

Specification

Product	SMD(Micro) Fuse
Type	N1206 F Series
Approved by	

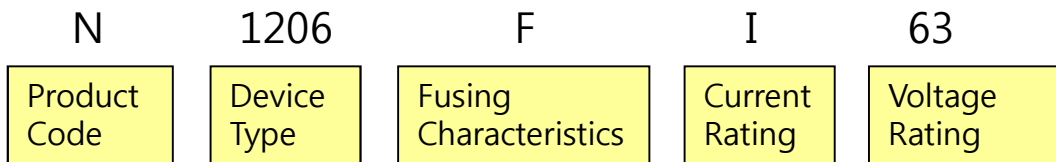
1. Scope

- This specification covers the detail requirements for SMD Micro fuse type of N1206 F Series

2. Classification

- Type designation shall be the following form

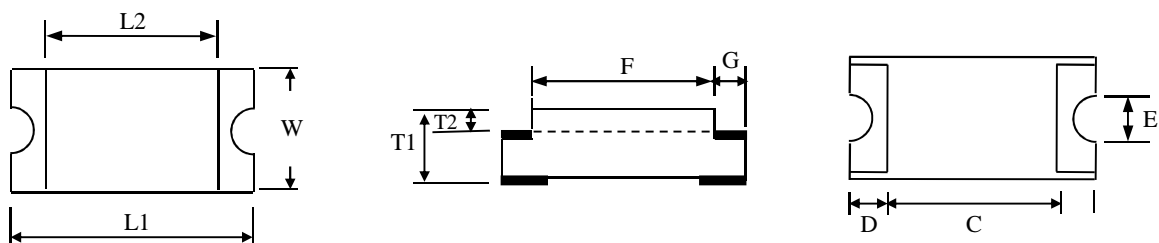
* For Example



* T : Time Delay for DC, F : Fast Acting for DC A : Time Delay for AC, C : Fast Acting for AC
--

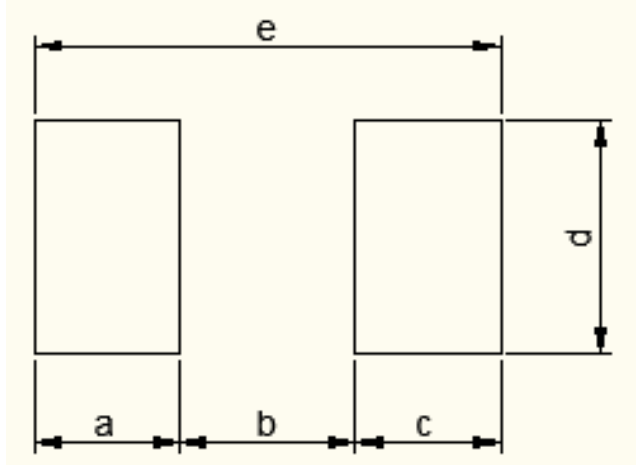
3. Dimensions

- The fuse shall be designed and dimensions in accordance with this figure



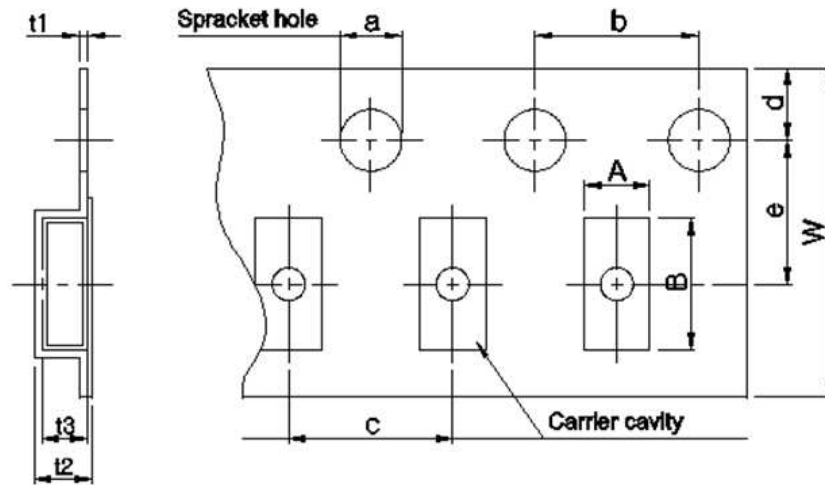
Device Type	Dimensions (mm) ± 0.1mm									
	L1	L2	W	T1	T2	C	D	E	F	G
N1206 F Series	3.2	2.4	1.6	1.0	(0.5)	2.1	0.55	1.0	2.4	0.4

4. Recommended Pad Layouts



Device Type	Dimensions (mm) $\pm 0.1\text{mm}$				
	a	b	c	d	e
N1206 F Series	1.4	1.7	1.4	2.26	4.5

5. Taping dimension



Type	A	B	a	b	c	d	e	t1	t2	t3	W
N1206	1.8 ±0.1	3.2 ±0.1	1.5 \varnothing 0~+0.1	4.0 ±0.05	4.0 ±0.05	1.75 ±0.1	3.5 ±0.05	1.35 ±0.05	1.4 ±0.05	1.1 ±0.05	PC 8mm

* PC : Polycarbonate Tape

6. Ratings

- The rating shall be in accordance with table

Type	Marking	Rated Current	Fusing Time	Rated Voltage	Op.Temp Range	Interrupting Rating (A)	Q'ty/ Reel
N1206 F Series	FC	0.50 A	Open within 5Sec. Max. at 200% of rated Current. Max 0.2 Sec. at 300% of rated Current	63VDC	-40 °C ~ + 125 °C	35A	2,500 pcs
	FD	0.75 A		63VDC		35A	
	FE	1.00 A		63VDC		35A	
	FF	1.25 A		63VDC		35A	
	FG	1.50 A		32VDC		35A	
	FH	1.75 A		32VDC		35A	
	FI	2.00 A		32VDC		35A	
	FJ	2.50 A		32VDC		35A	
	FK	3.00 A		32VDC		35A	
	FL	3.50 A		32VDC		35A	
	FM	4.00 A		32VDC		35A	
FO	5.00 A	32VDC	35A				

- Typical value of fusing time for fast acting type is 100 ~ 1000 mSec
Refer to attached Test report

7. Performance Characteristics

Unless otherwise specified, The standard range of condition for test is as follows :

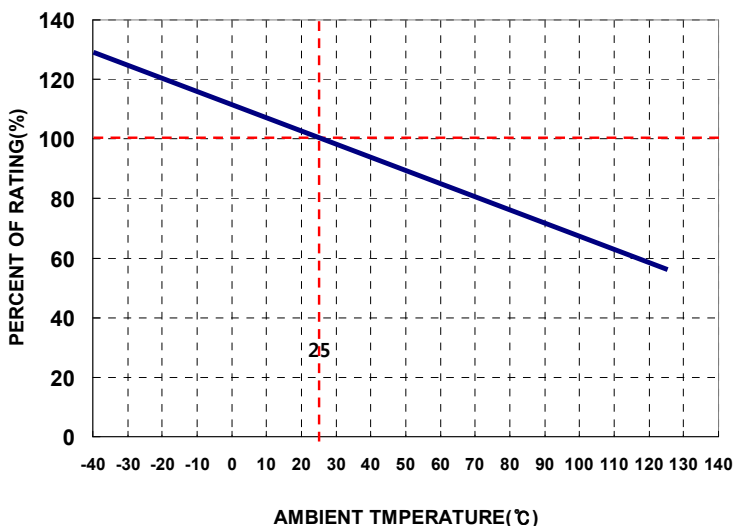
Ambient Temperature : 10°C - 50°C
 Humidity : 45% - 85%

Performance Test Table(1-2)

