

Riva Luting Plus Capsules SDI Limited

Version No: 7.1.1.1

Safety Data Sheet according to WHS and ADG requirements

Issue Date: 01/11/2019 Print Date: 15/10/2020 L.GHS.AUS.EN

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

Product Identifier Product name Riva Luting Plus Capsules Other means of identification

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

Not Available

Relevant identified uses Dental cement for dental restorations by dental professionals.

> http://www.sdi.com.au/ Ireland@sdi.com.au

Details of the supplier of the safety data sheet

Website

Email

Registered company name	SDI Limited	SDI (North America) Inc.	SDi
Address	3-15 Brunsdon Street Bayswater VIC 3153 Australia	1279 Hamilton Parkway Itasca IL 60143 United States	Rua Dr. Virgílio de Carvalho Pinto, 612 Pinheiros, Sao Paulo 05415-020 Brazil
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Email	info@sdi.com.au USA.Canada@sdi.com.au Brasil@sdi.d		Brasil@sdi.com.au
Registered company name SDI Dental Limited			
Address	Block 8, St Johns Court Santry Dublin 9 Ireland		
Telephone	+353 1 886 9577 (Business Hours) 800 0225 5734		
Fax	Not Available		

Emergency telephone number

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

SECTION 2 Hazards identification

Classification of the substance or mixture

Poisons Schedule	Not Applicable
Classification ^[1]	Skin Corrosion/Irritation Category 2, Eye Irritation Category 2A, Skin Sensitizer Category 1, Specific target organ toxicity - single exposure Category 3 (respiratory tract irritation), Specific target organ toxicity - repeated exposure Category 2
Legend:	1. Classification by vendor; 2. Classification drawn from HCIS; 3. Classification drawn from Regulation (EU) No 1272/2008 - Annex VI

Label elements

Hazard pictogram(s)





Signal word

Warning

Hazard statement(s)

. ,	
H315	Causes skin irritation.
H319	Causes serious eye irritation.

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H317 May cause an allergic skin reaction. H335 May cause respiratory irritation. May cause damage to organs through prolonged or repeated exposure. H373

Precautionary statement(s) Prevention

P260	Do not breathe mist/vapours/spray.	
P271	Use only outdoors or in a well-ventilated area.	
P280	Wear protective gloves/protective clothing/eye protection/face protection.	
P272	Contaminated work clothing should not be allowed out of the workplace.	

Precautionary statement(s) Response

P321	Specific treatment (see advice on this label).
P362	Take off contaminated clothing and wash before reuse.
P302+P352	IF ON SKIN: Wash with plenty of water.
P305+P351+P338	IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
P312	Call a POISON CENTER or doctor/physician 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.
P304+P340	IF INHALED: Remove victim to fresh air and keep at rest in a position comfortable for breathing.

Precautionary statement(s) Storage

-		_ -
	P405	Store locked up.
P403	3+P233	Store in a well-ventilated place. Keep container tightly closed.

Precautionary statement(s) Disposal

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

SECTION 3 Composition / information on ingredients

Substances

See section below for composition of Mixtures

Mixtures

CAS No	%[weight]	Name	
Not Available		compartment 1:	
868-77-9	10-25	2-hydroxyethyl methacrylate	
52628-03-2	15-20	2-hydroxyethyl methacrylate phosphate	
9003-01-4	5-15	acrylic acid homopolymer	
1830-78-0	5-10	glycerol dimethacrylate	
87-69-4	1-5	tartaric acid	
Not Available		compartment 2:	
Not Available		glass powder	

SECTION 4 First aid measures

Description of first aid measures

Eye Contact	If this product comes in contact with the eyes: Wash out immediately with fresh running water. Ensure complete irrigation of the eye by keeping eyelids apart and away from eye and moving the eyelids by occasionally lifting the upper and lower lids. Seek medical attention without delay; if pain persists or recurs seek medical attention. Removal of contact lenses after an eye injury should only be undertaken by skilled personnel.
Skin Contact	If skin contact occurs: 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	 If fumes or combustion products are inhaled remove from contaminated area. Seek medical attention.
Ingestion	 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.

