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Comments to U.S. Environmental Protection Agency
Docket: Repellency Awareness Graphic
Docket number: EPA-HQ-OPP-2013-0406

EPA's Proposed Repellency Awareness Graphic Is A Good First Step

Significant Improvements Are Needed to Protect Public Health and Inform Consumers

The Environmental Working Group is a not-for-profit public health and environmental research and advocacy organization based in Washington, D.C. The EWG staff conducts extensive research and analysis on an array of environmental and public health issues, including chemical contamination of food, water, consumer products and the environment. Last year, EWG released a consumer-focused report with guidance for the public on the safety and efficacy of insect repellents and the ingredients used in these products (EWG 2013A). Other notable EWG projects include consumer-focused websites evaluating the hazards associated with cleaning products, personal care products and their constituent ingredients (EWG 2014). Our analysis of cosmetic ingredient hazards, along with our modeling of sunscreen efficacy, forms the basis for an annual report that ranks sunscreen products (EWG 2013B).

After more than a year of research on insect repellents, EWG concluded that the lack of consistent efficacy testing and labeling of skin-applied repellents unnecessarily put consumers at risk from vector-borne illness. According to the federal Centers for Disease Control and Prevention, 5,650 American were infected with West Nile virus in 2012 and 286 of them died. (CDC 2013A). Confirmed and probable cases of Lyme disease rose to more than 30,000 in 2012, but the CDC has estimated that the true number of newly-diagnosed cases is probably 10 times that number (CDC 2013B, CDC 2014).

Currently, there is no convenient way for consumers to compare the general efficacy of different products: repellents with the same concentration of active ingredient are often labeled with very different protection times, when in practice they would be expected to perform similarly. In addition, the efficacy testing of various products against tick species is inconsistent. Consumers have no easy way to evaluate the efficacy of botanical pesticide products, technically called minimum risk pesticides.

The voluntary repellency awareness graphic proposed by the U.S. Environmental Protection Agency represents a small step towards solving these problems. But it falls short of providing the full measure of information that consumers need to make informed decisions about products that provide the greatest benefit while minimizing the risks of exposure to toxic chemicals.

EWG has identified five main issues that the EPA should address to better protect the health and safety of consumers:

- 1) Text should be added to product labels that says explicitly that products with a shorter protection time are not less effective;

- 2) The EPA should establish a mechanism so that botanical pesticides, also known as minimum risk products, can meet the repellency awareness graphic labeling requirement without going through the registration process required under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA);
- 3) All insect repellent products should be tested until failure;
- 4) The repellency awareness graphic and corresponding efficacy testing should be mandatory for all product registrations;
- 5) The EPA should consider products misbranded when they have vague labeling language and make baseless claims.

The rationale underpinning EWG's recommendations are as follows:

1. The EPA should add text to the repellency awareness graphic that explicitly conveys the message that products with a shorter protection time are not less effective.

The EPA has said that a model for the repellency awareness graphic is the labeling of sunscreen products with sun protection factor, or SPF. While the use of an SPF number on sunscreen products is well-established, the widespread use of this label does not imply consumer understanding. Particularly problematic is the market shift towards higher SPF labeled products that use a correspondingly higher concentration of active ingredients, when these SPF products only provide marginally better sunburn protection (EWG 2013C). These products now dominate the sunscreen market. The EPA's advice about repellents on its website says: "Shorter protection time does not mean the product is less effective" (EPA 2013). Yet this important recommendation is not discussed in the context of the proposed graphic. It would be a serious mistake not to integrate this information on product labels. If this information does not accompany the graphic, consumers will likely be driven towards products with unnecessarily higher concentrations of active ingredients based purely on the number of hours of protection time. The labeled protection time should have an upper limit based on the maximum time that a person would realistically be expected to stay outdoors during a day.

2. The EPA should establish a mechanism for botanically-based, so-called minimum risk repellent products to meet the repellency awareness graphic labeling requirement without requiring these products to go through FIFRA registration.

It is critical that bug repellents have labels that allow comparison between FIFRA-registered and botanical or minimum risk pesticides. Efficacy testing information is sparse for many of these products. Consumers need better information about botanicals in order to make truly informed decisions. At the same time, requiring minimum risk products to register under FIFRA would defeat the primary purpose of the minimum-risk designation.

3. The EPA should require that all products are tested until failure.

Efficacy testing for all products should be continued until the maximum claimable protection time or until efficacy failure as stated in the draft EPA efficacy testing guidelines (EPA 2010). It is troublesome that products expected to provide very similar levels of protection, such as 15% DEET products, are labeled to provide anywhere between 3 and 8 hours of protection, or not labeled with any protection time (S. C. Johnson & Son, Inc. 2010, EPA 2013). This is causing unnecessary consumer confusion.

4. The repellency awareness graphic and corresponding efficacy testing should be mandatory for all registrations.

Use of the graphic should not be voluntary. Repellent makers should be required to use the graphic, just as sunscreen makers are required to label their products with the results of efficacy testing. With no consistent labeling, consumers will have even greater difficulty evaluating product claims and understanding the overall efficacy of different products. The EPA must be aware from its experience in other regulatory arenas that voluntarily guidelines are typically quite ineffective.

5. The EPA should treat vague labeling language and baseless claims as misbranding.

Within the proposed voluntary repellency awareness guidance document, the EPA plans to “recommend” that both vague and baseless claims on repellent products be removed. The agency cites as examples claims like “repels for hours,” “provides protection hour after hour” and “waterproof.” This use of any vague and baseless claim should be considered prima facie evidence of misbranding unlawful under FIFRA. In the interest of public health, the EPA must take immediate action to remove products making these claims from the market.

Thank you for considering our comments. We look forward to working with the EPA on this important issue in the coming months.

David Q. Andrews
Senior Scientist
Environmental Working Group

Renee C. Sharp
Director of Research
Environmental Working Group

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