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

- **Product identifier**
  - **Trade name:** Opal™ Bond™ Flow & Opal™ Bond™ Flow Blue
  - **Article number:** 71050, 71161
  - **Index number:** SDS 75-001.10
- **Relevant identified uses of the substance or mixture and uses advised against**
  - Professional Orthodontic Adhesive

- **Application of the substance / the mixture** Professional Orthodontic Adhesive

- **Details of the supplier of the safety data sheet**
  - **Manufacturer/Supplier:** Ultradent Products Inc.
    505 W. Ultradent Drive (10200 S)
    South Jordan, UT 84095-3942
    USA
    onlineordersupport@ultradent.com

  - **EC Responsible Person**
    Ultradent Products GmbH
    Am Westhover Berg 30
    51149 Cologne Germany
    Email: infoDE@ultradent.com
    Emergency Phone: +49(0)2203-35-92-0

  - **Further information obtainable from:** Customer Service
  - **Emergency telephone number:**
    CHEMTREC (NORTH AMERICA) :(800) 424-9300
    (INTERNATIONAL) : +(703) 527-3887

2 Hazards identification

- **Classification of the substance or mixture**

  - **Classification according to Regulation (EC) No 1272/2008**
    - GHS07
    - 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.

- **Label elements**
  - **Labelling according to Regulation (EC) No 1272/2008**
    The Regulation EC 1272/2008 on classification, labeling and packaging of substances and mixtures (CLP) shall not apply to a medical device in the finished state used in direct physical contact with the human body according to Art. 1.5 (d). Therefore, the product is exempted from the CLP labeling requirements, and no SDS is required by Regulation 1907/2006, Art. 2 (6c), REACH. Therefore, all given data, classification, and information on this SDS are provided solely on a voluntary basis.
    - **Hazard pictograms** GHS07
    - **Signal word** Warning

- **Hazard-determining components of labelling:**
  - Triethylene Glycol Dimethacrylate
  - Organophosphine Oxide

(Contd. on page 2)
51.0.1 · Hazard statements
H315 Causes skin irritation.
H319 Causes serious eye irritation.
H317 May cause an allergic skin reaction.

· Precautionary statements
P101 If medical advice is needed, have product container or label at hand.
P102 Keep out of reach of children.
P103 Read label before use.
P261 Avoid breathing dust/fume/gas/mist/vapours/spray.
P264 Wash thoroughly after handling.
P272 Contaminated work clothing should not be allowed out of the workplace.
P280 Wear protective gloves / eye protection / face protection.
P302+P352 IF ON SKIN: Wash with plenty of water.
P305+P351+P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
P362+P364 Take off contaminated clothing and wash it before reuse.
P333+P313 If skin irritation or rash occurs: Get medical advice/attention.
P321 Specific treatment (see on this label).
P313 If eye irritation persists: Get medical advice/attention.
P501 Dispose of contents/container in accordance with local/regional/national/international regulations.

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

3 Composition/information on ingredients
· Chemical characterisation: Mixtures
· Description: Mixture of substances listed below with nonhazardous additions.
· Dangerous components:

<table>
<thead>
<tr>
<th>CAS</th>
<th>Description</th>
<th>Skin Sens.</th>
<th>Skin Corr.</th>
<th>Aquatic Chronic</th>
</tr>
</thead>
<tbody>
<tr>
<td>109-16-0</td>
<td>Triethylene Glycol Dimethacrylate</td>
<td>≥10-% ≤25%</td>
<td>1A, 1;</td>
<td>4</td>
</tr>
<tr>
<td>203-652-6</td>
<td>Trade Secret</td>
<td></td>
<td>1;</td>
<td></td>
</tr>
<tr>
<td>162881-26-7</td>
<td>Organophosphine Oxide</td>
<td>&lt;2%</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

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

4 First aid measures
· Description of first aid measures
· General information: Immediately remove any clothing soiled by the product.
· After inhalation: This product is a thick paste, therefore inhalation is extremely unlikely.
· After skin contact: Immediately wash with water and soap and rinse thoroughly.
· 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.
If swallowed in large quantities seek medical attention.
5 Firefighting measures

- Extinguishing media
- Suitable extinguishing agents:
  Foam, dry chemical, carbon dioxide
  Use fire extinguishing methods suitable to surrounding conditions.
- Special hazards arising from the substance or mixture: No further relevant information available.

6 Accidental release measures

- Personal precautions, protective equipment and emergency procedures: Wear protective clothing.
- Environmental precautions: Do not allow to enter sewers/surface or ground water.
- Methods and material for containment and cleaning up:
  Absorb with liquid-binding material (sand, diatomite, acid binders, universal binders, sawdust).
  Dispose contaminated material as waste according to item 13.
  Ensure adequate ventilation.
- 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:
  Avoid release to the environment
  Ensure good ventilation/exhaustion at the workplace.
  Prevent formation of aerosols.
- Information about fire - and explosion protection: No special measures required.
- Conditions for safe storage, including any incompatibilities
- Storage:
  Requirements to be met by storerooms and receptacles: No special requirements.
  Information about storage in one common storage facility: Not required.
- Further information about storage conditions:
  See product labelling.
  Keep container tightly sealed.

Specific end use(s): Professional Orthodontic Adhesive

8 Exposure controls/personal protection

- Additional information about design of technical facilities: No further data; see item 7.
51.0.1 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.

