

Suprasorb® X + PHMB

Antimicrobial HydroBalance wound dressing, sterile

REF 20540 – 20543

March 2023

1. Composition of the product

Suprasorb® X + PHMB Antimicrobial HydroBalance Wound Dressings and Packing Rope consist of:

- cellulose (3-5%)
- water (95-97%)
- polyhexamethylene biguanide (0,3%)
- transparent polyester film (backing sheets on both sides of the wound dressings)

This product data sheet covers the following items:

REF	Product description	Size
20540	Suprasorb® X + PHMB Antimicrobial HydroBalance Wound Dressing	2 x 2 in.
20541	Suprasorb® X + PHMB Antimicrobial HydroBalance Wound Dressing	3.5 x 3.5 in.
20542	Suprasorb® X + PHMB Antimicrobial HydroBalance Wound Dressing	5.5 x 8 in.
20543	Suprasorb® X + PHMB Antimicrobial HydroBalance Packing Rope	0.75 x 8.5 in.

2. Packaging, structure and composition

2.1 Unit container

1 piece = 1 four-edge sealed bag consisting of polyester, polyethylene and aluminium

2.2 Shelf container

5 pieces = 1 folding box (cellulose)
- instructions for use (cellulose)

2.3 Transit container

1 corrugated cardboard box (cellulose)

REF	pieces	Folding boxes
20540	90	18
20541	80	16
20542	65	13
20543	130	26

3. Manufacture

Suprasorb® X + PHMB Antimicrobial HydroBalance Wound Dressings and Packing Rope are produced according to specification in hygienic conditions, packed as described in their relevant packaging specification. The product is sterilized by gamma irradiation in compliance with DIN EN ISO 11137, part 1-3.

4. Description

Suprasorb® X + PHMB Antimicrobial HydroBalance Wound Dressings and Packing Rope are white to off-white, smooth antimicrobial dressings or rope, respectively, which are effective against a large spectrum of pathogens. Depending on the wound condition, the product can either provide the wound with moisture or absorb excess exudate.

5. Properties (see valid instructions for use)

- moisture can be donated to the wound or excess exudate absorbed
- creation of a moist wound environment
- atraumatic dressing changes
- easy to conform to the wounds particular shape and depth
- especially suitable for areas of the body which are difficult to dress
- the moist environment with a cooling effect is perceived by patients as pleasant and pain-relieving
- antimicrobial action against a broad spectrum of pathogens, such as MRSA and VRE*

*Pathogen spectrum detected in vitro, see first paragraph of instructions for use.

6. Intended purpose (see valid instructions for use)

Suprasorb® X+ PHMB Antimicrobial HydroBalance Wound Dressings / Rope aid wound healing, by donating moisture to and absorbing exudate from lightly to moderately exuding, superficial or deep wounds at risk of infection or infected wounds and inhibition of microbial activity.

7. Medical device classification

Suprasorb® X + PHMB Antimicrobial HydroBalance Wound Dressings or Rope respectively are medical devices of Class III in terms of Rule 14 (according to Regulation (EU) 2017/745).

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

The starting materials used in the manufacture of Suprasorb® X+ PHMB Antimicrobial HydroBalance Wound Dressings and Rope are safe when the products are used appropriately and for the intended purpose.

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 devices Suprasorb® X + PHMB Antimicrobial HydroBalance Wound Dressings and Rope and that they are designed, manufactured and packaged in such a way that they 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

Nata de Coco Pellicles contain the following ingredients:

- Heavy Metals: lead = 0,05 ppm, Cadmium = 0,02 ppm, Mercury =0,02 ppm
- Antimicrobial treatment: Heat treatment
- Preservative Agents: Citrine acid (0,8%)
- Material of microbial origin: Nata de Coco (as result of coconut milk fermentation using Acetobacter Xylinum)

The polyester film contains the following ingredients:

- Various colorants at < 5%

Preservative Agents: Cosmocil PG contains PHMB at 20% which is a known preservative Agent.

Heavy Metals:

- Arsenic (< 0,4 ppm)
- Cadmium (< 1,0 ppm)
- Mercury (< 1,0 ppm)
- Lead (< 5,0 ppm)
- Cobalt (< 1,0 ppm)
- Nickel (< 1,0 ppm)
- Vanadium (< 1,0 ppm)
- Silver (< 1,0 ppm)
- Gold (< 1,0 ppm)
- Iridium (< 1,0 ppm)
- Osmium (< 1,0 ppm)
- Palladium (< 1,0 ppm)
- Platinum (< 1,0 ppm)
- Rhodium (< 1,0 ppm)
- Selenium (< 1,0 ppm)
- Thallium (< 1,0 ppm)
- Barium (< 1,0 ppm)
- Chromium (< 5,0 ppm)
- Copper (< 1,0 ppm)
- Lithium (< 1,0 ppm)
- Molybdenum (< 1,0 ppm)

- Antimony (< 1,0 ppm)
- Tin (< 1,0 ppm)
- Aluminium (< 1,0 ppm)
- Calcium (< 10 ppm)
- Iron (< 5,0 ppm)
- Magnesium (< 1,0 ppm)
- Manganese (< 1,0 ppm)
- Zinc (< 100,0 ppm)

10. Stability

Stored appropriately – keep dry, protected from dust and sun and at temperatures between +5°C and +30°C - Suprasorb® X + PHMB Antimicrobial HydroBalance Wound Dressings and Rope have a shelf life of 3 years from the date 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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