



medical[®]
leather

a healthy focus on feet

Product Specific Information Document

Product name:	Spenco
Item code:	SP
Barcode:	N/A
CE Marking:	N/A
MDR Risk Classification:	Riskclass I
Product summary:	Spenco
Size / Contents product:	110 x 64 cm
Packaging size:	sheet, cutted shapes
Packaging unit:	per sheet, cutted shapes
Color:	black and taupe
Thickness:	1,6 mm and 3 mm
Shorevalue:	N/A
Implementation:	N/A
Storage advise:	not in direct sunlight
Maintenance advise:	N/A
Sterilisation advise:	N/A
Manufacturing date:	N/A
Shelf life:	N/A

Postbus 95, 5140 AB Waalwijk • Zanddonkweg 6, 5144 NX Waalwijk • The Netherlands
Telefoon +31 (0)416 37 69 87 • **Fax** +31(0)416 37 56 02 • **E-mail** info@medical-leather.nl •
Website www.medical-leather.nl **Rabobank** 1308.95.377 • **BIC Code** RABONL2U • **IBAN nr.** NL63 RABO 0130 8953 77 •
KVK 18124129 • **BTW nr.** NL8145 15 745 B01



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DECLARATION OF CONFORMITY

The undersigned
C.J. Maas – Leder LEFA BV. / Medical Leather
In reference
To the REACH Regulation 1907/2006/CE
Concerning the Registration, Evaluation, Authorization
And the restriction of chemical substances

DECLARES THAT

- Our company purchases and sells foam sheets through the transformation of polymers, mineral fillers, pigments and chemicals. Therefore, as a user, our company is not bound to any registration
- According to the REACH Regulation polymers are exempted from registration (article 2) as well as most of the raw materials used.
- Through the raw material suppliers and sheet suppliers, we were able to ascertain compliance with the REACH legislation. In fact, the chemical manufacturers, where provided, have taken steps as for regular registration.
 - With regard to the presence of hazardous substances (SVHC) mentioned in **the last list published by ECHA on 25/06/2020** we declare that our products, after curing, as supplied by us, has no hint of SVHC in a concentration above the threshold limit of 0.1%..

Pieve del Cairo, 22/07/2020

REACH Responsible
Pieter Maas

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MATERIAL SAFETY DATA SHEET

物质安全数据表

SECTION 1 – PRODUCT AND COMPANY IDENTIFICATION 物品及厂商资料

PRODUCT NAME 物品名称: Neoprene (WH-470)

GENERAL USE 物品应用: Insole

PRODUCT FORMULATION NAME: WH-470

CHEMICAL FAMILY: Polychloroprene/Chloroprene Rubber

MANUFACTURER / DEALER

Medical Leather
Zanddonkweg 6
5144 NX Waalwijk
The Netherlands

24HR. EMERGENCY TELEPHONE NUMBER 紧急联络电话 Same as above

CANUTEC (CANADIAN TRANSPORTATION):

CHEMTREC (US TRANSPORTATION):

EMERGENCY PHONE:

COMMENTS:

SECTION 2 – HAZARDS IDENTIFICATION 危害辨识数据

EMERGENCY OVERVIEW 紧急处理 This product is not expect to cause any emergency effect.

PHYSICAL APPEARANCE: Green Nylon fabric laminate with Neoprene

IMMEDIATE CONCERNS: May cause sensitization by skin contact.

POTENTIAL HEALTH EFFECTS 潜在健康危害效应

EYES: Wash off with water. If skin imitation occurs consult a physician.

SKIN: Wash off with water and soap. If skin imitation occurs consult a physician.

INGESTION: Call a physician immediately.

INHALATION: Move to fresh air and keep victim at rest. Consult a doctor in the event of any complaints.

SECTION 3 – COMPOSITION / INFORMATION ON INGREDIENTS 成分辨识资料

- SINGLE 纯物质

MATERIAL SAFETY DATA SHEET

物质安全数据表

INGREDIENTS: 成份名称	<i>Polychloroprene</i>
SYNONYMS: 同意字	<i>Neoprene</i>
COMICAL ABSTRACTS NUMBER (CAS No.): 化学文摘社登记号码	<i>9010-98-4</i>
PERCENTAGE FOR HAZARD INGREDIENTS: 危害物质成分百分比	<i>The data available do not support any physical or chemical hazard</i>

- MIXING 混合物

HAZARD INGREDIENTS (SPECIFIC) 危害物质成份名称	% 成份百分比	CAS NUMBER 化学文摘社登记号码	WHMIS HAZARD CLASSIFICATION & SYMBOLS 危害物质分类及标示
Neoprene	<90	9010-98-4	
Green Nylon Jersey	<10		
Glue (Solvent type) Toluene	<5	0108-88-3	

SECTION 4 – FIRST AID MEASURES 急救措施

EMERGENCY AND FIRST AID PROCEDURES 不同暴露途径之急救方式

EYES: Wash off with water. If skin irritation occurs consult a physician.

