

Safety Data Sheet

According to Regulation (EC) No1907/2006 As Amended by the Regulation (EU) 453/2010

IMPORTANT

Read this SDS before handling and disposing of this product and pass this information on to employees, customers and users of this product.

1. IDENTIFICATION

1.1 Product Identifier

Product Name	FlexiTemp PLUS
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1.2 Relevant identified uses of the substance of mixture and uses advised against

Product Use	Dental use only.
Description	Dental Product

1.3 Supplier of the Safety Data Sheet

Company Name	Perfection Plus Ltd
Company Address	6 Westwood Court, Brunel Road, Totton, Hants. SO40 3WX. UK
Company Phone No.	+44 (0) 2380 866 677
Website	www.perfectionplus.com
Telephone	0044 (0) 2380 866677
Email	Regulatory@perfectionplus.com
Email address of Competent Person	Regulatory@perfectionplus.com

1.4 Emergency telephone number


Emergency telephone number	0044 (0) 230 866 677 (8am – 5pm Monday to Friday)
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2. HAZARDS IDENTIFICATION

2.1 Classification of the substance or mixture

2.1.2. Classification - EC 1272/2008	Acute Tox. 4 Skin Irrit. 2 Skin Sens. 1 Eye Irrit. 2
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2.2 Label Elements

Hazard Pictograms	
Signal Word	Warning
Hazard Statement	H302: Harmful if swallowed. H315: Causes skin irritation. H317: May cause an allergic skin reaction. H319: Causes serious eye irritation.
Precautionary Statement: Prevention	P264 – Wash hands thoroughly after handling. P280 – Wear protective gloves/protective clothing/eye protection/ face protection.
Precautionary Statement: Response	P301+P312 – IF SWALLOWED: Call a POISON CENTRE/doctor if you feel unwell. P302+P352 – IF ON SKIN: Wash with plenty of water. P305+P351+P338 – IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do so. Continue rinsing. P330 – Rinse mouth. P333+P313 – If skin irritation or rash occurs: Get medical advice/attention. P337+P313 – If eye irritation persists: Get medical advice attention. P362+P364 – Take off contaminated clothing and wash before reuse.
Precaution Statement: Disposal	P501: Dispose of contents/container as required by national regulatory requirements.

2.3 Other hazards

Other hazards	Not applicable.
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3. COMPOSITION/INFORMATION ON INGREDIENTS

3.1 Substances

Not applicable.

3.2 Mixtures

Chemical Name	Index No.	CAS No.	EC No.	REACH Registration Number	CONC. (%w/w)	Classification
Mixture of methacrylates	-	-	-	-	30-40%	Acute Tox. 4H302; Skin Irrit. 2: H315; Skin Sens. 1: H317; Eye Irrit. 2: H319;

Full text of H- statements: see section 16.

4. FIRST AID MEASURES

4.1 Description of first aid measures

Inhalation	Remove the casualty from the hazardous area and take him to fresh air. If the casualty is not breathing give artificial respiration, notify emergency physician immediately.
Eye Contact	Rinse immediately with plenty of water for 15 minutes. Remove contact lenses, if present and easy to do. Continue rinsing. Refer for medical attention.
Skin contact	Take off contaminated clothing. Wash off with plenty of soap and water. Consult a physician. Wash contaminated clothing before reuse.
Ingestion	Never give anything by mouth to an unconscious person. Take casualty to the hospital. If the person is conscious rinse the mouth and spit the fluids out. DO NOT induce vomiting. During spontaneous vomiting - hold the head of the casualty low with the body in a prone position in order to avoid the penetration of vomit into the airways. Refer for immediate medical attention.

4.2 Most important symptoms and effects, both acute and delayed

Inhalation	No data available
Eye Contact	No data available
Skin contact	No data available
Ingestion	No data available

4.3 Indication of any immediate medical attention and special treatment needed

Inhalation	No data available
Eye Contact	No data available
Skin contact	No data available
Ingestion	No data available

General information

	If in doubt, consult a physician. Show this safety data sheet to the doctor in attendance.
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5. FIRE FIGHTING MEASURES

5.1 Extinguishing media

	Water spray, dry powder, carbon dioxide (CO ₂).
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5.2 Special hazards arising from the substance or mixture

	No data available.
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5.3 Advice for firefighters

	Wear self-contained breathing apparatus for firefighting.
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6. ACCIDENTAL RELEASE MEASURES

