

**REPORT No.: R2YN230113F11682E**Date: February 06, 2023

Page 1 of 5

ADC PLASTIC., JSC

No 30/64 Ly Ai, Song Phuong, Hoai Duc, Ha Noi, Viet Nam

Report on the submitted samples said to be:

Sample Description : Calmast MB120, MB130, MB150, MB170

Sample material : RESIN PE

Country of Origin : /

Manufacturer : ADC PLASTIC
Supplier : ADC PLASTIC
Sample Receiving Date : January 13, 2023

Testing Period : From January 13, 2023 to January 18, 2023

Results : Please refer to next page(s).

**Summary of Test Results:** 

TEST REQUEST CONCLUSION

US FDA CFR 177.1520 Olefin polymers

1. Density Pass

2. Maximum extractable fraction Pass

3. Maximum soluble fraction Pass

Signed for and on behalf of BACL

Checked by:

Nguyen Thanh Hang

Approved by: (

William Wei



**REPORT No.: R2YN230113F11682E** Date: February 06, 2023 Page 2 of 5

Results:

Tested part(s):

(1) Clear PE film (RESIN PE)

## 1. Density

Test method: With reference to 21 CFR 177.1520 d(1) or ASTM D792:2008, determined at 23°C.

Item	Unit	RL	Results	Limit
			(1)	
Density at 23°C	g/ml	/	0.91	0.85 – 1.00
Conclusion	1	1	Pass	1

### Note:

- N.D. = Not Detected or less than RL
- RL = Report Limit
- g/ml = Gram per milliliter
- °C = Degree Celsius

## 2. Maximum extractable fraction

Test method: With reference to 21 CFR 177.1520 (d)(3)(ii). Sample preparation in n-hexane at 50°C for 2 hours.

ltem	Unit	RL	Results	Limit
			(1)	
Maximum extractable fraction	% w/w	0.1	0.35	5.5
Conclusion	1	1	Pass	1

#### Note:

- N.D. = Not Detected or less than RL
- RL = Report Limit
- % w/w = Percentage of weight by weight
- °C = Degree Celsius



**REPORT No.: R2YN230113F11682E** Date: February 06, 2023 Page 3 of 5

## 3. Maximum soluble fraction

Test method: With reference to 21 CFR 177.1520 (d)(4)(ii). Sample preparation in xylene at 25°C.

Item	Unit	RL	Results	Limit
			(1)	
Maximum soluble fraction	% w/w	0.1	0.48	11.3
Conclusion	1	1	Pass	1

#### Note:

- N.D. = Not Detected or less than RL

- RL = Report Limit

- % w/w = Percentage of weight by weight

- °C = Degree Celsius

\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*



REPORT No.: R2YN230113F11682E Date: February 06, 2023 Page 4 of 5

## Photograph of Sample



BACL authenticate the photo on original report only



**REPORT No.: R2YN230113F11682E** Date: February 06, 2023 Page 5 of 5

## **Directions:**

- 1. This report cannot be reproduced except in full, without prior written approval of the Company.
- 2. Unless otherwise stated the results shown in this test report refer only to the sample(s) tested and such sample(s) are retained for 30 days only.
- 3. This report is valid only with a valid digital signature. The digital signature may be available only under the Adobe software above version 7.0.
- 4. Otherwise required by the applicant or Product Regulations, Decision Rule in this report did not consider the uncertainty.
- 5. The information which provided by the applicant, such as sample description, sample name, material component, style/item No., P.O. No., manufacture, age phase, the laboratory is not responsible for its authenticity and this information can affect the validity of the result in the test report.
- 6. The test samples were in good condition before testing.
- 7. The extended uncertainty given in this report is obtained by combining the standard uncertainty times the coverage factor K with the 95% confidence interval.

\*\*\* End of Report \*\*\*