SAFETY DATA SHEETS

This SDS packet was issued with item:

070447177

The safety data sheets (SDS) in this packet apply to the individual products listed below. Please refer to invoice for specific item number(s).

071805316

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).

070446948 070446955 070447433 071704550 071803352 071803360 071803626 071805324 071805332 071837202

Dentsply Prime & Bond NT

Dentsply (Australia)

Chemwatch Hazard Alert Code: **3**

Chemwatch: **4993-91**
Version No: **4.1.1.1**
Material Safety Data Sheet according to NOHSC and ADG requirements

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 Prime & Bond NT
Chemical Name	Not Applicable
Synonyms	Prime & Bond NT
Proper shipping name	ACETONE
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	For dental use only.

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. DANGEROUS GOODS. According to the Criteria of NOHSC, and the ADG Code.

CHEMWATCH HAZARD RATINGS

		Min	Max
Flammability	3		
Toxicity	1		
Body Contact	2		
Reactivity	1		
Chronic	0		

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

Poisons Schedule	S5

Continued...

Risk Phrases [1]	**R36/37/38**	Irritating to eyes, respiratory system and skin.
	R67	Vapours may cause drowsiness and dizziness.
	R66	Repeated exposure may cause skin dryness and cracking.
	R11	Highly flammable.
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	F, Xi

SAFETY ADVICE

S09	Keep container in a well ventilated place.
S16	Keep away from sources of ignition. No smoking.
S23	Do not breathe gas/fumes/vapour/spray.
S24	Avoid contact with skin.
S25	Avoid contact with eyes.
S26	In case of contact with eyes, rinse with plenty of water and contact Doctor or Poisons Information Centre.
S29	Do not empty into drains.
S33	Take precautionary measures against static discharges.
S37	Wear suitable gloves.
S39	Wear eye/face protection.
S40	To clean the floor and all objects contaminated by this material, use water and detergent.
S41	In case of fire and/or explosion, DO NOT BREATHE FUMES.
S43	In case of fire use...
S46	If swallowed, seek medical advice immediately and show this container or label.
S51	Use only in well ventilated areas.
S56	Dispose of this material and its container at hazardous or special waste collection point.
S64	If swallowed, rinse mouth with water (only if the person is conscious).

Other hazards

	Inhalation, skin contact and/or ingestion may produce health damage*.
	Possible respiratory and skin sensitizer*.
	HARMFUL-May cause lung damage if swallowed.
	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
67-64-1	>60	acetone
Not Available	30	methacrylate, typically
80-62-6	NotSpec.	methyl methacrylate

SECTION 4 FIRST AID MEASURES

Description of first aid measures

Eye Contact	If this product comes in contact with the eyes: ▸ Wash out immediately with fresh running water.

Continued...

	▸ 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. ▸ Seek medical attention without delay; if pain persists or recurs seek medical attention. ▸ Removal of contact lenses after an eye injury should only be undertaken by skilled personnel.
Skin Contact	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.
Inhalation	▸ If fumes or combustion products are inhaled remove from contaminated area. ▸ Lay patient down. Keep warm and rested. ▸ Prostheses such as false teeth, which may block airway, should be removed, where possible, prior to initiating first aid procedures. ▸ Apply artificial respiration if not breathing, preferably with a demand valve resuscitator, bag-valve mask device, or pocket mask as trained. Perform CPR if necessary. ▸ Transport to hospital, or doctor, without delay.
Ingestion	▸ For advice, contact a Poisons Information Centre or a doctor at once. ▸ Urgent hospital treatment is likely to be needed. ▸ 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. ▸ Give water to rinse out mouth, then provide liquid slowly and as much as casualty can comfortably drink. ▸ Transport to hospital or doctor without delay.

Indication of any immediate medical attention and special treatment needed

For acute or short term repeated exposures to acetone:

- Symptoms of acetone exposure approximate ethanol intoxication.
- About 20% is expired by the lungs and the rest is metabolised. Alveolar air half-life is about 4 hours following two hour inhalation at levels near the Exposure Standard; in overdose, saturable metabolism and limited clearance, prolong the elimination half-life to 25-30 hours.
- There are no known antidotes and treatment should involve the usual methods of decontamination followed by supportive care.

