

Allergen Extract Potency—Exposure to Extreme Temperatures

Vials of allergen extracts used for immunotherapy should be shipped in a manner that ensures the potency and purity of the product regardless of time of year shipped. Allergen extracts must be stored at 2–8° C (35–46° F) upon receipt. Refrigerated storage is essential for long-term stability and potency of the extracts. While the label storage temperature recommendation is refrigeration, it has been determined that short-term exposure to temperature extremes during shipping does not adversely affect extract potency and stability.

ALK–Abelló, the supplier of immunotherapy treatment sets for Heska, has conducted a shipping temperature exposure validation study on a variety of allergen extracts. The study was performed to determine the temperatures to which allergenic extracts are subjected during shipment to various climates within the United States, at different times of the year, and whether those temperatures adversely affect the potency of the product.

Immunotherapy vials containing various combinations of pollen or mite mixtures were shipped from Port Washington, NY to Phoenix, AZ or Austin, TX in the summer months. Upon receipt, the inside of the shipping container holding the vials had reached an average temperature of 27° C or 81° F (max 34° C or 94° F).*

An elevated temperature stability study was also conducted. Immunotherapy vials were subjected to temperatures between 35–38° C (95–102° F) for a 72-hour period. Despite the elevated temperature, potency of the extracts was retained.*

Similar studies conducted during the winter months demonstrate retention of integrity, potency and purity with current packaging and shipping methods.

These analyses demonstrate that the potency of allergen extracts packaged according to established procedures and shipped during hot summer months, as well as cold winter months, is not adversely affected by the short-term temperature extremes. For optimal long-term stability and potency, please follow label recommendations for storage of allergen extracts at 2–8° C (35–46° F) upon receipt.

*Data on file

For questions or further assistance, please call
Heska's Medical and Technical Support Services at **1-800-GO HESKA, option 5.**

