



SAFETY DATA SHEET

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Product: PERMITE; LOJIC +; GS-80; GS-80 SPHERICAL; F400; ULTRACAPS +;
ULTRACAPS S; SDI ADMIX; SDI SPHERICAL & NEW ULTRAFINE CAPSULES.

Date / Revised: 25.06.2015

Revision: 15

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

1.1 Product identifier:

Product Name: Permite; Lojic +; GS-80, GS-80 Spherical; F400; Ultracaps +;
Ultracaps S; SDI Admix; SDI Spherical and New Ultrafine.
- Capsules.

1.2 Relevant identified use:

Relevant use:

Dental professional 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: DANGER





2. Hazard Identification..continued

These products contain mercury. It is toxic if inhaled and acute exposure may cause allergic reactions including dermatitis, digestion and respiratory disorders.

California Prop 65 Warning

This product contains mercury, a chemical known to the State of California to cause birth defects or other reproductive harm.

GHS Classification:

Acute Tox. 2

Repr. 1B

STOT RE 1

Aquatic Acute 1

Aquatic Chronic 1

Materials are contained in two compartments. However, under normal conditions of use, contact with these materials by the user is generally not expected.

Hazard statement(s)

- H330 Fatal if inhaled.
- H360D May damage the unborn child.
- H372 Causes damage to organs through prolonged or repeated exposure.
- H400 Very toxic to aquatic life.
- H410 Very toxic to aquatic life with long lasting effects.

Precautionary statement(s):

Prevention:

- P201 Obtain special instructions before use.
- P202 Do not handle until all safety precautions have been read and understood.
- P260 Do not breathe fumes/vapours.
- P264 Wash hands thoroughly after handling.
- P270 Do not eat, drink or smoke when using this product.
- P271 Use only outdoors or in a well-ventilated area.
- P284 Wear respiratory protection.
- P280 Wear protective gloves/clothing.
- P281 Use personal protective equipment as required.

Response:

- P304+P340: IF INHALED: Remove victim to fresh air and keep at rest in a position comfortable for breathing.
- P310 Immediately call a POISON CENTRE or doctor/physician.
- P320 Specific treatment is urgent- refer to first aid instructions Section 4.
- P308+P313 IF exposed or concerned: Get medical advice/attention.
- P301+P310 IF SWALLOWED: Immediately call a POISON CENTRE or doctor/physician.
- P321 Specific treatment, refer to First Aid instructions Section 4.
- P330 Rinse mouth.
- P363 Wash contaminated clothing before re-use.

Storage:

- P405 Store locked up.

Disposal

- P501 Dispose of contents/ container to an approved waste disposal plant.



3. Composition / Information on ingredients

Capsules

<u>Hazardous ingredients:</u>	<u>Wt. %</u>	<u>CAS No.</u>	<u>EC No.</u>	<u>Index No.</u>
Mercury, metallic (40-50% of total product)	100	7439-97-6	231-106-7	080-001-00

Hazard class: Acute Tox. 2, Repr 1B, STOT RE 1, Aquatic Acute 1, Aquatic Chronic 1.
Hazard statement codes: H330, H360D, H372, H400, H410.

4. First Aid Measures

- General advice: Contains metallic mercury. In case of accident or if you feel unwell, seek medical advice immediately (show label and instructions for use where possible).
- If inhaled: Very toxic by inhalation. Remove to fresh air. Seek medical attention. If not breathing give artificial respiration.
May cause respiratory disorders including inflammation and fluid retention. Inhalation of mercury vapours at high concentration can cause dyspnea, coughing, fever, severe nausea, vomiting, excess salivation, kidney damage with renal shutdown.
- If ingested: Call a physician immediately. Rinse mouth and give large amounts of water.
- On skin contact: Wash skin with soap and water. Remove contaminated clothing. May cause irritation and allergic reaction. If irritation develops, if feeling unwell, or if concerned, get medical advice/attention.
- On contact with eyes: Do not let victim rub eyes or keep them closed. Extensive irrigation with tepid water is required (at least 15 minutes). Obtain medical advice if irritation persists. May cause irritation and allergic reaction. If irritation develops, if feeling unwell, or if concerned, get medical advice/attention.

