1. IDENTIFICATION OF THE SUBSTANCE/PREPARATION AND COMPANY/UNDERTAKING

1.1 Product identifier
Trade name

AMALGAM POLIDENT »NON GAMMA 2«

1.2 Relevant identifier uses of the substance or mixture and uses advised against
Recommended use
Alloy powder and mercury in capsules-dental amalgam for posterior restorations.
Details of the supplier of the Safety Data Sheet

1.3 Manufacturer/supplier
Polident d.o.o.,
Dental Products Industry
Volčja Draga 42, 5293 Volčja Draga,
Slovenija
Tel.: 00386 5 3304840, Fax: 00386 5 3304870
E-mail: polident@polident.si
Information provided by
00386 5 3304859
Emergency telephone number
00386 5 3304840

2. HAZARDS IDENTIFICATION

2.1 Classification of the substance or mixture
Mixture
Classification
Very toxic and dangerous for the environment.
Adverse human health effects
Mercury vapour is very toxic. Mercury may accumulate in the body which may cause adverse health effects.
Adverse environmental effects
Mercury is very toxic to aquatic organisms and may cause long-term adverse aquatic environmental effects.
Classification according to Regulation (EC) No. 1272/2008
Specific target organ toxicity-repeated exposure, Category 1
Acute aquatic toxicity, Category 1
Chronic aquatic toxicity, Category 1
Reproductive toxicity, Category 1B
Acute toxicity-inhalation, Category 2
Classification according to Directive 67/548/EEC or Directive 1999/45/EC
May cause harm to the unborn child.
Very toxic by inhalation.
Toxic: danger of serious damage to health by prolonged exposure through inhalation.
Very toxic to aquatic organisms may cause long-term adverse effects in the aquatic environment.

2.2 Label elements
Labelling according to Regulation (EC) No. 1272/2008
The product is classified and labelled according to the CLP regulation.
Hazard pictograms

GHS06  GHS08  GHS09

Signal word
Danger

Hazard statements
H330 Fatal if inhaled.
H360 May damage fertility or the unborn child.
H372 Causes damage to organs through prolonged or repeated exposure.
H410 Very toxic to aquatic life with long lasting effects.

Precautionary statements
P201 Obtain special instructions before use.
P260 Do not breathe dust/fume/gas/mist/vapours/spray.
P273 Avoid release to the environment.
P284 Wear respiratory protection.
P310 Immediately call a Poison Center or doctor / physician.
P501 Dispose of contents / container to an approved waste disposal plant.

Labelling according to Directive 67/548/EEC or Directive 1999/45/EC
Indications of danger

Risk Phrases
R26 Also very toxic by inhalation.
R48/23 Also toxic: danger of serious damage to health by prolonged exposure through inhalation.
R50/53 Very toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment.
R61 May cause harm to the unborn child.

Safety Phrases
S7 Keep container tightly closed.
S45 In case of accident or if you feel unwell, seek medical advice immediately.
S53 Avoid exposure-obtain special instructions before use.
S60 This material and its container must be disposed of as hazardous waste.
S61 Avoid release to the environment. Refer to special instructions/Safety data sheets.

2.3 Other hazards

Results of PBT and vPvB assessment
PBT: Not applicable.
vPvB: Not applicable.

3. COMPOSITION/INFORMATION ON INGREDIENTS
3.1 Chemical characterization: Mixtures
Description
Product contents metal powder/alloy and mercury.

<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Mercury, Hg</td>
<td>50</td>
<td>080-001-00-0</td>
<td>231-106-7</td>
<td>7439-97-6</td>
<td>Repr. 1B</td>
<td>H330</td>
<td>T+, N</td>
<td>R26</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Acute Tox.2</td>
<td>H360</td>
<td>R48/23</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>STOT RE 1</td>
<td>H372</td>
<td>R50/53</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Aquatic Acute 1</td>
<td>H410</td>
<td>R61</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Aquatic Chronic 1</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

4. FIRST AID MEASURES

4.1 Description of first aid measures

General information

Inhalation
Expose to fresh air. Obtain medical attention.

Skin contact
Take off contaminated clothing. Wash off immediately with water and soap. Obtain medical attention.

Eye contact
Rinse opened eye with plenty of water for at least 15 minutes. Obtain medical attention.

