

Safety data sheet
according to 1907/2006/EC, Article 31

Printing date 26.04.2013

Version number 2


Revision: 26.04.2013

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

- **1.1 Product identifier**
- **Trade name:** Dytract eXtra
- **Application:** Compomer
- **1.2 Relevant identified uses of the substance or mixture and uses advised against**
No further relevant information available.
- **Application of the substance / the preparation** Dental filling material
- **1.3 Details of the supplier of the safety data sheet**
- **Manufacturer/Supplier:**
DENTSPLY DeTrey GmbH
De-Trey-Str. 1
D-78467 Konstanz
GERMANY
Tel.: +49-(0)7531-583-0
Fax: +49-(0)7531-583-104
email: KonstanzDEU.info-sdb@dentsply.com
- **Further information obtainable from:**
 - Departement Analytical Research / Research & Development for technical information
 - Departement Marketing & Sales for distribution of the safety data sheets
- **1.4 Emergency telephone number:** +49-(0)7531-583-0 8:00 - 17:00 (GMT + 1:00)

2 Hazards identification

- **2.1 Classification of the substance or mixture**
 - **Classification according to Directive 67/548/EEC or Directive 1999/45/EC**
Xi; Irritant
R36/38: Irritating to eyes and skin.
Xi; Sensitising
R43: May cause sensitisation by skin contact.
 - **Information concerning particular hazards for human 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.
 - **Classification system:**
The classification is according to the latest editions of the EU-lists, and extended by company and literature data.

 - **2.2 Label elements**
 - **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
- **Hazard-determining components of labelling:**
Dimethacrylate Resin
Butanedioic acid, 1,4-bis[2-[(2-methyl-1-oxo-2-propen-1-yl)oxy]ethyl] ester 2,3 dicarboxylic acid
 - **Risk phrases:**
36/38 Irritating to eyes and skin.
43 May cause sensitisation by skin contact.

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- **Safety phrases:**

- 23 Do not breathe gas/fumes/vapour/spray (appropriate wording to be specified by the manufacturer).
- 24/25 Avoid contact with skin and eyes.
- 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 soap and water.
- 37 Wear suitable gloves.
- 60 This material and its container must be disposed of as hazardous waste.

- **2.3 Other hazards**

- **Results of PBT and vPvB assessment**

- **PBT:** Not applicable.
- **vPvB:** Not applicable.

3 Composition/information on ingredients

- **3.2 Chemical characterization: Mixtures**

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

- **Dangerous components:**

CAS: 105883-40-7	Urethan dimethacrylate resin ☒ Xi R36/38 ⚠ Skin Irrit. 2, H315; Eye Irrit. 2, H319	2.5-10%
CAS: 41637-38-1	Dimethacrylate Resin ☒ Xi R36/37/38; ☒ Xi R43 ⚠ Skin Irrit. 2, H315; Eye Irrit. 2, H319; Skin Sens. 1, H317; STOT SE 3, H335	2.5-10%
CAS: 7783-48-4 EINECS: 232-000-3	strontium fluoride ☒ Xi R36/37/38 ⚠ Skin Irrit. 2, H315; Eye Irrit. 2, H319; STOT SE 3, H335	2.5-10%
	Butanedioic acid, 1,4-bis[2-[(2-methyl-1-oxo-2-propen-1-yl)oxy]ethyl] ester 2,3 dicarboxylic acid ☒ Xi R36/37/38; ☒ Xi R43 ⚠ Skin Irrit. 2, H315; Eye Irrit. 2, H319; Skin Sens. 1, H317; STOT SE 3, H335	2.5-10%
CAS: 3290-92-4	Trimethylolpropane Trimethacrylate (TMPTMA) ☒ N R51/53 ⚠ Aquatic Chronic 2, H411	≤ 2.5%

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

4 First aid measures

- **4.1 Description of 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.
- **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.

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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**
Formation of toxic gases is possible during heating or in case of fire.
- **5.3 Advice for firefighters**
- **Protective equipment:** Self-contained respiratory protective device.

6 Accidental release measures

- **6.1 Personal precautions, protective equipment and emergency procedures** Wear protective clothing.
- **6.2 Environmental precautions:** Do not allow to enter sewers/ surface or ground water.
- **6.3 Methods and material for containment and cleaning up:**
Absorb with liquid-binding material (sand, diatomite, acid binders, universal binders, sawdust).
Ensure adequate ventilation.
Clean the affected area carefully; suitable cleaners are:
- **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.

