

SAFETY DATA SHEETS

This SDS packet was issued with item:

071250448

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

071132547 071250463 071250471 071250489 071250497 071250513 071250521 071250539 071410844 71132547
71250448 71250463 71250471 71250489 71250497 71250513 71250521 71250539



Glacier, Wave, Wave MV, Wave HV, ROK, ICE, Luna, Aura, Aura Bulk Fill, Aura eASY, Aura Easyflow and LC Opaquer

SDI Limited

Version No: 8.1.1.1

Safety Data Sheet according to WHMIS 2015 requirements

Issue Date: 01/11/2019

Print Date: 09/10/2020

L.GHS.CAN.EN

SECTION 1 Identification

Product Identifier

Product name	Glacier, Wave, Wave MV, Wave HV, ROK, ICE, Luna, Aura, Aura Bulk Fill, Aura eASY, Aura Easyflow and LC Opaquer
Synonyms	Not Available
Other means of identification	Not Available

Recommended use of the chemical and restrictions on use

Relevant identified uses	For filling of cavitated teeth by dental professionals.
--------------------------	---

Name, address, and telephone number of the chemical manufacturer, importer, or other responsible party

Registered company name	SDI Limited	SDI (North America) Inc.	SDI Dental Limited
Address	3-15 Brunston Street Bayswater VIC 3153 Australia	1279 Hamilton Parkway Itasca IL 60143 United States	Block 8, St Johns Court Santry Dublin 9 Ireland
Telephone	+61 3 8727 7111 (Business Hours)	+1 630 361 9200 (Business hours) 1 800 228 5166	+353 1 886 9577 (Business Hours) 800 0225 5734
Fax	+61 3 8727 7222	+1 630 361 9222	Not Available
Website	www.sdi.com.au	http://www.sdi.com.au	http://www.sdi.com.au/
Email	info@sdi.com.au	USA.Canada@sdi.com.au	Ireland@sdi.com.au
Registered company name	SDi		
Address	Rua Dr. Virgílio de Carvalho Pinto, 612 Pinheiros, Sao Paulo 05415-020 Brazil		
Telephone	+55 11 3092 7100 (Business Hours)		
Fax	+55 11 3092 7101		
Website	http://www.sdi.com.au/		
Email	Brasil@sdi.com.au		

Emergency phone number

Association / Organisation	SDI Limited	SDI Dental Limited	SDi
Emergency telephone numbers	+61 3 8727 7111	+61 3 8727 7111	+61 3 8727 7111
Other emergency telephone numbers	ray.cahill@sdi.com.au	Not Available	Not Available

SECTION 2 Hazard(s) identification

Classification of the substance or mixture

NFPA 704 diamond



Note: The hazard category numbers found in GHS classification in section 2 of this SDSs are NOT to be used to fill in the NFPA 704 diamond. Blue = Health Red = Fire Yellow = Reactivity White = Special (Oxidizer or water reactive substances)

Classification	Skin Corrosion/Irritation Category 2, Eye Irritation Category 2B, Skin Sensitizer Category 1, Specific target organ toxicity - single exposure Category 3 (respiratory tract irritation), Acute Aquatic Hazard Category 2
----------------	---

Label elements

Hazard pictogram(s)	
---------------------	--

Glacier, Wave, Wave MV, Wave HV, ROK, ICE, Luna, Aura, Aura Bulk Fill, Aura eASY, Aura Easyflow and LC Opaquer

Signal word	Warning
-------------	----------------

Hazard statement(s)

H315	Causes skin irritation.
H320	Causes eye irritation.
H317	May cause an allergic skin reaction.
H335	May cause respiratory irritation.
H401	Toxic to aquatic life.

Physical and Health hazard(s) not otherwise classified

Not Applicable

Precautionary statement(s) Prevention

P271	Use only outdoors or in a well-ventilated area.
P280	Wear protective gloves/protective clothing/eye protection/face protection.
P261	Avoid breathing mist/vapours/spray.
P273	Avoid release to the environment.
P272	Contaminated work clothing should not be allowed out of the workplace.

