

## **SAFETY DATA SHEETS**

**This SDS packet was issued with item:**

071851211

**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).**

078326900

# DENTSPLY TIMELINE VLC

Chemwatch Independent Material Safety Data Sheet  
Issue Date: 1-Oct-2009  
C9317TC

CHEMWATCH 4613-1  
Version No:4  
CD 2009/3 Page 1 of 6

## Section 1 - CHEMICAL PRODUCT AND COMPANY IDENTIFICATION

### PRODUCT NAME

DENTSPLY TIMELINE VLC

### SYNONYMS

"Timeline VLC Baseline Composition with Dentin Primer"

### PRODUCT USE

Dental adhesive.

### SUPPLIER

Company: DENTSPLY (AUSTRALIA) PTY LTD

Address:

11- 21 Gilby Road

Mount Waverley

VIC 3149

AUSTRALIA

Telephone: 1300 55 29 29

Emergency Tel: 1300 55 29 29 (Hours of operation:

Monday - Friday 9:00 am - 5:00 pm EST; General  
information only)

Fax: +61 3 9538 8260

## Section 2 - HAZARDS IDENTIFICATION

### STATEMENT OF HAZARDOUS NATURE

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

### POISONS SCHEDULE

None

### RISK

- Harmful if swallowed.
- Contact with acids liberates very toxic gas.

### SAFETY

- Avoid contact with eyes.
- Wear suitable protective clothing.
- To clean the floor and all objects contaminated by this material use water and detergent.
- Keep away from food drink and animal feeding stuffs.
- In case of contact with eyes rinse with plenty of water and contact Doctor or Poisons Information Centre.
- If swallowed IMMEDIATELY contact Doctor or Poisons Information Centre. (show this container or label).

## Section 3 - COMPOSITION / INFORMATION ON INGREDIENTS

NAME	CAS RN	%
urethane dimethacrylate monomer	105883-40-7	30-65
barium sulfate	7727-43-7	1-25
glass beads	65997-17-3.	1-20
sodium fluoride	7681-49-4	<5
dipentaerythritol pentaacrylate phosphate		<5
silica amorphous, fumed	68611-44-9	<2

## Section 4 - FIRST AID MEASURES

### SWALLOWED

- - IF SWALLOWED, REFER FOR MEDICAL ATTENTION, WHERE POSSIBLE, WITHOUT DELAY.
- For advice, contact a Poisons Information Centre or a doctor.

### EYE

- If this product comes in contact with the eyes:
  - Wash out immediately with fresh 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.

# DENTSPLY TIMELINE VLC

## Chemwatch Independent Material Safety Data Sheet

Issue Date: 1-Oct-2009

C9317TC

CHEMWATCH 4613-1

Version No:4

CD 2009/3 Page 2 of 6

Section 4 - FIRST AID MEASURES

### SKIN

- If skin contact occurs:
  - Immediately remove all contaminated clothing, including footwear.
  - Flush skin and hair with running water (and soap if available).

### INHALED

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

### NOTES TO PHYSICIAN

- for poisons (where specific treatment regime is absent):

### BASIC TREATMENT

- Establish a patent airway with suction where necessary.
  - Watch for signs of respiratory insufficiency and assist ventilation as necessary.
- Treat symptomatically.

## Section 5 - FIRE FIGHTING MEASURES

### EXTINGUISHING MEDIA

- - Water spray or fog.
- Foam.

### FIRE FIGHTING

- - Alert Fire Brigade and tell them location and nature of hazard.
- Wear breathing apparatus plus protective gloves for fire only.

### FIRE/EXPLOSION HAZARD

- - Non combustible.
  - Not considered a significant fire risk, however containers may burn.
- Decomposition may produce toxic fumes of: carbon monoxide (CO), carbon dioxide (CO<sub>2</sub>), phosphorus oxides (PO<sub>x</sub>), sulfur oxides (SO<sub>x</sub>), 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

### PERSONAL PROTECTION

Glasses:  
Chemical goggles.

Gloves:  
PVC chemical resistant type.

Respirator:  
Particulate

## Section 6 - ACCIDENTAL RELEASE MEASURES

### MINOR SPILLS

- - Clean up all spills immediately.
- Avoid contact with skin and eyes.

### MAJOR SPILLS

- - Clear area of personnel and move upwind.
- Alert Fire Brigade and tell them location and nature of hazard.

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

## Section 7 - HANDLING AND STORAGE

### PROCEDURE FOR HANDLING

- - Avoid all personal contact, including inhalation.
- Wear protective clothing when risk of exposure occurs.

### SUITABLE CONTAINER

- - Polyethylene or polypropylene container.
- Packing as recommended by manufacturer.

# DENTSPLY TIMELINE VLC

Chemwatch Independent Material Safety Data Sheet  
Issue Date: 1-Oct-2009  
C9317TC

CHEMWATCH 4613-1  
Version No:4  
CD 2009/3 Page 3 of 6  
Section 7 - HANDLING AND STORAGE

## STORAGE INCOMPATIBILITY

■ - Avoid strong acids, acid chlorides and acid anhydrides..

Barium sulfate (barytes)

- reacts violently with dimethyl sulfoxide, sodium acetylide, finely divided carbon, aluminium, magnesium, zirconium, and possibly other active metals, especially at elevated temperatures

- is incompatible with potassium, phosphorus (ignites when primed with nitrate-calcium silicide).

