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TECHNICAL REPORT

SATRA TECHNOLOGY SERVICES (DONGGUAN) LTD UNIT 110, XINZHONGYIN GARDEN XIPING, NANCHENG DISTRICT DONGGUAN CITY Guangdong Province China	SATRA reference:	CHM2024722	
		2522	1
	Report ID/Issue number:	52473/2	
	Your reference:	CHT2024383	
	Date samples received:	27/05/2025	
	Date(s) work carried out:	29/05/2025 to 04/06/2025	
	Date of report:	27/06/2025	

Testing Requirements

EN 16523-1:2015+A1:2018 resistance to permeation by chemicals on gloves described as Synthetic Latex Exam Gloves. Color: Cream White.

This report is a reissue referenced as CHM2024722 Report ID 52473/2 Issue 2, and supersedes CHM2024722 Report ID 52473/1 Issue 1, dated 9th June 2025 to combine CHM2024722 Hydrogen Peroxide results with CHM2022955 40% Sodium Hydroxide and 37% Formaldehyde results.

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For SATRA's statements regarding the confidentiality, publication and dissemination of this report, decision rules and UKAS accreditation please see the final page of this technical report.

Report Signed by:

Jacob Griffin

Report Signatory

WORK REQUESTED:

Samples of gloves described as Synthetic Latex Exam Gloves. Color: Cream White were received on the 27th May 2025 for testing in accordance with EN 16523-1:2015+A1:2018 and assessment in accordance with the requirements of EN ISO 374-1:2016+A1:2018.

Customer:
Shandong Intco Medical Products Co Ltd
Qiwang Road, Naoshan Industrial Park
Qingzhou SHANDONG 262506
China

SAMPLES SUBMITTED:

Samples described as Synthetic Latex Exam Gloves. Color: Cream White

CONCLUSION:

When assessed in accordance with the requirements of EN ISO 374-1:2016+A1:2018 the samples of gloves described as Synthetic Latex Exam Gloves. Color: Cream White achieved the following performance levels:

Chemical	Performance level
40% Sodium hydroxide (CAS: 1310-73-2)	*6
30% Hydrogen peroxide (CAS: 7722-84-1)	2
37% Formaldehyde (CAS: 50-00-0)	*3

* results from CHM2024955 Report ID 51458/1 Issue 1, samples were received on 14th April 2025

Full results are reported in the following tables.

TESTING REQUIRED:

- EN 16523-1:2015+A1:2018 - Determination of material resistance to permeation by chemicals - Part 1: Permeation by liquid chemical under conditions of continuous contact

RESULTS AND REQUIREMENTS:

EN ISO 374-1:2016+A1:2018 - Protective gloves against dangerous chemicals and micro-organisms - Part 1: Terminology and performance requirements for chemical risks. Table 1: Permeation performance levels.

Permeation performance level	Measured breakthrough time (minutes)
1	>10
2	>30
3	>60
4	>120
5	>240
6	>480

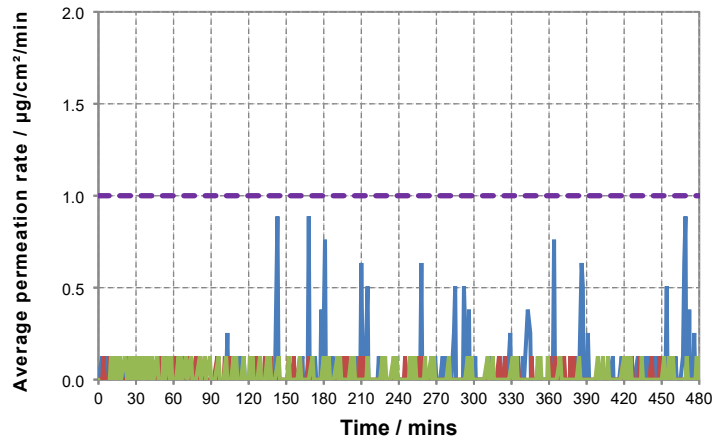
Performance levels are based on the lowest individual result achieved per chemical.

Test/Property	Sample reference:	Synthetic Latex Exam Gloves Cream White		Performance
EN 16523-1:2015 +A1:2018 in accordance with SATRA SOP CAT-009 Using PTFE permeation cells with standardised dimensions	Test information:	Chemical: 40% Sodium Hydroxide		Level 6
		Normalised permeation rate (NPR): 1 µg/cm²/min		
		Detection technique: Conductimetry (continuous measurement)		
		Collection medium: Deionised water (closed loop)		
		Collection medium stirring rate: (each cell constant to within ± 10%) 45 – 65 ml/min		
		Test temperature: (23 ± 1) °C		
	Specimen	**Thickness (mm)⌂**	**Breakthrough time (mins)**	
	1	0.09	>480	
	2	0.12	>480	
	3	0.10	>480	
		Test result:	**>480**	
		UoM:	**<1**	
Visual appearance of specimens after testing:		Swollen		

Test specimens were washed in deionised water prior to conditioning in accordance with EN 16523-1:2015+A1:2018. This modification was to remove extractable substances from the gloves that otherwise might have interfered with the conductivity detection technique.

PERMEATION RATE GRAPHS

Challenge chemical: 40% Sodium Hydroxide .



