DENTSPLY International

DENTSPLY PROFESSIONAL

Safety Data Sheet

Safety Data Sheet (in compliance with Regulation (EC) 1907/2006, Regulation (EC) 1272/2008 and Regulation (EC) 453/2010)

Date Issued: March 2002 Document Number: 537857 Date Revised: 11 September 2014 Revision Number: 8

1. IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND OF THE COMPANY/UNDERTAKING

1.1 Product Identifier:

Trade Name (as labeled): Delton® Light Cure Opaque (DDS) Sealant

Part/Item Number: 2696, 26961, 26965

1.2 Relevant Identified Uses of the Substance or Mixture and Uses Advised Against:

Recommended Use: Preventive sealing of pits and fissures in the primary

and secondary dentition in combination with the acid-

etch technique.

Restrictions on Use: For Professional Use Only. Do not use on persons

hypersensitive to methacrylates or other formula

ingredients.

1.3 Details of the Supplier of the Safety Data Sheet:

Manufacturer/Supplier Name: DENTSPLY Professional

Manufacturer/Supplier Address: 1301 Smile Way

York, PA 17404

Manufacturer/Supplier Telephone Number: 800-989-8826 or 717-767-8502 (Product Information)

Email address: ProfessionalMSDS@dentsply.com

1.4 Emergency Telephone Number:

Transportation Emergency Contact Number: 800-424-9300 Chemtrec

2. HAZARDS IDENTIFICATION

2.1 Classification of the Substance or Mixture:

GHS Classification:		
Health	Environmental	Physical
Eye Irritant Category 2 (H319)	Not Hazardous	Not Hazardous
Skin Irritant Category 2 (H315)		
Skin Sensitizer Category 1 (H317)		
Specific Target Organ Toxicity -		
Single Exposure Category 3 (H335)		

EU Classification: Xi, R36/37/38, R43

2.2 Label Elements:

Signal Word: Warning



Contains: Aromatic and aliphatic dimethacrylates

Hazard Phrases	Precautionary Phrases
H315 Causes skin irritation.	P261 Avoid breathing mist, vapors or spray.
H319 Causes serious eye irritation.	P264 Wash thoroughly after handling.
H317 May cause an allergic skin reaction.	P271 Use only outdoors or in a well-ventilated area.
H335 May Cause respiratory irritation.	P272 Contaminated work clothing should not be allowed
	out of the work place.
	P280 Wear protective gloves, eye protection, and face protection.
	P302 + P352 IF ON SKIN: Wash with plenty of water.
	P333 + P313 If skin irritation occurs: Get medical
	attention.
	P362 + P364 Take off contaminated clothing and wash it
	before reuse.
	P305 + P351 + P338 IF IN EYES: Rinse cautiously with
	water for several minutes. Remove contact lenses, if
	present, and easy to do.
	P337 + P313 If eye irritation persists: Get medical
	attention.
	IF INHALED: Remove person to fresh air and keep
	comfortable for breathing.
	P312 Call a POISON CENTER if you feel unwell.
	P403 + P233 Store in a well-ventilated place. Keep
	container tightly closed.
	P405 Store locked up.
	P501 Dispose of contents and container in accordance with
	local and national regulations.

2.3 Other Hazards: None known.

3. COMPOSITION/INFORMATION ON INGREDIENTS

3.2 Mixture:

Hazardous Components	C.A.S. #	EINECS #	Classification	WT %
Aromatic and aliphatic dimethacrylates	Mixture	Mixture	Xi, R36/37/38, R43 Skin Irrit Cat 2 (H315), Eye Irrit Cat 2 (H319), Skin Sens. Cat 1 (H317), STOT SE 3 (H335)	90-100
Dichlorodimethyl Silane-, reaction products with silica	68611-44-9	271-893-4	Not Classified	1-10
Ethyl 4– dimethylaminobenzoate	10287-53-3	233-634-3	Not Classified	1-5
Titanium Dioxide	13463-67-7	236-675-5	Carc. Cat 2 (H351)	1-5

Note: The Titanium Dioxide in this product is not unbound or respirable. Therefore, no warning is required.

The exact concentration is being withheld as a trade secret.

Refer to Section 16 for the full text of the GHS and EU Classifications.