6.1 Personal precautions, protective equipment and emergency procedures

	Use personal protective equipment. Avoid vapour formation. Avoid breathing vapours. Ensure adequate ventilation.
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6.2 Environmental precautions

	Do not allow product to enter drains.
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6.3 Methods and material for containment and cleaning up

	Use personal protective equipment when cleaning. Soak up spills with inert absorbent material. Collect spills and put it into appropriate container if it is safe to do so. Dispose in a safe manner in accordance with national regulatory requirements.
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6.4 Reference to other sections

	See section 13 for disposal information.
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7. HANDLING AND STORAGE

7.1 Precautions for safe handling

	Use personal protective equipment when handling. Keep away from food, drink and animal feed. Do not eat or drink, smoke when using this product. Avoid contact with eyes and skin.
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7.2 Conditions for safe storage, including any incompatibilities

	Keep in cool, well-ventilated place. Keep away from heat and direct sunlight. Storage temperature: 4-28°C.
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7.3 Specific end use(S)

	For professional use in dentistry only.
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8. EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1 Control parameters

8.1.1 Exposure Limit Values

	No exposure guidelines have been established. ACGIH, NIOSH and ASHA have not developed exposure limits for this product.
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8.2 Exposure controls

Provide adequate ventilation. Storage properly (p.7). Preventive medical check-ups should be arranged.



8.2.1 Appropriate engineering controls

	Handle in accordance with good industrial hygiene and safety practice. Wash hands before breaks and at the end of workday
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8.2.2 Individual protection measures

	Wear chemical protective clothing.
Eye/face protection	Wear eye / face protection equipment. Safety glasses with side-shields, conforming to EN 166.
Hand protection	Handle with gloves. Gloves must be inspected prior to use. Use proper glove removal technique (without touching glove's outer surface) to avoid skin contact with this product. Dispose of contaminated gloves after use in accordance with applicable laws and good laboratory practices. Wash and dry hands. For permanent contact in work areas without heightened risk of injury (e.g. laboratory) gloves made of the following material are suitable: PVC, neoprene, rubber. The selected protective gloves have to satisfy the specifications of EU Directive 89/686/EEC and the standard EN 374 derived from it.
Skin protection	Impervious clothing. The type of protective equipment must be selected according to the concentration and amount of the dangerous substance at the specific workplace.
Respiratory protection	Not necessary with efficient local exhaust. If you need to protect the airways use respirators, that have been tested and approved by the relevant governmental standards, such as CEN (EU) or NIOSH (USA).

8.2.3 Environmental exposure controls

	Do not let enter the environment.
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9. PHYSICAL AND CHEMICAL PROPERTIES

9.1. Information on basic physical and chemical properties

Appearance	paste	Flash point °C	No data available
Odour	Specific	Initial boiling point °C	No data available

10. STABILITY AND REACTIVITY
10.1 Reactivity

	No data available.
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10.2 Chemical stability

	Stable under recommended storage conditions.
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10.3 Possibility of hazardous reactions

	No data available.
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10.4 Conditions to avoid

	High temperatures and direct sunlight.
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10.5 Incompatible materials

	Strong oxidising agents, acids, bases
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10.6 Hazardous decomposition products

	No data available.
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11. TOXICOLOGICAL INFORMATION
11.1 Information on toxicological effects

Acute toxicity	No data available.
Skin corrosion/irritation	Uncured medical device may cause skin irritation.
Serious eye damage/irritation	Uncured medical device may cause serious eye irritation.
Respiratory of skin sensitisation	Uncured medical device may cause an allergic skin reaction.
Germ cell mutagenicity	No data available.
Carcinogenicity	IARC: Titanium dioxide Group 2B – Possibly carcinogenic to humans.
Reproductive toxicity	No data available.
STOT-single exposure	No data available.
STOT-repeated exposure	No data available.
Aspiration hazard	No data available.
Repeated or prolonged exposure	No data available.

