

SECRET SCENTS

For _____ DATE _____

Rx

Disclose
fragrance
ingredients

M.D.

DISPENSE AS WRITTEN

**HOW HIDDEN
FRAGRANCE ALLERGENS
HARM PUBLIC HEALTH**



**WOMEN'S VOICES
FOR THE EARTH**

OUR HEALTH. OUR FUTURE. TOXIC FREE.

FEBRUARY 2013

SECRET SCENTS

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Fragrance affects us all. For some, it can enhance a moment, invoke a memory, or even improve a mood. As consumers, we seek it out in all kinds of products we use in our everyday lives. And for many of us, there's a positive sensory experience associated with fragrance. But unfortunately, this may not be without consequence. In addition to the potential health consequences of certain fragrance ingredients linked to cancer, interference with hormones, and reproductive harm, a significant portion of the population suffers from fragrance-related allergies.

Almost 20% of the general population is sensitized to at least one allergen,¹ and studies find that fragrance is one of the most frequently identified substances causing allergic reactions.² Fragrance allergy affects 2 to 11 percent of the general population.^{3,4} This translates to tens of millions of people globally affected by fragrance. Women are disproportionately impacted by fragrance allergies, and the rates in children have been rising dramatically in the last few decades.^{5,6}

Yet, affected populations are kept in the dark by the fragrance industry, which keeps fragrance ingredients a secret because they claim that it will hurt their competitive edge if the information is released. This policy of secrecy has a two-fold effect on public health: it makes fragrance allergy both harder to diagnose *and* harder to treat. For example, a person may be able to identify a fragranced product that causes their allergy, but it becomes overwhelmingly complex without ingredient information for the health care provider to identify which ingredient in the product might actually be causing the allergy. Even when a health care provider has identified the ingredient to which a patient is allergic, it can be almost impossible for the patient to avoid the allergen in a household product because fragrance ingredients, including known allergens, are usually not disclosed on product labels or websites. Allergy patients are left with the unfortunate and extraordinarily limiting option of attempting to avoid all fragranced products.


Thus, the lack of information on ingredients in fragrance is a major public health problem. Allergic patients routinely suffer unnecessarily and incur significant health costs associated with those allergies. Disclosing fragrance ingredients, including those ingredients which have been identified by scientific bodies as allergens, is an imperative step that could have a significant global health benefit. The fragrance industry is opposed to this approach and has maintained the need to keep fragrance ingredients a secret from the public. While the sector claims that secrecy is vital to their business model,⁷ it is an unconvincing argument. Current technology allows for highly sophisticated reverse engineering of fragrances, a common practice of fragrance formulators and their competitors.⁸ Thus, if a company's competitor can correctly identify the majority of fragrance ingredients, it stands to reason that the next step would be to disclose them to consumers who really need the information to protect their health.

The solution is simple: Fragrance ingredients, including allergens, should be disclosed to consumers to allow them to protect their health and avoid the substances they wish to avoid.

** This report focuses solely on allergy associated with fragrance. However, allergy is neither the only nor the most severe health problem caused by fragrance. While beyond the scope of this report, it should be noted that neurotoxic effects, respiratory effects, immune system impacts and others are all associated with fragrance and deserve greater investigation and attention than they have received.*

The solution is simple: Fragrance ingredients, including allergens, should be disclosed to consumers to allow them to protect their health and avoid the substances they wish to avoid.

What is Fragrance Allergy?



Fragrance allergy is a condition in which physical symptoms (rash, possibly breathing problems, etc.) are caused by exposure to a fragrance ingredient. The diagnosis of fragrance allergy includes both a) evidence of sensitization to a fragrance ingredient (commonly determined by a patch test conducted by a dermatologist to confirm the individual reacts to the substance), and b) a demonstration of a pattern of clinical relevance (i.e. demonstrable skin or airway symptoms) following exposure to substances containing the fragrance ingredient.⁹ Skin symptoms can include red bumps, itchiness, redness and blisters on the skin. Fragrance allergy most commonly manifests on the hands, face, lower legs and feet, and can also occur in the armpits from specific exposures such as use of deodorant.¹⁰ Respiratory effects from fragrance allergy have also been documented, although more research is still needed to better understand the mechanisms for these effects. Fragrance allergy can occur as occasional flare-ups or can manifest as an ongoing chronic condition. In very rare cases,

extremely acute reactions, such as anaphylactic shock, have occurred due to fragrance exposure.^{11,12}

What is Fragrance Sensitization?

Not everyone reacts the same way to exposure to fragrance. Before one becomes allergic to fragrance, one must first become sensitized to a fragrance allergen. Sensitization can occur when a person is exposed to a profound level of a sensitizing fragrance allergen, or is exposed repeatedly to a fragrance allergen resulting in meeting their own pre-set

People are allergic to specific fragrance allergens, not to “fragrance” in general. A fragrance can be made up of hundreds of different chemicals. Imagine having a food allergy and being told nothing more specific than “you are allergic to food.”

Fragrance allergy and its related symptoms have many different names in the literature including allergic contact dermatitis, eczema, rash, etc. In this report, the term “fragrance allergy” is used to indicate sensitization and elicitation following exposure with clinically relevant symptoms. “Fragrance sensitization” is used when referring simply to a positive patch test, without further evidence of clinical relevance.

biological threshold for tolerance to that chemical. When a person's threshold is met, this causes a change to the person's immune system. Consequent exposures to the allergen can result in an immune response, which can manifest as a rash or other symptoms. Once sensitized, a person will react to the fragrance allergen at considerably lower exposure levels than a person who is not sensitized. Unfortunately, sensitization is a lifelong burden. Once sensitized to an allergen, a person is sensitized for life. With repeated and compulsive avoidance of the allergen, a person may become less reactive, but the condition cannot be reversed. The only option to prevent allergic reactions, once sensitized, is to avoid the allergen in question.



