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中国认可
国际互认
检测
TESTING
CNAS L9939

TEST REPORT

Report No.:	FCM2443258 (EN)
Sample Name:	Polyethylene bag
Applicant:	Changzhou Dreure Medical Material Co., LTD.
Manufacturer:	Changzhou Dreure Medical Material Co., LTD.

南京海关危险货物与包装检测中心

NANJING CUSTOMS DISTRICT TESTING CENTER FOR DANGEROUS GOODS AND PACKAGING

国家食品接触材料检测重点实验室

STATE KEY TESTING LABORATORY OF FOOD CONTACT MATERIALS

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Test Report

Information of Applicant (provided by the client):

Applicant: Changzhou Dreure Medical Material Co., LTD.

Address: No.502 Changting RD, Wujin Economic Development Zone, Changzhou City, Jiangsu Province, P.R. China

Sample Information (provided by the client):

Sample Name: Polyethylene bag

Manufacturer: Changzhou Dreure Medical Material Co., LTD.

Material: LDPE

Description: 750mm×900mm×0.1mm

Quantity: 10 pcs

Batch No.: B2410420

Manufacturing Date: 2024.11.08

Test Information:

Sample No.: FCM2443258

Date Received: 2024/11/14

Test Period: 2024/11/14~2024/11/29

Test Requirement: In accordance with the client's requirements: (EU) No 10/2011 and its amendment and correction regulations

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

Conclusion: Please refer to next page(s).

Signature: Issue Date:2024/12/02

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Information of Use (provided by the client)

Contact Food	Use Condition	Use S/V	Cleaning Requirement
/	/	Unknown	/

Summary of Test Items and Results

Test Item	Resource of Restriction and Requirement	Conclusion
Overall migration	(EU) No 10/2011 and its amendment and correction regulations	Pass
Migration of heavy metals	(EU) No 10/2011 and its amendment and correction regulations	Pass
Sum of primary aromatic amines released	(EU) No 10/2011 and its amendment and correction regulations	Pass

Remark: **(1)LOD/LOQ =Limit of Detection/Limit of Quantification.**
(2)N.D.=not detected (less than LOD/LOQ).
(3)The test result between LOD and LOQ is for reference only.
(4)When the limit is expressed as "Non-detectable", the limit of detection/ quantification is equivalent to LOD/LOQ specified in the test method, except for the specific requirements listed in standards.

Test Information: **(1)Correction S/V:6dm² /1L (kg) .**

Test Result

1. Overall migration

1.1. Test condition: 3%(w/v) acetic acid, 40℃, 10d

Test Item	Test Result	Restriction and Requirement	Assessment	Test Method
Overall migration, mg/dm ²	1.8	≤10	Pass	EN 1186-3:2022

1.2. Test condition: 10%(v/v) ethanol, 40℃, 10d

Test Item	Test Result	Restriction and Requirement	Assessment	Test Method
Overall migration, mg/dm ²	2.9	≤10	Pass	EN 1186-3:2022

2. Migration of heavy metals

2.1. Test condition: 3%(w/v) acetic acid, 40℃, 10d

Test Item	Test Result	LOD/LOQ	Restriction and Requirement	Assessment	Test Method
Migration of mercury (Hg), mg/kg	N.D.	0.01/-mg/L	Non-detectable(LOD: 0.01mg/kg)	Pass	Q/DPTC-ZL-3-F-240
Migration of lead (Pb), mg/kg	N.D.	0.01/-mg/L	Non-detectable(LOD: 0.01mg/kg)	Pass	Q/DPTC-ZL-3-F-240

