



Fragrance Materials Association of the United States

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U.S. Fragrance Association Finds New Cosmetics Report Misleading – Fragrance Safety Is No Secret

Washington, D.C., May 13, 2010 – The Campaign for Safe Cosmetics (CSC) published a report on May 12, 2010 entitled “Not So Sexy - The Health Risks of Secret Chemicals in Fragrance” which includes alarmist phrases such as: “can trigger allergic reactions”, “disrupt hormones”, “end up inside people’s bodies”. The Fragrance Materials Association of the United States (FMA) says the reality is that fragrances are safe. The industry has a long and comprehensive safety testing program for its materials. Materials are also independently assessed for safety. Fragrance materials are not secret but publically available at www.ifraorg.org. Sponsors of the CSC report have been made aware of all of these facts but have chosen to ignore them. The industry discusses some of the report’s inaccuracies below:

What Secret Chemicals?

There are no ‘secret chemicals’ in fragrances. The International Fragrance Association (IFRA) has published a list of 3,163 fragrance ingredients used in consumer products, publicly accessible at www.ifraorg.org. One CSC report contributor, the Environmental Working Group, recently applauded the fragrance industry ingredient disclosure, saying “It’s pretty big news that ... [IFRA] decided to publish an alphabetical list of ingredients that its members reportedly use to make consumer products. Why’d they do it? Simple: consumers want more transparency ... And while this isn’t exactly the kind of transparency we had in mind ... it’s a step.”

The CSC report ignores the facts – the fragrance industry is hiding **no** materials from consumers.

Fragrance Counterfeiting

You know about counterfeit DVDs and handbags. Did you also know of the huge industry that exists to counterfeit fragrances? Fragrances are mixtures of materials combined to give a unique aroma that makes a fragrance recognizable and different from other fragrances. The exact “recipe” of the fragrance mixture is proprietary only because it cannot be protected like new technology can, by a patent, for example. Therefore, the formula is very valuable to its creator and it is not normal practice to publish it.

Industry’s Safety Program

Because we care passionately about our products and about the people who use and enjoy them every day, our industry dedicates significant resources to assure the safety of fragrance ingredients. The Research Institute for Fragrance Materials (RIFM) has responsibility for the safety assessment of fragrance ingredients. At RIFM’s core is an independent expert panel, with expertise in dermatology, respiratory and reproductive medicine, and environmental science, with responsibility for the final determinations of safe use conditions for fragrance ingredients. The safety program is founded on testing fragrance materials and either establishing ‘Safe Use Levels’, or prohibiting their use, based on studying their potential effects on people and the environment. Currently the safety program contains 174 ‘Standards’, which restrict, or prohibit, the use of selected fragrance materials. Further, RIFM has over 1200 publications in peer reviewed scientific literature on safety determinations of fragrance materials. This is part of the normal scientific process. Find more at www.rifm.org.

To ensure that the fragrance industry adheres to its safety standards IFRA has a Compliance Program. Every year 50 products from a selection of 450, gathered from stores in 10 different countries,

are tested. If a product does not comply with its Code of Practice and Standards, IFRA works with the manufacturer to ensure compliance.

The existence and complexity of the fragrance industry's safety program has been shared with several of the groups sponsoring the CSC report, so it is disturbing that they have chosen to completely ignore these facts.

Sensitizers

Through the fragrance industry's safety program RIFM aims to identify, when possible, safe use levels for sensitizers, based on scientific evidence, and not on speculation. Practically all substances in our environment can be harmful at some level of exposure. Even water, the very essence of life, can be fatal if too much is ingested too quickly, or if it is inhaled. Likewise, some food products can be problematic if ingested at very high levels. Irritants and sensitizers can have an adverse effect if applied to the skin at concentrations that exceed a level known to be 'irritating' or 'sensitizing'. As with food and water, these materials, however, can be safely applied to the skin at levels known not to produce irritation or sensitization.

Musk Materials

Galaxolide and Tonalide have been thoroughly investigated in the USA and Europe by the U.S. Food and Drug Administration (FDA) and EU Commission, respectively, and have repeatedly been found to have no safety concerns when used as recommended in fragrance compounds. These polycyclic musk compounds are among the most thoroughly researched and tested fragrance ingredients in use.

Endocrine Disruptors

The CSC report claims that several secret chemicals found could affect hormonal systems in the body but failed to acknowledge that the materials identified have been evaluated for safety and are suitable for use in fragrances. In fact none of the chemicals identified have shown clear evidence of causing harm to the unborn child or affecting human health.