Fragrance allergens are commonly found in a variety of scented products.

Common Fragrance Allergens

Fragrances are incorporated into many consumer household products, from cosmetics, to cleaning products, to children's toys. Fragrance can add a touch of glamour, instill a sense of well-being, or simply enhance the sensory experience of a product. Not surprisingly, manufacturers of household products have capitalized on consumers' desire for fragrance's effects, offering an ever-expanding array of products in new and exciting scents. In fact, the importance of fragrance to the marketing of household products has been so pronounced, that the use of fragrance ingredients in products has doubled since 1990.¹³ While fragrance can be vitally important to the appeal of a product, it usually comprises no more than 2% of a product's ingredients.

Not all fragrance ingredients are allergens. However, there are several commonly used fragrance ingredients that are known sensitizers.

Most common fragrance allergens used in cosmetic products¹⁴:

Geraniol: rose scent

Eugenol: spicy, clove-like aroma

Hydrocitronellol: floral aroma, suggestive of Lily of the Valley

A-amylcinnamal: jasmine-like scent

Cinnamal: floral scent

Isoeugenol: spicy, clove-like aroma

Some cosmetic product categories are associated with more cases of fragrance allergy than others. This is generally a result of product types with the greatest skin contact, combined with the highest concentrations of fragrance allergens.¹⁵

Most common cosmetic products associated with fragrance allergy:¹⁶

Deodorants

Colognes/Fine Perfumes

Lotions

Cleaning products also frequently contain fragrance, yet the scents may contain some different allergens than cosmetic products.

Most common fragrance allergens used in cleaning products:^{17,18}

Limonene: citrus scent

Hexyl cinnamal: floral aroma, chamomile

Citronellol: citrus/floral scent

Butylphenyl methylpropional: floral aroma

Linalool: citrus, orange, lemon scent

Geraniol: rose scent

Benzyl Salicylate: herbal balsam scent

Almost 20% of the general population is sensitized to at least one kind of allergen.

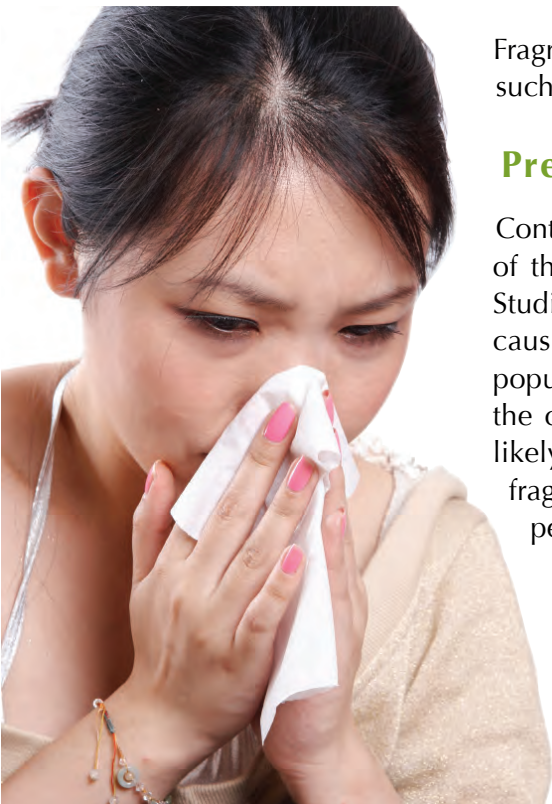
There is less data available on which types of cleaning products are most commonly associated with fragrance allergy. However, there have been documented cases of fragrance allergy associated with exposure to geraniol from dishwashing liquid and limonene from hand soap.^{19,20}

Fragrance allergens can also be found in flavorants in foods and in products such as incense used in religious ceremonies.²¹

Prevalence of Fragrance Allergy

Contact allergy is relatively common, with estimates of almost 20% of the general population having an allergy to at least one substance.²² Studies find that fragrance is one of the most frequently identified allergens causing sensitization. Estimates of fragrance sensitization in the general population range from 2% to 11% depending on the study.^{23,24} Due to the complexity in diagnosing fragrance sensitization, these estimates are likely underestimating the true number of people who are sensitized to fragrance.^{25,26} This means that in the United States there are millions of people, at least, sensitive to fragrance allergens.

Some epidemiological studies have focused on special populations, most commonly patients of dermatology clinics. These studies are looking at patients who have developed skin rashes or other conditions. Within this population, fragrance has been identified as one of the most common culprits. Approximately 10% to 15% of dermatology patients are diagnosed with fragrance sensitization.^{27,28,29}



HEALTH PROBLEMS ASSOCIATED WITH FRAGRANCE ALLERGY

Women's Health

Fragrance allergy has become disproportionately a women's health burden. Numerous studies have documented that women are two to three times more likely to suffer from fragrance sensitization than men.^{30,31,32} Studies also show that women become sensitized to fragrance at a much earlier age than men.³³ Women are most likely to be sensitized at ages 20-29 years, whereas men usually do not become sensitized until 50-59 years old.³⁴ While the reason for these disparities is not fully understood, the leading hypothesis is that the most likely cause is the disproportionate exposure by women to fragranced products.³⁵ Personal care products, perfumes, and scented cleaning products are all more likely to be used by women in greater quantities and with greater frequency than men. As sensitization is a permanent condition, the earlier sensitization leads to many additional years of allergy suffering for women. In addition, women's quality of life is more greatly impaired by fragrance than men's. Women are twice as likely as men to report adverse symptoms such as eye irritation and breathing problems from exposure to fragrance.³⁶ Fragrance allergy frequently manifests in symptoms on the hands. Women have more than twice the likelihood of hand eczema than men.³⁷ Women are also significantly more likely than men to report that fragrance allergy affects their life frequently, even daily.³⁸

