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

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

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 X-ray film

1.3 Details of the supplier of the safety data sheet
   · Manufacturer/Supplier:
     Kulzer GmbH
     Leipziger Straße 2, 63450 Hanau (Germany)  
     Tel.: +49 (0)800 4372522
   · Informing department: E-Mail: msds@kulzer-dental.com

1.4 Emergency telephone number: Emergency CONTACT (24-Hour-Number): +49 (0)6132-84463

SECTION 2: Hazards identification

2.1 Classification of the substance or mixture
   · Classification according to Regulation (EC) No 1272/2008
     The product is not classified according to the CLP regulation.

2.2 Label elements
   · Labelling according to Regulation (EC) No 1272/2008 Void
     · Hazard pictograms Void
     · Signal word Void
     · Hazard statements Void

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: -
   · Dangerous components: Void
   · 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
   · General information No special measures required.
   · After inhalation Supply fresh air; consult doctor in case of symptoms.
   · After skin contact Instantly wash with water and soap and rinse thoroughly.
   · After eye contact Rinse opened eye for several minutes under running water.
   · After swallowing Rinse out mouth and then drink plenty of water.
     In case of persistent symptoms consult doctor.

4.2 Most important symptoms and effects, both acute and delayed
   No further relevant information available.

(Contd. on page 2)
SECTION 5: Firefighting measures

5.1 Extinguishing media

· Suitable extinguishing agents
  CO2, extinguishing powder or water jet. Fight larger fires with water jet 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.
· Additional information -

SECTION 6: Accidental release measures

6.1 Personal precautions, protective equipment and emergency procedures

· Not required.

6.2 Environmental precautions

· No special measures required.

6.3 Methods and material for containment and cleaning up

· Collect mechanically.

6.4 Reference to other sections

No dangerous materials are released.

SECTION 7: Handling and storage

7.1 Precautions for safe handling

· No special measures required.

7.2 Conditions for safe storage, including any incompatibilities

· Storage
  · Requirements to be met by storerooms and containers: Store in cool location.
  · Information about storage in one common storage facility: Not required.
  · Further information about storage conditions: None.

7.3 Specific end use(s)

No further relevant information available.

SECTION 8: Exposure controls/personal protection

8.1 Control parameters

· Components with critical 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 compilation were used as basis.

8.2 Exposure controls

· Personal protective equipment
  · General protective and hygienic measures
    The usual precautionary measures should be adhered to in handling the chemicals.
  · 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 trough 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 neccessary

· **Body protection:** Light weight protective clothing

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**SECTION 9: Physical and chemical properties**

· **9.1 Information on basic physical and chemical properties**
  · **General Information**
    · **Appearance:**
      - **Form:** Foil
      - **Colour:** According to product specification
      - **Smell:** Odourless
      - **Odour threshold:** Not determined.
    
    · **pH-value:** Not applicable.
  
  · **Change in condition**
    - **Melting point/Melting range:** Not determined
    - **Boiling point/Boiling range:** Not determined
  
  · **Flash point:** Not applicable
  
  · **Inflammability (solid, gaseous)** Not determined.
  
  · **Ignition temperature:**
    - **Decomposition temperature:** Not determined.
  
  · **Self-inflammability:** Product is not selfigniting.
  
  · **Danger of explosion:** Product is not explosive.

· **Critical values for explosion**
  - **Lower:** Not determined.
  - **Upper:** Not determined.

· **Steam pressure:** Not applicable.

· **Density at 20 °C**
  - **Relative density**
    - Not determined.
  - **Vapour 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.

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**SECTION 10: Stability and reactivity**

- **10.1 Reactivity** No further relevant information available.
- **10.2 Chemical stability**
  - Conditions to be avoided: No decomposition if used and stored 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** None

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**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: Based on available data, the classification criteria are not met.
      - Serious eye damage/irritation: Based on available data, the classification criteria are not met.
  - 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.

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**SECTION 12: Ecological information**

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

12.5 Results of PBT and vPvB assessment
   · PBT: Not applicable.
   · vPvB: Not applicable.

12.6 Other adverse effects No further relevant information available.

SECTION 13: Disposal considerations

13.1 Waste treatment methods
   · Recommendation Smaller quantities can be disposed with household garbage.

* 09 01 07 photographic film and paper containing silver or silver compounds
   · Uncleaned packagings:
     · Recommendation: Packaging can be reused or recycled after cleaning.

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.

   · Transport/Additional information: -
   · UN "Model Regulation": Void

SECTION 15: Regulatory information

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

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

- **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

- *Data compared to the previous version altered.*