Fragrance Ingredient Disclosure

Introduction

Although it's just one little word on the ingredient label, "fragrance" can contain dozens, even hundreds, of chemicals—including known carcinogens, hormone-disruptors and other toxic offenders. Fragrance manufacturers claim the formulas are confidential business information, and sometimes even keep them secret from the companies that sell their products.

Without required fragrance ingredient disclosure, it is impossible for consumers to avoid problematic ingredients or for researchers and regulators to understand the full universe of ingredients used to formulate cosmetic products.

Recently introduced federal cosmetic safety legislation will continue to extend this “trade secret” privilege to fragrance suppliers. However, with a growing body of evidence linking fragrance chemicals to chronic disease and vast improvements in reverse engineering technology, fragrance houses no longer deserve this special protection. Full ingredient disclosure is needed now.

Health Concerns

Fragrance Sensitization and Allergens
Contact with fragrance ingredients can result in sensitization, which is the process by which an individual develops an allergy to specific chemicals through repeated exposure.¹ Affecting up to eleven percent of the general population,² fragrance sensitization may result in mild reactions to ingredients. Further contact increases sensitivity and worsens the allergy to the point where minimal exposures cause severe allergic reactions, such as contact dermatitis.³

Fragrance chemicals can become major sensitizers through air oxidation, photo-activation, skin enzyme catalysis or cross-sensitizing – a process by which a person becomes sensitized to substances different from the substance to which the person is already sensitized.⁴ Once sensitized, the only way to prevent the development of a severe, irreversible allergy is to avoid further exposure.
Fragrance allergy affects 2 to 11 percent of the general population.\textsuperscript{5,6} This translates to tens of millions of people globally affected by fragrance, and studies suggest that sensitivity is on the rise. According to the American Academy of Dermatology (AAD), fragrances are considered the leading cause of cosmetic contact dermatitis.\textsuperscript{7} Reactions to both natural and synthetic fragrance ingredients can range from contact dermatitis (characterized by redness, swelling, and irritation of the skin) to sneezing, coughing, or eye irritation. In total, the European Union’s Scientific Committee on Consumer Safety has identified eighty-two fragrance substances as “established contact allergens in humans,” including popular fragrance chemicals like cinnamal, eugenol, and citral. Currently, 26 have to be listed on the label of EU products that contain them.\textsuperscript{8}

Dermatologists normally suggest avoiding an allergen to prevent these reactions. But, without fragrance ingredient disclosure, it is difficult for consumers to read labels in order to avoid products or for doctors to advise patients how to avoid specific allergens.

To prevent allergic reactions, sensitive individuals are currently directed to choose fragrance-free products. This is not realistic guidance. The range of fragrance-free products is extremely limited since the vast majority of cosmetic products on the market contain fragrance. Hair product choice, in particular, is highly fragranced: more than 95 percent of shampoos, conditioners, and styling products contain fragrance.\textsuperscript{9} To make matters worse, the Food and Drug Administration does not regulate the terms “fragrance free” or “unscented.”\textsuperscript{10} Many “unscented” products contain masking fragrance which have additional ingredients added to hide the odor of the formula, but do not have fragrance listed on the ingredient label.\textsuperscript{11} So, even when consumers choose “fragrance-free,” they may still be exposed to fragrance allergens. Fragrance ingredient disclosure would help individuals with allergies or other chemical sensitivities find safer products, while reducing the overall number of allergic reactions that cost society emotionally and economically.

**Respiratory Diseases and Irritation**

Since fragrance ingredients are volatile, they easily enter the air as gases and expose the eyes and naso-respiratory tract. For asthmatics, the effect of exposure may be more severe. Like second hand smoke\textsuperscript{12}, even low concentrations of fragrance ingredients can provoke asthmatic episodes.\textsuperscript{13} Inhalation exposure to common sanitizing agents called quaternary ammonium compounds (QACs) has been linked to occupational asthma.\textsuperscript{14} Other common fragrance ingredients such as benzyl salicylate, benzyl benzoate, butoxyethanol are known skin, eye, nose and throat irritants which can cause severe symptoms such as a burning sensation, nausea, vomiting and damage to the liver and kidneys.\textsuperscript{15,16,17} European Union’s Scientific Committee on Consumer Safety has identified the fragrance ingredients cinnamal and citral as “established contact allergens in humans.”\textsuperscript{18}

**Carcinogens in Fragrance**

In 2011, the International Fragrance Association (IFRA) published a list of 2,339 possible fragrance materials used by IFRA affiliated members, including fragrance suppliers, who use
chemicals from this list or “palette” of ingredients to formulate fine fragrances and fragranced cosmetics and personal care products. The IFRA list of possible fragrance ingredients includes chemicals listed as carcinogens by California’s Prop 65 Program and the National Toxicology Program (NTP) such as pyridine, benzophenone, methyleugenol and styrene.

