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

SGS Job No. :	CP19-039166 - GZ
Date of Sample Received :	19 Jul 2019
Testing Period :	19 Jul 2019 - 24 Jul 2019
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 Lead, Mercury, Cadmium, 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.

Signed for and on behalf of
SGS-CSTC Standards Technical Services Co., Ltd. Guangzhou Branch

Violet Shi

Violet,Shi
Approved Signatory

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Test Results :

Test Part Description :

Specimen No.	SGS Sample ID	Description
SN1	CAN19-141331.001	Black fabric sheet

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+A1:2017, IEC 62321-5:2013, IEC 62321-7-2:2017 , IEC 62321-6:2015 and IEC 62321-8:2017, analyzed by ICP-OES , UV-Vis and GC-MS .

Test Item(s)	Limit	Unit	MDL	001
Cadmium (Cd)	100	mg/kg	2	ND
Lead (Pb)	1,000	mg/kg	2	ND
Mercury (Hg)	1,000	mg/kg	2	ND
Hexavalent Chromium (CrVI)	1,000	mg/kg	8	ND
Sum of PBBs	1,000	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	1,000	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
Pentabromodiphenyl ether	-	mg/kg	5	ND

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Test Item(s)	Limit	Unit	MDL	*001*
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
Dibutyl phthalate (DBP)	1,000	mg/kg	50	ND
Butyl benzyl phthalate (BBP)	1,000	mg/kg	50	ND
Bis (2-ethylhexyl) phthalate (DEHP)	1,000	mg/kg	50	ND
Diisobutyl Phthalates (DIBP)	1,000	mg/kg	50	ND

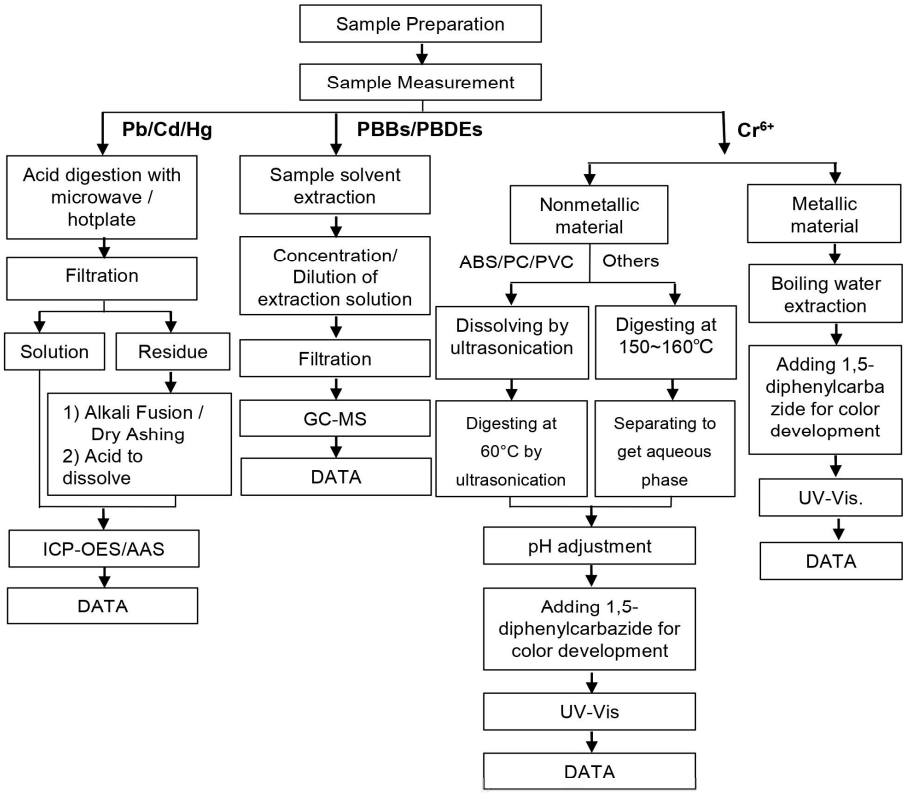
Notes :

(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:12586 37,25

ATTACHMENTS

Pb/Cd/Hg/Cr^{6+}/PBBs/PBDEs Testing Flow Chart

1) These samples were dissolved totally by pre-conditioning method according to below flow chart. (Cr^{6+} and PBBs/PBDEs test method excluded).