Ingestion
Drink plenty of water. Induce vomiting, provided that the person is fully conscious. Obtain immediately medical attention.

4.2 Most important symptoms and effects, both acute and delayed

None known.

4.3 Indication of any immediate medical attention and special treatment needed

Treat symptomatically.

5. FIRE – FIGHTING MEASURES

5.1 Extinguishing media

Suitable extinguishing media
Water spray, foam, dry powder, carbon dioxide.

Unsuitable extinguishing media for safety reasons
Water with full yet.

5.2 Special hazards arising from the substance or mixture

High temperatures increase mercury vaporization, smoke may contain toxic mercury. Avoid inhaling smoke.

5.3 Advice for firefighters

Wear respiratory protection apparatus and suitable protective clothing.

6. ACCIDENTAL RELEASE MEASURES

6.1 Personal precautions, protective equipment and emergency procedures

Wear protective equipment: respiratory protective apparatus and suitable protective clothing. Keep unprotected persons at a distance. Avoid inhalation aerosols/vapours and skin contact.

6.2 Environmental precautions

Do not allow mercury to enter drains, soil and waterways.

6.3 Methods and material for containment and cleaning up

Collect spillage with pipette or dust pan, place in plastic container and cover with water. Seal container well. Clean contaminated areas thoroughly. Dispose absorbed material in accordance with local and national regulations.

6.4 Reference to other sections

For information on safe handling see Section 7.
For information on personal protection equipment see Section 8.
For information on disposal information see Section 13.

7. HANDLING AND STORAGE

7.1 Precautions for safe handling

Safe handling advice
Handle with care. Only adequate trained persons may deal with product. For use in dentistry only. Keep away from children. No eating, drinking or smoking during handling with product. Follow the usual good standards of occupational hygiene.

**Information on fire and explosion protection**
See Section 5.

### 7.2 Conditions for safe storage, including any incompatibilities
**Storage**
Requirements for storage areas
Keep container tightly closed and store in a cool, dry place.

**Empiry date**
Considering the instructions for safety storage and handling the expiry date of the product is five years.

### 7.3 Specific end use(s)
None.

### 8. EXPOSURE CONTROLS /PERSONAL PROTECTION

#### 8.1 Control parameters
**Ingredients with limit values that require monitoring at the workplace:**

**Exposure limit values:**
- Mercury (skin): 0,05 mg/m$^3$ OSHA
- Silver: 0,01 mg/m$^3$ OSHA
- Tin: 2,0 mg/m$^3$ OSHA
- Copper: 1,0 mg/m$^3$ OSHA

#### 8.2 Exposure controls
**Appropriate engineering controls**
Do not eat, drink or smoke at the workplace. Follow the usual good standards of occupational hygiene and dental practise. Ensure adequate ventilation of work place.
Store work clothing separately. Remove contaminated clothing immediately.

**Individual protection measures, such as personal protective equipment**

**Eye/face protection**
Wear tightly sealed goggles.

**Skin protection**
Wear suitable protective gloves.
Protective clothing should be used in order to avoid exposure.

**Respiratory protection**
In the case of short term exposure use suitable mask. In the event of particularly high levels of vapours a self contained breathing apparatus is appropriate.

**Thermal hazards**
None.

**Environmental exposure controls**
Ensure effective control measures when working within the boundaries as specified in section 6.2.

### 9. PHYSICAL AND CHEMICAL PROPERTIES

#### 9.1 Information on basic physical and chemical properties

**Appearance**

**Form and Colour:** Powder - grey alloy
Mercury – silver liquid

**Odour:** odourless

**pH – value:** not applicable

**Changes in condition:**

**Melting point (˚C):** not applicable
Boiling point (°C): 357,3 °C (Mercury)
Flash point (°C): incombustible
Relative evaporation rate (Ether=1): Not available
Flammability (solid, gas): Incombustible
Auto Ignition temperature (°C): Not applicable
Decomposition temperature (°C): Not applicable
Lower explosion limit (%vv/v): Not applicable
Upper explosion limit (%vv/v): Not applicable
Vapour pressure (mmHg): 0,0012 at 20°C (Mercury)
Vapour density (Air=1): 6,9 (Mercury)
Density (g/cm³): 13,6 (Mercury), 3,3 (alloy)
Viscosity (mPas): Not applicable
Solubility in water: Insoluble
Solubility (quantitative): Insoluble in organic solvents
Partition coefficient (n-Octanol/water): Not applicable
Explosive properties: Not applicable
Oxidising properties: Not applicable

