

SAFETY DATA SHEET

PRODUCTS RELATED TO THIS MSDS

PRODUCT	MATERIAL
BRACKETS METAL	SS 17-4 PH
TUBES BONDABLE	SS 17-4 PH + 316L (MESH BASE)
TUBES WELDABLE	SS 17-4 PH
BUTTONS BONDABLE	SS 17-4 PH + 316L (MESH BASE)
BUTTONS WELDABLE	SS 17-4 PH
BT2	SS 17-4 PH + 316L (MESH BASE)
TS2	SS 17-4 PH + 316L (MESH BASE)
LINGUAL CLEAT BONDABLE/WELDABLE	SS 316 L
CRIMPABLE HOOK	SS 316 L
CRIMPABLE STOP	SS 316 L
LINGUAL SHEATHS	SS 316 L
ACTIVA	SS 316 L

IDENTIFICATION OF THE MATERIAL

Raw materials used are basically stainless steel alloy (Aisi 300/600 - 316L, 17 - 4Ph).

CHEMICAL COMPOSITION


1.	Up to	0.07% C
2.	Up to	18% Cr
3.	Up to	14% Ni (316L only)
4.	Up to	5% Ni (17-4PH only)
5.	Up to	2% Mn
6.	Up to	3% Mo (316L only)
7.	Up to	1% Si (depending from carbon's level contained)
8.	Up to	0.45%Nb (17-4 Ph only)
9.	Up to	5% Cu
10.	Balance	Fe

PHYSICAL - CHEMICAL PROPERTIES AND FLAMMABILITY

Appearance	Solid	Color	Silver-grey
Odor	Odorless	Safety Data	None
Ph-value	None		
<i>Change of status</i>			
Bowling point	n.a.	Melting point	1400 – 1550 °C
Combustion rate	n.a.	Flammability	n.a.

ORTHODONTIC MANUFACTURER SIA SRL

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	<p style="text-align: center;">SCHEMA SICUREZZA (Medical Safety Data Sheet)</p>	<p>Revisione 2 Pagina 2 di 2</p> <p>Rif. ISO 9002 §/ /EN 46002 § 4.2</p> <p>Modello 5/1 Revisione 1</p> <p>Data 02/08/2018</p> <p>MSDS B-E.docx</p>
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Ignition temperature	n.a.	Auto-ignition temperature	n.a.
Comburent capability	n.a.	Explosion limit	n.a.
Vapor pressure	n.a.	Density at 20°	7,7 – 8.1 g/cm ³
<i>Solubility and scattering features</i>			
Soluble in water	Insoluble	Soluble in fat	Insoluble
Scattering coefficient	None		

REACTIVITY

Stability and reactivity: stable and not reactive

⇒

HAZARDS IDENTIFICATION

Information on toxicity: no toxic effects caused by the material in massive form or during the usual orthodontic process have been noticed.

Possible hazards during the working process:

⇒ **Effects of overexposure:** inhalation is very serious. A prolonged excessive exposition to dust, mist and fumes of this alloy may contribute to chronic respiratory ailments.

⇒ **Possible cancer hazard:** Nickel is treated as a potential agent, being included in the NTP and IARC lists. Some scientific studies have found an excessive incidence of cancer of the respiratory tract among workers involved in certain steps of nickel refining processes. However, several studies on workers exposed to various forms of nickel and its compounds have not shown any increased risk of cancer.

⇒ **Primary routes of entry:** inhalation of dust and fumes.

According to the Directive 67/548/EEC all products with a minimum Nickel content of 1% are classified in the same way as suspect carcinogen (category 3) and irritating for skin. Products which these sheets refer to, have form of massive metal alloy, therefore nickel cannot develop as possible hazardous material. No toxic effects caused by the material in massive form or during the normal orthodontic practices have been noticed. A prolonged and frequent contact may cause skin irritation and other allergic reactions in subjects sensitive to nickel.

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PRODUCTS RELATED TO THIS MSDS

NICKEL TITANIUM CLIP FOR SELF LIGATING BRACKETS & TUBES

IDENTIFICATION OF THE MATERIAL

Chemical Nature, Sales Name, Use: Metal Alloy - Nickel-base Alloy strip shape

CHEMICAL COMPOSITION

		CAS #	Exposure Limit (OSHA) in mg/m³	Threshold Limit Value in mg/m³
Up to	55% of Ni	7440-02-0	5*	10'
Up To	Balance of Ti	7440-32-6	5*	10'

* = respirable fraction of dust

' = exposure limits for metal or insoluble metal oxide of the metal

PHYSICAL - CHEMICAL PROPERTIES AND FLAMMABILITY

Appearance	Solid	Color	Metallic-grey
Odor	Odorless	Safety Data	None
Ph-value	None		
<i>Change of status</i>			
Bowling point	n.a.	Melting point	1371 – 1482 °C
Combustion rate	n.a.	Flammability	Not ignitable
Extinguishing Media	Sand, dolomite, graphite power or sodium chloride work best.	Auto-ignition temperature	n.a.
Comburent capability	n.a.	Explosion limit	n.a.
Vapor pressure	n.a.	Density at 20°	n.a.
<i>Solubility and scattering features</i>			
Soluble in water	Insoluble	Soluble in fat	Insoluble
Scattering coefficient	None		

REACTIVITY

⇒ **Stability and reactivity:** stable and not reactive

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SPECIAL PROTECTION INFORMATION

Nitinol alloys in the form shipped require no special protection for handling. For specific processing, the following should be observed:

FIRST AID MEASURES

Inhalation: Use local ventilation and/or respiratory protective equipment to limit exposure to airborne dusts. If sudden overexposure does occur: remove victim to fresh air, begin artificial respiration, if victim is not breathing.

Skin contact: Exposure or repeated contact may irritate the skin. Avoid frequent and prolonged contact. Wear suitable protective clothing and gloves. In case of contact: brush off skin and clothing. Wash with soap and water. Remove metallic particles and cleanse wounds

Ingestion: Seek prompt medical help.

Eyes: Flush eyes with water.

HAZARDS IDENTIFICATION

Information on toxicity: Product tested for bio-compatibility with results concluding negative toxicological reaction.


Although Nitinol alloys do not constitute a physical or health hazard in the form sold, subsequent operations such as abrading, melting, welding, cutting or processing in any other fashion may produce potentially hazardous dust or fumes which can be inhaled, swallowed, or come into contact with skin or eyes.

Possible hazards during the working process:

⇒ **Effects of overexposure:** Special protective clothing is not normally needed. Provide local exhaust ventilation in areas where metal fumes or dusts are.

⇒ **Primary routes of entry:** inhalation of dust and fumes.

⇒ **Possible cancer hazard:** Nickel is treated as a potential agent, being included in the NTP and IARC lists. Some scientific studies have found an excessive incidence of cancer of the respiratory tract among workers involved in certain steps of nickel refining processes.

	<p style="text-align: center;">SCHEDA SICUREZZA (Medical Safety Data Sheet)</p>	<p>Revisione 1 Pagina 3 di 3 Rif. ISO 9002 §/ /EN 46002 § 4.2 Modello 5/1 Revisione 1 Data 02/08/2018 MSDS B1-E.docx</p>
SAFETY DATA SHEET		

However, several studies on workers exposed to various forms of nickel and its compounds have not shown any increased risk of cancer.

According to the Directive 67/548/EEC all products with a minimum Nickel content of 1% are classified in the same way as suspect carcinogen (category 3) and irritating for skin. Products which these sheets refer to, have form of massive metal alloy, therefore nickel cannot develop as possible hazardous material. No toxic effects caused by the material in massive form or during the normal orthodontic practices have been noticed. A prolonged and frequent contact may cause skin irritation and other allergic reactions in subjects sensitive to nickel.

For purposes of this MSDS, occupational exposure to alloys is taken to mean dusts, fumes, or solutions containing metals that can become airborne or can spill on skin or in the eye. Occupational exposure to alloys does not include solid products (i.e. ingots or castings), provided no particle generating operations, such as grinding or cutting, occur. In most industrial situations, the significant routes of exposure would include inhalation, skin and eye contact. Titanium metal is considered relatively nontoxic.

DISPOSAL CONSIDERATION

⇒ **Solid forms:** Articles made of titanium are not hazardous. No special disposal regulations apply.

⇒ **Dusts and Fines:** If airborne, Titanium fines can burn. When ignited, titanium is very difficult to extinguish. Before being disposed of titanium fines should be stabilized (solidified or diluted with sand or other non combustible substances) to prevent being ignited. Titanium alloys can be landfilled as an industrial waste.

REGULATORY INFORMATION

⇒ **Hazardous:** Nitinol and Nitinol alloys are not hazardous.

FURTHER INFORMATION

⇒ **General information:** The information contained herein is based on the present state of our knowledge and is intended to describe our products from the point of view of safety requirements. Therefore, it should not be construed as guaranteeing specific properties. Users should make their own investigations to determine the suitability of the information for their particular purposes.

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