Peroxides, Type B

Eye Irrit. 2: Serious eye damage/eye irritation, Hazard Category 2

Skin Sens. 1: Sensitisation - Skin, Hazard Category 1

\* Data compared to the previous version altered.

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