

# Test Report

Number TWNC01014014

Sep 02, 2021

Result

See test conducted

(See note)

**Pass** 

Issue Date

Maymom, LLC

No. 20-7, Aly. 19, Ln. 333,

Zhongzheng Rd., Zhunan Township, Miaoli County 350, Taiwan (R.O.C.)

Sample Description:

Applicant:

One (1) Group of Submitted Samples Said To Be:

Item Name : Breast Pump Parts\_adapter

Item No. : X029W-Mba Manufacturer : Maymom LLC : Maymom LLC Buyer

Country of Origin : Taiwan

Goods Exported To : USA,UK,CA,China,DE,AU,FR,IT,ES,AU,SG : The batch No. of X029W-Mba is R20210611-14. Remark

**Date Sample Received** : Aug 25, 2021 Date Test Started : Aug 26, 2021

Test Conducted:

As requested by the applicant, for details please refer to attached pages.

Conclusion:

**Tested Sample** Standard **Tested Components of** Test for F.D.A. Regulation on Polypropylene

**Submitted Samples** As per U.S. 21 CFR F.D.A. Regulation part 177.1520 Clauses

(c)(1.1) and (d)

See test conducted **Overall Migration Test** 

As per applicant's request

Specific Migration of Bisphenol A (BPA) Test for Repeated Use

Plastic Food Contacting Materials/Articles

With reference to European Commission Regulation (EU)

No. 10/2011 and its amendments

Note: One migration was conducted per client's request; however, the result met the migration limit.

Authorized By:

On behalf of Intertek Testing Services

Taiwan Limited

Matt Wang Director

Signed by:

Thomas Chou Manager

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homasChou





Test Conducted:

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# 1. Test for F.D.A. Regulation on Polypropylene

As per the U.S. 21 CFR Food and Drug Administration part 177.1520 clauses (c)(1.1) and (d) with modification on density and melting point.

Test Sample: Semitransparent plastic part (excluding metal part)

	Test Item	<u>Result</u>	<u>Limit</u>
(A)	Density (By Sink-Float Method)	0.891	0.880 - 0.913
(B)	Melting Point	162 ℃	160 - 180 ℃(1.1a)
(C)	Maximum Extractable Fraction in N-Hexane	3.20 %(W/W)	6.4 %(W/W)
(D)	Maximum Soluble Fraction in Xylene	8.19 %(W/W)	9.8 %(W/W)

Remarks: % = Percentage based on the residue by weight

# 2. Overall Migration Test

With reference to Commission Regulation (EU) No. 10/2011 and its Amendments, the migration test was conducted once.

I. Test Condition: 40 °C for 2 hours

II. Test Result:

Food Simulant: 50%(w/v) ethanol

**Tested Sample** Result (mg/dm<sup>2</sup>) Semitransparent plastic part ND (excluding metal part)

Remarks: = Not detected ND

Detection limit =  $1 \text{ mg/dm}^2$ 

Solvents & test condition were selected based on applicant's request.







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# 3. Specific Migration of Bisphenol A (BPA) Test for Repeated Use Plastic Food Contacting Materials/Articles

With reference to European Commission regulation (EU) No. 10/2011 and its amendments, the migration test shall be carried out three times on a signal tested sample for repeated use materials and articles.

I. Test Condition:

40°C for 2 hours

II. Test Result

Food Simulant: 50%(w/v) ethanol

Result (mg/kg food) **Tested Sample** Limit (mg/kg food) 2<sup>nd</sup> Test Semitransparent plastic part ND 0.05 (excluding metal part)(#)

Remarks: = Not detected ND

Detection limit = 0.05 mg/kg food

= The result was expressed in mg/kg applying a surface to volume ratio of 6 dm² per kg,

which was quoted for samples that are containers or are comparable to containers or which can be filled, with a capacity of less than 500 milliliters or more than 10 liters.

Solvents & test condition were selected based on applicant's request.

According to point 2.1.6 in Annex V to (EU) No. 10/2011 amended by (EU) No. 2020/1245, the specific migration in the second test shall not exceed the level observed in the first test, and the specific migration in the third test shall not exceed the level observed in the second test. Compliance with the specific migration limit shall be verified on the basis of the level of the specific migration found in the

third test.







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## Sample photo:



End of Report

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