

Test Report

No. SHAEC2114751901

Date: 19 Jul 2021

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ZHEJIANG NANHUA BIOLOGICAL TECHNOLOGY CO.,LTD.

BUILDING2, NO.129, YUNXING ROAD, XIEQIAO TOWN, HAINING CITY, ZHEJIANG PROVINCE, CHINA

The following sample(s) was/were submitted and identified on behalf of the clients as : Nano crystalline

SGS Job No. : SP21-021952 - SH

Date of Sample Received : 14 Jul 2021

Testing Period : 14 Jul 2021 - 19 Jul 2021

Test Requested : Selected test(s) as requested by client.

Test Method : Please refer to next page(s).

Test Results : Please refer to next page(s).

Conclusion : Based on the performed tests on submitted sample(s), the results of Cadmium, Lead, Mercury, Hexavalent chromium, Polybrominated biphenyls (PBBs), Polybrominated diphenyl ethers (PBDEs) and Phthalates such as Bis(2-ethylhexyl) phthalate (DEHP), Butyl benzyl phthalate (BBP), Dibutyl phthalate (DBP) and Diisobutyl phthalate (DIBP) comply with the limits as set by RoHS Directive (EU) 2015/863 amending Annex II to Directive 2011/65/EU.

When tested as specified, Dimethyl fumarate(DMF) content of the submitted sample comply with Commission Regulation (EU) No 412/2012 and Entry 61 of Annex XVII of REACH Regulation (EC) No 1907/2006

Signed for and on behalf of
SGS-CSTC Standards Technical Services (Shanghai) Co., Ltd.

Carol Luo

Carol Luo
Approved Signatory

scan to see the report



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Test Results :

Test Part Description :

Specimen No.	SGS Sample ID	Description
SN1	SHA21-147519.001	Black grain

Remarks :

- (1) 1 mg/kg = 0.0001%
- (2) MDL = Method Detection Limit
- (3) ND = Not Detected (< MDL)
- (4) "-" = Not Regulated

RoHS Directive (EU) 2015/863 amending Annex II to Directive 2011/65/EU

Test Method : With reference to IEC 62321-4:2013+AMD1:2017, IEC62321-5:2013, IEC62321-7-2:2017, IEC 62321-6:2015 and IEC62321-8:2017, analyzed by ICP-OES, AAS, UV-Vis and GC-MS.

Test Item(s)	Limit	Unit	MDL	001
Cadmium (Cd)	100	mg/kg	2	ND
Lead (Pb)	1000	mg/kg	2	31
Mercury (Hg)	1000	mg/kg	2	ND
Hexavalent Chromium (Cr(VI))	1000	mg/kg	8	ND
Sum of PBBs	1000	mg/kg	-	ND
Monobromobiphenyl	-	mg/kg	5	ND
Dibromobiphenyl	-	mg/kg	5	ND
Tribromobiphenyl	-	mg/kg	5	ND
Tetrabromobiphenyl	-	mg/kg	5	ND
Pentabromobiphenyl	-	mg/kg	5	ND
Hexabromobiphenyl	-	mg/kg	5	ND
Heptabromobiphenyl	-	mg/kg	5	ND
Octabromobiphenyl	-	mg/kg	5	ND
Nonabromobiphenyl	-	mg/kg	5	ND
Decabromobiphenyl	-	mg/kg	5	ND
Sum of PBDEs	1000	mg/kg	-	ND
Monobromodiphenyl ether	-	mg/kg	5	ND
Dibromodiphenyl ether	-	mg/kg	5	ND
Tribromodiphenyl ether	-	mg/kg	5	ND
Tetrabromodiphenyl ether	-	mg/kg	5	ND



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<u>Test Item(s)</u>	<u>Limit</u>	<u>Unit</u>	<u>MDL</u>	<u>001</u>
Pentabromodiphenyl ether	-	mg/kg	5	ND
Hexabromodiphenyl ether	-	mg/kg	5	ND
Heptabromodiphenyl ether	-	mg/kg	5	ND
Octabromodiphenyl ether	-	mg/kg	5	ND
Nonabromodiphenyl ether	-	mg/kg	5	ND
Decabromodiphenyl ether	-	mg/kg	5	ND
Di-butyl Phthalate (DBP)	1000	mg/kg	50	ND
Benzyl Butyl Phthalate (BBP)	1000	mg/kg	50	ND
Di-2-Ethyl Hexyl Phthalate (DEHP)	1000	mg/kg	50	ND
Diisobutyl Phthalates (DIBP)	1000	mg/kg	50	ND

Notes :

- (1) The maximum permissible limit is quoted from RoHS Directive (EU) 2015/863. IEC 62321 series is equivalent to EN 62321 series
https://www.cenelec.eu/dyn/www/f?p=104:30:1742232870351101:::FSP_ORG_ID,FSP_LANG_ID:1258637,25
- (2) The restriction of DEHP, BBP, DBP and DIBP shall apply to medical devices, including in vitro medical devices, and monitoring and control instruments, including industrial monitoring and control instruments, from 22 July 2021.

Commission Regulation (EU) No 412/2012 and Entry 61 of Annex XVII of REACH Regulation (EC) No 1907/2006 - Dimethyl fumarate(DMF)

Test Method : Solvent extraction, analysis was performed by GC-MS.

<u>Test Item(s)</u>	<u>Limit</u>	<u>Unit</u>	<u>MDL</u>	<u>001</u>
Dimethyl fumarate(DMF)	0.1	mg/kg	0.1	ND



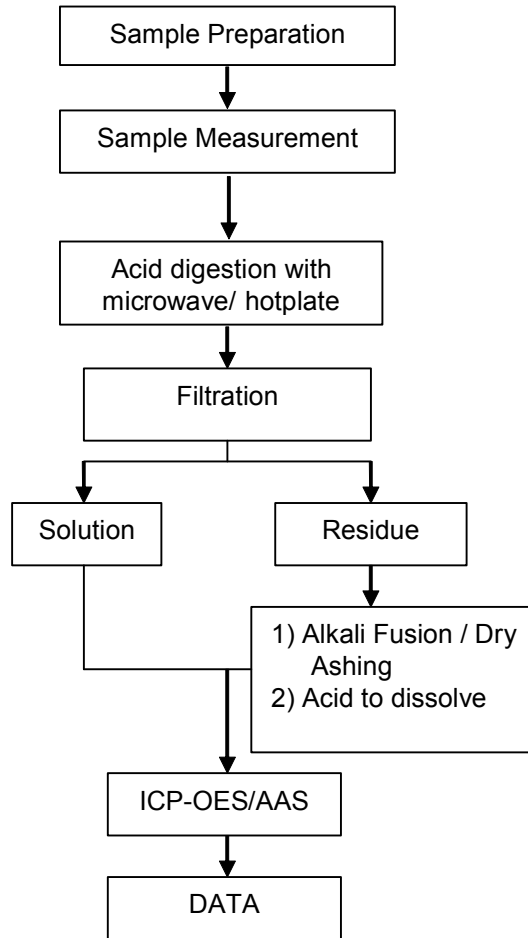
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Elements (IEC62321) Testing Flow Chart

1) These samples were dissolved totally by pre-conditioning method according to below flow chart.

