



Riva Star

SDI Limited

Version No: 9.1

Safety data sheet according to REACH Regulation (EC) No 1907/2006, as amended by UK REACH Regulations SI 2019/758

Issue Date: 10/03/2023

Print Date: 22/11/2023

L.REACH.GB.EN

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

1.1. Product Identifier

| | |
|-------------------------------|--|
| Product name | Riva Star |
| Chemical Name | Not Applicable |
| Synonyms | Not Available |
| Proper shipping name | AMMONIA SOLUTION, relative density between 0.880 and 0.957 at 15 °C in water, with more than 10% but not more than 35% ammonia |
| Chemical formula | Not Applicable |
| Other means of identification | Not Available |

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

| | |
|--------------------------|---|
| Relevant identified uses | (Riva Star is comprised of Riva Star Step 1 and Riva Star Step 2) for use as a tooth desensitising and anti-caries agent. |
| Uses advised against | No specific uses advised against are identified. |

1.3. Details of the manufacturer or supplier of the safety data sheet

| Registered company name | SDI Limited | SDI (North America) Inc. | SDI HOLDINGS PTY LTD DO |
|-------------------------|--|---|---|
| Address | 3-15 Brunsdon Street Bayswater VIC 3153 Australia | 1279 Hamilton Parkway Itasca IL 60143 United States | Rua Dr. Reinaldo Schmithausen 3141 – Cordeiros Itajaí – SC – CEP 88310-004 Brazil |
| Telephone | +61 3 8727 7111 | +1 630 361 9200 | +55 11 3092 7100 |
| Fax | +61 3 8727 7222 | Not Available | Not Available |
| Website | www.sdi.com.au | www.sdi.com.au | http://www.sdi.com.au/ |
| Email | info@sdi.com.au | USA.Canada@sdi.com.au | Brasil@sdi.com.au |

| | |
|-------------------------|--|
| Registered company name | SDI Germany GmbH |
| Address | Hansestrasse 85 Cologne D-51149 Germany |
| Telephone | +49 0 2203 9255 0 |
| Fax | +49 0 2203 9255 200 |
| Website | www.sdi.com.au |
| Email | germany@sdi.com.au |

1.4. Emergency telephone number

| | | |
|-----------------------------------|-----------------------------------|-------------------------------------|
| Association / Organisation | SDI Limited | CHEMWATCH EMERGENCY RESPONSE (24/7) |
| Emergency telephone numbers | 131126 Poisons Information Centre | +44 20 3901 3542 |
| Other emergency telephone numbers | +61 3 8727 7111 | +44 808 164 9592 |

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


SECTION 2 Hazards identification

2.1. Classification of the substance or mixture

| | |
|---|--|
| Classified according to GB-CLP Regulation, UK SI 2019/720 and UK SI 2020/1567 [1] | H290 - Corrosive to Metals Category 1, H314 - Skin Corrosion/Irritation Category 1A, H400 - Hazardous to the Aquatic Environment Acute Hazard Category 1 |
| Legend: | 1. Classification by vendor; 2. Classification drawn from GB-CLP Regulation, UK SI 2019/720 and UK SI 2020/1567 |

2.2. Label elements

Riva Star

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

| | |
|-------------|---------------|
| Signal word | Danger |
|-------------|---------------|

Hazard statement(s)

| | |
|------|--|
| H290 | May be corrosive to metals. |
| H314 | Causes severe skin burns and eye damage. |
| H400 | Very toxic to aquatic life. |

Supplementary statement(s)

Not Applicable

Precautionary statement(s) Prevention

| | |
|------|--|
| P260 | Do not breathe mist/vapours/spray. |
| P264 | Wash all exposed external body areas thoroughly after handling. |
| P280 | Wear protective gloves, protective clothing, eye protection and face protection. |
| P234 | Keep only in original packaging. |
| P273 | Avoid release to the environment. |

Precautionary statement(s) Response

| | |
|----------------|--|
| P301+P330+P331 | IF SWALLOWED: Rinse mouth. Do NOT induce vomiting. |
| P303+P361+P353 | IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water [or shower]. |
| P305+P351+P338 | IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. |
| P310 | Immediately call a POISON CENTER/doctor/physician/first aider. |
| P363 | Wash contaminated clothing before reuse. |
| P390 | Absorb spillage to prevent material damage. |
| P391 | Collect spillage. |
| P304+P340 | IF INHALED: Remove person to fresh air and keep comfortable for breathing. |

Precautionary statement(s) Storage

| | |
|------|------------------|
| P405 | Store locked up. |
|------|------------------|

Precautionary statement(s) Disposal

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

2.3. Other hazards

Ingestion may produce health damage*.

Cumulative effects may result following exposure*.

REACH - Art.57-59: The mixture does not contain Substances of Very High Concern (SVHC) at the SDS print date.

SECTION 3 Composition / information on ingredients

3.1.Substances

See 'Composition on ingredients' in Section 3.2

3.2.Mixtures

| 1. CAS No 2.EC No 3.Index No 4.REACH No | [%weight] | Name | Classified according to GB-CLP Regulation, UK SI 2019/720 and UK SI 2020/1567 | SCL / M-Factor | Nanoform Particle Characteristics |
|--|-----------|---|---|-----------------------------|-----------------------------------|
| Not Available | | each 0.05ml capsule of Riva Star Step 1 contains: | Not Applicable | Not Applicable | Not Available |
| 1. 7775-41-9 2.231-895-8 3.Not Available 4.Not Available | 35-40 | <u>silver(I) fluoride</u> * | Acute Toxicity (Oral, Dermal and Inhalation) Category 3, Skin Corrosion/Irritation Category 1A, Serious Eye Damage/Eye Irritation Category 1; H301+H311+H331, H314, H318 [1] | Not Available | Not Available |
| 1. 1336-21-6 2.215-647-6 3.007-001-01-2 4.01-2119982985-14-XXXX | 15-20 | <u>ammonia</u> | Corrosive to Metals Category 1, Skin Corrosion/Irritation Category 1B, Serious Eye Damage/Eye Irritation Category 1, Acute Toxicity (Inhalation) Category 4, Hazardous to the Aquatic Environment Acute Hazard Category 1; H290, H314, H318, H332, H400 [1] | STOT SE 3; H335: C ≥ 5 % | Not Available |

Continued...

