

Dentsply Gutta Core

Dentsply (Australia) Pty Ltd

Chemwatch Hazard Alert Code: 1

Chemwatch: 35-4235

Version No: 3.1.1.1

Safety Data Sheet according to WHS and ADG requirements

Issue Date: 23/04/2013

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S.GHS.AUS.EN

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

Product Identifier

Product name	Dentsply Gutta Core
Synonyms	Gutta Core
Other means of identification	Not Available

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

Relevant identified uses	Obturing root canals.
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Details of the supplier of the safety data sheet

Registered company name	Dentsply (Australia) Pty Ltd
Address	11-21 Gilby Road Mount Waverley VIC 3149 Australia
Telephone	1300 55 29 29
Fax	+61 3 9538 8260
Website	www.dentsply.com.au
Email	clientservices@dentsply.com

Emergency telephone number

Association / Organisation	Poisons Information Centre (AUSTRALIA)
Emergency telephone numbers	13 11 26 - AUSTRALIA (24 hour service)
Other emergency telephone numbers	Not Available

SECTION 2 HAZARDS IDENTIFICATION

Classification of the substance or mixture

NON-HAZARDOUS CHEMICAL. NON-DANGEROUS GOODS. According to the WHS Regulations and the ADG Code.

CHEMWATCH HAZARD RATINGS

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

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

Poisons Schedule	Not Applicable
Classification	Not Applicable

Label elements

GHS label elements	Not Applicable
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SIGNAL WORD	NOT APPLICABLE
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Hazard statement(s)

Not Applicable

Precautionary statement(s) Prevention

Not Applicable

Precautionary statement(s) Response

Not Applicable

Precautionary statement(s) Storage

Not Applicable

Precautionary statement(s) Disposal

Continued...

Not Applicable

SECTION 3 COMPOSITION / INFORMATION ON INGREDIENTS**Substances**

See section below for composition of Mixtures

Mixtures

CAS No	%[weight]	Name
1314-13-2	>50	<u>zinc oxide</u>
7440-33-7	>30	<u>tungsten</u>
9003-31-0	<30	<u>isoprene homopolymer</u>
13463-67-7	<20	<u>titanium dioxide</u>
26125-61-1	<10	<u>poly(terephthaloylchloride-p-phenylene diamine)</u>
78-63-7	<10	<u>2,5-dimethyl-2,5-di-(tert-butylperoxy)hexane</u>
7631-86-9	<10	<u>silica amorphous</u>
471-34-1	<5	<u>calcium carbonate</u>
3290-92-4	<5	<u>trimethylolpropane trimethacrylate</u>
64741-88-4	<1	<u>paraffinic distillate, heavy, solvent-refined (mild)</u>
557-05-1	<1	<u>zinc stearate</u>
124-30-1	<1	<u>octadecylamine</u>
57-11-4	<1	<u>stearic acid</u>

SECTION 4 FIRST AID MEASURES**Description of first aid measures**

Eye Contact	<p>If this product comes in contact with eyes:</p> <ul style="list-style-type: none"> ▶ Wash out immediately with water. ▶ If irritation continues, seek medical attention. ▶ Removal of contact lenses after an eye injury should only be undertaken by skilled personnel.
Skin Contact	<p>If skin contact occurs:</p> <ul style="list-style-type: none"> ▶ 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	<ul style="list-style-type: none"> ▶ If fumes, aerosols or combustion products are inhaled remove from contaminated area. ▶ Other measures are usually unnecessary.
Ingestion	<ul style="list-style-type: none"> ▶ Immediately give a glass of water. ▶ First aid is not generally required. If in doubt, contact a Poisons Information Centre or a doctor.

Indication of any immediate medical attention and special treatment needed

Treat symptomatically.

SECTION 5 FIREFIGHTING MEASURES**Extinguishing media**

- ▶ Water spray or fog.
- ▶ Alcohol stable foam.
- ▶ Dry chemical powder.
- ▶ Carbon dioxide.

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
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Advice for firefighters

Fire Fighting	<ul style="list-style-type: none"> ▶ Alert Fire Brigade and tell them location and nature of hazard. ▶ Wear full body protective clothing with breathing apparatus. ▶ Prevent, by any means available, spillage from entering drains or water course. ▶ Consider evacuation (or protect in place).
Fire/Explosion Hazard	<ul style="list-style-type: none"> ▶ The material is not readily combustible under normal conditions. ▶ However, it will break down under fire conditions and the organic component may burn. ▶ Not considered to be a significant fire risk. ▶ Heat may cause expansion or decomposition with violent rupture of containers. <p>Combustion products include:</p> <ul style="list-style-type: none"> , carbon monoxide (CO) , carbon dioxide (CO2) , ammonia , hydrogen cyanide

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	, nitrogen oxides (NOx) , metal oxides , other pyrolysis products typical of burning organic material. May emit corrosive fumes.
HAZCHEM	Not Applicable

SECTION 6 ACCIDENTAL RELEASE MEASURES

Personal precautions, protective equipment and emergency procedures

See section 8

Environmental precautions

See section 12

Methods and material for containment and cleaning up

Minor Spills	Clean up all spills immediately. Avoid contact with skin and eyes. Place in suitable containers for disposal.
Major Spills	<ul style="list-style-type: none"> ▶ Clean up all spills immediately. ▶ Secure load if safe to do so. ▶ Bundle/collect recoverable product. ▶ Collect remaining material in containers with covers for disposal.

