



Stela Capsule

SDI Limited

Version No: 2.1

Safety Data Sheet (Conforms to Annex II of REACH (1907/2006) - Regulation 2020/878)

Issue Date: 25/08/2023

Print Date: 21/06/2024

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

1.1. Product Identifier

Product name	Stela Capsule
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	Professional dental use: For filling of cavitated teeth 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 Brunson 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	+353 1 443 4289
Other emergency telephone numbers	+61 3 8727 7111	+61 3 9573 3188

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


SECTION 2 Hazards identification

2.1. Classification of the substance or mixture

Classification according to regulation (EC) No 1272/2008 [CLP] and amendments [1]	H315 - Skin Corrosion/Irritation Category 2, H317 - Sensitisation (Skin) Category 1, H319 - Serious Eye Damage/Eye Irritation Category 2, H335 - Specific Target Organ Toxicity - Single Exposure (Respiratory Tract Irritation) Category 3
Legend:	1. Classification by vendor; 2. Classification drawn from Regulation (EU) No 1272/2008 - Annex VI

2.2. Label elements

Stela Capsule

Hazard pictogram(s)	
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Signal word	Warning
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Hazard statement(s)

H315	Causes skin irritation.
H317	May cause an allergic skin reaction.
H319	Causes serious eye irritation.
H335	May cause respiratory irritation.

Supplementary statement(s)

Not Applicable

Precautionary statement(s) Prevention

P271	Use only a well-ventilated area.
P280	Wear protective gloves, protective clothing, eye protection and face protection.
P261	Avoid breathing mist/vapours/spray.
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 and soap.
P305+P351+P338	IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
P312	Call a POISON CENTER/doctor/physician/first aider/if you feel unwell.
P333+P313	If skin irritation or rash occurs: Get medical advice/attention.
P337+P313	If eye irritation persists: Get medical advice/attention.
P362+P364	Take off contaminated clothing and wash it before reuse.
P304+P340	IF INHALED: Remove person to fresh air and keep comfortable for breathing.

Precautionary statement(s) Storage

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

Precautionary statement(s) Disposal

P501	Dispose of contents/container to authorised hazardous or special waste collection point in accordance with any local regulation.
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Material contains diurethane dimethacrylate, glycerol dimethacrylate, ytterbium(III) fluoride, 10-methacryloyloxydecyl dihydrogen phosphate.

2.3. Other hazards

Ingestion may produce health damage*.

Cumulative effects may result following exposure*.

Limited evidence of a carcinogenic effect*.

Possible respiratory sensitizer*.

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	Classification according to regulation (EC) No 1272/2008 [CLP] and amendments	SCL / M- Factor	Nanoform Particle Characteristics
1. 72869-86-4 2. 276-957-5 3. 616-087-00-9	10-25	<u>diurethane</u> <u>dimethacrylate</u>	Sensitisation (Skin) Category 1, Serious Eye Damage/Eye Irritation Category 2, Hazardous to the Aquatic	Not Available	Not Available

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Stela Capsule

1. CAS No 2. EC No 3. Index No 4. REACH No	% [weight]	Name	Classification according to regulation (EC) No 1272/2008 [CLP] and amendments	SCL / M-Factor	Nanoform Particle Characteristics
4.01-2119381661-37-XXXX 01-0000015956-58-XXXX 01-2120751202-68-XXXX			Environment Long-Term Hazard Category 2; H317, H319, H411 [2]	Acute M factor: Not Available Chronic M factor: Not Available	
1. 1830-78-0 2. 217-388-4 3. Not Available 4. Not Available	5-15	<u>glycerol dimethacrylate</u>	Skin Corrosion/Irritation Category 2, Serious Eye Damage/Eye Irritation Category 2, Specific Target Organ Toxicity - Single Exposure (Respiratory Tract Irritation) Category 3; H315, H319, H335 [1]	Not Available Acute M factor: Not Available Chronic M factor: Not Available	Not Available
1. 112945-52-5 2. 271-893-4 3. Not Available 4. Not Available	1-10	<u>silica amorphous, fumed</u>	Not Classified [1]	Not Available Acute M factor: Not Available Chronic M factor: Not Available	Not Available
1. 13760-80-0 2. 237-354-2 3. Not Available 4. 01-2120754122-65-XXXX	3-7	<u>ytterbium(III) fluoride</u> *	Acute Toxicity (Oral, Dermal and Inhalation) Category 4, Skin Corrosion/Irritation Category 2, Serious Eye Damage/Eye Irritation Category 2, Specific Target Organ Toxicity - Single Exposure (Respiratory Tract Irritation) Category 3; H302+H312+H332, H315, H319, H335 [1]	Not Available Acute M factor: Not Available Chronic M factor: Not Available	Not Available
1. 85590-00-7 2. Not Available 3. Not Available 4. Not Available	1-5	<u>10-methacryloyloxydecyl dihydrogen phosphate</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 4; H315, H317, H319, H335, H413 [1]	Not Available Acute M factor: Not Available Chronic M factor: Not Available	Not Available
Legend:	1. Classification by vendor; 2. Classification drawn from Regulation (EU) No 1272/2008 - Annex VI; 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.
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. ▶ Lay patient down. Keep warm and rested. ▶ Prostheses such as false teeth, which may block airway, should be removed, where possible, prior to initiating first aid procedures. ▶ Apply artificial respiration if not breathing, preferably with a demand valve resuscitator, bag-valve mask device, or pocket mask as trained. Perform CPR if necessary. ▶ Transport to hospital, or doctor, without delay.
Ingestion	<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

Continued...

Stela Capsule

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	▶ Avoid contamination with oxidising agents i.e. nitrates, oxidising acids, chlorine bleaches, pool chlorine etc. as ignition may result
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5.3. Advice for firefighters

Fire Fighting	<ul style="list-style-type: none"> ▶ Alert Fire Brigade and tell them location and nature of hazard. ▶ May be violently or explosively reactive. ▶ Wear full body protective clothing with breathing apparatus. ▶ Prevent, by any means available, spillage from entering drains or water course. ▶ Fight fire from a safe distance, with adequate cover. ▶ If safe, switch off electrical equipment until vapour fire hazard removed. ▶ Use water delivered as a fine spray to control the fire and cool adjacent area. ▶ Avoid spraying water onto liquid pools. ▶ Do not approach containers suspected to be hot. ▶ Cool fire exposed containers with water spray from a protected location. ▶ If safe to do so, remove containers from path of fire. ▶ Alert Fire Brigade and tell them location and nature of hazard. ▶ Wear breathing apparatus plus protective gloves. ▶ Prevent, by any means available, spillage from entering drains or water courses. ▶ Use water delivered as a fine spray to control fire and cool adjacent 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"> ▶ Combustible. ▶ Slight fire hazard when exposed to heat or flame. ▶ Heating may cause expansion or decomposition leading to violent rupture of containers. ▶ On combustion, may emit toxic fumes of carbon monoxide (CO). ▶ May emit acrid smoke. ▶ Mists containing combustible materials may be explosive. <p>Combustion products include:</p> <p>carbon monoxide (CO) carbon dioxide (CO₂) nitrogen oxides (NO_x) silicon dioxide (SiO₂) metal oxides other pyrolysis products typical of burning organic material.</p> <p>May emit clouds of acrid smoke May emit poisonous fumes. 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	<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 breathing apparatus plus protective gloves. ▶ 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.

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Stela Capsule

- ▶ 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.
- ▶ **DO NOT touch the spill material**

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"> ▶ Most acrylic monomers have low viscosity therefore pouring, material transfer and processing of these materials do not necessitate heating. ▶ Viscous monomers may require heating to facilitate handling. To facilitate product transfer from original containers, product must be heated to no more than 60 deg. C. (140 F.), for not more than 24 hours. ▶ Do NOT use localised heat sources such as band heaters to heat/ melt product. ▶ Do NOT use steam. ▶ Hot boxes or hot rooms are recommended for heating/ melting material. The hot box or hot room should be set a maximum temperature of 60 deg. C. (140 F.). ▶ Do NOT overheat - this may compromise product quality and /or result in an uncontrolled hazardous polymerisation. ▶ If product freezes, heat as indicated above and mix gently to redistribute the inhibitor. Product should be consumed in its entirety after heating/ melting; avoid multiple "reheats" which may affect product quality or result in product degradation. ▶ Product should be packaged with inhibitor(s). Unless inhibited, product may polymerise, raising temperature and pressure, possibly rupturing container. Check inhibitor level periodically, adding to bulk material if needed. In addition, the product's inhibitor(s) require the presence of dissolved oxygen. Maintain, at a minimum, the original headspace in the product container and do NOT blanket or mix with oxygen-free gas as it renders the inhibitor ineffective. Ensure air space (oxygen) is present during product heating / melting. ▶ Store product indoors at temperatures greater than the product's freezing point (or greater than 0 deg. C. (32 F.)) if no freezing point available and below 38 deg. C (100 F.). ▶ Avoid prolonged storage (longer than shelf-life) storage temperatures above 38 deg. C (100 F.). ▶ Store in tightly closed containers in a properly vented storage area away from heat, sparks, open flame, strong oxidisers, radiation and other initiators. ▶ Prevent contamination by foreign materials. ▶ Prevent moisture contact. ▶ Use only non-sparking tools and limit storage time. Unless specified elsewhere, shelf-life is 6 months from receipt. ▶ 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	<ul style="list-style-type: none"> ▶ Polymerisation may occur slowly at room temperature. ▶ Storage requires stabilising inhibitor content and dissolved oxygen content to be monitored. Refer to manufacturer's recommended levels. ▶ DO NOT overfill containers so as to maintain free head space above product. ▶ Blanketing or sparging with nitrogen or oxygen free gas will deactivate stabiliser. ▶ Store below 38 deg. C. ▶ Store in original containers. ▶ Keep containers securely sealed. ▶ Store in a cool, dry, well-ventilated area. ▶ Store away from incompatible materials and foodstuff containers. ▶ Protect containers against physical damage and check regularly for leaks. ▶ Observe manufacturer's storage and handling recommendations contained within this SDS.

7.2. Conditions for safe storage, including any incompatibilities

Suitable container	<ul style="list-style-type: none"> ▶ Metal can or drum ▶ Packaging as recommended by manufacturer. ▶ Check all containers are clearly labelled and free from leaks.
Storage incompatibility	<p>for multifunctional acrylates:</p> <ul style="list-style-type: none"> ▶ Avoid exposure to free radical initiators (peroxides, persulfates) , iron, rust, oxidisers, and strong acids and strong bases. ▶ Avoid heat, flame, sunlight, X-rays or ultra-violet radiation. ▶ Storage beyond expiration date, may initiate polymerisation. Polymerisation of large quantities may be violent (even explosive) · Avoid reaction with water, alcohols and detergent solutions. Isocyanates are electrophiles, and as such they are reactive toward a variety of nucleophiles including alcohols, amines, and even water. Upon treatment with an alcohol, an isocyanate forms a urethane linkage. If a di-isocyanate is treated with a compound containing two or more hydroxyl groups, such as a diol or a polyol, polymer chains are formed, which are known as polyurethanes. Reaction between a di-isocyanate and a compound containing two or more amine groups, produces long polymer chains known as polyureas. · Isocyanates and thioisocyanates are incompatible with many classes of compounds, reacting exothermically to release toxic gases. Reactions with amines, strong bases, aldehydes, alcohols, alkali metals, ketones, mercaptans, strong oxidisers, hydrides, phenols, and peroxides can cause vigorous releases of heat. Acids and bases initiate polymerisation reactions in these materials. · Isocyanates also can react with themselves. Aliphatic di-isocyanates can form trimers, which are structurally related to cyanuric acid. Isocyanates participate in Diels-Alder reactions, functioning as dienophiles · Isocyanates easily form adducts with carbodimides, isothiocyanates, ketenes, or with substrates containing activated CC or CN bonds.

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Stela Capsule

	<ul style="list-style-type: none"> · Some isocyanates react with water to form amines and liberate carbon dioxide. This reaction may also generate large volumes of foam and heat. Foaming spaces may produce pressure in confined spaces or containers. Gas generation may pressurise drums to the point of rupture. · Do NOT reseal container if contamination is expected · Open all containers with care · Base-catalysed reactions of isocyanates with alcohols should be carried out in inert solvents. Such reactions in the absence of solvents often occur with explosive violence. · Isocyanates will attack and embrittle some plastics and rubbers. · The isocyanate anion is a pseudohalide (syn pseudohalogen) whose chemistry, resembling that of the true halogens, allows it to substitute for halogens in several classes of chemical compounds.. The behavior and chemical properties of the several pseudohalides are identical to that of the true halide ions. <ul style="list-style-type: none"> ▶ Avoid strong acids, bases. ▶ Stable under controlled storage conditions provided material contains adequate stabiliser / polymerisation inhibitor. ▶ Bulk storages may have special storage requirements ▶ WARNING: Gradual decomposition in strong, sealed containers may lead to a large pressure build-up and subsequent explosion. Rapid and violent polymerisation possible at temperatures above 32 deg c.
Hazard categories in accordance with Regulation (EC) No 2012/18/EU (Seveso III)	Not Available
Qualifying quantity (tonnes) of dangerous substances as referred to in Article 3(10) for the application of	Not Available

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
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
EU Consolidated List of Indicative Occupational Exposure Limit Values (IOELVs)	ytterbium(III) fluoride	Inorganic Fluorides	2.5 mg/m3	Not Available	Not Available	Skin
Ireland Occupational Exposure Limits	ytterbium(III) fluoride	Fluorides, inorganic	2.5 mg/m3	Not Available	Not Available	IOELV

Emergency Limits

Ingredient	TEEL-1	TEEL-2	TEEL-3
diurethane dimethacrylate	120 mg/m3	1,300 mg/m3	7,900 mg/m3
silica amorphous, fumed	18 mg/m3	100 mg/m3	630 mg/m3
ytterbium(III) fluoride	30 mg/m3	330 mg/m3	2,000 mg/m3

Ingredient	Original IDLH	Revised IDLH
diurethane dimethacrylate	Not Available	Not Available
glycerol dimethacrylate	Not Available	Not Available
silica amorphous, fumed	Not Available	Not Available
ytterbium(III) fluoride	Not Available	Not Available
10-methacryloyloxydecyl dihydrogen phosphate	Not Available	Not Available

Occupational Exposure Banding

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

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


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Stela Capsule

Ingredient	Occupational Exposure Band Rating	Occupational Exposure Band Limit
10-methacryloyloxydecyl dihydrogen phosphate	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

