The Role of Excipient Selection in Formulating Topical Therapies for Atopic Dermatitis

Atopic dermatitis (AD) is a common inflammatory skin condition characterized by pruritis, xerosis, and atopy that affects both the pediatric and adult populations. In AD, excipient mildness plays an essential role in topical formulation development due to the skin's predisposition to irritation and hypersensitivity.

The excipients of 57 topical formulations (20 moisturizers, 30 topical corticosteroids, 6 topical calcineurin inhibitors, and 1 topical phosphodiesterase-4 inhibitor) exemplifying the four recommended treatment modalities were identified and ordered based on frequency of occurrence. Studied dosage forms included: creams, lotions, gels, ointments, balms, foams, sprays, and solutions.

Ingredient	Frequency	Percentage
Water	38	66.67%
Petrolatum	31	54.39%
Glyceryl Monostearate	20	35.09%
Glycerin	19	33.33%
Mineral Oil	17	29.82%

Ingredient	Frequency	Percentage
Propylene Glycol	17	29.82%
Cetyl Alcohol	14	24.56%
Citric Acid Monohydrate	14	24.56%
White Wax	13	22.81%
Propylparaben	12	21.05%

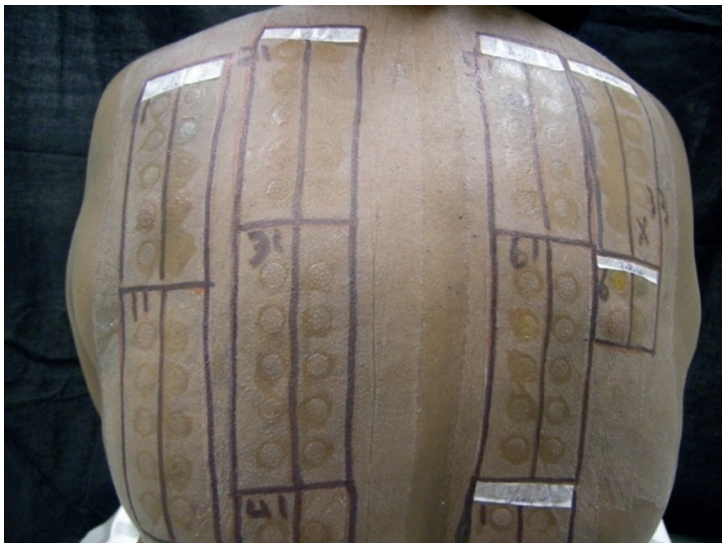
Results

A total of 204 different excipients were identified in the 57 formulations. The ten most frequently utilized excipients are shown in the list above.

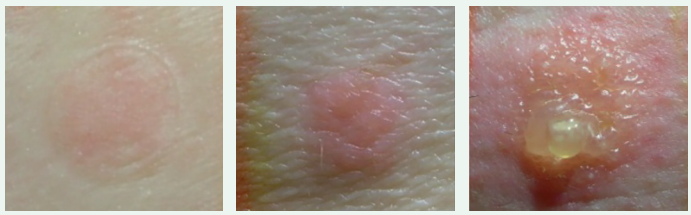
Due to the high predisposition towards hypersensitivity in AD patients, the excipient selection process requires unique considerations to minimize the risk of eliciting irritation and allergic reactions. Patch testing is considered the "gold standard" for evaluating contact dermatitis and can be used to identify irritants.

Method

Five hundred highly sensitive and allergic patients with a history of dermatitis of undetermined cause were patch tested to identify sensitivities or allergies to standard irritants and allergens. Chambers containing 35% BASF excipient dissolved in either water or petrolatum were applied to the skin for a duration of 48 hours and then removed. At 48, 72, and 96 hours post-application, the patched areas were scored on a scale of 1 to 3. The scoring method is described below.



Appearance after test period



1+: Erythema, induration or papules (palpable)
2+: Same plus larger papules or early vesicles
3+: Vesicular and/or spreading reaction

Scoring method

Product	Chemical name
Kollicream® 3C	Cocoyl Caprylocaprate
Kollicream® IPM	Isopropyl Myristate
Kollicream® OD	Octyldodecanol
Kollicream® CP 15	Cetyl Palmitate 15
Kollicream® PS 60	Polysorbate 60
Kollicream® PEG 300	Polyethylene Glycol 300
Soluplus®	Polyvinyl Caprolactam – Polyvinyl Acetate – Polyethylene Glycol Graft Copolymer

Results

The BASF excipients listed above were tested at a high concentration (35%) for a prolonged duration of time (48 hours) on highly sensitive patients. Of the 500 patients tested, none demonstrated any signs of irritation or allergenicity (score = 0). Patch testing can be used to optimize patient outcomes and compliance through the identification of mild and non-irritating excipients for topical formulation development.

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