Using the Mean Kinetic Temperature (MKT) as a parameter to determine whether perishable goods have been transported and stored correctly.

The Mean Kinetic Temperature (MKT) is defined by the ICH (International Conference on Harmonization) 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”. The MKT yields a higher temperature than a simple arithmetic mean and may be calculated using the Arrhenius equation.

The mean kinetic temperature quantifies the cumulative thermal stress to which a product has been subjected when placed at varying temperatures during transport or storage. The MKT gives the higher temperatures a greater weight by computing the natural logarithm of the absolute temperature.

Haynes' formula may be used to calculate the MKT. This yields higher temperatures than the arithmetic mean and takes into account the Arrhenius equation from which Haynes derived his formula:

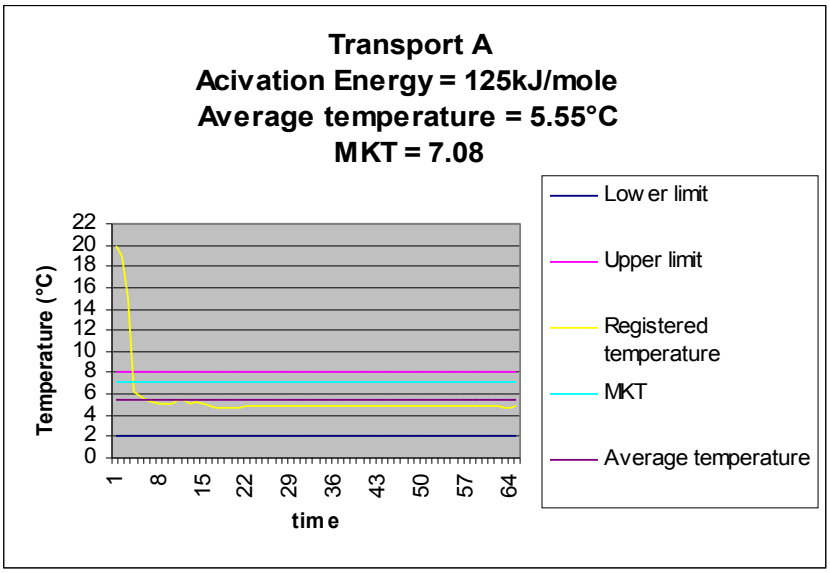
$$T_k = \frac{\Delta H / R}{-\ln \frac{e^{\frac{-\Delta H}{RT_1}} + e^{\frac{-\Delta H}{RT_2}} + \ldots + e^{\frac{-\Delta H}{RT_n}}}{n}}$$

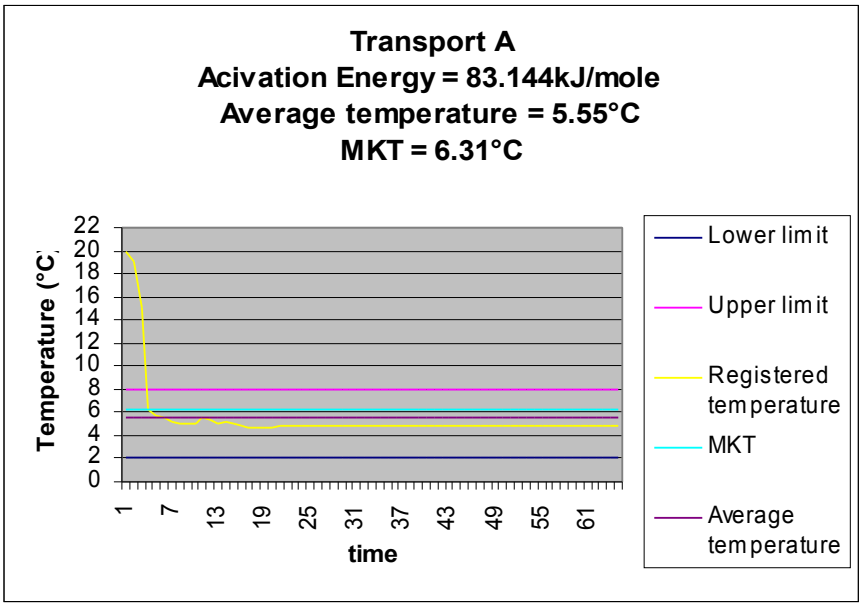
Tk	=	MKT in ºK
ΔH	=	Heat of activation or activation energy
R	=	The universal gas constant (8.3144 · 10-3 kJ.mole-1 · ºK-1)
Ti	=	Temperature in ºK
n	=	The total number of equal time periods over which data has been collected.