12. ECOLOGICAL INFORMATION
12.1 Toxicity

	No data available
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12.2 Persistence and degradability

	No data available
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12.3 Bio accumulative potential

	No data available
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12.4 Mobility in soil

	No data available
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12.5 Results of PBT and vPvB assessment

	No data available
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12.6 Other adverse effects

	No data available
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13. DISPOSAL CONSIDERATIONS
13.1 Waste treatment methods

	Disposal should be in compliance with all local, state or national legislation. Offer surplus and non-recyclable solutions to a licensed disposal company. Contaminated packaging dispose of as unused product. Do not remove the information from the package.
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General information

	18 WASTES FROM HUMAN OR ANIMAL HEALTH CARE AND/OR RELATED RESEARCH (except kitchen and restaurant wastes not arising from immediate health care). 18 01 wastes from natal care, diagnosis, treatment or prevention of disease in humans. 18 01 06 chemicals consisting of or containing dangerous substances.
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Disposal Methods

	Do not empty in to drains. For disposal within the EC, the appropriate code according to the European Waste Catalogue (EWC) should be used.
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14. TRANSPORT INFORMATION
14.1 UN number

ADR/RID, IMDG, IATA	Not regulated
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14.2 UN proper shipping name

ADR/RID, IMDG, IATA	Not dangerous goods.
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14.3 Transport hazard class(es)

ADR/RID, IMDG, IATA	-
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14.4 Packing group

Packing Group	-
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14.5 Environmental hazards

Environmental hazards	No
Marine pollutant	No

14.6 Special precautions for user

	Read safety instructions, SDS and emergency procedures before handling. Ensure that persons transporting the product know what to do in the event of an accidental spillage.
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14.7 Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code

	No data available.
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15. REGULATORY INFORMATION
15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture

Regulations	This safety datasheet complies with the requirements of Regulation (EC) No 1907/2006 as amended by Regulation (EU) No 453/2010. Other Regulations: EINECS: Components of mixture are on the European Inventory of Existing Commercial Chemical Substances. This safety data sheet information is not a professional risk assessment.
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15.2 Chemical Safety Assessment

	No data available.
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16. OTHER INFORMATION
Other information

Text of Hazard and Precautionary Statements	H302: Harmful if swallowed. H315: Causes skin irritation. H317: May cause an allergic skin reaction. H319: Causes serious eye irritation. P264: Wash hands thoroughly after handling. P280: Wear protective gloves/protective clothing/eye protection/face protection. P301+P312: IF SWALLOWED: Call a POISON CENTER/ doctor if you feel unwell. P302+P352: IF ON SKIN: Wash with plenty of water. P305+P351+P338: IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. P330: Rinse mouth. P333+P313: If skin irritation or rash occurs: Get medical advice/ attention. P337+P313: If eye irritation persists: Get medical advice/attention. P362+P364: Take off contaminated clothing and wash before reuse. P501: Dispose of contents/container to as required by national regulatory requirements.
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Abbreviations and acronyms used in the safety data sheet	16.6.1. EC – European Commission 16.6.2. GHS – Globally Harmonized System 16.6.3. CLP – Classification Labelling Packaging Regulation; Regulation (EC) No 1272/2008 16.6.4. CAS No – Chemical Abstracts Service number 16.6.5. EC No – EINECS and ELINCS Number (see also EINECS and ELINCS) 16.6.6. PBT - Persistent, Bio accumulative and toxic substance 16.6.7. vPvB – Very Persistent and Very Bio accumulative 16.6.8. ADR – European Agreement concerning the International Carriage of Dangerous Goods by Road
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Further information

The information used in this SDS is supplied by UAB Medicinos Linija, karaliauciaus str. 29, LT-78348 Siauliai, Lithuania. The above information is believed to be correct but does not purport to be all inclusive and shall be used only as a guide. The information in this document is based on the present state of our knowledge and is applicable to the product with regard to appropriate safety precautions. It does not represent any guarantee of the properties of the product.

This SDS is relevant for large quantities of product, the instructions for safe use of quantities typically used during a normal procedure is as referenced in the Instructions for Use.

The conditions or methods for handling, storage, lone use and/or in combination with other products and disposal are beyond our control. The product should not be used for purposes other than specified in p.7.3 purposes.

For this and other reasons, we do not assume responsibility and expressly disclaim liability for loss, damage or expense arising out of or in any way connected with the handling, storage, use or disposal of the product. UAB Medicinos Linija and Perfection Plus Ltd shall not be held liable for any damage resulting from handling or from contact with the above product.

This SDS was prepared and is to be used only for this product. If the product is used as a component in or in combination with another product, this SDS information may not be applicable. User is responsible for the legal, regulatory compliance.

Key literature references and sources for data: <http://echa.europa.eu>

Training advice: How to properly handle chemical substances / Mixtures employees must be trained in accordance with national requirements.