

Printing date 09/05/2012 Version number 4 Reviewed on 09/05/2012

#### 1 Identification of the substance/mixture and of the company/undertaking

- · Product identifier
- · Trade name: IPS Margin Bulid-Up Liquid
- · Relevant identified uses of the substance or mixture and uses advised against
- · Application of the substance / the preparation Auxiliary for manufacture of dental prothesis
- · 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 MSDS Assistance: US: 1-800-533-6825 Canada: 1-800-263-8182

#### 2 Hazards identification

- · Classification of the substance or mixture
- · Classification according to Directive 67/548/EEC or Directive 1999/45/EC Not applicable.
- · Information concerning particular hazards for human and environment:

The product does not have to be labelled due to the calculation procedure of international guidelines.

· Classification system:

The classification was made according to the latest editions of international substances lists, and expanded upon from company and literature data.

- · Label elements
- · Labelling according to EU guidelines:

The product is not subject to identification regulations according to directives on hazardous materials.

- · Classification system:
- · NFPA ratings (scale 0 4)



Health = 0 Fire = 0Reactivity = 0

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· HMIS-ratings (scale 0 - 4)



- · Other hazards
- · Results of PBT and vPvB assessment
- $\cdot \textit{\textbf{PBT:}} \ \textit{Not applicable}.$
- · vPvB: Not applicable.

### 3 Composition/information on ingredients

- · Chemical characterization: Mixtures
- · Description: Mixture of the substances listed below with nonhazardous additions.
- · Dangerous components: Void

#### 4 First aid measures

- · Description of first aid measures
- · General information: No special measures required.
- · After inhalation: Supply fresh air; consult doctor in case of complaints.
- · After skin contact:

Rinse with water.

Generally the product does not irritate the skin.

· 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.

#### 5 Firefighting measures

- · Extinguishing media
- · Suitable extinguishing agents:

The product is not flammable.

Use fire fighting measures that suit the environment.

- · 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 Not required.
- · Environmental precautions: No special measures required.
- · Methods and material for containment and cleaning up:

Absorb with liquid-binding material (sand, diatomite, acid binders, universal binders, sawdust).

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· 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: Keep receptacle tightly sealed.
- · 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:

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 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.

Wash hands before breaks and at the end of work.

Keep away from foodstuffs, beverages and feed.

- · Breathing equipment: Not required.
- · Protection of hands:

The glove material has to be impermeable and resistant to the product/ the substance/ the preparation. Due to missing tests no recommendation to the glove material can be given for the product/ the preparation/ the chemical mixture.

Selection of the glove material on consideration of the penetration times, rates of diffusion and the degradation

· Material of gloves

The selection of the suitable gloves does not only depend on the material, but also on further marks of quality and varies from manufacturer to manufacturer. As the product is a preparation of several substances, the resistance of the glove material can not be calculated in advance and has therefore to be checked prior to the application.

· 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.

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· Eye protection: Safety glasses

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Information on basic physical and ch General Information	nemical properties		
Appearance:			
Form:	Fluid		
Color:	Colorless		
Odor:	Odorless		
Odour threshold:	Not determined.		
pH-value:	Not determined.		
Change in condition			
Melting point/Melting range:	Undetermined.		
Boiling point/Boiling range:	100°C (212 °F)		
Flash point:	Not applicable.		
Flammability (solid, gaseous):	Not applicable.		
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 at 20°C (68 °F):	23 hPa (17 mm Hg)		
Density:	Not determined.		
Relative density	Not determined.		
Vapour density	Not determined.		
Evaporation rate	Not determined.		
Solubility in / Miscibility with			
Water:	Fully miscible.		
Segregation coefficient (n-octonol/wo	ater): Not determined.		
Viscosity:			
•	Not determined.		
Viscosity: Dynamic: Kinematic:	Not determined. Not determined.		
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.

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## 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:

The product is not subject to classification according to internally approved calculation methods for preparations:

- · Carcinogenic categories
- · 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: Generally 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:

Smaller quantities can be disposed of with household waste.

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.
- · Recommended cleansing agent: Water, if necessary with cleansing agents.

#### 14 Transport information

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

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

### 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):

None of the ingredients is listed.

· TSCA (Toxic Substances Control Act):

All ingredients are listed.

- · 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)

None of the ingredients is listed.

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

None of the ingredients is listed.

· OSHA-Ca (Occupational Safety & Health Administration)

None of the ingredients is listed.

· Product related hazard informations:

The product is not subject to identification regulations according to directives on hazardous materials.

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- · National regulations:
- Other regulations, limitations and prohibitive regulations
  The product is a medical device according to the EC-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.

### 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.

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