MADGETECH
WE BUILD DATA LOGGERS

Application Note

Mean Kinetic Temperature

What is Mean Kinetic Temperature?

Mean Kinetic Temperature (MKT) is a simplified way of expressing the overall effect of temperature fluctuations during storage or shipment of perishable goods. Consider the following example:

EXAMPLE:
A dozen eggs sat:
In a 20°C room for 2 hours
In a 2°C refrigerator for 4 hours
And on a 25°C loading dock for 1 hour
Using MKT we can calculate that the temperature profile of the eggs was "thermally equivalent" to storing them at 10.096°C for 7 hours.

How is Mean Kinetic Temperature Calculated?

Technically speaking, MKT is an expression of cumulative thermal stress experienced by a product at varying temperatures during storage and distribution. In other words, MKT is a calculated, single temperature that is analogous to the effects of temperature variations over a period of time.

MKT is not a simple weighted average. The calculation of MKT gives the higher temperatures a greater weight when computing the average than would a simple numerical average or an arithmetic mean. This weighting is determined by a geometric transformation— the natural logarithm of the absolute temperature.

The International Conference on Harmonization (ICH) stability testing guidelines define MKT as 'a single derived temperature which, if maintained over a defined period, would afford the same thermal challenge to a pharmaceutical product as would have been experienced over a range of both higher and lower temperatures for an equivalent defined period'.

By using this unequal weighting pf the higher temperatures in a temperature series, MKT takes into consideration the accelerated rate of thermal degradation of materials at these higher temperatures. Therefore, MKT provides for the non-linear effect of temperature.

MKT is expressed as:

$$\frac{\Delta H/R}{-ln\left(\frac{e^{-\Delta H/RT_1}+e^{-\Delta H/RT_2}+\ldots+e^{-\Delta H/RT_n}}{n}\right)}$$

Where: ΔH = activation energy (typically from 60 to 100 kJ/mol for solids and liquids)
R = 8.314472 J/mol-K (universal gas constant)
T = temperature in degrees K
n = the number of sample periods over which data is collected

Note: ln is the natural log and e^x is the natural log base.

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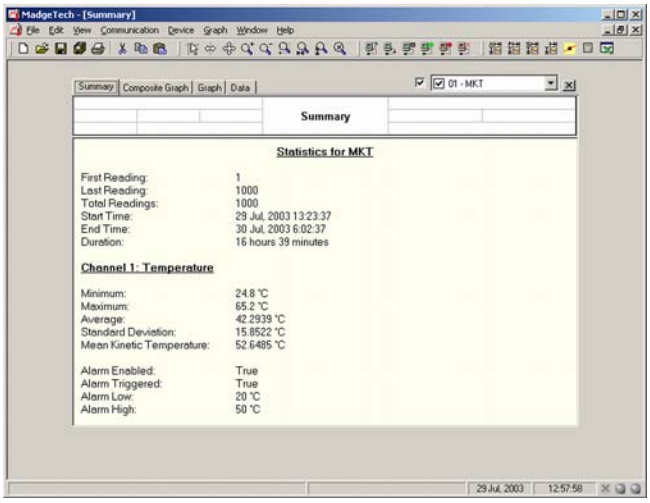
Why is MKT Important in the Life of Pharmaceuticals and Perishable Goods?

The pharmaceutical and food industries are two closely regulated markets. The FDA provides regulations that require warehouse and shipment temperatures to be closely controlled and monitored. In addition, The FDA requires well documented verification of these storage environments and any corrective actions taken if temperatures exceed specified storage conditions. The calculation of MKT is regarded by the FDA as an action taken to verify if a particular perishable has exceeded storage conditions.

In addition to compliance with the FDA regulations, MKT can help distributors and manufacturers determine if improper storage and handling of goods that may have occurred during shipment and/or unloading, has affected the shelf life of their product.

How Does MadgeTech Make MKT Simple?

MadgeTech's software Automatically calculates MKT for any of our temperature loggers as shown in the summary report below:



The MadgeTech algorithm has been validated against the United States Pharmacopeia (USP) and will yield a value within 0.1°C for all inputs. It is also important to note that the MadgeTech software uses constants that are more recent and marginally more accurate than the USP. MadgeTech obtains these constants from the CODATA/ NIST recommended values.

The software assumes activation energy of 83.14472 kJ/mol for its calculation. In fact, any value between 60 and 100 kJ/mol, which covers most solids and liquids, will have only a small effect on the final value.

Of course, extreme temperature even over a very small time period can damage most foods or pharmaceuticals. Per the above example, putting an egg in a 75°C oven for 1/2 hour will bring the MKT to 45.4°C, but the egg ill be irreversibly damaged (ie. Cooked). Consequently, there are maximum and minimum temperature limits established by the FDA. MadgeTech data loggers make monitoring these extremes easy with user settable alarm limits so out-of-limit temperatures can be easily identified.

Any data downloaded from a MadgeTech temperature data logger offers the user instant access to MKT and the vital information that our users need to comply with FDA regulations and/or make cost effective decisions on the acceptance or storage of perishable goods.

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