

## Suprasorb® P + PHMB non-adhesive

### Antimicrobial foam dressing

REF 34540 - 34547

November 2022

#### 1. Composition of the product

The Suprasorb® P + PHMB non adhesive consists of:

- Polyurethane film (top layer)
- Polyurethane foam, hydrophilic
- Perforated polyurethane film (wound contact layer)
- Polyhexamethylene biguanide (PHMB)

This product data sheet covers the following items:

REF 34540	Suprasorb® P + PHMB non-adhesive	5 x 5 cm
REF 34541	Suprasorb® P + PHMB non-adhesive	7.5 x 7.5 cm
REF 34542	Suprasorb® P + PHMB non-adhesive	10 x 10 cm
REF 34543	Suprasorb® P + PHMB non-adhesive	10 x 20 cm
REF 34544	Suprasorb® P + PHMB non-adhesive	15 x 15 cm
REF 34545	Suprasorb® P + PHMB non-adhesive	20 x 20 cm

#### 2. Packaging, structure, and composition

##### 2.1 Unit Container

1 piece = 1 four-edge sealed pouch consisting of cellulose, polyester and polyethylene

##### 2.2 Shelf Container

1 cellulose folding box  
 - Instructions for use, made from cellulose

REF	pieces
34540 - 34542	10
34543 - 34545	5

## 2.3 Transit Container

1 corrugated cardboard box made from cellulose

REF	pieces	Folding boxes
34540 - 34542	100	10
34543 - 34545	50	10

## 3. Manufacture

The information about production is the responsibility of the legal manufacturer:

RESORBA Medical GmbH  
Am Flachmoor 16  
90475 Nuremberg  
Germany

## 4. Description

Suprasorb® P + PHMB non-adhesive antimicrobial foam dressing is a sterile antimicrobial wound dressing, consisting of a hydrophilic polyurethane foam which is designed to absorb exudate. This is laminated to a printed, low friction, waterproof polyurethane film which provides a bacterial barrier to the wound. The wound contact layer side of the dressing has a clear perforated film which protects the wound bed from adhering to the dressing by preventing the formation of granulation tissue into the pores of the foam, thus reducing trauma on dressing removal. The perforations in the wound contact layer allow the uptake of exudate and prevent excess fluid causing maceration to healthy skin.

## 5. Properties (see valid instructions for use)

- Reliable exudate management
- Broad antimicrobial action
- Rapid and prolonged antimicrobial effect
- With a perforated wound contact layer
- Waterproof with bacterial barrier

## 6. Intended purpose

The Suprasorb® P + PHMB non-adhesive antimicrobial foam dressings are intended for use by healthcare professionals for the treatment of moderate to heavily exuding chronic and acute wounds that are infected or at the risk of infection. The dressings are for use during the healing process.

**7. Medical device classification**

The Suprasorb® P + PHMB non-adhesive is a medical device of Class III in terms of Rule 13.

(Council Directive 93/42/EEG concerning medical devices, Annex IX)

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

The information about biological assessment and compatibility is the responsibility of the legal manufacturer:

RESORBA Medical GmbH  
Am Flachmoor 16  
90475 Nuremberg  
Germany

**9. Requirements regarding the safety/harmlessness of the constituents**

We currently have no information on ingredients of concern.

**10. Stability**

Stored appropriately (at temperatures not exceeding 25°C or reaching below 5°C), the foam dressings have a shelf life of 2 years.

**11. Disposal**

The user is advised to observe current national legislation, norms, and guidelines regulating the disposal of medical waste.

Packaging materials must also be disposed of in compliance with applicable national requirements.

**12. Legal manufacturer:**

The following legal manufacturer hereby confirms the accuracy of the information provided in this product data sheet:

Legal manufacturer:  
**RESORBA Medical GmbH**  
Am Flachmoor 16  
90475 Nuremberg  
Germany

Distributor:  
**Lohmann & Rauscher GmbH & Co. KG**  
Westerwalstraße 4  
56579 Rengsdorf  
Germany

29 Nov 2022 /   
Date, Signature

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Date, Signature