

Formaldehyde Release From Personal Care Products: Chromotropic Acid Method Analysis

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Background: Preservatives such as formaldehyde and formaldehyde releasers (F/FRs) are found in personal care products. Studies from Europe and Israel have indicated that products with undeclared F/FRs on product labels may have detectable levels of formaldehyde.

Objective: The aim of the study was to determine the presence of formaldehyde in samples of US personal care products.

Methods: Fifty-four baby and adult products were tested with the chromotropic acid method. A blinded investigator graded the color change as mild, moderate, or strong.

Results: All 8 products declaring F/FRs resulted in a deep purple color change, indicating a strong reaction. Of the 46 products with undeclared F/FRs, 4 (8.6%) were found to release formaldehyde. All 4 resulted in a light purple color change, indicating a mild reaction.

Conclusions: Overall, 4 of 54 products (7.4%) had label information, which did not match chromotropic acid method testing results. Clinicians and formaldehyde-allergic individuals should be aware of the limitations of product ingredient labeling in managing allergic contact dermatitis to formaldehyde.

Formaldehyde is a naturally occurring organic compound present in the Earth's atmosphere and in living organisms.¹ Formaldehyde is used in a wide variety of industrial applications including production of resins, plastics, plywood, and building materials. It is also found in consumer items such as permanent-press clothing. Aqueous solutions of formaldehyde are bactericidal and fungicidal. As such, formaldehyde and formaldehyde releasers (F/FRs), including bronopol, imidazolidinyl urea, diazolidinyl urea, quaternium-15, and dimethyloldimethyl hydantoin (DMDM) are excellent preservatives.

Because of these properties, F/FRs are commonly used in personal care products (PCPs) worldwide.² De Groot and Veenstra³ investigated the frequency of F/FR use in Dutch and US products. Of the 496 Dutch product ingredient labels reviewed, 122 (24.6%) were found to have either free formaldehyde or a formaldehyde releaser.

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Of the 8057 US products listed on the Food and Drug Administration Voluntary Cosmetic Registration Program Database, 1916 (23.8%) were found to contain F/FRs. The amount of formaldehyde released is affected by environmental factors such as pH, temperature, and age of product.⁴

Allergic contact dermatitis to F/FRs is well recognized.^{5–7} The North American Contact Dermatitis Group reported an 8.5% prevalence of positive patch test reactions to formaldehyde in patients undergoing patch testing for suspicion of allergic contact dermatitis; formaldehyde was the fourth most common allergen after nickel, methylisothiazolinone, and fragrance mix.⁸ Because, in part, of this high prevalence, formaldehyde was named the Contact Allergen of the Year in 2015 by the American Contact Dermatitis Society.⁹

The National Toxicology Program Report on Carcinogens recently categorized formaldehyde as “known to be a human carcinogen.”¹⁰ Because of the rising consumer concerns regarding carcinogenicity,^{11–13} many countries have regulated formaldehyde-related chemicals. Japan and Sweden have banned formaldehyde in cosmetics. In the European Union, upper limits for concentrations of F/FRs in PCPs are as follows: 0.2% formaldehyde, 0.1% bronopol, 0.6% imidazolidinyl urea, 0.5% diazolidinyl urea, 0.2% quaternium-15, and 0.6% DMDM hydantoin. Along with these restrictions, any product that contains more than 0.05% formaldehyde must be labeled with the warning “contains formaldehyde.”¹⁴ In the United States, the Food and Drug Administration requires that a list of all ingredients appear on the outer label of the product,¹⁵ but the concentration limit of formaldehyde in products is not required.

