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Undeclared Formaldehyde Levels in Patient Consumer Products: Formaldehyde Test Kit Utility

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Abstract

Formaldehyde allergic contact dermatitis (ACD) may be due to products with free formaldehyde or formaldehyde-releasing agents, however, assessment of formaldehyde levels in such products is infrequently conducted. The present study quantifies total releasable formaldehyde from “in-use” products associated with formaldehyde ACD and tests the utility of commercially available formaldehyde spot test kits. Personal care products from 2 patients with ACD to formaldehyde were initially screened at the clinic for formaldehyde using a formaldehyde spot test kit. Formaldehyde positive products were sent to the laboratory for confirmation by gas chromatography-mass spectrometry. In addition, 4 formaldehyde spot test kits were evaluated for potential utility in a clinical setting. Nine of the 10 formaldehyde spot test kit positive products obtained from formaldehyde allergic patients had formaldehyde with total releasable formaldehyde levels ranging from 5.4 to 269.4 μg/g. Of these, only 2 shampoos tested listed a formaldehyde-releasing agent in the ingredients or product literature. Subsequently, commercially available formaldehyde spot test kits were evaluated in the laboratory for ability to identify formaldehyde in personal care products. Chemical based formaldehyde spot test were more reliable than the enzymatic based test in identifying product releasable formaldehyde content. It is concluded that product labeled ingredient lists and available information are often inadequate to confirm the potential for formaldehyde exposure and chemical based spot test kits may have utility for identification of potential formaldehyde exposure from personal care products.

Keywords

Formaldehyde-Releaser; Formaldehyde; Allergic Contact Dermatitis; Formaldehyde Spot Test Kit

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Introduction

Formaldehyde, the American Contact Dermatitis Society (ACDS) 2015 allergen of the year, can be found as a preservative/antimicrobial in many consumer and industrial products. Formaldehyde may be added directly to the product, or released through addition of formaldehyde-releasing agents. Many chemicals are capable of releasing formaldehyde. Some common releasers include 1,3-dimethylol-5,5-dimethylhydantoin (DMDM hydantoin), imidazolidinyl urea, diazolidinyl urea and Quaternium-15. Groot et al. [1] identified 42 different formaldehyde-releasers from the literature, but noted that for 7 in that list "the data are inadequate to label them as such beyond doubt". In a recent study examining the prevalence of preservatives and reported rates of contact allergy using data derived from the Contact Allergen Management Program (CAMP) most of the formaldehyde releasers included in the search were among the top 20 preservatives found across all products [2].

The rate of decomposition to release formaldehyde is chemical species, matrix, pH, temperature and time dependent [3]. Thus, amount of free formaldehyde present in a product may not represent that dermally delivered or the bioavailable dose under usage conditions. This is further complicated by residence time/dermal contact of a product. Products can be crudely divided into "leave-on", "rinse-off" and "other" categories. Sun screens, topical medications, moisturizer creams and cosmetics are examples of "stay-on" products. "Rinse-off" products include shampoos, body wash, and hand soaps. The "other" category encompasses formaldehyde-releaser exposures that are incidental or variable with respect to contact time with the skin. Occupational exposure to cutting fluids, pesticides and hair styling products [4] containing formaldehyde-releasers as well as clothing [5, 6] may fall into the "other" category where exposure time is more variable.

The present study sought to determine the levels of total releasable formaldehyde associated with cases of contact allergy and the potential utility of formaldehyde spot tests (i.e. tests that can be conducted in the clinic) for semi-quantitative assessment of formaldehyde levels in such products. Two patients reporting to the University of San Francisco Dermatitis patch test clinic that were patch test positive toward formaldehyde provided products to the clinic that were potentially associated with their contact dermatitis. The products were initially screened in the clinic using the Serim® residual formaldehyde test strips. Products testing positive for formaldehyde at the clinic were sent to the National Institute for Occupational Safety and Health (NIOSH), Morgantown, WV for quantitative total releasable formaldehyde analyses by gas chromatographic-mass spectrometric analyses following derivatization with *O*-(2,3,4,5,6-pentafluorobenzyl)hydroxylamine (PFBHA) [7, 8, 9]. In addition, enzyme and chemical based formaldehyde spot test kits were evaluated for potential use for semi-quantitative formaldehyde measurement in personal care products.