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: As for adjacent fire. Water spray, Foam, Carbon Dioxide, dry Chemical and other "ABC" Class may be used.
- Special protective equipment: In fires involving large quantities of product, use self-contained breathing apparatus and full protective equipment.
- Unusual Fire and Explosion Hazards: Mercury is not flammable and is relatively stable although it can react with many metals to form amalgams.



5. Fire Fighting Measures

Explosion Sensitivity to Mechanical Impact: Not sensitive.

Explosion Sensitivity to Static Discharge: Not sensitive.

Unsuitable extinguishing media: None specified.

Specific hazards arising from the mixture:

Mercury vapours generated during fires involving these products are toxic; additionally, this element can be irritating to contaminated tissue. Therefore, this product presents a severe health hazard to firefighters.

Advice for firefighters:

Wear self contained breathing apparatus and full protective equipment.

Move fire exposed containers, if it can be done without risk to firefighters.

Apply cooling water to sides of containers that are exposed to flame until well after fire is out.

Decontaminate all equipment thoroughly after the conclusion of fire-fighting activities. If possible, prevent run-off water from entering storm drains, bodies of water, or other environmentally sensitive areas.

Further information:

Hazardous decomposition products may be produced. (Refer to Section 10).

6. Accidental Release Measures

Spillages:

Mercury presents a health hazard if incorrectly handled, and is dangerous for the environment. Spillages of mercury should be removed immediately, including from places which are difficult to access.

Wearing protective clothing, use a plastic syringe to draw it up.

Smaller quantities can be covered by sulphur powder and removed.

Avoid inhalation of the vapour.

Personal precautions:

Wear appropriate MSHA approved respirator, gloves, safety goggles and protective clothing to prevent skin contact and inhalation.

Environmental precautions:

Prevent any spillage from entering drains or waterways.

Methods for cleaning and containment of spills:

Avoid contact with skin and eyes, and avoid inhalation. Pick up with dust pan or method that does not break up mercury into smaller droplets, etc. Store in a sealed plastic container, away from heat and flame, until disposal via an approved Recycler and according to local regulations. Ensure adequate ventilation.



7. Handling and storage

<u>Handling:</u>	Do not breathe powder and avoid exposed mercury surfaces. Wear appropriate gloves, goggles/face protection and protective clothing to prevent skin contact. Wash thoroughly after handling. Keep away from food, drink and around animal feed stuffs.
<u>Storage:</u>	Store only in unopened original containers. Keep container tightly closed and dry. Storage in large quantities (as in warehouse) should be in a ventilated, cool area. Do not store in metal containers. Keep away from sources of ignition and elevated temperatures, recommended <25°C.
<u>Distribution:</u>	During distribution, to our customers, this product can be transported in non-refrigerated conditions between 15° to 25° C. This product can also withstand temperatures up to 40° C for short periods (2 to 3 days) and intermittent peaks up to 50°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

Control parameters:

Occupational exposure limits:

8-Hour TWAs: Mercury - 0.025 mg/m³ (Skin) (ACGIH); 0.05 mg/m³ (Skin) (OSHA/UK & NOHSC/Australia); 0.1 mg/m³ (Short term) (Germany);

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 mg/m³ (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 goggles.

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



9. Physical and chemical properties

Form and Colour:	Silver alloy powder and mercury in separate compartments of a plastic capsule. Silver alloy – grey fine metallic powder. Mercury – Silver-white heavy liquid metal.
Odour:	Odourless
Melting point / melting range:	(Mercury): -38.9°C
Boiling point / boiling range:	(Mercury): 356.6°C
Flammable:	Not applicable
Flash point:	Not applicable
Explosion limits:	Not applicable
Ignition temperature:	Not applicable
Vapour pressure:	(Mercury) 0.0012 mmHg at 20°C
Specific Gravity:	(Mercury) 13.6 g/cm ³
% Volatiles:	Not applicable
Solubility in water:	Insoluble
Solubility in other solvents:	Insoluble in alcohol
pH value:	Not applicable.
Partition co-efficient (n-octanol/water):	Not determined
Viscosity:	Not determined
Evaporation rate:	Not determined
Relative vapour density (air = 1):	(Mercury): - 6.9
Auto-ignition temperature:	Not available
Decomposition temperature:	Not available
Explosive Properties:	no data available

