



medical[®]
leather

a healthy focus on feet

Product Specific Information Document

Product name:	Poron Medical
Item code:	PP
Barcode:	N/A
CE Marking:	N/A
MDR Risk Classification:	Riskclass I

Product summary:	Poron Medical
Size / Contents product:	1 sqm, 11,5cm x 12,5 m
Packaging size:	plate, cutted shapes, wheel
Packaging unit:	per plate
Color:	beige
Thickness:	1,5, 3,0, 4,75, 6,4 en 9,5 mm
Shorevalue:	15 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

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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



medical
leather®

a healthy focus on feet

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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Test Report

No. SHAEC1714582301

Date: 14 Jul 2017

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Medical Leather

Zanddonkweg 6, 5144 NX Waalwijk, The Netherlands

The following sample(s) was/were submitted and identified on behalf of the clients as : 4790-79TS5B-xxxxx-04
SGS Job No. : SP17-024391 - SUZ

Date of Sample Received : 10 Jul 2017

Testing Period : 10 Jul 2017 - 14 Jul 2017

Test Requested : Selected test(s) as requested by client.

Test Method : Please refer to next page(s).

Test Results : Please refer to next page(s).

Signed for and on behalf of
SGS-CSTC Standards Technical Services (Shanghai) Co., Ltd.

Marry Ma

Marry Ma

Approved Signatory



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Test Report

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Test Results :

Test Part Description :

Specimen No.	SGS Sample ID	Description
SN1	SHA17-145823.001	Black foam with adhesive+transparent PET

Remarks :

- (1) 1 mg/kg = 0.0001%
- (2) MDL = Method Detection Limit
- (3) ND = Not Detected (< MDL)
- (4) "-" = Not Regulated

RoHS Directive (EU) 2015/863 amending Annex II to Directive 2011/65/EU

- Test Method :
- (1) With reference to IEC 62321-5:2013, determination of Cadmium by ICP-OES.
 - (2) With reference to IEC 62321-5:2013, determination of Lead by ICP-OES.
 - (3) With reference to IEC 62321-4:2013, determination of Mercury by ICP-OES.
 - (4) With reference to IEC 62321-7-2:2017, determination of Hexavalent Chromium by Colorimetric Method using UV-Vis and/or with reference to IEC 62321-5:2013, determination of Chromium by ICP-OES.
 - (5) With reference to IEC 62321-6:2015, determination of PBBs and PBDEs by GC-MS.
 - (6) With reference to EN 14372:2004, determination of phthalates by GC-MS.

Test Item(s)	Limit	Unit	MDL	001
Cadmium (Cd)	100	mg/kg	2	ND
Lead (Pb)	1000	mg/kg	2	ND
Mercury (Hg)	1000	mg/kg	2	ND
Hexavalent Chromium (Cr(VI))	1000	mg/kg	8	ND
Sum of PBBs	1000	mg/kg	-	ND
Monobromobiphenyl	-	mg/kg	5	ND
Dibromobiphenyl	-	mg/kg	5	ND
Tribromobiphenyl	-	mg/kg	5	ND
Tetrabromobiphenyl	-	mg/kg	5	ND
Pentabromobiphenyl	-	mg/kg	5	ND
Hexabromobiphenyl	-	mg/kg	5	ND
Heptabromobiphenyl	-	mg/kg	5	ND
Octabromobiphenyl	-	mg/kg	5	ND
Nonabromobiphenyl	-	mg/kg	5	ND
Decabromobiphenyl	-	mg/kg	5	ND



SGS-CSTC (Shanghai) Technical Service (Shanghai) Co., Ltd.
Testing Center-Chemical Laboratory

