

ALK has been in the allergenic extract market for more than 95 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.

This technical memo is provided as a guidance document to describe the composition of allergenic extract vial stoppers, as well as diluent stoppers. Our Medical Scientific Affairs Team is available to personally address any additional questions you may have. ALK is dedicated to providing you with quality products and excellent service.

Latex in Allergenic Extract Stoppers

Stoppers closures in vials manufactured by ALK-Abello Inc use a modest portion of dry natural rubber and are not completely latex free. According to West Pharmaceuticals, stoppers used in ALK products contain 13.9% dry natural rubber. The sections below describe our current knowledge of the latex content our products' stoppers and the potential leaching of latex allergen into the solutions contained in these vials.

Latex allergens exhibit cross-reactivity with several food allergens. There are literature reports that latex is sometimes cross-reactive with banana, avocado, kiwi, papaya, and mango.¹

We are not aware of any reactions from allergen transferred from pharmaceutical stoppers. However, a scientific publication reported that small amounts of latex allergen may be transferred from latex stoppers to liquid contained in pharmaceutical vials.² The authors tested five types of vial stoppers from three stopper manufacturers. Two types of stoppers contained dry natural rubber. The other three types of stopper were synthetic and contained no dry natural rubber. A brief overview of the study is provided below:

- Vials of sterile phenolated saline with human serum albumin were prepared with each type of stopper.
- The vials were inverted and stored so that the solution was in continuous contact with the stoppers.
- A subset of vials of each type of vial was penetrated 40 times with a 21 gauge needle to simulate a multi-dose vial.
- Five grams of each type of stopper were cut in half and extracted for 24 hours in the same solution.
- Eleven latex-allergic patients and 10 non-allergic patients were skin tested with each solution. The patients were tested by skin prick first, then by intradermal injection.

Study Results:

- No latex allergen was detectable in the solutions exposed in vials.
- The cut stoppers that contained latex did leach latex allergens into the extraction solution.
- Of eleven latex-allergic patients, none reacted to the solutions from the vials closed with synthetic stoppers. Four allergic patients did

have positive intradermal tests to solutions from vials with latex stoppers. Seven had no reaction.

Conclusion and Recommendations:

The stoppers studied by Primeau et al. contained approximately 80% more natural dry rubber than the style used by ALK. Additionally, those vials were stored inverted. These data suggest that highly sensitive latex-allergic patients may react to latex allergens from vial closures under certain atypical conditions. Although the risk is slight, physicians should exercise their clinical judgement in treating patients with known or suspected latex allergies. In vitro tests are available to detect latex-specific IgE.

We recommend that vials be stored upright and that the site of insertion of needles be moved to minimize coring of the stoppers. For more information about coring, please see our Coring Technical Memo.³

Diluent and Sterile Empty Vial Stoppers

ALK diluents and sterile empty vials utilize stoppers that are manufactured from synthetic materials and do not contain dry natural rubber. These include NSP and HSA and 50% Glycerin diluent products.

ALK Commitment

ALK is committed to helping Allergy Specialists maintain uniformity of care for their patients. Please do not hesitate to contact your Allergy Consultant, Customer Service (800.325.7354) or 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 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. Perkin JE. The latex and food allergy connection. J Am Diet Assoc. 2000;100(11):1381-4.
2. Primeau et al. JACI 2001. Jun;107(6):958-62.
3. ALK Coring Technical Memo

