

January 10, 2025**Re: Low Temperature Excursions During Shipping**

Dear Healthcare Professional:

There was a weather-related shipping delay with your order. Because of unusually severe temperatures across the US, FedEx delivery was stalled and packages were held at their Memphis facility, where outside temperatures peaked in the low 30s.

You may have questions about the potential effects on the allergenic products in your order. The purpose of this letter is to provide you with information that supports our assessment that there is no anticipated risk that the shipping delay adversely effected the allergenic products in your order. Please consider the following:

- Cold storage (2-8° C/ 35-46° F) is the recommended storage conditions for both glycerinated allergenic extracts and lyophilized venom material. In general, proteins are more stable at lower temperatures in a lyophilized form.
- A HollisterStier shipping assessment concluded that it is considered safe to ship any glycerinated allergenic extract or diluent, uncontrolled, to destinations with a temperate climate, provided the product is not in transit for a period exceeding 66 days. The shipments in question have been in transit for approximately one week, and therefore, are sufficiently within this range.¹
- Allergenic extracts containing 50% glycerin will not freeze unless the temperature reaches -26° C (approximately -15° F).² This temperature threshold was not reached while held in Memphis; therefore, there is low risk of product experiencing freeze-thaw cycles.
- For lyophilized venom, the routine manufacturing process exposes the materials to temperatures below 2-8° C, with no negative effects on product quality. For example, drug substance is stored at -20° C for up to 5 years. The low water content of the lyophilized material mitigates against protein degradation due to freezing. In addition, the final drug product contains mannitol, which acts as a cryoprotectant.

Should additional discussion or further clarification be required, please contact Customer Technical Service at 1.800.495.7437.

Sincerely,

Ben VanGerpen
Chief Scientific Officer

1. HollisterStier Report 009290.

2. Reference for freezing point of 50% glycerin: Lane, LB. Industrial & Engineering Chemistry 1925 17 (9), page 924

