



medical[®]
leather

a healthy focus on feet

Product Specific Information Document

Product name: PU Diabet
Item code: PU D
Barcode: N/A
CE Marking: N/A
MDR Risk Classification: Riskclass I

Product summary: PU Diabet
Size / Contents product: 1 sqm
Packaging size: Plate, cutted shapes, wheel
Packaging unit: Per plate, cutted shape, wheel
Color: Salmon pink
Thickness: 2, 3, 4 and 6mm
Shorevalue: 5 – 10 ShoreA
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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PRODUCT SAFETY INFORMATION SHEET

1. IDENTIFICATION OF THE SUBSTANCE/PREPARATION AND OF THE COMPANY/UNDERTAKING

TRADE NAME: Poron Medical® Urethanes

CHEMICAL FAMILY: Cellular Polyurethane

HMIS RATING: H 0 F 1 R 0

USE OF ARTICLE: Insulation, Padding

DATE ISSUED: February 15, 2016

COMPANY/UNDERTAKING IDENTIFICATION: Medical Leather
Zanddonkweg 6
5144 NX Waalwijk

2. HAZARDS IDENTIFICATION

CLASSIFICATION OF THE MATERIAL: NE

LABELING REQUIREMENTS: NE

EFFECTS OF OVEREXPOSURE: None are expected with normal handling. Cutting and other finishing operations may create polyurethane dust. If an excessive quantity of dust is inhaled, it may cause nasal and respiratory irritation. Ventilation and personal protection should be similar to all operations generating nuisance dust.

INHALATION: Remove to fresh air-seek medical attention if necessary.

EYE CONTACT: Dust may cause irritation. Safety glasses are recommended in all industrial operations. Flush eyes with water and seek medical attention.

SKIN CONTACT: Wash thoroughly with soap and water.

INGESTION: None known.

CHRONIC: None known.

3. COMPOSITION/INFORMATION ON INGREDIENTS

This material is produced as an "article" as defined in 20 CFR 1910.1200 and REGULATION (EC) N° 1907/2006 is therefore exempt from the Hazard Communication Standard and REACH. Since this material does not release and will not result in exposure to a hazardous chemical under normal conditions of use, no Safety Data Sheet is required.

<u>Chemical Name</u>	<u>CAS No.</u>	<u>EINECS /ELINCS</u>	<u>%</u>	<u>OSHA PEL</u>	<u>ACGIH TLV</u>	<u>China OEL</u>
Polyurethane Foam	9010-69-9	232-723-4	>73	NE	NE	NE
Alumina Trihydrate	21645-51-2	244-492-7	<16	15 mg/m ³	10 mg/m ³ (as al)	NA
Titanium Oxide	13463-67-7	236-675-7	<12	15 mg/m ³ (Total Dust)	10 mg/m ³	NA
Silicon Dioxide	7631-86-9	231-545-4	<1	<u>5 mg/m³</u> (resp.)	3 mg/m ³ (Resp)	NA

4. FIRST-AID MEASURES

INHALATION:	Remove to fresh air. Obtain medical attention if symptoms persist.
EYE CONTACT:	Flush eyes with large amounts of water for 15 to 20 minutes. Obtain medical attention if symptoms persist.
SKIN CONTACT:	Immediately take off all contaminated clothing and flush area with water for 15 to 20 minutes. Obtain medical attention if symptoms persist.
INGESTION:	NA

5. FIRE-FIGHTING MEASURES

FLASH POINT:	NE °C (°F)	Flammable Limits:	LEL	<u>NA</u>	UEL	<u>NA</u>
AUTOIGNITION TEMPERATURE:	NE °C (°F)					
EXTINGUISHING MEDIA:	<u>X</u> Water Spray	<u>X</u> Foam	<u>X</u> CO ₂			
	<u>X</u> Dry Chemical	<u>X</u> Other –				
SPECIAL FIRE FIGHTING PROCEDURES:	Decomposition in a fire may produce toxic fumes. Firefighters should be equipped with self-contained breathing apparatus.					
UNUSUAL FIRE AND EXPLOSION HAZARDS:	May release hazardous vapors during a fire.					

6. ACCIDENTAL RELEASE MEASURES

PERSONAL PRECAUTIONS:	None needed.
ENVIRONMENTAL PRECAUTIONS:	None needed.
CLEANING METHODS:	Sweep or shovel into appropriate container for disposal. Avoid creation of nuisance dust.

