



Gingival Barrier

SDI Limited

Version No: 11.1

Safety Data Sheet according to the Health and Safety at Work (Hazardous Substances) Regulations 2017

Issue Date: 10/03/2023

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L.GHS.NZL.EN

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

Product Identifier

Product name	Gingival Barrier
Chemical Name	Not Applicable
Synonyms	Not Available
Chemical formula	Not Applicable
Other means of identification	Not Available

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

Relevant identified uses	For tissue isolation by dental professionals.
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Details of the manufacturer or supplier of the safety data sheet

Registered company name	SDI Limited	SDI (North America) Inc.	SDI Germany GmbH
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Registered company name	SDI HOLDINGS PTY LTD DO
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Telephone	+55 11 3092 7100
Fax	Not Available
Website	http://www.sdi.com.au/
Email	Brasil@sdi.com.au

Emergency telephone number

Association / Organisation	SDI Limited	CHEMWATCH EMERGENCY RESPONSE (24/7)
Emergency telephone numbers	131126 Poisons Information Centre	+64 800 700 112
Other emergency telephone numbers	+61 3 8727 7111	+61 3 9573 3188

Once connected and if the message is not in your preferred language then please dial 01

SECTION 2 Hazards identification

Classification of the substance or mixture

Classification [1]	Skin Corrosion/Irritation Category 2, Sensitisation (Skin) Category 1, Serious Eye Damage/Eye Irritation Category 2, Hazardous to the Aquatic Environment Long-Term Hazard Category 2
Legend:	1. Classification by vendor; 2. Classification drawn from CCID EPA NZ; 3. Classification drawn from Regulation (EU) No 1272/2008 - Annex VI
Determined by using GHS/HSNO criteria	6.3A, 6.4A, 6.5B (contact), 9.1B

Label elements

Hazard pictogram(s)	
Signal word	Warning

Gingival Barrier

Hazard statement(s)

H315	Causes skin irritation.
H317	May cause an allergic skin reaction.
H319	Causes serious eye irritation.
H411	Toxic to aquatic life with long lasting effects.

Precautionary statement(s) Prevention

P280	Wear protective gloves, protective clothing, eye protection and face protection.
P261	Avoid breathing mist/vapours/spray.
P273	Avoid release to the environment.
P264	Wash all exposed external body areas thoroughly after handling.
P272	Contaminated work clothing should not be allowed out of the workplace.

Precautionary statement(s) Response

P302+P352	IF ON SKIN: Wash with plenty of water.
P305+P351+P338	IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
P333+P313	If skin irritation or rash occurs: Get medical advice/attention.
P337+P313	If eye irritation persists: Get medical advice/attention.
P362+P364	Take off contaminated clothing and wash it before reuse.
P391	Collect spillage.

Precautionary statement(s) Storage

Not Applicable

Precautionary statement(s) Disposal

P501	Dispose of contents/container to authorised hazardous or special waste collection point in accordance with any local regulation.
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SECTION 3 Composition / information on ingredients

Substances

See section below for composition of Mixtures

Mixtures

CAS No	%[weight]	Name
109-16-0	10-15	triethylene glycol dimethacrylate
72869-86-4	65-70	diurethane dimethacrylate
Legend:	1. Classification by vendor; 2. Classification drawn from CCID EPA NZ; 3. Classification drawn from Regulation (EU) No 1272/2008 - Annex VI; 4. Classification drawn from C&L; * EU IOELVs available	

SECTION 4 First aid measures

Description of first aid measures

Eye Contact	If this product comes in contact with the eyes: <ul style="list-style-type: none"> 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. 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: <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	Seek medical attention.

Indication of any immediate medical attention and special treatment needed

Treat symptomatically.

SECTION 5 Firefighting measures

Extinguishing media

- ▶ Foam.
- ▶ Dry chemical powder.
- ▶ BCF (where regulations permit).
- ▶ Carbon dioxide.
- ▶ Water spray or fog - Large fires only.

