SAFETY DATA SHEETS

This SDS packet was issued with item:

071830538

The safety data sheets (SDS) in this packet apply to one or more components included in the items listed below. Items listed below may require one or more SDS. Please refer to invoice for specific item number(s).

071830496 071830520

Safety data sheet
According to 91/155 EEC

Printing date 03/26/2012 *Version number 6* *Revision: 03/22/2012*

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

· **Product identifier**

· **Trade name: Seal&Protect**
· **Application of the substance / the preparation** Dental sealing material

· **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

Supplier for CANADA:
Dentsply Canada
161 Vinyl Court
Woodbridge, ON L4L4A3

Tel.: (905) 851 6060 or 1-800-263-1437
Fax: (905) 851-9809

· **Further information obtainable from:**
- Departement Analytical Research / Research & Development for technical information
- Departement Marketing & Sales for distribution of the safety data sheets
· **Emergency telephone number:** +49-(0)7531-583-0

2 Composition/information on ingredients

· **Chemical characterization: Mixtures**
· **Description:** Mixture of substances listed below with nonhazardous additions.

· **Dangerous components:**

67-64-1	acetone Xi R36; F R11 R66-67	25-50%
	methacrylate with the exception of thosespecified elsewhere in this Annex Xi R36/37/38	25-50%
	acrylates with the exception of those specified elsewhere in this Annex Xi R36/37/38; N R51/53	2.5-10%
3380-34-5	triclosan Xi R36/38; N R50/53	2.5-10%

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

3 Hazards identification

· **Classification of the substance or mixture**

· **Classification according to Directive 67/548/EEC or Directive 1999/45/EC**
Xi; Irritant
R36/37/38: Irritating to eyes, respiratory system and skin.
F; Highly flammable
R11: Highly flammable.
N; Dangerous for the environment

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R50/53: Very toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment.

R67: Vapours may cause drowsiness and dizziness.

· **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.

· **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
F Highly flammable
N Dangerous for the environment

· **Risk phrases:**
11 Highly flammable.
36/37/38 Irritating to eyes, respiratory system and skin.
50/53 Very toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment.
67 Vapours may cause drowsiness and dizziness.

· **Safety phrases:**
9 Keep container in a well-ventilated place.
16 Keep away from sources of ignition - No smoking.
23 Do not breathe gas/fumes/vapour/spray (appropriate wording to be specified by the manufacturer).
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 water.
37 Wear suitable gloves.
57 Use appropriate container to avoid environmental contamination.
60 This material and its container must be disposed of as hazardous waste.

4 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.

5 Firefighting measures

· **Suitable extinguishing agents**
CO2, powder or water spray. Fight larger fires with water spray or alcohol resistant foam.
· **For safety reasons unsuitable extinguishing agents** Water with full jet.
· **Special hazards arising from the substance or mixture** No further relevant information available.
· **Protective equipment:** Wear self-contained respiratory protective device

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6 Accidental release measures

· **Personal precautions, protective equipment and emergency procedures**
Wear protective equipment. Keep unprotected persons away.
· **Environmental precautions:**
Inform respective authorities in case of seepage into water course or sewage system.
Do not allow to enter sewers/ surface or ground water.
· **Methods and material for containment and cleaning up:**
Absorb with liquid-binding material (sand, diatomite, acid binders, universal binders, sawdust).
Ensure adequate ventilation.
· **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

· **Handling** Product is intended for dental use only.
· **Precautions for safe handling** Observe normal care for working with chemicals.
· **Information about fire - and explosion protection:**

Keep ignition sources away - Do not smoke.

Protect against electrostatic charges.
· **Storage**
· **Requirements to be met by storerooms and receptacles:**
Store only in the original receptacle.
Store in a cool location.
· **Information about storage in one common storage facility:** Not required.
· **Further information about storage conditions:**
Keep receptacle tightly sealed.
Store in cool, dry conditions in well sealed receptacles.
· **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.

· **Ingredients with limit values that require monitoring at the workplace:**	
67-64-1 acetone	
TLV	Short-term value: 2375 mg/m3, 1000 ml/m3 Long-term value: 1780 mg/m3, 750 ml/m3

· **Additional information:** The lists valid during the making were used as basis.
· **Personal protective equipment**
· **General protective and hygienic measures**
The usual precautionary measures are to be adhered to when handling chemicals.
Wash hands before breaks and at the end of work.
Avoid contact with the eyes and skin.
· **Respiratory protection:** Use suitable respiratory protective device in case of insufficient ventilation.
· **Protection of hands:**

Protective gloves.

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The glove material has to be impermeable and resistant to the product/ the substance/ the preparation.
Due to missing tests no recommendation to the glove material can be given for the product/ the preparation/ the chemical mixture.
Selection of the glove material on consideration of the penetration times, rates of diffusion and the degradation

· ***Material of gloves***
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 trough time has to be found out by the manufacturer of the protective gloves and has to be observed.

· ***Eye protection:***

Tightly sealed goggles.

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

9 Physical and chemical properties

· ***General Information***	
· ***Appearance:***	
Form:	*Fluid*
Colour:	*Yellow*
· ***Odour:***	*Characteristic*
· ***Change in condition***	
Melting point/Melting range:	*undetermined*
Boiling point/Boiling range:	*55°C*
· ***Flash point:***	*-19°C*
· ***Ignition temperature:***	*465°C*
· ***Self-igniting:***	*Product is not selfigniting.*
· ***Danger of explosion:***	*Product is not explosive. However, formation of explosive air/vapour mixtures are possible.*
· ***Explosion limits:***	
Lower:	*2.6 Vol %*
Upper:	*13.0 Vol %*
· ***Vapour pressure at 20°C:***	*233 hPa*
· ***Density at 20°C:***	*0.96 g/cm³*
· ***Solubility in / Miscibility with***	
Water:	*Partly miscible*
· ***Other information***	*No further relevant information available.*

10 Stability and reactivity

· ***Thermal decomposition / conditions to be avoided:*** *No decomposition if used according to specifications.*
· ***Incompatible materials:*** *No further relevant information available.*

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· **Hazardous decomposition products:** No dangerous decomposition products known

11 Toxicological information

· **Acute toxicity:**
· **Primary irritant effect:**
· **on the skin:**
Irritant to skin and mucous membranes.
The unpolymerized product may be irritant to the skin for succeptible persons.
· **on the eye:** Strong irritant with the danger of severe eye injury.
· **Sensitization:**
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

· **Aquatic toxicity:** No further relevant information available.
· **Persistence and degradability** No further relevant information available.
· **Behaviour in environmental systems:**
· **Bioaccumulative potential** No further relevant information available.
· **Ecotoxical effects:**
· **Remark:** Very toxic for fish
· **Additional ecological information:**
· **General notes:**
Water danger class 3 (German Regulation) (Self-assessment): extremely hazardous for water.
Do not allow product to reach ground water, water course or sewage system, even in small quantities.
Danger to drinking water if even extremely small quantities leak into the ground.
Also poisonous for fish and plankton in water bodies.
Very toxic for aquatic organisms

13 Disposal considerations

· **Waste treatment methods**
· **Recommendation**

Must not be disposed together with household garbage. Do not allow product to reach sewage system.

