



Material Safety Data Sheet

CEE 91/155 and CEE/93/112 Directives

ORTHOPLUS

28, rue Ampère – BP 28 - 91430 Igny France – Tél./Fax: (33) 1 69 41 90 28/ (33) 1 60 19 32 22 orthoplus@orthoplus.fr

1. Identification of the substance/device and manufacturer:

1.1 Device names: **FUNCTIONAL EDUCATORS EF Line: EF Class III standard & small, EFT Slim, EF Class II large-standard & slim, EF Braces evolution, EF Guide evolution, EF Protect evolution, EF Start evolution, EF Kid, EF TMJ, EF Class II 2 Steps, EF Profil, EFT evolution, Lips interceptor. All these EF are translucent only.**

2. Composition, information on ingredients:

Composition	CAS N°	wt%
2.1 PVC 40 and 70 SHA Blue Cristal. Ref. SCE0140 and SCQ0294. Chemical characteristics: Polyvinyl chloride. Plasticized and thermal stabilized composition with calcium and zinc made of additives.	9002-86-2	40 <Cn<58
2.2 Phthalate Free Plasticizer: 1,2-Cyclohexanedicarboxylic acid, diisononyl ester.	1664 12-78-8	35<Cn<58,5
2.3 Epoxydized soybean oil	8013-07-08	1,5<Cn<7

3. Hazards identification:

- **Classification of the mix as per the rule (CE) n°1272/2008**
Is not a dangerous mix as per the rule (CE) n°1272/2008
- **Labeling data**
No need to label the raw material. Medical devices produced with the raw material have to be labeled.
- **Other hazards**
Thermal decomposition toxic products (see clause 5)

4. First aid measures:

- **Contact with the eyes and the skin : NA**



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5. Fire fighting measures:

- Specifics Hazards

Thermal decomposition of the raw material in bulk in toxics and corrosives products: hydrochloric gas, carbon monoxide and micro particulates of carbon may provide pulmonary suffocation.

No specific hazards and measures to be taken regarding the medical device itself.

6. Accidental release measures:

- Personal Precaution:

NA

- Environmental Precaution:

Do not release in the environment.

-Cleaning methods :

See Instructions for Use (IFU).

7. Handling and storage: NA

8. Exposure controls/personal protection: NA

9. Physical and chemical properties:

- Aspect

Physic stage : solid

- Temperature of decomposition

The decomposition is related to the temperature and the exposure time

- Flash point

N/A

- Auto flammability temperature

>320°C

- **Density at 20°C** : about between 1,10 and 1,19 g/cm³

- Solubility

Water : insoluble

Solvent oil : more or less soluble into solvents like ketones, tetrahydrofurane, dimethylsulfoxide

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10. Stability and reactivity:

- **Reactivity** : NA

- **Chemical stability** : stable

-**Possible hazardous reactions** : NA

-**Conditions to avoid**

Ignition sources

-**Incompatible materials**

Acetal-based polymers or amine : accelerated decomposition of the PVC

11. Toxicological information:

Information about the Toxicological effects

- **Acute Toxicity**

_ Ingestion : can be considered as harmless

- **Local Effects**

_ *Inhalation*

No toxic product can be easily extracted or inhaled

_ *Contact with skin and eyes* :

Can be considered as non-irritating for the skin

Little or no irritant for the eyes(mechanical action)

- **CMR effects**

Carcinogenicity : NA

Germ cell Mutagenicity: NA

Teratogenicity : NA

Toxicity for the reproductive organ : NA

12. Ecological information:

Do not contain PBT substances (persistent, bioaccumulative, toxic) neither substances vPvB (very persistent, very bioaccumulative).

13. Disposal considerations:

Product disposal

Recycle or send to factory treatment for special waste under regulation.

Disposal of packaging

Recycle if possible



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14. Transport information:

No special rules.

15. Regulatory information:

SVHC : no.

No chemical security evaluation done.

This preparation does not present any hazard for the human health by inhalation, ingestion or contact with the skin due to its shape.

16. Other information:

This document applies as it is, meets the specifications supplied by the seller.
In case of combinations or mixtures, make sure that no new dangers can occur.

- Recommended use

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

The information contained herein is given in good faith and based on our latest knowledge of the product, at the edition date.

Users' attention is drawn to the possible risks incurred when a product is used for other purposes than those for which it is intended.

This sheet must be used and reproduced for prevention and security purposes