[Ellenhorn and Barceloux: Medical Toxicology]

Management:
Measurement of serum and urine acetone concentrations may be useful to monitor the severity of ingestion or inhalation.
Inhalation Management:

- Maintain a clear airway, give humidified oxygen and ventilate if necessary.
- If respiratory irritation occurs, assess respiratory function and, if necessary, perform chest X-rays to check for chemical pneumonitis.
- Consider the use of steroids to reduce the inflammatory response.
- Treat pulmonary oedema with PEEP or CPAP ventilation.

Dermal Management:

- Remove any remaining contaminated clothing, place in double sealed, clear bags, label and store in secure area away from patients and staff.
- Irrigate with copious amounts of water.
- An emollient may be required.

Eye Management:

- Irrigate thoroughly with running water or saline for 15 minutes.
- Stain with fluorescein and refer to an ophthalmologist if there is any uptake of the stain.

Oral Management:

- No **GASTRIC LAVAGE OR EMETIC**
- Encourage oral fluids.

Systemic Management:

- Monitor blood glucose and arterial pH.
- Ventilate if respiratory depression occurs.
- If patient unconscious, monitor renal function.
- Symptomatic and supportive care.

The Chemical Incident Management Handbook:
Guy's and St. Thomas' Hospital Trust, 2000
BIOLOGICAL EXPOSURE INDEX
These represent the determinants observed in specimens collected from a healthy worker exposed at the Exposure Standard (ES or TLV):

Determinant	Sampling Time	Index	Comments
Acetone in urine	End of shift	50 mg/L	NS

NS: Non-specific determinant; also observed after exposure to other material

SECTION 5 FIREFIGHTING MEASURES

Extinguishing media

	▸ Alcohol stable foam. ▸ Dry chemical powder. ▸ BCF (where regulations permit). ▸ Carbon dioxide.

Continued...

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. ‣ May be violently or explosively reactive. ‣ Wear breathing apparatus plus protective gloves in the event of a fire. ‣ Prevent, by any means available, spillage from entering drains or water course.
Fire/Explosion Hazard	‣ Hot organic vapours or mist are capable of sudden spontaneous combustion when mixed with air even at temperatures below their published autoignition temperatures. ‣ The temperature of ignition decreases with increasing vapour volume and vapour/air contact times and is influenced by pressure change. ‣ Ignition may occur under elevated-temperature process conditions especially in processes performed under vacuum subjected to sudden ingress of air or in processes performed at elevated pressure, where sudden escape of vapours or mists to the atmosphere occurs. ‣ Liquid and vapour are highly flammable.

SECTION 6 ACCIDENTAL RELEASE MEASURES

Personal precautions, protective equipment and emergency procedures

Minor Spills	‣ Remove all ignition sources. ‣ Clean up all spills immediately. ‣ Avoid breathing vapours and contact with skin and eyes. ‣ Control personal contact with the substance, by using protective equipment.
Major Spills	‣ Clear area of personnel and move upwind. ‣ Alert Fire Brigade and tell them location and nature of hazard. ‣ May be violently or explosively reactive. ‣ Wear breathing apparatus plus protective gloves.

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

SECTION 7 HANDLING AND STORAGE

Precautions for safe handling

Safe handling	‣ Avoid all personal contact, including inhalation. ‣ Wear protective clothing when risk of exposure occurs. ‣ Use in a well-ventilated area. ‣ Prevent concentration in hollows and sumps.
Other information	‣ Store in original containers in approved flame-proof area. ‣ No smoking, naked lights, heat or ignition sources. ‣ **DO NOT** store in pits, depressions, basements or areas where vapours may be trapped. ‣ Keep containers securely sealed.

Conditions for safe storage, including any incompatibilities

Suitable container	‣ Packing as supplied by manufacturer. ‣ Plastic containers may only be used if approved for flammable liquid. ‣ Check that containers are clearly labelled and free from leaks. ‣ For low viscosity materials (i) : Drums and jerry cans must be of the non-removable head type.
Storage incompatibility	‣ Avoid reaction with oxidising agents

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	acetone	Acetone	1185 mg/m3 / 500 ppm	2375 mg/m3 / 1000 ppm	Not Available	Not Available

Continued...

