

PRODUCT LIABILITY UPDATE**Formaldehyde Designated as a “Known Human Carcinogen”**

A report released June 10, 2011 by the Department of Health and Human Services (HHS) identified formaldehyde as a “known human carcinogen.” The *12th Report on Carcinogens* is a congressionally mandated, science-based, public health document prepared by the National Toxicology Program (NTP) for the secretary of HHS. The report identifies agents, substances, mixtures, and exposure circumstances that are known, or reasonably anticipated, to cause cancer in humans.

FORMALDEHYDE IS EVERYWHERE

Formaldehyde is an organic chemical compound often used with other chemical compounds as a polymer base. These polymers are used in a wide variety of consumer products, from automobiles to building materials to health and beauty products. Produced commercially since the early 1900s, in recent years formaldehyde ranks among the top 25 highest volume chemicals produced in the United States.

Formaldehyde, commonly known for its use in the embalming process, is a ubiquitous chemical used in numerous industries. It is found in building materials such as particleboard, plywood, and fiberboard; glues and adhesives; permanent-press fabrics; paper product coatings; and certain insulation materials. Formaldehyde also is used as an antimicrobial agent in many cosmetic products including soaps, shampoos, hair preparations, deodorants, lotions, make-up, mouthwashes, and nail products. In addition, formaldehyde is often used as an industrial fungicide, germicide, and disinfectant.

CAUSE FOR CONCERN

Formaldehyde is classified as a probable human carcinogen by the U.S. Environmental Protection Agency (EPA) and a known human carcinogen by the World Health Organization’s International Agency for Research on Cancer. In litigation, plaintiffs have claimed that formaldehyde is associated with nasal sinus cancer, nasopharyngeal cancer, and on occasion, leukemia. Sweden and Japan have banned its use in cosmetics. It also is banned in certain applications in Europe under the Biocidal Products Directive. In the United States, while not banned outright, various governmental bodies, such as the Food and Drug Administration (FDA) and EPA, regulate the allowable amount of formaldehyde in consumer products and have been moving toward lower and lower allowable amounts.

Recently, formaldehyde has been scrutinized in the U.S. media due to scares related to food from Indonesia and Vietnam, where formaldehyde solution was added to extend shelf life. There also has been increased focus on the presence of formaldehyde in health and beauty products produced for



U.S. consumers, such as shampoo and soaps. This includes products formulated for use on infants and children, despite the conclusion by the FDA's Cosmetic Ingredient Review Expert Panel that when formaldehyde makes up less than 0.2 percent of a cosmetic product applied to the skin, it is safe for the majority of consumers.

WHAT THE REPORT SAYS

The *Report on Carcinogens* identifies agents, substances, mixtures, or exposures in two categories: (1) known to be a human carcinogen; and (2) reasonably anticipated to be a human carcinogen. HHS cautions: “[a] listing in the Report on Carcinogens does not by itself mean that a substance will cause cancer. Many factors, including the amount and duration of exposure, and an individual’s susceptibility to a substance, affect whether a person will develop cancer.”

Formaldehyde was first listed in HHS’ *2nd Report on Carcinogens* in 1981 as a substance that was “reasonably anticipated” to be a human carcinogen after laboratory studies showed it caused nasal cancer in rats. It maintained that designation until the *11th Report on Carcinogens* was released in 2005. According to HHS, there now exists sufficient evidence from studies in humans demonstrating that individuals with higher measures of exposure to formaldehyde are at increased risk for certain types of rare cancers, including nasopharyngeal, sinonasal, and myeloid leukemia.

INDUSTRY CONCERNS AND OPPOSITION

The chemical manufacturing industry has strongly opposed the proposed designation of formaldehyde as a known human carcinogen, delaying the release of the *12th Report on Carcinogens* by almost five years. Upon release of the report on June 10, American Chemistry Council (ACC) president and chief executive officer Calvin M. Dooley expressed disappointment that HHS had moved forward with listing formaldehyde as a known human carcinogen, and noted that ACC was “extremely concerned that politics may have hijacked the scientific process.” He also called the designation of formaldehyde as a carcinogen an “unfounded classification ... [that will] unnecessarily alarm consumers,” and stated that the report “ignores the finding from the independent, government-mandated National Academy of Sciences report which strongly questioned whether the scientific evidence supports a connection between formaldehyde and leukemia.” Some in the industry, including ACC, have promised to continue fighting the designations in the report and will appeal elements of its findings.

Despite conflicting scientific positions on how formaldehyde can affect human health, it is unclear whether the HHS report will spur tighter U.S. formaldehyde regulations. EPA, which has been trying to update its chemical risk assessment for formaldehyde since 1998, issued its long-awaited draft IRIS risk assessment on formaldehyde in June 2010. The assessment linked exposure to formaldehyde to a variety of adverse health effects, including leukemia and other types of cancer. The National Academy of Sciences (NAS), however, criticized the EPA assessment, sharply disagreeing with the conclusion that formaldehyde causes respiratory cancers, leukemia, and other health problems including asthma, damage to the nervous system, or infertility in women. NAS



agreed, however, that EPA sufficiently supported its conclusions that formaldehyde can irritate eyes, noses, and throats, and can cause respiratory lesions. Until the ongoing IRIS assessment is finalized, EPA will continue to list formaldehyde as a “probable” carcinogen and will not be able to set more stringent standards for the chemical.

MINIMIZING LITIGATION RISK

The designation of formaldehyde as a carcinogen may spur an increase in formaldehyde litigation. Thus, companies that manufacture or sell building materials, glues and adhesives, permanent-press fabrics, cosmetics, paper product coatings, and certain insulation materials might find themselves embroiled in “bet-the-company” litigation. Potential claims include, but are not limited to, negligence, failure-to-warn, design defect, breach of warranties, and medical monitoring. Medical monitoring claims, through which consumers can require the manufacturer to establish a fund to pay for future medical tests and surveillance, are particularly likely in mass tort cases. With respect to formaldehyde, as with other “toxins of the moment,” education and prevention are essential to minimizing the risk of potential litigation.

FOR MORE INFORMATION

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