

Cyto-Plex™ Carboxylated Particles Firefli™ Red Fluorescent Polystyrene Particles

1. DESCRIPTION This product line consists of carboxyl-modified polystyrene microspheres of two different nominal diameters (4 and 5 µm) dyed with a fluorescent dye which emits in the far red region of the visible spectrum. The intensity of the fluorescent dye is available in twelve levels, evenly spaced and well-separated from each other on the fluorescence intensity histogram (log scale).

2. PHYSICAL DATA

| | | |
|---------------------------------|---|---|
| Nominal Particle Diameter: | 5 µm | Catalog Number: FM5CR03 (1 mL), FM5CR03B (5 mL) |
| Nominal Particle Concentration: | 1 x 10 ⁸ particles/mL | |
| Cyto-Plex Fluorescence Level: | Level 3 | |
| Material: | Dyed Polystyrene Microspheres in deionized water containing 2 mM Sodium Azide and 0.05% (w/v) Tween™ 20 | |
| Surface Characteristics: | Carboxyl-modified | |
| Nominal Density: | 1.05 g/cm ³ | |
| Appearance: | Light blue | |
| Dye: | Dark red fluorescent, VIS excitation | |
| Excitation Maximum: | 650 nm | |
| Emission Maximum: | 700 nm | |
| Dyed Particle Batch Number: | FM5CR03-007 | Undyed Particle Batch Number: W500C-010 |

Packaging Lot Number: 225030

Expiration Date: MAY'22

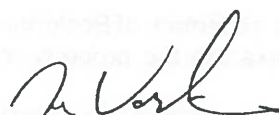
CERTIFICATE OF ANALYSIS

The following analysis was performed on batch number FM5CR03-007:

| | | |
|----------------------------|-----------------------|---|
| 1. Fluorescence Intensity: | 440 | FL3 mean channel number (test lot) |
| | 438 | FL3 mean channel number (reference lot) |
| | 1% | % difference in mean channel number, test vs. ref. |
| 2. FI Peak Distribution: | 11% CV | by flow cytometry |
| 3. Particle Diameter*: | 5.6 µm | by electrical resistance |
| 4. Size Distribution*: | ≤ 3% CV | by electrical resistance |
| 5. Charge Density*: | 42 µeq/g | by conductometric titration |
| 6. Size Uniformity: | 99% | by flow cytometry (% of total particles in main FSC peak) |
| 7. Particles/mL: | 1.0 x 10 ⁸ | by flow cytometry |

CAUTION: Raw Material; requires processing and validation before diagnostic use.

**These measurements are made on the material before dyeing.*



Joseph G. Vasiliou, Senior Metrology Engineer
Thermo Fisher Scientific

4-27-2020
Date

3. MEASUREMENT METHODOLOGY Particle diameter and size distributions are obtained by Beckman Coulter Multisizer™ 3 analysis of microspheres before dyeing. Charge density is determined on undyed particles by conductometric titration of carboxyl groups with NaOH after ion exchange resin cleaning of the particle suspension. Carboxyl content is reported in microequivalents of carboxyl per gram of particles. Particle count is determined by flow cytometry analysis using Thermo Scientific FC7 count control beads. FL3 mean fluorescent intensity (MFI) is measured on a BD FACSVerse™ flow cytometer versus a corresponding reference lot and % difference in channel number is reported.

4. OPERATING INSTRUCTIONS For ease of use, these products are packaged in an aqueous suspension with preservative. They must be thoroughly dispersed in the bottle to assure consistent samples. To disperse the particles, vortex for ~5 seconds or gently invert the bottle several times then immerse in a low power ultrasonic bath for ~5 seconds. Do not shake the bottle, as this will increase the possibility of flocculation. Dispense immediately after dispersion.

5. CERTIFICATE Except for the purposes of record keeping, this certificate may not be reproduced. Rebottling or relabeling invalidates the certification of these products.

6. SAFETY AND HANDLING PRECAUTIONS Avoid aerosol production in the workplace while handling these products. Wear a suitable filter respirator when necessary. Avoid inhalation or ingestion of the particles. These products should only be used by trained scientific personnel.

7. STORAGE AND DISPOSAL Store upright and keep the bottle tightly sealed to avoid contamination. Store at 2-8°C, but do not freeze the suspensions. In case of spills, wash or wipe the area thoroughly. Dispose of as normal laboratory waste. There are no special disposal procedures. Each bottle has a limited shelf life and should not be used after its expiration date.

8. LIMITED WARRANTY These products are intended for laboratory use by trained scientific personnel. Determination of their suitability for a specific end-use is the responsibility of the user, who assumes all liability for loss or damage arising out of the use of the product. Rebottling or relabeling voids the warranty and certification. Microgenics Corporation's warranty is limited to replacement of defective products if returned with our authorization within 60 days of purchase date.

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