**Endocrine Disrupters**
In a 2010 study, 17 tested fragrances contained an average of 4 hormone-disrupting ingredients each, including synthetic musks and diethyl phthalate. Synthetic musks mimic and displace natural hormones, which can potentially disrupt important endocrine and biological processes. High levels of musk ketone and musk xylene in women’s blood may also be associated with gynecological abnormalities such as ovarian failure and infertility. These findings provide human evidence for findings that suggest endocrine disruption in other species. In another example of endocrine disruption, diethyl phthalate has been linked to unusual reproductive development in baby boys and sperm damage in adult men.

**Neurotoxic Chemicals**
In 1986, the National Academy of Sciences targeted fragrance as one of the six categories of chemicals that should be given priority for neurotoxicity testing. Since then, animal studies have linked fragrance ingredient p-cymene to headache, weakness, and irritability, along with the reduction in number and density of brain synapses. In addition, research has shown that the synthetic musks tonalide and galaxolide induce brain cell degeneration, which can lead to degenerative disorders such as Parkinson’s disease.

**Environmental Toxicants**
Fragrance chemicals also represent a serious threat to the environment. Synthetic musks end up in wastewater, drinking water, soil and indoor air. Musk also bio-accumulates in the fatty tissue of aquatic wildlife, and travels through the food chain into salmon and shrimp. In a 2010 study of fragranced products, each product emitted volatile organic compounds that have been identified as toxic or hazardous under federal law. Despite releasing toxic compounds like chloromethane and methylene into the air, fragrance remains unregulated. The continual contamination of our air, soil and water resources has even identified some fragrance chemicals as persistent organic pollutants (POPs).

**Fragrance Industry Regulation**
Lack of full fragrance disclosure negatively impacts consumers, manufacturers and regulators. The Research Institute for Fragrance Materials (RIFM), responsible for the bulk of fragrance ingredient testing, does not make all of its safety data available to those outside of the fragrance industry and, as a result, there is very little safety information on many fragrance ingredients in the public domain. The complete list of fragrance ingredients with potential allergenic, carcinogenic, endocrine-disrupting, or neurotoxic properties may be much larger than current estimates.
Consumers aren’t the only ones who suffer from a lack of fragrance ingredient disclosure. Fragrance suppliers are not required by law to provide full ingredient disclosure to manufacturers or regulators either. This means 1) consumers get incomplete information regarding the ingredients in their personal care products; 2) manufacturers are unable to fully substantiate the safety of all the ingredients in their products nor provide consumers with the full ingredient disclosure they are asking for; and 3) regulators are unable to determine the full scope of ingredients on the market being used to formulate cosmetics. American fragrance houses have held on to this special privilege, even as other industries and European fragrance suppliers have become more transparent about the fragrance ingredients in their products (e.g. disclosing 26 allergens). 38

The reality is that there is no such thing as a “secret formula” anymore. With enough time and as little as a few thousand dollars some perfume and fragrances can be reverse engineered using gas chromatography-mass spectrometry so that its components are known to anyone with the means and interest. Reverse engineering technology eliminates fragrance suppliers’ arguments that their secret fragrances could only be replicated if they offered full ingredient disclosure. As a result, fragrances no longer deserve trade secret protection and suppliers do not have the legal right to keep ingredient information hidden from the public. Full fragrance ingredient disclosure will allow consumers to make safer and more informed decisions, benefit manufacturers who want to practice a higher level of transparency and provide regulators with the information they need to more effectively regulate the safety of cosmetic products.

**Chemicals of Concern**

The International Fragrance Association (IFRA) lists 2,339 materials that are reported as being used in fragrance compounds. 39 Of these 2,339 ingredients, the following 30 chemicals have evidence linking them to health effects including cancer, reproductive toxicity, allergies and sensitivities.

