SAFETY DATA SHEET

SECTION 1. Identification of the substance/mixture and of the company/undertaking

1.1 Product identifier
Trade Name:
  **Robot Points/Hybrid Points/TPE Diamonds/Gingi Curettage**

1.2 Relevant identified uses of the substance or mixture and uses advised against
Relevant identified uses: Dental material
Uses advised against: No further data

1.3 Details of the supplier of the safety data sheet
Company/Undertaking identification
  Manufacturer's Name: SHOFU DENTAL GmbH
  Address: Am Brüll 17, 40878 Ratingen, Germany
  Phone: +49 (0) 2102-8664-0
  Fax: +49 (0) 2102-8664-64
  E-Mail: info@shofu.de
  Section in Charge: Quality Management & Regulatory Affairs

1.4 Emergency Telephone Number
  +49-2102-8664-53 (SHOFU DENTAL GmbH) 24 hours / 7 days

SECTION 2. Hazards identification

2.1 Classification of the substance or mixture
CLASSIFICATION (EC 1272/2008)
  Skin Sens. 1  H317  May cause an allergic skin reaction.
  Carc.2  H351  Suspected of causing cancer.

2.2 Label elements
LABEL IN ACCORDANCE WITH (EC) NO.1272/2008

  GHS08

HAZARD-DETERMINING COMPONENTS OF LABELLING
  Nickel

SIGNAL WORD
  Danger

HAZARD STATEMENTS
  H317  May cause an allergic skin reaction.
  H351  Suspected of causing cancer.

PRECAUTIONARY STATEMENTS
  P302+P352  IF ON SKIN: Wash with plenty of soap and water.
  P363  Wash contaminated clothing before reuse.
  P314  Get medical advice/attention if you feel unwell.
  P333+P313  If skin irritation or rash occurs: Get medical advice/attention.
2.3 Other hazards

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

SECTION 3. Composition/information on ingredients

3.1 Chemical characterization: Mixtures
3.2 Description: Mixture of substances listed below with nonhazardous additions.
3.3 Dangerous components:
   - Nickel (bonding layer)  Cas: 7440-02-0
     EINECS: 231-111-4
     Skin Sens. 1 H317, Carc.2 H351
   - Natural diamond grit
   - Stainless steel base and shank
   - Chromium plate layer

3.4 Additional information: For the wording of the listed risk phrases refer to section 2.

SECTION 4. First-aid measures

4.1 Description of first aid measures
   - Eye contact: Wash immediately plenty of water and seek medical advice, since the grinding
dust cause scratched harm to the cornea if contact.
   - Skin contact: No special measures required.
   - Ingestion: No special measures required.
   - Inhalation: Remove from exposure. (if inhaled the dust from grinding)

4.2 Most important symptoms and effects, both acute and delayed
   - No further relevant information available.

4.3 Indication of any immediate medical attention and special treatment needed
   - No further relevant information available.

SECTION 5. Fire-fighting measures

5.1 Extinguishing Media:
   - The product is not flammable.

5.2 Special hazards arising from the substance or mixture:
   - No further relevant information available.

5.3 Advice for firefighters:
   - No further relevant information available.

SECTION 6. Accidental release measures

6.1 Personal precautions, protective equipment and emergency procedures:
   - Don't breathe dust.
6.2 Environmental Precautions:
No special measures required.

6.3 Methods and material for containment and cleaning up:
Pick up and collect in a suitable container.

6.4 Reference to other section:
See Section 7 for information on safe handling.
See Section 8 for information on personal protection equipment.
See Section 13 for disposal information.

SECTION 7. Handling and storage

7.1 Precautions for safe handling:
Use in accordance with instruction. In case of grinding and polishing, wear dust mask and safety glasses, and using dust respirator and local exhaust.

7.2 Conditions for safe storage, including any incompatibilities:
Store in a dry place. Take measures to avoid mechanical and chemical damage.

