

SAFETY DATA SHEETS

This SDS packet was issued with item:

071811579

N/A

Dentsply Prisma VLC Dycal Baseliner Composition

Hazard Alert Code:
HIGH

Chemwatch Material Safety Data Sheet

Version No: 3

Chemwatch 4993-49

Issue Date: 2-Feb-2009

X9317SP

Section 1 - CHEMICAL PRODUCT AND COMPANY IDENTIFICATION

PRODUCT NAME

Dentsply Prisma VLC Dycal Baseliner Composition

SYNONYMS

?

PRODUCT USE

? Medicine

SUPPLIER

Company: Dentsply (AUSTRALIA) Pty Ltd

Address:

11-21 Gilby Road

Mount Waverley

VIC, 3149

Australia

Telephone: +61 3 9538 8240

Telephone: 1300 552 929

Emergency Tel: **1300 552 929 (Hrs. Mon.-Fri. 9am-5p)**

Fax: +61 3 9538 8260

Website: www.dentsply.com.au

Section 2 - HAZARDS IDENTIFICATION

STATEMENT OF HAZARDOUS NATURE

HAZARDOUS SUBSTANCE. NON-DANGEROUS GOODS. According to the Criteria of NOHSC, and the ADG Code.

CHEMWATCH HAZARD RATINGS

	Min	Max
Flammability:	0	Blue
Toxicity:	0	Blue
Body Contact:	3	Blue to Yellow
Reactivity:	1	Blue to Green
Chronic:	2	Blue to Yellow

Min/Nil=0
Low=1
Moderate=2
High=3
Extreme=4



POISONS SCHEDULE

None

RISK

- Causes burns.
- Risk of serious damage to eyes.
- May cause SENSITISATION by skin contact.
- Harmful to aquatic organisms, may cause long-term adverse effects in the aquatic environment.
- Cumulative effects may result following exposure*.
- Possible respiratory sensitiser*.

* (limited evidence).

SAFETY

- Keep locked up.
- Avoid contact with skin.
- Avoid contact with eyes.
- Wear suitable protective clothing.
- Wear suitable gloves.
- Wear eye/ face protection.
- To clean the floor and all objects contaminated by this material, use water and detergent.

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- Take off immediately all contaminated clothing.
- In case of contact with eyes, rinse with plenty of water and contact Doctor or Poisons Information Centre.
- In case of accident or if you feel unwell, IMMEDIATELY contact Doctor or Poisons Information Centre (show label if possible).
- In case of accident by inhalation: remove casualty to fresh air and keep at rest.

Section 3 - COMPOSITION / INFORMATION ON INGREDIENTS

NAME	CAS RN	%
urethane dimethacrylate resin		55-60
calcium hydroxide	1305-62-0	<25
barium sulfate	7727-43-7	<25
triethylene glycol dimethacrylate	109-16-0	5-10

Section 4 - FIRST AID MEASURES

SWALLOWED

- If swallowed do NOT induce vomiting.
- If vomiting occurs, lean patient forward or place on left side (head-down position, if possible) to maintain open airway and prevent aspiration.
- Observe the patient carefully.
- Never give liquid to a person showing signs of being sleepy or with reduced awareness; i.e. becoming unconscious.

EYE

- If this product comes in contact with the eyes:
 - Immediately hold eyelids apart and flush the eye continuously with running water.
 - Ensure complete irrigation of the eye by keeping eyelids apart and away from eye and moving the eyelids by occasionally lifting the upper and lower lids.
 - Continue flushing until advised to stop by the Poisons Information Centre or a doctor, or for at least 15 minutes.
 - Transport to hospital or doctor without delay.

SKIN

- If skin contact occurs:
 - Immediately remove all contaminated clothing, including footwear.
 - Flush skin and hair with running water (and soap if available).
 - Seek medical attention in event of irritation.

INHALED

- If fumes, aerosols or combustion products are inhaled remove from contaminated area.
- Other measures are usually unnecessary.

NOTES TO PHYSICIAN

Treat symptomatically.

For acute or short-term repeated exposures to highly alkaline materials:

- Respiratory stress is uncommon but present occasionally because of soft tissue edema.
- Unless endotracheal intubation can be accomplished under direct vision, cricothyroidotomy or tracheotomy may be necessary.
- Oxygen is given as indicated.
- The presence of shock suggests perforation and mandates an intravenous line and fluid administration.

Section 5 - FIRE FIGHTING MEASURES

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EXTINGUISHING MEDIA

- Water spray or fog.
- Foam.
- Dry chemical powder.
- BCF (where regulations permit).

FIRE FIGHTING

- Alert Fire Brigade and tell them location and nature of hazard.
- Wear full body protective clothing with breathing apparatus.
- Consider evacuation (or protect in place).
- Use water delivered as a fine spray to control fire and cool adjacent area.

FIRE/EXPLOSION HAZARD

- Non combustible.
- Not considered a significant fire risk, however containers may burn.

Decomposition may produce toxic fumes of: carbon dioxide (CO₂), other pyrolysis products typical of burning organic material.

May emit poisonous fumes.

May emit corrosive fumes.

FIRE INCOMPATIBILITY

- Avoid contamination with oxidising agents i.e. nitrates, oxidising acids, chlorine bleaches, pool chlorine etc. as ignition may result

HAZCHEM

None

Section 6 - ACCIDENTAL RELEASE MEASURES

MINOR SPILLS

- Clean up all spills immediately.
- Avoid contact with skin and eyes.
- Wear impervious gloves and safety goggles.
- Trowel up/scrape up.
- Clean up all spills immediately.
- Avoid breathing vapours/ aerosols or dusts and avoid contact with skin and eyes.
- Place in a suitable, labelled container for waste disposal.

MAJOR SPILLS

Minor hazard.

- Clear area of personnel.
- Alert Fire Brigade and tell them location and nature of hazard.
- Control personal contact with the substance, by using protective equipment as required.
- Prevent spillage from entering drains or water ways.

Personal Protective Equipment advice is contained in Section 8 of the MSDS.

Section 7 - HANDLING AND STORAGE

PROCEDURE FOR HANDLING

- Limit all unnecessary personal contact.
- Wear protective clothing when risk of exposure occurs.
- Use in a well-ventilated area.
- When handling DO NOT eat, drink or smoke.

SUITABLE CONTAINER

- Polyethylene or polypropylene container.
- Packing as recommended by manufacturer.
- Check all containers are clearly labelled and free from leaks.

STORAGE INCOMPATIBILITY

- Reacts with aluminium / zinc producing flammable, explosive hydrogen gas
- Avoid strong acids, acid chlorides, acid anhydrides and chloroformates.

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- Avoid reaction with oxidising agents

STORAGE REQUIREMENTS

- Store in original containers.
- Keep containers securely sealed.
- Store in a cool, dry, well-ventilated area.
- Store away from incompatible materials and foodstuff containers.

Section 8 - EXPOSURE CONTROLS / PERSONAL PROTECTION

EXPOSURE CONTROLS

Source	Material	TWA ppm	TWA mg/m ³	STEL ppm	STEL mg/m ³	Peak ppm	Peak mg/m ³	TWA F/CC	Notes
Australia Exposure Standards	calcium hydroxide (Calcium hydroxide)		5						
Australia Exposure Standards	barium sulfate (Barium sulphate (a))		10						(see Chapter 14)

The following materials had no OELs on our records

- triethylene glycol dimethacrylate: CAS:109-16-0

PERSONAL PROTECTION



RESPIRATOR

- Type A Filter of sufficient capacity. (AS/NZS 1716 & 1715, EN 143:2000 & 149:2001, ANSI Z88 or national equivalent)

EYE

- Safety glasses with side shields
- Chemical goggles.
- Contact lenses may pose a special hazard; soft contact lenses may absorb and concentrate irritants. A written policy document, describing the wearing of lens or restrictions on use, should be created for each workplace or task. This should include a review of lens absorption and adsorption for the class of chemicals in use and an account of injury experience. Medical and first-aid personnel should be trained in their removal and suitable equipment should be readily available. In the event of chemical exposure, begin eye irrigation immediately and remove contact lens as soon as practicable. Lens should be removed at the first signs of eye redness or irritation - lens should be removed in a clean environment only after workers have washed hands thoroughly. [CDC NIOSH Current Intelligence Bulletin 59], [AS/NZS 1336 or national equivalent]

