



Personal Care and Related Products Division
3M Center Bldg 220-3W-10
St. Paul, MN 55144-1000

PRODUCT SPECIFICATION

Product Name: 3M™ MonitorMark™ 9860B
Date August 19, 2004
Supersedes: July 30, 2003
Reason for reissue Add TM

Issue: 2

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1. General Description & Use:

MonitorMark™ TTI's can be used to monitor any product exhibiting time temperature abuse sensitivity. They are used primarily in conjunction with secondary package (case, box, etc.) in order to monitor storage and distribution conditions or to evaluate packaging. The indicators monitor temperature exposure, not product quality. Their purpose is to signal when product quality should be checked. Some typical applications include monitoring of drugs and vaccines, medical diagnostic kits, blood substances and ophthalmic solutions.

The 3M brand MonitorMark™ Time Temperature Indicator is a rectangular flat laminate containing layers of paper, film, adhesive and other components. Overall size is 3 1/4" x 3/4" (95mm x 19mm). The heart of the indicator is a porous wick indicator track strip, one end of which is positioned over a reservoir pad containing a blue-dyed specialty chemical having a desired melt point. Before activation, a removable activation strip separates the indicator track from the reservoir. A paperboard layer over these components contains viewing windows and is topped with a clear protective film over layer. A pressure-sensitive adhesive on the underside of the indicator allows convenient attachment to most clean, dry surfaces.

MonitorMark™ time temperature indicators will show initial color in 24 hours or less when exposed to 5 ±1°C. When exposed to a constant temperature 2°C above the threshold temperature for a time period equal to the stated cumulative run out time of 48 hr, the runout distance will be within specification limits.

Prior to activation and use MonitorMark™ 9860B must be placed in a cool environment of less than -4°C for a period of at least 2 hours. Also the surface to which the tag is attached must be below +4°C.

2. General Requirements:

In accordance with OSHA's Hazardous Communications' Regulation, this material is not currently defined as a hazardous substance. Any change in this status shall be promptly documented and communicated by the supplier.

3M will verify that product quality is consistent and meets the finished product specifications outlined therein.

3M will minimize product contamination. Storage facilities will be clean and orderly.



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3. Sampling, Inspection, and Product Characteristics:

3M will assure that samples selected are representative of the lot. A lot is considered to be from continuous daily production using same raw materials. The lot number of a production batch shall be assigned using a Julian date system based on the day of manufacture; for example, a lot number of 9035 would represent the 35th day of 1999. A lot number of 3180 would represent the 180th day of 2003. The day is set as the last day of reservoir production. The lot number is either embossed numbers on each tag or printed on each tag following the word "lot".

Quality Characteristics:

The run-out distance of the Monitor Mark™ 9860B is tested according TM-3950 at a temperature being 2°C above the target threshold temperature. The specification is based on the average of 24 indicators.

| Property | Min | Target | Max. |
|--|-------|-------------------|-------|
| Run Out Test (distance from left edge of first window) | 38 mm | 41 mm | 46 mm |
| Run Out Test Temperature | 6.7°C | 7°C | 7.3°C |
| Run Out Test Time | | 48 hr | |
| Missing or partial top film | | No defect allowed | |
| Inadequate die cutting | | No defect allowed | |
| Smeared or slurred printing | | No defect allowed | |
| Inadequate sealing of top and/or bottom assembly | | No defect allowed | |
| Missing adhesive | | No defect allowed | |
| Illegible or wrong date code | | No defect allowed | |
| MonitorMark tags per box | 100 | | |

4. Quality Testing and Reporting:

If required, a C of C or other specific quality information can be provided. Arrangements can be made through your 3M Sales Representative.

5. Storage Recommendations and Shelf life:

Product as supplied in original packaging will maintain stated properties for a period of 2 years from date stamped on shipping container when stored at a temperature between 50-80°F (10-27°C) and a relative humidity between 40-60 percent.



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6. Packaging and Labeling:

Product is supplied in boxes of 100 tags each with lot number printed on the outside of the box.

7. Returned Goods:

The customer should contact their 3M Sales Representative immediately. The customer should set aside tags of questionable quality and identify with the 3M lot number, date of inspection, invoice number and an explanation on why the material is questionable.

It is the responsibility of the customer to maintain the cleanliness and condition of the set aside material as it was at the time of rejection and package for return to the vendor in a manner that will preserve this condition. Maintaining these conditions will assist in determining the proper corrective action.

Important Legal Information:

Product and Safety Information: User is solely responsible for determining the suitability of 3M samples and products for the intended use including any necessary safety or toxicity assessment. 3M provides Material Safety Data Sheets with samples and will provide results of toxicity testing upon request. In every case before using any product in full scale production users should make their own tests to determine to their own satisfaction whether the product is of acceptable quality and is suitable for their particular purposes under their own operating conditions.

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