· **Uncleaned packaging:**
· **Recommendation:** Disposal must be made according to official regulations.
· **Recommended cleansing agents:** Water, if necessary together with cleansing agents.

14 Transport information

· **UN-Number**	
· **TDG, IMDG, IATA**	UN1090
· **UN proper shipping name**	
· **TDG**	1090 ACETONE, mixture

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· **IMDG**	ACETONE, mixture, MARINE POLLUTANT
· **IATA**	ACETONE, mixture

· **Transport hazard class(es)**

· **TDG (Transport dangerous goods):**

· **TDG class:**	3 (F1) Flammable liquids.
· **Label**	3

· **IMDG**

· **Class**	3 Flammable liquids.
· **Label**	3

· **IATA**

· **Class**	3 Flammable liquids.
· **Label**	3
· **Packing group**	
· **TDG, IMDG, IATA**	II
· **Environmental hazards:**	Product contains environmentally hazardous substances: triclosan
· **Marine pollutant:**	Yes
	Symbol (fish and tree)
· **Special marking (TDG):**	Symbol (fish and tree)
· **Special precautions for user**	Warning: Flammable liquids.
· **Danger code (Kemler):**	33
· **EMS Number:**	F-E,S-D
· **Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code**	Not applicable.
· **Transport/Additional information:**	
· **TDG**	
· **Tunnel restriction code**	D/E

15 Regulatory information

· **National regulations**

· **Technical instructions (air):**

Class	Share in %
III	45.0

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· ***Waterhazard class:*** *Water danger class 3 (Self-assessment): extremely hazardous for water.*

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.

· ***Department issuing MSDS:*** *Analytical Research*
· ***Contact:*** *HotLine for urgent technical support: +49-7531-583-333*

CDN

Safety Data Sheet

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

Date Issued: 1 January 2003
Document Number: 558899
Date Revised: 25 August 2017
Revision Number: 6

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

1.1 Product Identifier:

Trade Name (as labeled): **SEAL & PROTECT™ Protective Sealant for Exposed Dentin**

Part/Item Number: **658010**

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

Recommended Use: **Dental Sealant for Teeth**

Restrictions on Use: **For Professional Use Only. Do not use on persons hypersensitive to acrylates 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 Damage Category 1 (H318) Skin Corrosion Category 1 (H314) Skin Sensitization Category 1 (H317) Specific Target Organ Toxicity - Single Exposure Category 3 (H336)	Aquatic Acute Toxicity Category 1 (H400) Aquatic Chronic Toxicity Category 2 (H411)	Flammable Liquid Category 2 (H225)

EU Classification: Highly Flammable (F), Corrosive (C), Dangerous for the Environment (N) R11, R34, R43, R66, R67, R50/53

2.2 Label Elements:

Signal Word: Danger

Contains: Acetone, Urethane Dimethyl Resin, Dipentarythritol Pentaacrylate Phosphate, Triclosan

Hazard Phrases	Precautionary Phrases
H225 Highly flammable liquid and vapor. H314 Causes severe skin burns and eye damage. H317 May cause an allergic skin reaction. H336 May cause drowsiness or dizziness. H400 Very toxic to aquatic life. H411 Toxic to aquatic life with long lasting effects.	P210 Keep away from heat, sparks, open flames, or hot surfaces.-No smoking. P233 Keep container tightly closed. P240 Ground or bond container and receiving equipment. P241 Use explosion-proof electrical, ventilating, or lighting equipment. P242 Use only non-sparking tools. P243 Take precautionary measures against static discharge. P260 Do not breathe mist, vapors or spray. P264 Wash thoroughly after handling. P271 Use only outdoors or in a well-ventilated area. P272 Contaminated work clothing should not be allowed out of the workplace. P273 Avoid release to the environment. P280 Wear protective gloves, protective clothing, eye protection or face protection. P305+P351+P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. P310 Immediately call a POISON CENTER or doctor. P303+P361+P353 IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water or shower. P310 Immediately call a POISON CENTER or doctor. P363 Wash contaminated clothing before reuse. P304+P340 IF INHALED: Remove to fresh air and keep at rest in a position comfortable for breathing. P312 Call a POISON CENTER or doctor if you feel unwell. P301+P330+P331 IF SWALLOWED: Rinse mouth. Do NOT induce vomiting. P370+P378 In case of fire: Use carbon dioxide, alcohol foam or dry chemical for extinction. P391 Collect spillage. P403+P235 Store in a well-ventilated place. Keep cool. 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 %
Acetone	67-64-1	200-662-2	F, Xi R11, R36, R66, R67 Flam. Liq. Cat 2, H225 Eye Irrit. Cat 2A, H319 STOT SE Cat 3, H336 EUH066	40-50
Urethane Dimethyl Resin	Proprietary	Proprietary	Xi R43 Skin Sens. Cat 1, H317	20-30
Dipentarythritol Pentaacrylate Phosphate	87699-25-0	None	C R34, R43 Skin Corr. Cat 1, H314 Eye Dam. Cat 1, H318 Skin Sens. Cat 1, H317	10-20
Trimethylolpropane Trimethylacrylate	3290-92-4	221-950-4	N R51/53 Aquatic Chronic Cat 2, H411	1-10
2,4,4'-Trichloro-2'-hydroxydiphenyl ether (Triclosan)	3380-34-5	222-182-2	Xi, N R36/38, R50/53 Eye Irrit. Cat 2A, H319 Skin Irrit. Cat 2, H315 Aquatic Acute Cat 1, H400 Aquatic Chronic Cat 1, H410	1-5

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 Description of First Aid Measures:	
Eye	Immediately flush eyes with plenty of water for at least 20 minutes while holding the eyelids apart. Remove contact lenses, if present and easy to do. Get immediate medical attention.
Skin	Immediately flush skin with plenty of water for 20 minutes while removing contaminated clothing and shoes. Get immediate medical attention. Launder clothing before re-use. (Discard contaminated shoes).
Inhalation	Immediately remove victim to fresh air. If breathing is difficult, have qualified personnel administer oxygen. If breathing has stopped, administer artificial respiration. Get immediate medical attention.
Ingestion	Do NOT induce vomiting unless directed to do so by medical personnel. If the victim is conscious and alert, have them rinse their mouth with water. Never give anything by mouth to an unconscious or convulsing person. Get immediate medical attention.