HANDS/FEET

- Wear chemical protective gloves, eg. PVC.
- Wear safety footwear or safety gumboots, eg. Rubber

NOTE:

- The material may produce skin sensitisation in predisposed individuals. Care must be taken, when removing gloves and other protective equipment, to avoid all possible skin contact.
- Contaminated leather items, such as shoes, belts and watch-bands should be removed and destroyed.

OTHER

- Overalls.
- P.V.C. apron.
- Barrier cream.
- Skin cleansing cream.

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ENGINEERING CONTROLS

■ Engineering controls are used to remove a hazard or place a barrier between the worker and the hazard. Well-designed engineering controls can be highly effective in protecting workers and will typically be independent of worker interactions to provide this high level of protection.

The basic types of engineering controls are:

Process controls which involve changing the way a job activity or process is done to reduce the risk.

Enclosure and/or isolation of emission source which keeps a selected hazard "physically" away from the worker and ventilation that strategically "adds" and "removes" air in the work environment.

Section 9 - PHYSICAL AND CHEMICAL PROPERTIES

APPEARANCE

Creamy paste with slight acrylic odour; does not mix with water.

PHYSICAL PROPERTIES

Does not mix with water.

Sinks in water.

Alkaline.

State	Non Slump Paste	Molecular Weight	Not Applicable
Melting Range (°C)	Not Available	Viscosity	Not Available
Boiling Range (°C)	Not Applicable	Solubility in water (g/L)	Immiscible
Flash Point (°C)	Not Applicable	pH (1% solution)	Not Available
Decomposition Temp (°C)	Not Available	pH (as supplied)	Not Available
Autoignition Temp (°C)	Not Available	Vapour Pressure (kPa)	Not Applicable
Upper Explosive Limit (%)	Not Applicable	Specific Gravity (water=1)	1.4
Lower Explosive Limit (%)	Not Applicable	Relative Vapour Density (air=1)	Not Applicable
Volatile Component (%vol)	Not Available	Evaporation Rate	Not Applicable

Section 10 - CHEMICAL STABILITY

CONDITIONS CONTRIBUTING TO INSTABILITY

■ Product is considered stable and hazardous polymerisation will not occur.

For incompatible materials - refer to Section 7 - Handling and Storage.

Section 11 - TOXICOLOGICAL INFORMATION

POTENTIAL HEALTH EFFECTS

ACUTE HEALTH EFFECTS

SWALLOWED

■ The material has NOT been classified by EC Directives or other classification systems as "harmful by ingestion". This is because of the lack of corroborating animal or human evidence. The material may still be damaging to the health of the individual, following ingestion, especially where pre-existing organ (eg. liver, kidney) damage is evident. Present definitions of harmful or toxic substances are generally based on doses producing mortality rather than those producing morbidity (disease, ill-health). Gastrointestinal tract discomfort may produce nausea and vomiting. In an occupational setting however, ingestion of insignificant quantities is not thought to be cause for concern.

EYE

■ This material can cause eye irritation and damage in some persons.

SKIN

■ This material can cause inflammation of the skin oncontact in some persons.

The material may accentuate any pre-existing dermatitis condition.

Skin contact is not thought to have harmful health effects (as classified under EC Directives); the material may still produce health damage following entry through wounds, lesions or abrasions.

Entry into the blood-stream, through, for example, cuts, abrasions or lesions, may produce systemic injury

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with harmful effects. Examine the skin prior to the use of the material and ensure that any external damage is suitably protected.

INHALED

■ Not normally a hazard due to non-volatile nature of product.

The material can cause respiratory irritation in some persons. The body's response to such irritation can cause further lung damage.