**Acetaldehyde**

Acetaldehyde adversely affects kidneys and the reproductive, nervous and respiratory systems. 40 This chemical is listed as known or suspected to cause cancer in California’s Proposition 65. 41 Both the International Agency for Research on Cancer and the National Toxicology Program classify acetaldehyde as potentially carcinogenic to humans. 42,43

**Benzophenone**

Benzophenone is linked to endocrine disruption and organ system toxicity, 44 and experimental studies suggest benzophenone may lead to several kinds of tumors. 45 Derivatives of benzophenone, such as benzophenone-1 (BP-1) and oxybenzone (BP-3), are potential endocrine disruptors. 46 Benzophenone is listed as a possible human carcinogen under California’s Proposition 65. 47
Butylated hydroxyanisole (BHA)
Studies demonstrating BHA’s potential to disrupt endocrine functioning led the European Commission on Endocrine Disruption to list BHA as a Category 1 priority substance.48,49 This chemical is also listed as a carcinogen on California’s Proposition 65.50

Butylated hydroxytoluene (BHT)
BHT irritates the eyes and skin and may adversely affect one’s growth rate and liver.51 The American Conference of Governmental Industrial Hygienists (ACGIH) has determined that there is moderate evidence that BHT is a human respiratory irritant.52

Benzyl Salicylate
Benzyl salicylate is a fragrance allergen and a potential endocrine disruptor.53,54 The European Union restricts its use and requires that it is listed on product labels.55,56

Benzyl Benzoate
Benzyl benzoate is a skin and eye irritant and may severely irritate, burn and sting the genitalia and scalp.57 The European Union requires that it is listed individually on products and restricts quantity use.58

Butoxyethanol
Butoxyethanol is a skin, eye, nose and throat irritant. Exposure can lead to blood in the urine, vomiting and nausea with long-term damage to the kidneys, liver, lymphoid system, nervous system, respiratory system and blood cells.59 Butoxyethanol is also a reproductive toxicant. The International Agency for Research on Cancer confirms the carcinogenicity of butoxyethanol in experimental animals.60 Both the European Union and Canada restrict butoxyethanol in consumer products.61,62

Butylphenyl methylpropional
Also known by its brand name Lilial, butylphenyl methylpropionale is a scent chemical restricted in the European Union.63 Its potential for dermal sensitization motivated the International Fragrance Association to also restrict its use in fragrance products.64

Chloromethane (methyl chloride)
Chloromethane can have both acute and chronic effects on the nervous system and also adversely impacts the liver, kidneys and skin.65 It is listed under California’s Proposition 65 as a developmental toxicant.66

Cinnamal
The European Union’s Scientific Committee on Consumer Safety has identified cinnamal as an “established contact allergens in humans.”67 Cinnamal is a known human immune system toxicant or allergen.68 Reactions can range from contact dermatitis to anaphylaxis.69

Citral
The European Union’s Scientific Committee on Consumer Safety has identified citral as an “established contact allergens in humans.”70 Citral is a known fragrance allergen and irritant.71 Reactions can range from clinical dermatitis to eczema.
**Dichloromethane (methylene chloride)**
Dichloromethane is linked to mammary gland tumors in experimental animals and may be an occupational carcinogen. It is reasonably anticipated to be a human carcinogen according to the National Toxicology Program and possibly carcinogenic to humans according to the International Agency for Research on Cancer. Its use in fragrance products is restricted by the European Commission and prohibited by the U.S. Food and Drug Administration.

**Diethyl phthalate (DEP)**
DEP is an irritant of eyes, skin and the respiratory tract. It is a potential endocrine disruptor and has been linked to reproductive and nervous system toxicity.

**Essential Oil Mixtures**
Despite being fragrance ingredients of ‘natural origin,’ some essential oils are allergens and their allergenicity is no different than synthetic fragrance ingredients. The FDA treats essential oil ingredients the same as other personal care product ingredients. The International Fragrance Agency restricts citrus oils and other plant-derived organic chemicals containing essential oils due to their phototoxic effects. Essential oils may contain ingredients such as pulegone or methyleugenol that may be carcinogenic and alter endocrine functioning.

**Eugenyl methyl ether (Methyleugenol)**
It can affect multiple endocrine systems and induce mammary gland tumors in experimental animals. Methyluegenol is a naturally occurring substance used in essential oils. It is a possible human carcinogen according to California’s Proposition 65, the National Toxicology Program, and the International Agency for Research on Cancer.

