

Safety data sheet

according to 1907/2006/EC, Article 31

Printing date 23.05.2017

Version number 6

Revision: 23.05.2017

SECTION 1: Identification of the substance/mixture and of the company/undertaking

- **1.1 Product identifier**
- **Trade name:** *Poly-F Plus*
- **1.2 Relevant identified uses of the substance or mixture and uses advised against**
- **Application of the substance / the mixture** Zinc polycarboxylate cement
- **Uses advised against** No further relevant information available.
- **1.3 Details of the supplier of the safety data sheet**
- **Manufacturer/Supplier:**
DENTSPLY DeTrey GmbH
De-Trey-Str. 1
D-78467 Konstanz
GERMANY
Tel.: +49-(0)7531-583-0
Fax: +49-(0)7531-583-104
email: KonstanzDEU.info-sdb@dentsplysirona.com
- **Further information obtainable from:**
 - Departement Research & Development for technical information
 - Departement Marketing & Sales for distribution of the safety data sheets
- **1.4 Emergency telephone number:** +49-(0)7531-583-0 8:00 - 17:00 (GMT + 1:00)

SECTION 2: Hazards identification

- **2.1 Classification of the substance or mixture**
- **Classification according to Regulation (EC) No 1272/2008**

Skin Irrit. 2	H315 Causes skin irritation.
Eye Dam. 1	H318 Causes serious eye damage.
Aquatic Acute 1	H400 Very toxic to aquatic life.
Aquatic Chronic 1	H410 Very toxic to aquatic life with long lasting effects.

- **2.2 Label elements**
- **Labelling according to Regulation (EC) No 1272/2008**
The product is classified and labelled according to the CLP regulation.
- **Hazard pictograms**



GHS05 GHS09

- **Signal word** *Danger*
- **Hazard-determining components of labelling:**
tin difluoride
- **Hazard statements**
 - H315 Causes skin irritation.
 - H318 Causes serious eye damage.
 - H410 Very toxic to aquatic life with long lasting effects.
- **Precautionary statements**

P280	Wear protective gloves / eye protection / face protection.
P273	Avoid release to the environment.
P305+P351+P338	IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
P310	Immediately call a POISON CENTER/doctor.
P321	Specific treatment (see on this label).
P501	Dispose of contents/container in accordance with local/regional/national/international regulations.

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Additional information:

As this product is a medical device in the meaning of Directive 93/42/EEC and intended for use by the end consumer and is applied in an invasive manner or body contact, it is exempt from the labelling requirements according to regulation 1272/2008.

2.3 Other hazards**Results of PBT and vPvB assessment**

• **PBT:** Not applicable.

• **vPvB:** Not applicable.

SECTION 3: Composition/information on ingredients

3.2 Chemical characterisation: Mixtures

• **Description:** Mixture of substances listed below with nonhazardous additions.

Dangerous components:

CAS: 1314-13-2 EINECS: 215-222-5	zinc oxide ⚠ Aquatic Acute 1, H400; Aquatic Chronic 1, H410	50-100%
CAS: 9003-01-4	Poly acrylic acid ⚠ Skin Irrit. 2, H315; Eye Irrit. 2, H319; STOT SE 3, H335	10-25%
CAS: 1309-48-4 EINECS: 215-171-9	magnesium oxide substance with a Community workplace exposure limit	2.5-<10%
CAS: 7783-47-3 EINECS: 231-999-3	tin difluoride ⚠ Eye Dam. 1, H318; ⚠ Acute Tox. 4, H302; Skin Irrit. 2, H315	2.5-<10%

• **Additional information** For the wording of the listed hazard phrases refer to section 16.

SECTION 4: First aid measures

4.1 Description of first aid measures

• **After inhalation** Supply fresh air; consult doctor in case of complaints.

• **After skin contact** Immediately wash with water and soap and rinse thoroughly.

After eye contact

Rinse opened eye for several minutes under running water. If symptoms persist, consult a doctor.

• **After swallowing** If symptoms persist consult doctor.

• **4.2 Most important symptoms and effects, both acute and delayed** No further relevant information available.

• **Information for doctor** No further relevant information available.

4.3 Indication of any immediate medical attention and special treatment needed

No further relevant information available.

SECTION 5: Firefighting measures

5.1 Extinguishing media**Suitable extinguishing agents**

CO₂, powder or water spray. Fight larger fires with water spray or alcohol resistant foam.