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>Local exhaust ventilation usually required. If risk of overexposure exists, wear approved respirator. Correct fit is essential to obtain adequate protection. Supplied-air type respirator may be required in special circumstances. Correct fit is essential to ensure adequate protection. An approved self contained breathing apparatus (SCBA) may be required in some situations.</p> <p>Provide adequate ventilation in warehouse or closed storage area. 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"> <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"> <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.)	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4: Large hood or large air mass in motion	4: Small hood-local control only																				
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	<p>NOTE:</p> <ul style="list-style-type: none"> ▶ The material may produce skin sensitisation in predisposed individuals. Care must be taken, when removing gloves and other protective equipment, to avoid all possible skin contact. ▶ Contaminated leather items, such as shoes, belts and watch-bands should be removed and destroyed. <p>General warning: Do NOT use latex gloves! Use only recommended gloves - using the wrong gloves may increase the risk:</p> <table border="1"> <tbody> <tr> <td> <p>Exposure condition</p> <p>Short time use; (few minutes less than 0.5 hour)</p> <p>Little physical stress</p> </td> <td> <p>Use of thin nitrile rubber gloves:</p> <p>Nitrile rubber (0.1 mm)</p> <p>Excellent tactility ("feel"), powder-free</p> <p>Disposable</p> <p>Inexpensive</p> <p>Give adequate protection to low molecular weight acrylic monomers</p> </td> </tr> <tr> <td> <p>Exposure condition</p> <p>Medium time use;</p> <p>less than 4 hours</p> </td> <td> <p>Use of medium thick nitrile rubber gloves</p> <p>Nitrile rubber, NRL (latex) free; <0.45 mm</p> <p>Moderate tactility ("feel"), powder-free</p> <p>Disposable</p> </td> </tr> </tbody> </table>	<p>Exposure condition</p> <p>Short time use; (few minutes less than 0.5 hour)</p> <p>Little physical stress</p>	<p>Use of thin nitrile rubber gloves:</p> <p>Nitrile rubber (0.1 mm)</p> <p>Excellent tactility ("feel"), powder-free</p> <p>Disposable</p> <p>Inexpensive</p> <p>Give adequate protection to low molecular weight acrylic monomers</p>	<p>Exposure condition</p> <p>Medium time use;</p> <p>less than 4 hours</p>	<p>Use of medium thick nitrile rubber gloves</p> <p>Nitrile rubber, NRL (latex) free; <0.45 mm</p> <p>Moderate tactility ("feel"), powder-free</p> <p>Disposable</p>																
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	Physical stress (opening drums, using tools, etc.)	Moderate price Gives adequate protection for most acrylates up to 4 hours Do NOT give adequate protection to low molecular weight monomers at exposures longer than 1 hour
	Exposure condition Long time Cleaning operations	Nitrile rubber, NRL (latex) free; >0.56 mm low tactility ("feel"), powder free High price Gives adequate protection for most acrylates in combination with commonly used solvents up to 8 hours Do NOT give adequate protection to low molecular weight monomers at exposures longer than 1 hour Avoid use of ketones and acetates in wash-up solutions.
	Where none of this gloves ensure safe handling (for example in long term handling of acrylates containing high levels of acetates and/ or ketones, use laminated multilayer gloves. Guide to the Classification and Labelling of UV/EB Acrylates Third edition, 231 October 2007 - Cefic <ul style="list-style-type: none"> ▶ Isocyanate resistant materials include Teflon, Viton, nitrile rubber and some PVA gloves. ▶ Protective gloves and overalls should be worn as specified in the appropriate national standard. ▶ Contaminated garments should be removed promptly and should not be re-used until they have been decontaminated. ▶ NOTE: Natural rubber, neoprene, PVC can be affected by isocyanates 	
Body protection	See Other protection below	
Other protection	<ul style="list-style-type: none"> ▶ Overalls. ▶ P.V.C apron. ▶ Barrier cream. ▶ Skin cleansing cream. ▶ Eye wash unit. 	

Respiratory protection

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

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

Required Minimum Protection Factor	Half-Face Respirator	Full-Face Respirator	Powered Air Respirator
up to 10 x ES	A-AUS P2	-	A-PAPR-AUS / Class 1 P2
up to 50 x ES	-	A-AUS / Class 1 P2	-
up to 100 x ES	-	A-2 P2	A-PAPR-2 P2 ^

^ - Full-face

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

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	Tooth coloured viscous flowable paste; does not mix with water.		
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 Applicable	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	Immiscible	pH as a solution (1%)	Not Applicable
Vapour density (Air = 1)	Not Available	VOC g/L	Not Available
Nanoform Solubility	Not Available	Nanoform Particle Characteristics	Not Available
Particle Size	Not Available		

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Stela Capsule

9.2. Other information

Not Available

SECTION 10 Stability and reactivity

10.1.Reactivity	See section 7.2
10.2. Chemical stability	<ul style="list-style-type: none"> ▶ Stable under controlled storage conditions provided material contains adequate stabiliser / polymerisation inhibitor. ▶ Bulk storages may have special storage requirements ▶ WARNING: Gradual decomposition in strong, sealed containers may lead to a large pressure build-up and subsequent explosion. Rapid and violent polymerisation possible at temperatures above 32 deg c. ▶ Unstable in the presence of incompatible materials. ▶ Product is considered stable. ▶ 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 hazard classes as defined in Regulation (EC) No 1272/2008

Inhaled	<p>Evidence shows, or practical experience predicts, that the material produces irritation of the respiratory system, in a substantial number of individuals, following inhalation. In contrast to most organs, the lung is able to respond to a chemical insult by first removing or neutralising the irritant and then repairing the damage. The repair process, which initially evolved to protect mammalian lungs from foreign matter and antigens, may however, produce further lung damage resulting in the impairment of gas exchange, the primary function of the lungs. Respiratory tract irritation often results in an inflammatory response involving the recruitment and activation of many cell types, mainly derived from the vascular system.</p> <p>Inhalation of vapours may cause drowsiness and dizziness. This may be accompanied by narcosis, reduced alertness, loss of reflexes, lack of coordination and vertigo.</p> <p>No report of respiratory illness in humans as a result of exposure to multifunctional acrylates has been found. Similarly evidence of systemic damage does not appear to exist.</p> <p>Inhalation hazard is increased at higher temperatures.</p> <p>The toxicology of rare earth metal oxides has been determined by pathological and biochemical examination of rodents exposed to the oxides by oral, intraperitoneal or endotracheal routes. Weakly expressed general toxic action of the oxides is seen in acute and prolonged exposure. The dusts cause pronounced changes in the lungs. (The oxides of the rare earth metals are significantly less toxic than their salts.)</p> <p>Symptoms of exposure to rare earth oxides are coughing, congestion, granuloma in lungs and haemoglobinaemia.</p> <p>Rare earths may cause impairment of blood clotting.</p> <p>Exposure to rare earth oxide vapours has been reported to result in sensitivity to heat, itching, and an increased awareness of odour and taste, bronchiolitis, sub-acute bronchiolitis (inflammation of the bronchial tubes), acute transient chemical pneumonitis (inflammation of the lungs caused by chemical irritation), focal hypertrophy (excessive development of an organ), emphysema, regional bronchiolar stricturing, cellular eosinophilia (abnormal increase in the number of leucocytes with cytoplasmic inclusions, in the blood that is characteristic of allergic reactions), and, in some cases, fatal delayed chemical hyperemia (excess of blood in a body part).</p> <p>Intratracheal administration to animals of some rare earth oxides, has been reported to cause changes ranging from mild to marked fibrosis (a condition marked by the increase of interstitial fibrous tissue), emphysema (a condition of the lungs marked by abnormal dilation of the air spaces and distension of its walls), small white nodules, granulomas (a mass or nodule of chronically inflamed tissue with granulations that are generally associated with an infective process), giant cells, and accumulation of dust in the lungs.</p> <p>In rare fatal cases of exposure to the rare-earth fluoride and/or oxide mixtures, delayed chemical hyperaemia has occurred. Lung granulomas have also been seen in experimental animals.</p> <p>Acute effects from inhalation of high vapour concentrations may be chest and nasal irritation with coughing, sneezing, headache and even nausea.</p>
Ingestion	Accidental ingestion of the material may be damaging to the health of the individual.
Skin Contact	<p>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.</p> <p>The material may accentuate any pre-existing dermatitis condition</p> <p>All multifunctional acrylates (MFA) produce skin discomfort and are known or suspected skin sensitisers. Aerosols generated in the industrial process are reported to produce dermatitis - vapours generated by the heat of milling may also occur in sufficient concentration to produce dermatitis. Because exposure to industrial aerosols of MFA may also include exposure to various resin systems, photo-initiators, solvents, hydrogen-transfer agents, stabilisers, surfactants, fillers and polymerisation inhibitors, toxic effects may arise due to a range of chemical actions.</p> <p>Open cuts, abraded or irritated skin should not be exposed to this material</p> <p>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.</p>
Eye	Evidence exists, or practical experience predicts, that the material may cause eye irritation in a substantial number of individuals and/or may produce significant ocular lesions which are present twenty-four hours or more after instillation into the eye(s) of experimental animals. 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	Long-term exposure to respiratory irritants may result in disease of the airways involving difficult breathing and related systemic problems. Practical experience shows that skin contact with the material is capable either of inducing a sensitisation reaction in a substantial number of individuals, and/or of producing a positive response in experimental animals.

