



Certificate Of FDA Registration

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 MATERIAL CO.,LTD
Add:TANGSHAN TOWN,HUANTAI COUNTY,
ZIBO CITY, SHANDONG PROVINCE

Product Description

PTFE Molding Powder

Lot No.

140425060

Test Date

09-May-2014 to 16-May-2014

Test Requested

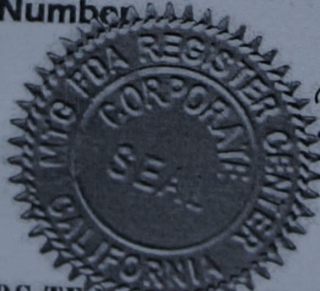
US FDA 21 CFR 177.1550

Test Laboratory

NSF International

Registration Number

16810829446



Jacky M. Chuang

Executive Director

Date: 06.03.2014

MTG STANDARDS TESTING & CERTIFICATION CENTER www.fda.cn.org

This certification affirms 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 Biosubstance Preparation and Inspection 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.



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NSF International

NSF International.
789 Dixboro Road, Ann Arbor, Michigan 48105-9723 USA
1-800-NSF-MARK 734-769-8010
www.nsf.org

TEST REPORT

Send To: C0096491

Facility: C0096493

SHANDONG DONGYUE POLYMER MATERIAL CO.,LTD

TANGSHAN TOWN, HUANTAI COUNTRY, ZIBO CITY, SHANDONG PROVINCE

CHINA

SHANDONG DONGYUE POLYMER MATERIAL CO.,LTD

TANGSHAN TOWN, HUANTAI COUNTRY, ZIBO CITY, SHANDONG PROVINCE

CHINA

Result Complete

Report Date 26-May-2014

Customer Name SHANDONG DONGYUE POLYMER MATERIAL CO.,LTD

Description PTFE Molding Powder (Lot No.: 140425060)

Test Type Test Only

Job Number J-00139768

Sample Reception Date 09-May-2014

Testing Completion Date 16-May-2014

Summary of Results

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

Report Authorization

Kerri S. LeVanseler

Kerri Levanseler - Director, Chemistry Laboratory

Date 26-May-2014

FI20140526050342

J-00139768

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1. Determination of total extractives residue according to US FDA 21 CFR 177.1550**1.1 Testing procedure:**

Extract samples at the extractive solvent and 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	ND(0.1)	≤3.1	PASS
Extractives residue (n-heptane)	Reflux temperature, 2hr	mg/dm ²	0.2	≤3.1	PASS
Extractives residue (50% ethanol)	Reflux temperature, 2hr	mg/dm ²	2.5	≤3.1	PASS
Extractives residue (Ethyl acetate)	Reflux temperature, 2hr	mg/dm ²	ND(0.1)	≤3.1	PASS

Remark

ND=Not Detected, less than reporting limit.



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

2.1 Testing procedure:

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

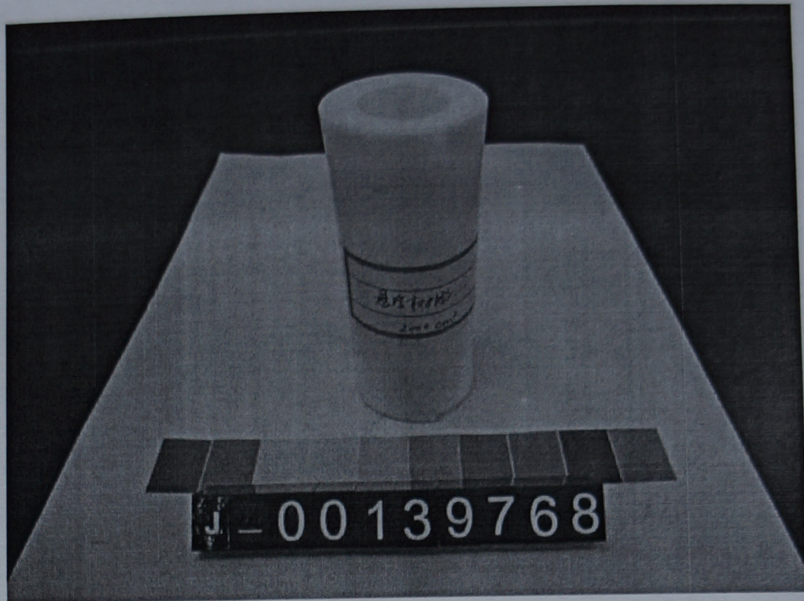
2.2 Testing result:

Testing Parameter	Testing Condition	Unit	Result	Acceptance	Conclusion
Fluoride extractives (water)	Reflux temperature, 2hr	mg/dm ²	ND(0.02)	≤0.46	PASS
Fluoride extractives (n-heptane)	Reflux temperature, 2hr	mg/dm ²	ND(0.02)	≤0.46	PASS
Fluoride extractives (50% ethanol)	Reflux temperature, 2hr	mg/dm ²	ND(0.02)	≤0.46	PASS
Fluoride extractives (Ethyl acetate)	Reflux temperature, 2hr	mg/dm ²	ND(0.02)	≤0.46	PASS

Remark

- 1) ND=Not Detected, less than reporting limit.
- 2) Client claim the material of sample is PTFE
- 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.

Picture of Sample



PTFE Molding Powder

End of Report