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

SECTION 7 HANDLING AND STORAGE

Precautions for safe handling

Safe handling	<ul style="list-style-type: none"> ▶ Limit all unnecessary personal contact. ▶ Wear protective clothing when risk of exposure occurs. ▶ Use in a well-ventilated area. ▶ When handling DO NOT eat, drink or smoke.
Other information	<ul style="list-style-type: none"> ▶ Store in original containers. ▶ Keep containers securely sealed. ▶ Store in a cool, dry, well-ventilated area. ▶ Store away from incompatible materials and foodstuff containers.

Conditions for safe storage, including any incompatibilities

Suitable container	▶ Packaging as recommended by manufacturer.
Storage incompatibility	None known

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	zinc oxide	Zinc oxide (dust) / Zinc oxide (fume)	10 mg/m ³ / 5 mg/m ³	10 mg/m ³	Not Available	Not Available
Australia Exposure Standards	titanium dioxide	Titanium dioxide	10 mg/m ³	Not Available	Not Available	Not Available
Australia Exposure Standards	silica amorphous	Silica - Amorphous: Precipitated silica / Silica - Amorphous: Silica gel / Precipitated silica / Silica gel	10 mg/m ³	Not Available	Not Available	Not Available
Australia Exposure Standards	silica amorphous	Silica - Amorphous: Diatomaceous earth (uncalcined) / Diatomaceous earth (uncalcined)	10 mg/m ³	Not Available	Not Available	Not Available
Australia Exposure Standards	silica amorphous	Silica - Amorphous: Fume (thermally generated)(respirable dust)	2 mg/m ³	Not Available	Not Available	Not Available
Australia Exposure Standards	silica amorphous	Silica - Amorphous: Fumed silica (respirable dust) / Fumed silica (respirable dust)	2 mg/m ³	Not Available	Not Available	Not Available
Australia Exposure Standards	calcium carbonate	Calcium carbonate	10 mg/m ³	Not Available	Not Available	Not Available
Australia Exposure Standards	zinc stearate	Stearates	10 mg/m ³	Not Available	Not Available	Not Available
Australia Exposure Standards	stearic acid	Stearates	10 mg/m ³	Not Available	Not Available	Not Available


EMERGENCY LIMITS

Ingredient	Material name	TEEL-1	TEEL-2	TEEL-3
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zinc oxide	Zinc oxide	10 mg/m3	15 mg/m3	2,500 mg/m3
tungsten	Tungsten	10 mg/m3	330 mg/m3	2,000 mg/m3
titanium dioxide	Titanium oxide; (Titanium dioxide)	30 mg/m3	330 mg/m3	2,000 mg/m3
silica amorphous	Silica gel, amorphous synthetic	18 mg/m3	200 mg/m3	1,200 mg/m3
silica amorphous	Silica, amorphous fumed	18 mg/m3	100 mg/m3	630 mg/m3
silica amorphous	Siloxanes and silicones, dimethyl, reaction products with silica; (Hydrophobic silicon dioxide, amorphous)	120 mg/m3	1,300 mg/m3	7,900 mg/m3
silica amorphous	Silica, amorphous fume	45 mg/m3	500 mg/m3	3,000 mg/m3
silica amorphous	Silica amorphous hydrated	18 mg/m3	220 mg/m3	1,300 mg/m3
calcium carbonate	Limestone; (Calcium carbonate; Dolomite)	45 mg/m3	500 mg/m3	3,000 mg/m3
calcium carbonate	Carbonic acid, calcium salt	45 mg/m3	210 mg/m3	1,300 mg/m3
zinc stearate	Zinc stearate	30 mg/m3	330 mg/m3	2,000 mg/m3
stearic acid	Octadecanoic acid, n-; (Stearic acid)	14 mg/m3	150 mg/m3	910 mg/m3

Ingredient	Original IDLH	Revised IDLH
zinc oxide	2,500 mg/m3	500 mg/m3
tungsten	Not Available	Not Available
isoprene homopolymer	Not Available	Not Available
titanium dioxide	N.E. mg/m3 / N.E. ppm	5,000 mg/m3
poly(terephthaloylchloride-p-phenylene diamine)	Not Available	Not Available
2,5-dimethyl-2,5-di-(tert-butylperoxy)hexane	Not Available	Not Available
silica amorphous	N.E. mg/m3 / N.E. ppm	3,000 mg/m3
calcium carbonate	Not Available	Not Available
trimethylolpropane trimethacrylate	Not Available	Not Available
paraffinic distillate, heavy, solvent-refined (mild)	Not Available	Not Available
zinc stearate	Not Available	Not Available
octadecylamine	Not Available	Not Available
stearic acid	Not Available	Not Available

