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

CDN

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.

| 67-64-1 | acetone 🗙 Xi R36; 📸 F R11 | 25-50% |
|-----------|--|---------|
| | R66-67 | |
| | 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 \bowtie Xi R36/37/38; w 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

| · Classificatio Xi; Irritant | n according to Directive 67/548/EEC or Directive 1999/45/EC |
|---------------------------------|---|
| R36/37/38: | Irritating to eyes, respiratory system and skin. |
| F; Highly fla | mmable |
| R11: | Highly flammable. |
| N; Dangerou | is for the environment |
| | (Contd. on page 2) |

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| R50/53: | (Contd. of page 1) Very toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment. |
|---|--|
| The product preparation • Classification | Vapours may cause drowsiness and dizziness. n concerning particular hazards for human and environment: ct has to be labelled due to the calculation procedure of the "General Classification guideline for ns of the EU" in the latest valid version. ion system: ication is according to the latest editions of the EU-lists, and extended by company and literature |
| · Label elem | ents |
| | according to EU guidelines: ct has been classified and marked in accordance with EU Directives / Ordinance on Hazardous |
| · Code letter | and hazard designation of product: |
| × | Xi Irritant F Highly flammable N Dangerous for the environment |
| 36/37/38 Ir 50/53 V | es: lighly flammable. ritating to eyes, respiratory system and skin. ery toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment. apours may cause drowsiness and dizziness. |
| · Safety phro | |
| 9 Keep co 16 Keep aw 23 Do not l 26 In case 28 After co | ntainer in a well-ventilated place. vay from sources of ignition - No smoking. breathe gas/fumes/vapour/spray (appropriate wording to be specified by the manufacturer). of contact with eyes, rinse immediately with plenty of water and seek medical advice. ntact with skin, wash immediately with plenty of water. uitable gloves. |
| 57 Use app | propriate container to avoid environmental contamination. terial and its container must be disposed of as hazardous waste. |
| 1 Finst aid | measures |

- 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

 \cdot 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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Trade name: Seal&Protect

(Contd. of page 2)

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.
- \cdot 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
- \cdot 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.

(Contd. on page 4)

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(Contd. of page 3) 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.

| 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/vapou 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/cm ³ |
| 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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Trade name: Seal&Protect

(Contd. of page 4)

· 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.
- \cdot 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.

| TINI NI, | | |
|----------------------------------|-----------------------|--|
| · UN-Number · TDG, IMDG, IATA | UN1090 | |
| · UN proper shipping name | | |
| $\cdot TDG$ | 1090 ACETONE, mixture | |

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Trade name: Seal&Protect

| IMDG | (Contd. of page 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 Label Packing group | 3 Flammable liquids. 3 |
| TDG, IMDG, IATA | II |
| Environmental hazards: | Product contains environmentally hazardous substance |
| Marine pollutant: | triclosan 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 Anne MARPOL73/78 and the IBC Code | ex II of Not applicable. |
| Transport/Additional information: | |
| TDG | |
| Tunnel restriction code | D/E |
| | |
| 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



SAFETY DATA SHEET

Document Number: 558899 Revision Number: 4 Date Revised: 11/18/2010

SECTION 1 – PRODUCT IDENTIFICATION

Product Name: SEAL & PROTECT[™] Protective Sealant for Exposed Dentin Product Identifier (Par/Item Number): 658010, 658011 UN Number: UN1090 UN Dangerous Goods Classification: DOT Hazard Class: 3, PG II, IATA Hazard Class: 3, PG II, IMDG Class: 3, PG II

Product Use: Dental Sealant for Teeth Restrictions on Use: Do not use on persons hypersensitive to acrylates or other formula ingredients

Manufacturer/Supplier: DENTSPLY Professional Manufacturer/Supplier Address: 1301 Smile Way, York, PA 17404 Product Information Telephone Number: 1-800-989-8826 or 717-767-8502 Transit Emergency Contact Telephone Number: 800-424-9300 Chemtrec Email Address: ProfessionalMSDS@dentsply.com

SECTION 2 – HAZARDS IDENTIFICATION

Emergency Overview: Extremely Flammable Liquid and Vapor. Corrosive. Vapor may cause flash fire. Causes eye and skin burns. May cause skin sensitization. Inhalation of vapors or mist may cause respiratory irritation and central nervous system effects such as headache, dizziness, nausea, central nervous depression, narcosis and unconsciousness. Harmful if swallowed.

<u>EU Preparation Classification (1999/45/EC)</u>: Highly Flammable (F), Corrosive (C), (N) Dangerous for the Environment R11, R34, R43, R66, R67, R50/53

SECTION 3 – COMPOSITION INFORMATION ON INGREDIENTS

| Ingredient | CAS No./EINECS No. | Percent | EC Substance Classification (67/548/EEC) |
|---|-----------------------|---------|--|
| Acetone | 67-64-1 / 200-662-2 | 40-50% | F; Xi R11, R36, R66, R67 |
| Dipentarythritol Pentaacrylate Phosphate | 87699-25-0 | 10-20% | C R34, R43 |
| Urethane Dimethyl Resin | Proprietary | 20-30% | Xi R36/38, R43 |
| 2,4,4'-Trichloro-2'-hydroxydiphenyl ether (Triclosan) | 3380-34-5 / 222-182-2 | 1-5 | Xi, N R36/38, R50/53 |
| Trimethylolpropane Trimethylacrylate | 3290-92-4 / 221-950-4 | 1-10% | Xi R43 |

See Section 16 for further information on EU Classification.

