

Riva Silver Capsules

SDI Limited

Version No: 7.1

Safety Data Sheet according to WHS Regulations (Hazardous Chemicals) Amendment 2020 and ADG requirements

Issue Date: **10/03/2023** Print Date: **17/11/2023** L.GHS.AUS.EN

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

Product Identifier

Product name	Riva Silver Capsules
Chemical Name	Not Applicable
Synonyms	Not Available
Chemical formula	Not Applicable
Other means of identification	Not Available

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

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

Details of the manufacturer or supplier of the safety data sheet

Registered company name	SDI Limited	SDI (North America) Inc.	SDI Germany GmbH
Address	3-15 Brunsdon Street Bayswater VIC 3153 Australia	1279 Hamilton Parkway Itasca IL 60143 United States	Hansestrasse 85 Cologne D-51149 Germany
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Registered company name	SDI HOLDINGS PTY LTD DO		
Address	Rua Dr. Reinaldo Schmithausen 3141 – Cordeiros Itajaí – SC – CEP 88310-004 Brazil		
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Telephone	+55 11 3092 7100
Fax	Not Available
Website	http://www.sdi.com.au/
Email	Brasil@sdi.com.au

Emergency telephone number

Association / Organisation	SDI Limited	CHEMWATCH EMERGENCY RESPONSE (24/7)
Emergency telephone numbers	131126 Poisons Information Centre	+61 1800 951 288
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

Classification of the substance or mixture

Poisons Schedule	Poisons Schedule Not Applicable	
Classification ^[1]	Skin Corrosion/Irritation Category 2, Serious Eye Damage/Eye Irritation Category 2A, Specific Target Organ Toxicity - Single Exposure (Respiratory Tract Irritation) Category 3	
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

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Hazard statement(s)

H315	Causes skin irritation.
H319	Causes serious eye irritation.
H335	May cause respiratory irritation.

Precautionary statement(s) Prevention

P271	Use only outdoors or in a well-ventilated area.
P261	Avoid breathing mist/vapours/spray.
P280	Wear protective gloves, protective clothing, eye protection and face protection.
P264	Wash all exposed external body areas thoroughly after handling.

Precautionary statement(s) Response

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.
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 person to fresh air and keep comfortable for breathing.
P332+P313	If skin irritation occurs: Get medical advice/attention.
P362+P364	Take off contaminated clothing and wash it before reuse.

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 contains
9003-01-4	30	acrylic acid homopolymer
87-69-4	10	tartaric acid
Not Available		Compartment 2 contains
Not Available	40-60	glass powder
9003-01-4	<10	acrylic acid homopolymer
Not Available	30-50	alloy powder
Legend: 1. Classification by vendor; 2. Classification drawn from HCIS; 3. Classification drawn from Regulation (EU) No 1272/2008 - Annex VI; 4. Classification drawn from C&L * EU IOELVs available		

SECTION 4 First aid measures

Description of first aid measures

Eye Contact	If this product comes in contact with the eyes: Number 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	 Immediately give a glass of water. First aid is not generally required. If in doubt, contact a Poisons Information Centre or a doctor. Seek medical attention.

Indication of any immediate medical attention and special treatment needed

Treat symptomatically.

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SECTION 5 Firefighting measures

Extinguishing media

Foam is generally ineffective.

Special hazards arising from the substrate or mixture

Special hazards arising from the substrate or mixture	
Fire Incompatibility	None known.
Advice 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 poisonous fumes. May emit corrosive fumes.

SECTION 6 Accidental release measures

HAZCHEM

Personal precautions, protective equipment and emergency procedures

Not Applicable

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. Avoid contact with incompatible materials. When handling, DO NOT eat, drink or smoke. Safe handling ▶ 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.

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Other information

Store between 5 and 25 deg. C Do not store in direct sunlight.

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

Conditions for safe storage, including any incompatibilities

Suitable container

- DO NOT repack. Use containers supplied by manufacturer only.
- Check that containers are clearly labelled and free from leaks

Storage incompatibility

TEEL-1

SECTION 8 Exposure controls / personal protection

Control parameters

Occupational Exposure Limits (OEL)

INGREDIENT DATA

Not Available

Ingredient

Emergency Limits

tartaric acid	1.6 mg/m3	17 mg/m3		100 mg/m3
Ingredient	Original IDLH		Revised IDLH	
acrylic acid homopolymer	Not Available		Not Available	
tartaric acid	Not Available		Not Available	
glass powder	Not Available		Not Available	
acrylic acid homopolymer	Not Available		Not Available	

TEEL-2

Occupational Exposure Banding

Ingredient	Occupational Exposure Band Rating	Occupational Exposure Band Limit
acrylic acid homopolymer	E	≤ 0.01 mg/m³
tartaric acid	E	≤ 0.01 mg/m³
acrylic acid homopolymer	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

Exposure controls

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

TEEL-3

The basic types of engineering controls are:

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

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

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

General exhaust is adequate under normal operating conditions. Local exhaust ventilation may be required in special circumstances. If risk of overexposure exists, wear approved respirator. Supplied-air type respirator may be required in special circumstances. Correct fit is essential to ensure adequate protection. Provide adequate ventilation in warehouses and enclosed storage areas. Air contaminants generated in the workplace possess varying "escape" velocities which, in turn, determine the "capture velocities" of fresh circulating air required to effectively remove the contaminant.