Barium fumes are respiratory irritants. Over-exposure to barium dusts and fume may result in rhinitis, frontal headache, wheezing, laryngeal spasm, salivation and anorexia.

CHRONIC HEALTH EFFECTS

■ Substance accumulation, in the human body, may occur and may cause some concern following repeated or long-term occupational exposure.

Asthma-like symptoms may continue for months or even years after exposure to the material ceases. This may be due to a non-allergenic condition known as reactive airways dysfunction syndrome (RADS) which can occur following exposure to high levels of highly irritating compound.

There is some evidence that inhaling this product is more likely to cause a sensitisation reaction in some persons compared to the general population.

There is limited evidence that, skin contact with this product is more likely to cause a sensitisation reaction in some persons compared to the general population.

Barium compounds may cause high blood pressure, airway irritation and damage the liver, spleen and bone marrow. Prolonged exposure may cause a lung inflammation and scarring. Symptoms of this include a worsening dry cough, shortness of breath on exertion, increased chest expansion and weakness. Stringy phlegm in the cough appears later, with more difficulty in breathing and a further loss of lung capacity. Barium sulfate does not cause permanent scarring of the lungs.

Sensitisation may give severe responses to very low levels of exposure, i.e. hypersensitivity. Sensitised persons should not be allowed to work in situations where exposure may occur.

TOXICITY AND IRRITATION

■ Not available. Refer to individual constituents.

SENSITISER

Ingredient	Australia Final Report on Hazard Classification of Common Skin Sensitisers	Recommended for Hazard Classification (R43)	No
triethylene glycol dimethacrylate			

Section 12 - ECOLOGICAL INFORMATION

Harmful to aquatic organisms, may cause long-term adverse effects in the aquatic environment.

Ecotoxicity

Ingredient	Persistence: Water/Soil	Persistence: Air	Bioaccumulation	Mobility
calcium hydroxide	No Data Available	No Data Available	LOW	
barium sulfate	No Data Available	No Data Available		
triethylene glycol dimethacrylate	LOW	No Data Available	LOW	HIGH

Section 13 - DISPOSAL CONSIDERATIONS

- Recycle wherever possible or consult manufacturer for recycling options.
- Consult State Land Waste Management Authority for disposal.
- Recycle containers if possible, or dispose of in an authorised landfill.
- Containers may still present a chemical hazard/ danger when empty.
- Return to supplier for reuse/ recycling if possible.

Otherwise:

- If container can not be cleaned sufficiently well to ensure that residuals do not remain or if the container cannot be used to store the same product, then puncture containers, to prevent re-use, and bury at an authorised landfill.
- Where possible retain label warnings and MSDS and observe all notices pertaining to the product.

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Section 14 - TRANSPORTATION INFORMATION

HAZCHEM:

None (ADG7)

NOT REGULATED FOR TRANSPORT OF DANGEROUS GOODS: UN, IATA, IMDG

Section 15 - REGULATORY INFORMATION

POISONS SCHEDULE

None

REGULATIONS

Regulations for ingredients

calcium hydroxide (CAS: 1305-62-0, 1332-69-0) is found on the following regulatory lists;

"Australia Exposure Standards", "Australia Hazardous Substances", "Australia High Volume Industrial Chemical List (HVICL)", "Australia Inventory of Chemical Substances (AICS)", "Australia Therapeutic Goods Administration (TGA) Substances that may be used as active ingredients in Listed medicines", "CODEX General Standard for Food Additives (GSFA) - Additives Permitted for Use in Food in General, Unless Otherwise Specified, in Accordance with GMP", "GESAMP/EHS Composite List - GESAMP Hazard Profiles", "IMO IBC Code Chapter 17: Summary of minimum requirements", "IMO MARPOL 73/78 (Annex II) - List of Noxious Liquid Substances Carried in Bulk", "International Council of Chemical Associations (ICCA) - High Production Volume List", "OECD List of High Production Volume (HPV) Chemicals"

barium sulfate (CAS: 7727-43-7, 13462-86-7) is found on the following regulatory lists;