Precautionary statement(s) Response

P321	Specific treatment (see advice on this label).
P302+P352	IF ON SKIN: Wash with plenty of water and soap.
P305+P351+P338	IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
P312	Call a POISON CENTER/doctor/physician/first aider/if you feel unwell.
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.
P304+P340	IF INHALED: Remove person to fresh air and keep comfortable for breathing.

Precautionary statement(s) Storage

P405	Store locked up.
P403+P233	Store in a well-ventilated place. Keep container tightly closed.

Precautionary statement(s) Disposal

P501	Dispose of contents/container to authorised hazardous or special waste collection point in accordance with any local regulation.
-------------	--

SECTION 3 Composition / information on ingredients**Substances**

See section below for composition of Mixtures

Mixtures

CAS No	%[weight]	Name
72869-86-4	3-20	<u>diurethane dimethacrylate</u>
109-16-0	0.01-7	<u>triethylene glycol dimethacrylate</u>
24448-20-2	15-18	<u>2,2-bis[4-(2-methacryloxy)ethoxy]phenyl]propane</u>

SECTION 4 First-aid measures**Description of first aid measures**

Eye Contact	<p>If this product comes in contact with the eyes:</p> <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	<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. <p>If irritation continues, seek medical attention.</p>
Ingestion	Seek medical attention.

Indication of any immediate medical attention and special treatment needed

Continued...

Glacier, Wave, Wave MV, Wave HV, ROK, ICE, Luna, Aura, Aura Bulk Fill, Aura eASY, Aura Easyflow and LC Opaquer

Treat symptomatically.

SECTION 5 Fire-fighting measures

Extinguishing media

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

Special hazards arising from the substrate or mixture

Fire Incompatibility	None known.
-----------------------------	-------------

Special protective equipment and precautions for fire-fighters

Fire Fighting	<ul style="list-style-type: none"> ▶ Alert Fire Brigade and tell them location and nature of hazard. ▶ May be violently or explosively reactive. ▶ Wear full body protective clothing with breathing apparatus. ▶ Prevent, by any means available, spillage from entering drains or water course. ▶ Fight fire from a safe distance, with adequate cover. ▶ If safe, switch off electrical equipment until vapour fire hazard removed. ▶ Use water delivered as a fine spray to control the fire and cool adjacent area. ▶ Avoid spraying water onto liquid pools. ▶ 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.
Fire/Explosion Hazard	<ul style="list-style-type: none"> ▶ Non combustible. ▶ Not considered a significant fire risk, however containers may burn. <p>May emit corrosive fumes. Decomposes on heating and produces: carbon dioxide (CO₂) carbon monoxide (CO)</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.
----------------------	--

Continued...

Glacier, Wave, Wave MV, Wave HV, ROK, ICE, Luna, Aura, Aura Bulk Fill, Aura eASY, Aura

Easyflow and LC Opaquer

Other information	Store between 10 and 25 deg. C. Do not store in direct sunlight.
-------------------	---

Conditions for safe storage, including any incompatibilities

Suitable container	DO NOT repack. Use containers supplied by manufacturer only. Check that containers are clearly labelled and free from leaks
Storage incompatibility	Avoid storage with reducing agents.