Several methods have been developed to detect the presence of formaldehyde. The chromotropic acid method is a semiquantitative

TABLE 1. Studies Involving Chemical Analysis of Formaldehyde in Personal Care Products

Study Author, Country of Publication, Year	Test Method	Total Products Tested	Products With Declared F/FRs		Products Not Declaring F/FRs		Details
			Positive Test	Negative Test	Positive Test	Negative Test	
Hauksson et al, ¹⁹ Sweden, 2015	CAM	245	32/58 (55.2%)	26/58 (44.8%)	26/187 (13.9%)	161/187 (86.1%)	Investigated F in 245 products brought in by patients
Gruvberger et al, ²⁰ Sweden, 1998	HPLC	88	34/NR	NR	1/NR	NR	Investigated 9 preservatives in 88 moisturizers. Overall, 10.2% had a preservative not declared.
Rastogi, ²¹ Denmark, 2000	HPLC	67	12/NR	NR	22/NR	NR	Investigated 23 different preservatives in 67 skin creams; overall, 45% (n = 30) labels were incorrect.
Horev et al, ²² Israel, 2015	CAM and HPLC	60	NR	3/NR	2/NR	NR	Twenty-two tested positive for F that did not declare formaldehyde. Investigated 60 products for formaldehyde, DMDM hydantoin, MI, and MCI/MI; overall, 10 were mislabeled (either direction; 16.7%); 3 had a preservative not declared; 7 declared but was not found on testing
Malinauskienė et al, ²³ Lithuania, 2015	CAM and HPLC	42	12/NR	NR	8/NR	NR	Investigated 42 products for formaldehyde; of products testing positive with no F/FR declared, 1 product released formaldehyde at 532 ppm by HPLC; 7 released <2.5 mg/mL by CAM.
Ham et al, ²⁴ United States, 2018	GCMS	10	2/2	0/0	7/8	1/8	Investigated 10 "in-use" products that were positive with clinic spot test. Nine products had detectable levels of F by GCMS; 2/9 declared F; 7/9 did not declare F.
Current study	CAM	54	8/8 (100%)	0/8 (0%)	4/46 (8.7%)	38/46 (92.3%)	7.4% of products had mislabeling for formaldehyde.

Abbreviations: CAM, chromatographic acid method; F/FRs, formaldehyde/formaldehyde releasers; GCMS, gas chromatography–mass spectrometry; HPLC, high-performance liquid chromatography; MI, methylisothiazolinone; MCI/MI, methylchloroisothiazolinone/methylisothiazolinone; NR, not reported.

colorimetric method used to detect the presence of formaldehyde release.¹⁶ It was first described in 1959 by Blohm¹⁷ and can be used to test a variety of products and materials, including PCPs. Briefly, chromotropic acid powder is dissolved in concentrated sulfuric acid, a clear solution (4 mg/mL). This solution changes color from clear to purple in the presence of formaldehyde. The chromotropic acid method can detect the presence of formaldehyde in as little concentration as 2.5 ppm and is widely used because of its simplicity and sensitivity. In some European patch test clinics, this method is routinely used to test patient products for the presence of formaldehyde.¹⁸

Although efforts have been made to regulate ingredient labels for PCPs, studies suggest that ingredient labels may not contain accurate information regarding the presence of certain chemicals, including formaldehyde (Table 1).^{19–24} The purpose of this study was to evaluate the release of formaldehyde from US products using the chromotropic acid method.

METHODS

This experiment was conducted at the Department of Dermatology Laboratory, University of Minnesota. Equipment and material collection began in July 2017, and the chromotropic acid method tests were conducted between December 2017 and February 2018.

PCP Selection

Test products were obtained from 2 sources: (1) the commercial retailer Target® and (2) skin care product samples from the dermatology clinic. Convenience sampling methodology provided a variety of lotions, creams, and cleansers. The primary investigator (A.N.) purchased approximately every 10th item on shelves from both the baby product and adult moisturizer areas of a local Target store. Additional products were also chosen to ensure that most brands on display had at least 1 representative product. Additional products were chosen so that at least 1 representative product of major brands of the 2 chosen areas was included. Skin care product samples were obtained from the Park Nicollet Contact Dermatitis Clinic. After collection, each product was labeled and stored at room temperature. If the product ingredients were not found on the container, an Internet search was conducted to retrieve ingredients.

Chromotropic Acid Method

Chromotropic acid disodium salt dihydrate and concentrated sulfuric acid (95%–98%) were purchased from MilliporeSigma (Burlington, MA). Each of these was stored with appropriate precautions in a dedicated acid storage cabinet.

