

## Suprasorb® F Film Dressing, off the role

REF 20467, 20468, 20469, 82084, 82063, 82064

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### 1. Composition of the product

The Suprasorb® F Film Dressing off the role consists of a film made of polyurethane and coated with a polyacrylate adhesive. The product is provided with a polyethylene support film. The adhesive side of the product is covered with a white silicone paper. The support film and the cover paper are bonded on both long sides with a transparent adhesive strip made of polyester film/polyarylate adhesive. A strip of paper is glued centrally lengthwise on the release paper forming a release tab. Release tab and release paper are cut centrally. The end of the roll is fixed with a hot melt adhesive point.

This product data sheet covers the following items:

REF	REF*	Product description	Size
20467	82084	Suprasorb® F Film Dressing, off the role	10 cm x 1 m
20468	82063		10 cm x 10 m
20469	82064		15 cm x 10 m

\*(French market)

### 2. Packaging, structure and composition

#### 2.1 Unit Container

see 2.2

#### 2.2 Shelf Container

1 piece = 1 folding box made of cellulose,  
instructions for use made of cellulose

#### 2.3 Transit Container

1 corrugated cardboard box made of cellulose

REF	pieces
20467, 20468 / 82084, 82063	16
20469 / 82064	10

### 3. **Manufacture**

The Suprasorb® F Film Dressing off the role is produced according to specification in hygienic conditions and packed as described in its relevant packaging specification.

### 4. **Description**

The Suprasorb® F Film Dressing of the role is a highly conformable, water vapour permeable, self-adhesive and transparent dressing.

### 5. **Properties**

- easy application
- safe, yet flexible fit affords high wearing comfort
- elastic and conformable
- protects from external contamination
- maintains the moist wound environment
- can be worn in the shower
- when used as a primary dressing, inspection of the wound is possible without removal of the dressing
- permeable to water vapour

### 6. **Intended purpose**

The Suprasorb® F Film Dressing off the role is intended for supportive prophylaxis of skin areas at risk of pressure ulcers, fixation in wound treatment and for the initial care for minor, superficial wounds.

### 7. **Medical device classification**

The Suprasorb® F Film Dressing off the role is a medical device of class I according to rule 4, case 1 (Regulation (EU) 2017/745).

### 8. **Biological evaluation and biocompatibility, DIN EN ISO 10993**

The starting materials used in the manufacture of Suprasorb® F Film Dressing off the role are safe if the product is used appropriately.

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® F Film Dressing off the role 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. Requirements regarding the safety/harmlessness of the constituents

### Substances in release paper and application aid:

The release paper has a maximum content of rosin and rosin derivatives of 0.5% (CAS: 68201-60-5). Furthermore, in order to ensure its function as release liner silicone is included (max. 7%).

### Substances in polyurethane (incl. PE-carrier):

According to the supplier's information, there are no ingredients of concern in the polyurethane and the carrier film.

### Substances in adhesive:

According to the supplier's information, there are no ingredients of concern in the adhesive.

### Substances in edge bonding:

According to information provided by the supplier, apart from silicone in the PET carrier (to ensure the release function) and rosin/rosin derivatives in the adhesive, no other ingredients of concern are contained.

### Ingredients in the adhesive with which the application aid sticks on the cover paper:

According to the supplier's information, there are no ingredients of concern in the adhesive.

### Ingredients in the adhesive with which the end of the roll is fixed:

According to the supplier's information, there are no ingredients of concern in the adhesive.

## 10. Stability

Stored appropriately (keep dry, protected from dust and sun) Suprasorb® F Film Dressing of the role has a shelf life of 5 years from the date of manufacture.

## 11. 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.

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Signed by

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