- Avoid reaction with oxidising agents.

## STORAGE REQUIREMENTS

■ - Store in original containers.

- Keep containers securely sealed.

No special storage precautions required.

## Section 8 - EXPOSURE CONTROLS / PERSONAL PROTECTION

### EXPOSURE CONTROLS

Source	Material	TWA mg/m <sup>3</sup>	TWA F/CC	Notes
Australia Exposure Standards	barium sulfate (Barium sulphate (a))	10		(see Chapter 14)
Australia Exposure Standards	glass beads (Synthetic mineral fibres (SMF))	0.5	0.5	(see Chapter 14)

The following materials had no OELs on our records

• urethane dimethacrylate monomer:

CAS:105883- 40- 7

## PERSONAL PROTECTION

### RESPIRATOR

Particulate

### EYE

■ - Safety glasses with side shields.

- Chemical goggles.

### HANDS/FEET

■ - Wear chemical protective gloves, eg. PVC.

- Wear safety footwear or safety gumboots, eg. Rubber.

### OTHER

■ - Overalls.

- P.V.C. apron.

### ENGINEERING CONTROLS

■ General exhaust is adequate under normal operating conditions. Local exhaust ventilation may be required in special circumstances.

## Section 9 - PHYSICAL AND CHEMICAL PROPERTIES

### APPEARANCE

Creamy paste with a characteristic odour; does not mix with water.

### PHYSICAL PROPERTIES

Does not mix with water.

Sinks in water.

Contact with acids liberates very toxic gas.

Molecular Weight: Not Applicable

Melting Range (°C): Not Available

Solubility in water (g/L): Immiscible

pH (1% solution): Not Applicable

Volatile Component (%vol): Not Available

Relative Vapour Density (air=1): Not Applicable

Lower Explosive Limit (%): Not Applicable

Autoignition Temp (°C): Not Available

State: Non Slump Paste

Boiling Range (°C): Not Applicable

Specific Gravity (water=1): 2.2

pH (as supplied): Not Applicable

Vapour Pressure (kPa): Not Applicable

Evaporation Rate: Not Applicable

Flash Point (°C): Not Applicable

Upper Explosive Limit (%): Not Applicable

Decomposition Temp (°C): Not Available

Viscosity: Not Available

# DENTSPLY TIMELINE VLC

Chemwatch Independent Material Safety Data Sheet  
Issue Date: 1-Oct-2009  
C9317TC

CHEMWATCH 4613-1  
Version No:4  
CD 2009/3 Page 4 of 6

## Section 10 - CHEMICAL STABILITY AND REACTIVITY INFORMATION

### CONDITIONS CONTRIBUTING TO INSTABILITY

- - Presence of heat source and direct sunlight.
  - Presence of incompatible materials.
  - Product is considered stable.
- For incompatible materials - refer to Section 7 - Handling and Storage.

## Section 11 - TOXICOLOGICAL INFORMATION

### POTENTIAL HEALTH EFFECTS

#### ACUTE HEALTH EFFECTS

- Harmful if swallowed.

#### CHRONIC HEALTH EFFECTS

- Not applicable.

### TOXICITY AND IRRITATION

- Not available. Refer to individual constituents.

#### URETHANE DIMETHACRYLATE MONOMER:

- No significant acute toxicological data identified in literature search.

#### BARIUM SULFATE:

- No significant acute toxicological data identified in literature search.

#### GLASS BEADS:

- No data of toxicological significance identified in literature search.

#### SODIUM FLUORIDE:

- unless otherwise specified data extracted from RTECS - Register of Toxic Effects of Chemical Substances.

#### TOXICITY

Oral (human) LDLo: 71 mg/kg  
Oral (woman) LDLo: 90 mg/kg  
Oral (human) TDLo: 0.21 mg/kg  
Oral (woman) TDLo: 7 mg/kg  
Oral (man) TDLo: 1662 mg/kg  
Oral (rat) LD50: 52 mg/kg

#### IRRITATION

Eye (rabbit): 20 mg/24h- Moderate

■ The material may produce moderate eye irritation leading to inflammation. Repeated or prolonged exposure to irritants may produce conjunctivitis. 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. The substance is classified by IARC as Group 3:

NOT classifiable as to its carcinogenicity to humans.

Evidence of carcinogenicity may be inadequate or limited in animal testing.

#### SILICA AMORPHOUS, FUMED:

- unless otherwise specified data extracted from RTECS - Register of Toxic Effects of Chemical Substances.

#### TOXICITY

Oral (rat) LD50: >5000 mg/kg

#### IRRITATION

Nil Reported [Wacker]

- For silica amorphous:

When experimental animals inhale synthetic amorphous silica (SAS) dust, it dissolves in the lung fluid and is rapidly eliminated. If swallowed, the vast majority of SAS is excreted in the faeces and there is little accumulation in the body.