SKIN: Wash off with water and soap. If skin irritation occurs consult a physician.

INGESTION: Call a physician immediately.

INHALATION: Move to fresh air and keep victim at rest. Consult a doctor in the event of any complaints.

SECTION 5 – FIRE FIGHTING MEASURES 灭火措施

FLASHPOINT AND METHOD: Do not apply

FLAMMABLE LIMITS: Do not apply

AUTOIGNITION TEMPERATURE: Do not apply

FLAMMABLE CLASS: Do not apply

FLAME PROPAGATION OR BURNING RATE OF SOLIDS: Do not apply

GENERAL HAZARD 灭火可能遭遇之危害: Do not apply

EXTINGUISHING MEDIA 灭火方式 (适用灭火器): All type of extinguishing agent permitted.

SECTION 6 – ACCIDENTAL RELEASE MEASURES 泄漏处理方法

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SMALL SPILL 轻微泄漏之处理程序: Not Applicable

LARGE SPILL 严重泄漏之处理程序: Not Applicable

ENVIRONMENTAL PRECAUTIONS

WATER SPILL: Not Applicable

LAND SPILL: Not Applicable

SECTION 7 – HANDLING AND STORAGE 安全处置与储存方法**HANDLING PROCEDURES AND EQUIPMENT 处置方法及设备:**

Keep area well ventilated.

STORAGE REQUIREMENTS 储存方法及条件:

Keep in a cooling area.

SECTION 8 – EXPOSURE CONTROL / PERSONAL PROTECTION 暴露预防措施**EXPOSURE GUIDELINES**

OSHA HAZARDOUS COMPONENTS			
		EXPOSURE LIMITS	
		Supplier OEL	
CHEMICAL NAME		ppm	mg / m ³
Toluene	TWA	100	
	STEL	125	

ENGINEERING CONTROLS 特殊工程控制参数: Ventilation Recommended**PERSONAL PROTECTIVE EQUIPMENT 个人防护设**

EYES AND FACE: wear goggle

SKIN: wear rubber gloves

RESPIRATORY: Not applicable

WORK HYGIENIC PRACTICES: Not applicable

COMMENTS:

MATERIAL SAFETY DATA SHEET

物质安全数据表

SECTION 9 – PHYSICAL AND CHEMICAL PROPERTIES 物理及化学性质

PHYSICAL STATE 物质状态: Solid

ODOR 气味: Ester-like, characteristic

COLOR 颜色: Fabric with Green color, Neoprene in Black

SECTION 10 – STABILITY AND REACTIVITY 安定性及反应性

STABLE: Stable under normal conditions

CONDITIONS TO AVOID: Avoid temperature above 200 degree C. Keep away from heat and open flame.

HAZARDOUS DECOMPOSITION PRODUCTS 危害分解物: Not applicable

INCOMPATIBLE MATERIALS 不兼容物质: Not applicable

SECTION 11 – TOXICOLOGICAL INFORMATION 毒性资料

No toxicological information is available on the product, but some is available on the ingredients defined in section 3.

ACUTE 急毒性

EYES: Mildly irritating (human being, 300 ug/3days)

DERMAL LD₅₀:

ORAL LD₅₀: (rat) 450 mg/kg

INHALATION LC₅₀: (rat) 11800 mg/m³

EYE EFFECTS 對眼睛的影響: Mildly irritating (human being)

SKIN EFFECTS 對皮膚的影響: Irritating

CARCINOGENICITY 致癌性分类

IARC 致癌性分类: Classification Group 2 B

NTP:

OSHA:

SECTION 12 – ECOLOGICAL INFORMATION 生态资料

ENVIRONMENTAL DATA:

MATERIAL SAFETY DATA SHEET

物质安全数据表

No ecological information is known on the product

SECTION 13 – DISPOSAL CONSIDERATIONS 废弃处置方法

DISPOSAL METHOD 废弃处置方法:

FOR LARGE SPILLS: Do not apply

PRODUCT DISPOSAL: disposal according to the local legislation

SECTION 14 – TRANSPORT INFORMATION 运送资料

Free for transport regulations

SECTION 15 – REGULATORY INFORMATION 法规资料

National regulations: Questions related to national regulations should be directed toward national officials or the supplier.

SECTION 16 – OTHER INFORMATION 其它资料

REASON FOR ISSUE: The date is issued directly and only for Spenco. Registered Trademark of Spenco Medical Corp.

APPROVED BY: Jimmy Chu

TITLE: Director Manager

PREPARED BY: Medical Leather

INFORMATION CONTACT: Zanddonkweg 6
5144 NX Waalwijk, The Netherlands

REVISION SUMMARY:

MANUFACTURER SUPPLEMENTAL NOTES:

DATA SOURCES:

MANUFACTURER DISCLAIMER: