

Material Safety Data Sheet

CEE 91/155 and CEE/93/112 Directives

ORTHO PLUS

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1. Identification of the substance/device : Calcium Sulfate Hemihydrate

1.1 Device name : **ORTHO PLASTER / PLATRE ORTHODONTIQUE DUR**

2. Composition, information on ingredients: Calcium Sulfate Hemihydrate

Composition	CAS N°	wt%
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3. Hazards identification:

Hazard Ratings :

Health = 0 - Flammability = 0 - Reactivity = 0

Legend :

0 = minimal - 1=slight - 2=moderate - 3=serious - 4=severe

Hazardous ingredients :

TLV mg/m³ : 5.0% (Respirable Dust) 10.0% (Total Dust)

OSHA PEL mg/m³ : 5.0% (Respirable Dust) 15.0% (Total Dust)

4. Health hazard data - First aid measures:

Effects of Acute and Chronic Over Exposure: material may develop sufficient heat to cause burning or dry skin. Particles may cause eye irritation.

Emergency and First Aid Procedure :

- **Eyes:** flush immediately with water to remove particles, if irritation continues see a physician.
- **Skin :** wash with water
- **Inhalation :** remove to fresh air
- **Ingestion :** hardens when wetted may cause obstruction

5. Fire and explosion hazard data:

Flash point : not combustible

Flammable (Explosive) Limit : LEL – N/A URL – N/A

Extinguishing Media : not combustible

Special fire fighting procedures and equipment : N/A

Unusual fire and explosion hazard : when heated to decomposition it emits toxic fumes of CaO & SO₂

6. Accidental release measures:

Steps to be taken in case material is released or spilled: sweep up. Avoid creating dust. Slurry may plug drain.

7. Handling and storage:

Avoid high humidity or moisture

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8. Exposure controls/personal protection:

Personal Precaution:

- **Respiratory protection** : Occupational Safety and Health Administration approved respiration for nuisance dust if above TLV
- **Ventilation**: local exhaust if above TLV.
- **Protective gloves** : N/A
- **Eyes protection** : dust goggles or safety glasses
- **Other personal protective equipment** : N/A

9. Physical and chemical properties:

Boiling point : no data available

Appearance and Odor : white and odorless powder

Vapor pressure (mm Hg) : no data available

Vapor density (air 1 atm) : no data available

Solubility in water : no data available

Specific gravity (H₂O=1) : 2.6-3.2

% Volatile by Volume (%) : 0

Evaporation rate : N/A

10. Reactivity data:

Product stability : stable

Conditions to avoid : high humidity, high temperature

Incompatibility (materials to avoid) : acids

Hazardous decomposition of products : above 1450)C – SO₂ & CaO

Hazardous polymerization : will not occur

Conditions to avoid polymerization : N/A

11. Toxicological information:

12. Ecological information:

13. Disposal considerations:

Waste disposal procedures: normal disposal as for any dry inert powder.

Neutralizing agent : N/A

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14. Transport information:

Applicable regulations :

- IMOC : N/A
- Tariff 6D : N/A
- Shipping name : N/A
- I.D. number : N/A
- Report quantity : N/A
- Hazard Class : N/A
- Military air (AFR 71-4) : N/A
- 49 CFR : N/A
- Net explosive weight : N/A
- Unit container : N/A
- DOT SPSC container : N/A
- DOT Exempt / DOD / CCN : N/A
- IATA : N/A
- Aerosol Propellant(s) : N/A
- Labels : N/A
- Limited Quantity : N/A

15. Regulatory information:

1) CE Directives

_ Directive 94/62/CE, on packaging and waste packages.

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

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.

The information and recommendations contained herein are based on the data believed to be correct as of the date of issue (20 May 2009). No guarantee or warranty of any kind, expressed or implied is made with respect to the information contained herein.