

Test Report

Report No.: RGST201225120

Date: Jan 07, 2021

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Applicant : Fujian Jixiang Medical Technology Co., Ltd.
客户/申请商 : 福建集翔医疗科技有限公司
Address : No. 29 Tingzhou Avenue, Cewu Town, Changting County, Fujian Province, China
地址 : 福建省长汀县策武镇汀州大道南路 29 号

Report on the submitted sample(s) said to be:

委托检验的样品及申请者对样品的说明如下:

Sample(s) Name : NITRILE GLOVES
样品名称 : 丁腈手套
Sample(s) received date : Dec 25, 2020
样品接收日期 : 2020-12-25
Testing period : From Dec 05, 2020 to Jan 06, 2021
样品测试周期 : 2020-12-25 至 2021-01-06

Test Request

测试要求

(1) As specified by client, to determine the Overall Migration in the submitted sample(s) in accordance with European Commission Regulation (EC) No 1935/2004 and European Commission Resolution AP (2004)4 on rubber materials intended to come into contact with foodstuffs .

依据客户要求, 参考欧盟委员会法规(EC) No 1935/2004 和欧洲委员会决议 AP(2004)4 与食品接触的橡胶材料, 对委托样品进行全面迁移测试。

(2) As specified by client, to determine the Specific Migration of Primary Aromatic Amine in the submitted sample(s) in accordance with European Commission Regulation (EC) No 1935/2004 and European Commission Resolution AP (2004)4 on rubber materials intended to come into contact with foodstuffs.

依据客户要求, 参考欧盟委员会法规(EC) No 1935/2004 和欧洲委员会决议 AP(2004)4 与食品接触的橡胶材料, 对委托样品进行初级芳香胺特定迁移测试。

Conclusion

结论

Pass

合格

Pass

合格



Ben

Ben Miao

Technical Manager

技术经理

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Test Request

测试要求

(3) As specified by client, to determine the Specific Migration of Nitrosamines and Nitrosatable substances in the submitted sample(s) in accordance with European Commission Regulation (EC) No 1935/2004 and Council of Europe Resolution AP (2004)4 on rubber materials intended to come into contact with foodstuffs.

依据客户要求，参考欧盟委员会法规(EC) No 1935/2004 和欧洲委员会决议AP(2004)4与食品接触的橡胶材料，对委托样品进行亚硝胺和亚硝基胺化合物特定迁移测试。

Conclusion

结论

Pass

合格

Photograph(s) of Sample

样品照片



GST authenticate the photo on original report only

此图片仅限于随 GST 正本报告使用

Specimen Description:

样品描述:

No 序号.	Test part(s) name 测试部件名称
1	Purple gloves (Material: Butyronitrile) 紫色手套 (材质: 丁腈)

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Results:

结果:

(1) Overall Migration- European Commission Regulation (EC) No 1935/2004 and European Commission Resolution AP (2004)4 on rubber materials intended to come into contact with foodstuffs .

全面迁移-欧盟委员会法规(EC) No 1935/2004和欧洲委员会决议AP(2004)4与食品接触的橡胶材料

Test Method: With reference to EN 1186-1:2002 & EN 1186-3:2002 & EN 1186-14:2002

测试方法: 参考 EN 1186-1:2002 & EN 1186-3:2002 & EN 1186-14:2002

模拟液	Unit 单位	Time 时间	Temperature 温度	MDL 方法 检测限	Maximum Permissible Limit 最大允许限值	Result(s) 结果
						1
3%(w/v) acetic acid in aqueous solution 3%(w/v) 乙酸溶液	mg/dm ²	2H	25°C	3	10	4.48
10% (v/v) ethanol in aqueous solution 10% (v/v)乙醇溶液	mg/dm ²	2H	25°C	3	10	3.34
20% (v/v) ethanol in aqueous solution 20% (v/v)乙醇溶液	mg/dm ²	2H	25°C	3	10	4.34
50% (v/v) ethanol in aqueous solution 50% (v/v)乙醇溶液	mg/dm ²	2H	25°C	3	10	5.53

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(2) Specific Migration of Primary Aromatic Amine- European Commission Regulation (EC) No 1935/2004 and European Commission Resolution AP (2004)4 on rubber materials intended to come into contact with foodstuffs .

