3M FAX COVER SHEET
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5129 '97 NOV 24 P3:39

TO: Catherine M. DeRoever
Company: Center for Food Safety and Applied Nutrition
Phone: (202) 205-4251
Fax: (202) 205-4970

FROM: Rich Matner
Company: 3M
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Fax: 612-737-1994

DATE: Nov 11,1997
# of Pages: 9
(includes cover page)

COMMENTS:
Dear Ms. DeRoever,

3M corporation would like the opportunity to describe a series of time/temperature indicator tags that can be applied to individual cases of temperature sensitive food products, such as produce, to indicate the temperature exposure history of the food during transportation and handling. These time/temperature indicator tags are currently used by the medical industry to indicate the temperature exposure history of pharmaceuticals and blood products and have been available from 3M for over 15 years. If information of this kind is of value, I would appreciate the opportunity to address the Microbial Safety meeting.

Included in this fax is a copy of technical data on the Time Temperature Indicators that are available from 3M.

Best Regards,

Rich Matner
Marketing Manager
Microbiology Products

97N-0451

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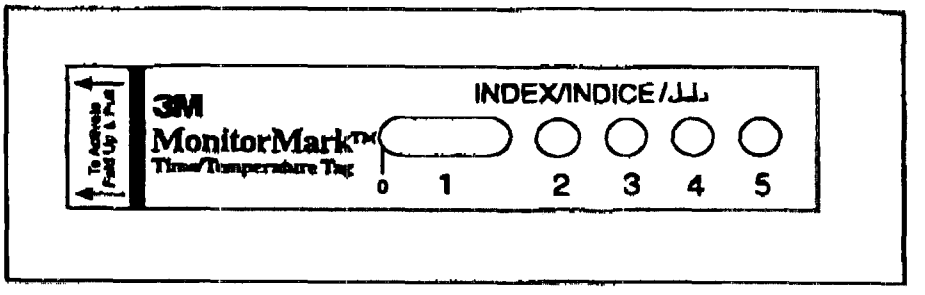
3M Data Page

MonitorMark™ Time/Temperature Indicators

Description:
MonitorMark™ Time/Temperature Indicators are monitoring tools that provide a visual, non-reversible indication of time and temperature exposure above a pre-set threshold temperature. This is accomplished by the appearance and migration of blue color, left to right, through a series of viewing windows.



MonitorMark™ Indicator

Product Construction:
The MonitorMark Time/Temperature Indicator is a rectangular flat laminate containing layers of paper, film, adhesive and other components. Overall size is 3-3/4" x 3/4". The heart of the indicator is an indicator track strip (porous wick) 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 film activation strip separates the wick from the reservoir. Over the indicator track strip is a paperboard layer containing viewing windows. This is topped with a clear film protective overlayer. A pressure sensitive adhesive on the underside allows convenient attachment to most clean, dry surfaces.

Function:
After proper pre-use conditioning (see Handling and Use Guidelines) the user activates the indicator by pulling and removing the activation strip. This allows contact between the reservoir pad and the end of the overlying indicator track (porous wick). At this point the indicator track (visible under the viewing windows) is a plain white color. Upon exposure to temperatures exceeding the threshold response temperature the chemical in the reservoir melts and begins to migrate along the track. Thus, blue coloring first appears at the left edge of the first viewing window and gradually moves left to right to the end of the track. The rate of the blue color movement is dependent on the temperature and the amount of chemical in the reservoir.

Uses:
MonitorMark Time/Temperature Indicators can be used to monitor any product exhibiting time/temperature abuse sensitivity. They are used primarily on the secondary package (the case, box, etc.) and are often used to evaluate and monitor storage, distribution, and packaging. **The indicators are to monitor temperature exposure, not product quality. Their purpose is to signal when quality should be checked.** Some typical applications include monitoring of refrigerated and frozen foods, drugs and vaccines, medical diagnostic kits, toner powders, photosensitive products, industrial coatings and resins, solder paste.

