



Riva Protect Capsules

SDI (North America) Inc.

Version No: 6.1.1.1
Safety Data Sheet according to OSHA HazCom Standard (2012) requirements

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

SECTION 1 Identification

Product Identifier

Product name	Riva Protect Capsules
Synonyms	Not Available
Other means of identification	Not Available

Recommended use of the chemical and restrictions on use

Relevant identified uses	Dental professional use: For fissure and tooth protection.
--------------------------	--

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

Registered company name	SDI (North America) Inc.	SDI Limited	SDi
Address	1279 Hamilton Parkway Itasca IL 60143 United States	3-15 Brunsdon Street Bayswater VIC 3153 Australia	Rua Dr. Virgílio de Carvalho Pinto, 612 Pinheiros, Sao Paulo 05415-020 Brazil
Telephone	+1 630 361 9200 (Business hours) 1 800 228 5166	+61 3 8727 7111 (Business Hours)	+55 11 3092 7100 (Business Hours)
Fax	+1 630 361 9222	+61 3 8727 7222	+55 11 3092 7101
Website	http://www.sdi.com.au	www.sdi.com.au	http://www.sdi.com.au/
Email	USA.Canada@sdi.com.au	info@sdi.com.au	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
Website	http://www.sdi.com.au/
Email	Ireland@sdi.com.au

Emergency phone 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 Hazard(s) identification

Classification of the substance or mixture

NFPA 704 diamond



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

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

Label elements

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

Riva Protect Capsules

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

Hazard statement(s)

H315	Causes skin irritation.
H319	Causes serious eye irritation.
H335	May cause respiratory irritation.
H412	Harmful to aquatic life with long lasting effects.

Hazard(s) not otherwise classified

Not Applicable

Precautionary statement(s) Prevention

P271	Use only outdoors or in a well-ventilated area.
P261	Avoid breathing mist/vapours/spray.
P273	Avoid release to the environment.
P280	Wear protective gloves/protective clothing/eye protection/face protection.

Precautionary statement(s) Response

P321	Specific treatment (see advice on this label).
P362	Take off contaminated clothing and wash before reuse.
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.
P337+P313	If eye irritation persists: Get medical advice/attention.
P302+P352	IF ON SKIN: Wash with plenty of water.
P304+P340	IF INHALED: Remove victim to fresh air and keep at rest in a position comfortable for breathing.
P332+P313	If skin irritation occurs: Get medical advice/attention.

Precautionary statement(s) Storage

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

Precautionary statement(s) Disposal

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

SECTION 3 Composition / information on ingredients

Substances

See section below for composition of Mixtures

Mixtures

CAS No	%[weight]	Name
Not Available		compartment 1 (powder)
Not Available	90	<u>glass powder</u>
9003-01-4	10	<u>acrylic acid homopolymer</u>
Not Available		compartment 1 (liquid)
9003-01-4	25	<u>acrylic acid homopolymer</u>
87-69-4	10	<u>tartaric acid</u>

The specific chemical identity and/or exact percentage (concentration) of composition has been withheld as a trade secret.

SECTION 4 First-aid measures

Description of first aid measures

Eye Contact	<p>If this product comes in contact with the eyes:</p> <ul style="list-style-type: none"> ▶ Immediately hold eyelids apart and flush the eye continuously with running water. ▶ Ensure complete irrigation of the eye by keeping eyelids apart and away from eye and moving the eyelids by occasionally lifting the upper and lower lids. ▶ Continue flushing until advised to stop by the Poisons Information Centre or a doctor, or for at least 15 minutes. ▶ Transport to hospital or doctor without delay. ▶ Removal of contact lenses after an eye injury should only be undertaken by skilled personnel.
Skin Contact	<p>If skin contact occurs:</p> <ul style="list-style-type: none"> ▶ Immediately remove all contaminated clothing, including footwear. ▶ Flush skin and hair with running water (and soap if available). ▶ Seek medical attention in event of irritation.

Riva Protect Capsules

Inhalation	<ul style="list-style-type: none"> ▶ If fumes or combustion products are inhaled remove from contaminated area. ▶ Seek medical attention.
Ingestion	<ul style="list-style-type: none"> ▶ Immediately give a glass of water. ▶ First aid is not generally required. If in doubt, contact a Poisons Information Centre or a doctor. <p>Seek medical attention.</p>

Most important symptoms and effects, both acute and delayed

See Section 11

Indication of any immediate medical attention and special treatment needed

Treat symptomatically.