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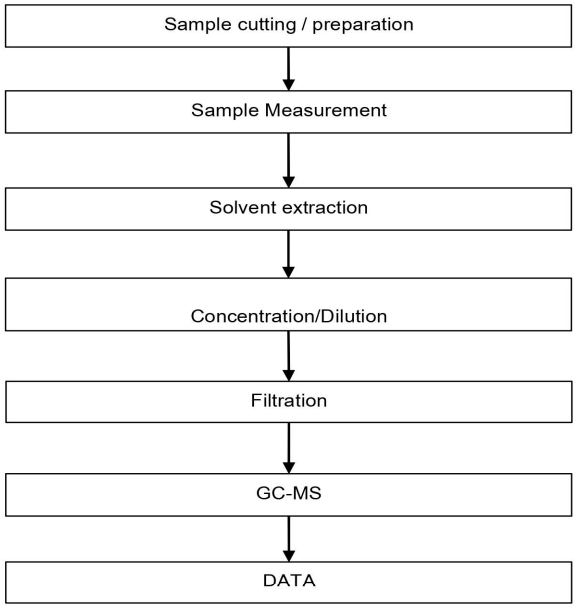
ATTACHMENTS

Phthalates Testing Flow Chart



Sample photo:

CAN19-141331.001

SGS authenticate the photo on original report only

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Sample name: Nonwoven fabric
Batch No./Date: 20200320

Above sample(s) was/were submitted and certified by the client, SGS quoted the information with no responsibility as to the accuracy, adequacy and/or completeness.

SGS job No.: GZCPCH200301146
Date of receipt: 2020-03-25
Testing period: 2020-03-25~2020-04-14

TEST(S) REQUESTED:
Selected test(s) as requested by applicant:
Please refer to next page(s).

TEST METHOD(S):
Please refer to next page(s).

TEST RESULT(S):
Please refer to next page(s).

This test report has been drafted in English and maybe translated into other languages, The English version shall prevail.

Signed for and on behalf of SGS

.....
Authorized Signature
Denny Li

TEST RESULT:
Test request: Dermal Irritation Test*

Test method: with reference to ISO 10993-10:2010, Biological evaluation of medical devices-Part 10: Tests for irritation and skin sensitization.

Test environment: Rabbit room of conventional condition. The license number of using laboratory animals is No. SYXK(粤) 2018-0086; Room temperature 21~23℃,Relative humidity 55~65%.

Test animal: New Zealand white albino rabbits, weighing between 2.1kg and 2.3kg at the start of the test,were used. They were supplied by Guangdong Medical Laboratory Animal Center (Sanshui Base). The production license number of laboratory animals is No. SCXK(粤)2019-0035. The animal certificate number is No. 44411600006527.
No. of animals/sex: 3/♀:♂=2:1

Preparation of Sample: The sample was cut to 2.5 cm×2.5 cm /piece and moistened with deionized water as test substance.

Observation period: 1±0.1h, 24±2h, 48±2h and 72±2h hours following removal of the test substance, use only 24±2h, 48±2h and 72±2h observations for calculations.

Test procedures: (1) Preparation of test animals. Selected three healthy young adult New Zealand white albino rabbits. Fur was shaved 24h before the test (approximately 10cm×15cm). (2) Procedures for testing. The test substance was applied to the test sides as shown in Figure 1 of test method with a gauze patch respectively Applied the control patch of gauze (was moistened with deionized water) on the control site indicated in Figure 1 of test method. And then the application sites were wrapped with a non-irritation tape and bandage for 4 hours. At the end of the contact time, removed the dressings and marked the sites, removed and wiped the residual test substance using warm water. Examined for signs of erythema and edema, recorded the dermal reactions at each observation period according to "Table 1" and "Table 2" in test method.

Result(s):
The Primary Irritation Index(PII) of the test substance is 0.

The scores of the test substance

Observation period	(1±0.1)h								(24±2) h							
Skin reaction	Erythema-eschar				Edema				Erythema-eschar				Edema			
Skin application site / Rabbit Number	Test Site		Control Site		Test Site		Control Site		Test Site		Control Site		Test Site		Control Site	
	L	R	L	R	L	R	L	R	L	R	L	R	L	R	L	R
1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
2	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
3	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0

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Observation period	(48±2) h								(72±2) h							
Skin reaction	Erythema-eschar				Edema				Erythema-eschar				Edema			
Skin application site / Rabbit Number	Test Site		Control Site		Test Site		Control Site		Test Site		Control Site		Test Site		Control Site	
	L	R	L	R	L	R	L	R	L	R	L	R	L	R	L	R
1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
2	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
3	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0

Note: 1. L= Left, R = Right
2. *Test was carried out by external laboratory assessed as competent.

Reference information:

ISO 10993-10:2010 Table2- Primary or cumulative irritation index categories in a rabbit

Mean score	Response category
0~0.4	Negligible
0.5~1.9	Slight
2~4.9	Moderate
5~8	Severe

SAMPLE DESCRIPTION: Sheet sample

Photo Appendix

*** End of Report***

Sample name: Nonwoven fabric
Batch No./Date: 20200320

Above sample(s) was/were submitted and certified by the client, SGS quoted the information with no responsibility as to the accuracy, adequacy and/or completeness.

