

Printing date 09/20/2013 Version number 5 Reviewed on 09/20/2013

1 Identification

- · Product identifier
- Trade name: MultiCore HB / Flow (Catalyst)
- Relevant identified uses of the substance or mixture and uses advised against No further relevant information available.
- · Application of the substance / the preparation Two-component core build-up material
- · Details of the supplier of the safety data sheet
- · Manufacturer/Supplier:

Ivoclar Vivadent Inc.

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USA

Tel. +1 800 533 6825

Fax +1 716 691 2285

Ivoclar Vivadent Inc.

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L5T 2Y2

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- · 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 Hazard(s) identification

- · Classification of the substance or mixture
- · Classification according to Directive 67/548/EEC or Directive 1999/45/EC

Irritant

Irritating to eyes and skin. May cause sensitisation by skin contact.

· 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:

Medical devices as defined in Directive 93/42/EEC and which are invasive or used in direct physical contact with the human body, are exempted from the provisions of Dangerous Substance Directive 1999/45/EC usually if they are in the finished state and intended for the final user.

· Code letter and hazard designation of product:



Irritant

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· Hazard-determining components of labeling:

urethane dimethacrylate triethyleneglycol dimethacrylate

· Risk phrases:

Irritating to eyes and skin.

May cause sensitisation by skin contact.

· Safety phrases:

Avoid contact with skin.

In case of contact with eyes, rinse immediately with plenty of water and seek medical advice.

Wear suitable gloves.

This material and its container must be disposed of as hazardous waste.

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



Health = 1Fire = 0Reactivity = 0

· HMIS-ratings (scale 0 - 4)



1 Health = 1 Fire = 0

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

3 Composition/information on ingredients

· **Description:** Mixture of the substances listed below with nonhazardous additions.

· Dangerous components:					
1565-94-2	Bis-GMA	2.5-25%			
72869-86-4	urethane dimethacrylate	2.5-10%			
109-16-0	triethyleneglycol dimethacrylate	2.5-10%			
94-36-0	dibenzoyl peroxide	≤ 2.5%			

4 First-aid measures

- · Description of first aid measures
- · 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.
- · After eye contact:

Rinse opened eye for several minutes under running water. If symptoms persist, consult a doctor.

- · After swallowing: If symptoms persist consult doctor.
- · Information for doctor:
- · Most important symptoms and effects, both acute and delayed No further relevant information available.

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· Indication of any immediate medical attention and special treatment needed No further relevant information available.

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 Not required.
- · Environmental precautions: 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:

Store in a cool place.

Protect from exposure to the light.

Protect from heat and direct sunlight.

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.

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- · Exposure controls
- · Personal protective equipment:
- · General protective and hygienic measures:

Usual hygienic measures for dental practice.

Keep away from foodstuffs, beverages and feed.

Wash hands before breaks and at the end of work.

Avoid contact with the eyes and skin.

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



Protective gloves

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.

· Eye protection: Safety glasses

1 1	9 Physical	ana c	nemical	properi	ies

Inforn	ation	on	basic	physical	and	chemical	properties
~							

· General Information

· Appearance:

Form: Pasty

Color: According to product specification

Odor: Characteristic
Odour threshold: Not determined.

· pH-value: Not determined.

· Change in condition

Melting point/Melting range:Undetermined.Boiling point/Boiling range:Undetermined.

· Auto igniting: Product is not selfigniting.

• Danger of explosion: Product does not present an explosion hazard.

Not applicable.

· Explosion limits:

· Flash point:

Lower: Not determined. Upper: Not determined.

· Vapor pressure: Not determined.

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· Density:	Not determined.
· Relative density	Not determined.
· Vapour density	Not determined.
· Evaporation rate	Not determined.

· Solubility in / Miscibility with

Water: Nearly insoluble.

- · Partition coefficient (n-octanol/water): Not determined.
- · Viscosity:

Dynamic: Not determined. **Kinematic:** 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

Protect from exposure to the light.

Keep away from heat and direct sunlight.

- · 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: Irritant to skin and mucous membranes.
- · on the eye: Irritating effect.
- · Sensitization: Sensitization possible through skin contact.
- · Additional toxicological information:

The product shows the following dangers according to internally approved calculation methods for preparations:

Irritant

· Carcinogenic categories

· IARC (International Agency for Research on Cancer)				
7631-86-9	silicon dioxide, chemically prepared	3		
94-36-0	dibenzoyl peroxide	3		
· NTP (National Toxicology Program)				
None of the ingredients is listed.				

12 Ecological information

- · Toxicity
- · Aquatic toxicity: No further relevant information available.

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- · 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

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.

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

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.

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· Section 313 (Specific toxic chemical listings):

94-36-0 dibenzoyl peroxide

· 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)

13760-80-0 ytterbium trifluoride	A4
94-36-0 dibenzoyl peroxide	A4

· 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:

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· Hazard symbols:



Irritant

$\cdot \textit{Hazard-determining components of labeling:}$

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· Risk phrases:

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May cause sensitisation by skin contact.

· Safety phrases:

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In case of contact with eyes, rinse immediately with plenty of water and seek medical advice. Wear suitable gloves.

This material and its container must be disposed of as hazardous waste.

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- · 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.

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.

USA