Women working in occupations involving exposure to fragrance are at much greater risk of developing fragrance allergy. In a study of over 50,000 allergy patients in Europe, women-dominated occupations were significantly more likely to be associated with fragrance allergy. Massage therapists, cosmetologists, household workers and housewives were among the most common occupations of allergy patients with fragrance sensitivity.³⁹ Another study found that hairdressers, who are predominately women, frequently develop fragrance sensitivity.⁴⁰ In a study of female cleaning workers with contact dermatitis, fragrance was also found to be among the top substances causing their al-



Female-dominated occupations are significantly more likely to be associated with fragrance allergy, such as massage therapists, cosmetologists, household workers, and stylists.

Children are easily exposed to fragrance allergens in toys through skin contact, oral ingestion and inhalation. Concern about this exposure has led the European Union to ban 55 highly allergenic fragrance ingredients from use in toys and to require labeling for an additional 11 fragrance allergens.

lergy.⁴¹ One commonality of these women-dominated occupations is “wet work.” Wet work is work done with hands exposed frequently to water and detergents. This exposure alters the skin barrier on the hands, increasing the ability of hands to absorb other chemicals. Wet work has been shown to increase irritation as it can lower the thresholds of exposure that would normally cause irritation.⁴² Women doing wet work who have impaired skin barriers are thus even more vulnerable to the fragrance allergens commonly present in their work as well.

Children’s Health

Children have more recently been recognized to be impacted by fragrance allergy. There is significant exposure to fragrances in children’s products and young children’s skin is considerably more vulnerable than the skin of adults. Children’s skin is not fully developed until puberty, meaning it is thinner and absorbs chemicals more easily.⁴³ Children also have a higher ratio of skin surface area to body weight, so smaller exposures can have more dramatic impacts in children than in adults.⁴⁴

Reports show that allergic contact dermatitis in children was relatively rare thirty years ago but is currently diagnosed among children with regularity.⁴⁵ Beyond better recognition, one theory for this dramatic increase is that children now have greater exposure to potential allergens (such as fragrance), increasing the chance of sensitivity. Research has shown that the diagnosis of eczema in children has also been increasing worldwide in the last decade.⁴⁶ While the exact cause of this increase is unknown, it is concerning that studies show that children with eczema are commonly sensitized to fragrance. One recent study in the UK found that 18% of children

diagnosed with eczema were sensitized to fragrance, with girls having even higher rates of sensitization than boys.⁴⁷ In the U.S., the North American Contact Dermatitis Group study found 5.1% of children who were patients were sensitized to fragrance, and 4.1% of children demonstrated relevant fragrance allergy.⁴⁸

In addition to scented personal care products such as lotions and baby cologne, a fragrance source of concern to children is fragrance-infused toys and art supplies. Several studies have examined fragranced toys and detected substantial emissions of fragrance allergens.^{49,50} Examples of fragranced children’s products include stuffed animals, dolls, pencils, erasers



and markers. Children are easily exposed to fragrance allergens in toys through skin contact, oral ingestion and inhalation.^{51,52} Concern about this exposure has led the European Union to ban 55 highly allergenic fragrance ingredients from use in toys and to require labeling for an additional 11 fragrance allergens.⁵³

There have been some measures taken by industry to reduce fragrance allergens to levels below which sensitization should occur.⁵⁴ It appears these measures to prevent sensitization to fragrance may be failing, as large numbers of children today are still being sensitized to fragrance from their everyday exposures.

A Lifelong Problem

Fragrance allergy is a lifelong burden to the patient. While fragrance allergy might appear to be a mere nuisance from an outside perspective, it can actually have significant impacts on a person's quality of life. Hand eczema, for example, is a very common manifestation of fragrance allergy, particularly for women exposed occupationally or through housework at home. More than 70% of patients with hand eczema choose to seek professional medical care for their condition.⁵⁵ Twenty percent of hand eczema patients report requiring more than a week of sick leave from their jobs due to their condition, and ten percent of patients report leaving or changing their job as a result of their hand eczema.⁵⁶ Hairdressers particularly have higher rates of changing or leaving their jobs due to hand eczema than other occupations.⁵⁷ In a German study, 9.4% of chronic hand eczema patients had been hospitalized at least once as a result of their disease.⁵⁸ In a study on patients diagnosed with fragrance allergy, 17% reported taking sick leave from work as a result of their illness.⁵⁹ Even in less extreme cases, both the appearance of hand eczema (redness, rashes) and the frequent itching take an enormous social and emotional toll on a patient. An Australian study of eczema sufferers found 21% reporting that they were embarrassed by their skin and 28% said that their eczema influenced what clothes they wore.⁶⁰ In a Swedish study, 80% of hand eczema patients reported a disturbance to their social and emotional lives as a result of their condition.⁶¹ A study of patients diagnosed specifically with fragrance allergy also found that 45% reported that it significantly affected their daily living. Women reported this to be true more often than men.⁶²



Health care costs associated specifically with fragrance allergy have not been estimated. However, healthcare costs of eczema and contact dermatitis (both common results of fragrance allergy) are significant. In the United States, the costs to insurance companies and Medicaid for the treatment of contact dermatitis and eczema ranges from nearly \$1 billion up to \$3.8 billion per year. These annual costs are similar to the costs of other diseases such as emphysema and epilepsy.⁶³ Dermatitis and eczema patients routinely incur hundreds of dollars in out-of-pocket costs for the treatment of their condition each year.^{64,65,66}

DIAGNOSIS AND TREATMENT OF FRAGRANCE ALLERGY

The best practices for dermatologists caring for patients with fragrance allergy include taking a detailed environmental history to determine possible exposures, patch testing for suspected allergens, and educating their patients on avoidance strategies. Unfortunately, due to the proprietary nature of fragrance ingredients, practitioners are limited in their ability to assess and diagnose which specific allergens are of greatest significance. Occasionally, a patient can associate a reaction with a product, and generally they will then avoid the product. However, for those that cannot, health care providers are faced with determining which fragrance allergens are the problem and whether they are present in the product in question. Additionally, they are faced with finding an alternative product which does not contain the patients' allergens, a difficulty if the allergens aren't disclosed for the product.