No	Test Item	Test Condition	Requirement
1	Resistivity Test	<ul style="list-style-type: none"> Temp : Ambient Applied t for 1 hour and 15Min off at 110% of rated current 	Duration : 100 Hours (Endurance Test) Measure Voltage drop. Do not exceed 10%
2	Time/Current Characteristic	<ul style="list-style-type: none"> Apply 200% of rated current 	Fusing Time : Fast acting : 5sec Max
3	Temperature Rise	<ul style="list-style-type: none"> Measure the temperature at surface of device 	75°C Max
4	Cycling Test	<ul style="list-style-type: none"> Lower temperature : -40°C Upper temperature : +125°C 	No. of cycling Time : 5 No Open during Cycling
5	Surge Test	<ul style="list-style-type: none"> Apply 135% of rated current with programmable Load On/Off time 	No. of Cycling : 30,000
6	Terminal bond strength of the face plating	<ul style="list-style-type: none"> <u>JIS C 0051:1994 Sub-clause 7.4.1</u> (1) Bending value:3mm (Among the fulcrums:90mm) (2)Duration:10s ± 1s 	Change of internal resistance: ±3% No evidence of mechanical damage
7	Resistance to soldering Heat	<ul style="list-style-type: none"> (1) Test by a piece (2) Temp. of solder bath:260°C ± 5°C (3) Immersion time: 10s ± 1s (4) After immersion into solder, leaving the room temp. for 1h or more, and then measure the internal resistance 	No evidence of appearance damage Electrical characteristics shall be satisfied

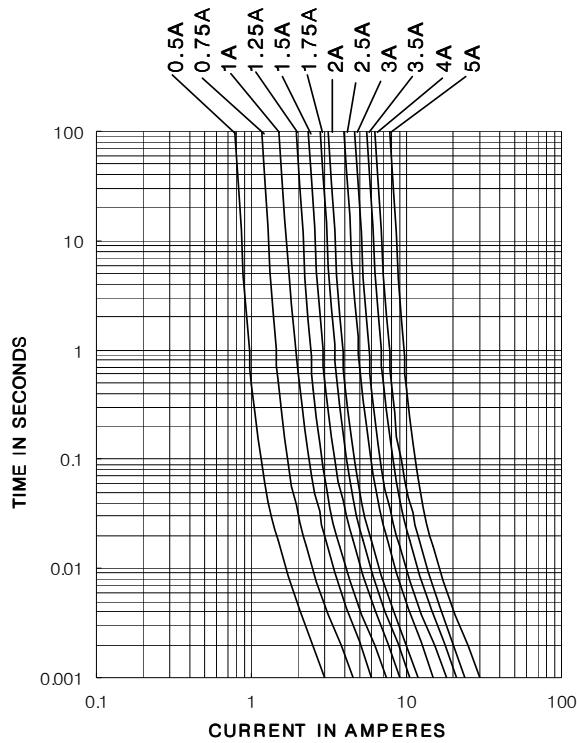
No	Test Item	Test Condition	Requirement
7		<ul style="list-style-type: none"> Reflow soldering (1) Pre-heating: $150^{\circ}\text{C} \pm 5^{\circ}\text{C}$, 120s max (2) Peak: $240^{\circ}\text{C} \pm 5^{\circ}\text{C}$, 10s Max (3) After immersion into solder, leaving the room temp. for 1h or more, and then measure the internal resistance 	
8	Solderability	<ul style="list-style-type: none"> JIS C 0054:1994 (1) Test by a piece (2) Flux: Rosin-Methanol (3) Temp. of solder: bath: $235^{\circ}\text{C} \pm 5^{\circ}\text{C}$ (4) Immersion time: 2s $\pm 0.5\text{s}$ 	The surface of terminal immersed shall be min. of 95% covered with a New coating of solder
9	Endurance test	<ul style="list-style-type: none"> (1) Test condition: Nominal ambient Temp. and Relative humidity (2) Test potential: <ol style="list-style-type: none"> Cycle of 1h "ON" and 15min. "OFF" at 1.05 times rated current for 100 cycles After above the test, 1.25 times rated current for 1h 	The voltage drop across the fuse after the test shall not have increased by more than 10% of the value measured before test

8. Derating Curve



- For operation at ambient temperature in exceed 70°C , The Load shall be derated with Figure
- Normal derating should be 75% Max for all products

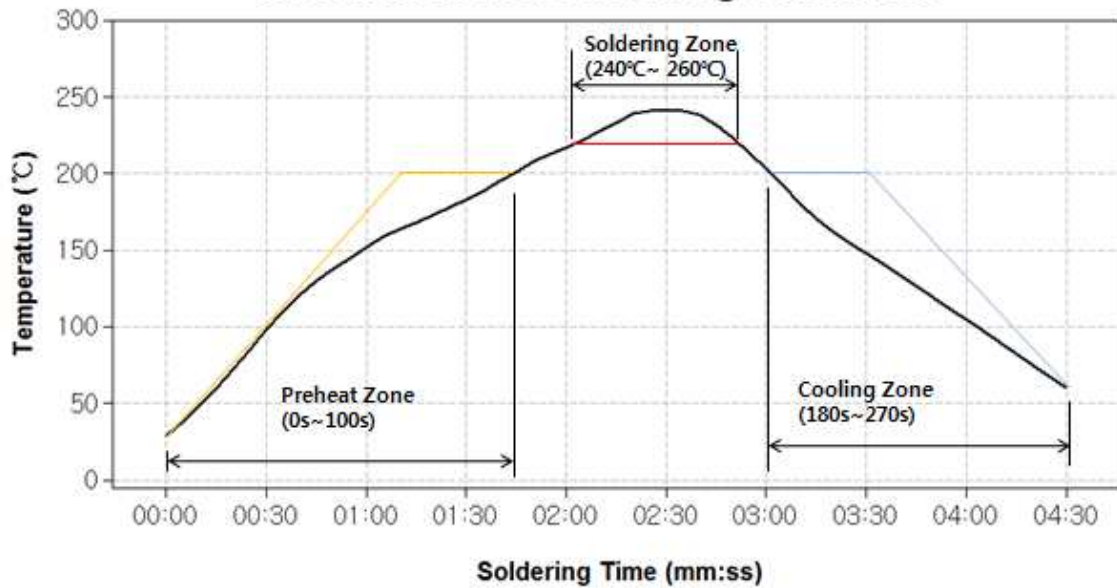
9. Time/Current Characteristics



N1206 F Series

10. Reflow condition

Recommended soldering condition



Recommended Re-flow Temp & Speed
Max 260 Degree 0.6m/Minute

● Certification (UL)



File E328408 Vol 1 Auth. Page 1 Issued: 2009-07-05
 Revised: 2012-08-13

FOLLOW-UP SERVICE PROCEDURE
 (TYPE R)

COMPONENT - FUSES, SUPPLEMENTAL
 (JDYX2, JDYX8)

Complementary Product Category

Manufacturer: SEE ADDENDUM FOR MANUFACTURER LOCATIONS


Applicant: 1817204 (Party Site)
 SM HI-TECH CO LTD
 (100517-358) 974-5 GOYEONRI UNGCHONMYON
 ULJUGUN ULSAN 689-871 KOREA

Recognized Company: 1817204 (Party Site)
 SAME AS APPLICANT
 (100517-358)

This Follow-Up Service Procedure authorizes the above Manufacturer(s) to use the marking specified by UL LLC, or any authorized licensee of UL LLC, including the UL Contracting Party, only on products when constructed, tested and found to be in compliance with the requirements of this Follow-Up Service Procedure and in accordance with the terms of the applicable service agreement with UL Contracting Party and any applicable Service Terms. The UL Contracting Party for Follow-Up Services is listed on addendum to this Follow-Up Service Procedure ("UL Contracting Party"). UL Contracting Party and UL LLC are referred to jointly herein as "UL."

UL further defines responsibilities, duties and requirements for both Manufacturers and UL representatives in the document titled, "UL Mark Surveillance Requirements" that can be located at the following web-site: <http://www.ul.com/fus> and in the document titled "UL and Subscriber Responsibilities" that can be located at the following website: <http://www.ul.com/responsibilities>. Manufacturers without Internet access may obtain the current version of these documents from their local UL customer service representative or UL field representative. For assistance, or to obtain a paper copy of these documents or the applicable Service Terms, please contact UL's Customer Service at <http://www.ul.com/global/eng/pages/corporate/contactus>, select a location and enter your request, or call the number listed for that location.