SECTION 8 Exposure controls / personal protection

Control parameters

Occupational Exposure Limits (OEL)

INGREDIENT DATA

Not Available

Emergency Limits

Ingredient	Material name	TEEL-1	TEEL-2	TEEL-3
diurethane dimethacrylate	Diurethane dimethacrylate	120 mg/m3	1,300 mg/m3	7,900 mg/m3
triethylene glycol dimethacrylate	Methacrylic acid, diester with triethylene glycol: (Polyester TGM3)	33 mg/m3	360 mg/m3	2,100 mg/m3

Ingredient	Original IDLH	Revised IDLH
diurethane dimethacrylate	Not Available	Not Available
triethylene glycol dimethacrylate	Not Available	Not Available
2,2-bis[4-(2-methacryloxy)ethoxy]phenyl]propane	Not Available	Not Available

Ingredient	Occupational Exposure Band Rating	Occupational Exposure Band Limit
diurethane dimethacrylate	E	≤ 0.1 ppm
triethylene glycol dimethacrylate	E	≤ 0.1 ppm
2,2-bis[4-(2-methacryloxy)ethoxy]phenyl]propane	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

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. 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.

Employers may need to use multiple types of controls to prevent employee overexposure.

General exhaust is adequate under normal operating conditions. Local exhaust ventilation may be required in special circumstances. If risk of overexposure exists, wear approved respirator. Supplied-air type respirator may be required in special circumstances. Correct fit is essential to ensure adequate protection. Provide adequate ventilation in warehouses and enclosed 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.

Type of Contaminant:

Air Speed:

0.25-0.5 m/s (50-100 f/min)	aerosols, fumes from pouring operations, intermittent container filling, low speed conveyor transfers, welding, spray
0.5-1 m/s (100-200 f/min.)	drift, plating acid fumes, pickling (released at low velocity into zone of active generation)
1-2.5 m/s (200-500 f/min.)	direct spray, spray painting in shallow booths, drum filling, conveyor loading, crusher dusts, gas discharge (active generation into zone of rapid air motion)
2.5-10 m/s (500-2000 f/min.)	grinding, abrasive blasting, tumbling, high speed wheel generated dusts (released at high initial velocity into zone of very high rapid air motion)


Within each range the appropriate value depends on:

Lower 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
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,

Glacier, Wave, Wave MV, Wave HV, ROK, ICE, Luna, Aura, Aura Bulk Fill, Aura eASY, Aura Easyflow and LC Opaquer

	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.
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. 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]
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	<ul style="list-style-type: none"> ▶ Overalls. ▶ P.V.C apron. ▶ Barrier cream. ▶ Skin cleansing cream. ▶ Eye wash 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	Tooth coloured viscous/ flowable paste with ester-like odour, insoluble in water.		
Physical state	Free-flowing Paste	Relative density (Water = 1)	1.5-2.0
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	Not Available
Melting point / freezing point (°C)	Not Available	Viscosity (cSt)	Not Available
Initial boiling point and boiling range (°C)	Gel before boiling	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	Immiscible	pH as a solution (1%)	Not Available
Vapour density (Air = 1)	Not Available	VOC g/L	Not Available

SECTION 10 Stability and reactivity

Glacier, Wave, Wave MV, Wave HV, ROK, ICE, Luna, Aura, Aura Bulk Fill, Aura eASY, Aura Easyflow and LC Opaquer

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	Limited evidence or practical experience suggests that the material may produce irritation of the respiratory system, in a significant number of individuals, following inhalation. In contrast to most organs, the lung is able to respond to a chemical insult by first removing or neutralising the irritant and then repairing the damage. The repair process, which initially evolved to protect mammalian lungs from foreign matter and antigens, may however, produce further lung damage resulting in the impairment of gas exchange, the primary function of the lungs. Respiratory tract irritation often results in an inflammatory response involving the recruitment and activation of many cell types, mainly derived from the vascular system.
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	Practical experience shows that skin contact with the material is capable either of inducing a sensitisation reaction in a substantial number of individuals, and/or of producing a positive response in experimental animals.