Riva Star

| 1. CAS No 2. EC No 3. Index No 4. REACH No | %[weight] | Name | Classified according to GB-CLP Regulation, UK SI 2019/720 and UK SI 2020/1567 | SCL / M-Factor | Nanoform Particle Characteristics |
|---|-----------|--|---|----------------|-----------------------------------|
| 1. 7732-18-5 2. 231-791-2 3. Not Available 4. Not Available | balance | water | Not Classified [1] | Not Available | Not Available |
| Not Available | | Riva Star Step 2 contains: | Not Applicable | Not Applicable | Not Available |
| Not Available | 100 | Ingredients determined not to be hazardous | Not Applicable | Not Applicable | Not Available |
| Legend: 1. Classification by vendor; 2. Classification drawn from GB-CLP Regulation, UK SI 2019/720 and UK SI 2020/1567; 3. Classification drawn from C&L; * EU IOELVs available; [e] Substance identified as having endocrine disrupting properties | | | | | |

SECTION 4 First aid measures

4.1. Description of first aid measures

| | |
|---------------------|--|
| Eye Contact | <p>If this product comes in contact with the eyes:</p> <ul style="list-style-type: none"> ▶ Immediately hold eyelids apart and flush the eye continuously with 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. ▶ Continue flushing until advised to stop by the Poisons Information Centre or a doctor, or for at least 15 minutes. ▶ Transport to hospital or doctor without delay. ▶ 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 or combustion products are inhaled remove from contaminated area. ▶ Seek medical attention. |
| Ingestion | <ul style="list-style-type: none"> ▶ If swallowed do NOT induce vomiting. ▶ If vomiting occurs, lean patient forward or place on left side (head-down position, if possible) to maintain open airway and prevent aspiration. ▶ Observe the patient carefully. ▶ Never give liquid to a person showing signs of being sleepy or with reduced awareness; i.e. becoming unconscious. ▶ Give water to rinse out mouth, then provide liquid slowly and as much as casualty can comfortably drink. ▶ Seek medical advice. |

4.2 Most important symptoms and effects, both acute and delayed

See Section 11

4.3. Indication of any immediate medical attention and special treatment needed

Treat symptomatically.

SECTION 5 Firefighting measures

5.1. Extinguishing media

- ▶ Dry chemical powder.
- ▶ BCF (where regulations permit).
- ▶ Carbon dioxide.

5.2. Special hazards arising from the substrate or mixture

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

5.3. Advice for firefighters

| | |
|------------------------------|---|
| Fire Fighting | <ul style="list-style-type: none"> ▶ Alert Fire Brigade and tell them location and nature of hazard. ▶ Wear full body protective clothing with breathing apparatus. ▶ Prevent, by any means available, spillage from entering drains or water course. ▶ 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"> ▶ Non combustible. ▶ Not considered to be a significant fire risk. ▶ Acids may react with metals to produce hydrogen, a highly flammable and explosive gas. ▶ Heating may cause expansion or decomposition leading to violent rupture of containers. ▶ May emit corrosive, poisonous fumes. May emit acrid smoke. <p>Decomposition may produce toxic fumes of: nitrogen oxides (NOx) ammonia</p> |

SECTION 6 Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

Continued...

Riva Star

See section 8

6.2. Environmental precautions

See section 12

6.3. Methods and material for containment and cleaning up

| | |
|---------------------|--|
| Minor Spills | <ul style="list-style-type: none"> ▶ Drains for storage or use areas should have retention basins for pH adjustments and dilution of spills before discharge or disposal of material. ▶ Check regularly for spills and leaks. ▶ Clean up all spills immediately. ▶ Avoid breathing vapours and contact with skin and eyes. ▶ Control personal contact with the substance, by using protective equipment. ▶ Contain and absorb spill with sand, earth, inert material or vermiculite. ▶ Wipe up. ▶ Place in a suitable, labelled container for waste disposal. |
| Major Spills | <ul style="list-style-type: none"> ▶ Clear area of personnel and move upwind. ▶ Alert Fire Brigade and tell them location and nature of hazard. ▶ Wear full body protective clothing with breathing apparatus. ▶ Prevent, by any means available, spillage from entering drains or water course. ▶ Stop leak if safe to do so. ▶ Contain spill with sand, earth or vermiculite. ▶ Collect recoverable product into labelled containers for recycling. ▶ Neutralise/decontaminate residue (see Section 13 for specific agent). ▶ Collect solid residues and seal in labelled drums for disposal. ▶ Wash area and prevent runoff into drains. ▶ After clean up operations, decontaminate and launder all protective clothing and equipment before storing and re-using. ▶ If contamination of drains or waterways occurs, advise emergency services. |

6.4. Reference to other sections

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

SECTION 7 Handling and storage

7.1. 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. ▶ Avoid contact with moisture. ▶ 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. |
| Fire and explosion protection | See section 5 |
| Other information | <p>Do not store in direct sunlight.</p> <p>Store in a dry and well ventilated-area, away from heat and sunlight.</p> <p>Store between 2 and 8 deg C.</p> |

7.2. Conditions for safe storage, including any incompatibilities

| | |
|--|---|
| Suitable container | ▶ DO NOT repack. Use containers supplied by manufacturer only. |
| Storage incompatibility | ▶ Avoid contact with copper, aluminium and their alloys. |
| Hazard categories in accordance with Regulation (EC) No 1272/2008 | E1: Hazardous to the Aquatic Environment in Category Acute 1 or Chronic 1 |
| Qualifying quantity (tonnes) of dangerous substances as referred to in Article 3(10) for the application of | E1 Lower- / Upper-tier requirements: 100 / 200 |

7.3. Specific end use(s)

See section 1.2

SECTION 8 Exposure controls / personal protection

8.1. Control parameters

| Ingredient | DNELs Exposure Pattern Worker | PNECs Compartment |
|------------|--|----------------------|
| water | Dermal 0.02 mg/kg bw/day (Systemic, Chronic) Inhalation 0.12 mg/m ³ (Systemic, Chronic) Inhalation 0.11 mg/m ³ (Local, Chronic) Dermal 5 mg/kg bw/day (Systemic, Acute) Inhalation 2.5 mg/m ³ (Systemic, Acute) | Not Available |

Continued...