4.2 Most Important Symptoms and Effects, Both Acute and Delayed:
May cause severe eye and skin irritation and burns. May cause skin sensitization. Inhalation of vapors or mist may cause respiratory irritation and central nervous system effects such as headache, dizziness, drowsiness, nausea and unconsciousness. May be harmful if swallowed.

4.3 Indication of Any Immediate Medical Attention and Special Treatment Needed:
Immediate medical attention is required for all routes of exposure.
Note to Physicians (Treatment, Testing, and Monitoring): Treat symptomatically.

5. FIRE-FIGHTING MEASURES

5.1 Extinguishing Media:	Use carbon dioxide, alcohol foam or dry chemical.

5.2 Special Hazards Arising from the Substance or Mixture:
This product is highly flammable and forms explosive mixtures with air. Vapors are heavier than air and will travel along surfaces to remote ignition sources and flash back. Closed containers may explode if exposed to extreme heat. Decomposition may release carbon monoxide, carbon dioxide, methacrylates and acrylates.

5.3 Advice for Fire-Fighters:	
Fire Fighting Procedures:	Use water to cool exposed containers and structures and disperse flammable vapors. Fight fire from safe distance or protected location.
Precautions for Fire Fighters:	Do not enter fire area without proper protection. Firefighters should wear full emergency equipment and an approved positive pressure self-contained breathing apparatus. Do not allow run-off from firefighting to enter drains or water courses.

6. ACCIDENTAL RELEASE MEASURES

6.1 Personal Precautions, Protective Equipment and Emergency Procedures:
Evacuate spill area and keep unprotected personnel away. Remove all sources of ignition. Ventilate area with explosion proof equipment. Wear appropriate protective clothing. Prevent contact with skin, eyes or clothing. Do not breathe vapors or mists.

6.2 Environmental Precautions:
This product is very toxic to the environment, prevent spill from entering drains or natural waterways. Report releases as required by local, state, and national authorities.

6.3 Methods and Material for Containment and Cleaning up:
Contain and collect using inert absorbent materials and place in appropriate containers for disposal. Use non-sparking tools and equipment. If spill has not ignited, use water spray to disperse the vapors and protect personnel attempting to stop leak.

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:
Prevent contact with the eyes, skin and clothing. Do not breathe vapors or mists. Wear protective clothing and equipment as described in Section 8. Use only with adequate ventilation. Wash thoroughly with soap and water after handling. Keep containers closed when not in use. Keep product away from heat, sparks, flames and all other sources of ignition. Do not permit smoking in use or storage areas. Use with non-sparking tools and explosion proof equipment. Electrically bond and

ground containers for transfer. Do not cut, drill, grind or weld on or near containers, even empty containers. Empty containers retain product residues that can be hazardous. Follow all SDS precautions when handling empty containers.
7.2 Conditions for Safe Storage, Including Any Incompatibilities:
Store in accordance with regulations for the storage of flammable liquids. Store in a container in a dry, cool, well ventilated location away from heat, direct sunlight and all sources of ignition. Store 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:		
Acetone	United States	500 ppm TWA, 750 ppm STEL ACGIH TLV 1000 ppm TWA OSHA PEL
	Germany	500 ppm TWA, 1000 ppm STEL (15 min average value) DFG MAK
	United Kingdom	500 ppm TWA, 1500 ppm STEL UK WEL
	European Union	500 ppm TWA EU OEL
Urethane Dimethyl Resin	United States	None Established
	Germany	None Established
	United Kingdom	None Established
	European Union	None Established
Dipentarythritol Pentaacrylate Phosphate	United States	None Established
	Germany	None Established
	United Kingdom	None Established
	European Union	None Established
Trimethylolpropane Trimethylacrylate	United States	1 mg/m3 TWA AIHA WEEL (Skin)
	Germany	None Established
	United Kingdom	None Established
	European Union	None Established
2,4,4'-Trichloro-2'-hydroxydiphenyl ether (Triclosan)	United States	None Established
	Germany	None Established
	United Kingdom	None Established
	European Union	None Established
Biological Exposure Limits: Acetone: Acetone in urine, End of shift, 50 mg/L.		

8.2 Exposure Controls:
Appropriate Engineering Controls: Use with adequate local exhaust ventilation to maintain exposure levels below the occupational exposure limits. Use explosion-proof equipment where required.
Individual Protection Measures (PPE): **Specific Eye/face Protection:** Chemical splash goggles are recommended to avoid eye contact. **Specific Skin Protection:** Wear impervious gloves such as butyl rubber gloves. Clothing with long sleeves may be needed when working with large quantities. **Specific Respiratory Protection:** None should be needed for normal use. If the exposure limits are exceeded, an approved organic vapor respirator appropriate for the form and concentration of the contaminants should be used. Selection and use of respiratory equipment must be in accordance with applicable regulations and good industrial hygiene practice. **Specific Thermal Hazards:** None required.

9. PHYSICAL AND CHEMICAL PROPERTIES

9.1 Information on Basic Physical and Chemical Properties:

Appearance:	Light yellow liquid	**Explosive limits:**	**LEL:** 2.6% **UEL:** 13%
Odor:	Acetone odor	**Vapor pressure (mmHg):**	223 mmHg @ 20°C (68°F)
Odor threshold:	Not determined	**Vapor density:**	Not determined
pH:	Not applicable	**Relative density:**	0.9 g/m3
Melting/freezing point:	-95°C (-139°F)	**Solubility(ies):**	Not miscible or difficult to mix with water
Initial boiling point and boiling range:	55°C (131°F)	**Partition coefficient: n-octanol/water:**	Not determined
Flash point:	-19°C (-2°F)	**Auto-ignition temperature:**	Not determined
Evaporation rate:	Not determined	**Decomposition temperature:**	Not determined
Flammability (solid, gas):	Not determined	**Viscosity:**	Not determined
Explosive Properties:	Not determined	**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 at normal temperatures and conditions.
10.3 Possibility of Hazardous Reactions: Acetone mixed with chloroform in the presence of a base will result in highly

exothermic reactions.