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Test Item(s)	Limit	Unit	MDL	001
Sum of PBDEs	1000	mg/kg	-	ND
Monobromodiphenyl ether	-	mg/kg	5	ND
Dibromodiphenyl ether	-	mg/kg	5	ND
Tribromodiphenyl ether	-	mg/kg	5	ND
Tetrabromodiphenyl ether	-	mg/kg	5	ND
Pentabromodiphenyl ether	-	mg/kg	5	ND
Hexabromodiphenyl ether	-	mg/kg	5	ND
Heptabromodiphenyl ether	-	mg/kg	5	ND
Octabromodiphenyl ether	-	mg/kg	5	ND
Nonabromodiphenyl ether	-	mg/kg	5	ND
Decabromodiphenyl ether	-	mg/kg	5	ND
Di-butyl Phthalate (DBP)	1000	mg/kg	30	ND
Benzyl Butyl Phthalate (BBP)	1000	mg/kg	30	ND
Di-2-Ethyl Hexyl Phthalate (DEHP)	1000	mg/kg	30	ND
Diisobutyl Phthalates (DIBP)	1000	mg/kg	30	ND

Notes :

(1) The maximum permissible limit is quoted from RoHS Directive (EU) 2015/863.

IEC 62321 series is equivalent to EN 62321 series.
 (2) The test of Hexavalent Chromium (Cr(VI)) is deemed to be "ND" since the result of total chromium content of Chromium (Cr) content is greater than the MDL of Hexavalent Chromium (Cr(VI)), confirmation test of Hexavalent Chromium (Cr(VI)) is not required.
 The European Union (EU) Commission Directive (EU) 2015/863 was published in the Official Journal of the European Union (OJEU) to include the phthalates BBP, DBP, DEHP and DIBP into Annex X of the RoHS Directive (EU) 2011/65. The new law restricts each phthalate to no more than 0.1% in each homogeneous material of electronic equipment.
 The restriction of DEHP, BBP, DBP and DIBP shall apply to medical devices, including in vitro medical devices, and monitoring and control instruments, including industrial monitoring and control instruments, placed on the market before 22 July 2019, and of medical devices, including in vitro medical devices, and monitoring and control instruments, including industrial monitoring and control instruments, placed on the market before 22 July 2019.
 The restriction of DEHP, BBP and DBP shall not apply to toys which are already subject to the restriction of DEHP, BBP and DBP through entry 51 of Annex XVII to Regulation (EC) No 1907/2006.

Halogen



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Test Method : With reference to EN 14582: 2007, analysis was performed by Ion Chromatograph (IC).

<u>Test Item(s)</u>	<u>Unit</u>	<u>MDL</u>	<u>001</u>
Fluorine (F)	mg/kg	50	ND
Chlorine (Cl)	mg/kg	50	ND
Bromine (Br)	mg/kg	50	ND
Iodine (I)	mg/kg	50	ND

Remark: Test was conducted on composite of random parts of the item as per client's request and the test result is the overall result.