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Test Item	Test Result	LOD/LOQ	Restriction and Requirement	Assessment	Test Method
Migration of chromium (Cr), mg/kg	N.D.	0.01/-mg/L	Non-detectable(LOD: 0.01mg/kg)	Pass	Q/DPTC-ZL-3-F-240
Migration of arsenic (As), mg/kg	N.D.	0.01/-mg/L	Non-detectable(LOD: 0.01mg/kg)	Pass	Q/DPTC-ZL-3-F-240
Migration of cadmium (Cd), mg/kg	N.D.	0.002/-mg/L	Non-detectable(LOD: 0.002mg/kg)	Pass	Q/DPTC-ZL-3-F-240
Migration of antimony (Sb), mg/kg	N.D.	0.03/-mg/L	≤0.04	Pass	Q/DPTC-ZL-3-F-240
Migration of terbium (Tb), mg/kg	N.D.	0.01/-mg/L	≤0.05	Pass	Q/DPTC-ZL-3-F-240
Migration of lanthanum (La), mg/kg	N.D.	0.01/-mg/L	≤0.05	Pass	Q/DPTC-ZL-3-F-240
Migration of gadolinium (Gd), mg/kg	N.D.	0.01/-mg/L	≤0.05	Pass	Q/DPTC-ZL-3-F-240
Migration of europium (Eu), mg/kg	N.D.	0.01/-mg/L	≤0.05	Pass	Q/DPTC-ZL-3-F-240
Migration of nickel (Ni), mg/kg	N.D.	0.02/-mg/L	≤0.02	Pass	Q/DPTC-ZL-3-F-240
Migration of aluminium (Al), mg/kg	N.D.	0.5/-mg/L	≤1	Pass	Q/DPTC-ZL-3-F-240
Migration of zinc (Zn), mg/kg	N.D.	0.1/-mg/L	≤5	Pass	Q/DPTC-ZL-3-F-240
Migration of manganese (Mn), mg/kg	N.D.	0.1/-mg/L	≤0.6	Pass	Q/DPTC-ZL-3-F-240
Migration of lithium (Li), mg/kg	N.D.	0.1/-mg/L	≤0.6	Pass	Q/DPTC-ZL-3-F-240
Migration of iron (Fe), mg/kg	N.D.	0.1/-mg/L	≤48	Pass	Q/DPTC-ZL-3-F-240
Migration of copper (Cu), mg/kg	N.D.	0.1/-mg/L	≤5	Pass	Q/DPTC-ZL-3-F-240
Migration of cobalt (Co), mg/kg	N.D.	0.01/-mg/L	≤0.05	Pass	Q/DPTC-ZL-3-F-240
Migration of barium (Ba), mg/kg	N.D.	0.1/-mg/L	≤1	Pass	Q/DPTC-ZL-3-F-240
Sum of migration of europium (Eu), gadolinium(Gd), lanthanum(La) and terbium(Tb), mg/kg	＜0.05	/	≤0.05	Pass	/

3. Sum of primary aromatic amines released

3.1. Test condition: 3%(w/v) acetic acid, 40℃, 10d

Test Item	Test Result	LOD/LOQ	Restriction and Requirement	Assessment	Test Method
Migration of 2,4-diaminotoluene, mg/kg	N.D.	1.0/3.0μg/kg	Non-detectable(LOD: 0.002mg/kg)	Pass	GB 31604.52-2021

