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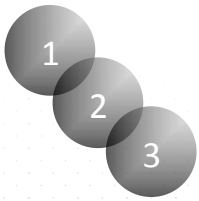
Thermal Cover Test Data - Is it GDP Compliant?

We're generally aware that test data is crucial to supporting the risk based approach of GDP (Good Distribution Practice). However, data can be like statistics - it can be developed to tell you what you want to see! With a variety of potential thermal cover vendors available in the market place, how do you know what to look for?

It would be impossible to provide test data for all occasions, pallet types and product loads, there are simply too many variables and complexity. The three step approach is commonly used when appraising procurement and selection of thermal covers.

Three Step Approach

1. Obtain base test data from vendors, ideally triplicate testing
2. Carry out local site tests to establish preferred solutions
3. Commission independent chamber testing, and/or carry out real life testing through supply chain lanes.

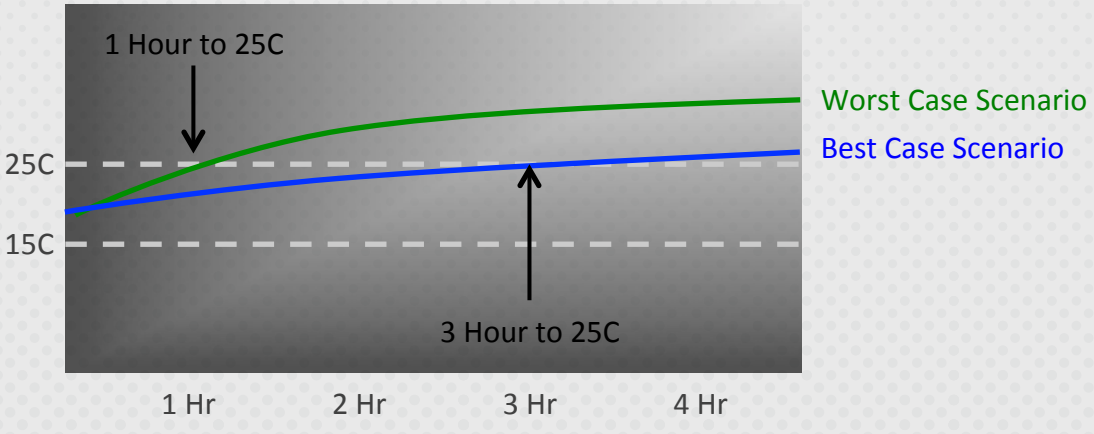


Vendor Test Data

The lack of global guidelines on testing of thermal pallet covers results in a variety of test data presented to the market place that is hugely difficult to compare. However, the initial information provided should help to take the first step of selection.

Although vendors want to communicate how good their solutions are, credible companies recognise that they have to supply 'worst case scenario' data to give full reassurance to QA and supply chain managers.

Example Test Data



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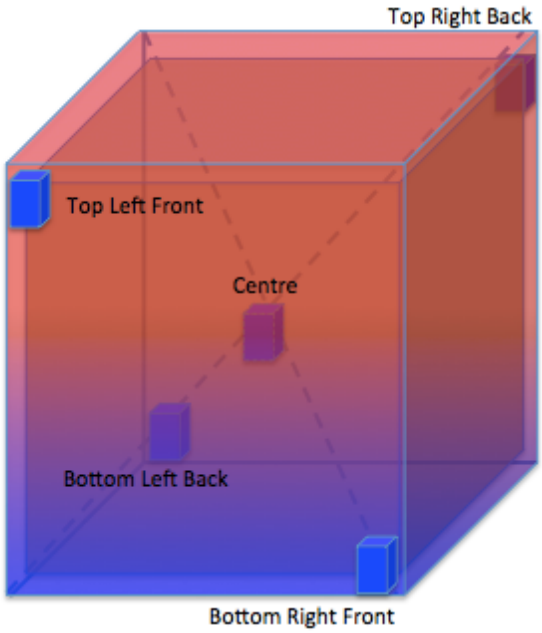
Assessing Thermal Pallet Cover Test Data

Monitor Positions

The positioning of 'calibrated' temperature monitors is critical to data presentation and can make considerable impact to any performance data presented.

