



medical[®]
leather

a healthy focus on feet

Product Specific Information Document

Product name:	Poron XRD
Item code:	PP XRD
Barcode:	N/A
CE Marking:	N/A
MDR Risk Classification:	Riskclass I
Product summary:	Poron XRD
Size / Contents product:	1 sqm
Packaging size:	plate, cutted shapes
Packaging unit:	per plate
Color:	yellow
Thickness:	2, 3 en 4 mm
Shorevalue:	5-7 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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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

TEST REPORT

Medical Leather

Zanddonkweg 6, 5144 NX Waalwijk

REPORT NO.KE/2019/11326

DATE: 2019/01/17

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THE FOLLOWING SAMPLE(S) WAS/WERE SUBMITTED AND IDENTIFIED BY/ON BEHALF OF THE CLIENT AS :

SAMPLE DESCRIPTION : XRDMA-XXXXX-65.
COLOR : VIVID YELLOW.
MATERIAL COMPOSITION : POLYURETHANE FOAM.
COUNTRY OF ORIGIN : USA.
COUNTRY OF DESTINATION : USA.
PO : 1700010269.
SAMPLE RECEIVED : 2019/01/11.
TESTING PERIOD : 2019/01/11 TO 2019/01/17.
SAMPLE SUBMITTED BY : Medical Leather

TEST REQUESTED : (1) AS SPECIFIED BY CLIENT, WITH REFERENCE TO RoHS 2011/65/EU ANNEX II AND AMENDING DIRECTIVE (EU) 2015/863 TO DETERMINE CADMIUM, LEAD, MERCURY, CR(VI), PBBs, PBDEs, DBP, BBP, DEHP, DIBP CONTENTS IN THE SUBMITTED SAMPLE(S).
(2) PLEASE REFER TO NEXT PAGES FOR THE OTHER ITEM(S).

TEST RESULT(S) : PLEASE REFER TO NEXT PAGE(S).


Ray Chang Ph.D. / Manager Tech
Signed for and on behalf of
SGS Taiwan Limited
Chemical Laboratory-Kaohsiung



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TEST RESULT(S) :

TEST ITEM(S)	UNIT	METHOD	MDL	RESULT
CADMIUM (Cd)	ppm	WITH REFERENCE TO IEC 62321-5:2013 AND PERFORMED BY ICP-OES.	2	n.d.
MERCURY (Hg)	ppm	WITH REFERENCE TO IEC 62321-4:2013 AND PERFORMED BY ICP-OES.	2	n.d.
LEAD (Pb)	ppm	WITH REFERENCE TO IEC 62321-5:2013 AND PERFORMED BY ICP-OES.	2	n.d.
CHROMIUM VI	ppm	WITH REFERENCE TO IEC 62321-7-2:2017 AND PERFORMED BY UV-VIS.	8	n.d.
POLYBROMINATED BIPHENYL	---	---	---	---
MONOBROMOBIPHENYL	ppm	WITH REFERENCE TO IEC 62321-6: 2015 AND PERFORMED BY GC/MS.	5	n.d.
DIBROMOBIPHENYL	ppm	WITH REFERENCE TO IEC 62321-6: 2015 AND PERFORMED BY GC/MS.	5	n.d.
TRIBROMOBIPHENYL	ppm	WITH REFERENCE TO IEC 62321-6: 2015 AND PERFORMED BY GC/MS.	5	n.d.
TETRABROMOBIPHENYL	ppm	WITH REFERENCE TO IEC 62321-6: 2015 AND PERFORMED BY GC/MS.	5	n.d.
PENTABROMOBIPHENYL	ppm	WITH REFERENCE TO IEC 62321-6: 2015 AND PERFORMED BY GC/MS.	5	n.d.
HEXABROMOBIPHENYL	ppm	WITH REFERENCE TO IEC 62321-6: 2015 AND PERFORMED BY GC/MS.	5	n.d.

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TEST ITEM(S)	UNIT	METHOD	MDL	RESULT
HEPTABROMOBIPHENYL	ppm	WITH REFERENCE TO IEC 62321-6: 2015 AND PERFORMED BY GC/MS.	5	n.d.
OCTABROMOBIPHENYL	ppm	WITH REFERENCE TO IEC 62321-6: 2015 AND PERFORMED BY GC/MS.	5	n.d.
NONABROMOBIPHENYL	ppm	WITH REFERENCE TO IEC 62321-6: 2015 AND PERFORMED BY GC/MS.	5	n.d.
DECABROMOBIPHENYL	ppm	WITH REFERENCE TO IEC 62321-6: 2015 AND PERFORMED BY GC/MS.	5	n.d.
SUM OF PBBs	ppm	---	---	n.d.
POLYBROMINTED BIPHENYL ETHERS (PBDEs)	---	---	---	---
MONOBROMODIPHENYL ETHER	ppm	WITH REFERENCE TO IEC 62321-6: 2015 AND PERFORMED BY GC/MS.	5	n.d.
DIBROMODIPHENYL ETHER	ppm	WITH REFERENCE TO IEC 62321-6: 2015 AND PERFORMED BY GC/MS.	5	n.d.
TRIBROMODIPHENYL ETHER	ppm	WITH REFERENCE TO IEC 62321-6: 2015 AND PERFORMED BY GC/MS.	5	n.d.
TETRABROMODIPHENYL ETHER	ppm	WITH REFERENCE TO IEC 62321-6: 2015 AND PERFORMED BY GC/MS.	5	n.d.
PENTABROMODIPHENYL ETHER	ppm	WITH REFERENCE TO IEC 62321-6: 2015 AND PERFORMED BY GC/MS.	5	n.d.
HEXABROMODIPHENYL ETHER	ppm	WITH REFERENCE TO IEC 62321-6: 2015 AND PERFORMED BY GC/MS.	5	n.d.
HEPTABROMODIPHENYL ETHER	ppm	WITH REFERENCE TO IEC 62321-6: 2015 AND PERFORMED BY GC/MS.	5	n.d.

