SATRA Technology Centre Ltd
Wyndham Way, Telford Way, Kettering,
Northamptonshire, NN16 8SD United Kingdom
Tel: +44 (0) 1536 410000
email: info@satra.com
www.satra.com

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TECHNICAL REPORT

SATRA Technology Europe Ltd Bracetown Business Park Clonee County Meath Dublin 15 Ireland	SATRA reference:	CHM2010891	
		2433	1
	Report ID/Issue number:	43958/1	
	Your reference:	STE2010519	
	Date samples received:	16/08/2024	
	Date(s) work carried out:	29/08/2024 to 20/09/2024	
	Date of report:	20/09/2024	

Testing Requirements

Regulation 2016/425 Module C2 testing of gloves described as MASTERFUL in accordance with EN 16523-1:2015+A1:2018 resistance to permeation by chemicals against 40% Sodium Hydroxide & 37% Formaldehyde

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Report Signed by:

Lorna Harding

Report Signatory

WORK REQUESTED:

Samples of gloves described as MASTERFUL were received by SATRA Technology UK on the 16th August 2024 for testing in accordance with EN 16523-1:2015+A1:2018 and with the performance requirements of EN ISO 374-1:2016+A1:2018 to demonstrate ongoing production compliance with Module C2 of Regulation (EU) 2016/425.

Sample Reference:	MASTERFUL
Lot/Batch Code:	83414 28705
Date of Manufacture:	11/2023
Expiry Date:	11/2028
Sample Colour:	Blue
Sample Size:	XLarge
Date Sample(s) Received by SATRA Technology Europe:	12/08/2024
Sample(s) were obtained from:	Not provided.
Test area:	Palm
Customer:	DCK GRUP İÇ DIŞ TİCARET MEDİKAL LTD.ŞTİ. MACUN MAH. BATI BULV. ATB İŞ MERKEZİ E BLOK 1/108 YENİMAHALLE Ankara 06374
Initial testing/ Retest:	Initial testing

SAMPLES SUBMITTED:

Samples described as MASTERFUL

CONCLUSION:

When assessed in accordance with the requirements of EN ISO 374-1:2016+A1:2018 the samples of gloves described as MASTERFUL achieved the following performance levels:

Chemical	Performance level
40% Sodium hydroxide (CAS: 1310-73-2)	6
37% Formaldehyde (CAS: 50-00-0)	5

Mean thickness of 20 specimens prepared from the palm area of the gloves (mm)	0.10

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
- Indicative thickness measurements of 20 specimens prepared from the palm area of the gloves

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.

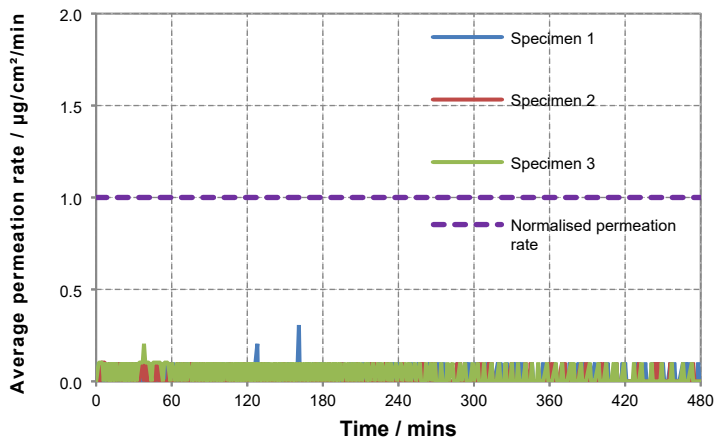
Permeation performance level	Measured breakthrough time (minutes)
1	>10
2	>30
3	>60
4	>120
5	>240
6	>480

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

Test/Property	Sample reference:	MASTERFUL		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	0.11	>480	
	3	0.09	>480	
		Test result:	**>480**	
		UoM:	**<1**	
Visual appearance of specimens after testing:		Swollen and discoloured		

PERMEATION RATE GRAPHS

Challenge chemical: 40% Sodium Hydroxide .



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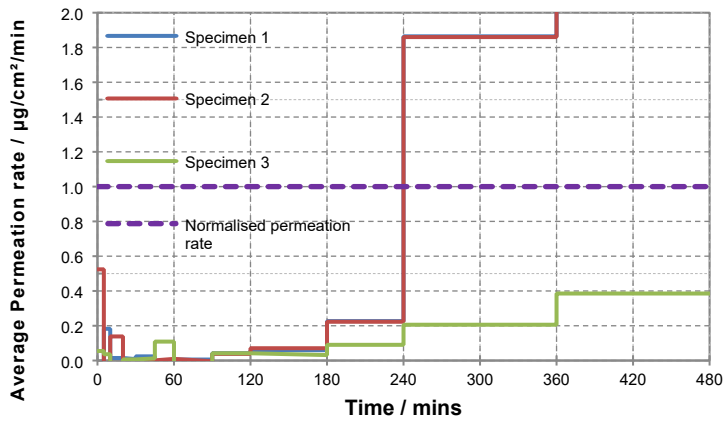
Test/Property	Sample reference:	MASTERFUL		Performance
EN 16523-1:2015 +A1:2018 in accordance with SATRA SOP CAT-025 Using PTFE permeation cells with standardised dimensions	**Test information:**	Chemical: 37% Formaldehyde		**Level 5**
		Normalised permeation rate (NPR): 1 µg/cm²/min		
		Detection technique: 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	0.10	Between 241 to 360	
	2	0.10	Between 241 to 360	
	3	0.09	>480	
		Test result:	**Between 241 to 360**	
		UoM:	**See below**	
Visual appearance of specimens after testing:		Swollen and discoloured		

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.

PERMEATION RATE GRAPHS

Challenge chemical: 37% Formaldehyde.



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

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- ⌂ 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.

Indicative thickness measurements of 20 specimens prepared from the palm area of the gloves

Thickness measurement (mm)			
1	0.11	**11**	0.09
2	0.09	**12**	0.11
3	0.10	**13**	0.10
4	0.10	**14**	0.09
5	0.10	**15**	0.10
6	0.11	**16**	0.11
7	0.11	**17**	0.12
8	0.10	**18**	0.10
9	0.10	**19**	0.08
10	0.10	**20**	0.08
Mean thickness (mm)		**0.10**	

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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.

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