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Fuses, Supplemental - Component

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SM HI-TECH CO LTD
174-5 GOYEONRI UNGCHONMYON
JLJUGUN, ULSAN 689-871 REPUBLIC OF KOREA

E328408

Cat. No.	Size	Amps	V ac/dc	Interrupting Rating (A)
N-1206 TC, N-1206 TD, N-1206 TE, N-1206 TF; N-1206 FC, N-1206 FD, N-1206 FE, N-1206 FF	1.6 x 3.2 x 0.8	0.5- 1.25	63 V dc	50
N-1206 TG, N-1206 TH, N-1206 TI, N-1206 TJ, N-1206 TK; N-1206 TL, N-1206 TM, N-1206 TO; N-1206 FG, N-1206 FH, N-1206 FI, N-1206 FJ, N-1206 FK; N-1206 FL, N-1206 FM, N-1206 FO	1.6 x 3.2 x 0.8	1.5-5	32 V dc	35
N-1206 CE, N-1206 CG, N-1206 CI, N-1206 CJ, N-1206 CK, N-1206 CL, N-1206 CM, N-1206 CN, N-1206 CO, N-1206 CP, N-1206 AE, N-1206 AG, N-1206 AI, N-1206 AJ, N-1206 AK, N-1206 AL, N-1206 AM, N-1206 AN, N-1206 AO	1.6 x 3.2 x 0.8	1 - 7	125/250Vac	35
N-0603 FD, N-0603 FE, N-0603 FF, N-0603 FG, N-0603 FH, N-0603 FI, N-0603 FJ, N-0603 FK, N-0603 FL, N-0603 FM, N-0603 FN, N-0603 FO, N-0603 FP, N-0603 FQ	1.6 x 0.8 x 0.5	0.75-5	32/63 Vdc	35
N-0603 TD, N-0603 TE, N-0603 TF, N-0603 TG, N-0603 TH, N-0603 TI, N-0603 TJ, N-0603 TK, N-0603 TL, N-0603 TM, N-0603 TN, N-0603 TO	1.6 x 0.8 x 0.5	0.75- 4.0	32/63 Vdc	35
N-6125 AE, N-6125 AI, N-6125 AK, N-6125 AM, N-6125 AO	6.1 x 2.5x 0.8	1 - 4	125/250 Vac	35
N-6125 CE, N-6125 CG, N-6125 CI, N-6125 CJ, N-6125 CK, N-6125 CL, N-6125 CM, N-6125 CN, N-6125 CO	6.1 x 2.5 x 0.8	1-5	125/250 Vac	35
N-6125 HCP, N-6125 HCQ, N-6125 HCR	6.1 x 2.5 x 0.8	6.3-10	65/125 Vdc125 Vac	35
N-6125 HCS	6.1 x 2.5 x 0.8	12	65/125 Vdc125 Vac	50
N-4524 CE, N-4524 CG, N-4524 CI, N-4524 CJ, N-4524 CK, N-4524 CL, N-4524 CM, N-4524 CN, N-4524 CO, N-4524 AE, N-4524 AG, N-4524 AI, N-4524 AJ, N-4524 AK, N-4524 AL, N-4524 AM, N-4524 AN, N-4524 AO	4.5 x 2.4 x 0.6	1 - 5	125/250 Vac	35

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● Certification (RoHS), (Halogen Free-Br, Cl)



Test Report No. F690101/LF-CTSAYGU15-04571

Issued Date : 2015. 07. 09

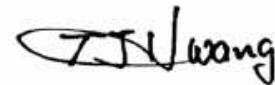
Page 1 of 6

SM HI-TECH CO., LTD.
16 Goyeongongdan1-gil, Ungchon-myun
Ulju-gun, Ulsan
Korea

The following sample(s) was/were submitted and identified by/on behalf of the client as:-

SGS File No.	: AYGU15-04571
Product Name	: SMD FUSE
Item No./Part No.	: N/A
Received Date	: 2015. 07. 06
Test Period	: 2015. 07. 06 to 2015. 07. 09
Test Comments	: By the applicant's specific request, the sampling and testing was performed only for the part indicated in the photo without disassembly.
Test Results	: For further details, please refer to following page(s)

SGS Korea Co., Ltd.
/ Gimhae Laboratory



Thomas Hwang / Lab Manager

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Issued Date : 2015. 07. 09

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Sample No. : AYGU15-04571.001
 Sample Description : SMD FUSE
 Item No./Part No. : N/A
 Materials : FR4 PCB, EPOXY RESIN, COPPER WIRE

Heavy Metals

Test Items	Unit	Test Method	MDL	Results
Cadmium (Cd)	mg/kg	With reference to IEC 62321-5:2013(Determination of Cadmium by ICP-OES)	0.5	N.D.
Lead (Pb)	mg/kg	With reference to IEC 62321-5:2013(Determination of Lead by ICP-OES)	5	N.D.
Mercury (Hg)	mg/kg	With reference to IEC 62321-4:2013(Determination of Mercury by ICP-OES)	2	N.D.
Hexavalent Chromium (Cr VI)	mg/kg	with reference to IEC 62321:2008 (Determination of Hexavalent Chromium by spot test/Colorimetric Method using UV-Vis)	1	N.D.
Antimony (Sb)	mg/kg	With reference to EPA 3052(1996), US EPA 6010B(1996), ICP	10	N.D.

Flame Retardants-PBBs/PBDEs

Test Items	Unit	Test Method	MDL	Results
Monobromobiphenyl	mg/kg	With reference to IEC 62321:2008 (Determination of PBBs and PBDEs by GC-MS)	5	N.D.
Dibromobiphenyl	mg/kg	With reference to IEC 62321:2008 (Determination of PBBs and PBDEs by GC-MS)	5	N.D.
Tribromobiphenyl	mg/kg	With reference to IEC 62321:2008 (Determination of PBBs and PBDEs by GC-MS)	5	N.D.
Tetrabromobiphenyl	mg/kg	With reference to IEC 62321:2008 (Determination of PBBs and PBDEs by GC-MS)	5	N.D.
Pentabromobiphenyl	mg/kg	With reference to IEC 62321:2008 (Determination of PBBs and PBDEs by GC-MS)	5	N.D.
Hexabromobiphenyl	mg/kg	With reference to IEC 62321:2008 (Determination of PBBs and PBDEs by GC-MS)	5	N.D.
Heptabromobiphenyl	mg/kg	With reference to IEC 62321:2008 (Determination of PBBs and PBDEs by GC-MS)	5	N.D.
Octabromobiphenyl	mg/kg	With reference to IEC 62321:2008 (Determination of PBBs and PBDEs by GC-MS)	5	N.D.
Nonabromobiphenyl	mg/kg	With reference to IEC 62321:2008 (Determination of PBBs and PBDEs by GC-MS)	5	N.D.
Decabromobiphenyl	mg/kg	With reference to IEC 62321:2008 (Determination of PBBs and PBDEs by GC-MS)	5	N.D.
Monobromodiphenyl ether	mg/kg	With reference to IEC 62321:2008 (Determination of PBBs and PBDEs by GC-MS)	5	N.D.
Dibromodiphenyl ether	mg/kg	With reference to IEC 62321:2008 (Determination of PBBs and PBDEs by GC-MS)	5	N.D.

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Sample No. : AYGU15-04571.001
Sample Description : SMD FUSE
Item No./Part No. : N/A
Materials : FR4 PCB, EPOXY RESIN, COPPER WIRE

Flame Retardants-PBBs/PBDEs

Test Items	Unit	Test Method	MDL	Results
Tribromodiphenyl ether	mg/kg	With reference to IEC 62321:2008 (Determination of PBBs and PBDEs by GC-MS)	5	N.D.
Tetrabromodiphenyl ether	mg/kg	With reference to IEC 62321:2008 (Determination of PBBs and PBDEs by GC-MS)	5	N.D.
Pentabromodiphenyl ether	mg/kg	With reference to IEC 62321:2008 (Determination of PBBs and PBDEs by GC-MS)	5	N.D.
Hexabromodiphenyl ether	mg/kg	With reference to IEC 62321:2008 (Determination of PBBs and PBDEs by GC-MS)	5	N.D.
Heptabromodiphenyl ether	mg/kg	With reference to IEC 62321:2008 (Determination of PBBs and PBDEs by GC-MS)	5	N.D.
Octabromodiphenyl ether	mg/kg	With reference to IEC 62321:2008 (Determination of PBBs and PBDEs by GC-MS)	5	N.D.
Nonabromodiphenyl ether	mg/kg	With reference to IEC 62321:2008 (Determination of PBBs and PBDEs by GC-MS)	5	N.D.
Decabromodiphenyl ether	mg/kg	With reference to IEC 62321:2008 (Determination of PBBs and PBDEs by GC-MS)	5	N.D.