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Test Report ATTACHMENTS

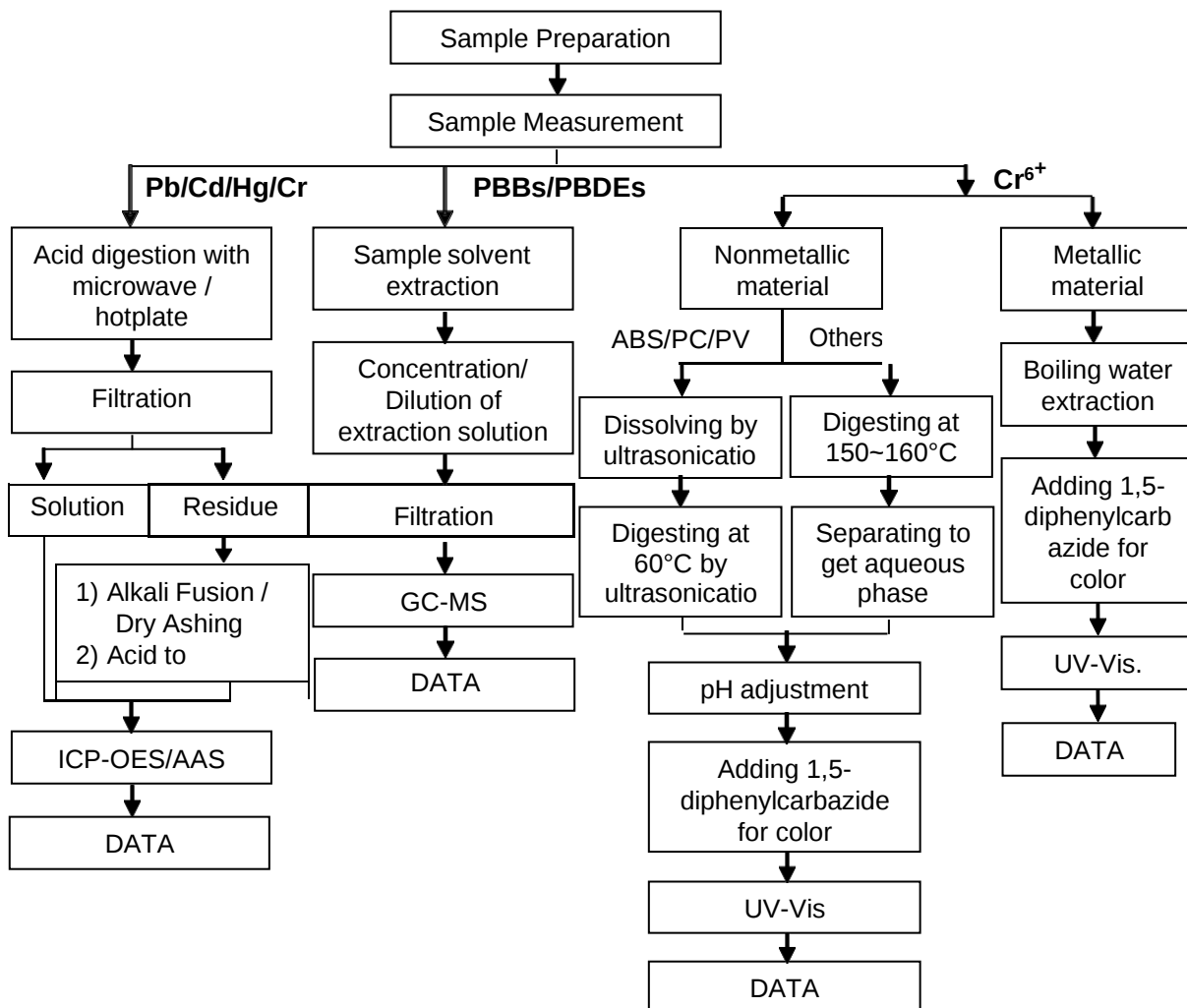
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Pb/Cd/Hg/Cr⁶⁺/PBBs/PBDEs Testing Flow Chart

- 1) Name of the person who made testing: Meria Jin/Gary Xu/Sean Li/Sielina Song
- 2) Name of the person in charge of testing: Jan Shi/Jessy Huang/Luna Xu/Shara Wang
- 3) These samples were dissolved totally by pre-conditioning method according to below flow chart.
(Cr⁶⁺ and PBBs/PBDEs test method excluded)



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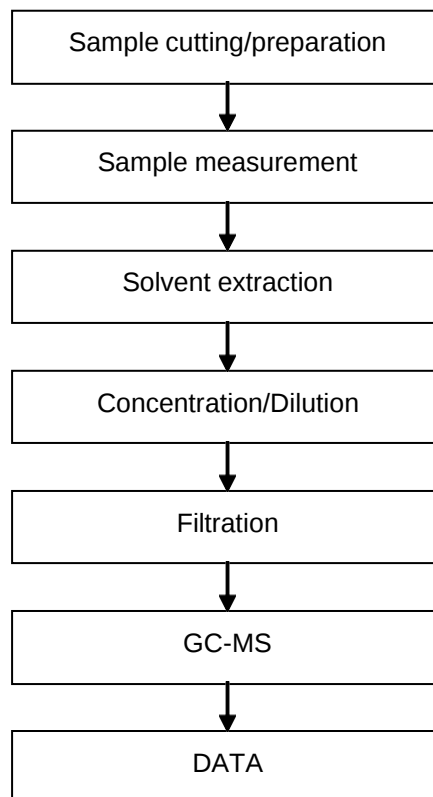
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Phthalates Testing Flow Chart

- 1) Name of the person who made testing: Sherlock Gao
- 2) Name of the person in charge of testing: Jessy Huang