SECTION 5 Fire-fighting measures

Extinguishing media

Foam is generally ineffective.

Special hazards arising from the substrate or mixture

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

Special protective equipment and precautions for fire-fighters

Fire Fighting	<ul style="list-style-type: none"> ▶ Alert Fire Brigade and tell them location and nature of hazard. ▶ 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: carbon dioxide (CO₂) other pyrolysis products typical of burning organic material. May emit poisonous fumes. May emit corrosive fumes.</p>

SECTION 6 Accidental release measures

Personal precautions, protective equipment and emergency procedures

See section 8

Environmental precautions

See section 12

Methods and material for containment and cleaning up

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

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

SECTION 7 Handling and storage

Precautions for safe handling

Safe handling	<ul style="list-style-type: none"> ▶ Avoid all personal contact, including inhalation. ▶ Wear protective clothing when risk of exposure occurs. ▶ Use in a well-ventilated area. ▶ Prevent concentration in hollows and sumps.
----------------------	--

Continued...

Riva Protect Capsules

	<ul style="list-style-type: none"> ▶ DO NOT enter confined spaces until atmosphere has been checked. ▶ DO NOT allow material to contact humans, exposed food or food utensils. ▶ Avoid contact with incompatible materials. ▶ When handling, DO NOT eat, drink or smoke. ▶ Keep containers securely sealed when not in use. ▶ Avoid physical damage to containers. ▶ Always wash hands with soap and water after handling. ▶ Work clothes should be laundered separately. Launder contaminated clothing before re-use. ▶ Use good occupational work practice. ▶ Observe manufacturer's storage and handling recommendations contained within this SDS. ▶ Atmosphere should be regularly checked against established exposure standards to ensure safe working conditions are maintained.
Other information	<p>Store in a dry and well ventilated-area, away from heat and sunlight. Do not store in direct sunlight. Store between 5 and 25 deg. C.</p>

Conditions for safe storage, including any incompatibilities

Suitable container	▶ DO NOT repack. Use containers supplied by manufacturer only.
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
tartaric acid	Tartaric acid	1.6 mg/m ³	17 mg/m ³	100 mg/m ³

Ingredient	Original IDLH	Revised IDLH
glass powder	Not Available	Not Available
acrylic acid homopolymer	Not Available	Not Available
acrylic acid homopolymer	Not Available	Not Available
tartaric acid	Not Available	Not Available

Occupational Exposure Banding

Ingredient	Occupational Exposure Band Rating	Occupational Exposure Band Limit
acrylic acid homopolymer	E	≤ 0.01 mg/m ³
acrylic acid homopolymer	E	≤ 0.01 mg/m ³
tartaric acid	E	≤ 0.01 mg/m ³

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


MATERIAL DATA

Exposure controls

Appropriate engineering controls	<p>Engineering controls are used to remove a hazard or place a barrier between the worker and the hazard. Well-designed engineering controls can be highly effective in protecting workers and will typically be independent of worker interactions to provide this high level of protection.</p> <p>The basic types of engineering controls are:</p> <p>Process controls which involve changing the way a job activity or process is done to reduce the risk.</p> <p>Enclosure and/or isolation of emission source which keeps a selected hazard "physically" away from the worker and ventilation that strategically "adds" and "removes" air in the work environment. Ventilation can remove or dilute an air contaminant if designed properly. The design of a ventilation system must match the particular process and chemical or contaminant in use.</p> <p>Employers may need to use multiple types of controls to prevent employee overexposure.</p> <p>General exhaust is adequate under normal operating conditions. Local exhaust ventilation may be required in special circumstances. If risk of overexposure exists, wear approved respirator. Supplied-air type respirator may be required in special circumstances. Correct fit is essential to ensure adequate protection. Provide adequate ventilation in warehouses and enclosed storage areas. Air contaminants generated in the workplace possess varying "escape" velocities which, in turn, determine the "capture velocities" of fresh circulating air required to effectively remove the contaminant.</p>	
	Type of Contaminant:	Air Speed:
	solvent, vapours, degreasing etc., evaporating from tank (in still air).	0.25-0.5 m/s (50-100 f/min)
	aerosols, fumes from pouring operations, intermittent container filling, low speed conveyer transfers, welding, spray drift, plating acid fumes, pickling (released at low velocity into zone of active generation)	0.5-1 m/s (100-200 f/min.)
	direct spray, spray painting in shallow booths, drum filling, conveyer loading, crusher dusts, gas discharge (active generation into zone of rapid air motion)	1-2.5 m/s (200-500 f/min.)
	grinding, abrasive blasting, tumbling, high speed wheel generated dusts (released at high initial velocity into zone of very high rapid air motion)	2.5-10 m/s (500-2000 f/min.)
Within each range the appropriate value depends on:		
Lower end of the range	Upper end of the range	