"Australia - Australian Capital Territory - Environment Protection Regulation: Ambient environmental standards (Domestic water supply - inorganic chemicals)", "Australia - Australian Capital Territory - Environment Protection Regulation: Ambient environmental standards (STOCK - inorganic chemicals)", "Australia - Australian Capital Territory - Environment Protection Regulation: Pollutants entering waterways taken to cause environmental harm (Domestic water supply quality)", "Australia - Australian Capital Territory - Environment Protection Regulation: Pollutants entering waterways taken to cause environmental harm (STOCK)", "Australia Drinking Water Guideline Values For Physical and Chemical Characteristics", "Australia Exposure Standards", "Australia Hazardous Substances", "Australia High Volume Industrial Chemical List (HVICL)", "Australia Inventory of Chemical Substances (AICS)", "International Air Transport Association (IATA) Dangerous Goods Regulations", "International Council of Chemical Associations (ICCA) - High Production Volume List", "OECD List of High Production Volume (HPV) Chemicals", "WHO Guidelines for Drinking-water Quality - Chemicals for which guideline values have not been established"

triethylene glycol dimethacrylate (CAS: 109-16-0) is found on the following regulatory lists;

"Australia Final Report on Hazard Classification of Common Skin Sensitisers", "Australia Inventory of Chemical Substances (AICS)", "International Council of Chemical Associations (ICCA) - High Production Volume List", "OECD List of High Production Volume (HPV) Chemicals"

No data for Dentsply Prisma VLC Dycal Baseliner Composition (CW: 4993-49)

Section 16 - OTHER INFORMATION

Denmark Advisory list for selfclassification of dangerous substances

Substance	CAS	Suggested codes
triethylene glycol dimethacrylate	109- 16- 0	R43

Ingredients with multiple CAS Nos

Ingredient Name	CAS
calcium hydroxide	1305-62-0, 1332-69-0
barium sulfate	7727-43-7, 13462-86-7

■ Classification of the preparation and its individual components has drawn on official and authoritative sources as well as independent review by the Chemwatch Classification committee using available literature references.

A list of reference resources used to assist the committee may be found at:
www.chemwatch.net/references.

■ The (M)SDS is a Hazard Communication tool and should be used to assist in the Risk Assessment. Many

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factors determine whether the reported Hazards are Risks in the workplace or other settings.

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www.Chemwatch.net

Issue Date: 2-Feb-2009

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**DENTSPLY/International
DENTSPLY/Caulk
Safety Data Sheet**

954500

1. Identification

Product Name Prisma[®] VLC Dycal[®]	SDS Code Number 954500
Substance Identity Prisma[®] VLC Dycal[®] Baseline Composition	Date of Last Revision 05/16/13
Manufacturer: DENTSPLY Caulk	Address 38 West Clarke Avenue Milford DE 19963-1805 http://www.caulk.com http://www.dentsply.com
Grades or Minor Variant Identities Not Applicable	Information Telephone Number (302) 422-4511 (8:00 AM – 4:30 PM Eastern Time)
Product Use (for Canada) Not Applicable	Emergency Telephone Number (302) 422-4511 (8:00 AM – 4:30 PM Eastern Time)

2. Hazard(s) Identification



WARNING

CAUSES SKIN IRRITATION

Wash hands thoroughly after handling.

Wear protective gloves.

IF ON SKIN: Wash with plenty of soap and water.

If skin irritation occurs: Get Medical Advice/attention.

Take off contaminated clothing and wash before reuse.

3. Composition/Information on Ingredients

Hazardous Components	C.A.S. Number	Exposure Limits	%
Urethane dimethacrylate resin	105883-40-7	Not Established	< than 65
Polymerizable dimethacrylate resins	109-16-0	Not Established	< than 10
Barium Sulfate	7727-43-7	10 mg/m ³	< than 25
Calcium Hydroxide	1305-62-0	5 mg/m ³	< than 25

