

## Test Report

No. SHAEC1809517503

Date: 15 May 2018

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SHANGHAI FUSHEN INDUSTRY CO.,LTD/MDK(SHANGHAI) MEDICAL PACKING CO.,LTD  
RM.801,NO.188,EAST NANDAN ROAD

The following sample(s) was/were submitted and identified on behalf of the clients as : TYVEK AND PE

SGS Job No. : SP18-015115 - SH

Date of Sample Received : 09 May 2018

Testing Period : 09 May 2018 - 15 May 2018

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.

*Dora Hu*

Dora Hu  
Approved Signatory



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Test Results :

### Test Part Description :

Specimen No.	SGS Sample ID	Description
SN1	SHA18-095175.002	White soft solid

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, UV-Vis and GC-MS.

Test Item(s)	Limit	Unit	MDL	002
Cadmium (Cd)	100	mg/kg	2	ND
Lead (Pb)	1000	mg/kg	2	ND
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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Test Item(s)	Limit	Unit	MDL	002
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  
[http://www.cenelec.eu/dyn/www/f?p=104:30:1742232870351101:::FSP\\_ORG\\_ID,FSP\\_LANG\\_ID:1258637,25](http://www.cenelec.eu/dyn/www/f?p=104:30:1742232870351101:::FSP_ORG_ID,FSP_LANG_ID:1258637,25)
- (2)On 4 June 2015, Commission Directive (EU) 2015/863 was published in the Official Journal of the European Union (OJEU) to include the phthalates BBP, DBP, DEHP and DIBP into ANNEX II of the Rohs Recast Directive. The new law restricts each phthalate to no more than 0.1% in each homogeneous material of an electrical product.
- (3)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.
- (4)The restriction of DEHP, BBP, DBP and DIBP shall not apply to cables or spare parts for the repair, the reuse, the updating of functionalities or upgrading of capacity of EEE placed on the market before 22 July 2019, and of medical devices, including in vitro medical devices, and monitoring and control instruments, including industrial monitoring and control instruments, placed on the market before 22 July 2021.
- (5)The restriction of DEHP, BBP and DBP shall not apply to toys which are already subject to the restriction of DEHP, BBP and DBP through entry 51 of Annex XVII to Regulation (EC) No 1907/2006.

### Halogen

Test Method : With reference to EN 14582: 2016 , analysis was performed by IC.

Test Item(s)	Unit	MDL	002
Fluorine (F)	mg/kg	50	ND
Chlorine (Cl)	mg/kg	50	ND
Bromine (Br)	mg/kg	50	ND



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<u>Test Item(s)</u>	<u>Unit</u>	<u>MDL</u>	<u>002</u>
Iodine (I)	mg/kg	50	ND

### 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>002</u>
Dimethyl fumarate(DMF)	0.1	mg/kg	0.1	ND



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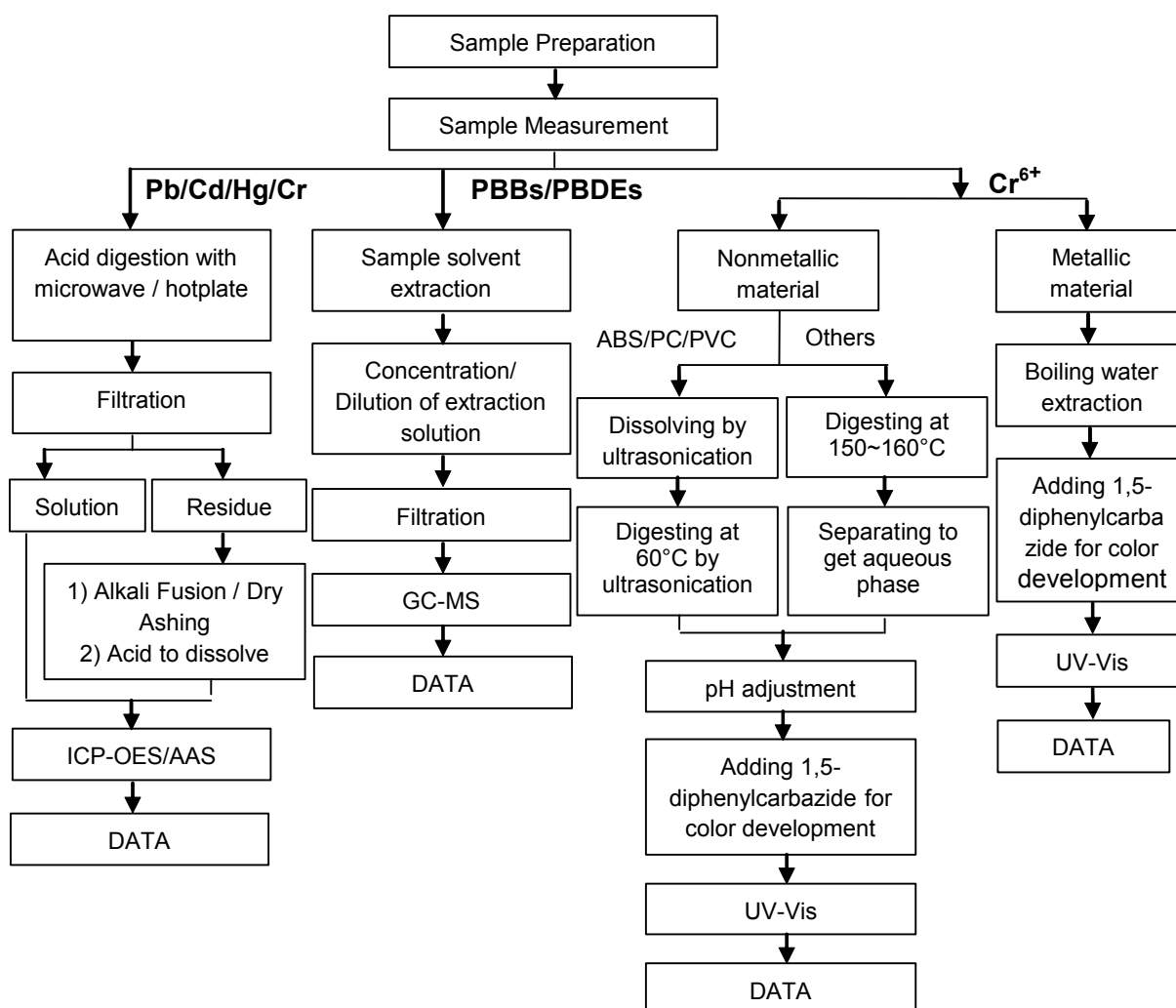
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### ATTACHMENTS

### Pb/Cd/Hg/Cr<sup>6+</sup>/PBBs/PBDEs Testing Flow Chart

- 1) Name of the person who made testing: Meria Jin/Gary Xu/ Xiaolong Yang/Sielina Song
- 2) Name of the person in charge of testing: Jan Shi/Myra Ma/Luna Xu/Shara Wang
- 3) These samples were dissolved totally by pre-conditioning method according to below flow chart. (Cr<sup>6+</sup> and PBBs/PBDEs test method excluded)



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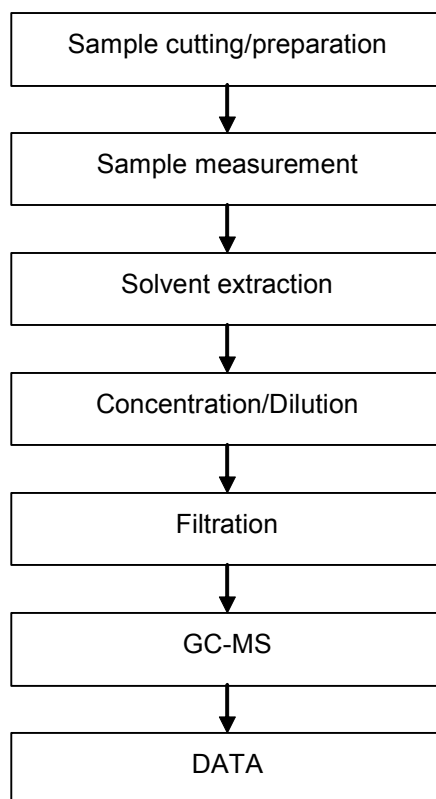
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### Phthalates Testing Flow Chart

- 1) Name of the person who made testing: Sherlock Gao
- 2) Name of the person in charge of testing: Jessy Huang



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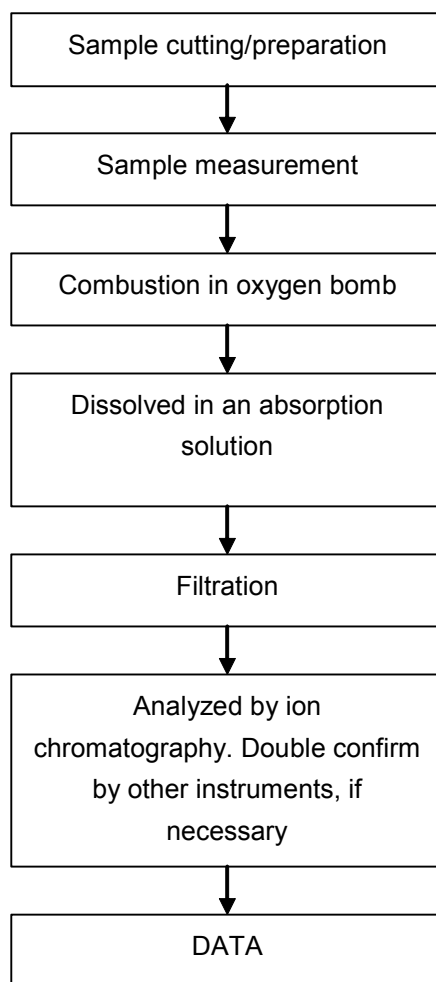
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### Halogen Testing (oxygen bomb) Flow Chart

- 1) Name of the person who made testing: Kevin Xu
- 2) Name of the person in charge of testing: Sisily Yin



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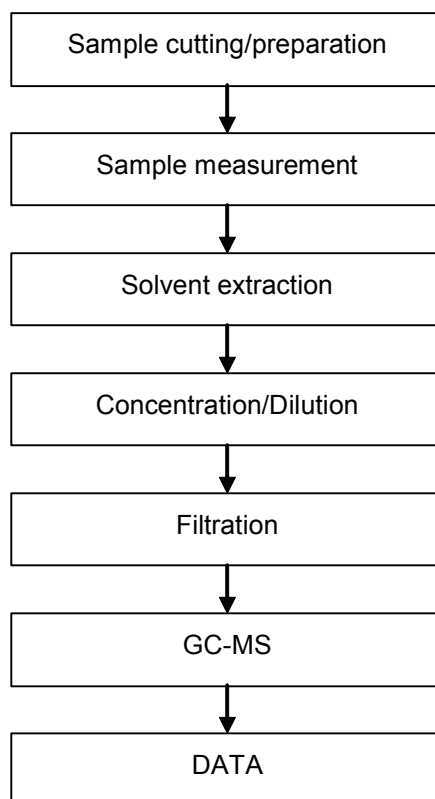
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### DMF (Dimethyl fumarate) Testing Flow Chart

- 1) Name of the person who made testing: Alex Deng
- 2) Name of the person in charge of testing: Myra ma



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