10.4 Conditions to Avoid: Avoid visible light, high temperatures and humidity. Keep away from heat, sparks, and all ignition sources.

10.5 Incompatible materials: Avoid oxidizing agents, alkali metals and halogens.

10.6 Hazardous Decomposition Products: Decomposition may release carbon monoxide, carbon dioxide, methacrylates and acrylates.

11. TOXICOLOGICAL INFORMATION

11.1 Information on Toxicological Effects:

Potential Health Effects:
Eyes: Causes severe irritation or burns with redness, tearing, pain and burns. Corneal damage may occur.
Skin: Causes severe skin irritation and possible burns. May cause allergic skin reaction. Severe reaction may result in breathing difficulties.
Ingestion: Ingestion may cause mucous membrane and gastrointestinal burns and nervous system depression with symptoms of headache, dizziness, nausea, vomiting, weakness, fatigue, confusion, drunken behavior, and unconsciousness.
Inhalation: Inhalation of vapors may cause mucous membrane and respiratory irritation with a burning sensation of the nose and throat, watering of the eyes, and difficulty in breathing. High vapor concentrations may cause central nervous system depression with symptoms of headache, dizziness, drowsiness, nausea, vomiting, and unconsciousness.

Chronic Health Effects: Prolonged overexposure to acetone may cause effects on the kidneys and liver based on animal data.

Irritation: Acetone: Not irritating to guinea pig skin and slightly irritating to rabbit eyes. Trimethylolpropane Trimethylacrylate: Not irritating to rabbit skin and eyes. Triclosan:

Corrosivity: This product is classified as corrosive to skin and eyes.

Sensitisation: Trimethylolpropane Trimethylacrylate: Not sensitizing in an in-vivo guinea pig maximization test.

Carcinogenicity: Triclosan: In a 90 week carcinogenicity study, Syrian hamsters were fed triclosan at 15, 75 and 250 mg/kg/day. At the completion of the study there was no evidence of treatment-related neoplastic changes at 250 mg/kg. Treatment-related non-neoplastic findings were seen in kidneys, epididymides, testes and stomach at 250 mg/kg. None of the components of this product are listed as carcinogens by OSHA, IARC, NTP, ACGIH or the EU Directive.

Mutagenicity: Acetone: Acetone (reagent grade) was evaluated by the standard plate incorporation method in the Ames Salmonella reverse mutation assay with strains TA98, TA100, TA1535, TA1537, & TA1538. Experiments were done in triplicate with & without metabolic activation (S9 fractions from Aroclor-treated Sprague-Dawley rats). Results were negative in these strains. Triclosan: Negative in AMES Test, in vitro unscheduled DNA synthesis in mammalian cells, in vitro mammalian cell gene mutation assay, and in vivo chromosome aberration assay.

Medical Conditions Aggravated by Exposure:
Individuals with pre-existing skin, respiratory, liver and kidney disease may be at increased risk from exposure.

Acute Toxicity Data:

Acetone: Oral Rat LD50 - 5800 mg/kg; Inhalation Rat LC50 - 76 mg/L/4 hr, Skin rabbit LD50 - >5000 mg/kg

Urethane Dimethyl Resin: No toxicity data available.

Dipentarythritol Pentaacrylate Phosphate: No toxicity data available.

Trimethylolpropane Trimethylacrylate: Oral rat LD50 ->2000 mg/kg; Skin rabbit LD50->2000 mg/kg

Triclosan: Oral rat LD50 ->5000 mg/kg; Skin rabbit LD50 - >6000 mg/kg,

Reproductive Toxicity Data: Acetone: Developmental toxicity was assessed in pregnant CD-1 mice exposed to 0, 440, 2,200 and 6,600 ppm (1,060, 5,300, 15,900 mg/m3) acetone vapors in exposure chambers (whole-body exposure) from gestation days 6 to 17 (6 h/d, 7 d/w). As a higher dose level of 11,000 ppm induced narcosis within several hours, the high-

dose level was reduced to 6,600 ppm from the second day of exposure. The pregnant mice did not exhibit overt signs of maternal toxicity other than a statistically significant increase in the mean absolute or relative liver weights at 6,600 ppm. There was no effect on the number of implantations, the mean percent of live pups/litter, or the fetal sex ratio. Developmental toxicity was indicated at 6,600 ppm as a statistically significant reduction of fetal weights and a slight, but statistically significant increase in the percent incidence of late reabsorptions. The incidence of fetal malformations or variations was not altered by the acetone exposure. Triclosan: In a 30 day developmental study, rats were administered 15, 50 and 150 mg/kg/day. At the completion of the study, no effects indicating maternal toxicity were seen at 15 and 50 mg/kg. No developmental or teratogenicity toxicity was observed at 150 mg/kg.

Specific Target Organ Toxicity (STOT):

Single Exposure: Acetone: In a three week study with guinea pigs, a 50% solution was placed on the skin dermally three times a week. Cataracts developed by the third month post-treatment. Triclosan: Fifty human subjects were treated with a 0.5% of triclosan solution in a 1% soap solution. Triclosan was found not to be a sensitizer and the irritation potential depended on concentration. Tests also showed that Triclosan was not a photosensitizing agent

Repeated Exposure: Acetone: Groups of 10 Fischer 344 rats were given 2,500, 5,000, 10,000, 20,000 or 50,000 ppm acetone continuously in drinking water for 13 weeks. Reticulocytopenia and erythrocytopenia were observed in rats given doses ≥ 5,000 ppm. In groups of rats exposed to ≥ 20,000 ppm acetone, liver and kidney weight ratios increased; leukocytosis and thrombocytopenia were observed; and splenic pigmentation was observed in males. In the 50,000 ppm group final mean body weights were 19% (males) and 7% (females) lower than that of controls; caudal and right epididymis weight and sperm motility was decreased in the males. The NOAEL and the LOAEL were established at 2,500 and 5,000 ppm, respectively.