Halogen Contents

Test Items	Unit	Test Method	MDL	Results
Bromine(Br)	mg/kg	EN 14582:2007 , IC	30	N.D.
Chlorine(Cl)	mg/kg	EN 14582:2007 , IC	30	291

- NOTE: (1) N.D. = Not detected.(<MDL)
 (2) mg/kg = ppm
 (3) MDL = Method Detection Limit
 (4) - = No regulation
 (5) Negative = Undetectable / Positive = Detectable
 (6) ** = Qualitative analysis (No Unit)
 (7) * = Boiling-water-extraction:
 Negative = Absence of CrVI coating
 Positive = Presence of CrVI coating; the detected concentration in boiling-water-extraction solution is equal or greater than 0.02 mg/kg with 50 cm2 sample surface area.

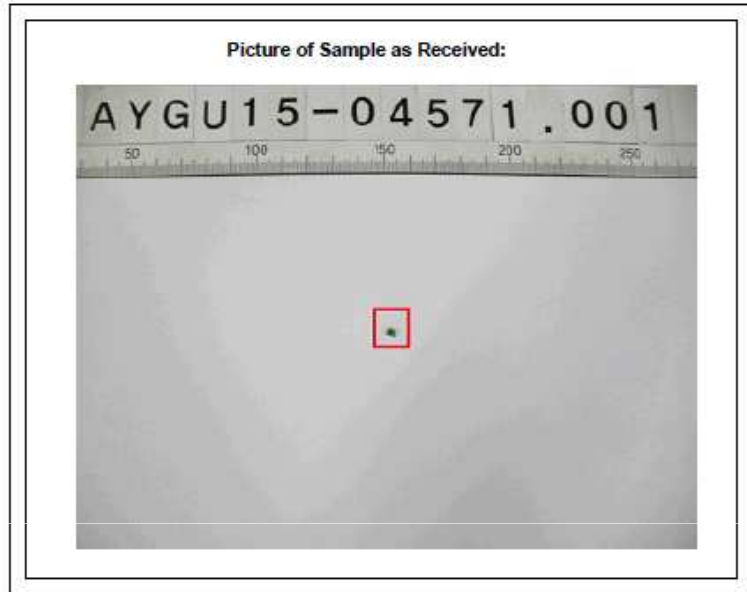
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Issued Date : 2015. 07. 09

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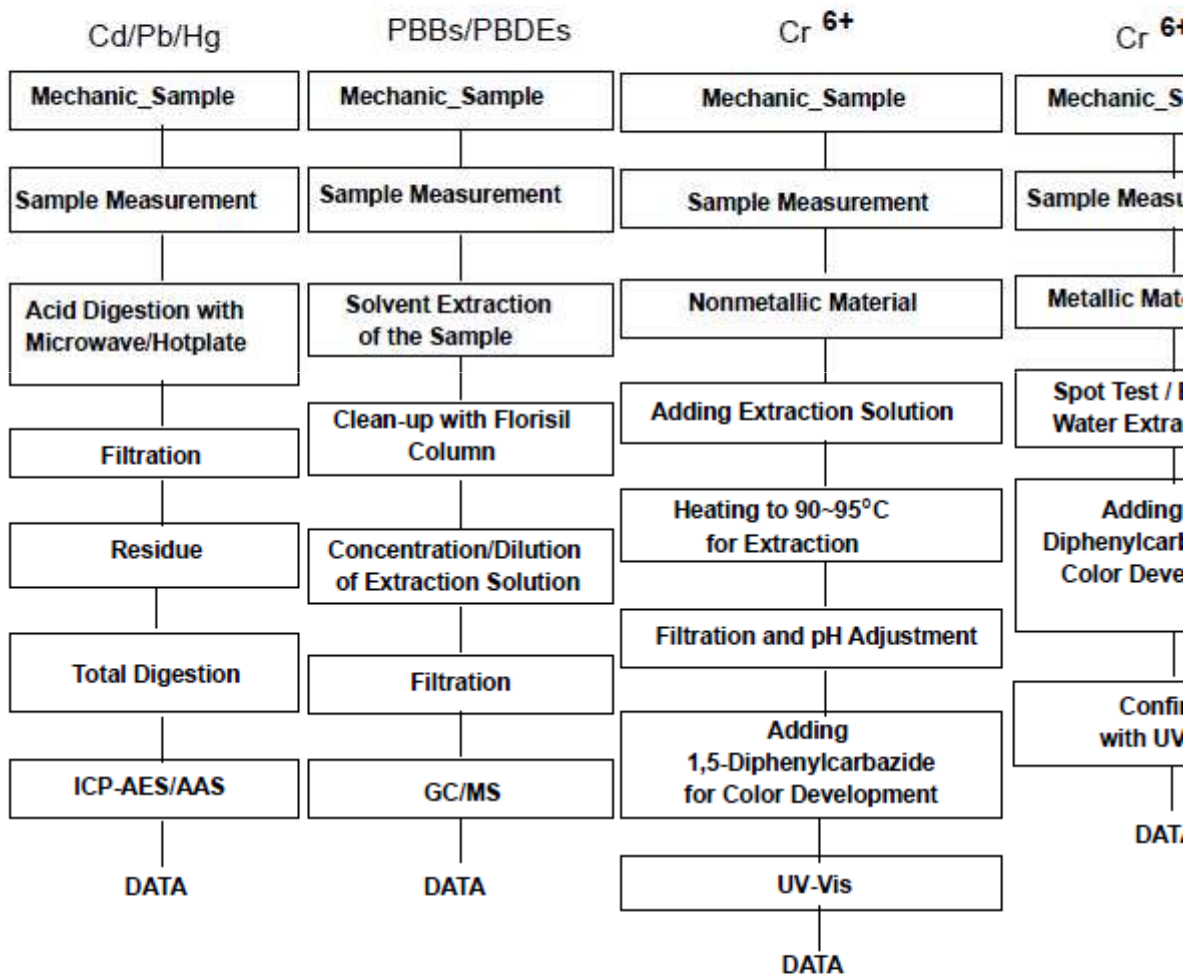
204, GBMC, 88 Somang-gil, Juchon-myeon, Gimhae-si, Gyeongsang, Korea 621-642
T +82 (0)55 310 8801 F +82 (0)55 310 8809 <http://www.sgsgroup.kr>



Test Report No. F690101/LF-CTSAYGU15-04571

Issued Date : 2015. 07. 09

Testing Flow Chart for RoHS: Cd/Pb/Hg/Cr⁶⁺ /PBBs&PBDEs Testing



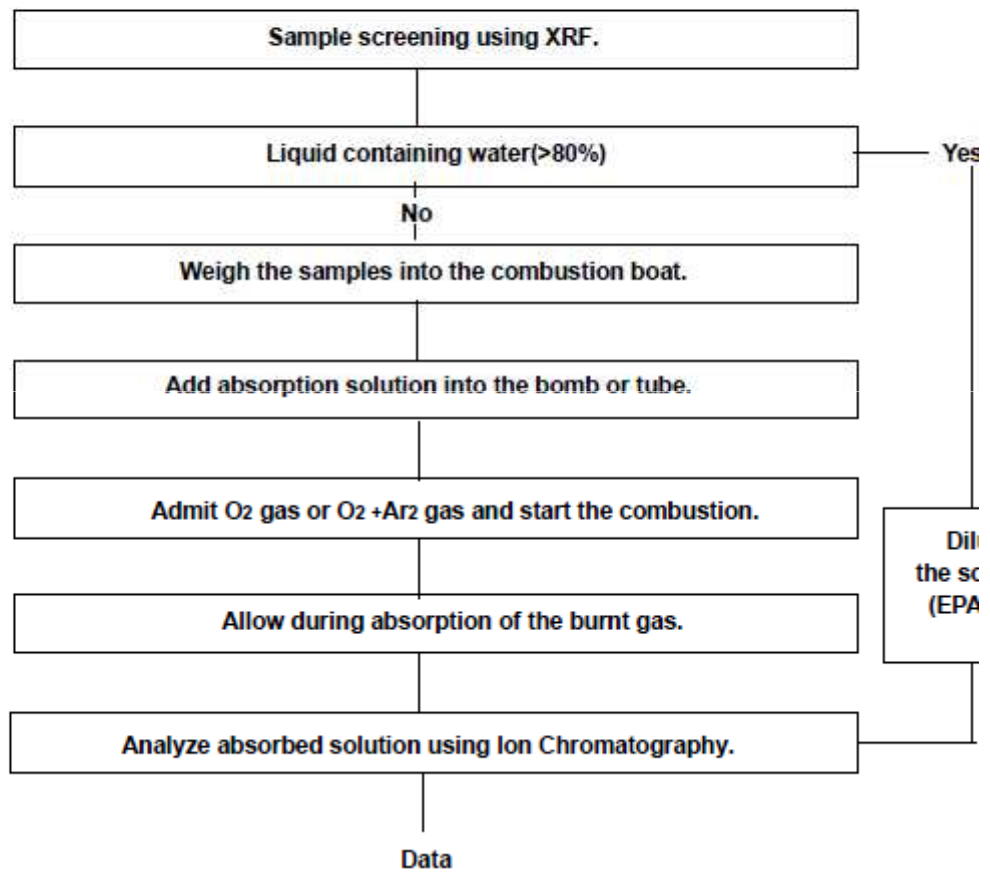
The samples were dissolved totally by pre-conditioning method according to above flow chart for Cd,Pb,Hg.
 Section Chief : Shapless Park