Riva Star

| Ingredient | DNELs Exposure Pattern Worker | PNECs Compartment |
|------------|---|----------------------|
| | Inhalation 0.33 mg/m ³ (Local, Acute) Dermal 0.35 mg/kg bw/day (Systemic, Chronic) * Inhalation 0.144 mg/m ³ (Systemic, Chronic) * Oral 0.08 mg/kg bw/day (Systemic, Chronic) * Inhalation 0.03 mg/m ³ (Local, Chronic) * Dermal 2.5 mg/kg bw/day (Systemic, Acute) * Inhalation 1.96 mg/m ³ (Systemic, Acute) * Oral 2.5 mg/kg bw/day (Systemic, Acute) * Inhalation 0.09 mg/m ³ (Local, Acute) * | |

* Values for General Population

Occupational Exposure Limits (OEL)

INGREDIENT DATA

| Source | Ingredient | Material name | TWA | STEL | Peak | Notes |
|--------------------------------------|--------------------|----------------------------------|------------------------|---------------|---------------|---------------|
| UK Workplace Exposure Limits (WELs). | silver(I) fluoride | Fluoride (inorganic as F) | 2.5 mg/m ³ | Not Available | Not Available | Not Available |
| UK Workplace Exposure Limits (WELs). | silver(I) fluoride | Silver (soluble compounds as Ag) | 0.01 mg/m ³ | Not Available | Not Available | Not Available |

Emergency Limits

| Ingredient | TEEL-1 | TEEL-2 | TEEL-3 |
|------------|--------|---------|-----------|
| ammonia | 61 ppm | 330 ppm | 2,300 ppm |

| Ingredient | Original IDLH | Revised IDLH |
|--------------------|----------------------|---------------|
| silver(I) fluoride | 10 mg/m ³ | Not Available |
| ammonia | Not Available | Not Available |
| water | Not Available | Not Available |

Occupational Exposure Banding

| Ingredient | Occupational Exposure Band Rating | Occupational Exposure Band Limit |
|------------|-----------------------------------|----------------------------------|
| ammonia | 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

8.2. Exposure controls

| | | |
|--|--|----------------------------------|
| 8.2.1. 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 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.</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.) |
| | 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 |
| 3: Intermittent, low production. | 3: High production, heavy use | |
| 4: Large hood or large air mass in motion | 4: Small hood-local control only | |
| <p>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</p> | | |

Continued...

Riva Star

| | |
|---|---|
| | more when extraction systems are installed or used. |
| 8.2.2. Individual protection measures, such as personal protective equipment |  |
| Eye and face protection | <ul style="list-style-type: none"> ▶ Safety glasses with side shields ▶ Chemical goggles. [AS/NZS 1337.1, EN166 or national equivalent] ▶ 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]. |
| 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 | <p>No special equipment needed when handling small quantities.</p> <p>OTHERWISE:</p> <ul style="list-style-type: none"> ▶ Overalls. ▶ Barrier cream. ▶ Eyewash unit. |

Respiratory protection

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

Where the concentration of gas/particulates in the breathing zone, approaches or exceeds the "Exposure Standard" (or ES), respiratory protection is required. Degree of protection varies with both face-piece and Class of filter; the nature of protection varies with Type of filter.

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

^ - Full-face

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

8.2.3. Environmental exposure controls

See section 12

SECTION 9 Physical and chemical properties**9.1. Information on basic physical and chemical properties**

| | | | |
|---|--|--|----------------|
| Appearance | Clear, colourless liquid with ammonia odour. | | |
| Physical state | Liquid | Relative density (Water = 1) | 1.2 |
| Odour | Not Available | Partition coefficient n-octanol / water | Not Available |
| Odour threshold | Not Available | Auto-ignition temperature (°C) | Not Available |
| pH (as supplied) | Not Available | Decomposition temperature (°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 |
| Nanoform Solubility | Not Available | Nanoform Particle Characteristics | Not Available |
| Particle Size | Not Available | | |

9.2. Other information

Not Available

SECTION 10 Stability and reactivity

| | |
|---|---|
| 10.1.Reactivity | See section 7.2 |
| 10.2. Chemical stability | Product is considered stable and hazardous polymerisation will not occur. |
| 10.3. Possibility of hazardous reactions | See section 7.2 |
| 10.4. Conditions to avoid | See section 7.2 |
| 10.5. Incompatible materials | See section 7.2 |
| 10.6. Hazardous decomposition products | See section 5.3 |

SECTION 11 Toxicological information**11.1. 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 can produce chemical burns within the oral cavity and gastrointestinal tract following ingestion. Accidental ingestion of the material may be damaging to the health of the individual. |
| Skin Contact | The material can produce chemical burns following direct contact with the skin. Open cuts, abraded or irritated skin should not be exposed to this material Entry into the blood-stream through, for example, cuts, abrasions, puncture wounds or lesions, may produce systemic injury with harmful effects. Examine the skin prior to the use of the material and ensure that any external damage is suitably protected. |
| Eye | The material can produce chemical burns to the eye following direct contact. Vapours or mists may be extremely irritating. |
| Chronic | Limited evidence suggests that repeated or long-term occupational exposure may produce cumulative health effects involving organs or biochemical systems. Repeated or prolonged exposure to acids may result in the erosion of teeth, inflammatory and ulcerative changes in the mouth and necrosis (rarely) of the jaw. Bronchial irritation, with cough, and frequent attacks of bronchial pneumonia may ensue. Gastrointestinal disturbances may also occur. Chronic exposures may result in dermatitis and/or conjunctivitis. The impact of inhaled acidic agents on the respiratory tract depends upon a number of interrelated factors. These include physicochemical characteristics, e.g., gas versus aerosol; particle size (small particles can penetrate deeper into the lung); water solubility (more soluble agents are more likely to be removed in the nose and mouth). Given the general lack of information on the particle size of aerosols involved in occupational exposures to acids, it is difficult to identify their principal deposition site within the respiratory tract. Acid mists containing particles with a diameter of up to a few micrometers will be deposited in both the upper and lower airways. They are irritating to mucous epithelia, they cause dental erosion, and they produce acute effects in the lungs (symptoms and changes in pulmonary function). Asthmatics appear to be at particular risk for pulmonary effects. |

| | | |
|---------------------------|--|---|
| Riva Star | TOXICITY | IRRITATION |
| | Not Available | Not Available |
| silver(I) fluoride | TOXICITY | IRRITATION |
| | Not Available | Not Available |
| ammonia | TOXICITY | IRRITATION |
| | Inhalation(Rat) LC50: 2000 ppm4h ^[2] Oral (Rat) LD50: 350 mg/kg ^[2] | Eye (rabbit): 0.25 mg SEVERE Eye (rabbit): 1 mg/30s SEVERE |
| water | TOXICITY | IRRITATION |
| | Oral (Rat) LD50: >90000 mg/kg ^[2] | 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

| | |
|---|---|
| AMMONIA | The material may produce severe irritation to the eye causing pronounced inflammation. Repeated or prolonged exposure to irritants may produce conjunctivitis. |
| SILVER(I) FLUORIDE & AMMONIA | 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. |

Riva Star

| | | | |
|---|--|---------------------------------|---|
| SILVER(I) FLUORIDE & AMMONIA & WATER | No significant acute toxicological data identified in literature search. | | |
| 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

11.2 Information on other hazards

11.2.1. Endocrine disrupting properties

No evidence of endocrine disrupting properties were found in the current literature.

