

Safety Data Sheet

according 1907/2006/EG, article 31 – 2015/830/EU

Version No. 1

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M+W Select Poly Flex

1. Name of the substance or mixture and the company

1.1. Product identifier

M+W Select Poly Flex

1.2. Relevant identified uses of the substance or mixture and uses advised against

PCT-G blanks for the manufacture of individual dental restorations

1.3. Details of the supplier providing the safety data sheet

Company name: Whitepeaks Dental Solutions Ltd
Street: Weikenrott 17
Town: 46499 Hamminkeln
Country: Germany
Telephone/Fax: +49 281 2064580/ +49 281 206458 13
Email: info@whitepeaks-dental.de
Website: www.whitepeaks-dental.de

1.4. Emergency number

Emergency information: +49 281 206458 0 (only available during office hours)

2. Potential hazards

2.1. Classification of the substance or mixture

Regulation (EC) No 1272/2008
The product is not classified as hazardous according to Regulation (EC) No. 1272/2008.

2.2. Labelling elements

Labelling according to Regulation (EC) No. 1272/2008	Not applicable
applicable Hazard pictograms	Not applicable
applicable	
Signal word	Not applicable
Hazard statements	Not applicable

2.3. Other hazards

A PBT/vPvB assessment is not available as a chemical safety assessment is not required.

3. Composition/information on ingredients

3.1. Substances

This product is a mixture.

3.2. Mixtures**Chemical characterisation/description**

Mixture of the following substances with non-hazardous admixtures:

Substance	Formula	CAS No.	Einecs No.	Hazard categories	Percentage
Glycol-modified polycyclohexylenedimethylene terephthalate	PCT-G			---	100

**Substances with occupational exposure limits/
maximum workplace concentrations/biological tolerance values**

None

Additional information

The hazard and safety information in sections 4-8 and 12 does not refer to the product itself, but to the dust released during processing and handling.

4. First aid measures**4.1. Description of first aid measures General information**

Consult a doctor if health problems occur.

After inhalation

Provide fresh air. Consult a doctor if symptoms persist.

After skin contact

Wash off with plenty of soap and water, rinse well. Use skin protection cream, as the dust removes the skin's natural moisture.

After eye contact

Rinse eyes thoroughly with water while keeping eyelids open. Consult a doctor if symptoms persist.

After swallowing

Rinse mouth immediately and drink plenty of water. Consult a doctor if symptoms persist.

4.2. Most important acute and delayed symptoms and effects

No further relevant information is available.

4.3. Indications for immediate medical attention or special treatment

No further relevant information is available.

5. Firefighting measures**5.1. Extinguishing media****Suitable extinguishing media**

Water spray, foam extinguishing agent, dry extinguishing agent (powder), carbon dioxide (CO₂)

Unsuitable extinguishing media

Full water jet

5.2. Special hazards arising from the substance or mixture

In case of fire, release of carbon monoxide, carbon dioxide, nitrogen oxides and organic decomposition products is possible.

5.3. Firefighting information

The product itself does not burn, but the dust generated during processing may catch fire due to heat or ignition sources/sparks. Adapt extinguishing measures to the surroundings. Avoid inhaling fire gases. Only remain in the danger zone with self-contained breathing apparatus. Prevent extinguishing water from entering surface water, groundwater and sewage systems.

6. Measures in case of accidental release

6.1. Personal precautions, protective equipment and emergency procedures

Ensure adequate fresh air supply. Use extraction. Do not inhale dust. Avoid contact with mouth, skin and eyes. Use personal protective equipment.

6.2. Environmental precautions

Do not allow to enter the environment.

6.3. Methods and material for containment and cleaning

Collect mechanically. Vacuum up. Ensure adequate ventilation. Avoid dust formation. Collect in suitable, closed containers and dispose of.

6.4. Reference to other sections

Safe handling	see Section 7
Personal protective equipment	See Section 8
Disposal	See Section 13

7. Handling and storage

7.1. Precautions for safe handling Precautions for safe handling

Ensure adequate fresh air supply. Use extraction. Do not inhale dust. Avoid contact with mouth and eyes. Use personal protective equipment.

General hygiene measures

Do not eat, drink or smoke in areas where work is being carried out. Wash hands after use. Remove contaminated clothing and protective equipment before entering areas where food is being consumed.

Fire and explosion protection

The product itself is not explosive when in compact form. However, the dust produced during processing can form explosive mixtures with air. Dust formation should therefore be avoided. Keep away from sources of ignition. No smoking.

Further information on handling

Observe workplace exposure limits.

7.2. Conditions for safe storage, taking into account incompatibilities

Store in a dry place. Store in the original container.

7.3. Specific end uses

Blank materials for the manufacture of individual dental restorations

8. Exposure limits and monitoring/personal protective equipment

8.1. Parameters to be monitored

Occupational exposure limits (TRGS 900)

General dust limit value

Alveolar fraction

Inhalable fraction

1.25 mg/m³, peak limit 2(II)

10 mg/m³, peak limit 2(II)

Maximum workplace concentration (MAK and BAT values list)

General dust limit value

Alveolar fraction

inhalable fraction

see section Vf, 0.3 mg/m³, peak limit
II(8), risk group C, hazard category 4
cf. sections Vf and g, 4.0 mg/m³

Additional information: The lists valid at the time of compilation served as a basis.