### CARCINOGEN

Continuous glass filament	International Agency for Research on Cancer (IARC) Carcinogens	Group	3
Fluorides (inorganic, used in drinking-water)	International Agency for Research on Cancer (IARC) Carcinogens	Group	3

## Section 12 - ECOLOGICAL INFORMATION

No data

### Ecotoxicity

Ingredient	Persistence: Water/Soil	Persistence: Air	Bioaccumulation	Mobility
Dentsply Timeline VLC		No data		
urethane dimethacrylate monomer		No data		
barium sulfate		No data		
glass beads		No data		
sodium fluoride		No data		
silica amorphous, fumed		No data		

# DENTSPLY TIMELINE VLC

Chemwatch Independent Material Safety Data Sheet  
Issue Date: 1-Oct-2009  
C9317TC

CHEMWATCH 4613-1  
Version No:4  
CD 2009/3 Page 5 of 6  
Section 12 - ECOLOGICAL INFORMATION

## Section 13 - DISPOSAL CONSIDERATIONS

- - Containers may still present a chemical hazard/ danger when empty.
- Return to supplier for reuse/ recycling if possible.
- DO NOT allow wash water from cleaning or process equipment to enter drains.
- It may be necessary to collect all wash water for treatment before disposal.
- Recycle wherever possible or consult manufacturer for recycling options.
- Consult State Land Waste Authority for disposal.

## Section 14 - TRANSPORTATION INFORMATION

HAZCHEM: None (ADG7)

NOT REGULATED FOR TRANSPORT OF DANGEROUS GOODS: ADG7, UN, IATA, IMDG

## Section 15 - REGULATORY INFORMATION

POISONS SCHEDULE: None

### REGULATIONS

Regulations for ingredients

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

"Australia Exposure Standards", "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 Representative List of High Production Volume (HPV) Chemicals"

**glass beads (CAS: 65997-17-3) is found on the following regulatory lists;**

"Australia Inventory of Chemical Substances (AICS)", "Australia Standard for the Uniform Scheduling of Drugs and Poisons (SUSDP) - Appendix A", "OECD Representative List of High Production Volume Chemicals"

**sodium fluoride (CAS: 7681-49-4) is found on the following regulatory lists;**

"Australia Hazardous Substances", "Australia High Volume Industrial Chemical List (HVICL)", "Australia Inventory of Chemical Substances (AICS)", "Australia Standard for the Uniform Scheduling of Drugs and Poisons (SUSDP) - Appendix F (Part 3)", "International Council of Chemical Associations (ICCA) - High Production Volume List", "OECD Representative List of High Production Volume Chemicals", "The Australia Group Export Control List: Chemical Weapons Precursors"

**silica amorphous, fumed (CAS: 68611-44-9,112945-52-5,60842-32-2) is found on the following regulatory lists;**

"Australia Inventory of Chemical Substances (AICS)", "International Council of Chemical Associations (ICCA) - High Production Volume List", "OECD Representative List of High Production Volume Chemicals"

**No data for Dentsply Timeline VLC (CW: 4613-1)**

No data for urethane dimethacrylate monomer (CAS: , 105883-40-7)

## Section 16 - OTHER INFORMATION

### INGREDIENTS WITH MULTIPLE CAS NUMBERS

Ingredient Name

barium sulfate

silica amorphous, fumed

CAS

7727- 43- 7, 13462- 86- 7

68611- 44- 9, 112945- 52- 5, 60842- 32- 2

- 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](http://www.chemwatch.net/references).

- The (M)SDS is a Hazard Communication tool and should be used to assist in the Risk Assessment. Many factors determine whether the reported Hazards are Risks in the workplace or other settings.

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## DENTSPLY TIMELINE VLC

Chemwatch Independent Material Safety Data Sheet  
Issue Date: 1-Oct-2009  
C9317TC

CHEMWATCH 4613-1  
Version No:4  
CD 2009/3 Page 6 of 6  
Section 16 - OTHER INFORMATION

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*This is the end of the MSDS.*

# Dentsply Timeline VLC

## Dentsply (Australia)

Chemwatch: 4613-1

Version No: 4.1.1.1

Material Safety Data Sheet according to NOHSC and ADG requirements

Chemwatch Hazard Alert Code: 2

Issue Date: 01/01/2013

Print Date: 14/10/2014

Initial Date: Not Available

S.Local.AUS.EN

## SECTION 1 IDENTIFICATION OF THE SUBSTANCE / MIXTURE AND OF THE COMPANY / UNDERTAKING

### Product Identifier

Product name	Dentsply Timeline VLC
Chemical Name	Not Applicable
Synonyms	Timeline VLC, Timeline VLC Baseline Composition with Dentin Primer
Proper shipping name	Not Applicable
Chemical formula	Not Applicable
Other means of identification	Not Available
CAS number	Not Applicable

### Relevant identified uses of the substance or mixture and uses advised against

Relevant identified uses	Dental adhesive.
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### Details of the manufacturer/importer

Registered company name	Dentsply (Australia)
Address	11-21 Gilby Road Mount Waverley 3149 VIC Australia
Telephone	+61 3 9538 8240
Fax	+61 3 9538 8260
Website	www.dentsply.com.au
Email	Not Available

### Emergency telephone number

Association / Organisation	Not Available
Emergency telephone numbers	1300 552 929 (Mon-Fri 9am-5pm)
Other emergency telephone numbers	1300 552 929 (Mon-Fri 9am-5pm)

## SECTION 2 HAZARDS IDENTIFICATION

### Classification of the substance or mixture

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

#### CHEMWATCH HAZARD RATINGS

	Min	Max
Flammability	0	
Toxicity	2	
Body Contact	2	
Reactivity	1	
Chronic	2	

0 = Minimum  
1 = Low  
2 = Moderate  
3 = High  
4 = Extreme

Poisons Schedule	Not Applicable	
Risk Phrases <sup>[1]</sup>	R36/37/38	Irritating to eyes, respiratory system and skin.
	R22	Harmful if swallowed.
	R32	Contact with acids liberates very toxic gas.