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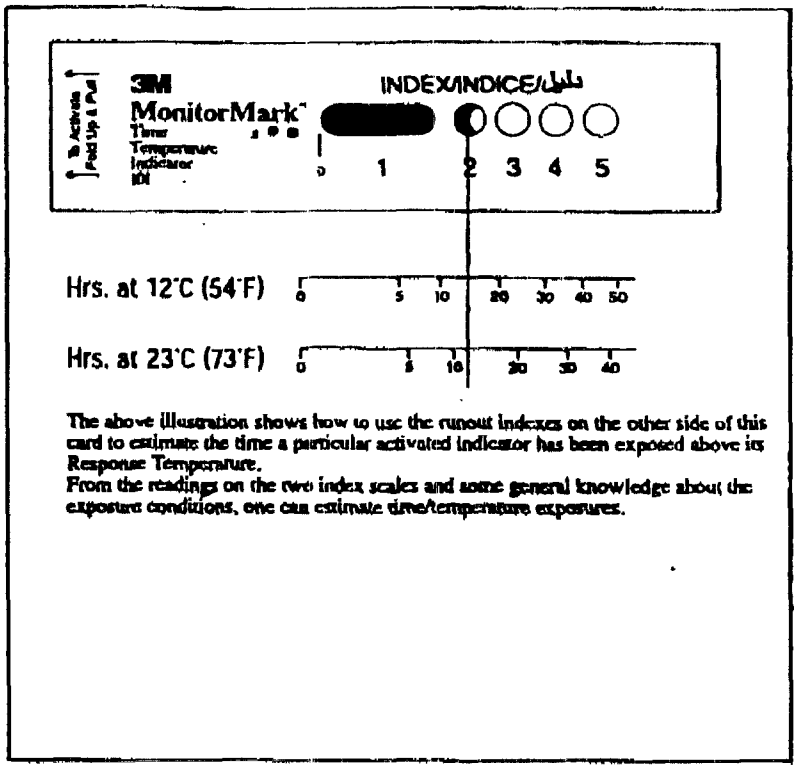
MonitorMark™ Time/Temperature Indictor (continued)

Runout Interpretation:

The appearance of any blue color in the indicator's first window signals that the indicator's pre-set threshold temperature has been exceeded. The extent of color movement ("runout") through the indicator's windows provides a measure of accumulated time spent above the threshold temperature. A short exposure at a relatively high temperature will produce coloration comparable to a longer exposure at a lower temperature. Response cards are used to interpret the time/temperature relationship for each indicator. Usually, the runout distance versus time relationship for at least two temperatures is provided.



Typical Response Card

Product Line Availability:

Time necessary for the blue color to progress left to right to the end of the indicator at a temperature 2°C above the activation temperature.

***Dual Temperature Indicator** incorporates a 10°C time/temperature indicator and a 34°C go/no-go threshold indicator having a separate window which shows blue if the temperature exceeds 34°C (93°F):

Product Number	Activation Temperature	Operating Runout Time
I15	-15°C (5°F)	48 hours
5I	5°C (41°F)	48 hours
10I	10°C (50°F)	48 hours
10L	10°C (50°F)	1 week
26I, 26L, 26N	26°C (79°F)	48 hr., 1 week, 2 weeks
31L	31°C (88°F)	1 week
10N/34AA**	10°C (50°F) for time/temperature portion 34°C (93°F) for threshold indicator portion	2 weeks Immediate (0-3 hr.)

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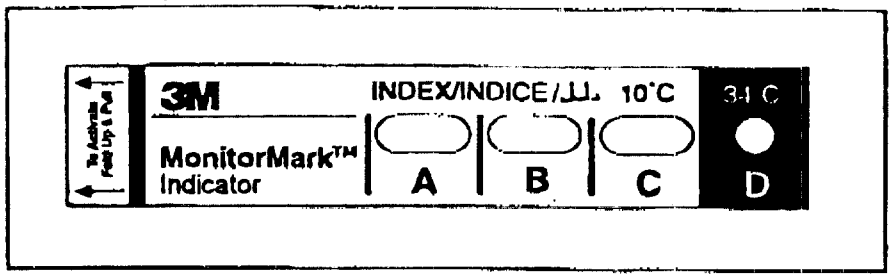
MonitorMark™ Time/Temperature Indictor (continued)



10N/34AA Dual Temperature Indicator

Size:
Size: 3-3/4" x 3/4" x 1/16" thick (approx.)
Packed: 100 per box, 5 boxes per case (500)

Reliability:
MonitorMark Time/Temperature Indicators will show initial color in 24 hours or less when exposed to the stated threshold temperature, ± 1°C. When exposed to a constant temperature 2°C above the threshold temperature for a time period equal to the stated cumulative runout time, the runout distance will be within ± 6% of the target maximum established for that indicator.

Handling and Use Guidelines:

Pre-Use Conditioning:
To prevent premature response, Time/Temperature Indicators must be conditioned prior to removing the activation strip and activating the indicator. This insures that the response chemical is solid and not liquid prior to removing the activation strip. Condition indicators for a minimum of two hours in a suitable refrigerator, freezer, or chamber at the temperatures suggested in the table:

Once conditioned and ready for use the indicators can be maintained at any temperature below their threshold temperature.

Note that it is the indicators that must be cooled to the conditioning temperatures listed above, not the product that is going to be monitored. The product need only be maintained below its critical temperature.

