

SCHEDA SICUREZZA (Medical Safety Data Sheet)

Revisione 0 Pagina 1 di 3

Rif. ISO 9002 §/ /EN 46002 § 4.2

Modello 5/1 Revisione 0

Data 02/08/2018

MSDS O-E.docx

SAFETY DATA SHEET

PRODUCTS RELATED TO THIS MSDS			
PRODUCT	MATERIAL		
RPE LEONARDO	AISI 301 (carter) +303 (body and pin) +316L (arms)		
RPE XP	AISI +303 (body and pin) +316L (arms)		
SCREWS	AISI 303 (body and pin)		

IDENTIFICATION OF THE MATERIAL

Raw material used is stainless steel alloy (Aisi 303 - Aisi 301 - Aisi 3156L).

CHEMICAL COMPOSITION

Aisi 303 Element / Weight (%)					
Fe	С	SI	Mn	P	S
Balance	≤0.15	< 1.00	< 3.50	<0.20	0.15 ~ 0.35
Cr	Ni	N	Cu		
17~19	8~10	< 0.11	< 1.0		

Aisi 301 Element / Weight (%)					
Fe	С	SI	Mn	P	S
Balance	≤0.15	≤ 2.00	≤ 2.00	< 0.045	< 0.03
Cr	Ni	N	Cu	Mo	
16~19	6~9.50	< 0.11	< 1.0	≤ 0.80	

Aisi 316L Element / Weight (%)					
Fe	С	SI	Mn	P	S
Balance	≤0.03	≤ 1.00	≤ 2.00	< 0.045	< 0.03
Cr	Ni	N	Mo		
16~19	10 ~ 15	< 0.11	2.0 ~ 3.0		



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Revisione 0 Pagina 2 di 3

Rif. ISO 9002 §/ /EN 46002 § 4.2

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PHYSICAL - CHEMICAL PROPERTIES AND FLAMMABILITY

Appearance	Solid	Colour	Silver-grey	
Odour	Odourless	Safety Data	None	
Ph-value	None			
	Chan	ge of status		
Bowling point	n.a.	Melting point	1315 − 1537 °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°	$7,5 - 8.5 \text{ g/cm}^3$	
	Solubility and	scattering features		
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.



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Revisione 0 Pagina 3 di 3

Rif. ISO 9002 §/ /EN 46002 § 4.2

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MSDS O-E.docx

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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.