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Substances that can cause occupational asthma (also known as asthmagens and respiratory sensitisers) can induce a state of specific airway hyper-responsiveness via an immunological, irritant or other mechanism. Once the airways have become hyper-responsive, further exposure to the substance, sometimes even to tiny quantities, may cause respiratory symptoms. These symptoms can range in severity from a runny nose to asthma. Not all workers who are exposed to a sensitiser will become hyper-responsive and it is impossible to identify in advance who are likely to become hyper-responsive.

Substances that can cause occupational asthma should be distinguished from substances which may trigger the symptoms of asthma in people with pre-existing air-way hyper-responsiveness. The latter substances are not classified as asthmagens or respiratory sensitisers. Wherever it is reasonably practicable, exposure to substances that can cause occupational asthma should be prevented. Where this is not possible the primary aim is to apply adequate standards of control to prevent workers from becoming hyper-responsive.

Activities giving rise to short-term peak concentrations should receive particular attention when risk management is being considered. Health surveillance is appropriate for all employees exposed or liable to be exposed to a substance which may cause occupational asthma and there should be appropriate consultation with an occupational health professional over the degree of risk and level of surveillance.

On the basis, primarily, of animal experiments, concern has been expressed by at least one classification body that the material may produce carcinogenic or mutagenic effects; in respect of the available information, however, there presently exists inadequate data for making a satisfactory assessment.

Limited evidence suggests that repeated or long-term occupational exposure may produce cumulative health effects involving organs or biochemical systems.

The synthetic, amorphous silicas are believed to represent a very greatly reduced silicosis hazard compared to crystalline silicas and are considered to be nuisance dusts.

When heated to high temperature and a long time, amorphous silica can produce crystalline silica on cooling. Inhalation of dusts containing crystalline silicas may lead to silicosis, a disabling pulmonary fibrosis that may take years to develop. Discrepancies between various studies showing that fibrosis associated with chronic exposure to amorphous silica and those that do not may be explained by assuming that diatomaceous earth (a non-synthetic silica commonly used in industry) is either weakly fibrogenic or nonfibrogenic and that fibrosis is due to contamination by crystalline silica content.

Ytterbium is a member of the so-called heavy-group (the yttriums) of the rare earths (or lanthanoids). No occupational diseases or cases of poisoning in workers producing rare earth elements have been described.

Lanthanoids entering the human body due to exposure to various industrial processes can affect metabolic processes. Trivalent lanthanoid ions, especially lanthanum 3+ and gadolinium 3+, can interfere with calcium channels in human and animal cells. Lanthanoids can also alter or even inhibit the action of various enzymes. Lanthanoid ions found in neurons can regulate synaptic transmission, as well as block some receptors (for example, glutamate receptors). Lanthanoids target the liver causing fatty liver degeneration and a decrease in liver glycogen and blood glucose levels.

Lanthanoids because of their high density can produce significant abnormalities in a chest X-ray. Lanthanoids are generally not fibrogenic and lesions typically have little or no clinical importance. Occasional cases of suspected pneumoconiosis have however been reported. The toxicity of all elements in the yttrium group has been investigated in workers and animals alike. Effects on peripheral blood including a decrease haemoglobin and erythrocyte content and changes in the leucocyte formula have been recorded. Animal lungs show productive inflammation and a tendency to develop nodular or diffuse sclerosis following administration by intratracheal injection. The main risks to workers involved in the production of rare earths are due to dust inhalation.

Based on the available toxicity data, the rare earth chlorides appear to have moderate acute and chronic toxicity. However these substances cause severe eye irritation and severe irritation in abraded skin. They are poorly absorbed by the gastrointestinal tract and by unbroken skin but slight liver damage has been demonstrated in subchronic oral toxicity studies at high doses. The literature indicates that chronic inhalation exposure to the rare earth chlorides may cause pneumoconiosis in humans. There are no indications of carcinogenicity in the rare earth chlorides. Mutagenicity studies on these substances have mixed results, but are predominantly negative.

* IUPAC currently recommends the name lanthanoid rather than lanthanide, as the suffix "-ide" generally indicates negative ions whereas the suffix "-oid" indicates similarity to one of the members of the containing family of elements. In the older literature, the name "lanthanon" was often used.

Repeated exposure to synthetic amorphous silicas may produce skin dryness and cracking.

Available data confirm the absence of significant toxicity by oral and dermal routes of exposure.

Numerous repeated-dose, subchronic and chronic inhalation toxicity studies have been conducted in a number of species, at airborne concentrations ranging from 0.5 mg/m³ to 150 mg/m³. Lowest-observed adverse effect levels (LOAELs) were typically in the range of 1 to 50 mg/m³. When available, the no-observed adverse effect levels (NOAELs) were between 0.5 and 10 mg/m³. Differences in values may be due to particle size, and therefore the number of particles administered per unit dose. Generally, as particle size diminishes so does the NOAEL/LOAEL. Exposure produced transient increases in lung inflammation, markers of cell injury and lung collagen content. There was no evidence of interstitial pulmonary fibrosis.

Persons with a history of asthma or other respiratory problems or are known to be sensitised, should not be engaged in any work involving the handling of isocyanates.

The chemistry of reaction of isocyanates, as evidenced by MDI, in biological milieu is such that in the event of a true exposure of small MDI doses to the mouth, reactions will commence at once with biological macromolecules in the buccal region and will continue along the digestive tract prior to reaching the stomach. Reaction products will be a variety of polyureas and macromolecular conjugates with for example mucus, proteins and cell components.

This is corroborated by the results from an MDI inhalation study. Following an inhalation exposure of rats to radiolabelled MDI, 79% of the dose was excreted in faeces. The faecal excretion in these animals was considered entirely due to ingestion of radioactivity from grooming and ingestion of deposited material from the nasopharyngeal region via the mucociliary escalator, i.e. not following systemic absorption. The faecal radioactivity was tentatively identified as mixed molecular weight polyureas derived from MDI. Diamine was not present. Thus, for MDI and diisocyanates in general the oral gavage dosing route is inappropriate for toxicological studies and risk assessment.

It is expected that oral gavage dosing will result in a similar outcome to that produced by TDI or MDI, that is (1) reaction with stomach contents and (2) polymerization to solid polyureas.