Test Report No. F690101/LF-CTSAYGU15-04571

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Flow Chart for Halogen Test



*** End of Report ***

● Certification (REACH)



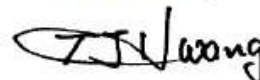
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SM HI-TECH CO., LTD.
16 Goyeongongdan1-gil, Ungchon-myun
Uiju-gun, Ulsan
Korea

The following sample(s) was/were submitted and identified by/on behalf of the client as:-

SGS File No.	: AYGU15-04572
Product Name	: SMD FUSE
Item/Part Name	: N/A
Received Date	: 2015. 07. 06
Test Period	: 2015. 07. 06 ~ 2015. 07. 13
Test Requested	: One hundred-Sixty One (161) substances in the Candidate List of Substances of Very High Concern (SVHC) for authorization published by European Chemicals Agency (ECHA) on December 17, 2014 regarding Regulation (EC) No 1907/2006 concerning the REACH. Two(2) substances in the Public Consultation List of potential Substances of Very High Concern (SVHC) published by European Chemicals Agency (ECHA) on March 2, 2015 regarding Regulation (EC) No 1907/2006 concerning the REACH.
Test Method	: Please refer to next page(s).
Test Result(s)	: Please refer to next page(s).
Summary	: According to the specified scope and analytical technique, concentrations of all SVHC are <0.1% in the submitted sample(s).

SGS Korea Co., Ltd
/Gimhae Laboratory



Thomas Hwang / Gimhae Lab Mgr.

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Test Method:

SGS In-House method - Analyzed by ICP-OES, PLM, UV/VIS, LC/MS, GC/MS and colorimetric method

Remarks:

- The chemical analysis of specified SVHC is performed by means of currently available analytical techniques against the following SVHC related documents published by ECHA:
<http://echa.europa.eu/web/quest/candidate-list-table> (Candidate list)
http://echa.europa.eu/proposals-to-identify-substances-of-very-high-concern-previous-consultations?p_p_id=substancetypelist_WAR_substanceportlet&p_p_lifecycle=0&p_p_state=normal&p_p_mode=view&p_p_col_id=column-1&p_p_col_pos=2&p_p_col_count=4&substancetypelis
 (Proposals to identify SVHC consultations)
 This list is under evaluation by ECHA and may subject to change in the future.
- In accordance with Regulation (EC) No 1907/2006, any producer or importer of articles shall notify ECHA, in accordance with paragraph 2 of Article 7, if a substance meets the criteria in Article 57 and is identified in accordance with Article 59(1) of the Regulation, if (a) the substance is present in those articles in quantities totaling over one tonne per producer or importer per year; and (b) the substance is present in those articles above a concentration of 0.1 % weight by weight (w/w).
- Article 33 of Regulation (EC) No 1907/2006 requires supplier of an article containing a substance meeting the criteria in Article 57 and identified in accordance with Article 59(1) in a concentration above 0.1 % weight by weight (w/w) shall provide the recipient of the article with sufficient information, available to the supplier, to allow safe use of the article including, as a minimum, the name of that substance in the Candidate List.
- SGS adopts the interpretation of ECHA for SVHC in article unless indicated otherwise. Detail explanation is available at the following link:
http://webstage.contribute.sgs.net/corpreach/documents/SGS-CTS_SVHC-paper-EN-11.pdf
- Test results in this report are based on the tested sample. This report refers to testing result of composite material group by equal weight proportion. The material in each composite test group may come from one article.
- If a SVHC is found over the reporting limit, client is suggested to identify the component which contains the SVHC and the exact concentration of the SVHC by requesting further quantitative analysis from the laboratory.

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Test Result(s)

Substance Name	CAS number	EC number	Concentration (%)	Reporting Limit (%)	Classification
Alkanes, C10-13, chloro (Short Chain Chlorinated Paraffins)	85535-84-8	287-476-5	N.D.	0.05	PBT
Anthracene	120-12-7	204-371-1	N.D.	0.05	PBT
Benzyl butyl phthalate (BBP)	85-68-7	201-622-7	N.D.	0.05	Toxic for Reproduction
Bis(2-ethylhexyl)phthalate (DEHP)	117-81-7	204-211-0	N.D.	0.05	Toxic for Reproduction
Bis(tributyltin)oxide	56-35-9	200-268-0	N.D.	0.05	PBT
Cobalt dichloride*	7646-79-9	231-589-4	N.D.	0.005	Carcinogen Toxic for Reproduction
4,4-Diaminodiphenylmethane	101-77-9	202-974-4	N.D.	0.05	Carcinogen
Diarsenic pentaoxide*	1303-28-2	215-116-9	N.D.	0.005	Carcinogen
Diarsenic trioxide*	1327-53-3	215-481-4	N.D.	0.005	Carcinogen
Dibutyl phthalate (DBP)	84-74-2	201-557-4	N.D.	0.05	Toxic for Reproduction
Hexabromocyclododecane (HBCDD) and all major diastereoisomers identified (α -HBCDD, β -HBCDD, γ -HBCDD)	25637-99-4 3194-55-6 (134237-51-7, 134237-50-6, 134237-52-8)	247-148-4 221-695-9	N.D.	0.05	PBT
Lead hydrogen arsenate*	7784-40-9	232-064-2	N.D.	0.005	Carcinogen Toxic for Reproduction
Sodium dichromate* (Sodium dichromate, dehydrate)	10588-01-9 (7789-12-0)	234-190-3	N.D.	0.005	Carcinogen Mutagen Toxic for Reproduction
5-tert-butyl-2,4,6-trinitro-m-xylene (musk xylene)	81-15-2	201-329-4	N.D.	0.05	vPvB
Triethyl arsenate*	15606-95-8	427-700-2	N.D.	0.005	Carcinogen

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Substance Name	CAS number	EC number	Concentration (%)	Reporting Limit (%)	Classification
Di-isobutyl phthalate(DIBP)	84-69-5	201-553-2	N.D.	0.05	Toxic for Reproduction
2,4-Dinitrotoluene	121-14-2	204-450-0	N.D.	0.05	Carcinogen
Tris(2-chloroethyl) phosphate	115-96-8	204-118-5	N.D.	0.05	Toxic for Reproduction
Anthracene oil	90640-80-5	292-602-7	N.D.	0.05	PBT; vPvB Carcinogen
Anthracene oil, anthracene paste; distn. Lights	91995-17-4	295-278-5	N.D.	0.05	PBT; vPvB Carcinogen Mutagen
Anthracene oil, anthracene paste, anthracene fraction	91995-15-2	295-275-9	N.D.	0.05	PBT; vPvB Carcinogen Mutagen
Anthracene oil, anthracene-low	90640-82-7	292-604-8	N.D.	0.05	PBT; vPvB Carcinogen Mutagen
Anthracene oil, anthracene paste	90640-81-6	292-603-2	N.D.	0.05	PBT; vPvB Carcinogen Mutagen
Coal tar pitch, high temperature	65996-93-2	266-028-2	N.D.	0.05	PBT; vPvB Carcinogen
Lead sulfochromate yellow (C.I. Pigment Yellow 34)*	1344-37-2	215-693-7	N.D.	0.005	Carcinogen Toxic for Reproduction
Lead chromate molybdate sulfate red (C.I. Pigment Red 104)*	12656-85-8	235-759-9	N.D.	0.005	Carcinogen Toxic for Reproduction
Lead chromate*	7758-97-6	231-846-0	N.D.	0.005	Carcinogen Toxic for Reproduction
Acrylamide	79-06-01	201-173-7	N.D.	0.05	Carcinogen Mutagen

