



1 Identification of substance:

- **Product details:**
- **Trade name:** Dyract eXtra
- **Application:** *Componer*
- **Application of the substance / the preparation:** *Dental filling material*
- **Manufacturer/Supplier:**
*DENTSPLY DeTrey GmbH
 De-Trey-Str. 1
 D-78467 Konstanz
 GERMANY*
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- Tel.: +49-(0)7531-583-0
 Fax: +49-(0)7531-583-104*
- **Further information obtainable from:**
 - *Departement Analytical Research / Research & Development for technical information*
 - *Departement Marketing & Sales for distribution of the safety data sheets*
- **Information in case of emergency:** +49-(0)7531-583-0

2 Hazards identification

- **Hazard description:**
Xi Irritant
- **Information concerning to particular hazards to man and environment**
*The product has to be labelled due to the calculation procedure of the "General Classification guideline for preparations of the EU" in the latest valid version.
 R 36/37/38 Irritating to eyes, respiratory system and skin.*
- **Classification system**
The classification is according to the latest editions of the EU-lists, and extended by company and literature data.

3 Composition/information on ingredients

- **Chemical characterization**
- **Description:** *Mixture of substances listed below with nonhazardous additions.*

- **Dangerous components:**

| | | |
|---|--|----------------|
| | <i>methacrylate with the exception of those specified elsewhere in this Annex Xi; R 36/37/38</i> | <i>10-25%</i> |
| <i>CAS: 7783-48-4 EINECS: 232-000-3</i> | <i>strontium fluoride Xn; R 20/21/22</i> | <i>2.5-10%</i> |

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

4 First aid measures

- **After inhalation** *Supply fresh air; consult doctor in case of complaints.*
- **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.*

5 Fire fighting measures

- **Suitable extinguishing agents**
CO₂, powder or water spray. Fight larger fires with water spray or alcohol resistant foam.

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- **Special hazards caused by the substance, its products of combustion or resulting gases:**
Formation of toxic gases is possible during heating or in case of fire.
- **Protective equipment:** *Wear self-contained respiratory protective device*

6 Accidental release measures

- **Person-related safety precautions:** *Wear protective clothing.*
- **Measures for environmental protection:** *Do not allow to enter sewers/ surface or ground water.*
- **Measures for cleaning/collecting:**
*Absorb with liquid-binding material (sand, diatomite, acid binders, universal binders, sawdust).
Ensure adequate ventilation.
Clean the affected area carefully; suitable cleaners are:
Ethylalcohol*

7 Handling and storage

- **Handling** *Product is intended for dental use only.*
- **Information for safe handling:** *Observe normal care for working with chemicals.*
- **Information about fire - and explosion protection:** *No special measures required.*
- **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:**
*Keep receptacle tightly sealed.
Protect from heat and direct sunlight.*

8 Exposure controls and personal protection gear

- **Additional information about design of technical facilities:** *No further data; see item 7.*
- **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.*
- **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:** *Not required.*
- **Protection of hands:**
*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.

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- **Eye protection:** Safety glasses
- **Body protection:** Protective work clothing.

9 Physical and chemical properties:

• General Information

| | |
|----------------|---|
| Form: | <i>paste</i> |
| Colour: | <i>According to product specification</i> |
| Odour: | <i>Characteristic</i> |

• Change in condition

| | |
|-------------------------------------|---------------------|
| Melting point/Melting range: | <i>undetermined</i> |
| Boiling point/Boiling range: | <i>undetermined</i> |

• **Flash point:** *Not applicable*

• **Self-igniting:** *Product is not selfigniting.*

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

• **Density:** *Not determined*

• Solubility in / Miscibility with

Water: *Not miscible or difficult to mix*

10 Stability and reactivity

- **Thermal decomposition / conditions to be avoided:** *No decomposition if used according to specifications.*
- **Dangerous reactions** *No dangerous reactions known*
- **Dangerous decomposition products:** *No dangerous decomposition products known*

11 Toxicological information

• Acute toxicity:

• Primary irritant effect:

• on the skin:

Irritant to skin and mucous membranes.

The unpolymerized product may be irritant to the skin for susceptible persons.

• on the eye: Irritating effect.

• Sensitization:

Repeated or prolonged contact with the not polymerized product may cause sensitization for acrylates / methacrylates.

• Additional toxicological information:

The product shows the following dangers according to the calculation method of the General EU Classification Guidelines for Preparations as issued in the latest version.

Irritant

12 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.

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13 Disposal considerations

- **Product:**
- **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.

14 Transport information

- **Land transport ADR/RID (cross-border)**
- **ADR/RID class:** -

- **Maritime transport IMDG:**
- **IMDG Class:** -
- **Marine pollutant:** No

- **Air transport ICAO-TI and IATA-DGR:**
- **ICAO/IATA Class:** -

15 Regulations

- **Labelling according to EU guidelines:**
The product has been classified and marked in accordance with EU Directives / Ordinance on Hazardous Materials
- **Code letter and hazard designation of product:**



Xi Irritant

- **Risk phrases:**
36/37/38 Irritating to eyes, respiratory system and skin.
- **Safety phrases:**
23 Do not breathe gas/fumes/vapour/spray (appropriate wording to be specified by the manufacturer).
26 In case of contact with eyes, rinse immediately with plenty of water and seek medical advice.
28 After contact with skin, wash immediately with plenty of water.
36/37 Wear suitable protective clothing and gloves.
60 This material and its container must be disposed of as hazardous waste.
- **National regulations**
- **Waterhazard class:** Water hazard class 1 (Self-assessment): slightly hazardous for water.

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.

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The attached safety data sheet covers the dangers and measures to be taken when large quantities of material are released, for example due to accidents during transport or storage by the dealer.

For quantities of material typically used in clinical practice, information necessary for safe use and storage of the product is given in the DFU.

• **Relevant R-phrases**

20/21/22 Harmful by inhalation, in contact with skin and if swallowed.

36/37/38 Irritating to eyes, respiratory system and skin.

• **Department issuing MSDS: Analytical Research**

• **Contact: HotLine for urgent technical support: +49-7531-583-333**

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