Technical Data Sheet

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455-A265
Disposable Nitrile Gloves



Technical Data Sheet Applicable To:

455-A265-S089-X31	Disposable Blue Nitrile Gloves Box of 100 Small
455-A265-S090-X31	Disposable Blue Nitrile Gloves Box of 100 Medium
455-A265-S091-X31	Disposable Blue Nitrile Gloves Box of 100 Large
455-A265-S092-X31	Disposable Blue Nitrile Gloves Box of 100 X-Large

Industry Usage:
These disposable blue metal detectable nitrile gloves are perfect for use within a food manufacturing or processing environment. Offering great strength & durability and manufactured from 100% nitrile, these food industry gloves are latex & powder free and suitable for food handling.

Features and Benefits:
- Metal Detectable to reduce foreign object contamination risks
- Ambidextrous for quick selection
- Textured fingertips for more secure grip
- Latex-free and Powder-free
- Tear resistant providing greater durability
- Thickness: 4MIL (101.6 µm)
- Medium: Length 243mm (9.56”), Width 85mm (3.34”)
- Large: Length 244mm (9.60”), Width 95mm (3.74”)
- X-Large: Length 245mm (9.64”), Width 105mm (4.13”)

Material and Compliance Information:

- Medium: Length 243mm (9.56″), Width 85mm (3.34″)
- Large: Length 244mm (9.60″), Width 95mm (3.74″)
- X-Large: Length 245mm (9.64″), Width 105mm (4.13″)

- Type: Metal Detectable Nitrile Disposable Glove, Powder Free, Online Single Chlorinated, Non-sterile
- Material: 100% Synthetic Nitrile Latex
- Colour: Blue
- Design and Feature: Ambidextrous, finger textured, beaded cuff
- Powder: No powder lubricant added
- Storage Condition: The gloves shall maintain their properties when stored in a dry condition. Avoid direct sunlight
- Shelf life: The gloves shall have shelf life of 3 years from the date of manufactured with the above storage condition.
- Size Marking: The size of gloves shall be marked in the check box on every carton with black ink
- Application: Metal detectable nitrile gloves can be detected using metal detector which are commonly used in flood & beverages industries to detect fragments of metal presence and becoming an indicator for contaminated batches
- PFAS: These gloves do not contain any perfluoroalkyl and polyfluoroalkyl substances (PFAS)

2. Performance Requirements

Sampling Plan: ISO 2859 Single Normal

#	Characteristics	Inspection Level	Acceptable Quality Level	Reference Standard
2.1	Dimensions	S2	4.0	ASTM D6319-19
2.2	Physical Properties	S2	4.0	ASTM D6319-19
2.3	Freedom from Holes Air Pump Test	GI	4.0	In house practice
2.4 I II	Visual Defects: Major Visual Minor Visual	GI	 2.5 4.0	In house practice
2.5 I II III	Packaging Defects: Regulatory Visual Critical incl. Gloves Counting	 GI GI SE	 ** 4.0 4.0	In house practice
2.6	Powder Free Residue	N-5	N/A	ASTM D6319-19 ASTM D6124-06 (2017)
2.7	Mix Size/Mix Glove/Mix Hand	Not Allowed		

3. Performance Specification

Dimensions

Description	**Size**	**Standard (mm)**
Length, mm	All Sizes	Min 240
Palm Width, mm	M L XL	94 +/- 3 105 +/- 3 113 +/- 3
Thickness, mm *Single wall	All Sizes	Finger: 0.11 +/- 0.02 Typical Value 0.12 to 0.13 Palm 0.07 +/- 0.02 Typical Value: 0.07 to 0.09

Physical Properties

Description	Standard	
	Before Aging	After Aging
Elongation at Break, %	Min 500 Typical value: 500 to 600	Min 400 Typical value: 400 to 550
Tensile Strength, MPa	Min 14 Typical Value: 14 to 18	Min 14 Typical value: 14 to 18

Freedom from Holes

The sample size and allowable number of non-conforming gloves in the samples shall be determined in accordance with Sampling Plan ISO 2859-1 Single Normal using inspection and acceptable quality level as stated in Section II: Performance Requirements.

Visual Defects

The sample size and allowable number of non-conforming gloves in the samples for both major and minor defects shall be determined in accordance with Sampling Plan ISO 2859-1 Single Normal using inspection and acceptable quality level as stated in Section II: Performance Requirements.

Packaging Defects

The sample size and allowable number of non-conforming in the samples for regulatory, visual and critical packaging effects shall be determined in accordance to Sampling Plan ISO 2859-1 Single Normal using inspection and acceptable quality level as stated in Section II: Performance Requirements, Gloves Counting _ 100pcs by count by Dispenser.

Powder Free Residue

Maximum 2mg per glove.

4. Certificate of Analysis

The following is a report on the analysis of two (2) samples per size. The sample was tested in accordance with the test method(s) stipulated.

Product: Glove

Test Parameter: Migration using 50% Ethanol and 3% Acetic Acid

Method: Overall Migration Test (EU No. 10/2011)

Factory: F9

Glove Sample	Simulant	
	50% Ethanol (mg/dm3)	3% Acetic Acid (mg/dm3)
Blue MDG CW40 (M Size)	7.74	9.10
EU No. 10/2011 Overall Migration Standard	≤ 10 mg/dm3	≤ 10 mg/dm3

Remark:
The glove sample passes the overall migration test by using both 50% ethanol and 3% acetic acid

Test Report

1. Freedom from holes and Visual Defects

Size	**Holes**			**Visual Defect, Inspection Level: G1**			**Result**			
Inspection Level: G1, AQL 4.0				**Major Defects, AQL 2.5**			**Minor Defects, AQL 4.0**			
	Sample size, pcs	Acceptance, pcs	Defects, pcs	Sample size, pcs	Acceptance, pcs	Defects, pcs	Sample size, pcs	Acceptance, pcs	Defects, pcs	
S	200	14	7	200	10	6	200	14	7	Pass
M	200	14	7	200	10	4	200	14	5	Pass
L	200	14	8	200	10	5	200	14	6	Pass

2. Dimensions
Inspection Level: S2, AQL 4.0
Result: Pass
Acceptance: 1

Sample No.	**Size**	**Length, mm**	**Width, mm**	**Thickness single wall, mm**
Fingertip	**Palm**			
1	S	244	86	0.13	0.08
2		243	87	0.12	0.09
3		245	85	0.12	0.08
4		245	86	0.13	0.08
5	M	244	98	0.13	0.09
6		245	96	0.13	0.07
7		245	96	0.12	0.08
8		248	97	0.12	0.07
9	L	246	105	0.13	0.09
10		244	106	0.11	0.08
11		245	106	0.12	0.08
12		246	107	0.12	0.07
13		246	106	0.13	0.09

ASTM D6319 – 19 Requirment **Size**	**Length, mm**	**Width, mm**	**Thickness, mm**
XS	≥220	70 ± 10	Finger and palm Single wall Min0.05
S		80 ± 10	
M	≥230	95 ± 10	
L		110 ± 10	
XL		120 ± 10	
XXL		130 ± 10	

3. Physical Properties
   Inspection Level: S2, AQL 4.0
   Result: Pass
   Acceptance: 1

Sample No.	Size	Before Aging		After Accelerated Aging	
Tensile Strength, Mpa		Elongation, %	Tensile Strength, Mpa		Elongation, %
1	S	18.2	620	16.2	482
2		16.5	580	15.6	489
3		18.5	625	16.2	465
4		17.8	620	16.0	472
5	M	19.8	618	16.2	485
6		18.8	665	15.8	536
7		19.4	680	16.2	528
8		18.5	645	15.2	532
9	L	16.8	650	16.5	528
10		19.8	636	15.4	550
11		17.5	623	15.8	532
12		16.8	668	15.5	508
13		17.6	683	15.2	520

ASTM D6319 – 19 Requirement	Before Aging	After Accelerated Aging	
Tensile	Elongation	Tensile	Elongation
Min 14 MPa	Min 500%	Min 14 MPa	Min 400%

4. Powder Residue
   Sampling Size, N=5
   Requirement: Max 2 mg/glove

Size	**Mg / glove**	**Result**
S	0.8	Pass
M	1.0	Pass
L	1.2	Pass

Migration Testing

Subject

Overall migration for 'Metal Detectable Nitrile Examination Powder Free Glove' sample.

Sample Submission Date

22nd February 2023

Description of Sample

One packet of glove sample labelled as follows was received.

Number	**Product Description**	**Ref No.**
1	Metal detectable nitrile examination powder free glove	RA/131/02/2023/D2

Date of Analysis

27th February 2023 – 3rd March 2023

Amendments This test report 7191304035-CHM23-03-TSL-CR1 was amended from test report 7191304035-CHM23-03-TSL-CR1 on 28th April 2023 as per the clients request to remove the sample

photo.

Method of Test

The sample was analysed for the following tests according to Commission Regulation (EU) No 10/2011.

1. Preparation of Test Specimen

Only the exterior of the glove sample was performed for the test.

2. Overall migration content with aqueous food simulant (20% Ethanol)

According to BS EN 1186-9:2002 – Test methods for overall migration into aqueous food simulants by article filling.

Results

Table 1 Overall migration content with food simulants for the 'metal detectable nitrile examination powder free glove' sample.

Type of Simulant	Testing Condition*1	Surface Area (dm^2)	Volume of Extractant (ml)	Overall Migration (mg/md^2)	Commission Regulation (EU) No 10/2011 Requirement for Overall Migration Content (mg/dm^2)*2
3% Acetic Acid	40°C, 2 hours	5.42	265	4.5	<10

*1 The testing conditions were specified by client.

*2 Analytical tolerance is $2mg/dm^2$ or 12mg/kg for aqueous simulants and $3mg/dm^2$ or 20mg/kg for fatty food simulants.

Based on the above results, the 'metal detectable nitrile examination powder free glove, RA/131/02/2023/D2 met the overall migration requirements under Commission Regulation (EU) No 10/2011 – 'Plastic materials and articles shall not transfer their constituents to food stuffs in quantities exceeding 10 milligrams of total constituents released per dm^2 of food contact surface (mg/dm^2) (overall migration limit)'.

Metal Detectable Nitrile Examination Powder Free Glove

Job Ref No 2023-05-18-017
Ref No RA/220/05/2023/D2
Date sample received 18th May 2023
Testing period 18th May 2023 – 26th May 2023

Test Requested	Conclusion
US FDA 21 CFR 177.2600 (Rubber Articles) – Determination of Amount of Extractives	PASS

Test Results

US FDA 21 CFR 177.2600 (Rubber Articles) – Determination of Amount of Extractives

Method With reference to US FDA 21 CFR

177.2600 For use in contact with aqueous

food.

Extractant	Test Condition	Result ($mg/inch^2$)	Reporting Limit ($mg/inch^2$)	Permissible Limit ($mg/inch^2$)
Distilled Water	Reflux temp for 7 hours	2.2	0.2	20
	Succeeding 2 hours of extraction	0.6	0.2	1
Comment	–	PASS	–	–

Extractant	Test Condition	Result (mg/inch^2)	Reporting Limit (mg/inch^2)	Permissible Limit (mg/inch^2)
n-Hexane	Reflux temp for 7 hours	0.7	0.2	175
	Succeeding 2 hours of extraction	N.D.	0.2	4
Comment	–	PASS	–	–

Note 1. mg/inch^2 milligram per square inch
2 N.D. = Not Detected

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