Continued...

Riva Protect Capsules

	1: Room air currents minimal or favourable to capture 2: Contaminants of low toxicity or of nuisance value only. 3: Intermittent, low production. 4: Large hood or large air mass in motion	1: Disturbing room air currents 2: Contaminants of high toxicity 3: High production, heavy use 4: Small hood-local control only
	<p>Simple theory shows that air velocity falls rapidly with distance away from the opening of a simple extraction pipe. Velocity generally decreases with the square of distance from the extraction point (in simple cases). Therefore the air speed at the extraction point should be adjusted, accordingly, after reference to distance from the contaminating source. The air velocity at the extraction fan, for example, should be a minimum of 1-2 m/s (200-400 f/min) for extraction of solvents generated in a tank 2 meters distant from the extraction point. Other mechanical considerations, producing performance deficits within the extraction apparatus, make it essential that theoretical air velocities are multiplied by factors of 10 or more when extraction systems are installed or used.</p>	
Personal protection		
Eye and face protection	<ul style="list-style-type: none"> ▶ 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	
Body protection	See Other protection below	
Other protection	No special equipment needed when handling small quantities. OTHERWISE: <ul style="list-style-type: none"> ▶ Overalls. ▶ Barrier cream. ▶ Eyewash unit. 	

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
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

Riva Protect Capsules

Information on toxicological effects

Inhaled	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.
Ingestion	The material has NOT been classified by EC Directives or other classification systems as "harmful by ingestion". This is because of the lack of corroborating animal or human evidence. The material may still be damaging to the health of the individual, following ingestion, especially where pre-existing organ (e.g liver, kidney) damage is evident. Present definitions of harmful or toxic substances are generally based on doses producing mortality rather than those producing morbidity (disease, ill-health). Gastrointestinal tract discomfort may produce nausea and vomiting. In an occupational setting however, ingestion of insignificant quantities is not thought to be cause for concern.
Skin Contact	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. Limited evidence suggests that repeated or long-term occupational exposure may produce cumulative health effects involving organs or biochemical systems.

Riva Protect Capsules	TOXICITY	IRRITATION
	Not Available	Not Available
glass powder	TOXICITY	IRRITATION
	Not Available	Not Available
acrylic acid homopolymer	TOXICITY	IRRITATION
	Not Available	Eye: adverse effect observed (irreversible damage) ^[1] Skin: no adverse effect observed (not irritating) ^[1]
acrylic acid homopolymer	TOXICITY	IRRITATION
	Not Available	Eye: adverse effect observed (irreversible damage) ^[1] Skin: no adverse effect observed (not irritating) ^[1]
tartaric acid	TOXICITY	IRRITATION
	5000 mg/kg ^[2]	Not Available
Legend:	1. Value obtained from Europe ECHA Registered Substances - Acute toxicity 2.* Value obtained from manufacturer's SDS. Unless otherwise specified data extracted from RTECS - Register of Toxic Effect of chemical Substances	

glass powder	No significant acute toxicological data identified in literature search.
TARTARIC ACID	<p>for simple alpha-hydroxy carboxylic acids and their salts:</p> <p>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."</p> <p>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.</p> <p>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.</p> <p>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.</p> <p>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.</p> <p>The toxicology of simple alpha hydroxy carboxylic acids cluster is characterised by five compounds sharing the functional group defining the cluster name</p> <p>Experimental data available for members of the simple alpha-hydroxy carboxylic acids indicate a low acute, repeated-dose, reproductive and developmental toxicity.</p>

