



FRAGRANCE MATERIALS ASSOCIATION OF THE UNITED STATES

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Document Control Office
Office of Pollution Prevention and Toxics (OPPT)
Environmental Protection Agency
1200 Pennsylvania Avenue, NW
Washington, D.C. 20460-0001

**RE: Docket EPA-HQ-OPPT-2007-1016, “Citizen Petition to EPA and CPSC
Regarding Air Fresheners”**

To whom it may concern:

On behalf of the Fragrance Materials Association of the United States, we are writing to respond to the request for comments from interested members of the public on a petition received by the Environmental Protection Agency (EPA) and the Consumer Product Safety Commission (CPSC) from the Natural Resources Defense Council, the Sierra Club, the Alliance for Healthy Homes, and the National Center for Healthy Housing (“Citizen Petition to EPA and CPSC Regarding Air Fresheners” dated September 19, 2007) requesting that EPA and CPSC take certain regulatory actions with respect to air freshener products and their producers. 72 Fed.Reg.60016-60018 (Oct. 23, 2007).

With the following comments, FMA respectfully requests that the Environmental Protection Agency deny the Citizen Petition.

The Fragrance Materials Association of the United States (FMA)

The Fragrance Materials Association of the United States (FMA) welcomes the opportunity to submit these comments in response to the EPA notice and in opposition to the Citizen Petition. FMA represents the manufacturers of fragrances and fragrance materials for use in a wide variety of products, including fine fragrances, shampoos, soaps and detergents. FMA has been in existence since 1980, but traces its history to the Essential Oil Dealers Association founded in 1927. The members of FMA are committed to the formulation of safe fragrances using substances which have been extensively researched, reviewed by a panel of experts and results published in peer reviewed scientific literature. We will elaborate on this process further on in these comments.

Phthalates

Claims by the Natural Resources Defense Council, et al, that some air fresheners may cause health problems because they contain phthalates are baseless and irresponsible. The Citizen Petition alleges that exposure concerns originate from fragrances and DEP. “Phthalates” is a broad term that refers to a wide variety of compounds of differing chemical structure. Not all phthalates are the same; the chemical profiles of phthalates differ significantly. Safety concerns have been raised most recently in Europe about Dibutyl Phthalate (DBP) and Diethyl Hexyl Phthalate (DEHP). However, neither DBP nor DEHP are permitted for use in cosmetic products in Europe. The U.S fragrance industry has instructed its members to use only diethyl phthalate in fragrances and not use DBP and DEHP. **Therefore the only phthalate that should be used in fragrances is diethyl phthalate (DEP) for which there exists voluminous safety data.**

While some reports continue to raise questions about “phthalates” in general, it is important to define the specific chemicals of concern, as well as the scientific legitimacy of the associated data. The scientific validity of some frequently cited research remains, and it has been seriously questioned through the process of scientific peer review. For example, recent studies reporting the potential association of “phthalates” with male reproductive biomarkers are inconsistent and have been rejected by government experts who have reviewed these data and found the conclusions to be based on insufficient evidence. In addition, a recent study found no effects on reproductive or thyroid hormone levels in males who topically applied DEP repeatedly for 28 days.

Moreover, since DEP has not been demonstrated to have a potential for adverse reproductive effects, it is inaccurate to imply that there are concerns similar to those for other phthalates. DEP presents no safety concern from use in fragrances; it has a very strong safety profile. DEP is commonly used in cosmetics, toothbrushes and food packaging. It is used in fragrances as a solvent to blend fragrance ingredients and as a fixative to make fragrances last longer when applied to the skin. DEP has been extensively tested and subjected to a wide array of technical reviews in both the United States and Europe.

In 2002, the Cosmetic Ingredient Review (CIR) Expert Panel, after completing an extensive review of all the literature on diethyl phthalate (DEP), announced its decision to not reopen the safety assessment of DEP and other phthalates.¹ Based on the available information included in its peer reviewed literature report, the CIR Expert Panel concluded that DEP is safe for use in cosmetic products in the present practices of use and concentrations. The CIR is an FDA-sanctioned independent body of toxicologists and dermatologists that regularly review compounds used in cosmetics and personal care products.

Moreover, the Food and Drug Administration continues to evaluate available data on DEP, and has not taken any action to restrict the use of DEP in fragrances.

In a recent review completed in March of this year by the European Commission's Scientific Committee on Consumer Products (SCCP), the SCCP reconfirmed that DEP is safe for use in cosmetics and represents no quantifiable risk for the consumer. The SCCP also found that none of the latest information on DEP would change its longstanding conclusion. ² The SCCP is the regulatory arm of the European Union comparable to the U.S. Food and Drug Administration.

