

Material Safety Data Sheet according to (EC) 1907/2006		
Tradename:	IMPRELON®	
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Section 1. Identification of the substance/preparation and of the company/undertaking

1.1 Product identifier

Name of product: **IMPRELON®**

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

Polystyrol (PS)

CAS-Number:

9003-53-6

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.

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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

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Skin protection

None

Respiratory protection

Provide suction extractors if dust is formed.

Environmental exposure controls

No further information available.

Section 9. Physical and chemical properties

9.1 Information on basic physical and chemical properties

	transparent	white	nature
Physical state	solid	solid	solid
Colour	transparent	white	nature
Odour	odourless	odourless	odourless
Density ISO 1183	1,05 g/cm ³	1,05 g/cm ³	1,05 g/cm ³
Water absorption after 24 h at 23 °C ISO 62-4	< 0,1 %	< 0,1 %	< 0,1 %
Tensile strength ISO 527-3	55 MPa	17 MPa	> 18 MPa
Flexional strength ISO 178	103 MPa	-	-
Impact strength 23 °C ISO 8256	14 KJ/m ²	> 30 KJ/m ²	-
Notched 23 °C ISO 179	-	6 KJ/m ²	-
Yield strain ISO 527	3 %	< 2 %	> 2 %
Yield stress ISO 527	-	17,5 MPa	-
Elongation at tear ISO 527	> 3 %	> 50 %	> 8 %
E-modulus ISO 527	3200 MPa	1850 MPa	2500 MPa
Hardness Shore A ISO 53505	-	-	-
Hardness Shore D ISO 53505	-	-	-
Rockwell Hardness ISO2039-1 H358/30	150	80	-
Vicat softening point ISO 306 Method A	106 °C	-	-
Vicat softening point ISO 306 Method A	101 °C	90 °C	-
Thermoform resistance ISO 75 Method A	86 °C	78 °C	-
Thermoform resistance ISO 75 Method B	98 °C	89 °C	-
Continuous stress temperature ISO 75	80 °C	70 °C	-

Section 10. Stability and reactivity

10.2 Chemical stability

The product is stable under storage at normal ambient temperatures.

10.3 Possibility of hazardous reactions

No further information available.

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.

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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.

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

Dispose according to legislation.

Contaminated packaging

Completely emptied packages can be recycled.
Dispose according to legislation.

Section 14. Transport Information

14.7 Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code

No applicable

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Section 15. Regulatory Information

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

National regulatory information

Additional Information

Observe in addition any national regulations!

Section 16. Other Information

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 Harmonized 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 %
LD50	Lethal dose, 50 %

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.