smileflex

ABN 92 406 109 452

Smileflex™ Comfort Guard+

Product and Safety Data Sheet

1. MANUFACTURE INFORMATION

Product name: Comfort Guard+

Product intended use: For the temporary treatment of teeth bruxism.

Manufacturer: Smileflex

ABN 92 406 109 452 smileflex.com.au

Country of manufacture: Australia

2. MATERIAL INTENDED USE

The material is thermoformed to fabricate intra-oral appliances such as:

Application Thickness recommendation

Bruxism splints 2.5mm

The thickness recommendation is a non-binding suggestion based on market observation.

3. COMPOSITION

CAS No.: 24937-78-8

Designation: Ethylene-vinyl acetate

(EVA)

4. MATERIAL PROPERTIES

General properties:

Properties	Guideline	Value
Form	-	rubbery, soft
Colour	-	transparent
Odour	-	inodorous
Density	ISO 1193	0.94g/cm ³
Water absorption	ISO 62/1	-
Water solubility	-	insoluble



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4. MATERIAL PROPERTIES (cont.)

Mechanical properties:

Properties	Guideline	Value
Tensile strength	ISO 527	24MPa
Flectional strength	ISO 178	-
Impact strength, 23 °C	ISO 179/1eU	-
Notch impact, 23 °C	ISO 179/1eA	-
Yield stress	ISO 527	-
Elongation at break	ISO 527	1000%
E-modulus	ISO 527	-
Hardness shore A/ shore D	ISO 868	80 Shore A
Ball indentation hardness	ISO 2039/1	-
Thermal properties:		
Properties	Guideline	Value
Vicat softening point	ISO 306	40°C
Temperature resistance, 1.8 MPa	ISO 75	-
Glass transition temperature	ISO 11357	-

Biological properties:

The material has been tested for biocompatibility according to DIN EN ISO 10993-1 and does not affect the user's biological safety. The material is non-toxic and not made with Latex, does not contain DEHP (or other Phthalates), or Bisphenol A (BPA), and is monomer and gluten free.

5. GENERAL INFORMATION

Storage instructions: Use provided protective case. Keep away from sunlight. Keep dry.

Recommended storage temperature: 5°C-35°C

Instructions for cleaning and maintenance: Best results are achieved with cleansing tablets.

Further cleaning agents: Soap, curd soap, liquid soap and dish liquid. Do not use any strongly perfumed soaps.

Not suitable cleaning agents: Toothpaste, mouthwash and water that is hotter than 50°C.

Sterilisation: A sterilisation with gas and plasma (<50°C) is possible. As a result of the thermolability, the product is not autoclavable.

The information on this data sheet corresponds to the best of our knowledge at the time of publishing. The information is not guaranteed assurance of product properties and does not constitute a contractual legal understanding. Input errors and mistakes reserved. Modification date: 2023-10-08



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