



Sun protection for drugs in transit



The latest triple-action air cargo covers from DuPont provide vital sun protection to pharmaceuticals that are exposed to potentially damaging solar radiation during their journey to market





Pharmaceuticals is a huge global industry with a total market value approaching a trillion dollars. Pharmaceutical production is concentrated in a small number of manufacturing centres and the resulting drugs and medicines typically travel halfway around the world in their journey from factory to pharmacy.

Temperature-related spoilage of pharmaceuticals during air transportation is a huge problem for the industry and regulatory authorities around the world are introducing stringent controls to ensure that the safety and efficacy of these products is not compromised by unacceptable temperature deviations during transport and storage. The most recent of these regulations is the European "Good Distribution Practice" (GDP) and this seeks to ensure that manufacturers and shippers maintain a safe and satisfactory 'coolchain' for their products during transit.

In recent months the world has witnessed a succession of temperature extremes generally attributed to global warming and believed to be part of a long-term pattern of greater weather severity and uncertainty. It is a trend that has not gone unnoticed by an industry that relies on being able to keep goods in transit under strictly controlled temperature conditions.

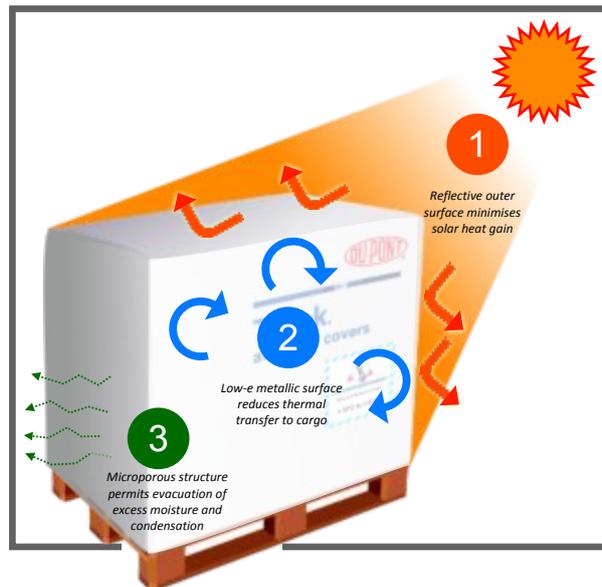
"As the frequency and intensity of extreme weather events accelerates so does the need for improved temperature control of pharmaceutical products during their transportation to market," says Tony Wright of Exelsius Ltd, a respected coolchain consultancy.

Weakest Link

One of the weakest links in the pharmaceutical coolchain, however, relates to a high incidence of solar radiation spikes during external air handling operations, a problem that is causing some manufacturers to switch from fast and efficient air carriage to the considerably slower sea freight; an option offering relatively poor traceability and flexibility.

"Solar radiation is a prime cause of air-freight temperature excursions," continues Tony Wright. "This is a huge concern for major pharma companies who at any given point in time will have millions of pounds worth of merchandise in transit across the globe. A single temperature excursion can wipe out the entire value of a shipment causing enormous commercial, logistical and reputational loss."

This is the issue which the DuPont corporation is addressing with its new range of 'triple action' Tyvek® air cargo covers. These are lightweight 'thermal blankets' that provide a reliable and affordable means of protecting pharmaceutical products that must be kept within the 'controlled room temperature' (CRT) temperature band of +15°C to +25°C in accordance with the latest EU legislation.



New Generation Protection

The new generation, Tyvek® Air Cargo covers are a typical coolchain passive protection component designed to provide cost-effective off-the-shelf CRT protection for pharmaceuticals. The Tyvek® solution employs a unique triple-action approach to temperature control which renders them a very effective and cost-efficient solution to CRT control (see Fig 1).

During early validation tests for the Tyvek® covers DuPont observed first hand the significant, but oft-ignored, effects of solar radiation on palletised pharma products. Temperature spikes of up to 15 degrees celsius above ambient were being regularly measured under normal outdoor conditions. Other similar direct sunlight tests have recorded surface temperatures as high as 70 degrees celsius or more and these are temperatures that can be further magnified by local conditions such as the 'mirror' effect of nearby glass or metal clad buildings.

Moisture Problems

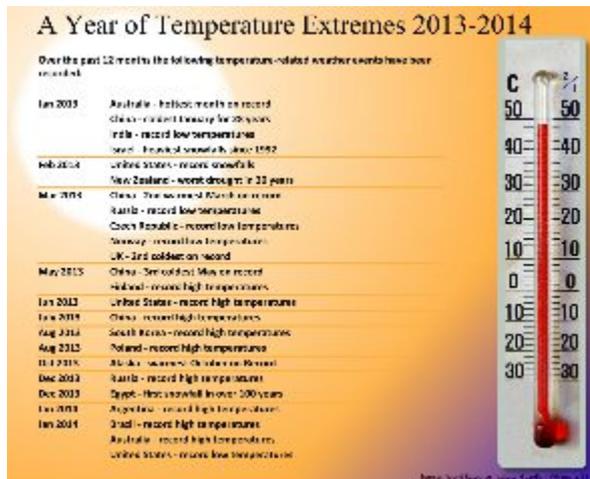
The high humidity in hot coastal locations such as Dubai brings a further problem for pharmaceutical distributors, that of condensation. Condensation occurs when the air surrounding the merchandise, which has been heated during, for example outside loading or unloading operations, is cooled rapidly perhaps when it enters the temperature-controlled cargo-belly of a freight plane or when it is taken indoors to a temperature-controlled storage zone or when it is transferred to a refrigerated truck. The resulting moisture release can be highly damaging to merchandise and to both its packaging and labelling.