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Gingival Barrier

Special hazards arising from the substrate or mixture

Fire Incompatibility	None known.
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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 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. DO NOT approach containers suspected to be hot. Cool fire exposed containers with water spray from a protected location. If safe to do so, remove containers from path of fire. Equipment should be thoroughly decontaminated after use.
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. Decomposes on heating and may produce toxic fumes of carbon monoxide (CO). May emit acrid smoke. <p>Other decomposition products include: carbon dioxide (CO₂) May emit corrosive fumes.</p>

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	<ul style="list-style-type: none"> Clean up all spills immediately. Avoid contact with skin and eyes. Wear impervious gloves and safety goggles. Trowel up/scrape up. Place spilled material in clean, dry, sealed container. Flush spill area with water.
Major Spills	<p>Minor hazard.</p> <ul style="list-style-type: none"> Clear area of personnel. Alert Fire Brigade and tell them location and nature of hazard. Control personal contact with the substance, by using protective equipment as required. Prevent spillage from entering drains or water ways. Contain spill with sand, earth or vermiculite. Collect recoverable product into labelled containers for recycling. Absorb remaining product with sand, earth or vermiculite and place in appropriate containers for disposal. Wash area and prevent runoff into drains or waterways. If contamination of drains or waterways occurs, advise emergency services.

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"> 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. DO NOT enter confined spaces until atmosphere has been checked. DO NOT allow material to contact humans, exposed food or food utensils. Avoid contact with incompatible materials. When handling, DO NOT eat, drink or smoke. Keep containers securely sealed when not in use. Avoid physical damage to containers. Always wash hands with soap and water after handling. Work clothes should be laundered separately. Launder contaminated clothing before re-use. Use good occupational work practice. Observe manufacturer's storage and handling recommendations contained within this SDS. Atmosphere should be regularly checked against established exposure standards to ensure safe working conditions are maintained.
Other information	<p>Store between 10 and 25 deg. C. Do not store in direct sunlight.</p>

Conditions for safe storage, including any incompatibilities

Suitable container	<ul style="list-style-type: none"> DO NOT repack. Use containers supplied by manufacturer only. Check that containers are clearly labelled and free from leaks
Storage incompatibility	<ul style="list-style-type: none"> Avoid storage with reducing agents.

SECTION 8 Exposure controls / personal protection

Gingival Barrier

Control parameters

Occupational Exposure Limits (OEL)

INGREDIENT DATA

Not Available

Emergency Limits

Ingredient	TEEL-1	TEEL-2	TEEL-3
triethylene glycol dimethacrylate	33 mg/m3	360 mg/m3	2,100 mg/m3
diurethane dimethacrylate	120 mg/m3	1,300 mg/m3	7,900 mg/m3

Ingredient	Original IDLH	Revised IDLH
triethylene glycol dimethacrylate	Not Available	Not Available
diurethane dimethacrylate	Not Available	Not Available


Occupational Exposure Banding