Exposure controls

Appropriate engineering controls	<p>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.</p> <p>The basic types of engineering controls are:</p> <p>Process controls which involve changing the way a job activity or process is done to reduce the risk.</p> <p>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.</p>
Personal protection	
Eye and face protection	<p>No special equipment for minor exposure i.e. when handling small quantities.</p> <p>OTHERWISE:</p> <ul style="list-style-type: none"> ▶ Safety glasses with side shields. ▶ 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	<p>No special equipment needed when handling small quantities.</p> <p>OTHERWISE: Wear general protective gloves, e.g. light weight rubber gloves.</p>
Body protection	See Other protection below
Other protection	<p>No special equipment needed when handling small quantities.</p> <p>OTHERWISE:</p> <ul style="list-style-type: none"> ▶ Overalls. ▶ Barrier cream. ▶ Eyewash unit.
Thermal hazards	Not Available

Respiratory protection

Type A-P 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 10 x ES	A-AUS P2	-	A-PAPR-AUS / Class 1 P2

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up to 50 x ES	-	A-AUS / Class 1 P2	-
up to 100 x ES	-	A-2 P2	A-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)

None under normal operating conditions.

SECTION 9 PHYSICAL AND CHEMICAL PROPERTIES

Information on basic physical and chemical properties

Appearance	Pink coating on gray carrier solid.		
Physical state	Manufactured	Relative density (Water = 1)	2
Odour	Not Available	Partition coefficient n-octanol / water	Not Available
Odour threshold	Not Available	Auto-ignition temperature (°C)	Not Available
pH (as supplied)	Not Available	Decomposition temperature	300
Melting point / freezing point (°C)	50	Viscosity (cSt)	Not Available
Initial boiling point and boiling range (°C)	Not Available	Molecular weight (g/mol)	Not Applicable
Flash point (°C)	Not Available	Taste	Not Available
Evaporation rate	Not Available	Explosive properties	Not Available
Flammability	Not Available	Oxidising properties	Not Available
Upper Explosive Limit (%)	Not Available	Surface Tension (dyn/cm or mN/m)	Not Applicable
Lower Explosive Limit (%)	Not Available	Volatile Component (%vol)	Not Available
Vapour pressure (kPa)	Not Available	Gas group	Not Available
Solubility in water (g/L)	Not Available	pH as a solution (1%)	Not Available
Vapour density (Air = 1)	Not Available	VOC g/L	7.11

SECTION 10 STABILITY AND REACTIVITY

Reactivity	See section 7
Chemical stability	Product is considered stable and hazardous polymerisation will not occur.
Possibility of hazardous reactions	See section 7
Conditions to avoid	See section 7
Incompatible materials	See section 7
Hazardous decomposition products	See section 5

SECTION 11 TOXICOLOGICAL INFORMATION

Information on toxicological effects

Inhaled	Not normally a hazard due to physical form of product.
Ingestion	if swallowed , mildly discomforting
Skin Contact	Not normally a hazard due to physical form of product.
Eye	Not normally a hazard due to physical form of product.
Chronic	Long-term exposure to the product is not thought to produce chronic effects adverse to the health (as classified by EC Directives using animal models); nevertheless exposure by all routes should be minimised as a matter of course.

Dentsply Gutta Core	TOXICITY	IRRITATION
	Not Available	Not Available
zinc oxide	TOXICITY	IRRITATION
	Oral (rat) LD50: >5000 mg/kg ^[1]	Eye (rabbit) : 500 mg/24 h - mild
		Skin (rabbit) : 500 mg/24 h- mild
tungsten	TOXICITY	IRRITATION
	dermal (rat) LD50: >2000 mg/kg ^[1]	Eyes (rabbit) 500mg/24h-mild