Diagnosing the Problem

To screen for allergic reactions, dermatologists will commonly administer a series of patch tests to a patient that has developed an allergic rash. The patch tests are small skin exposures to a host of different potential allergens, each of which is marked. The patches that result in skin reactions thus identify the substances to which the patient is sensitized. With fragrance, the diagnosis is complicated by the limited number of specific fragrance ingredients available for testing compared to the vast number of chemicals used by the fragrance industry.



Furthermore, the patch test for fragrance allergies is frequently not done on individual fragrance allergens but is instead done on mixes of fragrance allergens, e.g. FM1 (Fragrance Mix 1). This mix contains eight common fragrance allergens found in many, but not all, fragrances. To complement this, a second fragrance mix (FM2) with a different mix of allergens may also be used. In some cases, a dermatologist may also conduct a follow-up patch test for individual fragrance allergens. The problem with this approach is that none of the tests will sufficiently identify all fragrance allergy patients, as many of the fragrance

chemicals are not contained in the Fragrance Mixes. Thus, the studies measuring how many people have fragrance sensitization routinely underestimate the true number.⁶⁷

Treating Symptoms

Dermatologists often characterize fragrance allergy and the resultant dermatitis as frustrating because the diagnosis is complex and the avoidance of fragrance allergens is extremely difficult.⁶⁸ If the allergic reaction has already occurred, anti-itch creams or ointments can provide some relief from symptoms. In more severe cases, antihistamines, corticosteroids or antibiotics may be prescribed to help reduce or control symptoms. However, these are only temporary solutions, as sensitization to fragrance is an irreversible condition, meaning the potential for reactions to reoccur is a lifelong problem.

Even these temporary solutions pose their own complications. Moisturizing lotion, for example, is commonly recommended to allergy patients to avoid dry skin conditions which can predispose to flare-ups. Lotions, however, routinely contain fragrance, including common fragrance allergens. In a 2008 study of more than 250 over-the-counter moisturizer lotions sold at a popular U.S. chain drug store, 83% were found to list “fragrance” or fragrance allergens among the ingredients.⁶⁹ Medical ointments requiring a doctor’s prescription can also contain fragrance allergens. A study examining a European database of ingredients in over 3,000 topical pharmaceutical products found that 10% of these products contained fragrance ingredients.⁷⁰ Further analysis of medical records was able to identify 48 specific topical pharmaceutical products which had been confirmed as the cause of contact dermatitis in dermatology patients.⁷¹

Avoiding Allergens

The best recommendation health care providers can make is to advise patients to avoid the fragrance allergens that cause the allergy. Yet, dermatologists and their patients are caught in a dilemma because information about fragrance allergens in products is simply not available.

The fragrance industry has long held trade secrets on fragrances, regardless of the potential health effects an ingredient may present. The components of any particular fragrance—which can consist of 100 or more chemicals—are rarely disclosed by manufacturers. Standard practice is simply to list the word “fragrance” or “parfum” among the ingredients in a product without describing the ingredients that make up that fragrance. This means



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that while a patient can be tested to determine which allergies are causing a reaction, they cannot determine which household products might contain the problem ingredient the patient is allergic to.

The American Contact Dermatitis Society offers a useful database to their members called CAMP, the Contact Allergen Management Program.⁷² The database allows health care providers to identify consumer products which do not contain contact allergens. It includes ingredient information from many major personal care products manufacturers. However, it is limited to simply identifying products which contain “fragrance” and does not provide more detailed information about which fragrance allergens are incorporated in the product. Thus, the patient must choose from the relatively few options for fragrance-free products.

Fragrance-free Products

Fragrance-free products do exist, but the market for them is very limited. Studies of currently available personal care products in the U.S. indicate that fragrance is included in the vast majority of many types of products.⁷³ For example, hair care products almost universally contain fragrance. Ninety-six percent of shampoos, 98% of conditioners and 97% of hair styling products contain fragrance.⁷⁴ Finding a fragrance-free hair care product that also meets the needs and desires of the fragrance-allergic patient can be exceptionally difficult without the disclosure of fragrance allergens. Other personal care products also routinely contain fragrance. Ninety-one percent of antiperspirants, 95% of shaving products, 83% of moisturizers, and 63% of sunscreens contain fragrance.^{75,76} Even make-up products which one might not think of as being scented also frequently contain fragrance. Ninety-one percent of lip moisturizers, 71% of lipsticks, 50% of foundations, and 1/3 of all blushes and eyeliners contain fragrance.^{77,78} The pervasiveness of fragrance in these products that consumers apply to their skin makes it extremely difficult to avoid.