Ingredient	Occupational Exposure Band Rating	Occupational Exposure Band Limit
triethylene glycol dimethacrylate	E	≤ 0.1 ppm
diurethane dimethacrylate	E	≤ 0.1 ppm

Notes: Occupational exposure banding is a process of assigning chemicals into specific categories or bands based on a chemical's potency and the adverse health outcomes associated with exposure. The output of this process is an occupational exposure band (OEB), which corresponds to a range of exposure concentrations that are expected to protect worker health.

MATERIAL DATA

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. 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. Ventilation can remove or dilute an air contaminant if designed properly. The design of a ventilation system must match the particular process and chemical or contaminant in use.</p> <p>Employers may need to use multiple types of controls to prevent employee overexposure.</p> <p>General exhaust is adequate under normal operating conditions. Local exhaust ventilation may be required in specific circumstances. If risk of overexposure exists, wear approved respirator. Correct fit is essential to obtain adequate protection. Provide adequate ventilation in warehouse or closed storage areas. Air contaminants generated in the workplace possess varying "escape" velocities which, in turn, determine the "capture velocities" of fresh circulating air required to effectively remove the contaminant.</p>	
	Type of Contaminant:	Air Speed:
	solvent, vapours, degreasing etc., evaporating from tank (in still air).	0.25-0.5 m/s (50-100 f/min)
	aerosols, fumes from pouring operations, intermittent container filling, low speed conveyer transfers, welding, spray drift, plating acid fumes, pickling (released at low velocity into zone of active generation)	0.5-1 m/s (100-200 f/min.)
	direct spray, spray painting in shallow booths, drum filling, conveyer loading, crusher dusts, gas discharge (active generation into zone of rapid air motion)	1-2.5 m/s (200-500 f/min.)
Individual protection measures, such as personal protective equipment	grinding, abrasive blasting, tumbling, high speed wheel generated dusts (released at high initial velocity into zone of very high rapid air motion).	2.5-10 m/s (500-2000 f/min.)
	Within each range the appropriate value depends on:	
	Lower end of the range	Upper end of the range
	1: Room air currents minimal or favourable to capture	1: Disturbing room air currents
	2: Contaminants of low toxicity or of nuisance value only.	2: Contaminants of high toxicity
Eye and face protection	3: Intermittent, low production.	3: High production, heavy use
	4: Large hood or large air mass in motion	4: Small hood-local control only
	Simple theory shows that air velocity falls rapidly with distance away from the opening of a simple extraction pipe. Velocity generally decreases with the square of distance from the extraction point (in simple cases). Therefore the air speed at the extraction point should be adjusted, accordingly, after reference to distance from the contaminating source. The air velocity at the extraction fan, for example, should be a minimum of 1-2 m/s (200-400 f/min) for extraction of solvents generated in a tank 2 meters distant from the extraction point. Other mechanical considerations, producing performance deficits within the extraction apparatus, make it essential that theoretical air velocities are multiplied by factors of 10 or more when extraction systems are installed or used.	
		