4. FIRST AID MEASURES

4.1 Descripti	on of First Aid Measures:
Eye	Flush victim's eyes with water for several minutes, while holding the eyelids apart. Get medical attention if irritation persists.
Skin	Remove contaminated clothing. Wash skin thoroughly with soap and water for several minutes. Get medical attention if irritation develops. Launder clothing before re-use.
Inhalation	Move victim to fresh air and keep at rest in a position comfortable for breathing. If breathing is difficult, have qualified personnel administer oxygen, and obtain immediate medical attention.
Ingestion	If conscious, wash mouth out with water. Do not induce vomiting. Never give anything by mouth to an unconscious or convulsing person. Get medical attention if you feel unwell.

4.2 Most Important Symptoms and Effects, Both Acute and Delayed:

May cause eye and skin irritation. Contact with skin may illicit an allergic reaction. If swallowed, may cause gastrointestinal irritation. Inhalation of vapors may cause respiratory irritation.

4.3 Indication of Any Immediate Medical Attention and Special Treatment Needed:

Immediate medical attention should not be required.

Note to Physicians (Treatment, Testing, and Monitoring): Treat symptomatically.

5. FIRE-FIGHTING MEASURES

5.1 Extinguishing Media:	Use carbon dioxide, foam, dry chemical or water fog
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5.2 Special Hazards Arising from the Substance or Mixture:

Heat of fire may cause an exothermic autopolymerization reaction. Emits toxic fumes under fire conditions. Closed containers may explode due to pressure build up when exposed to extreme heat. Decomposition may release oxides of oxides of carbon and irritating smoke and fumes.

5.3 Advice for Fire-Fighters	:				
Fire Fighting Procedures:	Cool exposed intact containe	Cool exposed intact containers with water spray.			
Precautions for Fire Fighters:	Firefighters should wear full emergency equipment and approved positive pressure self-contained breathing apparatus.				
Recommended Protective Equipment for Fire Fighters:					
EYES/FACE	HANDS RESPIRATORY THERMAL				
Cy					

6. ACCIDENTAL RELEASE MEASURES

6.1 Personal Precautions, Protective Equipment and Emergency Procedures:

Avoid contact with skin, eyes or clothing. Avoid breathing vapors

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EYES/FACE	HANDS	RESPIRATORY	SKIN

6.2 Environmental Precautions:

Prevent entry into sewers and waterways. Report releases as required by local and national authorities. Avoid contact with skin, eyes or clothing. Avoid breathing vapors. Wear appropriate protective clothing as described in Section 8.

6.3 Methods and Material for Containment and Cleaning up:

Contain and absorb spills with inert material and transfer to a suitable container for disposal. Wash spill site with water and detergent. Do not allow spills to enter sewers or waterways.

6.4 Reference to Other Sections:

Refer to Section 8 for Personal Protective Equipment and Section 13 for Disposal information.

7. HANDLING AND STORAGE

7.1 Precautions for Safe Handing:

Avoid contact with eyes, skin, and clothing. Avoid breathing mists. Wash thoroughly after handling. Wear protective clothing and equipment as described in Section 8. Use with adequate ventilation. Keep away from heat, sparks and flames.

Empty containers retaining product residues can be hazardous. Follow all SDS precautions when handling empty containers.

7.2 Conditions for Safe Storage, Including Any Incompatibilities:

Store in a cool, dry, well-ventilated area. Keep container tightly closed when not in use. Protect from physical damage. Keep away from oxidizers and other incompatible materials.

7.3 Specific End Use (s): For professional use only.

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1 Control Parameters:		
Occupational Exposure Limits:		
Aromatic and aliphatic dimethacrylates	United States	None Established
	Germany	None Established
	United Kingdom	None Established
	European Union	None Established
Dichlorodimethyl Silane-, reaction products with silica	United States	6 mg/m3 TWA manufacturer recommended
	Germany	6 mg/m3 TWA manufacturer recommended
	United Kingdom	6 mg/m3 TWA manufacturer recommended
	European Union	6 mg/m3 TWA manufacturer recommended
Ethyl 4-dimethylaminobenzoate	United States	None Established
	Germany	None Established
	United Kingdom	None Established
	European Union	None Established
Titanium Dioxide	United States	15 mg/m3 TWA OSHA PEL (Total dust) 10 mg/m3 TWA ACGIH TLV
	Germany	None Established
	United Kingdom	10 mg/m3 (Inhalable), 4 mg/m3 (Respirable) TWA UK
	European Union	None Established
Biological Exposure Limits: None Est	ablished	

8.2 Exposure Controls:

Appropriate Engineering Controls: Use with adequate general or local exhaust ventilation to minimize exposures levels.

Individual Protection Measures (PPE):

Specific Eye/face Protection: Chemical safety goggles with side shields should be worn if needed to avoid eye contact.

Specific Skin Protection: Wear rubber or other impervious gloves to avoid skin contact. Consult glove supplier for thickness and breakthrough times.

Specific Respiratory Protection: None should be needed under normal use. If ventilation is inadequate, an approved respirator or supplied air respirator appropriate should be used. Respirator selection and use should be based on contaminant type, form and concentration. Follow applicable regulations and good Industrial Hygiene practice.

Specific Thermal Hazards: None required.

Recommended Personal Protective Equipment				
EYES/FACE	HANDS	RESPIRATORY	SKIN	

9. PHYSICAL AND CHEMICAL PROPERTIES

9.1 Information on Basic Physical and Chemical Properties:

Appearance:	White liquid. Will polymerize to form an opaque film.	Explosive limits:	LEL: Not applicable UEL: Not applicable
Odor:	Methacylate odor	Vapor pressure (mmHg):	Not applicable
Odor threshold:	Not determined	Vapor density:	Not applicable
рН:	Not applicable	Relative density:	1.2
Melting/freezing point:	Not determined	Solubility(ies):	Not available
Initial boiling point and boiling range:	Not applicable	Partition coefficient: n-octanol/water:	Not applicable
Flash point:	Not applicable	Auto-ignition temperature:	Not applicable
Evaporation rate:	Not applicable	Decomposition temperature:	Not determined
Flammability (solid, gas):	Not applicable	Viscosity:	400-600 cps (@ 50 rpm)
Explosive Properties:	Not explosive	Oxidizing Properties:	Not an oxidizer

9.2 Other Information: None available

10. STABILITY AND REACTIVITY

10.1 Reactivity: None known.

10.2 Chemical Stability: Stable under normal condition.

10.3 Possibility of Hazardous Reactions: Polymerization can occur. Conditions leading to polymerization are excessive heat, oxygen-free atmosphere inhibitor depletion (due to excessive aging), direct sunlight, and contamination with polymerization catalysts.

10.4 Conditions to Avoid: Heat, sparks, open flame and other ignition sources, elevated temperatures, direct sunlight.

10.5 Incompatible materials: Avoid contact with oxidizing agents, reducing agents, strong bases.

10.6 Hazardous Decomposition Products: Thermal decomposition may release oxides of carbon and irritating smoke and fumes.

11. TOXICOLOGICAL INFORMATION

11.1 Information on Toxicological Effects:

Potential Health Effects:

Eyes: Liquid and vapors can cause moderate to severe irritation with excessive tearing, redness and blinking.

Skin: Skin contact may cause irritation. May cause allergic skin reaction (skin sensitization) with prolonged contact.

Ingestion: May cause mouth, throat and gastrointestinal irritation, nausea and vomiting.

Inhalation: Vapors or mists may cause respiratory tract irritation with coughing, mucous production and shortness of breath.

Chronic Health Effects: None known.

Irritation: No data available.

Corrosivity: No data available.

Sensitisation: No data available

Carcinogenicity:

This product contains Titanium dioxide, which is a classified as a Category 2B by IARC. However, the Titanium dioxide in this product is not unbound or respirable and is therefore not classified. None of the other components of this product are listed as carcinogens by OSHA, IARC, NTP, ACGIH or the EU CLP.

Mutagenicity: No data available.

Medical Conditions Aggravated by Exposure:

Individuals with pre-existing eye and skin conditions may be at increased risk from exposure.

Acute Toxicity Data:

Aromatic and aliphatic dimethacrylates: Oral rat LD50: 10,837 mg/kg

Dichlorodimethyl Silane-, reaction products with silica: Oral rat LD50: >5000 mg/kg

Ethyl 4-dimethylaminobenzoate: Oral rat LD50: >5,000 mg/kg

Titanium Dioxide: Oral rat LD50: 9,000 mg/kg

Reproductive Toxicity Data: No data available.

Specific Target Organ Toxicity (STOT):

Single Exposure: No data available.

Repeated Exposure: No data available.

12. ECOLOGICAL INFORMATION

12.1 Toxicity:

No ecotoxicity data available

12.2 Persistence and Degradability: No data is currently available

12.3 Bio-accumulative Potential: No data is currently available

12.4 Mobility in Soil: No data is currently available

12.5 Results of PBT and vPvB Assessment: Not applicable.

12.6 Other Adverse Effects: None

13. DISPOSAL CONSIDERATIONS

13.1 Waste Treatment Methods:

Regulations: Dispose in accordance with all national and local regulations.