Cleaning products are another major source of fragrance allergen exposure. While statistics on the prevalence of fragrance in cleaning products are not available, fragrance appears to be a major driver for innovation in the cleaning products industry.⁷⁹ Most products from dishwashing soap to laundry detergent to all purpose cleaners are marketed in a variety of scents to entice the consumer. And, naturally, air fresheners almost always contain fragrance. As a result, household product manufacturers purchase nearly 1/2 of all the fragrance sold globally.⁸⁰ As with personal care products,

there is almost no disclosure of fragrance allergens in cleaning products. The industry standard is merely to disclose the presence of “fragrance” on ingredient disclosure websites.⁸¹ Fragrance-free cleaning products do exist for most categories and brands. However, there is often only one fragrance-free option per product type in each brand.

This lack of fragrance ingredient information leads to the very real possibility that affected individuals are rejecting fragranced products they would enjoy and that would not cause any reactions for them, simply because they cannot distinguish them from problem products. In fact, one survey found that 45% of fragrance allergic patients are able to find some scented products they can tolerate.⁸² Unfortunately, the trial-and-error process for finding tolerable products is made much more difficult without the transparent disclosure of fragrance ingredients.

Lack of Information Hinders Healthcare

The failure of manufacturers to disclose fragrance ingredient information to their consumers, or even to health care providers, results in many people suffering from unnecessary exposures and suboptimal patient care by doctors. While the fragrance industry does address the need for dermatologists to have more information about fragrance compositions to aid in treating their patients with suspected fragrance allergy, the practical application of this policy tends to be onerous and time-consuming for the dermatologist.

Part of the Code of Practice of the International Fragrance Association (IFRA) states:

“It is IFRA Policy that the fragrance manufacturer, in cooperation with the consumer product manufacturer, respond promptly to requests for information from physicians treating patients who are suspected of having suffered adverse reaction to products containing fragrances.”⁸³

CAN FRAGRANCE CAUSE OR EXACERBATE ASTHMA?

While there is some scientific debate on whether fragrance can be termed an asthma-causing agent, research indicates that there is good reason for asthmatics to be concerned about exposure to fragrance.

Asthma patients routinely report experiencing respiratory symptoms such as chest tightness, trouble breathing, and wheezing in response to fragrance.¹⁰² Surveys of asthmatics also find that air irritants such as perfumes, sprays or intense odors are frequently cited as triggers of their asthma.^{103,104}

Several experimental studies exposing patients to perfumes have documented significant respiratory effects such as decreased lung function (FEV), increased chest tightness, shortness of breath, and coughing.^{105,106,107} Other studies conducted by fragrance industry researchers have found no significant respiratory effects from perfume exposure in non-asthmatics and mild asthmatics.¹⁰⁸ Fragrance exposure at work is also known to exacerbate occupational asthma.¹⁰⁹ Hairdressers and perfume salespeople, especially, appear to be at risk for exacerbations of asthma by fragrance.^{110,111}

Certainly more research is needed to better understand the biological mechanisms causing respiratory effects from fragrance exposure. Increased disclosure of fragrance ingredients would aid researchers in these efforts, as they could better characterize the exposures leading to respiratory symptoms. Meanwhile, avoidance of fragrance is strongly recommended for asthma patients that have identified fragrance as a trigger of their symptoms.

However, it is extremely difficult for dermatologists to actually get the information they need. The manufacturer sends samples of the fragrance (or fractions of that fragrance) to the dermatologist for patch testing on the patient. Gradually, by being sent multiple samples each containing pieces of the formula, the dermatologist can narrow down the suspected fragrance allergens of interest. The process generally requires multiple patient visits over a series of months or even years. Not surprisingly, IFRA admits that its member companies receive few requests from dermatologists for help with investigations of this kind.⁸⁴ It is simply too onerous and costly for the average practitioner to pursue. Even if successful, the results are not entirely useful to the patient. Knowing the specific fragrance allergen that causes the allergy is relatively meaningless if one is still unable to identify which products do not contain the allergen.

The simple act of disclosure of fragrance allergens in consumer products would aid both dermatologists and their patients in the diagnosis and treatment of their condition. In fact, disclosure of fragrance allergens is supported by the American Academy of Dermatology that issued a position statement which reads:

“The American Academy of Dermatology (AAD) supports identification of the common allergens of fragrances in all formulations of cosmetics, prescription and non-prescription drugs... The Academy believes that consumers should be provided with all of the product information that they need to make the best choices to protect their health. The addition of fragrance to a product, whether to enhance the appeal of the product or to mask an unappealing odor, creates an avoidable risk of irritant or allergic reaction to fragrance-sensitive persons.”⁸⁵



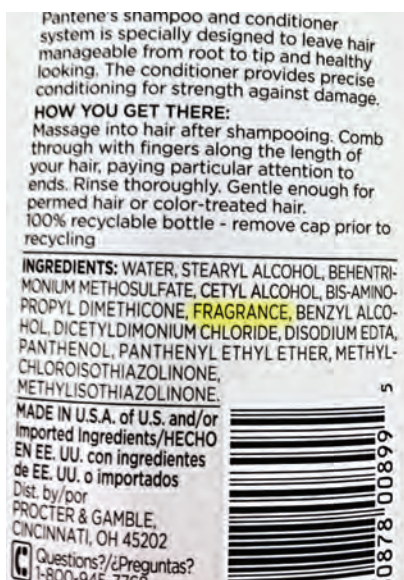
Requirements for Allergen Disclosure

In the European Union, cosmetics and cleaning products manufacturers are required to disclose the presence of 26 common fragrance allergens that occur above a threshold level in their products.^{86,87} This policy is a good start and has allowed European consumers, for the first time, the opportunity to avoid fragrance allergens of concern. However, the 26 allergens are not the only ingredients needing disclosure. In a 2012 scientific opinion, the EU Scientific Committee of Consumer Safety (SCCS) identified 82 substances commonly used in fragrance (which include the original 26) that are known contact allergens.⁸⁸ It seems appropriate that these substances should also be disclosed to the U.S. consumer, at a minimum.