Glacier, Wave, Wave MV, Wave HV, ROK, ICE, Luna, Aura, Aura Bulk Fill, Aura eASY, Aura Easyflow and LC Opaquer	TOXICITY	IRRITATION
	Not Available	Not Available
diurethane dimethacrylate	TOXICITY	IRRITATION
	Not Available	Eye: no adverse effect observed (not irritating) ^[1] Skin: no adverse effect observed (not irritating) ^[1]
triethylene glycol dimethacrylate	TOXICITY	IRRITATION
	Oral (mouse) LD50: 10750 mg/kg ^[2] Oral (rat) LD50: 10837 mg/kg ^[2]	Eye: no adverse effect observed (not irritating) ^[1] Skin: no adverse effect observed (not irritating) ^[1]
2,2-bis[4-(2-methacryloxy)ethoxy]phenyl]propane	TOXICITY	IRRITATION
	Not Available	Not Available
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</p>
----------------------------------	---

Glacier, Wave, Wave MV, Wave HV, ROK, ICE, Luna, Aura, Aura Bulk Fill, Aura eASY, Aura Easyflow and LC Opaquer

	<p>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 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>
2,2-BIS[4-(2-METHACRYLOXY)ETHOXY]PHENYL]PROPANE	<p>No significant acute toxicological data identified in literature search.</p> <p>The chemical structure of hydroxylated diphenylalkanes or bisphenols consists of two phenolic rings joined together through a bridging carbon. This class of endocrine disruptors that mimic oestrogens is widely used in industry, particularly in plastics Bisphenol A (BPA) and some related compounds exhibit oestrogenic activity in human breast cancer cell line MCF-7, but there were remarkable differences in activity. Several derivatives of BPA exhibited significant thyroid hormonal activity towards rat pituitary cell line GH3, which releases growth hormone in a thyroid hormone-dependent manner. However, BPA and several other derivatives did not show such activity. Results suggest that the 4-hydroxyl group of the A-phenyl ring and the B-phenyl ring of BPA derivatives are required for these hormonal activities, and substituents at the 3,5-positions of the phenyl rings and the bridging alkyl moiety markedly influence the activities.</p> <p>Bisphenols promoted cell proliferation and increased the synthesis and secretion of cell type-specific proteins. When ranked by proliferative potency, the longer the alkyl substituent at the bridging carbon, the lower the concentration needed for maximal cell yield; the most active compound contained two propyl chains at the bridging carbon. Bisphenols with two hydroxyl groups in the para position and an angular configuration are suitable for appropriate hydrogen bonding to the acceptor site of the oestrogen receptor.</p>
DIURETHANE DIMETHACRYLATE	Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test, oral (OECD 422), rat:
DIURETHANE DIMETHACRYLATE & TRIETHYLENE GLYCOL 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>
DIURETHANE DIMETHACRYLATE & TRIETHYLENE GLYCOL DIMETHACRYLATE & 2,2-BIS[4-	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

Glacier, Wave, Wave MV, Wave HV, ROK, ICE, Luna, Aura, Aura Bulk Fill, Aura eASY, Aura Easyflow and LC Opaquer

(2-METHACRYLOXY)ETHOXY)PHENYL]PROPANE	high levels of highly irritating compound. Key criteria for the diagnosis of RADS include the absence of preceding respiratory disease, in a non-atopic individual, with abrupt onset of persistent asthma-like symptoms within minutes to hours of a documented exposure to the irritant. A reversible airflow pattern, on spirometry, with the presence of moderate to severe bronchial hyperreactivity on methacholine challenge testing and the lack of minimal lymphocytic inflammation, without eosinophilia, have also been included in the criteria for diagnosis of RADS. 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. Industrial bronchitis, on the other hand, is a disorder that occurs as result of exposure due to high concentrations of irritating substance (often particulate in nature) and is completely reversible after exposure ceases. The disorder is characterised by dyspnea, cough and mucus production.
DIURETHANE DIMETHACRYLATE & 2,2-BIS[4-(2-METHACRYLOXY)ETHOXY)PHENYL]PROPANE	<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>Monalkyl 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>

