

**SAFETY DATA SHEET**

**PRODUCTS RELATED TO THIS MSDS**

**SVOP BAND PUSHER**

Raw materials used are basically stainless steel alloy (**Aisi - 316LS**) for the head and Aluminum AL6026 for the handle. Removable cap is made of vulcanizate TPE medical grade. Aluminum has a surface treatment to increase sterilization resistance (18 $\mu$ m anodizing)

**CHEMICAL COMPOSITION**

**AISI 316LS**

1.	Up to	0.07% C
2.	Up to	18% Cr
3.	Up to	14% Ni
4.	Up to	2% Mn
5.	Up to	3% Mo
6.	Up to	1% Si
7.	Up to	0.45% Nb
8.	Up to	5% Cu
9.	Balance	Fe

**ALUMINUM**

10.	Up to	0.6% – 1.20% Mg
11.	Up to	0.2% – 1.00% Mn
12.	Up to	0.0% – 0.70% Fe
13.	Up to	0.6% – 1.40% Si
14.	Up to	0.2% – 0.50% Cu
15.	Up to	0.0% – 0.40% Pb
16.	Up to	0.5% – 1.50% Bi
17.	Up to	0.0% – 0.30% Zn
18.	Up to	0.0% – 0.05% Sn
19.	Up to	0.0% – 0.30% Cr
20.	Up to	0.0% – 0.20% Ti
21.	Up to	0.0% – 0.15% Others
22.	Balance	Aluminum Al

**TPE 8281-75 MED**

Thermoplastic Vulcanizate Medical Grade. Compliant to USP (U.S. Pharmacopeia) Class VI, EU and China RoHS, ISO 10993, ISO 1183, ISO 865

**ORTHODONTIC MANUFACTURER SIA SRL**

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**PHYSICAL - CHEMICAL PROPERTIES AND FLAMMABILITY**

<b>AISI 316 LS</b>			
Appearance	Solid	Colour	Silver-grey
Odour	Odourless	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.
Ignition temperature	n.a.	Auto-ignition temperature	n.a.
Comburent capability	n.a.	Explosion limit	n.a.
Vapour pressure	n.a.	Density at 20°	7,7 – 8.1 g/cm <sup>3</sup>
<i>Solubility and scattering features</i>			
Soluble in water	Insoluble	Soluble in fat	Insoluble
Scattering coefficient	None		

<b>ALUMINUM</b>			
Appearance	Solid	Colour	Silver-grey
Odour	Odourless	Safety Data	None
Ph-value	None		
<i>Change of status</i>			
Bowling point	n.a.	Melting point	580 – 650 C°
Combustion rate	n.a.	Flammability	n.a.
Ignition temperature	n.a.	Auto-ignition temperature	n.a.
Comburent capability	n.a.	Explosion limit	n.a.
Vapour pressure	n.a.	Density at 20°	2.62 g/cm <sup>3</sup>
<i>Solubility and scattering features</i>			
Soluble in water	Insoluble	Soluble in fat	Insoluble
Scattering coefficient	None		

<b>TPE 8281-75 MED</b>			
Appearance	Solid	Colour	Natural
Specific Gravity	0,920	Shore Hardness A 73°F	79
Odour	Odourless	Safety Data	None
Ph-value	None		
<i>Change of status</i>			
Bowling point	n.a.	Melting point	n.a.
Combustion rate	n.a.	Flammability	n.a.
Ignition temperature	n.a.	Auto-ignition temperature	n.a.
Comburent capability	n.a.	Explosion limit	n.a.
Vapour pressure	n.a.	Density at 20°	0,920 g/cm <sup>3</sup>
<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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## **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.

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## SCHEDA SICUREZZA (Medical Safety Data Sheet)

Revisione 2 Pagina 4 di 4  
Rif. ISO 9002 §/ /EN 46002 § 4.2  
Modello 5/1 Revisione 2  
Data 02/08/2018

MSDS N4-E.docx

### SAFETY DATA SHEET

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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