

Sodium Hydroxymethylglycinate

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Sodium hydroxymethylglycinate (SHMG) is a preservative used in many commercially available products, including shampoos, conditioners, soaps, moisturizers, body sprays, baby wipes, room sprays, cleaning agents, and pesticides. It is in a class of chemicals known as formaldehyde-releasing preservatives. Notably, members of this class have been associated with allergic contact dermatitis, possibly due to the agents themselves, the formaldehyde they release, or both. Studies on SHMG in animals have demonstrated potential for sensitization and dermatitis, and formaldehyde-allergic patients have been reported to improve when products containing SHMG are avoided. Patients and providers need to be aware of this preservative.

SODIUM HYDROXYMETHYLGLYCINATE (SHMG) is a clear pale-yellow liquid that is used as a preservative in many commercially available products. In the literature, it is also referred to as sodium hydroxymethyl aminoacetate, glycine *N*-(hydroxymethyl)-sodium salt, *N*-hydroxymethylglycine (mono) sodium salt, and also by the trade names Suttocide A (International Specialty Products, Inc., Wayne, NJ) and Integra 44 (Sutton Laboratories, Chatham, NJ). SHMG is a derivative of glycine and is thought to have antimicrobial activity against gram-negative and gram-positive organisms, yeasts, and mold.¹ Generally, it is used at concentrations of 0.1 to 0.5% and is a common ingredient in shampoos, conditioners, soaps, moisturizers, body sprays, baby wipes, room sprays, cleaning agents, and pesticides. SHMG belongs to a group of chemicals known as formaldehyde-releasing preservatives or formaldehyde donors.

SHMG in aqueous solution decomposes to sodium glycinate and formaldehyde. Available data describing the biodegradability of SHMG are limited because there has been difficulty identifying the compound under experimental conditions.² However, theoretically, given that one molecule of formaldehyde is formed by the decomposition of each molecule of SHMG, the total free formaldehyde content in a product containing 0.5% SHMG would correspond to 0.118%.² Studies have shown that levels as low as 200 to 300 parts per million (ppm) (0.02–0.03%) of

free formaldehyde in cosmetic products have induced dermatitis upon short-term use on normal skin.³

More than 35 formaldehyde releasers have been identified, but those most common in personal hygiene products include quaternium-15, imidazolidinylurea, diazolidinylurea, dimethylol dimethyl hydantoin, bronopol, benzylhemiformal,⁴ and SHMG. These chemicals have all been shown through patch-test confirmation to be inducers of allergic contact dermatitis,^{4–6} with the exception of SHMG, which is not currently under patch-test investigation. However, as recently observed by Jacob and Hsu, formaldehyde-allergic children were noted to improve when they discontinued using children's personal hygiene products containing SHMG.⁷

In the United States, the reported rates of sensitization to formaldehyde, based on tertiary care center patch-test data, are consistently around 8 to 9%, whereas those for formaldehyde-releasing preservatives are on the rise.⁸ For example, as described by the North American Contact Dermatitis Group (NACDG), the rate of sensitization to quaternium-15 rose from 9.3% in the NACDG's 2001–2002 study period to 10.3% in the 2005–2006 period.^{8,9} In a study of 81 patients known to have formaldehyde-related contact dermatitis, 79% (64 of 81) were found to also be sensitized to formaldehyde-releasing compounds,¹⁰ indicating that it is important for patients in this population to avoid not only formaldehyde but formaldehyde-releasing agents as well.

In 2002, the European Union ruled that the maximum authorized concentration of SHMG that could be included in cosmetic products was 0.5% and determined that the evidence suggested a risk of low sensitization or no sensitization at this concentration.² However, it also stated that, because SHMG is a potential allergen according to maximization tests in guinea pigs, sensitivity to the compound could possibly develop if it becomes more widely

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used in cosmetic products.² Currently, there are no reported sensitization studies in humans regarding the use of this compound, but the Material Safety Data Sheet from Sutton Laboratories (Chatham, NJ) for SHMG states that SHMG causes moderate skin irritation and may cause an allergic skin reaction.¹¹ According to the Skin Deep Cosmetic Safety Database, 267 products currently contain this compound, whereas only 170 did in 2007.¹² In fact, SHMG is increasingly being used as a paraben replacement in products labeled “natural” or “organic.”¹²

The general public is often under the impression that products marketed as “natural,” “organic,” or “baby” are safe and nonallergenic. However, a recent review by Corazza and colleagues showed that up to 6.22% of patients have reported an adverse reaction to “natural” products.¹³

Given the increased use of SHMG and formaldehyde-releasing preservatives, an awareness of potential sensitization to these products, including SHMG, may be necessary. The European Union Cosmetics Directive stipulates that all finished products containing formaldehyde or substances that release formaldehyde must be labeled with the warning “contains formaldehyde” when the concentration of free formaldehyde in the finished product exceeds 0.05% by weight (500 ppm).² Unfortunately, given that standard objective testing of products for levels is unavailable, the amount of formaldehyde in these products cannot be readily determined. A recent independent study by The Campaign for Safe Cosmetics, reported in March 2009, tested 28 infant, baby, and child products and found that 23 (82%) of the products tested contained formaldehyde at levels ranging from 54 to 610 ppm. One product, Baby Magic Baby Lotion (Ascendia Brands, Inc., Hamilton, NJ), contained formaldehyde at levels that would trigger warning label requirements in Europe (more than 500 ppm, or .05%).^{2,14} This suggests a need for legislative directives, monitoring, and a reform of cosmetic policies. Because commercial patch testing for SHMG is currently unavailable, patients need to be aware of this formaldehyde source, as do physicians when trying to help formaldehyde-allergic patients select products and avoidance regimens.

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