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Material Safety Data Sheet acc. to ISO 11014

Printing date 05/21/2015

Version number 4

Reviewed on 03/12/2015

1 Identification

- · Product identifier
- · Trade name: SR Ivocap High Impact Polymer
- Relevant identified uses of the substance or mixture and uses advised against No further relevant information available.
- \cdot Application of the substance / the mixture Denture base 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(s) identification

- · Classification of the substance or mixture
- Skin Sens. 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/vapors/spray Do not get in eyes, on skin, or on clothing.

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(Contd. of page 1) Wear protective gloves/protective clothing/eye protection/face protection. Dispose of contents/container in accordance with local/regional/national/international regulations. · Classification system: · NFPA ratings (scale 0 - 4) Health = 0Fire = 1Reactivity = 0· HMIS-ratings (scale 0 - 4) HEALTH 1 Health = 1FIRE 1 Fire = 1**REACTIVITY O** *Reactivity* = 0· Other hazards Dust generation Particular danger of slipping on leaked/spilled product. · Results of PBT and vPvB assessment · PBT: Not applicable. · vPvB: Not applicable. **3** Composition/information on ingredients · Chemical characterization: Mixtures · Description: Mixture of the substances listed below with nonhazardous additions. · Dangerous components: 94-36-0 dibenzoyl peroxide 0.3-<1% **4** First-aid measures · Description of first aid measures · General information: No special measures required. · 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.

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.
- · 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.

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5 Fire-fighting 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.

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: Do not allow product to reach sewage system or any water course. Do not allow to enter sewers/ surface or ground water.
- 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:
- 94-36-0 dibenzoyl peroxide
- EL Long-term value: 5 mg/m^3
- 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:
- \cdot General protective and hygienic measures:

Usual hygienic measures for dental practice.

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Keep away from foodstuffs, beverages and feed. 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. · Material of gloves Butyl rubber, BR Chloroprene rubber, CR Natural rubber, NR Nitrile rubber, NBR Fluorocarbon rubber (Viton) 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

Information on basic physical and	chemical properties	
General Information		
Appearance:		
Form:	Powder	
Color:	According to product specification	
Odor:	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 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:	Not determined.	
Relative density	Not determined.	
Vapour density	Not applicable.	
Evaporation rate	Not applicable.	

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Solubility in / Miscibility with	1	
Water:	Nearly insoluble.	
Partition coefficient (n-octan	ol/water): 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.
- · 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:
- · Primary irritant effect:
- on the skin: No irritant effect.
- on the eye: No irritating effect.
- Sensitization: No sensitizing effects known.
- · Additional toxicological information: No further relevant information available.

· Carcinogenic categories

· IARC (International Agency for Research on Cancer)

9011-14-7 polymethylmethacrylate

94-36-0 dibenzoyl peroxide

· NTP (National Toxicology Program)

None of the ingredients is listed.

· OSHA-Ca (Occupational Safety & Health Administration)

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:

Water hazard class 1 (Self-assessment): slightly hazardous for water

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(Contd. of page 5) Do not allow undiluted product or large quantities of it to reach ground water, water course or sewage system.

· 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.

14 Transport information

· UN-Number · DOT, TDG, ADN, IMDG, IATA	Void
· UN proper shipping name · DOT, TDG, ADN, IMDG, IATA	Void
· Transport hazard class(es)	
· DOT, TDG, ADN, IMDG, IATA · Class	Void
· Packing group · DOT, TDG, 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":	-

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):

94-36-0 dibenzoyl peroxide

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· TSCA (Toxic Substances Control Act):

9011-14-7 polymethylmethacrylate

94-36-0 dibenzoyl peroxide

· Proposition 65

· Chemicals known to cause cancer:

None of the ingredients is listed.

· Chemicals known to cause reproductive toxicity for females:

None of the ingredients is listed.

· Chemicals known to cause reproductive toxicity for males:

None of the ingredients is listed.

· Chemicals known to cause developmental toxicity:

None of the ingredients is listed.

· Carcinogenic categories

· EPA (Environmental Protection Agency)

None of the ingredients is listed.

• TLV (Threshold Limit Value established by ACGIH)

94-36-0 dibenzoyl peroxide

· NIOSH-Ca (National Institute for Occupational Safety and Health)

None of the ingredients is listed.

· 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/vapors/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. 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.

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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 preparation / last revision 05/21/2015 / 3
 Abbreviations and acronyms: IMDG: International Maritime Code for Dangerous Goods DOT: US Department of Transportation IATA: International Air Transport Association ACGIH: American Conference of Governmental Industrial Hygienists 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) Skin Sens. 1: Sensitisation - Skin, Hazard Category 1
 * Data compared to the previous version altered.