Properties (Physical/Chemical) Affecting Disposal: This product will polymerize when exposed to sunlight. Empty containers retaining product residues can be hazardous. Follow all SDS precautions when handling empty containers.

Waste Treatment Recommendations: Dispose in accordance with national and local regulations.

14. TRANSPORT INFORMATION

	14.1 UN Number	14.2 UN Proper Shipping Name	14.3 Hazard Class(s)	14.4 Packing Group	14.5 Environmental Hazards
DOT	None	Not Regulated	None	None	Not applicable
ADR/RID	None	Not Regulated	None	None	Not applicable
IMDG	None	Not Regulated	None	None	Not applicable
IATA/ICAO	None	Not Regulated	None	None	Not applicable

14.6 Special Precautions for User: Not applicable.

14.7 Transport in Bulk According to Annex II of MARPOL 73/78 and the IBC Code: Not applicable.

15. REGULATORY INFORMATION

15.1 Safety, Health and Environmental Regulations/Legislation Specific for the Substance or Mixture:

U.S. Federal Regulations

Comprehensive Environmental Response and Liability Act of 1980 (CERCLA): 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.

Toxic Substances Control Act (TSCA): This product is a medical device and not subject to chemical notification requirements.

Clean Water Act (CWA): This material is not regulated under the Clean Water Act.

Clean Air Act (CAA): This material is not regulated under the Clean Air Act.

Superfund Amendments and Reauthorization Act (SARA) Title III Information:

SARA Section 311/312 (40 CFR 370) Hazard Categories:

Immediate Hazard:	Yes	Pressure Hazard:	No	

Delayed Hazard:	No	Reactivity Hazard:	No
Fire Hazard:	No		

This product contains the following toxic chemical(s) subject to reporting requirements of SARA Section 313 (40 CFR 372):

Components	C.A.S. #	WT %
None		

State Regulations

California: This product contains the following substances known to the state of California to cause cancer and/or reproductive toxicity:

Components	C.A.S. #	WT %
Toluene	108-88-3	0.05%

International Regulations

Canadian Workplace Hazardous Materials Information System (WHMIS): Medical devices are not subject to WHMIS.

Canadian Environmental Protection Act: This product is a medical device and not subject to chemical notification requirements.

This SDS has been prepared according to the criteria of the Controlled Products Regulation (CPR) and the SDS contains all of the information required by the CPR.

European Inventory of Existing Chemicals (EINECS): This product is a medical device and not subject to chemical notification requirements.

EU REACH: All components requiring registration have been pre-registered.

Australian Inventory of Chemical Substances: This product is a medical device and not subject to chemical notification requirements.

China Inventory of Existing Chemicals and Chemical Substances: This product is a medical device and not subject to chemical notification requirements.

Japanese Existing and New Chemical Substances: This product is a medical device and not subject to chemical notification requirements.

Korean Existing Chemicals List: This product is a medical device and not subject to chemical notification requirements.

Philippine Inventory of Chemicals and Chemical Substances: This product is a medical device and not subject to chemical notification requirements.

15.2 Chemical Safety Assessment: None required.

16. OTHER INFORMATION	
HMIS Hazard Rating:	

Health -2 Flammability -0 Physical Hazard -0

Full text of Classification abbreviations used in Section 2 and 3:

Xi Irritant

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

R43 May cause sensitization by skin contact

Carc Cat 2 Carcinogen Category 2

Eye Irrit Cat 2 Eye Irritant Category 2

Skin Irrit Cat 2 Skin Irritant Category 2

Skin Sens Cat 1 Skin Sensitizer Category 1

STOT SE 3 Specific Target Organ Toxicity Category 3

H315 Causes skin irritation.

H317 May cause an allergic skin reaction.

H319 Causes serious eye irritation.

H335 May cause respiratory irritation.

H351 Suspected of causing cancer.

Supersedes: 24 June 2011

Date Revised: 11 September 2014

Revision Summary: Converted MSDS to Reach SDS. Updated all sections. Updated part numbers.

Data Sources: US NLM ChemID Plus and HSDB, Substance SDS for components, IUCLID Dataset EU Chemical Bureau,

ESIS, Country websites for occupational exposure limits.