	No special equipment for minor exposure i.e. when handling small quantities. OTHERWISE: <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. This should include a review of lens absorption and adsorption for the class of chemicals in use and an account of injury experience. Medical and first-aid personnel should be trained in their removal and suitable equipment should be readily available. In the event of chemical exposure, begin eye irrigation immediately and remove contact lens as soon as practicable. Lens should be removed at the first signs of eye redness or irritation - lens should be removed in a clean environment only after workers have washed hands thoroughly. [CDC NIOSH Current Intelligence Bulletin 59], [AS/NZS 1336 or national equivalent]	

Gingival Barrier

Skin protection	See Hand protection below
Hands/feet protection	<ul style="list-style-type: none"> ▶ Wear chemical protective gloves, e.g. PVC. ▶ Wear safety footwear or safety gumboots, e.g. Rubber ▶ Rubber Gloves
Body protection	See Other protection below
Other protection	No special equipment needed when handling small quantities. OTHERWISE: <ul style="list-style-type: none"> ▶ Overalls. ▶ Barrier cream. ▶ Eyewash unit.

Respiratory protection

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

Selection of the Class and Type of respirator will depend upon the level of breathing zone contaminant and the chemical nature of the contaminant. Protection Factors (defined as the ratio of contaminant outside and inside the mask) may also be important.

Required minimum protection factor	Maximum gas/vapour concentration present in air p.p.m. (by volume)	Half-face Respirator	Full-Face Respirator
up to 10	1000	A-AUS / Class1	-
up to 50	1000	-	A-AUS / Class 1
up to 50	5000	Airline *	-
up to 100	5000	-	A-2
up to 100	10000	-	A-3
100+			Airline**

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

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

Appearance	Blue coloured viscous/ flowable paste with ester-like odour.		
Physical state	Free-flowing Paste	Relative density (Water = 1)	Not Available
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 (°C)	Not Available
Melting point / freezing point (°C)	Not Available	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 Available
Lower Explosive Limit (%)	Not Available	Volatile Component (%vol)	Not Available
Vapour pressure (kPa)	Not Available	Gas group	Not Available
Solubility in water	Not Available	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	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	The material is not thought to produce adverse health effects or irritation of the respiratory tract (as classified by EC Directives using animal
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Gingival Barrier

	models). Nevertheless, good hygiene practice requires that exposure be kept to a minimum and that suitable control measures be used in an occupational setting.
Ingestion	The material has NOT been classified by EC Directives or other classification systems as "harmful by ingestion". This is because of the lack of corroborating animal or human evidence. The material may still be damaging to the health of the individual, following ingestion, especially where pre-existing organ (e.g liver, kidney) damage is evident. Present definitions of harmful or toxic substances are generally based on doses producing mortality rather than those producing morbidity (disease, ill-health). Gastrointestinal tract discomfort may produce nausea and vomiting. In an occupational setting however, ingestion of insignificant quantities is not thought to be cause for concern.
Skin Contact	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.
Eye	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.
Chronic	There exists limited evidence that shows that skin contact with the material is capable either of inducing a sensitisation reaction in a significant number of individuals, and/or of producing positive response in experimental animals.
Gingival Barrier	TOXICITY
	Not Available
	IRRITATION
	Not Available
triethylene glycol dimethacrylate	TOXICITY
	dermal (mouse) LD50: >2000 mg/kg ^[1]
	IRRITATION
	Eye: no adverse effect observed (not irritating) ^[1]
	Oral (Mouse) LD50; 10750 mg/kg ^[2]
	Skin: no adverse effect observed (not irritating) ^[1]
diurethane dimethacrylate	TOXICITY
	dermal (rat) LD50: >2000 mg/kg ^[1]
	IRRITATION
	Eye: no adverse effect observed (not irritating) ^[1]
	Oral (Rat) LD50: >2000 mg/kg ^[2]
	Skin: no adverse effect observed (not irritating) ^[1]
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