7. HANDLING AND STORAGE

HANDLING:	Hot wire cutting operations should be exhausted to prevent exposure to irritating vapors. Wear suitable protective equipment, refer to Section 8.
STORAGE:	Keep in a cool, well-ventilated area.

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

RESPIRATORY PROTECTION:	None needed under normal conditions. If material is heated and odors are noticeable and/or irritating a respirator meeting NIOSH requirements should be used. A qualified individual should evaluate each situation.
<u>VENTILATION</u>	
LOCAL:	Recommended for all industrial operations.
GENERAL:	Recommended for all industrial operations.
<u>PERSONAL PROTECTION</u>	
HAND:	Gloves to avoid skin contact if desired.
EYE:	Safety glasses with side-shields are recommended in all industrial operations
SKIN:	None required.

OTHER:

Safety shower/eyewash in the area.

9. PHYSICAL AND CHEMICAL PROPERTIES

APPEARANCE:	Cellular Urethane Foam Roll or Sheet (Various Colors Available)
ODOR:	Slight, Characteristic
PHYSICAL STATE:	Solid
BOILING POINT:	NA °C (°F)
MELTING POINT:	NE °C (°F)
FREEZING POINT:	NA °C (°F)
FLASH POINT:	NE °C (°F)
WATER SOLUBILITY:	In-Soluble
VAPOR DENSITY:	NA
VAPOR PRESSURE:	NA
SPECIFIC GRAVITY:	0.2-0.53 (Water = 1)
PARTITION COEFFICIENT:	NA
EVAPORATION RATE:	NA
RELATIVE DENSITY:	NA
VISCOSITY:	NA
AUTO-IGNITION TEMPERATURE:	NA °C (°F)
DECOMPOSITION TEMPERATURE:	NA °C (°F)PH:
	NA
FLAMMABILITY:	NA

10. STABILITY AND REACTIVITY

STABLE	<input checked="" type="checkbox"/>	UNSTABLE	<input type="checkbox"/>
CONDITIONS TO AVOID:		Heat, high temperatures.	
MATERIALS TO AVOID:		Acids, bases, and oxidizers.	
HAZARDOUS POLYMERIZATION:	<input type="checkbox"/>	May Occur	<input checked="" type="checkbox"/> Does Not Occur
HAZARDOUS DECOMPOSITION PRODUCTS:		CO, CO ₂ , Oxides of nitrogen, HCN, and traces of incompletely burned carbon compounds.	

11. TOXICOLOGICAL INFORMATION

CARCINOGENIC STATUS: NA

12. ECOLOGICAL INFORMATION

ECOTOXICITY: NA

13. DISPOSAL CONSIDERATION

PHYSICAL/CHEMICAL PROPERTIES AFFECTING DISPOSAL: None

ENVIRONMENTAL TOXICITY DATA: NA
WASTE DISPOSAL METHOD: Dispose of in accordance with applicable federal, state, provincial, and local laws and regulations.

14. TRANSPORT INFORMATION

UN NUMBER: Not Regulated
UN PROPER SHIPPING NAME: Not Regulated
HAZARD CLASS (ES): Not Regulated

PACKING GROUP:
ENVIRONMENTAL HAZARDS:

Not Regulated
NE

15. REGULATORY INFORMATION

INTERNATIONAL REGULATIONS:

Canadian (DSL/NDSL):	Listed
Australian (ACIS):	NE
Korea (KECI):	NE
Japan (ENCS, MITI):	NE
REACH Directive	Material is Classified as an Article
China (SEPA)	Article - exempt
EU Directive 2011/95/EC (RoHS):	Does not contain any intentionally added substances mentioned by the RoHS directive.

European:

Symbol Not classified according to directive 1999/45/EC & 2001/60/EC (dangerous preparations).

TSCA

(Toxic Substances Control Act):

All materials are listed or exempt from TSCA listing.

CERCLA

NA

(Comprehensive Emergency Response, Compensation, and Liability Act):

SARA TITLE III

NA

(Superfund Amendments and Reauthorization Act):

311/312 HAZARD CATEGORIES: None

This product contains the following toxic chemicals subject to the reporting requirements of Section 313 of the Emergency Planning and Community Right-To-Know Act of 1986 and 40 CFR 372:

CAS #
3264-82-2

CHEMICAL NAME
Nickel Compound

PERCENT BY WEIGHT
<2

16. OTHER INFORMATION

NA = Not Applicable
NE = Not Established
NC = Not Classified

FILE: 99176-Poron Medical UrethanesPSI-02152016.doc

PREPARED BY: Michal Werbecki

REVIEWED BY: Curtis Kempton

Date Prepared: 02/15/2016

THE INFORMATION CONTAINED HEREIN IS BASED ON DATA CONSIDERED ACCURATE. HOWEVER, NO WARRANTY IS EXPRESSED OR IMPLIED REGARDING THE ACCURACY OF THESE DATA OR THE RESULT TO BE OBTAINED FROM THE USE THEREOF.

