

Test Report No. 7191238357-EEC20/01-WBH
dated 17 Jul 2020



PSB Singapore

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SUBJECT:

Testing of Gloves submitted by Jiangxi Rainbow Medical Products Co., Ltd
on 03 Jun 2020.

TESTED FOR:

Jiangxi Rainbow Medical Products Co., Ltd
East Side of Jianshe Road Penghuwan Industrial Area Pengze,
Jiujiang City, Jiangxi Province,
China.

TEST DATE:

03 Jun 2020 to 01 Jul 2020, 15 Jul 2020 to 16 Jul 2020

DESCRIPTION OF SAMPLES:

S/N	Product Description	Colour	Lot No.	Size	Sample received (pieces)	Manufacturer
1	Clear Vinyl Glove (Powder Free)	Clear	4700006319	M	500	Jiangxi Rainbow Medical Products Co., Ltd



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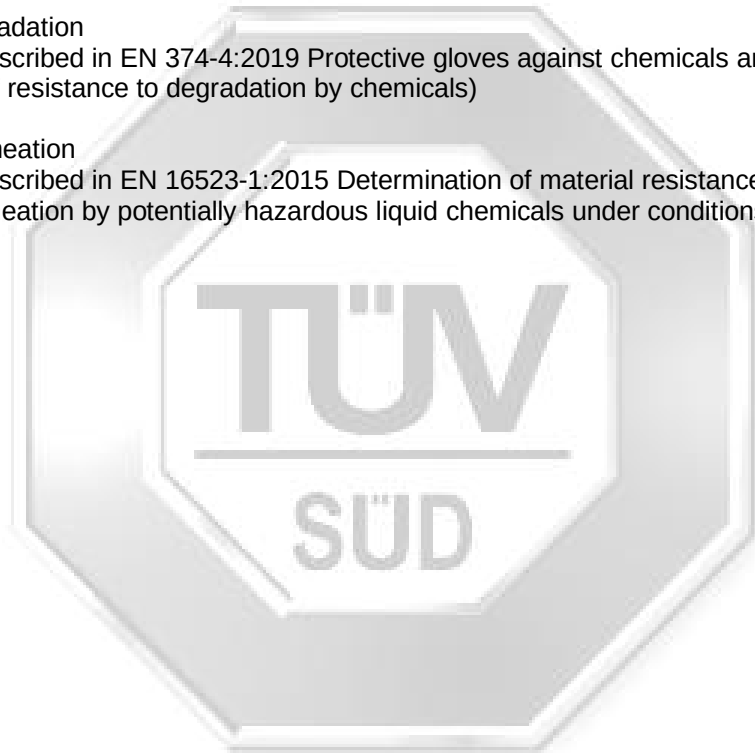
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METHOD OF TEST:

The tests were conducted in accordance with the following test standards:

EN ISO 374-1:2016 Protective gloves against dangerous chemicals and micro-organisms
Part 1: Terminology and performance requirements for chemical risks

- Clause 5.1 General requirements
(Test method described in EN 420:2003+A1:2009 Protective gloves – General requirements and test methods)
- Clause 5.2 Penetration
(Test method described in EN 374-2:2014 Protective gloves against dangerous chemicals and micro-organisms – Part 2: Determination of resistance to penetration)
- Clause 5.3 Degradation
(Test method described in EN 374-4:2019 Protective gloves against chemicals and micro-organisms. Determination of resistance to degradation by chemicals)
- Clause 5.4 Permeation
(Test method described in EN 16523-1:2015 Determination of material resistance to permeation by chemicals. Permeation by potentially hazardous liquid chemicals under conditions of continuous contact)



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RESULTS:

