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CNAS L2954

Final Report

Report Number: SDWH-M202005587-1(E)

Physical Properties Shelf Life Test of Nitrile gloves Accelerated Aged for 1 Year Accelerated Aged for 3 Years

Sponsor: GUANG DONG KINGFA SCI.& TECH.CO.,LTD

Address: No.28 Delong Ave.,Shijiao Town,Qingcheng District,Qing
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Supplementary Explanation

- (1) Please apply for rechecking within 15 days of receiving the report if there are any objections.
- (2) Any erasure or without special inspection and testing seal renders the report null and void.
- (3) The report is only valid when signed by the persons who edited, checked and approved it.
- (4) The results relate only to the articles tested.
- (5) The report shall not be reproduced except in full without the written approval of the institute.
- (6) Conclusion determination basis is not in the scope of accreditation.

Verification Dates

Test Article Receipt	2020-10-13
Protocol Effective Date	2020-10-21
Technical Initiation Date	2020-10-29
Technical Completion Date	2021-02-23
Final Report Completion Date	2021-03-08

Edited by: Wang Deheng 2021-03-08
Date

Reviewed by: Jiang Changyuan 2021-03-08
Study Director Date

Approved by: Wang Yifei 2021-03-08
Authorized Signatory Date

Sanitation & Environment Technology Institute, Soochow University



Summary

1 Test Article

Test Article Name	Nitrile gloves
Manufacturer	GUANG DONG KINGFA SCI.& TECH.CO.,LTD
Address	No.28 Delong Ave.,Shijiao Town,Qingcheng District,Qing yuan,Guangdong,China
Model	KS-ST RT021
Lot/Batch	25007018/25007019/25007020

2 Main Reference

Medical gloves for single use Part 4: Requirements and testing for shelf life determination (EN455-4:2009)

Standard Guide for Accelerated Aging of Sterile Barrier Systems for Medical Devices (ASTM F 1980-16)

3 Test Method

Watertightness test and physical property test were performed both before and after the test glove were accelerated aged for 33 days and 97 days.

Study protocol number: SDWH-PROTOCOL-M202005587-1.

4 Conclusion

The test glove could achieve the physical properties shelf life for 3 years under this test condition.

Test Report

1 Purpose

The test was designed to validate the physical properties shelf life of the test gloves.

2 Reference

Medical gloves for single use Part 4: Requirements and testing for shelf life determination (EN455-4:2009)

Standard Guide for Accelerated Aging of Sterile Barrier Systems for Medical Devices (ASTM F 1980-16)

3 Compliance

ISO/IEC 17025:2017 General requirements for the competence of testing and calibration laboratories (CNAS—CL01 Accreditation criteria for the competence of testing and calibration laboratories) China National Accreditation Service for Conformity Assessment LABORATORY ACCREDITATION CERTIFICATE Registration No. CNAS L2954

RB/T 214—2017 Competence assessment for inspection body and laboratory mandatory approval—General requirements for inspection body and laboratory Certification and Accreditation Administration of the People's Republic of China INSPECTION BODY AND LABORATORY MANDATORY APPROVAL Certificate No. CMA 180015144061

4 Identification of Test Article

Test Article Name	Nitrile gloves
Manufacturer	GUANG DONG KINGFA SCI.& TECH.CO.,LTD
Address	No.28 Delong Ave.,Shijiao Town,Qingcheng District,Qing yuan,Guangdong,China
Test Article Initial State	Non-sterile
CAS Number	Not supplied by sponsor (N/S)
Model	KS-ST RT021
Size	M
Lot/Batch	25007018/25007019/25007020
Raw Material	Nitrile
Packaging Material	N/A
Physical State	Solid
Color	BLUE
Density	N/A
Stability	N/A
Solubility	N/A
Storage Condition	Room temperature
Intended Use	N/A
Additional Information	N/A

The information about the test article was supplied by the sponsor wherever applicable.

