

Chlorinated PowderFree Nitrile Examination Gloves TF 005

Attachment 2

# DECLARATION OF CONFORMITY

Plant of Manufacture:

COMFORT RUBBER GLOVES INDUSTRIES SDN BHD

Lot 821 & 2209, Jalan Matang,

34750 Matang, Perak,

Malaysia.

Lot 1874, Jalan Kampung Dew,

Simpang Halt, 34700 Simpang, Taiping, Perak, Malaysia.

Contact Person

Telephone Number

Facsimile No. Position

605-847 2777 / 2888 605-847 9108 / 6250

Mr. Ng Kok Howe

QA & QMS Manager

(Quality Management Representative) garyng@comfort-rubber.com.my

E-mail

Competent Authority

Certificate No.

SGS United Kingdom Ltd Systems & Services Certification

MY09/77229

Product

Chlorinated PowderFree Nitrile Examination Gloves.

Classification

Conformity Assessment Route

Rule 1

Class 1

Intended Use

It is a disposable device intended for medical purpose that is worn on the

examiner's hands to prevent contamination between patient and

examiner.

Hereby declare that product described as Chlorinated PowderFree Nitrile Examination Gloves is in conformity with the provision of Regulation (EU) 2017/745 of The European Parliament and of The Council (Non-Invasive Devices - Rule 1). Where such is the case, with the national standard transposing harmonized standard Nos. EN 455-1, EN 455-2, EN 455-3 and EN 455-4.

Signed

Name Position

Ng Kok Howe QA Manager

Date

25 October 2019



## DECLARATION OF CONFORMITY

Plant of Manufacture:

COMFORT RUBBER GLOVES INDUSTRIES SDN BHD

Lot 821, Jalan Matang, 34750 Matang, Perak,

Malaysia.

Lot 1874, Jalan Kampung Dew,

Simpang Halt, 34700 Simpang, Taiping, Perak, Malaysia.

Contact Person

Mr. Ng Kok Howe

Telephone Number

605-847 2777 / 2888 605-847 9108 / 6250

Facsimile No. Position

QA Manager

(Quality Management Representative)

E-mail

garyng@comfort-rubber.com.my

Competent Authority Certificate No.

:

SGS United Kingdom Ltd Systems & Services Certification

MY09/77230

Product

Powder Free Natural Rubber and Nitrile Examination Gloves.

PPE Classification

Category III

Conformity Assessment Route

Module D

Intended Use

The Personal Protective Equipment glove is designed to be worn or held by

an individual for protection against one or more health and safety hazards.

We herewith declare that the above mentioned products meet the provisions of the Personal Protective Equipment (PPE) by the Regulation (EU) 2016/425 of The European Parliment and Of The Council for Personal Protective Equipment. All supporting documentation is retained under the premises of the manufacturers.

Standards Applied

EN 16523-1:2015 - Determination of material resistance to permeation by chemicals. Permeation by liquid chemical through a protective clothing

material

EN 374-Part 2:2003 - Protective gloves against chemicals and micro-

organisms. Determination of resistance to penetration

EN-374-part 3:2003 - Protective gloves against chemicals and micro-

organisms. Determination of resistance to permeation by chemicals



EN 374-4:2013 - Protective gloves against chemicals and micro-organisms. Determination of resistance to degradation by chemicals

EN 14362-1 – Arylamines coming from prohibited azo dyes in textiles, EN 374-2 (2014) – Determination of resistance of water leak and air leak

EN 420 - Protective gloves - General requirements and test methods

EN 388:2016 - Protective gloves against mechanical risks

ISO 374-5:2016 - Protective Gloves Against Dangerous Chemicals And Micro-Organisms - Part 5: Terminology And Performance Requirements For Micro-Organisms Risks

Signed

Name : Ng Kok Howe Position : QA Manager

Date : 21st May 2020



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Tel: +44 (0) 1536 410000 Fax +44 (0) 1536 410626 email: info@satra.com www.satra.com

Customer details: Comfort Rubber Gloves Industries Sdn.Bhd

Lot 821

Jalan Matang 34750 Matang

Perak Malaysia SATRA reference: CHM0292515/1948/LC

/B

Your reference:

Date of report: 20th January 2020

Samples received: 21st November 2019

Date(s) work

9th to 10th January

carried out: 2020

# **TECHNICAL REPORT**

Subject: EN 374-4:2019 determination of resistance to degradation by chemicals on

gloves described as Nitrile Powder Free Examination Gloves PFNBR244.

### 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: Lucy Cove Position: Technologist

Department: Chemical & Analytical Technology

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## **WORK REQUESTED:**

Samples of gloves described as Nitrile Powder Free Examination Gloves PFNBR244 were received on the 21<sup>st</sup> November 2019 for testing in accordance with EN 374-4:2019.

## **SAMPLE SUBMITTED:**



CHNOLOGY

Samples described as Nitrile Powder Free Examination Gloves PFNBR244

### **CONCLUSION:**

When assessed in accordance with EN 374-4:2019 the samples of gloves described as Nitrile Powder Free Examination Gloves PFNBR244 achieved the following degradation results:

Chemical	Mean degradation / %
99% Acetic acid (CAS: 64-19-7)	91.7
37% Formaldehyde (CAS: 50-00-0)	-13.7
30% Hydrogen peroxide (CAS: 7722-84-1)	3.2
n-Heptane (CAS: 142-82-5)	52.9
96% Sulphuric acid (CAS: 7664-93-9)	100.0
40% Sodium hydroxide (CAS: 1310-73-2)	-24.6

Comfort Rubber Gloves Industries Sdn.Bhd SATRA Reference: CHM0292515/1948/LC/B

Date: 20<sup>th</sup> Januar

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Signed:



### **TESTING REQUIRED:**

• EN 374-4:2019. Protective gloves against chemicals and micro-organisms. Part 4: Determination of resistance to degradation by chemicals.

### **RESULTS:**

Sample description:	Nitrile Pow	Nitrile Powder Free Examination Gloves PFNBR244		
Challenge chemical:	99% A	99% Acetic acid (CAS: 64-19-7)		
Test temperature / °C:	(23 ± 1)			
Degradation / %:	Glove 1	Glove 2	Glove 3	
Degradation / %.	91.6	91.9	91.8	
Mean degradation (DR) / %:		91.7		
Standard deviation (σ <sub>DR</sub> ) / %:	<1			
UoM /±%:	56.0			
Appearance of samples after testing:	Swollen			

Sample description:	Nitrile Powder Free Examination Gloves PFNBR244		
Challenge chemical:	37% Formaldehyde (CAS: 50-00-0)		
Test temperature / °C:	20 21 00	(23 ± 1)	IN, VALO
De madation (Q)	Glove 1	Glove 2	Glove 3
Degradation / %:	-36.4	-5.2	0.4
Mean degradation (DR) / %:	000	-13.7	- 11) N, 1V
Standard deviation (σ <sub>DR</sub> ) / %:	19.8		
UoM /±%:	7.7		
Appearance of samples after testing:	Marion.	Swollen	34 MIN.

Sample description:	Nitrile Powder Free Examination Gloves PFNBR244			
Challenge chemical:	30% Hydrogen peroxide (CAS: 7722-84-1)			
Test temperature / °C:	(23 ± 1)			
Down dation (9/)	Glove 1	Glove 2	Glove 3	
Degradation / %:	10.2	-9.0	8.4	
Mean degradation (DR) / %:	3.2			
Standard deviation (σ <sub>DR</sub> ) / %:		10.6	00/2	
UoM / ± %:	8.0			
Appearance of samples after testing:	: Swollen			

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Signed:

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Sample description:	Nitrile Powder Free Examination Gloves PFNBR244			
Challenge chemical:	n-Heptane (CAS: 142-82-5)			
Test temperature / °C:	(23 ± 1)			
Degradation / %:	Glove 1	Glove 2	Glove 3	
Degradation 7 %.	44.0	54.9	59.8	
Mean degradation (DR) / %:		52.9		
Standard deviation (σ <sub>DR</sub> ) / %:		8.1		
UoM /±%:		11.8		
Appearance of samples after testing:	Swollen			

Sample description:	Nitrile Powder Free Examination Gloves PFNBR244		
Challenge chemical:	96% Sulphuric acid (CAS: 7664-93-9)		
Test temperature / °C:	(23 ± 1)		
Degradation / %:	Glove 1	Glove 2	Glove 3
Degradation / %.	100.0	100.0	100.0
Mean degradation (DR) / %:	100.0		
Standard deviation (σ <sub>DR</sub> ) / %:	N/A		
UoM / ± %:	N/A		
Appearance of samples after testing:	Disintegrated		

Sample description:	Nitrile Powder Free Examination Gloves PFNBR244		
Challenge chemical:	40% Sodium hydroxide (CAS: 1310-73-2)		
Test temperature / °C:	(23 ± 1)		
Doggodetion / 9/.	Glove 1	Glove 2	Glove 3
Degradation / %:	-35.9	-22.5	-15.4
Mean degradation (DR) / %:	J'Z	-24.6	174,050
Standard deviation (σ <sub>DR</sub> ) / %:	W. MOL	10.4	7 7 7
UoM /±%:	7.5		
Appearance of samples after testing:	Swollen		

**NOTE:** Where the test specimens gave an increased puncture force after chemical exposure, the result is reported as a negative degradation.

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### TERMS AND CONDITIONS FOR THE SALE OF GOODS AND/OR THE PROVISION OF SERVICES

#### 1. GENERAL

- Work done, Services undertaken or the sale of Goods are subject to the terms and conditions detailed below and (subject to clause 5.2) all other conditions, warranties and representations, expressed or implied by statute relating thereto are hereby excluded.
- SATRA Technology Centre Limited, its subsidiaries and associated companies (hereinafter referred to as "SATRA") may perform Services for or supply Goods to persons or entities (public, private or governmental) issuing instructions (hereinafter termed the "Client"). Each also known individually as a Party, or jointly as
- These terms and conditions will apply to the Contract between SATRA and the Client to the exclusion of any other terms which the Client may seek to impose or which may be implied by trade, custom, practice or course of dealing 1.3
- Unless otherwise agreed in writing no party other than the Client is entitled to provide instructions or information relating to the Goods or Services required or to the delivery of goods, results, reports or 1.4 certificates
- 1.5 All references in these terms and conditions to:
- (a)
- (b)
- the "Contract" is the contract between SATRA and the Client for the supply of Goods or Services which is made subject to these terms and conditions; and "Services" are the work or services to be supplied or performed under the Contract (including where relevant the supply of software, components and consumables); and "Goods" are the equipment, consumables or other physical items sold under the Contract (including documents, drawings or other information required in order to operate the equipment). (c)
- All drawings, descriptive matter, specifications and advertising material (including brochures and catalogue are issued or published with the sole purpose of giving an indication of the goods or services being describ and shall not form part of the Contract.
- Where SATRA and the Client agree that the sale of Goods shall be governed by Incoterms 2010 (or any 1.7 subsequent revision thereto) then the sale shall be governed by the relevant Incoterms mode of transport which is agreed by SATRA and the Client.

#### 2. FEES AND PAYMENT

- 2 1 Where SATRA has agreed to perform the Services or supply the Goods on the basis of credit then payment Where SATRA has agreed to perform the Services or supply the Goods on the basis of credit then payment terms are net 21 days from date of invoice, unless otherwise specified and may require part payment prior to delivery of the Services or Goods. In the event of the Client failing to make payment as agreed SATRA will be entitled to withhold delivery of the Goods or Services or cancel the Contract. SATRA reserves the right to charge interest on any overdue payments at a rate of 1.5% per month accruing on a daily basis from the date the invoice is due until the date payment is received.
- Where the provision of Services or the sale of Goods is subject to a proforma invoice then SATRA shall not be obliged to start working on the provision of the Goods or Services until after payment in full has been made as cleared funds to SATRA. 2.2
- SATRA reserves the right to charge for any and all expenses incurred as a result of performing the Services required by the Client. Although SATRA will try and provide an estimate of such expenses these may change as a result of circumstances out of SATRA's control. 2.3
- Unless otherwise agreed in writing, the price for the Goods or Services shall be the price set in the order acknowledgement. SATRA shall not be bound by any price quoted which is not in writing. Prices for the sale of Goods include packing cases and materials but not carriage or installation which will be quoted separately and as agreed with the Client. 2.4
- 2.5 Quotations are valid from the date of issue for a period of 90 days unless otherwise specified or agreed in
- Should the Client become insolvent, bankrupt, subject to an administration order, enter into liquidation or receivership, or make arrangements with creditors SATRA reserves the right to cancel the Contract and terminate the supply of the Goods or Services. Where the Contract with SATRA is terminated all outstanding monies due from the Client to SATRA shall be immediately payable, and any materials supplied by SATRA to the Client returned. Termination of the Contract shall be without prejudice to any of SATRA's accrued rights. 2.6
- 2.7 All invoices issued by SATRA are payable in full. The Client is responsible for payment of withholding and any other taxes and all import duties. Payments made to SATRA shall not be reduced by such amounts.
- The Client shall not be entitled to withhold or defer payment due to SATRA as a result of any dispute or counter claim that it may allege against SATRA.
- 2.9 SATRA reserves the right to bring action against the Client in order to collect unpaid fees, including court action. All fees associated with such actions shall be paid for by the Client including legal fees and related
- Where unforeseen costs arise as a result of provision of the Goods or carrying out the Services SATRA shall inform the Client immediately but reserves the right to charge additional costs to cover said costs and 2.10

#### INTELLECTUAL PROPERTY RIGHTS 3.

- All intellectual property rights belonging to a Party prior to entry into the Contract shall remain with that Party. Nothing in this Contract shall allow transfer of any intellectual property rights from one Party to the other. 3.1
- event of certification services the use of certification marks by the Client may be subject to national nternational laws and regulations. The responsibility for the use of these certification marks lies solely
- All intellectual property rights in reports, drawings, graphs, charts, photographs or any other material (in whatever medium) produced by SATRA pursuant to this Contract shall belong to SATRA. The Client shall have the right to use said material in accordance with the terms of this Contract. 3.3
- The Client agrees and acknowledges that SATRA retains any and all propriety rights in concepts, ideas and inventions that may arise during the preparation or provision of any report (including any deliverables provided by SATRA to the Client) and the provision of the Services to the Client. 3.4
- All intellectual property rights in any software supplied to the Client shall belong to SATRA or SATRA's licensors. With respect to the sale of SATRA Timeline, SATRASUMM and SATRA Visionstitch, provided that the Client is a member of SATRA and has paid its annual Smartcare fee then the Client will be entitled to use the software for its own internal use and will be entitled to receive minor software upgrades and fixes. SATRA may however terminate the supply of software upgrades and fixes for older versions of software which it no longer considers viable to support. The Client's rights to use the software neceive software upgrades and fixes will terminate if the Client has not paid its annual Smartcare fee. Major upgrades are not included within the entitlement to upgrades but may be offered by SATRA from time to time for an additional fee. 3.5
  - SATRA shall observe all statutory provisions with regard to data protection including but not limited to the provisions of the Data Protection Act 2018 and the EU General Data Protection Regulation (CDPR) Regulation (EU) 2016/679. To the extent that SATRA processes or gets access to personal data in connection with the Services or otherwise in connection with this Contract, it shall take all reasonable technical and organisational measures to ensure the security of such data (and guard against unauthorised or unlawful processing, accidental loss, destruction or damage to such data).