9.2 Other information
None.

10. STABILITY AND REACTIVITY
10.1 Reactivity
The product is not reactive under normal handling and storage conditions.

10.2 Chemical stability
The product is stable under normal handling and storage conditions.

10.3 Possibility of hazardous reactions
None under normal handling and storage.

10.4 Conditions to avoid
Intense heating. Highly toxic fumes emits when heating.

10.5 Incompatible materials
Strong oxidizers, alkali metals, acetylenes, azides, ammonia, amines, halogens, carbides, metals, acids.

10.6 Hazardous decomposition products
Mercury oxide and mercury vapour-highly toxic fumes emits when heating.

11. TOXICOLOGICAL INFORMATION
11.1 Information on toxicological effects
Acute toxicity
Inhalation: May cause allergic reactions, respiratory disorders.
Skin irritation
May cause irritation and redness.
Eye contact
May cause irritation and redness.
Sensitization
Sensitization possible through skin contact. Not a respiratory sensitizer.
CMR effects
Repr. 1B
Repeated dose toxicity
Chronic exposure
Mercury accumulation in the body may cause serious adverse effects. Exposure of persons with kidney, respiratory and nervous system disorders may be more susceptible.
Further information on toxicology
Alloy and mercury are predosed in capsules therefore danger of exposure to mercury vapour is low.

12. ECOLOGICAL INFORMATION
12.1 Toxicity
Hazardous to the aquatic environment
Inorganic Hg-compounds in general: P.promelas:LC50=0,19mg/l, Hg-ions: L. idus: LC50=0,013
mg/l, Algae: Sc. Quadricauda, toxic effects when ≥ 0.07 mg/l
Mercury is very toxic to aquatic organisms and dangerous for ground and surface water.

12.2 Persistence and degradability
Slow process of transformation of mercury into organic mercury.

12.3 Bioaccumulative potential
Slow process of transformation of mercury into organic mercury. Organic mercury may bioaccumulate in fish.

12.4 Mobility in soil
No further relevant information available.

12.5 Results of PBT and vPvB assessment
PBT: Not applicable.
vPvB: Not applicable.

12.6 Other adverse effects: No further relevant information available.

13. DISPOSAL CONSIDERATIONS

13.1 Waste treatment methods
Product: Disposal should be made in accordance with local, state and national legislation.
Uncleaned packaging: Disposal should be made in accordance with local, state and national legislation.

14. TRANSPORT INFORMATION

14.1 UN number: 2809

14.2 UN proper shipping name
MERCURY

14.3 Transport hazard class(es)
ADR, IMDG, IATA

14.4 Packing group
ADR, IMDG, IATA: III

14.5 Environmental hazards
Marine pollutant: Not classified as a marine pollutant.

14.6 Special precautions for user
Warning: Corrosive substances
Danger code (Kemler): 80
EMS Number: F-A,S-B

14.7 Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code
Not applicable.

14.8 Transport additional information
ADR
Limited quantities (LQ): 5 kg
Transport category: 3
Tunnel restriction code: E

15. REGULATORY INFORMATION

15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture
Product is a medical device class IIa according to Directive 93/42/EEC. EN ISO 13897 Dentistry-Amalgam capsules and EN ISO 24234 Dentistry-Mercury and alloys for dental amalgam must be considered.
Labeling according to EN ISO 24234 must be ensured.

15.2 Chemical Safety Assessment
A chemical safety assessment has not been carried out for this mixture.

16. OTHER INFORMATION
This information is based on our present knowledge and experience. They are intended as a description of the products safety requirements and are not to be seen as a guarantee of certain product’s features.

**Relevant phrases**

All relevant R, S, H and P phrases are listed in Section 2.

**Full wording of phrases in Section 3:**

- Repr. 1B – Reproductive toxicity (Category 1B)
- Acute Tox.2 – Acute toxicity, inhalation (Category 2)
- STOT RE 1 – Specific target organ toxicity – repeated exposure (Category 1)
- Aquatic Acute 1 – Acute aquatic toxicity (Category 1)
- Aquatic Chronic 1 – Chronic aquatic toxicity (Category 1)

New versions of Safety Data Sheet will be *laying printed* for the data compared to the previous version altered.