

Instruction for use: Erkoflex-bleach, transparent



Labeling:

Consult accompanying documents

Read instructions for use

Single use only

For prescription use only

EC-directive 93/42/EEC



Storage:

Keep away from sunlight



Keep dry

5 °C/41 °F 35 °C/95 °F

Recommended storage temperature

Indications for use (general):

Thermoforming Sheet Materials and Accessories are indicated for the fabrication of orthodontic and dental appliances.

Intended Use:

Erkoflex-bleach is thermoformed to fabricate intra-oral appliances such as bleaching trays, fluoride trays, medication trays.

Contraindications:

- Before use on patients with a history of allergic reactions to plastics it has to be clarified that there is no specific allergic reaction on Erkoflex-bleach (EVA).

Warning:

- Use strictly limited for the fabrication of orthodontic and dental appliances.
- The use is subject to the responsibility of a therapist.
- For prescription use only.
- Allergic reactions are unlikely but possible.
- Improper manufacturing of the plastic appliance may cause the appliance to crack/break, resulting in sharp edges, loose pieces and possible aspiration of pieces.

Precautions:

- Erkoflex-bleach is not recommended for other dental appliances than as described above under intended use.
- Single use only.
- Pay attention to the storage instructions.



(manufacturer)

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Chemical characteristics:

EVA, ethyl-vinyl-acetate • Insulating foil: PE, polyethylene. Harmless to health. Thermoplast with tested biocompatibility. Insoluble in water, inactive, harmless to ground water.



Disposal/Recycling: General recycling for plastic if available, otherwise general waste.

Material informations:

Flexible material with high elasticity and dimensional stability. Does not bond to acrylate.

Availabilities: Thickness 1.0 mm, 120 and 125 mm round and 125 x 125 mm square.

Please refer to the Erkodent Material Card, Catalogue, Thermoforming Technique Brochure or to www.erkodent.com

Technical data:

Density, 0.93 g/cm ²	Water absorption, 0.2 %	Tensile strength, 31 N/mm ²	Flexional strength, -
Impact strength, no break	Notch impact, no break	Yield stress, 27 MPa	Elongation at break, 650 %
E-modulus, 70 N/mm ²	Hardness, Shore A95	Ball indent. hardness, -	Vicat softening point, 73 °C
Temp. resistance, 62 °C	Glass trans. temp., 93 °C	Shrinkage (intended use), < 2.0 %	

Plastification and working instructions: (only Erkodent thermoforming units)

Always place the sheet in the devices in such a way that the spacer/insulating foil is pointing towards the model. Please refer to the Erkodent unit instructions for a step-by-step thermoforming process. Sheet data such as heating time or thermoforming temperature are integrated in the internal data base of the thermoforming unit. Please select sheet type and thickness (Erkoflex-bleach 1.0 mm) and follow the working steps indicated by the unit or by the unit instructions. (Erkoform-RVE/-3 and Erkopress ES 200 E units: sheet data in the accompanying unit documents).

For units without control: Test softness of foil with an instrument. If permanent impressions result, thermoform, see picture.

Finishing: (see brochure thermoforming technique)

Recommended finishing set Quick 3 (110 830), also scissors 1.0 mm.

The spacer foil will be taken off only after thermoforming and finishing.