### SUSPENSION OR TERMINATION OF SERVICES

- Cancellation by the Client of orders for Goods or Services will only be acceptable by prior agreement with SATRA and a charge will usually be made. 4.1
- SATRA shall not be liable for any delay or failure in providing the Goods or Services due to circumstances beyond its reasonable control (including any failure by the Client to comply with its obligations). If any such circumstances arise which prevent SATRA from delivering the Goods or completing the Services, then SATRA will be entitled to cancel or reschedule the delivery of Goods or Services at its discretion. In the event of cancellation SATRA will be entitled to retain all fees paid by the Client for Goods or Services already supplied but will refund to the Client and Fees paid by the Client for Goods or Services which have not yet been supplied. The Client will not be liable for any non-refundable expenses already incurred by SATRA in relation to Goods or Services not yet supplied unless the cancellation is due to the Clients failure to comply with its obligations under the Contract.

#### LIABILITY AND INDEMNIFICATION 5.

- Reports are issued on the basis of information, documents and or samples submitted to SATRA by the Client. 5 1 Reports are issued on the basis of information, documents and or samples submitted to SATRA by the Client, or on behalf of the Client and are provided solely for the benefit of the Client who is responsible for acting as it sees fit on the basis of such reports and findings. Subject to clause 5.2, neither SATRA nor any of its employees, agents or subcontractors shall be liable to the Client or any third party for any actions taken or not taken on the basis of such findings and reports, nor for any incorrect results arising as a result of unclear, erroneous, incomplete, misleading or false information provided to SATRA.
- Nothing in these terms and conditions shall limit or exclude SATRA's liability for
- death or personal injury caused by its negligence or the negligence of its employees or agents; fraud or fraudulent misrepresentation; breach of the terms implied by Section 12 of the Sale of Goods Act 1979; defective products under the Consumer Protection Act 1987; or any other liability which cannot be limited or excluded by applicable law.

- (a) (b) (c) (d) (e)
- 5.3 Subject to clause 5.2 SATRA shall not be liable to the Client whether in contract, tort (including negligence), breach of statutory duty or otherwise arising under or in connection with the Contract for loss of profits, sales, contracts, anticipated savings, loss or damage to goodwill or any indirect or consequential loss.
- Subject to clause 5.2 SATRA's total aggregate liability to the Client, whether in contract, tort (including negligence), breach of statutory duty or otherwise arising under or in connection with the Contract shall be limited to the total amount of fees for the Services or the price of the Goods (excluding any value added tax or other sales tax or expenses) payable by the Client to SATRA under the Contract or £100,000 whichever is the lower figure. 5.4

#### MISCELL ANEOUS 6.

- If any one or more provisions of these conditions are found to be illegal or unenforceable in any respect, the validity, legality and enforceability of the remaining provisions shall not in any way be affected or impaired thereby. 6.1
- During the course of providing the Goods or Services and for a period of one year thereafter the Client shall not directly or indirectly entice, encourage or make any offer to SATRA's employees to leave their employment with SATRA.
- The use of SATRAs corporate name or registered marks for advertising purposes is not permitted without SATRA's prior written authorisation. 6.3
- All reports and documentation which are supplied to the Client under the Contract remain the property of 6.4 SATRA until paid in full. Under no circumstances will a Client's purchase order override SATRA's retention of title in accordance with this clause.
- The Client acknowledges that in entering into this Contract it has not relied on any representation, warranty, 6.5 collateral contract or other assurance (except those set out or referred to in these terms and conditions) made by or on behalf of SATRA or any other party before entering into the Contract. The Client waives all rights and remedies that, but for this clause, might otherwise be available to it in respect of any such representation, warranty, collateral contract or other assurance.
- All provisions of the Contract that limit or exclude the liability of SATRA are intended also to be for the benefit of SATRA's holding company (called SATRA, and being a company limited by guarantee and incorporated in England and Wales with company number 00153475), and shall accordingly be enforceable by such holding company as well as or instead of by SATRA, and on the basis that any limit on the liability of SATRA shall apply to it and to such holding company in the aggregate.

- Unless specifically excluded in the terms of an individual contract between SATRA and the Client, the following shall apply to all deliverables including, reports, advice, drawings, photographs, specifications, data 7.1 or other forms of media.
- 7.2 Deliverables referred to in clause 7.1 shall not be disclosed to third parties or used in litigation without the consent of SATRA.
- Where SATRA has given consent to disclosure of any service deliverables referred to in clause 7.1, the Client shall draw the attention of the third party to these terms of business and the basis on which SATRA undertakes testing, reporting and advising. The Client shall indemnify SATRA for any failure to do so. 7.3
- The service deliverables referred to in clause 7.1 are submitted to the Client as confidential documents. Confidentiality shall continue to apply after completion of the business, but shall cease to apply to information or knowledge which has come into the public domain through no breach of this Contract by the Client. 74
- The Client shall not disassemble, remove parts or carry out any form of analysis on goods or materials sold by SATRA for the purposes of reverse engineering or obtaining information on the construction, content or composition of the item without the consent of SATRA. 7.5

### 8.

8.1 No amendment to this Contract shall be effective unless it is in writing, expressly stated to amend this Contract and signed by an authorised signatory of both Parties

#### DISPUTE RESOLUTION 9.

- 9.1 If there should be a dispute between the parties to this Agreement they undertake to act with goodwill and to use all reasonable endeavours to resolve that dispute
- Failure to resolve any dispute by discussions between the parties shall, in the first instance, be referred to a mediator for resolution. The parties shall attempt to agree upon the appointment of a mediator, upon receipt, by either of them, of a written notice to concur in such appointment. Should the parties fail to agree within 21 days, either party, upon giving written notice, may apply to the President or the Vice President, for the time being, of the Chartered Institute of Arbitrators, for the appointment of a mediator. 92
- Should the mediation fail, in whole or in part, either party may, upon giving written notice, and within twenty-eight days thereof, apply to the President or the Vice President, for the time being, of the Chartered Institute of Arbitrators, for the appointment of a single arbitrator, for final resolution. The arbitrator shall have no connection with the mediator or the mediation proceedings, unless both parties have consented in writing. The arbitration shall be governed by both the Arbitration Act 1996 and the Controlled Cost Rules of the

Signed:

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Comfort Rubber Gloves Industries Sdn.Bhd SATRA Reference: CHM0292515/1948/LC/B 20th January 2020 Date:





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### TERMS AND CONDITIONS FOR THE SALE OF GOODS AND/OR THE PROVISION OF SERVICES

Chartered Institute of Arbitrators (2000 Edition), or any amendments thereof, which Rules are deemed to be incorporated by reference into this clause. The seat of the arbitration shall be England and Wales.

The laws of England shall govern the interpretation of this Contract. Subject to clauses 9.1, 9.2 and 9.3 any The laws or England shall govern the interpretation of this Contract, Subject to clauses 9.1, 9.2 and 9.3 any dispute arising out of or in connection with the Contract shall be subject to the exclusive jurisdiction of the courts of England. However, the Party obtaining a judgement in such courts shall be entitled to enforce it in any court it chooses.

### PROVISION OF SERVICES

- SATRA shall provide Services using reasonable care and skill and in accordance with the Clients specific instructions and as confirmed by SATRA as part of the Contract review process.
- Estimates for completion of the Services are made in good faith and date from receipt of a written order, payment of a proforma invoice if required, full information and samples to enable SATRA to proceed. While SATRA will make every effort to fulfil them, such estimates are subject to unforseen events and if not achieved, cannot give rise to any claim. Time will not be of the essence in relation to the performance of the 10.2
- Results given in test reports or certificates refer only to samples submitted for analysis to SATRA. 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. 10.3
- SATRA may delegate all or part of the Services to a subcontractor and the Client authorises SATRA to disclose all information required to undertake the Services. 10.4
- Where the Client requests SATRA to witness testing of other services being undertaken by a third party the Client agrees that SATRAs sole responsibility is to be present at the time of the work and to forward the results or confirm that the service has been undertaken. The Client agrees that unless otherwise agreed SATRA is not responsible for the condition or calibration of any equipment unless provided by SATRA. 10.5
- Unless otherwise agreed in advance, test samples will be retained for 6 weeks from the date of the final report after which time they will be disposed of and SATRA shall cease to have any responsibility for such 10.6

Where the nature of the samples or the Services undertaken results in specialist disposal then SATRA reserves the right to pass the cost of such disposal onto the Client. Storage for longer periods may be possible only if agreed in advance and may incur a storage charge payable by the Client.

Where practical and agreed in advance, samples may be returned at the Client's expense. However, samples are in most instances partially or fully destroyed as part of the work undertaken and SATRA cannot guarantee that samples will be returned in an "as new" condition.

- Where SATRA receives documents reflecting engagements between the Client and third parties or documents belonging to third parties, such documents shall be considered as being for information only and shall not release the Client from any or all obligations to SATRA. 10.7
- SATRA reserves the right to make changes to the Services, provided that such changes do not materially affect the nature or quality of the provision of these Services or where they are necessary in order to ensure that any applicable laws or safety requirements are complied with.
- The Client acknowledges that SATRA by providing the Services, neither takes the place of the Client or any third party or releases them from any of their obligations. 10.9

#### CLIENT RESPONSIBILITIES RELATING TO THE PROVISION OF SERVICES 11

- 11.1 The Client shall provide sufficient samples, information, instructions and documents as required to enable SATRA to carry out the Services in accordance with the methods, standards or other specifications as
- Where applicable the Client shall allow access by members of SATRA staff to such premises where the Services are to be performed and provide any specialist equipment and personnel. 11 2
- The Client shall inform SATRA in advance of any known hazards, dangers or other safety matters relating to samples submitted to SATRA or on site visits made by SATRA. 11.3
- Where the Client fails to comply with any of its responsibilities SATRA reserves the right to suspend any Services until such time as the Client has complied and may require the Client to reimburse SATRA the amount of any additional costs arising from the suspension.

#### 12. **DELIVERY AND NON-DELIVERY OF GOODS**

- 12.1 Delivery dates for the supply of the Goods are approximate only and not guaranteed. Time of delivery is not of the essence of the Contract and SATRA shall not be liable for any delay in delivery of Goods.
- Should expedited delivery be requested and agreed. SATRA shall be entitled to make additional charges to 122 cover overtime or any other additional costs
- Delivery of the Goods shall take place at such location as SATRA and the Client agree. If the Client agrees to collect the Goods from SATRA's premises, then delivery will take place at those premises in which case the consignment of Goods as recorded by SATRA upon dispatch shall be evidence of the Goods received by the Client unless the Client can provide conclusive evidence to the contrary. 12.3
- SATRA shall not be liable for the non-delivery of Goods (even if caused by SATRA) unless the Client provides written notice of non-delivery in accordance with clause 13.2. Liability for non-delivery of Goods shall in any event be limited to replacing the Goods within a reasonable time frame or the issue of a credit note to the value of the Goods not delivered.
- Should delivery of the Goods be suspended or delayed by the Client for any reason SATRA reserves the right to charge for storage and for all expenses incurred, including loss of or wastage of resources that cannot otherwise be used. If the delay extends beyond 30 days SATRA shall be entitled to immediate payment for any Goods that are ready for delivery, and any other additional costs.
- If for any reason the Client fails to accept delivery of any of the Goods when they are ready for delivery, or SATRA is unable to deliver the Goods on time because the Client has not provided appropriate instructions, documents, licenses or authorisations then risk in the Goods shall pass to the Client, the Goods and/or Services shall be deemed to have been delivered; and SATRA may store the Goods until delivery, whereupon the Client shall be liable for all related costs and expenses (including, without limitation, storage 12.6 and insurance)

#### 13. RISK/TITLE OF GOODS

- Subject to clause 12.6 the risk in the Goods will transfer to the Client on delivery of the Goods unless SATRA and the Client have agreed that the sale of the Goods will be governed by Incoterms 2010 (or any subsequent revision thereto) in which case risk will transfer to the Client in accordance with the Incoterms mode of transport which is agreed by SATRA and the Client. 13 1
- 13.2 Company shall not accept responsibility for loss or damage in transit unless
- In the case of sales where delivery of Goods is made in the United Kingdom SATRA is notified by the Client within 10 days of the invoice date of non-arrival of Goods and within 3 days of the invoice date of receipt of Goods damaged in transit; or

- In all other cases the Client notifies SATRA on the non-arrival or damage in transit within a reasonable period of time as determined by SATRA.
- 13 3 Title to the Goods shall not pass to the Client until the earlier of when: -
- SATRA receives payment in full (in cash or cleared funds) for the Goods and any other Goods that SATRA has supplied to the Client in which case title to the Goods shall pass at the time of payment of all such sums;
- and
  the Client resells the Goods in accordance with clause 13.5 in which case title shall pass to the Client
  immediately before the time at which the resale by the Client occurs. b)
- 13.4 Until ownership of Goods has passed to the Client, the Client shall:
- hold the Goods as SATRA's bailee; store the Goods (at no cost to SATRA) separately from all other goods belonging to the Client or any third party in such a way that they remain readily identifiable as SATRA's property (including where the Goods have been sold to a 3rd party); a) b)
- not destroy, deface or obscure any identifying mark or packaging on or relating to the Goods; and
- c) d) maintain the Goods in satisfactory condition and keep them insured on SATRA's behalf for their full price against all risks to the reasonable satisfaction of SATRA. The Client shall obtain an endorsement of SATRA's interest in the goods on its insurance policy. On request the Client shall allow SATRA to inspect such Goods and shall produce the policy of insura
- The Client may resell the Goods before ownership has passed to it solely on condition that sale shall be effected in the ordinary course of the Client's business at full market value. 13.5
- If before title to the Goods passes to the Client, the Client becomes subject to any of the events referred to in clause 2.6 then without limiting any other right or remedy SATRA may have:
- a) the Client's right to resell the Goods or use them in the ordinary course of its business ceases immediately;
- and
  SATRA may at any time require the Client to deliver up all Goods in its possession that have not been resold
  or irrevocably incorporated into another product, and
  if the Client fails to do so promptly SATRA may exercise its rights under clause 13.7. b)
- c)
- The Client grants SATRA, its agents and employees an irrevocable licence at any time to enter any premises where the Goods are or may be stored in order to inspect them, or, where the Client's right to possession has terminated, to recover them. 13.7
- 13.8 On termination of the Contract, howsoever caused, SATRA's (but not the Client's) rights contained in this clause 13 shall remain in effect

#### 14. PATENTS

SATRA gives no indemnity against any claim of infringement of Letters Patent, Registered Design, Trade Mark or Copyright by the use of or sale of any article or material supplied to the Client. If its use is impossible without infringement of Letters Patent, Registered Design, Trade Mark or Copyright published at the date of the contract, SATRA will refund to the Client the purchase price of the said article or material provided that it is returned to SATRA free of charge. The Client warrants that any design or instruction furnished or given by the Client shall not be such as will cause SATRA to infringe any Letters Patent, Registered Design, Trade Mark or Copyright in the execution of the Client's order. 14.1