11.2.2. Other information

See Section 11.1

SECTION 12 Ecological information

12.1. Toxicity

| | Endpoint | Test Duration (hr) | Species | Value | Source |
|---------------------------|--|--------------------|---------------|---------------|---------------|
| Riva Star | Not Available | Not Available | Not Available | Not Available | Not Available |
| silver(I) fluoride | Not Available | Not Available | Not Available | Not Available | Not Available |
| ammonia | LC50 | 96h | Fish | 33.3mg/L | 4 |
| | EC50(ECx) | 96h | Crustacea | 0.83mg/L | 5 |
| water | 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 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 | | | | |

Very toxic to aquatic organisms.

DO NOT discharge into sewer or waterways.

12.2. Persistence and degradability

| Ingredient | Persistence: Water/Soil | Persistence: Air |
|------------|-------------------------|------------------|
| water | LOW | LOW |

12.3. Bioaccumulative potential

| Ingredient | Bioaccumulation |
|------------|---------------------------------------|
| | No Data available for all ingredients |

12.4. Mobility in soil

| Ingredient | Mobility |
|------------|---------------------------------------|
| | No Data available for all ingredients |

12.5. Results of PBT and vPvB assessment

| | P | B | T |
|-------------------------|---------------|---------------|---------------|
| Relevant available data | Not Available | Not Available | Not Available |
| PBT | ✗ | ✗ | ✗ |
| vPvB | ✗ | ✗ | ✗ |
| PBT Criteria fulfilled? | No | | |
| vPvB | No | | |

12.6. Endocrine disrupting properties

No evidence of endocrine disrupting properties were found in the current literature.

12.7. Other adverse effects

No evidence of ozone depleting properties were found in the current literature.



SECTION 13 Disposal considerations

13.1. Waste treatment methods

| | |
|------------------------------|---|
| Product / Packaging disposal | <ul style="list-style-type: none"> ▶ DO NOT allow wash water from cleaning or process equipment to enter drains. ▶ It may be necessary to collect all wash water for treatment before disposal. ▶ In all cases disposal to sewer may be subject to local laws and regulations and these should be considered first. ▶ Where in doubt contact the responsible authority. <p>Consult State Land Waste Management Authority for disposal. Bury residue in an authorised landfill.</p> |
| Waste treatment options | Not Available |
| Sewage disposal options | Not Available |

SECTION 14 Transport information

Labels Required

| | |
|------------------|--|
| |  |
| Marine Pollutant |  |
| HAZCHEM | 2X |

Land transport (ADR-RID)

| | | |
|------------------------------------|--|----------------|
| 14.1. UN number or ID number | 2672 | |
| 14.2. UN proper shipping name | AMMONIA SOLUTION, relative density between 0.880 and 0.957 at 15 °C in water, with more than 10% but not more than 35% ammonia | |
| 14.3. Transport hazard class(es) | Class | 8 |
| | Subsidiary Hazard | Not Applicable |
| 14.4. Packing group | III | |
| 14.5. Environmental hazard | Environmentally hazardous | |
| 14.6. Special precautions for user | Hazard identification (Kemler) | 80 |
| | Classification code | C5 |
| | Hazard Label | 8 |
| | Special provisions | 543 |
| | Limited quantity | 5 L |
| | Tunnel Restriction Code | E |

Air transport (ICAO-IATA / DGR)

| | | |
|------------------------------------|---|----------------|
| 14.1. UN number | 2672 | |
| 14.2. UN proper shipping name | Ammonia solution relative density (specific gravity) between 0.880 and 0.957 at 15°C in water, with more than 10% but not more than 35% ammonia | |
| 14.3. Transport hazard class(es) | ICAO/IATA Class | 8 |
| | ICAO / IATA Subsidiary Hazard | Not Applicable |
| | ERG Code | 8L |
| 14.4. Packing group | III | |
| 14.5. Environmental hazard | Environmentally hazardous | |
| 14.6. Special precautions for user | Special provisions | A64 A803 |
| | Cargo Only Packing Instructions | 856 |
| | Cargo Only Maximum Qty / Pack | 60 L |
| | Passenger and Cargo Packing Instructions | 852 |
| | Passenger and Cargo Maximum Qty / Pack | 5 L |
| | Passenger and Cargo Limited Quantity Packing Instructions | Y841 |

Riva Star

Passenger and Cargo Limited Maximum Qty / Pack

1 L

Sea transport (IMDG-Code / GGVSee)

| | | |
|------------------------------------|---|----------------|
| 14.1. UN number | 2672 | |
| 14.2. UN proper shipping name | AMMONIA SOLUTION relative density between 0.880 and 0.957 at 15Å°C in water, with more than 10% but not more than 35% ammonia | |
| 14.3. Transport hazard class(es) | IMDG Class | 8 |
| | IMDG Subsidiary Hazard | Not Applicable |
| 14.4. Packing group | III | |
| 14.5. Environmental hazard | Marine Pollutant | |
| 14.6. Special precautions for user | EMS Number | F-A, S-B |
| | Special provisions | Not Applicable |
| | Limited Quantities | 5 L |

Inland waterways transport (ADN)

| | | |
|------------------------------------|--|----------------|
| 14.1. UN number | 2672 | |
| 14.2. UN proper shipping name | AMMONIA SOLUTION, relative density between 0.880 and 0.957 at 15 °C in water, with more than 10% but not more than 35% ammonia | |
| 14.3. Transport hazard class(es) | 8 | Not Applicable |
| 14.4. Packing group | III | |
| 14.5. Environmental hazard | Environmentally hazardous | |
| 14.6. Special precautions for user | Classification code | C5 |
| | Special provisions | 543 |
| | Limited quantity | 5 L |
| | Equipment required | PP, EP |
| | Fire cones number | 0 |

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 |
|--------------------|---------------|
| silver(I) fluoride | Not Available |
| ammonia | Not Available |
| water | Not Available |

14.7.3. Transport in bulk in accordance with the IGC Code

| Product name | Ship Type |
|--------------------|---------------|
| silver(I) fluoride | Not Available |
| ammonia | Not Available |
| water | Not Available |

If packed as Chemical kits the following classification may be considered if all ICAO/IATA transport requirements are met: Chemical Kit UN3316 - Class 9, SP A44 & A163.

