

SGS

Test Report No. NGBEC200505001 Date: 29 Oct 2020 Page 1 of 4

Test Results:

Test Part Description:

Specimen No. SGS Sample ID Description Material (claimed by the client)
SN1 NGB20-050502 001 white gloves TPE

Remarks:

(1) mg/dm² = milligram per square decimeter
(2) mg/kg = milligram per kilogram
(3) °C = degree Celsius
(4) = less than
(5) MDL = Method Detection Limit
(6) ND = Not Detected (= < MDL)

German Food, Articles of Daily Use and Feed Code of September 1, 2005 (LFGB), Section 30 and 31 with amendments, European Commission Regulation (EU) No 10/2011 with amendments and BFR recommendations-Specific migration of heavy metal

Test Method: With reference to Commission Regulation (EU) No 10/2011 of 14 January 2011 Annex III and Annex V for selection of condition and EN 1186-1:2002 for selection of test methods; EN 1186-14:2002 substitute test

Simulant Used	Time	Temperature	Max. Permissible Limit	Result of 001	Overall Migration
10% Ethanol (W/V) Aqueous Solution	2 Days	40°C	10mg/dm²	<3.0mg/dm²	
3% Acetic Acid (W/V) Aqueous Solution	2 Days	40°C	10mg/dm²	<3.0mg/dm²	
95% Ethanol (V/V) Aqueous Solution (Refined Olive Oil Substitute)	2 Days	40°C	10mg/dm²	<3.0mg/dm²	
Vaccuum Refined Olive Oil Substitute	0 Days	20°C	10mg/dm²	<3.0mg/dm²	

Notes:

(1) Analytical tolerance of aqueous simulants is 2 mg/dm²
(2) Analytical tolerance of fatty food simulants is 3 mg/dm²
(3) Test condition & simulant were specified by client.
(4) Report the first migration result.

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

Its Xiao
Approved Signatory

Member of the SGS Group (SIS SA)

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Test Method: With reference to EN13130-1:2004, analysis was performed by ICP-OES

Sample 001

Simulant Used: 3% Acetic Acid (W/V) Aqueous Solution
Test Condition: 40°C 2.0 h(s)

Test Items	Max. Permissible Limit	MDL	Test Result
Migration time	-	-	-
Asbestos	-	0.01g/g	ND
Aluminum (Al)	1	mg/kg	0.1
Barium (Ba)	1	mg/kg	0.25
Cadmium (Cd)	0.05	mg/kg	0.01
Copper (Cu)	5	mg/kg	0.25
Iron (Fe)	48	mg/kg	0.25
Lithium (Li)	0.6	mg/kg	0.5
Manganese (Mn)	0.6	mg/kg	0.25
Zinc (Zn)	5	mg/kg	0.5
Nickel (Ni)	0.02	mg/kg	0.02

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FDA 21 CFR 177.2600-Total Extractives

Test Method: With reference to FDA 21 CFR 177.2600

Simulant Used	Time	Temperature	Max. Permissible Limit	Result of 001	Total Extractives
Distilled Water	7 Days	Reflux temperature	20mg/inch²	<0.5mg/inch²	
Succeeding Extraction	2 Days	Reflux temperature	1mg/inch²	<0.5mg/inch²	
n-Hexane	7 Days	Reflux temperature	175mg/inch²	2.0mg/inch²	
Succeeding Extraction	2 Days	Reflux temperature	4mg/inch²	<0.5mg/inch²	

Notes:

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(2) mg/inch² = milligram per square inch

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SATRA Technology Services (Dongguan) Ltd
Unit 110, Xinzhongyin Garden, Xiping
Nansheng District, Dongguan City
Guangdong Province, China
Tel: +86 (0) 769 22888020
email: info@satratec.com

Customer details:

SATRA reference: CHT0305959 /2050

Your reference: HQ316

Date of report: 22 December 2020

Samples received: 7 December 2020

Date(s) work carried out: 18 December 2020

Subject:

EN ISO 21420: 2020 size & dexterity & innocuousness test, EN ISO 374-2: 2019 air leak and water leak, EN ISO 374-5: 2016 viruses test on Disposable Hybrid Poly Gloves, Powder free, referenced as HQ316, colour: clear, size: L/8

TECHNICAL REPORT

Conditions of Issue:

This report may be forwarded to other parties provided that it is not changed in any way. It must not be published, for example by including it in advertisements, without the prior, written permission of SATRA.