12. ECOLOGICAL INFORMATION

12.1 Toxicity:

Acetone: 96 hr LC50 Fathead minnow- 6210-8120 mg/L;48 hr EC50 Daphnia pulex 8800 mg/L (nominal)
Trimethylolpropane Trimethylacrylate: 96 hr LC50 Rainbow trout – 1-10 mg/L; 48 hr EC50 Daphnia magna - >9.22 mg/L
Triclosan: 96 hr LC50 Brachydanio rerio- 0.54 mg/L; 48 hr EC50 Daphnia magna-0.427 mg/L (Acute M-Factor= 100, Chronic M-Factor=1)

This product is classified as very toxic to aquatic life and toxic to the aquatic environment with long-term adverse effects. Releases to the environment should be avoided.

12.2 Persistence and Degradability: Acetone: Readily Biodegradable (84% in 20 days). Trimethylolpropane Trimethylacrylate: Not readily biodegradable. Triclosan: Not readily biodegradeable - 55.2-65.6% in 28 days.

12.3 Bio-accumulative Potential: Acetones is expected to have a low potential to bioaccumulation. Triclosan: The potential for bioaccumulation is expected to be low to moderate.

12.4 Mobility in Soil: Acetone is expected to have very high mobility in soil. Triclosan is expected to be immobile in soil.

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: Empty containers retain product residues that 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	UN1090	Acetone Solution	3	II	Not applicable
ADR/RID	UN1090	Acetone Solution	3	II	Not applicable
IMDG	UN1090	Acetone Solution	3	II	Not applicable
IATA/ICAO	UN1090	Acetone Solution	3	II	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 has a Reportable Quantity (RQ) of 10,000 lbs. (based on the RQ for Acetone of 5,000 lbs present at 40-50%). Releases above the RQ must be reported to the National Response Center. 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:	**Yes**	**Reactivity Hazard:**	**No**
Fire Hazard:	**Yes**		

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 %
Methanol	67-56-1	0.865%
Toluene	108-88-3	<42 ppm
Propylene Oxide	75-56-9	≤1.42 ppm

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: This product is an approved drug and not subject to chemical notification requirements.

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 – 3 Flammability – 3 Physical Hazard– 0

Full text of Classification abbreviations used in Section 2 and 3:
C Corrosive
F Highly Flammable
N Dangerous for the Environment.
Xi Irritant
R11 Highly flammable
R34 Causes burns.
R36 Irritating to eyes.
R36/38 Irritating to eyes and skin.
R43 May cause sensitization by skin contact.
R50/53 Very toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment.

R51/53 Toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment.
R66 Repeated exposure may cause skin dryness or cracking.
R67 Vapors may cause drowsiness and dizziness.
Aquatic Acute Cat 1Aquatic Acute Toxicity Category 1
Aquatic Chronic Cat 1 Aquatic Chronic Toxicity Category 1
Aquatic Chronic Cat 2 Aquatic Chronic Toxicity Category 2
Eye Dam. Cat 1Eye Damage Category 1
Eye Irrit. Cat 2A Eye Irritant Category 2A
Flam. Liq. Cat 2 Flammable liquid and vapor Category 2
Skin Corr. Cat 1 Skin Corrosion Category 1
Skin Irrit. Cat 2 Skin Irritation Category 2
Skin Sens. Cat 1 Skin Sensitizer Category 1
STOT SE Cat 3 Specific Target Organ Toxicity Single Exposure Category 3
H225 Highly flammable liquid and vapor.
H314 Causes severe skin burns and eye damage.
H315 Causes skin irritation.
H317 May cause an allergic skin reaction.
H318 Causes serious eye damage.
H319 Causes serious eye irritation.
H336 May cause drowsiness or dizziness.
H400 Very toxic to aquatic life.
H410 Very toxic to aquatic life with long lasting effects.
H411 Toxic to aquatic life with long lasting effects.
EUH066 Repeated exposure may cause skin dryness or cracking.

Supersedes: 18 November 2010
Date Revised: 06 February 2014
Revision Summary: Converted MSDS to Reach SDS. Updated all sections.
Date Revised: 25 August 2017
Revision Summary: revised part numbers, logo, removed pictograms, conducted 3 year review with no content changes.

Data Sources: US NLM ChemID Plus and HSDB, Substance SDS for components, IUCLID Dataset EU Chemical Bureau, ESIS, Country websites for occupational exposure limits.

Safety Data Sheet

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

Date Issued: 1 January 2003
Document Number: 558899
Date Revised: 25 August 2017
Revision Number: 6

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

1.1 Product Identifier:

Trade Name (as labeled): **SEAL & PROTECT™ Protective Sealant for Exposed Dentin**

Part/Item Number: **658010**

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

Recommended Use: **Dental Sealant for Teeth**

Restrictions on Use: **For Professional Use Only. Do not use on persons hypersensitive to acrylates 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 Damage Category 1 (H318) Skin Corrosion Category 1 (H314) Skin Sensitization Category 1 (H317) Specific Target Organ Toxicity - Single Exposure Category 3 (H336)	Aquatic Acute Toxicity Category 1 (H400) Aquatic Chronic Toxicity Category 2 (H411)	Flammable Liquid Category 2 (H225)

EU Classification: Highly Flammable (F), Corrosive (C), Dangerous for the Environment (N) R11, R34, R43, R66, R67, R50/53

2.2 Label Elements:

Signal Word: Danger

Contains: Acetone, Urethane Dimethyl Resin, Dipentarythritol Pentaacrylate Phosphate, Triclosan