4. First Aid Measures

Routes of Exposure	First Aid Instructions	Immediate Medical Attention	Delayed Effects
Eye	Rinse opened eye for several minutes under running water. If symptoms persist consult physician	Not Applicable	Not Applicable
Skin	Immediately wash with soap and water and rinse thoroughly	Not Applicable	Not Applicable
Inhalation	Not Applicable	Not Applicable	Not Applicable
Ingestion	Not Applicable	Not Applicable	Not Applicable
Mucosa	Rinse tissue for several minutes under running water. If symptoms persist consult physician	Not Applicable	Not Applicable

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

5. Fire Fighting Measures

Flame Propagation or Burning Rate (for Solids) Not Applicable	Properties Contributing to Fire Intensity Not Applicable	Flammability Classification: Not Applicable	Other: Not Applicable
Extinguishing Media: CO ₂ , extinguishing powder, foam carbon dioxide or water spray. Fight larger fires with water spray or alcohol resistant foam.		Extinguishing Media to Avoid: Water with full jet.	
Protection and Procedures for Firefighters: Firefighters should wear self-contained respiratory protective devices.			
Unusual Fire and Explosion Hazards: Formation of toxic, irritating gases is possible from the decomposition of the dimethacrylate resins. Product does not present an explosion hazard.			

6. Accidental Release Measures

Containment Techniques: Material is a paste and as such will not flow.
Spill/Leak Clean-up Procedures and Equipment: Wear protective clothing and scoop up bulk material and place in a labeled plastic or metal container. Avoid gross skin contact to minimize the possibility of contact dermatitis to susceptible persons. Ensure adequate ventilation.

Evacuation Procedures: Not Applicable	Special Instructions: Not Applicable	Reporting Requirements: Not Applicable
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7. Handling and Storage

Handling Practices and Warnings: Product is intended for dental use only. Handling of this product should be by trained dental healthcare professionals only. Observe normal care for working with chemicals.

Storage Practices and Warnings: Store only in the original package. Keep package tightly sealed. Store in a dry area. Protect from exposure to direct light. Store away from food and beverages.

8. Exposure Control / Personal Protection



Occupational Exposure Limits: Not Applicable		
Engineering Controls: Not Applicable		
Individual Protection Measures	Personal Protective Equipment for Normal Use	Personal Protective Equipment for Emergencies
Eye/Face	Safety Glasses	Not Applicable
Skin	The glove material has to be impermeable and resistant to the product.	Not Applicable
Inhalation	Not Required	Not Applicable
Body Protection	Protective work clothing	Not Applicable

9. Physical and Chemical Characteristics

Appearance: Creamy light yellow viscous paste.	Odor: Characteristic sweet acrylic ester odor.
Normal Physical State: High Viscosity Liquid (Paste)	Melting Point: Not Applicable
Specific Gravity: 1.4 g/cm ³	Solubility in Water: Not soluble
Vapor Pressure (mm Hg): Not Applicable	pH: Not Applicable
Flashpoint Method: Not Applicable	Vapor Density (AIR=1): Not Applicable
Other: Not Applicable	Evaporation Rate (Butyl Acetate =1): Not Applicable
	Autoignition Temperature: Not Applicable, Product will not autoignite.
	LEL: Not Applicable UEL: Not Applicable

10. Stability and Reactivity Data

Incompatibility (Materials to Avoid): Strong Oxidizing materials.	
Hazardous Products Produced During Decomposition: No dangerous decomposition products known if used according to Directions for Use.	
Hazardous Polymerization: <input type="checkbox"/> May Occur <input checked="" type="checkbox"/> May Not Occur	Conditions to Avoid: None known
Stability? <input checked="" type="checkbox"/> Stable <input type="checkbox"/> Unstable	Conditions to Avoid: None known