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Treat symptomatically.

SECTION 5 Firefighting measures

Extinguishing media

Foam is generally ineffective.

Special hazards arising from the substrate or mixture

Fire Incompatibility	None known.
dvice for firefighters	
Fire Fighting	 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	 ▶ 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. Combustion products include: carbon dioxide (CO2) other pyrolysis products typical of burning organic material. May emit clouds of acrid smoke May emit poisonous fumes. May emit corrosive fumes.
HAZCHEM	Not Applicable

SECTION 6 Accidental release measures

Personal precautions, protective equipment and emergency procedures

See section 8

Environmental precautions

See section 12

Methods and material for containment and cleaning up

Minor Spills	 Clean up all spills immediately. Avoid contact with skin and eyes. 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	 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. 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.

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

SECTION 7 Handling and storage

Precautions for safe handling ▶ 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. Safe handling ▶ 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.

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Use good occupational work practice.

Dbserve manufacturer's storage and handling recommendations contained within this SDS.

Atmosphere should be regularly checked against established exposure standards to ensure safe working conditions are maintained.

Other information

Store between 5 and 25 deg. C.

Store in a dry and well ventilated-area, away from heat and sunlight.

Conditions for safe storage, including any incompatibilities

Suitable container

- Packaging as recommended by manufacturer.
- Check that containers are clearly labelled and free from leaks

Storage incompatibility

None known

SECTION 8 Exposure controls / personal protection

Control parameters

Occupational Exposure Limits (OEL)

INGREDIENT DATA

Not Available

Emergency Limits

Ingredient	Material name	TEEL-1	TEEL-2	TEEL-3
2-hydroxyethyl methacrylate	Hydroxyethyl methacrylate, 2-	1.9 mg/m3	21 mg/m3	1,000 mg/m3
tartaric acid	Tartaric acid	1.6 mg/m3	17 mg/m3	100 mg/m3

Ingredient	Original IDLH	Revised IDLH
2-hydroxyethyl methacrylate	Not Available	Not Available
2-hydroxyethyl methacrylate phosphate	Not Available	Not Available
acrylic acid homopolymer	Not Available	Not Available
glycerol dimethacrylate	Not Available	Not Available
tartaric acid	Not Available	Not Available

Occupational Exposure Banding

Ingredient	Occupational Exposure Band Rating	Occupational Exposure Band Limit		
2-hydroxyethyl methacrylate	E	≤ 0.1 ppm		
2-hydroxyethyl methacrylate phosphate	E	≤ 0.1 ppm		
acrylic acid homopolymer	E	≤ 0.01 mg/m³		
glycerol dimethacrylate	E	≤ 0.1 ppm		
tartaric acid	E ≤ 0.01 mg/m³			
Notes:	Occupational exposure banding is a process of assigning chemicals into specific categories or bands based on a chemical's potency and the adverse health outcomes associated with exposure. The output of this process is an occupational exposure band (OEB), which corresponds to a range of exposure concentrations that are expected to protect worker health.			

MATERIAL DATA

NOTE D: Certain substances which are susceptible to spontaneous polymerisation or decomposition are generally placed on the market in a stabilised form. It is in this form that they are listed on Annex I

When they are placed on the market in a non-stabilised form, the label must state the name of the substance followed by the words "non-stabilised"

European Union (EU) List of harmonised classification and labelling hazardous substances, Table 3.1, Annex VI, Regulation (EC) No 1272/2008 (CLP) - up to the latest ATP

Exposure controls

CARE: Use of a quantity of this material in confined space or poorly ventilated area, where rapid build up of concentrated atmosphere may occur, could require increased ventilation and/or protective gear

Engineering controls are used to remove a hazard or place a barrier between the worker and the hazard. Well-designed engineering controls can be highly effective in protecting workers and will typically be independent of worker interactions to provide this high level of protection.

The basic types of engineering controls are:

Process controls which involve changing the way a job activity or process is done to reduce the risk.

