Material Safety Data Sheet according to (EC) 1907/2006



Tradename:

Lingual/palatal sheath

Section 1. Identification of the substance/preparation and of the company/undertaking

 1.1 Product identifier

 Name of product:
 Lingual/palatal sheath

Product group: UFI:

1.2 Relevant identified uses of the substance or mixture and uses advised against

Use of the substance/mixture Manufacture of dental appliances

1.3 Details of the supplier of the safety data sheet Manufacturer / Distributor

SCHEU-DENTAL GmbH Am Burgberg 20 D-58642 Iserlohn Tel. +49 (2374) 9288-0 Fax +49 (2374) 9288-90

eMail: service@SCHEU-DENTAL.com Internet: www.SCHEU-DENTAL.com

Section 2. Hazards identification

2.1 Classification of the substance or mixture

Classification according to Directive 67/548/EEC or 1999/45/EC Not classified as hazardous according to Directive 1999/45/EC.

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

Not classified as hazardous according to Regulation (EC) No. 1272/2008

2.2 Label elements

None

Hazard statements

H317 May cause an allergic skin reaction.

Contains nickel.

2.3 Other hazards

Section 3. Composition / information on ingredients

3.1 Substances Not applicable

3.2 Mixtures Chemical characterization Not applicable

Chemical characterization

Designation: Stainless steel 1.4310 X10CrNi18-8



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Components:

Description	CAS No	Quantity
Carbon (C)	7440-44-0	= 0.05 - 0.15 %
Silicon (Si)	7440-21-3	≤ 2.00 %
Manganese (Mn)	7439-96-5	≤ 2.00 %
Phosphorus (P)	7723-14-0	≤ 0.045 %
Sulfur (S)	7704-34-9	≤ 0.015 %
Chromium (Cr)	7440-47-3	= 16.00 - 19.00 %
Molybdenum (Mo)	7439-98-7	≤ 0.80 %
Nickel (Ni)	7440-02-0	= 6.00 - 9.50 %
Vanadium (V)	7440-62-2	
Miscellaneous	7727-37-9	N ≤ 0.11 %

Section 4. First aid measures

4.1 Description of first aid measures

No information available.

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

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

Section 5. Firefighting measures

5.1 Extinguishing media Suitable extinguishing media Not applicable

Unsuitable extinguishing media Not applicable

5.2 Special hazards arising from the substance or mixture

5.3 Advice for firefighters

Section 6. Accidental release measures

6.1 Personal precautions, protective equipment and emergency procedures

6.2 Environmental precautions

6.3 Methods and material for containment and cleaning up

6.4. Reference to other sections

Safe handling: see section 7 Personal protection equipment: see section 8 Disposal: see section 13

Section 7. Handling and Storage

7.1 Precautions for safe handling No special conditions required Advice on protection against fire and explosion

7.2 Conditions for safe storage, including any incompatibilities

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Advice on storage compatibility No special conditions required

No special conditions required

7.3 Specific end use(s) Dental applications

Further information on storage conditions No special conditions required

Section 8. Exposure controls / personal protection

8.1 Control parameters

8.2 Exposure controls

Eye/face protection Protective glasses

Hand protection Protective gloves

Body protection Wear suitable protective clothing at work.

Section 9. Physical and chemical properties

9.1 Information on basic physical and chemical properties

Properties	Value
Physical state	solid
Colour	grey
Odour	odourless
Changes of state	
Melting point	1400 - 1450 °C
Initial boiling point and boiling range	not applicable
Flash point	not applicable
Flammability solid	not applicable
Flammability gas	not applicable
Lower explosion limit	not applicable
Upper explosion limit	not applicable
Auto-ignition	not applicable
Decomposition temperature	not applicable
Vapor pressure	not applicable
Density	not applicable
Solubility in water	not applicable
Partition coefficient (log POW)	not applicable
Vapor density	not applicable
Evaporation rate	not applicable

9.2 Other information

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Section 10. Stability and reactivity

10.2 Chemical stability

No hazardous reactions by intended use.

10.3 Possibility of hazardous reactions

10.4 Conditions to avoid

10.5. Incompatible materials

10.6. Hazardous decomposition products

No decomposition by intended use.

Section 11. Toxicological Information

11.1 Information on toxicological effects

Acute toxicity

Based on available data, the classification criteria are not met.

Irritation and corrosivity

Based on available data, the classification criteria are not met.

Sensitising effects

May cause allergic skin reactions (nickel) Sensitization is possible in predisposed persons.

STOT-single exposure

Based on available data, the classification criteria are not met.

Severe effects after repeated or prolonged exposure

Based on available data, the classification criteria are not met.

Carcinogenic / mutagenic / toxic / effects for reproduction

Based on available data, the classification criteria are not met.

Aspiration hazard

Based on available data, the classification criteria are not met.

Further information

A biological evaluation was carried out for the material in accordance with DIN EN ISO 10993-1. It meets the requirements regarding biocompatibility for medical devices.

Section 12. Ecological Information

12.1 Toxicity

A biological evaluation was carried out for the material in accordance with DIN EN ISO 10993-1. It meets the requirements regarding biocompatibility for medical devices.

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 an vPvB assessment

No further relevant information available.



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12.6. Endocrine disrupting properties

No further relevant information available.

12.7. Other adverse effects

No further relevant information available.

Further information

Section 13. Disposal considerations

13.1 Waste treatment methods

Advice on disposal

Dispose according to legislation.

Wastes Code product 17 04

Metals (including alloys)

Section 14. Transport Information

Land transport (ADR/RID)

14.1. UN number:	
14.2. UN proper shipping name:	No dangerous good in sense of these transport regulations.
14.3. Transport hazard class(es):	
14.4. Packing group:	

Inland waterways transport (ADN)

14.1. UN number:	
14.2. UN proper shipping name:	No dangerous good in sense of these transport regulations.
14.3. Transport hazard class(es):	
14.4. Packing group:	

Marine transport (IMDG)

14.1. UN number:	
14.2. UN proper shipping name:	No dangerous good in sense of these transport regulations.
14.3. Transport hazard class(es):	
14.4. Packaging group:	

Air transport (ICAO)

14.1. UN number:	
14.2. UN proper shipping name:	No dangerous good in sense of these transport regulations.
14.3. Transport hazard class(es):	
14.4. Packaging group:	

14.5. Environmental hazards

ENVIRONMENTALLY HAZARDOUS: No

14.6. Special precautions for user

No information available.

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

Not applicable



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Section 15. Regulatory Information

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

National regulatory information

Additional Information

15.2 Chemical Safety Assessment

Section 16. Other Information

Abbreviations and acronyms

Accord européen sur le transport des marchandises dangereuses par Route
(European Agreement concerning the International Carriage of Dangerous Goods by Road)
International Maritime Code for Dangerous Goods
International Air Transport Association
Globally Harmonized System of Classification and Labelling of Chemicals
European Inventory of Existing Commercial Chemical Substances
European List of Notified Chemical Substances
Chemical Abstracts Service
Lethal concentration, 50 %
Lethal dose, 50 %

Further information

The information in this safety data sheet is correct to the best of our knowledge, information and belief at the date of printing. The information is intended to provide you with guidelines for the safe handling of the product mentioned in this safety data sheet during storage, processing, transportation and disposal. The information is not transferable to other products. If the product is mixed, blended or processed with other materials or subjected to processing, the information in this safety data sheet cannot be transferred to the new material produced in this way, unless expressly stated otherwise.

Serious incidents in connection with the use of the product shall be reported immediately to the manufacturer (<u>gmra@scheudental.com</u>) and the competent authority.