Methods

Patient information, Patch Test and Initial Product Screening for Formaldehyde

Two patients that had presented to the clinic with widely scattered eczematous eruptions, that cleared upon treatment with 0.05% clobetasol cream, once a week for approximately 3

weeks were initially patch tested with the North American Contact Dermatitis Group Series utilizing the International Contact Dermatitis Research Group (ICDRG) methodology with readings at 48 and 96 h. To minimize the likelihood of false positives due to excited skin syndrome, confirmatory retest formaldehyde patch test were conducted in both patients with 1% and 2% formaldehyde solutions (Chemotechnique Diagnostics, Vellinge, Sweden) with the same results. No other clinically relevant reactions were observed. These 2 patients with 2+ patch test reactions provided personal care products that they felt may be the source(s) of their ACD. These products were initially screened at the clinic using a residual formaldehyde spot test strip product (Serim, Elkhart, IN) that is marketed to measure the concentration of residual formaldehyde after rinsing hemodialysis dialyzers and dialysate lines. Ten products that were Serim® formaldehyde spot test kit positive were then sent to the NIOSH chemistry laboratory for formaldehyde content quantification. At the clinic, the formaldehyde result was noted as positive or negative and the low reliability of the Serim® test for formaldehyde detection in personal care products was not known. Only those testing positive were forwarded to the NIOSH laboratory for quantitative analyses.

NIOSH Chemistry Laboratory Analysis

The 10 consumer products obtained by the NIOSH chemistry laboratory from the University of San Francisco Dermatitis clinic were stored at room temperature in the containers as received until analysis. Product samples included two different shampoos, a body wash, a fabric softener, a mosquito insect itch spray, a sunscreen, two brands of hydrocortisone cream (2.5%), and two brands of moisturizing lotion (Table 1). Several of the products were not received in their original containers and did not include the product content labels. In these cases product content was obtained by searching the internet for product brand specific content literature. In the study assessing the utility of various commercially available formaldehyde test kits, 8 products including shampoos, body washes, a hair conditioner and sunscreen were used to evaluate the formaldehyde test kits.

Laboratory Calibration Standards for formaldehyde quantification

Standard solutions (0.1, 0.2, 0.5, 1.0, and 10.0 ppm) of formaldehyde with and without addition of the internal standard (formaldehyde-^{13}C, d_2 solution, Sigma-Aldrich/Fluka, St. Louis, MO; 4.0 ppm) were made by adding aliquots of stock formaldehyde (37% in H_2O; Ultra Scientific, N. Kingstown, RI) to 25 mL of 18 MΩ cm DI H2O in 40 mL clear screw cap vials. To these vials, 100 μL of 250 mM *O*-(2,3,4,5,6-pentafluorobenzyl)hydroxylamine hydrochloride (PFBHA, Sigma-Aldrich/Fluka) was added and then shaken vigorously for 1 minute. Vials were then placed in a 70 °C water bath for 2 hours. After removing the vial from the water bath and allowing to cool to room temperature, 10.0 mL of toluene (Sigma-Aldrich/Fluka) was added to the vial. The vial was then shaken for 30 seconds and allowed to separate into a toluene layer and aqueous layer. 100 μL of the toluene layer was placed in a 2 mL autosampler vial with a 100 μL glass insert (Restek, Bellefonte, PA). 1 μL of the extract was analyzed by gas chromatography-mass spectrometry (GC/MS) (conditions described below). Each calibration concentration was analyzed in triplicate.