DIURETHANE DIMETHACRYLATE	<p>* Possible carcinogen; possible sensitizer; possible irreversible effects * Polysciences MSDS The skin sensitising potential of the test substance was investigated in a Local Lymph Node Assay (LLNA) in mice according to OECD Guideline 429 and in compliance with GLP (Vogel, 2009). The highest technically achievable test substance concentration was 50% (w/w) in dimethylformamide. To determine the highest non-irritant test concentration, a pre-test was performed in two animals. Two mice were treated with concentrations of 25 and 50% each on three consecutive days. No signs of irritation or systemic toxicity were observed at the tested concentrations. In the main study, four female CBA/CaOlaHsd mice per test group were treated with the test substance at concentrations of 10, 25 and 50% (w/w) in dimethylformamide or with vehicle alone for three consecutive days by open application on the ears (25 µL/ear). Three days after the last exposure, all animals were injected with 3H-methyl thymidine and approximately after five hours the draining (auricular) lymph nodes were excised and pooled for each test group. After precipitating the DNA of the lymph node cells, radioactivity measurements were performed. Treatment with test substance concentrations of 10, 25 and 50% (w/w) in dimethylformamide resulted in DPM values per lymph node of 1266.3, 1363.5 and 3562.1, respectively. The SI values calculated for the substance concentrations 10, 25 and 50% were 1.58, 1.70 and 4.44, respectively. The EC3 value was calculated to be 36.9%. Based on the results, the test substance was regarded as a skin sensitizer under the conditions of the test. Repeat Dose Toxicity: NOAEL = 100 mg/kg bw/day for males NOAEL = 300 mg/kg bw/day for females The lowest observed adverse effect level (LOAEL) in male animals is 300 mg/kg bw/day. According to Annex I of Regulation (EC) No 1272/2008 classification as STOT RE Category 2 is applicable, when significant toxic effects observed in a 90-day repeated-dose study conducted in experimental animals are seen to occur within the guidance value ranges of 10 < C = 100 mg/kg bw/day. These guidance values can be used as a basis to extrapolate equivalent guidance values for toxicity studies of greater or lesser duration, using dose/exposure time extrapolation similar to Habers rule for inhalation, which states essentially that the effective dose is directly proportional to the exposure concentration and the duration of exposure. The assessment shall be done on a case-by- case basis; for a 28-day study the guidance value is increased by a factor of three. The available repeated dose toxicity study was conducted in combination with the reproductive/developmental toxicity screening test. Male animals were exposed to the test substance for 56 days. Thus, the guidance value is increased by a factor of 1.6 leading to a guidance value range of 16 < C = 160 mg/kg bw/day for a classification as STOT RE Category 2. The LOAEL of 300 mg/kg/bw/day in the present study is above the guidance value for a classification with regard to repeated exposure. Thus, the available data on oral repeated dose toxicity do not meet the criteria for classification according to Regulation (EC) No 1272/2008, and is therefore conclusive but not sufficient for classification. Genetic toxicity: The available data on genetic toxicity are not sufficient for classification according to Regulation (EC) No 1272/2008. Gene mutation in bacteria A bacterial gene mutation assay with the test substance was performed in accordance with OECD Guideline 471 and in compliance with GLP (Paulus, 2009). In two independent experiments, the Salmonella typhimurium strains TA 97a, TA 98, TA 100, TA 102 and TA 1535 were exposed to the test substance dissolved in DMSO using either the preincubation or the plate incorporation method. Test substance concentrations of 50, 150, 500, 1501 and 5004 µg/plate were selected for the plate incorporation test with and without metabolic activation. In the second experiment, 312, 624, 1247, 2493 and 4986 µg/plate were selected for the preincubation method with and without metabolic activation. No signs of cytotoxicity were observed up to and including the limit concentration. Up to 5000 µg/plate, the test substance did not induce an increase in the mutation frequency of the tester strains in the presence and absence of a metabolic activation system. The determined vehicle values for the spontaneous revertants of the controls and all positive control values were within the range of historical data. Under the conditions of this experiment, the test substance did not show mutagenicity in the selected S. typhimurium strains in the presence and absence of metabolic activation. In vitro cytogenetic An in vitro micronucleus assay was performed with the test substance (Schweikl, 2001). In two independent experiments, Chinese hamster lung fibroblasts were exposed to the test substance dissolved in DMSO at concentrations of 11.75, 23.5, 35.25 µg/mL for 24 h in the absence of metabolic activation. Cytotoxicity of the test substance was observed and the TC50 value was assessed to be 24 µg/mL. At cytotoxic concentration levels of the test substance (= 24 µg/mL) the numbers of micronuclei were slightly increased in the absence of metabolic activation. Ethyl methanesulphonate was used as positive control and produced a distinct increase in micronuclei frequency indicating that the test conditions were adequate. Under the conditions of this experiment, the potential of the test substance to induce micronuclei is equivocal. In vitro mutagenicity in mammalian cells An in vitro HPRT assay was performed with the test substance (Schweikl, 1998). In three replicate cultures Chinese hamster lung fibroblasts were exposed to the test substance dissolved in DMSO at concentrations of 11.75, 23.5, 35.25 µg/mL for 24 h in the absence of metabolic activation. Cytotoxicity of the test substance was observed at concentrations = 23.5 µg/mL. No mutagenic activity of UDMA was detected. Ethyl methanesulphonate was used as positive control and produced a distinct increase in mutant frequency indicating that the test conditions were adequate. Thus, under the conditions of this experiment, the test substance did not show mutagenicity in V79 cells without metabolic activation. Due to the positive result in</p>
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Gingival Barrier