Appropriate engineering controls

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

Within each range the appropriate value depends on:

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

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

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Individual protection measures, such as personal protective equipment





more when extraction systems are installed or used.





- Safety glasses with side shields.
- ► Chemical goggles. [AS/NZS 1337.1, EN166 or national equivalent]

Eye and face protection

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

- ▶ Wear chemical protective gloves, e.g. PVC.
- Wear safety footwear or safety gumboots, e.g. Rubber
- Rubber Gloves

Body protection

See Other protection below

- Other protection
- Overalls.P.V.C apron.
- ► Barrier cream.
- Skin cleansing cream.
- ► Eye wash unit.

SECTION 9 Physical and chemical properties

Information on basic physical and chemical properties

Appearance	Smooth, light-grey coloured paste with slightly characteristic odour, partially mixes with water.		
Physical state	Non Slump Paste	Relative density (Water = 1)	1.0
Odour	Not Available	Partition coefficient n-octanol / water	Not Available
Odour threshold	Not Available	Auto-ignition temperature (°C)	Not Available
pH (as supplied)	Not Available	Decomposition temperature (°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	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 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.

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Ingestion Accidental ingestion of the material may be damaging to the health of the individual. 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) Skin Contact 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. 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 Eye 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. Long-term exposure to respiratory irritants may result in disease of the airways involving difficult breathing and related systemic problems. Chronic Limited evidence suggests that repeated or long-term occupational exposure may produce cumulative health effects involving organs or biochemical systems. TOXICITY IRRITATION **Riva Silver Capsules** Not Available Not Available TOXICITY IRRITATION Eye: adverse effect observed (irreversible damage) $^{[1]}$ Dermal (rabbit) LD50: >2000 mg/kg^[1] acrylic acid homopolymer Inhalation(Rat) LC50: >5.1 mg/l4h^[1] Skin: no adverse effect observed (not irritating)^[1] Oral (Rat) LD50: 146-468 mg/kg[1] TOXICITY IRRITATION dermal (rat) LD50: >2000 mg/kg^[1] Not Available tartaric acid Oral (Rat) LD50: $>=2000 <=5000 \text{ mg/kg}^{[1]}$ TOXICITY IRRITATION glass powder Not Available Not Available TOXICITY IRRITATION Dermal (rabbit) LD50: >2000 mg/kg^[1] Eye: adverse effect observed (irreversible damage)^[1] acrylic acid homopolymer Inhalation(Rat) LC50: >5.1 mg/l4h[1] Skin: no adverse effect observed (not irritating)^[1] Oral (Rat) LD50: 146-468 mg/kg[1] Legend: 1. Value obtained from Europe ECHA Registered Substances - Acute toxicity 2. Value obtained from manufacturer's SDS. Unless otherwise specified data extracted from RTECS - Register of Toxic Effect of chemical Substances

Convulsions, haemorrhage recorded.

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.

TARTARIC ACID

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 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),

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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, 2-hydroxy- (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

glass powder

No significant acute toxicological data identified in literature search

ACRYLIC ACID HOMOPOLYMER & TARTARIC

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.

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 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

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.

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.

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. 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.

ACRYLIC ACID HOMOPOLYMER

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.

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.

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 unrinsed 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. Final Safety Assessment: Crosslinked Alkyl Acrylates as Used in Cosmetics. Nov 2011

Cosmetic Ingredient Review (CIR) Expert Panel

http://ntp.niehs.nih.gov/ntp/roc/nominations/2013/publiccomm/attachmentcir_508.pdf

The substance is classified by IARC as Group 3:

NOT classifiable as to its carcinogenicity to humans

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

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

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Toxicity

	Endpoint	Test Duration (hr)	Species	Value	Source
Riva Silver Capsules	Not Available	Not Available	Not Available Not Available		Not Available
	Endpoint	Test Duration (hr)	Species	Value	Source
	EC50	72h	Algae or other aquatic plants	0.13-0.205mg/l	2
acrylic acid homopolymer	EC50	48h	Crustacea	47mg/l	2
	EC10(ECx)	72h	Algae or other aquatic plants	0.03-0.031mg/l	2
	LC50	96h	Fish	27mg/l	2
	Endpoint	Test Duration (hr)	Species	Value	Source
	EC50	72h	Algae or other aquatic plants	51.404mg/l	2
	EC50	48h	Crustacea	Crustacea 93.313mg/l	
tartaric acid	EC50	96h	Algae or other aquatic plants	Algae or other aquatic plants 23616mg/L	
	NOEC(ECx)	72h	Algae or other aquatic plants	3.125mg/l	2
	LC50	96h	Fish	>100mg/l	2
	Endpoint	Test Duration (hr)	Species	Value	Source
glass powder	Not Available	Not Available	Not Available	Not Available	Not Available
	Endpoint	Test Duration (hr)	Species	Value	Sourc
	EC50	72h	Algae or other aquatic plants	0.13-0.205mg/l	2
acrylic acid homopolymer	EC50	48h	Crustacea	47mg/l	2
	EC10(ECx)	72h	Algae or other aquatic plants	0.03-0.031mg/l	2
	LC50	96h	Fish	27mg/l	2
Legend:	Ecotox databas		CHA Registered Substances - Ecotoxicological Infon Aquatic Hazard Assessment Data 6. NITE (Japan)		

DO NOT discharge into sewer or waterways.

Persistence and degradability

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

Bioaccumulative potential

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

Mobility in soil

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

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.

 $\mbox{\ensuremath{\,^{\blacktriangleright}}}$ 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

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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

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
acrylic acid homopolymer	Not Available
tartaric acid	Not Available
glass powder	Not Available
acrylic acid homopolymer	Not Available

14.7.3. Transport in bulk in accordance with the IGC Code

Product name	Ship Type
acrylic acid homopolymer	Not Available
tartaric acid	Not Available
glass powder	Not Available
acrylic acid homopolymer	Not Available

SECTION 15 Regulatory information

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

acrylic acid homopolymer is found on the following regulatory lists

Australian Inventory of Industrial Chemicals (AIIC)

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

tartaric acid is found on the following regulatory lists

Australian Inventory of Industrial Chemicals (AIIC)

glass powder is found on the following regulatory lists

Not Applicable

acrylic acid homopolymer is found on the following regulatory lists

Australian Inventory of Industrial Chemicals (AIIC)

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

National Inventory Status

National Inventory	Status		
Australia - AIIC / Australia Non-Industrial Use	Yes		
Canada - DSL	Yes		
Canada - NDSL	No (acrylic acid homopolymer; tartaric acid; acrylic acid homopolymer)		
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 - FBEPH	Yes		
Legend:	Yes = All CAS declared ingredients are on the inventory No = One or more of the CAS listed ingredients are not on the inventory. These ingredients may be exempt or will require registration.		

SECTION 16 Other information

Revision Date	10/03/2023
Initial Date	15/12/2015

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Riva Silver Capsules

Print Date: 17/11/2023

SDS Version Summary

Version	Date of Update	Sections Updated
6.1	23/12/2022	Classification review due to GHS Revision change.
7.1	10/03/2023	Classification change due to full database hazard calculation/update.

Other information

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

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

Definitions and abbreviations

- ▶ PC TWA: Permissible Concentration-Time Weighted Average
- ▶ PC STEL: Permissible Concentration-Short Term Exposure Limit
- ► IARC: International Agency for Research on Cancer
- ACGIH: American Conference of Governmental Industrial Hygienists
- ▶ STEL: Short Term Exposure Limit
- ► TEEL: Temporary Emergency Exposure Limit。
- ▶ IDLH: Immediately Dangerous to Life or Health Concentrations
- ES: Exposure Standard
- ► OSF: Odour Safety Factor
- ▶ NOAEL: No Observed Adverse Effect Level
- ▶ LOAEL: Lowest Observed Adverse Effect Level
- ► TLV: Threshold Limit Value
- LOD: Limit Of Detection
- ► OTV: Odour Threshold Value
- ▶ BCF: BioConcentration Factors
- ▶ BEI: Biological Exposure Index
- ► DNEL: Derived No-Effect Level
- ▶ PNEC: Predicted no-effect concentration
- ► AIIC: Australian Inventory of Industrial Chemicals
- DSL: Domestic Substances List
- ▶ NDSL: Non-Domestic Substances List
- ▶ IECSC: Inventory of Existing Chemical Substance in China
- ▶ EINECS: European INventory of Existing Commercial chemical Substances
- ► ELINCS: European List of Notified Chemical Substances
- ► NLP: No-Longer Polymers
- ► ENCS: Existing and New Chemical Substances Inventory
- ► KECI: Korea Existing Chemicals Inventory
- ▶ NZIoC: New Zealand Inventory of Chemicals
- ▶ PICCS: Philippine Inventory of Chemicals and Chemical Substances
- ► TSCA: Toxic Substances Control Act
- ► TCSI: Taiwan Chemical Substance Inventory
- ► INSQ: Inventario Nacional de Sustancias Químicas
- ► NCI: National Chemical Inventory
- FBEPH: Russian Register of Potentially Hazardous Chemical and Biological Substances

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

Other information:

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