### 15.

SATRA warrants that on delivery and for a period of 12 months from the date of delivery or within the shelf 15.1 life of the Goods (whichever is the shorter period) the Goods shall be free from defects in design, material and workmanship

#### DEFECTIVE GOODS 16.

(Page 6 of 6)

- 16 1 Subject to clauses 16.6 and 16.7 if:
- a)
- b) c)
- the Client gives notice in writing to SATRA in accordance with clause 16.3 and during the period referred to in clause 15.1 that the Goods do not comply with the warranty in that clause; and SATRA is given a reasonable opportunity of examining such Goods; and the Client (if asked to do so by SATRA) returns such Goods to SATRA's place of business then SATRA will, at its option, repair or replace the defective Goods or Fefund the price of the defective Goods in full. SATRA reserves the right to repair the Goods at the Client's premises.
- The Client must inspect all Goods upon delivery. Failure to do so may result in further charges being applied
- 16.3 If Goods are found to be faulty, defective or damaged the Client must inform SATRA in writing as soon as reasonably possible and in any event within 10 working days of the fault, damage or defect being discovered.
- Without prejudice to clause 16.1 if no notice of rejection has been received by SATRA within 3 months of 164 delivery, the Client shall be deemed to have accepted the Goods
- SATRA will pay the reasonable costs of carriage, packaging and insurance for any defective Goods which are returned by the Client provided that SATRA is liable under clause 16.1 to repair or replace the defective Goods. If SATRA determines that the Goods are not defective or if SATRA is not liable to repair or replace the Goods due to the circumstances under clauses 16.6 or 16.7 then the Client will be responsible for the 16.5 payment of such costs
- SATRA shall not be under any liability to repair or at its option replace or pay for the repair or replacement of any Goods which are found to be defective if: 16.6
- the defect is caused or substantially caused by wear and tear, overloading, misuse, neglect, modification or attempted modification carried out by any organisation other than by SATRA or their approved agents, or use with ancillary equipment not approved in writing by SATRA, or default in proper maintenance or cleaning;
- or the Client authorises or carries out any repair or replacement of any Goods without first affording SATRA a b)
- reasonable opportunity to replace or repair them; or the Client has breached any of the terms of the Contract under which the Goods were supplied; or the Goods have been manufactured to a design or specification or in compliance with other information provided by the Client and the defect has arisen as a result of that design, specification or information; c) d)
- Where Goods or parts of Goods are not manufactured by SATRA then SATRA shall be liable for defects only 16.7 to the extent that SATRA obtains redress from the manufacturer or supplier thereof provided that:
- SATRA shall not be obliged to take any step to attempt to obtain such redress except at the request and expense of the Client and upon provision by the Client of a full indemnity as to costs for which SATRA may a) expense of the Client a thereby become liable
- nothing in this condition 16.7 shall have effect as to impose upon SATRA any additional liability or obligations other than those referred to in condition 16.1 b) an those referred to in condition 16.1.
- Except as provided in clause 16.1 SATRA shall have no liability to the Client arising from any failure of the Goods to comply with the warranty in clause 15.1. 16.8

Terms and conditions - September 2019

Comfort Rubber Gloves Industries Sdn.Bhd SATRA Reference: CHM0292515/1948/LC/B 20th January 2020 Date:

Signed:

1-ine

# Test Report No. 7191063861-MEC13/01-CSL dated 12 Jul 2013



**Note:** This report is issued subject to the Testing and Certification Regulations of the TÜV SÜD Group and the General Terms and Conditions of Business of TÜV SÜD PSB Pte Ltd. In addition, this report is governed by the terms set out within this report.

Choose certainty.
Add value.

### SUBJECT:

Testing of Examination Gloves submitted by Comfort Rubber Gloves Industries Sdn. Bhd. on 27 Jun 2013.

### **TESTED FOR:**

Comfort Rubber Gloves Industries Sdn. Bhd. Lot 821, Jalan Matang, 34750 Matang, Taiping, Perak Darul Ridzuan, Malaysia.

Attn: Mr Kwok / Ms Zaleha

### **TEST DATE:**

03 Jul 2012 to 11 Jul 2012

### **DESCRIPTION OF SAMPLES:**

S/N	Product Description	Lot No.	Size	Colour	Sample received (pieces)
1	Non-Sterile, Powder Free Nitrile  Examination Gloves	30606S12-L2	М	Dark Blue	495

### **METHOD OF TEST:**

EN 455-1:2000 Medical gloves for single use

Part 1: Requirements and testing for freedom from holes

EN 455-2:2009+A1:2011 Medical gloves for single use Part 2: Requirements and testing for physical properties

you been Su



Laboratory: TÜV SÜD PSB Pte. Ltd. No.1 Science Park Drive Singapore 118221 Phone: +65-6885 1333 Fax: +65-6776 8670 E-mail: testing@tuv-sud-psb.sg www.tuv-sud-psb.sg Co. Reg: 199002667R Regional Head Office: TÜV SÜD Asia Pacific Pte. Ltd. 3 Science Park Drive, #04-01/05 The Franklin, Singapore 118223

# Test Report No. 7191063861-MEC13/01-CSL dated 12 Jul 2013



## **RESULTS:**

Sample: Non-Sterile, Powder Free Nitrile Examination Gloves (Size: M) - Lot no. 30606S12-L2

S/N	Tests	Requirement	Number tested (pieces)	Non- complia nce allowed (pieces)	Median	Min	Max	Actual no. of non- compliers found	Inferred results
1	Freedom from holes	Shall not leak	315	10	- 3	ı	-	8	Passed
2	Dimension a)Length (mm)	Median Length for size M: ≥ 240	13	1	243	241	248	ı	Passed
	b)Width (mm)	Median Width for size M: 95 ± 10	13	-	95	94	96	1	Passed
3	Strength a)Force at break (N)	Median Force at Break for nitrile: ≥ 6.0	13	Ţ	8.0	7.8	8.3		Passed
	b)Force at break after challenge testing (N)	Median Force at Break for nitrile: ≥ 6.0	13 S	ÜD	8.3	7.8	9.0	-	Passed

Yeo Poh Kwang Higher Associate Engineer Snareen Chan

Engineer

Mechanical Centre

# Test Report No. 7191063861-MEC13/01-CSL dated 12 Jul 2013



## **APPENDIX:**



Photo : Non-Sterile, Powder Free Nitrile Examination Gloves (Size: M) - Lot no. 30606S12-L2



### Test Report No. 7191063861-MEC13/01-CSL dated 12 Jul 2013



### Please note that this Report is issued under the following terms:

- This report applies to the sample of the specific product/equipment given at the time of its testing/calibration. The results are not used to indicate or imply that they are applicable to other similar items. In addition, such results must not be used to indicate or imply that TÜV SÜD PSB approves, recommends or endorses the manufacturer, supplier or user of such product/equipment, or that TÜV SÜD PSB in any way "guarantees" the later performance of the product/equipment. Unless otherwise stated in this report, no tests were conducted to determine long term effects of using the specific product/equipment.
- The sample/s mentioned in this report is/are submitted/supplied/manufactured by the Client. TÜV SÜD PSB therefore assumes no responsibility for the accuracy of information on the brand name, model number, origin of manufacture, consignment or any information supplied.
- Nothing in this report shall be interpreted to mean that TÜV SÜD PSB has verified or ascertained any endorsement or marks from any other testing authority or bodies that may be found on that sample.
- This report shall not be reproduced wholly or in parts and no reference shall be made by the Client to TÜV SÜD PSB or to the report or results furnished by TÜV SÜD PSB in any advertisements or sales promotion.
- Unless otherwise stated, the tests were carried out in TÜV SÜD PSB Pte Ltd, No.1 Science Park Drive Singapore 118221.



# Comfort Rubber Gloves Industries S/B TENSILE STRENGTH TEST RESULT (EN 455-2)

(UNAGED)

Force @ Break:- Min 6 N

Type of glove: OCF48NBBL Lot No.: 00101F304-10

Off Line Lot No.: Size: M-240mm Sample: ONLINE

Tensile Machine Id: P838-M

Ruler Id: P568-M

Oven Id:

Die Cutter Id: P594-M Tested Date: 10-01-2020

est No.	Weight	Width	Specimen area	FAB	Tensile Strength	Elongation
mm	g	mm	mm²	N	MPa	%
1	4.673	3.000	0.240	8.577	35.736	678
2	4.667	3.000	0.240	7.412	30.884	700
3	4,853	3.000	0.240	7.793	32,471	627
4	4.776	3.000	0.240	7.747	32.279	596
5	4,848	3.000	0.240	8.273	34.470	686
6	4.835	3.000	0.240	8.119	33.830	642
7	4.744	3.000	0.240	8.081	33.670	663
8	4.740	3.000	0.240	7.079	29.495	581
9	4.836	3.000	0.240	7.778	32.408	596
10	4.772	3.000	0.240	8,243	34.345	717
11	4,445	3.000		7,675	31.980	677
	4.872	3,000		7.949	33.119	667
12	4.869	3,000		6.393	26.637	662
13		3.000		7.778	32.410	653
Average	4.764	3.000		7.793	32,47	663
Median	4.776			0.569		2 47
SD s-1	0.119	0.000		8.577		5 71
Max.	4.872	3.000		6.393		7 58
Min.	4.445	3.000	0.240	0,555		_

Tested By: ILLI NAJWA (Lab Assistant and above) verified By: \_\_\_\_\_ Kamal (Lab Sr. Supervisor and above)

# Comfort Rubber Gloves Industries S/B TENSILE STRENGTH TEST RESULT (EN 455-2)

(AGED)

Type of glove: OCF48NBBL

Lot No.: 00101F304-10

Off Line Lot No.: Size;M-240mm Sample: ONLINE

Tensile Machine Id: P499-M

Oven ID:P191-M Die Cutter ID:P594-M Tested Date: 15-1-2020 Force @ Break: - Min 6 N

Test No.	Weight	Width	Specimen area	FAB	Tensile Strength	Elongation
mm	g	mm	mm²	N	MPa	%
1	4.667	3.00	0.240	10.146	42.273	524
2	4.853	3.00	0.240	7.867	32.780	513
3	4.776	3.00	0.240	9.338	38.910	556
4	4.848	3.00	0.240	8.989	37.456	510
5	4.835	3.00	0.240	9.614	40.057	479
6	4.744	3.00	0.240	8.999	37.495	49
7	4.836	3.00	0.240	9.402	39.176	52
8	4.740	3.00	0.240	8.956	37.316	51
9	4.772	3.00	0.240	8.713	36.305	48
10	4.772	3.00	0.240	9.595	39.981	45
11	4.445	3.00	0.240	8.969	37.372	53
12	4.872	3.00	0.240	8.012	33.385	46
13	4.869	3.00	0.240	9.720	40.499	44
Average	4,771	3.00	0.240	9.102	37.923	50
Median	4.776	3.00	0.240	8.999	37.495	51
SD s-1	0.115	0.00	0.000	0.649	2.702	3
Max.	4.872	3.00	0.240	10.146	42.273	59
Min.	4.445	3.00	0.240	7.867	32.780	44

Tested By: ILLI NAJWA

(Lab Assistant and above)

Kamai Verified By: .....



# LEMBAGA GETAH MALAYSIA

# MALAYSIAN RUBBER BOARD



Malaysian Rubber Board, 47000 Sungai Buloh, Selangor. Tel: (6)03-61459471 Fax: (6)03-61412907

Email: gtacr@lgm.gov.my Website: http://www.lgm.gov.my/gtacr







Report no.

LGM/BTK/UPB/5.10/CP/1911/0251-0253

Your reference no.

November 29, 2019

Comfort Rubber Gloves Industries Sdn. Bhd, Lot 821, Jalan Matang, 34750 Matang, Taiping, Perak Darul Ridzuan, Malaysia.

Fax No: 605 8476250

Attn: Sumathi Saravana Sami

### ANALYTICAL TEST RESULTS

We report the following results:

Your letter dated

19/11/2019

Date of sample received

22/11/2019

Date of testing

28/11/2019

Subject

**Powder Content Test** Powder Free Nitrile Examination Gloves 4.8g (Blue)

**Products Description** Quantity tested

5pcs

Test Method

ASTM D6124-11

Size

M

No.	Lab. Reference No.	Sample Reference	Residual Powder Content (mg/glove)
2.	0252	Lot No: 90820F10604	0.16

### "BERKHIDMAT UNTUK NEGARA"

Ruhida Ab. Rahim

(IMM NO.: A 2542/5226/07)

Research Officer

Malaysian Rubber Board For Director General

Page 2 of 3

### COMFORT RUBBER GLOVES INDUSTRIES SDN. BHD.

### ACCELERATED AGEING TEST FOR SHELF LIFE DETERMINATION (EN STANDARD)

REPORT

PRODUCT DETAILS

PRODUCT CODE

OCF48NBBL

DIPPING LOT NO.

: 70511M2406

PRODUCT TYPE

Nitrile Powder Free Examination Gloves

70511M2410

 $4.8 gm \pm 0.2$ 

70511M2411

MACHINE NO. / PLANT

24/F3

CLAIMED SHELF LIFE: 3 Years

FREQUENCY OF TESTING

	Time Interval	Lot	Time Zer	ro	166 ± 2 h (	70°c)	90 ± 1 day (	50°c)
Result		No.	Specification	Actual	Specification	Actual	Specification	Actual
QA		1	(AOI 15	0	(AOI 15	1	(AOI 15	0
Inspection *80pcs	Barrier	2	(AQL 1.5, Acc/Rej=3/4)	2	(AQL 1.5, Acc/Rej=3/4)	1	(AQL 1.5, Acc/Rej=3/4)	2
*80pcs		3	Accincy 3/4)	0	Acc/Rej-3/4)	0	Accinej-3/4)	0
Physical	Force	1		6.95		7.17		7.32
Properties	At	2	Min 6N	7.08	Min 6N	7.39	Min 6N	7.06
*13pcs	Break	3		7.59		8.06		7.82

**EVALUATION** 

Meet as EN 455-2 for Physical Properties Test.

Meet as EN 455-1 for QA Inspection Barrier (Freedom from holes)

\*The above data are average results for QA Inspection and Physical Properties is 80 pcs and 13 pcs respectively.

### FORM / ATTACHMENT

Daily Physical Dimension Inspection (SOP-QA-QA-003/F3)

Force At Break Result (EN STD)

### CONCLUSION

For the first test at Time Zero, the result passed.

For the test at  $166 \pm 2 \text{ h}$  (70°c), the result passed.

For the test at  $90 \pm 1$  day  $(50^{\circ}c)$ , the result passed.

All tests meet the requirements according to EN 455-4.

The shelf life of Nitrile Powder Free Examination Gloves, 4.8gm +/- 0.2 can be claimed for three (3) years.

Prepared by / Date:

NUR AMIRA

27/12/5013

Approved by / Date:

Lab and Compounding

Manager:

400 CHONG HUAY

QA & QMS Manager:

f. S. Symathi

# COMFORT RUBBER GLOVES INDUSTRIES SDN. BHD. INSPECTION DATA SHEET

SAMPLING PLAN - General Inspection Level (G1)

FACTORY

50°C\$ 3 90 Days

DATE

13-12-17

LINE NO.

Lo7 (1)

SHIFT

MOTHING

		Sai	mple Pl	an: Ge	neral L	ispectio	n Leve	11 (GI	)		
		n=	=50	n=	-80	n =	125	n=	200	n =	315
١	AQL	Acc	/ Rej	Acc	/ Rej	Acc	/ Rej	Acc	/ Rej	Acc	/ Rej
I	1.0	[1]	[2]	[2]	[3]	[3]	[4]	[5]	[6]	[7]	[8]
ĺ	1.5	[2]	[3]	[3]	[4]	[5]	[6]	[7]	[8]	[10]	[11]
I	2.5	[3]	[4]	[5]	[6]	[7]	[8]	[10]	[11]	[14]	[15]
I	4.0	[5]	[6]	[7]	[8]	[10]	[11]	[14]	[15]	[21]	[22]

A SUMMANNA FILLIS

Production Lot Number		20	SIIA	6 3 /1	00		-	_		-	D.	1	т				000	A	BBL	
	A.C	20	SHIN	194	06				_		Pr	oduct	Type	_			ocps	COVE	ALL.	
Production Time	06	00		-		_			_			-		-						
Size Sample Size (pcs)	80	6	-					-	-			-								
		_						_			_									
CRITICAL DEFECTS (Accept	0, Reject-1	)							_											
Mixed Size/Mixed Type	-	/							_			-		_						
Embedded Debris / Insect	<del>-/</del>	-				_						-								
VH/Knocking/Touching	1/				41000				_			_								
Forn/Tear	10		7							- 200										
WATER TEST DEFECTS (AQ		ept-	, Rej	ect- 5	A )															
Pinhole Finger	0	-		-					_			-		_						
Pinhole Palm	0											_		_						
Pinhole Crotch	0							_	_			_								
Pinhole Thumb	0	_		_					_			_								
Pinhole Wrist/Cuff								_												
MAJOR VISUAL DEFECTS (A	IQL ; A	ccept-	, Re	ject-	)												71107			
Lump > 2 mm <sup>2</sup>		/							_											1
Dirt / Stain > 0.5mm <sup>2</sup>		_/																22.0		
Defective Bead		_/																		0156
Rolled Cuff		/							_											
Tacky > 10 mm																10 == 1/// P				
Pinkish																				
Sticky Pleat	1													O CONTE						
Excessive Powder	1																10000			
Under Cure	$\perp \perp$									Care and										
Crack line																				
Thin Spot/Thin Layer											-									
Inverted Finger / Unturned	$\perp I$							1/15/												
Discolor																				
Odor	_/																			-
Others	1							1.11												
MINOR VISUAL DEFECTS (A	QL 4.0 ; A	ccept-	, R	eject-	)								****			-				
Lump < 2 mm²					sissiones bes					-										
Dirt < 0.5mm <sup>2</sup>																				
Defective Bead							-													
Thin Spot/Thin Layer																			-	
Tacky < 10 mm	/							-												100
Others										700					-					_
Total Critical Defects	~											$\neg$	1110/11							_
Total Water Test Defects	-					-						_					-			
Total Major Visual Defects	1	)			or Whells	ille elle	and the second	0310										-		
Total Minor Visual Defects	-											-			78. 1			1000		
Critical Result	A	R	А	R	A	R	A		R	A	1	R	A	R	Α	R	1,1	p	14	1.
Water Test Result	- A	R	A	R	A	R	A	_	R	A	-	R	A	R	A	R	A	R	A	-F
Major Visual Result	A	R	A	R	A	R	A	_	R	A	-	R	A	R	A	R	A		A	F
Minor Visual Result	A	R	A	R	A	R	A	1	R	A	_	R	A	R	A	R	A	R	A	F
AQL	0.6			1,,	-10	144	10		TV.	14	1	11/2	IVI	IK.	JA.		A	R	A	F
Disposition	P							-	-			$\dashv$								
Inspection Time	10.0	00 am					-			-							-			
Signature	1c par	P. /	Ž			-	_					-								

Verified By: R. Pangala

ISSUE DATE:31.1.2017

SOP-QA-QA-003/F1/16

PAGE 1 OF 1

# COMFORT RUBBER GLOVES IND. SDN. BHD.

**Daily Physical Dimension Inspection** 

Factory:	socis	90 das	VS				Date:	13-10-17	
Line no:	L07 (1)						Shift:	MORATAG	
Lot Size:	20 p cs		S2 - AOL :	u.O	18	ACC:	1	DEI.	

Lot No.	Type	Time	Size	#	Width		(mm)	& WEI	ckness (n	am)	Avg. 10pcs	Inspected	Disassitis
		0.750.00.0			(mm)	1	2	Cuff		Finger	Weight (g)	by	Dispositio
ł	- 100	31-		1	95	JAM	JAG	0.08	0.09				
- 1				2	95	163	345	0-07	and the second s				
1				3	95	14.3	J44	0.07	0.09	0.13			Pass
8	OCFABNBAL			4	98	145	345	0.07	0-09				1 455
705111N 340G	88			5	96	MO	241	0.07	0.09	0./2			
*	ANG	0000	١. ١	6	94	345	つなり	0-06	0.08	0-12			
00	\$	96	14	7	96	244	CAG	0-07	-	0-/3			П
a				8	96	346	CAL	800		0/2			Fail
- 1	8			9	95	741	SAAC	0.08					1 an
- 1				10	96	2447	24	PO-07	0.09	0.10			
l	50 50 50 50 50 50 50			11	98	245	JAL	0 - 08	0.09	0/3			
1				12	94	240	242	0.04	0.09	0.19			
				13	96	UNE	242	800	0.60	073			Fail:
				1									7 (1)
- 1	100			2									
				3									Pass
- 1				4				,					1 455
- 1				5									
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- 1				7				-					
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				13									Fail:
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181				5									
- 1				6									
- 1				7									
				8	$\overline{}$								Fail
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- 1				11									
ل				12	-								
			1 1	13						S			

Notest Acknowledged By:

Production Supervisor

### COMFORT RUBBER GLOVES INDUSTRIES SDN. BHD. INSPECTION DATA SHEET

SAMPLING PLAN - General Inspection Level (G1)

FACTORY

DATE

LINE NO.

SHIFT

	Sai	npie Pi	an: Ger	ieral li	ispectio	n Leve	11 (GI)	)		
_	n=	50	n=	-80	n=	125	n=	200	n =	315
AQL	Acc	/ Rej	Acc	/ Rej	Acc	/ Rej	Acc	/ Rej	Acc	/ Rej
1.0	[1]	[2]	[2]	[3]	[3]	[4]	[5]	[6]	[7]	[8]
1.5	[2]	[3]	[3]	[4]	[5]	[6]	[7]	[8]	[10]	[11]
2.5	[3]	[4]	[5]	[6]	[7]	[8]	[10]	[11]	[14]	[15
4.0	[5]	[6]	[7]	[8]	[10]	[11]	[14]	[15]	[21]	[22

Production Lot Number	70.	5///	MALN	٥					F	roduct	Type			0	CF 408	NOGE	1	
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RITICAL DEFECTS (Accept-0				_														-
lixed Size/Mixed Type	, respect 1)	7		T		- 1							-	Т		- T		_
mbedded Debris / Insect		+		-		$\dashv$		-		_		_		-+		_		-
H/Knocking/Touching	/	_	-	-		$\dashv$		_		_		-+		_		$\rightarrow$		_
orn/Tear		+		-		-				-		-+		-+		-		
VATER TEST DEFECTS (AQL	/ · C Accent	3	, Rejec	. 4	7 )							- L						_
Pinhole Finger	1 S Accept	1	, Kejec	1	,	-	ne hi			- 1	99 - H7-			7		1		_
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Pinhole Crotch	0	+		-										-		-+		
Pinhole Thumb	0	-		-		-	-		-	-						-+	-07/4-07	
Pinhole Wrist/Cuff	0	+	M. S. S.			-				-		-	-	$\rightarrow$		-		
	J		Dai										-					
MAJOR VISUAL DEFECTS (A	QL ; Acce	pt-	, Rej	ect-	)					_							-	-
Jump > 2 mm <sup>2</sup> Dirt / Stain > 0.5mm <sup>2</sup>	-	-/-	-				-00/4			-		-		-		-		
	-	1	-	-		-	880 AM = 880					-			-			_
Defective Bead		/-		-		-		-		-		-		-		-		
Rolled Cuff	-	4		-		-				-		-						
Facky > 10 mm	1	-											-			_		
Pinkish	1	-			222323				V 555 5							_		_
Sticky Pleat	1 /	-		-								_				-		
Excessive Powder	-									_								
Under Cure	1																	
Crack line	1	_		_														
Thin Spot/Thin Layer	11	_		0.00														
inverted Finger / Unturned																		
Discolor	1/																	
Odor	1/															- DIAKUN		20900
Others	/																15°.	
MINOR VISUAL DEFECTS (A	QL 4.0 ; Acc	ept-	, Re	ject-	)					MONTH.		S. 15						
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Dirt < 0.5mm <sup>2</sup>																		
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Others	V	3.30				5//1000-11/							Consumers				- 0,000	
Total Critical Defects	-																	
Total Water Test Defects	2																	
Total Major Visual Defects	-																	
Total Minor Visual Defects	-													-				
Critical Result	A	R	A	R	A	R	А	R	Α	R	A	R	A	R	A	R	A	
Water Test Result	CA	R	A	R	Α	R	A	R	A	R	А	R	A	R	Α	R	A	
Major Visual Result	A	R	Α	R	A	R	A	R	A	R	A	R	A	R	Α	R	A	
Minor Visual Result	A	R	Α	R	A	R	A	R	A	R	A	R	Α	R	A	R	A	
AQL	1.0											-				1		_
Disposition	9				Service and			2/12/2002					-			A245		_
Inspection Time	10.00 10.000	qm.															C	
Signature	M May 0	- //	4 Fib. 300	*			1		-						-			-

# COMFORT RUBBER GLOVES IND. SDN. BHD.

## **Daily Physical Dimension Inspection**

Factory: 50'cd , 90 says Date: Line no: 107 (2) Shift: Lot Size: 80 pcs S2-AQL: 4.0 , n = 18 ACC:

Lot No.	Туре	Time	Size	#	Width	Length	(mm)	& WEI	GHT ckness (n		4 10	I	- N
					(mm)	1	2	Cuff		Finger	Avg. 10pcs Weight (g)	Inspected by	Disposition
				1	96	240	343	0-08			8 (6)	- 3	
1			1	2	95	240	240	0.08	0.10	0.14			
- 1			1 1	3	96	243	240		0.09				Pass
9	×		1	4	95	240	240	0.07	0.09	0.13			F 455
76	88	_	M	5	96	240	242	0-0A	0.09	0.13			
40511MJA10	OCF 468 N BOL	1000	1	6	95	242	140	0-08		014			
40	3	0,		7	96	140	142	0.08					
to	0		1 1	8	95	146	JAJ	0-08	0.09	-			Fail
			1 1	9	93	245	2423	0.08	0.09				ran
1			1 1	10	96	2400	دمدد	0.08					
			1 1	11	96	243		০তর	D .09	-			
1				12	95	J40	242	0.08	0-10				
				13	96	240	243	0.08	0.09				Fail:
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- 1			1	2				-					
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2				4									Pass
- 3				5									
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	1000		1 1	12	1		1	1		1		1 1	

Checked By: Nagadas Verified By: Q.A Leader

Acknowledged By: \_\_\_\_\_\_\_

Production Supervisor

### COMFORT RUBBER GLOVES INDUSTRIES SDN. BHD.

### INSPECTION DATA SHEET

SAMPLING PLAN - General Inspection Level (G1)

FACTORY

50°C13 90 Days

Sample Plan: General Inspection Level 1 (G1)

DATE

13-17-14

LINE NO.

(6) 704

SHIFT -

MORANA

	n=50	n =		n =		n=		n =	315											
AQL	Acc / Rej	Acc		Acc /	-	Acc	-	Acc	-											
1.0	[1] [2]	[2]	[3]	[3]	[4]	[5]	[6]	[7]	[8]											
1.5	[2] [3]	[3]	[4]	[5]	[6]	[7]	[8]	[10]	[11]											
2.5 4.0	[3] [4]	[5]	[6]	[7]	[8]	[10]	[11]	[14]	[15]											
4,0	[5] [6]	[7]	[8]	[10]	[11]	[14]	[15]	[21]	[22]											
Produ	ection Lot Num	ber		7051	W3	414					Pı	oduct	Туре			00	EW81	OBBI	5	
Pr	roduction Time		14	00																
	Size			٨					0.85		man, men									
Sa	imple Size (pcs)	)	8	0																
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lixed Siz	e/Mixed Type	V/61		7					9,400			1100/11						- N - 2/2		
mbedded	d Debris / Insec	t																		
H/Knoc	king/Touching		/																	
orn/Tear																		T		_
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	Vrist/Cuff	-	1	)								$\neg$						+		141
	VISUAL DEFE	CTS (AC	-	Accept-		Reject-	-	)					Miles of the						10-111-0	_
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	in > 0.5mm <sup>2</sup>			-										$\neg$		THE STREET		$\neg$	o o elliste	-
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	Finger / Unturn	nea	+/-		+-		+	*:::-	-			-								_
Discolor			+/-		+		+	-	-			-	-	-	-			-		
Odor Others			₩-		+-		+													
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-	VISUAL DEFE	CTS (A	QL, 4,0	; Accept	<del>/</del>	, Reject-	_	)	T			_		_						
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Defectiv			+	_	+		+		-											_
	ot/Thin Layer		1		+		-		-									-		
Tacky <	10 mm	-	+/-		+-		-		-	-										-
Others			<del>/</del> -		+		-													_
	itical Defects				-		-		-											_
	ater Test Defec			0	-		-		-					10.00						
	ajor Visual Def		+=	_	-		-		-											
	inor Visual Def	ects	+		1		-		-									$\perp$		_
Critical R			A			A F	-	R		R	A	R	Α	R	A	R	A	R	Α	_
	est Result		1	-	_	A F	-	R		R	A	R	A	R	A	R	A	R	A	_
Major Vi	isual Result			A R			-	A R		R	A	R	A	R	A	R	A	R	A	_
	isual Result			R	1	A F	1	R	A	R	A	R	A	R	A	R	A	R	A	
AQL				1.65											7.77					
Dispositi	ion		-	0							Carrie Villa		22/3/17/20							
AUSTUS Z. CALL				. AMO	The second second															-

Verified By: 1. Pangalai
Q.A. Leader
DCN NO:F180

\* AQL - Acceptance Quality Level

Inspection Time Signature

ISSUE DATE:31.1.2017

A - Accept

10.000m

SOP-QA-QA-003/F1/16

R - Reject

PAGE 1 OF 1

# COMFORT RUBBER GLOVES IND. SDN. BHD.

**Daily Physical Dimension Inspection** 

Factory: Socala 90 Mys

Date: Shift: 13-10-17

Line no: 467 (3) Lot Size: & pcs

S2 - AQL:  $4 \cdot 0$ , n = 13, ACC: 1, REJ:

Mornlag

Lot No.	т	T:	10:		****			& WEI					
Lot No.	Туре	Time	Size	#	Width		(mm)		ickness (r		Avg. 10pcs	Inspected	Disposition
-			-		(mm)	1	2	Cuff	Palm	Finger	Weight (g)	by	
				1_	96	246	345	0.07					
				2	96	DAKC PAKE	346	0.04	0-09	0 /3			/
				3	98	250	249	\$00	0.09	0.13			Pass
8				4	96	245	746	0.04	0.09	0.13			
70511113611A	OCF IT BANB BL			5	95	0446	346	0.04	0.09	0.13			
*	8v	1400	N	6	95	240	46	007	0.09	012			
18	#	#		7	96	240	147	0-07	0.09	0.13		-	
10	8			8	95	342	146	0-07	0.09	0.13			Fail
				9	96	3AAC	245	0.04	0.09	0/3			
				10	95	343	243	0-07	009	0.13			
				11	96	34	CAC	0.04	0.109	0.13			
				12	95	343	SASA	007	0.09	013			
				13	960	CAC	344	0.04	0.09	0.11			Fail:
				1									
				2									
				3									Pass
				4									1 455
				5									
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				9			-					1	Fail
	1			_				-					
				10				-					
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				13	t.		l		1			1	Fail:

**Production Supervisor** 

## Comfort Rubber Gloves Industries S/B

# TENSILE STRENGTH TEST RESULT (EN STD)

(AGED)

Type of glove: OCF48NBBL (90 Days)

Lot No.:70511m2406 (Lot 1)

Off Line Lot No.: Size: M-240mm Sample: Mira QA Tested date: 15-12-2017

Force at Break

Aged:- Min 6 Newton

Test No.	Weight g	Width mm	Area mm²	FAB N	T.Strength MPa	Elongation %
1	4.928	3.00	0.24	7.36	30.65	602
2	4.936	3.00	0.24	6.58	27.44	580
3	4.970	3.00	0.24	7.19	29.94	496
4	4.962	3.00	0.24	7.31	30.48	574
5	5.079	3.00	0.24	7.62	31.75	517
6	5.126	3.00	0.24	7.36	30.67	527
7	5.015	3.00	0.24	6.98	29.09	515
8	4.976	3.00	0.24	8.16	34.00	521
9	4.931	3.00	0.24	8.11	33.81	565
10	5.126	3.00	0.24	6.22	25.91	491
11	5.106	3.00	0.24	7.81	32.53	536
12	5.126	3.00	0.24	7.28	30.33	481
13	5.106	3.00	0.24	7.12	29.67	533
Average	5.030	3.00	0.24	7.32	30.48	534
SD(N-1)	0.083	0.00	0.00	0.55	2.28	37
Medium	5.015	3.00	0.24	7.31	30.48	527
Maximun	5.126	3.00	0.24	8.16	34.00	602
Minimum	4.928	3.00	0.24	6.22	25.91	481

Tested by: Nur

(Lab assistant and above)

Verified by: Nora.

# Comfort Rubber Gloves Industries S/B

## TENSILE STRENGTH TEST RESULT (EN STD)

(AGED)

Type of glove: OCF48NBBL (90 Days)

Lot No.:70511m2410 (Lot 2)

Off Line Lot No.: Size: M-240mm Sample: Mira QA

Tested date: 15-12-2017

## Force at Break

Aged:- Min 6 Newton

Test No.	Weight g	Width mm	Area mm²	FAB N	T.Strength MPa	Elongation
1	4.806	3.00	0.24	7.48	31.15	569
2	4.927	3.00	0.24	6.81	28.36	520
3	4.991	3.00	0.24	6.98	29.10	529
4	4.963	3.00	0.24	7.09	29.53	530
5	5.012	3.00	0.24	6.53	27.22	672
6	4.963	3.00	0.24	7.52	31.34	530
7	4.951	3.00	0.24	7.89	32.86	492
8	4.981	3.00	0.24	7.22	30.10	528
9	4.987	3.00	0.24	6.61	27.56	513
10	4.893	3.00	0.24	7.58	31.58	571
11	4.981	3.00	0.24	6.76	28.19	728
12	4.987	3.00	0.24	6.58	27.41	518
13	4.893	3.00	0.24	6.69	27.88	483
Average	4.949	3.00	0.24	7.06	29.41	553
SD(N-1)	0.056	0.00	0.00	0.45	1.85	71
Medium	4.963	3.00	0.24	6.98	29.10	529
Maximun	5.012	3.00	0.24	7.89	32.86	728
Minimum	4.806	3.00	0.24	6.53	27.22	483

Tested by: Nur (Lab assistant and above)

Verified by: Nora.

# Comfort Rubber Gloves Industries S/B

TENSILE STRENGTH TEST RESULT (EN STD)

(AGED)

Type of glove: OCF48NBBL (90 Day)

Lot No.:70511m2411 (Lot 3)

Off Line Lot No.: Size: M-240mm Sample: Mira QA

Tested date: 15-12-2017

Force at Break

Aged:- Min 6 Newton

Test No.	Weight g	Width mm	Area mm²	FAB N	T.Strength MPa	Elongation
1	4.977	3.00	0.24	8.35	34.78	568
2	4.902	3.00	0.24	8.46	35.25	785
3	4.931	3.00	0.24	7.63	31.78	514
4	4.878	3.00	0.24	7.25	30.20	540
5	4.126	3.00	0.24	8.09	33.71	517
6	4.931	3.00	0.24	8.48	35.32	610
7	4.978	3.00	0.24	7.08	29.49	599
8	4.931	3.00	0.24	7.24	30.15	512
9	4.952	3.00	0.24	7.89	32.87	573
10	4.980	3.00	0.24	6.56	27.33	528
11	4.973	3.00	0.24	7.99	33.27	610
12	4.962	3.00	0.24	8.63	35.98	834
13	4.965	3.00	0.24	8.00	33.32	565
Average	4.884	3.00	0.24	7.82	32.57	597
SD(N-1)	0.230	0.00	0.00	0.63	2.63	101
Medium	4.952	3.00	0.24	7.99	33.27	568
Maximun	4.980	3.00	0.24	8.63	35.98	834
Minimum	4.126	3.00	0.24	6.56	27.33	512

Tested by: Nur (Lab assistant and above)

Verified by: Nora -



SATRA Technology Centre Ltd Wyndham Way, Telford Way, Kettering, Northamptonshire, NN16 8SD United Kingdom Tel: +44 (0) 1536 410000

Fax +44 (0) 1536 410626 email: info@satra.com www.satra.com



Customer details: Comfort Rubber Gloves Industries Sdn.Bhd

Lot 821

Jalan Matang 34750 Matang

Perak Malaysia SATRA reference: CHM0292515/1948/LC

/A

Your reference:

Date of report: 20th January 2020

Samples received: 21st November 2019

Date(s) work

7th to 17th January

carried out: 2020

# **TECHNICAL REPORT**

Subject: EN 16523-1:2015+A1:2018 resistance to permeation by chemicals on gloves

described as Nitrile Powder Free Examination Gloves PFNBR244.

### 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.

Tests marked ≠ fall outside the UKAS Accreditation Schedule for SATRA. All interpretations of results of such tests and the comments based upon them are outside the scope of UKAS accreditation and are based on current SATRA knowledge.

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: Lucy Cove Position: Technologist

Department: Chemical & Analytical Technology

(Page 1 of 12)





### **WORK REQUESTED:**

Samples of gloves described as Nitrile Powder Free Examination Gloves PFNBR244 were received on the 21<sup>st</sup> November 2019 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.

### **SAMPLES SUBMITTED:**



CHNOLOGY

Samples described as Nitrile Powder Free Examination Gloves PFNBR244

### **CONCLUSION:**

When assessed in accordance with the requirements of EN ISO 374-1:2016+A1:2018 the samples of gloves described as Nitrile Powder Free Examination Gloves PFNBR244 achieved the following performance levels:

Chemical	Performance level
n-Heptane (CAS: 142-82-5)	1, 1, 1
40% Sodium hydroxide (CAS: 1310-73-2)	6
96% Sulphuric acid (CAS: 7664-93-9)	The samples tested did not meet with the minimum breakthrough time for a performance level 1 to be achieved
99% Acetic acid (CAS: 64-19-7)	The samples tested did not meet with the minimum breakthrough time for a performance level 1 to be achieved
30% Hydrogen peroxide (CAS: 7722-84-1)	The samples tested did not meet with the minimum breakthrough time for a performance level 1 to be achieved
37% Formaldehyde (CAS: 50-00-0)	5

Full results are reported in the following tables.

Comfort Rubber Gloves Industries Sdn.Bhd SATRA Reference: CHM0292515/1948/LC/A

Date: 20<sup>th</sup> January 2020

Signed:

(Page 2 of 12)





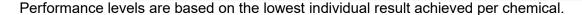
### **TESTING REQUIRED:**

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



Comfort Rubber Gloves Industries Sdn.Bhd SATRA Reference: CHM0292515/1948/LC/A

Date: 20<sup>th</sup> January 2020

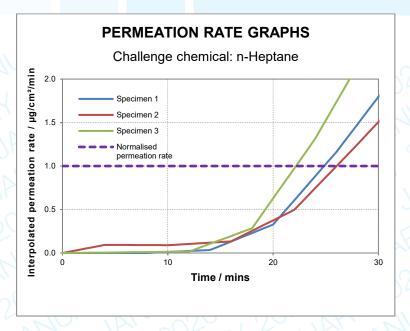
Signed:

(Page 3 of 12)





Test/Property	Sample reference:	Nitrile Powder Free PFNE	Performance	
		Chemical:	n-Heptane	
		Normalised permeation ra	ate (NPR): 1 µg/cm²/min	
EN 16523-1:2015		Detection technique:	GC-FID (periodic measurement)	
+A1:2018 in	information:	Collection medium:	Dry air (open loop)	
accordance with SATRA		Collection medium flow ra	ate: 335 – 380 ml/min	
SOP CAT-005		Test temperature:	(23 ± 1) °C	Level 1
	Specimen	Thickness	Breakthrough time	
Using stainless		(mm)∆	(mins)▲	
steel permeation	1	0.10	24	
cells with standardised	2	0.10	26	
dimensions	3	0.10	22	
		Test result:	22	
		UoM:	± 1	
Visual appearance of specimens after testing:			Shrunken	



Comfort Rubber Gloves Industries Sdn.Bhd SATRA Reference: CHM0292515/1948/LC/A

Date: 20<sup>th</sup> January 2020

Signed:

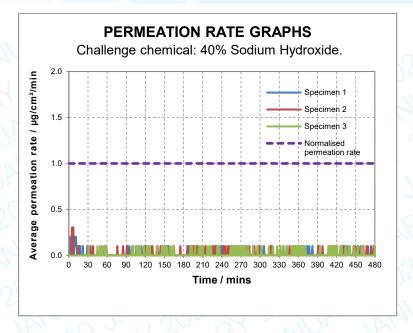
(Page 4 of 12)

l-ine





Test/Property	Sample reference	Performance		
		Chemical: 40°	% Sodium hydroxide	
		Normalised permeation	rate (NPR): 1 μg/cm²/min	
EN 16523-1:2015	Test	Detection technique:	Conductimetry (continuous measurement)	
+A1:2018 in	informatio	n: Collection medium: De	eionised water (closed loop)	
accordance with SATRA		Collection medium stirr (each cell constant to within		
SOP CAT-009		Test temperature:	(23 ± 1) °C	Level 6
551 5711 555	Specimen	Thickness	Breakthrough time	
Using PTFE		' (mm)△	(mins)	
permeation cells	1	0.09	>480	
with standardised dimensions	2	0.09	>480	
aimensions	3	0.09	>480	
		Test result:	>480	
		UoM:	<1	
Visual appearance of specimens after testing:			Discoloured	



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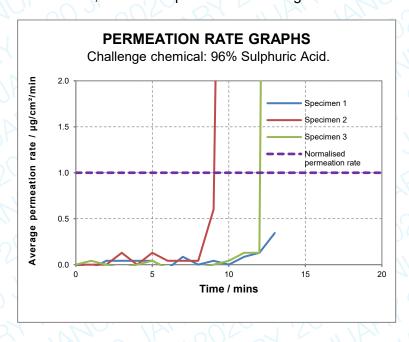
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Test/Property	Sample reference:		Nitrile Powder Free Examination Gloves PFNBR244		
		Chemical: 96°	% Sulphuric acid		
		Normalised permeation ra	ate (NPR): 1 µg/cm²/min		
EN		Detection technique:	Conductimetry		
16523-1:2015	Test		continuous measurement)	The samples	
+A1:2018 in	information	Collection medium: Dei	onised water (closed loop)	tested did not	
accordance with SATRA		Collection medium stirrin (each cell constant to within		meet with the minimum	
SOP CAT-009		Test temperature:	(23 ± 1) °C	breakthrough	
	Specimen	Thickness	Breakthrough time	time for a	
Using PTFE	Specimen	(mm)∆	(mins)	performance	
permeation cells	1	0.08	14*	level 1 to be	
with standardised dimensions	2	0.09	10	achieved	
difficitions	3	0.09	13		
		Test result:	10		
		UoM:	<1		
Visual appearance of specimens after testing:		Swollen, brittle, d	lisintegrated, discoloured a	ind flaky	

\* The conductivity of the collection medium rose above the working range of the detection system. However, before this point a breakthrough had not occurred.



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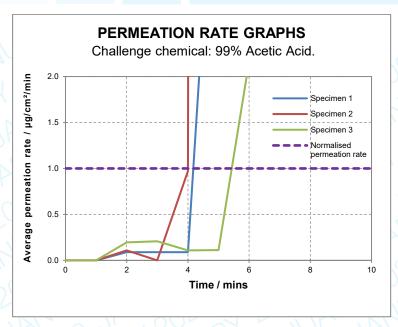
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Test/Property	Sample reference		Nitrile Powder Free Examination Gloves PFNBR244		
		Chemical: 9	9% Acetic acid		
		Normalised permeation ra	ate (NPR): 1 µg/cm²/min		
EN 16523-1:2015	Test		Conductimetry continuous measurement)	The samples tested did not	
+A1:2018 in	information	Collection medium: Dei	onised water (closed loop)		
accordance with SATRA		Collection medium stirrin (each cell constant to within		meet with the minimum	
SOP CAT-009		Test temperature:	(23 ± 1) °C	breakthrough	
001 0711 000	Specimen	Thickness	Breakthrough time	time for a	
Using PTFE	Specimer	(mm)∆	(mins)	performance	
permeation cells	1	0.10	5	level 1 to be	
with standardised dimensions	2	0.10	5	achieved	
differisions	3	0.09	6		
		Test result:	5		
		UoM:	±1		
Visual appearance of specimens after testing:		Swe	ollen and discoloured		



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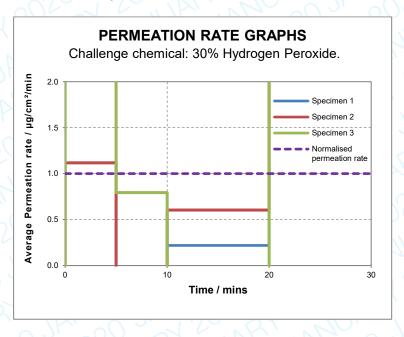
l-ine





Test/Property	Sample reference	Nitrile Powder Free PFNE	Performance	
		Chemical: 30%	Hydrogen peroxide	
		Normalised permeation ra	ate (NPR): 1 µg/cm²/min	
EN 16523-1:2015	Test	Detection technique:	Electrochemical detector (periodic measurement)	The samples
+A1:2018 in	informatio	n: Collection medium: Dei	onised water (closed loop)	tested did not
accordance with SATRA		Collection medium stirrin (each cell constant to within		meet with the minimum
SOP CAT-025		Test temperature:	(23 ± 1) °C	breakthrough
	Specime	Thickness	Breakthrough time	time for a
Using PTFE	Specime	' (mm)∆	(mins) <sup>▼</sup>	performance
permeation cells	1	0.10	Between 21 to 30	level 1 to be
with standardised dimensions	2	0.10	Between 21 to 30	achieved
difficitsions	3	0.10	<5	
		Test result:	<5	
		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. The readings from specimens 1 and 2 after 5 minutes were considered to be outliers and not breakthroughs.