Enclosure and/or isolation of emission source which keeps a selected hazard "physically" away from the worker and ventilation that strategically "adds" and "removes" air in the work environment. Ventilation can remove or dilute an air contaminant if designed properly. The design of a ventilation system must match the particular process and chemical or contaminant in use.

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

Appropriate engineering controls

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.

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.

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.)

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grinding, abrasive blasting, tumbling, high speed wheel generated dusts (released at high initial velocity into zone of very high rapid air motion)

2.5-10 m/s (500-2000 f/min.)

Within each range the appropriate value depends on:

Lower end of the range	Upper end of the range
1: Room air currents minimal or favourable to capture	1: Disturbing room air currents
2: Contaminants of low toxicity or of nuisance value only.	2: Contaminants of high toxicity
3: Intermittent, low production.	3: High production, heavy use
4: Large hood or large air mass in motion	4: Small hood-local control only

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.

Personal protection











Eve and face protection

Safety glasses with side shields.

Chemical goggles. Contact lenses may pose a special hazard; soft contact lenses may absorb and concentrate irritants. A written policy document, describing the wearing of lenses or restrictions on use, should be created for each workplace or task. This should include a review of lens absorption and adsorption for the class of chemicals in use and an account of injury experience. Medical and first-aid personnel should be trained in their removal and suitable equipment should be readily available. In the event of chemical exposure, begin eye irrigation immediately and remove contact lens as soon as practicable. Lens should be removed at the first signs of eye redness or irritation - lens should be removed in a clean environment only after workers have washed hands thoroughly. [CDC NIOSH Current Intelligence Bulletin 59], [AS/NZS 1336 or national equivalent]

Skin protection See Hand protection below Hands/feet protection

► Rubber Gloves

PVC gloves

Body protection

See Other protection below

Other protection

- 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)

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

Required minimum protection factor	Maximum gas/vapour concentration present in air p.p.m. (by volume)	Half-face Respirator	Full-Face Respirator
up to 10	1000	A-AUS / Class1 P2	-
up to 50	1000	-	A-AUS / Class 1 P2
up to 50	5000	Airline *	-
up to 100	5000	-	A-2 P2
up to 100	10000	-	A-3 P2
100+			Airline**

^{* -} Continuous Flow ** - Continuous-flow or positive pressure demand

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

- Cartridge respirators should never be used for emergency ingress or in areas of unknown vapour concentrations or oxygen content.
- The wearer must be warned to leave the contaminated area immediately on detecting any odours through the respirator. The odour may indicate that the mask is not functioning properly, that the vapour concentration is too high, or that the mask is not properly fitted. Because of these limitations, only restricted use of cartridge respirators is considered appropriate.
- Cartridge performance is affected by humidity. Cartridges should be changed after 2 hr of continuous use unless it is determined that the humidity is less than 75%, in which case, cartridges can be used for 4 hr. Used cartridges should be discarded daily, regardless of the length of time used

SECTION 9 Physical and chemical properties

Information on basic physical and chemical properties

Appearance Smooth, pale-coloured paste with slight characteristic odour, partially mixes with water.			
Physical state Non Slump Paste Relative density (Water = 1) Not Available			
Odour	Not Available	Partition coefficient n-octanol / water	Not Available
Odour threshold	Not Available	Auto-ignition temperature (°C)	Not Available
pH (as supplied)	Not Available	Decomposition temperature	Not Available

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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	Partly miscible	pH as a solution (1%)	Not Available
Vapour density (Air = 1)	Not Available	VOC g/L	Not Available

SECTION 10 Stability and reactivity

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

SECTION 11 Toxicological information

Information on toxicological effects

Inhaled	Evidence snows, 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
iiiiaieu	system.
	Inhalation hazard is increased at higher temperatures.
	Acute effects from inhalation of high concentrations of vapour are pulmonary irritation, including coughing, with nausea; central nervous system depression - characterised by headache and dizziness, increased reaction time, fatigue and loss of co-ordination

Ingestion Accidental ingestion of the material may be damaging to the health of the individual.