SECTION 4 – FIRST AID MEASURES

<u>Eye Contact</u>: Immediately flush eyes with large quantities of water for at least 15 minutes, holding the eyelids apart. Get immediate medical attention.

<u>Skin Contact</u>: Remove contaminated clothing. Immediately wash skin thoroughly with soap and water for 15 minutes. If rash, irritation or symptoms develop, get medical attention. Launder clothing before reuse. (Discard contaminated shoes).

<u>Ingestion</u>: Aspiration Hazard. DO NOT INDUCE VOMITING. If conscious, rinse mouth with water. Never give anything by mouth to an unconscious or convulsing person. If vomiting occurs spontaneously, keep head below hips to prevent aspiration into the lungs. Get immediate medical attention. <u>Inhalation</u>: 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.

SECTION 5 – FIRE FIGHTING PROCEDURES

Extinguishing Media: Use carbon dioxide, alcohol foam or dry chemical. Use water to cool exposed containers and structures and disperse flammable vapors.

<u>Firefighting Procedures</u>: Firefighters should wear full emergency equipment and approved positive pressure, self-contained breathing apparatus. Do not allow run-off from fire fighting to enter drains or water courses.

<u>Unusual Fire/Explosion Hazards</u>: This product is extremely 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.

Known or Anticipated Hazardous Products of Combustion: Carbon monoxide, carbon dioxide, methacrylates and acrylates.

SECTION 6 – ACCIDENTAL RELEASE MEASURES

<u>Accidental Release Measures</u>: Evacuate spill area and keep unprotected personnel away. Remove all sources of ignition. Ventilate area with explosion proof equipment. Wear appropriate protective clothing as described in Section 8. 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. Do not flush to sewer! Report releases as required by local, state and federal authorities.

Personal Precautions: Avoid contact with skin, eyes or clothing.

<u>Environmental Precautions</u>: Prevent entry into sewers and waterways. Keep away from drains, surface and groundwater.

SECTION 7 – HANDLING AND STORAGE

<u>Handling</u>: Avoid contact with the eyes, skin and clothing. Avoid breathing vapors. 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 retaining product residues can be hazardous. Follow all MSDS precautions when handling empty containers.

<u>Storage</u>: Store in accordance with regulations for the storage of flammable liquids. Store in a dry, well ventilated area away from heat, direct sunlight and all sources of ignition. Store away from oxidizers and other incompatible materials.

SECTION 8 – EXPOSURE CONTROL/PERSONAL PROTECTION

Occupational Exposure Limits:

| Acetone | 1000 ppm PEL-TWA |
|---|----------------------------|
| | 500 ppm TLV-TWA |
| | 750 ppm TLV-STEL |
| | 500 ppm TWA DFG MAK |
| | 500 ppm TWA UK WEL |
| | 1500 ppm STEL UK WEL |
| Dipentarythritol Pentaacrylate Phosphate | None Established |
| Urethane Dimethyl Resin | None Established |
| 2,4,4'-Trichloro-2'-hydroxydiphenyl ether (Triclosan) | None Established |
| Trimethylolpropane Trimethylacrylate | 1 mg/m3 skin TWA AIHA WEEL |

<u>Engineering Controls</u>: Use with adequate local exhaust ventilation to maintain exposures below the occupational exposure limits. Use explosion proof equipment where required.

Personal Protective Equipment:

Eye Protection: Chemical safety glass or chemical splash goggles.

Skin Protection: Wear impervious gloves such as butyl rubber gloves.

<u>Respiratory Protection</u>: 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.

<u>Other Protective Clothing or Equipment</u>: Clothing with long sleeves may be needed when working with large quantities.

SECTION 9 – PHYSICAL AND CHEMICAL PROPERTIES

<u>Appearance and Odor</u>: Light yellow liquid with an acetone odor.

| Boiling Point: 131°F (55°C) | Melting Point: -139°F (-95°C) |
|---|--|
| Freezing Point: Not available | Specific Gravity: 0.9 g/m ³ |
| Solubility in Water: Not miscible or difficult to mix | pH: Not applicable |
| with water | |
| Vapor Pressure (mmHg): 223 mmHg @ 20°C | Vapor Density: Not available |
| Evaporation Rate: Not available | Viscosity: Not applicable |
| <u>% Volatile by Volume</u> : <50 | Flashpoint: -2°F (-19°C) |
| Flammable Limits in Air: | Autoignition Temperature: Not determined |
| LEL: 2.6% UEL: 13% | |

SECTION 10 – STABILITY AND REACTIVITY

Stability: Stable

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

Incompatibility with Other Materials: Avoid oxidizing agents, alkali metals and halogens. <u>Hazardous Decomposition Products</u>: Carbon monoxide, carbon dioxide, methacrylates and acrylates. <u>Hazardous Polymerization</u>: Will not occur.

SECTION 11 – TOXICOLOGICAL INFORMATION

Potential Health Effects:

<u>Eyes</u>: Causes severe irritation or burns with redness, tearing, pain and burns. Corneal damage may occur.