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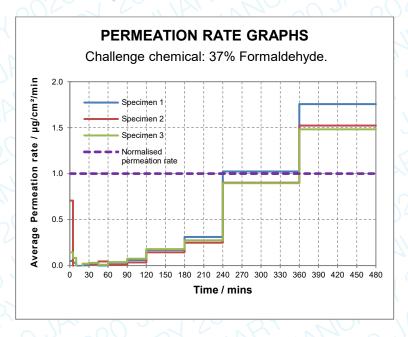
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Test/Property	Sample reference:	Nitrile Powder Free	Performance	
		Chemical: 37	7% Formaldehyde	
		Normalised permeation	rate (NPR): 1 µg/cm²/min	
EN 16523-1:2015	Test	Detection technique:	HPLC-DAD (periodic measurement)	
+A1:2018 in	information:	Collection medium: De	ionised water (closed loop)	
accordance with SATRA		Collection medium stirri		
SOP CAT-025		Test temperature:	(23 ± 1) °C	Level 5
00.000	Specimen	Thickness	Breakthrough time	
Using PTFE		(mm)∆	(mins) <sup>▼</sup>	
permeation cells	1	0.09	Between 241 to 360	
with standardised	2	0.10	Between 361 to 480	
dimensions	3	0.09	Between 361 to 480	
		Test result:	Between 241 to 360	
		UoM:	See below	
Visual appearance of specimens after testing:		Sw	rollen 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.



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.
- A The collection medium from each cell is analysed once every 6 minutes. Due to the complexity of the detection technique, the minimum sampling frequency for final results ≤ 60 minutes as specified in table 1 of EN 16523-1:2015+A1:2018 is not possible. Breakthrough time is calculated using linear interpolation between the discrete sampling points.
- ▼ 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.

TECHNOLOGY

Comfort Rubber Gloves Industries Sdn.Bhd SATRA Reference: CHM0292515/1948/LC/A

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# **TECHNICAL REPORT**



#### TERMS AND CONDITIONS FOR THE SALE OF GOODS AND/OR THE PROVISION OF SERVICES

#### 1. GENERAL

- Work done, Services undertaken or the sale of Goods are subject to the terms and conditions detailed below and (subject to clause 5.2) all other conditions, warranties and representations, expressed or implied by statute relating thereto are hereby excluded.
- SATRA Technology Centre Limited, its subsidiaries and associated companies (hereinafter referred to as "SATRA") may perform Services for or supply Goods to persons or entities (public, private or governmental) issuing instructions (hereinafter termed the "Client"). Each also known individually as a Party, or jointly as
- These terms and conditions will apply to the Contract between SATRA and the Client to the exclusion of any other terms which the Client may seek to impose or which may be implied by trade, custom, practice or course of dealing 1.3
- Unless otherwise agreed in writing no party other than the Client is entitled to provide instructions or information relating to the Goods or Services required or to the delivery of goods, results, reports or 1.4 certificates
- 1.5 All references in these terms and conditions to:
- (a)
- (b)
- the "Contract" is the contract between SATRA and the Client for the supply of Goods or Services which is made subject to these terms and conditions; and "Services" are the work or services to be supplied or performed under the Contract (including where relevant the supply of software, components and consumables); and "Goods" are the equipment, consumables or other physical items sold under the Contract (including documents, drawings or other information required in order to operate the equipment). (c)
- All drawings, descriptive matter, specifications and advertising material (including brochures and catalogue are issued or published with the sole purpose of giving an indication of the goods or services being describ and shall not form part of the Contract.
- Where SATRA and the Client agree that the sale of Goods shall be governed by Incoterms 2010 (or any 1.7 subsequent revision thereto) then the sale shall be governed by the relevant Incoterms mode of transport which is agreed by SATRA and the Client.

#### 2. FEES AND PAYMENT

- 2 1 Where SATRA has agreed to perform the Services or supply the Goods on the basis of credit then payment Where SATRA has agreed to perform the Services or supply the Goods on the basis of credit then payment terms are net 21 days from date of invoice, unless otherwise specified and may require part payment prior to delivery of the Services or Goods. In the event of the Client failing to make payment as agreed SATRA will be entitled to withhold delivery of the Goods or Services or cancel the Contract. SATRA reserves the right to charge interest on any overdue payments at a rate of 1.5% per month accruing on a daily basis from the date the invoice is due until the date payment is received.
- Where the provision of Services or the sale of Goods is subject to a proforma invoice then SATRA shall not be obliged to start working on the provision of the Goods or Services until after payment in full has been made as cleared funds to SATRA. 2.2
- SATRA reserves the right to charge for any and all expenses incurred as a result of performing the Services required by the Client. Although SATRA will try and provide an estimate of such expenses these may change as a result of circumstances out of SATRA's control. 2.3
- Unless otherwise agreed in writing, the price for the Goods or Services shall be the price set in the order acknowledgement. SATRA shall not be bound by any price quoted which is not in writing. Prices for the sale of Goods include packing cases and materials but not carriage or installation which will be quoted separately and as agreed with the Client. 2.4
- 2.5 Quotations are valid from the date of issue for a period of 90 days unless otherwise specified or agreed in
- Should the Client become insolvent, bankrupt, subject to an administration order, enter into liquidation or receivership, or make arrangements with creditors SATRA reserves the right to cancel the Contract and terminate the supply of the Goods or Services. Where the Contract with SATRA is terminated all outstanding monies due from the Client to SATRA shall be immediately payable, and any materials supplied by SATRA to the Client returned. Termination of the Contract shall be without prejudice to any of SATRA's accrued rights. 2.6
- 2.7 All invoices issued by SATRA are payable in full. The Client is responsible for payment of withholding and any other taxes and all import duties. Payments made to SATRA shall not be reduced by such amounts.
- The Client shall not be entitled to withhold or defer payment due to SATRA as a result of any dispute or counter claim that it may allege against SATRA.
- 2.9 SATRA reserves the right to bring action against the Client in order to collect unpaid fees, including court action. All fees associated with such actions shall be paid for by the Client including legal fees and related
- Where unforeseen costs arise as a result of provision of the Goods or carrying out the Services SATRA shall inform the Client immediately but reserves the right to charge additional costs to cover said costs and 2.10

#### INTELLECTUAL PROPERTY RIGHTS 3.

- All intellectual property rights belonging to a Party prior to entry into the Contract shall remain with that Party. Nothing in this Contract shall allow transfer of any intellectual property rights from one Party to the other. 3.1
- event of certification services the use of certification marks by the Client may be subject to national laws and regulations. The responsibility for the use of these certification marks lies solely
- All intellectual property rights in reports, drawings, graphs, charts, photographs or any other material (in whatever medium) produced by SATRA pursuant to this Contract shall belong to SATRA. The Client shall have the right to use said material in accordance with the terms of this Contract. 3.3
- The Client agrees and acknowledges that SATRA retains any and all propriety rights in concepts, ideas and inventions that may arise during the preparation or provision of any report (including any deliverables provided by SATRA to the Client) and the provision of the Services to the Client. 3.4
- All intellectual property rights in any software supplied to the Client shall belong to SATRA or SATRA's licensors. With respect to the sale of SATRA Timeline, SATRASUMM and SATRA Visionstitch, provided that the Client is a member of SATRA and has paid its annual Smartcare fee then the Client will be entitled to use the software for its own internal use and will be entitled to receive minor software upgrades and fixes. SATRA may however terminate the supply of software upgrades and fixes for older versions of software which it no longer considers viable to support. The Client's rights to use the software not receive software upgrades and fixes will terminate if the Client has not paid its annual Smartcare fee. Major upgrades are not included within the entitlement to upgrades but may be offered by SATRA from time to time for an additional fee. 3.5
  - SATRA shall observe all statutory provisions with regard to data protection including but not limited to the provisions of the Data Protection Act 2018 and the EU General Data Protection Regulation (CDPR) Regulation (EU) 2016/679. To the extent that SATRA processes or gets access to personal data in connection with the Services or otherwise in connection with this Contract, it shall take all reasonable technical and organisational measures to ensure the security of such data (and guard against unauthorised or unlawful processing, accidental loss, destruction or damage to such data).

#### SUSPENSION OR TERMINATION OF SERVICES

- Cancellation by the Client of orders for Goods or Services will only be acceptable by prior agreement with SATRA and a charge will usually be made. 4.1
- SATRA shall not be liable for any delay or failure in providing the Goods or Services due to circumstances beyond its reasonable control (including any failure by the Client to comply with its obligations). If any such circumstances arise which prevent SATRA from delivering the Goods or completing the Services, then SATRA will be entitled to cancel or reschedule the delivery of Goods or Services at its discretion. In the event of cancellation SATRA will be entitled to retain all fees paid by the Client for Goods or Services already supplied but will refund to the Client and Fees paid by the Client for Goods or Services which have not yet been supplied. The Client will not be liable for any non-refundable expenses already incurred by SATRA in relation to Goods or Services not yet supplied unless the cancellation is due to the Clients failure to comply with its obligations under the Contract.

#### LIABILITY AND INDEMNIFICATION 5.

- Reports are issued on the basis of information, documents and or samples submitted to SATRA by the Client. 5 1 Reports are issued on the basis of information, documents and or samples submitted to SATRA by the Client, or on behalf of the Client and are provided solely for the benefit of the Client who is responsible for acting as it sees fit on the basis of such reports and findings. Subject to clause 5.2, neither SATRA nor any of its employees, agents or subcontractors shall be liable to the Client or any third party for any actions taken or not taken on the basis of such findings and reports, nor for any incorrect results arising as a result of unclear, erroneous, incomplete, misleading or false information provided to SATRA.
- Nothing in these terms and conditions shall limit or exclude SATRA's liability for
- death or personal injury caused by its negligence or the negligence of its employees or agents; fraud or fraudulent misrepresentation; breach of the terms implied by Section 12 of the Sale of Goods Act 1979; defective products under the Consumer Protection Act 1987; or any other liability which cannot be limited or excluded by applicable law.

- (a) (b) (c) (d) (e)
- 5.3 Subject to clause 5.2 SATRA shall not be liable to the Client whether in contract, tort (including negligence), breach of statutory duty or otherwise arising under or in connection with the Contract for loss of profits, sales, contracts, anticipated savings, loss or damage to goodwill or any indirect or consequential loss.
- Subject to clause 5.2 SATRA's total aggregate liability to the Client, whether in contract, tort (including negligence), breach of statutory duty or otherwise arising under or in connection with the Contract shall be limited to the total amount of fees for the Services or the price of the Goods (excluding any value added tax or other sales tax or expenses) payable by the Client to SATRA under the Contract or £100,000 whichever is the lower figure. 5.4

#### MISCELL ANEOUS 6.

- If any one or more provisions of these conditions are found to be illegal or unenforceable in any respect, the validity, legality and enforceability of the remaining provisions shall not in any way be affected or impaired thereby. 6.1
- During the course of providing the Goods or Services and for a period of one year thereafter the Client shall not directly or indirectly entice, encourage or make any offer to SATRA's employees to leave their employment with SATRA.
- The use of SATRAs corporate name or registered marks for advertising purposes is not permitted without SATRA's prior written authorisation. 6.3
- All reports and documentation which are supplied to the Client under the Contract remain the property of 6.4 SATRA until paid in full. Under no circumstances will a Client's purchase order override SATRA's retention of title in accordance with this clause.
- The Client acknowledges that in entering into this Contract it has not relied on any representation, warranty, 6.5 collateral contract or other assurance (except those set out or referred to in these terms and conditions) made by or on behalf of SATRA or any other party before entering into the Contract. The Client waives all rights and remedies that, but for this clause, might otherwise be available to it in respect of any such representation, warranty, collateral contract or other assurance.
- All provisions of the Contract that limit or exclude the liability of SATRA are intended also to be for the benefit of SATRA's holding company (called SATRA, and being a company limited by guarantee and incorporated in England and Wales with company number 00153475), and shall accordingly be enforceable by such holding company as well as or instead of by SATRA, and on the basis that any limit on the liability of SATRA shall apply to it and to such holding company in the aggregate.

- Unless specifically excluded in the terms of an individual contract between SATRA and the Client, the following shall apply to all deliverables including, reports, advice, drawings, photographs, specifications, data 7.1 or other forms of media.
- 7.2 Deliverables referred to in clause 7.1 shall not be disclosed to third parties or used in litigation without the consent of SATRA.
- Where SATRA has given consent to disclosure of any service deliverables referred to in clause 7.1, the Client shall draw the attention of the third party to these terms of business and the basis on which SATRA undertakes testing, reporting and advising. The Client shall indemnify SATRA for any failure to do so. 7.3
- The service deliverables referred to in clause 7.1 are submitted to the Client as confidential documents. Confidentiality shall continue to apply after completion of the business, but shall cease to apply to information or knowledge which has come into the public domain through no breach of this Contract by the Client. 74
- The Client shall not disassemble, remove parts or carry out any form of analysis on goods or materials sold by SATRA for the purposes of reverse engineering or obtaining information on the construction, content or composition of the item without the consent of SATRA. 7.5

#### 8.

8.1 No amendment to this Contract shall be effective unless it is in writing, expressly stated to amend this Contract and signed by an authorised signatory of both Parties

#### DISPUTE RESOLUTION 9.

- 9.1 If there should be a dispute between the parties to this Agreement they undertake to act with goodwill and to use all reasonable endeavours to resolve that dispute
- Failure to resolve any dispute by discussions between the parties shall, in the first instance, be referred to a mediator for resolution. The parties shall attempt to agree upon the appointment of a mediator, upon receipt, by either of them, of a written notice to concur in such appointment. Should the parties fail to agree within 21 days, either party, upon giving written notice, may apply to the President or the Vice President, for the time being, of the Chartered Institute of Arbitrators, for the appointment of a mediator. 92
- Should the mediation fail, in whole or in part, either party may, upon giving written notice, and within twenty-eight days thereof, apply to the President or the Vice President, for the time being, of the Chartered Institute of Arbitrators, for the appointment of a single arbitrator, for final resolution. The arbitrator shall have no connection with the mediator or the mediation proceedings, unless both parties have consented in writing. The arbitration shall be governed by both the Arbitration Act 1996 and the Controlled Cost Rules of the

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Comfort Rubber Gloves Industries Sdn.Bhd SATRA Reference: CHM0292515/1948/LC/A 20th January 2020 Date:



# **TECHNICAL REPORT**



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#### TERMS AND CONDITIONS FOR THE SALE OF GOODS AND/OR THE PROVISION OF SERVICES

Chartered Institute of Arbitrators (2000 Edition), or any amendments thereof, which Rules are deemed to be incorporated by reference into this clause. The seat of the arbitration shall be England and Wales.

