Material Safety Data Sheet according to (EC) 1907/2006

Tradename:

DURAN® +

Section 1. Identification of the substance/preparation and of the company/undertaking

1.1 Product identifier
Name of product: DURAN®+

Product group:
UFI:

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

Use of the substance/mixture
Thermoplastic foils for the manufacture of appliances and splints for dental and orthodontic treatments.

1.3 Details of the supplier of the safety data sheet
Manufacturer / Distributor

SCHEU-DENTAL GmbH
Am Burgberg 20
D-58642 Iserlohn
Tel. +49 (2374) 9288-0
Fax +49 (2374) 9288-90

eMail: service@SCHEU-DENTAL.com
Internet: www.SCHEU-DENTAL.com

Section 2. Hazards identification

2.1 Classification of the substance or mixture

Classification according to Directive 67/548/EEC or 1999/45/EC
The mixture is not classified as hazardous according to Directive 1999/45/EC.

Classification according to Regulation (EC) No 1272/2008 [CLP]
This mixture is not classified as hazardous according to Regulation (EC) No. 1272/2008

2.2 Label elements
None

Section 3. Composition / information on ingredients

3.2 Mixtures
Chemical characterization
Polyethylenterephthalat-Glycol (PETG) /
Polyethylen (PE)

With a removable PE-protective film.

CAS-Number:
25640-14-6 / 9002-88-4

Section 4. First aid measures

4.1 Description of first aid measures

General information
When using do not eat, drink or smoke.
Provide suction extractors if dust is formed.

After inhalation
No further information available.

After contact with skin
No further information available.

After contact with eyes
No further information available.

After ingestion
No further information available.

Section 5. Firefighting measures

5.1 Extinguishing media
Suitable extinguishing media
Alcohol resistant foam, Carbon dioxide (CO2), Extinguishing powder, Water mist

Unsuitable extinguishing media
Full water jet

5.2 Special hazards arising from the substance or mixture
No further information available.

5.3 Advice for firefighters
Collect contaminated fire extinguishing water separately. Do not allow entering drains or surface water.

Section 6. Accidental release measures

6.1 Personal precautions, protective equipment and emergency procedures
Safe handling: see section 7
Personal protection equipment: see section 8

6.2 Environmental precautions
No further information available.

6.3 Methods and material for containment and cleaning up
No further information available.

Section 7. Handling and Storage

7.1 Precautions for safe handling

Advice on protection against fire and explosion

7.2 Conditions for safe storage, including any incompatibilities

Advice on storage compatibility
Store dry and dark at 5 - 35 °C.

7.3 Specific end use(s)
Thermoplastic foils for the manufacture of appliances and splints for dental and orthodontic treatments.

Further information on storage conditions
No further information available.

Section 8. Exposure controls / personal protection

8.1 Control parameters

8.2 Exposure controls

Protective and hygiene measures
None

Eye/face protection
None

Hand protection
None

Skin protection
None

Respiratory protection
Provide suction extractors if dust ist formed.

Environmental exposure controls
No further information available.

Section 9. Physical and chemical properties

9.1 Information on basic physical and chemical properties

General properties

Properties	Guideline	Value
Physical state	-	solid
Colour	-	transparent
Odour	-	odourless
Density	ISO 1183	1,27 g/cm³
Water absorption after 24 h at 23 °C	ASTM D 570	0,1 – 0,2 %
Mechanical properties		
Tensile strength	ISO 527	49 - 53 Mpa
Flexural modulus	ISO 178	1900 - 2100 MPa
Flexural strength	ISO 178	67 - 69 Mpa
Izod Impact Strength, Notched @ 23 °C	ISO 180	6 - 12 kJ/m²
Rockwell Hardness	ASTM D 785	106 - 115
Thermal properties		
Glass transition temperature	DSC	80 °C
Vicat softening point	ASTM D 1525	83 °C - 85 °C

Section 10. Stability and reactivity

10.2 Chemical stability
No decomposition by intended use.

10.3 Possibility of hazardous reactions
No further information aivailable.

10.4 Conditions to avoid
The product must not be got into groundwater, waters or canalisation.

10.6. Hazardous decomposition products
No decomposition by intended use.

Section 11. Toxicological Information

11.1 Information on toxicological effects

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

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

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

STOT-single exposure
Based on available data, the classification criteria are not met.

Severe effects after repeated or prolonged exposure
Based on available data, the classification criteria are not met.

Carcinogenic / mutagenic / toxic / effects for reproduction
Based on available data, the classification criteria are not met.

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

Further information
A biological evaluation was carried out for the material in accordance with DIN EN ISO 10993-1.
It meets the requirements regarding biocompatibility for medical devices.

Section 12. Ecological Information

12.1 Toxicity
A biological evaluation was carried out for the material in accordance with DIN EN ISO 10993-1.
It meets the requirements regarding biocompatibility for medical devices.

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.

12.5. Results of PBT an vPvB assessment
No further relevant information available.

12.6. Endocrine disrupting properties
No further relevant information available.

12.7. Other adverse effects
No further relevant information available.

Further information

Section 13. Disposal considerations

13.1 Waste treatment methods

Advice on disposal
The material can be recycled after separation or deposed of like commercial or household waste.
Dispose according to legislation.

Section 14. Transport Information

No hazardous material according to transport regulations.

14.7 Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code
No applicable

Section 15. Regulatory Information

15.1 Safety, health an environmental regulations/legislation specific for the substance or mixture

National regulatory information

Additional Information

15.2 Chemical Safety Assessment
Chemical safety assessments for this material was not carried out.

Section 16. Other Information

Further information
The aforementioned data are given most conscientiously but without any obligation. Any processing details are provided merely for guidance: it is the user's responsibility to check the suitability of the product for the intended application.

Serious incidents in connection with the use of the product shall be reported immediately to the manufacturer and the competent authority.