SECTION 1: Identification of the substance/mixture and of the company/undertaking

1.1 Product identifier
   Trade name: MultiCore HB / Flow (Base)

1.2 Relevant identified uses of the substance or mixture and uses advised against
   No further relevant information available.

1.3 Details of the supplier of the safety data sheet
   Manufacturer/Supplier:
   Ivoclar Vivadent AG
   Bendererstrasse 2
   9494 Schaan
   PRINCIPALITY OF LIECHTENSTEIN
   Tel: +423 235 35 35
   Fax: +423 235 33 60

1.4 Emergency telephone number: +423 / 235 33 13 (Ivoclar Vivadent AG, 9494 Schaan, Liechtenstein)

SECTION 2: Hazards identification

2.1 Classification of the substance or mixture
   Classification according to Regulation (EC) No 1272/2008
   Skin Irrit. 2 H315 Causes skin irritation.
   Eye Irrit. 2 H319 Causes serious eye irritation.
   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.

2.3 Hazard pictograms
   GHS07

2.4 Signal word Warning

2.5 Hazard-determining components of labelling:
   Bis-GMA
   urethane dimethacrylate
   triethylene glycol dimethacrylate

Hazard statements
   H315 Causes skin irritation.
   H319 Causes serious eye irritation.
   H317 May cause an allergic skin reaction.

Precautionary statements
   P261 Avoid breathing dust/fume/gas/mist/vapours/spray.
   P280 Wear protective gloves / eye protection / face protection.
   P302+P352 IF ON SKIN: Wash with plenty of water.
   P321 Specific treatment (see on this label).

(Contd. on page 2)
SECTION 3: Composition/information on ingredients

3.2 Chemical characterisation: Mixtures
Description: Mixture of substances listed below with nonhazardous additions.

| CAS: 13760-80-0 | ytterbium trifluoride | Skin Irrit. 2, H315; Eye Irrit. 2, H319; STOT SE 3, H335 |
| CAS: 36425-15-7 | Bis-GMA | Skin Irrit. 2, H315; Eye Irrit. 2, H319; Skin Sens. 1, H317 |
| CAS: 72869-86-4 | urethane dimethacrylate | Eye Irrit. 2, H319; Skin Sens. 1, H317; Aquatic Chronic 3, H412 |
| CAS: 109-16-0 | triethylene glycol dimethacrylate | Skin Irrit. 2, H315; Eye Irrit. 2, H319; Skin Sens. 1, H317; STOT SE 3, H335 |

Additional information: For the wording of the listed hazard phrases refer to section 16.

SECTION 4: First aid measures

4.1 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.

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: Not required.
- 6.2 Environmental precautions: Do not allow to enter sewers/surface or ground water.
- 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.

SECTION 7: Handling and storage

- 7.1 Precautions for safe handling
  - Only adequately trained personnel should handle this product.
  - For use in dentistry only.
- 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 exposure to the light.
      - Protect from heat and direct sunlight.
      - Keep container tightly sealed.
- 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:
    - 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 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 and dental laboratories.
      - Keep away from foodstuffs, beverages and feed.
      - Wash hands before breaks and at the end of work.
      - Avoid contact with the eyes and skin.
    - Respiratory protection: 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.

  - **Not suitable are gloves made of the following materials:**
    Commercial medical gloves do not provide protection against the sensitizing effect of methacrylates.

  - **Eye protection:** Safety glasses

### SECTION 9: Physical and chemical properties

- **9.1 Information on basic physical and chemical properties**
  - **General Information**
    - **Appearance:**
      - Form: Pasty
      - Colour: According to product specification
    - **Odour:** Characteristic
    - **Odour threshold:** Not determined.
  - **pH-value:** Not determined.
  - **Change in condition**
    - Melting point/freezing point: Undetermined.
    - Initial boiling point and boiling range: Undetermined.
  - **Flash point:** Not applicable.
  - **Auto-ignition temperature:** Product is not self-igniting.
  - **Explosive properties:** Product does not present an explosion hazard.
  - **Explosion limits:**
    - Lower: Not determined.
    - Upper: Not determined.
  - **Vapour pressure:** Not determined.
  - **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.
SECTION 10: Stability and reactivity

10.1 Reactivity No further relevant information available.
10.2 Chemical stability
Stable under normal handling and storage conditions.
Photoreactive (Danger of polymerization).
10.3 Possibility of hazardous reactions No decomposition if used according to specifications.
10.4 Conditions to avoid
Protect from exposure to the light.
Keep away from heat and direct sunlight.
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
11.2 Acute toxicity Based on available data, the classification criteria are not met.
11.3 Skin corrosion/irritation Causes skin irritation.
11.4 Serious eye damage/irritation Causes serious eye irritation.
11.5 Respiratory or skin sensitisation May cause an allergic skin reaction.
11.6 Additional toxicological information: No further relevant information available.
11.7 Germ cell mutagenicity Based on available data, the classification criteria are not met.
11.8 Carcinogenicity Based on available data, the classification criteria are not met.
11.9 Reproductive toxicity Based on available data, the classification criteria are not met.
11.10 STOT-single exposure Based on available data, the classification criteria are not met.
11.11 STOT-repeated exposure Based on available data, the classification criteria are not met.
11.12 Aspiration hazard Based on available data, the classification criteria are not met.

SECTION 12: Ecological information

12.1 Toxicity
12.2 Aquatic toxicity: No further relevant information available.
12.3 Persistence and degradability No further relevant information available.
12.4 Bioaccumulative potential No further relevant information available.
12.5 Mobility in soil No further relevant information available.
12.6 Additional ecological information:
General notes: Water hazard class 2 (German Regulation) (Self-assessment): hazardous for water
Do not allow product to reach ground water, water course or sewage system.
Danger to drinking water if even small quantities leak into the ground.
12.7 Results of PBT and vPvB assessment
PBT: Not applicable.
vPvB: Not applicable.
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.

Uncleaned packaging:
Recommendation: Disposal must be made according to official regulations.

SECTION 14: Transport information

14.1 UN-Number
ADR/RID/ADN, ADN, IMDG, IATA Void

14.2 UN proper shipping name
ADR/RID/ADN, ADN, IMDG, IATA Void

14.3 Transport hazard class(es)
ADR/RID/ADN, ADN, IMDG, IATA Class Void

14.4 Packing group
ADR/RID/ADN, IMDG, IATA Void

14.5 Environmental hazards:
Marine pollutant: No

14.6 Special precautions for user
Not applicable.

14.7 Transport in bulk according to Annex II of Marpol 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

SECTION 15: Regulatory information

15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture
REGULATION (EC) No 1907/2006 ANNEX XVII Conditions of restriction: 3

National regulations:
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
H315 Causes skin irritation.
Trade name: **MultiCore HB / Flow (Base)**

- **H317** May cause an allergic skin reaction.
- **H319** Causes serious eye irritation.
- **H335** May cause respiratory irritation.
- **H412** Harmful to aquatic life with long lasting effects.

**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)
- vPvB: very Persistent and very Bioaccumulative
- Skin Irrit. 2: Skin corrosion/irritation – Category 2
- Eye Irrit. 2: Serious eye damage/eye irritation – Category 2
- Skin Sens. 1: Skin sensitisation – Category 1
- STOT SE 3: Specific target organ toxicity (single exposure) – Category 3
- Aquatic Chronic 3: Hazardous to the aquatic environment - long-term aquatic hazard – Category 3

* Data compared to the previous version altered.