



1. Identification of the substance/mixture and of the Company/undertaking:

1.1 Product identifier:

Product Name: Riva Silver Capsules

1.2 Relevant identified use:

Relevant use: For filling of cavitated teeth by dental professionals.

1.3 Details of the supplier of the Safety Data Sheet:

Manufacturer / Supplier

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2. Hazard Identification

Classification of the substance/mixture:

SIGNAL WORD: WARNING



Exclamation mark

GHS Classification:

Skin irritant 2

Eye Irritant 2

STOT SE (respiratory tract) 3



2. Hazard Identification

Hazard statement(s):

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

Precautionary statement(s):

Prevention:

- P261 Avoid breathing dust/ fume/ gas/ mist/ vapours/ spray.
- P264 Wash skin thoroughly after handling.
- P271 Use in a well-ventilated area.
- P280 Wear protective gloves/ eye protection/ face protection.

Response:

- P302 + P352 IF ON SKIN: Wash with plenty of soap and water.
- P304 + P340 IF INHALED: Remove victim to fresh air and keep at rest in a position comfortable for breathing.
- 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.
- P321 Specific treatment (see supplemental first aid instructions in the instructions for use and first aid section).
- P403+P233 Store in a well-ventilated place. Keep container tightly closed.
- P332 + P313 If skin irritation or rash occurs: Get medical advice/ attention.
- P337 + P313 If eye irritation persists: Get medical advice/ attention.
- P362 Take off contaminated clothing and wash before reuse.

Storage:

- P405 Store locked up.

Disposal:

- P501 Dispose of contents/container in accordance with local regulations.

Other information: Materials in the two compartments are irritants. However, under normal conditions of use, contact with these materials is generally not expected.

3. Composition / Information on ingredients

<u>Composition:</u>	<u>CAS No.</u>	<u>Wt. %</u>
Compartment 1:		
Polyacrylic Acid	9003-01-4	30.0
Tartaric acid	87-69-4	10.0
Compartment2:		
Glass Powder*	-	40-60

* The specific chemical entity has been withheld as a trade secret.



4. First Aid Measures

- Eye (contact): Flush opened eye with running. Remove contact lenses, if present and easy to do. Continue rinsing for 15 minutes. Seek medical attention.
- Skin (contact): Remove contaminated clothing. Wash skin with plenty of water. If irritation occurs seek medical attention.
- Ingestion: Drink plenty of water. Seek medical attention if feeling unwell.
- Inhalation: Remove to fresh air. Seek medical attention if irritation develops or if feeling unwell.
- Most important effects, acute and delayed:
The most important known symptoms and effects are described in section 2 and/or in section 11.
- Indication of any immediate medical attention and special treatment needed: No data available.
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5. Fire Fighting Measures

- Suitable extinguishing media: Foam type.
- Unusual Fire and Explosion Hazards: None known.
- Unsuitable extinguishing media: None known.
- Specific hazards arising from the mixture:
- Combustion products: Emits unpleasant and pungent smoke when admitted to heat beyond boiling point. No other data available.
- Special protective equipment: No special protective equipment required.
- Advice for firefighters: Wear self-contained breathing apparatus for fire fighting if necessary.
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6. Accidental Release Measures

- For non-emergency personnel:
- Personal precautions: Do not get into eyes, on skin or clothing.
- Environmental Precautions: Do not let product enter drains
- Method for Cleaning and containment of Spills: Pick up and arrange disposal without creating dust. Sweep up and shovel. Keep in suitable closed containers for disposal. Wash the spillage area clean with water.
- Removal of ignition sources, provision of sufficient ventilation, control of dust: Wear approved respirator if required.
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7. Handling and storage

Precautions for safe handling:	Store sealed containers away from heat and light.
Conditions for safe storage, including any biocompatibilities:	Storage by the end user (Dental Clinic) is recommended to be at temperatures between 4° - 25°C (39° - 77°F) and should be kept away from direct sunlight.
Distribution:	During distribution, to our customers, this product can be transported in non-refrigerated conditions between 15° to 25° C.
Specific end use:	Apart from the use mentioned in section 1.2, there are no other uses for the product.

8. Exposure controls and personal protection

Respiratory protection:	None required.
Hand protection:	Rubber, latex or PVC gloves.
Eye protection:	Recommended.
General safety and hygiene measures:	None.

9. Physical and chemical properties

Appearance:	Smooth, light-grey coloured paste
Odour:	Slightly characteristic odour
Boiling point:	Approx. 100°C (212°F)
Melting point:	Not applicable
Specific gravity:	2.0 g/cm ³
Flash point:	Not applicable
Flammable:	Not flammable
Autoflammability:	Not applicable
Explosive properties:	Does not present an explosion hazard
Oxidizing properties:	Not applicable
Vapour pressure (@ 20°C):	Approx. 23 hPa
Relative density:	<1.0
Solubility:	Miscible
Auto-ignition temperature:	Not applicable
Decomposition temperature:	Not applicable
Initial boiling point and boiling range:	Not known
pH:	Not applicable



10. Stability and Reactivity

Reactivity:	No data available.
Chemical Stability:	Stable under normal conditions.
Conditions to avoid:	Avoid excessive heat.
Materials to avoid:	None.
Hazardous decomposition products:	None when used as directed.
Hazardous reactivity (polymerization):	No hazardous reactions known.

11. Toxicological information

Acute toxicity:	Contact with skin and eyes may cause irritation.
Serious eye damage/irritation:	May cause irritation due to foreign body reaction.
Skin corrosion/irritation:	Possible skin irritant.
Respiratory or skin sensitisation:	Not expected due to product containment and dosage size.
Ingestion:	Irritant not likely in small amounts.
Germ cell mutagenicity:	No data available.
Carcinogenicity:	IARC: No component of this product present at levels greater than or equal to 0.1% is identified as probable, possible or confirmed human carcinogen by IARC. (IARC: International Agency for Research on Cancer, by the World Health Organisation (WHO)).
Reproductive toxicity:	No data available.
Specific target organ toxicity – single exposure:	May cause irritation to eyes, skin and inhalation.
Specific target organ toxicity – repeated exposure:	No data available.

12. Ecological information

Self assessment:	Not readily biodegradable. Avoid large quantities entering drains, surface water or ground water.
Ecotoxicity:	No data available.
Persistence and biodegradability:	No data available.
Bioaccumulative potential:	No data available.
Mobility in soil:	No data available.
Results of PBT and VPvB assessment:	PBT/vPvB assessment not available as chemical safety assessment not required/not conducted.
Other adverse effects (such as hazardous to ozone layer):	No data available.



13. Disposal considerations

Dispose of in accordance with local official regulations.

Contaminated packaging: Dispose of contaminated packaging as hazardous waste in accordance with local official regulations.

14. Transport Information

This product is not considered to be a dangerous good within the meaning of transportation regulations.

15. Regulatory information

This product is regulated by: TGA
Medical Devices Directive 93/42/EEC
FDA
National regulations

16. Other information

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

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