10. Stability and Reactivity

Reactivity:	No data available.
Chemical Stability:	Stable under recommended storage conditions.
Thermal decomposition:	No decomposition under normal conditions
Substance(s) to avoid:	Strong oxidizers
Hazardous reactions:	Mixtures of mercury with acetylene, ammonia, chlorine dioxide, methyl azide, chlorates, nitrates, or hot sulfuric acid can be explosive. Readily amalgamates with most metals.
Hazardous decomposition products:	Slightly volatile at room temperature, atmospheric pressure. When exposed to high temperatures, mercury vaporizes to extremely toxic fumes.



11. Toxicological information

Critical hazards to man:	Very toxic by inhalation. Toxic - danger of serious damage to health by prolonged exposure through inhalation. Acute exposure may cause allergic reactions including dermatitis, digestion and respiratory disorders. May cause harm to the unborn child.
Critical hazards to the environment:	Dangerous for the environment.
Serious eye damage/irritation:	Irritating to eyes.
Skin corrosion/irritation:	May cause allergic skin reactions. May be irritant or corrosive.
Respiratory or skin sensitisation:	Very toxic by inhalation.
Ingestion:	Very hazardous by ingestion. May cause damage to blood, kidneys, liver, brain, peripheral nervous system, central nervous system.
Germ cell mutagenicity:	No data available.
Carcinogenicity:	Classified A5 (not suspected for human) by ACGIH. 3 (not classifiable for human) by IARC.
None available regarding product.	Some information supplied for ingredient(s).
LCLo / Inhalation / Rabbit:	(Mercury) 29 mg/m ³ /30 Hour
Chronic Health Effects:	Inhalation of mercury vapours, dusts or organic vapours, or skin absorption or mercury over long periods can cause mercurialism. Symptoms include tremors, inflammation of mouth and gums, excessive salivation, stomatitis, blue lines on gums, pain and numbness in extremities, weight loss, mental depression, and nervousness. Exposure may aggravate kidney disorders, chronic respiratory disease and nervous system disorders. May cause damage to blood, kidneys, liver, brain, peripheral nervous system, central nervous system.

Alloy powder and mercury are in pre-dosed capsules, so the danger of exposure to mercury vapours is low.

12. Ecological information

German "Wassergefährdungs Klasse (WGK):3

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

Self-Assessment:	Possibly hazardous short term degradation products are not likely. However, long term degradation products may arise.
Ecotoxicity:	No data available.
Persistence and biodegradability:	No data available.
Bioaccumulative potential:	No data available.



12. Ecological information

Mobility in soil:	No data available.
Other adverse effects:	Very toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment

13. Disposal considerations

Product: Dispose of in accordance with local regulations.

The 1991 Environmental Protection (Duty of Care) Regulations SI No. 2839 and amendments should be noted (United Kingdom).

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

14. Transport information

IATA:	
Product:	Amalgam Capsule
Contains:	Mercury
Proper Shipping Name:	Mercury contained in manufactured articles
UN Number:	UN 3506
Packing Group:	III
Class (sub risk):	8 (6.1) Corrosive & Toxic
IATA Limits:	EQ - E0 (not permitted as excepted quantity) LQ - Forbidden for passenger and cargo aircraft CAO - no limit PAX - no limit

Not classified as Dangerous Goods for sea, road and rail transport.

15. Regulatory information

These products are regulated by: TGA
Medical Devices Directives 93/42/EEC
FDA
National regulations

16. Other information

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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.

Date of preparation/revision: 25 June 2015.

Department issuing SDS: Research and Development

Contact: R&D Director
