DentsplySirona Safety Data Sheet



| 1. Ide | ntification |
|---|---|
| Product Identification | SDS Code Number |
| Dyract [®] eXtra | 585400 |
| Substance Identity | Date of Last Revision |
| Dyract [®] eXtra Compomer | 11/04/19 |
| Manufacturer Address | Distributor Address |
| DENTSPLY/DeTrey GmbH | DENTSPLY/Caulk |
| DeTrey-Str.1 | 38 West Clarke Avenue |
| 78467 Konstanz, Germany | Milford DE 19963-1805 |
| | http://www.dentsplysirona.com |
| Grades or Minor Variant Identities | Company Telephone Number (Product Inquiries) (302) 422- |
| Not Applicable | 4511 (8:00 AM – 4:30 PM Eastern Time) |
| Product Use (for Canada) | Emergency Telephone Number |
| Light Curing Compomer / Dental Filling Material | CHEMTREC: 1-800-424-9300 (24 hours) |
| | (Outside U.S. +1-703-527-3887) CCN6510 |

2. Hazard(s) Identification



MAY CAUSE AN ALLERGIC SKIN REACTION (GHS07)

Wash hands thoroughly after handling. Wear protective gloves IF ON SKIN: Wash with plenty of soap and water. If skin irritation occurs: Get Medical Advice/attention. Take off contaminated clothing and wash before reuse.

3. Composition/Information on Ingredients

| Hazardous Components | C.A.S. Number | Exposure Limits | % |
|-------------------------------------|---------------|-----------------|------|
| Polymerizable dimethacrylate resin | 105883-40-7 | Not Established | < 35 |
| Polymerizable trimethacrylate resin | 3290-92-4 | Not Established | < 10 |
| Polymerizable dimethacrylate resin | 24448-20-2 | Not Established | < 35 |
| Polymerizable dimethacrylate resin | 109-16-0 | Not Established | < 10 |
| Strontium Fluoride | 7783-48-4 | 2.5 mg/m3 | < 10 |

Other Information: Colorants are inorganic iron oxides.

4. First Aid Measures

| Routes of Exposure | First Aid Instructions | Immediate Medical Attention | Delayed Effects |
|---------------------------|--|-----------------------------|-----------------|
| Eye | Rinse opened eye for several minutes under running water. If symptoms persist consult physician | Not Applicable | Not Applicable |
| Skin | Immediately wash with soap and water and rinse thoroughly | Not Applicable | Not Applicable |
| Inhalation | Not Applicable | Not Applicable | Not Applicable |
| Ingestion | Not Applicable | Not Applicable | Not Applicable |
| Mucosa | Rinse tissue for several minutes under running water. If symptoms persist consult physician | Not Applicable | Not Applicable |
| Note to Physicians (Treat | ting, Testing and Monitoring): Treat symptomatically. | | |

5. Fire Fighting Measures

| Flame Propagation or Burning Rate | Properties Contributing to Fire Intensity | Flammability Classification: Not Applicable | Other: Not Applicable |
|---|---|--|-----------------------|
| (for Solids) Not Applicable | Not Applicable | | |
| Extinguishing Media: CO ₂ , extinguishing powder, foam carbon dioxide or water | | Extinguishing Media to Avoid: Water with full jet. | |
| spray. Fight larger fires with water spray or alcohol resistant foam. | | | |
| Protection and Procedures for Firefighters: Firefighters should wear self-contained respiratory protective devices. | | | |

Unusual Fire and Explosion Hazards: Formation of toxic, irritating gases is possible from the decomposition of the dimethacrylate resins. Product does not present an explosion hazard.

6. Accidental Release Measures

 Containment Techniques: Material is a paste and as such will not flow.

 Spill/Leak Clean-up Procedures and Equipment: Wear protective clothing and scoop up bulk material and place in a labeled plastic or metal container.

 Avoid gross skin contact to minimize the possibility of contact dermatitis to susceptible persons. Ensure adequate ventilation.

 Evacuation Procedures: Not Applicable
 Special Instructions: Not Applicable
 Reporting Requirements: Not Applicable

7. Handling and Storage

Handling Practices and Warnings: Product is intended for dental use only. Handling of this product should be by trained dental healthcare professionals only. Observe normal care for working with chemicals.

Storage Practices and Warnings: Store only in the original package. Keep package tightly sealed. Store in a dry area. Protect from exposure to direct light. Store away from food and beverages.

8. Exposure Control / Personal Protection



| Occupational Exposure Limits: Not Applicable | | |
|--|--|---|
| Engineering Controls: Not Applicable | | |
| Individual Protection Measures | Personal Protective Equipment for Normal Use | Personal Protective Equipment for Emergencies |
| Eye/Face | Safety Glasses | Not Applicable |
| Skin | The glove material has to be impermeable and resistant to the product. | Not Applicable |
| Inhalation | Not Required | Not Applicable |
| Body Protection | Protective work clothing | Not Applicable |

9. Physical and Chemical Characteristics

| Appearance: Various shades of viscous paste. | | Odor: Characteristic sweet acrylic ester odor. | |
|--|---|---|--|
| Normal Physical State: High Viscosity Liquid (Paste) | | Melting Point: Not Applicable | |
| Specific Gravity: 2.1 g/cm ³ | Solubility in Water: Not soluble | pH: Not Applicable | |
| Vapor Pressure (mm Hg): Not Applicable | Vapor Density (AIR=1): Not Applicable | Evaporation Rate (Butyl Acetate =1): Not Applicable | |
| Flashpoint Method: Not Applicable | Flammable (Explosive) Limits in Air | Autoignition Temperature: Not Applicable, | |
| | LEL: Not Applicable UEL: Not Applicable | le Product will not autoignite. | |
| | ELE: Not replicate OLE: Not replicable | riodaet will not autorganto. | |