Australia Exposure Standards	methyl methacrylate	Methyl methacrylate	208 mg/m3 / 50 ppm	416 mg/m3 / 100 ppm	Not Available	Not Available

EMERGENCY LIMITS

Ingredient	TEEL-0	TEEL-1	TEEL-2	TEEL-3
Dentsply Prime & Bond NT	Not Available	Not Available	Not Available	Not Available

Ingredient	Original IDLH	Revised IDLH
acetone	20,000 ppm	2,500 [LEL] ppm
methacrylate, typically	Not Available	Not Available
methyl methacrylate	4,000 ppm	1,000 ppm

Exposure controls

Appropriate 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.
Personal protection	
Eye and face protection	‣ Chemical goggles. ‣ Full face shield may be required for supplementary but never for primary protection of eyes. ‣ 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.
Skin protection	See Hand protection below
Hands/feet protection	‣ Wear chemical protective gloves, e.g. PVC. ‣ Wear safety footwear or safety gumboots, e.g. 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.
Body protection	See Other protection below
Other protection	‣ Overalls. ‣ PVC Apron. ‣ PVC protective suit may be required if exposure severe. ‣ Eyewash unit.
Thermal hazards	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 Prime & Bond NT

Material	CPI
BUTYL	A
BUTYL/NEOPRENE	A
PE/EVAL/PE	A
PVDC/PE/PVDC	A
SARANEX-23 2-PLY	B
TEFLON	B
CPE	C
HYPALON	C
NATURAL RUBBER	C
NATURAL+NEOPRENE	C

Respiratory protection

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

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 5 x ES	Air-line*	AX-2	AX-PAPR-2 ^
up to 10 x ES	-	AX-3	-
10+ x ES	-	Air-line**	-

* - Continuous Flow; ** - Continuous-flow or positive pressure demand
^ - 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

Continued...

NEOPRENE	C
NITRILE	C
NITRILE+PVC	C
PVA	C
PVC	C
SARANEX-23	C
VITON/NEOPRENE	C

* 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.

boiling point organic compounds(below 65 degC)

SECTION 9 PHYSICAL AND CHEMICAL PROPERTIES

Information on basic physical and chemical properties

Appearance	Yellow, highly flammable liquid with a characteristic odour; does not mix with water.

Physical state	Liquid	**Relative density (Water = 1)**	Not Available
Odour	Not Available	**Partition coefficient n-octanol / water**	Not Available
Odour threshold	Not Available	**Auto-ignition temperature (°C)**	465
pH (as supplied)	Not Available	**Decomposition temperature**	Not Available
Melting point / freezing point (°C)	Not Available	**Viscosity (cSt)**	Not Available
Initial boiling point and boiling range (°C)	55	**Molecular weight (g/mol)**	Not Applicable
Flash point (°C)	<0	**Taste**	Not Available
Evaporation rate	Not Available	**Explosive properties**	Not Available
Flammability	Flammable.	**Oxidising properties**	Not Available
Upper Explosive Limit (%)	13.0	**Surface Tension (dyn/cm or mN/m)**	Not Available
Lower Explosive Limit (%)	2.6	**Volatile Component (%vol)**	64.6
Vapour pressure (kPa)	233 hPa	**Gas group**	Not Available
Solubility in water (g/L)	Immiscible	**pH as a solution(1%)**	Not Available
Vapour density (Air = 1)	Not Available	**VOC g/L**	Not Available

SECTION 10 STABILITY AND REACTIVITY

Reactivity	See section 7
Chemical stability	▸ Unstable in the presence of incompatible materials. ▸ Product is considered stable. ▸ Hazardous polymerisation will not occur.
Possibility of hazardous reactions	See section 7
Conditions to avoid	See section 7
Incompatible materials	See section 7

Continued...