Hazard Phrases	Precautionary Phrases
H225 Highly flammable liquid and vapor. H314 Causes severe skin burns and eye damage. H317 May cause an allergic skin reaction. H336 May cause drowsiness or dizziness. H400 Very toxic to aquatic life. H411 Toxic to aquatic life with long lasting effects.	P210 Keep away from heat, sparks, open flames, or hot surfaces.-No smoking. P233 Keep container tightly closed. P240 Ground or bond container and receiving equipment. P241 Use explosion-proof electrical, ventilating, or lighting equipment. P242 Use only non-sparking tools. P243 Take precautionary measures against static discharge. P260 Do not breathe mist, vapors or spray. P264 Wash thoroughly after handling. P271 Use only outdoors or in a well-ventilated area. P272 Contaminated work clothing should not be allowed out of the workplace. P273 Avoid release to the environment. P280 Wear protective gloves, protective clothing, eye protection or face protection. P305+P351+P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. P310 Immediately call a POISON CENTER or doctor. P303+P361+P353 IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water or shower. P310 Immediately call a POISON CENTER or doctor. P363 Wash contaminated clothing before reuse. P304+P340 IF INHALED: Remove to fresh air and keep at rest in a position comfortable for breathing. P312 Call a POISON CENTER or doctor if you feel unwell. P301+P330+P331 IF SWALLOWED: Rinse mouth. Do NOT induce vomiting. P370+P378 In case of fire: Use carbon dioxide, alcohol foam or dry chemical for extinction. P391 Collect spillage. P403+P235 Store in a well-ventilated place. Keep cool. 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 %
Acetone	67-64-1	200-662-2	F, Xi R11, R36, R66, R67 Flam. Liq. Cat 2, H225 Eye Irrit. Cat 2A, H319 STOT SE Cat 3, H336 EUH066	40-50
Urethane Dimethyl Resin	Proprietary	Proprietary	Xi R43 Skin Sens. Cat 1, H317	20-30
Dipentarythritol Pentaacrylate Phosphate	87699-25-0	None	C R34, R43 Skin Corr. Cat 1, H314 Eye Dam. Cat 1, H318 Skin Sens. Cat 1, H317	10-20
Trimethylolpropane Trimethylacrylate	3290-92-4	221-950-4	N R51/53 Aquatic Chronic Cat 2, H411	1-10
2,4,4'-Trichloro-2'-hydroxydiphenyl ether (Triclosan)	3380-34-5	222-182-2	Xi, N R36/38, R50/53 Eye Irrit. Cat 2A, H319 Skin Irrit. Cat 2, H315 Aquatic Acute Cat 1, H400 Aquatic Chronic Cat 1, H410	1-5

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 Description of First Aid Measures:	
Eye	Immediately flush eyes with plenty of water for at least 20 minutes while holding the eyelids apart. Remove contact lenses, if present and easy to do. Get immediate medical attention.
Skin	Immediately flush skin with plenty of water for 20 minutes while removing contaminated clothing and shoes. Get immediate medical attention. Launder clothing before re-use. (Discard contaminated shoes).
Inhalation	Immediately remove victim to fresh air. If breathing is difficult, have qualified personnel administer oxygen. If breathing has stopped, administer artificial respiration. Get immediate medical attention.
Ingestion	Do NOT induce vomiting unless directed to do so by medical personnel. If the victim is conscious and alert, have them rinse their mouth with water. Never give anything by mouth to an unconscious or convulsing person. Get immediate medical attention.

4.2 Most Important Symptoms and Effects, Both Acute and Delayed:
May cause severe eye and skin irritation and burns. May cause skin sensitization. Inhalation of vapors or mist may cause respiratory irritation and central nervous system effects such as headache, dizziness, drowsiness, nausea and unconsciousness. May be harmful if swallowed.

4.3 Indication of Any Immediate Medical Attention and Special Treatment Needed:
Immediate medical attention is required for all routes of exposure.
Note to Physicians (Treatment, Testing, and Monitoring): Treat symptomatically.

5. FIRE-FIGHTING MEASURES

5.1 Extinguishing Media:	Use carbon dioxide, alcohol foam or dry chemical.

5.2 Special Hazards Arising from the Substance or Mixture:
This product is highly flammable and forms explosive mixtures with air. Vapors are heavier than air and will travel along surfaces to remote ignition sources and flash back. Closed containers may explode if exposed to extreme heat. Decomposition may release carbon monoxide, carbon dioxide, methacrylates and acrylates.

5.3 Advice for Fire-Fighters:	
Fire Fighting Procedures:	Use water to cool exposed containers and structures and disperse flammable vapors. Fight fire from safe distance or protected location.
Precautions for Fire Fighters:	Do not enter fire area without proper protection. Firefighters should wear full emergency equipment and an approved positive pressure self-contained breathing apparatus. Do not allow run-off from firefighting to enter drains or water courses.

6. ACCIDENTAL RELEASE MEASURES

6.1 Personal Precautions, Protective Equipment and Emergency Procedures:
Evacuate spill area and keep unprotected personnel away. Remove all sources of ignition. Ventilate area with explosion proof equipment. Wear appropriate protective clothing. Prevent contact with skin, eyes or clothing. Do not breathe vapors or mists.

6.2 Environmental Precautions:
This product is very toxic to the environment, prevent spill from entering drains or natural waterways. Report releases as required by local, state, and national authorities.

6.3 Methods and Material for Containment and Cleaning up:
Contain and collect using inert absorbent materials and place in appropriate containers for disposal. Use non-sparking tools and equipment. If spill has not ignited, use water spray to disperse the vapors and protect personnel attempting to stop leak.

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:
Prevent contact with the eyes, skin and clothing. Do not breathe vapors or mists. Wear protective clothing and equipment as described in Section 8. Use only with adequate ventilation. Wash thoroughly with soap and water after handling. Keep containers closed when not in use. Keep product away from heat, sparks, flames and all other sources of ignition. Do not permit smoking in use or storage areas. Use with non-sparking tools and explosion proof equipment. Electrically bond and

ground containers for transfer. Do not cut, drill, grind or weld on or near containers, even empty containers. Empty containers retain product residues that can be hazardous. Follow all SDS precautions when handling empty containers.
7.2 Conditions for Safe Storage, Including Any Incompatibilities:
Store in accordance with regulations for the storage of flammable liquids. Store in a container in a dry, cool, well ventilated location away from heat, direct sunlight and all sources of ignition. Store 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:		
Acetone	United States	500 ppm TWA, 750 ppm STEL ACGIH TLV 1000 ppm TWA OSHA PEL
	Germany	500 ppm TWA, 1000 ppm STEL (15 min average value) DFG MAK
	United Kingdom	500 ppm TWA, 1500 ppm STEL UK WEL
	European Union	500 ppm TWA EU OEL
Urethane Dimethyl Resin	United States	None Established
	Germany	None Established
	United Kingdom	None Established
	European Union	None Established
Dipentarythritol Pentaacrylate Phosphate	United States	None Established
	Germany	None Established
	United Kingdom	None Established
	European Union	None Established
Trimethylolpropane Trimethylacrylate	United States	1 mg/m3 TWA AIHA WEEL (Skin)
	Germany	None Established
	United Kingdom	None Established
	European Union	None Established
2,4,4'-Trichloro-2'-hydroxydiphenyl ether (Triclosan)	United States	None Established
	Germany	None Established
	United Kingdom	None Established
	European Union	None Established
Biological Exposure Limits: Acetone: Acetone in urine, End of shift, 50 mg/L.		