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Substance Name	CAS number	EC number	Concentration (%)	Reporting Limit (%)	Classification
Boric acid*	10043-35-3 11113-50-1	233-139-2 234-343-4	N.D.	0.005	Toxic for Reproduction
Disodium tetraborate, anhydrous*	1330-43-4 12179-04-3 1303-96-4	215-540-4	N.D.	0.005	Toxic for Reproduction
Tetraboron disodium heptaoxide, hydrate*	12267-73-1	235-541-3	N.D.	0.005	Toxic for Reproduction
Trichloroethylene	79-01-6	201-167-4	N.D.	0.05	Carcinogen
Sodium chromate*	7775-11-3	231-889-5	N.D.	0.005	Carcinogen Mutagen Toxic for Reproduction
Ammonium dichromate*	7789-09-5	232-143-1	N.D.	0.005	Carcinogen Mutagen Toxic for Reproduction
Potassium dichromate*	7778-50-9	231-906-6	N.D.	0.005	Carcinogen Mutagen Toxic for Reproduction
Potassium chromate*	7789-00-6	232-140-5	N.D.	0.005	Carcinogen Mutagen

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Substance Name	CAS number	EC number	Concentration (%)	Reporting Limit (%)	Classification
Cobalt(II) sulphate*	10124-43-3	233-334-2	N.D.	0.005	Carcinogen Toxic for Reproduction
Cobalt(II) dinitrate*	10141-05-6	233-402-1	N.D.	0.005	Carcinogen Toxic for Reproduction
Cobalt(II) carbonate*	513-79-1	208-169-4	N.D.	0.005	Carcinogen Toxic for Reproduction
Cobalt(II) diacetate*	71-48-7	200-755-8	N.D.	0.005	Carcinogen Toxic for Reproduction
2-Methoxyethanol	109-86-4	203-713-7	N.D.	0.05	Toxic for Reproduction
2-Ethoxyethanol	110-80-5	203-804-1	N.D.	0.05	Toxic for Reproduction
Chromium trioxide*	1333-82-0	215-607-8	N.D.	0.005	Carcinogen Mutagen
Acids generated from chromium trioxide and their oligomers: Chromic acid Dichromic acid Oligomers of chromic acid and dichromic acid	7738-94-5 13530-68-2 -	231-801-5 236-881-5 -	N.D.	0.005	Carcinogen
1-methyl-2-pyrrolidone	872-50-4	212-828-1	N.D.	0.05	Toxic for Reproduction
2-ethoxyethyl acetate	111-15-9	203-839-2	N.D.	0.05	Toxic for Reproduction
1,2-benzenedicarboxylic acid, di-C6-8-branched alkyl esters, C7-rich	71888-89-6	276-158-1	N.D.	0.05	Toxic for Reproduction
1,2-benzenedicarboxylic acid, di-C7-11-branched and linear alkyl esters	68515-42-4	271-084-6	N.D.	0.05	Toxic for Reproduction
1,2,3-trichloropropane	96-18-4	202-486-1	N.D.	0.05	Carcinogen Toxic for Reproduction
Hydrazine	7803-57-8 302-01-2	206-114-9	N.D.	0.05	Carcinogen
Strontium chromate*	7789-06-2	232-142-6	N.D.	0.005	Carcinogen

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Substance Name	CAS number	EC number	Concentration (%)	Reporting Limit (%)	Classification
1,2-Dichloroethane	107-06-2	203-458-1	N.D.	0.05	Carcinogenic
2,2'-dichloro-4,4'-methylenedianiline (MOCA)	101-14-4	202-918-9	N.D.	0.05	Carcinogenic
2-Methoxyaniline o-Anisidine	90-04-0	201-963-1	N.D.	0.05	Carcinogenic
4-(1,1,3,3-tetramethylbutyl) phenol, (4-tert-Octylphenol)	140-66-9	205-426-2	N.D.	0.05	Equivalent level of concern having probable serious effects to the environment
Aluminosilicate Refractory Ceramic Fibres* (RCF)	650-017-00-8 (Index no.)	-	N.D.	0.005	Carcinogenic
Arsenic acid*	7778-39-4	231-901-9	N.D.	0.005	Carcinogenic
Bis(2-methoxyethyl) ether	111-96-6	203-924-4	N.D.	0.05	Toxic for reproduction
Bis(2-methoxyethyl) phthalate	117-82-8	204-212-6	N.D.	0.05	Toxic for reproduction
Calcium arsenate*	7778-44-1	231-904-5	N.D.	0.005	Carcinogenic
Dichromium tris(chromate)*	24613-89-6	246-356-2	N.D.	0.005	Carcinogenic
Formaldehyde, oligomeric reaction products with aniline (technical MDA)	25214-70-4	500-036-1	N.D.	0.05	Carcinogenic
Lead diazide*	13424-46-9	236-542-1	N.D.	0.005	Toxic for reproduction
Lead dipicrate*	6477-64-1	229-335-2	N.D.	0.005	Toxic for reproduction
Lead styphnate*	15245-44-0	239-290-2	N.D.	0.005	Toxic for reproduction
N,N-dimethylacetamide (DMAC)	127-19-5	204-826-4	N.D.	0.05	Toxic for reproduction
Pentazinc chromate octahydroxide*	49663-84-5	256-418-0	N.D.	0.005	Carcinogenic
Phenolphthalein	77-09-8	201-004-7	N.D.	0.05	Carcinogenic
Potassium hydroxyocta-oxodizincatedichromate*	11103-86-9	234-329-8	N.D.	0.005	Carcinogenic
Trilead diarsenate*	3687-31-8	222-979-5	N.D.	0.005	Carcinogenic Toxic for reproduction

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Substance Name	CAS number	EC number	Concentration (%)	Reporting Limit (%)	Classification
Zirconia Aluminosilicate Refractory Ceramic Fibres (Zr-RCF)*	650-017-00-8 (Index no.)	-	N.D.	0.005	Carcinogenic
1,2-bis(2-methoxyethoxy) ethane (TEGDME; triglyme)	112-49-2	203-977-3	N.D.	0.05	Toxic for reproduction
1,2-dimethoxyethane; ethylene glycol dimethyl ether (EGDME)	110-71-4	203-794-9	N.D.	0.05	Toxic for reproduction
Diboron trioxide*	1303-86-2	215-125-8	N.D.	0.005	Toxic for reproduction
Formamide	75-12-7	200-842-0	N.D.	0.05	Toxic for reproduction
Lead(II) bis(methanesulfonate)*	17570-76-2	401-750-5	N.D.	0.005	Toxic for reproduction
TGIC(1,3,5-tris (oxiranyl methyl)-1,3,5-triazine-2,4,6-(1H,3H,5H)-trione)	2451-62-9	219-514-3	N.D.	0.05	Mutagenic
β-TGIC (1,3,5-tris[(2S and 2R)-2,3-epoxypropyl]-1,3,5-triazine-2,4,6-(1H,3H,5H)-trione)**	59653-74-6	423-400-0	N.D.	0.05	Mutagenic
4,4'-bis(dimethylamino) benzophenone (Michler's ketone)	90-94-8	202-027-5	N.D.	0.05	Carcinogenic
N,N,N',N'-tetramethyl-4,4'-methylenedianiline (Michler's base)	101-61-1	202-959-2	N.D.	0.05	Carcinogenic
[4-[4,4'-bis(dimethylamino) benzhydrylidene]cyclohexa-2,5-dien-1-ylidene] dimethylammonium chloride (C.I. Basic Violet 3)	548-62-9	208-953-6	N.D.	0.05	Carcinogenic
[4-[[4-anilino-1-naphthyl][4-(dimethylamino)phenyl]methylene]cyclohexa-2,5-dien-1-ylidene] dimethylammonium chloride (C.I. Basic Blue 26)	2580-56-5	219-943-6	N.D.	0.05	Carcinogenic
α,α-Bis[4-(dimethylamino) phenyl]-4 (phenylamino) naphthalene-1-methanol (C.I. Solvent Blue 4)	6786-83-0	229-851-8	N.D.	0.05	Carcinogenic
4,4'-bis(dimethylamino)-4''-(methylamino)trityl alcohol	561-41-1	209-218-2	N.D.	0.05	Carcinogenic