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	Oral (rat) LD50: >2000 mg/kg ^[1]	Skin (rabbit) 500mg/24h-mild
isoprene homopolymer	TOXICITY	IRRITATION
	Not Available	Not Available
titanium dioxide	TOXICITY	IRRITATION
	Inhalation (rat) LC50: >2.28 mg/l/4hr ^[1]	Skin (human): 0.3 mg /3D (int)-mild *
	Inhalation (rat) LC50: >3.56 mg/l/4hr ^[1]	
	Inhalation (rat) LC50: >6.82 mg/l/4hr ^[1]	
	Inhalation (rat) LC50: 3.43 mg/l/4hr ^[1]	
	Inhalation (rat) LC50: 5.09 mg/l/4hr ^[1]	
	Oral (rat) LD50: >2000 mg/kg ^[1]	
poly(terephthaloylchloride-p-phenylene diamine)	TOXICITY	IRRITATION
	Oral (rat) LD50: >7500 mg/kg ^[2]	Skin (-) (-) Non-irritant *
2,5-dimethyl-2,5-di-(tert-butylperoxy)hexane	TOXICITY	IRRITATION
	Dermal (rabbit) LD50: 4100 mg/kg ^[2]	Not Available
	Oral (rat) LD50: >3200 mg/kg ^[2]	
silica amorphous	TOXICITY	IRRITATION
	Dermal (rabbit) LD50: >2000 mg/kg ^[1]	Eye (rabbit): non-irritating *
	Inhalation (rat) LC50: >0.139 mg/l/14hr ^[2]	Skin (rabbit): non-irritating *
	Oral (rat) LD50: 3160 mg/kg ^[2]	
calcium carbonate	TOXICITY	IRRITATION
	dermal (rat) LD50: >2000 mg/kg ^[1]	Eye (rabbit): 0.75 mg/24h - SEVERE
	Oral (rat) LD50: >2000 mg/kg ^[1]	Skin (rabbit): 500 mg/24h-moderate
trimethylolpropane trimethacrylate	TOXICITY	IRRITATION
	dermal (rat) LD50: >2000 mg/kg ^[1]	Skin (rabbit): 500 mg - mild
	Oral (rat) LD50: >2000 mg/kg ^[1]	
paraffinic distillate, heavy, solvent-refined (mild)	TOXICITY	IRRITATION
	Dermal (rabbit) LD50: >2000 mg/kg ^[1]	Not Available
	Inhalation (rat) LC50: >3.9 mg/l/4hr ^[1]	
	Inhalation (rat) LC50: >4.7 mg/l/4hr ^[1]	
	Inhalation (rat) LC50: >5 mg/l/4hr ^[1]	
	Inhalation (rat) LC50: >5.2 mg/l/4hr ^[1]	
	Inhalation (rat) LC50: >5.3 mg/l/4hr ^[1]	
	Inhalation (rat) LC50: 10.5 mg/l/4hr ^[1]	
	Inhalation (rat) LC50: 5.7 mg/l/4hr ^[1]	
	Inhalation (rat) LC50: 9.6 mg/l/4hr ^[1]	
Oral (rat) LD50: >2000 mg/kg ^[1]		
zinc stearate	TOXICITY	IRRITATION
	Oral (rat) LD50: >10000 mg/kg ^[2]	Not Available
octadecylamine	TOXICITY	IRRITATION
	dermal (rat) LD50: >2000 mg/kg ^[1]	Eye (rabbit): SEVERE
	Oral (rat) LD50: 1200 mg/kg ^[1]	Skin (rabbit): 20 mg/24h moderate
stearic acid	TOXICITY	IRRITATION
	Dermal (rabbit) LD50: >2000 mg/kg ^[1]	Skin (human): 75 mg/3d-l-mild
	Oral (rat) LD50: >2000 mg/kg ^[1]	Skin (rabbit):500 mg/24h-moderate

Legend:

1. Value obtained from Europe ECHA Registered Substances - Acute toxicity 2.* Value obtained from manufacturer's SDS. Unless otherwise specified data extracted from RTECS - Register of Toxic Effect of chemical Substances