11. Toxicological Information

Toxicity Data, Epidemiology Studies, Carcinogenicity, Neurological Effects, Genetic Effects, Reproductive Effects, or Structure Activity Data: Product is an irritant to the skin and mucous membranes. The unpolymerized product may be an irritant to the skin in susceptible persons. On the eye the product has an irritating effect. Sensitization: Repeated or prolonged contact with the unpolymerized material may cause sensitization for persons allergic to acrylates and methacrylates. This product shows the following dangers according to internally approved calculation methods for composite materials: Irritant.					
Emergency Overview Material is irritating to eyes, respiratory system and skin.					
Routes of Exposure	Signs and Symptoms	Single, Repeated, or Lifetime Exposure	Severity (Mild, Moderate, Severe)	Acute and Chronic Health Effect(s)	Target Organ(s)
Eye	Material can cause irritation.	Single	Moderate	Irritation and possible corneal damage	Not Applicable
Skin	Material may be an irritant	Single & Repeated	Moderate	Irritation or possible allergic response. Severe allergic response may result in breathing difficulties.	Not Applicable
Inhalation	Not Applicable	Not Applicable	Not Applicable	Not Applicable	Not Applicable
Ingestion	Material is not harmful if swallowed using clinically relevant quantities	Not Applicable	Mild	Not Applicable	Not Applicable
Mucosa	Material can cause irritation.	Single	Mild	Inflammation of the mucosa	Not Applicable
Medical Conditions Aggravated by Exposure Open sores and wounds of the skin. Individuals with known sensitivity to methacrylates, acrylates, or urethane dimethacrylate resin used in Dental restorative products.					
Carcinogenicity NTP?: Not listed IARC monographs?: Not listed OSHA regulated?: No All components of this product are in compliance with the inventory listing Requirements of the U. S. Toxic Substances Control Act (TSCA) Chemical Substance Inventory.					
Potential Environmental Effects Do not allow to enter sewers/ surface or ground water.					
NFPA Hazard Classification Ratings (Scale 0-4), Health = 1, Fire = 1, Reactivity = 0					

12. Ecological Information

Toxicity Data, Environmental Fate, Physical/Chemical Data, or other Data Supporting Environmental Hazard Statements: Water Hazard class I (Self-assessment): slightly hazardous for water. Do not allow undiluted product or large quantities of it to reach ground water, water streams or sewage system.
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13. Disposal Considerations

Regulations: Must not be disposed of together with household garbage. Do not allow product to reach sewage system. Dispose of material as solid waste in a closed container. Dispose of in accordance with Federal, State and Local regulations
Properties (Physical/Chemical) Affecting Disposal: Dispose of material as solid waste in a closed container.

14. Transport Information

Regulated for Shipping: No. Not Regulated	DOT Shipping Name: Not Regulated	Packing Group: Not Applicable
Do Changes in Quantities, packaging, or shipment method change product classification? No	DOT Hazard Class: Not Applicable	UN Number: Not Applicable

15. Regulatory Information

This product has been classified in accordance with the hazard criteria of the Globally Harmonized System of Classification and Labeling of Chemicals and the SDS contains all of the information required by the Canadian Controlled Products Regulations.
U.S. Federal Regulations: <u>CERCLA 103 Reportable Quantity</u> : This product is not subject to CERCLA reporting requirements. Many states have more stringent release reporting requirements. Report spills required under federal, state and local regulations
<u>Section 313 Toxic Chemicals</u> : This product contains the following chemicals subject to Annual Release Reporting Requirements Under SARA Title III, Section 313 (40 CFR 372): None
<u>Section 302 Extremely Hazardous Substances (TPQ)</u> : None
<u>EPA Toxic Substances Control Act (TSCA) Status</u> : All of the components of this product are listed on the TSCA inventory.
<u>U.S. State Regulations California Proposition 65</u> : This product does not contain any chemicals, which are on the California Proposition 65 list.
<u>International Regulations: Canadian Environmental Protection Act</u> : This product is a medical device and not subject to chemical notification requirements.
<u>European Community Labeling</u> : Not a dangerous preparation.
<u>European Inventory of New and Existing Chemicals Substances (EINECS)</u> : This product is a medical device and not subject to chemical notification requirements.
Other: Not Applicable

16. Other Information

To the best of our knowledge this product does not contain gluten, wheat grains, flaxseed, natural rubber, or natural latex. All components are synthetically produced; none are derived from animal products. This information is based on our present knowledge. However, this shall not constitute a guarantee for any specific products features and shall not establish a legally valid contractual relationship. 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.
