

Sponsor: Nathan D'Onofrio Filtra-Systems Company, LLC 23900 Haggerty Rd. Farmington Hills, MI 48335

Flammability of Clothing Textiles GLP Report

Test Article: (2) Sample Lots: F & L

Purchase Order: 89748-13565 Study Number: 1364608-S01 Study Received Date: 18 Nov 2020

Testing Facility: Nelson Laboratories, LLC

6280 S. Redwood Rd.

Salt Lake City, UT 84123 U.S.A.

Test Procedure(s): Standard Test Protocol (STP) Number: STP0073 Rev 07

Deviation(s): None

Summary: This procedure was performed to evaluate the flammability of plain surface clothing textiles by measuring the ease of ignition and the speed of flame spread. The parameter of time is used to separate materials into different classes, thereby assisting in a judgment of fabric suitability for clothing and protective clothing material. The test procedure was performed in accordance with the test method outlined in 16 CFR Part 1610 (a) Step 1 - testing in the original state. Step 2 - Refurbishing and testing after refurbishing, was not performed. All test method acceptance criteria were met.

Test Article Side Tested: Outside Surface

Orientation: Machine

Test Criteria for Specimen Classification (See 16 CFR Part 1610.7):

Class	Plain Surface Textile Fabric
1	Burn time ≥3.5 seconds, IBE, or DNI
2	Not applicable to plain surface textile fabrics
3	Burn time <3.5 seconds

DNI = Test Article did not ignite

IBE = Test Article ignited, but extinguished





Sean Shepherd electronically approved

Sean Shepherd

07 Jan 2021 15:13 (+00:00)

Study Completion Date and Time

801-290-7500

Study Director

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Results: Testing was performed on samples as they were received. If refurbishing is needed, it is up to the sponsor to provide appropriate samples for testing before and after refurbishing. The test articles submitted by the sponsor achieved a Class 1 flammability rating. Lot F:

Replicate Number	Time of Flame Spread
1	IBE
2	IBE
3	IBE
4	IBE
5	IBE

Lot L:

Replicate Number	Time of Flame Spread
1	IBE
2	IBE
3	IBE
4	IBE
5	IBE

Test Method Acceptance Criteria: Flame length must be approximately 16 mm (~\sqrt{s}\) in) from the flame tip to the opening in the gas nozzle.

Procedure: Test articles were prepared by cutting the material into approximately 50 x 150 mm swatches. Preliminary testing to establish the orientation and side of the test article to test was performed. The side and orientation that burned the fastest was used to test the test articles. Each test article was clamped into the specimen holder and placed in an oven maintained at 105 ± 3°C for 30 ± 2 minutes. The test articles were then placed in a desiccator for a minimum of 15 minutes prior to testing.

The flame length of the flammability tester was adjusted to approximately 16 mm prior to testing. Test articles were placed on the flammability rack and the stop cord was strung through the guides. The flammability timer was zeroed and testing was started. When the flame reached the stop cord, the timer stopped, and the results were recorded. Testing was terminated for test articles that did not exhibit flame spread beyond the initial application of the flame.



Quality Assurance Statement

Compliance Statement: The test was conducted in accordance with the USFDA (21 CFR Parts 58, 210, 211, and 820) Regulations. This final report reflects the raw data.

Activity	Date
Study Initiation	10 Dec 2020
Phase Inspected by Quality Assurance: Flammability Test	23 Dec 2020
Audit Results Reported to Study Director	23 Dec 2020
Audit Results Reported to Management	23 Dec 2020

Scientists	Title
Adrianne Sandall	Supervisor
Sean Shepherd	Study Director

Data Disposition: The study plan, raw data and final report from this study are archived at Nelson Laboratories, LLC or an approved off-site location.

Bridger James electronically approved

Quality Assurance

06 Jan 2021 23:13 (+00:00)

Date and Time