- ▶ Reaction with stomach contents is very plausibly described in case reports of accidental ingestion of polymeric MDI based glue in domestic animals. Extensive polymerization and CO₂ liberation resulting in an expansion of the gastric content is described in the stomach, without apparent acute chemical toxicity
- ▶ Polyurea formation in organic and aqueous phases has been described. In this generally accepted chemistry of hydrolysis of an isocyanate the initially produced carbamate decarboxylates to an amine which. The amine, as a reactive intermediate, then reacts very readily with the present isocyanate to produce a solid and inert polyurea. This urea formation acts as a pH buffer in the stomach, thus promoting transformation of the diisocyanate into polyurea, even under the acidic conditions.

At the absorptive tissues in the small intestine, these high molecular reaction products are likely to be of very low bioavailability, which is substantiated by the absence of systemic toxicity in acute oral bioassays with rats at the OECD limit dose (LC₅₀>2 g/kg bw).

The respiratory tract may be regarded as the main entry for systemically available isocyanates as evidenced following MDI exposures.

A detailed summary on urinary, plasma and in vitro metabolite studies is provided below. Taken together, all available studies provide convincing evidence that MDI-protein adduct and MDI-metabolite formation proceeds:

- ▶ via formation of a labile isocyanate glutathione (GSH)-adduct,
- ▶ then transfer to a more stable adduct with larger proteins, and
- ▶ without formation of free MDA. MDA reported as a metabolite is actually formed by analytical workup procedures (strong acid or base hydrolysis) and is not an identified metabolite in urine or blood

Sensitisation may give severe responses to very low levels of exposure, in situations where exposure may occur.

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	Not Available	Not Available
diurethane dimethacrylate	TOXICITY	IRRITATION
	dermal (rat) LD50: >2000 mg/kg ^[2]	Eye: adverse effect observed (irritating) ^[1]
	Oral (Rat) LD50: >2000 mg/kg ^[2]	Eye: no adverse effect observed (not irritating) ^[1]
		Skin: no adverse effect observed (not irritating) ^[1]
glycerol dimethacrylate	TOXICITY	IRRITATION
	Not Available	Not Available
silica amorphous, fumed	TOXICITY	IRRITATION
	Inhalation (Rat) LC50: 0.45 mg/L4h ^[2]	Not Available
	Oral (Rat) LD50: >5000 mg/kg ^[2]	
ytterbium(III) fluoride	TOXICITY	IRRITATION
	Oral (Rat) LD50: >2000 mg/kg ^[1]	Skin: no adverse effect observed (not irritating) ^[1]
10-methacryloyloxydecyl dihydrogen phosphate	TOXICITY	IRRITATION
	Not Available	Not Available

Legend:

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

DIURETHANE DIMETHACRYLATE

* 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 assay in vitro micronucleus assay was performed with the test substance (Schweikl, 2001). In two independent experiments, Chinese hamster lung fibroblasts were exposed to the test substance dissolved in DMSO at concentrations of 11.75, 23.5, 35.25 µg/mL for 24 h in the absence of metabolic activation. Cytotoxicity of the test substance was observed and the TC50 value was assessed to be 24 µg/mL. At cytotoxic concentration levels of the test substance (= 24 µg/mL) the numbers of micronuclei were slightly increased in the absence of metabolic activation. Ethyl methanesulphonate was used as positive control and produced a distinct increase in micronuclei frequency indicating that the test conditions were adequate. Under the conditions of this experiment, the potential of the test substance to induce micronuclei is equivocal. In vitro mutagenicity in mammalian cells An in vitro HPRT assay was performed with the test substance (Schweikl, 1998). In three replicate cultures Chinese hamster lung fibroblasts were exposed to the test substance dissolved in DMSO at concentrations of 11.75, 23.5, 35.25 µg/mL for 24 h in the absence of metabolic activation. Cytotoxicity of the test substance was observed at concentrations = 23.5 µg/mL. No mutagenic activity of UDMA was detected. Ethyl methanesulphonate was used as positive control and produced a distinct increase in mutant frequency indicating that the test conditions were adequate. Thus, under the conditions of this experiment, the test substance did not show mutagenicity in V79 cells without metabolic activation. Due to the positive result in the in vitro micronucleus test without metabolic activation at cytotoxic concentrations a micronucleus test in vivo should be conducted to conclude on genotoxic potential of the test substance. Reproductive toxicity: The available data on toxicity to reproduction do not meet the criteria for classification according to Regulation (EC) 1272/2008, and are therefore conclusive but not sufficient for classification. reproductive toxicity: NOAEL >= 1000 mg/kg bw/day for males and females of the parental generation systemic toxicity: NOAEL = 100 mg/kg bw/day for males and 300 mg/kg bw/day for females of the parental generation A reliable sub-acute study regarding reproductive/developmental toxicity is available for the test substance. The potential reproductive or developmental toxicity of the test substance was assessed in a sub-acute combined repeated dose toxicity study with the reproductive/developmental toxicity screening test in Hsd.Han: Wistar rats performed according to OECD Guideline

