



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

### PRODUCT SPECIFICATION

Product Name:	3M™ MonitorMark™ 9860H	Issue: 2
Date	August 19, 2004	
Supersedes:	July 30, 2003	
Reason for reissue	Add TM	

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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 31 ±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 168 hr (1 week), the runout distance will be within specification limits.

Prior to activation and use MonitorMark™ 9860H must be placed in a cool environment of less than 26°C for a period of at least 2 hours. Also the surface to which the tag is attached must be below 30°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 35<sup>th</sup> day of 1999. A lot number of 3180 would represent the 180<sup>th</sup> 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™ 9860 H 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	32.7 °C	33 °C	33.3 °C
Run Out Test Time		168 hr	
Missing or partial top film		No defect allowed	
Inadequate die cutting		No defect allowed	
Smearred 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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