



Certificate Of FDA Compliance

201904-202103

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 Huaxia Shenzhou New Material Co.,Ltd
Tangshan Town,Huantai Country,Zibo City ,Shandong Province,China

Product

Perfluorinated Ethylene-Propylene Copolymer
602、 611、 612、 610、 618、 628

Test Requested

With reference to U.S. F.D.A.
C.F.R.21 Part 177.1550

Report No.

J-00331942

Test Performing

01-Apr-2019~09-Apr-2019

Test Laboratory

NSF International

Registration

11368306636



Jacky M. Chuang

Executive Director

Date: 04-16-2019

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 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.

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 HUAXIA SHENZHOU NEW
MATERIAL CO.,LTD.

SHANDONG HUAXIA SHENZHOU NEW
MATERIAL CO.,LTD.

TANGSHAN TOWN,HU ANTAI COUNTRY,ZIBO CITY,
SHANDONG PROVINCE,CHINA

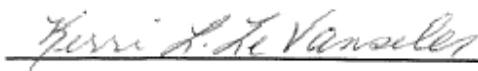
TANGSHAN TOWN,HU ANTAI COUNTRY,ZIBO CITY,
SHANDONG PROVINCE,CHINA

Result	Complete	Report Date	11-Apr-2019
Customer Name	SHANDONG HUAXIA SHENZHOU NEW MATERIAL CO.,LTD.		
Description	PERFLUORINATED ETHYLENE-PROPYLENE COPOLYMER		
Model Name	602,611,612,610,618,628		
Test Type	Test Only		
Job Number	J-00331942		
Sample Reception Date	01-Apr-2019		
Testing Date	01-Apr-2019~09-Apr-2019		

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



Date 11-Apr-2019

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	1.0	≤3.1	PASS
Extractives residue (n-heptane)	Reflux temperature, 2hr	mg/dm ²	1.0	≤3.1	PASS
Extractives residue (50% ethanol)	Reflux temperature, 2hr	mg/dm ²	0.5	≤3.1	PASS
Extractives residue (ethyl acetate)	Reflux temperature, 2hr	mg/dm ²	0.8	≤3.1	PASS

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

2.1 Testing procedure:

Extract samples with the extractive solvent at extractive 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	0.054	≤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	0.11	≤0.46	PASS
Fluoride extractives (ethyl acetate)	Reflux temperature, 2hr	mg/dm ²	0.029	≤0.46	PASS

Remark

- 1) ND=Not Detected, less than reporting limit.
- 2) Client claim the sample is perfluorinated ethylene propylene copolymer.
- 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) "*"The test is done by an authorized subcontracted lab.
- 5) Shanghai Laboratory was authorized by Ann Arbor to conduct the testing.
- 6) Sample from: Provided by the client.

Picture of Sample



End of Report