8.2 Exposure Controls:
Appropriate Engineering Controls: Use with adequate local exhaust ventilation to maintain exposure levels below the occupational exposure limits. Use explosion-proof equipment where required.
Individual Protection Measures (PPE): **Specific Eye/face Protection:** Chemical splash goggles are recommended to avoid eye contact. **Specific Skin Protection:** Wear impervious gloves such as butyl rubber gloves. Clothing with long sleeves may be needed when working with large quantities. **Specific Respiratory Protection:** None should be needed for normal use. If the exposure limits are exceeded, an approved organic vapor respirator appropriate for the form and concentration of the contaminants should be used. Selection and use of respiratory equipment must be in accordance with applicable regulations and good industrial hygiene practice. **Specific Thermal Hazards:** None required.

9. PHYSICAL AND CHEMICAL PROPERTIES

9.1 Information on Basic Physical and Chemical Properties:

Appearance:	Light yellow liquid	**Explosive limits:**	**LEL:** 2.6% **UEL:** 13%
Odor:	Acetone odor	**Vapor pressure (mmHg):**	223 mmHg @ 20°C (68°F)
Odor threshold:	Not determined	**Vapor density:**	Not determined
pH:	Not applicable	**Relative density:**	0.9 g/m3
Melting/freezing point:	-95°C (-139°F)	**Solubility(ies):**	Not miscible or difficult to mix with water
Initial boiling point and boiling range:	55°C (131°F)	**Partition coefficient: n-octanol/water:**	Not determined
Flash point:	-19°C (-2°F)	**Auto-ignition temperature:**	Not determined
Evaporation rate:	Not determined	**Decomposition temperature:**	Not determined
Flammability (solid, gas):	Not determined	**Viscosity:**	Not determined
Explosive Properties:	Not determined	**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 at normal temperatures and conditions.
10.3 Possibility of Hazardous Reactions: Acetone mixed with chloroform in the presence of a base will result in highly

exothermic reactions.

10.4 Conditions to Avoid: Avoid visible light, high temperatures and humidity. Keep away from heat, sparks, and all ignition sources.

10.5 Incompatible materials: Avoid oxidizing agents, alkali metals and halogens.

10.6 Hazardous Decomposition Products: Decomposition may release carbon monoxide, carbon dioxide, methacrylates and acrylates.

11. TOXICOLOGICAL INFORMATION

11.1 Information on Toxicological Effects:

Potential Health Effects:
Eyes: Causes severe irritation or burns with redness, tearing, pain and burns. Corneal damage may occur.
Skin: Causes severe skin irritation and possible burns. May cause allergic skin reaction. Severe reaction may result in breathing difficulties.
Ingestion: Ingestion may cause mucous membrane and gastrointestinal burns and nervous system depression with symptoms of headache, dizziness, nausea, vomiting, weakness, fatigue, confusion, drunken behavior, and unconsciousness.
Inhalation: Inhalation of vapors may cause mucous membrane and respiratory irritation with a burning sensation of the nose and throat, watering of the eyes, and difficulty in breathing. High vapor concentrations may cause central nervous system depression with symptoms of headache, dizziness, drowsiness, nausea, vomiting, and unconsciousness.

Chronic Health Effects: Prolonged overexposure to acetone may cause effects on the kidneys and liver based on animal data.

Irritation: Acetone: Not irritating to guinea pig skin and slightly irritating to rabbit eyes. Trimethylolpropane Trimethylacrylate: Not irritating to rabbit skin and eyes. Triclosan:

Corrosivity: This product is classified as corrosive to skin and eyes.

Sensitisation: Trimethylolpropane Trimethylacrylate: Not sensitizing in an in-vivo guinea pig maximization test.

Carcinogenicity: Triclosan: In a 90 week carcinogenicity study, Syrian hamsters were fed triclosan at 15, 75 and 250 mg/kg/day. At the completion of the study there was no evidence of treatment-related neoplastic changes at 250 mg/kg. Treatment-related non-neoplastic findings were seen in kidneys, epididymides, testes and stomach at 250 mg/kg. None of the components of this product are listed as carcinogens by OSHA, IARC, NTP, ACGIH or the EU Directive.

Mutagenicity: Acetone: Acetone (reagent grade) was evaluated by the standard plate incorporation method in the Ames Salmonella reverse mutation assay with strains TA98, TA100, TA1535, TA1537, & TA1538. Experiments were done in triplicate with & without metabolic activation (S9 fractions from Aroclor-treated Sprague-Dawley rats). Results were negative in these strains. Triclosan: Negative in AMES Test, in vitro unscheduled DNA synthesis in mammalian cells, in vitro mammalian cell gene mutation assay, and in vivo chromosome aberration assay.

Medical Conditions Aggravated by Exposure:
Individuals with pre-existing skin, respiratory, liver and kidney disease may be at increased risk from exposure.

Acute Toxicity Data:

Acetone: Oral Rat LD50 - 5800 mg/kg; Inhalation Rat LC50 - 76 mg/L/4 hr, Skin rabbit LD50 - >5000 mg/kg

Urethane Dimethyl Resin: No toxicity data available.

Dipentarythritol Pentaacrylate Phosphate: No toxicity data available.