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Stela Capsule

	<p>422 and in compliance with GLP. Three groups of 12 male and 12 female rats received the test substance in polyethylene glycol as vehicle at doses of 100, 300 or 600 mg/kg bw/day orally via gavage at concentrations of 0, 25, 75 and 150 mg/mL corresponding to a 4 mL/kg bw dosing volume. A control group of 12 animals/sex received the vehicle only. In addition, 5 animals/sex were added to the control and high dose group to assess the reversibility of any effects observed at the high dose level (recovery group). All animals of the parental generation were dosed prior to mating (14 days) and throughout mating. In addition, males received the test item or vehicle after mating up to the day before necropsy (altogether for 56 days). Females were additionally exposed through the gestation period and up to lactation days 13 - 21, i.e. up to the day before necropsy (altogether for 56, 57 or 64 days). Observations included mortality, clinical signs, body weight, food consumption, mating, pregnancy and delivery process, lactation as well as development of offspring. The dams were allowed to litter, and rear their offspring up to day 13 post-partum. Litters were weighed and offspring were observed for possible abnormalities and were euthanized on post-natal day 13 or shortly thereafter. Blood samples were collected for determination of serum levels of thyroid hormones (T4) from all pups per litter at termination on post-natal day 13. No adverse effect on mortality, clinical signs, body weight or necropsy findings were detected in the offspring terminated as scheduled. Thyroid hormone levels (T4) in pups on post-natal day 13 were not affected. The anogenital distance (male and female) or nipple retention (male) was not affected due to treatment with the test substance. For the parental animals pale livers and histopathological changes in the liver (hepatic lipidosis) were observed at 300 mg/kg bw/day for males and 1000 mg/kg bw/day for females. Thus, under the conditions of this study, the NOAEL of the test substance for systemic toxicity of the parental generation following oral administration via gavage for 56 days is 100 mg/kg bw/day in male Wistar rats. The corresponding NOAEL in female Wistar rats following oral administration via gavage for 56, 57 or 64 days is 300 mg/kg bw/day. The corresponding NOAEL for the offspring is 1000 mg/kg bw/day. * REACH Dossier</p>
<p>GLYCEROL DIMETHACRYLATE</p>	<p>The material may produce severe irritation to the eye causing pronounced inflammation. Repeated or prolonged exposure to irritants may produce conjunctivitis.</p> <p>The material may cause skin irritation after prolonged or repeated exposure and may produce a contact dermatitis (nonallergic). This form of dermatitis is often characterised by skin redness (erythema) and swelling the epidermis. Histologically there may be intercellular oedema of the spongy layer (spongiosis) and intracellular oedema of the epidermis.</p>
<p>SILICA AMORPHOUS, FUMED</p>	<p>For silica amorphous:</p> <p>Derived No Adverse Effects Level (NOAEL) in the range of 1000 mg/kg/d.</p> <p>In humans, synthetic amorphous silica (SAS) is essentially non-toxic by mouth, skin or eyes, and by inhalation. Epidemiology studies show little evidence of adverse health effects due to SAS. Repeated exposure (without personal protection) may cause mechanical irritation of the eye and drying/cracking of the skin.</p> <p>When experimental animals inhale synthetic amorphous silica (SAS) dust, it dissolves in the lung fluid and is rapidly eliminated, and the vast majority of SAS is excreted in the faeces and there is little accumulation in the body. Following absorption across the gut, SAS is eliminated via urine without modification in animals and humans. SAS is not expected to be broken down (metabolised) in mammals. After ingestion, there is limited accumulation of SAS in body tissues and rapid elimination occurs. Intestinal absorption has not been calculated, but appears to be insignificant in animals and humans. SASs injected subcutaneously are subjected to rapid dissolution and removal. There is no indication of metabolism of SAS in animals or humans based on chemical structure and available data. In contrast to crystalline silica, SAS is soluble in physiological media and the soluble chemical species that are formed are eliminated via the urinary tract without modification.</p> <p>Both the mammalian and environmental toxicology of SASs are significantly influenced by the physical and chemical properties, particularly those of solubility and particle size. SAS has no acute intrinsic toxicity by inhalation. Adverse effects, including suffocation, that have been reported were caused by the presence of high numbers of respirable particles generated to meet the required test atmosphere. These results are not representative of exposure to commercial SASs and should not be used for human risk assessment. Though repeated exposure of the skin may cause dryness and cracking, SAS is not a skin or eye irritant, and it is not a sensitiser.</p> <p>Repeated-dose and chronic toxicity studies confirm the absence of toxicity when SAS is swallowed or upon skin contact.</p> <p>Long-term inhalation of SAS caused some adverse effects in animals (increases in lung inflammation, cell injury and lung collagen content), all of which subsided after exposure.</p> <p>Numerous repeated-dose, subchronic and chronic inhalation toxicity studies have been conducted with SAS in a number of species, at airborne concentrations ranging from 0.5 mg/m³ to 150 mg/m³. Lowest-observed adverse effect levels (LOAELs) were typically in the range of 1 to 50 mg/m³. When available, the no-observed adverse effect levels (NOAELs) were between 0.5 and 10 mg/m³. The difference in values may be explained by different particle size, and therefore the number of particles administered per unit dose. In general, as particle size decreases so does the NOAEL/LOAEL.</p> <p>Neither inhalation nor oral administration caused neoplasms (tumours). SAS is not mutagenic in vitro. No genotoxicity was detected in in vivo assays. SAS does not impair development of the foetus. Fertility was not specifically studied, but the reproductive organs in long-term studies were not affected.</p> <p>For Synthetic Amorphous Silica (SAS)</p> <p>Repeated dose toxicity</p> <p>Oral (rat), 2 weeks to 6 months, no significant treatment-related adverse effects at doses of up to 8% silica in the diet.</p> <p>Inhalation (rat), 13 weeks, Lowest Observed Effect Level (LOEL) = 1.3 mg/m³ based on mild reversible effects in the lungs. Inhalation (rat), 90 days, LOEL = 1 mg/m³ based on reversible effects in the lungs and effects in the nasal cavity.</p> <p>For silane treated synthetic amorphous silica:</p> <p>Repeated dose toxicity: oral (rat), 28-d, diet, no significant treatment-related adverse effects at the doses tested.</p> <p>There is no evidence of cancer or other long-term respiratory health effects (for example, silicosis) in workers employed in the manufacture of SAS. Respiratory symptoms in SAS workers have been shown to correlate with smoking but not with SAS exposure, while serial pulmonary function values and chest radiographs are not adversely affected by long-term exposure to SAS.</p> <p>For silane, dichlorodimethyl-, reaction products with silica</p> <p>Acute oral toxicity is very low for treated silica. Acute inhalation toxicity was only tested for inhalable particles and is not relevant for the material used industrially. Changes in respiratory organs (inflammatory processes) after repeated exposure were reversible in animals that survived the exposure and were observed above the valid TLV values, only. If TLV values are maintained no health hazards are expected. Repeated dose toxicity is sufficiently investigated. Treated silica is not mutagenic. The NOAEL for repro/developmental toxicity is 500 mg/kg bw.</p> <p>Acute toxicity: In a limit test giving 10% in the diet (5000 mg/kg bw) to rats the acute oral LD50 was determined to be higher than 5000 mg/kg bw. In another study administering single doses of 2500 and 5000 mg/kg bw to rats the LD50 was also concluded to be higher than 5000 mg/kg bw. In an acute oral toxicity study giving still higher single doses in olive oil the LD50 appeared to be above 7900 mg/kg bw. No signs of toxicity were observed in any of these studies.</p> <p>All inhalation testing has been conducted with a substance that differs significantly from the commercial product based on particle size. In these animal tests the experimental design caused the particle size to be reduced resulting in nearly 100% of the particle fraction being below 10 µm and capable of entering the deep lung (alveolar particle fraction). The alveolar fraction is responsible for the toxicological effects (suffocation; overloading of the lung due to poor dust clearance mechanisms) which were observed with LC50 values of > 477, 450, 520-1120, and >2280 mg/m³ and corresponding mass median aerodynamic diameters (MMAD) of 2.9 µm, 1.24 µm, 0.8 – 0.9 µm and 0.15 µm, respectively. In comparison to the particle size used in these acute inhalation animal tests, only minor amounts (less than 1 %) of the commercially available commercial substance have been measured as respirable (alveolar fraction < 10 µm MMAD) using test method EN/DIN 481 (ref.35). Using the same method > 99% of the particle fraction is in excess of 90 µm and can only reach the upper airways (nasal passages and throat) or cannot be inhaled at all. Therefore the tests do not represent the toxicological behavior of the commercial product and are not considered relevant for inclusion in the hazard definition/hazard assessment of the commercial substance.</p> <p>Genetic toxicity: The test substance was not mutagenic in the Bacterial Reverse Mutation Assay (Ames test) with <i>Salmonella typhimurium</i> TA98, TA100, TA1535, TA1537 and TA1538 strains and with <i>E. coli</i> WP2 uvrA strain. Also an in vitro chromosomal aberration study in CHO cells gave negative results.</p>

