

FOCUS on Phthalates

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June 2019

(REVISED FROM FEBRUARY 2013 VERSION)

FOCUS ON PHTHALATES: MYTH VS. FACT

Phthalates are a **class** of plasticizers, some of which have been used for more than 80 years to soften or “plasticize” vinyl plastics in order to make them flexible. They are found in many useful everyday vinyl products, from decorative coated fabrics and upholstery to wall coverings, flooring and medical devices like blood bags. For coated fabrics, phthalates’ useful properties make them easy to process, as well as more durable, versatile and affordable. ■ Phthalates are colorless liquids with little or no odor and low volatility. People outside our industry often refer to phthalates as a single substance when, in fact, there are at least 14 different types of phthalates currently used in commerce. Each individual phthalate differs from the other, an important factor when considering which best meets the requirements for each specific flexible vinyl product. ■ Phthalates normally used in the coated fabrics industry continue to be considered safe for this application. This conclusion is supported by multiple government agency reviews from the United States, Europe, Canada and Australia. Despite this, phthalates, as a class, are the subject of misleading claims that result in unnecessary concern and confusion. This FOCUS is intended to help customers distinguish fact from myth in product claims.

MYTH: ALL PHTHALATES ARE THE SAME.

FACT: Each individual phthalate possesses distinct physical and chemical properties and are not interchangeable. These differences are important when considering their use in specific applications and safety profiles.

For example, only certain phthalates are suitable for plasticizing vinyls. In the same vein, while some phthalates with low molecular weight, such as those used in cosmetics, require special authorization for use in regions like Europe, other phthalates with higher molecular weight are considered safe for intended use and are not restricted.¹



MYTH: WE DON'T KNOW MUCH ABOUT THE POTENTIAL HAZARDS AND RISKS OF PHTHALATES.

FACT: Phthalates are among the most thoroughly studied class of compounds in the world. The US Centers for Disease Control and Prevention (CDC) has been collecting data on phthalates for more than 15 years. The data confirms that exposure to phthalates is considerably lower than safe levels established by government regulatory agencies around the world.

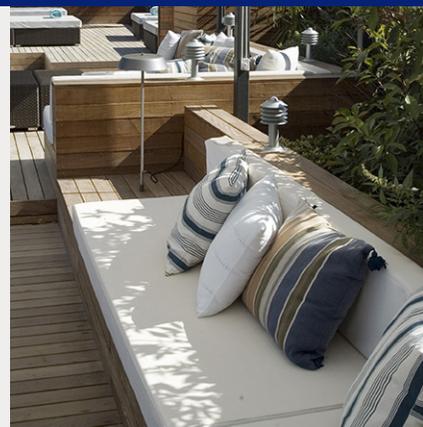
High molecular weight phthalates like DINP and DIDP have been the subject of multiple reviews by governmental agencies around the world; from Australia^{2,3} to the US,⁴ EU⁵ and Canada.⁶ The results of these reviews support the safety of high molecular weight phthalates when used as intended, in various applications such as flooring, wall coverings and coated fabrics.

Q: DO PHTHALATES LEACH OUT OF PRODUCTS AND CAUSE HARM?

A: PHTHALATES ARE TIGHTLY BOUND WITHIN THE VINYL MATRIX AND DO NOT MIGRATE EASILY. THEY ALSO DO NOT ACCUMULATE IN THE HUMAN BODY.

HMW phthalates are used in durable products (such as leather alternatives) because of their compatibility with PVC and low volatility. Depending on the conditions of use, some limited migration is possible; however, specific plasticizers are chosen for their permanence and durability to ensure long-term performance of the vinyl articles.

For more information about phthalates, visit the resource center from the American Chemistry Council: <http://phthalates.americanchemistry.com> and European Plasticisers: <http://www.europeanplasticisers.eu>



MYTH: PHTHALATES ARE RESTRICTED VIA PROP 65 IN CALIFORNIA.

FACT: Prop 65 is simply a right-to-know law. It does not ban or restrict the use of a chemical in the state of California. If a product contains any of the listed chemicals, at least one must be reported by name in a prescribed manner.

A Prop 65 listing does not mean that the chemical is unsafe for intended use, banned or restricted in the state of California. For example, aspirin is listed on Prop 65 as causing effects in females and the developing fetus, yet it is commonly prescribed as a safe and effective pain reliever. In the same vein, some phthalates like DINP and DIDP are listed on California's Prop 65 as 'known to the State of California' to cause cancer and developmental effects respectively. However, DINP is not considered to pose a risk for cancer anywhere else in the world. As for DIDP, it is considered safe enough to be approved for use in children's toys, without restrictions, in the US.

MYTH: PHTHALATES INTERFERE WITH HUMAN MALE REPRODUCTIVE DEVELOPMENT.

FACT: Not all phthalates are the same. There is sufficient evidence that high molecular weight phthalates like DINP and DIDP do not interfere with human male reproductive development.

The European Chemicals Agency recently reviewed several human studies incorporating more than 1,500 boys and young men across Europe. Their report found no correlation between DINP exposure and male reproductive disorders in men. The US Consumer Product Safety Commission has declared that DIDP does not affect human male reproductive development and has permitted its use in children's toys, without restrictions.

MYTH: PHTHALATES ARE MAKING US FAT.

FACT: No studies connect phthalate exposure to obesity in humans; the key causes are increased calorie consumption and less exercise.

While the World Health Organization (WHO) has declared that obesity has reached epidemic proportions worldwide (at least 300 million adults are considered to be clinically obese), there is no evidence that phthalates are to blame.⁷ The WHO considers the key causes to be "increased consumption of energy-dense foods high in saturated fats and sugars, and reduced physical activity." While the diet is also a source of phthalate exposure from food packaging, it is more likely that the increase in obesity is directly related to an increase in the consumption of an unhealthy diet, with phthalates a non-causal circumstantial association.⁸

MYTH: PHTHALATES ARE FREQUENTLY DETECTED AT HIGH LEVELS IN HUMANS.

FACT: Modern human biomonitoring methods show that exposures to phthalates are low and below recommended levels set by government agencies for most applications.

Government biomonitoring studies have indicated the presence of hundreds of natural and manmade chemicals in the human body. The mere presence of something in the body does not equate with harm. The inherent toxicity of the chemical, the dose and length of exposure are important factors. Phthalates begin to break down within minutes and are eliminated from the body within hours. The CDC has found average phthalate exposures to be a hundred to a thousand times below concentrations (or at 1/100 to 1/1,000 of the no observed effect levels or NOEL) set by US federal agencies to be protective of human health.

¹ June 2018 final ECHA RAC opinion on DINP
² Australia NICNAS factsheet on DINP
³ Australia NICNAS factsheet on DIDP
⁴ US CPSC phthalate rule (October 20, 2017)
⁵ ECHA March 16, 2018 press release on DINP classification
⁶ Health Canada Draft Screening Assessment on phthalates
⁷ WHO 2010. Obesity and overweight
⁸ Sharpe RM, Drake AJ (2013) Obesogens and obesity—an alternative view? Obesity 21:1081-1083



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