

# Suprasorb<sup>®</sup> F Film Dressing, off the roll

# REF 20467, 20468, 20469

January 2019

# 1. Composition of the product

The Suprasorb<sup>®</sup> F Film Dressing, off the roll consists of:

- film: polyurethane film, coated with a polyacrylate adhesive
- support film: polyester, coated on both sides with polyethylene and siliconized on one side
  cover paper: siliconized paper
- adhesive strips: polyester film and polyacrylate adhesive
- application aid: white, bleached silicone paper, under the siliconized layer green L&R scatter printed

This product data sheet covers the following items:

REF	Product description	Size	
20467	Suprasorb $^{\otimes}$ F Film Dressing, off the roll	10 cm x 1 m /	4 in. x 1.1 yd.
20468	Suprasorb $^{\ensuremath{\mathbb{R}}}$ F Film Dressing, off the roll	10 cm x 10 m /	4 in. x 11 yd.
20469	Suprasorb <sup>®</sup> F Film Dressing, off the roll	15 cm x 10 m /	6 in. x 11 yd.

# 2. Packaging, structure and composition

#### 2.1 Unit container

see 2.2

#### 2.2 Shelf container

1 piece = 1 Folding box, made of cellulose

### 2.3 Transit container

1 Corrugated cardboard box made of cellulose

REF	Folding boxes
20467, 20468	16
20469	10

#### 3. Manufacture

Suprasorb<sup>®</sup> F Film Dressing, off the roll is produced according to specification in hygienic conditions and packed as described in its relevant packaging specification.

#### 4. Description

The film dressing consists of a polyurethane film which is coated with a polyacrylate adhesive. The product is equipped with a support film made of polyester which is covered on both sides with PE and siliconized on one side. The adhesive side is covered with a white siliconized paper.

Transparent adhesive strips are affixed along the long sides of the support film and cover paper. A paper strip is adhered lengthwise to the middle of the cover paper as an application aid. The application aid and cover paper are separated in the middle. The product is available in various sizes.

### 5. **Properties**

Transparent, elastic film dressing that is permeable to water vapour with adhesive that is free of natural latex, colophony and colophony derivates.

- high comfort due to easy application
- particularly thin and flexible
- repels bacteria and fluids
- impermeable to water
- supports wound healing by maintaining moist wound healing environment, thereby assisting the natural healing process

# 6. Intended purpose

Suprasorb<sup>®</sup> F Film Dressing, off the roll is intended to be used for prophylaxis (especially of decubitus ulcers) and dressing retention.

#### 7. Medical device classification

Suprasorb<sup>®</sup> F Film Dressing, off the roll is a medical device of Class I in terms of Rule 4. (Council Directive 93/42/EEC concerning medical devices, Annex IX)

#### 8. Biological evaluation and biocompatibility (DIN EN ISO 10993)

The starting materials used in the manufacture of the Suprasorb<sup>®</sup> F Film Dressing, off the roll are safe if the product is used appropriately and for the purposes intended.

The purpose of this documentation and the statements made therein is to show that there is no risk involved in the use of the medical device Suprasorb<sup>®</sup> F Film Dressing, off the roll rolled and that it is designed, manufactured and packaged in such a way that it will not compromise the clinical condition or the safety of patients, or the safety and health of users and other persons when used under the conditions and for the purposes intended.

# 9. Stability

Stored appropriately Suprasorb<sup>®</sup> F Film Dressing, off the roll has a shelf life of 5 years.

#### 10. Disposal

The user is advised to observe current national legislation, norms and guidelines, regulating the disposal of medical refuse. Packaging materials must also be disposed of in compliance with applicable national requirements.

Lohmann & Rauscher International GmbH & Co. KG D-56579 Rengsdorf signed by

Peter Grillitsch Head of Global Marketing