Samples

For liquid test products, 1 mL of each PCP was measured into a 30-mL glass weighing bottle. For solid objects (eg, baby wipes), a 1 × 1-cm piece was cut out and placed in 1 mL of distilled water within a

30-mL glass bottle. One milliliter of formalin (formaldehyde 37% aqueous) and 1 mL of distilled water were placed into separate 30-mL glass weighing bottles as positive and negative controls, respectively.

Reagent

In the chemical fume hood, the chromotropic reagent solution was prepared by dissolving chromotropic acid powder into concentrated sulfuric acid at 4 mg/mL. A total of 0.5 mL of the reagent solution was pipetted into 1-mL glass vials. These small vials were left uncapped. A small vial containing the reagent solution was then placed in each of the 30-mL glass weighing bottles (containing the PCP samples). Each bottle was stoppered (Fig. 1), covered with aluminum foil, and left in the fume hood for approximately 48 hours.¹⁹

At 48 hours, the aluminum foil was removed and photographs of samples and controls were obtained at uniform distance and lighting. A separate investigator (E.W.), who was not involved in the laboratory procedures and was blinded to product names and ingredients, viewed photographs of samples and controls and graded the purple color changes as “mild,” “moderate,” or “strong” (Fig. 2). The slightest purple color change represented a product that released formaldehyde at approximately 2.5 ppm, and a strong purple color change represented a product that released formaldehyde at 40 ppm or greater.

For quality control, every 10th product was tested twice. In addition, testing was repeated for (1) any product with an unexpected or questionable color change and (2) all positives ($n = 3$). For



Figure 1. Front and back views of a 30-mL stoppered bottle with 1 mL of a product (in this case, distilled water as a negative control) at the base and an uncapped small vial containing a reagent solution.



Figure 2. Examples (from left to right) of products with mild, moderate, and strong formaldehyde release.

discrepancies in results between the first and second tests, subsequent retesting was performed to verify results.

RESULTS

Products and Labeling

A total of 54 PCPs were tested including lotions/creams/balms, skin cleansers, sunscreens, shampoos, conditioners, prescription creams, shave creams, and wipes; 19 (35.2%) were baby products, and 1 laundry detergent was tested (Table 2). Eight products (15%) were categorized as containing F/FRs. One product (a prescription scabicide) specifically listed formaldehyde; the remaining 7 (soaps/cleansers and lotions/creams) declared DMDM hydantoin, quaternium-15, or diazolidinyl urea. Forty-six tested PCPs (85%) had no F/FRs declared as ingredients.

Formaldehyde Release From Products

All 8 products that listed F/FRs on the label resulted in a deep purple color change with the chromotropic acid method testing, indicating a strong reaction (Table 3). Of the 46 products that did not declare F/FRs, 4 (8.6%) were found to release formaldehyde. All 4 resulted in a light purple color change, indicating a mild reaction (Table 4). These 4 products were lotions/creams.

DISCUSSION

This single-blinded investigation of the release of formaldehyde from PCPs using the chromotropic acid method resulted in several important findings. First, it confirms that products declaring F/FRs

release formaldehyde; all 8 test products in this category had strong color change with the chromotropic acid method. Second, we found that 8.7% (4/46) of products that did not declare F/FR ingredients actually released detectable levels of formaldehyde. This has significant clinical implications.

Expected Results

It is not surprising that all of the PCPs in our study that declared F/FRs on the label resulted in strong positive results with the

TABLE 2. Tested Products

Tested Products	No. Tested
Type	
Baby products (n = 19)	
Soap/cleanser	10 (52.6)
Lotion/cream/balm	6 (31.6)
Sunscreen	1 (5.3)
Laundry detergent	1 (5.3)
Wipe	1 (5.3)
Nonbaby products (n = 35)	
Lotion/cream/balm	25 (71.4)
Soap/cleanser	4 (11.4)
Sunscreen	2 (5.7)
Shampoo	1 (2.9)
Conditioner	1 (2.9)
Prescription (Rx) scabies cream	1 (2.9)
Shave cream	1 (2.9)

Values are number (percentage).