The NRDC report on phthalates: "Masking the Danger: Toxic Chemicals in Air Fresheners," September, 2007, characterized the levels of DEP found in sampled air fresheners to be "very high" and "shocking." The fact is that the amount of DEP detected by NRDC falls well below use level standards for this material. The U.S. Cosmetic Ingredients Review Panel (CIR) provides a standard use level of up to 2% DEP within a total cosmetic product. The highest level of DEP found in the NRDC product samples was ONLY one third of the CIR permissible use level in a cosmetics product **that is applied directly to the human body.**

The NRDC report also mischaracterizes the safety profile of diethyl phthalate (DEP) by asserting that "human studies have repeatedly associated exposure to DEP in a mixture of phthalates with adverse reproductive outcomes." The NRDC report references three reports, none of which indicate that DEP presence in the various mixtures studied caused any negative effects. These reports simply demonstrate the presence of DEP and mere presence does not equate to genuine risk. Diethyl phthalate is safe for use in fragrances and is among the most thoroughly tested substance in the class of phthalates.

The Safety of Fragrance Ingredients - The Research Institute for Fragrance Materials (RIFM)

The safety of fragrance ingredients is a top priority for the fragrance industry. Fragrance material suppliers take substantial and effective product stewardship measures to assure the safety of these products. New scientific data is constantly evaluated to ensure that the highest standards are applied to the creation of fragrances.

The principal means by which fragrance material producers and fragrance manufacturers address the safety of such materials is through their membership in the Research Institute for Fragrance Materials (RIFM). RIFM is a non-profit organization whose members include fragrance raw material suppliers and fragrance manufacturers as well as end use companies, i.e., manufacturers of consumer products such as air fresheners and cosmetics. Fragrance material standard-setting involves a step-wise process, beginning with initial substance evaluations conducted by RIFM. RIFM's evaluations are then reviewed by an independent panel of expert dermatologists, pathologists, environmental scientists and toxicologists, who form the RIFM Expert Panel, REXPAN. REXPAN members are renowned international scientific experts who are independent of the fragrance industry. The REXPAN conclusions are published in peer-reviewed scientific journals. These conclusions regarding safe use form the basis for global industry standards, which are set by the International Fragrance Association.

The International Fragrance Association (IFRA) Code of Practice

The International Fragrance Association (IFRA) is a European-based organization with world-wide responsibility whose goal is to ensure that fragrance materials are safe for consumer use and the environment. IFRA continues to set strict safety standards for the use of fragrance ingredients. IFRA member companies, which include all major suppliers of fragrance, must adhere to the IFRA Code of Practice and agree to produce fragrances to meet these high standards of safety. In addition, the IFRA Code of Practice requires that fragrance material suppliers submit an IFRA Conformity Certificate (IFRA Certificate) for each fragrance material supplied to a customer. Customarily, major consumer product manufacturers require the IFRA Certificate as part of their consumer product safety dossier. The IFRA Certificate must include a statement that the Code of Practice has been followed with respect to the fragrance material and must identify any applicable Standards which may include specified use-level concentrations. The complete IFRA Code of Practice can be found at www.ifraorg.org

To ensure that its standards are being met, IFRA recently began a compliance program to test consumer products on the market which contain materials subject to IFRA standards for the presence of banned substances and for conformance with restrictions established in IFRA standards. The results of the most recent round of compliance measures indicate that all tested products were found to be free of any banned fragrance ingredients. A second round of product testing is underway.

Conclusion

Based on the comments provided herein, FMA respectfully urges the agency to deny the Citizen Petition. Furthermore, FMA strongly supports the comments submitted by the Consumer Specialty Products Association (CSPA) regarding the safe use of phthalates in air fresheners and fragrances used in other consumer products. FMA further supports the evidence presented by CSPA that the Citizen Petition fails to demonstrate that air freshener products “may present an unreasonable risk of injury to the health or the environment.”

People have enjoyed fragrances for thousands of years. Fragrances contribute to our individuality, self-esteem and personal hygiene. Fragrances date as far back as the Egyptians who used aromatic plants to create massage oils, medicines, embalming preparations, skin care products, fragrant perfumes and cosmetics.

Under conditions of intended use, **and** even under reasonably foreseeable misuse, fragrance ingredients are safe. In addition to a long history of safe use, a well-established program exists within the fragrance industry for objective evaluation of the safety of its materials and this is backed up by government requirements that establish expectations for safety substantiation of chemicals.

FMA would be pleased to discuss these matters further with EPA or provide any additional information which may be required.

Respectfully submitted,

A handwritten signature in black ink that reads "Glenn Roberts". The signature is written in a cursive, flowing style.

Glenn Roberts
Executive Director

References

1. Dibutyl Phthalate, Diethyl Phthalate, and Dimethyl Phthalate Re-review Summary February 7, 2003; JACT (4(3): 267-303, 1985, confirmed November, 2002; IJT24 (S1): 34-42, 2005, confirmed September, 2005
2. Scientific Committee on Consumer Products (SCCP), "Opinion on Phthalates in Cosmetic Products, FR/07/69, adopted at its 11th plenary meeting of March 21, 2007