And the problem doesn't stop there. The use of clear or black cargo coverings creates a very powerful 'greenhouse effect' as the sun's rays are absorbed and trapped. This was another phenomenon observed in the Tyvek® validation tests. Temperature differences of as much as 43 degrees celsius were recorded between clear shrinkwrap and Tyvek® when exposed to solar radiation during recent tests in Florida. This is because common packaging materials such as stretchwrap and bubblewrap can provide a 'greenhouse effect' by trapping

sunshine the surface temperature the product packaging can easily reach dangerous levels.

"Many route qualification programmes rely on data derived from average ambient temperature conditions and fail to take into account the huge solar exposure effects that can be encountered during loading and off-loading operations, often the result of unplanned delays or disruptions," says Aynur.



heat and increasing the surface temperature of the pharma merchandise way beyond the surrounding air temperature. The triple-action Tyvek® air cargo covers restrict this solar heat gain because of its exceptional reflective properties in both the visible and infrared radiation wavelengths.

Huge Losses

Aynur Rasulovala-Rzepa is a Special Products Consultant and Manager at one of Dubai's top cargo agencies, International Transport Services FZCO. In this Gulf city, summer temperatures in the shade are routinely in the mid-40s but can easily be several degrees higher than this during particularly hot spells. These, however, are the temperatures in the shade. Where pharmaceutical shipments are exposed to direct

Deadly Heat: *Pharmaceuticals queued outside on an airport loading zone are subject to exactly the same solar gain phenomenon that you get when you leave a car parked in the sun. In fact controlled tests by DuPont showed that an inside-outside temperature difference of 27 degrees Celsius can be readily achieved in sunshine conditions. In the case of pharma shipments that are exposed to direct sunshine, many factors will affect the temperatures experienced but even in the winter months radiated solar heat can result in surface temperatures well beyond the safety zone for most pharmaceutical products."*

"Even brief exposures and occasional sunny intervals can cause huge and surprisingly fast temperature spikes. For this reason we recommend using Tyvek® cargo covers as these provide shipments with a further line of defence against temperature excursions."

Solar gain is a serious problem that, unless countered, will undermine the validity of many 'qualified' logistics provisions according to Marina Valente, Marketing Manager for Tyvek® Air Cargo Covers.

"One of the problems lies in the fact that many operators are



Degrees of Change: *Accelerating temperature extremes is a problem that is going to intensify: "It is very likely that heat waves will be more intense, more frequent and longer lasting in a future warmer climate" according to the IPCC Intergovernmental Panel on Climate Change. The World Meteorological Organization (WMO) agrees; according to a recent report more national temperature records were reported broken than in any previous decade and going forward it is going to intensify.*

continuing to use standard packaging materials or ineffective cargo covers based on commercial bubble-wrap and similar materials," she says.

"In many cases these dramatically exaggerate the solar gain effect making a serious problem even worse. Being unprepared for the level of temperature surges that we have been experiencing here in Brazil, and in particular by using the wrong type of cover materials, can leave pharma manufacturers exposed to potentially huge losses."

Triple action protection

Tyvek® Air Cargo Covers employ a combination of three complementary mechanisms to provide 'best-in-class' thermal security. This triple-action approach has been specifically developed to address the heat flow mechanisms that are at work in the fluctuating temperature scenarios often found in air cargo logistics.

The first tier of protection comprises a white micro-fibre exterior surface which provides a reflective barrier against the

highly detrimental effects of solar radiation. The second tier of protection comes from a low emissivity, shiny metallic layer on the internal surface of the cover. This presents a radiant heat barrier to help maintain core package temperatures. The third protective tier relates to the micro-porous structure of the cover material which, being vapour permeable, permits the escape of damaging condensation which can form during hot-cold thermal cycles. It is also of importance where goods must be protected from freezing since excess moisture can exacerbate cooling effects.

The result is a unique, state-of-the-art protective envelope with the unique triple action capability providing powerful protection against excessive radiated heat. The Tyvek® covers have been extensively researched and tested and are already in widespread use with several operators.

Cargolux, Europe's largest all-cargo carrier, is one of the companies that has tested and adopted the new generation covers from DuPont. "The enhanced Tyvek® air cargo covers enable Cargolux to considerably minimize the risk exposure when transporting temperature sensitive pharmaceutical and healthcare shipments, especially in critical control point areas, i.e. during loading or when being handled on tarmac," says Franco Nanna, Head of Management Network Support at Cargolux. "They allow us to optimize our service offering through tailored cool chain solutions on a customer by customer business case".

The message is clear: pharmaceutical manufacturers and their logistics providers must not only be prepared for the possibility of accidental or unforeseen exposures to excessive ambient heat during the different phases of transport, they must also factor in the high risk of unforeseen or accidental exposure to high levels of solar radiation.