<u>Skin</u>: Causes severe skin irritation and possible burns. May cause allergic skin reaction. Severe reaction may result in breathing difficulties.

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<u>Ingestion</u>: Ingestion may cause mucous membrane and gastrointestinal burns and nervous system depression with symptoms of headache, dizziness, narcosis, nausea, vomiting and diarrhea. Aspiration into the lungs during ingestion or vomiting may cause serious lung damage which may be fatal. <u>Inhalation</u>: Inhalation of vapors or mists may cause mucous membrane and respiratory irritation and central nervous system depression with symptoms of headache, dizziness, nausea, central nervous depression, narcosis and unconsciousness.

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

<u>Carcinogenicity</u>: None of the components of this product are listed as carcinogens by OSHA, IARC, NTP or the EU Directives.

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

Acute Toxicity Data: Acetone

Dipentarythritol Pentaacrylate Phosphate Urethane Dimethyl Resin 2,4,4'-Trichloro-2'-hydroxydiphenyl ether (Triclosan) Trimethylolpropane Trimethylacrylate Oral Rat LD50 – 5,800 mg/kg Inhalation Rat LC50 – 50,100 mg/m3/8hr No data available Oral Rat LD50 – 3,700 mg/kg Skin Rabbit LD50 – 9,300 mg/kg Oral Rat LD50 – 5,660 uL/kg Skin Rabbit LD50 – 16 mL/kg

SECTION 12 – ECOLOGICAL INFORMATION

Acetone

Dipentarythritol Pentaacrylate Phosphate Urethane Dimethyl Resin 2,4,4'-Trichloro-2'-hydroxydiphenyl ether (Triclosan) Trimethylolpropane Trimethylacrylate 96 hr/LC50 rainbow trout: > 5540 mg/L 24 hr/LC50 Goldfish 5,000 mg/L No data available No data available 96 hr/LC50 rainbow trout: 0.288 mg/L No data available

SECTION 13 – DISPOSAL CONSIDERATIONS

Dispose in accordance with national and local regulations.

SECTION 14 – TRANSPORT INFORMATION

DOT Shipping Name: Acetone Solution DOT Hazard Class: 3, PG II UN Number: UN1090 DOT Labels Required (49CFR172.101): Flammable Liquid

IATA Shipping Name: Acetone Solution IATA Hazard Class: 3, PG II UN Number: UN1090 IATA Hazard Labels Required: Flammable Liquid

IMDG Shipping Name: Acetone Solution IMDG Class: 3, PG II UN Number: UN1090 IMDG Label: Flammable Liquid

SECTION 15 – REGULATORY INFORMATION

U.S. FEDERAL REGULATIONS:

<u>CERCLA 103 Reportable Quantity</u>: This product has a Reportable Quantity (RQ) of 10,000 lbs. based on the RQ for Acetone of 5,000 lbs. 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.

SARA TITLE III:

Hazard Category For Section 311/312: Acute Health, Chronic Health, Fire Hazard. 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

<u>EPA Toxic Substances Control Act (TSCA) Status</u>: This product is a medical device and not subject to chemical notification requirements.

U.S. STATE REGULATIONS:

<u>California Proposition 65</u>: This product contains the following substances known to the State of California to cause cancer: Toluene <42 ppm

INTERNATIONAL REGULATIONS:

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

Canadian WHMIS Classification: Medical devices are not subject to WHMIS.

European Community Labeling:





Highly Flammable



Dangerous for The Environment

R34 Causes burns.
R43 May cause sensitisation by skin contact.
R66 Repeated exposure may cause skin dryness or cracking.
R67 Vapours may cause drowsiness and dizziness.
R51/53 Toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment.
S16 Keep away from sources of ignition - No Smoking!
S25 Avoid contact with eyes.
S45 In case of accident or if you feel unwell seek medical advice immediately (show the label where possible).
S36/37/39 Wear suitable protective clothing, gloves and eye/face protection.
S51 Use only in well ventilated areas.

S60 This material and/or its container must be disposed of as hazardous waste.

<u>European Inventory of New and Existing Chemicals Substances (EINECS)</u>: This product is a medical device and not subject to chemical notification requirements.

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

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

<u>Japanese Existing and New Chemical Substances</u>: 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.

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

SECTION 16- OTHER INFORMATION

HMIS Hazard Rating: Health –3 Fire Hazard – 3 Reactivity – 0

EU Classes and Risk Phrases for Reference (See Sections 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 R66 Repeated exposure may cause skin dryness or cracking. R67 Vapours may cause drowsiness and dizziness.