Results given in this report refer only to the samples submitted for analysis and tested by SATRA. Comments are for guidance only.

A satisfactory test report in no way implies that the product tested is approved by SATRA and no warranty is given as to the performance of the product tested. SATRA shall not be liable for any subsequent loss or damage incurred by the client as a result of information supplied in the report.

The uncertainty of the results (UoM) in this report is based on a standard uncertainty multiplied by a coverage factor k=2, which provides a coverage probability of approximately 95%.

Report signed by: Anthony Mak
Position: General Manager
Department: China Testing

(Page 1 of 11)

TECHNICAL REPORT

WORK REQUESTED

Samples described as Disposable Hybrid Poly Gloves, Powder free, referenced as HQ316, colour: clear, size: L/8 were received by SATRA on 7 December 2020 for testing in accordance with EN ISO 21420: 2020, EN ISO 374-2: 2019 and EN ISO 374-5: 2016.

SAMPLE SUBMITTED

Samples described as Disposable Hybrid Poly Gloves, Powder free, referenced as HQ316, colour: clear, size: L/8

TESTING REQUESTED

EN ISO 21420: 2020 Clause 5.1 – Sizing and measurement of gloves
EN ISO 21420: 2020 Clause 5.2 – Dexterity
EN ISO 21420: 2020 Clause 4.2 – Innocuousness of protective gloves
EN ISO 374-5: 2016 Clause 5.3 – Protection against viruses (ISO 15604: 2004 Procedure B)
EN 374-2: 2019 Clause 7.2 – Air leak
EN 374-2: 2019 Clause 7.3 – Water leak

CONCLUSION

The samples described Disposable Hybrid Poly Gloves, Powder free, referenced as HQ316, colour: clear, size: L/8 were found to achieve the following results:

EN ISO 21420: 2020 Clause 5.1 – See below table
EN ISO 21420: 2020 Clause 5.2 – Level 5
EN 374-2: 2019 Clause 7.2 – Pass
EN 374-2: 2019 Clause 7.3 – Pass
EN ISO 374-5: 2016 Clause 5.3 – Pass
EN ISO 21420: 2020 Clause 4.2 – Pass PAHs, pH value, Phthalates and DMF

Detailed results are included on the following page(s)

(Page 2 of 11)

TECHNICAL REPORT

Testing

Testing was carried out in accordance with EN ISO 21420: 2020 and EN 374-2: 2019.
Samples for testing were conditioned for at least 24 hours in a conditioned environment maintained at (23±2) °C and (50±5) % relative humidity.

Requirements

Table 1 – Requirements for EN ISO 21420: 2020 Clause 5.2 Dexterity

Performance level	1	2	3	4	5
Diameter of dexterity pin (mm)	11.0	9.5	8.0	6.5	5.0

Table 2 – Requirements for EN ISO 374-2: 2019

Clause 7.2 Air leak	No leak to be detected
Clause 7.3 Water leak	No leak to be detected

(Page 3 of 11)

TECHNICAL REPORT

Test Results

Table 3 – EN ISO 21420: 2020 Test Results

Clause / Test	Requirement	Test Results	UoM (See note 1)	Result
5.1 Glove length, comfort and fit	N/A	Size	1 2 3	± 1.10 mm
		Length (mm)	255 256 257	
		Comfortable on fit		
5.2 Dexterity	See table 1	Size	Minimum pin diameter / mm	N/A
		8	5.0	
		8	5.0	

Additional Information / Notes

Note 1 – Estimated uncertainty of measurement applied at point of test (e.g. to applied force or to tolerance limits) to ensure product meets requirements of the standard.

(Page 4 of 11)

TECHNICAL REPORT

Table 4 – EN ISO 374-2: 2019 Test Results

Clause / Test	Test Results	UoM	Result
7.2 Air leak test	Total air pressure used	3.1 kPa	N/A
	Sample size	8	
	No leaks detected		
7.3 Water leak test	Sample size	8	N/A
	No leaks detected		
	No leaks detected		

(Page 5 of 11)