Skin Contact

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.

The material may accentuate any pre-existing dermatitis condition

Open cuts, abraded or irritated skin should not be exposed to this material

Entry into the blood-stream through, for example, cuts, abrasions, puncture wounds or lesions, may produce systemic injury with harmful effects. Examine the skin prior to the use of the material and ensure that any external damage is suitably protected.

Eye

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.

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

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

Riva Luting Plus Capsules	TOXICITY Not Available	IRRITATION Not Available	
	TOXICITY	IRRITATION	
2-hydroxyethyl methacrylate	Oral (guinea pig) LD50: =4680 mg/kg ^[2]	Eye (rabbit): SEVERE *	
	Oral (mouse) LD50: =3275 mg/kg ^[2]	Eye: adverse effect observed (irritating) ^[1]	
	Oral (mouse) LD50: =5457 mg/kg ^[2]	Skin (rabbit): non-irritating*	
	Oral (mouse) LD50: =5888 mg/kg ^[2]	Skin: no adverse effect observed (not irritating) ^[1]	
	Oral (rat) LD50: =5050 mg/kg ^[2]		

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	TOXICITY	IRRITATION
2-hydroxyethyl methacrylate phosphate	Not Available	Eye: adverse effect observed (irritating) ^[1]
		Skin: adverse effect observed (corrosive) ^[1]
		Skin: no adverse effect observed (not irritating) ^[1]
	TOXICITY	IRRITATION
acrylic acid homopolymer	Not Available	Eye: adverse effect observed (irreversible damage) ^[1]
		Skin: no adverse effect observed (not irritating) $[1]$
	TOXICITY	IRRITATION
glycerol dimethacrylate	Not Available	Not Available
	TOXICITY	IRRITATION
tartaric acid	5000 mg/kg ^[2]	Not Available
Legend:	Nalue obtained from Europe ECHA Registered Substar specified data extracted from RTECS - Register of Toxic Letters	nces - Acute toxicity 2.* Value obtained from manufacturer's SDS. Unless otherwise Effect of chemical Substances
2-HYDROXYETHYL		
METHACRYLATE	Dermal (rabbit): >5000 mg/kg* Effects persist beyond 21 of	days
2-HYDROXYETHYL METHACRYLATE PHOSPHATE	No significant acute toxicological data identified in literatur	re search.
ACRYLIC ACID HOMOPOLYMER	No significant acute toxicological data identified in literature search. Polycarboxylates are of low toxicity by all exposure routes examined. Homopolymers(P-AA) are of low acute toxicity to the rat (LD50 - 5 g/kg bw/d) and are not irritating to the rabbit's skin and, at the most, slightly irritating to the eye. Further P-AA has no sensitising potential. The adverse effect after repeated inhalation dosing (91-d/rat) was a mild, reversible pulmonary irritation. This effect is considered as not substance related owing to the physical property of the respirable dust, which caused local and not systemic lung effects. There was neither evidence for a genotoxic potential of PAA using a variety of genetic endopriors in-vitro and in-vivon.or for developmental toxicity or reprotoxicity in the rat. Based upon the available data, it is considered that exposure to polycarboxylates does not imply any particular hazard to humans The Cosmetic Ingredient Review (CIR) Expert Panel noted that these crosslinked alkyl acrylates are macromolecules that are not expected to pass through the stratum comeum of the skin, so significant dermal absorption is not expected. Therefore, topically applied cosmetics are not expected to result in systemic or reproductive and developmental toxicity or to have genotoxic or carcinogene effects using the particular products containing these ingredients are reportedly used sround the eyes, on the lips, and on other mucous membranes. Thus, crosslinked alkyl acrylates could be absorbed systemically through the relatively moist, instant uncous membranes is likely to be not significant, primarily because of the relatively independent and assorption through healthy intext mucous membranes is likely to be not significant, primarily because of the relatively independent and assorption through healthy intext mucous membranes is likely to be not significant, primarily because of the relatively independent and assorption through the relatively and particular primarily because of the relatively independent	

GLYCEROL DIMETHACRYLATE

Evidence of carcinogenicity may be inadequate or limited in animal testing.

