

Flammability of Clothing Textiles GLP Report

Test Article: BTL Respirator
C-FIT Healthcare Respirator
Study Number: 1346711-S01
Study Received Date: 28 Sep 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 06
Customer Specification Sheet (CSS) Number: 202005378 Rev 01
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
2	Not applicable to plain surface textile fabrics
3	Burn time < 3.5 seconds

The 16 CFR Part 1610 standard specifies that 10 replicates are to be tested if, during preliminary testing, only 1 test article exhibits flame spread and it is less than 3.5 seconds or the test articles exhibit an average flame spread less than 3.5 seconds. Five replicates are to be tested if no flame spread is observed upon preliminary testing, if only 1 test article exhibits flame spread and it is equal to or greater than 3.5 seconds, or if the average flame spread is equal to or greater than 3.5 seconds. In accordance with the standard, 5 replicates were tested for this study.



Sean Shepherd electronically approved
Study Director

Sean Shepherd

30 Nov 2020 16:40 (+00:00)
Study Completion Date and Time

Results:

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

IBE = Test Article ignited, but extinguished

Test Method Acceptance Criteria: Flame length must be approximately 16 mm (~5/8 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	12 Nov 2020
Phase Inspected by Quality Assurance: Preliminary Test	19 Nov 2020
Audit Results Reported to Study Director	20 Nov 2020
Audit Results Reported to Management	20 Nov 2020

Scientists	Title
Adrienne 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.

Camille Coffey electronically approved
Quality Assurance

30 Nov 2020 16:23 (+00:00)
Date and Time