

TEST REPORT

Test information						
Applicant	: Ningbo Home-Dollar Imp.& Exp.Corp.					
Address	:	69 Guangyuan Road, Jiangbei District, Ningbo,China.				
Sample Description	:	MIXING BOWL.				
PO#	:	Not provided.				
Style #	:	G25350.				
Country of origin	:	China.				
Export to	:	USA.				
Buyer	:	REGENT PRODUCTS CORP.				
Receiving Date	:	July 05, 2022.				
Test period	beriod : July 05, 2022.~July 08, 2022.					
Test Requested	:	Tests requested in accordance to client requirement.				
		TEST ITEMS	CONCLUSION			

<u>TEST ITEMS</u>	CONCLUSION
Soluble fraction in Xylene – US FDA 21 CFR 177.1520	PASS
Extractable fraction in n-hexane – US FDA 21 CFR 177.1520	PASS
Density at 23°C– US FDA 21 CFR 177.1520	PASS
Melting point – US FDA 21 CFR 177.1520	PASS

Signed for and on behalf of RTS TEST CO., LTD.(Zhanang) ANDA 10 RTS 25 **BINBIN ZOU**

Approved signatory

Zhejiang RTS Test Co., LTD. Phone: +86(0)579-85640080 Email: <u>ruiyl-8@z]-rts.com</u> <u>http://www.itslab.com</u> 新江含义全中翻江街道英才创业园 B 区 7 幢 2-4 层. 2-4/f, Building 7, Block B, Ying cai Business Park, Choujiang Street, Yiwu, Zhejiang.

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Date : 2022-07-08

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Sample image:



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Test result:

A.*Soluble fraction in xylene – US FDA 21 CFR 177.1520:(Unit: w/w %)

Test method: With reference to US FDA 21 CFR 177.1520.

Test Number	Item/ component description(s)	Material (claimed by the client)
A3	Green PP bowl	PP

Simulant Used	Time	Temp	Detection limit	Test result A3	Maximum Permissible Limit
Soluble fraction in xylene, w/w %	1h	25°C	0.5	2.38	9.8

Note:

1)N.D= Not detected, less than Detection limit.

2)%(w/w) = percentage of weight by weight.

3) Maximum permissible Limit is reference to 21 CFR 177.1520(c) 1.1a.

B.*Extractable fraction in n-hexane – US FDA 21 CFR 177.1520:(Unit: w/w %)

Test method: With reference to US FDA 21 CFR 177.1520.

Test Number		Item/ component description(s)				Material (claimed by the client)	
A2	White PP bowl					PP	
Simulant Used		Time	Temp	Detection limit	Test re A2		Maximum permissible Limit
Extractable fraction in n-hexane at reflux temperature , w/w %		2h	reflux temperature	0.5	1.5	0	6.4

Note:

1)N.D= Not detected, less than Detection limit.

2)%(w/w) = percentage of weight by weight.

3) Maximum permissible Limit is reference to 21 CFR 177.1520(c) 1.1a.

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C.* Density at 23°C - US FDA 21 CFR 177.1520:(Unit: g/cm³)

Test method: With reference to US FDA 21 CFR 177.1520 d(1).

Test Number Iten		n/ component description(s)	Material (claimed by the client)
A1	Blue PP bowl		PP
Test item(s)		Test result	Maximum permissible
		A1	Limit
Density at 23°C, g/cm³ Comment		0.910	0.880-0.913

Note:

1) Maximum permissible Limit is reference to 21 CFR 177.1520(c) 1.1a.

D.*Melting point – US FDA 21 CFR 177.1520:(Unit: °C)

Test method: With reference to US FDA 21 CFR 177.1520 d(2).

Test Number	Iter	n/ component description(s)	Material (claimed by the client)
A1	Blue PP bowl		PP
Test item(s)		Test result	Maximum permissible
		A1	Limit
Melting point,℃		169.3	160-180

Note:

1) Maximum permissible Limit is reference to 21 CFR 177.1520(c) 1.1a.

----- End of Report -----

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