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Substance Name	CAS number	EC number	Concentration (%)	Reporting Limit (%)	Classification
Bis(pentabromophenyl) ether (DecaBDE)	1163-19-5	214-604-9	N.D.	0.05	PBT vPvB
Pentacosafuorotridecanoic acid	72629-94-8	276-745-2	N.D.	0.05	vPvB
Tricosafuorododecanoic acid	307-55-1	206-203-2	N.D.	0.05	vPvB
Henicosafuoroundecanoic acid	2058-94-8	218-165-4	N.D.	0.05	vPvB
Heptacosafuorotetradecanoic acid	376-06-7	206-803-4	N.D.	0.05	vPvB
4-(1,1,3,3-tetramethylbutyl) phenol, ethoxylated - covering well-defined substances and UVCB substances, polymers and homologues	-	-	N.D.	0.05	Equivalent level of concern - probable serious effects on the environment
4-Nonylphenol, branched and linear – substances with a linear and/or branched alkyl chain with a carbon number of 9 covalently bound in position 4 to phenol, covering also UVCB- and well-defined substances which include any of the individual isomers or a combination thereof	-	-	N.D.	0.05	Equivalent level of concern - probable serious effects on the environment
Diazene-1,2-dicarboxamide (C,C'-azodi(formamide))	123-77-3	204-650-8	N.D.	0.05	Equivalent level of concern - probable serious effects on human health
Cyclohexane-1,2-dicarboxylic anhydride (Hexahydrophthalic anhydride - HHPA)	85-42-7	201-604-9	N.D.	0.05	Equivalent level of concern - probable serious effects on human health

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Substance Name	CAS number	EC number	Concentration (%)	Reporting Limit (%)	Classification
Hexahydromethylphthalic anhydride, Hexahydro-4-methylphthalic anhydride, Hexahydro-1-methylphthalic anhydride, Hexahydro-3-methylphthalic anhydride	25550-51-0, 19438-60-9, 48122-14-1, 57110-29-9	247-094-1, 243-072-0, 256-356-4, 260-566-1	N.D.	0.05	Equivalent level of concern - probable serious effects on human health
Methoxy acetic acid	625-45-6	210-894-6	N.D.	0.05	Toxic for reproduction equivalent level of concern -probable serious effects on human health and the environment
1,2-Benzenedicarboxylic acid, dipentylester, branched and linear	84777-06-0	284-032-2	N.D.	0.05	Toxic for reproduction
Diisopentylphthalate (DIPP)	605-50-5	210-088-4	N.D.	0.05	Toxic for reproduction
N-pentyl-isopentylphthalate	-	-	N.D.	0.05	Toxic for reproduction
1,2-Diethoxyethane	629-14-1	211-076-1	N.D.	0.05	Toxic for reproduction
N,N-dimethylformamide; dimethyl formamide	68-12-2	200-679-5	N.D.	0.05	Toxic for reproduction
Dibutyltin dichloride (DBT)	683-18-1	211-670-0	N.D.	0.05	Toxic for reproduction
Acetic acid, lead salt, basic*	51404-69-4	257-175-3	N.D.	0.005	Toxic for reproduction
Basic lead carbonate (trilead bis(carbonate)dihydroxide)*	1319-46-6	215-290-6	N.D.	0.005	Toxic for reproduction
Lead oxide sulfate (basic lead sulfate)*	12036-76-9	234-853-7	N.D.	0.005	Toxic for reproduction
[Phthalato(2-)]dioxotrilead (dibasic lead phthalate)*	69011-06-9	273-688-5	N.D.	0.005	Toxic for reproduction

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Substance Name	CAS number	EC number	Concentration (%)	Reporting Limit (%)	Classification
Dioxobis(stearato)trilead*	12578-12-0	235-702-8	N.D.	0.005	Toxic for reproduction
Fatty acids, C16-18, lead salts*	91031-62-8	292-966-7	N.D.	0.005	Toxic for reproduction
Lead bis(tetrafluoroborate)*	13814-96-5	237-486-0	N.D.	0.005	Toxic for reproduction
Lead cyanamidate*	20837-86-9	244-073-9	N.D.	0.005	Toxic for reproduction
Lead dinitrate*	10099-74-8	233-245-9	N.D.	0.005	Toxic for reproduction
Lead oxide (lead monoxide)*	1317-36-8	215-267-0	N.D.	0.005	Toxic for reproduction
Lead tetroxide (orange lead)*	1314-41-6	215-235-6	N.D.	0.005	Toxic for reproduction
Lead titanium trioxide*	12060-00-3	235-038-9	N.D.	0.005	Toxic for reproduction
Lead Titanium Zirconium Oxide*	12626-81-2	235-727-4	N.D.	0.005	Toxic for reproduction
Pentalead tetraoxide sulphate*	12065-90-6	235-067-7	N.D.	0.005	Toxic for reproduction
Pyrochlore, antimony lead yellow*	8012-00-8	232-382-1	N.D.	0.005	Toxic for reproduction
Silicic acid, barium salt, lead-doped*	68784-75-8	272-271-5	N.D.	0.005	Toxic for reproduction
Silicic acid, lead salt*	11120-22-2	234-363-3	N.D.	0.005	Toxic for reproduction
Sulfurous acid, lead salt, dibasic*	62229-08-7	263-467-1	N.D.	0.005	Toxic for reproduction
Tetraethyllead*	78-00-2	201-075-4	N.D.	0.005	Toxic for reproduction
Tetralead trioxide sulphate*	12202-17-4	235-380-9	N.D.	0.005	Toxic for reproduction

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Substance Name	CAS number	EC number	Concentration (%)	Reporting Limit (%)	Classification
Trilead dioxide phosphonate*	12141-20-7	235-252-2	N.D.	0.005	Toxic for reproduction
Furan	110-00-9	203-727-3	N.D.	0.05	Carcinogenic
Propylene oxide; 1,2-epoxypropane; methyloxirane	75-56-9	200-879-2	N.D.	0.05	Carcinogenic Mutagenic
Diethyl sulphate	64-67-5	200-589-6	N.D.	0.05	Carcinogenic Mutagenic
Dimethyl sulphate	77-78-1	201-058-1	N.D.	0.05	Carcinogenic
3-ethyl-2-methyl-2-(3-methylbutyl)-1,3-oxazolidine	143860-04-2	421-150-7	N.D.	0.05	Toxic for reproduction
Dinoseb	88-85-7	201-861-7	N.D.	0.05	Toxic for reproduction
4,4'-methylenedi-o-toluidine	838-88-0	212-658-8	N.D.	0.05	Carcinogenic
4,4'-oxydianiline and its salts	101-80-4	202-977-0	N.D.	0.05	Carcinogenic Mutagenic
4-Aminoazobenzene; 4-Phenylazoaniline	60-09-3	200-453-6	N.D.	0.05	Carcinogenic
4-methyl-m-phenylenediamine (2,4-toluene-diamine)	95-80-7	202-453-1	N.D.	0.05	Carcinogenic
6-methoxy-m-toluidine (p-cresidine)	120-71-8	204-419-1	N.D.	0.05	Carcinogenic
Biphenyl-4-ylamine	92-67-1	202-177-1	N.D.	0.05	Carcinogenic
o-aminoazotoluene	97-56-3	202-591-2	N.D.	0.05	Carcinogenic
o-Toluidine; 2-Aminotoluene	95-53-4	202-429-0	N.D.	0.05	Carcinogenic
N-methylacetamide	79-16-3	201-182-6	N.D.	0.05	Toxic for reproduction
1-bromopropane; n-propyl bromide	106-94-5	203-445-0	N.D.	0.05	Toxic for reproduction

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Substance Name	CAS number	EC number	Concentration (%)	Reporting Limit (%)	Classification
Cadmium	7440-43-9	231-152-8	N.D.	0.005	Carcinogenic
Cadmium oxide*	1306-19-0	215-146-2	N.D.	0.005	Carcinogenic
Dipentyl phthalate (DPP)	131-18-0	205-017-9	N.D.	0.05	Toxic for reproduction
4-Nonylphenol, branched and linear, ethoxylated [substances with a linear and/or branched alkyl chain with a carbon number of 9 covalently bound in position 4 to phenol, ethoxylated covering UVCB- and well-defined substances, polymers and homologues, which include any of the individual isomers and/or combinations thereof]	-	-	N.D.	0.05	Equivalent level of concern having probable serious effects to the environment
Ammonium pentadecafluorooctanoate (APFO)	3825-26-1	223-320-4	N.D.	0.05	Toxic for reproduction
Pentadecafluorooctanoic acid (PFOA)	335-67-1	206-397-9	N.D.	0.05	Toxic for reproduction