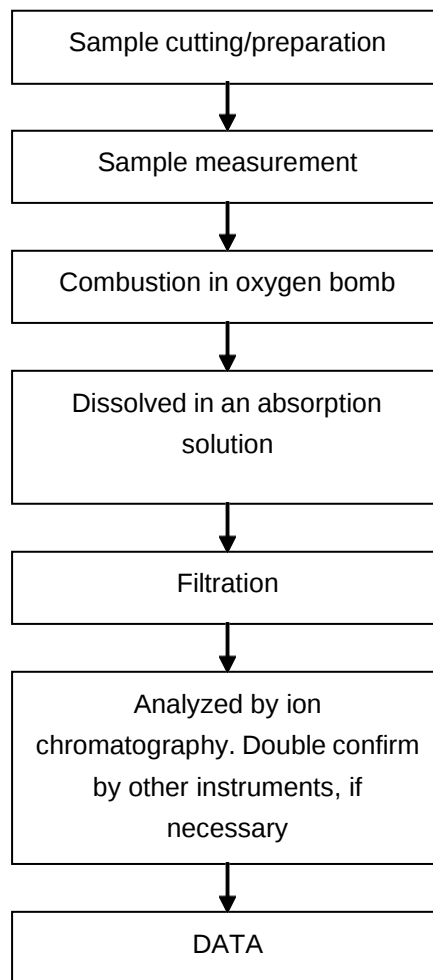
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Halogen Testing (oxygen bomb) Flow Chart

- 1) Name of the person who made testing: Kevin Xu
- 2) Name of the person in charge of testing: Sisily Yin



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Sample photo:



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Typical Product Properties

PORON® 4790-79RL-15006,15008-04PBLK - Data Sheet - Preliminary

Foam	PROPERTY	TEST METHOD	VALUE	
	Description		79RL-15006	79RL-15008
	Density, kg/m ³ (lb./ft ³)	ASTM D 3574-95 Test A	240 (15)	
	Tolerance		± 10%	
	Thickness, mm (PET + foam) (inches)	With digital tester (ONO SOKKI)	0.15 (0.006)	0.20 (0.008)
	Tolerance		± 15%	± 15%
	Standard Color (Code)		Black (04)	
	Compression Force Deflection, Kpa (psi)	Modified ASTM D 3574: PTP-0033	13.7~41.3 2~6	

Release PET	PROPERTY	TEST METHOD	VALUE
	PHYSICAL		
	Thickness, mm		0.05
	Release force, g/in	Trade Standard	15
	Breaking Strength, Mpa	GB/T1040.3-2006: MD, TD	≥150
	Elongation, %	GB/T1040.3-2006: MD, TD	≤200
	Shelf life, month	From date of Manufacture	10

MATERIAALVEILIGHEIDSGEINFORMATIEBLAD ("MSDS")

1. IDENTIFICATIE VAN DE SUBSTANTIE/HET PREPARAAT EN VAN HET BEDRIJF/DE ORGANISATIE

HANDELSNAAM: Poron Medical® Urethanen
CHEMISCHE FAMILIE: Cellulaire polyurethaan
HMIS BEOORDELING: H 0 F 1 R 0
PRODUCT GEBRUIKT VOOR: Isolatie, opvulling
UITGIFTEDATUM: 15 februari 2016
BEDRIJFS-/ORGANISATIE-IDENTIFICATIE: Medical Leather
Zanddonkweg 6
5144 NX Waalwijk
The Netherlands

2. GEVARENIDENTIFICATIE

CLASSIFICATIE VAN HET PRODUCT NV

PRODUCT

LABELINGVEREISTEN NV

OVERMATIGE BLOOTSTELLINGSEFFECTEN: Geen verwacht bij normale hantering. Snijden en andere finishing werkzaamheden kunnen polyurethaanstof veroorzaken. Indien een overmatige hoeveelheid stof wordt geïnhaleerd, kan dit irritatie van de neus en ademhalingswegen veroorzaken. De ventilatie en persoonlijke beschermingsuitrusting moeten dezelfde zijn voor alle werkzaamheden die stofoverlast veroorzaken.

