SAFETY DATA SHEETS

This SDS packet was issued with item:

070863951

The safety data sheets (SDS) in this packet apply to the individual products listed below. Please refer to invoice for specific item number(s).

070804955 070863886 070863894 070863902 070863910 070863936 070863944 070863969 070863977 070863985 070863993 070864454 070864462 070864470 070864488 070864496 070866467 070866475 070866483 070866491 070866509 070866517 070866525 070866541 070866558 070866566 070866574 070866582



DentsplySirona Safety Data Sheet

1. Identification

| Product Name | SDS Code Number |
|--|---|
| TPH Spectra® ST & TPH Spectra® ST Effects | K102067-02 |
| Substance Identity | Date of Last Revision |
| Universal Composite Restorative | 4/20/18 |
| Manufacture Address: | Distributor Address: |
| Dentsply DeTrey GmbH | Dentsply LLC |
| De-Trey-Str. 1 | 38 West Clarke Avenue |
| 78467 Kontanz | Milford DE 19963-1805 USA |
| Germany | http://www.dentsplysirona.com |
| Grades or Minor Variant Identities | Company Telephone Number (Product Inquiries) |
| Not Applicable | (302) 422-4511 (8:00 AM – 4:30 PM Eastern Time) |
| Product Use (for Canada) | Emergency Telephone Number |
| Light Curing Composite/Dental Filling Material | CHEMTREC: 1-800-424-9300 (24 hours) |
| | (Outside U.S. +1-703-527-3887) CCN6510 |
| De-Trey-Str. 1 78467 Kontanz Germany Grades or Minor Variant Identities Not Applicable | 38 West Clarke Avenue Milford DE 19963-1805 USA http://www.dentsplysirona.com Company Telephone Number (Product Inquiries) (302) 422-4511 (8:00 AM – 4:30 PM Eastern Tim Emergency Telephone Number CHEMTREC: 1-800-424-9300 (24 hours) |

2. Hazard(s) Identification



CAUSES SKIN IRRITATION CAUSES SERIOUS EYE IRRITATION MAY CAUSE AN ALLERGIC SKIN REACTION Wash hands thoroughly after handling. Wear protective gloves.

3 Composition/Information on Ingradients

| 5. Composition/information on ingredients | | | | |
|---|---------------|-----------------|-------------|--|
| Hazardous Components | C.A.S. Number | Exposure Limits | % | |
| Urethane modified Bis-GMA dimethacrylate | 126646-17-1 | Not Established | 2.5 - < 10 | |
| 2, 6-di-tert-butyl-p-cresol | 128-37-0 | Not Established | 0.1 - ≤ 2.5 | |
| Polymerizable dimethacrylate resin | 109-16-0 | Not Established | 2.5 - < 10 | |
| Ytterbium trifluoride | 13760-80-0 | Not Established | 2.5 - < 10 | |
| Ethoxylated Bisphenol A Dimethacrylate | 41637-38-1 | Not Established | 2.5 - < 10 | |

Other Information: Colorants are inorganic iron oxides and titanium dioxide.

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. | Not Applicable | Not Applicable |
| | If symptoms persist consult physician | | |
| Skin | Immediately wash with soap and water and rinse thoroughly | Not Applicable | Not Applicable |
| Inhalation | Supply fresh air; consult doctor in case of complaints | Not Applicable | Not Applicable |
| Ingestion Rinse thoroughly. If symptoms persist consult physician. | | Not Applicable | Not Applicable |
| Mucosa | Rinse tissue for several minutes under running water. | Not Applicable | Not Applicable |
| | If symptoms persist consult physician | | |
| Note to Physicians (Treating, Testing and Monitoring): Treat symptomatically. | | | |

5 Fire Fighting Measures

| 5. The 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 | n hazard. | | |

6 Accidental Release Measures

| o. 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 | Personal Protective Equipment for Normal Use Personal Protective Equipment for Emergencies | | |
| Measures | 1 1 | 1 1 | |
| Eye/Face | Safety Glasses | Not Applicable | |
| Skin | The glove material has to be impermeable and resistant | Not Applicable | |
| | to the product. | | |
| Inhalation | Not Required if room is well-ventilated | Not Applicable | |
| Body Protection | Protective work clothing | Not Applicable | |

9. Physical and Chemical Characteristics

| yvi nysiem una Chemical Characteristics | | | |
|---|---|---|--|
| Appearance: Various shades of viscous paste. | | Odor: Characteristic sweet acrylic ester odor. | |
| Normal Physical State: Very High Viscosity Li | quid (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 | Product will not autoignite. | |
| Other: Not Applicable | | | |

10. Stability and Reactivity Data

| Incompatibility (Materials to Avoid): Strong Oxidizing materials. | |
|---|---|
| Hazardous Products Produced During Decomposition: No danger | ous 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.

| Routes of Exposure | Signs and Symptoms | Single, Repeated, or Lifetime Exposure | Severity (Mild, Moderate, Severe) | Acute and Chronic Health Effect(s) | Target Organ(s) |
|-----------------------|---|---|--------------------------------------|--|-----------------|
| Eye | Material can cause irritation. | Single | Moderate | Irritation and possible corneal damage | Not Applicable |
| Skin | Material may be an irritant | Single & Repeated | Moderate | Irritation or possible allergic response. Severe allergic response may result in breathing difficulties. | Not Applicable |
| Inhalation | Not Applicable | Not Applicable | Not Applicable | Not Applicable | Not Applicable |
| Ingestion | Material is not harmful if swallowed using clinically relevant quantities | Not Applicable | Mild | Not Applicable | Not Applicable |
| Mucosa | Material can cause irritation. | Single | Mild | Inflammation of the mucosa | Not Applicable |

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 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. Provided to the product of the p

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.

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.

regardy value continuation 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