Revision Date: 9/24/10

Supercedes: 01/03

Printing date 05.04.2013

*

Version number 7

Revision: 04.04.2013

| | tion of the substance/mixture and of the company/undertaking |
|--|--|
| · 1.1 Product | tidentifier |
| • 1.2 Relevar No further i | e: <u>Seal&Protect</u> at identified uses of the substance or mixture and uses advised against relevant information available. a of the substance / the preparation Dental sealing material |
| • Manufactu DENTSPLY De-Trey-St D-78467 K GERMANY Tel.: +49-(Fax: +49-(| onstanz |
| - Departem - Departem | <i>Formation obtainable from:</i> ent Analytical Research / Research & Development for technical information ent Marketing & Sales for distribution of the safety data sheets ncy telephone number: +49-(0)7531-583-0 8:00 - 17:00 (GMT + 1:00) |
| 2 Hazards | dentification |
| . 2.1 Classifi | cation of the substance or mixture |
| • Classificati Xi; Irritant R36/37/38: | on according to Directive 67/548/EEC or Directive 1999/45/EC Irritating to eyes, respiratory system and skin. |
| F; Highly f | |
| R11: | Highly flammable. |
| N; Dangero | pus for the environment |
| R50/53: | |
| | Very toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment. |
| The product preparation Has a narce • Classificati | Vapours may cause drowsiness and dizziness. n concerning particular hazards for human and environment: t has to be labelled due to the calculation procedure of the "General Classification guideline for ts of the EU" in the latest valid version. potizing effect. |
| • Information The product preparation Has a narco • Classificati | Vapours may cause drowsiness and dizziness. n concerning particular hazards for human and environment: to thas to be labelled due to the calculation procedure of the "General Classification guideline for so of the EU" in the latest valid version. potizing effect. on system: cation is according to the latest editions of the EU-lists, and extended by company and literature data. |
| Information The product preparation Has a narco Classificati The classifi 2.2 Label en Labelling a | Vapours may cause drowsiness and dizziness. In concerning particular hazards for human and environment: Set has to be labelled due to the calculation procedure of the "General Classification guideline for the soft he EU" in the latest valid version. Soft the EU" in the latest valid version. Soft system: cation is according to the latest editions of the EU-lists, and extended by company and literature data. Iements Cording to EU guidelines: |
| Information The product preparation Has a narco Classificati The classificati 2.2 Label ender Labelling a The product Materials | Vapours may cause drowsiness and dizziness. In concerning particular hazards for human and environment: Set has to be labelled due to the calculation procedure of the "General Classification guideline for the soft he EU" in the latest valid version. Soft of the EU" in the latest valid version. Soft of system: cation is according to the latest editions of the EU-lists, and extended by company and literature data. Rements |
| Information The product preparation Has a narco Classificati The classificati 2.2 Label ender Labelling a The product Materials | Vapours may cause drowsiness and dizziness. In concerning particular hazards for human and environment: It has to be labelled due to the calculation procedure of the "General Classification guideline for to the EU" in the latest valid version. It is according to the latest editions of the EU-lists, and extended by company and literature data. Itements Itements Itements is according to and marked in accordance with EU Directives / Ordinance on Hazardous |
| Information The product preparation Has a narce Classificati The classifi 2.2 Label end Labelling a The product Materials Code letter Code letter Risk phrase | Vapours may cause drowsiness and dizziness. In concerning particular hazards for human and environment: It has to be labelled due to the calculation procedure of the "General Classification guideline for is of the EU" in the latest valid version. Detizing effect. In system: cation is according to the latest editions of the EU-lists, and extended by company and literature data. Hements ccording to EU guidelines: It has been classified and marked in accordance with EU Directives / Ordinance on Hazardous and hazard designation of product: Xi Irritant F Highly flammable N Dangerous for the environment EX: |
| Information The product preparation Has a narco Classificati The classifi 2.2 Label ender Labelling a The product Materials Code letter Code letter Risk phrase 11 H | Vapours may cause drowsiness and dizziness. In concerning particular hazards for human and environment: It has to be labelled due to the calculation procedure of the "General Classification guideline for is of the EU" in the latest valid version. Detizing effect. In system: cation is according to the latest editions of the EU-lists, and extended by company and literature data. Hements ccording to EU guidelines: It has been classified and marked in accordance with EU Directives / Ordinance on Hazardous and hazard designation of product: Xi Irritant F Highly flammable N Dangerous for the environment |

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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.
- *Keep away from sources of ignition No smoking.*
- 23 Do not breathe gas/fumes/vapour/spray (appropriate wording to be specified by the manufacturer).
- 24/25 Avoid contact with skin and eyes.
- 26 In case of contact with eyes, rinse immediately with plenty of water and seek medical advice.
- 57 Use appropriate container to avoid environmental contamination.
- · 2.3 Other hazards
- · Results of PBT and vPvB assessment
- · PBT: Not applicable.
- · **vPvB:** Not applicable.

3 Composition/information on ingredients

· 3.2 Chemical characterization: Mixtures

• **Description:** Mixture of substances listed below with nonhazardous additions.

| CAS: 67-64-1 | acetone | 25-50% |
|-------------------------------------|--|---------|
| EINECS: 200-662-2 | Xi R36; 🔥 F R11 R66-67 | |
| | 🛞 Flam. Liq. 2, H225; 🚸 Eye Irrit. 2, H319; STOT SE 3, H336 | - |
| CAS: 105883-40-7 | Urethan dimethacrylate resin 🗙 Xi R36/38 | 10-25% |
| | 🚺 Skin Irrit. 2, H315; Eye Irrit. 2, H319 | - |
| | acrylates with the exception of those specified elsewhere in this Annex \mathbf{X} Xi R36/37/38; \mathbf{W} N R51/53 | 2.5-10% |
| | Aquatic Chronic 2, H411; | - |
| CAS: 3290-92-4 | Trimethylolpropane Trimethacrylate (TMPTMA) | 2.5-10% |
| | Aquatic Chronic 2, H411 | - |
| CAS: 3380-34-5 EINECS: 222-182-2 | triclosan 🗙 Xi R36/38; 🎇 N R50/53 | 2.5-10% |
| | Aquatic Acute 1, H400; Aquatic Chronic 1, H410; (1) Skin Irrit. 2, H315; Eye Irrit. 2, H319 | _ |
| CAS: 128-37-0 | 2,6-di-tert-butyl-p-cresol | ≤ 2.5% |
| EINECS: 204-881-4 | N R50/53 | |
| | 🐼 Aquatic Acute 1, H400; Aquatic Chronic 1, H410 | - |

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

4 First aid measures

• 4.1 Description of 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.

