

## Material Safety Data Sheet

CEE 91/155 and CEE/93/112 Directives

**ORTHO PLUS**

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### 1. Identification of the substance/device :

1.1 Device name : **EXPANSION SCREWS**

### 2. Composition, information on ingredients:

Composition	CAS N°	wt%
2.1 Stainless Steel : Cr = 17-19% Ni=8-10% Mn=1-2% Fe=rest	/	/
2.2 Nickel – Silver : Cu=41-45% Ni=9-11% Zn=rest	/	/
2.3 Polyamide : NH(CH <sub>2</sub> ) <sub>5</sub> CO	/	/
2.4 Polyethylene : C <sub>2</sub> H <sub>4</sub>	/	/
2.5 Palladium : Pd	/	/
2.6 Gold : Au	/	/

### 3. Hasards identification:

### 4. First aid measures:

### 5. Fire fighting measures:

Risk of fire : none

### 6. Accidental release measures:

Safety devices : not required

### 7. Handling and storage:

### 8. Exposure controls/personal protection:

### 9. Physical and chemical properties:

	Tensile Strength	Elongation A5	Hardness
Stainless Steel :	800 – 900 N/mm <sup>2</sup>	20%	260 HV 10
Nickel – Silver :	250 – 300 N/mm <sup>2</sup>	9%	90 HV 10
Polyamide :	not tested	not tested	62° Shore
Polyethylene :	not tested	not tested	45° Shore

### 10. Stability and reactivity:

### 11. Toxicological information:

Toxical action : none

Allergical action: persons who are allergic against nickel can get eruptions. Remedy : stop therapy immediately.

Dangers caused by the product : none

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**12. Ecological information:**

**13. Disposal considerations:**

**14. Transport information:**

**15. Regulatory information:**

**1) CE Directives**

- \_ Directive 2002/72/CE, on plastics materials in contact with food.
  - \_ European Resolution AP(89) 1 : On colorings in plastics materials intended to be in contact with food
  - \_ Directive 94/62/CE, on packaging and waste packages.
  - \_ Regulatory CE 2004/1935, on materials and objects intended to be in contact with food.
  - \_ Medical Device Directive 93/42 CEE
  - \_ **Material Safety Data Sheet :**
- D.91/155/CEE modified by D.93/112/CEE : on hazards matters and preparations.
- \_ **Classification/Labeling**
- Directive n° 67-548-CEE 27 june 1967

**2) French Regulatory**

- \_ Code de la Santé Publique Livre-5bis « Dispositions relatives aux dispositifs médicaux » : Ch1, Ch2 et Ch3
  - \_ **Material Safety Data Sheet**
- Arrêté du 5.01.1993 : substances et préparations dangereuses
- \_ **Hasards préparations**
- Arrêté du 21.02.1990 modifié par arrêté du 25.11.1993

**3) Application**

Only for single use. Device has to be built into the appliance of a dental technician. A doctor has to overgrow the therapy. The patient has to keep the appliance clean, especially the expansion screw. Tartar and lime can block the function of the screws.

**16. Other information:**

**- Recommended use**

While the information and recommendations set forth on this data sheet are believed to be accurate as received from our suppliers, ORTHO PLUS makes no warranty with respect thereto and disclaims all liability from reliance thereon.