ivoclar vivadeni:

Safety Data Sheet according to HPR, Schedule 1

Printing date 07/17/2019

Version number 4

Reviewed on 07/09/2019

1 Identification

· Product identifier

Trade name: SR Ivocron: Dentin, Schneide, Hals, Gingiva, Intensiv Pulver

• Application of the substance / the mixture Crowns- and bridges material

Details of the supplier of the safety data sheet
Manufacturer/Supplier: Ivoclar Vivadent Inc.
175 Pineview Drive, Amherst, N.Y. 14228 USA Tel. +1 800 533 6825 Fax +1 716 691 2285

Ivoclar Vivadent Inc. 1-6600 Dixie Road Mississauga, Ontario L5T 2Y2 Canada Phone: +1 905 670 8499 Fax: +1 905 670 3102

 Information department: Quality Assurance / Regulatory Affairs
 Emergency telephone number: 24 Hour Emergency Assistance: Emergency-Call USA - Infotrac: 1-800-535-5053 Emergency-Call Canada - Canutec: 1-613-996-6666

General SDS Assistance: US: 1-800-533-6825 Canada: 1-800-263-8182

2 Hazard identification

- · Classification of the substance or mixture
- Skin Sensitizer Category 1 H317 May cause an allergic skin reaction.
- · Label elements
- · GHS label elements

The product is classified and labeled according to the Globally Harmonized System (GHS).

· Hazard pictograms



- · Signal word Warning
- · Hazard-determining components of labeling:
- dibenzoyl peroxide
- · Hazard statements
- *May cause an allergic skin reaction.* • *Precautionary statements*
- Avoid breathing dust/fume/gas/mist/vapours/spray.
- Do not get in eyes, on skin, or on clothing.

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

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

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Trade name: SR Ivocron: Dentin, Schneide, Hals, Gingiva, Intensiv Pulver

(Contd. of page 1) · Classification system: · NFPA ratings (scale 0 - 4) Health = 0Fire = 1Reactivity = 0· HMIS-ratings (scale 0 - 4) HEALTH • Health = 0FIRE 1 Fire = 1**REACTIVITY O** *Reactivity* = 0Other hazards Dust generation Particular danger of slipping on leaked/spilled product. **3** Composition/Information on ingredients · Chemical characterization: Mixtures · Description: Mixture of the substances listed below with nonhazardous additions. · Dangerous components: CAS: 94-36-0 dibenzoyl peroxide $\leq 1\% \text{ w/w}$ 4 First aid measures · 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. • Information for doctor: • Most important symptoms and effects, both acute and delayed No further relevant information available. · Indication of any immediate medical attention and special treatment needed No further relevant information available. **5** Firefighting measures • Extinguishing media

• Suitable extinguishing agents:

CO2, extinguishing powder or water spray. Fight larger fires with water spray or alcohol resistant foam.

- Special hazards arising from the substance or mixture No further relevant information available.
- Advice for firefighters

· Protective equipment: No special measures required.

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6 Accidental release measures

• Personal precautions, protective equipment and emergency procedures

Avoid formation of dust.

Particular danger of slipping on leaked/spilled product.

• Environmental precautions: No special measures required.

- Methods and material for containment and cleaning up: Pick up mechanically.
- · 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.

7 Handling and storage

· Handling:

- · Precautions for safe handling
- Only adequately trained personnel should handle this product.
- For use in dentistry only.
- · Information about protection against explosions and fires: No special measures required.
- · 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.
- · Specific end use(s) No further relevant information available.

8 Exposure controls/ Personal protection

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

· Control parameters

- · Components with limit values that require monitoring at the workplace:
- CAS: 94-36-0 dibenzoyl peroxide
- EL Long-term value: 5 mg/m³
- EV Long-term value: 5 mg/m³

• Additional information: The lists that were valid during the creation were used as basis.

- · 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.

- Breathing equipment: 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.