Stela Capsule

	<p>Repeat dose toxicity: A 24-month oral feeding study administering a 100 mg/kg dose to 20 male and 20 female rats resulted in a NOAEL of 100 mg/kg. No clinical signs or treatment-related changes (e.g. bodyweight) were observed. There were no carcinogenic effects. A 6-month oral feeding study showed no treatment-related effects at the given dose of 500 mg/kg bw to rats (40/sex) resulting in a NOAEL of 500 mg/kg bw; a slight progressive – but reversible – transformation of the adrenal cortex in females was attributed to chronic stress. Another oral feeding study (5-8 weeks) exposed rats (5/sex/treatment) to a dose of 500, 1000 or 2000 mg/kg bw initially and increasing these doses gradually to 4000, 8000 and 16000 mg/kg bw, respectively. Decrease in body weight and food consumption combined with apathy and decreased grooming activity and decreased cytoplasmic glycogen in hepatocytes may indicate a starving condition of these animals. At the highest dose group four animals died. The NOAEL was determined to be 500 mg/kg bw (LOAEL = 1000 mg/kg bw). In a limited reported study where a dose of 500 or 1000 mg/kg bw was administered by gavage to 30 rats no treatment-related effects could be found, resulting in a NOAEL of 1000 mg/kg bw.</p> <p>A 13-week inhalation study exposing 70 animals/sex to 35 mg/m³ resulted in granuloma-like lesions of the lungs, accumulations of alveolar macrophages, alveolar spaces filled with granular material, debris and polymorphonuclear leucocytes, alveolar bronchiolisation, interstitial fibrosis and enlarged mediastinal lymph nodes. In a 2-week study administering 0, 31, 87 or 420 mg/m³ to a total number of 40 rats/sex 4 males and 2 females died at the top dose level. The rats at the top dose level showed severe respiratory distress and apathy. A dose-related decrease in body weight was observed at 87 mg/m³ and higher. The lungs showed similar effects as those observed in the 13-week inhalation study. A 3-day study and an 8-12-month study both with a concentration of 50 mg/m³ to rats yielded similar results to the above studies in the lungs and the size of the particles was determined to be smaller than 7 µm. Changes in respiratory organs (inflammatory processes) observed in inhalative repeated dose toxicity testing were reversible in animals that survived the exposure. There was no indication of silicosis. Concentrations of the substances with toxicological effects in inhalative toxicity testing were above the valid TLV values (10mg/m³ USA). If TLV values are maintained no health hazards are expected.</p> <p>Reproductive and developmental toxicity: Two studies are included on repro/developmental toxicity. A 6-month, 1-generation study in rats combining fertility and prenatal toxicity testing administered 500 mg/kg bw in the food to 10 females and 2 males. No treatment-related effects were observed in the parents or in the offspring. Therefore the NOAEL for parents and offspring was 500 mg/kg. No effects on the female/male gonads were observed. In a 2-generation reproduction study 20 male and 20 female rats were given 100 mg/kg bw via oral feed for 24 months (see also repeated dose). No abnormalities were observed in the offspring resulting in a NOAEL of 100 mg/kg bw.</p>
YTTERBIUM(III) FLUORIDE	<p>Symptoms of acute lanthanide toxicity in rats are immediate defecation, writhing, ataxia (the inability to coordinate voluntary muscular movement), sedation, laboured respiration and reduced activity. Death is due mainly to respiratory and cardiac failure. The rare earths exhibit low toxicity following ingestion but may be toxic by the intraperitoneal route and mildly toxic when administered by the subcutaneous route. The production of skin and lung granulomas, following exposure, may also occur.</p> <p>for typical lanthanides:</p> <p>The symptoms of toxicity of the rare earth elements include writhing, ataxia, labored respiration, walking on the toes with arched back and sedation. The rare earth elements exhibit low toxicity by ingestion exposure. However, the intraperitoneal route may be highly toxic while the subcutaneous route is poison to moderately toxic. The production of skin and lung granulomas after exposure to them requires extensive protection to prevent such exposure.</p> <p>Chronic Inhalation Toxicity: An accumulation of insoluble lanthanide particles has been observed in the respiratory tract of humans following chronic occupational exposure and in rodents following chronic exposure to a similar lanthanide cerium oxide. Lymphoid hyperplasia in the bronchial lymph nodes was the critical inhalation health effect identified by the USEPA in a 2008 toxicological review of cerium oxide.</p> <p>Developmental/Reproductive Toxicity: Lanthanum carbonate, did not affect fertility or produce any harm to the fetus in a rat study.</p> <p>Mutagenicity: Cerium oxide, was negative in the Ames bacterial mutagenic test using bacterial strains TA135, TA1537, TA98, TA100, TA102, and WP2uvrA., and in the mouse in vivo micronucleus assay.</p> <p>Carcinogenicity: Lanthanum carbonate, was not carcinogenic in a two-year oral rat study. Not assessed by IARC, NTP, or USEPA.</p>
DIURETHANE DIMETHACRYLATE	<p>Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test, oral (OECD 422), rat:</p>
DIURETHANE DIMETHACRYLATE & 10-METHACRYLOYLOXYDECYL DIHYDROGEN PHOSPHATE	<p>The following information refers to contact allergens as a group and may not be specific to this product.</p> <p>Contact allergies quickly manifest themselves as contact eczema, more rarely as urticaria or Quincke's oedema. The pathogenesis of contact eczema involves a cell-mediated (T lymphocytes) immune reaction of the delayed type. Other allergic skin reactions, e.g. contact urticaria, involve antibody-mediated immune reactions. The significance of the contact allergen is not simply determined by its sensitisation potential: the distribution of the substance and the opportunities for contact with it are equally important. A weakly sensitising substance which is widely distributed can be a more important allergen than one with stronger sensitising potential with which few individuals come into contact. From a clinical point of view, substances are noteworthy if they produce an allergic test reaction in more than 1% of the persons tested.</p>
DIURETHANE DIMETHACRYLATE & GLYCEROL DIMETHACRYLATE & YTTERBIUM(III) FLUORIDE & 10-METHACRYLOYLOXYDECYL DIHYDROGEN PHOSPHATE	<p>Asthma-like symptoms may continue for months or even years after exposure to the material ends. This may be due to a non-allergic condition known as reactive airways dysfunction syndrome (RADS) which can occur after exposure to high levels of highly irritating compound. Main criteria for diagnosing RADS include the absence of previous airways disease in a non-atopic individual, with sudden onset of persistent asthma-like symptoms within minutes to hours of a documented exposure to the irritant. Other criteria for diagnosis of RADS include a reversible airflow pattern on lung function tests, moderate to severe bronchial hyperreactivity on methacholine challenge testing, and the lack of minimal lymphocytic inflammation, without eosinophilia. RADS (or asthma) following an irritating inhalation is an infrequent disorder with rates related to the concentration of and duration of exposure to the irritating substance. On the other hand, industrial bronchitis is a disorder that occurs as a result of exposure due to high concentrations of irritating substance (often particles) and is completely reversible after exposure ceases. The disorder is characterized by difficulty breathing, cough and mucus production.</p>
DIURETHANE DIMETHACRYLATE & GLYCEROL DIMETHACRYLATE	<p>UV (ultraviolet)/ EB (electron beam) acrylates are generally of low toxicity</p> <p>UV/EB acrylates are divided into two groups; "stenomeric" and "eurymeric" acrylates.</p> <p>The first group consists of well-defined acrylates which can be described by a simple idealised chemical; they are low molecular weight species with a very narrow weight distribution profile.</p> <p>The eurymeric acrylates cannot be described by an idealised structure and may differ fundamentally between various suppliers; they are of relatively high molecular weight and possess a wide weight distribution.</p> <p>Stenomeric acrylates are usually more hazardous than the eurymeric substances. Stenomeric acrylates are also well defined which allows comparison and exchange of toxicity data - this allows more accurate classification.</p> <p>The stenomerics cannot be classified as a group; they exhibit substantial variation.</p> <p>Based on the available oncogenicity data and without a better understanding of the carcinogenic mechanism the Health and Environmental Review Division (HERD), Office of Toxic Substances (OTS), of the US EPA previously concluded that all chemicals that contain the acrylate or methacrylate moiety (CH₂=CHCOO or CH₂=C(CH₃)COO) should be considered to be a carcinogenic hazard unless shown otherwise by adequate testing.</p> <p>This position has now been revised and acrylates and methacrylates are no longer <i>de facto</i> carcinogens.</p>
DIURETHANE DIMETHACRYLATE & GLYCEROL DIMETHACRYLATE & 10-METHACRYLOYLOXYDECYL DIHYDROGEN PHOSPHATE	<p>Where no "official" classification for acrylates and methacrylates exists, there has been cautious attempts to create classifications in the absence of contrary evidence. For example</p> <p>Monoalkyl or monoarylestere of acrylic acids should be classified as R36/37/38 and R51/53</p> <p>Monoalkyl or monoaryl estere of methacrylic acid should be classified as R36/37/38</p>
YTTERBIUM(III) FLUORIDE & 10-	<p>No significant acute toxicological data identified in literature search.</p>