TABLE 3. Chromotropic Acid Test Results for Products With Declared Formaldehyde/Formaldehyde Releasers**Personal Care Products (PCPs) With Declared Formaldehyde Releasers**

Study ID	PCP Category	Grade	Formaldehyde	DMDM Hydantoin	Quaternium-15	Diazolidinyl Urea
11	Soap/cleanser	Strong		X		
27	Soap/cleanser*	Strong			X	
40	Lotion/cream	Strong		X		
43	Lotion/cream	Strong		X		
50	Lotion/cream	Strong				X
54	Lotion/cream	Strong				X
55	Lotion/cream	Strong		X		
12	Rx scabies cream	Strong	X			

*Baby product.

chromotropic acid method. Although this is expected, some studies have noted negative results for formaldehyde analysis in products that declared F/FRs. Hauksson et al¹⁹ reported that 44.8% (26/56) of in-use products provided by patients that declared F/FRs did not actually have detectable formaldehyde on analysis. It is possible that formaldehyde evaporated during manufacture or patient use. In contrast, none of our products that declared F/FRs tested negative.

Unexpected Results

We found that 8.7% of the products (4/46) that did not list F/FRs on the label were positive on the chromotropic acid test. These findings are similar to other studies. Malinauskiene et al²³ tested 42 moisturizers on the Lithuanian market using the chromotropic acid method; 8 products that did not declare F/FRs were positive for formaldehyde. Using the chromotropic acid method, Hauksson et al¹⁹ tested 245 PCPs; a total of 52 (21.2%) were mislabeled (26 had undeclared F/FRs, and 26 declared F/FRs, which were not detected). Gruvberger et al²⁰ used high-performance liquid chromatography (HPLC) to test 100 different moisturizers on the Swedish market for 9 different preservatives, including formaldehyde; overall, 10.2% of tested products had a preservative that did not appear on the label. Horev et al²² used both the chromotropic acid method and HPLC to test 60 various PCPs on the Israeli market for free formaldehyde and for DMDM hydantoin; 3 products that declared DMDM hydantoin tested negative, whereas 2 that did not declare DMDM hydantoin tested positive. Recently, Ham et al²⁴ tested 10 “in-use” patient products; 7 of the 8 products that did not declare F/FRs had detectable levels of formaldehyde on gas chromatography-mass spectrometry. Rastogi²¹ analyzed 67 skin creams on the market in Denmark for formaldehyde, DMDM hydantoin, and isothiazolinones using HPLC and found overall that 16.7% of labels were incorrect (3 had an undeclared preservative, and 7 had declared preservatives, which were not detected). These findings underscore that incorrect labeling is not unique to F/FRs because many other preservatives including parabens, isothiazolinones, and phenoxyethanol have been detected on testing in products that are not labeled as such.^{20–22}

There are several possible explanations for formaldehyde presence in products with undeclared F/FRs. First, it is possible that manufacturers are not aware that their products contain formaldehyde. For example, formaldehyde could be present in 1 or more raw materials but not intentionally added as a preservative. Second, auto-oxidation and degradation of other ingredients may produce formaldehyde. Polyethylene glycol and surfactants can undergo these changes; heat and humidity can amplify this process.^{25–27} A review of the ingredients in our 4 products (Table 4) found a surfactant (glyceryl glucoside), but not polyethylene glycol. False-positive results have been reported with the chromotropic acid method for products containing aldehydes, oils, or polysorbates.²⁴ Two of the products with undeclared formaldehyde in our study contained a sorbate ingredient. It is also possible that formaldehyde may be released from the product packaging (melamine or carbamide-formaldehyde resin), thereby contaminating the product with this chemical.²⁸

Baby Products

In 2011, Johnson and Johnson¹² decided to remove F/FR ingredients from their baby products. Since that time, many other US companies have followed suit. Of the 19 baby products in this study, only 1 (a body cleanser) declared a formaldehyde releaser, quaternium-15. That product tested positive for formaldehyde release, as expected. None of the 4 products that did not declare F/FRs, which tested positive for formaldehyde release, were baby products.

Implications

It is unclear what concentration of formaldehyde is necessary to induce clinical allergic contact dermatitis; the threshold likely varies between individuals. The Cosmetic Ingredient Review Expert Panel has recommended that the concentration of formaldehyde not exceed 0.2% (2000 ppm) in US PCPs.² Studies have shown, however, that those patients already sensitized to formaldehyde may have clinical reactions to products that contain even lower concentrations of this chemical. Hauksson and colleagues¹⁸ conducted a controlled

TABLE 4. Ingredients of the 4 Positive Products With Undeclared Formaldehyde/Formaldehyde Releasers

Product Type	Product			
	A	B	C	D
	Cream	Lotion	Lotion	Cream
Ingredients				
1,2-Hexanediol			X	
Arginine hydrochloride			X	
Alanine			X	
Benzyl alcohol	X			
Bisabolol	X			
BHT		X		
<i>Butyrospermum parkii</i> (shea) butter			X	
Behentrimonium methosulfate				X
Carbomer				X
Carnitine			X	
Caprylic/capric triglyceride				X
Cetearyl alcohol		X	X	X
Ceteareth-20		X		X
Cetyl alcohol				X
Ceramide 1, 3, 6-II				X
Ceramide 3			X	
Cholesterol				X
Citrulline			X	
Dicaprylyl ether			X	
Dimethicone	X			X
Disodium EDTA				X
Glutamic acid			X	
Glycerin	X		X	X
Glyceryl glucoside			X	
Glyceryl monostearate		X		
Glycogen			X	
Histidine hydrochloride			X	
Hyaluronic acid				X
Isopropyl stearate	X		X	
Lactic acid	X		X	
Lanolin alcohol	X			
Lysine hydrochloride			X	
Magnesium sulfate	X			
Mannitol			X	
Microcrystalline wax	X			
Mineral oil	X			
Nylon-12			X	
Octyldodecanol	X			
Panthenol	X			
Paraben				X
Phenoxyethanol			X	
Polyglyceryl-2 dipolyhydroxystearate	X			
Polyglyceryl-3 diisostearate	X			X
Polyglyceryl-4 diisostearate/ polyhydroxystearate/sebacate			X	
Polysorbate 20				X
Potassium phosphate, dipotassium phosphate				X

TABLE 4. (Continued)

Product Type	Product			
	A	B	C	D
	Cream	Lotion	Lotion	Cream
Potassium sorbate			X	
Propylene glycol		X		
Phytosphingosine				X
Serine			X	
Simethicone		X		
Sodium chloride			X	
Sodium lactate	X		X	
Sodium lauroyl lactylate				X
Sodium PCA			X	
Sorbic acid		X		
Sorbitol solution		X		
Sucrose			X	
Threonine			X	
Urea	X		X	
Water	X	X	X	X
White petrolatum		X		
Xanthan gum				X

BHT, butylated hydroxytoluene; PCA, pyroglutamic acid.

study of 15 formaldehyde-allergic individuals with repeated open application tests on experimentally induced sodium lauryl sulfate dermatitis for 4 weeks with 4 different moisturizers, which released various amounts of formaldehyde (high, medium, and low). Nine (60%) had reappearance or worsening of dermatitis on the test areas; 4 of those reacted to the moisturizers with the lowest concentration of formaldehyde.¹⁸

The major clinical implication of this study is that products that do not declare F/FRs may still release formaldehyde. Although products in this category from our study had a mild color change on chromotropic acid method testing, this low level may be sufficient to elicit allergic contact dermatitis in sensitized individuals. This is an important issue to consider in managing patients with an F/FR allergy who do not clear with usual product label-guided avoidance measures. These patients may need to attempt a few different product lines before successfully finding products that do not cause a flare in their dermatitis, because those products considered “safe” may not actually be so.

Limitations

This study has several limitations. First, the chromotropic acid method is semiquantitative. We used a visual grading system to categorize formaldehyde release as mild, moderate, or strong. In addition, product selection was not truly randomized; the convenience method used to collect test samples of PCPs was designed to provide a broad representation of products. Finally, although this study was conducted in Minneapolis, Minnesota, and major brand products are unlikely to vary greatly in different regions of the United States, ingredients could vary greatly in different countries.

CONCLUSIONS

This study found that 4 of 46 products (7.4%) that did not declare F/FRs had detectable formaldehyde by the chromotropic acid method testing. Clinicians and formaldehyde-allergic individuals should be aware of the limitations of product ingredient labeling in managing allergic contact dermatitis.

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