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December 1, 2000

COURTNEY M. PRICE
VICE PRESIDENT
CHEMSTAR



Ms. Kate Rawson
Editor, The Rose Sheet
5550 Friendship Blvd., Suite One
Chevy Chase, MD 20815-7278

Dear Sir/Madam:

I am writing on behalf of the Phthalate Esters Panel (Panel) of the American Chemistry Council regarding the article entitled "Phthalates Carcinogenicity Potential In Consumer Products, CDC Study," which appeared in the October 23 edition of *The Rose Sheet*. As you may know, phthalates are a key ingredient found in many products that have improved the quality of life for families, businesses and hospitals for over 50 years. As such, I am very concerned by the inaccurate and potentially misleading nature of this article as it could result in raising undue concern on the part of your readership. I'd like to address my concerns more specifically in this letter, and I would strongly encourage you to contact a representative of the Panel in the future prior to any additional articles on phthalates.

The article is inaccurate regarding its main premise, the "planned carcinogenicity testing" of phthalates. The Panel has verified with both the National Institute of Environmental Health Sciences (NIEHS) and Centers for Disease Control (CDC) that neither organization plans any carcinogenicity studies on phthalates. For your information, most of the major phthalates have already undergone carcinogenicity testing. In February of this year, the International Agency for Research on Cancer (IARC), the world's leading authority on cancer, concluded that, DEHP, the most widely used phthalate, cannot be classified as being carcinogenic to humans.

The Rose Sheet article further misleads by failing to provide a context for the phthalate levels reported in the CDC biomonitoring study, as reported in the October issue of *Environmental Health Perspectives*. Such context, however, was provided in letters to the editor published in that same issue of EHP — one from researchers at NIEHS and CDC, the other from Dr. Raymond David of the Phthalate Esters Panel (see Attachments 1 and 2). These letters note that exposures to the most commonly used phthalates are consistent with previous estimates and are within safe limits derived by the U.S. Environmental Protection Agency (EPA). Using separate methodologies, both sets of authors used the CDC biomonitoring data to assess actual exposures. Although the exposure assessments were independently derived, the median, 95th percentile and maximum exposures to the various phthalates determined by each group are very similar to each other (see Table 1 of the Panel letter and Table 2 of the NIEHS/CDC letter). As pointed out in the Panel letter, the maximum exposures are at or within EPA — determined "safe" levels (known as RfD's). Those EPA levels incorporate conservative margins of safety so that even exposures at or slightly above the RfD does not necessarily indicate risks to health.



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The broad comments indicating that phthalates cause "cancer, birth defects and adverse hormone reactions in laboratory animals" do not take into account the very large doses of phthalates that are required to induce effects in rodents, or the differences between rodents and humans in responding to phthalates, or the scientific uncertainties, which government and the scientific community are currently addressing concerning hormone disruption.

Since its inception 27 years ago, the Panel and its members have sponsored health and safety research on phthalates. This cutting-edge research always follows the strictest government and scientific standards to promote reproducibility, reliability and accuracy. Resulting data are peer-reviewed and published in respected scientific journals. The Panel shares its data with government agencies around the globe, including the U.S. EPA, the U.S. Food and Drug Administration, the National Toxicology Program, the Consumer Product Safety Commission and IARC. I have asked Marian Stanley, Manager of the Phthalate Esters Panel (703-741-5623), to call you to arrange for a full briefing about health and safety research on phthalates.

In summary, independent scientists, international government bodies and phthalate producers have conducted extensive studies about the safety, health and environmental effects of phthalates. This substantial body of scientific data does not present credible evidence that people are harmed by phthalates. There have been no confirmed reports of adverse health effects (including no human reproductive or developmental effects), in children or adults. Consumers and downstream customers can remain confident about using products that contain phthalates.

Sincerely yours,

Courtney M. Price/HCS

Courtney M. Price
Vice President, CHEMSTAR

cc: Dr. John Brock, Centers for Disease Control and Prevention
Dr. Michael Cunningham, National Institute of Environmental Health Sciences
Dr. Michael Shelby, National Institute of Environmental Health Sciences
Mr. Gerald McEwen, Cosmetics, Toiletry and Fragrance Association
Mr. Glenn Roberts, Fragrance Manufacturers Association