Riva Protect Capsules

	<p>The simple alpha hydroxy carboxylic acids are eye and skin irritants but are not expected to be skin sensitizers. 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.</p> <p>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 EPA's 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 eye 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 sensitizers 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, 2-hydroxy- (50-21-5), which is considered a reasonable analogue to the rest of the cluster.</p> <p>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</p> <p>Convulsions, haemorrhage recorded.</p>	
<p>ACRYLIC ACID HOMOPOLYMER & TARTARIC ACID</p>	<p>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, on spirometry, with the presence of moderate to severe bronchial hyperreactivity on methacholine challenge testing and the lack of minimal lymphocytic inflammation, without eosinophilia, have also been included in the criteria for diagnosis of RADS. RADS (or asthma) following an irritating inhalation is an infrequent disorder with rates related to the concentration of and duration of exposure to the irritating substance. Industrial bronchitis, on the other hand, is a disorder that occurs as result of exposure due to high concentrations of irritating substance (often particulate in nature) and is completely reversible after exposure ceases. The disorder is characterised by dyspnea, cough and mucus production.</p>	
<p>ACRYLIC ACID HOMOPOLYMER</p>	<p>Polycarboxylates are of low toxicity by all exposure routes examined.</p> <p>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.</p> <p>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.</p> <p>There was neither evidence for a genotoxic potential of PAA using a variety of genetic endpoints in-vitro and in-vivo, nor 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</p> <p>The Cosmetic Ingredient Review (CIR) Expert Panel noted that these crosslinked alkyl acrylates are macromolecules that are not expected to pass through the stratum corneum 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 carcinogenic effects upon use.</p> <p>The Panel noted that cosmetic products containing these ingredients are reportedly used around the eyes, on the lips, and on other mucous membranes. Thus, crosslinked alkyl acrylates could be absorbed systemically through the relatively moist, n stratum cornea of the conjunctiva, lips, and other mucous membranes, and through ingestion when applied to the lips. However, the Panel noted that any absorption through healthy intact mucous membranes is likely to be not significant, primarily because of the relatively large molecular sizes. Furthermore, the chemically inert nature of the polymers precludes degradation to smaller absorbable species.</p> <p>Absorption of the polymers and their residual monomers in cosmetic products also would be limited after application to the lips or eye area based on the relatively small fractions of the applied products that might be inadvertently ingested or make direct contact with the conjunctiva.</p> <p>The Carbomers (Carbopols) are synthetic, high molecular weight, nonlinear polymers of acrylic acid, cross-linked with a polyalkenyl polyether. The Carbomer polymers are used in cosmetics and emulsifying agents at concentrations up to 50%. Acute oral animal studies showed that Carbomers-910, -934, -934P, -940, and -941 have low toxicities when ingested. Rabbits showed minimal skin irritation and zero to moderate eye irritation when tested with Carbomers-910 and -934. Subchronic feeding of rats and dogs with Carbomer-934 in the diet resulted in lower than normal body weights, but no pathological changes were observed. Dogs chronically fed Carbomer-934P manifested gastrointestinal irritation and marked pigment deposition within Kupffer cells of the liver. Clinical studies with Carbomers showed that these polymers have low potential for skin irritation and sensitization at concentrations up to 100%. Carbomer-934 demonstrated low potential for phototoxicity and photo-contact allergenicity. On the basis of the available information presented and as qualified in the report, it is concluded that the Carbomers are safe as cosmetic ingredients.</p> <p>Little toxicity data is available for acrylic crosspolymers; the acute dermal and oral toxicity data that were found indicated that these ingredients are not very toxic. The little genotoxicity data that were available reported negative results in Ames tests. Carcinogenicity data were not found in the published literature for the polymers, but data were available for the monomers.</p> <p>In an alternative method study, acrylates/vinyl neodecanoate crosspolymer was predicted to be a non-irritant. The non-human studies reported no to slight irritation with undiluted and weak sensitization with 2% aq., acrylates/C10-30 alkyl acrylate crosspolymer, no irritation with acrylates crosspolymer at 30% in olive oil, and no irritation or sensitization with sodium acrylates crosspolymer-2 (concentration not specified). Mostly, human testing with undiluted acrylates/C10-30 alkyl acrylate crosspolymer, acrylates crosspolymer, and acrylates/ethylhexyl acrylate crosspolymer, up to 2.5% aq. acrylates/vinyl isodecanoate crosspolymer, 1% aq. dilutions of formulations containing 2% acrylates/vinyl neodecanoate crosspolymer, and formulations containing up to 2.6% lauryl methacrylate/glycol dimethacrylate crosspolymers do not indicate any dermal irritation or sensitization. The only exception was a weak irritant response noted during an intensified Shelanski human repeated insult patch test (HRIPT) with undiluted acrylates/C10-30 alkyl acrylate crosspolymer.</p> <p>Alternative test methods for ocular irritation indicated that acrylates/vinyl isodecanoate crosspolymer and a formulation containing 1% lauryl methacrylate/glycol dimethacrylate crosspolymer are not likely ocular irritants. In studies using rabbits, undiluted acrylates/C10-30 alkyl acrylate crosspolymer produced minimal to moderate irritation, and it was considered a borderline irritant in unrinse rabbit eyes. Acrylates crosspolymer, at 50% in olive oil, and sodium acrylates crosspolymer-2 did not appear to be ocular irritants in rabbit eyes. Two different risk assessments evaluating the carcinogenic endpoint for benzene that may be present in acrylates/ C10-30 alkyl acrylates crosspolymer resulted in different lifetime risk. One found that the risk was within the range associated with a 10exp 6 cancer risk, while the other reported a 20-fold greater risk.</p> <p>Final Safety Assessment: Crosslinked Alkyl Acrylates as Used in Cosmetics. Nov 2011</p> <p>Cosmetic Ingredient Review (CIR) Expert Panel http://ntp.niehs.nih.gov/ntp/roc/nominations/2013/publiccomm/attachmentcir_508.pdf</p> <p>The substance is classified by IARC as Group 3: NOT classifiable as to its carcinogenicity to humans.</p> <p>Evidence of carcinogenicity may be inadequate or limited in animal testing.</p>	
<p>Acute Toxicity</p>	<p>✗</p>	<p>Carcinogenicity</p> <p>✗</p>
<p>Skin Irritation/Corrosion</p>	<p>✓</p>	<p>Reproductivity</p> <p>✗</p>
<p>Serious Eye Damage/Irritation</p>	<p>✓</p>	<p>STOT - Single Exposure</p> <p>✓</p>

