SECTION 1: Identification of the substance/mixture (Product) and of the company/undertaking

1.1 Product identifier

Trade name: myRing Classico

1.2 Relevant identified uses of the Product and uses advised against

Medical Device Class I (according to 93/42/EEC) – Rule 5
Main use of the product: As a help for dental fillings, in class II restorations

1.3 Details of the supplier of the safety data sheet

Manufacturer/Supplier:
Polydentia SA
Via Cantonale 47
6805 Mezzovico-Vira (Switzerland)

Phone: 0041 (0) 91 946 29 48
Fax: 0041 (0) 91 946 32 03
Email: info@polydentia.com

1.4 Emergency telephone number:
+41 (0) 91 946 29 48

SECTION 2: Hazards identification

2.1 Classification of the substance or mixture

The mixture has been assessed and/or tested for its physical, health and environmental hazards and the following classification applies.
This material is not considered hazardous to health.

Classification according to Regulation(EC) No 1272/2008 [CLP]

Health: Not Classified

2.2 Label elements

This material is not considered hazardous to the health according to Regulation(EC) No 1272/2008[CLP].

This product may not require a label according to Article 17 of CLP (see section 1.3 of Annex I) (Table 3.1).

Classification according to Regulation(EC) No 1272/2008 [CLP]

Precautionary statement(s)

Response: P305: IF IN EYES:
P351: Rinse cautiously with water for several minutes.
P302+P352: IF ON SKIN: Wash with plenty of soap and water.
P333+P313: If skin irritation or rash occurs: Get medical advice / attention
Storage: P232: Protect from moisture.

2.3 Other hazards

Immediate concerns: None

SECTION 3: Composition / information on ingredients

3.1 Substances

Not applicable

3.2 Mixtures

<table>
<thead>
<tr>
<th>Chemical Name</th>
<th>CAS</th>
<th>EINECS No.</th>
<th>Wt.%</th>
<th>Classification according to Regulation(EC) No 1272/2008 [CLP]</th>
</tr>
</thead>
<tbody>
<tr>
<td>Nichel Metal</td>
<td>7440-02-0</td>
<td>231-111-4</td>
<td>&gt;=50%</td>
<td>Carc. Cat. 3,T,Xi; R43-48/23</td>
</tr>
<tr>
<td>Chromium</td>
<td>7440-47-3</td>
<td>231-157-5</td>
<td>&lt;5%</td>
<td>substance with a Community workpl exposure limit</td>
</tr>
<tr>
<td>Cobalt</td>
<td>7440-48-4</td>
<td>231-158-0</td>
<td>&lt;3%</td>
<td>Xn; R42/43-53</td>
</tr>
</tbody>
</table>

+ Thermoplastic part (overmolded)

Additional information:

Nickel is not carcinogenic in solid form.

For full text of H-statements and R-phrases: see SECTION 16.

SECTION 4: First aid measures

4.1. Description of first aid measures

Following eyes: Hold eyelids apart and flush eyes with plenty of water for at least 15 minutes.

Following skin: Wash with soap and water. Get medical attention if irritation develops or persists.

Following ingestion: While ingestion of large enough quantities to cause health effects is unlikely. Consult a physician if it occurs.

Following inhalation: No specific treatment is necessary since this material is not likely to be hazardous by inhalation. If exposed to excessive levels of dusts or fumes, remove to fresh air and get medical attention if cough or other symptoms develop.
4.2. Most important symptoms and effects, both acute and delayed

Eyes: None expected for this product.
Skin: May cause skin irritation and sensitization.
Ingestion: Not likely to be ingested.
Inhalation: None expected for this product.

4.3. Indication of any immediate medical attention and special treatment needed

Notes to physician: Not Applicable

SECTION 5: Fire fighting measures

5.1. Extinguishing media

Suitable extinguishing media:
- Type "D" extinguishing media.
- CO2 or Dry chemical fire extinguisher.

Extinguishing media which must not be used for safety reasons:
None

5.2. Special hazards arising from the substance or mixture

Do not inhale explosion and combustion gases.
Burning produces heavy smoke.

5.3. Advice for fire fighters

Use suitable breathing apparatus.
Collect contaminated fire extinguishing water separately. This must not be discharged into drains.
Move undamaged containers from immediate hazard area if it can be done safely.

SECTION 6: Accidental release measure

6.1. Personal precautions, protective equipment and emergency procedures

Special protective equipment: No special requirements for this product.

6.2. Environmental precautions

Water spill: Not Applicable

6.3. Methods and material for containment and cleaning up

Small spill: Not Applicable
Large spill: Not Applicable

6.4. Reference to other sections

Reference to other sections: Not Applicable
SECTION 7: Handling and storage

7.1. Precautions for safe handling

Handling: No special measures required.
Storage: Store in a dry area.