Stela Capsule

METHACRYLOYLOXYDECYL
DIHYDROGEN PHOSPHATE

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

Stela Capsule	Endpoint	Test Duration (hr)	Species	Value	Source
	Not Available	Not Available	Not Available	Not Available	Not Available
diurethane dimethacrylate	Endpoint	Test Duration (hr)	Species	Value	Source
	NOEC(ECx)	72h	Algae or other aquatic plants	0.21mg/l	2
	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
glycerol dimethacrylate	Endpoint	Test Duration (hr)	Species	Value	Source
	Not Available	Not Available	Not Available	Not Available	Not Available
silica amorphous, fumed	Endpoint	Test Duration (hr)	Species	Value	Source
	NOEC(ECx)	24h	Crustacea	>=10000mg/l	1
ytterbium(III) fluoride	Endpoint	Test Duration (hr)	Species	Value	Source
	EC50	48h	Crustacea	>0.52mg/l	2
	NOEC(ECx)	48h	Crustacea	0.52mg/l	2
10-methacryloyloxydecyl dihydrogen phosphate	Endpoint	Test Duration (hr)	Species	Value	Source
	Not Available	Not Available	Not Available	Not Available	Not Available
Legend:	Extracted from 1. IUCLID Toxicity Data 2. Europe ECHA Registered Substances - Ecotoxicological Information - Aquatic Toxicity 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
glycerol dimethacrylate	LOW	LOW

12.3. Bioaccumulative potential

Ingredient	Bioaccumulation
glycerol dimethacrylate	LOW (LogKOW = 1.1616)

12.4. Mobility in soil

Ingredient	Mobility
glycerol dimethacrylate	LOW (Log KOC = 10)

12.5. Results of PBT and vPvB assessment

Continued...

Stela Capsule

	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"> ▶ Containers may still present a chemical hazard/ danger when empty. ▶ Return to supplier for reuse/ recycling if possible. <p>Otherwise:</p> <ul style="list-style-type: none"> ▶ If container can not be cleaned sufficiently well to ensure that residuals do not remain or if the container cannot be used to store the same product, then puncture containers, to prevent re-use, and bury at an authorised landfill. ▶ Where possible retain label warnings and SDS and observe all notices pertaining to the product. ▶ 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. ▶ DO NOT recycle spilled material. ▶ Consult State Land Waste Management Authority for disposal. ▶ Neutralise spill material carefully and decontaminate empty containers and spill residues with 10% ammonia solution plus detergent or a proprietary decontaminant prior to disposal. ▶ DO NOT seal or stopper drums being decontaminated as CO2 gas is generated and may pressurise containers. ▶ Puncture containers to prevent re-use. ▶ Bury or incinerate residues at an approved site.
Waste treatment options	Not Available
Sewage disposal options	Not Available

SECTION 14 Transport information**Labels Required**

Marine Pollutant	NO
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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	
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

Continued...

Stela Capsule

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. Maritime transport in bulk according to IMO instruments

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
diurethane dimethacrylate	Not Available
glycerol dimethacrylate	Not Available
silica amorphous, fumed	Not Available
ytterbium(III) fluoride	Not Available
10-methacryloyloxydecyl dihydrogen phosphate	Not Available

14.7.3. Transport in bulk in accordance with the IGC Code

Product name	Ship Type
diurethane dimethacrylate	Not Available
glycerol dimethacrylate	Not Available
silica amorphous, fumed	Not Available
ytterbium(III) fluoride	Not Available
10-methacryloyloxydecyl dihydrogen phosphate	Not Available

Continued...

Stela Capsule

SECTION 15 Regulatory information

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

diurethane dimethacrylate is found on the following regulatory lists

Europe EC Inventory

European Union - European Inventory of Existing Commercial Chemical Substances (EINECS)

European Union (EU) Regulation (EC) No 1272/2008 on Classification, Labelling and Packaging of Substances and Mixtures - Annex VI

glycerol dimethacrylate is found on the following regulatory lists

Europe EC Inventory

European Union - European Inventory of Existing Commercial Chemical Substances (EINECS)

silica amorphous, fumed is found on the following regulatory lists

Europe EC Inventory

European Union - European Inventory of Existing Commercial Chemical Substances (EINECS)

International WHO List of Proposed Occupational Exposure Limit (OEL) Values for Manufactured Nanomaterials (MNMS)

ytterbium(III) fluoride is found on the following regulatory lists

EU Consolidated List of Indicative Occupational Exposure Limit Values (IOELVs)

Europe EC Inventory

European Union - European Inventory of Existing Commercial Chemical Substances (EINECS)

International Agency for Research on Cancer (IARC) - Agents Classified by the IARC Monographs - Not Classified as Carcinogenic

Ireland Occupational Exposure Limits

10-methacryloyloxydecyl dihydrogen phosphate 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.

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

Seveso Category	Not Available

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 - AIC / Australia Non-Industrial Use	No (glycerol dimethacrylate; ytterbium(III) fluoride; 10-methacryloyloxydecyl dihydrogen phosphate)
Canada - DSL	No (diurethane dimethacrylate; glycerol dimethacrylate; ytterbium(III) fluoride; 10-methacryloyloxydecyl dihydrogen phosphate)
Canada - NDSL	No (silica amorphous, fumed; 10-methacryloyloxydecyl dihydrogen phosphate)
China - IECSC	No (10-methacryloyloxydecyl dihydrogen phosphate)
Europe - EINEC / ELINCS / NLP	No (10-methacryloyloxydecyl dihydrogen phosphate)
Japan - ENCS	No (diurethane dimethacrylate; 10-methacryloyloxydecyl dihydrogen phosphate)
Korea - KECI	No (10-methacryloyloxydecyl dihydrogen phosphate)
New Zealand - NZIoC	No (10-methacryloyloxydecyl dihydrogen phosphate)
Philippines - PICCS	No (glycerol dimethacrylate; ytterbium(III) fluoride; 10-methacryloyloxydecyl dihydrogen phosphate)
USA - TSCA	No (10-methacryloyloxydecyl dihydrogen phosphate)
Taiwan - TCSI	No (10-methacryloyloxydecyl dihydrogen phosphate)
Mexico - INSQ	No (diurethane dimethacrylate; glycerol dimethacrylate; ytterbium(III) fluoride; 10-methacryloyloxydecyl dihydrogen phosphate)
Vietnam - NCI	No (ytterbium(III) fluoride)
Russia - FBEPH	No (diurethane dimethacrylate; glycerol dimethacrylate; 10-methacryloyloxydecyl dihydrogen phosphate)
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	25/08/2023
Initial Date	25/08/2023

Full text Risk and Hazard codes

H302+H312+H332	Harmful if swallowed, in contact with skin or if inhaled.
H411	Toxic to aquatic life with long lasting effects.

Continued...

Stela Capsule

H413	May cause long lasting harmful effects to aquatic life.
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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

- ▶ AICC: 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

Classification and procedure used to derive the classification for mixtures according to Regulation (EC) 1272/2008 [CLP]

Classification according to regulation (EC) No 1272/2008 [CLP] and amendments	Classification Procedure
Skin Corrosion/Irritation Category 2, H315	Calculation method
Sensitisation (Skin) Category 1, H317	Calculation method
Serious Eye Damage/Eye Irritation Category 2, H319	Calculation method
Specific Target Organ Toxicity - Single Exposure (Respiratory Tract Irritation) Category 3 , H335	Calculation method

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.

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