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

Glacier, Wave, Wave MV, Wave HV, ROK, ICE, Luna, Aura, Aura Bulk Fill, Aura eASY, Aura Easyflow and LC Opaquer	Endpoint	Test Duration (hr)	Species	Value	Source
	Not Available	Not Available	Not Available	Not Available	Not Available
diurethane dimethacrylate	Endpoint	Test Duration (hr)	Species	Value	Source
	LC50	96	Fish	10.1mg/L	2
	EC50	48	Crustacea	>0.001-0.2mg/L	2
	EC50	72	Algae or other aquatic plants	>0.68mg/L	2
	EC100	24	Crustacea	>0.001-0.2mg/L	2
	NOEC	24	Crustacea	0.001-0.2mg/L	2
triethylene glycol dimethacrylate	Endpoint	Test Duration (hr)	Species	Value	Source
	LC50	96	Fish	16.4mg/L	2
	EC50	72	Algae or other aquatic plants	72.8mg/L	2
	NOEC	72	Algae or other aquatic plants	18.6mg/L	2
2,2-bis[4-(2-methacryloxy)ethoxy)phenyl]propane	Endpoint	Test Duration (hr)	Species	Value	Source
	Not Available	Not Available	Not Available	Not Available	Not Available

Legend: Extracted from 1. IUCLID Toxicity Data 2. Europe ECHA Registered Substances - Ecotoxicological Information - Aquatic Toxicity 3. EPIWIN Suite V3.12 (QSAR) - 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

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)

Continued...

Glacier, Wave, Wave MV, Wave HV, ROK, ICE, Luna, Aura, Aura Bulk Fill, Aura eASY, Aura Easyflow and LC Opaquer**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.
------------------------------	--

SECTION 14 Transport information**Labels Required**

Marine Pollutant	NO
------------------	----

Land transport (TDG): 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**

This product has been classified in accordance with the hazard criteria of the Controlled Products Regulations and the SDS contains all the information required by the Controlled Products Regulations.

diurethane dimethacrylate is found on the following regulatory lists

Canada Non-Domestic Substances List (NDSL)

triethylene glycol dimethacrylate is found on the following regulatory lists

Canada Categorization decisions for all DSL substances

Canada Domestic Substances List (DSL)

2,2-bis[4-(2-methacryloxy)ethoxy]phenyl]propane is found on the following regulatory lists

Canada Categorization decisions for all DSL substances

Canada Domestic Substances List (DSL)

National Inventory Status

National Inventory	Status
Australia - AIIC	Yes
Australia - Non-Industrial Use	No (diurethane dimethacrylate; triethylene glycol dimethacrylate; 2,2-bis[4-(2-methacryloxy)ethoxy]phenyl]propane)
Canada - DSL	No (diurethane dimethacrylate)
Canada - NDSL	No (triethylene glycol dimethacrylate; 2,2-bis[4-(2-methacryloxy)ethoxy]phenyl]propane)
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 - ARIPS	No (diurethane dimethacrylate; 2,2-bis[4-(2-methacryloxy)ethoxy]phenyl]propane)
Legend:	Yes = All CAS declared ingredients are on the inventory No = One or more of the CAS listed ingredients are not on the inventory and are not exempt from listing(see specific ingredients in brackets)

SECTION 16 Other information

Revision Date	01/11/2019
Initial Date	02/11/2015

SDS Version Summary

Version	Issue Date	Sections Updated
7.1.1.1	08/02/2017	Ingredients

Continued...

Glacier, Wave, Wave MV, Wave HV, ROK, ICE, Luna, Aura, Aura Bulk Fill, Aura eASY, Aura Easyflow and LC Opaquer

Version	Issue Date	Sections Updated
8.1.1.1	01/11/2019	One-off system update. NOTE: This may or may not change the GHS classification

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
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

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:

Prepared by: SDI Limited
3-15 Brunson Street, Bayswater Victoria, 3153, Australia
Phone Number: +61 3 8727 7111
Department issuing SDS: Research and Development
Contact: Technical Director