Recently, personal care product companies in the U.S. have begun to disclose allergens. A review of a personal care products database discovered more than 200 personal care products companies and brands that are voluntarily disclosing the 26 EU fragrance allergens on the labels of some or all of their products.⁸⁹ Some major manufacturers such as Estee Lauder, Chanel, L'oreal, Bath & Body Works and others are leading the industry in voluntarily providing this important information about allergens to their U.S. customers (as they are already doing in Europe). Interestingly, the most common product category for allergen disclosure is fine fragrances. Fine fragrance manufacturers, which produce the most expensive scented products, arguably have the most to lose from the exposure of trade secrets due to the threat of counterfeiting. However, many fine fragrance manufacturers are choosing to voluntarily disclose the allergens in their fragrances in the U.S. Disclosing allergens in the perfume industry does not appear to result in any financial risks to these businesses. While the practice of disclosing allergens in personal care products is far from comprehensive, the precedent has been set that this practice is both feasible and acceptable to manufacturers.

Cleaning product manufacturers are lagging in allergen disclosure. Only a handful of cleaning product manufacturers offer product-specific allergen

U.S. Pantene® conditioner label (left) vs. E.U. Pantene® conditioner label (right).



In the E.U. manufacturers of household products are required to disclose the presence of 26 common fragrance allergens. Many of these companies make the same products in the U.S., but don't disclose allergens because it's not required by U.S. law.

disclosure on their products. Instead, some manufacturers have chosen to disclose their fragrance “palettes,” a long list of hundreds or even thousands of chemicals used in all of their fragrances, in any product. While these lists include allergens, the disclosure is not product-specific and therefore customers with allergies are unable to choose the products free of their allergens.

The Self-Regulating Fragrance Industry

The fragrance industry is largely a self-regulated industry, with few governmental regulations affecting their current operations and practices. Instead, the International Fragrance Association (IFRA), the fragrance industry’s main trade association and representative body, has taken on the role of self-regulation. IFRA claims that its primary purpose is “to ensure the safety of fragrance materials through a dedicated science program.”⁹⁰ This program is implemented by requiring that each IFRA member adopt a Code of Practice which includes usage restrictions on certain fragrance ingredients. The standards are based on research conducted and compiled by the self-described “scientific arm of IFRA,” the Research Institute for Fragrance Materials (RIFM). The research is then evaluated by RIFM’s independent expert panel of dermatologists, pathologists and toxicologists. While the panel may in fact be independent, they can only make decisions based on the information provided to them. Currently, the medical research on fragrance materials is largely conducted by RIFM or by the fragrance manufacturers themselves. In part, this is because these are the entities with the best access to the fragrance materials and the insight and knowledge of what needs to be studied. The essential problem with this form of self-

regulation is the inherent conflict of interest between the intent to establish safety standards and the potential financial effect of these standards on the fragrance manufacturers.

The lack of transparency in the use of fragrance ingredients makes it especially difficult for the independent researcher to create a useful and relevant research program to assess the health impacts of fragrance materials. Thus, the research is commonly conducted by researchers hired by companies that have a financial stake in the results. In addition, the data generated by RIFM and the manufacturers is usually proprietary and often unpublished.⁹¹

Only the conclusions of these research studies are available through RIFM’s publication of safety assessments of fragrance materials in peer-reviewed journals. The actual studies these safety assessments are based on are often unavailable to the public. This lack of scientific

The lack of transparency in the use of fragrance ingredients makes it especially difficult for the independent researcher to create a useful and relevant research program to assess the health impacts of fragrance materials.



transparency is problematic in that it makes replication and verification of findings difficult to obtain.

The fragrance industry's self-regulation has not served the public well. The lack of transparency in ingredients leads to skepticism, which is not assuaged by the industry's internally driven research and safety program. It is difficult to put one's trust of the safety of fragrance ingredients in the hands of those who are financially benefiting from the use of those same ingredients. Policies to regulate the industry from the outside are needed to protect public health from the potential health impacts of fragrance materials.

BESIDES ALLERGENS, WHAT OTHER HAZARDOUS CHEMICALS MAY BE FOUND IN FRAGRANCE?

The International Fragrance Association (IFRA) now publishes a list of all the chemicals used by their member companies in producing fragrance.⁹² The list contains over 3,200 different chemicals. Unfortunately, these fragrance chemicals are rarely, if ever, disclosed in ingredient lists of fragranced products, making each exposure to fragrance an unquantifiable health risk to consumers. Highlighted here are some notable hazardous chemicals included in the list.

Phthalates

There are two forms of phthalates, diethyl phthalate (DEP) and diisononyl phthalate (DINP). DINP is an endocrine disrupter, meaning it can interfere with the hormone system, and is linked to reproductive harm.⁹³ Exposure to DEP has been associated with decreased sperm counts and decreased anogenital distance in baby boys.^{94,95}

Carcinogens

There are ten chemicals that have been listed as reasonably anticipated to cause cancer in humans. These chemicals include: p-dichlorobenzene, pyridine, styrene, styrene oxide, methyl eugenol, acetaldehyde,

methyl isobutyl ketone, 2,4 hexadienal, titanium oxide and butylated hydroxyanisole.