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TEST ITEM(S)	UNIT	METHOD	MDL	RESULT
OCTABROMODIPHENYL ETHER	ppm	WITH REFERENCE TO IEC 62321-6: 2015 AND PERFORMED BY GC/MS.	5	n.d.
NONABROMODIPHENYL ETHER	ppm	WITH REFERENCE TO IEC 62321-6: 2015 AND PERFORMED BY GC/MS.	5	n.d.
DECABROMODIPHENYL ETHER	ppm	WITH REFERENCE TO IEC 62321-6: 2015 AND PERFORMED BY GC/MS.	5	n.d.
SUM OF PBDEs	ppm	---	---	n.d.
PHTHALATES	---	---	---	---
DI-ISOBUTYL PHTHALATE (DIBP) (CAS NO.84-69-5)	ppm	WITH REFERENCE TO IEC 62321-8:2017. ANALYSIS WAS PERFORMED BY GC/MS.	50	n.d.
DIBUTYL PHTHALATE (DBP) (CAS NO.84-74-2)	ppm	WITH REFERENCE TO IEC 62321-8:2017. ANALYSIS WAS PERFORMED BY GC/MS.	50	n.d.
BUTYL BENZYL PHTHALATE (BBP) (CAS NO.85-68-7)	ppm	WITH REFERENCE TO IEC 62321-8:2017. ANALYSIS WAS PERFORMED BY GC/MS.	50	n.d.
BIS(2-ETHYLHEXYL) PHTHALATE (DEHP) (CAS NO.117-81-7)	ppm	WITH REFERENCE TO IEC 62321-8:2017. ANALYSIS WAS PERFORMED BY GC/MS.	50	n.d.
DI ISONONYL PHTHALATE (DINP) (CAS NO.28553-12-0/68515-48-0)	ppm	WITH REFERENCE TO IEC 62321-8:2017. ANALYSIS WAS PERFORMED BY GC/MS.	50	n.d.
DI-ISO-DECYL PHTHALATE (DIDP) (CAS NO.26761-40-0/68515-49-1)	ppm	WITH REFERENCE TO IEC 62321-8:2017. ANALYSIS WAS PERFORMED BY GC/MS.	50	n.d.
DI-N-OCTYL PHTHALATE (DNOP) (CAS NO.117-84-0)	ppm	WITH REFERENCE TO IEC 62321-8:2017. ANALYSIS WAS PERFORMED BY GC/MS.	50	n.d.

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TEST ITEM(S)	UNIT	METHOD	MDL	RESULT
HALOGEN (F, Cl, Br, I) CONTENT	---	---	---	---
HALOGEN-FLUORINE (F) (CAS No.: 14762-94-8)	ppm	WITH REFERENCE TO BS EN 14582:2016. ANALYSIS WAS PERFORMED BY IC.	50	n.d.
HALOGEN-CHLORINE (Cl) (CAS No.: 22537-15-1)	ppm	WITH REFERENCE TO BS EN 14582:2016. ANALYSIS WAS PERFORMED BY IC.	50	450
HALOGEN-BROMINE (Br) (CAS No.: 10097-32.2)	ppm	WITH REFERENCE TO BS EN 14582:2016. ANALYSIS WAS PERFORMED BY IC.	50	n.d.
HALOGEN-IODINE (I) (CAS No.: 14362-44-8)	ppm	WITH REFERENCE TO BS EN 14582:2016. ANALYSIS WAS PERFORMED BY IC.	50	n.d.

NOTE 1 : mg/kg=ppm

NOTE 2 : MDL = METHOD DETECTION LIMIT.

NOTE 3 : n.d. = NOT DETECTED.

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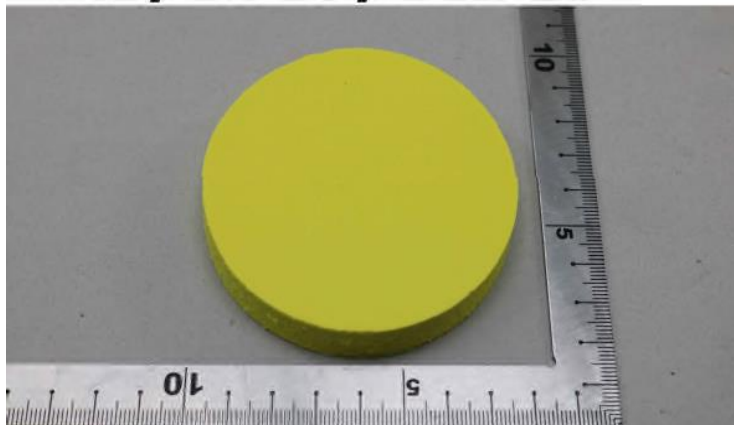
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SAMPLE PHOTO

(The tested sample / part is marked by an arrow if it's shown on the photo.)

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** END OF REPORT **

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