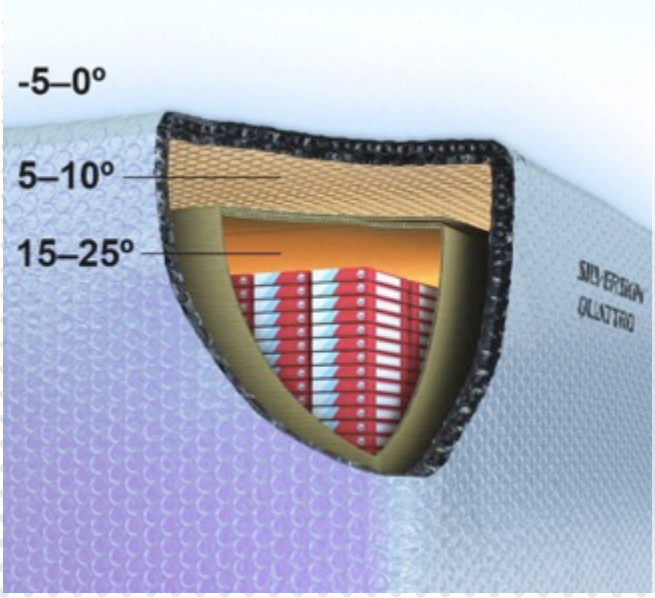
Temperature change is most rapid at the corners of the pallet where there is little surrounding mass to protect it. Hot temperatures and direct sunlight cause the top corners of the pallet to change temperature more rapidly, cold temperatures, where cold air is heavier and falls to the lower points, causes the bottom corners of the pallet to change more quickly.

Calibrated temperature monitors positioned in the top and bottom corners will demonstrate the highest rate of change and 'worst case scenario'.



Product Temperature verses 'Outside The Packaging' verses Ambient Temperatures

Although the product temperature is most critical, it can be a challenge to position monitors next to the product inside the packaging. The closest position available is often outside the packaging (often a cardboard box) but under the thermal cover.



The temperature outside the packaging (but under the cover) will usually be quite different than the product temperature and show a greater rate of change. If there is a requirement to keep this air temperature at the same temperature as the product, a great level of insulation will be required to achieve this, thus increasing the cost.

Because monitors are often positioned outside the packaging, it's important for the vendor to show performance in these positions when presenting test data, again in the upper and lower corners.

Monitors positioned to record the ambient data should also be used so that a relationship between inside and outside can be viewed.

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Mass Percentage

Mass is another critical element that can impact highly on performance data being presented. Extensive discussions over the years with customers and partners have concluded that 20% mass is acceptable as an initial benchmark. This provides enough mass within the load to retain some thermal energy that can be measured. Using empty boxes makes it difficult to measure any load apart from air space, which is known to change temperature far more rapidly than any product mass.

Mass Type

Different types of product mass have a variety of temperature change rates. Drums of API powder will hold temperature for longer than packages of blister pack solid dose for example. As it would be challenging to test all the variations of product load, the industry will accept testing of neutral mass as an initial test medium.

The mass should be spread equally across the pallet load e.g. equal numbers in each box, and represent 20% mass through the pallet capacity.

Pallet Size

The larger the pallet, the more product mass can be added, and the better the thermal performance. To observe ‘worst case scenario’, the test pallet should be one of the smaller and shorter sizes commonly used, e.g. Euro Pallet (800mm x 1200mm) at approximate 900mm - 1000mm high.

Pallet Cover Configuration

Most users of 'single use' reflective pallet covers use just the top only, far less use both the top and base to completely encompass the load. Test data should be available for both configurations. Top only configurations work well in hot ambient threats, especially where the main threat is from the sun. Where there is cold ambient threat, better protection is gained using the top and base.