## Dentsply Timeline VLC

### Legend:

1. Classified by Chemwatch; 2. Classification drawn from HSIS ; 3. Classification drawn from EC Directive 1272/2008 - Annex VI



Relevant risk statements are found in section 2

Indication(s) of danger	Xn
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### SAFETY ADVICE

<b>S13</b>	Keep away from food, drink and animal feeding stuffs.
<b>S25</b>	Avoid contact with eyes.
<b>S26</b>	In case of contact with eyes, rinse with plenty of water and contact Doctor or Poisons Information Centre.
<b>S36</b>	Wear suitable protective clothing.
<b>S37</b>	Wear suitable gloves.
<b>S39</b>	Wear eye/face protection.
<b>S40</b>	To clean the floor and all objects contaminated by this material, use water and detergent.
<b>S46</b>	If swallowed, seek medical advice immediately and show this container or label.
<b>S50</b>	Do not mix with acids, accelerators or promoters
<b>S56</b>	Dispose of this material and its container at hazardous or special waste collection point.
<b>S64</b>	If swallowed, rinse mouth with water (only if the person is conscious).

### Other hazards

	Limited evidence of a carcinogenic effect*.
	Cumulative effects may result following exposure*.

## SECTION 3 COMPOSITION / INFORMATION ON INGREDIENTS

### Substances

See section below for composition of Mixtures

### Mixtures

CAS No	%[weight]	Name
105883-40-7	30-65	<a href="#">urethane dimethacrylate monomer</a>
7727-43-7	1-25	<a href="#">barium sulfate</a>
65997-17-3.	1-20	<a href="#">glass beads</a>
7681-49-4	<5	<a href="#">sodium fluoride</a>
Not Available	<5	dipentaerythritol pentaacrylate phosphate
68611-44-9	<2	<a href="#">silica amorphous, fumed</a>

## SECTION 4 FIRST AID MEASURES

### Description of first aid measures

<b>Eye Contact</b>	<p>If this product comes in contact with the eyes:</p> <ul style="list-style-type: none"> <li>Wash out immediately with fresh running water.</li> <li>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.</li> <li>Seek medical attention without delay; if pain persists or recurs seek medical attention.</li> <li>Removal of contact lenses after an eye injury should only be undertaken by skilled personnel.</li> </ul>
<b>Skin Contact</b>	<p>If skin contact occurs:</p> <ul style="list-style-type: none"> <li>Immediately remove all contaminated clothing, including footwear.</li> <li>Flush skin and hair with running water (and soap if available).</li> <li>Seek medical attention in event of irritation.</li> </ul>
<b>Inhalation</b>	<ul style="list-style-type: none"> <li>If fumes, aerosols or combustion products are inhaled remove from contaminated area.</li> <li>Other measures are usually unnecessary.</li> </ul>

## Dentsply Timeline VLC

## Ingestion

- ▶ **IF SWALLOWED, REFER FOR MEDICAL ATTENTION, WHERE POSSIBLE, WITHOUT DELAY.**
- ▶ For advice, contact a Poisons Information Centre or a doctor.
- ▶ Urgent hospital treatment is likely to be needed.
- ▶ In the mean time, qualified first-aid personnel should treat the patient following observation and employing supportive measures as indicated by the patient's condition.
- ▶ If the services of a medical officer or medical doctor are readily available, the patient should be placed in his/her care and a copy of the MSDS should be provided. Further action will be the responsibility of the medical specialist.
- ▶ If medical attention is not available on the worksite or surroundings send the patient to a hospital together with a copy of the MSDS.

**Where medical attention is not immediately available or where the patient is more than 15 minutes from a hospital or unless instructed otherwise:**

- ▶ **INDUCE** vomiting with fingers down the back of the throat, **ONLY IF CONSCIOUS**. Lean patient forward or place on left side (head-down position, if possible) to maintain open airway and prevent aspiration.

**NOTE:** Wear a protective glove when inducing vomiting by mechanical means.

## Indication of any immediate medical attention and special treatment needed

As in all cases of suspected poisoning, follow the ABCDEs of emergency medicine (airway, breathing, circulation, disability, exposure), then the ABCDEs of toxicology (antidotes, basics, change absorption, change distribution, change elimination).

For poisons (where specific treatment regime is absent):

## BASIC TREATMENT

- ▶ Establish a patent airway with suction where necessary.
- ▶ Watch for signs of respiratory insufficiency and assist ventilation as necessary.
- ▶ Administer oxygen by non-rebreather mask at 10 to 15 L/min.
- ▶ Monitor and treat, where necessary, for pulmonary oedema.
- ▶ Monitor and treat, where necessary, for shock.
- ▶ Anticipate seizures.
- ▶ **DO NOT** use emetics. Where ingestion is suspected rinse mouth and give up to 200 ml water (5 ml/kg recommended) for dilution where patient is able to swallow, has a strong gag reflex and does not drool.