Hazardous decomposition products	See section 5

SECTION 11 TOXICOLOGICAL INFORMATION

Information on toxicological effects

Inhaled	Inhalation of vapours or aerosols (mists, fumes), generated by the material during the course of normal handling, may be damaging to the health of the individual. Evidence shows, or practical experience predicts, that the material produces irritation of the respiratory system, in a substantial 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.
Ingestion	Accidental ingestion of the material may be damaging to the health of the individual.
Skin Contact	Skin contact with the material may damage the health of the individual; systemic effects may result following absorption. 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.
Eye	Evidence exists, or practical experience predicts, that the material may cause severe eye irritation in a substantial number of individuals and/or may produce significant ocular lesions which are present twenty-four hours or more after instillation into the eye(s) of experimental animals. Eye contact may cause significant inflammation with pain. Corneal injury may occur; permanent impairment of vision may result unless treatment is prompt and adequate. Repeated or prolonged exposure to irritants may cause inflammation characterised by a temporary redness (similar to windburn) of the conjunctiva (conjunctivitis); temporary impairment of vision and/or other transient eye damage/ulceration may occur.
Chronic	Limited evidence suggests that repeated or long-term occupational exposure may produce cumulative health effects involving organs or biochemical systems. 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.

Dentsply Prime & Bond NT	**TOXICITY**	**IRRITATION**
	Not Available	Not Available
acetone	**TOXICITY**	**IRRITATION**
	Dermal (rabbit) LD50: 20000 mg/kg	Eye (human): 500 ppm - irritant
	Inhalation (rat) LC50: 50100 mg/m3/8 hr	Eye (rabbit): 20mg/24hr -moderate
	Oral (rat) LD50: 5800 mg/kg	Eye (rabbit): 3.95 mg - SEVERE
		Skin (rabbit): 500 mg/24hr - mild
		Skin (rabbit):395mg (open) - mild
	Not Available	Not Available
methyl methacrylate	**TOXICITY**	**IRRITATION**
	Dermal (rabbit) LD50: >5000 mg/kg	Eye (rabbit): 150 mg
	Dermal (rabbit) LD50: 35500 mg/kg *	Skin (rabbit): 10000 mg/kg (open)
	Inhalation (rat) LC50: 3750 ppm *	
	Oral (rat) LD50: 7872 mg/kg	
	Not Available	Not Available

Not available. Refer to individual constituents.

Continued...

ACETONE	The material may cause skin irritation after prolonged or repeated exposure and may produce a contact dermatitis (nonallergic). This form of dermatitis is often characterised by skin redness (erythema) and swelling epidermis. Histologically there may be intercellular oedema of the spongy layer (spongiosis) and intracellular oedema of the epidermis. for acetone: The acute toxicity of acetone is low.
METHYL METHACRYLATE	The following information refers to contact allergens as a group and may not be specific to this product. Contact allergies quickly manifest themselves as contact eczema, more rarely as urticaria or Quincke's oedema. The pathogenesis of contact eczema involves a cell-mediated (T lymphocytes) immune reaction of the delayed type. Other allergic skin reactions, e.g. contact urticaria, involve antibody-mediated immune reactions. Inhalation (human) TCLo: 60 mg/m3(15 ppm) [* Manuf. Rohm Haas]

Acute Toxicity	⊘	**Carcinogenicity**	⊘
Skin Irritation/Corrosion	✔	**Reproductivity**	⊘
Serious Eye Damage/Irritation	✔	**STOT - Single Exposure**	✔
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
acetone	LOW (Half-life = 14 days)	MEDIUM (Half-life = 116.25 days)
methyl methacrylate	HIGH	HIGH

Bioaccumulative potential

Ingredient	Bioaccumulation
acetone	LOW (BCF = 3.162)
methyl methacrylate	LOW (BCF = 2.305)

Mobility in soil

Ingredient	Mobility
acetone	HIGH (KOC = 1.981)
methyl methacrylate	LOW (KOC = 10.14)

SECTION 13 DISPOSAL CONSIDERATIONS

Waste treatment methods

Product / Packaging disposal	▸ Consult manufacturer for recycling options and recycle where possible . ▸ Consult State Land Waste Management Authority for disposal. ▸ Incinerate residue at an approved site. ▸ Recycle containers if possible, or dispose of in an authorised landfill.

SECTION 14 TRANSPORT INFORMATION

Labels Required

Continued...