	<p>the in vitro micronucleus test without metabolic activation at cytotoxic concentrations a micronucleus test in vivo should be conducted to conclude on genotoxic potential of the test substance. Reproductive toxicity: The available data on toxicity to reproduction do not meet the criteria for classification according to Regulation (EC) 1272/2008, and are therefore conclusive but not sufficient for classification. reproductive toxicity: NOAEL >= 1000 mg/kg bw/day for males and females of the parental generation systemic toxicity: NOAEL = 100 mg/kg bw/day for males and 300 mg/kg bw/day for females of the parental generation A reliable sub-acute study regarding reproductive/developmental toxicity is available for the test substance. The potential reproductive or developmental toxicity of the test substance was assessed in a sub-acute combined repeated dose toxicity study with the reproductive/developmental toxicity screening test in Hsd.Han: Wistar rats performed according to OECD Guideline 422 and in compliance with GLP. Three groups of 12 male and 12 female rats received the test substance in polyethylene glycol as vehicle at doses of 100, 300 or 600 mg/kg bw/day orally via gavage at concentrations of 0, 25, 75 and 150 mg/mL corresponding to a 4 mL/kg bw dosing volume. A control group of 12 animals/sex received the vehicle only. In addition, 5 animals/sex were added to the control and high dose group to assess the reversibility of any effects observed at the high dose level (recovery group). All animals of the parental generation were dosed prior to mating (14 days) and throughout mating. In addition, males received the test item or vehicle after mating up to the day before necropsy (altogether for 56 days). Females were additionally exposed through the gestation period and up to lactation days 13 - 21, i.e. up to the day before necropsy (altogether for 56, 57 or 64 days). Observations included mortality, clinical signs, body weight, food consumption, mating, pregnancy and delivery process, lactation as well as development of offspring. The dams were allowed to litter, and rear their offspring up to day 13 post-partum. Litters were weighed and offspring were observed for possible abnormalities and were euthanized on post-natal day 13 or shortly thereafter. Blood samples were collected for determination of serum levels of thyroid hormones (T4) from all pups per litter at termination on post-natal day 13. No adverse effect on mortality, clinical signs, body weight or necropsy findings were detected in the offspring terminated as scheduled. Thyroid hormone levels (T4) in pups on post-natal day 13 were not affected. The anogenital distance (male and female) or nipple retention (male) was not affected due to treatment with the test substance. For the parental animals pale livers and histopathological changes in the liver (hepatic lipidosis) were observed at 300 mg/kg bw/day for males and 1000 mg/kg bw/day for females. Thus, under the conditions of this study, the NOAEL of the test substance for systemic toxicity of the parental generation following oral administration via gavage for 56 days is 100 mg/kg bw/day in male Wistar rats. The corresponding NOAEL in female Wistar rats following oral administration via gavage for 56, 57 or 64 days is 300 mg/kg bw/day. The corresponding NOAEL for the offspring is 1000 mg/kg bw/day. * REACH Dossier</p> <p>UV (ultraviolet)/ EB (electron beam) acrylates are generally of low toxicity</p> <p>UV/EB acrylates are divided into two groups; "stenomeric" and "eurymeric" acrylates.</p> <p>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.</p> <p>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.</p> <p>Stenomeric acrylates are usually more hazardous than the eurymeric substances. Stenomeric acrylates are also well defined which allows comparison and exchange of toxicity data - this allows more accurate classification.</p> <p>The stenomerics cannot be classified as a group; they exhibit substantial variation.</p> <p>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.</p> <p>This position has now been revised and acrylates and methacrylates are no longer <i>de facto</i> carcinogens.</p> <p>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</p> <p>Monoalkyl or monoarylesters of acrylic acids should be classified as R36/37/38 and R51/53</p> <p>Monoalkyl or monoaryl esters of methacrylic acid should be classified as R36/37/38</p>
TRIETHYLENE GLYCOL DIMETHACRYLATE & DIURETHANE DIMETHACRYLATE	<p>The following information refers to contact allergens as a group and may not be specific to this product.</p> <p>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. The significance of the contact allergen is not simply determined by its sensitisation potential: the distribution of the substance and the opportunities for contact with it are equally important. A weakly sensitising substance which is widely distributed can be a more important allergen than one with stronger sensitising potential with which few individuals come into contact. From a clinical point of view, substances are noteworthy if they produce an allergic test reaction in more than 1% of the persons tested.</p> <p>Asthma-like symptoms may continue for months or even years after exposure to the material ends. This may be due to a non-allergic condition known as reactive airways dysfunction syndrome (RADS) which can occur after exposure to high levels of highly irritating compound. Main criteria for diagnosing RADS include the absence of previous airways disease in a non-atopic individual, with sudden onset of persistent asthma-like symptoms within minutes to hours of a documented exposure to the irritant. Other criteria for diagnosis of RADS include a reversible airflow pattern on lung function tests, moderate to severe bronchial hyperreactivity on methacholine challenge testing, and the lack of minimal lymphocytic inflammation, without eosinophilia. RADS (or asthma) following an irritating inhalation is an infrequent disorder with rates related to the concentration of and duration of exposure to the irritating substance. On the other hand, industrial bronchitis is a disorder that occurs as a result of exposure due to high concentrations of irritating substance (often particles) and is completely reversible after exposure ceases. The disorder is characterized by difficulty breathing, cough and mucus production.</p>
DIURETHANE DIMETHACRYLATE	Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test, oral (OECD 422), rat:

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 either not available or does not fill the criteria for classification
 ✓ – Data available to make classification

SECTION 12 Ecological information

Toxicity

Gingival Barrier	Endpoint	Test Duration (hr)	Species	Value	Source
	Not Available	Not Available	Not Available	Not Available	Not Available
triethylene glycol dimethacrylate	Endpoint	Test Duration (hr)	Species	Value	Source
	EC50	72h	Algae or other aquatic plants	72.8mg/l	2
	LC50	96h	Fish	16.4mg/l	2

Continued...

Gingival Barrier

	NOEC(ECx)	72h	Algae or other aquatic plants	18.6mg/l	2
diurethane dimethacrylate	Endpoint	Test Duration (hr)	Species	Value	Source
	EC50	72h	Algae or other aquatic plants	>0.68mg/l	2
	EC50	48h	Crustacea	>1.2mg/l	2
	LC50	96h	Fish	10.1mg/l	Not Available
	NOEC(ECx)	72h	Algae or other aquatic plants	0.21mg/l	2
Legend: <i>Extracted from 1. IUCLID Toxicity Data 2. Europe ECHA Registered Substances - Ecotoxicological Information - Aquatic Toxicity 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</i>					

DO NOT discharge into sewer or waterways.

Persistence and degradability

Ingredient	Persistence: Water/Soil	Persistence: Air
triethylene glycol dimethacrylate	LOW	LOW

Bioaccumulative potential

Ingredient	Bioaccumulation
triethylene glycol dimethacrylate	LOW (LogKOW = 1.88)

Mobility in soil

Ingredient	Mobility
triethylene glycol dimethacrylate	LOW (KOC = 10)

SECTION 13 Disposal considerations

Waste treatment methods

Product / Packaging disposal	Consult State Land Waste Management Authority for disposal. Bury residue in an authorised landfill.
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Ensure that the hazardous substance is disposed in accordance with the Hazardous Substances (Disposal) Notice 2017

Disposal Requirements

Packages that have been in direct contact with the hazardous substance must be only disposed if the hazardous substance was appropriately removed and cleaned out from the package. The package must be disposed according to the manufacturer's directions taking into account the material it is made of. Packages which hazardous content have been appropriately treated and removed may be recycled.

The hazardous substance must only be disposed if it has been treated by a method that changed the characteristics or composition of the substance and it is no longer hazardous. Only dispose to the environment if a tolerable exposure limit has been set for the substance.

Only deposit the hazardous substance into or onto a landfill or sewage facility or incinerator, where the hazardous substance can be handled and treated appropriately.

SECTION 14 Transport information

Labels Required

Marine Pollutant	
HAZCHEM	Not Applicable

Land transport (UN): 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

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

Not Applicable

14.7.2. Transport in bulk in accordance with MARPOL Annex V and the IMSBC Code

Product name	Group
triethylene glycol dimethacrylate	Not Available
diurethane dimethacrylate	Not Available

14.7.3. Transport in bulk in accordance with the IGC Code

Product name	Ship Type
triethylene glycol dimethacrylate	Not Available

Gingival Barrier

Product name	Ship Type
diurethane dimethacrylate	Not Available

SECTION 15 Regulatory information

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

This substance is to be managed using the conditions specified in an applicable Group Standard

HSR Number	Group Standard
HSR002521	Animal Nutritional and Animal Care Products Group Standard 2020
HSR002530	Cleaning Products Subsidiary Hazard Group Standard 2020
HSR002535	Gases under Pressure Mixtures Subsidiary Hazard Group Standard 2020
HSR002503	Additives Process Chemicals and Raw Materials Subsidiary Hazard Group Standard 2020
HSR002606	Lubricants Lubricant Additives Coolants and Anti freeze Agents Subsidiary Hazard Group Standard 2020
HSR002612	Metal Industry Products Subsidiary Hazard Group Standard 2020
HSR002624	N.O.S. Subsidiary Hazard Group Standard 2020
HSR002638	Photographic Chemicals Subsidiary Hazard Group Standard 2020
HSR002644	Polymers Subsidiary Hazard Group Standard 2020
HSR002647	Reagent Kits Group Standard 2020
HSR002648	Refining Catalysts Group Standard 2020
HSR002653	Solvents Subsidiary Hazard Group Standard 2020
HSR002670	Surface Coatings and Colourants Subsidiary Hazard Group Standard 2020
HSR002684	Water Treatment Chemicals Subsidiary Hazard Group Standard 2020
HSR100425	Pharmaceutical Active Ingredients Group Standard 2020
HSR002600	Leather and Textile Products Subsidiary Hazard Group Standard 2020
HSR002544	Construction Products Subsidiary Hazard Group Standard 2020
HSR002549	Corrosion Inhibitors Subsidiary Hazard Group Standard 2020
HSR002552	Cosmetic Products Group Standard 2020
HSR002558	Dental Products Subsidiary Hazard Group Standard 2020
HSR002565	Embalming Products Subsidiary Hazard Group Standard 2020
HSR002571	Fertilisers Subsidiary Hazard Group Standard 2020
HSR002573	Fire Fighting Chemicals Group Standard 2021
HSR002578	Food Additives and Fragrance Materials Subsidiary Hazard Group Standard 2020
HSR002585	Fuel Additives Subsidiary Hazard Group Standard 2020
HSR002596	Laboratory Chemicals and Reagent Kits Group Standard 2020
HSR100757	Veterinary Medicines Limited Pack Size Finished Dose Group Standard 2020
HSR100758	Veterinary Medicines Non dispersive Closed System Application Group Standard 2020
HSR100759	Veterinary Medicines Non dispersive Open System Application Group Standard 2020
HSR100592	Agricultural Compounds Special Circumstances Group Standard 2020
HSR100756	Active Ingredients for Use in the Manufacture of Agricultural Compounds Group Standard 2020

