

CPSDS

CPSDS-0005

Revision: C

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Product: 2nd Skin Moist Pads (Sterile)-MBP

Date: 09/1/15

Product #: 07-SS-104

Catalog Number(s):	4700100	2nd Skin® Moist Burn Pad, 2 X 1 ½
	4703500	2nd Skin® Moist Burn Pad, 2 X 1 ½ International
	4707600	2nd Skin® Moist Burn Pad, 2 X 1 ½ Bulk
	4712200	2nd Skin® Moist Burn Pad, 2 X 1 ½ (25 Pack)
	4701900	2nd Skin® Moist Burn Pad, 2 X 3
	4708400	2nd Skin® Moist Burn Pad, 2 X 3 Canada
	4710000	2nd Skin® Moist Burn Pad, 2 X 3 International
	4706800	2nd Skin® Moist Burn Pad, 2 X 3 Bulk
	4712100	2nd Skin® Moist Burn Pad, 2 X 3 (25 Pack)
	4702700	2nd Skin® Moist Burn Pad, 3 X 4
	4704300	2nd Skin® Moist Burn Pad, 3 X 4 International
	4705000	2nd Skin® Moist Burn Pad, 3 X 4 Bulk
	4712000	2nd Skin® Moist Burn Pad, 3 X 4 (25 Pack)

Document History

Rev	By	Reason	Change #	Date	Reviewed By
A	HW	Initial release of new documentation process	CR-10-10-012	10/26/10	DDC
B	HLM	Updated Logo and Date	CR-14-01-001	01/03/14	Engineering
C	NB	Removing word material to conform to standards	CR 15-09-001	9/1/15	Engineering

Approved by:



Date:

9/3/15

CONTROLLED DOCUMENT

CONFIDENTIAL – This document contains company confidential and/or proprietary information. Do not copy, distribute or otherwise communicate the contents of this document without written express consent of Spenco Medical Corporation.

CONSUMER PRODUCT SAFETY DATA SHEET

This Consumer Product Safety Data Sheet is intended solely for the end-user and/or any agent distributing or selling this product. The product designated in Section I has been commercialized within the United States of America in accordance with the appropriate local, state, and/or federal regulatory agencies. Those individuals that come into contact with any of the components of this product in a manufacturing setting should refer to the Safety Data Sheets (SDS) on file at his/her workplace.

SECTION I:	Product Identification
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Product Name: **2nd Skin Moist Pads (Sterile)**

Catalog Number(s):	4700100	2nd Skin® Moist Burn Pad, 2 X 1 ½
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	4712000	2nd Skin® Moist Burn Pad, 3 X 4 (25 Pack)

Emergency Phone Number (USA): **800-877-3626**

Date Prepared: **September 1, 2015**

SECTION II:	Composition / Ingredients
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Polyethylene oxide CAS # 25322-68-3	5.50%
Methyl paraben CAS # 96-76-3	0.18%
Propyl paraben CAS # 94-13-3	0.05%
Water CAS # 7732-18-5	~94.30%
Nylon scrim	

SECTION III: Intended Use

The 2nd Skin Moist Burn Pads are intended to protect and soothe minor burns.

SECTION IV: Handling & Storage

No special handling or storage conditions are required for these products. Keep the product in a cool, dry environment. Confirm the product has not expired and has not been tampered with or damaged prior to use.

SECTION V: Safety & Biocompatibility

This product is provided sterile.

This product has successfully passed the tripartite requirement for biocompatibility in accordance with ISO 10993. Test reports are maintained on file at Spenco Medical Corp.

Part 5, Cytotoxicity = PASS

Part 10, Irritation = PASS

Part 10, Sensitization = PASS

SECTION VI: Regulatory Information

The United States Food & Drug Administration classifies this product as a Class I device (Product Code NAE) per Code of Federal Regulations (CFR) 878.4022.

The information contained herein is based on available data and is believed to be truthful and accurate. All materials may present unknown hazards and should be used only for its intended purpose.