INHALATIE: In de frisse lucht brengen; indien noodzakelijk medische hulp inroepen.

OOGCONTACT: Stof kan irritatie veroorzaken. Voor alle industriële werkzaamheden wordt een veiligheidsbril aanbevolen. Spoel de ogen met water en roep medische hulp in.

HUDCONTACT: Grondig met water en zeep wassen.

INGESTIE: Geen bekend.

CHRONISCH: Geen bekend.

3. SAMENSTELLING VAN/INFORMATIE OVER DE INGREDIËNTEN

Dit materiaal wordt vervaardigd als een "artikel" zoals gedefinieerd in 20 CFR 1910.1200 en REGLEMENTERING (EC) No. 1907/2006, en is om die reden vrijgesteld van de Hazard Communication Standard (*Norm m.b.t. gevarencommunicatie*) en van REACH. Aangezien dit materiaal niet wordt vrijgezet en onder normale gebruikscondities geen blootstelling aan een gevaarlijke chemische stof tot gevolg heeft, is geen Veiligheidsinformatieblad vereist.

<u>Chemische naam</u>	<u>CAS-nr.</u>	<u>EINECS /ELINCS</u>	<u>%</u>	<u>OSHA PEL</u>	<u>ACGIH TLV</u>	<u>China OEL</u>
Polyurethaanschuim	9010-69-9	232-723-4	>73	NV	NV	NV
Aluminiumtrihydraat	21645-51-2	244-492-7	<16	15 mg/m ³	10 mg/m ³ (as al)	N.v.t.
Titaanoxide	13463-67-7	236-675-7	<12	15 mg/m ³ (totale stof)	10 mg/m ³	N.v.t.
Siliciumdioxide	7631-86-9	231-545-4	<1	<u>5 mg/m³</u> (resp.)	3 mg/m ³ (Resp.)	N.v.t.

VENTILATIE

PLAATSELIJK:

Aanbevolen bij alle industriële werkzaamheden.

ALGEMEEN:

Aanbevolen bij alle industriële werkzaamheden.

PERSOONLIJKE BESCHERMING

HANDEN:

Indien gewenst handschoenen dragen om huidcontact te vermijden.

OGEN

Veiligheidsbril met zijbescherming wordt aanbevolen voor alle industriële werkzaamheden.

HUID:

Geen vereist.

ANDERE:

Veiligheidsdouche/oogwasinstallatie in het gebied.

9. FYSIEKE EN CHEMISCHE EIGENSCHAPPEN

VOORKOMEN:

Cellulaire urethaan-schuimrol of -blad (leverbaar in verschillende kleuren).

GEUR:

Licht, karakteristiek

FYSIEKE STAAT:

Vast

KOOKPUNT:

N.v.t. °C (°F)

SMELTPUNT:

N.v. °C (°F)

VRIESPUNT:

N.v.t. °C (°F)

VLAMPUNT

N.v. °C (°F)

OPLOSBAARHEID IN WATER:

Niet oplosbaar

DAMPDICHTHEID

N.v.t.

DAMPDRUK:

N.v.t.

SPECIFIEKE ZWAARTEKRACHT

0.2 – 0.53 (water = 1)

VERDELINGSCOËFFICIËNT:

N.v.t.

VERDAMPINGSSNELHEID:

N.v.t.

RELATIEVE DICHTHEID:

N.v.t.

VISCOSITEIT:

N.v.t.

ZELFONTSTEKINGSTEMPERATUUR:

N.v.t. °C (°F)

DECOMPOSITIETEMPERATUUR:

N.v.t. °C (°F)

PH:

N.v.t.

ONTVLAMBAARHEID:

N.v.t.

10. STABILITEIT EN REACTIVITEIT

STABIEL ☒

ONSTABIEL ☐

TE VERMIJDEN CONDITIES:

Hitte, hoge temperaturen

TE VERMIJDEN MATERIALEN:

Zuren, basen en oxidatiemiddelen

GEVAARLIJKE POLYMERISATIE:

☐ kan voorkomen ☒ komt niet voor

GEVAARLIJKE DECOMPOSITIE-

PRODUCTEN:

CO, CO₂, stikstofoxides, HCN en sporen van onvolledig verbrande koolstofverbindingen.