[illegible]	Conditioning temperature (minimum)
-15°C (5°F)	-25°C (-13°F), freezer at lowest setting or special chamber
5°C (41°F)	-4°C (25°F) or freezer
10°C (50°F)	5°C (41°F) or freezer
26°C (79°F)	22°C (72°F) or refrigerator
31°C (88°F)	27°C (81°F) or refrigerator

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MonitorMark™ Time/Temperature Indictor (continued)

Correct Surface Temperature During Indicator Activation:
At the moment the Time/Temperature Indicator is activated by pulling the activation strip, the surface to which it is attached (the carton, an instruction card, the product itself, etc.) must be at a temperature below the response temperature of the indicator. Otherwise, the heat from the carton or card may be enough to cause a premature response in the indicator.

For example, in the case of a product being monitored with a 5°C indicator, avoid the sequence of placing the indicator on a warm carton or instruction card, activating it, and then placing the complete unit in a cool place to cool it below 5°C. Rather, cool everything below 5°C and then activate the indicator.

Storage:
Store MonitorMark Time/Temperature Indicators in a controlled environment at 72°F or below at 20-60% relative humidity. Keep away from heating vents, hot pipes, direct sun. Storage at refrigerated or freezer conditions will extend shelf life.

Terms and Conditions of Sale for products sold by 3M Identification and Converter Systems Division can be found in the ICSD Price Book and in appropriate price schedules.
Technical Data: All physical properties, statements, and recommendations are either based on tests we believe to be reliable or our experience, but they are not guaranteed. 3M recommends each user determine the suitability of the products for the intended use.
Warranty and Limited Remedy: The Following warranty is made in lieu of all other warranties, expressed or implied, including, but not limited to, implied warranty of merchantability, the implied warranty of fitness for a particular purpose and any implied warranty arising out of a course of dealing, a custom or usage of trade: 3M warrants its products will be free from all defects. If a product is proved to be defective, then the exclusive remedy and 3M's and seller's sole obligation shall be, at 3M's option, to replace the quantity of the product which is proved to be defective or to refund the purchase price.
Limitation of Liability: 3M and seller shall not be liable for direct, indirect, special, incidental or consequential damages based upon breach of warranty, breach of contract, negligence, strict liability or any other legal theory. The foregoing Warranty and Limited Remedy and Limitation of Liability may be changed only by a written agreement signed by authorized officers of 3M and seller.

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Data Page

MonitorMark™ Customer Activated Threshold Indicators

Description:
MonitorMark™ Customer Activated Threshold Indicators are monitoring tools that provide a visual, non-reversible record if temperature exposure exceeds a critical threshold temperature. This is accomplished by the appearance of blue color in the indicator's circular window. Customer Activated Threshold Indicators (CAT Indicators) are equipped with an activation strip which must be removed by the user before monitoring can occur. The activation strip prevents premature indicator response and allows shipment and storage at temperatures exceeding the threshold without special packaging and handling procedures being required. The activation strip, the lower threshold temperatures available, and the dimensions, differentiate the CAT Indicator from MonitorMark High Temperature Threshold Indicators.

Response Temperatures Available:
- -15°C (5°F)
- 5°C (41°F)
- 10°C (50°F)
- 17°C (63°F)
- 26°C (79°F)

Product Construction:
The MonitorMark CAT Indicator is a rectangular flat laminate containing layers of paper, film, and adhesive. Overall size is 1-1/4" x 3/4". The heart of the indicator is a porous wick layer over a reservoir pad containing a blue dyed specialty chemical having a desired melt point. A film activation strip separates the wick from the reservoir. Over the wick is a paperboard layer containing a circular viewing window and a clear film protective overlayer. A pressure sensitive adhesive on the underside allows convenient attachment to most clean, dry surfaces.

Function:
After proper pre-use conditioning (see Handling and Use Guidelines) the user activates the indicator by pulling and removing the activation strip. This allows contact between the reservoir pad and the overlying porous wick. At this point the porous wick (visible in the circular viewing window) is a plain white color. Upon exposure to temperatures exceeding the threshold response temperature the dyed specialty organic chemical in the reservoir melts and begins to diffuse through the porous wick. This causes a blue random coloring to appear in the viewing window. Typically, a dot or two of blue appears first followed by spreading of the blue color to cover the entire viewing window.