Other: Not Applicable

10. Stability and Reactivity Data

| Incompatibility (Materials to Avoid): Strong Oxidizing materials. | | |
|--|---------------------------------|--|
| Hazardous Products Produced During Decomposition: No dangerous decomposition products known if used according to Directions for Use. | | |
| Hazardous Polymerization: May Occur May Not Occur | Conditions to Avoid: None known | |
| Stability? Stable Unstable | Conditions to Avoid: None known | |

11.Toxicological Information

Toxicity Data, Epidemiology Studies, Carcinogenicity, Neurological Effects, Genetic Effects, Reproductive Effects, or Structure Activity Data: Product is an irritant to the skin and mucous membranes. The unpolymerized product may be an irritant to the skin in susceptible persons. On the eye the product has an irritating effect. Sensitization: Repeated or prolonged contact with the unpolymerized material may cause sensitization for persons allergic to acrylates and methacrylates. This product shows the following dangers according to internally approved calculation methods for composite materials: Irritant. Emergency Overview Material is irritating to eyes, respiratory system and skin. Severity (Mild, Acute and Chronic Health Effect(s) Routes of Single, Repeated, or Target Organ(s) Lifetime Exposure Exposure Signs and Symptoms Moderate, Severe) Eye Material can cause Single Moderate Irritation and possible corneal damage Not Applicable irritation. Skin Material may be an Single & Repeated Moderate Irritation or possible allergic response. Not Applicable irritant Severe allergic response may result in breathing difficulties Not Applicable Not Applicable Not Applicable Not Applicable Not Applicable Inhalation Ingestion Material is not harmful if Not Applicable Mild Not Applicable Not Applicable swallowed using clinically relevant quantities Mucosa Material can cause Single Mild Inflammation of the mucosa Not Applicable irritation Medical Conditions Aggravated by Exposure Open sores and wounds of the skin. Individuals with known sensitivity to methacrylates, acrylates, or urethane dimethacrylate resin used in Dental restorative products.

 Carcinogenicity
 NTP?: Not listed
 IARC monographs?: Not listed
 OSHA regulated?: No All components of this product are in compliance with the inventory listing Requirements of the U. S. Toxic Substances Control Act (TSCA) Chemical Substance Inventory.

 Potential Environmental Effects Do not allow to enter sewers/ surface or ground water.
 NFPA Hazard Classification Ratings (Scale 0-4), Health = 1, Fire = 1, Reactivity = 0

12.Ecological Information

Toxicity Data, Environmental Fate, Physical/Chemical Data, or other Data Supporting Environmental Hazard Statements: Water Hazard class1 (Selfassessment): slightly hazardous for water. Do not allow undiluted product or large quantities of it to reach ground water, water streams or sewage system.

13.Disposal Considerations

Regulations: Must not be disposed of together with household garbage. Do not allow product to reach sewage system. Dispose of material as solid waste in a closed container. Dispose of in accordance with Federal, State and Local regulations Properties (Physical/Chemical) Affecting Disposal: Dispose of material as solid waste in a closed container.

14.Transport Information

| Regulated for Shipping: No. Not Regulated | DOT Shipping Name: Not Regulated | Packing Group: Not Applicable |
|--|----------------------------------|-------------------------------|
| Do Changes in Quantities, packaging, or shipment | DOT Hazard Class: Not Applicable | UN Number: Not Applicable |
| method change product classification? No | | |

15.Regulatory Information

| This product has been classified in accordance with the hazard criteria of the Globally Harmonized System of Classification and |
|---|
| Labeling of Chemicals and the SDS contains all of the information required by the Canadian Controlled Products Regulations. |
| U.S. Federal Regulations: CERCLA 103 Reportable Quantity: This product is not subject to CERCLA reporting requirements. Many states have more |
| stringent release reporting requirements. Report spills required under federal, state and local regulations |
| Section 313 Toxic Chemicals: This product contains the following chemicals subject to Annual Release Reporting Requirements Under SARA Title III, |
| Section 313 (40 CFR 372): None |
| Section 302 Extremely Hazardous Substances (TPQ): None |
| EPA Toxic Substances Control Act (TSCA) Status: All of the components of this product are listed on the TSCA inventory. |
| U.S. State Regulations California Proposition 65: This product does not contain any chemicals, which are on the California Proposition 65 list. |
| International Regulations: Canadian Environmental Protection Act: |
| This product is a medical device and not subject to chemical notification requirements. |
| European Community Labeling: Not a dangerous preparation. |
| Europeen Inventory of New and Evisting Chamicals Substances (EINECS): |

European Inventory of New and Existing Chemicals Substances (EINECS):

This product is a medical device and not subject to chemical notification requirements.

Other: Not Applicable

16.Other Information

To the best of our knowledge this product does not contain gluten, wheat grains, flaxseed, natural rubber, or natural latex.

All components are synthetically produced; none are derived from animal products.

This information is based on our present knowledge. However, this shall not constitute a guarantee for any specific products 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.