Data cited by the CSC report refers to two types of studies: those that are of limited speculative epidemiological association, and at best only raise questions that require further research to determine if there is any cause for concern; or studies in animal cells that show a minimal ability of these materials to behave like estrogen, to the extent that their activity is a million times less than that of estrogen.

Both the EU Commission and U.S. Environmental Protection Agency (EPA) continue to investigate potential endocrine disrupting chemicals but to date have not determined that any pose a significant health risk. A noted example is diethyl phthalate (DEP) which has been reviewed by the European Commission Scientific Committee on Consumer Products and determined to be safe for use.

Diethyl Phthalate (DEP)

'Phthalate' is a term referring to a family of compounds of similar chemical structure. In the same way that all vegetables are not the same, not all phthalates are the same; the biological profiles differ significantly. Diethyl phthalate (DEP) is commonly used in toothbrushes, food packaging, cosmetics, and in fragrances to help blend ingredients.

In the U.S., the Cosmetic Ingredient Review (CIR) Expert Panel, after completing a review of all literature on DEP in 2002, concluded that DEP is safe for use in cosmetic products under present conditions of use and concentrations. Again, in 2005, the CIR undertook an additional review and concluded that there was no reason to change their original opinion. The CIR, comprised of independent

physicians and scientists, has liaison members from the U.S. Food and Drug Administration, the Consumer Federation of America, and the Personal Care Products Council.

Most recently, in 2008 the U.S. Congress omitted DEP from a list of phthalates of concern.

The CSC report also refers to a 2007 Scientific Committee for Consumer Safety (SCSS) study. In fact, the SCSS reconfirmed that DEP is safe for use in cosmetics. It also found that none of the latest information on DEP would change its longstanding conclusion. The SCSS is one of the scientific advisory bodies of the European Union advising regulators on scientific questions involving the safety of consumer products.

In the U.S., the Food and Drug Administration continues to evaluate available data on DEP and has not determined a need to restrict its use in fragrances. No other regulatory body in the world has seen the need to ban the use of DEP.

Consumers need not worry about the presence of DEP in their fragranced products.

Bio-Accumulation

There are many chemicals that we ingest, inhale or are otherwise exposed to, that are present in our bodies at any moment. The key is not whether these are simply *present*, but whether their presence is potentially harmful to us. Neither the presence of chemicals, nor their bioaccumulation, automatically means that there is cause for alarm.

Through modern technology we are able to detect minuscule amounts of substances, whether in consumer products or in a human body. The presence of a small amount of a specific substance does not mean that it is having any discernible adverse effect on us or on future generations. We are all subject to frequent public scares about the presence of a variety of man-made chemicals in our bodies. The CSC report inaccurately depicts the effect of certain chemicals found in our body. Out of context these announcements sound alarming, but three things remain important:

1. Our bodies are able to process and remove harmful substances. Biological systems are made to deal with the world around us and are incredibly adaptable.
2. The concentration of the chemical: we can detect some chemicals in the body in parts per billion. A part per billion is equivalent to one grain of sugar in an Olympic swimming pool; or one step in 23 trips around the world. This level is insignificant.
3. The presence of a chemical in our bodies does not mean it is doing harm. Our bodies contain traces of many substances that we are in contact with, natural and synthetic, some beneficial and some harmful at certain levels. To understand whether the presence of any chemical, natural or synthetic, is problematic, we need to know how much of it is present and examine what type of effect, if any, it is having.

Industry Commitment to Sound Science

The fragrance industry has a long history of a robust safety assessment program; the details of this program have been shared with many governmental and regulatory bodies over the years, and the same openness has been offered to several of the special interest groups that have supported the publication of the CSC report.

When objective science is used as a judgment criterion, however, we are confident that consumers will realize that they are being misled. Fragrance materials are safe, the industry makes

ingredient details publically available, and consumers should feel assured that they can continue to enjoy these products in the same way they have for years.

About FMA

The Fragrance Materials Association of the United States (FMA) represents companies that invent and then manufacture mixtures of fragrance ingredients for use in a wide variety of products, including soaps, shampoos and detergents. FMA and its members are committed to the formulation of safe fragrances using substances which have been extensively researched and reviewed by a panel of experts and results published in peer reviewed scientific literature. FMA is the U.S. member of the global International Fragrance Association (IFRA). All FMA members abide by the IFRA Code of Practice and IFRA Standards.

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