



ABN 46 342 108 677

Smileflex® Elite Sports Mouthguard Product and Safety Data Sheet

1. MANUFACTURING INFORMATION

Product name: Elite Sports Mouthguard
Product intended use: To minimise the risk of teeth and facial damage during high-impact sports.
Manufacturer: Smileflex Pty Ltd
ABN 46 342 108 677
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
Sports Mouthguards	6.0mm

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

3. COMPOSITION

CAS No.:	24937-78-8	24937-78-8
Designation:	Ethylene-vinyl acetate (EVA 4mm)	Ethylene-vinyl acetate (EVA 2mm)

4. MATERIAL PROPERTIES

General properties:

Properties	Guideline	Value – EVA 4mm	Value – EVA 2mm
Form	-	rubbery, soft	rubbery, soft
Colour	-	transparent, coloured	transparent
Odour	-	inodorous	inodorous
Density	ISO 1193	0.95g/cm ³	0.95g/cm ³
Water absorption	ISO 62	-	-
Water solubility	-	insoluble	insoluble

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4. MATERIAL PROPERTIES (cont.)

Mechanical properties:

Properties	Guideline	Value – EVA 4mm	Value – EVA 2mm
Tensile strength	ISO 527	33MPa	33MPa
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%	1000%
E-modulus	ISO 527	-	-
Hardness shore A/ shore D	ISO 868	Shore A 83	Shore A 83
Ball indentation hardness	ISO 2039/1	-	-

Thermal properties:

Properties	Guideline	Value – EVA 4mm	Value – EVA 2mm
Vicat softening point	ISO 306	44°C	44°C
Temperature resistance, 1.8 MPa	ISO 75	-	-
Glass transition temperature	ISO 11357	-	-

Biological properties:

The materials have been tested for biocompatibility according to DIN EN ISO 10993-1 and do not affect the user's biological safety. The materials are non-toxic and not made with Latex, do not contain DEHP (or other Phthalates), or Bisphenol A (BPA), and are 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. Solvent-based cleaning agents cause delamination of product layers.

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: 2024-05-06