SECTION 15 Regulatory information

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

silver(I) fluoride is found on the following regulatory lists

International Agency for Research on Cancer (IARC) - Agents Classified by the IARC Monographs - Not Classified as Carcinogenic
UK Workplace Exposure Limits (WELs).

ammonia is found on the following regulatory lists

Great Britain GB mandatory classification and labelling list (GB MCL)

water is found on the following regulatory lists

Not Applicable

Additional Regulatory Information

Not Applicable

This safety data sheet is in compliance with the following EU legislation and its adaptations - as far as applicable - : Directives 98/24/EC, - 92/85/EEC, - 94/33/EC, - 2008/98/EC, - 2010/75/EU; Commission Regulation (EU) 2020/878; Regulation (EC) No 1272/2008 as updated through ATPs.

Continued...

Information according to 2012/18/EU (Seveso III):

| | |
|------------------------|----|
| Seveso Category | E1 |
|------------------------|----|

15.2. Chemical safety assessment

No Chemical Safety Assessment has been carried out for this substance/mixture by the supplier.

National Inventory Status

| National Inventory | Status |
|---|---|
| Australia - AIIC / Australia Non-Industrial Use | Yes |
| Canada - DSL | No (silver(I) fluoride) |
| Canada - NDSL | No (ammonia; water) |
| China - IECSC | No (silver(I) fluoride) |
| Europe - EINEC / ELINCS / NLP | Yes |
| Japan - ENCS | Yes |
| Korea - KECI | Yes |
| New Zealand - NZIoC | Yes |
| Philippines - PICCS | No (silver(I) fluoride) |
| USA - TSCA | Yes |
| Taiwan - TCSI | Yes |
| Mexico - INSQ | No (silver(I) fluoride) |
| Vietnam - NCI | Yes |
| Russia - FBEPH | Yes |
| 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 | 16/11/2015 |

Full text Risk and Hazard codes

| | |
|-----------------------|---|
| H301+H311+H331 | Toxic if swallowed, in contact with skin or if inhaled. |
| H318 | Causes serious eye damage. |
| H332 | Harmful if inhaled. |

SDS Version Summary

| Version | Date of Update | Sections Updated |
|---------|----------------|---|
| 8.1 | 10/12/2021 | Classification change due to full database hazard calculation/update. |
| 9.1 | 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.

For detailed advice on Personal Protective Equipment, refer to the following EU CEN Standards:

- EN 166 Personal eye-protection
- EN 340 Protective clothing
- EN 374 Protective gloves against chemicals and micro-organisms
- EN 13832 Footwear protecting against chemicals
- EN 133 Respiratory protective devices

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
- ▶ 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:

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



Gingival Barrier

SDI Limited

Version No: 11.1

Safety data sheet according to REACH Regulation (EC) No 1907/2006, as amended by UK REACH Regulations SI 2019/758

Issue Date: 10/03/2023

Print Date: 20/11/2023

L.REACH.GB.EN

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

1.1. Product Identifier

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

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

| | |
|--------------------------|--|
| Relevant identified uses | For tissue isolation by dental professionals. |
| Uses advised against | No specific uses advised against are identified. |

1.3. Details of the manufacturer or supplier of the safety data sheet

| Registered company name | SDI Limited | SDI (North America) Inc. | SDI Germany GmbH |
|-------------------------|--|---|--|
| Address | 3-15 Brunsdon Street Bayswater VIC 3153 Australia | 1279 Hamilton Parkway Itasca IL 60143 United States | Hansestrasse 85 Cologne D-51149 Germany |
| Telephone | +61 3 8727 7111 | +1 630 361 9200 | +49 0 2203 9255 0 |
| Fax | +61 3 8727 7222 | Not Available | +49 0 2203 9255 200 |
| Website | www.sdi.com.au | www.sdi.com.au | www.sdi.com.au |
| Email | info@sdi.com.au | USA.Canada@sdi.com.au | germany@sdi.com.au |

| | |
|-------------------------|---|
| Registered company name | SDI HOLDINGS PTY LTD DO |
| Address | Rua Dr. Reinaldo Schmithausen 3141 – Cordeiros Itajaí – SC – CEP 88310-004 Brazil |
| Telephone | +55 11 3092 7100 |
| Fax | Not Available |
| Website | http://www.sdi.com.au/ |
| Email | Brasil@sdi.com.au |

1.4. Emergency telephone number

| | | |
|-----------------------------------|-----------------------------------|-------------------------------------|
| Association / Organisation | SDI Limited | CHEMWATCH EMERGENCY RESPONSE (24/7) |
| Emergency telephone numbers | 131126 Poisons Information Centre | +44 20 3901 3542 |
| Other emergency telephone numbers | +61 3 8727 7111 | +44 808 164 9592 |

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

SECTION 2 Hazards identification

2.1. Classification of the substance or mixture

| | |
|---|---|
| Classified according to GB-CLP Regulation, UK SI 2019/720 and UK SI 2020/1567 [1] | H315 - Skin Corrosion/Irritation Category 2, H317 - Sensitisation (Skin) Category 1, H319 - Serious Eye Damage/Eye Irritation Category 2, H411 - Hazardous to the Aquatic Environment Long-Term Hazard Category 2 |
| Legend: | 1. Classification by vendor; 2. Classification drawn from GB-CLP Regulation, UK SI 2019/720 and UK SI 2020/1567 |

2.2. 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. |

Supplementary statement(s)

Not Applicable

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. |
|------|--|

2.3. Other hazards

May produce discomfort of the eyes and skin*.

Vapours potentially cause drowsiness and dizziness*.