Uses:
Potential applications include monitoring temperature abuse of refrigerated or frozen foods, fresh produce, drugs, vaccines, candies, industrial parts in process, etc. **The indicators monitor temperature, not product quality. Their purpose is to signal when quality should be checked.**

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MonitorMark™ Customer Activated Threshold Indictor (continued)

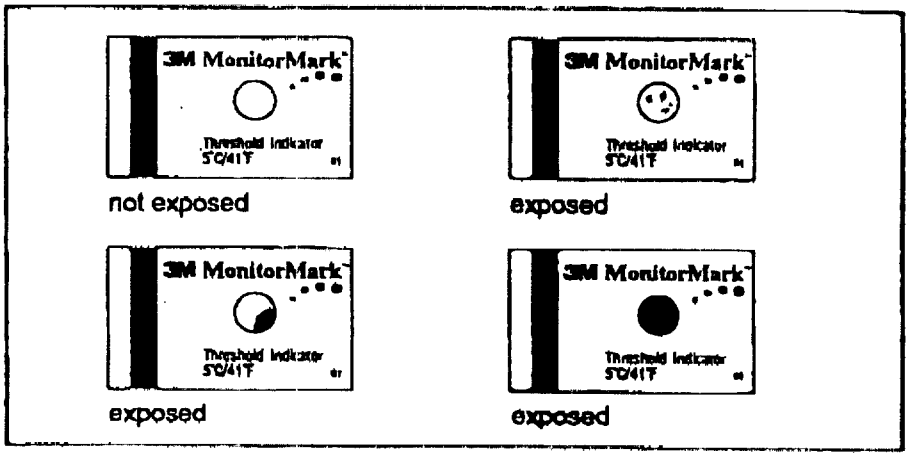
Reading the Indicator:
The appearance of any blue color, not the point at which blue color covers the entire viewing window, signals that the threshold temperature has been exceeded. Typically, exposure at two degrees C above the nominal threshold temperature results in the appearance of initial blue color in 5-10 minutes. It is not necessary to see further progression of the blue color. CAT Indicators will trigger at ± 1°C of the stated response temperature when exposed in a temperature chamber where the temperature is increased in one degree C increments once each hour.

Storage:
Store CAT Indicators in a controlled environment at 72°F or below at 20-60% relative humidity. Keep away from heating vents, hot pipes, direct sun. Storage at refrigerated or freezer conditions will extend shelf life.

Shelf Life:
If stored at the conditions listed above, shelf life is two years from date of manufacture.

Size:
Indicator size: 1-1/4" x 3/4" x 1/16" thick (approx.) Packed 120 indicators/ box, 5 boxes/ case (600 indicators)

Examples, Threshold Temperature Exposure



Handling and Use Guidelines:

Pre-Use Conditioning:
To prevent premature response, CAT Indicators must be conditioned prior to removing the activation strip and activating the indicator. This insures that the response chemical is solid and not liquid prior to removing the activation strip. Condition indicators for a minimum of two hours in a suitable refrigerator, freezer, or chamber at the temperatures suggested in the table:

Once conditioned and ready for use the indicators can be maintained at any temperature below their threshold temperature.

Note that it is the indicators that must be cooled to the conditioning temperatures listed above, not the product that is going to be monitored. The product need only be maintained below its critical temperature.

Indicator Response Temperature	Conditioning Temperature (2 hour minimum)
-15°C (5°F)	-25°C (-13°F), freezer at lowest setting or special chamber
5°C (41°F)	-4°C (25°F) or freezer
10°C (50°F)	5°C (41°F) or freezer
17°C (63°F)	14°C (57°F) or refrigerator
26°C (79°F)	22°C (72°F) or refrigerator

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MonitorMark™ Customer Activated Threshold Indictor (continued)

Correct Surface Temperature When Activating Indicator:
At the time the CAT Indicator is activated by pulling the activation strip, the surface to which it is attached (the carton, an instruction card, the product itself, etc.) must be at a temperature below the response temperature of the indicator. Otherwise, the heat from the carton or card may be enough to cause a premature response in the indicator.

For example, in the case of a product being monitored with a 5°C indicator, avoid the sequence of placing the indicator on a warm carton or instruction card, activating it, and then placing the unit in a cool place for cooling below 5°C. Rather, cool all components below 5°C and then activate the indicator.

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MonitorMark™ Customer Activated Threshold Indictor (continued)

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Technical Data: All physical properties, statements, and recommendations are either based on tests we believe to be reliable or our experience, but they are not guaranteed. 3M recommends each user determine the suitability of the products for the intended use.
Warranty and Limited Remedy: The Following warranty is made in lieu of all other warranties, expressed or implied, including, but not limited to, implied warranty of merchantability, the implied warranty of fitness for a particular purpose and any implied warranty arising out of a course of dealing, a custom or usage of trade: 3M warrants its products will be free from all defects. If a product is proved to be defective, then the exclusive remedy and 3M's and seller's sole obligation shall be, at 3M's option, to replace the quantity of the product which is proved to be defective or to refund the purchase price.
Limitation of Liability: 3M and seller shall not be liable for direct, indirect, special, incidental or consequential damages based upon breach of warranty, breach of contract, negligence, strict liability or any other legal theory. The foregoing Warranty and Limited Remedy and Limitation of Liability may be changed only by a written agreement signed by authorized officers of 3M and seller.

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