

Distearyl phthalic acid amide, a new contact allergen

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Contact dermatitis of the scalp is usually caused by hair treatments such as dyes, conditioners, or other hairdressing products. Less often, it has been associated with the use of other chemicals (preservatives, emulsifiers, etc.) contained in hair-care products and cosmetics, and antifungals (1–4).

This report describes the first case of allergic contact dermatitis caused by distearyl phthalic acid amide, an additive used as an emulsifier in various toiletries and pharmaceutical preparations.

Case Report

A 46-year-old woman with seborrhoeic dermatitis was advised by her doctor to use Kelual DS shampoo (Pierre Fabre Ibérica SA, Barcelona, Spain). One day after using it, she had intense pruritus of the scalp, which she attributed to her seborrhoeic dermatitis. Two days later she used it again, and immediately developed erythema on the forehead and around the nose, with mild oedema. Over the course of the day the lesions spread to the scalp, face, neck, and chest, with a micropapular rash on the hands and forearms. The pruritus and dermatitis lesions were confined to the areas that came into contact with the shampoo. Subsequently, nodular lesions consistent with enlarged lymph nodes appeared behind the ears and in the cervical region. In the next few days, fine scaling developed in the affected areas, with eyelid oedema (Fig. 1).

Delayed hypersensitivity skin tests were carried out, following international guidelines (5), with TRUE

Test[®] allergens (Stallergenes Ibérica SA, Barcelona, Spain), sesquiterpene lactone mix, *N*-isopropyl-*n*'-phenyl-*p*-phenylenediamine, primin, hydroxyisohexyl 3-cyclohexene carboxaldehyde, and mercury (AllergEAZE, Martí Tor Laboratories SA, Barcelona, Spain). The results were all negative. An open application test performed with a sample of undiluted Kelual DS shampoo on the volar forearm gave a positive reactions at 48 hr, with erythema, oedema, and microvesicles. A corticosteroid cream was immediately applied, and the local reaction diminished. A request for the composition and ingredients of the shampoo was sent to Pierre Fabre Laboratories, and a sample of its 14 constituents was received (Table 1).

Patch tests were carried out with all 14 components of the shampoo, diluted according to de Groot recommendations (6). We applied the shampoo components on the patient's back, according to a standardized protocol, with Finn Chambers[®] mounted on Curatest[®] (Lohmann and Rauscher SA, Barcelona, Spain), for 48 hr, with full occlusion. After 48 and 96 hr, positive reactions were observed only to distearyl phthalic acid amide (number 11, +++; Fig. 2c). The skin tests were subsequently repeated with the shampoo components in a different order, as well as with some shampoo ingredients from a different source (polysorbate 20, methylisothiazolinone, quaternium-15, sodium lauryl sulfate, parfum mix, DMDM hydantoin, benzoic acid, ciclopirox olamine, polyethylene glycol and isopropyl alcohol; Martí Tor Laboratories and Ifidesa Aristegui SA, Madrid, Spain). Again, the only positive result was obtained with distearyl phthalic acid amide.

To rule out an irritant reaction to distearyl phthalic acid amide, further patch testing with lower concentrations was performed. After 48 and 96 hr, reactions were observed to distearyl phthalic acid amide 0.1% pet. (++) and 1% pet. (+++) (Fig. 2c). None of 5 healthy control individuals reacted to distearyl phthalic acid amide.

Finally, a use test with distearyl phthalic acid amide at 3%, 1% and 0.1% pet. was performed. After 48 and

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Fig. 1. Clinical presentation (itchy eczematous lesions on contact sites).

Table 1. Chemical name and concentration used for testing (%)

1.	Polyethylene glycol 7-glyceryl cocoate	20%
2.	Pyrithione zinc	2%
3.	Polysorbate 20	7%
4.	β -Glycyrrhetic acid	0.3%
5.	Acetamide MEA	2%
6.	Cetareth-60 myristyl glycol	3.5%
7.	Purified water	100%
8.	Coco-glucoside	5%
9.	Polyquaternium-10	0.25%
10.	Lauryl betaine	1%
11.	Distearyl phthalic acid amide	3%
12.	Ciclopirox olamine	1.5%
13.	Sodium laureth sulfate	18.5%
14.	Fragrance	0.3%

Shampoo components provided by Pierre Fabre Ibérica SA.

96 hr, positive reactions were observed, with substantial erythema, oedema, and microvesicles (covering the place of application), to the three concentrations, the reaction being most intense with the 3% concentration (Fig. 2a,b).

Discussion

Distearyl phthalic acid amide [chemical name: benzoic acid, 2-(dioctadecylamino)carbonyl- (Fig. 3); CAS no. 87787-81-3] is an emulsifier and suspending agent for silicones, pyrithione zinc, selenium sulfide, etc. It provides uniform emulsification and suspension of active ingredients, increasing their stability even at high temperatures. In the current case, the patient clearly associated the first use of Kelual DS shampoo with a dermatitis reaction confined to areas that came into contact with the shampoo. Skin tests showed clearly that the shampoo component distearyl phthalic acid amide was the aetiological agent

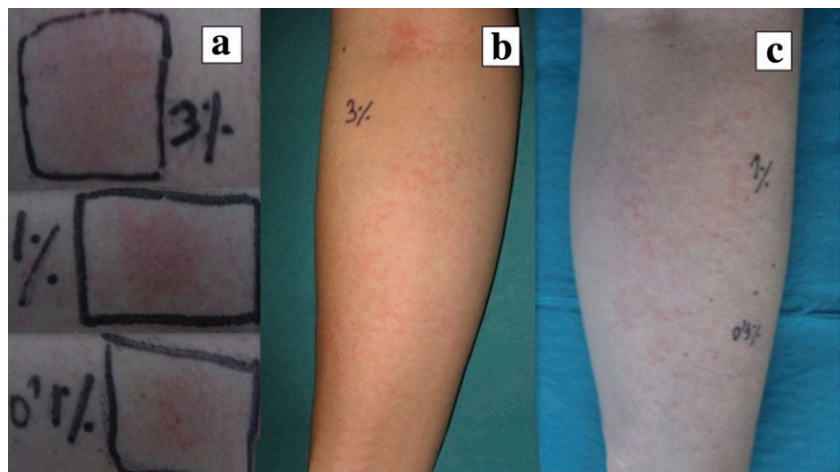


Fig. 2. Positive patch (a) and use (b,c) test results with distearyl phthalic acid amide at 3%, 1% and 0.1%.

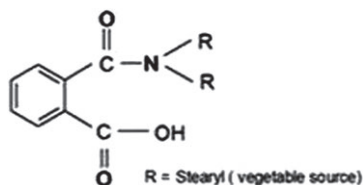


Fig. 3. Chemical structure of distearyl phthalic acid amide.

responsible for this reaction. The patient is completely sure that she did not use this shampoo before the reaction. For the past 20 years she had been using Pitiriasin[®], an anti-dandruff shampoo, to control her seborrheic dermatitis; this does not contain distearyl phthalic acid amide, so the primary source of the chemical causing the patient's sensitization is unknown to us. There is no reference in the literature to this chemical as a cause of

dermatitis, so the main conclusion from this study is that distearyl phthalic acid amide is a new causative agent of contact dermatitis. The patient was told not to use the shampoo concerned, or other products containing this chemical, and to check the composition of toiletries before using them.

This is the first report of allergic contact dermatitis caused by distearyl phthalic acid amide. As shown, the patient's specific products should always be considered for patch testing if contact dermatitis is suspected to be caused by constituents of, for instance, shampoos or pharmaceutical preparations.

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