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 date sheet

Company/Undertaking identification

Manufacturer's Name: SHOFU DENTAL GmbH
Address: An der Pönt 70, 40885 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

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

(Contd. on page2)

(Contd. on page1)

P304+P341

IF INHALED: If breathing is difficult, remove victim to fresh air and keep at rest in a position comfortable for breathing.

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:

Cas: 7440-02-0 EINECS: 231-111-4	Nickel (bonding layer) 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.

(Contd. on page3)

(Contd. on page2)

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.
Relative Density:	Not determined.
Solubility: water solubility	Insoluble

(Contd. on page4)

(Contd. on page3)

Partition coefficient: n-octanol/water	Not determined.
Auto-ignition temperature	Not determined.
Decomposition temperature	Not determined.
Viscosity	Not determined.
Explosive properties	Not applicable.
Oxidising properties	Not applicable.

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.

(Contd. on page5)

(Contd. on page4)

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.

(Contd. on page6)

(Contd. on page5)

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