

**E.C. – Safety Data Sheet
(91/155/EEC)
Maximat Plus Tensioning Instrument**

POLYDENTIA SA
Status 15.03.2012/AR
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1.1 Identification of the substance/preparation and of the company

Information on the product:
“**Maximat Plus Tensioning Instrument**”

Medical Device Class (according to 93/42/EEC): I – Rule 5
Main use of the product: **Tensioning system for dental matrices**

1.2 Information on the manufacturer:

Polydentia SA
Strada Cantonale
CH-6805 Mezzovico-Vira
Phone: +41 (0) 91 946 29 48
Fax : +41 (0) 91 946 32 03
Email : info@polydentia.com

1.3 Information provided by:

Phone: +41 (0) 91 946 29 48 Emergency telephone: +41 (0) 91 946 29 48

2. Composition (Substance)

PPSU (Polyphenylsulfone)

3. Hazards identification

Physical and chemical hazards for people and environment: none
The preparation is not classified as dangerous according to Directive 1999/45/EC.

4. First aid measures

After inhalation: Material cannot be inhaled under normal conditions.
After contact with skin: No special measures required.
After contact with eyes: No special measures required.
After ingestion: No first aid necessary.

5. Fire fighting measures

Suitable extinguishing media: Extinguishing powder, foam, sand, CO2
Extinguishing media which must not be used for safety reasons: Class UL94 V-O without alogens
Special hazards caused by the material, its products of combustion or flue gases: Low level of Hydrogen cyanide (HCN), Carbon monoxide (CO)
Protective equipment for fire fighting: No special measures required.

6. Accidental release measures

Personal precautions: No special measures required.
Environmental precautions: Avoid spreading and prevent the product from entering sewers or surface waters.
Methods for cleaning up: Sweep and scrap into a waste bin.

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7. Handling and storage

Handling

Precautions for safe handling: No special protective measures required.

Precautions against fire and explosion: No special precautions are required.

Storage

Conditions for storage rooms and vessels: None known

Advice for storage of incompatible materials: Not applicable

Further information for storage: Keep the pack tightly close

8. Exposure controls / Personal protection

Additional information about the technical concept of the product: None

Exposure limited and controlled: Not applicable

General protection and hygiene measures: Not required

Respiratory protection: Not required

Eye protection: Not required

Skin protection: Not required

Soft oral tissue protection: Not required

9. Physical and chemical properties

Appearance: solid

Odour: odourless

Colour: Various Colors

Melting Point/Melting Range : 350°C

Mold temperature : 220 °C

Boiling Point/Boiling Range : Not applicable

Flash point: Not applicable

Lower explosion limit: Not applicable

Upper explosion limit: Not applicable

Vapour pressure: Not applicable

Density at 20°C : >1,41 g/cm³

Water solubility: insoluble

10. Stability and reactivity

Thermal decomposition / Condition to be avoided: No decomposition if used according to specifications

Dangerous reactions : No dangerous reactions known

Dangerous products of decomposition : No dangerous decomposition products known

11. Toxicological information

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When used and handled according to specifications, the product does not have any harmful effects according to our experience and the information provided to us.

12. Ecological information

Product not soluble and not hazardous for water.

13. Disposal consideration

Avoid spreading and prevent the product from entering sewers or surface waters.
Used products can be discharged into a waste bin, according to any national or regional provisions which may be in force.

14. Transport information

Land ADR/RID: No hazardous material
Sea: INO/IMDG: No hazardous material
Air transport ICAO-II/IATA-DGR: No hazardous material
UN regulation: - /

Customs Harmonized Tariff No. 9018.4900

15. Regulatory information

None of the ingredients is listed.
Mark as ECC-guideline / Not necessary to mark
National regulations / Classification as VFB / Not subordinated

Warning Label:

R sets: none

S sets: none

16. Other information

Recommended use: for dental professional use

Restriction of use: keep away from children

This Safety Data Sheet completes the Technical Data Sheet of the product, but it doesn't replace it. It is based on our present-day knowledge and has been issued according to the Safety Data Sheet of the raw material supplier.