## ADVANCED TREATMENT

- ▶ Consider orotracheal or nasotracheal intubation for airway control in unconscious patient or where respiratory arrest has occurred.
- ▶ Positive-pressure ventilation using a bag-valve mask might be of use.
- ▶ Monitor and treat, where necessary, for arrhythmias.
- ▶ Start an IV D5W TKO. If signs of hypovolaemia are present use lactated Ringers solution. Fluid overload might create complications.
- ▶ Drug therapy should be considered for pulmonary oedema.
- ▶ Hypotension with signs of hypovolaemia requires the cautious administration of fluids. Fluid overload might create complications.
- ▶ Treat seizures with diazepam.
- ▶ Proparacaine hydrochloride should be used to assist eye irrigation.

BRONSTEIN, A.C. and CURRANCE, P.L.

EMERGENCY CARE FOR HAZARDOUS MATERIALS EXPOSURE: 2nd Ed. 1994

Treat symptomatically.

## SECTION 5 FIREFIGHTING MEASURES

## Extinguishing media

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

## Special hazards arising from the substrate or mixture

## Fire Incompatibility

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

## Advice for firefighters

## Fire Fighting

- ▶ Alert Fire Brigade and tell them location and nature of hazard.
- ▶ Wear breathing apparatus plus protective gloves in the event of a fire.
- ▶ Prevent, by any means available, spillage from entering drains or water courses.
- ▶ Use fire fighting procedures suitable for surrounding area.

## Fire/Explosion Hazard

▶ Non combustible.  
 ▶ Not considered a significant fire risk, however containers may burn.  
 Decomposition may produce toxic fumes of: , carbon monoxide (CO), carbon dioxide (CO<sub>2</sub>), phosphorus oxides (PO<sub>x</sub>), sulfur oxides (SO<sub>x</sub>), other pyrolysis products typical of burning organic material May emit poisonous fumes May emit corrosive fumes.

## Dentsply Timeline VLC

## SECTION 6 ACCIDENTAL RELEASE MEASURES

## Personal precautions, protective equipment and emergency procedures

Minor Spills	<ul style="list-style-type: none"> <li>▶ Clean up all spills immediately.</li> <li>▶ Avoid contact with skin and eyes.</li> <li>▶ Wear impervious gloves and safety goggles.</li> <li>▶ Trowel up/scrape up.</li> </ul>
Major Spills	<ul style="list-style-type: none"> <li>▶ Clear area of personnel and move upwind.</li> <li>▶ Alert Fire Brigade and tell them location and nature of hazard.</li> <li>▶ Wear breathing apparatus plus protective gloves.</li> <li>▶ Prevent, by any means available, spillage from entering drains or water course.</li> </ul>
Personal Protective Equipment advice is contained in Section 8 of the MSDS.	

## SECTION 7 HANDLING AND STORAGE

## Precautions for safe handling

Safe handling	<ul style="list-style-type: none"> <li>▶ Avoid all personal contact, including inhalation.</li> <li>▶ Wear protective clothing when risk of exposure occurs.</li> <li>▶ Use in a well-ventilated area.</li> <li>▶ Prevent concentration in hollows and sumps.</li> </ul>
Other information	<ul style="list-style-type: none"> <li>▶ Store in original containers.</li> <li>▶ Keep containers securely sealed.</li> <li>▶ Store in a cool, dry, well-ventilated area.</li> <li>▶ Store away from incompatible materials and foodstuff containers.</li> </ul>

## Conditions for safe storage, including any incompatibilities

Suitable container	<ul style="list-style-type: none"> <li>▶ Polyethylene or polypropylene container.</li> <li>▶ Packing as recommended by manufacturer.</li> <li>▶ Check all containers are clearly labelled and free from leaks.</li> </ul>
Storage incompatibility	<ul style="list-style-type: none"> <li>▶ Avoid strong acids, acid chlorides, acid anhydrides and chloroformates.</li> </ul> <p>Barium sulfate (barytes)</p> <ul style="list-style-type: none"> <li>▶ reacts violently with dimethyl sulfoxide, sodium acetylide, finely divided carbon, aluminium, magnesium, zirconium, and possibly other active metals, especially at elevated temperatures</li> <li>▶ is incompatible with potassium, phosphorus (ignites when primed with nitrate-calcium silicide)</li> <li>▶ Avoid reaction with oxidising agents</li> </ul>

## PACKAGE MATERIAL INCOMPATIBILITIES

Not Available

## SECTION 8 EXPOSURE CONTROLS / PERSONAL PROTECTION

## Control parameters

## OCCUPATIONAL EXPOSURE LIMITS (OEL)

## INGREDIENT DATA

Source	Ingredient	Material name	TWA	STEL	Peak	Notes
Australia Exposure Standards	barium sulfate	Barium sulphate (a)	10 mg/m3	Not Available	Not Available	Not Available
Australia Exposure Standards	sodium fluoride	Fluorides (as F)	2.5 mg/m3	Not Available	Not Available	Not Available

## EMERGENCY LIMITS


Ingredient	TEEL-0	TEEL-1	TEEL-2	TEEL-3
Dentsply Timeline VLC	Not Available	Not Available	Not Available	Not Available

Ingredient	Original IDLH	Revised IDLH
urethane dimethacrylate monomer	Not Available	Not Available
barium sulfate	Not Available	Not Available
glass beads	Not Available	Not Available
sodium fluoride	500 mg/m3	250 mg/m3

