

Document Title : Protocol for Stability Study Under Accelerated Aging Condition (EN 455- 4)	Document Ref. No : GX2-PSL-EN455- 4/002-18
Product Type : 9" (3mil) Powder Free Nitrile Gloves	Page 1 of 6

PROTOCOL

THREE YEAR SHELF LIFE

**STABILITY STUDY UNDER ACCELERATED AGING
CONDITION**

(EN455- 4)

FOR

9" (3 mil) Powder Free Nitrile Gloves

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1.0 INTRODUCTION

1.1 Purpose

Accelerated aging study was conducted to estimate the product shelf life in accordance to EN 455-4 (Shelf Life Study for Accelerated Aging for Medical Gloves) while pending the completion of the real time aging studies for product expiration dating claim labeling. This product also will be tested in accordance to EN 455-1 (Requirements and testing for freedom from holes) and EN 455-2 (Requirements and testing for physical properties). A maximum shelf life of 3 years shall be assigned based on the accelerated aging studied. The shelf life may be extended as real time aging studies data is generated.

1.2 Scope

To evaluate the effects of accelerated aging (Time and Temperature) on physical properties of **9" (3 mil) Powder Free Nitrile Gloves**. This study will cover EN 455-4 (Shelf Life Study for Accelerated Aging for Medical Gloves) requirement and will be tested accordance to EN 455-1 (Requirements and testing for freedom from holes) and EN 455-2 (Requirements and testing for physical properties).

1.3 Summary of the protocol:

- 1.3.1 3 lots of sample were collected from dipping machine for shelf life study.
- 1.3.2 The samples shall be tested in accordance in accordance to EN 455-4 (Shelf Life Study for Accelerated Aging for Medical Gloves) including EN 455-1 (Requirements and testing for freedom from holes) and EN 455-2 (Requirements and testing for physical properties).
- 1.3.3 Samples of gloves packaged in its consumer packaging shall be placed in 70±2°C air oven for 166±2 hours (7 days) and 50±2°C (90±1 day).
- 1.3.4 Temperature of the aging chamber or incubator should be monitored and recorded as below:

Time Interval	Test Interval
166±2 hrs	At least once per day
90±1 day	At least once per week

- 1.3.5 The following are the identified product name and batch number for accelerated aging performance testing.

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Product	Glove Size	Lot
9" (3 mil) Powder Free Nitrile Gloves	M	Lot 1
	M	Lot 2
	M	Lot 3

*Lot number traceability will be reported in study report

REFERENCES

- | | | |
|-----|----------------|-----------------------------------------------------------------------------------------------|
| 2.1 | EN 455 - 1 | Medical gloves for single use – Part 1: Requirements and testing for freedom from holes |
| 2.2 | EN 455 - 2 | Medical Gloves for single use – Part 2: Requirements and testing for physical properties |
| 2.3 | EN 455 - 4 | Medical Gloves for single use – Part 4: Requirements and testing for shelf life determination |
| 2.4 | ISO : 2859 - 1 | International Standard – Sampling Procedure and Table for Inspection by Attributes B45 |
| 2.5 | SOP-L/3.4 2 | Shelf Life Study for Accelerated Aging for Medical Gloves – ASTM D 7160 and EN 455, Part 4 |
| 2.6 | PS 037B/16-01 | Product Specification for 9" (3 mil) Gen-X Powder Free Nitrile Gloves (M-3.5g) |

3.0 RESPONSIBILITY

Activity	Responsible
1. Protocol	Ms Nabillah
2. Aging samples (submit to Lab)	Ms Kumari
3. Physical Properties	Mr Naqiudin/Mr Amirul
4. Water leak test, Visual Inspection, Physical Dimension	Mr Naqiudin/Mr Amirul
3. Data Collection/Analysis/Reporting	Ms Nabillah

4.0 TESTING REQUIREMENT

4.1 **Accelerated aging at 70±2°C for (166 ± 2 hours) and 50±2°C for (90±1 day)**

4.1.1 The gloves will be tested for Water Leak Test (EN 455-1), Visual Inspection and Physical Dimension (EN 455-2) before aging (control) and after aging (70±2°C x 166 ± 2 hrs) and (50±2°C x 90±1 day). The

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sampling plan is as shown in Table 1 and acceptance criteria as shown in Table 2.