Consumer Product Sample Preparation and Procedure

Several mass amounts (100–800 mg) of each consumer product were initially analyzed by the PFBHA-GC/MS method to determine optimal mass with respect to PFBHA-formaldehyde recovery and detection and that optimal mass was then used for quantitative analyses. Each product was added to 25 mLof 18 MΩ cm DI H_2O in 40 mL clear screw cap vials with and without internal standard (4 ppm). To these vials, 100 μL of 250 mM PFBHA was added and then shaken vigorously for 1 minute. Vials were then placed in a 70 °C water bath for 2 hours. These vials were then treated according to procedure (described above) for the calibration standards. All samples were analyzed in triplicate, except for 3 products where sufficient sample was not available. Density was determined in triplicate for liquid products where sufficient sample was available by pipetting 1 mL of each using a positive displacement pipette onto a weigh boat on a tared laboratory balance. This allowed for reporting the results on both a per mass and per volume basis.

Three chemical reaction based and one enzyme based formaldehyde spot test kits were assessed by comparison to the GC/CI-MS measurements. These were (1) Quantofix® Formaldehyde, Macherey-Nagel GmbH & Co., KG, (2) MQuant™, EMD Millipore Corp., Billerica, MA, (3) MColortest™, EMD Millipore Corp., Billerica, MA, (4) Serim® (enzyme based), Elkhart, IN. All test kit analyses were conducted according to manufacturer procedures on undiluted (neat) personal care products, on products diluted 6 fold with water, and undiluted products that had low or no formaldehyde after addition to a final 60 mg formaldehyde/L concentration. All but the MColortest™ are colorimetric test strip assays. The MColortest™ requires visual comparison of the color of the test solution to a color chart. Preliminary experiments found that dyes used in products interfered with direct color evaluation of the MColortest™ vials and thus further testing of this kit was not done. Only the 2 shampoos and the body wash supplied by the patients/clinic had sufficient sample volume to use in this part of the study. The remainder of the consumer products used to test the test strip kits were purchased off-the-shelf by the chemistry laboratory. None of these additional products listed formaldehyde or a known formaldehyde releaser on their labels.

GC/MS Analysis

All samples were analyzed using an Agilent (Santa Clara, CA) 7890B GC coupled to an Agilent 240 Internal EI/CI ion trap mass spectrometer. Samples were analyzed in both electron ionization (EI) and chemical ionization (CI) modes with liquid acetonitrile serving as the CI reagent. Compound separation was achieved by an Agilent (Santa Clara, CA) HP-5MS (0.25 mm I.D., 30 m long, 1 μm film thickness) column and the following GC oven parameters: 40 °C for 2 min, then 5 °C min^{-1} to 200 °C, then 25 °C min^{-1} to 280 °C and held for 5 min. One μL of each sample was injected in the splitless mode with the injector temperature at 130 °C. The ion trap mass analyzer was tuned using perfluorotributylamine (FC-43). Full-scan mass spectra were collected in the *m/z* range 40–1000. A single peak was in the observed in the GC/MS chromatogram for the PFBHA-formaldehyde oxime and the PFBHA-^{13}C-formaldehyde-d_2 oxime (which co-eluted) at 15.6 minutes. The main ions (% relative peak height) from EI spectra of the PFBHA-formaldehyde oxime only are 81(2), 99(5), 117(10), 165(15), 181(100), 195(25), and 198(0.01). The main ions (% relative peak height) from EI spectra of the PFBHA-^{13}C-formaldehyde-d_2 oxime only are 81(4), 99(5),

117(15), 161(20), 181(100), 195(12), and 198(50). PFBHA-formaldehyde recovery from each sample was adjusted based on percent recovery of the 4 ppm formaldehyde isotope added using the 198 ion from of the PFBHA-^{13}C-formaldehyde-d_2 oxime. Quantification of amount of total releasable formaldehyde from patients' provided products was calculated using the 195 ion from sample analyses conducted in parallel with those in which the formaldehyde isotope had been added. Doubling of the derivatization time from 2 to 4 hrs at 70 °C did not increase the amount of measureable free formaldehyde from formaldehyde-releaser containing products suggesting the procedures employed were sufficient for complete hydrolysis of formaldehyde-releasers (data not shown). In the study for evaluation of the formaldehyde test kits, quantification of the formaldehyde was done from the CI spectra (GC/CI-MS) from isotopic dilution of the PFBHA-formaldehyde oxime 226 ion/ PFBHA-^{13}C-formaldehyde-d_2 oxime 229 ion.

