

12/08/2021

Dear Medical Professional:

This letter is in response to your inquiry regarding stability of allergenic extracts under various storage conditions. There are several variables to consider, including the length of time, dilution, and temperatures. We can provide you with the information below, for your consideration.

As standard practice, allergenic extracts are shipped without refrigeration, using overnight delivery service, with two exceptions noted below. As described below, the data states that standardized glycerinated extracts can remain potent up to four days at 37° Centigrade.

Allergenic extracts are recommended to be stored at 2-8° Centigrade as noted on the labels. This is to insure maximum potency of the products during the labeled shelf life. It has been noted in various allergy literature that storage at temperatures above the recommended range can accelerate the deterioration of an extract, particularly for non-glycerin extracts and for diluted extracts. We have very limited specific data on our several hundred extracts, most of which have no established U.S. standard of potency for measuring activity.

We do have some limited data from in-house studies done on various standardized extracts, which do have established U.S. standard of potency. These studies show these standardized allergenic extracts (Cat, Mite, Short Ragweed and most Grasses) can remain potent up to four days at 37° Centigrade. Two standardized Grass extracts, Timothy and Red Top at 100,000 BAU/mL, require shipment with cold pack at this time. We have no data past 4 days.

We do also have data from an unpublished in-house study which indicate that freeze-dried Venom products complied with all release specifications for potency when stored at 25 degrees Centigrade, for up to six months. We have no data past six months.

We have studied shipments that go to various areas of the country at various times, including Arizona in the summer. Field studies indicated temperatures as high as 104F for products in transit in the summer, though this extreme temperature is reached only briefly.

**A Jubilant Life Sciences Company**

OUR VALUES



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**Allergy Products Division**

For the category of products with standards of potency, our data show they are quite stable under summertime shipping conditions. Only one lot in 400 lots of the least stable product would be expected to fail if tested for potency after shipping for four days during the peak of summer to Phoenix Arizona, (average temperature 95F) followed by storage in the refrigerator for the expiration period, 36 months. Because only about 0.3% of packages arrive after 2 days, the chance that a product would be adversely affected during routine shipment, even to Phoenix in the summer, is very, very small.

We recommend storing allergenic extracts at 2-8 degrees C when not in use. In order to maintain maximum potency, keeping extracts out of refrigeration during an entire work day is not recommended.

We hope this information is helpful. If there are further questions, please feel free to contact Customer Service/Technical Services at 1-800-495-7437.

Sincerely,

Megan Steeber  
Customer Service Rep

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