## Dentsply Timeline VLC

dipentaerythritol pentaacrylate phosphate	Not Available	Not Available
silica amorphous, fumed	N.E. mg/m3 / N.E. ppm	3,000 mg/m3

## Exposure controls

<b>Appropriate engineering controls</b>	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.
<b>Personal protection</b>	
<b>Eye and face protection</b>	<ul style="list-style-type: none"> <li>▶ Safety glasses with side shields.</li> <li>▶ Chemical goggles.</li> <li>▶ Contact lenses may pose a special hazard; soft contact lenses may absorb and concentrate irritants. A written policy document, describing the wearing of lenses or restrictions on use, should be created for each workplace or task.</li> </ul>
<b>Skin protection</b>	See Hand protection below
<b>Hands/feet protection</b>	<ul style="list-style-type: none"> <li>▶ Wear chemical protective gloves, e.g. PVC.</li> <li>▶ Wear safety footwear or safety gumboots, e.g. Rubber</li> </ul>
<b>Body protection</b>	See Other protection below
<b>Other protection</b>	<ul style="list-style-type: none"> <li>▶ Overalls.</li> <li>▶ P.V.C. apron.</li> <li>▶ Barrier cream.</li> </ul>
<b>Thermal hazards</b>	Not Available

## Recommended material(s)

## GLOVE SELECTION INDEX

Glove selection is based on a modified presentation of the:

**"Forsberg Clothing Performance Index".**

The effect(s) of the following substance(s) are taken into account in the **computer-generated** selection:

Dentsply Timeline VLC

Material	CPI
NATURAL RUBBER	A
NEOPRENE	A
NITRILE	A
PVC	A

\* CPI - Chemwatch Performance Index

A: Best Selection

B: Satisfactory; may degrade after 4 hours continuous immersion

C: Poor to Dangerous Choice for other than short term immersion

**NOTE:** As a series of factors will influence the actual performance of the glove, a final selection must be based on detailed observation. -

\* Where the glove is to be used on a short term, casual or infrequent basis, factors such as "feel" or convenience (e.g. disposability), may dictate a choice of gloves which might otherwise be unsuitable following long-term or frequent use. A qualified practitioner should be consulted.

## Respiratory protection

Where the concentration of gas/particulates in the breathing zone, approaches or exceeds the "Exposure Standard" (or ES), respiratory protection is required.

Degree of protection varies with both face-piece and Class of filter; the nature of protection varies with Type of filter.

Required Minimum Protection Factor	Half-Face Respirator	Full-Face Respirator	Powered Air Respirator
up to 10 x ES	-AUS P2	-	-PAPR-AUS / Class 1 P2
up to 50 x ES	-	-AUS / Class 1 P2	-
up to 100 x ES	-	-2 P2	-PAPR-2 P2 ^

^ - Full-face

A(All classes) = Organic vapours, B AUS or B1 = Acid gasses, B2 = Acid gas or hydrogen cyanide(HCN), B3 = Acid gas or hydrogen cyanide(HCN), E = Sulfur dioxide(SO2), G = Agricultural chemicals, K = Ammonia(NH3), Hg = Mercury, NO = Oxides of nitrogen, MB = Methyl bromide, AX = Low boiling point organic compounds(below 65 degC)

## SECTION 9 PHYSICAL AND CHEMICAL PROPERTIES

## Information on basic physical and chemical properties

<b>Appearance</b>	Creamy paste with a characteristic odour; does not mix with water.		
<b>Physical state</b>	Non Slump Paste	<b>Relative density (Water = 1)</b>	2.2
<b>Odour</b>	Not Available	<b>Partition coefficient n-octanol / water</b>	Not Available

## Dentsply Timeline VLC

<b>Odour threshold</b>	Not Available	<b>Auto-ignition temperature (°C)</b>	Not Available
<b>pH (as supplied)</b>	Not Applicable	<b>Decomposition temperature</b>	Not Available
<b>Melting point / freezing point (°C)</b>	Not Available	<b>Viscosity (cSt)</b>	Not Available
<b>Initial boiling point and boiling range (°C)</b>	Not Available	<b>Molecular weight (g/mol)</b>	Not Applicable
<b>Flash point (°C)</b>	Not Available	<b>Taste</b>	Not Available
<b>Evaporation rate</b>	Not Applicable	<b>Explosive properties</b>	Not Available
<b>Flammability</b>	Not Available	<b>Oxidising properties</b>	Not Available
<b>Upper Explosive Limit (%)</b>	Not Applicable	<b>Surface Tension (dyn/cm or mN/m)</b>	Not Available
<b>Lower Explosive Limit (%)</b>	Not Applicable	<b>Volatile Component (%vol)</b>	Not Available
<b>Vapour pressure (kPa)</b>	Not Applicable	<b>Gas group</b>	Not Available
<b>Solubility in water (g/L)</b>	Immiscible	<b>pH as a solution(1%)</b>	Not Applicable
<b>Vapour density (Air = 1)</b>	Not Applicable	<b>VOC g/L</b>	Not Available