• **For safety reasons unsuitable extinguishing agents** Water with full jet.

5.2 Special hazards arising from the substance or mixture

Formation of toxic gases is possible during heating or in case of fire.

5.3 Advice for firefighters

• **Protective equipment:** No special measures required.

SECTION 6: Accidental release measures

6.1 Personal precautions, protective equipment and emergency procedures

Wear protective equipment. Keep unprotected persons away.

Avoid formation of dust.

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- **6.2 Environmental precautions:** Do not allow to enter sewers/ surface or ground water.
- **6.3 Methods and material for containment and cleaning up:**
Pick up mechanically.
Dispose contaminated material as waste according to item 13.
- **6.4 Reference to other sections**
See Section 7 for information on safe handling
See Section 8 for information on personal protection equipment.
See Section 13 for disposal information.

SECTION 7: Handling and storage

- **7.1 Precautions for safe handling**
Thorough dedusting.
Observe normal care for working with chemicals.
- **Handling** Product is intended for dental use only.
- **Information about fire - and explosion protection:** No special measures required.
- **7.2 Conditions for safe storage, including any incompatibilities**
- **Storage**
- **Requirements to be met by storerooms and receptacles:** Store only in the original receptacle.
- **Information about storage in one common storage facility:** Not required.
- **Further information about storage conditions:** Keep receptacle tightly sealed.
- **7.3 Specific end use(s)** No further relevant information available.

SECTION 8: Exposure controls/personal protection

- **Additional information about design of technical facilities:** No further data; see item 7.
- **8.1 Control parameters**

- **Ingredients with limit values that require monitoring at the workplace:**

CAS: 1309-48-4 magnesium oxide

WEL	Long-term value: 10* 4** mg/m ³ (as Mg) *inhalable dust **fume and respirable dust
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CAS: 7783-47-3 tin difluoride

WEL	Short-term value: 4 mg/m ³ Long-term value: 2 mg/m ³ as Sn
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- **Regulatory information** WEL: EH40/2011
- **Additional information:** The lists valid during the making were used as basis.
- **8.2 Exposure controls**
- **Personal protective equipment**
- **General protective and hygienic measures**
Keep away from foodstuffs, beverages and feed.
Immediately remove all soiled and contaminated clothing
Wash hands before breaks and at the end of work.
Avoid contact with the eyes and skin.
- **Respiratory protection:** Not necessary if room is well-ventilated.
- **Protection of hands:**



Protective gloves.

The glove material has to be impermeable and resistant to the product/ the substance/ the preparation.

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Due to missing tests no recommendation to the glove material can be given for the product/ the preparation/ the chemical mixture.

Selection of the glove material on consideration of the penetration times, rates of diffusion and the degradation

· **Material of gloves**

The selection of the suitable gloves does not only depend on the material, but also on further marks of quality and varies from manufacturer to manufacturer. As the product is a preparation of several substances, the resistance of the glove material can not be calculated in advance and has therefore to be checked prior to the application.

· **Penetration time of glove material**

The exact break through time has to be found out by the manufacturer of the protective gloves and has to be observed.

· **Eye protection:**



Tightly sealed goggles.

· **Body protection:** Protective work clothing.

SECTION 9: Physical and chemical properties

· **9.1 Information on basic physical and chemical properties**

· **General Information**

· **Appearance:**

Form:	Powder
Colour:	Yellowish
Odour:	Odourless
Odour threshold:	Not determined.

· **pH-value:** Acidic

· **Change in condition**

Melting point/freezing point:	undetermined
Initial boiling point and boiling range:	Undetermined.

· **Flash point:** Not applicable

· **Flammability (solid, gaseous)** Not determined.

· **Ignition temperature:** Not applicable

· **Decomposition temperature:** Not determined.

· **Auto-ignition temperature:** Product is not selfigniting.

· **Explosive properties:** Product does not present an explosion hazard.

· **Explosion limits:**

Lower:	Not determined.
Upper:	Not determined.

· **Vapour pressure:** Not applicable.

Density:	Not determined
Relative density	Not determined.
Vapour density	Not applicable.
Evaporation rate	Not applicable.

· **Solubility in / Miscibility with**

Water:	Partly soluble
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· **Partition coefficient: n-octanol/water:** Not determined.