REACH - Art.57-59: The mixture does not contain Substances of Very High Concern (SVHC) at the SDS print date.

SECTION 3 Composition / information on ingredients

3.1. Substances

See 'Composition on ingredients' in Section 3.2

3.2. Mixtures

| 1. CAS No 2. EC No 3. Index No 4. REACH No | %[weight] | Name | Classified according to GB-CLP Regulation, UK SI 2019/720 and UK SI 2020/1567 | SCL / M-Factor | Nanoform Particle Characteristics |
|--|--|--|---|----------------|-----------------------------------|
| 1. 109-16-0 2. 203-652-6 3. Not Available 4. 01-2119969287-21-XXXX | 10-15 | <u>triethylene glycol dimethacrylate</u> | Skin Corrosion/Irritation Category 2, Sensitisation (Skin) Category 1, Serious Eye Damage/Eye Irritation Category 2, Specific Target Organ Toxicity - Single Exposure (Respiratory Tract Irritation) Category 3, Hazardous to the Aquatic Environment Long-Term Hazard Category 2; H315, H317, H319, H335, H411 [1] | Not Available | Not Available |
| 1. 72869-86-4 2. 276-957-5 3. 616-087-00-9 4. 01-2119381661-37-XXXX 01-0000015956-58-XXXX 01-2120751202-68-XXXX | 65-70 | <u>diurethane dimethacrylate</u> | Sensitisation (Skin) Category 1, Serious Eye Damage/Eye Irritation Category 2, Hazardous to the Aquatic Environment Long-Term Hazard Category 2; H317, H319, H411 [2] | Not Available | Not Available |
| Legend: | 1. Classification by vendor; 2. Classification drawn from GB-CLP Regulation, UK SI 2019/720 and UK SI 2020/1567; 3. Classification drawn from C&L; * EU IOELVs available; [e] Substance identified as having endocrine disrupting properties | | | | |

SECTION 4 First aid measures

4.1. 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. |
|-------------|---|

Continued...

Gingival Barrier

| | |
|---------------------|---|
| Skin Contact | <p>If skin contact occurs:</p> <ul style="list-style-type: none"> ▶ Immediately remove all contaminated clothing, including footwear. ▶ Flush skin and hair with running water (and soap if available). ▶ Seek medical attention in event of irritation. |
| Inhalation | <ul style="list-style-type: none"> ▶ If fumes, aerosols or combustion products are inhaled remove from contaminated area. ▶ Other measures are usually unnecessary. |
| Ingestion | Seek medical attention. |

4.2 Most important symptoms and effects, both acute and delayed

See Section 11

4.3. Indication of any immediate medical attention and special treatment needed

Treat symptomatically.

SECTION 5 Firefighting measures

5.1. Extinguishing media

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

5.2. Special hazards arising from the substrate or mixture

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

5.3. 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

6.1. Personal precautions, protective equipment and emergency procedures

See section 8

6.2. Environmental precautions

See section 12

6.3. 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. |

6.4. Reference to other sections

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

SECTION 7 Handling and storage

Gingival Barrier

7.1. 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. |
| Fire and explosion protection | See section 5 |
| Other information | Store between 10 and 25 deg. C. Do not store in direct sunlight. |

7.2. 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 | ▶ Avoid storage with reducing agents. |
| Hazard categories in accordance with Regulation (EC) No 1272/2008 | E2: Hazardous to the Aquatic Environment in Category Chronic 2 |
| Qualifying quantity (tonnes) of dangerous substances as referred to in Article 3(10) for the application of | E2 Lower- / Upper-tier requirements: 200 / 500 |

7.3. Specific end use(s)

See section 1.2

SECTION 8 Exposure controls / personal protection

8.1. Control parameters

| Ingredient | DNELs Exposure Pattern Worker | PNECs Compartment |
|-----------------------------------|--|---|
| triethylene glycol dimethacrylate | Dermal 13.9 mg/kg bw/day (Systemic, Chronic) Inhalation 48.5 mg/m ³ (Systemic, Chronic) <i>Dermal 8.33 mg/kg bw/day (Systemic, Chronic) *</i> <i>Inhalation 14.5 mg/m³ (Systemic, Chronic) *</i> <i>Oral 8.33 mg/kg bw/day (Systemic, Chronic) *</i> | 0.016 mg/L (Water (Fresh)) 0.016 mg/L (Water - Intermittent release) 0.002 mg/L (Water (Marine)) 0.185 mg/kg sediment dw (Sediment (Fresh Water)) 0.018 mg/kg sediment dw (Sediment (Marine)) 0.027 mg/kg soil dw (Soil) 1.7 mg/L (STP) |
| diurethane dimethacrylate | Dermal 1.3 mg/kg bw/day (Systemic, Chronic) Inhalation 3.3 mg/m ³ (Systemic, Chronic) <i>Dermal 0.7 mg/kg bw/day (Systemic, Chronic) *</i> <i>Inhalation 0.6 mg/m³ (Systemic, Chronic) *</i> <i>Oral 0.3 mg/kg bw/day (Systemic, Chronic) *</i> | 0.01 mg/L (Water (Fresh)) 0.1 mg/L (Water - Intermittent release) 0.001 mg/L (Water (Marine)) 0.851 mg/kg sediment dw (Sediment (Fresh Water)) 0.46 mg/kg sediment dw (Sediment (Marine)) 0.167 mg/kg soil dw (Soil) 1 mg/L (STP) |

* Values for General Population

Occupational Exposure Limits (OEL)

INGREDIENT DATA

| Source | Ingredient | Material name | TWA | STEL | Peak | Notes |
|---------------|---------------|---------------|---------------|---------------|---------------|---------------|
| Not Available | Not Available | Not Available | Not Available | Not Available | Not Available | Not Available |

Not Applicable

Emergency Limits

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

| 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 |
|------------|-----------------------------------|----------------------------------|
|------------|-----------------------------------|----------------------------------|


Continued...