5 Equipment and Reagents

5.1 Equipment

Equipment Name	Equipment Number	Calibration Expire
Ruler	SDWH463	2021-07-06
Computer control tensile tester	SDWH872	2021-03-11
High temperature and high humidity aging box	SDWH314	2021-09-29
High temperature and low humidity aging box	SDWH315	2021-09-02

6 Test Methods and Results

6.1 Accelerated Aging Test

6.1.1 Test condition: Accelerated Aging Temperature (60°C), High RH (70%), Low RH (20%), $Q_{10}=2$

6.1.2 Parameters:

Aging Time	Q_{10}	T_{AA}	T_{RT}	AAF	Desired RT	AAT
1 y	2	60°C	25°C	11.3	365Days	33 Days
3 y	2	60°C	25°C	11.3	1095Days	97 Days

Q_{10} : Arrhenius reaction rate function states that a 10°C increase or decrease in temperature of a homogeneous process results in approximately, a two times or 1/2-time change in the rate of a chemical reaction ($Q_{10}=2$).

T_{AA} : Selected Accelerated Aging Temperature (°C);

T_{RT} : Ambient Temperature (°C).

AAF (Accelerated Aging factor) = $Q_{10}^{[(T_{AA}-T_{RT})/10]}$.

Desired RT: Desired simulated Real Time.

AAT: Accelerated Aging Time to simulate a Desired RT; AAT = Desired RT/AAF

6.1.3 Calculation for accelerated aging time:

Accelerated Aging factor (AAF) = $Q_{10}^{[(T_{AA}-T_{RT})/10]} = 2^{[(60-25)/10]} = 11.3$

Accelerated Aging Time of 1y (AAT) = Desired (RT)/AAF = 365/11.3 = 33 days

Accelerated Aging Time of 3y (AAT) = Desired (RT)/AAF = 1095/11.3 = 97 days

6.1.4 Aging schedule:

1y Equivalent 33 Days	Date
High RH = 70%: 16 Days	From 2020-10-29 to 2020-11-14
Low RH = 20%: 17 Days	From 2020-11-14 to 2020-12-01
3y Equivalent 97 Days	Date
High RH = 70%: 48 Days	From 2020-10-29 to 2020-12-16
Low RH = 20%: 49 Days	From 2020-12-16 to 2021-02-03

6.1.5 Watertightness test and physical property test were performed both before and after the test glove were accelerated aged for 33 days and 97 days.

6.2 Watertightness Test

6.2.1 Test samples: 50 pieces/Batch.

6.2.2 Vertically positioned the filling tube to fit the glove and attached the glove to the filling tube, overlapping the cuff by a maximum of 40 mm over the end of the tube and secured it to obtain a watertight seal without damaging the globe.

6.2.3 Added 1000 ± 50 ml of water at a temperature of (15 to 35)°C into the open end of the filling tube, allowing the water to pass freely into the glove.

6.2.4 Immediately inspected the glove visually for water leakage. Allowed the glove to hang and visually inspected the glove for water leakage again after a period of 2 min to 3 min.

6.2.5 Disregard leakages within 40 mm of the cuff.

6.2.6 Results: List in **Table**.

6.3 Physical property test

6.3.1 Obtained one dumb-bell test piece from each of 13 gloves/batch using a cutter from the palm, back of the hand or cuff areas of each glove in the test sample, avoiding textured areas if possible and taking the test pieces in the direction of the longitudinal axis of the glove;

6.3.2 Determined the force at break of the 13 test pieces after conditioning at $23 \pm 2^\circ\text{C}$ and $50 \pm 5\%$ relative humidity for 24 hours under test condition and cross-head speed of 500 mm/min;

6.3.3 Recorded the force at break, in Newtons, for each of the 13 samples.

6.3.4 Results: List in **Table**.

7 Conclusion

The test glove could achieve the physical properties shelf life for 3 years under this test condition.

8 Record Storage

All raw data pertaining to this study and a copy of the final report are to be retained in designated SDWH archive.

9 Confidentiality Agreement

Statements of confidentiality were as agreed upon prior to study initiation.