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Test Item	Test Result	LOD/LOQ	Restriction and Requirement	Assessment	Test Method
Migration of 2,4-diaminoanisole, mg/kg	N.D.	1.0/3.0μg/kg	Non-detectable(LOD: 0.002mg/kg)	Pass	GB 31604.52-2021
Migration of 4,4'-oxydianiline, mg/kg	N.D.	1.0/3.0μg/kg	Non-detectable(LOD: 0.002mg/kg)	Pass	GB 31604.52-2021
Migration of 4,4'-diaminodiphenylmethane, mg/kg	N.D.	1.0/3.0μg/kg	Non-detectable(LOD: 0.002mg/kg)	Pass	GB 31604.52-2021
Migration of benzidine, mg/kg	N.D.	1.0/3.0μg/kg	Non-detectable(LOD: 0.002mg/kg)	Pass	GB 31604.52-2021
Migration of o-anisidine, mg/kg	N.D.	1.0/3.0μg/kg	Non-detectable(LOD: 0.002mg/kg)	Pass	GB 31604.52-2021
Migration of o-toluidine, mg/kg	N.D.	1.0/3.0μg/kg	Non-detectable(LOD: 0.002mg/kg)	Pass	GB 31604.52-2021
Migration of 4-chloroaniline, mg/kg	N.D.	1.0/3.0μg/kg	Non-detectable(LOD: 0.002mg/kg)	Pass	GB 31604.52-2021
Migration of 2-methoxy-5-methylaniline, mg/kg	N.D.	1.0/3.0μg/kg	Non-detectable(LOD: 0.002mg/kg)	Pass	GB 31604.52-2021
Migration of 3,3'-dimethyl-4,4'-diaminodiphenylmethane, mg/kg	N.D.	1.0/3.0μg/kg	Non-detectable(LOD: 0.002mg/kg)	Pass	GB 31604.52-2021
Migration of 3,3'-dimethoxybenzidine, mg/kg	N.D.	1.0/3.0μg/kg	Non-detectable(LOD: 0.002mg/kg)	Pass	GB 31604.52-2021
Migration of 3,3'-dimethylbenzidine, mg/kg	N.D.	1.0/3.0μg/kg	Non-detectable(LOD: 0.002mg/kg)	Pass	GB 31604.52-2021
Migration of 2,4,5-trimethylaniline, mg/kg	N.D.	1.0/3.0μg/kg	Non-detectable(LOD: 0.002mg/kg)	Pass	GB 31604.52-2021
Migration of 2-naphthylamine, mg/kg	N.D.	1.0/3.0μg/kg	Non-detectable(LOD: 0.002mg/kg)	Pass	GB 31604.52-2021
Migration of 4-chloro-o-toluidine, mg/kg	N.D.	1.0/3.0μg/kg	Non-detectable(LOD: 0.002mg/kg)	Pass	GB 31604.52-2021
Migration of 4,4'- thiodianiline, mg/kg	N.D.	1.0/3.0μg/kg	Non-detectable(LOD: 0.002mg/kg)	Pass	GB 31604.52-2021
Migration of biphenyl-4-amine, mg/kg	N.D.	1.0/3.0μg/kg	Non-detectable(LOD: 0.002mg/kg)	Pass	GB 31604.52-2021
Migration of 5-nitro-o-toluidine, mg/kg	N.D.	1.0/3.0μg/kg	Non-detectable(LOD: 0.002mg/kg)	Pass	GB 31604.52-2021
Migration of 4-(phenylazo)aniline, mg/kg	N.D.	1.0/3.0μg/kg	Non-detectable(LOD: 0.002mg/kg)	Pass	GB 31604.52-2021

Test Item	Test Result	LOD/LOQ	Restriction and Requirement	Assessment	Test Method
Migration of 3,3'-dichlorobenzidine, mg/kg	N.D.	1.0/3.0μg/kg	Non-detectable(LOD: 0.002mg/kg)	Pass	GB 31604.52-2021
Migration of 4,4'-methylene-bis-(2-chloroaniline), mg/kg	N.D.	1.0/3.0μg/kg	Non-detectable(LOD: 0.002mg/kg)	Pass	GB 31604.52-2021
Migration of o-aminoazotoluene, mg/kg	N.D.	1.0/3.0μg/kg	Non-detectable(LOD: 0.002mg/kg)	Pass	GB 31604.52-2021
Migration of 1,4-benzenediamine, mg/kg	N.D.	1.0/3.0μg/kg	/	/	GB 31604.52-2021
Migration of aniline, mg/kg	N.D.	1.0/3.0μg/kg	/	/	GB 31604.52-2021
Migration of 2,6-xylidine, mg/kg	N.D.	1.0/3.0μg/kg	/	/	GB 31604.52-2021
Migration of 2,4-xylidine, mg/kg	N.D.	1.0/3.0μg/kg	/	/	GB 31604.52-2021
Sum of migration of 1,4-benzenediamine, aniline, 2,6-xylidine, 2,4-xylidine, mg/kg	＜0.010	/	≤0.01	Pass	/

The picture of submitted sample



***** END *****

声　明

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