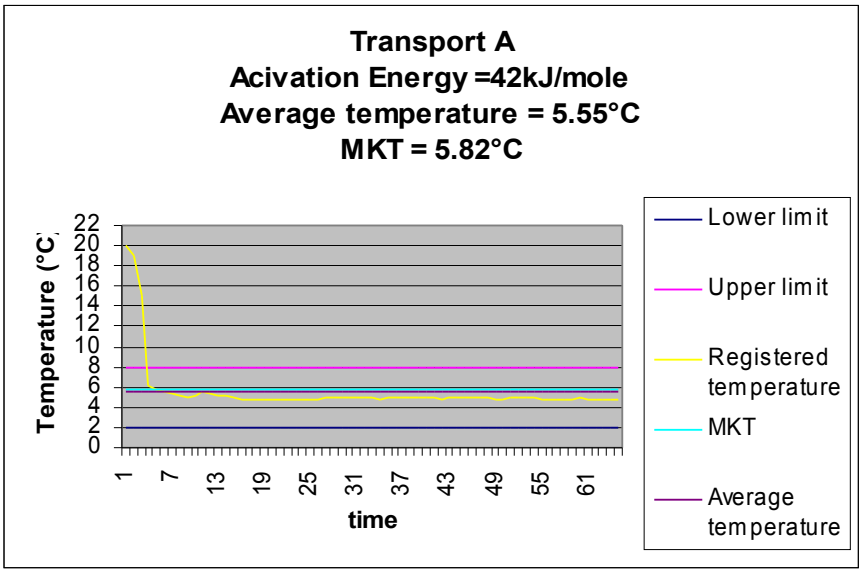
The practical use of this equation is less complex than it seems. Most pharmaceutical or biological products have an activation energy (ΔH) in the range 42 – 125 kJ/mole. A value of around 83 is considered typical for pharmaceuticals or foodstuffs.

Let us examine a few examples of storage during transport and the MKT values we would obtain under various conditions. It will be clearly seen that using the MKT is the simplest and quickest manner, especially for store-keepers and logistics operators, to determine whether transport/storage conditions has adversely affected the products.
A shipment can be accepted if the MKT is below a maximum limit for correct storage, unless otherwise agreed by the supplier and the customer; furthermore, the closer the MKT is to the minimum limit for correct conservation, the better is the quality of the storage conditions.

Let us examine a transport with varying activation energy:

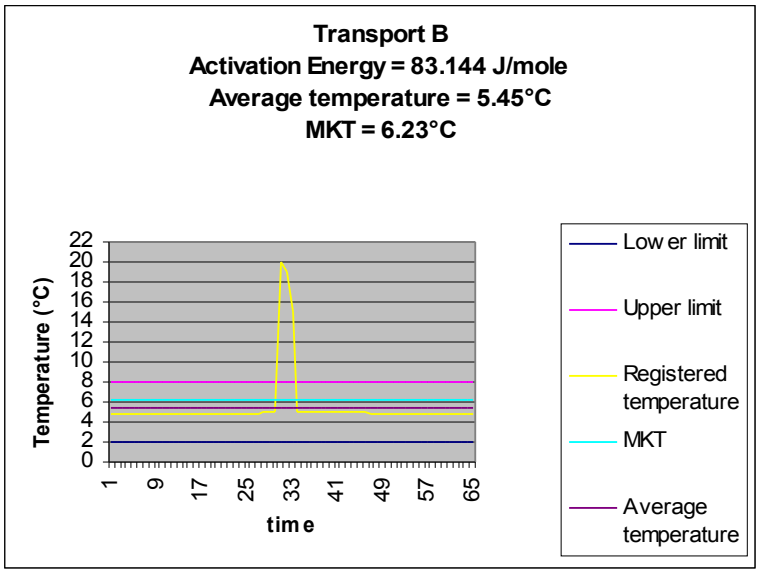


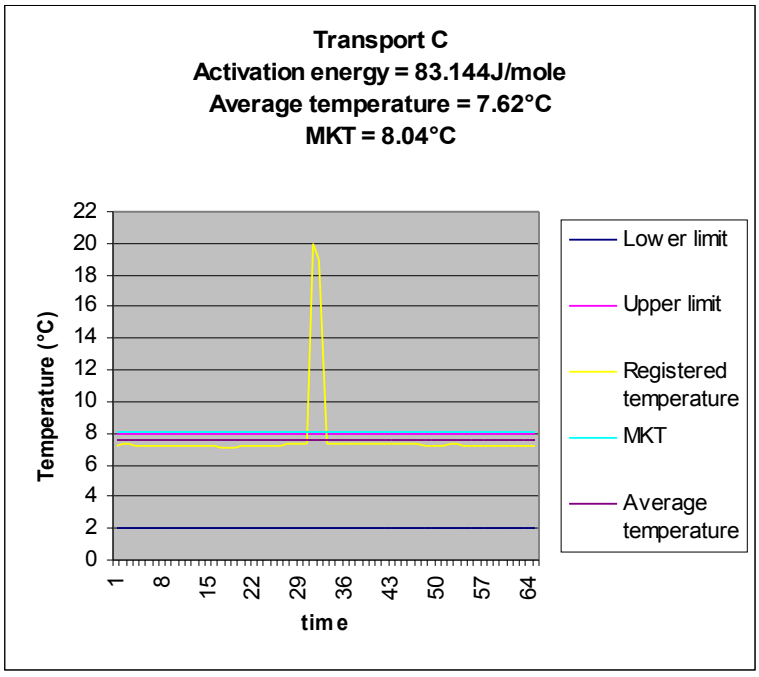


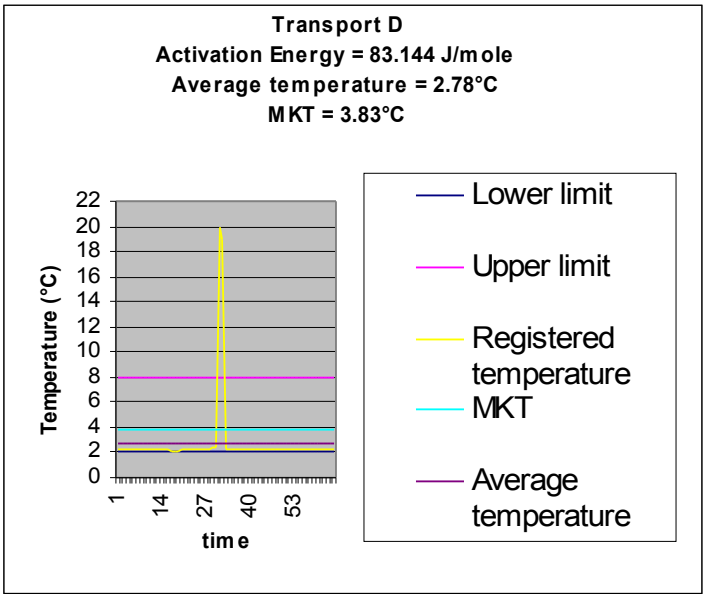


As can be observed, the higher the activation energy, the higher will be the result of the MKT value.

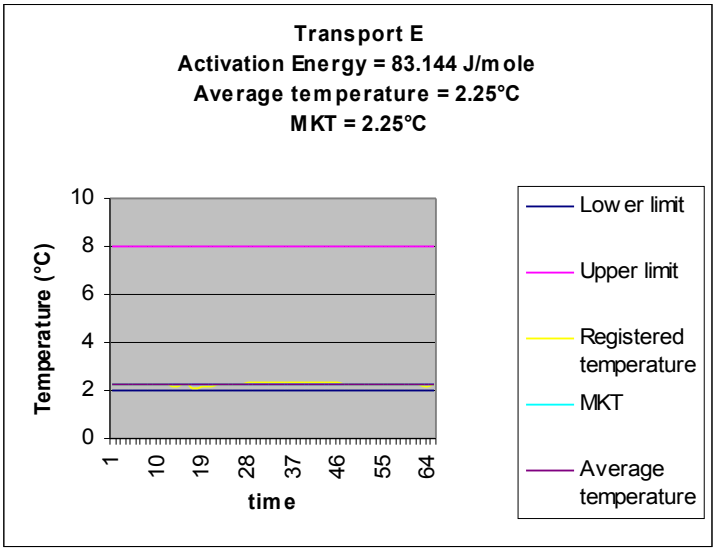
Let us now see what happens if, during transport, the product is subjected to a peak of temperature above the limit for correct conservation.
We note that, if one had to simply consider the maximum temperature reached as the basis for accepting the goods, all the shipments whose temperatures are shown below would have been rejected. Using the MKT as a basis for decision, it is clear that two of the shipments are in actual fact acceptable.







When goods are stored at a constant temperature, the MKT is, obviously, equal to the arithmetic mean, as shown below.



One last observation on the accuracy of temperature recorders:
If one uses an instrument with an uncertainty of +-1%C one knows, considering the examples above (with an upper limit of 8°C), that a temperature band from 7°C to 9°C exists within which we do not know the actual value of temperature. If we use such an instrument to contest a delivery we have to accept even those values between 8°C and 9°C because our instrument, for example, could be reading 8.5°C when the actual temperature could be 7.5°C. Conversely, if the delivery firms use their own instruments with similar uncertainty, they cannot declare with certainty that the same transport was between 7°C and 8°C, because even if their instrument reads 7.5°C, the actual temperature could have been 8.5°C.

Tecnosoft supplies calibrated Data Loggers with an uncertainty below 0.25°C. Each Data Logger is supplied with its unique calibration certificate.

Sergio Rossi
Tecnosoft srl
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