8.2. Exposure controls/personal protection Suitable engineering controls

Technical measures and the use of suitable working methods take precedence over the use of personal protective equipment. Ensure good ventilation. This can be achieved by local extraction or general exhaust ventilation.

Protective and hygiene measures

Ensure good ventilation. Use extraction. Do not inhale dust. Avoid contact with mouth and eyes. Do not smoke, eat or drink while working. Keep away from food and drink. Wash hands after use. Remove contaminated clothing and protective equipment before entering areas where food is consumed.

Respiratory protection

If extraction/ventilation is inadequate, wear respiratory protection (do not inhale dust).

Eye/face protection

Wear safety goggles.

Hand protection

Wear protective gloves.

Body protection

Use light protective clothing.

Limitation and monitoring of environmental exposure

See sections 6 and 7.

9. Physical and chemical properties

9.1. Information on basic physical and chemical properties

Appearance	Solid
Colour	Various colours
Odour	Odourless
Odour threshold	Not applicable
pH	Not applicable
Melting point	260-282
Freezing point	Not determined
Boiling point/boiling range	Not determined
Flash point	Not applicable
Evaporation rate	Not applicable
Flammability (solid, gaseous)	Not applicable
Upper/lower flammability or explosion limits	Not applicable
Vapour pressure/density	Not determined
Relative density (20°C)	approx. 1.02 g/cm ³
Solubility in water/miscibility	practically insoluble in water
Solubility in other solvents	Not determined
Distribution coefficient: n-octanol/water	Not determined
Spontaneous ignition	Not self-igniting
Decomposition temperature	Not determined
Viscosity	Not determined
Explosive properties	The product itself is not explosive in its compact form. However, the dust produced during processing can form explosive mixtures with air. Dust formation should therefore be avoided.
Oxidising properties	Not fire-promoting

9.2. Other information

No further relevant information is available.

10. Stability and reactivity

10.1. Reactivity

No further relevant information is available.

10.2. Chemical stability

The product is chemically stable under normal environmental conditions (room temperature).

10.3. Possibility of hazardous reactions

No dangerous reactions are known when used as intended.

10.4. Conditions to avoid

Avoid extreme temperatures and direct sunlight.

10.5. Incompatible materials

No further relevant information is available.

10.6. Hazardous decomposition products

None when used as intended. In case of fire, release of carbon monoxide, carbon dioxide, nitrogen oxide and organic decomposition products is possible.

11. Toxicological information**11.1. Information on toxicological effects**

The product itself does not cause any toxic reactions and is not allergenic. When handled and stored properly, no harmful reactions are known according to the available information. The following information does not refer to the product itself, but to the dust generated during processing.

Acute toxicity

Based on the available data, the classification criteria are not met.

Irritation and corrosive effects (skin irritation/corrosion/serious eye damage/irritation)

Based on the available data, the classification criteria are not met.

Respiratory/skin sensitisation

Based on the available data, the classification criteria are not met.

Germ cell mutagenicity

Based on the available data, the classification criteria are not met.

Carcinogenicity

Based on the available data, the classification criteria are not met.

Reproductive toxicity

Based on the available data, the classification criteria are not met.

Specific target organ toxicity after single exposure

Based on the available data, the classification criteria are not met.

Specific target organ toxicity after repeated exposure

Based on the available data, the classification criteria are not met.

Aspiration hazard

Based on the available data, the classification criteria are not met.

12. Environmental information

No environmental problems are expected when used properly.

12.1. Toxicity

No further relevant information is available.

12.2. Persistence and degradability

No further relevant information is available.

12.3. Bioaccumulation potential

No further relevant information is available.

12.4. Mobility in soil

No further relevant information is available.

12.5. Results of the PBT and vPvB assessment

A PBT/vPvB assessment is not available as a chemical safety assessment is not required.

12.6. Other adverse effects

No further relevant information is available.

13. Disposal information**13.1. Waste treatment methods**

Dispose of product and packaging in accordance with local/regional/national/international regulations.

14. Transport information**14.1. UN number**

Not applicable

14.2. Proper UN shipping name

Not applicable

14.3. Transport hazard classes

Not applicable

14.4. Packaging group

Not applicable

14.5. Environmental hazards

Markings for environmentally hazardous substances

No

14.6. Special precautions for users

See sections 6 - 8

14.7. Bulk transport in accordance with Annex II of the MARPOL Convention and the IBC Code
Not applicable

15. Legal provisions

15.1. Regulations on safety, health and environmental protection/specific legal provisions for the substance or mixture

The product is not subject to labelling requirements under EC directives/GefStoffV.

The product falls under EC Directive 93/42/EEC for medical devices and Regulation (EU) 2017/745 (MDR).

15.2. Substance safety assessment

A substance safety assessment has not been carried out.

16. Other information

The information in this safety data sheet is based on our current knowledge and experience and refers to the product in its delivery condition. The information is intended to provide guidance on the product during storage, processing, transport and disposal. It is not transferable to other products. If the product is mixed, blended or processed with other materials, or subjected to processing, the information in this safety data sheet cannot be transferred to the new material produced in this way, unless expressly stated otherwise. However, no warranty, guarantee or assurance, either explicit or implicit, is given for the accuracy, reliability and/or completeness of this information. We urge persons receiving this information to verify the suitability and completeness of this information for their specific application.