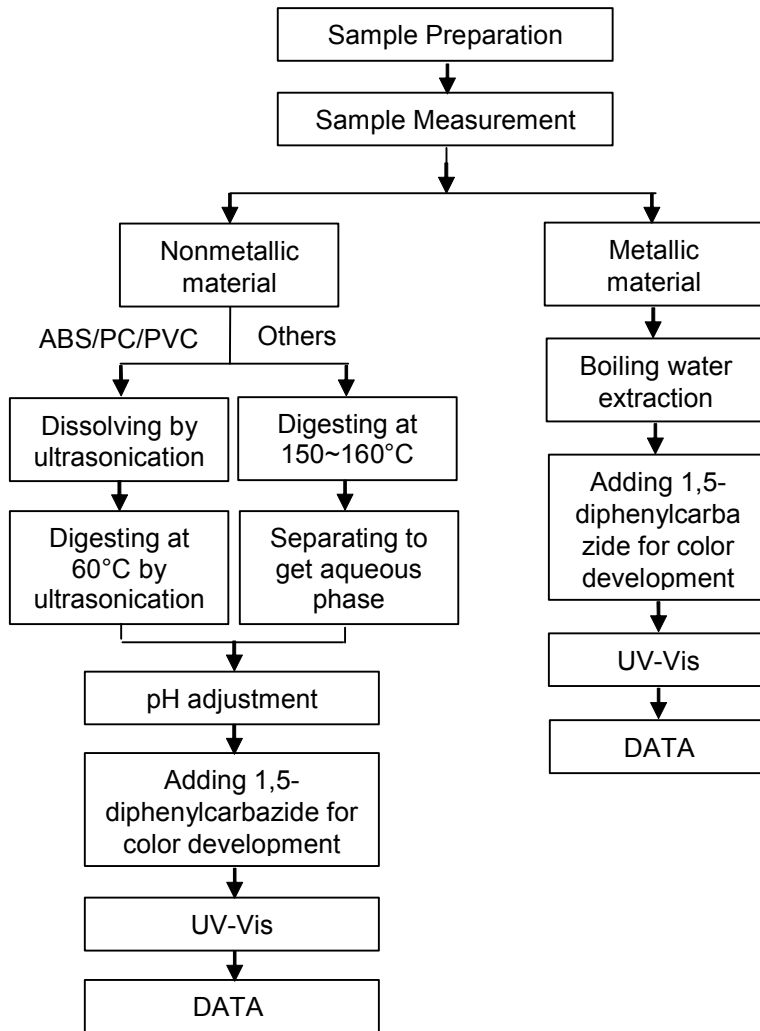


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Hexavalent Chromium (Cr(VI)) Testing Flow Chart

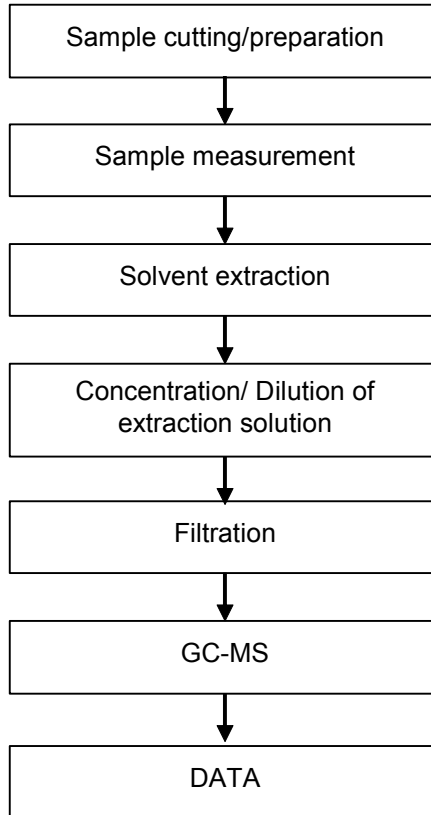


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PBBs/PBDEs Testing Flow Chart

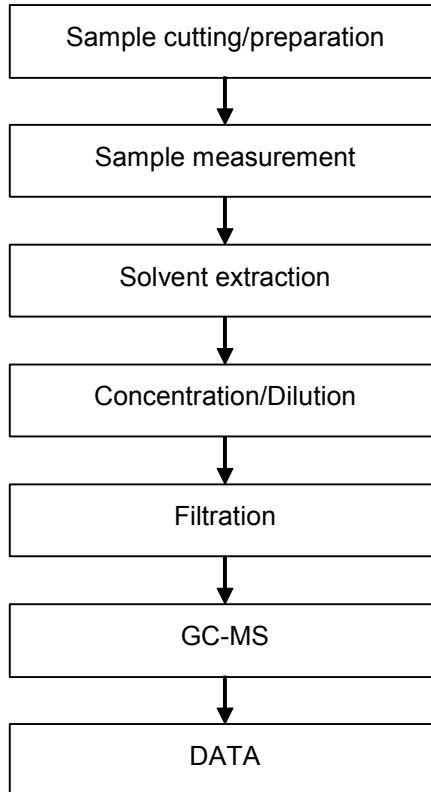


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Phthalates Testing Flow Chart

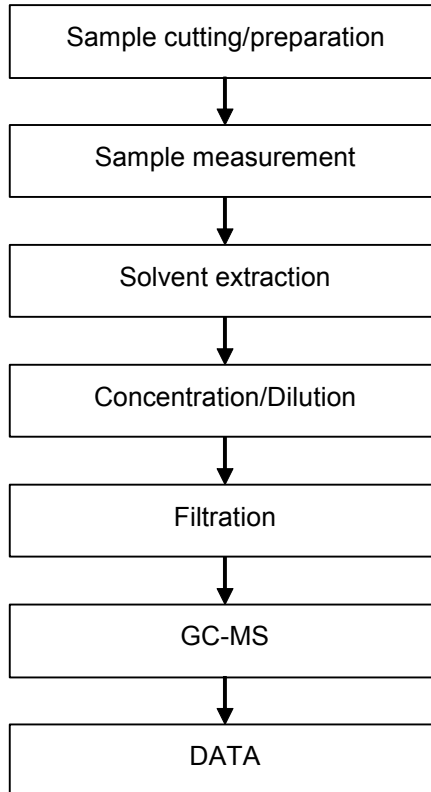


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DMF (Dimethyl fumarate) Testing Flow Chart



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