**Formaldehyde**
Authoritative entities on chemical hazards agree that formaldehyde is a known human carcinogen. It is banned in cosmetics and toiletries in Japan and Sweden while the European Union and Canada restricts its use. California’s Proposition 65 states that in its gas form, formaldehyde is a probable carcinogen. In occupational settings, formaldehyde is a cancer hazard and immune system sensitizer.

**Geraniol**
The European Union Scientific Committee on Consumer Safety (SCCS) recognizes geraniol as a consumer allergen.

**Ethanolamines (MEA, DEA, TEA)**
A mixture of ethanolamines and preservatives that break down into nitrogen can form nitrosamines. Nitrosamines are a class of more than a dozen different chemicals, which the International Agency for Research on Cancer lists individually as possible and known carcinogens. The National Toxicology Program Report on Carcinogens lists 15 individual nitrosamines as reasonably anticipated human carcinogens.

**Methanol**
Methanol is a developmental toxicant according to California’s Proposition 65, and the European Union has concentration restrictions of methanol in cosmetics.

**Methylene**
The clean air act identifies methylene as a hazardous air pollutant. Methylene chloride is a volatile organic compound (VOC) that is classified as toxic or hazardous under federal laws.

**Oxybenzone (BP-3)**
This UV-filter is a derivative of benzophenone and a potential endocrine disruptor. Oxybenzone can accumulate in the blood, kidneys and liver and may be toxic to liver cells. The European Union restricts oxybenzone at up to 10 percent maximum concentration in cosmetics.

**P-Cymene**
Animal studies show that inhalation exposure to p-cymene causes a reduction in number and density of brain synapses.

**Propyl paraben (Propyl p-hydroxybenzoate)**
Propyl paraben is a possible endocrine disruptor. Denmark banned propyl paraben and other paraben forms in cosmetic products for children up to 3 years old, which then motivated the European Commission to implement restrictions reducing the concentrations of propyl paraben in cosmetic products.

**Pyridine**
Consumption of pyridine-contaminated food increases the likelihood of tumor formation in the breast, prostate and colon. California’s Prop 65 Program and the National Toxicology Program (NTP) list pyridine as a carcinogen.

**Quaternary Ammonium Compounds (e.g. benzalkonium chloride)**
Inhalation exposure to quaternary ammonium compounds (QACs) has been linked to occupational asthma. Sensitization and irritation of the mucous membranes and the skin has also been observed in professional and domestic cleaners.

**Resorcinol**
Resorcinol changes liver, kidney and spleen functioning and adversely affects the cardiovascular and nervous system. The European Commission lists this chemical as a Category 1 endocrine disruptor, and the European Union restricts concentrations and requires labeling of products that contain these chemicals. In Japan, the form Resorcin is banned in all types of cosmetics.

**Styrene**
Styrene can be toxic to red blood cells and the liver when taken orally and toxic to the central nervous system when inhaled. It is reasonably anticipated to be a human carcinogen and is a Category 1 endocrine disruptor in living organisms according to the European Commission.
**Synthetic Musks (Tonalide, Galaxolide, Musk Ketone, Musk Xylene)**

These chemicals are used in fragrances and added to personal care products. Synthetic musks are highly bioaccumulative and have been detected in breast milk, body fat, and the cord blood of newborn babies.\(^{129,130,131,132}\) Studies show that these compounds may disrupt hormone systems\(^{133,134,135,136,137}\) and may be reproductive,\(^{138,139}\) development,\(^{140,141}\) and organ system toxicants.\(^{142,143}\)

**Titanium dioxide**

Inhalation exposure can damage lungs and the respiratory system. TiO\(_2\) may be an occupational carcinogen\(^{144}\) and is listed as carcinogenic on California’s Proposition 65.\(^{145}\) The International Agency for Research on Cancer also lists this chemical as a possible human carcinogen.\(^{146}\)

**1,4-Dioxane**

1,4-dioxane is a byproduct of a process to make other chemicals less harsh. Because it is a contaminant produced during manufacturing, the FDA does not require 1,4-dioxane to be listed as an ingredient on product labels. However, this chemical is known or suspected to cause cancer or birth defects according to California’s Proposition 65.\(^{147}\) The International Agency for Research on Cancer lists this chemical as possibly carcinogenic to humans while the National Toxicology Program categories 1,4-dioxane as reasonably anticipated to be carcinogenic to humans.\(^{148,149}\)

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