

Suprasorb[®] H

Hydrocolloid Dressing

REF 108830, 108831, 108832, 108860, 108861, 108862,
108863, 108864, 108865, 108866, 108867

February 2022

1. Composition of the product:

Suprasorb[®] H Hydrocolloid Dressing consists of:

- Polyurethane film layer (protective layer)
- Hydrocolloid paste layer
- Release paper layer (silicone-coated paper)

This product data sheet covers the following items:

REF	Product description	Dimensions
108830	Suprasorb [®] H Hydrocolloid Dressing, standard	10 x 10 cm
108831		15 x 15 cm
108832		20 x 20 cm
108860	Suprasorb [®] H Hydrocolloid Dressing, thin	5 x 5 cm
108861		5 x 10 cm
108862		5 x 20 cm
108863		10 x 10 cm
108864		15 x 15 cm
108865		20 x 20 cm
108866	Suprasorb [®] H Hydrocolloid Dressing, border	14 x 14 cm
108867	Suprasorb [®] H Hydrocolloid Dressing, sacrum	14 x 16 cm

2. **Packaging, structure and composition**

2.1 **Basic packaging / Unit Container**

1 Unit = 1 four-side seal pouch, consisting of paper(cellulose)/film

2.2 **Commercial packaging / Shelf Container**

1 folding box made of paper (cellulose)
inside 1 instructions for use (cellulose)

REF	Pcs./Unit
108831, 108832, 108864 - 108867	5
108830, 108860 - 108863	10

2.3 Shipping packaging / Transit Container

1 corrugated cardboard box made of cellulose

REF	Pcs.	Folding boxes
108860	1.650	165
108863	720	72
108830	660	66
108861	480	48
108862	250	25
108866,108867	200	40
108831, 108832, 108864, 108865	50	10

3. Manufacture

Suprasorb® H Hydrocolloid Dressing is produced in accordance with ISO 13485, CE, MFDS and USA FDA regulations. This product is produced under highly controlled cleanroom conditions.

The accuracy of the information about production is the responsibility of the legal manufacturer (T&L Co., Ltd.).

4. Description

Suprasorb® H Hydrocolloid Dressing has a two-layer construction composed of an absorbent hydrocolloid matrix laminated to a breathable polyurethane film backing. The hydrocolloid matrix rapidly absorbs exudate to form a cohesive gel. In addition to excellent absorbency, the breathable polyurethane film backing provides a consistently high rate of moisture vapour transmission.

Together, these features ensure an optimal moist wound environment and minimise the chance of damage to healthy peri-wound skin.

5. Properties

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6. Intended purpose

Suprasorb® H Hydrocolloid Dressing is primarily indicated for the management of light to medium exuding pressure sores, leg ulcers, superficial burns, superficial partial-thickness burns, donor sites, diabetic ulcers, post-operative wounds and skin abrasions.

7. Medical device classification

Suprasorb[®] H Hydrocolloid Dressing is a medical device of Class IIb. - Medical Device Directive 93/42/EEC. Conformity Assessment Route MDD Annex II.3 Full QA System.

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

Suprasorb[®] H Hydrocolloid Dressing is in contact with breached or compromised surface for a prolonged period (>24 h to 30 day). Biocompatibility was evaluated as cytotoxicity, sensitisation, irritation test.

The test results met the requirements of the ISO 10993.

The accuracy of the information about the biological assessment and compatibility is the responsibility of the legal manufacturer (T&L Co., Ltd.).

9. Stability

Stored appropriately- at temperatures of 1-30°C -Suprasorb[®] H - Hydrocolloid Dressing has 3-years shelf life.

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.

11. Legal manufacturer

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

Legal manufacturer:

T&L Co., Ltd.
70-17, Wonam-ro, Won-gok-myeon
Anseong-si, Gyeonggi-do, 17554
Korea

Distributor:

Lohmann & Rauscher GmbH & Co. KG
Westerwaldstraße 4
56579 Rengsdorf
Germany



Date, Signature

February 15, 2022

HanJin Kim / Junior Managing
Director, Overseas Sales Division.



Peter.Grill@et.LRMed.com, Feb 15, 2022 9:33:32 AM UTC

Date, Signature