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- | | |
|--------------------------------|--|
| · Viscosity: | |
| dynamic: | Not applicable. |
| kinematic: | Not applicable. |
| · Solvent content: | |
| Organic solvents: | 0.0 % |
| · Solids content: | 100.0 % |
| · 9.2 Other information | No further relevant information available. |

SECTION 10: Stability and reactivity

- **10.1 Reactivity** No further relevant information available.
- **10.2 Chemical stability**
- **Thermal decomposition / conditions to be avoided:** No decomposition if used according to specifications.
- **10.3 Possibility of hazardous reactions** No dangerous reactions known
- **10.4 Conditions to avoid** No further relevant information available.
- **10.5 Incompatible materials:** No further relevant information available.
- **10.6 Hazardous decomposition products:** No dangerous decomposition products known

SECTION 11: Toxicological information

- **11.1 Information on toxicological effects**
- **Acute toxicity** Based on available data, the classification criteria are not met.

· **LD/LC50 values relevant for classification:**

ATE (Acute Toxicity Estimates)

Oral	LD50	9000 mg/kg (rat)
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CAS: 1314-13-2 zinc oxide

Oral	LD50	>5000 mg/kg (rat)
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CAS: 9003-01-4 Poly acrylic acid

Oral	LD50	2500 mg/kg (rat)
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CAS: 7783-47-3 tin difluoride

Oral	LD50	360 mg/kg (rat)
Dermal	LD50	>2000 mg/kg (rat)

- **Primary irritant effect:**
- **Skin corrosion/irritation**
Causes skin irritation.
- **Serious eye damage/irritation**
Causes serious eye damage.
- **Respiratory or skin sensitisation** Based on available data, the classification criteria are not met.
- **CMR effects (carcinogenicity, mutagenicity and toxicity for reproduction)**
- **Germ cell mutagenicity** Based on available data, the classification criteria are not met.
- **Carcinogenicity** Based on available data, the classification criteria are not met.
- **Reproductive toxicity** Based on available data, the classification criteria are not met.
- **STOT-single exposure** Based on available data, the classification criteria are not met.
- **STOT-repeated exposure** Based on available data, the classification criteria are not met.
- **Aspiration hazard** Based on available data, the classification criteria are not met.

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SECTION 12: Ecological information

· 12.1 Toxicity

· Aquatic toxicity:

CAS: 1314-13-2 zinc oxide

LC50/96h 1.1 mg/l (Fish acute toxicity study)

EC50/48h 0.098 mg/L (daphnia magna)

CAS: 9003-01-4 Poly acrylic acid

LC50/96h 168-280 mg/l (daphnia magna)

580-2000 mg/l (Fish acute toxicity study)

· **12.2 Persistence and degradability** No further relevant information available.· **12.3 Bioaccumulative potential** No further relevant information available.· **12.4 Mobility in soil** No further relevant information available.

· Ecotoxicological effects:

· **Remark:** Very toxic for fish· **Additional ecological information:**

· General notes:

Do not allow product to reach ground water, water course or sewage system.

Must not reach sewage water or drainage ditch undiluted or unneutralised.

Also poisonous for fish and plankton in water bodies.

Very toxic for aquatic organisms

· 12.5 Results of PBT and vPvB assessment

· **PBT:** Not applicable.· **vPvB:** Not applicable.· **12.6 Other adverse effects** No further relevant information available.

SECTION 13: Disposal considerations

· 13.1 Waste treatment methods

· Recommendation



Must not be disposed together with household garbage. Do not allow product to reach sewage system.

· European waste catalogue

18 01 06* chemicals consisting of or containing hazardous substances

HP 14 Ecotoxic

· Uncleaned packaging:

· **Recommendation:** Disposal must be made according to official regulations.

SECTION 14: Transport information

· 14.1 UN-Number

· **ADR, IMDG, IATA**

UN3077

· 14.2 UN proper shipping name

· **ADR**3077 ENVIRONMENTALLY HAZARDOUS SUBSTANCE,
SOLID, N.O.S. (zinc oxide)· **IMDG**ENVIRONMENTALLY HAZARDOUS SUBSTANCE,
SOLID, N.O.S. (zinc oxide), MARINE POLLUTANT

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· IATA	ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (zinc oxide)
· 14.3 Transport hazard class(es)	
· ADR	
	
· Class	9 (M7) Miscellaneous dangerous substances and articles.
· Label	9
· IMDG, IATA	
	