The laws of England shall govern the interpretation of this Contract. Subject to clauses 9.1, 9.2 and 9.3 any The laws or England shall govern the interpretation of this Contract, Subject to clauses 9.1, 9.2 and 9.3 any dispute arising out of or in connection with the Contract shall be subject to the exclusive jurisdiction of the courts of England. However, the Party obtaining a judgement in such courts shall be entitled to enforce it in any court it chooses.

#### PROVISION OF SERVICES

- SATRA shall provide Services using reasonable care and skill and in accordance with the Clients specific instructions and as confirmed by SATRA as part of the Contract review process.
- Estimates for completion of the Services are made in good faith and date from receipt of a written order, payment of a proforma invoice if required, full information and samples to enable SATRA to proceed. While SATRA will make every effort to fulfil them, such estimates are subject to unforeseen events and if not achieved, cannot give rise to any claim. Time will not be of the essence in relation to the performance of the 10.2
- Results given in test reports or certificates refer only to samples submitted for analysis to SATRA. 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. 10.3
- SATRA may delegate all or part of the Services to a subcontractor and the Client authorises SATRA to disclose all information required to undertake the Services. 10.4
- Where the Client requests SATRA to witness testing of other services being undertaken by a third party the Client agrees that SATRAs sole responsibility is to be present at the time of the work and to forward the results or confirm that the service has been undertaken. The Client agrees that unless otherwise agreed SATRA is not responsible for the condition or calibration of any equipment unless provided by SATRA. 10.5
- Unless otherwise agreed in advance, test samples will be retained for 6 weeks from the date of the final report after which time they will be disposed of and SATRA shall cease to have any responsibility for such 10.6

Where the nature of the samples or the Services undertaken results in specialist disposal then SATRA reserves the right to pass the cost of such disposal onto the Client. Storage for longer periods may be possible only if agreed in advance and may incur a storage charge payable by the Client.

Where practical and agreed in advance, samples may be returned at the Client's expense. However, samples are in most instances partially or fully destroyed as part of the work undertaken and SATRA cannot guarantee that samples will be returned in an "as new" condition.

- Where SATRA receives documents reflecting engagements between the Client and third parties or documents belonging to third parties, such documents shall be considered as being for information only and shall not release the Client from any or all obligations to SATRA. 10.7
- SATRA reserves the right to make changes to the Services, provided that such changes do not materially affect the nature or quality of the provision of these Services or where they are necessary in order to ensure that any applicable laws or safety requirements are compiled with.
- The Client acknowledges that SATRA by providing the Services, neither takes the place of the Client or any third party or releases them from any of their obligations. 10.9

#### CLIENT RESPONSIBILITIES RELATING TO THE PROVISION OF SERVICES 11

- 11.1 The Client shall provide sufficient samples, information, instructions and documents as required to enable SATRA to carry out the Services in accordance with the methods, standards or other specifications as
- Where applicable the Client shall allow access by members of SATRA staff to such premises where the Services are to be performed and provide any specialist equipment and personnel. 11 2
- The Client shall inform SATRA in advance of any known hazards, dangers or other safety matters relating to samples submitted to SATRA or on site visits made by SATRA. 11.3
- Where the Client fails to comply with any of its responsibilities SATRA reserves the right to suspend any Services until such time as the Client has complied and may require the Client to reimburse SATRA the amount of any additional costs arising from the suspension.

#### 12. **DELIVERY AND NON-DELIVERY OF GOODS**

- 12.1 Delivery dates for the supply of the Goods are approximate only and not guaranteed. Time of delivery is not of the essence of the Contract and SATRA shall not be liable for any delay in delivery of Goods.
- Should expedited delivery be requested and agreed. SATRA shall be entitled to make additional charges to 122 cover overtime or any other additional costs
- Delivery of the Goods shall take place at such location as SATRA and the Client agree. If the Client agrees to collect the Goods from SATRA's premises, then delivery will take place at those premises in which case the consignment of Goods as recorded by SATRA upon dispatch shall be evidence of the Goods received by the Client unless the Client can provide conclusive evidence to the contrary. 12.3
- SATRA shall not be liable for the non-delivery of Goods (even if caused by SATRA) unless the Client provides written notice of non-delivery in accordance with clause 13.2. Liability for non-delivery of Goods shall in any event be limited to replacing the Goods within a reasonable time frame or the issue of a credit note to the value of the Goods not delivered.
- Should delivery of the Goods be suspended or delayed by the Client for any reason SATRA reserves the right to charge for storage and for all expenses incurred, including loss of or wastage of resources that cannot otherwise be used. If the delay extends beyond 30 days SATRA shall be entitled to immediate payment for any Goods that are ready for delivery, and any other additional costs.
- If for any reason the Client fails to accept delivery of any of the Goods when they are ready for delivery, or SATRA is unable to deliver the Goods on time because the Client has not provided appropriate instructions, documents, licenses or authorisations then risk in the Goods shall pass to the Client, the Goods and/or Services shall be deemed to have been delivered; and SATRA may store the Goods until delivery, whereupon the Client shall be liable for all related costs and expenses (including, without limitation, storage 12.6 and insurance)

#### 13. RISK/TITLE OF GOODS

- Subject to clause 12.6 the risk in the Goods will transfer to the Client on delivery of the Goods unless SATRA and the Client have agreed that the sale of the Goods will be governed by Incoterms 2010 (or any subsequent revision thereto) in which case risk will transfer to the Client in accordance with the Incoterms mode of transport which is agreed by SATRA and the Client. 13 1
- 13.2 Company shall not accept responsibility for loss or damage in transit unless
- In the case of sales where delivery of Goods is made in the United Kingdom SATRA is notified by the Client within 10 days of the invoice date of non-arrival of Goods and within 3 days of the invoice date of receipt of Goods damaged in transit; or

- In all other cases the Client notifies SATRA on the non-arrival or damage in transit within a reasonable period of time as determined by SATRA.
- 133 Title to the Goods shall not pass to the Client until the earlier of when: -
- SATRA receives payment in full (in cash or cleared funds) for the Goods and any other Goods that SATRA has supplied to the Client in which case title to the Goods shall pass at the time of payment of all such sums;
- and
  the Client resells the Goods in accordance with clause 13.5 in which case title shall pass to the Client
  immediately before the time at which the resale by the Client occurs. b)
- 13.4 Until ownership of Goods has passed to the Client, the Client shall:
- hold the Goods as SATRA's bailee; store the Goods (at no cost to SATRA) separately from all other goods belonging to the Client or any third party in such a way that they remain readily identifiable as SATRA's property (including where the Goods have been sold to a 3rd party); a) b)
- not destroy, deface or obscure any identifying mark or packaging on or relating to the Goods; and c) d)
- maintain the Goods in satisfactory condition and keep them insured on SATRA's behalf for their full price against all risks to the reasonable satisfaction of SATRA. The Client shall obtain an endorsement of SATRA's interest in the goods on its insurance policy. On request the Client shall allow SATRA to inspect such Goods and shall produce the policy of insura
- The Client may resell the Goods before ownership has passed to it solely on condition that sale shall be effected in the ordinary course of the Client's business at full market value. 13.5
- If before title to the Goods passes to the Client, the Client becomes subject to any of the events referred to in clause 2.6 then without limiting any other right or remedy SATRA may have:
- a) the Client's right to resell the Goods or use them in the ordinary course of its business ceases immediately;
- and
  SATRA may at any time require the Client to deliver up all Goods in its possession that have not been resold
  or irrevocably incorporated into another product, and
  if the Client fails to do so promptly SATRA may exercise its rights under clause 13.7. b)
- c)
- The Client grants SATRA, its agents and employees an irrevocable licence at any time to enter any premises where the Goods are or may be stored in order to inspect them, or, where the Client's right to possession has terminated, to recover them. 13.7
- 13.8 On termination of the Contract, howsoever caused, SATRA's (but not the Client's) rights contained in this clause 13 shall remain in effect

#### 14. PATENTS

SATRA gives no indemnity against any claim of infringement of Letters Patent, Registered Design, Trade Mark or Copyright by the use of or sale of any article or material supplied to the Client. If its use is impossible without infringement of Letters Patent, Registered Design, Trade Mark or Copyright published at the date of the contract, SATRA will refund to the Client the purchase price of the said article or material provided that it is returned to SATRA free of charge. The Client warrants that any design or instruction furnished or given by the Client shall not be such as will cause SATRA to infringe any Letters Patent, Registered Design, Trade Mark or Copyright in the execution of the Client's order. 14.1

#### 15.

SATRA warrants that on delivery and for a period of 12 months from the date of delivery or within the shelf 15.1 life of the Goods (whichever is the shorter period) the Goods shall be free from defects in design, material and workmanship

#### DEFECTIVE GOODS 16.

- 16 1 Subject to clauses 16.6 and 16.7 if:
- a)
- b) c)
- the Client gives notice in writing to SATRA in accordance with clause 16.3 and during the period referred to in clause 15.1 that the Goods do not comply with the warranty in that clause; and SATRA is given a reasonable opportunity of examining such Goods; and the Client (if asked to do so by SATRA) returns such Goods to SATRA's place of business then SATRA will, at its option, repair or replace the defective Goods or refund the price of the defective Goods in full. SATRA reserves the right to repair the Goods at the Client's premises.
- The Client must inspect all Goods upon delivery. Failure to do so may result in further charges being applied
- 16.3 If Goods are found to be faulty, defective or damaged the Client must inform SATRA in writing as soon as reasonably possible and in any event within 10 working days of the fault, damage or defect being discovered.
- Without prejudice to clause 16.1 if no notice of rejection has been received by SATRA within 3 months of 164 delivery, the Client shall be deemed to have accepted the Goods
- SATRA will pay the reasonable costs of carriage, packaging and insurance for any defective Goods which are returned by the Client provided that SATRA is liable under clause 16.1 to repair or replace the defective Goods. If SATRA determines that the Goods are not defective or if SATRA is not liable to repair or replace the Goods due to the circumstances under clauses 16.6 or 16.7 then the Client will be responsible for the 16.5 payment of such costs
- SATRA shall not be under any liability to repair or at its option replace or pay for the repair or replacement of any Goods which are found to be defective if: 16.6
- the defect is caused or substantially caused by wear and tear, overloading, misuse, neglect, modification or attempted modification carried out by any organisation other than by SATRA or their approved agents, or use with ancillary equipment not approved in writing by SATRA, or default in proper maintenance or cleaning;
- or the Client authorises or carries out any repair or replacement of any Goods without first affording SATRA a b)
- reasonable opportunity to replace or repair them; or the Client has breached any of the terms of the Contract under which the Goods were supplied; or the Goods have been manufactured to a design or specification or in compliance with other information provided by the Client and the defect has arisen as a result of that design, specification or information; c) d)
- Where Goods or parts of Goods are not manufactured by SATRA then SATRA shall be liable for defects only 16.7 to the extent that SATRA obtains redress from the manufacturer or supplier thereof provided that:
- SATRA shall not be obliged to take any step to attempt to obtain such redress except at the request and expense of the Client and upon provision by the Client of a full indemnity as to costs for which SATRA may a) expense of the Client a thereby become liable
- nothing in this condition 16.7 shall have effect as to impose upon SATRA any additional liability or obligations other than those referred to in condition 16.1 b) an those referred to in condition 16.1.
- Except as provided in clause 16.1 SATRA shall have no liability to the Client arising from any failure of the Goods to comply with the warranty in clause 15.1. 16.8

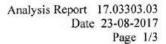
Terms and conditions - September 2019

Comfort Rubber Gloves Industries Sdn.Bhd SATRA Reference: CHM0292515/1948/LC/A 20th January 2020 Date:

Signed:

1-ine

(Page 12 of 12)





4.t

Comfort Rubber Gloves Industries Sdn.Bhd. Ms. Nur Amira Mohd Yusoff Lot 821 & 2209, Jalang Matang 34750 MATANG, TAIPING, PERAK Maleisië



Your notice of 06-06-2017

Your reference

Date 23-08-2017

# Analysis Report 17.03303.03

Required tests: ISO 16604 (2004)

Resistance to penetration by blood-borne pathogens - Test method using Phi-X174 bacteriophage

Identification number	Information given by the client	Date of receipt
T1712259	Nitrile Powder Free Examination Gloves - Product Type OCF40NBBL - Lot N° 70504M1510	06-06-2017

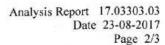
Hilde Rubben

### Order responsible

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The results of the analysis cover the received samples. Centexbel is not responsible for the representativeness of the samples. In assessing compliance with the specifications, we did not take into account the uncertainty on the test results.

INRICHTING ERKEND BIJ TOEPASSING VAN DE BESLUITWET VAN 30 JANUARI 1947 / ETABLISSEMENT RECONNU PAR APPLICATION DE L'ARRÊTE-LOI DU 30 JANVIER 1947





Reference:

T1712259 - Nitrile Powder Free Examination Gloves - Product Type

OCF40NBBL - Lot Nº 70504M1510

## <u>Resistance to penetration by blood-borne pathogens – Test method using Phi-X174</u> <u>bacteriophage</u>

Date of ending the test

21-06-2017

Standard used

ISO 16604 (2004)

Product standard

ISO 374-5 (2016)

Type of sample

Nitrile gloves

Dimension of the test specimens

7.5cm x 7.5cm

Number of test specimens

3

Sampling

1 test specimen per glove in the palm of hand

No

Paraffin-sealed edges

 $21 \pm 5$ °C and  $60 \pm 10$ %RH

Test specimens conditioning

The sample is not tested in conditioned area but

directly after conditioning.

Sterilization

None

Pre treatment performed

None

Side in contact with the bacteriophage

Outer side

suspension

opinge outer sie

Test procedure used

Procedure B (0 kPa 5 min + 14kPa 1 min + 0kPa 4 min - With screen)

Retaining screen specifications

Metal square mesh screen (open area >50%), limiting the deflection of the sample to  $\leq 5.0 \text{ mm}$ 

Surface tension of the bacteriophage

 $0.042 \pm 0.002 \text{ N/m}$ 

suspension

WASSESSNESS BOOK

Used bacteriophage

Bacteriophage Phi-X 174 (ATCC13706-B1)

Host bacteria

Escherichia coli (ATCC 13706)

Compatibility ratio

2.6

Deviation from the standard

The measure of the thickness and the mass have not

been done on the tested specimens.