Please refer to Section 8 of the SDS for any applicable tolerable exposure limit or Section 12 for environmental exposure limit.

triethylene glycol dimethacrylate is found on the following regulatory lists

New Zealand Hazardous Substances and New Organisms (HSNO) Act - Classification of Chemicals

New Zealand Hazardous Substances and New Organisms (HSNO) Act - Classification of Chemicals - Classification Data

New Zealand Inventory of Chemicals (NZIoC)

New Zealand Land Transport Rule: Dangerous Goods 2005 - Schedule 1 Quantity limits for dangerous goods

diurethane dimethacrylate is found on the following regulatory lists

New Zealand Inventory of Chemicals (NZIoC)

New Zealand Land Transport Rule: Dangerous Goods 2005 - Schedule 1 Quantity limits for dangerous goods

Additional Regulatory Information

Not Applicable

Hazardous Substance Location

Subject to the Health and Safety at Work (Hazardous Substances) Regulations 2017.

Hazard Class	Quantities
Not Applicable	Not Applicable

Certified Handler

Subject to Part 4 of the Health and Safety at Work (Hazardous Substances) Regulations 2017.

Class of substance	Quantities
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Continued...

Class of substance	Quantities
Not Applicable	Not Applicable

Refer Group Standards for further information

Maximum quantities of certain hazardous substances permitted on passenger service vehicles

Subject to Regulation 13.14 of the Health and Safety at Work (Hazardous Substances) Regulations 2017.

Hazard Class	Gas (aggregate water capacity in mL)	Liquid (L)	Solid (kg)	Maximum quantity per package for each classification
6.5A or 6.5B	120	1	3	

Tracking Requirements

Not Applicable

National Inventory Status

National Inventory	Status
Australia - AIIC / Australia Non-Industrial Use	Yes
Canada - DSL	No (diurethane dimethacrylate)
Canada - NDSL	No (triethylene glycol dimethacrylate)
China - IECSC	Yes
Europe - EINEC / ELINCS / NLP	Yes
Japan - ENCS	No (diurethane dimethacrylate)
Korea - KECI	Yes
New Zealand - NZIoC	Yes
Philippines - PICCS	Yes
USA - TSCA	Yes
Taiwan - TCSI	Yes
Mexico - INSQ	No (diurethane dimethacrylate)
Vietnam - NCI	Yes
Russia - FBEPH	No (diurethane dimethacrylate)
Legend:	Yes = All CAS declared ingredients are on the inventory No = One or more of the CAS listed ingredients are not on the inventory. These ingredients may be exempt or will require registration.

SECTION 16 Other information

Revision Date	10/03/2023
Initial Date	02/11/2015

SDS Version Summary

Version	Date of Update	Sections Updated
10.1	10/12/2021	Classification change due to full database hazard calculation/update.
11.1	10/03/2023	Classification change due to full database hazard calculation/update.

Other information

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

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
- ES: Exposure Standard
- 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
- DNEL: Derived No-Effect Level
- PNEC: Predicted no-effect concentration
- AIIC: Australian Inventory of Industrial Chemicals
- DSL: Domestic Substances List

Gingival Barrier

- NDSL: Non-Domestic Substances List
- IECSC: Inventory of Existing Chemical Substance in China
- EINECS: European INventory of Existing Commercial chemical Substances
- ELINCS: European List of Notified Chemical Substances
- NLP: No-Longer Polymers
- ENCS: Existing and New Chemical Substances Inventory
- KECI: Korea Existing Chemicals Inventory
- NZIoC: New Zealand Inventory of Chemicals
- PICCS: Philippine Inventory of Chemicals and Chemical Substances
- TSCA: Toxic Substances Control Act
- TCSI: Taiwan Chemical Substance Inventory
- INSQ: Inventario Nacional de Sustancias Químicas
- NCI: National Chemical Inventory
- FBEPH: Russian Register of Potentially Hazardous Chemical and Biological Substances

The information contained in the Safety Data Sheet is based on data considered to be accurate, however, no warranty is expressed or implied regarding the accuracy of the data or the results to be obtained from the use thereof.

Other information:

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