TUNGSTEN	<p>The material may be irritating to the eye, with prolonged contact causing inflammation. Repeated or prolonged exposure to irritants may produce conjunctivitis.</p> <p>Tungsten can cause a reduction in body temperature, and enlargement of the adrenal glands and kidneys if injected. Death may occur if it is given directly into the abdominal cavity.</p> <p>Substance has been investigated as a reproductive effector in female rodents- Oral TDL₀ 1.16 mg/kg</p>
TITANIUM DIOXIDE	<p>The material may produce moderate eye irritation leading to inflammation. Repeated or prolonged exposure to irritants may produce conjunctivitis. Exposure to titanium dioxide is via inhalation, swallowing or skin contact. When inhaled, it may deposit in lung tissue and lymph nodes causing dysfunction of the lungs and immune system. Absorption by the stomach and intestines depends on the size of the particle. It penetrated only the outermost layer of the skin, suggesting that healthy skin may be an effective barrier.</p> <p>WARNING: This substance has been classified by the IARC as Group 2B: Possibly Carcinogenic to Humans. * IUCLID</p>
POLY(TEREPHTHALOYLCHLORIDE-P-PHENYLENE DIAMINE)	<p>No components listed as carcinogenic. [DuPont]</p>
SILICA AMORPHOUS	<p>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. 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. Reports indicate high/prolonged exposures to amorphous silicas induced lung fibrosis in experimental animals; in some experiments these effects were reversible. [PATTYS]</p>
CALCIUM CARBONATE	<p>The material may produce severe irritation to the eye causing pronounced inflammation. Repeated or prolonged exposure to irritants may produce conjunctivitis.</p> <p>No evidence of carcinogenic properties. No evidence of mutagenic or teratogenic effects.</p>
TRIMETHYLOLPROPANE TRIMETHACRYLATE	<p>UV (ultraviolet)/ EB (electron beam) acrylates are generally of low toxicity UV/EB acrylates are divided into two groups; "stenomeric" and "eurymeric" acrylates. The first group consists of well-defined acrylates which can be described by a simple idealised chemical; they are low molecular weight species with a very narrow weight distribution profile. The eurymeric acrylates cannot be described by an idealised structure and may differ fundamentally between various suppliers; they are of relatively high molecular weight and possess a wide weight distribution. Stenomeric acrylates are usually more hazardous than the eurymeric substances. Based on the available oncogenicity data and without a better understanding of the carcinogenic mechanism the Health and Environmental Review Division (HERD), Office of Toxic Substances (OTS), of the US EPA previously concluded that all chemicals that contain the acrylate or methacrylate moiety (CH₂=CHCOO or CH₂=C(CH₃)COO) should be considered to be a carcinogenic hazard unless shown otherwise by adequate testing. This position has now been revised and acrylates and methacrylates are no longer <i>de facto</i> carcinogens. Where no "official" classification for acrylates and methacrylates exists, there has been cautious attempts to create classifications in the absence of contrary evidence. For example Monoalkyl or monoarylestere of acrylic acids should be classified as R36/37/38 and R51/53 Monoalkyl or monoaryl esters of methacrylic acid should be classified as R36/37/38 (SD +/- 2591 mg/kg) ** [American Industrial Hygiene Association]</p>
PARAFFINIC DISTILLATE, HEAVY, SOLVENT-REFINED (MILD)	<p>The materials included in the Lubricating Base Oils category are related from both process and physical-chemical perspectives; The potential toxicity of a specific distillate base oil is inversely related to the severity or extent of processing the oil has undergone, since:</p> <ul style="list-style-type: none"> ▶ The adverse effects of these materials are associated with undesirable components, and ▶ The levels of the undesirable components are inversely related to the degree of processing; ▶ Distillate base oils receiving the same degree or extent of processing will have similar toxicities; ▶ The potential toxicity of <i>residual base oils</i> is independent of the degree of processing the oil receives. ▶ The reproductive and developmental toxicity of the distillate base oils is inversely related to the degree of processing. <p>Unrefined & mildly refined distillate base oils contain the highest levels of undesirable components, have the largest variation of hydrocarbon molecules and have shown the highest potential carcinogenic and mutagenic activities. Highly and severely refined distillate base oils are produced from unrefined and mildly refined oils by removing or transforming undesirable components. for Unrefined and Mildly Refined Distillate Base Oils Acute toxicity: LD50s of >5000 mg/kg (bw) and >2g/kg (bw) for the oral and dermal routes of exposure, respectively, have been observed in rats dosed with an unrefined light paraffinic distillate. The same material was also reported to be "moderately irritating" to the skin of rabbits. When tested for eye irritation in rabbits, the material produced Draize scores of 3.0 and 4.0 (unwashed/washed eyes) at 24 hours, with the scores returning to zero by 48 hours. The material was reported to be "not sensitising" when tested in guinea pigs Repeat dose toxicity: 200, 1000 and 2000 mg/kg (bw)/day of an unrefined base oil has been applied undiluted to the skin of male and female rabbit. The test material was applied to the rabbits' skins 3 times/week for 4 weeks.</p> <p>WARNING: This substance has been classified by the IARC as Group 1: CARCINOGENIC TO HUMANS.</p>
ZINC STEARATE	<p>Fatty acid salts of low acute toxicity. Their potential to irritate the skin and eyes is dependent on chain length.</p>
OCTADECYLAMINE	<p>FND ether amines and FND amines are very similar in structure (length of chain or degree of saturation), function and toxicity. Acute exposure to FND ether amines by oral, dermal and inhalation may produce moderate to slight toxicity but repeated skin contact can be highly irritating. However, exposure did not produce any organ-specific toxicity, genetic, reproductive or developmental defect same as in FND amines.</p>
STEARIC ACID	<p>Equivocal tumorigen by RTEC criteria</p>
ZINC OXIDE & TUNGSTEN & TITANIUM DIOXIDE & CALCIUM CARBONATE & TRIMETHYLOLPROPANE TRIMETHACRYLATE & OCTADECYLAMINE & STEARIC ACID	<p>The material may cause skin irritation after prolonged or repeated exposure and may produce on contact skin redness, swelling, the production of vesicles, scaling and thickening of the skin.</p>
ISOPRENE HOMOPOLYMER & PARAFFINIC DISTILLATE, HEAVY, SOLVENT-REFINED (MILD)	<p>No significant acute toxicological data identified in literature search.</p>
POLY(TEREPHTHALOYLCHLORIDE-P-PHENYLENE DIAMINE) & SILICA AMORPHOUS	<p>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.</p>
CALCIUM CARBONATE & TRIMETHYLOLPROPANE TRIMETHACRYLATE & ZINC STEARATE & OCTADECYLAMINE &	<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. Key criteria for the diagnosis of RADS include the absence of preceding respiratory disease, in a non-atopic individual, with abrupt onset of persistent</p>

STEARIC ACID	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.
TRIMETHYLOLPROPANE TRIMETHACRYLATE & OCTADECYLAMINE	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.

