



ABN 92 406 109 452

Smileflex™ Pro Sports Mouthguard

Product and Safety Data Sheet

1. MANUFACTURING INFORMATION

Product name: Pro Sports Mouthguard
Product intended use: To minimise the risk of teeth and facial damage during medium-impact sports.
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 |
|--------------------|--------------------------|
| Sports Mouthguards | 5.0mm |

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 1mm) |

4. MATERIAL PROPERTIES

General properties:

| Properties | Guideline | Value – EVA 4mm | Value – EVA 1mm |
|------------------|-----------|-----------------------|-----------------------|
| 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 1mm |
|---------------------------|-------------|-----------------|-----------------|
| 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 1mm |
|---------------------------------|-----------|-----------------|-----------------|
| 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: 2023-10-08