7.2. Conditions for safe storage, including any incompatibilities

Shelf life: Not applicable

7.3. Specific end use(s)

Specific end use(s): As a help for dental fillings, in class II restorations
For professional use only

SECTION 8: Exposure controls / personal protection

8.1. Control parameters

Mixture components:

- Nickel (CAS: 7440-02-0)
  - OSHA - STE: 1 mg/m3
  - ACGIH - LTE(8h): 1.5 mg/m3 - Notes: A5, (I) - Dermatitis, pneumoconiosis
- Chromium (CAS: 7440-47-3)
  - EU - LTE(8h): 2 mg/m3 - Notes: Bold-type: Indicative Occupational Exposure Limit Values [2,3] and Limit Values for Occupational Exposure [4] (for references see bibliography)
- Cobalt (CAS: 7440-48-4)
  - ACGIH - LTE(8h): 0.02 mg/m3 - Notes: A3, BEI - Asthma, pulm func, myocardial eff

8.2. Exposure controls

Engineering controls: No special measures required.
Eye/face protection: Wear approved safety glasses with side shields or goggles where metal dust or fumes are present.
Skin protection: Wear suitable protective clothing and gloves.
Respiratory protection: Use approved respirator for dust and fumes where local exhaust or ventilation does not keep exposure below PEL or TLV levels.

Additional information:

Allergy Statement for Nickel: Warning This product contains nickel. A small percentage of the population is known to be allergic to nickel. If an allergic reaction occurs, direct the patient to consult a physician.
SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

<table>
<thead>
<tr>
<th>Property</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Odour:</td>
<td>Not Relevant</td>
</tr>
<tr>
<td>Odour threshold:</td>
<td>Not Relevant</td>
</tr>
<tr>
<td>pH:</td>
<td>Not Relevant</td>
</tr>
<tr>
<td>Melting point / freezing point:</td>
<td>&gt;1000°C</td>
</tr>
<tr>
<td>Initial boiling point and boiling range:</td>
<td>Not Relevant</td>
</tr>
<tr>
<td>Solid/gas flammability:</td>
<td>Not Relevant</td>
</tr>
<tr>
<td>Upper/lower flammability or explosive limits:</td>
<td>Not Relevant</td>
</tr>
<tr>
<td>Vapour density:</td>
<td>Not Relevant</td>
</tr>
<tr>
<td>Flash point:</td>
<td>Not Relevant</td>
</tr>
<tr>
<td>Evaporation rate:</td>
<td>Not Relevant</td>
</tr>
<tr>
<td>Vapour pressure:</td>
<td>Not Relevant</td>
</tr>
<tr>
<td>Relative density:</td>
<td>6.4 g/cm³</td>
</tr>
<tr>
<td>Solubility in water:</td>
<td>Not Relevant</td>
</tr>
<tr>
<td>Solubility in oil:</td>
<td>Not Relevant</td>
</tr>
<tr>
<td>Partition coefficient (n-octanol/water):</td>
<td>Not Relevant</td>
</tr>
<tr>
<td>Auto-ignition temperature:</td>
<td>Not Relevant</td>
</tr>
<tr>
<td>Decomposition temperature:</td>
<td>Not Relevant</td>
</tr>
<tr>
<td>Viscosity:</td>
<td>Not Relevant</td>
</tr>
<tr>
<td>Explosive properties:</td>
<td>Not Relevant</td>
</tr>
<tr>
<td>Oxidizing properties:</td>
<td>Not Relevant</td>
</tr>
</tbody>
</table>

9.2. Other information

<table>
<thead>
<tr>
<th>Property</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Miscibility:</td>
<td>Not Relevant</td>
</tr>
<tr>
<td>Fat Solubility:</td>
<td>Not Relevant</td>
</tr>
<tr>
<td>Conductivity:</td>
<td>Not Relevant</td>
</tr>
</tbody>
</table>

SECTION 10: Stability and reactivity

10.1. Reactivity
Stable under normal conditions

10.2. Chemical stability
Stable under normal conditions

10.3. Possibility of hazardous reactions
It may generate flammable gases, on contact with mineral acids.
It may catch fire on contact with mineral acids, azo, diazo and hydrazine compounds, halogenated organic substances, and powerful oxidising agents.

10.4. Conditions to avoid
Stable under normal conditions.

10.5. Incompatible materials
None in particular.

10.6. Hazardous decomposition products
SECTION 11: Toxicological information

11.1. Information on toxicological effects

Toxicological information of the Product: Not cytotoxic

According to: ISO 10993-5 Biological evaluation of medical device
Part 5: Tests for in vitro cytotoxicity

Toxicological information of the main substances found in the mixture: N.A.