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• *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

Physical and chemical properties		
· Information on basic physical and chemical properties · General Information		
Form:	Powder	
Color:	According to product specification	
Odor:	Characteristic	
· Odor 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.	
· Auto igniting:	Product is not selfigniting.	
• Danger of explosion:	Product does not present an explosion hazard.	
• Explosion limits:		
Lower:	Not determined.	
Upper:	Not determined.	
· Vapor pressure:	Not applicable.	
• Density at 20 •C:	$1.2 \ g/cm^3$	
Relative density	Not determined.	
· Vapor 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.	
• Other information	No further relevant information available.	

10 Stability and reactivity

· Reactivity No further relevant information available.

- · Chemical stability Stable under normal handling and storage conditions.
- Thermal decomposition / conditions to be avoided: No decomposition if used according to specifications.
- · Possibility of hazardous reactions No dangerous reactions known.

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Trade name: SR Ivocron: Dentin, Schneide, Hals, Gingiva, Intensiv Pulver

- Conditions to avoid No further relevant information available. • Incompatible materials: No further relevant information available.
- Hazardous decomposition products: None under normal conditions of storage and use.

11 Toxicological information

· Information on toxicological effects

• Acute toxicity:

• on the skin: No irritant effect.

• on the eye: No irritating effect.

- Sensitization: Sensitization possible through skin contact.
- Additional toxicological information: No further relevant information available.

· Carcinogenic categories

· IARC (International Agency for Research on Cancer)

CAS: 94-36-0 dibenzoyl peroxide

· NTP (National Toxicology Program)

None of the ingredients is listed.

12 Ecological information

· Toxicity

- Aquatic toxicity: No further relevant information available.
- *Persistence and degradability* No further relevant information available.
- · Behavior in environmental systems:
- · Bioaccumulative potential No further relevant information available.
- *Mobility in soil* No further relevant information available.
- Additional ecological information:
- · General notes: Not hazardous for water.
- · Results of PBT and vPvB assessment
- **PBT:** Not applicable.
- · vPvB: Not applicable.
- · Other adverse effects No further relevant information available.

13 Disposal considerations

· Waste treatment methods

· Recommendation:

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

- · Uncleaned packagings:
- Recommendation: Disposal must be made according to official regulations.

· UN-Number · DOT/TDG, ADR, ADN, IMDG, IATA	Void	
· UN proper shipping name · DOT/TDG, ADR, ADN, IMDG, IATA	Void	

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· Transport hazard class(es)	
· DOT, ADR, ADN, IMDG, IATA · Class	Void
· Packing group · DOT/TDG, ADR, IMDG, IATA	Void
• Environmental hazards: • Marine pollutant:	No
· Special precautions for user	Not applicable.
• Transport in bulk according to Annex II of MARPOL73/78 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":	Void

15 Regulatory information

· Safety, health and environmental regulations/legislation specific for the substance or mixture

· Sara

• Section 355 (extremely hazardous substances):

None of the ingredients is listed.

· Section 313 (Specific toxic chemical listings):

CAS: 94-36-0 dibenzoyl peroxide

• TSCA (Toxic Substances Control Act):

CAS: 94-36-0 dibenzoyl peroxide

GHS label elements

The product is classified and labeled according to the Globally Harmonized System (GHS). • *Hazard pictograms*



· Signal word Warning

• Hazard-determining components of labeling: dibenzoyl peroxide

· Hazard statements

May cause an allergic skin reaction.

· Precautionary statements

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

Do not get in eyes, on skin, or on clothing.

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

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

· National regulations:

• Other regulations, limitations and prohibitive regulations The product is a medical device according to the Directive 93/42/EEC.

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Trade name: SR Ivocron: Dentin, Schneide, Hals, Gingiva, Intensiv Pulver

This product is classified as a medical device under US and Canadian regulations and has been reviewed by the US Food and Drug Administration and Health Canada.

Chemical safety assessment: A Chemical Safety Assessment has not been carried out.

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.

 Date of the latest revision of the safety data sheet 07/17/2019 / 3
 Abbreviations and acronyms: IMDG: International Maritime Code for Dangerous Goods DOT: US Department of Transportation IATA: International Air Transport Association 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) NFPA: National Fire Protection Association (USA) HMIS: Hazardous Materials Identification System (USA) PBT: Persistent, Bioaccumulative and Toxic vPvB: very Persistent and very Bioaccumulative

• * Data compared to the previous version altered.