4.1.2 For physical properties this gloves will be tested accordance to EN455-2.

Table 1: Acceptance Criteria

Items	Units	Requirements	Inspection Level	Sampling plan Refer to EN 455- 4	
				Number of Sample (pcs./lot)	Acceptance criteria
Water leakage Test	N/A	-	G1	200	AQL 1.5 7 Acc./8 Rej.
Visual Inspection	N/A	-	G1	200	AQL 1.5 7 Acc./8 Rej.
Physical Dimension	mm	<u>Specification (PS 037B/16-01)</u> Cuff thickness : Min 0.05 Palm Thickness : Min 0.06 Finger Thickness : Min 0.07 Palm width (M size): 85-105 Length : ≥240mm	S2	13	AQL 4.0 1 Acc./2 Rej
Physical Properties (Before Aged)					
Force at Break (Median)	Newton (N)	Median ≥ 6.0 Newton	-	13	-
Physical Properties (After Aged)					
Force at Break (Median)	Newton (N)	Median ≥ 6.0 Newton	-	13	-

5.0 DEVIATIONS

5.1 Any deviation to this protocol must be agreed upon by QA/ Lab/ Manufacturing/Assistant General Manager. Deviations should be documented as part of the protocol and in the Test Summary to be reviewed and approved per the Executed Approval section.

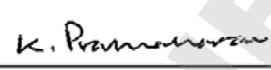
6.0 DISPOSITION OF PRODUCT

6.1 Tested product and any extra unused product will be safely disposed of at the test facility.

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Position : QA Engineer

Verified By :  am Date : 1/11/2018
Name : Ms. Nurul Ain
Position : QA Manager

Verified By :  Date : 1/11/2018
Name : Mr. Prabhakaran Kumaresan
Position : Deputy General Manager
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DOMINIQUE DUTSCHER S

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TECHNICAL REPORT FOR

**THREE YEAR SHELF LIFE
FOR**

**9" (3 mil) Powder Free Nitrile Gloves
(EN455- 4)**

**[STABILITY STUDY UNDER ACCELERATED AGING
CONDITION]**

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1.0 INTRODUCTION

1.1 Purpose

Accelerated aging study was conducted to estimate the product shelf life while pending the completion of the real time aging studies for product expiration dating claim labeling. A maximum shelf life of 3 years shall be assigned based on the accelerated aging studied. The shelf life may be extended as real time aging studies data is generated.

1.2 Scope

This Technical Report covers **9" (3 mil) Powder Free Nitrile Gloves**.

1.3 Summary of work done.

1.3.1 3 lots of sample produced from dipping machine were collected.

1.3.2 Upon completion, the samples were tested in accordance to Shelf Life Study for Accelerated Aging for Medical Gloves – EN 455 Part 4.

1.3.3 Samples of gloves packaged in its consumer packaging were placed in $70\pm 2^{\circ}\text{C}$ air oven for 166 ± 2 hours (7 days) and $50\pm 2^{\circ}\text{C}$ for 90 ± 1 days.