ROGERS CORPORATION ASSUMES NO RESPONSIBILITY FOR PERSONAL INJURY OR PROPERTY DAMAGE TO VENDEES, USERS OR THIRD PARTIES CAUSED BY THE MATERIAL. SUCH VENDEES OR USERS ASSUME ALL RISKS ASSOCIATED WITH THE USE OF THE MATERIAL.

Medical Leather
Zanddonkweg 6
5144 NX Waalwijk
The Netherlands

Certificate of Analysis

Report Date: 3/9/2021
Mfg Date: 2/16/2021
Cure Date: 2/18/2021
Shelf Life: 5 years from Mfg Date

Lot Number: 421021601
Product Description: PU Diabet
Part Number: 2305990

Property	Measured	Specification
Density (pcf)	19.9	18 - 22
Tensile (psi)	73.7	Min of 65
Elongation (%)	121.8	Min of 100
CLD - Lab (psi)	13.1	6 - 14
70 Cset (%)	1.1	Max of 10

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PORON Medical® Urethanes – Slow Recovery
Typical Physical Properties

PROPERTY	TEST METHOD	PRODUCT			
		PORON MSRVS (Very Soft)	PORON MSRS (Soft)	PORON MSRF (Firm)	PORON MSRVF (Very Firm)
Formulation					
Density, kg/m ³ (lb. / ft ³)	ASTM D 3574-95 Test A	15 (240)			
Specific Gravity		0.24			
Tolerance, %		+/- 10			
Standard Thickness		See Product Availability			
Tolerance, %		+/- 10			
Standard Width, mm (inch)		1372 (54)			
Standard Color (Code)		Sea Mist (73)	Light Jade (71)	Patina (79)	Dark Jade (80)
Air Permeability	Gurley Densometer	Open-Cell – Breathable			
Compression Set, % max.	ASTM D 3574 Test D @ 70°C (158°F)	10			
Compression Force Deflection, psi, (kPa)	0.2"/min. Strain Rate Force Measured @ 25% Deflection	0.3 - 3.5 (2 - 24)	1.5 - 6.5 (10 - 45)	3 - 18 (21 - 124)	4 - 22 (27 - 151)
Hardness, Durometer	Shore "O"	12	18	22	30
Hydrolysis Resistance, Compression Set, % max	ASTM D 3574 Test J / Test D after autoclaved 5 hrs @ 121°C (250°F)	Good Resistance 5			
Resilience, Shore Instrument Resiliometer, avg (Ball Rebound Tester)	ASTM D 2632-92, Vertical Rebound	4	4	7	8
Water Vapor Transfer, Typical g/m²/24hrs (g/ft²/24hrs)	Based on ASTM E 96-00	400 (> 37)			
Water Absorption, Typical % weight gain	Based on ASTM D 570	< 30%			
Antimicrobial, Fungal Resistance	ASTM G 21	Does not promote fungal growth.			
Skin Contact Primary Skin Irritation	ISO10993-10, 2010	Pass			
Tear Strength, pli, min. (kN/m)	ASTM D 624 Die C	4 (0.7)	5 (0.9)	10 (1.7)	12 (2.1)
Tensile Elongation, % min.	ASTM D 3574 Test E	120		100	
Tensile Strength, psi, min. (kPa)	ASTM D 3574 Test E	15 (104)	40 (276)	80 (552)	100 (689)
Temperature Resistance, max. Recommended Constant Use Recommended Intermittent Use	ASTM D 746-98	70°C (158°F) 121°C (250°F)			
Chemical Resistance		PORON® Urethanes are unaffected by mild organic acids and bases. They show modest swelling with oils and greases and other linear hydrocarbons. Strongly polar solvents will greatly swell PORON Urethanes. In most cases, physical properties recover to a great extent as the solvents evaporate.			

Notes:

1. Typical values are a representation of an average value for the population of the property. For specific information values, contact Rogers Corporation.
2. All metric conversions are approximate.
3. Additional technical services are available.

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