10 Deviation statement

There was no deviation from the approved study protocol which was judged to have any impact on the validity of the data.

Annex 1 Test Data

Table 1 The results of watertightness test (Lot/ Batch: 25007018)

	The Results (Zero-time)	The Results (1 year Aged)	The Results (3 years Aged)
Sample	50 Gloves	50 Gloves	50 Gloves
Number of Non-conforming	0 Glove	0 Glove	0 Glove
Criteria	≤2 Gloves	≤2 Gloves	≤2 Gloves
Conclusion	Acceptable	Acceptable	Acceptable

Table 2 The results of watertightness test (Lot/ Batch: 25007019)

	The Results (Zero-time)	The Results (1 year Aged)	The Results (3 years Aged)
Sample	50 Gloves	50 Gloves	50 Gloves
Number of Non-conforming	0 Glove	0 Glove	0 Glove
Criteria	≤2 Gloves	≤2 Gloves	≤2 Gloves
Conclusion	Acceptable	Acceptable	Acceptable

Table 3 The results of watertightness test (Lot/ Batch: 25007020)

	The Results (Zero-time)	The Results (1 year Aged)	The Results (3 years Aged)
Sample	50 Gloves	50 Gloves	50 Gloves
Number of Non-conforming	0 Glove	0 Glove	0 Glove
Criteria	≤2 Gloves	≤2 Gloves	≤2 Gloves
Conclusion	Acceptable	Acceptable	Acceptable

Table 4 The results of physical property test (Lot/ Batch: 25007018)

No.	Force at break (Zero-time) N	Force at break (1 year Aged) N	Force at break (3 years Aged) N
1	8.49	7.79	10.00
2	5.29	9.33	9.19
3	8.55	8.63	8.67
4	8.46	8.41	9.92
5	7.66	6.73	10.05
6	8.92	9.75	9.02
7	8.29	9.16	8.09
8	8.04	6.15	5.35
9	6.36	6.89	10.11
10	9.67	8.62	7.54
11	5.07	9.17	8.50
12	5.81	9.02	8.50
13	7.35	6.21	8.90
Median	8.04	8.62	8.90
Criteria	≥6.0	≥6.0	≥6.0
Conclusion	Acceptable	Acceptable	Acceptable

Table 5 The results of physical property test (Lot/ Batch: 25007019)

No.	Force at break (Zero-time) N	Force at break (1 year Aged) N	Force at break (3 years Aged) N
1	6.68	10.76	8.47
2	9.72	10.34	8.99
3	7.35	11.02	8.58
4	8.34	8.95	9.68
5	10.38	9.58	7.68
6	9.13	8.71	12.10
7	12.43	9.37	10.29
8	10.22	9.53	10.76
9	9.35	8.47	6.92
10	11.68	7.56	7.98
11	5.36	8.12	12.27
12	7.94	8.40	11.12
13	9.49	7.20	8.49
Median	9.35	8.95	8.99
Criteria	≥6.0	≥6.0	≥6.0
Conclusion	Acceptable	Acceptable	Acceptable

Table 6 The results of physical property test (Lot/ Batch: 25007020)

No.	Force at break (Zero-time) N	Force at break (1 year Aged) N	Force at break (3 years Aged) N
1	5.57	8.71	10.76
2	7.98	9.94	10.53
3	11.91	9.89	9.24
4	10.40	9.55	5.56
5	11.69	9.94	9.12
6	10.11	7.98	9.72
7	8.47	9.05	11.07
8	10.16	9.21	12.34
9	5.39	10.20	8.07
10	7.96	10.63	11.95
11	6.64	9.64	9.42
12	7.48	9.03	7.12
13	7.52	8.38	7.77
Median	7.98	9.55	9.42
Criteria	≥6.0	≥6.0	≥6.0
Conclusion	Acceptable	Acceptable	Acceptable

Annex 2 Photograph of Test Article



Annex 3 Information Provided by Sponsor

1 Production Process

Not supplied by sponsor.

2 Other Information

Batch Size:2000 pieces/batch.

End of Report