· Class	9 Miscellaneous dangerous substances and articles.
· Label	9
· 14.4 Packing group	
· ADR, IMDG, IATA	III
· 14.5 Environmental hazards:	Product contains environmentally hazardous substances: zinc oxide
· Marine pollutant:	Symbol (fish and tree)
· Special marking (ADR):	Symbol (fish and tree)
· Special marking (IATA):	Symbol (fish and tree)
· 14.6 Special precautions for user	Warning: Miscellaneous dangerous substances and articles.
· Danger code (Kemler):	90
· EMS Number:	F-A,S-F
· Stowage Category	A
· Stowage Code	SW23 When transported in BK3 bulk container, see 7.6.2.12 and 7.7.3.9.
· 14.7 Transport in bulk according to Annex II of Marpol and the IBC Code	Not applicable.
· Transport/Additional information:	
· ADR	
· Limited quantities (LQ)	5 kg
· Excepted quantities (EQ)	Code: E1 Maximum net quantity per inner packaging: 30 g Maximum net quantity per outer packaging: 1000 g
· Transport category	3
· Remarks:	Exemption according to ADR special provision 375: This substance is not subject to the other provisions of the ADR if packed in net quantities of 5L or 5kg per individual or inner packaging, provided that sub-sections 4.1.1.1, 4.1.1.2 and 4.1.1.4 to 4.1.1.8 are complied with.
· IMDG	
· Limited quantities (LQ)	5 kg
· Excepted quantities (EQ)	Code: E1 Maximum net quantity per inner packaging: 30 g Maximum net quantity per outer packaging: 1000 g

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· **UN "Model Regulation":**UN 3077 ENVIRONMENTALLY HAZARDOUS
SUBSTANCE, SOLID, N.O.S. (ZINC OXIDE), 9, III

SECTION 15: Regulatory information

- **15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture**
- **Directive 2012/18/EU**
- **Named dangerous substances - ANNEX I** None of the ingredients is listed.
- **Seveso category E1** Hazardous to the Aquatic Environment
- **Qualifying quantity (tonnes) for the application of lower-tier requirements** 100 t
- **Qualifying quantity (tonnes) for the application of upper-tier requirements** 200 t
- **15.2 Chemical safety assessment:** A Chemical Safety Assessment has not been carried out.

SECTION 16: Other information

This information is based on our present knowledge. However, this shall not constitute a guarantee for any specific product features and shall not establish a legally valid contractual relationship.

The attached safety data sheet covers the dangers and measures to be taken when large quantities of material are released, for example due to accidents during transport or storage by the dealer.

For quantities of material typically used in clinical practice, information necessary for safe use and storage of the product is given in the DFU.

- **Relevant phrases**

H302 Harmful if swallowed.
H315 Causes skin irritation.
H318 Causes serious eye damage.
H319 Causes serious eye irritation.
H335 May cause respiratory irritation.
H400 Very toxic to aquatic life.
H410 Very toxic to aquatic life with long lasting effects.

- **Department issuing SDS:** Research & Development
- **Contact:** HotLine for urgent technical support: +49-7531-583-350
- **Abbreviations and acronyms:**

ADR: Accord européen sur le transport des marchandises dangereuses par Route (European Agreement concerning the International Carriage of Dangerous Goods by Road)

IMDG: International Maritime Code for Dangerous Goods

IATA: International Air Transport Association

GHS: Globally Harmonised System of Classification and Labelling of Chemicals

EINECS: European Inventory of Existing Commercial Chemical Substances

ELINCS: European List of Notified Chemical Substances

CAS: Chemical Abstracts Service (division of the American Chemical Society)

LC50: Lethal concentration, 50 percent

LD50: Lethal dose, 50 percent

PBT: Persistent, Bioaccumulative and Toxic

vPvB: very Persistent and very Bioaccumulative

Acute Tox. 4: Acute toxicity – Category 4

Skin Irrit. 2: Skin corrosion/irritation – Category 2

Eye Dam. 1: Serious eye damage/eye irritation – Category 1

Eye Irrit. 2: Serious eye damage/eye irritation – Category 2

STOT SE 3: Specific target organ toxicity (single exposure) – Category 3

Aquatic Acute 1: Hazardous to the aquatic environment - acute aquatic hazard – Category 1

Aquatic Chronic 1: Hazardous to the aquatic environment - long-term aquatic hazard – Category 1

- *** Data compared to the previous version altered.**