Trimethylolpropane Trimethylacrylate: Oral rat LD50 ->2000 mg/kg; Skin rabbit LD50->2000 mg/kg

Triclosan: Oral rat LD50 ->5000 mg/kg; Skin rabbit LD50 - >6000 mg/kg,

Reproductive Toxicity Data: Acetone: Developmental toxicity was assessed in pregnant CD-1 mice exposed to 0, 440, 2,200 and 6,600 ppm (1,060, 5,300, 15,900 mg/m3) acetone vapors in exposure chambers (whole-body exposure) from gestation days 6 to 17 (6 h/d, 7 d/w). As a higher dose level of 11,000 ppm induced narcosis within several hours, the high-

dose level was reduced to 6,600 ppm from the second day of exposure. The pregnant mice did not exhibit overt signs of maternal toxicity other than a statistically significant increase in the mean absolute or relative liver weights at 6,600 ppm. There was no effect on the number of implantations, the mean percent of live pups/litter, or the fetal sex ratio. Developmental toxicity was indicated at 6,600 ppm as a statistically significant reduction of fetal weights and a slight, but statistically significant increase in the percent incidence of late reabsorptions. The incidence of fetal malformations or variations was not altered by the acetone exposure. Triclosan: In a 30 day developmental study, rats were administered 15, 50 and 150 mg/kg/day. At the completion of the study, no effects indicating maternal toxicity were seen at 15 and 50 mg/kg. No developmental or teratogenicity toxicity was observed at 150 mg/kg.

Specific Target Organ Toxicity (STOT):

Single Exposure: Acetone: In a three week study with guinea pigs, a 50% solution was placed on the skin dermally three times a week. Cataracts developed by the third month post-treatment. Triclosan: Fifty human subjects were treated with a 0.5% of triclosan solution in a 1% soap solution. Triclosan was found not to be a sensitizer and the irritation potential depended on concentration. Tests also showed that Triclosan was not a photosensitizing agent

Repeated Exposure: Acetone: Groups of 10 Fischer 344 rats were given 2,500, 5,000, 10,000, 20,000 or 50,000 ppm acetone continuously in drinking water for 13 weeks. Reticulocytopenia and erythrocytopenia were observed in rats given doses ≥ 5,000 ppm. In groups of rats exposed to ≥ 20,000 ppm acetone, liver and kidney weight ratios increased; leukocytosis and thrombocytopenia were observed; and splenic pigmentation was observed in males. In the 50,000 ppm group final mean body weights were 19% (males) and 7% (females) lower than that of controls; caudal and right epididymis weight and sperm motility was decreased in the males. The NOAEL and the LOAEL were established at 2,500 and 5,000 ppm, respectively.

12. ECOLOGICAL INFORMATION

12.1 Toxicity:

Acetone: 96 hr LC50 Fathead minnow- 6210-8120 mg/L;48 hr EC50 Daphnia pulex 8800 mg/L (nominal)
Trimethylolpropane Trimethylacrylate: 96 hr LC50 Rainbow trout – 1-10 mg/L; 48 hr EC50 Daphnia magna - >9.22 mg/L
Triclosan: 96 hr LC50 Brachydanio rerio- 0.54 mg/L; 48 hr EC50 Daphnia magna-0.427 mg/L (Acute M-Factor= 100, Chronic M-Factor=1)

This product is classified as very toxic to aquatic life and toxic to the aquatic environment with long-term adverse effects. Releases to the environment should be avoided.

12.2 Persistence and Degradability: Acetone: Readily Biodegradable (84% in 20 days). Trimethylolpropane Trimethylacrylate: Not readily biodegradable. Triclosan: Not readily biodegradeable - 55.2-65.6% in 28 days.

12.3 Bio-accumulative Potential: Acetones is expected to have a low potential to bioaccumulation. Triclosan: The potential for bioaccumulation is expected to be low to moderate.

12.4 Mobility in Soil: Acetone is expected to have very high mobility in soil. Triclosan is expected to be immobile in soil.

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: Empty containers retain product residues that 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	UN1090	Acetone Solution	3	II	Not applicable
ADR/RID	UN1090	Acetone Solution	3	II	Not applicable
IMDG	UN1090	Acetone Solution	3	II	Not applicable
IATA/ICAO	UN1090	Acetone Solution	3	II	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 has a Reportable Quantity (RQ) of 10,000 lbs. (based on the RQ for Acetone of 5,000 lbs present at 40-50%). Releases above the RQ must be reported to the National Response Center. 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:	**Yes**	**Reactivity Hazard:**	**No**
Fire Hazard:	**Yes**		

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 %
Methanol	67-56-1	0.865%
Toluene	108-88-3	<42 ppm
Propylene Oxide	75-56-9	≤1.42 ppm

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: This product is an approved drug and not subject to chemical notification requirements.

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 – 3 Flammability – 3 Physical Hazard– 0

Full text of Classification abbreviations used in Section 2 and 3:
C Corrosive
F Highly Flammable
N Dangerous for the Environment.
Xi Irritant
R11 Highly flammable
R34 Causes burns.
R36 Irritating to eyes.
R36/38 Irritating to eyes and skin.
R43 May cause sensitization by skin contact.
R50/53 Very toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment.

R51/53 Toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment.
R66 Repeated exposure may cause skin dryness or cracking.
R67 Vapors may cause drowsiness and dizziness.
Aquatic Acute Cat 1Aquatic Acute Toxicity Category 1
Aquatic Chronic Cat 1 Aquatic Chronic Toxicity Category 1
Aquatic Chronic Cat 2 Aquatic Chronic Toxicity Category 2
Eye Dam. Cat 1Eye Damage Category 1
Eye Irrit. Cat 2A Eye Irritant Category 2A
Flam. Liq. Cat 2 Flammable liquid and vapor Category 2
Skin Corr. Cat 1 Skin Corrosion Category 1
Skin Irrit. Cat 2 Skin Irritation Category 2
Skin Sens. Cat 1 Skin Sensitizer Category 1
STOT SE Cat 3 Specific Target Organ Toxicity Single Exposure Category 3
H225 Highly flammable liquid and vapor.
H314 Causes severe skin burns and eye damage.
H315 Causes skin irritation.
H317 May cause an allergic skin reaction.
H318 Causes serious eye damage.
H319 Causes serious eye irritation.
H336 May cause drowsiness or dizziness.
H400 Very toxic to aquatic life.
H410 Very toxic to aquatic life with long lasting effects.
H411 Toxic to aquatic life with long lasting effects.
EUH066 Repeated exposure may cause skin dryness or cracking.

Supersedes: 18 November 2010
Date Revised: 06 February 2014
Revision Summary: Converted MSDS to Reach SDS. Updated all sections.
Date Revised: 25 August 2017
Revision Summary: revised part numbers, logo, removed pictograms, conducted 3 year review with no content changes.

Data Sources: US NLM ChemID Plus and HSDB, Substance SDS for components, IUCLID Dataset EU Chemical Bureau, ESIS, Country websites for occupational exposure limits.