1 Identification

- Product identifier
  - Trade name: **Agfa Dentus M2 Comfort, Ortholux, E-Speed**

- Application of the substance / the mixture
  - Dental X-ray film

- Details of the supplier of the safety data sheet
  - Manufacturer/Supplier:
    Kulzer GmbH
    Leipziger Straße 2, 63450 Hanau (Germany)
    Tel.: +49 (0)800 4372522
  - Information department:
    Tel. +1 (800) 431-1785  Fax: +1 (800) 522-1545
    e-mail: customer.servicehnad@kulzer-dental.com
  - Emergency telephone number:
    GBK/Infotrac ID  105860: (domestic) 1 800 535 5053 or international (001) 352 323 3500

2 Hazard(s) identification

- Classification of the substance or mixture
  - The product is not classified according to the Globally Harmonized System (GHS).

- Label elements
  - GHS label elements Void
  - Hazard pictograms Void
  - Signal word Void
  - Hazard statements Void

- Classification system
  - NFPA ratings for USA (scale 0-4)
    - Health = 0
    - Fire = 0
    - Reactivity = 0
  - HMIS-Ratings (Scale 0-4)
    - Health = 0
    - Fire = 0
    - Reactivity = 0

- Results of PBT and vPvB assessment
  - PBT: Not applicable.
  - vPvB: Not applicable.

3 Composition/information on ingredients

- Chemical characterization: Mixtures
- Description: -
- Dangerous components: Void

(Contd. on page 2)
Trade name: Agfa Dentus M2 Comfort, Ortholux, E-Speed

4 First-aid measures

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

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.
- Additional information -

6 Accidental release measures

- Personal precautions, protective equipment and emergency procedures Not required.
- Environmental precautions: No special measures required.
- Methods and material for containment and cleaning up: Pick up mechanically.
- Reference to other sections No dangerous substances are released.

7 Handling and storage

- Handling
  - Precautions for safe handling No special measures required.
  - 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 in a cool location.
    - Information about storage in one common storage facility: Not required.
    - Further information about storage conditions: None.

(Contd. on page 3)
Trade name: **Agfa Dentus M2 Comfort, Ortholux, E-Speed**

- **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.
- **Exposure controls**
  - **Personal protective equipment**
    - **General protective and hygienic measures**
      The usual precautionary measures for handling chemicals should be followed.
    - **Breathing equipment**: Not required.
    - **Protection of hands**:
      Check protective gloves prior to each use for their proper condition.
      Recommended
      - **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.
      - **For the permanent contact of a maximum of 15 minutes gloves made of the following materials are suitable**:
        Butyl rubber, BR
        Nitrile rubber, NBR
  - **Eye protection**: Not absolutely necessary.
- **Body protection**: Light weight protective clothing

### 9 Physical and chemical properties

- **Information on basic physical and chemical properties**
  - **General Information**
    - **Appearance**:
      - **Form**: Foil
      - **Color**: According to product specification
      - **Odor**: Odorless
      - **Odor threshold**: Not determined.
  - **pH-value**: Not applicable.
- **Change in condition**
  - **Melting point/Melting range**: Undetermined
Trade name: Agfa Dentus M2 Comfort, Ortholux, E-Speed

- Boiling point/Boiling range: undetermined
- Flash point: Not applicable
- Flammability (solid, gaseous): Not determined.
- Ignition temperature:
  - Decomposition temperature: Not determined.
- Auto igniting: Product is not selfigniting.
- Danger of explosion: Product does not present an explosion hazard.
  - Explosion limits:
    - Lower: Not determined.
    - Upper: Not determined.
- Vapor pressure: Not applicable.
- Density at 20 °C (68 °F): 0 g/cm³ (0 lbs/gal)
  - Relative density: Not determined.
  - Vapor density: Not applicable.
  - Evaporation rate: Not applicable.
- Solubility in / Miscibility with
  - Water: Insoluble
- Partition coefficient (n-octanol/water): Not determined.
- Viscosity:
  - dynamic: Not applicable.
  - kinematic: Not applicable.
- Solvent content:
  - Solids content: 100.0 %
- Other information: No further relevant information available.

10 Stability and reactivity
- Reactivity: No further relevant information available.
- Possibility of hazardous reactions: No dangerous reactions known.
- Conditions to avoid: No further relevant information available.
- Incompatible materials: No further relevant information available.
- Hazardous decomposition products: none
- Additional information: -

11 Toxicological information
- Information on toxicological effects
  - Acute toxicity:
    - Primary irritant effect:
      - on the skin: No irritant effect.
      - on the eye: No irritating effect.
Trade name: **Agfa Dentus M2 Comfort, Ortholux, E-Speed**

- **Sensitization:** No sensitizing effects known.
- **Additional toxicological information:**
  The product is not subject to classification according to the calculation method of the General EU Classification Guidelines for Preparations as issued in the latest version:
  When used and handled according to specifications, the product does not have any harmful effects according to our experience and the information provided to us.
- **Carcinogenic categories**
  - **IARC (International Agency for Research on Cancer)**
    None of the ingredients is listed.
  - **NTP (National Toxicology Program)**
    None of the ingredients is listed.
  - **OSHA-Ca (Occupational Safety & Health Administration)**
    None of the ingredients is listed.

### 12 Ecological information

- **Toxicity**
  - **Aquatic toxicity:** No further relevant information available.
  - **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.
  - **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** Smaller quantities can be disposed of with household waste.
- **Uncleaned packagings:**
  - **Recommendation:** Packaging can be reused or recycled after cleaning.

### 14 Transport information

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Trade name: **Agfa Dentus M2 Comfort, Ortholux, E-Speed**

### 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.

**Cancerogenity categories**

- **TLV (Threshold Limit Value established by ACGIH)**
  None of the ingredients is listed.

**GHS label elements** Void

- **Hazard pictograms** Void
- **Signal word** Void
- **Hazard statements** Void

**Chemical safety assessment**: A Chemical Safety Assessment has not been carried out.

### 16 Other information

These data are based on our present knowledge. However, they shall not constitute a guarantee for any specific product features and shall not establish a legally valid contractual relationship.

- **Date of preparation / last revision** 06/03/2017 / 2
- **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
  - DOT: US Department of Transportation
  - IATA: International Air Transport Association
  - ACGIH: American Conference of Governmental Industrial Hygienists
  - 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)
  - NFPA: National Fire Protection Association (USA)
  - HMIS: Hazardous Materials Identification System (USA)
  - PBT: Persistent, Bioaccumulative and Toxic

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- vPvB: very Persistent and very Bioaccumulative
- OSHA: Occupational Safety & Health
- TLV: Threshold Limit Value
- PEL: Permissible Exposure Limit
- REL: Recommended Exposure Limit

* Data compared to the previous version altered.