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• 4.2 Most important symptoms and effects, both acute and delayed No further relevant information available. • 4.3 Indication of any immediate medical attention and special treatment needed

No further relevant information available.

5 Firefighting measures

· 5.1 Extinguishing media

· 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.
- · 5.2 Special hazards arising from the substance or mixture No further relevant information available.
- · 5.3 Advice for firefighters
- · Protective equipment: Self-contained respiratory protective device.

6 Accidental release measures

- 6.1 Personal precautions, protective equipment and emergency procedures Wear protective equipment. Keep unprotected persons away.
- 6.2 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.
- 6.3 Methods and material for containment and cleaning up: Absorb with liquid-binding material (sand, diatomite, acid binders, universal binders, sawdust). Dispose of the material collected according to regulations. Ensure adequate ventilation.
- **6.4 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

· 7.1 Precautions for safe handling

Ensure good ventilation/exhaustion at the workplace. Prevent formation of aerosols. Observe normal care for working with chemicals.

- Handling Product is intended for dental use only.
- · Information about fire and explosion protection:



Keep ignition sources away - Do not smoke.

Protect against electrostatic charges.

- · 7.2 Conditions for safe storage, including any incompatibilities
- · 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: Store away from oxidizing agents.

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• Further information about storage conditions:

Keep receptacle tightly sealed.

Store in cool, dry conditions in well sealed receptacles. • 7.3 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.
- · 8.1 Control parameters

· Ingredients with limit values that require monitoring at the workplace:

67-64-1 acetone

WEL Short-term value: 3620 mg/m³, 1500 ppm

Long-term value: 1210 mg/m³, 500 ppm

· DNELs

128-37-0 2,6-di-tert-butyl-p-cresol

Inhalative DNEL Werte 3.5 mg/m³ bw/day (rat)

• Additional information: The lists valid during the making were used as basis.

· 8.2 Exposure controls

- · 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.

The glove material has to be impermeable and resistant to the product/ the substance/ the preparation. 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. Natural rubber, NR

Recommended thickness of the material: $\geq 0.12 \text{ mm}$

Permeation: Level ≥ 1

· 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.

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*

· Body protection: Protective work clothing.

| 9 Physical and chemical prope | rties |
|---|--|
| 9.1 Information on basic physical of · General Information · Appearance: | and chemical properties |
| Form: | Fluid |
| Colour: | Yellow |
| · Odour: | Characteristic |
| · Odour threshold: | Not determined. |
| · pH-value: | Not determined. |
| Change in condition Melting point/Melting range: Boiling point/Boiling range: | undetermined 63 °C |
| · Flash point: | -17 °C (c.c. Abel) |
| · Flammability (solid, gaseous) | Not applicable. |
| · Ignition temperature: | 465 °C (Aceton) |
| • Decomposition temperature: | Not determined. |
| · 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 % (Aceton) |
| Upper: | 12.8 Vol % (Aceton) |
| · Vapour pressure at 20 •C: | 233 hPa |
| · Density at 20 °C: | $0.96 \ g/cm^3$ |
| · Relative density | Not determined. |
| · Vapour density | Not determined. |
| · Evaporation rate | Not determined. |
| · Solubility in / Miscibility with | |
| Water: | Partly miscible |
| · Partition coefficient (n-octanol/wa | ter): Not determined. |
| · Viscosity: | |
| dynamic: | Not determined. |
| kinematic: | Not determined. |
| · Solvent content: Organic solvents: | 45.0 % |
| Solids content: | 8.5 % |
| • 9.2 Other information | No further relevant information available. |

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10 Stability and reactivity

- · 10.1 Reactivity
- · 10.2 Chemical stability
- Thermal decomposition / conditions to be avoided: No decomposition if used according to specifications.
- · 10.3 Possibility of hazardous reactions No dangerous reactions known
- · 10.4 Conditions to avoid No further relevant information available.
- 10.5 Incompatible materials: No further relevant information available.
- 10.6 Hazardous decomposition products: No dangerous decomposition products known

11 Toxicological information

- · 11.1 Information on toxicological effects
- Acute toxicity:

· LD/LC50 values relevant for classification:

3290-92-4 Trimethylolpropane Trimethacrylate (TMPTMA)

Oral LD50 >2000 mg/kg (rat)

3380-34-5 triclosan

Oral LD50 3700 mg/kg (rat)

Dermal LD50 9300 mg/kg (rabbit)

128-37-0 2,6-di-tert-butyl-p-cresol

Oral LD50 2930 mg/kg (rat)

Dermal | LD50 | > 2000 mg/kg (rabbit)

· 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: Irritating effect.
- · 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

