Product: PERMITE; LOJIC +; GS-80; GS-80 SPHERICAL; F400; ULTRAFINE;

SDI ADMIX; SDI SPHERICAL, NEW ULTRAFINE AND ULTRATABS

ALLOY POWDER AND TABLETS.

Date / Revised: 15.09.2014 Revision: 3

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

1.1 Product identifier:

Product Name: Permite; Lojic +; GS-80, GS-80 Spherical; F400, Ultrafine, New

Ultrafine SDI Admix; SDI Spherical and Ultratabs.

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- Alloy powder and Tablets

1.2 Relevant identified use:

Relevant use:

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

1.3 Details of the supplier of the Safety Data Sheet

Manufacturer / Supplier

SDI Limited SDI Inc.

3-13 Brunsdon Street, Bayswater 729 N.Route 83, Suite 315 Victoria, 3153, Australia Bensenville 60106 IL, USA

<u>Telephone</u>: <u>Telephone</u>:

+61 3 8727 7111 (Business hours) 630 238 8300 (Business hours)

Southern Dental Industries Ltd

Block 8, St Johns Court

Swords Road

SDI Brasil Indústria e Comércio Ltda
Rua Dr. Virgílio de Carvalho Pinto, 612
Pinheiros, São Paulo, 05415-020

Santry, Dublin 9, Ireland Brasil

Telephone: Telephone:

+353 1 886 9577 (Business Hours) +55 11 3092 7100 (Business Hours)

Emergency contact number: +61 3 8727 7111

Email: ray.cahill@sdi.com.au (Technical Director, SDI Limited)

2. Hazard Identification:

Classification of the substance/mixture:

Non-hazardous material.

Signal word, hazard statement, precautionary statements:

Not applicable – non-hazardous substance.

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3. Composition / Information on ingredients

Tablets and Alloy Powder Non Toxic alloy powder; Non-Hazardous

<u>Ingredients</u> :	<u>Wt.%</u>	CAS No.
Silver	40-70%	7440-22-4
Copper	5-30%	7440-50-8
Tin	20-30%	7440-31-5
Indium	0-0.5%	7440-74-6
Zinc	0-0.5%	7440-66-6

4. First Aid Measures

If inhaled: Gently blow nose and irrigate with clean water if necessary. Consult physician if

irritation persists.

If swallowed consult a physician. Ingestion of alloy powder may cause GI tract

irritation, nausea or diarrhoea. A very low order of toxicity is expected.

On skin contact: Wash thoroughly with soap and water. Generally the product does not irritate

skin.

On contact with eyes: Do not rub eyes or keep them closed. Immediately irrigate the open eye with tepid

water (at least 15 minutes). Obtain medical advice if irritation or discomfort

persists

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.

5. Fire Fighting Measures

Suitable extinguishing media: CO₂, powder or water spray.

Unsuitable extinguishing media: None

Specific hazards arising from the mixture (i.e. Nature of any combustion products): None.

Special protective equipment: No special measures required.

Advice for firefighters: Wear safety equipment appropriate to the fire.

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6. Accidental Release Measures

Personal precautions: Use personal protective equipment to avoid contact or inhaling the alloy

powder during clean up. Ensure adequate ventilation.

For personal protection, see section 8.

Environmental precautions: Prevent any spillage from entering drains or waterways.

Method for Cleaning and containment of Spills: Pick up and arrange disposal without creating dust.

Sweep up and shovel. Keep in suitable labelled closed container for

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disposal. Wash the spillage area clean with water.

Removal of ignition sources, provision of sufficient ventilation, control of dust.

7. Handling and storage

Precautions for safe handling

Store sealed containers away from heat and light.

Avoid contact with skin and eyes. Avoid inhalation of vapour or mist.

For precautions, see section 2.

Conditions for safe storage, including any biocompatibilities:

No Special requirements. Protect from humidity and water.

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

8-Hour TWAs: Silver - 0.01 mg/m³ (OSHA/Germany); 0.1 mg/m³ (ACGIH/U.K. & NOHSC/Australia)

Tin - 2 mg/m³ (OSHA/ACGIH/Germany & NOHSC/Australia); 5 mg/m³ (U.K.);

Copper - 1 mg/m³ (OSHA/ACGIH/Germany/UK & NOHSC/Australia)

Indium - 0.1 mg/m³ (OSHA/UK & NOHSC/Australia)

Zinc - $1 \text{ mg/m}^3 \text{ (ACGIH)}$

These levels are not anticipated under foreseeable use conditions.

Personal protective equipment

Respiratory equipment: None required under normal use conditions.

Hand protection: Impervious gloves.

Eye protection: Safety glasses.

General safety and hygiene measures: Use only as directed. Wash hands after use.

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9. Physical and chemical properties

Form and Colour: Powder: Bluish-grey silver alloy powder

Tablets: Silver-grey compressed silver alloy powder

Odour: Odourless

Melting point / melting range: Undetermined (greater than 500°C)

Boiling point / boiling range: Undetermined (greater than 900°C)

Flash point: Not applicable Flammability (solid, gas): Not applicable **Explosion limits:** Not applicable Relative density: not established Ignition temperature: Not applicable % Volatiles: Not applicable Solubility in water: Insoluble Solubility in other solvents: 0.0% Solids content 100%

Auto-ignition temperature:

Decomposition temperature:

Not applicable

PH:

Not applicable

10. Stability and Reactivity

Reactivity: No data available

Conditions to avoid: None known

Materials to avoid: Strong mineral acids

Thermal decomposition: No decomposition under normal conditions

Hazardous decomposition products: No hazardous decomposition products known.

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11. Toxicological information

Acute toxicity: No irritant effect.

Serious eye damage/irritation: None known.

Skin corrosion/irritation:

None known.

Respiratory or skin sensitisation: None known.

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

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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.

Aspiration hazard: No data available.

12. Ecological information

Ecotoxicity: No data available.

Persistence and biodegradeability: No data available.

Bioaccumulative potential: No data available.

Mobility in soil: No data available.

Other adverse effects (such as hazardous to ozone layer): No data available.

German "Wassergefaehrdungs Klasse (WGK):3

This product must not enter effluent, ground water, surface water or the soil.

13. Disposal considerations

Product: Dispose of in accordance with local regulations.

Contaminated packaging:

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

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14. Transport information

Shipping name: None

Dangerous goods class: None

UN/NA Number: None ADR Number: None Packing Group: None

Class: None IATA Limits: N/A IMDG Limits: N/A

15. Regulatory information

These products are regulated by: TGA

Medical Devices Directives 93/42/EEC

FDA

National regulations for medical devices.

16. Other information

Prepared by: SDI Limited **Phone Number:** +61 3 8727 7111

3-13 Brunsdon Street, Bayswater Victoria, 3153, Australia

Date of preparation/revision: 15th September 2014.

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.

Department issuing SDS: Research and Development

R&D Director Contact: