



2008

RE: Possible irritant or allergic reactions to the adhesive or tape in T.R.U.E. TEST® (Allergen Patch Test) panels.

Dear Health Care Professional,

Per your inquiry, the tape (backing) in the T.R.U.E. TEST panels is composed of rayon fibers, and the individual patches are composed of polyester. The adhesive used in the panels is acrylate-based, as are most pressure-sensitive adhesives used in medicine today. Note that there is no natural rubber latex, rubber components, balsams or rosins in the adhesive or tape. Reactions to the T.R.U.E. TEST tape or adhesive are uncommon but can include irritant contact reactions. In clinical studies, reports of tape irritant reactions (collected for up to 3 weeks post treatment) were infrequent, usually mild in nature, and self-limiting.

In studies conducted in the U.S., tape irritant reactions ranged from 0.8 to 6%.(1) In three European studies, tape irritant reactions rarely occurred. In addition, these irritant reactions occurred at the same frequency as irritant reactions to Finn Chamber tape and adhesive.(2, 3, 4) Allergic contact reactions to T.R.U.E. TEST tape or adhesive rarely occur, because the acrylate-based adhesive is not a strong sensitizer. This type of adhesive is similar to that of hypoallergenic surgical tape, including tape used for patch test purposes (e.g., Scanpor). As noted in Fisher's Contact Dermatitis, acrylate adhesives were developed specifically to avoid allergic reactions and are processed to remove free monomers that might be allergenic.(5)

We hope this information has been helpful and encourage you to report suspected adverse effects to us if you believe your patient has experienced an allergic or irritant reaction to the adhesive. Please feel free to contact us at (800) 365-6868 so that we may continue to monitor the safety of T.R.U.E. TEST appropriately.

Sincerely,

Kim M. Sullivan  
V.P. Regulatory/Research  
(602) 225-0595 X274

References:

- (1) Product Information for T.R.U.E. TEST. Allerderm Laboratories, Inc. (T.R.U.E. TEST package insert)
- (2) T.R.U.E. TEST Study Group. Comparative multi-center studies with T.R.U.E. TEST and Finn Chambers in eight Swedish hospitals. *J Am Acad Dermatol* 1989; 21:846-849.
- (3) Rühnek-Forsbeck M, Fischer T, Meding B, *et al.* Comparative multi-center study with T.R.U.E. TEST and Finn Chamber patch test methods in eight Swedish hospitals. *ActaDerm Venereol (Stockh)* 1988; 68:123-128.
- (4) Wilkinson JD, Bruynzeel DP, Ducombs G, *et al.* European multi-center study of T.R.U.E. TEST, Panel 2. *Contact Dermatitis* 1990; 22:18-225.
- (5) Rietschel RL, Fowler JF. *Fisher's contact dermatitis*, 5th ed., Lippincott Williams and Williams, Philadelphia, 2001.