	
Marine Pollutant	NO
HAZCHEM	•2YE

Land transport (ADG)

UN number	1090
Packing group	II
UN proper shipping name	ACETONE
Environmental hazard	No relevant data
Transport hazard class(es)	Class: 3 Subrisk: Not Applicable
Special precautions for user	Special provisions: Not Applicable Limited quantity: 1 L

Air transport (ICAO-IATA / DGR)

UN number	1090
Packing group	II
UN proper shipping name	Acetone
Environmental hazard	No relevant data
Transport hazard class(es)	ICAO/IATA Class: 3 ICAO / IATA Subrisk: Not Applicable ERG Code: 3H
Special precautions for user	Special provisions: Not Applicable Cargo Only Packing Instructions: 364 Cargo Only Maximum Qty / Pack: 60 L Passenger and Cargo Packing Instructions: 353 Passenger and Cargo Maximum Qty / Pack: 5 L Passenger and Cargo Limited Quantity Packing Instructions: Y341 Passenger and Cargo Limited Maximum Qty / Pack: 1 L

Sea transport (IMDG-Code / GGVSee)

UN number	1090
Packing group	II
UN proper shipping name	ACETONE
Environmental hazard	No relevant data
Transport hazard class(es)	IMDG Class: 3 IMDG Subrisk: Not Applicable
Special precautions for user	EMS Number: F-E , S-D Special provisions: Not Applicable Limited Quantities: 1 L

Transport in bulk according to Annex II of MARPOL 73 / 78 and the IBC code

Source	Ingredient	Pollution Category
IMO MARPOL 73/78 (Annex II) - List of Noxious Liquid	methyl methacrylate	Y

Continued...

Substances Carried in Bulk		

SECTION 15 REGULATORY INFORMATION

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

acetone(67-64-1) is found on the following regulatory lists	"Australia Exposure Standards","Australia Inventory of Chemical Substances (AICS)","Australia Hazardous Substances Information System - Consolidated Lists"
methyl methacrylate(80-62-6) 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)","International Air Transport Association (IATA) Dangerous Goods Regulations - Prohibited List Passenger and Cargo Aircraft","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

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.

end of SDS

Safety data sheet
according to 1907/2006/EC, Article 31

Printing date 17.06.2015 *Version number 5* *Revision: 17.06.2015*

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

· **1.1 Product identifier**

· **Trade name: Prime & Bond NT**
· **1.2 Relevant identified uses of the substance or mixture and uses advised against**
· **Application of the substance / the mixture** Adhesive
· **Uses advised against** No further relevant information available.

· **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)

SECTION 2: Hazards identification

· **2.1 Classification of the substance or mixture**
· **Classification according to Regulation (EC) No 1272/2008**

Flam. Liq. 2	H225	Highly flammable liquid and vapour.
Skin Irrit. 2	H315	Causes skin irritation.
Eye Irrit. 2	H319	Causes serious eye irritation.
STOT SE 3	H336	May cause drowsiness or dizziness.
Aquatic Chronic 3	H412	Harmful to aquatic life with long lasting effects.

· **2.2 Label elements**
· **Labelling according to Regulation (EC) No 1272/2008**
As this product is a medical device in the meaning of Directive 93/42/EEC and intended for use by the end consumer and is applied in an invasive manner or body contact, it is exempt from the labelling requirements according to regulation 1272/2008.
The product is classified and labelled according to the CLP regulation.
· **Hazard pictograms**

GHS02 GHS07

· **Signal word** Danger

· **Hazard-determining components of labelling:**
acetone
· **Hazard statements**
H225 Highly flammable liquid and vapour.
H315 Causes skin irritation.
H319 Causes serious eye irritation.
H336 May cause drowsiness or dizziness.
H412 Harmful to aquatic life with long lasting effects.
· **Precautionary statements**

P210	Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking.
P241	Use explosion-proof electrical/ventilating/lighting/equipment.

(Contd. on page 2)

Safety data sheet
according to 1907/2006/EC, Article 31

Printing date 17.06.2015 *Version number 5* *Revision: 17.06.2015*

Trade name: Prime & Bond NT

(Contd. of page 1)

P303+P361+P353 IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water/shower.
P305+P351+P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
P405 Store locked up.
P501 Dispose of contents/container in accordance with local/regional/national/international regulations.