· 12.1 Toxicity

· Aquatic toxicity:

3290-92-4 Trimethylolpropane Trimethacrylate (TMPTMA)

EC50/48h >9.22 *mg/L* (*daphnia*)

LC50/96h 2 mg/l (fish)

3380-34-5 triclosan

EC50/48h 0.39 mg/L (daphnia)

LC50/96h 0.288 mg/l (fish)

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| 128-37-0 | 2,6- | di-tert-l | butyl-p | o-cresol |
|----------|------|-----------|---------|----------|
|----------|------|-----------|---------|----------|

EC50/72h >0.42 mg/l (algae)

LC50/48h >0.57 *mg/l* (*daphnia*)

LC50/96h >0.42 mg/l (fish)

· 12.2 Persistence and degradability No further relevant information available.

- 12.3 Bioaccumulative potential No further relevant information available.
- 12.4 Mobility in soil No further relevant information available.
- · Ecotoxical effects:
- *Remark:* Very toxic for fish
- \cdot Additional ecological information:
- · General notes:
- Also poisonous for fish and plankton in water bodies. Very toxic for aquatic organisms

Do not allow product to reach ground water, water course or sewage system.

Danger to drinking water if even small quantities leak into the ground.

- · 12.5 Results of PBT and vPvB assessment
- **PBT:** Not applicable.
- · vPvB: Not applicable.
- · 12.6 Other adverse effects No further relevant information available.

13 Disposal considerations

- · 13.1 Waste treatment methods
- · Recommendation



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

· European waste catalogue

18 01 06* chemicals consisting of or containing dangerous substances

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

| · 14.1 UN-Number · ADR, IMDG, IATA | UN1993 |
|---------------------------------------|--|
| | 0111770 |
| · 14.2 UN proper shipping name | |
| $\cdot ADR$ | 1993 FLAMMABLE LIQUID, N.O.S. (ACETONE, triclosan) |
| | ENVIRONMENTALLY HAZARDOUS |
| ·IMDG | FLAMMABLE LIQUID, N.O.S. (ACETONE, triclosan) |
| | MARINE POLLUTANT |
| · IATA | FLAMMABLE LIQUID, N.O.S. (ACETONE, triclosan) |

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|--|-------------------------------------|---------------------------|
| Trade name: Seal&Protect | | |
| | | (Contd. of page 7 |
| · 14.3 Transport hazard class(es) | | |
| · ADR | | |
| | | |
| × × | | |
| | | |
| · Class | 3 (F1) Flammable liquids. | |
| · Label | 3 | |
| · IMDG | | |
| \wedge \wedge | | |
| $\langle \Psi_{\gamma} \rangle$ | | |
| | | |
| · Class | 3 Flammable liquids. | |
| · Label | 3 | |
| · IATA | | |
| A | | |
| | | |
| | | |
| · Class | 3 Flammable liquids. | |
| · Label | 3 | |
| · 14.4 Packing group | | |
| · ADR, IMDG, IATA | II | |
| · 14.5 Environmental hazards: | Product contains environmental | lly hazardous substances: |
| · Marine pollutant: | triclosan Yes | |
| · Marine polititani. | Symbol (fish and tree) | |
| · Special marking (ADR): | Symbol (fish and tree) | |
| · 14.6 Special precautions for user | Warning: Flammable liquids. | |
| · Danger code (Kemler): | 33 | |
| · EMS Number: | <i>F-E,<u>S-E</u></i> | |
| 14.7 Transport in bulk according to Ann MARPOL73/78 and the IBC Code | nex II of Not applicable. | |
| · Transport/Additional information: | | |
| · ADR | | |
| · Limited quantities (LQ) | 1L | |
| • Transport category Tunnel restriction code | 2 D/F | |
| • Tunnel restriction code | D/E | |

15 Regulatory information

*

• 15.2 Chemical safety assessment: A Chemical Safety Assessment has not been carried out.

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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.

· Relevant phrases

- H225 Highly flammable liquid and vapour.
- H315 Causes skin irritation.
- H319 Causes serious eye irritation.
- H335 May cause respiratory 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.*
- R11 Highly flammable.
- *R36 Irritating to eyes.*
- R36/37/38 Irritating to eyes, respiratory system and skin.
- R36/38 Irritating to eyes and skin.
- *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 Vapours may cause drowsiness and dizziness.*

· Department issuing MSDS: Analytical Research

- · Contact: HotLine for urgent technical support: +49-7531-583-333
- \cdot * Data compared to the previous version altered.

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1 Identification of the substance/mixture and of the company/undertaking · 1.1 Product identifier · Trade name: Seal & Protect without Triclosan · 1.2 Relevant identified uses of the substance or mixture and uses advised against No further relevant information available. • Application of the substance / the preparation Dental sealing material \cdot 1.3 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 · Further information obtainable from: - Departement Analytical Research / Research & Development for technical information - Departement Marketing & Sales for distribution of the safety data sheets • 1.4 Emergency telephone number: +49-(0)7531-583-0 8:00 - 17:00 (GMT + 1:00) **2** Hazards identification · 2.1 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. Harmful to aquatic organisms, may cause long-term adverse effects in the aquatic environment. *R52/53-67*: 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. Has a narcotizing effect. · Classification system: The classification is according to the latest editions of the EU-lists, and extended by company and literature data. · 2.2 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 · Risk phrases: 11 Highly flammable. 36/37/38 Irritating to eyes, respiratory system and skin. 52/53 Harmful to aquatic organisms, may cause long-term adverse effects in the aquatic environment. (Contd. on page 2) GB Obtained by Global Safety Management, www.globalsafetynet.com (877) 683-7460

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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).