Results

Table 1 list the results of analyses of products associated with the 2 formaldehyde ACD cases and assessed to be formaldehyde positive by the Serim® test kit at the clinic. Approximately 2/3 of the patient supplied products screened by the clinic using the test strips were negative and not forwarded to the laboratory for further testing. Patients were symptom and sign free when using test strip negative products. All products sent to the laboratory, except brand A moisturizing cream had measureable levels of releasable formaldehyde ranging from 5.4 to 269.4 μg formaldehyde/g product.

Table 2 is the formaldehyde test strip readings from the semi-quantitative test kits when undiluted products were assayed as compared to the GC/CI-MS analyses of formaldehyde content in the laboratory. Only sufficient material was available for the Shampoo brands A and B and the Body Wash A from the clinic supplied products for re-evaluation using the formaldehyde spot test kits. Samples from these had higher levels of formaldehyde than previously measured by GC-MS analysis of the PFBHA derivative (Table 1). This suggests a non-uniform chemical distribution within the product bottles since aliquots were taken directly from the top of the containers without mixing to better reflect how the products are used. The hair conditioner and sun screen were negative for formaldehyde by GC/MS. Only 2/6 of the formaldehyde containing products were labeled with a known formaldehyde releaser. Both the Quantofix® and MQuant® tests were in good agreement with the GC/MS analyses, although the sunscreen produced a gel when chemical-kit reagents were added to the undiluted product which made assessment of the test strip difficult. The Serim® kit greatly underestimated formaldehyde content of products with high (>100 mg/L) formaldehyde levels and was unable to detect formaldehyde in those with lower levels when tested in the NIOSH laboratory. Undiluted products with lower concentrations or no formaldehyde were spiked with formaldehyde to an added final concentration of 60 mg formaldehyde/L product (Table 3). After spiking, all products were spot tests positive, although Shampoo C required additional development time to read beyond just a "trace" level. Care must be exercised when increasing the development time as the wetted test strips discolor with time.

Table 4 is the formaldehyde semi-quantitative test kit assessment as compared to the GC/CI-MS analyses of formaldehyde content of diluted products (1 part products + 5 parts water). Products that had sufficient levels of formaldehyde to be within the spot test ranges were tested following dilution. The sunscreen was also tested following dilution to minimize the gel formation interference. With dilution, formaldehyde was now detected by the Serim® spot test, although levels of total releasable formaldehyde were still considerably underestimated.

Discussion

Assessment of contact allergy that is potentially from formaldehyde-releasing agents poses multiple challenges with respect to clinical relevance, exposure assessment and analytical chemistry aspects. The common assumption is that the contact allergy elicited by formaldehyde-release agents is at least partially due to the formaldehyde [1]. There are multiple lines of evidence that support this assumption including the observation that multiple, non-structurally related formaldehyde releasers may produce allergic contact dermatitis in formaldehyde sensitized individuals. Aalto-Korte et al. (2008), in a study of occupational contact allergy to formaldehyde and formaldehyde-releasers, reported that 79% of formaldehyde allergic patients reacted to formaldehyde-releasers and that reactions to formaldehyde-releasers in the absence of formaldehyde allergy was rare [4]. They did, however, observe patch test reactions to one or more of the formaldehyde-releasers included in their study in the absence of a formaldehyde (1%) patch test positive reaction. This may be attributable to either a false-negative formaldehyde patch test or to reaction to the parent compound or non-formaldehyde hydrolysis product. Commercially available formaldehyde-releaser patch test reagents are supplied in either petrolatum or water. Emeis et al. (2010) reported that the formaldehyde-releaser petrolatum preparations did not have free formaldehyde, while those supplied in aqueous solutions had free formaldehyde ranging from 0.03 to 0.29 % (w/w) with pH's ranging from 4.0–9.5 [10]. Both the patch test vehicle and pH may potentially alter the rate of formaldehyde evolution and bioavailable for skin protein haptenation. This further confounds attempts to compare potency and prevalence of patch test reactivity between formaldehyde and the various releasing reagents.

