

ULR-TC659821000003269F

Test Report No.RPT/T(L)/21/003059

Dated 2021-03-15



TC-6598



South Asia



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South Asia

Applicant : **Medical Leather**
Zanddonkweg 6
5144 NX Waalwijk
The Netherlands

Attention : Mr.Asrar Ahmed,

Test Sample : Received on 2021-03-09 1:26 pm

Test Period : 2021-03-10 to 2021-03-15

Sample Description : Sample A:BUFF CALF LEATHER in Color : ROVERO K-123

Style Name : **Kongo - Gironde - Indus - Lena**

Name of Buyer/ Destination : **Self Reference**

Note : The submitted Samples were not drawn by laboratory.

Unless otherwise agreed upon, PASS or FAIL verdicts are given based on the measured values without any considerations of measurement uncertainties. Every test method has a measurement uncertainty which has been evaluated by the laboratory and are available on request. By taking measurement uncertainties into account it might happen that measured values can neither be assessed as PASS nor as FAIL

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Note: The test report is electronically generated. Hence original signature is not required.

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Laboratory:
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Mumbai-400072. India

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Purpose of Examination / Conclusion

Test	Results
Dimethylfumarate (DMFu)	Refer Result
Chlorinated Phenol	Refer Result
Free Formaldehyde	Refer Result
Extractable Heavy Metals	Refer Result
Total Cadmium Content	Refer Result
Total Lead Content	Refer Result
Detection of Banned Amines	Refer Result
Alkylphenol Ethoxylates	Refer Result
Chrome VI (After Ageing)	Refer Result
Total Mercury	Refer Result

Authorised By

C. Arun
(Authorised Signatory)

Please contact :

For any technical issues : R Mahalakshmi at Mahalakshmi.R@tuv-sud.in

For any complaint : Rajasekar M at Rajasekar.M@tuv-sud.in.

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naka, Andheri (East),
Mumbai-400072. India



Material List (As Identified By Laboratory)

Material No.	Component	Material	Color	Remark
A1	Buff Calf Leather	Leather	Rovero k-123	

Result Conclusion

Test	Composite Sampling (Material No.)	Conclusion	Remarks
Dimethylfumarate (DMFu)	A1	Refer Result	
Chlorinated Phenol	A1	Refer Result	
Free Formaldehyde	A1	Refer Result	
Extractable Heavy Metals	A1	Refer Result	
Total Cadmium Content	A1	Refer Result	
Total Lead Content	A1	Refer Result	
Detection of Banned Amines	A1	Refer Result	
Alkylphenol Ethoxylates	A1	Refer Result	
Chrome VI (After Ageing)	A1	Refer Result	
Total Mercury	A1	Refer Result	



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Test Results - Accredited Parameters

1.0 Dimethylfumarate (DMFu)

Test Method: Based on CEN ISO/TS 16186:2012, Equipment used: GC-MS

		A1 (mg/kg)
Di Methyl Fumarate (DMFu)	624-49-7	Not Detected
Limit of Quantification: 0.1 mg/kg		

Client
Specification

2.0 Chlorinated Phenol

Test Method: Based on DIN EN ISO 17070:2015 - KOH extraction with 16 hrs incubation,, Equipment Used: GC-MS

		A1 (mg/kg)
2,4,5 Trichlorophenol	95-95-4	Not Detected
2,4,6 Trichlorophenol	88-06-02	Not Detected
2,3,4 Trichlorophenol	15950-66-0	Not Detected
2,3,5 Trichlorophenol	933-78-8	Not Detected
2,3,6 Trichlorophenol	933-75-5	Not Detected
3,4,5 Trichlorophenol	609-19-8	Not Detected
2,3,5,6-Tetrachlorophenol	935-95-5	Not Detected
2,3,4,6-Tetrachlorophenol	58-90-2	Not Detected
2,3,4,5-Tetrachlorophenol	4901-51-3	Not Detected
Pentachlorophenol (PCP)	87-86-5	Not Detected
Limit of Quantification: 0.05 mg/kg		

Client
Specification

3.0 Free Formaldehyde

Test Method: Based on DIN EN ISO 17226-1 : 2018, Equipment Used: UPLC-DAD

Analytes	CAS No.	A1 (mg/kg)
Formaldehyde	50-00-0	Not Detected
Limit of Quantification: 10 mg/kg		

Client
Specification

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4.0 Extractable Heavy Metals

Test Method: Based on DIN EN ISO 17072-1:2019, Equipment Used: ICP-OES

	A1 (mg/kg)	Limit of Quantification (mg/kg)	Client Specification
Antimony (Sb)	<0.5	0.5	
Arsenic (As)	<0.1	0.1	
Selenium (Se)	<0.5	0.5	
Barium (Ba)	<0.5	0.5	
Cadmium (Cd)	<0.01	0.01	
Cobalt (Co)	<0.1	0.1	
Mercury (Hg)	<0.02	0.02	
Lead (Pb)	<0.1	0.1	
Copper (Cu)	<2.5	2.5	
Chromium (Cr)	10.5	0.1	
Nickel (Ni)	<0.1	0.1	