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 available but does not fill the criteria for classification
✔ – Data required to make classification available
☉ – Data Not Available to make classification

SECTION 12 ECOLOGICAL INFORMATION

Toxicity

Ingredient	Endpoint	Test Duration (hr)	Species	Value	Source
zinc oxide	LC50	96	Fish	0.439mg/L	2
zinc oxide	EC50	48	Crustacea	0.105mg/L	2
zinc oxide	EC50	72	Algae or other aquatic plants	0.042mg/L	4
zinc oxide	BCF	336	Fish	4376.673mg/L	4
zinc oxide	EC20	72	Algae or other aquatic plants	0.023mg/L	4
zinc oxide	NOEC	72	Algae or other aquatic plants	0.0049mg/L	2
tungsten	LC50	96	Fish	>181mg/L	2
tungsten	EC50	48	Crustacea	>163mg/L	2
tungsten	EC50	72	Algae or other aquatic plants	7.35mg/L	2
tungsten	EC50	72	Algae or other aquatic plants	>17.7mg/L	2
tungsten	NOEC	72	Algae or other aquatic plants	0.812mg/L	2
isoprene homopolymer	LC50	96	Fish	4.364mg/L	3
isoprene homopolymer	EC50	96	Algae or other aquatic plants	10.375mg/L	3
isoprene homopolymer	EC50	384	Crustacea	1.061mg/L	3
titanium dioxide	LC50	96	Fish	9.214mg/L	3
titanium dioxide	EC50	48	Crustacea	>10mg/L	2
titanium dioxide	EC50	72	Algae or other aquatic plants	5.83mg/L	4
titanium dioxide	EC20	72	Algae or other aquatic plants	1.81mg/L	4
titanium dioxide	NOEC	336	Fish	0.089mg/L	4
2,5-dimethyl-2,5-di-(tert-butylperoxy)hexane	LC50	96	Fish	1.679mg/L	3
silica amorphous	LC50	96	Fish	120.743mg/L	3
silica amorphous	EC50	48	Crustacea	ca.7600mg/L	1
silica amorphous	EC50	72	Algae or other aquatic plants	440mg/L	1
silica amorphous	EC50	384	Crustacea	28.000mg/L	3
silica amorphous	NOEC	72	Algae or other aquatic plants	60mg/L	1
calcium carbonate	LC50	96	Fish	>56000mg/L	4
calcium carbonate	EC50	72	Algae or other aquatic plants	>14mg/L	2
calcium carbonate	NOEC	72	Algae or other aquatic plants	14mg/L	2
trimethylolpropane trimethacrylate	LC50	96	Fish	0.731mg/L	3
trimethylolpropane trimethacrylate	EC50	48	Crustacea	>9.22mg/L	2
trimethylolpropane trimethacrylate	NOEC	768	Fish	0.138mg/L	2
paraffinic distillate, heavy, solvent-refined (mild)	EC50	48	Crustacea	>1000mg/L	1
paraffinic distillate, heavy, solvent-refined (mild)	EC50	96	Algae or other aquatic plants	>1000mg/L	1
paraffinic distillate, heavy, solvent-refined (mild)	EC50	96	Algae or other aquatic plants	>1000mg/L	1

Dentsply Gutta Core

paraffinic distillate, heavy, solvent-refined (mild)	NOEC	504	Crustacea	>1mg/L	1
zinc stearate	LC50	96	Fish	0.439mg/L	2
zinc stearate	EC50	48	Crustacea	0.413mg/L	2
zinc stearate	EC50	24	Crustacea	0.5mg/L	2
zinc stearate	NOEC	720	Fish	0.172mg/L	2
octadecylamine	LC50	96	Fish	0.016mg/L	3
octadecylamine	EC50	48	Crustacea	<1mg/L	2
octadecylamine	EC50	96	Algae or other aquatic plants	0.034mg/L	3
octadecylamine	EC50	48	Crustacea	1.7mg/L	4
stearic acid	EC50	48	Crustacea	>4.8mg/L	2
stearic acid	EC50	72	Algae or other aquatic plants	>0.9mg/L	2
stearic acid	EC50	504	Crustacea	>0.22mg/L	2
stearic acid	NOEC	504	Crustacea	>0.22mg/L	2