Several studies have identified additional hydrolysis products from formaldehyde releasers. (4hydroxymethyl-2,5-dioxo-imidazolidine-4-yl)-urea (HU), (3,4-bis-hydroxymethyl-2,5-dioxoimidazolidine-4-yl)-urea (BHU) were as major decomposition products in cosmetics from both diazolidinyl urea and imidazolidinyl urea [11, 12]. The authors suggested that patch testing with HU and BHU should be performed, but provided no data with respect to the allergenicity of these compounds. Kireche et al. (2010) reported that DMDM hydantoin was directly reactive toward amino acids, while the bronopol and methenamine breakdown products, bromoethanol and diaminomethane, respectively, were amino acid reactive [13]. Bronopol is a known contact allergen [14], and while we found no reports of diaminomethane allergy, diaminoethane (ethylenediamine) is a known contact allergen [15]. This suggest potential non-formaldehyde protein haptenation/allergic contact dermatitis products containing these formaldehyde releasers.

Hauksson et al. (2016) reported that 28% of the “rinse-off” cosmetic products (including soaps) with measurable levels of formaldehyde were labelled as containing either formaldehyde or formaldehyde-releasers [16]. The majority of the products assayed in the present study and found to contain formaldehyde were not all labeled as containing formaldehyde or one of the known formaldehyde releasing agents. Specifically, only the 2 shampoo labels indicated the presence of a formaldehyde-releaser (DMDM hydantoin). The fabric softener, moisturizer cream, mosquito insect itch spray and sunscreen were provided in labeled plastic containers by the clinic (although the brand of the mosquito insect itch spray was not indicated), but again such relevant information could not be found through a search of the product literature or on the product safety data sheets where brands were indicated. Thus, product labels and information are not always a reliable source for associating a specific agent to the patients contact allergy.

Similarly, it is difficult to determine the relevant analytical endpoint to assess allergenic risk from products that contain a formaldehyde-releasing agent. Many formaldehyde releasing agents may exist in equilibrium between the free and bound forms. Any perturbation to that system, such as addition of water, can alter that equilibrium. At present, the only method capable of truly measuring the level of free formaldehyde in a product is by nuclear magnetic resonance (NMR) spectroscopy, although to achieve sufficient sensitivity requires approximately 15 hrs of instrument time per analyses [17]. The relevance of free formaldehyde within a product is greater for “rinse-off” products. Skin contact to “rinse-off” products may range from 20 seconds (hand washing) up to 30 min (some hair conditioner applications), although such applications usually involve immediate addition of water or application of product to wet surfaces and at somewhat elevated temperatures. Lv et al. (2015) reported that upon addition of water formaldehyde release can occur quickly, especially with in the 1st hour, which suggest that the level of free formaldehyde within the neat product may have little relevance with respect to total formaldehyde exposure from application of even “rinse-off” products [3].

Other analytical methods have been used to assess free and total releasable formaldehyde within products. These have been reviewed by de Groot et al. (2009) [1]. The acetylacetone and chromotrophic acid semi-quantitative colorimetric methods are often used as spot test for formaldehyde. Both are measures of total releasable formaldehyde. Gryllak-Berger et al. (1992) compared both of these methods to a high performance liquid chromatographic method (HPLC) of 2,4-dinitrophenylhydrazine (DNPH) derivatized formaldehyde [18]. Both of these colorimetric methods are subject to false positive findings from potential nonspecific discoloration by other aldehydes, oils or polysorbates. The formaldehyde-DNPH reaction is run for 3 min before stabilization and thus is a closer estimate of free than of total releasable formaldehyde.