* results from CHM2024955 Report ID 51458/1 Issue 1, samples were received on 14th April 2025

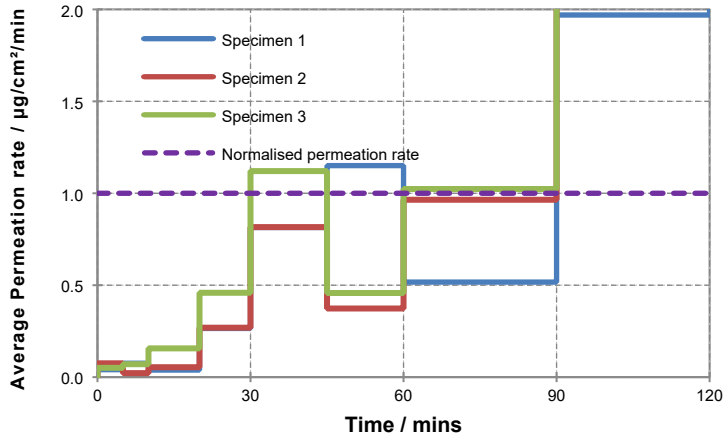
Test/Property	Sample reference:	Synthetic Latex Exam Gloves. Color: Cream White		Performance
EN 16523-1:2015 +A1:2018 in accordance with SATRA SOP CAT-025 Using PTFE permeation cells with standardised dimensions	**Test information:**	Chemical: 30% Hydrogen peroxide		**Level 2**
		Normalised permeation rate (NPR): 1 µg/cm²/min		
		Detection technique: Electrochemical detector (periodic measurement)		
		Collection medium: Deionised water (closed loop)		
		Collection medium stirring rate: (each cell constant to within ± 10%) 45 – 65 ml/min		
		Test temperature: (23 ± 1) °C		
	Specimen	**Thickness (mm)⌂**	**Breakthrough time (mins)▼**	
	1	0.11	Between 46 to 60	
	2	0.12	Between 91 to 120	
	3	0.12	Between 31 to 45	
		Test result:	**Between 31 to 45**	
		UoM:	**See below**	
Visual appearance of specimens after testing:		Swollen		

For SOP CAT-025, where both the P_1 and P_u are observed in the same sampling range, uncertainty is expressed as the time difference between the mid-point of the range and the previous sampling time. This uncertainty is included in the reported result.

Hydrogen peroxide is determined by discrete sampling; therefore the permeation rate graph is not a smooth curve.

PERMEATION RATE GRAPHS

Challenge chemical: 30% Hydrogen Peroxide.



SATRA Report Reference: CHM2024722 2522
Report ID/Issue number: 52473/2

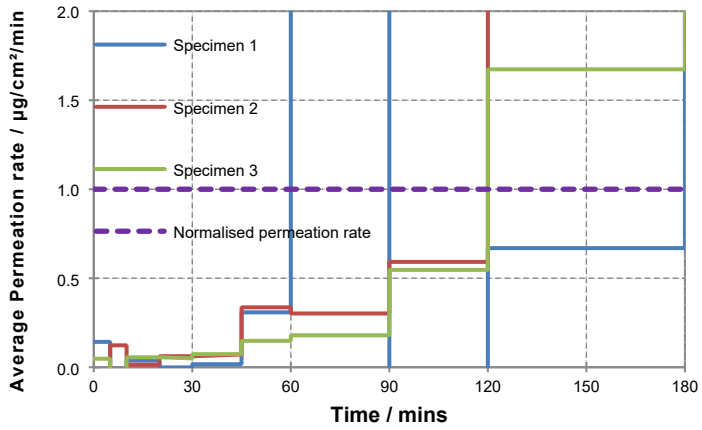
Test/Property	Sample reference:	*Synthetic Latex Exam Gloves Cream White		Performance
EN 16523-1:2015 +A1:2018 in accordance with SATRA SOP CAT-025 Using PTFE permeation cells with standardised dimensions	**Test information:**	Chemical: 37% Formaldehyde		**Level 3**
		Normalised permeation rate (NPR): 1 µg/cm²/min		
		Detection technique: HPLC-DAD (periodic measurement)		
		Collection medium: Deionised water (closed loop)		
		Collection medium stirring rate: (each cell constant to within ± 10%) 45 – 65 ml/min		
		Test temperature: (23 ± 1) °C		
	Specimen	**Thickness (mm)⌂**	**Breakthrough time (mins)▼**	
	1	0.09	Between 61 to 90	
	2	0.10	Between 121 to 180	
	3	0.09	Between 121 to 180	
		Test result:	**Between 61 to 90**	
		UoM:	**See below**	
Visual appearance of specimens after testing:		Swollen		

For SOP CAT-025, where both the P_1 and P_u are observed in the same sampling range, uncertainty is expressed as the time difference between the mid-point of the range and the previous sampling time. This uncertainty is included in the reported result.

Formaldehyde is determined by discrete sampling; therefore the permeation rate graph is not a smooth curve.

PERMEATION RATE GRAPHS

Challenge chemical: 37% Formaldehyde .



* results from CHM2024955 Report ID 51458/1 Issue 1, samples were received on 14th April 2025

SATRA Report Reference: CHM2024722 2522
Report ID/Issue number: 52473/2

⌂ EN 16523-1:2015+A1:2018 does not require the test specimen thicknesses to be reported, this information is indicative only.

▼ Breakthrough expressed as a range between discrete sampling points where the average permeation rate exceeds the NPR. Due to the complexity of the detection technique, the minimum sampling frequency as specified in table 1 of EN 16523-1:2015+A1:2018 is not possible.

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When reporting results against a conformance statement (Pass/Fail or the allocation of a class or level) then uncertainty of measurement is taken into account based on a non-binary acceptance which itself is based on the guard band being equal to the expanded uncertainty.

Where the result corrected for uncertainty falls within the tolerance of the conformance statement then the risk of the conformance statement being a false accept or false reject is up to 2.5% and SATRA will in this instance quote a Pass/Fail, class, or level.

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