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

- **1.1 Product identifier**
  - Trade name: CLEARFIL ST OPAQUER
  - Article number: 013
  - Registration number: Not applicable

- **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: Dental filling material

- **1.3 Details of the supplier of the safety data sheet**
  - Manufacturer:
    Kuraray Europe GmbH
    Philipp-Reis-Str. 4,
    65795 Hattersheim am Main
    Germany
    Phone: +49 (0)69 305 35 840
    Fax: +49 (0)69 305 35 640
    E-mail: dental@kuraray.de
  - Supplier:
    J & S Davis
    5 Whitworth Road, Stevenage,
    Hertfordshire, SG1 4QS
    Great Britain
    Tel: +44- (0) 1438 747344
    Fax: +44- (0)1438 758909
    E-mail: jsdsales@js-davis.co.uk
  - Further information obtainable from: Manufacturer or Supplier

- **1.4 Emergency telephone number:**
  - National Poisons information Service (London Centre)
    Guy’s & St. Thomas’ Hospital Trust
    Medical Toxicology Unit
    Avonley Road
    LONDON
    SE14 5ER
    Emergency telephone: (local) 0870 600 6266 or +44 20 7771 5394
    Administrative telephone: +44 20 7 771 53 10
    Facsimile number: +44 20 7 771 53 09

* **SECTION 2: Hazards identification**

- **2.1 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.

- **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 statements:
    H315 Causes skin irritation.
    H319 Causes serious eye irritation.

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

- 3.1 Chemical characterisation: Substances None
- 3.2 Chemical characterisation: Mixtures
   - Description: Mixture of substances listed below with nonhazardous additions.
   - Dangerous components:
     - None

<table>
<thead>
<tr>
<th>CAS: 1565-94-2</th>
<th>bisphenol A diglycidylmethacrylate</th>
<th>Skin Irrit. 2, H315; Eye Irrit. 2, H319</th>
<th>5-25%</th>
</tr>
</thead>
<tbody>
<tr>
<td>EINECS: 216-367-7</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>CAS: 109-16-0</th>
<th>triethylene glycol dimethacrylate</th>
<th>Skin Irrit. 2, H315; Eye Irrit. 2, H319; STOT SE 3, H335</th>
<th>&lt;10%</th>
</tr>
</thead>
<tbody>
<tr>
<td>EINECS: 203-652-6</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

- Other ingredients:
  - Silanated silica filler
  - Colloidal silica
  - Silanated colloidal silica
  - dl-Camphorquinone
  - Catalysts
  - Accelerators
  - Pigments

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:
    - 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:
    - Do not induce vomiting; call for medical help immediately.
    - 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:
  Wear self-contained respiratory protective device.
  Wear fully protective suit.

SECTION 6: Accidental release measures

6.1 Personal precautions, protective equipment and emergency procedures See Section 8.
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
  Ensure good ventilation/exhaustion at the workplace.
  Prevent formation of aerosols.
  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 in a cool location (2-25 °C).
  Information about storage in one common storage facility: Not required.
  Further information about storage conditions:
  Keep container tightly sealed.
  Store in cool, dry conditions in well sealed receptacles.
  Protect from heat and direct sunlight.
  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:
  Immediately remove all soiled and contaminated clothing
Trade name: CLEARFIL ST OPAQUER

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 trough time has to be found out by the manufacturer of the protective gloves and has to be observed.

- **Eye protection:**

![Tightly sealed goggles]

## SECTION 9: Physical and chemical properties

### 9.1 Information on basic physical and chemical properties

- **General Information**
  - **Appearance:**
    - Form: Pasty
    - Colour: Coloured
    - Odour: Odourless
  - **pH-value:** Not determined

- **Change in condition**
  - Melting point/Melting range: Not determined
  - Boiling point/Boiling range: Not determined

- **Flash point:** Not determined

- **Ignition temperature:** Not determined

- **Decomposition temperature:** Not determined

- **Danger of explosion:**
  - Product does not present an explosion hazard.

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

- **Oxidising properties:**
  - Not determined

- **Vapour pressure:**
  - Not determined

- **Density:** 1.1 g/cm³
- **Relative density**
  - Not determined
Trade name: CLEARFIL ST OPAQUER

· Vapour density: Not determined
· Evaporation rate: Not determined
· Solubility in / Miscibility with water: Insoluble
· Partition coefficient (n-octanol/water): Not applicable
· Viscosity: Not determined
· 9.2 Other information: No further relevant information available.

SECTION 10: Stability and reactivity

· 10.1 Reactivity: No further relevant information available.
· 10.2 Chemical stability
· Thermal decomposition / conditions to be avoided: No decomposition if used according to specifications.
· 10.3 Possibility of hazardous reactions: No dangerous reactions known.
· 10.4 Conditions to avoid: No further relevant information available.
· 10.5 Incompatible materials: No further relevant information available.
· 10.6 Hazardous decomposition products: Carbon monoxide and carbon dioxide

SECTION 11: Toxicological information

· 11.1 Information on toxicological effects
· Acute toxicity: Based on available data, the classification criteria are not met.
· Primary irritant effect:
· Skin corrosion/irritation
Causes skin irritation.
· Serious eye damage/irritation
Causes serious eye irritation.
· Respiratory or skin sensitisation: Based on available data, the classification criteria are not met.
· CMR effects (carcinogenicity, 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.

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.
· 12.5 Results of PBT and vPvB assessment
· PBT: Not applicable.
· vPvB: Not applicable.
SECTION 13: Disposal considerations

13.1 Waste treatment methods
Recommendation
Must not be disposed together with household garbage. Do not allow product to reach sewage system.

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

SECTION 14: Transport information

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

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

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

14.4 Packing group
ADR, 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.

UN "Model Regulation": Void

SECTION 15: Regulatory information

15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture
No further relevant information available.

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.
H319 Causes serious eye irritation.
H335 May cause respiratory irritation.

Abbreviations and acronyms:
Skin Irrit. 2: Skin corrosion/irritation – Category 2
Eye Irrit. 2: Serious eye damage/eye irritation – Category 2
STOT SE 3: Specific target organ toxicity (single exposure) – Category 3

* Data compared to the previous version altered.