24/25 Avoid contact with skin and eyes.

- 26 In case of contact with eyes, rinse immediately with plenty of water and seek medical advice.
- 61 Avoid release to the environment. Refer to special instructions/safety data sheets.

· 2.3 Other hazards

· Results of PBT and vPvB assessment

- · PBT: Not applicable.
- · vPvB: Not applicable.

3 Composition/information on ingredients

· 3.2 Chemical characterization: Mixtures

• Description: Mixture of substances listed below with nonhazardous additions.

| · Dangerous compone | ents: | |
|------------------------------------|--|---------------|
| CAS: 67-64-1 EINECS: 200-662-2 | acetone 🗙 Xi R36; 🔥 F R11 | 25-50% |
| | R66-67 🐼 Flam. Liq. 2, H225; 🚸 Eye Irrit. 2, H319; STOT SE 3, H336 | |
| CAS: 105883-40-7 | Urethan dimethacrylate resin 🔀 Xi R36/38 | 25-50% |
| | Skin Irrit. 2, H315; Eye Irrit. 2, H319 acrylates with the exception of those specified elsewhere in this Annex Xi R36/37/38; N R51/53 Aquatic Chronic 2, H411; Skin Irrit. 2, H315; Eye Irrit. 2, H319; STOT | 10-25% |
| CAS: 3290-92-4 | SE 3, H335 Trimethylolpropane Trimethacrylate (TMPTMA) N R51/53 Aquatic Chronic 2, H411 | 2.5-10% |
| CAS: 128-37-0 EINECS: 204-881-4 | 2,6-di-tert-butyl-p-cresol N R50/53 Aquatic Acute 1, H400; Aquatic Chronic 1, H410 | <i>≤</i> 2.5% |
| | on For the wording of the listed risk phrases refer to section 16 | |

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

4 First aid measures

- · 4.1 Description of 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.

• 4.2 Most important symptoms and effects, both acute and delayed No further relevant information available.

- 4.3 Indication of any immediate medical attention and special treatment needed
- No further relevant information available.

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5 Firefighting measures

- · 5.1 Extinguishing media
- · Suitable extinguishing agents CO2, sand, extinguishing powder. Do not use water.
- For safety reasons unsuitable extinguishing agents Water.

Water with full jet.

- 5.2 Special hazards arising from the substance or mixture No further relevant information available.
- · 5.3 Advice for firefighters
- · Protective equipment: Self-contained respiratory protective device.

6 Accidental release measures

- 6.1 Personal precautions, protective equipment and emergency procedures Wear protective equipment. Keep unprotected persons away.
- 6.2 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.
- 6.3 Methods and material for containment and cleaning up: Absorb with liquid-binding material (sand, diatomite, acid binders, universal binders, sawdust). Ensure adequate ventilation. Do not flush with water or aqueous cleansing agents
 6.4 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

 7.1 Precautions for safe handling Ensure good ventilation/exhaustion at the workplace.
 Prevent formation of aerosols.
 Observe normal care for working with chemicals.

- *Handling Product* is intended for dental use only.
- · Information about fire and explosion protection:



Keep ignition sources away - Do not smoke.

Protect against electrostatic charges.

- · 7.2 Conditions for safe storage, including any incompatibilities
- · 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: Store away from oxidizing agents.
- Further information about storage conditions: Keep receptacle tightly sealed. Store in cool, dry conditions in well sealed receptacles.

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• 7.3 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.

· 8.1 Control parameters

· Ingredients with limit values that require monitoring at the workplace:

67-64-1 acetone

WEL Short-term value: 3620 mg/m³, 1500 ppm

Long-term value: 1210 mg/m³, 500 ppm

· DNELs

128-37-0 2,6-di-tert-butyl-p-cresol

Inhalative DNEL Werte 3.5 mg/m³ bw/day (rat)

• Additional information: The lists valid during the making were used as basis.

· 8.2 Exposure controls

- · 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.

The glove material has to be impermeable and resistant to the product/ the substance/ the preparation. Selection of the glove material on consideration of the penetration times, rates of diffusion and the degradation

• *Material of gloves* Natural rubber, NR

Recommended thickness of the material: $\geq 0.12 \text{ mm}$

Permeation: Level ≥ 1

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.