UV (ultraviolet)/ EB (electron beam) acrylates are generally of low toxicity UV/EB acrylates are divided into two groups; "stenomeric" and "eurymeric" acrylates.

The first group consists of well-defined acrylates which can be described by a simple idealised chemical; they are low molecular weight species with a very narrow weight distribution profile.

The eurymeric acrylates cannot be described by an idealised structure and may differ fundamentally between various suppliers; they are of relatively high molecular weigh and possess a wide weight distribution.

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Stenomeric acrylates are usually more hazardous than the eurymeric substances. Stenomeric acrylates are also well defined which allows comparison and exchange of toxicity data - this allows more accurate classification. The stenomerics cannot be classified as a group; they exhibit substantial variation.

The material may produce severe irritation to the eye causing pronounced inflammation. Repeated or prolonged exposure to irritants may produce conjunctivitis.

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.

for simple alpha-hydroxy carboxylic acids and their salts:

The US Food and Drug Administration (FDA) received a total of 114 adverse dermatologic experience reports for alpha-hydroxy acids (AHA)containing skin care products between 1992 and February 2004, with the maximum number in 1994. The reported adverse experiences included burning (45), dermatitis or rash (35), swelling (29), pigmentary changes (15), blisters or welts (14), skin peeling (13), itching (12), irritation or tenderness (8), chemical burns (6), and increased sunburn (3). The frequency of such reports for skin exfoliating products that contain AHAs has been considerably lower in subsequent years. The more serious adverse reactions appear to occur most often with products that cause the greatest degree of exfoliation, such as "skin peelers."

Various studies confirmed previous industry studies indicating that applying AHAs to the skin results in increased UV sensitivity. After four weeks of AHA application, volunteers' sensitivity to skin reddening produced by UV increased by 18 percent. Similarly, the volunteers' sensitivity to UV-induced cellular damage doubled, on average, with considerable differences among individuals. Topical glycolic acid enhances photodamage by ultraviolet light.

However, the studies also indicated that this increase in sensitivity is reversible and does not last long after discontinuing use of the AHA cream. One week after the treatments were halted, researchers found no significant differences in UV sensitivity among the various skin sites Most AHAs are physiologic, natural, and non-toxic substances. All members of the group promote normal keratinization and desquamation. Those with multiple hydroxyl groups are moisturizing antioxidants, and are especially gentle for sensitive skin.

The studies did not identify exactly how AHAs bring about the increased UV sensitivity, although the effects did not appear to involve dramatic increases in UV-induced damage to DNA in the skin.

Previous FDA studies have indicated that a cosmetic-type cream base caused an AHA to penetrate more deeply into the skin when compared to an AHA solution without the usual cosmetic ingredients. However, further studies will be needed to learn how much, if at all, those cosmetic-type ingredients influence the AHA-related effects on UV sensitivity.

The toxicology of simple alpha hydroxy carboxylic acids cluster is characterised by five compounds sharing the functional group defining the cluster name

Experimental data available for members of the simple alpha-hydroxy carboxylic acids indicate a low acute, repeated-dose, reproductive and developmental toxicity

The simple alpha hydroxy carboxylic acids are eye and skin irritants but are not expected to be skin sensitisers.

Genotoxicity test data for two cluster members and a cancer bioassay for the calcium salt of propanoic acid, 2-hydroxy- yielded negative results and all other cluster members are considered to have little or no mutagenic or carcinogenic potential.

