



Certificate Of FDA Compliance

202006 - 202205

This is certified that:

At The Address Stated Below Has Completed U.S. FOOD And DRUG ADMINISTRATION Food Facility Registration And Test Through MANTONG.

Shandong Dongyue Polymer Materials Co., Ltd.
Add: 1707 Industrial Road ,Tangshan Town ,Huantai County,
Zibo City, Shandong Province

Product Description

PTFE Molding Powder

Report No.

J-00365530&J-00365531

Test Date

22-May-2020~01-Jun-2020

Test Requested

US FDA 21 CFR 177.1550

Test Laboratory

NSF International

Registration Number

16810829446



Jacky M. Chuang

Executive Director

Date: 06-18-2020

MTG STANDARDS TESTING & CERTIFICATION CENTER www.fdacn.org

This certification affirm that the above device and company was registered with U.S. Food and Drug Administration pursuant to section 305 of the United States Public Health and Bioterrorism Preparedness and response Act of 2002, P.L. 107-188, on the date stated above, and makes no other representations or warranties, nor does this certificate make any representations or warranties to any person or entity other than the named certificate holder, for whose sole benefit it is issued. MTG, CO., Inc. assumes no liability to any person or entity in connection with the foregoing. MTG is a private registration agent not affiliated with the U.S. Food and Drug Administration

Send To: C0096491**Facility: C0096493**SHANDONG DONGYUE POLYMER MATERIAL
CO.,LTD.1707 Industrial Road,Tangshan Town,Huantai
County,Zibo City,Shandong ProvinceSHANDONG DONGYUE POLYMER MATERIAL
CO.,LTD.1707 Industrial Road,Tangshan Town,Huantai
County,Zibo City,Shandong Province**Result Complete**

Report Date 04-Jun-2020

Customer Name SHANDONG DONGYUE POLYMER MATERIAL CO.,LTD.

Description PTFE Molding Powder

Test Type Test Only

Job Number J-00365530

Sample Reception Date 22-May-2020

Testing Date 22-May-2020~01-Jun-2020

Summary of Results

Testing Parameters and Standards	Result
Determination of fluoride extractives according to US FDA 21 CFR 177.1550	Complete

Report Authorization**Date** 04-Jun-2020

Kerri Levanseler - Manager, Laboratory Support Group

1. **Determination of fluoride extractives according to US FDA 21 CFR 177.1550**

1.1 Testing procedure:

Extract samples with the extractive solvent at extractive condition, and determine the fluoride extractives by ISE meter.

1.2 Testing result:

Testing Parameter	Testing Condition	Unit	Result	Acceptance	Conclusion
Extractives residue (water)	Reflux temperature, 2hr	mg/dm ²	ND(0.015)	≤0.46	PASS
Extractives residue (n-heptane)	Reflux temperature, 2hr	mg/dm ²	ND(0.015)	≤0.46	PASS
Extractives residue (50% ethanol)	Reflux temperature, 2hr	mg/dm ²	0.027	≤0.46	PASS
Extractives residue (Ethyl acetate)	Reflux temperature, 2hr	mg/dm ²	0.066	≤0.46	PASS

Remark

- 1) ND=Not Detected, less than reporting limit.
- 2) Client claim the sample is PTFE Molding Powder, sample tested is made of PTFE Molding Powder
- 3) End-product testing was performed to 21 CFR 177.1550 per Client request and that the acceptable results are based on the assumption that all material components have been confirmed by the formulator as compliant to 21 CFR and applicable FDA regulations for the intended end use.
- 4) Shanghai Laboratory was authorized by Ann Arbor to conduct the testing.
- 5) Sample from: Provided by the client.

Picture of Sample



PTFE Molding Powder
End of Report

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Result Complete

Report Date 04-Jun-2020

Customer Name SHANDONG DONGYUE POLYMER MATERIAL CO.,LTD.

Description PTFE Molding Powder

Test Type Test Only

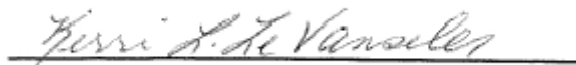
Job Number J-00365531

Sample Reception Date 22-May-2020

Testing Date 22-May-2020~01-Jun-2020

Summary of Results

Testing Parameters and Standards	Result
Determination of total extractives residue according to US FDA 21 CFR 177.1550	Complete



Report Authorization

Date 04-Jun-2020

Kerri Levanseler - Manager, Laboratory Support Group

1. **Determination of total extractives residue according to US FDA 21 CFR 177.1550**

1.1 Testing procedure:

Extract samples with the extractive solvent at extractive condition, weigh the residue and calculate total extractives in mg per square decimetre of the sample extracted.

1.2 Testing result:

Testing Parameter	Testing Condition	Unit	Result	Acceptance	Conclusion
Extractives residue (water)	Reflux temperature, 2hr	mg/dm ²	2.5	≤3.1	PASS
Extractives residue (n-heptane)	Reflux temperature, 2hr	mg/dm ²	1.3	≤3.1	PASS
Extractives residue (50% ethanol)	Reflux temperature, 2hr	mg/dm ²	1.2	≤3.1	PASS
Extractives residue (Ethyl acetate)	Reflux temperature, 2hr	mg/dm ²	0.4	≤3.1	PASS

Remark

- 1) Client claim the sample is PTFE Molding Powder, sample tested is made of PTFE Molding Powder
- 2) End-product testing was performed to 21 CFR 177.1550 per Client request and that the acceptable results are based on the assumption that all material components have been confirmed by the formulator as compliant to 21 CFR and applicable FDA regulations for the intended end use.
- 3) Shanghai Laboratory was authorized by Ann Arbor to conduct the testing.
- 4) Sample from: Provided by the client.

Picture of Sample



PTFE Molding Powder
End of Report