Synthetic musks

Several synthetic musks are used in fragrance including galaxolide, tonalide and musk ketone. Research indicates that synthetic musks are persistent, can bioaccumulate, are potential hormone disruptors, and may break down the body's defenses against other toxic chemical exposure.^{96,97,98}

Disinfectants

Fragrance can also include harsh disinfectant chemicals like triclosan and ammonium quaternary compounds. These chemicals are linked

to endocrine disruption and asthma.^{99,100}

Unknown Hazards

Other chemicals on the IFRA list are of concern because they have little health and safety data associated with them. One report by the European Union Scientific Committee on Consumer Safety identified 39 fragrance ingredients used in high volumes which had no human safety data associated with them at all.¹⁰¹ Unfortunately, the fragrance industry has not publicly released information on how commonly any of these chemicals are used, how much of the chemicals they add to the products, or in which types of fragranced products they are found.



In order to address this problem, federal regulatory changes are needed. The following proposals for federal laws will include language to increase disclosure of ingredients in household products, or disclosure of health and safety information for these ingredients, thereby helping to protect public health.

Cleaning Product Right To Know Act

The Cleaning Product Right to Know Act (H.R. 3457), introduced in the 112th Congress, is a bill that will increase and improve ingredient disclosure in the cleaning products industry. Specifically, the

bill requires cleaning product manufacturers to list ingredients of cleaning products on the label. Importantly, all fragrance ingredients, including allergens, will be required to be listed.

Safe Cosmetics Act

The Safe Cosmetics Act (H.R. 2359), introduced in the 112th Congress, is a bill to improve regulation of cosmetic and personal care products to better ensure these products are safe for consumers to use. The bill requires cosmetic companies to disclose fragrance ingredients on product labels and company websites. The bill also requires safety testing and the phase out of ingredients linked to cancer, birth defects and developmental harm.

Safe Chemicals Act

The Safe Chemicals Act (S. 847), introduced in the 112th Congress, is a bill to update the current law regulating chemicals in U.S. commerce, the Toxic Substances Control Act of 1976. The Safe Chemicals Act will require all chemicals to be proven safe before they end up in products like household cleaners, furniture and children's toys. The bill will require the chemical industry to disclose essential information on health and safety data.

Undisclosed fragrance allergens are contributing to a significant public health problem worldwide. Millions of people are affected by fragrance, suffering rashes or breathing problems unnecessarily, with limited ability to prevent their allergic symptoms. Disclosure of fragrance allergens in household products could alleviate this problem significantly by giving allergy patients and their doctors easy access to critical information. The argument for withholding this ingredient information as vital trade secrets simply wears thin given today's reverse engineering technology. Fragrance companies, their competitors and even counterfeiters have the ability to deconstruct and thereby recreate fragrances. While these copies are likely not identical in formula given the complexities of creating a fragrance, they are often close enough scents for the average consumer. A simple list of fragrance ingredients (without percentages or other key formulation details) poses almost no additional risk to the intellectual property of these companies. Yet the benefits of ingredient disclosure to allergy patients, health care professionals, researchers and everyday consumers could be dramatic. It is well overdue for the fragrance industry to shine some needed light on fragrance ingredients for the health of their customers.



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EUROPEAN UNION LIST OF 26 FRAGRANCE ALLERGENS REQUIRED TO BE DISCLOSED ON COSMETIC AND CLEANING PRODUCTS

<u>CHEMICAL NAME</u>	<u>CAS #</u>	<u>CHEMICAL NAME</u>	<u>CAS #</u>
AMYL CINNAMAL.....	122-40-7	FARNESOL	4602-84-0
AMYL CINNAMYL ALCOHOL ...	101-85-9	GERANIOL	106-24-1
ANISE ALCOHOL	105-13-5	HEXYL CINNAMAL.....	101-86-0
BENZYL ALCOHOL	100-51-6	HYDROXYISOHEXYL	31906-04-4/ 3-CYCLOHEXENE 51414-25-6
BENZYL BENZOATE	120-51-4	CARBOXALDEHYDE (HICC)	
BENZYL CINNAMATE.....	103-41-3	HYDROXYCITRONELLAL	107-75-5
BENZYL SALICYLATE.....	118-58-1	ISOEUGENOL	97-54-1
BUTYLPHENYL		alpha-ISOMETHYL IONONE.....	127-51-5
METHYLPROPIONAL (Lilial®) ...	80-54-6	(DL)-LIMONENE	138-86-3
CINNAMAL	104-55-2	LINALOOL	78-70-6
CINNAMYL ALCOHOL.....	104-54-1	METHYL 2-OCTYNOATE	111-12-6 (methyl heptin carbonate)
CITRAL.....	5392-40-5	EVERNIA FURFURACEA LICHEN ..	90028-67-4
CITRONELLOL	106-229/ 1117-61-9/ 7540-51-4	EXTRACT (Treemoss extract)	
COUMARIN	91-64-5	EVERNIA PRUNASTRI	90028-68-55
EUGENOL	97-53-0	(Oak moss and treemoss extract)	

Source: ec.europa.eu/enterprise/sectors/chemicals/files/legislation/allergenic_subst_en.pdf

EUROPEAN UNION LIST OF 82 KNOWN FRAGRANCE ALLERGENS IN HUMANS

<u>CHEMICAL NAME</u>	<u>CAS #</u>
ACETYLCEDRENE	32388-55-9
AMYL CINNAMAL*	122-40-7
AMYL CINNAMYL ALCOHOL*	101-85-9
AMYL SALICYLATE	2050-08-0
trans-ANETHOLE	4180-23-8
ANISE ALCOHOL*	105-13-5
BENZALDEHYDE	100-52-7
BENZYL ALCOHOL*	100-51-6
BENZYL BENZOATE*	120-51-4
BENZYL CINNAMATE*	103-41-3
BENZYL SALICYLATE*	118-58-1
BUTYLPHENYL	80-54-6
METHYLPROPIONAL (Lilial®)*	
CAMPHOR	76-22-2/ 464-49-3
beta-CARYOPHYLLENE (ox.)	87-44-5
CARVONE	99-49-0/ 6485-40-1/ 2244-16-8
CINNAMAL*	104-55-2
CINNAMYL ALCOHOL*	104-54-1
CITRAL*	5392-40-5
CITRONELLOL*	106-22-9/ 1117-61-9/ 7540-51-4
COUMARIN*	91-64-5
(DAMASCENONE) ROSE KETONE-4.....	23696-85-7
alpha-DAMASCONONE (TMCHB)	43052-87-5/ 23726-94-5

