

ALK has been in the allergenic extract market for more than 80 years. Since entering the US market in 1985, ALK has grown to be one of the top US extract suppliers, providing consistent, quality products to numerous markets offering allergy testing and treatment.

Phenol is used in solutions to preserve allergen extracts and in the diluents utilized to mix extracts for immunotherapy treatment. This technical memo is intended to serve as a guidance document to provide understanding behind the use and benefits of phenol in allergenic extracts. Additionally, our Medical Scientific Affairs Team is available to personally address any questions you may have.

Phenol

This report discusses (1) the use of phenol as a preservative; (2) the effect of phenol on allergen stability; and (3) patient sensitivity to phenol.

1) Phenol as a preservative

Allergen extract solutions are formulated as "Glycerinated" or "Aqueous". Aqueous extracts and diluents typically contain normal saline as the main component. Glycerinated extracts are defined as extracts that contain at least 50% glycerin (glycerol) by volume. Since allergy immunotherapy vials undergo multiple syringe entries, the FDA mandates that allergen solution must contain a preservative¹. Phenol at a 0.4% concentration or glycerin at a 50% or greater concentration is considered by the FDA to be an antimicrobial preservative; therefore allergen extracts rarely, if ever, become contaminated². All aqueous diluents used to dilute extracts contain 0.4% phenol. ALK has performed internal studies to show that solutions preserved with glycerin or phenol do not support bacterial growth.

2) Allergen Stability

Phenol is a chemical compound that can inhibit bacteria and fungi proliferation. There have been claims in the immunotherapy field that the presence of phenol can impact the potency of extracts. Studies in our laboratories, as well as others, including FDA mandated stability studies for standardized products, suggest otherwise.

3) Sensitization to phenol

The small amounts of phenol used in allergen extracts is considered safe and effective for microbial growth prevention. Phenol is not a mercury-based compound. Phenol is used as a preservative in many foods as well as many over the counter products.

For decades, the vast majority of immunotherapy treatment vials have contained 0.4% phenol and yet there are no good clinical case studies documenting sensitivity to the preservative. Although there are several anecdotal accounts of "phenol" sensitivity, most are to "phenolic" type compounds which are more complex chemicals than the simple phenol

used in extracts. Therefore, any conditions resulting from the exposure to phenol must be very rare. Nevertheless, if this unusual sensitivity is suspected, it can be detected by skin testing a patient with a phenol-containing diluent, like NSP.

When diluting patient treatment vials with NSP or HSA, the concentration of phenol remains unchanged. Physicians should use their best judgement when initiating patients that may have a suspected phenol sensitivity.

ALK Commitment

ALK is committed to helping Allergy Specialists maintain uniformity of care for their patients. Please do not hesitate to contact Medical Scientific Affairs (855.782.9323, science@alk.net, or submit your scientific questions to our 24/7 online helpdesk in a support ticket at: <https://alkinc.freshdesk.com>) should you have additional questions or concerns regarding a transition between ALK products.

This technical memo is not intended to replace physician judgment with respect to the clinical diagnosis and treatment of patients. All decisions regarding potential patient care are solely at the discretion of the treating physician.

References

1. USP Sterile Compounding Committee. Pharmaceutical compounding—Sterile preparations. In USP on Compounding: A Guide for the Compounding Practitioner. Revised Bulletin in online edition. U.S. Pharmacopeia, 1–61, 2008.
2. Nelson MR, and Cox L. Allergen immunotherapy extract preparation manual. In AAAAI Practice Management Resource Guide, 2012 ed. American Academy of Allergy, Asthma and Immunology, 1–39, 2012.