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Substance Name	CAS number	EC number	Concentration (%)	Reporting Limit (%)	Classification
Dihexyl phthalate	84-75-3	201-559-5	N.D.	0.05	Toxic for reproduction
Trixylyl phosphate	25155-23-1	246-677-8	N.D.	0.05	Toxic for reproduction
Imidazolidine-2-thione; 2-imidazoline-2-thiol	96-45-7	202-506-9	N.D.	0.05	Toxic for reproduction
Disodium 4-amino-3-[[4'-[(2,4-diaminophenyl)azo][1,1'-biphenyl]-4-yl]azo]-5-hydroxy-6-(phenylazo)naphthalene-2,7-disulphonate (C.I. Direct Black 38)	1937-37-7	217-710-3	N.D.	0.05	Carcinogenic
Disodium 3,3'-[[1,1'-biphenyl]-4,4'-diylbis(azo)]bis(4-aminonaphthalene-1-sulphonate) (C.I. Direct Red 28)	573-58-0	209-358-4	N.D.	0.05	Carcinogenic
Cadmium sulphide*	1306-23-6	215-147-8	N.D.	0.005	Carcinogenic Equivalent level of concern having probable serious effects to human health
Lead di(acetate)*	301-04-2	206-104-4	N.D.	0.005	Toxic for reproduction

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Substance Name	CAS number	EC number	Concentration (%)	Reporting Limit (%)	Classification
1,2-Benzenedicarboxylic acid, dihexyl ester, branched and linear	68515-50-4	271-093-5	N.D.	0.05	Toxic for reproduction
Cadmium chloride*	10108-64-2	233-296-7	N.D.	0.005	Carcinogenic Mutagenic Toxic for Reproduction Equivalent level of concern having probable serious effects to human health
Sodium perborate*; perboric acid, sodium salt*	-	239-172-9 234-390-0	N.D.	0.005	Toxic for reproduction
Sodium peroxometaborate*	7632-04-4	231-556-4	N.D.	0.005	Toxic for reproduction

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Substance Name	CAS number	EC number	Concentration (%)	Reporting Limit (%)	Classification
2-benzotriazol-2-yl-4,6-di-tert-butylphenol (UV-320)	3846-71-7	223-346-6	N.D	0.05	PBT vPvB
2-(2H-benzotriazol-2-yl)-4,6-ditertpentylphenol (UV-328)	25973-55-1	247-384-8	N.D	0.05	PBT vPvB
2-ethylhexyl 10-ethyl-4,4-dioctyl-7-oxo-8-oxa-3,5-dithia-4-stannatetradecanoate (DOTE)	15571-58-1	239-622-4	N.D	0.05	Toxic for Reproduction
Reaction mass of 2-ethylhexyl 10-ethyl-4,4-dioctyl-7-oxo-8-oxa-3,5-dithia-4-stannatetradecanoate and 2-ethylhexyl 10-ethyl-4-[[2-[(2-ethylhexyl)oxy]-2-oxoethyl]thio]-4-octyl-7-oxo-8-oxa-3,5-dithia-4-stannatetradecanoate (reaction mass of DOTE and MOTE)	-	-	N.D	0.05	Toxic for Reproduction
Cadmium fluoride	7790-79-6	232-222-0	N.D	0.005	Carcinogenic Mutagenic Toxic for Reproduction Equivalent level of concern having probable serious effects to human health
Cadmium sulphate	10124-36-4; 31119-53-6	233-331-6	N.D	0.005	Carcinogenic Mutagenic; Toxic for Reproduction Equivalent level of concern having probable serious effects to human health

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Substance Name	CAS number	EC number	Concentration (%)	Reporting Limit (%)	Classification
1,2-benzenedicarboxylic acid, di-C6-10-alkyl esters; 1,2-benzenedicarboxylic acid, mixed decyl and hexyl and octyl diesters with \geq 0.3% of dihexyl phthalate (EC No. 201-559-5)	68515-51-5 68648-93-1	271-094-0 272-013-1	N.D.	0.05	Toxic for Reproduction (Article 57 c)
5-sec-butyl-2-(2,4-dimethylcyclohex-3-en-1-yl)-5-methyl-1,3-dioxane [1], 5-sec-butyl-2-(4,6-dimethylcyclohex-3-en-1-yl)-5-methyl-1,3-dioxane [2] [covering any of the individual isomers of [1] and [2] or any combination thereof]	-	-	N.D.	0.05	vPvB (Article 57 e)

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Note:

1. RL = Reporting Limit

2. N.D. = Not detected (lower than RL)

N.A. = Not applicable for respective material type.

The submitted sample was found to contain significant amount of specific element(s) of SVHC. Upon further test verification and also information provided from client, the possibility that the element(s) content originate from SVHC is very unlikely, even though their presence cannot be exclude entirely. It may be assumed that the detected element(s) have a non-SVHC source.

3. Definition of classification is listed in Appendix A of this report in accordance with 67/548/EEC and Regulation (EC) No 1907/2006. For detail information, Detail explanation is available at the following link:

<http://echa.europa.eu/web/guest/candidate-list-table> (Candidate list)

http://echa.europa.eu/proposals-to-identify-substances-of-very-high-concern-previous-consultations?p_p_id=substancetypelist_WAR_substanceportlet&p_p_lifecycle=0&p_p_state=normal&p_p_mode=view&p_p_col_id=column-1&p_p_col_pos=2&p_p_col_count=4&substancetypelis
(Proposals to identify SVHC consultations)

4. *.The test result is based on the calculation of selected element(s) / marker(s) and to the worst-case scenario. For detail information, please refer to the SGS REACH website: www.reach.sgs.com/substance-of-very-high-concern-analysis-information-page.htm

The client is advised to review the chemical formulation to ascertain above metal substances present in the article.

RL = 0.005% is evaluated for element (i.e. cobalt, arsenic, lead, sodium, chromium, chromium(VI), silicon, aluminum, zirconium, boron, and potassium respectively), except molybdenum RL=0.0005%

0.1% (w/w) = 1,000 ppm = 1,000 mg/kg

5. **.β-TGIC is one of the isomers for TGIC compounds and hence, tested together. The reported test result is based the proposed ratio as according to ECHA dossier.

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Appendix A

Classification Definition under 67/548/EEC and Regulation (EC) No 1907/2006

Carcinogen Category 1: Substances known to be carcinogenic to man. There is sufficient evidence to establish a causal association between human exposure to a substance and the development of cancer.

Carcinogen Category 2: Substances which should be regarded as if they are carcinogenic to man. There is sufficient evidence to provide a strong presumption that human exposure to a substance may result in the development of cancer.
Generally on the basis of:
- appropriate long-term animal studies
- other relevant information.

Mutagen Category 1: Substances known to be mutagenic to man. There is sufficient evidence to establish a causal association between human exposure to a substance and heritable genetic damage.

Mutagen Category 2: Substances which should be regarded as if they are mutagenic to man. There is sufficient evidence to provide a strong presumption that human exposure to the substance may result in the development of heritable genetic damage, generally on the basis of:
- appropriate animal studies,
- other relevant information.

Toxic to Reproduction Category 1: Substances known to impair fertility in humans. There is sufficient evidence to establish a causal relationship between human exposure to the substance and impaired fertility.
Substances known to cause developmental toxicity in humans. There is sufficient evidence to establish a causal relationship between human exposure to the substance and subsequent developmental toxic effects in the progeny.

Toxic to Reproduction Category 2: Substances which should be regarded as if they impair fertility in humans. There is sufficient evidence to provide a strong presumption that human exposure to the substance may result in impaired fertility on the basis of:
- clear evidence in animal studies of impaired fertility in the absence of toxic effects, or, evidence of impaired fertility occurring at around the same dose levels as other toxic effects but which is not a secondary nonspecific consequence of the other toxic effects,
- other relevant information.
Substances which should be regarded as if they cause developmental toxicity to humans. There is sufficient evidence to provide a strong presumption that human exposure to the substance may result in developmental toxicity, generally on the basis of:
- clear results in appropriate animal studies where effects have been observed in the absence of signs of marked maternal toxicity, or at around the same dose levels as other toxic effects but which are not a secondary non-specific consequence of the other toxic effects,
- other relevant information.

PBT & vPvB: Substances which are persistent, bioaccumulative and toxic (PBT) or very persistent and very bioaccumulative (vPvB) pose a particular challenge to the chemicals safety management. For these substances a "safe" concentration in the environment cannot be established with sufficient reliability.

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