

Position Statement on The Chemical Identity of Fragrances (Approved by the Board of Directors: October 24, 1998)

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 urges the Cosmetic, Toiletry and Fragrance Association (CTFA) to work with national and international fragrance trade associations, manufacturers, the Food and Drug Administration (FDA) and the AAD to obtain agreement on the disclosure of fragrance ingredients.ⁱ

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.ⁱⁱ In the absence of identifying the common allergens of fragrances, the fragrance-sensitive consumer is often advised to avoid the use entirely of all cosmetics, prescription and over-the-counter (OTC) drugs which list the generic term 'fragrance' in the ingredient labeling.

Current Requirements for Ingredient Identification

Cosmetics, OTC and Prescription Drugs

At present, identification of ingredients for cosmetics relies upon voluntary disclosure by manufacturers to the FDA.ⁱⁱⁱ Labeling of cosmetics is subject to provisions of the Food, Drug and Cosmetic (FD&C) Act and the Fair Packaging and Labeling Act.^{iv} The Act requires that ingredients in cosmetics be listed in descending order by quantity. Fragrances, unless voluntarily disclosed by the manufacturer, must only be listed as 'fragrance'. There is no requirement that the specific content of a fragrance be disclosed.^v

The FDA mandates ingredient identification for over-the-counter (OTC) and prescription drugs.^{vi} Cosmetics which are also intended to treat or prevent disease, or affect the structure or functions of the human body (i.e. fluoride toothpaste, sun tan creams/oils) must comply with both cosmetic and drug provisions of the law.^{vii} The law requires the active ingredient(s) to be listed first, followed by all the inactive cosmetic ingredients. Products with such a dual classification must be scientifically proven safe and effective for their therapeutic claims before they are marketed.^{viii} While labeling requirements for OTC and prescription drugs^{ix} are significantly more rigorous, little is codified with regard to identification and labeling of inactive ingredients. In fact, according to language in a currently proposed FDA rule, "OTC drug products that are not also cosmetics are not currently required to list inactive ingredients on their labeling".^x For prescription drugs, there is also no requirement that the specific content of a fragrance be disclosed. The label must state simply, 'perfume'.^{xi}

Health Effects and Economic Impact of Fragrance Sensitivity

Academy *Guidelines of Care for Contact Dermatitis* note that a complaint of contact dermatitis is responsible for approximately 5.7 million physician visits a year.^{xii} While only a portion of these visits are the result of an exposure to an offending fragrance, medical literature estimates that one-percent of the general population suffers from fragrance allergies.^{xiii} This equates to 2.5 million individuals.^{xiv} Fragrance allergy is the number one cause of cosmetic contact dermatitis in the U.S.^{xv} Studies suggest that there is a trend of increasing sensitization to fragrances worldwide.^{xvi} In addition, studies of contact dermatitis resulting from product exposure list fragrance as among the top 5 causative agents.^{xvii} The economic impact of allergic dermatitis resulting from fragrance exposure is significant. An estimation of the dollar impact would have to consider the loss of sales to persons avoiding the use of products listing the generic 'fragrance' on the label, and the time lost from work. In the occupational setting, contact dermatitis accounts for more than 50 percent of all occupational illness, a portion of which is from fragrance.^{xviii}

Commitment to Effective Solution

The Academy acknowledges the concern expressed by the fragrance industry for the protection of trade secrets. The AAD believes we can work together to find an acceptable fragrance ingredient disclosure that preserves proprietary information.

ⁱ Research Institute for Fragrance Materials [RIFM]; International Fragrance Research Association [IFRA]. The Academy supports label disclosure of the common allergens in fragrances.

ⁱⁱ U.S. Food and Drug Administration [FDA], Center for Food Safety and Applied Nutrition, Office of Cosmetics Fact Sheet Fragrance Free and Unscented; December 19, 1994 "The terms 'fragrance free' and 'unscented' are presently used virtually without restriction, since the expressions have no legal definitions." In the case of products labeled with these terms, "manufacturers generally add fragrance ingredients to cover the offensive odor, but less than what is needed to impart a noticeable scent."