Glove Size	Lot	Lot No	$70\pm 2^{\circ}\text{C}$ for 166 ± 2 hours		$50\pm 2^{\circ}\text{C}$ for 90 ± 1 days	
			Date Start	Date End	Date Start	Date End
M	Lot 1	20180111-01	1/11/2018	8/11/2018	8/11/2018	6/2/2019
M	Lot 2	20180111-02	1/11/2018	8/11/2018	8/11/2018	6/2/2019
M	Lot 3	20180111-03	1/11/2018	8/11/2018	8/11/2018	6/2/2019

2.0 REFERENCES

- 2.1 EN 455 - 1 Medical gloves for single use – Part 1: Requirements and testing for freedom from holes
- 2.2 EN 455 - 2 Medical Gloves for single use – Part 2: Requirements and testing for physical properties
- 2.3 EN 455 - 4 Medical Gloves for single use – Part 4: Requirements and testing for shelf life determination
- 2.4 ISO : 2859 - 1 International Standard – Sampling Procedure and Table for Inspection by Attributes B45
- 2.5 PS 037B/16-01 Product Specification for 9" (3 mil) Gen-X Powder Free Nitrile Gloves (M-3.5g)

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3.0 RESULTS AND DISCUSSION

3.1. Accelerated aging at 70±2°C for 166±2 hours and 50±2°C for 90±1 days

- 3.1.1 As shown in Table 1, **all 3 lots** meet the AQL 1.5 requirement for visual test before (control) and after aging (70°C@166 ± 2 hours and 50±2°C (90±1 day) for visual test. This is due to the fact that no blocking, no stickiness issue, no donnability issue and no deterioration on glove were found.
- 3.1.2 This **Lot 1, Lot 2 and Lot 3** also meet the AQL 1.5 requirement for holes defects before aging (control). After accelerated aging also meet the AQL 1.5 requirement for hole. In addition, accelerated aging at aging does not adversely affect the gloves integrity.
- 3.1.3 As shown in Table 1, **all lot** meets the EN 455-2 requirement for physical properties (aged). Accelerated aging does enhance the properties of gloves and does not affect the gloves physical properties. From the table it showed that the Force at Break results after aging condition.
- 3.1.4 Based on Table 1, Physical Dimension before accelerated aging (control) meets the requirement. Accelerated aging condition for **9" (3 mil) Gen-X Powder Free Nitrile Gloves** also would not affect the Physical Dimension test and meets the requirement.

Table 1: Summary of result for visual, water tight test, physical properties and physical dimension

<i>Visual Inspection (G1, AQL 1.5, N=200, Acc-7, Rej-8)</i>									
	Lot 1			Lot 2			Lot 3		
	Control (0 days)	After aging @ 70°C x 166±2 hrs	After aging @ 50°C x 90days	Control (0 days)	After aging @ 70°C x 166±2 hrs	After aging @ 50°C x 90days	Control (0 days)	After aging @ 70°C x 166±2 hrs	After aging @ 50°C x 90days
Blocking	0/200	0/200	0/200	0/200	0/200	0/200	0/200	0/200	0/200
Stickiness	0/200	0/200	0/200	0/200	0/200	0/200	0/200	0/200	0/200
Donnability	0/200	0/200	0/200	0/200	0/200	0/200	0/200	0/200	0/200
Deterioration	0/200	0/200	0/200	0/200	0/200	0/200	0/200	0/200	0/200
Disposition	Pass	Pass	Pass	Pass	Pass	Pass	Pass	Pass	Pass
<i>Water Leakage Test (G1, AQL 1.5, N=200, Acc-7, Rej-8)</i>									
	Lot 1			Lot 2			Lot 3		
	Control (0 days)	After aging @ 70°C x 166±2 hrs	After aging @ 50°C x 90days	Control (0 days)	After aging @ 70°C x 166±2 hrs	After aging @ 50°C x 90days	Control (0 days)	After aging @ 70°C x 166±2 hrs	After aging @ 50°C x 90days
Holes/Leak ages	2/200	2/200	2/200	3/200	0/200	4/200	0/200	1/200	3/200
Disposition	Pass	Pass	Pass	Pass	Pass	Pass	Pass	Pass	Pass
<i>Physical Properties Test (N=13) Forced at Break : (Unaged & Aged: Median ≥ 6N)</i>									

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	Control (0 days)			After aging @ 70°C x 166±2 hrs			After aging @ 50°C x 90days		
	Data	Median	Total Reject/ Total Sample	Data	Median	Total Reject/ Total Sample	Data	Median	Total Reject/ Total Sample
Lot 1	6.82 6.82 6.93 6.40 7.54 6.46 6.96 6.80 7.22 7.10 6.48 6.75 6.99	6.82	0/13	7.97 7.50 6.64 7.75 6.15 6.83 7.91 7.69 6.97 8.42 6.47 6.30 6.54	6.97	0/13	7.45 8.07 7.85 6.45 8.46 7.79 6.73 8.25 7.85 8.11 8.21 6.98 8.16	7.85	0/13
Disposition:	Pass			Pass			Pass		
Lot 2	6.72 6.70 7.31 6.58 6.58 6.42 6.15 7.10 7.02 7.49 6.58 6.68 6.31	6.68	0/13	6.15 7.69 6.47 7.12 6.29 6.63 7.76 6.60 7.84 7.47 7.65 7.48 7.84	7.47	0/13	7.71 7.33 7.66 7.6 8.11 8.85 8.37 7.89 6.77 8.39 7.32 8.75 8.74	7.89	0/13
Disposition:	Pass			Pass			Pass		
Lot 3	6.58 6.60 7.60 7.13 6.62 7.73 6.41 7.89 6.92 7.69 7.43 7.66 7.07	7.13	2/13	6.92 6.32 7.11 6.22 7.12 6.35 7.76 6.57 6.16 6.91 6.93 6.90 6.11	6.90	0/13	9.34 7.00 7.59 8.9 7.84 8.47 8.35 8.47 7.73 8.73 7.37 8.36 6.85	8.35	0/13
Disposition:	Pass			Pass			Pass		
Physical Dimension Test Specification (PS 037B/16-01) Cuff Thickness (mm): Min 0.05; Palm Thickness (mm): Min 0.06; Finger Thickness (mm): Min 0.07; Palm width (mm): M: 95±10; Length (mm): Min 240									
	Control (0 days)			After aging @ 70°C x 166±2 hrs			After aging @ 50°C x 90days		
	Data	Median	Total Reject/	Data	Median	Total Reject/	Data	Median	Total Reject/

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		Total Sample		Total Sample		Total Sample		Total Sample	
Lot 1									
Cuff Thickness	0.06	0.06	0/13	0.05	0.06	0/13	0.05	0.05	0/13
	0.06			0.06					
	0.06			0.06					
	0.05			0.06					
	0.05			0.05					
	0.06			0.06					
	0.06			0.06					
	0.06			0.06					
	0.06			0.05					
	0.06			0.06					
	0.06			0.05					
	0.06			0.06					
	0.06			0.05					
	0.06			0.06					
Disposition	Pass			Pass			Pass		
Palm Thickness	0.07	0.07	0/13	0.07	0.07	0/13	0.07	0.06	0/13
	0.07			0.05					
	0.06			0.06					
	0.07			0.05					
	0.07			0.06					
	0.06			0.07					
	0.07			0.06					
	0.06			0.06					
	0.07			0.06					
	0.07			0.07					
	0.07			0.06					
	0.08			0.06					
	0.07			0.06					
	0.07			0.07					
0.08	0.06								
Disposition	Pass			Pass			Pass		
Finger Thickness	0.10	0.11	0/13	0.12	0.11	0/13	0.12	0.12	0/13
	0.11			0.12					
	0.12			0.11					
	0.11			0.12					
	0.11			0.12					
	0.12			0.11					
	0.10			0.12					
	0.10			0.11					
	0.11			0.10					
	0.12			0.12					
	0.12			0.11					
	0.12			0.12					
	0.12			0.11					
	0.12			0.12					
0.11	0.11								
Disposition	Pass			Pass			Pass		
Palm Width	95	95	0/13	96	96	0/13	96	96	0/13
	94			97					
	95			96					
	95			97					
	96			96					
	95			97					
	96			95					
	96			96					
	97			97					
	95			96					
	95			97					
	96			95					
	95			96					
	95			97					
95	97								
Disposition	Pass			Pass			Pass		

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Glove Length	244	245	0/13	245	245	0/13	243	242	0/13
	246			246			241		
	245			242			246		
	245			243			242		
	245			244			241		
	246			244			244		
	245			243			241		
	245			245			242		
	246			246			240		
	245			246			241		
	245			245			244		
	245			246			241		
	245			245			243		
	245			245			243		
Disposition:		Pass		Pass		Pass		Pass	
Lot 2									
Cuff Thickness	0.06	0.06	0/13	0.06	0.06	0/13	0.05	0.05	0/13
	0.06			0.06			0.05		
	0.05			0.05			0.06		
	0.06			0.06			0.05		
	0.06			0.06			0.05		
	0.06			0.06			0.06		
	0.07			0.06			0.05		
	0.06			0.06			0.06		
	0.06			0.06			0.05		
	0.07			0.06			0.06		
	0.06			0.07			0.05		
	0.05			0.06			0.05		
	0.06			0.05			0.06		
	0.05			0.06			0.05		
0.06	0.06	0.06							
Disposition:		Pass		Pass		Pass		Pass	
Palm Thickness	0.07	0.07	0/13	0.07	0.07	0/13	0.07	0.06	0/13
	0.08			0.07			0.06		
	0.08			0.07			0.07		
	0.07			0.06			0.06		
	0.08			0.07			0.06		
	0.07			0.07			0.06		
	0.08			0.07			0.06		
	0.07			0.06			0.06		
	0.07			0.07			0.06		
	0.07			0.06			0.07		
	0.08			0.07			0.05		
	0.08			0.07			0.06		
	0.07			0.06			0.07		
	0.07			0.06			0.07		
0.07	0.06	0.07							
Disposition:		Pass		Pass		Pass		Pass	
Finger Thickness	0.12	0.11	0/13	0.11	0.11	0/13	0.11	0.12	0/13
	0.10			0.12			0.13		
	0.11			0.12			0.11		
	0.10			0.11			0.12		
	0.12			0.10			0.13		
	0.11			0.11			0.12		
	0.11			0.12			0.11		
	0.12			0.11			0.12		
	0.11			0.11			0.13		
	0.10			0.12			0.13		
	0.13			0.11			0.13		
	0.12			0.12			0.12		
	0.12			0.11			0.11		
	0.12			0.11			0.11		
0.12	0.11	0.11							
Disposition:		Pass		Pass		Pass		Pass	
Palm Width	96	96	0/13	95	96	0/13	96	96	0/13
	95			96			96		

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	95			97			97		
	96			96			95		
	95			96			96		
	96			97			97		
	95			95			96		
	95			96			96		
	96			97			97		
	97			95			97		
	96			96			97		
	95			97			96		
	96			95			97		
Disposition:	Pass			Pass			Pass		
Glove Length	245			245			244		
	245			244			241		
	244			245			240		
	245			246			244		
	246			246			243		
	245	245	0/13	243	245	0/13	241	241	0/13
	246			246			241		
	245			245			243		
	245			244			241		
	246			246			241		
	245			245			243		
	246			246			241		
	245			245			243		
	245			245			243		
Disposition:	Pass			Pass			Pass		
Lot 3									
Cuff Thickness	0.06			0.06			0.05		
	0.06			0.06			0.06		
	0.07			0.05			0.06		
	0.06			0.06			0.05		
	0.06	0.06	0/13	0.06	0.06	0/13	0.05	0.05	0/13
	0.07			0.06			0.06		
	0.06			0.07			0.05		
	0.06			0.06			0.05		
	0.06			0.07			0.06		
	0.05			0.06			0.05		
	0.05			0.06			0.06		
	0.06			0.06			0.05		
	0.06			0.06			0.06		
Disposition:	Pass			Pass			Pass		
Palm Thickness	0.07			0.07			0.07		
	0.07			0.07			0.07		
	0.08			0.06			0.06		
	0.07			0.07			0.07		
	0.07			0.07			0.07		
	0.07	0.07	0/13	0.07	0.07	0/13	0.06	0.06	0/13
	0.08			0.06			0.05		
	0.07			0.07			0.06		
	0.07			0.07			0.07		
	0.07			0.06			0.06		
	0.08			0.07			0.07		
	0.07			0.07			0.06		
	0.07			0.07			0.05		
Disposition:	Pass			Pass			Pass		
Finger Thickness	0.12			0.11			0.11		
	0.11	0.11	0/13	0.12	0.11	0/13	0.13	0.12	0/13
	0.12			0.11			0.11		
	0.10			0.12			0.12		

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	0.12			0.11			0.13		
	0.10			0.11			0.11		
	0.10			0.12			0.13		
	0.12			0.11			0.12		
	0.12			0.12			0.1		
	0.11			0.12			0.13		
	0.10			0.11			0.12		
	0.12			0.11			0.11		
	0.11			0.11			0.13		
Disposition:	Pass			Pass			Pass		
Palm Width	95			95			96		
	96			96			97		
	97			95			95		
	96			96			96		
	96			97			96		
	97			95			97		
	96	96	0/13	96	96	0/13	95	96	0/13
	97			97			97		
	95			95			96		
	96			96			97		
	97			97			97		
	95			95			96		
	96			95			97		
Disposition:	Pass			Pass			Pass		
Glove Length	246			246			242		
	241			245			240		
	242			244			243		
	244			246			241		
	246			241			243		
	245			244			241		
	246	246	0/13	240	245	0/13	242	242	0/13
	246			245			244		
	246			245			241		
	244			244			243		
	246			246			242		
	243			245			240		
	246			245			244		
Disposition:	Pass			Pass			Pass		

DOMINIQUE

Document Title : Stability Study Under Accelerated Aging Condition Test Report (EN 455-4)	Document Ref. No: GX3-RSL-EN455-4/002-18
Product Type : 9" (3 mil) Powder Free Nitrile Gloves	Page 10 of 11

4.0 CONCLUSION

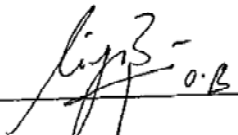
Based on result summary on Table 1, **9" (3 mil) Gen-X Powder Free Nitrile Gloves** meet as per EN 455-4 requirement and shall be labeled with 3 years of expiration date.

- 4.1 No adverse effect on visual defect was found under accelerated aging condition: 70°C@166±2hrs and 50°C@90±1days. The gloves meet the AQL 1.5 requirement for visual inspection.
- 4.2 No blocking, good donnability, no stickiness issue and deterioration on gloves were found under each accelerated aging condition.
- 4.3 No adverse effect on holes defect was found under accelerated aging condition (70°C@166±2hrs and 50°C@90±1days). The gloves meet the AQL 1.5 requirement for hole.
- 4.4 The gloves after each accelerated aging condition meet the EN 455-2 requirements for physical properties after accelerated aging.
- 4.5 This result of this accelerated aging study are applicable for all companies under Smart Glove Corporation Sdn. Bhd.

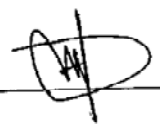
5.0 RECOMMENDATIONS

- 5.1 To conduct real time aging study to confirm the expiration date of 3 years and continue real time study up to 5 years.
- 5.2 Any extension of shelf life beyond 3 years shall be based on real time data

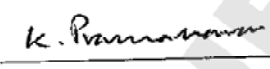
Document Title : Stability Study Under Accelerated Aging Condition Test Report (EN 455-4)	Document Ref. No: GX3-RSL-EN455-4/002-18
Product Type : 9" (3 mil) Powder Free Nitrile Gloves	Page 11 of 11

Prepared By : 
Name : Ms. Nur Nabillah
Position : QA Engineer

Date : 12/2/2019

Verified By :  am
Name : Ms. Nurul Ain
Position : QA Manager

Date : 12/02/2019.

Verified By : 
Name : Mr. Prabhakaran
Position : Deputy General Manager
Research & Development

Date : 12/2/2019

DOMINIQUE DUTSCHER S/P

Report No : CRSSA/25618/16
Company : GX Corporation Sdn Bhd (Specialty Plant)
Plot 6497-A, Lorong Haji Abdul Manan, 5 ¼ Milestone,
Sementa, Jalan Kapar, 42100 Klang, Selangor Darul Ehsan.

TEST REPORT

Product Description : Powder Free Nitrile Examination Gloves (Non – Sterile)
Size : M
Quantity Tested : 200 pieces
Test Conducted : Freedom from holes
Test Method : EN455 Part 1:2000
Testing Period : 01 Dec 2016 – 07 Dec 2016

Based on submitted samples, the following results obtained :-

Acceptable Quality Limit (AQL) : 1.5 Accept : 7 Found : 2

Result : Within AQL

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B.Sc. MMIC
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Report No : CRSSA/25619/16
Company : GX Corporation Sdn Bhd (Specialty Plant)
 Plot 6497-A, Lorong Haji Abdul Manan, 5 ¼ Milestone,
 Sementa, Jalan Kapar, 42100 Klang, Selangor Darul Ehsan.

TEST REPORT

Product Description : Powder Free Nitrile Examination Gloves (Non – Sterile)
 Size : M
 Quantity Tested : 13 pieces
 Test Conducted : Dimensions
 Test Method : EN 455 Part 2:2015
 Testing Period : 01 Dec 2016 – 07 Dec 2016

Based on submitted samples, the following results obtained :-

Size	M	M	M	M	M	M	M	M	M	M	M	M	M	Median
Width Median: ≤ 95±10mm	97	97	98	96	98	98	96	98	97	98	98	96	97	98
Length Median: ≥ 240 mm	245	240	245	243	243	243	242	240	250	245	241	248	240	243

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Report No : **CRSSA/25620/16**
 Company : **GX Corporation Sdn Bhd (Specialty Plant)**
Plot 6497-A, Lorong Haji Abdul Manan, 5 ¼ Milestone,
Sementa, Jalan Kapar, 42100 Klang, Selangor Darul Ehsan.

TEST REPORT

Product Description : Powder Free Nitrile Examination Gloves (Non – Sterile)
 Size : -
 Sample Quantity : 26 pieces
 Test Conducted : Force at Break During Shelf Life and After Challenge
 Test Method : EN 455 Part 2:2015
 Ageing : 70 ± 2 Deg C for 7 days
 Testing Period : 01 Dec 2016 – 15 Dec 2016

SIZE	SAMPLE NO.	Force at Break, N	
		<u>DURING SHELF LIFE</u>	<u>AFTER CHALLENGE</u>
M	1	9.2	7.6
	2	8.6	7.3
	3	10.0	7.7
	4	8.0	9.0
	5	9.0	8.5
	6	8.8	8.0
	7	8.8	8.8
	8	9.7	8.0
	9	8.3	8.1
	10	8.4	9.1
	11	8.1	7.8
	12	10.3	8.1
	13	9.8	8.6
Median		8.8	8.1
Requirement		≥ 6.0	≥ 6.0

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Report No : **CRSSA/25621/16**
Company : **GX Corporation Sdn Bhd (Specialty Plant)**
Plot 6497-A, Lorong Haji Abdul Manan, 5 ¾ Milestone,
Sementa, Jalan Kapar, 42100 Klang, Selangor Darul Ehsan.

TEST REPORT

Product Description : Powder Free Nitrile Examination Gloves (Non – Sterile)
Size :
Quantity Tested : 5 pieces
Test Conducted : Powder Content
Test Method : EN455 Part 3:2006
Testing Period : 01 Dec 2016 – 07 Dec 2016

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

<u>SIZE</u>	<u>Average Powder Mass per Glove</u>
M	0.14mg

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Darul Ehsan
Malaysia

SATRA reference: CHM0233424/1512/
DRWM/SMcD/A –
Issue 2

Your reference:

Date of report: 1st October 2015

For the attention of: Nurul Huda

Samples received: 20th March 2015

TECHNICAL REPORT

Subject:

Overall migration testing in accordance with BS EN 1186 and EU regulations 10/2011 on glove samples described as powder free nitrile examination glove (3 mil)

Issue 2 – This report replaces CHM0233424/1512/DRWM/A dated 9th April 2015

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.

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The uncertainty of the results in this report is based on a standard uncertainty multiplied by a coverage factor $k=2$, which provides for a confidence level of approximately 95%

Report signed by: S McDonald
Position: Chemical Technologist
Department: Chemical & Analytical Technology

(Page 1 of 4)

WORK REQUESTED:

Samples of gloves described as powder free nitrile examination glove (3 mil) were received on the 23rd March 2015 for assessment in accordance with the overall migration limit requirements of Commission Regulation No. 10/2011.

CONCLUSIONS:

When tested in accordance with BS EN 1186-7: 2002 the samples described as powder free nitrile examination gloves (3 mil) was found to meet with the overall migration limit requirements when assessed against 10% Ethanol and 3% Acetic acid for 2 hours at 40°C.

Results are given in the following tables.

TESTING REQUIRED:

- BS EN 1186 part 7: 2002 Materials and articles in contact with foodstuffs – Plastics Test methods for overall migration into aqueous food simulants using a pouch for 2 hours at 40°C.
 - 10% Ethanol (simulant A Commission Regulation No. 10/2011)
 - 3% Acetic Acid (simulant B in Commission Regulation No. 10/2011)

RESULTS AND REQUIREMENTS:

Migration into aqueous food simulants using a pouch

Pouch Method

The gloves were assessed by reversing the gloves to form a pouch and filling with each simulant. The surface area of each glove was calculated by determining the density of the glove, weighing the part of the glove that was in contact with the simulant and calculating the area assuming a homogeneous material.

Sample	Test Method	Global migration (mg/dm ²)		Mean Global migration (mg/dm ²)	Pass/Fail
		A	B		
Powder free examination glove (3 mil)	EN 1186-7 (10% Ethanol)	A	1.6	2.2	Pass
		B	1.6		
		C	3.4		
	EN 1186-7 (3% Acetic acid)	A	2.9	3.4	Pass
		B	2.4		
		C	4.9		
Requirement	-	-	-	<10 mg/dm²	-

APPENDICES:

The samples described as powder free nitrile examination glove (3 mil) are suitable for contact with the following food categories of foodstuffs as listed in 10/2011 Annex III, table 2.

Reference number	Description of foodstuffs
03	Chocolate, sugar and products thereof Confectionary products
03.03	Sugar and sugar products B. Molasses, sugar syrups, honey and the like
04	Fruit, vegetables and products thereof
04.01	Whole fruit, fresh or chilled, unpeeled
04.04	Whole vegetables, fresh or chilled
04.05	Processed vegetables: B. Fresh vegetables, peeled or cut
06	Animal products and eggs
06.02	Crustaceans and molluscs (including oysters, mussels, snails): A. Fresh within the shell
08	Miscellaneous Products
08.01	Vinegar

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 - ii. Where SATRA has given consent to disclosure, the Customer shall draw the attention of the third party to these terms of business and the basis on which SATRA undertakes test, reporting and advising. The Customer shall indemnify SATRA for any failure to do so.
 - iii. The above items are submitted to the Customer as confidential documents. Confidentiality shall continue to apply after completion of the business, but shall cease to apply to information or knowledge which may come into the public domain.
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Issue Date: 1st October 2009