5.0 Total Cadmium Content

Test Method: Based on DIN EN ISO 17072-2:2019, Equipment Used: ICP-OES

	A1 (mg/kg)	Client Specification
Total Cadmium	7440-43-9 <2.5	
Limit of Quantification: 2.5 mg/kg		

6.0 Total Lead Content

Test Method: Based on DIN EN ISO 17072-2:2019, Equipment Used: ICP-OES

	A1 (mg/kg)	Client Specification
Lead	7439-92-1 <2.5	
Limit of Quantification: 2.5 mg/kg		

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7.0 Detection of Banned Amines

Test Method: Based on DIN EN ISO 17234-1&2 : 2015, Equipment used: GC-MS

		A1 (mg/kg)	Client Specification
4-aminobiphenyl	92-67-1	Not Detected	
Benzidine	92-87-5	Not Detected	
4-chloro-o-toluidine	95-69-2	Not Detected	
2-naphthylamine	91-59-8	Not Detected	
o-aminoazotoluene	97-56-3	Not Detected	
2-amino-4-nitrotoluene	99-55-8	Not Detected	
p-chloroaniline	106-47-8	Not Detected	
2,4-diaminoanisole	615-05-4	Not Detected	
4,4'-diaminodiphenylmethane	101-77-9	Not Detected	
3,3'-dichlorobenzidine	91-94-1	Not Detected	
3,3'-dimethoxybenzidine	119-90-4	Not Detected	
3,3'-dimethylbenzidine	119-93-7	Not Detected	
3,3'-dimethyl-4,4'-diaminodiphenylmeth	838-88-0	Not Detected	
p-cresidine	120-71-8	Not Detected	
4,4'-methylene-bis-(2-chloroaniline)	101-14-4	Not Detected	
4,4'-oxydianiline	101-80-4	Not Detected	
4,4'-thiodianiline	139-65-1	Not Detected	
o-toluidine 2-aminotoluène	95-53-4	Not Detected	
2,4-Toluenediamine	95-80-7	Not Detected	
2,4,5-Trimethylaniline	137-17-7	Not Detected	
2-methoxyaniline	90-04-0	Not Detected	
p-aminoazobenzene	60-09-3	Not Detected	
2,4-xylidine	95-68-1	Not Detected	
2,6-xylidine	87-62-7	Not Detected	

Limit of Quantification: 5 mg/kg

8.0 Alkylphenol Ethoxylates

Test Method:Based on ISO/DIS 18218-1 : 2015, Equipment Used: LC-MS

Analytes	CAS no.	A1 (mg/kg)	Client Specification
NPEOs (Nonyl Phenol Ethoxylates) n=2 - 16	68412-34-4	Not Detected	
OPEOs (OctylPhenol Ethoylates) n=2 - 18	9002-93-1	Not Detected	

Limit of Quantification: 20 mg/kg

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9.0 Chrome VI (After Ageing)

Test Method: Based on DIN EN ISO 17075-2 : 2017, Ageing Condition: Duration: 24h, temperature 80±2 °C, RH: Max 5%. Equipment used: IC-UV/VIS

Analytes	CAS No.	A1 (mg/kg)
Chromium VI	7440-47-3	Not Detected

Client
Specification

Limit of Quantification: 3 mg/kg

10.0 Total Mercury

Test Method: Based on DIN EN ISO 17072-2:2019, Equipment Used: ICP-OES

		A1 (mg/kg)
Mercury (Hg)	7439-97-6	<0.1

Client
Specification

Limit of Quantification: 0.1 mg/kg

- END OF TEST REPORT -



medical[®]
leather

a healthy focus on feet

Product Specific Information Document

Product name: Kongo
Item code: KO
Barcode: N/A
CE Marking: N/A
MDR Risk Classification: Riskclass I

Product summary: Kongo 1,0 - 1,2mm
Size / Contents product: 6-9 sqft
Packaging size: hide
Packaging unit: per hide
Color: K121, K123, K124, K125, K126
Thickness: 1,0 - 1,2mm
Shorevalue: N/A
Implementation: non-perforated
Storage advise: not in direct sunlight
Maintenance advise: This leather can be cleaned with a mild, non alcoholic, cleaning substance
Sterilisation advise: N/A
Manufacturing date: N/A
Shelf life: N/A

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KVK 18124129 • BTW nr. NL8145 15 745 B01



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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Op al onze overeenkomsten zijn van toepassing de leverings- en betalingsvoorwaarden voor leder en andere artikelen, gedeponeerd bij de Kamer van Koophandel te Tilburg.