Acute oral toxicity of propanoic acid, 2-hydroxy- (2S)- (79-33-4) and propanoic acid, 2-hydroxy- (50-21-5) are low. The repeated-dose and developmental toxicity of the three tested simple alpha -hydroxy carboxylic acids is low. In EPAs High Production Volume Program, reproductive toxicity testing for propanoic acid, 2-hydroxy- (50-21-5) was deemed unnecessary because it is a normal component of human intermediary metabolism. Reproductive toxicity of acetic acid, 2-hydroxy- (79-14-1) has been tested and was found to be low. Low reproductive toxicity of the associated potassium salts is also expected to be low. Alpha-hydroxy carboxylic acids are severe eve irritants. Acetic acid. 2-hydroxy- (79-14-1). propanoic acid, 2-hydroxy- (2S)- (79-33-4) and propanoic acid, 2-hydroxy- (50-21-5) all produced positive skin irritation in rabbits. The members of this cluster are not expected to be skin sensitisers based on negative results in guinea pigs for both acetic acid, 2-hydroxy- (79-14-1) and propanoic acid, 2-hydroxy- (2S)- (79-33-4). Genotoxicity data for acetic acid, 2-hydroxy-(79-14-1) and propanoic acid, 2-hydroxy- (50-21-5) are negative, indicating that none of the cluster members are expected to be genotoxic. A 2-year drinking water study of the calcium salt of propanoic acid, 2-hydroxy- (50-21-5) in rats showed no evidence of carcinogenicity. An expert judgment based on mechanism-based structure-activity relationship considerations indicate little or no carcinogenic potential for any of the cluster members due to expected rapid metabolism/excretion and lack of genotoxic structural alert. This judgment is supported by the negative cancer and mutagenicity data for propanoic acid, 2hydroxy- (50-21-5), which is considered a reasonable analogue to the rest of the cluster.

Some products containing alpha-hydroxy acids (AHAs) have been marketed for uses such as treating acne, removing scars, and lightening discolorations. Among these are some products marketed as "skin peelers," which may contain relatively high concentrations of AHAs or other acids and are designed to remove the outer layer of the skin

Convulsions, haemorrhage recorded.

2-HYDROXYETHYL METHACRYLATE & 2-HYDROXYETHYL **METHACRYLATE PHOSPHATE**

TARTARIC ACID

The following information refers to contact allergens as a group and may not be specific to this product.

Contact allergies quickly manifest themselves as contact eczema, more rarely as urticaria or Quincke's oedema. The pathogenesis of contact eczema involves a cell-mediated (T lymphocytes) immune reaction of the delayed type. Other allergic skin reactions, e.g. contact urticaria, involve antibody-mediated immune reactions. The significance of the contact allergen is not simply determined by its sensitisation potential: the distribution of the substance and the opportunities for contact with it are equally important. A weakly sensitising substance which is widely distributed can be a more important allergen than one with stronger sensitising potential with which few individuals come into contact. From a clinical point of view, substances are noteworthy if they produce an allergic test reaction in more than 1% of the persons tested.

2-HYDROXYETHYL METHACRYLATE & 2-HYDROXYETHYL **METHACRYLATE** PHOSPHATE & GLYCEROL DIMETHACRYLATE

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

Monalkyl or monoarylesters of acrylic acids should be classified as R36/37/38 and R51/53

Monoalkyl or monoaryl esters of methacrylic acid should be classified as R36/37/38

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

This position has now been revised and acrylates and methacrylates are no longer de facto carcinogens.

2-HYDROXYETHYL **METHACRYLATE &** 2-HYDROXYETHYL METHACRYLATE PHOSPHATE & ACRYLIC ACID HOMOPOLYMER & **GLYCEROL DIMETHACRYLATE &** TARTARIC ACID

Asthma-like symptoms may continue for months or even years after exposure to the material ceases. This may be due to a non-allergenic condition known as reactive airways dysfunction syndrome (RADS) which can occur following exposure to high levels of highly irritating compound. Key criteria for the diagnosis of RADS include the absence of preceding respiratory disease, in a non-atopic individual, with abrupt onset of persistent asthma-like symptoms within minutes to hours of a documented exposure to the irritant. A reversible airflow pattern, or spirometry, with the presence of moderate to severe bronchial hyperreactivity on methacholine challenge testing and the lack of minimal lymphocytic inflammation, without eosinophilia, have also been included in the criteria for diagnosis of RADS. RADS (or asthma) following an irritating inhalation is an infrequent disorder with rates related to the concentration of and duration of exposure to the irritating substance Industrial bronchitis, on the other hand, is a disorder that occurs as result of exposure due to high concentrations of irritating substance (often particulate in nature) and is completely reversible after exposure ceases. The disorder is characterised by dyspnea, cough and mucus production

