NELSON LABORATORIES

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# Bacterial Filtration Efficiency (BFE) and Differential Pressure (Delta P) Final Report

Test Article: LK-22-BFE99-1
LK-22-BFE99-2
LK-22-BFE99-3
Laboratory Number: 817694
Study Received Date: 24 Apr 2015
Test Procedure(s): Standard Test Protocol (STP) Number: STP0004 Rev 11

**Summary:** The BFE test is performed to determine the filtration efficiency by comparing the upstream bacterial control counts to downstream test article counts. A suspension of *Staphylococcus aureus* was aerosolized using a nebulizer and delivered to the test article at a constant flow rate and challenge delivery. The challenge delivery is maintained at 2,200 ± 500 colony forming units (CFU) with a mean particle size (MPS) at 3.0 µm ± 0.3 µm. The aerosol droplets were drawn through a six-stage, viable particle, Andersen sampler for collection. This procedure allows a reproducible bacterial challenge to be delivered to test materials. This test method complies with ASTM F2101-07 and EN 14683:2014, Annex B.

The Delta P test determines the breathability by measuring the differential air pressure on either side of the test article using a manometer, at a constant flow rate. The Delta P test was designed to comply with MIL-M-36954C, Section 4.4.1.2 and complies with EN 14683:2014, Annex C.

All test method acceptance criteria were met. Testing was performed in compliance with US FDA good manufacturing practice (GMP) regulations 21 CFR Parts 210, 211 and 820.

Test Side: Less Patterned Side
BFE Area Tested: ~45.6 $cm^2$
BFE Flow Rate: 28.3 Liters per minute (L/min)
Delta P Flow Rate: 8 L/min
Conditioning Parameters: 85 ± 5% relative humidity (RH) and 21 ± 5°C for a minimum of 4 hours.

**Results:**

| Test Article | Percent BFE (%) | Delta P (mm $H_2O/cm^2$) | Delta P (Pa/$cm^2$) |
|---|---|---|---|
| LK-22-BFE99-1 | >99.9 | 2.4 | 23.5 |
| LK-22-BFE99-2 | >99.9 | 2.3 | 22.2 |
| LK-22-BFE99-3 | >99.9[a] | 2.5 | 24.2 |

[a] There were no detected colonies on any of the Andersen sampler plates for this test article.

Positive Control Average: 2,086 CFU
Negative Monitor Count: <1 CFU
MPS: 2.9 µm

Technical Reviewer

Study Director — Janelle R. Bentz, M.S.

15 May 2015
Study Completion Date

aq FRT0004-0001 Rev 13

The filtration efficiency percentages were calculated using the following equation:

$$\% BFE = \frac{C - T}{C} x\ 100$$

C = Positive control average
T = Plate count total recovered downstream of the test article
Note: The plate count total is available upon request

SGS

## 测试汇总

No. SHAHG1405722802　　日期: 2014年04月15日　　第1页,共4页

上海赛科石油化工有限责任公司
中国上海化学工业园区南银河路557号

以下测试之样品是由申请者所提供及确认：S2040 JBC0161

| | |
|---|---|
| SGS 工作编号： | SHHG1404010576SD - SH |
| 样品接收日期： | 2014年04月08日 |
| 测试周期： | 2014年04月08日 - 2014年04月15日 |
| 测试要求： | 根据客户要求测试 |
| 测试方法： | 请参见下一页 |
| 测试结果： | 请参见下一页 |

通标标准技术服务有限公司
授权签名

Serena Wang 王璟
批准签署人

**检测结果只对测试样品负责，仅供客户内部使用，不作为社会公正性数据。**

SGS 检测专用章 Testing Service



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测试结果:

测试样品描述:

| 样品编号 | SGS样品ID | 描述 | 材质 (客户提供) |
|---|---|---|---|
| SN1 | SHA14-057228.001 | 白色塑料粒子 | 聚丙烯 |

**FDA 21 CFR 177.1520-熔点**

测试要求: 应客户要求，按照食品与药品管理法规测试与食品接触的聚丙烯的熔点.

测试方法: 参考FDA 21 CFR 177.1520 方法.

| 测试项目 | 限值 | 001 |
|---|---|---|
| 熔点, °C* | 160-180 | 167 |

备注:

*这项测试由SGS宁波化学实验室检测

**FDA 21 CFR 177.1520-密度 (23°C)**

测试要求: 应客户要求，按照食品与药品管理法规测试与食品接触的聚丙烯的密度 (23°C).

测试方法: 参考FDA 21 CFR 177.1520d(1) 或 ASTM D792:2008 方法.

| 测试项目 | 限值 | 001 |
|---|---|---|
| 密度 (23°C), g / cm³ | 0.880-0.913 | 0.887 |

**FDA 21 CFR 177.1520-二甲苯中可溶性**

测试要求: 应客户要求，按照食品与药品管理法规测试与食品接触的聚丙烯的在二甲苯中可溶物含量.

测试方法: 参考FDA 21 CFR 177.1520 方法.

| 测试项目 | 限值 | *001* |
|---|---|---|
| 25°C下二甲苯中可溶性, w/w % | 9.8 | 0.9 |

FDA 21 CFR 177.1520-正己烷中萃取物含量

测试要求： 应客户要求，按照食品与药品管理法规测试与食品接触的聚丙烯的在正己烷中萃取物含量.

测试方法： 参考FDA 21 CFR 177.1520 方法.

| 测试项目 | 限值 | *001* |
|---|---|---|
| 正己烷中回流萃取, w/w % | 6.4 | 0.7 |



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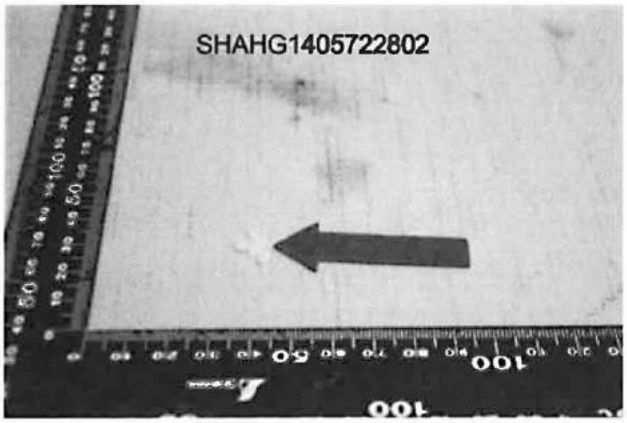
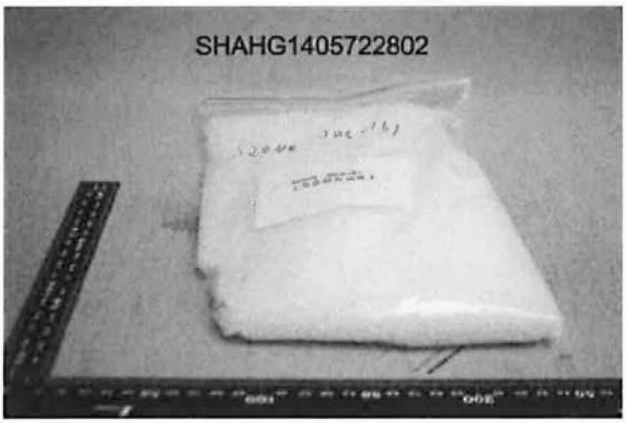
样品照片:




SHA14-057228.001

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*** 报告完 ***



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