Table 1: Results for tests according to EN ISO 374-1:2016 Clause 5.1-5.4

Sample: Clear Vinyl Glove (Powder Free), Lot No. 4700006319

Clause	Tests	Specification	Results	Inferred Result
5.1	General Requirement	Protective gloves against dangerous chemicals shall comply with the requirements given in EN 420:2009, Clause 4, Clause 5 and Clause 7.	Refer to Table 2 for results of EN 420:2009, Clause 4, Clause 5 The submitted glove and packaging not tested to EN 420 Clause 7 Marking and information as requested by client.	Passed Not tested
5.2	Penetration	Protective gloves shall not leak when tested according to EN 374-2:2014, 7.2 and 7.3. 7.2 Air leak test 7.3 Water leak test	No leakage for both tests	Passed
5.3	Degradation	The degradation (DR) shall be determined according to EN 374-4 for each chemical claimed in the marking and reported in the user instruction. Tested Chemical: 40% Sodium Hydroxide	Degradation Results (%)	NA
			Glove 1	
			Glove 2	
			Glove 3	
			Average	
			Standard Deviation	
5.4	Permeation	Each combination of protective glove/test chemical shall be classified according to Table A (see remark 5), using the results as given in EN 16523-1:2015, 8.5.1.1 or 8.5.1.3 for the normalized breakthrough time. Tested Chemical: 40% Sodium Hydroxide For Type C: The permeation performance shall be at least level 1 against minimum of one test chemical	Breakthrough Time (mins)	Passed
			Glove 1	
			Glove 2	
			Glove 3	
			Mean Value	
			Lowest Value	
			The breakthrough time occurred after 480 mins, the tested glove is classified as Level 6 No color change was observed on the glove test specimen after the test.	

RESULTS (cont'd):

Table 2: Results for EN 420:2003+A1:2009

Sample: Clear Vinyl Glove (Powder Free), Lot No. 4700006319

Test	EN 420:2003+A1:2009 Requirements		Results	Inferred Results
I. Determination of pH Value, pH value	> 3.5 and < 9.5		6.7	Passed
II. Sizing, minimum length of glove (mm)	Size	Minimum length of glove (mm)	240	Passed
	M (7)	230		
III. Dexterity, level of performance	Level of performance	Smallest pin diameter fulfilling test conditions (mm)	5	See remark 1
	1	11		
	2	9.5		
	3	8		
	4	6.5		
	5	5		

REMARKS:

1. A glove should allow as much dexterity as possible given its purpose.
2. For Clause 5.2 Penetration, the test sample will be four gloves of each size, with an overall minimum of 16 gloves per performed test (Air leak test and Water leak test). If one sample fails the penetration test, the test shall be reported as having failed.
3. For Clause 5.3 Degradation, the test specimens for each size will be 3 gloves and 6 specimens will be cut from each glove. For each glove, 3 specimens will be exposed to the challenge chemical (40% Sodium Hydroxide) and 3 specimens will be unexposed. After prepare the specimens, and exposed to 40% Sodium Hydroxide for 1 hour, puncture the specimen and record the peak force required.
4. For Clause 5.4 Permeation, The palm area of the glove sample was mounted between two halves of a test cell. The test cell consisted of a two-compartment cell with 40% Sodium Hydroxide on glove's normal outside surface and Ultrapure Water on the glove's normal inside surface. Testing were carried out at ambient temperature (23°C ± 2°C). The collecting medium were sampled and analysed for 40% Sodium Hydroxide at 10 min (level 1), 30 min (level 2), 60 min (level 3), 120 min (level 4), 240 min (level 5) and 480 min (level 6). The extracts were then analysed by Ion Chromatography. The results were used to calculate the permeation rate of 40% Sodium Hydroxide through the glove material. Based on the result, the minimum rate of sampling was determined. The tests were repeated at the sampling interval of 75 sec and collected until 10 mins. The extracts were then analysed by Ion Chromatography for the Normalised Permeation Rate. A blank test was carried out exactly with the same procedure except Ultrapure Water was used.

Note: Chemical transfer referred to the quantity of chemical which had passed through per cm² of glove sample at the termination of the test. The thickness of the glove is 0.07mm.

REMARKS (cont'd):

5. Table A Classification of Glove Levels According to Breakthrough Time for Clause 5.4 Permeation

Breakthrough Time (mins) *	Permeation performance level
> 10	1
> 30	2
> 60	3
> 120	4
> 240	5
> 480	6

* The breakthrough time is deemed to have occurred when the analytical equipment detects a permeation rate of 1 $\mu\text{g}/\text{cm}^2/\text{min}$.

6. NA: Not applicable for the submitted sample.



Lee Dai Yi
Engineer



Wong Bee Hui
Product Manager
Medical Health Services (NAM)

APPENDIX:



Photo: Clear Vinyl Glove (Powder Free), Lot No. 4700006319

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July 2011