<u>CHEMICAL NAME</u>	<u>CAS #</u>
cis-beta-DAMASCONONE	23726-92-3
delta-DAMASCONONE	57378-68-4
DIMETHYLBENZYL CARBINYL	151-05-3
ACETATE (DMBCA)	
EUGENOL*	97-53-0
FARNESOL*	4602-84-0
GERANIOL*	106-24-1
HEXADECANOLACTONE	109-29-5
HEXAMETHYLINDANOPYRAN	1222-05-5
HEXYL CINNAMAL*	101-86-0
HYDROXYISOHEXYL	31906-04-4/
3-CYCLOHEXENE	51414-25-6
CARBOXALDEHYDE (HICC)*	
HYDROXYCITRONELLAL*	107-75-5
ISOEUGENOL*	97-54-1
alpha-ISOMETHYL IONONE*	127-51-5
(DL)-LIMONENE*	138-86-3
LINALOOL*	78-70-6
LINALYL ACETATE	115-95-7
MENTHOL	1490-04-6/ 89-78-1/ 2216-51-5
6-METHYL COUMARIN	92-48-8
METHYL 2-OCTYNOATE*	111-12-6
METHYL SALICYLATE	119-36-8
3-METHYL-5-(2,2,3-TRIMETHYL-	67801-20-1
3-CYCLOPENTENYL)	
PENT-4-EN-2-OL	
alpha-PINENE and beta-PINENE	80-56-8 and 127-91-3, resp.

<u>CHEMICAL NAME</u>	<u>CAS #</u>
PROPYLIDENE PHTHALIDE	17369-59-4
SALICYLALDEHYDE	90-02-8
alpha-SANTALOL and	115-71-9 and
beta-SANTALOL	77-42-9 resp.
SCLAREOL	515-03-7
TERPINEOL (mixture of isomers)	8000-41-7
alpha-TERPINEOL	10482-56-1/ 98-55-5
Terpinolene	586-62-9
TETRAMETHYL	54464-57-2/
ACETYLOCTAHYDRONAPHTHALENES	54464-59-4/ 68155-66-8/ 68155-67-9
TRIMETHYL-BENZENEPROPANOL	103694-68-4
(Majantol)	
VANILLIN	121-33-5
CANANGA ODORATA and	83863-30-3/
Ylang-ylang oil	8006-81-3
CEDRUS ATLANTICA BARK OIL	92201-55-3/ 8000-27-9
CINNAMOMUM CASSIA LEAF OIL	8007-80-5/
and CINNAMOMUM ZEYLANICUM	84649-98-9
BARK OIL	
CITRUS AURANTIUM AMARA	8016-38-4/
FLOWER / PEEL OIL	72968-50-4
CITRUS BERGAMIA PEEL	89957-91-5
OIL EXPRESSED	
CITRUS LIMONUM PEEL	84929-31-7
OIL EXPRESSED	
CITRUS SINENSIS	97766-30-8/
(syn.: AURANTIUM DULCIS)	8028-48-6
PEEL OIL EXPRESSED	
CYMOPOGON CITRATUS /	89998-14-1/
SCHOENANTHUS OILS	8007-02-1/ 89998-16-3
EUCALYPTUS SPP. LEAF OIL	92502-70-0/ 8000-48-4
EUGENIA CARYOPHYLLUS LEAF /	8000-34-8
FLOWER OIL	

CHEMICAL NAME	CAS #
EVERNIA FURFURACEA	90028-67-4
LICHEN EXTRACT*	
EVERNIA PRUNASTRI*	90028-68-5
JASMINUM GRANDIFLORUM /	84776-64-7/ OFFICINALE 90045-94-6/ 8022-96-6
JUNIPERUS VIRGINIANA	8000-27-9/ 85085-41-2
LAURUS NOBILIS.....	8002-41-3/ 8007-48-5/ 84603-73-6
LAVANDULA HYBRIDA	91722-69-9
LAVANDULA OFFICINALIS	84776-65-8
MENTHA PIPERITA	8006-90-4/ 84082-70-2
MENTHA SPICATA	84696-51-5
MYROXYLON PEREIRAE	8007-00-9/ NARCISSUS SPP.Diverse
PELARGONIUM GRAVEOLENS	90082-51-2/ 8000-46-2
PINUS MUGO/PUMILA	90082-72-7/ 97676-05-6
POGOSTEMON CABLIN	8014-09-3/ 84238-39-1
ROSE FLOWER OIL (ROSA SPP.).....	Diverse
SANTALUM ALBUM	84787-70-2/ 8006-87-9
TURPENTINE (oil)	8006-64-2/ 9005-90-7/ 8052-14-0
VERBENA ABSOLUTE	8024-12-2

* Indicates this chemical is one of 26 EU allergens currently required to be disclosed on cosmetic and cleaning products.

Source: Scientific Committee on Consumer Safety (SCCS) Opinion on Fragrance Allergens in Cosmetic Products. 26-27 June 2012. Available at: ec.europa.eu/health/scientific_committees/consumer_safety/docs/sccs_o_102.pdf



WOMEN'S VOICES FOR THE EARTH

is a national organization that works to eliminate toxic chemicals that harm women's health by changing consumer behaviors, corporate practices and government policies.



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