Here we assessed the total potential releasable formaldehyde (free + bound formaldehyde). Although measurement of aldehydes following PFBHA derivatization is not uncommon, this methodology had not been previously evaluated or optimized for personal care product formaldehyde assessment as in the present study. Use of the formaldehyde isotope allows for direct determination of and adjustment for recoveries from the various products. Recoveries vary dependent on the product matrix and in general, decreased with increased product mass

added to our derivatization/extraction assay. The GC-MS method confirmed the presence of residual formaldehyde for all of the products tested by the Serim® test kit at the clinic except for the moisture cream suggesting that this was a false positive screening assay result. The Serim® test strip kit is based on an enzyme based oxidation of formaldehyde to formate, presumably thorough a formaldehyde dehydrogenase. Assay specificity would be dependent on the enzyme substrate specificity with potential interferences, both positive and negative, from other aldehydes and alcohols. A major advantage to the present GC-MS methodology is that low levels of formaldehyde can be accurately measured. For example the mosquito insect itch spray contained only 5.4 ppm total releasable formaldehyde.

A limited, preliminary evaluation of 4 commercially available formaldehyde test kits was conducted to test for their ability to semi-quantitatively measure total potential releasable formaldehyde from personal care products. Product color interfered with reading test color change of the reaction solution from the MColortest™ kit. Formaldehyde levels were assessed on test strips in the other kits and product color did not interfere with visual color change reading of the strips. Both the Quantofix™ and MQuant™ tests are based on formaldehyde chemical reactions, while the Serim® kit is enzyme based. Quantofix™ and MQuant™ results, in general, were in fairly good agreement with the GC-CI-MS laboratory based formaldehyde analyses of the products. The enzyme based assay consistently underestimated releasable formaldehyde. It is possible that the product matrix interfered with the enzyme structure and/or activity. The present study did not attempt to assess all commercially available formaldehyde spot test kits. Comparison of the test strip color change to the provided color charts is subject to variation in interpretation between test strip readers, but this was not evaluated. Potential interference from other preservatives, including other aldehydes was not assessed.

There are several limitations to the present study that need to be noted. Products were stored in both the clinic and the laboratory until analyses could be conducted. Potential loss of formaldehyde with storage may have occurred, especially at the product/air interface. Aliquots for analyses were taken from the top portion of each product (the portion next to be dispensed under normal use) and potential formaldehyde/formaldehyde releaser distribution within each product may have been non-uniform as indicated by the increased formaldehyde readings in aliquots assayed further down from the top of the bottles for Shampoo A and B. The clinic did not retain products that they assessed to be Serim® assay negative. In light of the high false negative results subsequently observed for that assay it is possible these products may have also contained formaldehyde/formaldehyde releasers. As discussed above it is not possible to assess the degree of allergenic hazard of a product from the present study as that would depend on how the product is used (“leave-on” or “rinse-off”), the level of free formaldehyde and how quickly formaldehyde is released from the formaldehyde releaser to the free form during use.

Recent years have seen a decreased usage of methylisothiazolinone (MI) as a preservative for aqueous components used in the production of a manufacturer’s final product. It is suspected that the high frequency of MI ACD may be influencing companies to substitute other preservatives in place of MI (and methylchloroisothiazolinone, MCI), including substitution with a formaldehyde releaser. Confirmation of the presence of a known or

suspected allergen/proallergen from products associated with ACD is essential for patient disease management and although the utility of semi-quantitative chemical reaction-based spot test may have value, this remains an area where greater manufacturers' cooperation is needed.

The present study demonstrates the utility of the of the PFBHA-formaldehyde GC-MS method for laboratory quantification of low levels of total releasable formaldehyde from consumer products, and potential utility of chemical reaction based spot test formaldehyde kits for use in either the laboratory or clinic. In agreement with that previously reported (11), less than a quarter of the products containing formaldehyde/formaldehyde-releasers were indicated as such by the label or product literature. This necessitates chemical analyses of products to provide such associations with outbreaks of ACD in formaldehyde sensitive patients.