7.3 Specific end use(s):
No further relevant information available

SECTION 8. Exposure controls/personal protection

8.1 Control parameters:
Ingredients with limit values that require monitoring at the workplace:
The product does not contain any relevant quantities of materials with critical values that have to be monitored at the workplace.

8.2 Exposure controls:
Respiratory Protection:
Dust respirator and/or local exhaust.

Skin Protection: Hand Protection
Not required.

Eye Protection: Safety goggles

SECTION 9. Physical and chemical properties

9.1 Information on basic physical and chemical properties
Appearance/Odor/Colour: Needle shape grinding instrument with metallic sheen.

Odour threshold Not determined.

pH Not determined.

Melting point/freezing point Not determined.

Boiling Point: Not determined.

Flash point: Not determined.

Evaporation rate Not determined.

Flammability (solid, gas) Not applicable.

Upper/lower flammability or explosive limits Not determined.

Vapour pressure Not determined.

Vapour density Not determined.
9.2 Other information

No further relevant information available.

SECTION 10. Stability and reactivity

10.1 Reactivity:
No further relevant information available.

10.2 Chemical stability:
Stable under normal temperatures and pressures.

10.3 Possibility of hazardous reactions:
No dangerous reactions known.

10.4 Condition to Avoid:
No further relevant information available.

10.5 Incompatible materials:
No further relevant information available.

10.6 Hazardous Decomposition Products:
None under normal conditions of storage and use.

SECTION 11. Toxicological information

11.1 Information on toxicological effects:
Acute toxicity: Based on available data, the classification criteria are not met.
Skin corrosion/irritation: Based on available data, the classification criteria are not met.
Eye damage/irritation: Based on available data, the classification criteria are not met.
Sensitization to the respiratory tract:
Based on available data, the classification criteria are not met.
Skin sensitization: Skin Sens. 1; H317 May cause an allergic skin reaction.
Germ cell mutagenicity/Genotoxicity:
Based on available data, the classification criteria are not met.
Carcinogenicity: Carc.2; H351 Suspected of causing cancer.
Reproductive toxicity: Based on available data, the classification criteria are not met.
Effects on or via lactation: Lack of data.
Specific target organ toxicity (single exposure):
Based on available data, the classification criteria are not met.
Specific target organ toxicity (repeated exposure):
Based on available data, the classification criteria are not met.
Aspiration hazard: Based on available data, the classification criteria are not met.
SECTION 12. Ecological information

12.1 Toxicity:
No further relevant information available.

12.2 Persistence and degradability:
No further relevant information available.

12.3 Bioaccumulative potential:
No further relevant information available.

12.4 Mobility in soil:
No further relevant information available.

12.5 Results of PBT and vPvB assessment:
Not applicable.

12.6 Other adverse effects:
No further relevant information available.

SECTION 13. Disposal considerations

13.1 Waste treatment methods:
Dispose of contents/container to in accordance with local/regional/national/international regulations.

SECTION 14. Transport information

14.1 UN number: Void
14.2 UN proper shipping name: Void
14.3 Transport hazard class(es): Void
14.4 Packing group: Void
14.5 Environmental hazards: No further relevant information available.
14.6 Special precautions for user: Not applicable.
14.7 Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code:
Not applicable.

SECTION 15. Regulatory information

15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture:
• EU REGULATIONS: See Section 2
• Other regulations, limitations and prohibitive regulations:
The product is a medical device according to the EC-directive 93/42/EEC.

15.2 Chemical safety assessment:
A Chemical Safety Assessment has not been carried out.

SECTION 16. Other information

This product is intended for use by dental professionals. (instrument/material)

Relevant phrases:
H317 May cause an allergic skin reaction.
H351 Suspected of causing cancer.
Abbreviations and acronyms:

   EINESC: European Inventory of Existing Commercial Chemical Substances
   CAS: Chemical Abstracts Service (division of the American Chemical Society)
   PBT: Persistent, Bioaccumulative and Toxic
   vPvB: very Persistent and very Bioaccumulative