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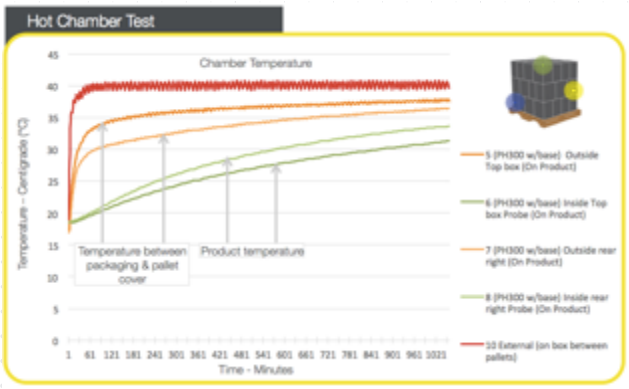
Assessing Thermal Pallet Cover Test Data

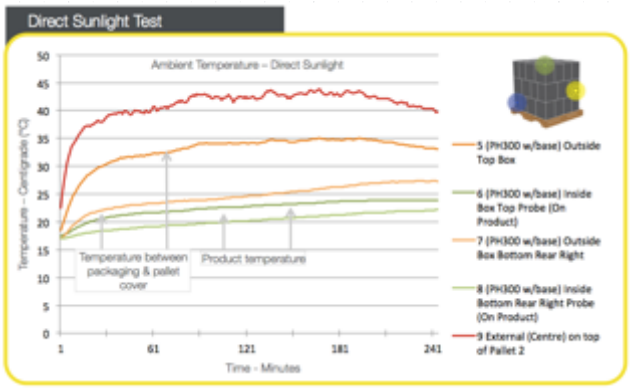
Chamber Test verses Direct Sun Testing

Chamber testing facilitates a controlled environment to carry out benchmark tests, keeping variables to the very minimum. Chamber tests also allow the user to see what happens to the load in a shaded environment such as the warehouse, truck or aircraft, where the main threat is the change of ambient air temperature.

When carried out professionally, outdoor direct sunlight testing will demonstrate the thermal protection provided against the harsh light spectrum transmitted by the sun. This will help determine the performance given during breaks in the supply chain such as the airport ramp time, transport between warehouses etc.

It would be ideal to see both chamber and direct sunlight tests if possible.





'Gradual Temperature Build' verses 'Impact Stress' Chamber Testing

During supply chain transportation, temperature change can often be rapid, e.g. from the aircraft or warehouse to a hot or cold ramp station etc. For this reason, it is advantageous to see 'Impact Stress Testing' where the test pallets are positioned directly into a test chamber preconditioned to the prescribed test ambient (e.g. +40C, -10C).

This also eliminates the potential variance between different test chambers on their 'temperature build time'. Some chambers are designed to rise at 0.5C per minute, others can rise at 2.0C per minute. This would naturally have quite an impact on the temperature change of the product if starting from an ambient temperature.

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Conclusion

Because of so many variables in the supply chain, calibrated chamber testing is crucial to any 'Performance Qualification' (PQ). Direct sunlight trials will support indication of performance in 'real world' situations.

Quality Assurance professionals should be aware of any possible variables in the test process that can impact test results so that fair comparisons can be made in the initial selection process.

About TP3 Global

Focusing on the passive protection of temperature sensitive cargo during transit, TP3 Global Ltd was founded in the UK and has manufacturing bases in the Americas, Europe and Asia. TP3 Global's SilverSkin™ range of thermal pallet covers are qualified as GDP compliant and designed for protection of cold chain and controlled room temperature shipment protection world wide. TP3 Global works with the world's largest Pharmaceutical, Healthcare and Perishable companies who have qualified SilverSkin™ insulated thermal pallet covers, blankets and wraps to support their cold chain, logistics and supply chain management needs.

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TAGS: thermal covers, quilts, blankets, cold chain, perishable cargo protection, logistics, supply chain management, reusable, passive temperature sensitive logistics, controlled ambient, controlled room temperature, clinical trials, military, America, USA, South West Europe, Europe, Asia

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