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Table 1.

Total Potential Formaldehyde Content by GC/MS from “In-Use” Patient Supplied Products Associated with Formaldehyde Allergic Contact Dermatitis

	Formaldehyde (μg/g) ± SD	**Density[2] (g/L)**	**Formaldehyde (mg/L)**
Shampoo A	117.0 ± 2.2	1.006	117.7
Shampoo B	117.0 ± 17.1	0.986	115.4
Body Wash A	21.7 ± 2.3	1.004	21.8
Fabric Softener	16.8 ± 1.3	1.009	17.0
Moisturizing Cream A	Not detected or N.D.		
Mosquito Insect Itch Spray	5.4 ± 0.2	0.849	4.6
2.5% Hydro cortisone Cream A	11.7 ± 2.5		
2.5% Hydro cortisone Cream B	24.1		
Sunscreen A[1]	269.4		
Moisturizing Cream B	24.4		

All are from duplicate or triplicate GC/MS measures except for the last 3 where only sufficient material was available for a single determination. All results were adjusted for recovery of labeled formaldehyde (ion 198 count from standard vs. addition to product) from the preparation. Recoveries ranged from essentially 100% to 50% (the sunscreen had low recovery).

[1]Product was received in a desiccated state by the laboratory possibly causing an over estimation (on a per mass basis) of that for the product at the time of use.

[2]Densities were determined only on liquid products to allow for conversion from formaldehyde mass/product mass to formaldehyde mass/ product volume.

Table 2.

Laboratory Evaluation: Formaldehyde Test Kit Strip[1] reading from Undiluted Products as Compared to Total Releasable Formaldehyde GC/CI-MS Analyses.

Product	Quantofix Range: 0–200 mg/L	MQuant Range: 0–100 mg/L	Serim Range: 0, Trace-5 mg/L	Total Releasable Formaldehyde GC/CI-MS mg/L
Shampoo A *#	>200	>100	2.5	260.0
Shampoo B *#	>200	>100	Trace	186.1
Shampoo C	10	10	0	8.1
Body Wash A #	20	40	0	33.6
Body Wash B	40–60	60	0	74.9
Hair and Body Wash	10	10	0	2.1
Hair Conditioner	0	0	0	0
Sunscreen B[2]	?	?	0	0

[1] Product color/composition interfered with reading the color change in the MColortest™, hence, could not be used.

[2] Sunscreen gelled upon addition of the sodium hydroxide kit reagent

* Product content label indicated a known formaldehyde releaser

Shampoo A, Shampoo B and Body Wash A were supplied by the patients/clinic.

Table 3.

Laboratory Formaldehyde Test Kit Strip Readings from Undiluted Formaldehyde Spiked Products

Product[1]	Quantofix (mg/L)	MQuant (mg/L)	Serim (mg/L)
Shampoo C	≥ 60	60	Trace[2]
Hair and Body Wash	≥ 60	60	>5
Hair Conditioner	≥ 60	60	>5
Sunscreen B	≥ 60	40–60	>5

[1] Products were spiked with an addition of 60 mg formaldehyde/L.

[2] Increasing the reaction time from 2 to 5 min resulted in a reading >5

Table 4.

Laboratory Formaldehyde Test Kit Readings of Personal Care Products Diluted 6 Fold With Water vs. Total Releasable Formaldehyde Content

Product	Quantofix (mg/L)	M Quant (mg/L)	Serim (mg/L)	Total Releasable Formaldehyde GC/CI-MS (mg/L)
Shampoo A	40	40	2.5	43.3
Shampoo B	10–20	20	Trace	31.0
Body Wash B	0–10	0–10	Trace	5.6
Body Wash C	10	0–10	Trace	12.5
Sunscreen B	0–10	0	0	0