SGS job No.: GZCPCH200301146
Date of receipt: 2020-03-25
Testing period: 2020-03-25~2020-04-16

TEST(S) REQUESTED:
Selected test(s) as requested by applicant:
Please refer to next page(s).

TEST METHOD(S):
Please refer to next page(s).

TEST RESULT(S):
Please refer to next page(s).

This test report has been drafted in English and maybe translated into other languages, The English version shall prevail.

Signed for and on behalf of SGS

.....
Authorized Signature
Denny Li

TEST RESULT:
Test request: Cytotoxicity*
Test method: With reference to ISO 10993-5: 2009<Biological evaluation of medical devices-Part5: Tests for in vitro cytotoxicity>

1. Summary:

According to the ISO 10993-5: 2009 *Biological evaluation of medical devices-Part5: Tests for in vitro cytotoxicity*, take advantage of Annex C: MTT cytotoxicity test to determination of cytotoxicity of test article(TA) extracts.

2. Materials:

2.1 Cell lines: L-929 cell (NCTC clone 929). Source: Kunming Cell Bank. Generation: 32.
2.2 Culture medium: DMEM with 10% fetal bovine serum (FBS, from Gibco, Lot: 2045512CP).
2.3 Test condition: Incubate at 37±1℃ and >90% humidity in air with 5% CO_2 (volume fraction).
2.4 TA storage conditions: Room temperature.
2.5 Test extract preparation: According to *ISO 10993-12: Biological evaluation of medical devices-Part12: Sample preparation and reference materials*, the TA was extracted following the extraction rate 0.1 g/mL with culture medium. The negative control and positive control materials were extracted following the extraction rate 0.2 g/mL with culture medium.
2.6 Blank control (BC): DMEM with 10% fetal bovine serum
2.7 Negative control (NC): Polyethylene, high density Granules, CAS#9002-88-4
2.8 Positive control (PC): Zinc Diethyldithiocarbamate, CAS#14324-55-1
2.9 Condition of extracts: Incubate at 37±1℃ and at 200 rpm/minute for 24±2 hours.

3. Methods:

3.1 Experimental Procedure:
3.1.1 All test sample and controls used the same pre-treatment and operating procedure. Took 0.6814 g of sample, added 6.81 mL DMEM culture solution containing 10% fetal bovine serum into glass bottle. Kept at 37±1℃ and 200 rpm / minute for 24±2 hours as original extraction（100%）.
3.1.2 The L-929 cells were cultured routinely in sterile flask. After the cells re-suspended in culture medium and the cell suspension was adjusted and seeded at a density of 1×10⁴ cells/100 μL/well into 96-well tissue culture microtitre plate and the PBS was dispensed into peripheral wells follow the rule

of 100 µL/ well. Subsequently, the plates were put in incubator for 24±2 hours to form a half-confluent monolayer.

3.1.3 The original extraction (100%) was distributed and diluted into 75%, 50% and 25%. Meanwhile, six replicates should be used for TA and controls. The plate was taken out from incubator and the medium was discarded. Then added 100 µL of treatment medium containing the appropriate concentration of TA extract (100%, 75%, 50% and 25%), the NC, PC and BC (medium-only). The plate was incubated for 24 ±0.5 hours.

3.1.4 Carefully removed the culture medium from the plates. 50 µL of MTT solution (1 mg/mL) was added into each well, and incubated for 2 hours±20 minutes at 37℃. The MTT solution was then removed, and 100 µL of isopropanol was added to each well. The absorbance was measured at 570 nm after swaying for 10-15 minutes in the dark.

3.2 Evaluation criteria:

$$\text{Viability}(\%) = \frac{OD_{570} \text{ of TA/PC/NC}}{OD_{570} \text{ of BC}} * 100$$

If viability is reduced to <70% of the BC, it has a cytotoxic potential.

The 50% extract of the TA should have at least the same or higher viability than the 100% extract; otherwise the test should be repeated.

3.3 Test quality check:

A test meets the acceptance criteria if the mean OD_{570} of blanks is ≥0.2.

A test meets acceptance criteria if the left and the right mean of the blanks do not differ by more than 15% from the mean of all blanks.

4. Results:

The results of show as table 1.

Table 1. The results of the test (Mean±SD)

Group	OD	Viability (%)
Blank control	1.0402±0.0643	100.00±6.45
Negative control	0.9742±0.0757	93.38±7.59
25%	1.0114±0.0850	97.12±8.52
50%	0.9422±0.0703	90.18±7.05
75%	0.8719±0.0437	83.12±4.38
100%	0.8141±0.0408	77.33±4.09
Positive control	0.2270±0.0271	18.46±2.72

Remark: *Test was carried out by external laboratory assessed as competent.

SAMPLE DESCRIPTION: Sheet sample

Photo Appendix

*** End of Report***