Acute Toxicity	×	Carcinogenicity	×
Skin Irritation/Corrosion	✓	Reproductivity	×
Serious Eye Damage/Irritation	✓	STOT - Single Exposure	✓

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Riva Luting Plus Capsules

Respiratory or Skin sensitisation STOT - Repeated Exposure Mutagenicity **Aspiration Hazard**

> 🗶 – Data either not available or does not fill the criteria for classification Legend: - Data available to make classification

SECTION 12 Ecological information

Toxicity

	Endpoint	Test Duration (hr)	Species	Value	Source
Riva Luting Plus Capsules	Not Available	Not Available	Not Available	Not Available	Not Available
	Endpoint	Test Duration (hr)	Species	Value	Source
	LC50	96	Fish	>100mg/L	2
-hydroxyethyl methacrylate	EC50	48	Crustacea	210mg/L	2
	EC50	72	Algae or other aquatic plants	>1-260mg/L	2
	NOEC	504	Crustacea	24.1mg/L	2
	Endpoint	Test Duration (hr)	Species	Value	Source
	LC50	96	Fish	>112mg/L	2
hydroxyethyl methacrylate phosphate	EC50	48	Crustacea	68mg/L	2
phosphate	EC50	72	Algae or other aquatic plants	39mg/L	2
	NOEC	72	Algae or other aquatic plants	>=30mg/L	2
	Endpoint	Test Duration (hr)	Species	Value	Sourc
	LC50	96	Fish	27mg/L	2
acrylic acid homopolymer	EC50	48	Crustacea	47mg/L	2
	EC50	72	Algae or other aquatic plants	0.75mg/L	2
	NOEC	72	Algae or other aquatic plants	0.03mg/L	2
	Endpoint	Test Duration (hr)	Species	Value	Source
glycerol dimethacrylate	Not Available	Not Available	Not Available	Not Available	Not Availabl
tartaric acid	Endpoint	Test Duration (hr)	Species	Value	Sourc
	LC50	96	Fish	>100mg/L	2
	EC50	48	Crustacea	93.313mg/L	2
	EC50	72	Algae or other aquatic plants	51.404mg/L	2
	EC0	32	Crustacea	135mg/L	2
	NOEC	72	Algae or other aquatic plants	3.125mg/L	2

V3.12 (QSAR) - Aquatic Toxicity Data (Estimated) 4. US EPA, Ecotox database - Aquatic Toxicity Data 5. ECETOC Aquatic Hazard Assessment Data 6. NITE (Japan) - Bioconcentration Data 7. METI (Japan) - Bioconcentration Data 8. Vendor Data

DO NOT discharge into sewer or waterways.

Persistence and degradability

Ingredient	Persistence: Water/Soil	Persistence: Air
2-hydroxyethyl methacrylate	LOW	LOW
acrylic acid homopolymer	LOW	LOW
glycerol dimethacrylate	LOW	LOW
tartaric acid	LOW	LOW

Bioaccumulative potential

Ingredient	Bioaccumulation	
2-hydroxyethyl methacrylate	LOW (BCF = 1.54)	
acrylic acid homopolymer	LOW (LogKOW = 0.4415)	
glycerol dimethacrylate	LOW (LogKOW = 1.1616)	
tartaric acid	LOW (LogKOW = -1.0017)	

Mobility in soil

Ingredient	Mobility
2-hydroxyethyl methacrylate	HIGH (KOC = 1.043)

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Ingredient	Mobility
acrylic acid homopolymer	HIGH (KOC = 1.201)
glycerol dimethacrylate	LOW (KOC = 10)
tartaric acid	HIGH (KOC = 1)

SECTION 13 Disposal considerations

Waste treatment methods

Product / Packaging disposal

- 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.

