

# **3M DRUG DELIVERY SYSTEMS DIVISION**

## **PRODUCT SPECIFICATION**

### **3M SCOTCHPAK™ PF200M**

**Specification No. PF200M - 3**

**Effective Date: February 28, 2007**

**Supersedes: August 22, 2006**

#### **1.0 SCOPE AND CLASSIFICATION**

**1.1 Scope - This specification covers a heat-sealable film that provides a strong, high-strength seal and possesses good barrier properties.**

**1.1.1 Name - Scotchpak™ Heat-Sealable Polyester Film**

**1.1.2 Product Number - No. PF200M**

**1.1.3 Characteristics**

- Translucent
- Occlusive
- Controlled caliper
- Matte finish
- Printable
- Non-Corona treated surface
- Heat-sealable

**Suggested heat seal conditions –**

**300 – 400°F (149 – 204°C)**

**0.2 – 2.0 seconds**

**20 – 60 psi**

**1.2 Classification**

**1.2.1 Types and Sizes - Scotchpak™ Heat-Sealable Polyester Film covered by this specification shall be of one type and of the following sizes as specified.**

**NOTE: These are typical specifications that may be adjusted to specific customer requirements.**

**Length: Maximum length 5000 yards**

**Width: Maximum finished individual roll width – 40 inches,  
Ordered width  $\pm 1/8$ " (0.125 inches) or 3.0 mm**

**Cores: 3 inch or 6 inch I.D. flush, cardboard or plastic**

**Splices: Single butt splice with 2" red cover polyester tape.  
There shall be a maximum of three splices per 5000 yards.**

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### 2.0 REQUIREMENTS

- 2.1 Rolls - The film shall be furnished in uniformly and smoothly wound rolls on suitable cores having an inside diameter of three or six inches. The film is wound heat sealable side in. The core shall have sufficient rigidity to prevent distortion of the roll under normal conditions of transportation and use. The film shall be in one (1) continuous strip, except that any single roll may contain splices as defined in Par. 1.2.1.
- 2.2 Physical Properties - The film shall comply with the requirements in Table 1 at time of manufacture.

TABLE 1

<u>Property</u>	<u>Specification</u>	<u>Test Method</u>
*Caliper, mils (average)	2.00 ± 0.14	TM-212
*Seal Strength, lbs/in (min)	7.6	TM-219
(target)	11.2	
(max)	17.4	

\*Denotes those tests conducted for final product release. Data from only those tests will be included on a typical Certificate of Analysis.

Note: 3M Test Methods are available upon request.

- 2.3 Workmanship - The film shall be a visually uniform product, reasonably free from defects which detract from its appearance or impair its functionality.

### 3.0 SAMPLING, INSPECTION AND TEST PROCEDURES

- 3.1 Supplier Responsibilities for Sampling, Inspection and Testing - Unless otherwise specified, sampling, inspection and testing for acceptance of each individual lot shall be performed by the supplier.
- 3.2 Lot - A lot shall consist of all material made by the same process from the same components and submitted for inspection at one time. Component traceability will be maintained for five (5) years.
- 3.3 Sampling - Samples shall be selected and tested in accordance with the supplier's normal commercial practice to verify compliance with requirements of this specification.
- 3.4 Testing - Specimens for testing shall be taken from each sample lot, unless specified otherwise in the test method (Table 1).

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### **4.0 PACKAGING**

4.1 The film shall be packed as specified in a new shipping container. The shipping container shall comply with applicable rules of Uniform Freight Classification to insure acceptance by common carrier for safe transportation at the lowest rate to destination.

#### **4.2 Identification**

4.2.1 Individual Rolls - Each roll will be identified with product number, lot number and roll number. This information is sufficient to insure traceability through production records to input material and process conditions.

4.2.2 Unit Package - Each unit package shall bear the name of the manufacturer, the name of the item, the size and the lot identification.

4.2.3 Shipping Container - Shipping containers shall be marked in accordance with commercial practice, including the name of the supplier, name of the item, size and quantity.

**NOTE: ANY ADDITIONAL LABELING REQUIREMENTS BY THE CUSTOMER SHOULD BE NOTED AT TIME OF ORDER ENTRY.**

### **5.0 STORAGE CONDITIONS**

Film should be stored at temperatures between 32-86 degrees Fahrenheit (0-30°C) and relative humidity less than 75 percent. This product will maintain the stated performance for a period of two years from the manufactured date, when stored under recommended storage conditions.

### **6.0 NOTES**

6.1 Purchasers must state quantity, width and length required and reference this product number on each order.

6.2 No formulation or construction changes, which will require a change to the Drug Master File, will be made without 3M's approval and purchaser's notification.

### **7.0 WARRANTY**

Specific warranties apply to this product. Warranty information is contained in the 3M Drug Delivery Systems Component Supply Agreement. Please contact your 3M DDS account manager for further details.