## SECTION 10 STABILITY AND REACTIVITY

<b>Reactivity</b>	See section 7
<b>Chemical stability</b>	<ul style="list-style-type: none"> <li>▸ Presence of heat source and direct sunlight</li> <li>▸ Unstable in the presence of incompatible materials.</li> <li>▸ Product is considered stable.</li> <li>▸ Hazardous polymerisation will not occur.</li> </ul>
<b>Possibility of hazardous reactions</b>	See section 7
<b>Conditions to avoid</b>	See section 7
<b>Incompatible materials</b>	See section 7
<b>Hazardous decomposition products</b>	See section 5

## SECTION 11 TOXICOLOGICAL INFORMATION

## Information on toxicological effects

<b>Inhaled</b>	Limited evidence or practical experience suggests that the material may produce irritation of the respiratory system, in a significant number of individuals, following inhalation. In contrast to most organs, the lung is able to respond to a chemical insult by first removing or neutralising the irritant and then repairing the damage. The repair process, which initially evolved to protect mammalian lungs from foreign matter and antigens, may however, produce further lung damage resulting in the impairment of gas exchange, the primary function of the lungs. Respiratory tract irritation often results in an inflammatory response involving the recruitment and activation of many cell types, mainly derived from the vascular system.
<b>Ingestion</b>	Limited evidence exists that exposure to the material may produce irreversible damage (other than carcinogenesis, mutagenesis and teratogenesis) following a single exposure by swallowing.
<b>Skin Contact</b>	Limited evidence exists, or practical experience predicts, that the material either produces inflammation of the skin in a substantial number of individuals following direct contact, and/or produces significant inflammation when applied to the healthy intact skin of animals, for up to four hours, such inflammation being present twenty-four hours or more after the end of the exposure period. Skin irritation may also be present after prolonged or repeated exposure; this may result in a form of contact dermatitis (nonallergic). The dermatitis is often characterised by skin redness (erythema) and swelling (oedema) which may progress to blistering (vesiculation), scaling and thickening of the epidermis. At the microscopic level there may be intercellular oedema of the spongy layer of the skin (spongiosis) and intracellular oedema of the epidermis.
<b>Eye</b>	Limited evidence exists, or practical experience suggests, that the material may cause eye irritation in a substantial number of individuals and/or is expected to produce significant ocular lesions which are present twenty-four hours or more after instillation into the eye(s) of experimental animals. Repeated or prolonged eye contact may cause inflammation characterised by temporary redness (similar to windburn) of the conjunctiva (conjunctivitis); temporary impairment of vision and/or other transient eye damage/ulceration may occur.

## Dentsply Timeline VLC

<b>Chronic</b>	<p>On the basis, primarily, of animal experiments, concern has been expressed by at least one classification body that the material may produce carcinogenic or mutagenic effects; in respect of the available information, however, there presently exists inadequate data for making a satisfactory assessment.</p> <p>Limited evidence suggests that repeated or long-term occupational exposure may produce cumulative health effects involving organs or biochemical systems.</p> <p>Workers exposed to barium compounds have been reported to show an increased incidence of hypertension, irritation of the respiratory system, and damage to the spleen, liver and bone marrow. Long term exposure to some barium compounds (especially inorganic species) may produce a condition known as baritosis, a form of benign pneumoconiosis.</p>	
<b>Dentsply Timeline VLC</b>	<b>TOXICITY</b> Not Available	<b>IRRITATION</b> Not Available
<b>urethane dimethacrylate monomer</b>	<b>TOXICITY</b> Not Available	<b>IRRITATION</b> Not Available
<b>barium sulfate</b>	<b>TOXICITY</b> Not Available	<b>IRRITATION</b> Not Available
<b>glass beads</b>	<b>TOXICITY</b> Not Available	<b>IRRITATION</b> Not Available
<b>sodium fluoride</b>	<b>TOXICITY</b> Oral (rat) LD50: 52 mg/kg Not Available	<b>IRRITATION</b> Eye (rabbit): 20 mg/24h-moderate Not Available
<b>silica amorphous, fumed</b>	<b>TOXICITY</b> Oral (rat) LD50: >5000 mg/kg Not Available	<b>IRRITATION</b> [Wacker] Not Available

Not available. Refer to individual constituents.

<b>URETHANE DIMETHACRYLATE MONOMER</b>	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. Key criteria for the diagnosis of RADS include the absence of preceding respiratory disease, in a non-atopic individual, with abrupt onset of persistent asthma-like symptoms within minutes to hours of a documented exposure to the irritant. A reversible airflow pattern, on spirometry, with the presence of moderate to severe bronchial hyperreactivity on methacholine challenge testing and the lack of minimal lymphocytic inflammation, without eosinophilia, have also been included in the criteria for diagnosis of RADS.
<b>BARIUM SULFATE</b>	No significant acute toxicological data identified in literature search.
<b>GLASS BEADS</b>	No data of toxicological significance identified in literature search.
<b>SODIUM FLUORIDE</b>	<p>The material may produce moderate eye irritation leading to inflammation. Repeated or prolonged exposure to irritants may produce conjunctivitis.</p> <p>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.</p>
<b>SILICA AMORPHOUS, FUMED</b>	<p>For silica amorphous:</p> <p>When experimental animals inhale synthetic amorphous silica (SAS) dust, it dissolves in the lung fluid and is rapidly eliminated. If swallowed, the vast majority of SAS is excreted in the faeces and there is little accumulation in the body. Following absorption across the gut, SAS is eliminated via urine without modification in animals and humans. SAS is not expected to be broken down (metabolised) in mammals.</p>