Consult State Land Waste Management Authority for disposal.

Bury residue in an authorised landfill.

SECTION 14 Transport information

Labels Required

Marine Pollutant	NO
HAZCHEM	Not Applicable

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

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

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

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

Not Applicable

SECTION 15 Regulatory information

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

2-hydroxyethyl methacrylate is found on the following regulatory lists

Australia Hazardous Chemical Information System (HCIS) - Hazardous Chemicals Australia Standard for the Uniform Scheduling of Medicines and Poisons (SUSMP) -

Schedule 5

2-hydroxyethyl methacrylate phosphate is found on the following regulatory lists

Australian Inventory of Industrial Chemicals (AIIC)

acrylic acid homopolymer is found on the following regulatory lists

Australian Inventory of Industrial Chemicals (AIIC)

Australian Inventory of Industrial Chemicals (AIIC)

International Agency for Research on Cancer (IARC) - Agents Classified by the IARC Monographs

glycerol dimethacrylate is found on the following regulatory lists

Not Applicable

tartaric acid is found on the following regulatory lists

Australian Inventory of Industrial Chemicals (AIIC)

National Inventory Status

National Inventory	Status		
Australia - AIIC	No (glycerol dimethacrylate)		
Australia - Non-Industrial Use	No (2-hydroxyethyl methacrylate; 2-hydroxyethyl methacrylate phosphate; acrylic acid homopolymer; glycerol dimethacrylate; tartaric acid)		
Canada - DSL	No (glycerol dimethacrylate)		
Canada - NDSL	No (2-hydroxyethyl methacrylate; 2-hydroxyethyl methacrylate phosphate; acrylic acid homopolymer; tartaric acid)		
China - IECSC	Yes		
Europe - EINEC / ELINCS / NLP	No (acrylic acid homopolymer)		
Japan - ENCS	Yes		
Korea - KECI	Yes		
New Zealand - NZIoC	Yes		
Philippines - PICCS	No (glycerol dimethacrylate)		
USA - TSCA	Yes		
Taiwan - TCSI	Yes		
Mexico - INSQ	No (2-hydroxyethyl methacrylate phosphate; glycerol dimethacrylate)		
Vietnam - NCI	Yes		
Russia - ARIPS	No (2-hydroxyethyl methacrylate phosphate; glycerol dimethacrylate)		

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Riva Luting Plus Capsules

National Inventory	Status
Legend:	Yes = All CAS declared ingredients are on the inventory No = One or more of the CAS listed ingredients are not on the inventory and are not exempt from listing(see specific ingredients in brackets)

SECTION 16 Other information

Revision Date	01/11/2019
Initial Date	10/11/2015

SDS Version Summary

Version	Issue Date	Sections Updated
6.1.1.1	10/05/2019	Classification, Ingredients
7.1.1.1	01/11/2019	One-off system update. NOTE: This may or may not change the GHS classification

Other information

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

The SDS is a Hazard Communication tool and should be used to assist in the Risk Assessment. Many factors determine whether the reported Hazards are Risks in the workplace or other settings. Risks may be determined by reference to Exposures Scenarios. Scale of use, frequency of use and current or available engineering controls must be considered.

Definitions and abbreviations

PC-TWA: Permissible Concentration-Time Weighted Average

PC-STEL: Permissible Concentration-Short Term Exposure Limit

IARC: International Agency for Research on Cancer

ACGIH: American Conference of Governmental Industrial Hygienists

STEL: Short Term Exposure Limit

TEEL: Temporary Emergency Exposure Limit。

IDLH: Immediately Dangerous to Life or Health Concentrations

OSF: Odour Safety Factor

NOAEL :No Observed Adverse Effect Level

LOAEL: Lowest Observed Adverse Effect Level

TLV: Threshold Limit Value LOD: Limit Of Detection

OTV: Odour Threshold Value

BCF: BioConcentration Factors

BEI: Biological Exposure Index

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

Other information:

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