· ***2.3 Other hazards***
· ***Results of PBT and vPvB assessment***
· ***PBT:*** *Not applicable.*
· ***vPvB:*** *Not applicable.*

SECTION 3: Composition/information on ingredients

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

· ***Dangerous components:***

CAS: 67-64-1 *EINECS: 200-662-2*	*acetone* *Flam. Liq. 2, H225; Eye Irrit. 2, H319; STOT SE 3, H336*	*50-100%*
CAS: 105883-40-7	*Urethane Dimethacrylate Resin* *Skin Irrit. 2, H315; Eye Irrit. 2, H319*	*10-<25%*
CAS: 87699-25-0	*Dipentaerythritol pentaacrylate phosphate* *Aquatic Chronic 2, H411; Skin Irrit. 2, H315; Eye Irrit. 2, H319; STOT SE 3, H335*	*3-<10%*
CAS: 2358-84-1	*Di(ethylene glycol) dimethacrylate* *Skin Irrit. 2, H315; Eye Irrit. 2, H319; STOT SE 3, H335*	*3-<10%*
CAS: 3290-92-4	*Trimethylolpropane Trimethacrylate (TMPTMA)* *Aquatic Chronic 2, H411*	*1-≤2.5%*
CAS: 128-37-0 *EINECS: 204-881-4*	*2,6-di-tert-butyl-p-cresol* *Aquatic Acute 1, H400; Aquatic Chronic 1, H410*	*0.3-<1%*

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

SECTION 4: First aid measures

· ***4.1 Description of first aid measures***
· ***General information*** *No special measures required.*
· ***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.*
· ***Information for doctor*** *No further relevant information available.*
· ***4.3 Indication of any immediate medical attention and special treatment needed***
No further relevant information available.

SECTION 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.*

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· ***5.3 Advice for firefighters***
· ***Protective equipment:*** *Self-contained respiratory protective device.*

SECTION 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.
Dilute with plenty of water.
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.
· ***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.

SECTION 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 in a cool location.
Store only in the original receptacle.
· ***Information about storage in one common storage facility:*** *Store away from oxidising agents.*
· ***Further information about storage conditions:*** *Store in cool, dry conditions in well sealed receptacles.*
· ***7.3 Specific end use(s)*** *No further relevant information available.*

SECTION 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)*

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

· ***8.2 Exposure controls***
· ***Personal protective equipment***
· ***General protective and hygienic measures***
Keep away from foodstuffs, beverages and feed.
Immediately remove all soiled and contaminated clothing
Wash hands before breaks and at the end of work.
Avoid contact with the eyes and skin.
· ***Respiratory protection:***
In case of brief exposure or low pollution use respiratory filter device. In case of intensive or longer exposure use self-contained respiratory protective device.
Not necessary if room is well-ventilated.
· ***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: ≥ 0.75 mm
Permeation: Level ≥2
· ***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.*

*
SECTION 9: Physical and chemical properties

· ***9.1 Information on basic physical and chemical properties***	
· ***General Information***	
· ***Appearance:***	
Form:	*Fluid*
Colour:	*Yellow*
· ***Odour:***	*Characteristic*
· ***Odour threshold:***	*Not determined.*
· ***pH-value:***	*Not determined.*
· ***Change in condition***	
Melting point/Melting range:	*undetermined*
Boiling point/Boiling range:	*60 °C*
· ***Flash point:***	*-19 °C (c.c. Abel)*
· ***Flammability (solid, gaseous)***	*Not applicable.*

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· **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/ vapour mixtures are possible.
· **Explosion limits:**	
Lower:	2.6 Vol %
Upper:	12.8 Vol %
· **Vapour pressure at 20 °C:**	233 hPa
· **Density at 20 °C:**	0.9 g/cm³
· **Relative density**	Not determined.
· **Vapour density**	Not determined.
· **Evaporation rate**	Not determined.
· **Solubility in / Miscibility with**	
Water:	Partly miscible
· **Partition coefficient (n-octanol/water):**	Not determined.
· **Viscosity:**	
dynamic:	Not determined.
kinematic:	Not determined.
· **Solvent content:**	
Organic solvents:	67.0 %
Solids content:	3.0 %
· **9.2 Other information**	No further relevant information available.