Riva Protect Capsules

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

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

SECTION 12 Ecological information

Toxicity

Riva Protect Capsules	Endpoint	Test Duration (hr)	Species	Value	Source
	Not Available	Not Available	Not Available	Not Available	Not Available
glass powder	Endpoint	Test Duration (hr)	Species	Value	Source
	Not Available	Not Available	Not Available	Not Available	Not Available
acrylic acid homopolymer	Endpoint	Test Duration (hr)	Species	Value	Source
	LC50	96	Fish	27mg/L	2
	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
acrylic acid homopolymer	Endpoint	Test Duration (hr)	Species	Value	Source
	LC50	96	Fish	27mg/L	2
	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
tartaric acid	Endpoint	Test Duration (hr)	Species	Value	Source
	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	

Legend: Extracted from 1. IUCLID Toxicity Data 2. Europe ECHA Registered Substances - Ecotoxicological Information - Aquatic Toxicity 3. EPIWIN Suite V3.12 (QSAR) - Aquatic Toxicity Data (Estimated) 4. US EPA, Ecotox database - Aquatic Toxicity Data 5. ECETOC Aquatic Hazard Assessment Data 6. NITE (Japan) - Bioconcentration Data 7. METI (Japan) - Bioconcentration Data 8. Vendor Data

DO NOT discharge into sewer or waterways.

Persistence and degradability

Ingredient	Persistence: Water/Soil	Persistence: Air
acrylic acid homopolymer	LOW	LOW
acrylic acid homopolymer	LOW	LOW
tartaric acid	LOW	LOW

Bioaccumulative potential

Ingredient	Bioaccumulation
acrylic acid homopolymer	LOW (LogKOW = 0.4415)
acrylic acid homopolymer	LOW (LogKOW = 0.4415)
tartaric acid	LOW (LogKOW = -1.0017)

Mobility in soil

Ingredient	Mobility
acrylic acid homopolymer	HIGH (KOC = 1.201)
acrylic acid homopolymer	HIGH (KOC = 1.201)
tartaric acid	HIGH (KOC = 1)

SECTION 13 Disposal considerations

Waste treatment methods

Product / Packaging disposal	
	<ul style="list-style-type: none"> ▶ DO NOT allow wash water from cleaning or process equipment to enter drains. ▶ It may be necessary to collect all wash water for treatment before disposal.

