

Technical Data Sheet

Plum QuickCool

1. Identification of the product and the company

1.1 Product identifier and intended use

Trade Name:	Plum QuickCool.
Intended Use:	Plum QuickCool is a non-sterile cooling gel intended to be used for minor burns.
Expiry date:	Printed on the sealed package.

1.2 Details of the supplier of the data sheet

Distributor	
Company:	Plum Safety ApS
Address:	Mandelalleen 1
Zip code:	5610
City:	Assens
Country:	Denmark
E-mail:	info@plum.eu
Phone:	+45 6916 9600
Fax:	+45 6916 9630


1.3 Legislative information

General information:	<p>As QuickCool is class IIa, non-sterile medical devices according to <i>Council Directive 93/42/EEC of 14 June 1993 and MDR2017/745 art. 120</i> concerning medical devices, they are certified by the Notified Body, Intertek Medical Notified Body AB, Kista, Sweden.</p> <p>No Safety Data Sheet is required for medical devices.</p> <p>Plum Safety ApS is certified according to <i>ISO 13485:2016 Medical devices – Quality management systems – Requirements for regulatory purposes</i>.</p> <p>AKLA AB, Parkgatan 15, 696 33 Askersund, Sweden is the legal manufacturer of Plum QuickCool.</p>
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2. General information about the product

Material requirements:	The materials in these products have been judged biocompatible according to the requirements of <i>ISO 10993-1:2020 Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process</i> .
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Physical properties and composition

	QuickCool Art. No. 5150 (REF 94370)
Material	3,5 g gel. <i>Ingredients: Purified water, Melaleuca Oil (1%), Emulsifiers and preservatives</i>
Primary Packing (Multi layered pouch)	PET 12 µm / ALU 9 µm / LDPE 35 µm
Secondary Packing (Box)	
Package dimensions	60x75x3 mm
Special features	<i>Can be used as first aid on minor thermal burns. Suitable as first aid on all skin areas. In case of eye contact rinse with water.</i>

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3. Side effects and malfunction

Side effects and malfunction:

The products are designed for skin contact and first aid use.

If side effects or malfunctions are experienced, please report these to Plum Safety ApS, info@plum.eu or phone +45 6916 9600, so that necessary remedial measures can be initiated.

Reporting of accidents and incidents. Vigilance. Serious incidents involving products made available on the EU market must be reported immediately to the National Competent Authority. All serious incidents must be reported no later than 15 days after discovery, in the event of a serious threat to public health within 2 days. In the event of death or an unexpected and serious deterioration of a person's state of health, reporting must take place within 10 days.

4. Storage

Shelf life:

5 years from production date

5. Other information

Do not reuse



Do not use if package is damaged

**Version history and indication of changes**

Version	Revision date (dd-mm-yyyy)	Responsible	Changes
1.2	14-04-2026	MAW	1.1 + 1.3 + 2
1.1	08-07-2025	MAW	1.3 + 2
1.0	20-06-2022	CL	

Other information

Additional information can be obtained by contacting info@plum.eu or by telephone +45 6916 9600.

TDS prepared by:

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