初级芳香胺特定迁移-欧盟委员会法规(EC) No 1935/2004和欧洲委员会决议AP(2004)4与食品接触的橡胶材料

Test Method: With reference to BS EN 13130-1:2004 & DIN 55610:1986

测试方法: 参考 BS EN 13130-1:2004 & DIN 55610:1986

Test condition: 3% (w/v)acetic acid in aqueous solution, 25°C, 2hours

测试条件: 3% (w/v)乙酸溶液, 25°C, 2 小时

Test Instrument: Gas Chromatography-Mass Spectrometer (GC-MS)

测试仪器: 气相色谱-质谱联用仪(GC-MS)

Test item(s) 测试项目	Unit 单位	MDL 方法检测限	Maximum Permissible Limit 最大允许限值	Result(s) 结果
				1
Specific Migration of Primary Aromatic Amine(PAA) 初级芳香胺特定迁移 (PAA)	mg/kg	0.01	Not Detected 不得检出	N.D.

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(3) Specific Migration of Nitrosamines and Nitrosatable substances - European Commission Regulation (EC) No 1935/2004 and European Commission Resolution AP (2004)4 on rubber materials intended to come into contact with foodstuffs .

亚硝胺和亚硝基胺化合物特定迁移-欧盟委员会法规(EC) No 1935/2004和欧洲委员会决议AP(2004)4与食品接触的橡胶材料

Test Method:

测试方法:

With reference to BS EN 13130-1:2004&BS EN 12868:2017

Test condition:

测试条件:

3% (w/v)acetic acid in aqueous solution, 40°C, 24hours

3% (w/v)乙酸溶液, 40°C, 24 小时

Test Instrument:

测试仪器:

Liquid Chromatography-Mass Spectrometer (LC-MS)

液相色谱-质谱联用仪

Test item(s) 测试项目	Unit 单位	MDL 方法检测限	Maximum Permissible Limit 最大允许限值	Result(s) 结果
				1
Migration of N-Nitrosamines 亚硝胺迁移	mg/kg	0.01	0.01	N.D.
Migration of N- Nitrosatable Substances 亚硝基胺化合物迁移	mg/kg	0.1	0.1	N.D.

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For N-Nitrosamines tested are:

测试以下亚硝胺:

N-Nitrosamine	CAS Number	Abbreviation
N-nitrosodibenzylamine N-亚硝基二苯胺	5336-53-8	NDBzA
N-nitrosodibutylamine N-亚硝基二丁胺	924-16-3	NDBA
N-nitrosodiethylamine N-亚硝基二乙胺	55-18-5	NDEA
N-nitrosodiisobutylamine N-亚硝基二异壬胺	1207995-62-7	NDiNA
N-nitrosodimethylamine N-亚硝基二甲胺	62-75-9	NDMA
N-nitrosodipropylamine N-亚硝基二丙胺	621-64-7	NDPA
N-nitrosomorpholine N-亚硝基吗啉	59-89-2	NMOR
N-nitroso-N-ethyl-N-phenylamine N-亚硝基乙基苯胺	612-64-6	NEPhA
N-nitroso-N-methyl-N-phenylamine N-亚硝基甲基苯胺	614-00-6	NMPhA
N-nitrosopiperidine N-亚硝基哌啶	100-75-4	NPIP
N-nitrosopyrrolidine N-亚硝基吡咯烷	930-55-2	NPYR

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Note 备注:

- mg/kg=milligram per kilogram
- mg/kg= 毫克每千克
- mg/dm² = milligram per square decimeter
- mg/dm² =毫克每平方分米
- N.D. =Not Detected (<MDL)
- N.D. =未检出 (小于方法检测限)
- Specific Migration of Nitrosamines and Nitrosatable substances is not included in CNAS Accreditation scope.
- 亚硝胺和亚硝基胺化合物特定迁移不在CNAS认可范围内.

*** End of Report ***

报告结束

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