ⁱⁱⁱ U.S. General Accounting Office Cosmetics Regulation; Information on Voluntary Actions Agreed to by FDA and the Industry; March 1990, HRD-90-58; Report to the Chairman, Subcommittee on Regulation, Business Opportunities, and Energy. Committee on Small Business, House of Representatives

^{iv} 21CFR701.3 Designation of Ingredients, Cosmetic Labeling. 15 U.S.C. Fair Packaging and Labeling Act, Ch. 39; §1451-1459

^v Foulke, Judith, staff writer, FDA Consumer, Cosmetic Ingredients: Understanding the Puffery; May 1992; revised February 1995. FDA Publication No. 95-5013. "The most well-known of industry-sponsored self-regulation is the Cosmetic Ingredient Review, sponsored by the CTFA. The CIR is accomplished by a panel of scientific and medical experts who evaluate cosmetic ingredients for safety and publish detailed reviews of available safety data... "In the absence of the CIR program, there would be no systematic examination of the safety of individual cosmetic ingredients." FDA has no statutory authority to require that the data be submitted to the agency.

FDA encourages industry cooperation through its voluntary reporting program. Cosmetics firms registered in the program voluntarily report manufacturing and formulation information... Adverse reactions such as skin irritations are also reported. Using the information, FDA can determine a baseline reaction rate for specific product categories... The agency gives participating companies this baseline information so they can compare their own adverse reaction rates to the FDA-established baseline." The FDA estimates that only 35 percent of companies eligible to register do so.

Conversation with Alan Andersen, Ph.D., Director and Scientific Coordinator, Cosmetic Ingredient Review. April 9, 1998. Question, why are fragrances not generally reviewed by the CIR? When the CIR began in 1976, fragrances were already being reviewed by the Research Institute for Fragrance Materials (RIFM) and the thought was to concentrate our efforts on all the ingredients for which no [evaluation] system currently existed.

^{vi} 21CFR201, subpart B, Labeling Requirements for Prescription Drugs and/or Insulin; and C, Labeling Requirements for Over-The-Counter Drugs

^{vii} U.S. FDA, Center for Food Safety and Applied Nutrition, Office of Colors and Cosmetics, Cosmetic Labeling Manual; October 1991.

^{viii} Foulke, Judith, staff writer, FDA Consumer, Decoding the Cosmetic Label; May 1994; FDA Consumer

^{ix} 21CFR201.50-59 subpart B, Labeling Requirements for Prescription Drugs and/or Insulin.

Federal Register, February 27, 1997. Vol. 62, No. 39, [Proposed Rule] [Page 9023-9062] Over-the-Counter Human Drugs, Proposed Labeling Requirements.
HHS, FDA, Center for Drug Evaluation and Research (CDER) February 1988, Procedural Guidance #2; Guidance for Industry National Uniformity for Non Prescription Drugs - Ingredient Listing for OTC Drugs

^x; Federal Register, February 27, 1997. Vol. 62, No. 39, [Proposed Rule] [Page 9036] Over-the-Counter Human Drugs, Proposed Labeling Requirements

^{xi} 21CFR200.100 Subpart D - Exemptions From Adequate Directions for Use

^{xii} The American Academy of Dermatology, Guidelines of Care for Contact Dermatitis; 1995. According to the Guidelines, "all age groups are affected", and there are slightly more women than men affected as measured by patients seen for diagnostic patch testing.

^{xiii} de Groot AC, Frosch PJ. Adverse reactions to fragrances. A clinical review. Contact Dermatitis 1997 Feb; 36(2): 57-86. Approximately ten percent of persons visiting physicians for patch testing are positive for fragrance; de Groot AC. Contact allergy for perfume ingredients in cosmetics and toilet articles. Ned Tijdschr Geneeskde 1997 Mar 22; 141(12): 571-574. *Abstract only, article in Dutch*

^{xiv} 1990 Census, 248.7 million

^{xv} Marks JG et al: North American Contact Dermatitis Group patch test results for the detection of delayed type hypersensitivity to topical allergens. J Am Acad Dermatol 1998; 38:911-18

^{xvi} *ibid*; Lim JT et al: Changing trends in the epidemiology of contact dermatitis in Singapore. Contact Dermatitis 1992; 26:321-326; Johansen JD, Menne T: The fragrance mix and its constituents: a 14 year material. Contact Dermatitis 1995; 32:18-23.

