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

1.1 Product identifier

Trade name: Heliomolar Flow

1.2 Relevant identified uses of the substance or mixture and uses advised against

No further relevant information available.

Application of the substance / the mixture Light-curing resin-based dental restorative material

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

Further information obtainable from:
Regulatory Affairs
sds@ivoclarvivadent.com

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.

Hazard pictograms

GHS07

Signal word Warning

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).
Trade name: Heliomolar Flow

(Contd. of page 1)

P305+P351+P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.

P501 Dispose of contents/container in accordance with local/regional/national/international regulations.

• Additional information:
  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 Regulation (EC) No 1272/2008 (CLP/GHS) usually if they are in the finished state and intended for the final user.

• 2.3 Other hazards
  • Results of PBT and vPvB assessment
    • PBT: Not applicable.
    • vPvB: Not applicable.

SECTION 3: Composition/information on ingredients

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

| CAS: 36425-15-7 | Bis-GMA | Skin Irrit. 2, H315; Eye Irrit. 2, H319; Skin Sens. 1, H317 | 10-25% |
| CAS: 13760-80-0 | ytterbium trifluoride | Skin Irrit. 2, H315; Eye Irrit. 2, H319; STOT SE 3, H335 | ≥10-<20% |
| CAS: 72869-86-4 | urethane dimethacrylate | Eye Irrit. 2, H319; Skin Sens. 1, H317; Aquatic Chronic 3, H412 | ≥10-<25% |
| CAS: 109-16-0 | triethylene glycol dimethacrylate | Skin Irrit. 2, H315; Eye Irrit. 2, H319; Skin Sens. 1, H317; STOT SE 3, H335 | ≥2.5-<10% |

• 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.

(Contd. on page 3)
**Trade name:** Heliomolar Flow

- **5.3 Advice for firefighters**
  - **Protective equipment:** No special measures required.

**SECTION 6: Accidental release measures**

- **5.1 Personal precautions, protective equipment and emergency procedures** Not required.
- **5.2 Environmental precautions:** Do not allow to enter sewers/surface or ground water.
- **5.3 Methods and material for containment and cleaning up:** Pick up mechanically.
- **5.4 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.
  - **Information about fire - and explosion protection:** No special measures required.
- **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**

- **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.
    - Wash hands before breaks and at the end of work.
    - Avoid contact with the eyes and skin.
    - Keep away from foodstuffs, beverages and feed.
  - **Respiratory protection:** Not required.
- **Protection of hands:**
  - **Protective gloves**

(Contd. on page 4)
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

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**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 applicable.

  - **Change in condition**
    - Melting point/freezing point: Undetermined.
    - Initial boiling point and boiling range: Undetermined.

  - **Flash point:** Not applicable.

  - **Flammability (solid, gas):** Not determined.

  - **Auto-ignition temperature:** Product is not selfigniting.

  - **Explosive properties:** Product does not present an explosion hazard.

  - ** Explosion limits:**
    - Lower: Not determined.
    - Upper: Not determined.

  - **Vapour pressure:** Not applicable.

  - **Density at 20 °C:** 1.94 g/cm³
  - **Relative density:** Not determined.
  - **Vapour density** Not applicable.
  - **Evaporation rate** Not applicable.

  - **Solubility in / Miscibility with water:** Nearly insoluble.

  - **Partition coefficient: n-octanol/water:** Not determined.

  - **Viscosity:**
    - Dynamic: Not applicable.
    - Kinematic: Not applicable.
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 dangerous reactions known.
- 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
  - Acute toxicity: Based on available data, the classification criteria are not met.
  - Skin corrosion/irritation
    Causes skin irritation.
  - Serious eye damage/irritation
    Causes serious eye irritation.
  - Respiratory or skin sensitisation
    May cause an allergic skin reaction.
  - Germ cell mutagenicity: Based on available data, the classification criteria are not met.
  - Carcinogenicity: Based on available data, the classification criteria are not met.
  - STOT-single exposure: Based on available data, the classification criteria are not met.
  - STOT-repeated exposure: Based on available data, the classification criteria are not met.
  - Aspiration hazard: Based on available data, the classification criteria are not met.
  - Additional toxicological information:  No further relevant information available.

SECTION 12: Ecological information

- 12.1 Toxicity
  - Aquatic toxicity:  No further relevant information available.
- 12.2 Persistence and degradability:  No further relevant information available.
- 12.3 Bioaccumulative potential:  No further relevant information available.
- 12.4 Mobility in soil:  No further relevant information available.
- Additional ecological information:
  - General notes:  Water hazard class 1 (German Regulation) (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.
  - PBT: Not applicable.
  - vPvB:  Not applicable.

(Contd. of page 6)
Trade name: Heliomolar Flow

12.6 Other adverse effects
No further relevant information available.

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.
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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)
PBT: Persistent, Bioaccumulative and Toxic
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.