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EWG Petitions CDC To Conduct Biomonitoring Studies for Common Sunscreen Chemicals

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**To: U.S. Department of Health and Human Services
Centers for Disease Control and Prevention
National Center for Environmental Health
Agency for Toxic Substances and Disease Registry
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Atlanta, GA 30341
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Environmental Working Group (EWG), a nonprofit research and advocacy organization with headquarters in Washington, D.C., is petitioning the Centers for Disease Control and Prevention to add common sunscreen chemicals to the CDC's Biomonitoring Program. EWG has been doing research on sunscreen ingredients since 2007, helping to educate the public about the importance of using sunscreens for health protection, as well as providing information about health risks that may be associated with certain ingredients used in sunscreen products.

In response to a significant increase in the use of sunscreens in the United States and the associated increased potential for systemic exposure to the ingredients in these products, in February 2019, the Food and Drug Administration proposed a new rule for sunscreen products.¹ The proposed rule would require sunscreen active ingredients to be assessed for their propensity to absorb through the skin and overall safety. Recently, the FDA completed tests on the absorbance of four common sunscreen active ingredients: avobenzone, oxybenzone, octocrylene, and ecamsule. As reported in a study published by the Journal of American Medical Association in May 2019,² application of all four tested sunscreen ingredients resulted in plasma concentrations that exceeded the 0.5 ng/mL threshold proposed by the FDA for waiving systemic carcinogenicity studies as well as developmental and reproductive toxicity studies. The systemic absorption of all four tested sunscreen ingredients supports the need for biomonitoring of the U.S. population as well as additional studies to determine the significance of these findings in people.

Although the use of sunscreen products is recommended by medical practitioners, the latest research has raised questions about both the safety and efficacy of ingredients in

¹ Department of Health and Human Services, Food and Drug Administration. 2019. Sunscreen Drug Products for Over-the-Counter Human Use. Proposed rule. Docket No. FDA-1978-N-0018. RIN 0910-AF43.

² Matta MK et al. 2019. Effect of Sunscreen Application Under Maximal Use Conditions on Plasma Concentration of Sunscreen Active Ingredients: A Randomized Clinical Trial. JAMA. 2019 May 6. doi: 10.1001/jama.2019.5586.



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sunscreen products currently sold in the U.S. The CDC already includes the sunscreen ingredient oxybenzone in the national biomonitoring tests. As CDC scientists reported in an article published in 2008, oxybenzone has been detected in 96.8 percent of samples from 2003-2004.³ A study based on the National Health and Nutrition Examination Survey for 2003-2006 and 2009-2012 found that the frequency of sunscreen use correlated with the levels of oxybenzone in the general U.S. population.⁴

FDA has expressed concerns about oxybenzone due to studies showing it may cause allergic reactions and potential endocrine disruption. The agency also expressed concern that children may be more vulnerable to harm because of the potential for greater absorption through the skin. Furthermore, the FDA study indicates that there are other sunscreen chemicals beyond oxybenzone that are entering into the bodies of people using products that contain these ingredients.

EWG is petitioning the CDC to add ecamsule and the other 11 sunscreen active ingredients the FDA has highlighted as needing further evaluation, including: avobenzene, octocrylene, homosalate, octisalate, octinoxate, cinoxate, dioxybenzone, ensulizole, meradimate, padimate O and sulisobenzene. In addition, the CDC should consider adding additional sunscreen ingredients, such inactive ingredients and any additional sunscreen active ingredients that are allowed for use in the future. Consumer product chemicals that end up in the bodies of people should be tracked diligently, and we urge the CDC to start an extended biomonitoring program for sunscreen chemicals.

Submitted by the Environmental Working Group

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³ Calafat AM, Wong LY, Ye X, Reidy JA, Needham LL. 2008. Concentrations of the sunscreen agent benzophenone-3 in residents of the United States: National Health and Nutrition Examination Survey 2003-2004. *Environ Health Perspect.* 116(7):893-7.

⁴ Zamoiski RD, Cahoon EK, Michal Freedman D, Linet MS. 2015. Self-reported sunscreen use and urinary benzophenone-3 concentrations in the United States: NHANES 2003-2006 and 2009-2012. *Environ Res.* 142:563-7.