- Exposure controls
- Personal protective equipment:
- General protective and hygienic measures:
  - Keep away from foodstuffs, beverages and feed.
  - Immediately remove all soiled and contaminated clothing.
  - Wash hands before breaks and at the end of work.
  - Avoid contact with the eyes and skin.
- Respiratory protection:
  - In case of brief exposure or low pollution use respiratory filter device. In case of intensive or longer exposure use self-contained respiratory protective device.
- 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 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 breakthrough time has to be found out by the manufacturer of the protective gloves and has to be observed.
- Eye protection:
  - Tightly sealed goggles

- Body protection: Protective work clothing

9 Physical and chemical properties
- Information on basic physical and chemical properties
- General Information
- Appearance:
  - Form: Paste
  - Colour: Blue Whitish
  - Odour: Acrylic
  - Odour threshold: Not determined.
- pH-value: Not applicable (non-aqueous)
Trade name: Opal™ Bond™ Flow & Opal™ Bond™ Flow Blue

10 Stability and reactivity

- **Reactivity** Stable
- **Chemical stability**
- **Thermal decomposition / conditions to be avoided:** No decomposition if used according to specifications.
- **Possibility of hazardous reactions:** No dangerous reactions known.
- **Conditions to avoid:**
  - Sparks
  - Light
  - Ignition sources
  - Heat
  - Flames
- **Incompatible materials:** No further relevant information available.
- **Hazardous decomposition products:** No dangerous decomposition products known.

(Contd. on page 6)
Safety data sheet
generated according to 1907/2006/EC, Article 31

Trade name: Opal™ Bond™ Flow & Opal™ Bond™ Flow Blue

11 Toxicological information

- Information on toxicological effects
  - Acute toxicity Based on available data, the classification criteria are not met.

- LD/LC50 values relevant for classification:

  109-16-0 Triethylene Glycol Dimethacrylate
  - Oral LD50 >5,000 mg/kg (rat)
  - LC50 Fish 16.4 mg/l (Fish) (Toxicity to fish)
  - Dermal LD50 >2,000 mg/kg (mouse)

  162881-26-7 Organophosphine Oxide
  - Oral LD50 >2,000 mg/kg (rat)
  - LC50 Fish >0.09 mg/l (Fish) (Toxicity to fish)
  - Dermal LD50 >2,000 mg/kg (rat)

- Primary irritant effect:
  - Skin corrosion/irritation Causes skin irritation.
  - Serious eye damage/irritation Causes serious eye irritation.
  - Respiratory or skin sensitisation May cause an allergic skin reaction.

- CMR effects (carcinogenity, mutagenicity and toxicity for reproduction)
  - Germ cell mutagenicity Based on available data, the classification criteria are not met.
  - Carcinogenicity Based on available data, the classification criteria are not met.
  - Reproductive toxicity 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.

12 Ecological information

- Toxicity
  - Aquatic toxicity:

    109-16-0 Triethylene Glycol Dimethacrylate
    - Biodegradability 28 days (Aerobic) (Biodegradability testing)
    - Aqua toxicity 32 mg/l (daphnia) (No Observed Effect Concentration)
    - EC50 >100 mg/l (Algae) (Toxicity to algae)

    162881-26-7 Organophosphine Oxide
    - EC50 (static) >1.175 mg/kg (daphnia) (Toxicity to aquatic invertebrates)
    - Aqua toxicity >20.008 mg/l (daphnia) (Daphnia Magna Reproduction Test)
    - Toxicity to Aquatic Plants (static) >0.26 mg/l (Plant) (Toxicity to algae)

- Persistence and degradability No further relevant information available.
- Behaviour 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 (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.

(Contd. on page 7)
• 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: Do not allow product to reach sewage system.

• European waste catalogue
  HP4  Irritant - skin irritation and eye damage
  HP13  Sensitising

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

14 Transport information

• UN-Number
  • ADR, ADN, IMDG, IATA: not regulated

• UN proper shipping name
  • ADR, ADN, IMDG, IATA: not regulated

• Transport hazard class(es)
  • ADR, ADN, IMDG, IATA: not regulated
  • Class: not regulated

• Packing group
  • ADR, IMDG, IATA: not regulated

• Environmental hazards:
  • Not applicable.

• Special precautions for user
  • Not applicable.

• Transport in bulk according to Annex II of Marpol and the IBC Code
  • Not applicable.

• UN "Model Regulation": not regulated

15 Regulatory information

• Safety, health and environmental regulations/legislation specific for the substance or mixture
  • REGULATION (EC) No 1907/2006 ANNEX XVII Conditions of restriction: 3
  • Chemical safety assessment:
    Device is biocompatible when used as directed by dental professionals per ISO 10993-1

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
  H314 Causes severe skin burns and eye damage.
  H317 May cause an allergic skin reaction.
  H318 Causes serious eye damage.
  H413 May cause long lasting harmful effects to aquatic life.

· Department issuing SDS: Regulatory Affairs
· Contact: Customer Service

· 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)
  VOC: Volatile Organic Compounds (USA, EU)
  LC50: Lethal concentration, 50 percent
  LD50: Lethal dose, 50 percent
  PBT: Persistent, Bioaccumulative and Toxic
  vPvB: very Persistent and very Bioaccumulative
  Skin Corr. 1A: Skin corrosion/irritation – Category 1A
  Skin Irrit. 2: Skin corrosion/irritation – Category 2
  Eye Dam. 1: Serious eye damage/eye irritation – Category 1
  Eye Irrit. 2: Serious eye damage/eye irritation – Category 2
  Skin Sens. 1: Skin sensitisation – Category 1
  Aquatic Chronic 4: Hazardous to the aquatic environment - long-term aquatic hazard – Category 4