^{xvii} -- articles in whole from literature search --

de Groot AC, Frosch PJ. Adverse reactions to fragrances. A clinical review. Contact Dermatitis 1997 Feb; 36(2): 57-86.

Fotiades J; Soter NA; Lim HW. Results of evaluation of 203 patients for photosensitivity in a 7.3-year period. J Am Acad Dermatol 1995 Oct; 33(4): 597-602.

Frosch PJ, Pilz B, Andersen KE, Burrows D, Camarasa JG, Dooms-Goossens A, Ducombs G, Fuchs T, Hannuksela M, Lachapelle JM, et al. Patch testing with fragrances: results of a multicenter study of the European Environmental and Contact Dermatitis Research Group with 48 frequently used constituents of perfumes. Contact Dermatitis 1995 Nov; 33(5): 333-342.

Gould JW; Mecurio MG; Elmetts CA. Cutaneous photosensitivity diseases induced by exogenous agents. J Am Acad Dermatol 1995 Oct; 33(4): 551-73; quiz 574-6.

Larsen WG. Perfume Dermatitis. J Am Acad Dermatol 1985 Jan; 12(1 Pt 1): 1-9.

Larsen WG. How to instruct patients sensitive to fragrances. J Am Acad Dermatol 1989 Oct; 21(4 Pt 2): 880-884.

The following are article abstracts only -- Cohen DE, Brancaccio RR. What is new in clinical research in contact dermatitis. Dermatol Clin 1997 Jan; 15(1): 137-48.

de Groot AC. Contact allergy to cosmetics: causative agents. Contact Dermatitis 1987 Jul; 17(1): 26-34.

de Groot AC. Contact allergy for perfume ingredients in cosmetics and toilet articles. Ned Tijdschr Geneeskde 1997 Mar 22; 141(12): 571-574. *Abstract only, article in Dutch.*

de Groot AC, van der Kley AM, Bruynzeel DP, Meinardi MM, Smeenk G, van Joost T, Pavel S. Frequency of false-negative reactions to the fragrance mix. Contact Dermatitis 1993 Mar; 28(3): 139-140.

de Groot AC, Bruynzeel DP, Bos JD, van der Meeren HL, van Joost T, Jagtman BA, Weyland JW. The allergens in cosmetics. Arch Dermatol 1988 Oct; 124(10): 1525-1529.

Eiermann HJ, Larsen W, Maibach HI, Taylor JS. Prospective study of cosmetic reactions: 1977-1980. North American Contact Dermatitis Group. J Am Acad Dermatol 1982 May; 6(5): 909-917.

Gendler E. Adverse reactions to cosmetics. Cutis 1987 Jun; 39(6): 525-6.

Guin JD, Berry VK. Perfume sensitivity in adult females. A study of contact sensitivity to a perfume mix in two groups of student nurses. J Am Acad Dermatol 1980 Sep; 3(3): 299-302.

Handley J, Burrows D. Allergic Contact Dermatitis from the synthetic fragrances Lyrall and acetyl cedrene in separate underarm deodorant preparations. Contact Dermatitis 1994 Nov; 31(5): 288-290.

Larsen W, Nakayama H, Lindberg M, Fischer T, Elsner P, Burrows D, Jordan W, Shaw S, Wilkinson J, Marks J Jr., Sugawara M, Nethercott J. Fragrance contact dermatitis: a worldwide multicenter investigation (Part I). Am J Contact Dermat 1996 Jun; 7(2):77-83.

^{xviii} Zamula, Evelyn, Contact Dermatitis: Solutions to Rash Mysteries; May 1990, FDA Consumer, the U.S. FDA

This Position Statement is provided for educational and informational purposes only. It is intended to offer physicians guiding principles and policies regarding the practice of dermatology. This Position Statement is not intended to establish a legal or medical standard of care. Physicians should use their personal and professional judgment in interpreting these guidelines and applying them to the particular circumstances of their individual practice arrangements.