



## Kinray is committed to the integrity of cold chain shipments

### Program Highlights

Kinray is committed to the safety of the refrigerated pharmaceuticals we ship to our customers. That is why we use a scientifically tested and performance qualified solution to ensure the refrigerated pharmaceuticals you receive are maintained at 36° to 46° degrees during shipping and delivery, regardless of the season (cold winters and hot summer temperatures) or the payload (a single vial or a full cooler box).

Pharmaceuticals arrive in boxes with insulated panels made of expanded polystyrene. Inside, orange phase change panels maintain the proper temperature of the product.

The phase change panels are composed of a proprietary product made of vegetable and plant oils that are a non-toxic, renewable resource and are bio-degradable and environmentally safe. This product has been submitted to and approved as a USDA Bio-Preferred product

One unique property of our phase change panels is that they solidify / freeze at 39°F (4°C) to prevent typical freezing temperatures of 32°F (0°C) and below that can harm many refrigerated pharmaceuticals. Some pharmaceuticals, such as vaccines and proteins, may experience reduced potency, efficacy or expiry when frozen. This process ensures that these products are never frozen and are maintained at 36°F to 46°F during shipment to your pharmacy.

Please visit [www.Kinray.com/Kinray\\_CC.html](http://www.Kinray.com/Kinray_CC.html) to watch a nine-minute video of the phase change packaging in action, learn more about the science and what to expect with your shipment.



### Why phase change materials?

For years, the industry standard for the packaging of refrigerated pharmaceuticals was the use of frozen water-based gel-packs inside of insulated containers. The challenge is that frozen water, at 32°F, is actually colder than the storage range of 36° to 46°F (2-8°C) for refrigerated pharmaceuticals. This initial “cold blast” was necessary to keep the temperature from rising above 46° degrees too quickly. Exposing refrigerated pharmaceuticals to freezing temperatures of 32° or below places them at risk of reduced efficacy, potency or expiry. While traditional gel-packs remain the accepted industry standard, Kinray has taken steps to improve the integrity the refrigerated pharmaceuticals that we ship to our customers.

Phase Change Materials (PCMs) are compounds that liquefy and solidify at specific temperatures. During this process they absorb, store, and release large amounts of energy. These natural properties of latent heat energy help maintain our product between 36° to 46° and buffer it from temperature swings. The PCMs recharge as ambient temperatures fluctuate, making them ideal for a multitude of everyday applications. The orange panels are conditioned in a freezer with a temperature below 32°F (0°C) and since their freezing point is 39°F (4°C), they adjust to 39° almost immediately and remain solid for a long period of time, especially when in the closed insulated cold chain cooler.

The Food and Drug Administration (FDA) has focused on cold chain over the past few years as additional research has demonstrated the potential of freezing pharmaceuticals with the use of the industry standard water-based frozen gel- packs. Many drug manufacturers have switched to phase change material for its superior performance to protect their valuable pharmaceuticals.

### Handling phase change panels

Kinray is committed to improving the integrity of the supply chain, so we ask our valued customers to work with us to increase patient safety.

The orange phase change panels start their journey in a solid frozen state. When you receive your product, the phase change panels may be **frozen solid** (the phase change panels freeze at 39°F), they may have **frozen slushy particles** present or they may just be **cool liquid** that feels like product that has just been removed from a refrigerator.

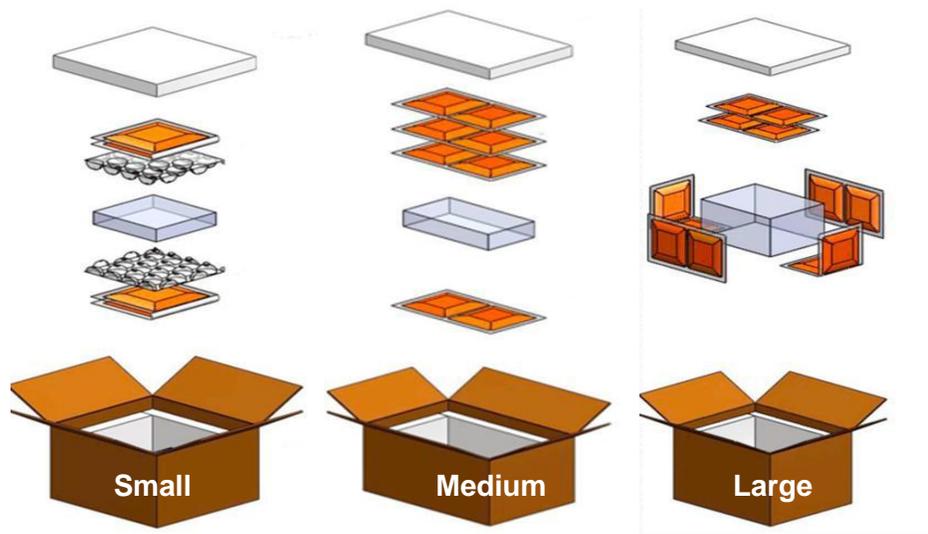


The phase change materials have been tested through thousands of freeze and thaw cycles without any performance loss. The clear film, however durable for many uses, will not last as long due to its flexible nature. To protect the film from surface abrasions that can occur in boxes with other products, the panels will be placed in zipped-lock bags to contain a leak, in the event that one occurs. Additionally, the plant-based material, while non-toxic and safe, can have solvent properties if the liquid is in contact with expanded polystyrene (EPS, a.k.a. foam). Canola oil has this same affect. Prolonged contact with EPS will result in what appears to be the foam melting, when in fact the phase change material has dissolved the foam's expansion properties. In the unlikely event that this happens and the plastic zipped-lock bag does not contain a leak, simply clean up with mild hand washing soap and dispose of the non-toxic material. **This product is non-toxic, environmentally friendly and is a USDA Bio- Preferred product.**

These panels are expensive, so we ask that you return them with the cooler boxes for re-use with future shipments.

## What to expect in your shipment

When you receive your product, the phase change panels may be **frozen solid** (the phase change panels freeze at 39°F), they may have **frozen slushy particles** present or they may just be **cool liquid** that feels like product that has just been removed from a refrigerator. The goal is to maintain the labeled storage range of 36°F to 46°F and not the typical freezing temperatures of 32°F or below that can actually damage or destroy many pharmaceuticals.



As always, refrigerated pharmaceuticals should be placed in a refrigerator as soon as possible after they arrive at your pharmacy, even if you intend to return the product to Kinray.

## How to return refrigerated product

In the event that you need to return product to Kinray, you will need to recondition the panels in a freezer overnight or until they are frozen solid. If you do not have a cooler box (with foam panels) or the appropriate number of phase change panels, you will need to request these through customer service or your sales representative. Please do not use other temperature controlling packaging (e.g., water-based frozen gel-packs). All other return policies will apply.

Proper packaging of returned product is important. Any item not packaged correctly cannot be returned to stock and will need to be destroyed by Kinray.

For your convenience, the number of orange phase change panels is on an orange sticker on the outside of the box.

These panels are expensive, so we ask that you return them with the cooler boxes for re-use with future shipments.

The packaging diagrams for each box are located at [www.Kinray.com/Kinray\\_CC.html](http://www.Kinray.com/Kinray_CC.html) or can be obtained through customer service.