Results

Test pressure

14 kPa

### Test validity

Controls	Number of PFU/ml of assay fluid	Pass/Fail results
Negative control (polyester film)	< 1 (No penetration)	Pass
Positive control (microporous PE film)	Penetration	Fail

Environmental plate results

0 PFU on each settle plate

 $5.1\ 10^8$   $4.9\ 10^8$ 

**Bacteriophage concentration** 

Starting bacteriophage challenge titer (PFU/ml) Ending bacteriophage challenge titer (PFU/ml)

## Sample results

Test specimen	Number of PFU/ml of assay fluid	Pass/Fail results
#1	< 1 (No penetration)	Pass
#2	< 1 (No penetration)	Pass
#3	< 1 (No penetration)	Pass

Pass = no penetration of bacteriophages through the specimen Fail = penetration of bacteriophages through the specimen



Test Report No. CRSSA/190818676-CA17838

Page 1 of 3

### **COMFORT RUBBER GLOVES INDUSTRIES SDN BHD** LOT 821, JALAN MATANG, 34750 MATANG, PERAK.

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

#### POWDER FREE NITRILE EXAMINATION GLOVES

SGS Job No. 2019-08-01-011 Date of Sample Received : 01st Aug 2019

01st Aug 2019 – 09th Aug 2019 Testing Period

Test Requested Please refer to the results summary

Test Method & Results Please refer to next page(s).

**Result Summary** 

Test Requested	Conclusion
Council of European Resolution AP (2004) 4	1
Rubber – Overall Migration	PASS

Date: 09th Aug 2019

SIGNED FOR AND ON BEHALF OF SGS (MALAYSIA) SDN BHD

CHEE TUCK CHOON SECTION HEAD IKM No. M/3983/6401/12/14

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Test Report No. CRSSA/190818676-CA17838 Date: 09th Aug 2019 Page 2 of 3

Test Results:

### Testing as per Council of European Resolution AP (2004) 4

Rubber - Overall Migration

Method: With reference to EN 1186-1:2002 for selection of conditions and test methods;

EN 1186-9:2002 aqueous food simulants by article filling method (1st Migration);

EN 1186-14:2002 substitute test.

Simulant Used	Test Condition	Result (mg/dm²)	Reporting Limit (mg/dm²)	Permissible Limit (mg/dm²)
3% Acetic Acid (W/V) Aqueous Solution	2 hours at 40°C	ND	3.0	10
10% Ethanol (V/V) Aqueous Solution	2 hours at 40°C	ND	3.0	10
20% Ethanol (V/V) Aqueous Solution	2 hours at 40°C	ND	3.0	10
50% Ethanol (V/V) Aqueous Solution	2 hours at 40°C	ND	3.0	10
Fatty food substitute				
95% Ethanol (V/V) Aqueous Solution	2 hours at 40°C	ND	3.0	10
Iso-octane	2 hours at 40°C	ND	3.0	10
Comment		PASS		

Sample Description : POWDER FREE NITRILE EXAMINATION GLOVES

Note: 1. mg/dm<sup>2</sup> = milligram per square decimeter

2. °C = degree Celsius 3. ND = Not Detected

4. Permissible Limit is according to Council of European Resolution AP (2004) 4.

### Remark:

- 1. Analytical tolerance of aqueous simulants is 2mg/dm<sup>2</sup> or 12mg/kg
- 2. Analytical tolerance of fatty food simulants is 3mg/dm<sup>2</sup> or 20mg/kg
- 3. Test condition & simulant were specified by client.

SIGNED FOR AND ON BEHALF OF SGS (MALAYSIA) SDN BHD

CHEE TUCK CHOON SECTION HEAD

IKM No. M/3983/6401/12/14

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Test Report No. CRSSA/190818676-CA17838

Page 3 of 3

Sample Photo:

### COMFORT RUBBER GLOVES INDUSTRIES SDN BHD CA17838

Date: 09th Aug 2019



SGS authenticate the photo on the original report only

\*\*\* End of Report \*\*\*

SIGNED FOR AND ON BEHALF OF SGS (MALAYSIA) SDN BHD

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YOUR REF: 10294616-A

**DATE RECEIVED:** MAR 28, 2016 **DATE REPORTED:** APR 07, 2016

**PAGE:** 1 of 1

**Report No** : CRSSA/06470/16

Company : Messrs. SGS (Malaysia) Sdn. Bhd.

No. 26, Jalan Anggerik Vanilla 31/93, Kota Kemuning,

40460 Shah Alam, Selangor D.E.

### TEST REPORT

Client : Comfort Rubber Gloves Industries Sdn. Bhd.

Product Description : Powder Free Nitrile Examination Gloves – Blue

Product Type : OCF35BL
Lot No. : 60221M05-02
Size : Medium
Quantity Tested : 26 pieces

Test Conducted : Tensile Strength & Ultimate Elongation

Test Method : ASTM D6319-10

Ageing :  $70 \pm 2$  Deg C for 168 hrs Testing Period : 28 Mar 2016 - 07 Apr 2016

Size	Sample	BEFORE	BEFORE AGEING		R AGEING
	No.	Tensile	Ultimate	Tensile	Ultimate
		Strength	Elongation	Strength	Elongation
		(MPa)	(%)	(MPa)	(%)
M	1	36.1	540	34.2	520
	2	33.1	540	32.3	500
	3	41.3	580	35.0	520
	4	33.9	540	37.7	540
	5	37.1	560	33.8	500
	6	31.6	520	39.8	540
	7	33.0	540	28.2	480
	8	33.3	540	38.1	540
	9	33.9	540	37.4	540
	10	33.1	520	38.7	540
	11	38.2	560	34.1	520
	12	35.9	540	34.0	520
	13	37.3	560	30.5	500
Requirements		14 min	500 min	14 min	400 min

SGS (MALAYSIA) SDN. BHD.

CHEE TUCK CHOON B.Sc. MMIC

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**YOUR REF: 10282805** 

**DATE RECEIVED:** DEC 01, 2015 **DATE REPORTED:** DEC 07, 2015

**PAGE:** 1 of 1

**Report No** : CRSSA/06471/16

Company : Messrs. SGS (Malaysia) Sdn. Bhd.

No. 26, Jalan Anggerik Vanilla 31/93, Kota Kemuning,

40460 Shah Alam, Selangor D.E.

### TEST REPORT

Client : Comfort Rubber Gloves Industries Sdn. Bhd.
Product Description : Powder Free Nitrile Examination Gloves – Blue

Product Type : OCF35BL
Lot No. : 60221M05-02
Size : Medium
Quantity Tested : 5 pieces

Test Conducted : Powder Content
Test Method : ASTM D 6319-10

Testing Period : 28 Mar 2016 – 07 Apr 2016

On testing the samples, the following results were obtained:-

SIZE Average Powder Mass per Glove

M 1.04 mg

SGS (MALAYSIA) SDN. BHD.

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May 18, 2016

# TEST REPORT -

PN 128129A

## CHEMICAL ANALYTICAL SERVICES

Prepared For:
Comfort Rubber Gloves Industries Sdn. Bhd.
Sumathi Saravana Sami
Lot 821, Jalan Matang, Taiping
Perak Darul Ridzuan
Malaysia

Prepared By:

Assistant Manager, Pharmaceutical Services

Approved By:

Ana C. Barbur, M.S.

Manager, Chemical, Microbiological, & Pharmaceutical Services



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May 18, 2016

Sumathi Saravana Sami
Comfort Rubber Gloves Industries Sdn. Bhd.

Page 1 of 3 - PN 128129A

SUBJECT:

Permeation testing per ASTM D 6978-05 on sample submitted by the above company.

RECEIVED:

One blue glove sample identified as Powder Free Nitrile Examination Gloves - Blue; Product Type:

OCF35BL; Lot# 60221M05-02.

### **TESTING CHEMOTHERAPY DRUGS:**

Table 1. List of the Testing Chemotherapy Drugs, Sources, and Expiration Dates

TESTING CHEMOTHERAPY DRUGS	DRUG SOURCE		
Carmustine (BCNU)	USP; Lot# F01274; Expiration 04/2017		
Cisplatin	USP; Lot# J0L420; Expiration 08/2016		
Cyclophosphamide (Cytoxan)	USP; Lot# R01530; Expiration 02/2017		
Dacarbazine (DTIC)	Teva; Lot# 31317605B; Expiration 11/2016		
Doxorubicin Hydrochloride	USP; Lot# L0K258; Expiration 06/2016		
Etoposide (Toposar)	Teva; Lot# 31317608B; Expiration 02/2017		
Fluorouracil	USP; Lot# I0G371; Expiration 09/2016		
Paclitaxel (Taxol)	Hospira; Lot# B036865AA; Expiration 05/2016		
Thiotepa	Sigma Aldrich; Lot# SLBM7142V; Expiration 12/2016		

### **COLLECTION MEDIA:**

The collection media, which were selected, are listed in Table 2.

Table 2. Collection Media for Testing Chemotherapy Drugs

TEST DRUG AND CONCENTRATION	COLLECTION MEDIUM		
Carmustine (BCNU), 3.3 mg/ml (3,300 ppm)	10% Ethanol Aqueous Solution		
Cisplatin, 1.0 mg/ml (1,000 ppm)	Distilled Water		
Cyclophosphamide (Cytoxan), 20 mg/ml (20,000 ppm)	Distilled Water		
Dacarbazine (DTIC), 10.0 mg/ml (10,000 ppm)	Distilled Water		
Doxorubicin Hydrochloride, 2.0 mg/ml (2,000 ppm)	Distilled Water		
Etoposide (Toposar), 20.0 mg/ml (20,000 ppm)	Distilled Water		
Fluorouracil, 50.0 mg/ml (50,000 ppm)	9.20 pH Sodium Hydroxide Solution		
Paclitaxel (Taxol), 6.0 mg/ml (6,000 ppm)	30% Methanol Aqueous Solution		
Thiotepa, 10.0 mg/ml (10,000 ppm)	Distilled Water		

Sumathi Saravana Sami
Comfort Rubber Gloves Industries Sdn. Bhd.

Page 2 of 3 - PN 128129A

### TESTING CONDITIONS:

Standard Test Method Used:

Deviation From Standard Test Method:

Analytical Method:

Testing Temperature: Collection System:

Specimen Area Exposed: Selected Data Points:

Number of Specimens Tested: Location Sampled From: ASTM D 6978-05

Used 1" Permeation Cell

UV/VIS Spectrometry 35.0°C ± 2.0

Closed Loop

5.067 cm2

25/test 3/test

Cuff area

### DETECTION METHOD OF CHEMICAL PERMEATION; UV/VIS ABSORPTION SPECTROMETRY:

Instrument:

Perkin Elmer UV/VIS Spectrometer Lambda 25

UV/VIS Absorption Spectrometry was used to measure the absorbance of test chemicals, which permeated through the specimens into the collection medium. The collection medium was circulated in a closed loop at 11 ml/minute of flow rate through the testing period. Data collection was performed according to the programmed schedule by means of UV Winlab software from the Perkin Elmer Corporation. The list of the characteristic wavelengths is shown below.

Table 3. Characteristic Wavelengths used in UV/VIS Absorption Spectrometry

TESTING CHEMOTHERAPY DRUGS	WAVELENGTH (nm)		
Carmustine (BCNU), 3.3 mg/ml (3,300 ppm)	229		
Cisplatin, 1.0 mg/ml (1,000 ppm)	199		
Cyclophosphamide (Cytoxan), 20 mg/ml (20,000 ppm)	200		
Dacarbazine (DTIC), 10.0 mg/ml (10,000 ppm)	320		
Doxorubicin Hydrochloride, 2.0 mg/ml (2,000 ppm)	232		
Etoposide (Toposar), 20.0 mg/ml (20,000 ppm)	205		
Fluorouracil, 50.0 mg/ml (50,000 ppm)	269		
Paclitaxel (Taxol), 6.0 mg/ml (6,000 ppm)	231		
Thiotepa, 10.0 mg/ml (10,000 ppm)	199		

### **SAMPLE CHARACTERISTICS:**

<u>Table 4. Thickness characteristics for the tested specimens: Powder Free Nitrile Examination Gloves – Blue; Product Type: OCF35BL; Lot# 60221M05-02</u>

Testing Chemotherapy	Thickness (mm)				Weight/Unit Area	
Drugs	Sample 1	Sample 1 Sample 2 Sample		Average (mm)	(g/m²)	
Carmustine (BCNU)	0.052	0.054	0.054	0.053		
Cisplatin	0.051	0.057	0.054	0.054		
Cyclophosphamide (Cytoxan)	0.053	0.054	0.054	0.054		
Dacarbazine (DTIC)	0.047	0.052	0.055	0.051		
Doxorubicin Hydrochloride	0.048	0.051	0.051	0.050	55.3	
Etoposide (Toposar)	0.051	0.055	0.055	0.054		
Fluorouracil	0.045	0.053	0.052	0.050		
Paclitaxel (Taxol)	0.049	0.051	0.053	0.051		
Thiotepa	0.052	0.055	0.053	0.053		

Sumathi Saravana Sami Comfort Rubber Gloves Industries Sdn. Bhd.

Page 3 of 3 - PN 128129A

### **RESULTS:**

Table 5. Permeation Test Results on: Powder Free Nitrile Examination Gloves - Blue; Product Type: OCF35BL; Lot# 60221M05-02

TEST CHEMOTHERAPY DRUG AND CONCENTRATION	MINIMUM BREAKTHROUGH DETECTION TIME (Specimen 1/2/3) (Minutes)	STEADY STATE PERM. RATE (Specimen 1/2/3) (µg/cm²/minute)	OTHER OBSERVATIONS
Carmustine (BCNU)	18.2	0.3	Moderate swelling
3.3 mg/ml (3,300 ppm)	(18.2,24.6,18.6)	(0.3,0.3,0.4)	and no degradation
Cisplatin 1.0 mg/ml (1,000 ppm)	No breakthrough up to 240 min.	N/A	Slight swelling and no degradation
Cyclophosphamide (Cytoxan) 20 mg/ml (20,000 ppm)	No breakthrough up to 240 min.	N/A	Slight swelling and no degradation
Dacarbazine (DTIC) 10.0 mg/ml (10,000 ppm)	No breakthrough up to 240 min.	N/A	Slight swelling and no degradation
Doxorubicin Hydrochloride 2.0 mg/ml (2,000 ppm)	No breakthrough up to 240 min.	N/A	Slight swelling and no degradation
Etoposide (Toposar) 20.0 mg/ml (20,000 ppm)	No breakthrough up to 240 min.	N/A	Slight swelling and no degradation
Fluorouracil 50.0 mg/ml (50,000 ppm)	No breakthrough up to 240 min.	N/A	Slight swelling and no degradation
Paclitaxel (Taxol) 6.0 mg/ml (6,000 ppm)	No breakthrough up to 240 min.	N/A	Moderate swelling and no degradation
Thiotepa 10.0 mg/ml (10,000 ppm)	57.3 (80.7,57.3,69.4)	0.5 (0.4,0.5,0.5)	Slight swelling and no degradation

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