11. TOXICOLOGISCHE INFORMATIE

CARCINOGEENSTATUS:

N.v.t.

12. ECOLOGISCHE INFORMATIE

ECOTOXICITEIT

N.v.t.

13. AFVOEROVERWEGINGEN

FYSIEKE/CHEMISCHE EIGENSCHAPPEN: Geen

AFVOERIMPACT:

MILIEU-TOXICITEITSINFORMATIE:

N.v.t.

AFVALVERWIJDERINGSMETHODE:

Afvoeren volgens de toepasselijke landelijke, provinciale en lokale wetten en wettelijke voorschriften.

14. TRANSPORTINFORMATIE

VN NUMMER:	Niet gereguleerd
JUISTE VN-VERZENDNAAM:	Niet gereguleerd
GEVARENKLASSE(N):	Niet gereguleerd
VERPAKKINGSGROEP	Niet gereguleerd
GEVAREN VOOR HET MILIEU:	NV

15. WETTELIJKE VOORSCHRIFTENINFORMATIE

INTERNATIONALE VOORSCHRIFTEN:

Canada (DSL/NDL):	Vermeld
Australië (ACIS):	NV
Korea (KECI):	NV
Japan (ENCS, MITI):	NV
REACH Richtlijn	Het product is geclassificeerd als een artikel
China (SEPA)	Artikel - Vrijgesteld
EU Richtlijn 2011/95/EC (RoHS):	Bevat geen opzettelijk toegevoegde stoffen zoals vermeld in de RoHS-richtlijn.
Europees: Symbool	Niet geclassificeerd volgens Richtlijn 1999/45/EC en 2001/60/EC (gevaarlijke preparaten).
TSCA (Toxic Substances Control Act) (Wet Giftige stoffencontrole):	
CERCLA (Comprehensive Emergency Response, Compensation, and Liability Act): (Wet op Globale respons in noodgevallen, compensatie en aansprakelijkheid):	N.v.t.
SARA TITLE III (Superfund Amendments and Reauthorization Act) (Wet Superfund- wijzigingen en herautorisaties):	N.v.t.
311/312 GEVARENCATEGORIEËN:	Geen

Dit product bevat de volgende giftige chemicaliën die onderhevig zijn aan de rapporteringseisen van sectie 313 van de Emergency Planning and Community Right-To-Know Act (Wet Planning in noodgevallen en Recht-op-informatie van de gemeenschap) van 1986 en 40 CFR 372:

CAS-NR.
3264-82-2

CHEMISCHE NAAM
Nikkelcompound

PERCENTAGE BIJ GEWICHT
<2

16. OVERIGE INFORMATIE

NVT = Niet van toepassing
NV = Niet vastgesteld
NG = Niet geclassificeerd

BESTAND: 99176-Poron Medical UrethanesPSI-02152016.doc

SAMENGESTELD DOOR: Michal Werbecki
GECONTROLEERD DOOR: Curtis Kempton

Preparatiedatum: 15/02/2016

DE HIERIN BEVATTE INFORMATIE IS GEBASEERD OP INFORMATIE DIE GEACHT WORDT JUIST TE ZIJN. ER WORDT ECHTER GEEN UITDRUKKELIJKE OF GEÏMPliceERDE GARANTIE GEGEVEN MET BETREKKING TOT DE NAUWKEURIGHEID VAN DEZE INFORMATIE OF TOT DE TE BEHALEN RESULTATEN DOOR HET GEBRUIK ERVAN.

MEDICAL LEATHER AANVAARDT GEEN VERANTWOORDELIJKHEID VOOR DOOR HET MATERIAAL VEROORZAAKT PERSOONLIJK LETSEL OF VEROORZAAKTE EIGENDOMSCHADE AAN KOPERS, GEBRUIKERS OF DERDEN. DIE KOPERS OF GEBRUIKERS AANVAARDEN ALLE MET HET MATERIAAL IN VERBAND STAANDE RISICO'S.