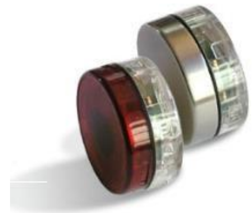
<u>Mean Kinetic Temperature (MKT)</u>

By: Douglas Wright, President



MKT or Mean Kinetic Temperature gives a far better representation of the effects of temperature change on sensitive materials such as pharmaceuticals and food products during storage and distribution. In many instances it can be shown that the 'shelf life' of sensitive materials is directly related to the MKT. Mean Kinetic Temperature can be calculated from a series of temperatures. It differs from other means (such as a simple numerical average or arithmetic mean) in that higher temperatures are given greater weight in computing the average. This weighting is determined by a calculation giving the natural logarithm of the temperature number.

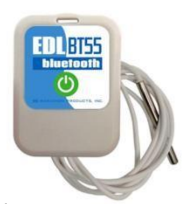
The key to the MKT calculation is that it gives increased weighting to higher temperature excursions than normal arithmetic methods, recognizing the accelerated rate of thermal degradation of materials at higher temperatures. This fact is simply demonstrated by the logarithmic growth curves of bacteria as temperatures increase. As defined by the United States Pharmacopoeia (USP), it is a "single calculated temperature at which the total amount of degradation over a particular period is equal to the sum of the individual degradations that would occur at various temperatures." It expresses the cumulative thermal stress experienced by a product at varying temperatures during storage and distribution.

You can calculate MKT yourself from the standard data using the Arrhenius equation. All the user has to do is enter the activation energy during set up (this can vary from 42-125 kJ/mol) and this can be determined by differential scanning calorimetry.

$$MKT = (-DH/R)/Ln\{(SUM(exp(-DH/R*Tn))))/n\}$$

where DH is the activation energy, R the universal Gas Constant (.0083144 kJ/molK), T is the temperature in Deg K, n the total number of equal time periods over which data are collected., Ln the natural log, exp the natural log base and SUM is the total over n periods.

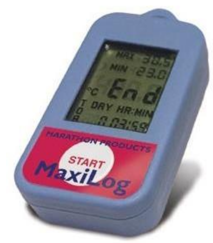
However, running our <u>Dataloggers</u> with various adjusted MKT values and comparing these relative to standard lab tests you can easily determine the MKT for most products. This is a much easier method.



Proper storage of products from production through usage is ideal but inevitably at some point and time temperature abuse will occur. While proper

cold storage, warehousing and distribution practices require that temperatures are monitored and controlled, there are typically gaps in this chain (loading/ unloading) and if 2 similar products are stored within the same parameters but one is kept cooler than the other, common logic states the product kept cooler has a longer shelf life. Depending on temperature conditions the effect may be dramatic, as outlined already MKT weights the higher temperatures in a series more than the lower temperatures. This is a more appropriate way of calculating an overall thermal effect because of the acceleration of thermally driven processes of degradation at higher temperatures.

MKT simply provides a method of monitoring the true shelf life of your product and with our Micro /Multi Use LCD Dataloggers/MaxiLog Dataloggers it is now possible to set alarms based on the MKT of your product. Rather than just basing alarms on the time above a specific temperature you can now better evaluate the shelf life of your products from that point on. MKT becomes especially valuable during transit where temperatures can vary significantly and traditional high/low limits may not give a true indication of the products efficacy. Products exposed to short periods above limits and yet stored at lower temperatures will most likely still be okay, whereas products that have been in range for the same time may be expired or much closer to expiry.



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