Gingival Barrier

| Ingredient | Occupational Exposure Band Rating | Occupational Exposure Band Limit |
|-----------------------------------|---|----------------------------------|
| triethylene glycol dimethacrylate | E | ≤ 0.1 ppm |
| diurethane dimethacrylate | E | ≤ 0.1 ppm |
| Notes: | <i>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.</i> | |

MATERIAL DATA

8.2. Exposure controls

| <p>8.2.1. Appropriate engineering controls</p> | <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> <table border="1" data-bbox="384 757 1495 1010"> <thead> <tr> <th>Type of Contaminant:</th> <th>Air Speed:</th> </tr> </thead> <tbody> <tr> <td>solvent, vapours, degreasing etc., evaporating from tank (in still air).</td> <td>0.25-0.5 m/s (50-100 f/min)</td> </tr> <tr> <td>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)</td> <td>0.5-1 m/s (100-200 f/min.)</td> </tr> <tr> <td>direct spray, spray painting in shallow booths, drum filling, conveyer loading, crusher dusts, gas discharge (active generation into zone of rapid air motion)</td> <td>1-2.5 m/s (200-500 f/min.)</td> </tr> <tr> <td>grinding, abrasive blasting, tumbling, high speed wheel generated dusts (released at high initial velocity into zone of very high rapid air motion).</td> <td>2.5-10 m/s (500-2000 f/min.)</td> </tr> </tbody> </table> <p>Within each range the appropriate value depends on:</p> <table border="1" data-bbox="384 1048 1118 1211"> <thead> <tr> <th>Lower end of the range</th> <th>Upper end of the range</th> </tr> </thead> <tbody> <tr> <td>1: Room air currents minimal or favourable to capture</td> <td>1: Disturbing room air currents</td> </tr> <tr> <td>2: Contaminants of low toxicity or of nuisance value only.</td> <td>2: Contaminants of high toxicity</td> </tr> <tr> <td>3: Intermittent, low production.</td> <td>3: High production, heavy use</td> </tr> <tr> <td>4: Large hood or large air mass in motion</td> <td>4: Small hood-local control only</td> </tr> </tbody> </table> <p>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.</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.) | 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.) | 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 | 3: Intermittent, low production. | 3: High production, heavy use | 4: Large hood or large air mass in motion | 4: Small hood-local control only |
|---|---|----------------------|------------|--|--------------------------------|---|----------------------------|--|----------------------------|--|---------------------------------|------------------------|------------------------|---|---------------------------------|--|----------------------------------|----------------------------------|-------------------------------|---|----------------------------------|
| 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.) | | | | | | | | | | | | | | | | | | | | |
| 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.) | | | | | | | | | | | | | | | | | | | | |
| 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 | | | | | | | | | | | | | | | | | | | | |
| 3: Intermittent, low production. | 3: High production, heavy use | | | | | | | | | | | | | | | | | | | | |
| 4: Large hood or large air mass in motion | 4: Small hood-local control only | | | | | | | | | | | | | | | | | | | | |
| <p>8.2.2. Individual protection measures, such as personal protective equipment</p> |  | | | | | | | | | | | | | | | | | | | | |
| <p>Eye and face protection</p> | <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] | | | | | | | | | | | | | | | | | | | | |
| <p>Skin protection</p> | <p>See Hand protection below</p> | | | | | | | | | | | | | | | | | | | | |
| <p>Hands/feet protection</p> | <ul style="list-style-type: none"> ▶ Wear chemical protective gloves, e.g. PVC. ▶ Wear safety footwear or safety gumboots, e.g. Rubber ▶ Rubber Gloves | | | | | | | | | | | | | | | | | | | | |
| <p>Body protection</p> | <p>See Other protection below</p> | | | | | | | | | | | | | | | | | | | | |
| <p>Other protection</p> | <p>No special equipment needed when handling small quantities.</p> <p>OTHERWISE:</p> <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.

Gingival Barrier

| 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)

8.2.3. Environmental exposure controls

See section 12

SECTION 9 Physical and chemical properties

9.1. 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 |
| Nanoform Solubility | Not Available | Nanoform Particle Characteristics | Not Available |
| Particle Size | Not Available | | |

9.2. Other information

Not Available

SECTION 10 Stability and reactivity

| | |
|--|---|
| 10.1.Reactivity | See section 7.2 |
| 10.2. Chemical stability | Product is considered stable and hazardous polymerisation will not occur. |
| 10.3. Possibility of hazardous reactions | See section 7.2 |
| 10.4. Conditions to avoid | See section 7.2 |
| 10.5. Incompatible materials | See section 7.2 |
| 10.6. Hazardous decomposition products | See section 5.3 |

SECTION 11 Toxicological information

11.1. 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 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. |

Continued...

Gingival Barrier

| | | |
|--|--|--|
| 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 | IRRITATION |
| | Not Available | Not Available |
| triethylene glycol dimethacrylate | TOXICITY | IRRITATION |
| | dermal (mouse) LD50: >2000 mg/kg ^[1] | 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 | IRRITATION |
| | dermal (rat) LD50: >2000 mg/kg ^[1] | 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 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 \geq 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</p> |
|----------------------------------|---|

Gingival Barrier

| | |
|---|--|
| | <p>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 UV/EB acrylates are divided into two groups; "stenomeric" and "eurymeric" acrylates. The first group consists of well-defined acrylates which can be described by a simple idealised chemical; they are low molecular weight species with a very narrow weight distribution profile. The eurymeric acrylates cannot be described by an idealised structure and may differ fundamentally between various suppliers; they are of relatively high molecular weight and possess a wide weight distribution. Stenomeric acrylates are usually more hazardous than the eurymeric substances. Stenomeric acrylates are also well defined which allows comparison and exchange of toxicity data - this allows more accurate classification. The stenomerics cannot be classified as a group; they exhibit substantial variation. Based on the available oncogenicity data and without a better understanding of the carcinogenic mechanism the Health and Environmental Review Division (HERD), Office of Toxic Substances (OTS), of the US EPA previously concluded that all chemicals that contain the acrylate or methacrylate moiety (CH₂=CHCOO or CH₂=C(CH₃)COO) should be considered to be a carcinogenic hazard unless shown otherwise by adequate testing. This position has now been revised and acrylates and methacrylates are no longer <i>de facto</i> carcinogens. Where no "official" classification for acrylates and methacrylates exists, there has been cautious attempts to create classifications in the absence of contrary evidence. For example Monoalkyl or monoarylestere of acrylic acids should be classified as R36/37/38 and R51/53 Monoalkyl or monoaryl esters of methacrylic acid should be classified as R36/37/38</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. 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. 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

11.2 Information on other hazards

11.2.1. Endocrine disrupting properties

No evidence of endocrine disrupting properties were found in the current literature.

11.2.2. Other information

See Section 11.1

SECTION 12 Ecological information

12.1. Toxicity

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

Continued...