7 Handling and storage

- **7.1 Precautions for safe handling**
Ensure good ventilation/exhaustion at the workplace.
Prevent formation of aerosols.
Observe normal care for working with chemicals.
- **Handling** Product is intended for dental use only.
- **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 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.
- **7.3 Specific end use(s)** No further relevant information available.

8 Exposure controls/personal protection

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

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- **8.1 Control parameters**

- **Ingredients with limit values that require monitoring at the workplace:**

Butanedioic acid, 1,4-bis[2-[(2-methyl-1-oxo-2-propen-1-yl)oxy]ethyl] ester 2,3 dicarboxylic acid

WEL	Short-term value: 0.2 mg/m ³
	Long-term value: 0.1 mg/m ³ as Sn; Sk

- **Additional information:** The lists valid during the making were used as basis.

- **8.2 Exposure controls**

- **Personal protective equipment**

- **General protective and hygienic measures**

The usual precautionary measures are to be adhered to when handling chemicals.

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 necessary if room is well-ventilated.

- **Protection of hands:**



Protective gloves.

The glove material has to be impermeable and resistant to the product/ the substance/ the preparation.

Selection of the glove material on consideration of the penetration times, rates of diffusion and the degradation

- **Material of gloves**

Natural rubber, NR

Recommended thickness of the material: ≥ 0.12 mm

Permeation: Level ≥ 1

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.

- **Eye protection:**

Safety glasses



Tightly sealed goggles.

- **Body protection:** Protective work clothing.

9 Physical and chemical properties

- **9.1 Information on basic physical and chemical properties**

- **General Information**

- **Appearance:**

Form: paste

Colour: According to product specification

- **Odour:** Characteristic

- **Odour threshold:** Not determined.

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· pH-value:	Not determined.
· Change in condition	
Melting point/Melting range:	undetermined
Boiling point/Boiling range:	undetermined
· Flash point:	Not applicable
· Flammability (solid, gaseous)	Not applicable.
· Ignition temperature:	
Decomposition temperature:	Not determined.
· Self-igniting:	Product is not selfigniting.
· Danger of explosion:	Product does not present an explosion hazard.
· Explosion limits:	
Lower:	Not determined.
Upper:	Not determined.
· Vapour pressure:	Not determined.
· Density:	Not determined
· Relative density	Not determined.
· Vapour density	Not determined.
· Evaporation rate	Not determined.
· Solubility in / Miscibility with Water:	Not miscible or difficult to mix
· Partition coefficient (n-octanol/water):	Not determined.
· Viscosity:	
dynamic:	Not determined.
kinematic:	Not determined.
· Solvent content:	
Organic solvents:	0.0 %
Solids content:	77.0 %
· 9.2 Other information	No further relevant information available.

10 Stability and reactivity

- **10.1 Reactivity**
- **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:** No dangerous decomposition products known

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11 Toxicological information

- **11.1 Information on toxicological effects**

- **Acute toxicity:**

- **LD/LC50 values relevant for classification:**

3290-92-4 Trimethylolpropane Trimethacrylate (TMPTMA)

Oral	LD50	>2000 mg/kg (rat)
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- **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:**

Sensitization possible through skin contact.

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

- **12.1 Toxicity**

- **Aquatic toxicity:**

3290-92-4 Trimethylolpropane Trimethacrylate (TMPTMA)

EC50/48h	>9.22 mg/L (daphnia)
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LC50/96h	2 mg/l (fish)
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- **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:**

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.

- **12.6 Other adverse effects** No further relevant information available.

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.

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· **European waste catalogue**

18 01 06* chemicals consisting of or containing dangerous substances

· **Uncleaned packaging:**· **Recommendation:** Disposal must be made according to official regulations.**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 MARPOL73/78 and the IBC Code** Not applicable.**15 Regulatory information**· **15.2 Chemical safety assessment:** A Chemical Safety Assessment has not been carried out.**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.

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 phrases**

H315 Causes skin irritation.

H317 May cause an allergic skin reaction.

H319 Causes serious eye irritation.

H335 May cause respiratory irritation.

H411 Toxic to aquatic life with long lasting effects.

R36/37/38 Irritating to eyes, respiratory system and skin.

R36/38 Irritating to eyes and skin.

R43 May cause sensitisation by skin contact.

R51/53 Toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment.

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- **Department issuing MSDS: Analytical Research**
- **Contact: HotLine for urgent technical support: +49-7531-583-333**
- *** Data compared to the previous version altered.**

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