

1. Identification of the substance/device :		
1.1 Device name :		DISJONCTEUR – EXPANSION SCREWS
2. Composition, information on ingredients:		
Composition	CAS N°	wt%
2.1 Stainless Steel - Cr - Ni - Mn - Fe		17-19 8-10 1-2 rest
2.2 Nickel – Silver - Cu - Ni - Zn		41-45 9-11 rest
2.3 Polyamide	/	/
2.4 Polyethylene	/	/
2.5 Palladium	/	/
2.6 Gold	/	/
3. Hazards identification:		
4. First aid measures:		
5. Fire fighting measures:		
6. Accidental release measures:		
7. Handling and storage:		
8. Exposure controls/personal protection: N/A		
9. Physical and chemical properties:		
- Stainless Steel : Tensile strength : 800-900N/mm ² - Elongation A5 : 20% - Hardness : 260 HV 10		
- Nickel – Silver Tensile strength : 250-300N/mm ² - Elongation A5 : 9% - Hardness : 90 HV 10		
- Polyamide : Tensile strength : not tested – Elongation A5 : not tested – Hardness : 62° Shore		
- Polyethylene : Tensile strength : not tested – Elongation A5 : not tested – Hardness : 45° Shore		
10. Stability and reactivity:		
11.		
12. Toxicological information:		
None		
13. Ecological information:		
14. Disposal considerations:		
15. Transport information:		

16. Regulatory information:

1) CE Directives

- _ Directive 2002/72/CE, on plastics materials in contact with food.
- _ Directive 2005/84/CE, on limitation of hazard matter (phthalates in toys and items nursery)
- _ Standard NF EN 71-3 (sept. 2000) : on toys security - part III – release of elements
- _ 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/LabelingCE

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

Hazards preparations

Arrêté du 21.02.1990 modifié par arrêté du 25.11.1993

17. Other informations:

Persons who are allergic against nickel can get eruptions. Remedy : Stop therapy immediately.

- Recommended use :

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 appliance clean, especially the expansion screw. Tartar and lime can block the function of the screws.

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.