Continued...

Riva Protect Capsules

▶ 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
------------------	----

Land transport (DOT): 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

glass powder is found on the following regulatory lists

Not Applicable

acrylic acid homopolymer is found on the following regulatory lists

International Agency for Research on Cancer (IARC) - Agents Classified by the IARC Monographs
US Toxic Substances Control Act (TSCA) - Chemical Substance Inventory

US TSCA Chemical Substance Inventory - Interim List of Active Substances

acrylic acid homopolymer is found on the following regulatory lists

International Agency for Research on Cancer (IARC) - Agents Classified by the IARC Monographs
US Toxic Substances Control Act (TSCA) - Chemical Substance Inventory

US TSCA Chemical Substance Inventory - Interim List of Active Substances

tartaric acid is found on the following regulatory lists

US DOE Temporary Emergency Exposure Limits (TEELs)
US Toxic Substances Control Act (TSCA) - Chemical Substance Inventory

US TSCA Chemical Substance Inventory - Interim List of Active Substances

Federal Regulations

Superfund Amendments and Reauthorization Act of 1986 (SARA)

Section 311/312 hazard categories

Flammable (Gases, Aerosols, Liquids, or Solids)	No
Gas under pressure	No
Explosive	No
Self-heating	No
Pyrophoric (Liquid or Solid)	No
Pyrophoric Gas	No
Corrosive to metal	No
Oxidizer (Liquid, Solid or Gas)	No
Organic Peroxide	No
Self-reactive	No
In contact with water emits flammable gas	No
Combustible Dust	No
Carcinogenicity	No
Acute toxicity (any route of exposure)	No
Reproductive toxicity	No
Skin Corrosion or Irritation	Yes
Respiratory or Skin Sensitization	No
Serious eye damage or eye irritation	Yes
Specific target organ toxicity (single or repeated exposure)	No
Aspiration Hazard	No
Germ cell mutagenicity	No
Simple Asphyxiant	No
Hazards Not Otherwise Classified	No

US. EPA CERCLA Hazardous Substances and Reportable Quantities (40 CFR 302.4)

None Reported

Continued...

Riva Protect Capsules

State Regulations

US. California Proposition 65

None Reported

National Inventory Status

National Inventory	Status
Australia - AIIC	Yes
Australia - Non-Industrial Use	No (acrylic acid homopolymer; acrylic acid homopolymer; tartaric acid)
Canada - DSL	Yes
Canada - NDSL	No (acrylic acid homopolymer; acrylic acid homopolymer; tartaric acid)
China - IECSC	Yes
Europe - EINEC / ELINCS / NLP	No (acrylic acid homopolymer; acrylic acid homopolymer)
Japan - ENCS	Yes
Korea - KECI	Yes
New Zealand - NZIoC	Yes
Philippines - PICCS	Yes
USA - TSCA	Yes
Taiwan - TCSI	Yes
Mexico - INSQ	Yes
Vietnam - NCI	Yes
Russia - ARIPS	Yes
Legend:	Yes = All CAS declared ingredients are on the inventory No = One or more of the CAS listed ingredients are not on the inventory 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
5.1.1.1	18/03/2016	Storage (suitable container)
6.1.1.1	01/11/2019	One-off system update. NOTE: This may or may not change the GHS classification

Other information

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

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

Definitions and abbreviations

PC—TWA: Permissible Concentration-Time Weighted Average
 PC—STEL: Permissible Concentration-Short Term Exposure Limit
 IARC: International Agency for Research on Cancer
 ACGIH: American Conference of Governmental Industrial Hygienists
 STEL: Short Term Exposure Limit
 TEEL: Temporary Emergency Exposure Limit.
 IDLH: Immediately Dangerous to Life or Health Concentrations
 OSF: Odour Safety Factor
 NOAEL :No Observed Adverse Effect Level
 LOAEL: Lowest Observed Adverse Effect Level
 TLV: Threshold Limit Value
 LOD: Limit Of Detection
 OTV: Odour Threshold Value
 BCF: BioConcentration Factors
 BEI: Biological Exposure Index

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

Other information:

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