

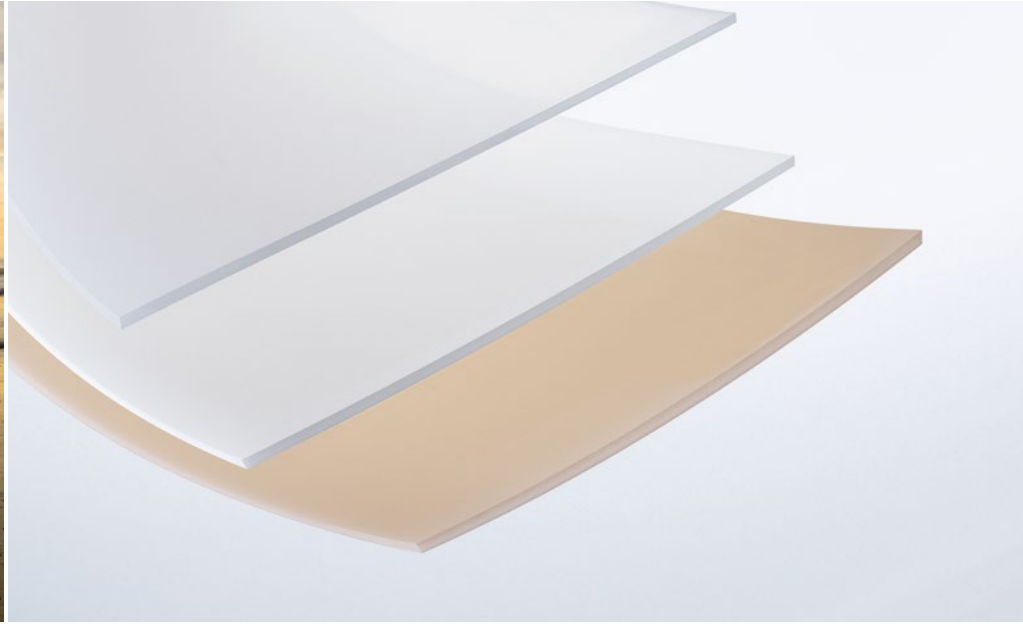
**SIMONA**



**SIMONA<sup>®</sup> SIMOLIFE EVA**

Flexible Plastic Sheets for Orthopaedic Products

## SIMONA® SIMOLIFE EVA flex/superflex – Dimensional stability, flexibility, skin compatibility



**Owing to their inherent material properties, SIMONA® SIMOLIFE EVA Sheets are the perfect choice for applications in the field of orthopaedics technology. With EVA flex and EVA superflex, SIMONA has developed a product range that meets a wide range of requirements with regard to flexibility of the specific material.**

Extruded from EVA, a copolymer of ethylene and vinyl acetate, the sheets combine outstanding formability with excellent dimensional stability.

SIMONA® SIMOLIFE EVA has been specially designed for the manufacture of inner sheaths used in arm and leg prosthetics.


In order to ensure the best possible fit for the amputee, a plaster mould is made of the limb in question prior to manufacturing the sheath. The sheets are heated in a convection or infrared oven and are then stretched seamlessly over a plaster mould by means of vacuum processing.

### **Certificates**

- Proof of biocompatibility:
  - Cytotoxicity testing in accordance with DIN EN ISO 10993 Part 5
  - Irritation and hypersensitivity testing in accordance with DIN EN ISO 10993 Part 10
- Physiological safety according to BfR, EU and FDA

# SIMONA® SIMOLIFE EVA flex/superflex – Product range and properties

## Product range

|   | SIMONA® SIMOLIFE<br>EVA flex |                                  | SIMONA® SIMOLIFE<br>EVA superflex |                         |
|---|------------------------------|----------------------------------|-----------------------------------|-------------------------|
| <b>Extruded sheets</b> (size/thickness in mm)                                     |                              |                                  |                                   |                         |
|  | 400 x 400                    | 3, 4, 6, 8, <b>9, 10, 12, 15</b> | 6, 8, 10, 12                      | 6, 9, <b>10, 12, 15</b> |
|   | 2000 x 1000                  | 3, 4, 6, 8, 9, 10, 12, 15        | -                                 | -                       |
|   | Colour                       | natural (translucent)            | skin-coloured                     | natural (translucent)   |

**Bold type** = available immediately; light-faced type = available on request  
Customised sizes and sheets with antibacterial properties available on request.



### + Excellent formability

SIMONA® SIMOLIFE EVA Sheets have excellent hot-forming properties. The material displays minimal shrinkage during cool-down, thus ensuring a high level of dimensional stability with uniform wall thickness distribution as well as best possible fit.

### + Very good skin compatibility

An inner sheath made of SIMONA® SIMOLIFE EVA combines the benefits of good adhesive properties with comfortable fit (“soft touch”). With properties including biocompatibility in accordance with DIN EN ISO 10993-5/-10 and resistance to sweat, cosmetics, skin creams and disinfectants, they offer excellent safety and extreme durability.

### + More than 35 years' experience

Acknowledged for its consistently high quality, SIMONA has been a trusted partner to the orthopaedic technology sector for many years. Regular audits and endurance tests are a valuable source of information for ongoing product development and refinement by our R&D engineers. This provides the basis for an innovative, premium-quality product range.



# SIMONA® SIMOLIFE EVA flex/superflex – Material specifications

## Material specifications

|  | <b>SIMONA® SIMOLIFE<br/>EVA flex</b> | <b>SIMONA® SIMOLIFE<br/>EVA superflex</b> |
|--|--------------------------------------|---|
| Density, g/cm <sup>3</sup> ,<br>DIN EN ISO 1183                  | 0.934                                | 0.955                                     |
| Tensile modulus of elasticity, MPa,<br>DIN EN ISO 527            | 75                                   | 19  |
| Shore hardness D,<br>DIN EN ISO 868                              | 39                                   | 29  |
| Crystalline melting range, °C,<br>DSC (10 °C/min)                | > 60                                 | > 60                                      |
| Heat-up temperature, °C<br>(oven temperature)                    | 150 – 160                            | 150 – 160                                 |
| Heat-up time, min/mm sheet thickness<br>(retention time in oven) | approx. 2                            | approx. 2                                 |
| Biocompatibility in accordance with<br>DIN EN ISO 10993-5/-10    | ✓                                    | ✓   |
| Physiological safety in accordance with<br>BFR, EU and FDA       | ✓                                    | ✓   |

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