Legend:

Extracted from 1. IUCLID Toxicity Data 2. Europe ECHA Registered Substances - Ecotoxicological Information - Aquatic Toxicity 3. EPIWIN Suite V3.12 - Aquatic Toxicity Data (Estimated) 4. US EPA, Ecotox database - Aquatic Toxicity Data 5. ECETOC Aquatic Hazard Assessment Data 6. NITE (Japan) - Bioconcentration Data 7. METI (Japan) - Bioconcentration Data 8. Vendor Data

Persistence and degradability

Ingredient	Persistence: Water/Soil	Persistence: Air
isoprene homopolymer	LOW	LOW
titanium dioxide	HIGH	HIGH
2,5-dimethyl-2,5-di-(tert-butylperoxy)hexane	HIGH	HIGH
silica amorphous	LOW	LOW
trimethylolpropane trimethacrylate	HIGH	HIGH
zinc stearate	LOW	LOW
octadecylamine	LOW	LOW
stearic acid	LOW	LOW

Bioaccumulative potential

Ingredient	Bioaccumulation
zinc oxide	LOW (BCF = 217)
isoprene homopolymer	LOW (LogKOW = 2.5803)
titanium dioxide	LOW (BCF = 10)
2,5-dimethyl-2,5-di-(tert-butylperoxy)hexane	HIGH (BCF = 5330)
silica amorphous	LOW (LogKOW = 0.5294)
trimethylolpropane trimethacrylate	MEDIUM (LogKOW = 4.39)
zinc stearate	LOW (LogKOW = 7.9444)
octadecylamine	LOW (LogKOW = 7.7102)
stearic acid	LOW (LogKOW = 8.23)

Mobility in soil

Ingredient	Mobility
isoprene homopolymer	LOW (KOC = 67.7)
titanium dioxide	LOW (KOC = 23.74)
2,5-dimethyl-2,5-di-(tert-butylperoxy)hexane	LOW (KOC = 161300)
silica amorphous	LOW (KOC = 23.74)
trimethylolpropane trimethacrylate	LOW (KOC = 7533)
zinc stearate	LOW (KOC = 11670)
octadecylamine	LOW (KOC = 319800)
stearic acid	LOW (KOC = 11670)

SECTION 13 DISPOSAL CONSIDERATIONS**Waste treatment methods**

Product / Packaging disposal

- ▶ Recycle wherever possible or consult manufacturer for recycling options.
- ▶ Consult State Land Waste Authority for disposal.
- ▶ Bury or incinerate residue at an approved site.
- ▶ Recycle containers if possible, or dispose of in an authorised landfill.

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

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

Not Applicable

SECTION 15 REGULATORY INFORMATION**Safety, health and environmental regulations / legislation specific for the substance or mixture****ZINC OXIDE(1314-13-2) IS FOUND ON THE FOLLOWING REGULATORY LISTS**

Australia Exposure Standards	Australia Inventory of Chemical Substances (AICS)
Australia Hazardous Substances Information System - Consolidated Lists	International Agency for Research on Cancer (IARC) - Agents Classified by the IARC Monographs

TUNGSTEN(7440-33-7) IS FOUND ON THE FOLLOWING REGULATORY LISTS

Australia Inventory of Chemical Substances (AICS)

ISOPRENE HOMOPOLYMER(9003-31-0) IS FOUND ON THE FOLLOWING REGULATORY LISTS

Australia Inventory of Chemical Substances (AICS)	International Air Transport Association (IATA) Dangerous Goods Regulations - Prohibited List Passenger and Cargo Aircraft
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TITANIUM DIOXIDE(13463-67-7) 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)	

POLY(TEREPHTHALOYLCHLORIDE-P-PHENYLENE DIAMINE)(26125-61-1) IS FOUND ON THE FOLLOWING REGULATORY LISTS

Not Applicable

2,5-DIMETHYL-2,5-DI-(TERT-BUTYLPEROXY)HEXANE(78-63-7) IS FOUND ON THE FOLLOWING REGULATORY LISTS

Australia Inventory of Chemical Substances (AICS)

SILICA AMORPHOUS(7631-86-9) IS FOUND ON THE FOLLOWING REGULATORY LISTS

Australia Exposure Standards	Australia Inventory of Chemical Substances (AICS)
Australia Hazardous Substances Information System - Consolidated Lists	International Agency for Research on Cancer (IARC) - Agents Classified by the IARC Monographs

CALCIUM CARBONATE(471-34-1) IS FOUND ON THE FOLLOWING REGULATORY LISTS

Australia Exposure Standards	Australia Inventory of Chemical Substances (AICS)
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TRIMETHYLOLPROPANE TRIMETHACRYLATE(3290-92-4) IS FOUND ON THE FOLLOWING REGULATORY LISTS

Australia Inventory of Chemical Substances (AICS)

