

**CURAPLAST® KIDS**  
**Hypoallergenic Adhesive Wound Dressing (Precuts)**

**REF: 30630**

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Translation: MI / P. Kellmann

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**1. Composition of the product:**

CURAPLAST® Kids adhesive wound dressings are constructed as follows:

- Film: polyethylene
- Adhesive: synthetic rubber adhesive  
(free of colophony and colophony derivatives)
- Wound pad: - viscose  
- polypropylene  
- polyethylene
- Cover: - siliconised paper

This product data sheet covers the following item:

REF 30630	CURAPLAST® Kids hypoallergenic adhesive wound dressing	1.7 x 6 cm
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**2. Packaging, structure and composition**

**2.1 Unit Container**

- see 2.2.

**2.2 Shelf Container**

- individually wrapped in a paper peel pouch (cellulose)
- a folding cardboard carton (cellulose) (15 pieces each)

**2.3 Transit Container**

- a corrugated cardboard box (cellulose)

### **3. Manufacture**

CURAPLAST® Kids adhesive wound dressings are manufactured to specification under hygienic conditions and presented packed as described in their respective packaging specification into a paper peel pouch, then into a folding cardboard carton and finally into a corrugated cardboard box.

### **4. Description**

CURAPLAST® Kids adhesive wound dressings consist of a white, decorated, perforated polyethylene film which is coated on one side with a synthetic rubber adhesive. The wound pad, which is situated on the adhesive side, consists of an absorbent viscose and polypropylene/polyethylene layer and a centrally placed polyethylene layer which does not stick to the wound. Two siliconised papers which are coated on one side and overlapping in the center serve as cover paper.

### **5. Properties**

CURAPLAST® Kids precuts are flexible adhesive wound dressings which do not stick to the wound. They are free of colophony and colophony derivatives, soft and conformable, and offer good adherence to the human skin.

### **6. Intended purpose**

CURAPLAST® Kids adhesive wound dressings are intended for dressing minor injuries.

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

As CURAPLAST® Kids adhesive wound dressings are used for the treatment of minor injuries, this medical product is in Class I according to Rule 4 (Annex IX of the Council Directive 93/42/EEC concerning medical devices).

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

Viscose is described in monographs in pharmacopoeia. It is known to be pharma-toxicologically harmless and indifferent. Because of its good biocompatibility, it is widely used in the textile industry.

Polypropylene and polyethylene are known to be pharma-toxicologically harmless and indifferent when used for the intended purpose.

The synthetic rubber adhesive is free of colophony and colophony derivatives.

Silicon is widely used for the manufacture of medical tubes and closures. Silicon is pharma-toxicologically harmless and indifferent when correctly used for the intended purpose.

All the starting materials used to produce CURAPLAST<sup>®</sup> Kids adhesive wound dressings are of such purity that the use of this product is safe for the purpose intended.

To date this company has received no notification of incidents involving this Lohmann & Rauscher product, neither has there been a need for a recall of this product for reasons of quality.

The purpose of this documentation and of the statements made therein is to show that there is no risk involved in the use of CURAPLAST<sup>®</sup> Kids and that CURAPLAST<sup>®</sup> Kids precuts 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 or other persons when used under the conditions and for the purposes intended.

## 9. Stability

Appropriately stored in cool and dry conditions CURAPLAST<sup>®</sup> Kids adhesive wound dressings have a shelf life of five years.

## 10. Disposal

Incineration or landfill disposal generates:

CURAPLAST<sup>®</sup> Kids adhesive wound dressings: CO<sub>2</sub> and H<sub>2</sub>O and traces of silicon dioxide

Packaging material: CO<sub>2</sub> and H<sub>2</sub>O

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

Lohmann & Rauscher International GmbH & CO. KG  
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signed by  
Dr. Martin Abel  
(Medical & Regulatory Affairs)