<b>Acute Toxicity</b>	✓	<b>Carcinogenicity</b>	⊖
<b>Skin Irritation/Corrosion</b>	✓	<b>Reproductivity</b>	⊖
<b>Serious Eye Damage/Irritation</b>	✓	<b>STOT - Single Exposure</b>	✓

## Dentsply Timeline VLC

Respiratory or Skin sensitisation	⊖	STOT - Repeated Exposure	⊖
Mutagenicity	⊖	Aspiration Hazard	⊖

Legend: ✔ – Data required to make classification available  
✘ – Data available but does not fill the criteria for classification  
⊖ – Data Not Available to make classification

## CMR STATUS

Not Applicable

## SECTION 12 ECOLOGICAL INFORMATION

## Toxicity

**DO NOT** discharge into sewer or waterways.

## Persistence and degradability

Ingredient	Persistence: Water/Soil	Persistence: Air
sodium fluoride	HIGH	HIGH

## Bioaccumulative potential

Ingredient	Bioaccumulation
sodium fluoride	LOW (BCF = 6.4)

## Mobility in soil

Ingredient	Mobility
sodium fluoride	LOW (KOC = 14.3)

## SECTION 13 DISPOSAL CONSIDERATIONS

## Waste treatment methods

Product / Packaging disposal	<ul style="list-style-type: none"> <li>Containers may still present a chemical hazard/ danger when empty.</li> <li>Return to supplier for reuse/ recycling if possible.</li> </ul> <p>Otherwise:</p> <ul style="list-style-type: none"> <li>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.</li> <li>Where possible retain label warnings and MSDS and observe all notices pertaining to the product.</li> </ul>
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## SECTION 14 TRANSPORT INFORMATION

## Labels Required

Marine Pollutant	NO
HAZCHEM	Not Applicable

Land transport (ADG): NOT REGULATED FOR TRANSPORT OF DANGEROUS GOODS

Air transport (ICAO-IATA / DGR): NOT REGULATED FOR TRANSPORT OF DANGEROUS GOODS

Sea transport (IMDG-Code / GGVSee): NOT REGULATED FOR TRANSPORT OF DANGEROUS GOODS

## SECTION 15 REGULATORY INFORMATION

## Safety, health and environmental regulations / legislation specific for the substance or mixture

urethane dimethacrylate monomer(105883-40-7) is found on the following regulatory lists	
barium sulfate(7727-43-7) is found on the following regulatory lists	"Australia Exposure Standards", "Australia Inventory of Chemical Substances (AICS)"

## Dentsply Timeline VLC

glass beads(65997-17-3.) is found on the following regulatory lists	"Australia Inventory of Chemical Substances (AICS)", "Australia Hazardous Substances Information System - Consolidated Lists"
sodium fluoride(7681-49-4) is found on the following regulatory lists	"Australia Exposure Standards", "International Agency for Research on Cancer (IARC) - Agents Classified by the IARC Monographs", "Australia Inventory of Chemical Substances (AICS)", "Australia Hazardous Substances Information System - Consolidated Lists"
silica amorphous, fumed(68611-44-9) is found on the following regulatory lists	"Australia Inventory of Chemical Substances (AICS)", "Australia Hazardous Substances Information System - Consolidated Lists"

## SECTION 16 OTHER INFORMATION

## Other information

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](http://www.chemwatch.net/references)

The (M)SDS is a Hazard Communication tool and should be used to assist in the Risk Assessment. Many factors determine whether the reported Hazards are Risks in the workplace or other settings. Risks may be determined by reference to Exposures Scenarios. Scale of use, frequency of use and current or available engineering controls must be considered.

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# DENTSPLY Milford

## Safety Data Sheet

922001

### 1. Identification

Product Name <b>TimeLine™ VLC Baseline Composition with Dentin Primer</b>	SDS Code Number <b>922001</b>
Substance Identity <b>TimeLine™ VLC Baseline Composition with Dentin Primer</b>	Date of Last Revision <b>05/05/16</b>
Manufacturer: DENTSPLY Milford	Address 38 West Clarke Avenue Milford DE 19963-1805 <a href="http://www.dentsply.com">http://www.dentsply.com</a>
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	127312-03-2	Not Established	< than 65
Barium Sulfate	7727-43-7	10 mg/m <sup>3</sup>	< than 25
Barium boron alumino silicate glass	65997-17-3	10 mg/m <sup>3</sup>	< than 20
Sodium fluoride	7681-49-4	2.5 mg/m <sup>3</sup>	< than 5
Dipentaerythritol pentaacrylate phosphate	87699-25-0	Not Established	< than 5

### 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 <sub>2</sub> , 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 paste.	Odor: Characteristic sweet acrylic ester odor.
Normal Physical State: High Viscosity Liquid (Paste)	Melting Point: Not Applicable
Specific Gravity: 1.4 g/cm <sup>3</sup>	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 class1 (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
Section 313 Toxic Chemicals: This product contains the following chemicals subject to Annual Release Reporting Requirements Under SARA Title III, Section 313 (40 CFR 372): None
Section 302 Extremely Hazardous Substances (TPQ): None
EPA Toxic Substances Control Act (TSCA) Status: All of the components of this product are listed on the TSCA inventory.
U.S. State Regulations <u>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.
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