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Product Data Sheet

1.0 Name of the product	Cutimed® Alginate
2.0 Product description	
2.1 Description	<p>Cutimed® Alginate is a sterile, non-medicated alginate dressing, consisting of mainly calcium alginate fiber. Cutimed® Alginate is made of natural fibers derived from seaweed. A hidden integrity layer in the dressing gives it high wet stability. It is designed to be a highly, fast absorbent and soft, sterile non-woven dressing. Cutimed® Alginate absorbs wound exudate and forms a gel-like covering over the wound, maintaining a moist wound healing environment which accelerates the healing process and helps to stop bleeding. The gel-like surface also keeps the dressing from adhering to the wound and enables a painless removal. The high wet strength of Cutimed® Alginate ensures the dressing remains integral while removing.</p>
2.2 Intended purpose	<p>Cutimed® Alginate is indicated for the management of moderate to heavily exuding partial to full thickness wounds, including:</p> <ol style="list-style-type: none"> 1. Surface trauma 2. Cavity wounds 3. Pressure ulcers 4. Diabetic foot ulcers 5. Venous/arterial leg ulcers 6. Donor sites 7. Post-surgical wounds <p>Cutimed® Alginate dressings are suitable for use under compression bandages.</p>
2.3 Instructions for use	Yes
2.4 Warnings and precautions for use	<ol style="list-style-type: none"> 1. This product is for single use. 2. Do not use if package is damaged. 3. The dressing is used on infected wounds only under the care of a healthcare professional. 4. The dressing is not indicated for surgical implantation and dry wounds. 5. The dressing is not recommended to control heavy bleeding. 6. If redness or allergic symptoms appear, please stop using this product. 7. Single product cannot stay on wound for more than 7 days. 8. The dressing is not recommended for infants less than 12 months of age or pregnant woman.
2.5 Contraindications	Cutimed® Alginate dressing should not be used on individuals who are sensitive to or who have had an allergic reaction to alginates or polyester.
2.6 Transport Precautions	not applicable
2.7 Duration of application	Single product cannot stay on wound for more than 7 days.

2.9 Composition	<div><div></div><div><div></div><div></div><div></div></div><div><div>1</div><div>2</div><div>1</div></div></div>									
	<table><tr><th>Designation (incl. no. in drawing)</th><th>Description</th><th>% of final product</th></tr><tr><td>Contact Layer (1)</td><td>Alginate Non-woven Layer</td><td>90-95</td></tr><tr><td>Middle Layer (2)</td><td>Polyester Layer</td><td>5-10</td></tr></table>	Designation (incl. no. in drawing)	Description	% of final product	Contact Layer (1)	Alginate Non-woven Layer	90-95	Middle Layer (2)	Polyester Layer	5-10
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Contact Layer (1)	Alginate Non-woven Layer	90-95								
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2.10 Product range	<table><tr><th>Size/ Color</th><th>Per folding box</th><th>Per shipper</th><th>Product code</th></tr><tr><td>5x5cm</td><td>10</td><td>600</td><td>72634-00012-00</td></tr><tr><td>10x10cm</td><td>10</td><td>400</td><td>72634-00013-00</td></tr><tr><td>10x20cm</td><td>10</td><td>200</td><td>72634-00014-00</td></tr><tr><td>2.5x30cm</td><td>5</td><td>400</td><td>72634-00015-00</td></tr></table>	Size/ Color	Per folding box	Per shipper	Product code	5x5cm	10	600	72634-00012-00	10x10cm	10	400	72634-00013-00	10x20cm	10	200	72634-00014-00	2.5x30cm	5	400	72634-00015-00
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2.12 Storage conditions	Dry, clean, below 40 °C, above 5 °C and without exposure to direct sunlight. Short storage periods outside of the storage conditions e.g. during transport, can be tolerated by the product.
2.13 Shelf life/ Storage time	36 months
2.14 Sterilization	Sterilized using irradiation
2.15 Reimbursement Information	For country specific information please reach out to your local Essity contact.


2.16 Key quality parameters	Characteristic	Method	Required value	Target
	Weight	Electronic balance BP 1993	140 - 200 g / m ²	170 g / m ²
	Free swell absorption	EN 13726-1	≥ 12 g / 100 cm ²	21 g / 100 cm ²
	Loss on drying	USP 34	≤ 25 %	19 %
	pH	EN 14079:2003	6.5 ± 1.5	5.8
	Dry Tensile strength	Essity internal	≥ 1 N / cm	6.7 N / cm
	Wet Tensile strength	Essity internal	≥ 1 N / cm	3.4 N / cm
	Elongation at break	ISO 1798:2008	≥ 20%	56%

3.0 Chemical substances of special concern to Essity


Essity has defined chemical substances that are of special concern and are subject to specific restrictions. A reference to the list of substances can be found in Annex A2 via the following link www.essity.com/gss

Deviations are covered in 3.1 Components.

3.1 Components	Raw materials used in product formulation	
	Substance	Included in formulation
	natural rubber Latex	No
	Lanolin and its derivatives	No
	Colophony	No
	Colophony derivatives	No
	Bisphenol A (BPA)	No
	Polyvinylchloride (PVC)	No
	Methylmethacrylate	No
	Butylacrylate	No
	Microplastics (<5 mm)	No
	Nanoparticles	No
	Fragrance/parfum	No
	Antibiotics	No
	Triclosan	No
	Chlorhexidine	No
	Polyhexanide	No
	Raw materials used in the packaging	
	Substance	Included in formulation
	Polyvinylchloride (PVC)	No
	Natural rubber latex	No
	Recycled material	partly in shipper case

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	<p>Raw materials used in the product formulation and in the packaging may contain small amounts of the substances listed above and not marked as included in formulation as well as amounts of other substances not listed above. As trace level analysis is not performed for each batch Essity cannot provide proof of absence.</p>
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History

Version / Date	Page / Item	Description of Change
01 / 09.2024	All	New creation based on MDD PDS. Changed Narts to MDR Products. Changed highly exuding to heavily exuding according to IFU. Added passus on storage conditions during transport.