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| 9.1 Information on basic physical a | und chemical properties |
|--------------------------------------|--|
| General Information | |
| Appearance: Form: | Fluid |
| Form: Colour: | Yellow |
| Odour: | Characteristic |
| Odour threshold: | Not determined. |
| pH-value: | Not determined. |
| Change in condition | |
| Melting point/Melting range: | undetermined |
| Boiling point/Boiling range: | 63 °C |
| Flash point: | -17 °C (c.c. Abel) |
| Flammability (solid, gaseous) | Not applicable. |
| Ignition temperature: | 465 °C |
| Decomposition temperature: | Not determined. |
| Self-igniting: | Product is not selfigniting. |
| Danger of explosion: | Product is not explosive. However, formation of explosive air/vapou mixtures are possible. |
| Explosion limits: | |
| Lower: | 2.6 Vol % (Aceton) |
| Upper: | 12.8 Vol % (Aceton) |
| Vapour pressure at 20 °C: | 233 hPa |
| Density: | Not determined |
| Relative density | Not determined. |
| Vapour density | Not determined. |
| Evaporation rate | Not determined. |
| Solubility in / Miscibility with | |
| Water: | Partly miscible |
| Partition coefficient (n-octanol/wat | t er): Not determined. |
| Viscosity: | |
| dynamic: | Not determined. |
| kinematic: | Not determined. |
| Solvent content: | |
| Organic solvents: | 47.0 % |
| Solids content: | 5.0 % |
| 9.2 Other information | No further relevant information available. |

10 Stability and reactivity

- · 10.1 Reactivity
- · 10.2 Chemical stability
- Thermal decomposition / conditions to be avoided: No decomposition if used according to specifications.
- · 10.3 Possibility of hazardous reactions No dangerous reactions known

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- · 10.4 Conditions to avoid No further relevant information available.
- 10.5 Incompatible materials: No further relevant information available.
- · 10.6 Hazardous decomposition products: No dangerous decomposition products known

11 Toxicological information

· 11.1 Information on toxicological effects

• Acute toxicity:

· LD/LC50 values relevant for classification:

3290-92-4 Trimethylolpropane Trimethacrylate (TMPTMA)

Oral LD50 >2000 mg/kg (rat)

128-37-0 2,6-di-tert-butyl-p-cresol

Oral LD50 2930 mg/kg (rat)

Dermal LD50 > 2000 mg/kg (rabbit)

· 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: Irritating effect.
- · 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

| • | 12.1 | Toxicity |
|---|------|----------|
|---|------|----------|

• Aquatic toxicity:

3290-92-4 Trimethylolpropane Trimethacrylate (TMPTMA)

EC50/48h >9.22 *mg/L* (*daphnia*)

LC50/96h 2 mg/l (fish)

128-37-0 2,6-di-tert-butyl-p-cresol

EC50/72h >0.42 mg/l (algae)

LC50/48h > 0.57 mg/l (daphnia)

LC50/96h > 0.42 mg/l (fish)

· 12.2 Persistence and degradability No further relevant information available.

- · 12.3 Bioaccumulative potential No further relevant information available.
- · 12.4 Mobility in soil No further relevant information available.
- · Ecotoxical effects:
- · **Remark:** Harmful to fish
- · Additional ecological information:
- · General notes:

Do not allow product to reach ground water, water course or sewage system.

Harmful to aquatic organisms

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· 12.5 Results of PBT and vPvB assessment

• **PBT:** Not applicable.

· **vPvB:** Not applicable.

· 12.6 Other adverse effects No further relevant information available.

13 Disposal considerations

· 13.1 Waste treatment methods

· Recommendation



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

· European waste catalogue

18 01 06* chemicals consisting of or containing dangerous substances

· Uncleaned packaging:

• **Recommendation:** Disposal must be made according to official regulations.

| 14.1 UN-Number ADR, IMDG, IATA | UN1993 |
|---|---|
| 14.2 UN proper shipping name ADR IMDG, IATA | 1993 FLAMMABLE LIQUID, N.O.S. (ACETONE) FLAMMABLE LIQUID, N.O.S. (ACETONE) |
| 14.3 Transport hazard class(es) | |
| ADR | |
| | |
| Class | 3 (F1) Flammable liquids. |
| Label | 3 |
| IMDG, IATA | |
| - Class | 3 Flammable liquids. |
| Label | 3 |
| 14.4 Packing group ADR, IMDG, IATA | II |
| 14.5 Environmental hazards: Marine pollutant: | No |
| 14.6 Special precautions for user | Warning: Flammable liquids. |

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| | | (Contd. of page 7 |
|--|--------------------------------|-------------------|
| · Danger code (Kemler): | 33 | |
| · EMS Number: | <i>F-E</i> , <u><i>S-E</i></u> | |
| · 14.7 Transport in bulk according to Anna | ex II of | |
| MARPOL73/78 and the IBC Code | Not applicable. | |
| · Transport/Additional information: | | |
| $\cdot ADR$ | | |
| · Limited quantities (LQ) | 1L | |
| · Transport category | 2 | |
| • Tunnel restriction code | D/E | |

15 Regulatory information

· 15.2 Chemical safety assessment: A Chemical Safety Assessment has not been carried out.

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.

· Relevant phrases

| 10000 tanti | P in as cs |
|-------------|---|
| H225 | Highly flammable liquid and vapour. |
| H315 | Causes skin irritation. |
| H319 | Causes serious eye irritation. |
| H335 | May cause respiratory 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. |
| R11 | Highly flammable. |
| R36 | Irritating to eyes. |
| R36/37/3 | 8 Irritating to eyes, respiratory system and skin. |
| R36/38 | Irritating to eyes and skin. |
| 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 | Vapours may cause drowsiness and dizziness. |
| · Contact: | ent issuing MSDS: Analytical Research HotLine for urgent technical support: +49-7531-583-333 compared to the pravious version altered |

• * Data compared to the previous version altered.

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