SECTION 10: Stability and reactivity

· **10.1 Reactivity** No further relevant information available.
· **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

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SECTION 11: Toxicological information

· **11.1 Information on toxicological effects**
· **Acute toxicity:**

· **LD/LC50 values relevant for classification:**		
ATE (Acute Toxicity Estimates)		
Inhalative	LC50/4 h	113 mg/l

67-64-1 acetone		
Oral	LD50	5800 mg/kg (rat)
Dermal	LD50	20000 mg/kg (rabbit)
Inhalative	LC50/4 h	76 mg/l (rat)
3290-92-4 Trimethylolpropane Trimethacrylate (TMPTMA)		
Oral	LD50	>2000 mg/kg (rat)

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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.
· **Sensitisation:**
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

SECTION 12: Ecological information

· **12.1 Toxicity**

· **Aquatic toxicity:**	
67-64-1 acetone	
EC50/48h	6100 mg/L (daphnia magna)
LC50/96h	5540 mg/l (Fish acute toxicity study)
3290-92-4 Trimethylolpropane Trimethacrylate (TMPTMA)	
EC50/48h	>9.22 mg/L (daphnia magna)
LC50/96h	2 mg/l (Fish acute toxicity study)
128-37-0 2,6-di-tert-butyl-p-cresol	
EC50/72h	>0.42 mg/l (Algea, gowth inhibition test)
LC50/48h	>0.57 mg/l (daphnia magna)
LC50/96h	>0.42 mg/l (Fish acute toxicity study)

· **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.
Danger to drinking water if even small quantities leak into the ground.
Harmful to aquatic organisms
· **12.5 Results of PBT and vPvB assessment**
· **PBT:** Not applicable.
· **vPvB:** Not applicable.
· **12.6 Other adverse effects** No further relevant information available.

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SECTION 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.*

SECTION 14: Transport information

· **14.1 UN-Number**
· **ADR, IMDG, IATA** *UN1090*

· **14.2 UN proper shipping name**
· **ADR** *1090 ACETONE mixture*
· **IMDG, IATA** *ACETONE mixture*

· **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.*
· **Danger code (Kemler):** *33*
· **EMS Number:** *F-E,S-D*

· **14.7 Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code** *Not applicable.*

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· ***Transport/Additional information:***

· ***ADR***	
· ***Limited quantities (LQ)***	*1L*
· ***Excepted quantities (EQ)***	*Code: E2* *Maximum net quantity per inner packaging: 30 ml* *Maximum net quantity per outer packaging: 500 ml*
· ***Transport category***	*2*
· ***Tunnel restriction code***	*D/E*
· ***IMDG***	
· ***Limited quantities (LQ)***	*1L*
· ***Excepted quantities (EQ)***	*Code: E2* *Maximum net quantity per inner packaging: 30 ml* *Maximum net quantity per outer packaging: 500 ml*
· ***UN "Model Regulation":***	*UN1090, ACETONE mixture, 3, II*

SECTION 15: Regulatory information

· ***15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture***
No further relevant information available.
· ***15.2 Chemical safety assessment:*** *A Chemical Safety Assessment has not been carried out.*

SECTION 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.

· ***Department issuing MSDS:*** *Analytical Research*
· ***Contact:*** *HotLine for urgent technical support: +49-7531-583-350*
· ***Abbreviations and acronyms:***
ADR: Accord européen sur le transport des marchandises dangereuses par Route (European Agreement concerning the International Carriage of Dangerous Goods by Road)
IMDG: International Maritime Code for Dangerous Goods
IATA: International Air Transport Association
GHS: Globally Harmonised System of Classification and Labelling of Chemicals
EINECS: European Inventory of Existing Commercial Chemical Substances
ELINCS: European List of Notified Chemical Substances
CAS: Chemical Abstracts Service (division of the American Chemical Society)
DNEL: Derived No-Effect Level (REACH)
LC50: Lethal concentration, 50 percent
LD50: Lethal dose, 50 percent
Flam. Liq. 2: Flammable liquids, Hazard Category 2
Skin Irrit. 2: Skin corrosion/irritation, Hazard Category 2
Eye Irrit. 2: Serious eye damage/eye irritation, Hazard Category 2

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STOT SE 3: Specific target organ toxicity - Single exposure, Hazard Category 3
Aquatic Acute 1: Hazardous to the aquatic environment - AcuteHazard, Category 1
Aquatic Chronic 1: Hazardous to the aquatic environment - Chronic Hazard, Category 1
Aquatic Chronic 2: Hazardous to the aquatic environment - Chronic Hazard, Category 2
Aquatic Chronic 3: Hazardous to the aquatic environment - Chronic Hazard, Category 3

· **** Data compared to the previous version altered.***