

〈技術報告〉

Kathon®CG – A Perspective in Sensitization

Jack N. Moss*

Summary

Kathon® CG biocide, a 3:1 mixture of 5-chloro-2-methyl-4-isothiazolin-3-one and 2-methyl-4-isothiazolin-3-one was introduced over 15 years ago as a broad spectrum biocide in toiletry and household products. These isothiazolines are also used as preservatives in industrial applications. Extensive toxicology studies have been conducted in animals and man. Like most preservatives, Kathon CG biocide produces delayed contact hypersensitivity in guinea pigs in a concentration dependent fashion. In human volunteers the threshold of sensitization was estimated to be 100 ppm, active ingredient in water. Recommended use levels range from 3-15 ppm a.i. in most applications. In Europe, wide country-to-country as well as clinic-to-clinic variation in sensitization prevalence rates ranging from less than 1% in the U.K. to over 6% in German and Italy have been reported. The causes of variation are not fully known but may be attributed to patient selection, relevance testing, misuse of preservatives. Recent reports from Finland and Italy suggest that prevalence rates may be decreasing. Unlike Europe the prevalence rates in U.S. determined through multicenter center studies, remains unchanged ranging from 1.7 to 1.9% during a 5-year period, despite a significant increase in the amount of Kathon CG biocide used during the same period. It is also noteworthy that preservatives such as formaldehyde, quaternium-15 and imidazolidynylurea show prevalence rates significantly higher than Kathon CG biocide. Most recently the U.S. Cosmetic Ingredient Review Panel concluded that Kathon CG biocide could be used safely up to 15 ppm a.i. in rinse-off products and up to 7.5 ppm a.i. in skin care products.