Gingival Barrier

| | | | | | |
|---------------------------|--|---------------------------|-------------------------------|--------------|---------------|
| | LC50 | 96h | Fish | 16.4mg/l | 2 |
| | 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: | 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 | | | | |

DO NOT discharge into sewer or waterways.

12.2. Persistence and degradability

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

12.3. Bioaccumulative potential

| Ingredient | Bioaccumulation |
|-----------------------------------|---------------------|
| triethylene glycol dimethacrylate | LOW (LogKOW = 1.88) |

12.4. Mobility in soil

| Ingredient | Mobility |
|-----------------------------------|----------------|
| triethylene glycol dimethacrylate | LOW (KOC = 10) |

12.5. Results of PBT and vPvB assessment

| | P | B | T |
|-------------------------|---------------|---------------|---------------|
| Relevant available data | Not Available | Not Available | Not Available |
| PBT | ✘ | ✘ | ✘ |
| vPvB | ✘ | ✘ | ✘ |
| PBT Criteria fulfilled? | No | | |
| vPvB | No | | |

12.6. Endocrine disrupting properties

No evidence of endocrine disrupting properties were found in the current literature.

12.7. Other adverse effects

No evidence of ozone depleting properties were found in the current literature.


SECTION 13 Disposal considerations

13.1. Waste treatment methods

| | |
|-------------------------------------|---|
| Product / Packaging disposal | Consult State Land Waste Management Authority for disposal. Bury residue in an authorised landfill. |
| Waste treatment options | Not Available |
| Sewage disposal options | Not Available |

SECTION 14 Transport information

Labels Required

| | |
|-------------------------|---|
| Marine Pollutant |  |
| HAZCHEM | Not Applicable |

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

| | |
|-------------------------------|----------------|
| 14.1. UN number or ID number | Not Applicable |
| 14.2. UN proper shipping name | Not Applicable |

Gingival Barrier

| | | |
|------------------------------------|--------------------------------|----------------|
| 14.3. Transport hazard class(es) | Class | Not Applicable |
| | Subsidiary Hazard | Not Applicable |
| 14.4. Packing group | Not Applicable | |
| 14.5. Environmental hazard | Not Applicable | |
| 14.6. Special precautions for user | Hazard identification (Kemler) | Not Applicable |
| | Classification code | Not Applicable |
| | Hazard Label | Not Applicable |
| | Special provisions | Not Applicable |
| | Limited quantity | Not Applicable |
| | Tunnel Restriction Code | Not Applicable |

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

| | | |
|------------------------------------|---|----------------|
| 14.1. UN number | Not Applicable | |
| 14.2. UN proper shipping name | Not Applicable | |
| 14.3. Transport hazard class(es) | ICAO/IATA Class | Not Applicable |
| | ICAO / IATA Subsidiary Hazard | Not Applicable |
| | ERG Code | Not Applicable |
| 14.4. Packing group | Not Applicable | |
| 14.5. Environmental hazard | Not Applicable | |
| 14.6. Special precautions for user | Special provisions | Not Applicable |
| | Cargo Only Packing Instructions | Not Applicable |
| | Cargo Only Maximum Qty / Pack | Not Applicable |
| | Passenger and Cargo Packing Instructions | Not Applicable |
| | Passenger and Cargo Maximum Qty / Pack | Not Applicable |
| | Passenger and Cargo Limited Quantity Packing Instructions | Not Applicable |
| | Passenger and Cargo Limited Maximum Qty / Pack | Not Applicable |

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

| | | |
|------------------------------------|------------------------|----------------|
| 14.1. UN number | Not Applicable | |
| 14.2. UN proper shipping name | Not Applicable | |
| 14.3. Transport hazard class(es) | IMDG Class | Not Applicable |
| | IMDG Subsidiary Hazard | Not Applicable |
| 14.4. Packing group | Not Applicable | |
| 14.5. Environmental hazard | Not Applicable | |
| 14.6. Special precautions for user | EMS Number | Not Applicable |
| | Special provisions | Not Applicable |
| | Limited Quantities | Not Applicable |

Inland waterways transport (ADN): NOT REGULATED FOR TRANSPORT OF DANGEROUS GOODS

| | | |
|------------------------------------|---------------------|----------------|
| 14.1. UN number | Not Applicable | |
| 14.2. UN proper shipping name | Not Applicable | |
| 14.3. Transport hazard class(es) | Not Applicable | Not Applicable |
| 14.4. Packing group | Not Applicable | |
| 14.5. Environmental hazard | Not Applicable | |
| 14.6. Special precautions for user | Classification code | Not Applicable |
| | Special provisions | Not Applicable |
| | Limited quantity | Not Applicable |
| | Equipment required | Not Applicable |
| | Fire cones number | Not Applicable |

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

Not Applicable

Continued...

Gingival Barrier

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 |
| diurethane dimethacrylate | Not Available |

SECTION 15 Regulatory information

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

triethylene glycol dimethacrylate is found on the following regulatory lists

Great Britain GB mandatory classification and labelling (GB MCL) technical reports

diurethane dimethacrylate is found on the following regulatory lists

Great Britain GB mandatory classification and labelling (GB MCL) technical reports

Great Britain GB mandatory classification and labelling list (GB MCL)

Additional Regulatory Information

Not Applicable

This safety data sheet is in compliance with the following EU legislation and its adaptations - as far as applicable - : Directives 98/24/EC, - 92/85/EEC, - 94/33/EC, - 2008/98/EC, - 2010/75/EU; Commission Regulation (EU) 2020/878; Regulation (EC) No 1272/2008 as updated through ATPs.

Information according to 2012/18/EU (Seveso III):

| Seveso Category | E2 |
|-----------------|----|
| | |

15.2. Chemical safety assessment

No Chemical Safety Assessment has been carried out for this substance/mixture by the supplier.

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 |

Full text Risk and Hazard codes

| | |
|------|-----------------------------------|
| H335 | May cause respiratory irritation. |
|------|-----------------------------------|

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

Gingival Barrier

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.

For detailed advice on Personal Protective Equipment, refer to the following EU CEN Standards:

- EN 166 Personal eye-protection
- EN 340 Protective clothing
- EN 374 Protective gloves against chemicals and micro-organisms
- EN 13832 Footwear protecting against chemicals
- EN 133 Respiratory protective devices

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
- ▶ 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:

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