

DEKRA Testing and Certification (Shanghai) Ltd., Guangzhou branch

Flashbay Electronics

Building2, Jixun Industrial Park, Xinjiao, Dong'ao Village, Shatian Town, Huiyang District, Huizhou City, Guangdong Province, P.R. China

# DEKRA Testing and Certification (Shanghai) Ltd., Guangzhou branch

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## **TEST REPORT**

**Test Report No.** : **4380674.56** Version 1

Project No. : 4380674.00

Test Report Date : 2021-09-27

Job No. : 21-01802

Applicant : Flashbay Electronics

Building2, Jixun Industrial Park, Xinjiao, Dong'ao Village, Shatian Town,

Huiyang District, Huizhou City, Guangdong Province, P.R. China

Product Name : Water Bottles

Country of Destination : Nova Clear

Test Requested : 1. U.S. 21 CFR F.D.A. Regulation Part 177.1520 Clause 1.1a and 1.1b for

polypropylene

2. U.S. F.D.A. Regulation 21 CFR Part 177.2600 rubber articles intended

for repeated use, Section (e) and (f)

3. U.S. 21 CFR F.D.A. Regulation Part 177.1240 Clause e for 1,4-

Cyclohexylene dimethylene terephthalate and 1,4-cyclohexylene

dimethylene isophthalate copolymer

Test Method : Please refer to next pages

Sample Received : 2021-09-13

Testing Period : 2021-09-13 to 2021-09-23

**Test Results** 

- following pages -



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#### Resume:

		Product Name: Water Bottles Model No.: Nova Clear		
No.	Parameter			
1.	Test for F.D.A. Regulation on polypropylene 21 CFR 177.1520	PASS		
2.	Test for F.D.A. Regulation on Rubber 21 CFR Part 177.2600	PASS		
3.	Test for F.D.A. Regulation on 1,4-Cyclohexylene dimethylene terephthalate and 1,4-cyclohexylene dimethylene isophthalate copolymer  21 CFR Part 177.1240	PASS		

Guangzhou, September 27, 2021 Signed for and on behalf of **DEKRA Testing and Certification (Shanghai) Ltd., Guangzhou branch** Chemical & Mechanical



Devin Ai Approved Signatory

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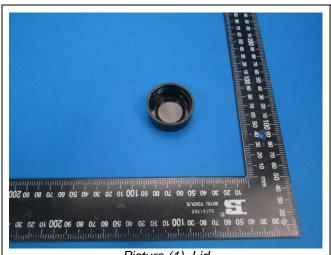


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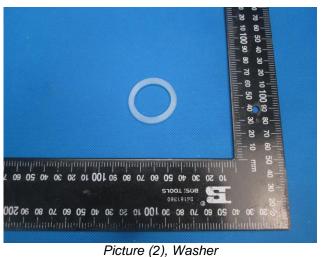
### **Sample Descriptions:**

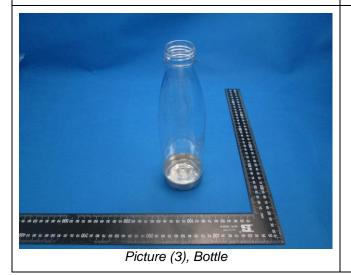
No.	Description(s)	Material(s) (claimed by applicant)
(1)	Lid	PP (Black)
(2)	Washer	Silicone (Transparent)
(3)	Bottle	Tritan (Transparent)

### Sample photos



Picture (1), Lid





(Blank)



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## **TEST RESULTS**

#### 1. U.S. 21 CFR F.D.A. Regulation Part 177.1520 Clause 1.1a and 1.1b for polypropylene

With reference to the U.S. Food and Drug Administration 21 CFR Part 177.1520 Clause 1.1a and 1.1b.

Parameter		Result (1)	MDL	Limit	
a)	Density	0.907		0.880-0.913	
b)	Melting Point (°C)	172.9		160-180 (1.1a) 150-180 (1.1b)	
c)	Maximum extractable fraction in n-hexane, % (w/w)	<0.5	0.5	6.4	
d)	Maximum extractable fraction in xylene, % (w/w)	0.79	0.5	9.8	

#### Remark:

1. % = Percentage

2. MDL = Method Detection Limit

# 2. <u>U.S. F.D.A. Regulation 21 CFR Part 177.2600 rubber articles intended for repeated use.</u> Section (e) and (f)

With reference to the U.S. Food and Drug Administration 21 CFR Part 177.2600 - rubber articles intended for repeated use, Section (e) and (f).

Parameter		Test condition	Result (mg/in²) (2)	MDL (mg/in²)	Limit (mg/in²)
(a)	Total extractives in water	Reflux temperature, first 7 hours	0.20	0.20	20
		Reflux temperature, succeeding 2 hours	<0.20	0.20	1
(b)	Total extractives in n-hexane	Reflux temperature, first 7 hours	3.73	0.20	175
(6)		Reflux temperature, succeeding 2 hours	<0.20	0.20	4

#### Remark:

1. mg/in<sup>2</sup> = Milligram per square inch



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# 3. <u>U.S. 21 CFR F.D.A. Regulation Part 177.1240 Clause e for 1,4-Cyclohexylene dimethylene terephthalate and 1,4-cyclohexylene dimethylene isophthalate copolymer</u>

With reference to the U.S. Food and Drug Administration 21 CFR Part 177.1240 clause e.

Parameter	Test condition	Result (%)	Limit (%)	
1 didilicici		(3)		
	Distilled water, Reflux temperature 2 hours	<0.05	0.05	
Total extractives	Ethyl acetate, Reflux temperature 6 hours	0.09	0.7	
	n- heptane, Reflux temperature 2 hours	<0.05	0.05	

Remark:

1. % = Percentage

---End of Report---