# **SAFETY DATA SHEETS**

# This SDS packet was issued with item:

070863944

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 070863951 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 <sub>2</sub> , 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 <sup>3</sup>	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