SECTION 12: Ecological information

12.1. Toxicity
Adopt good working practices, so that the product is not released into the environment.
Chromium - CAS: 7440-47-3
a) Aquatic acute toxicity:
Endpoint: LC50 - Species: Fish 14.3 mg/l - Duration h: 96 - Notes: Cyprinus carpio
Endpoint: saes1 - Species: Fish 2.4 mg/l - Duration h: 168 - Notes: Pimephales promelas
Endpoint: NOEC - Species: Fish 12 mg/l - Duration h: 168 - Notes: Pimephales promelas
Endpoint: EC50 - Species: Daphnia 0.07 mg/l - Duration h: 48 - Notes: Daphnia magna

12.2. Persistence and degradability
N.A.

12.3. Bioaccumulative potential
N.A.

12.4. Mobility in soil
N.A.

12.5. Results of PBT and vPvB assessment
vPvB Substances: None - PBT Substances: None

12.6. Other adverse effects
None

SECTION 13: Disposal considerations

13.1. Waste treatment methods
Recover, if possible. Send to authorised Treatment, Storage, and Disposal Facility or for incineration under controlled conditions. In so doing, comply with the local and national regulations currently in force.

SECTION 14: Transport information

14.1. UN number
Not classified as dangerous in the meaning of transport regulations.
14.2. UN proper shipping name
N.A.

14.3. Transport hazard class(es)
N.A.

14.4. Packing group
N.A.

14.5. Environmental hazards
ADR-Environmental Pollutant: No
IMDG-Marine pollutant: No

14.6. Special precautions for user
N.A.

14.7. Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code
N.A.

SECTION 15: Regulatory information

Please refer to Medical Devices Directive 93/42/EEC

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

Dir. 67/548/EEC (Classification, packaging and labelling of dangerous substances)
Dir. 99/45/EC (Classification, packaging and labelling of dangerous preparations)
Dir. 98/24/EC (Risks related to chemical agents at work)
Dir. 2000/39/EC (Occupational exposure limit values)
Dir. 2006/8/EC
Regulation (EC) n. 1907/2006 (REACH)
Regulation (EC) n. 1272/2008 (CLP)
Regulation (EC) n. 790/2009 (ATP 1 CLP) and (EU) n. 758/2013
Regulation (EU) n. 453/2010 (Annex I)
Regulation (EU) n. 286/2011 (ATP 2 CLP)
Regulation (EU) n. 618/2012 (ATP 3 CLP)
Regulation (EU) n. 487/2013 (ATP 4 CLP)
Regulation (EU) n. 944/2013 (ATP 5 CLP)
Regulation (EU) n. 605/2014 (ATP 6 CLP)

Restrictions related to the product or the substances contained according to Annex XVII Regulation (EC) 1907/2006 (REACH) and subsequent modifications:
Restrictions related to the product:
No restriction.
Restrictions related to the substances contained:
Restriction 27

Where applicable, refer to the following regulatory provisions:
Directive 2003/105/CE ('Activities linked to risks of serious accidents') and subsequent amendments.
1999/13/EC (VOC directive)
Provisions related to directives 82/501/EC (Seveso), 96/82/EC (Seveso II):
N.A.
15.2. Chemical safety assessment

No

SECTION 16: Other information

Full text of phrases referred to in Section 3:

R40 Limited evidence of a carcinogenic effect.
R42/43 May cause sensitization by inhalation and skin contact.
R43 May cause sensitization by skin contact.
R48/23 Toxic: danger of serious damage to health by prolonged exposure through inhalation.
R53 May cause long-term adverse effects in the aquatic environment.
H351 Suspected of causing cancer.
H372 Causes damage to organs through prolonged or repeated exposure.
H317 May cause an allergic skin reaction.
H334 May cause allergy or asthma symptoms or breathing difficulties if inhaled.
H413 May cause long lasting harmful effects to aquatic life.

This safety data sheet has been completely updated in compliance to Regulation 453/2010/EU.

This MSDS cancels and replaces any preceding release.

Manufacturer disclaimer:

FOR PROFESSIONAL USE ONLY:

Use as directed. The information and recommendations are taken from sources (raw material SDS(s) and manufacturer's knowledge) believed to be accurate; however, the manufacturer makes no warranty with respect to the accuracy of the information or the suitability of the recommendation and assumes no liability to any user thereof. Each user should review these recommendations in the specific context of the intended use and determine whether they are appropriate.