



FRAGRANCE MATERIALS ASSOCIATION OF THE UNITED STATES

1620 I Street, N.W., Suite 925

Washington, DC 20006

Telephone (202) 293-5800 • Facsimile (202) 463-8998

www.fmafragrance.org

THE TRUTH ABOUT PHTHALATES

What are phthalates?

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 differ significantly. One of the phthalates, diethyl phthalate or DEP, is commonly used in toothbrushes, food packaging and cosmetics. It is also used in fragrances to help blend fragrance ingredients and as a fixative to make fragrances last longer.

Are phthalates safe?

Safety concerns have been raised most recently in Europe about (DBP) and (DEHP). However, neither DBP nor DEHP are permitted for use in cosmetic products in Europe.

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.

The Cosmetic Ingredient Review (CIR) Expert Panel, which is comprised of physicians and scientists who have been publicly nominated by consumer, scientific and medical groups, government agencies and industry, after completing an extensive review of all the literature on DEP in 2002 and again in 2005, announced its decision to not reopen the safety assessment of DEP and other phthalates. 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 has three liaison members from the U.S. Food and Drug Administration (FDA), The Consumer Federation of America and the Cosmetic, Toiletry and Fragrance Association (CTFA).

Most recently, in a 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. The SCCP is the regulatory arm of the European Union comparable to the FDA.

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.

How does the fragrance industry determine whether or not their ingredients such as DEP are safe?

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.

Fragrance material standard-setting involves a step-wise process, beginning with initial substance evaluations conducted by RIFM (www.rifm.org). 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 (IFRA). IFRA sets strict safety standards for the use of fragrance ingredients and member companies must adhere to the IFRA Code of Practice and agree to produce fragrances to meet these high standards of safety.

How can the end product manufacturers be sure that the fragrances they are supplied are safe?

Customarily the 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 materials 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

The Natural Resources Defense Council (NRDC) recently released a report on phthalates: “Masking the Danger: Toxic Chemicals in Air Fresheners.” What is the Fragrance Materials Association’s reaction to this report?

The NRDC report mischaracterizes the safety profile of diethyl phthalate 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.

Resources

www.cir-safety.org Findings, Ingredients Safe as Used, page 3

U.S. Department of Health and Human Services, Agency for Toxic Substances and Disease Registry, Toxicological Profile for Diethyl Phthalate, June 1995

World Health Organization (WHO), Report on Diethyl Phthalate Chemical Assessment, Document 52, Geneva, 2003

European Commission SCHER (Scientific Committee on Health and Environmental Risks) Opinion on Emission of Chemicals by Air Fresheners, January 27, 2006,
http://ec.europa.eu/health/ph_risk/committees/04_scher/scher_opinions_en.htm

European Commission’s Scientific Committee on Consumer Products (SCCP) Opinion on Phthalates in Cosmetic Products, March 21, 2007,
http://ec.europa.eu/health/ph_risk/committees/04_sccp/docs/sccp_o_106.pdf

Scientific Committee on Consumer Products and Non-Food Products Intended for Consumers, December 9, 2003, <http://ec.europa.eu/health>