〈原　著〉

揮発性物質を含む製剤の皮膚一次刺激性評価法
——河合法とクローズドパッチテストとの比較——

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Safety Evaluation of Cosmetic Products Contained Volatile Ingredients
— The comparison with closed patch testing and nitrocellulose-replica method —

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Abstract

Closed patch testing is performed as useful clinical evaluation method for skin irritation by cosmetics, topical medicaments, and their ingredients. However, volatile ingredients and cosmetic products containing them often cause severe erythema, edema, and bulla by closed patch tesing which inhibits the volatilization of materials. On the other hand, nitrocellulose-replica method as semi-opened system is able to detect detail morphological changes of skin surface by microscopic scoring against irritants without erythema. In this study, we validated nitrocellulose-replica method as safety evaluation method for volatile ingredients (three light liquid isoparaffins and two volatile silicones) and mascara models containing them. For evaluation of mascara models containing 30% volatile ingredient, the correlation coefficient between 24 h score of closed patch testing and nitrocellulose-replica method was 0.910. In nitrocellulose-replica method, the correlation coefficient between irritation score of 30% volatile ingredients in petrolatum and mascara models was 0.929. Irritation scores of volatile ingredients by nitrocellulose-replica method showed linear dose response. On the other hand, induction of erythema by closed patch testing needed more than 70% concentration. These results suggested that nitrocellulose-replica method is useful sensitive evaluation system without severe irritations for volatile ingredients and cosmetic products.

Key words: nitrocellulose-replica method, volatile ingredients, skin irritation, closed patch testing, semi-opened.