

Bullous allergic reaction caused by colophonium in medical adhesives

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Colophonium (rosin, CAS no. 8050-09-7) is a complex mixture of > 100 different compounds derived from pine trees. It is a good tackifier, can be used as an emulsifier, and has acid properties without causing corrosion. Because of these properties, colophonium is used in various products, such as soldering fluxes, paper, cosmetics (depilatory waxes, soaps, hair gel, and nail polish), cutting fluids, insulation materials, and adhesives such as medical adhesives.

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Case Report

A 15-year-old atopic girl sprained her left ankle, which was thereafter fixated with Leukotape classic® and Klinidur Adhesive®. After several days, the patient reported at the Department of Dermatology with an itching, red, oedematous left ankle with vesicles and bullae up to 7 cm in diameter (Fig. 1a). Because of suspicion of allergic contact dermatitis caused by the medical adhesive, clobetasol ointment twice daily was prescribed. The bullous dermatitis gradually resolved within days.

Six weeks later, patch tests with our extended European baseline series, Leukotape classic® and Klinidur Adhesive® were performed with van der Bend chambers®, according to the International Contact Dermatitis Research Group criteria. After 36 hr, the patient removed the patches herself because of intense itching. Colophonium 20% pet. and both medical adhesives gave strong positive reactions at D3 (Fig. 1b) and D7.



Fig. 1. (a) Severe vesiculobullous dermatitis on the left ankle after the use of medical adhesives containing colophonium. (b) Patch test results on D3 showed strong positive reactions to medical adhesives.

Contact with the suppliers showed that colophonium was present in Leukotape Classic®, but the supplier of Klinidur Adhesive® denied the presence of colophonium. However, because of the severity of the allergic reaction and the positive reaction to Klinidur Adhesive®, we decided to contact the manufacturer for further product details. The manufacturer confirmed that colophonium was indeed a component of this product.

Discussion

Unmodified colophonium is a well-known sensitizer, and causes allergic reactions in 0.7–8.0% of the patients investigated with the European baseline series (1). It can be used in medical adhesives, although the current lack of product information makes identification of the presence of colophonium a time-consuming process for physicians and consumers (2).

According to EU legislation (EC) No. 1272/2008, colophonium is classified as an 'R43 chemical skin sensitizer' (3). Therefore, products containing > 1% colophonium

must be labelled with the risk phrase 'May cause sensitization by skin contact'. However, medical adhesives are excluded from EC No. 1272/2008, and are included in 93/42/EEC on medical devices (4). Therefore, the R43 restriction is not applicable, and suppliers may be unaware of the presence of colophonium in their medical adhesives. Meanwhile, these products are applied directly to the (often compromised) skin for prolonged periods under occlusion (5). These factors increase the risk of sensitization to components of medical adhesives. Therefore, we advocate the declaration of all well-known sensitizers in the product information of medical adhesives and restrictions on colophonium use.

This severe bullous allergic reaction stresses the importance of contacting manufacturers for product information instead of suppliers, and also indicates that there should be a strict legal requirement to label medical adhesives, even if only small amounts of colophonium are used.

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