Technical Note TN0001

TempDot. Plus **Time-Temperature Indicator Labels** How Do They Work?

Overview

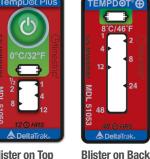
The unique blister design of the TempDot labels allows them to remain completely inert prior to use, and to be stored and shipped under most temperature conditions. Since the chemical dye is encapsulated in a blister, it cannot leak out into the progress indicator window until the labels are properly activated.

This is a beneficial feature, since most competitive products have a simple barrier film and can experience some amount of color bleeding into the white indicator window if exposed to high temperatures prior to activation. It means that in its unactivated state,

TempDot Plus requires no special handling or storage before use.

Once activated, TempDot Plus monitors the environment where it is located and will show accumulated time that it is exposed to temperatures above its threshold. Each model of the label has a specific threshold limit. If there are no excursions above the threshold, the progress indicator window will remain white, indicating there has been no temperature abuse.

TempDot Plus is a single-use, irreversible time/temperature indicator label for monitoring products sensitive to ascending temperature conditions. Each model has a specific temperature



Blister on Top

threshold and will track the cumulative time it is exposed to conditions above that threshold. An activated label can monitor a product even under long term storage, as long as it doesn't exceed the temperature threshold or the end of the label's

Model	Threshold Temperature	Stop Temperature	Cumulative Temp Exposure in Hours
51050	0°C/32°F	-7°C /19°F	1⁄2,1,2,4,8,12
51052	8°C/46°F	6°C /43°F	1⁄2,1,2,4,8
51053	8°C/46°F	6°C /43°F	1,2,4,8,12,24,48
51054	10°C/50°F	8°C /46°F	1⁄2,1,2,4,8
51055	24°C/75°F	18°C / 64°F	1⁄2,1,2,4,8,12
51056	30°C/86°F	25°C /77°F	1,2,4,8,12

shelf-life of 2 years. Every TempDot label has a unique serial number which can be noted on shipping documents or other records, for

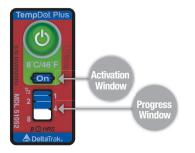
traceability

purposes.

Serial Number

The label is a water-resistant polymeric assembly of multiple layers of aluminum-plastic laminate. The layers include a non-toxic blue chemical





encapsulated in a blister, a white porous membrane, and a top overlay with two transparent windows, the activation window and the progress window. The blue dye is a proprietary thermo-sensitive chemical which is highly responsive to changes in temperature. It is Generally Recognized as Safe (GRAS), recognized by Food Chemicals Codex, and FDA approved (Title 21). Most models have the blister on top of the label, and some models have the blister on the back of the label.

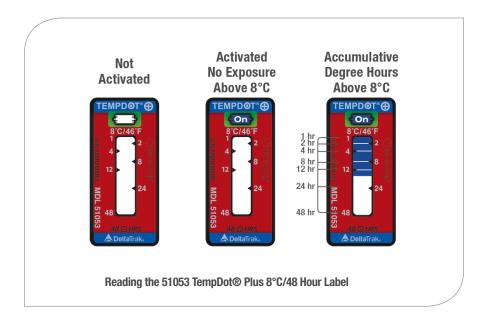
TempDot Plus works by diffusion; when the chemical dye liquifies, it moves across the white porous membrane. The dye is carefully formulated and calibrated to melt at a precise temperature point and diffuse at a controlled rate across the white indicator window when the label is held continuously at that temperature point (i.e. under isothermal conditions). Accuracy of the labels are within $\pm 2^{\circ}F/1^{\circ}C$, and time accuracy is $\pm 15\%$.

Activation is done by squeezing the blister button with a finger push,

using enough pressure to force the dye to flow into the first window. The dye must be in liquid form; this means users must activate the label only when the surrounding air temperature is above the stated threshold temperature of each specific model. If the room temperature is not above the threshold temperature, then the label must be heated above its threshold.

When activated, blue dye is absorbed by the white paper strip and diffuses Within 5 minutes after activation, the label must be placed in a temperature controlled environment at or below its stop temperature for 1 to 2 hours. This causes the blue dye to solidify and stop diffusing across the white paper strip, keeping it from going to the progress window.

The stop temperature is lower than the threshold temperature of the label because the freezing point of a liquid is always lower than its melting point. Freezing occurs when the first



by capillary action. As it turns blue, the word "ON" will appear in white letters in the activation window to confirm the label is ready for use. If the word "ON" does not appear, the blister should be pressed again to ensure all the dye is released from the blister. crystals form, which is typically at a temperature lower than its melting point, therefore the 'stopping point' (stop temperature) is lower than the precise 'starting point' or melting point (threshold temperature).

A properly activated label should be applied to the clean dry surface of a pre-cooled carton, package or individual units of products to be monitored. These can be in a temperature controlled environment above stop temperature, but must remain below threshold temperature.

When surrounding temperature rises above threshold, the dye melts and diffuses along the paper strip. It moves in one direction, irreversibly coloring the paper in the progress window with white lines appearing over the blue background as each time marker is reached. When temperature goes below the threshold, the dye solidifies and stops diffusing. Each subsequent temperature breach above threshold will cause the dye to melt again and continue moving until the progress window is filled with blue. This is the end point of the label's active life.

The higher the temperature rises surrounding the label, the faster the chemical travels along the paper strip, because higher temperatures increase the rate (time) at which the chemical dye melts and diffuses. Thus, a higher temperature correlates to faster time to reach the end point. In this way, the label is able to measure degree hours, or cumulative time of exposure to temperature excursions above threshold. This has a direct implication on the amount of possible damage, decreased quality, shelf life and/or efficacy of products when exposed to temperature abuse.

If the activated TempDot Plus remains under its threshold temperature, the dye will not diffuse into the progress window and it will remain white to indicate no temperature abuse has occurred.