PARAFFINIC DISTILLATE, HEAVY, SOLVENT-REFINED (MILD)(64741-88-4) IS FOUND ON THE FOLLOWING REGULATORY LISTS

Australia Hazardous Substances Information System - Consolidated Lists	Australia Inventory of Chemical Substances (AICS)
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ZINC STEARATE(557-05-1) IS FOUND ON THE FOLLOWING REGULATORY LISTS

Australia Exposure Standards	Australia Inventory of Chemical Substances (AICS)
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OCTADECYLAMINE(124-30-1) IS FOUND ON THE FOLLOWING REGULATORY LISTS

Australia Inventory of Chemical Substances (AICS)

STEARIC ACID(57-11-4) IS FOUND ON THE FOLLOWING REGULATORY LISTS

Australia Exposure Standards	Australia Inventory of Chemical Substances (AICS)
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National Inventory	Status
Australia - AICS	N (poly(terephthaloylchloride-p-phenylene diamine))
Canada - DSL	Y
Canada - NDSL	N (2,5-dimethyl-2,5-di-(tert-butylperoxy)hexane; trimethylolpropane trimethacrylate; paraffinic distillate, heavy, solvent-refined (mild); isoprene homopolymer; zinc stearate; octadecylamine; stearic acid; poly(terephthaloylchloride-p-phenylene diamine); tungsten)
China - IECSC	Y
Europe - EINEC / ELINCS / NLP	N (isoprene homopolymer; poly(terephthaloylchloride-p-phenylene diamine))

Japan - ENCS	N (paraffinic distillate, heavy, solvent-refined (mild); poly(terephthaloylchloride-p-phenylene diamine); tungsten)
Korea - KECI	Y
New Zealand - NZIoC	Y
Philippines - PICCS	Y
USA - TSCA	Y
Legend:	Y = All ingredients are on the inventory N = Not determined or one or more ingredients are not on the inventory and are not exempt from listing(see specific ingredients in brackets)

SECTION 16 OTHER INFORMATION

Other information

Ingredients with multiple cas numbers

Name	CAS No
zinc oxide	1314-13-2, 175449-32-8
isoprene homopolymer	9003-31-0, 104389-31-3, 104389-32-4
titanium dioxide	13463-67-7, 1317-70-0, 1317-80-2, 12188-41-9, 1309-63-3, 100292-32-8, 101239-53-6, 116788-85-3, 12000-59-8, 12701-76-7, 12767-65-6, 12789-63-8, 1344-29-2, 185323-71-1, 185828-91-5, 188357-76-8, 188357-79-1, 195740-11-5, 221548-98-7, 224963-00-2, 246178-32-5, 252962-41-7, 37230-92-5, 37230-94-7, 37230-95-8, 37230-96-9, 39320-58-6, 39360-64-0, 39379-02-7, 416845-43-7, 494848-07-6, 494848-23-6, 494851-77-3, 494851-98-8, 55068-84-3, 55068-85-4, 552316-51-5, 62338-64-1, 767341-00-4, 97929-50-5, 98084-96-9
silica amorphous	7631-86-9, 112945-52-5, 67762-90-7, 68611-44-9, 68909-20-6, 112926-00-8, 61790-53-2, 60676-86-0, 91053-39-3, 69012-64-2, 844491-94-7
calcium carbonate	471-34-1, 13397-26-7, 15634-14-7, 1317-65-3, 72608-12-9, 878759-26-3, 63660-97-9, 459411-10-0, 198352-33-9, 146358-95-4
trimethylolpropane trimethacrylate	3290-92-4, 102068-89-3, 107711-83-1, 107846-19-5, 108727-84-0, 109633-39-8, 112291-39-1, 117456-07-2, 118520-52-8, 12656-03-0, 177345-96-9, 186262-44-2, 27441-62-9, 37271-14-0, 38886-95-2, 39301-32-1, 66451-56-7, 73784-89-1, 96082-02-9
octadecylamine	124-30-1, 90640-32-7

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

A list of reference resources used to assist the committee may be found at:

www.chemwatch.net

The 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.

Definitions and abbreviations

PC – TWA: Permissible Concentration-Time Weighted Average
 PC – STEL: Permissible Concentration-Short Term Exposure Limit
 IARC: International Agency for Research on Cancer
 ACGIH: American Conference of Governmental Industrial Hygienists
 STEL: Short Term Exposure Limit
 TEEL: Temporary Emergency Exposure Limit,
 IDLH: Immediately Dangerous to Life or Health Concentrations
 OSF: Odour Safety Factor
 NOAEL :No Observed Adverse Effect Level
 LOAEL: Lowest Observed Adverse Effect Level
 TLV: Threshold Limit Value
 LOD: Limit Of Detection
 OTV: Odour Threshold Value
 BCF: BioConcentration Factors
 BEI: Biological Exposure Index

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TEL (+61 3) 9572 4700.