

REPELLENCY AWARENESS

GRAPHIC

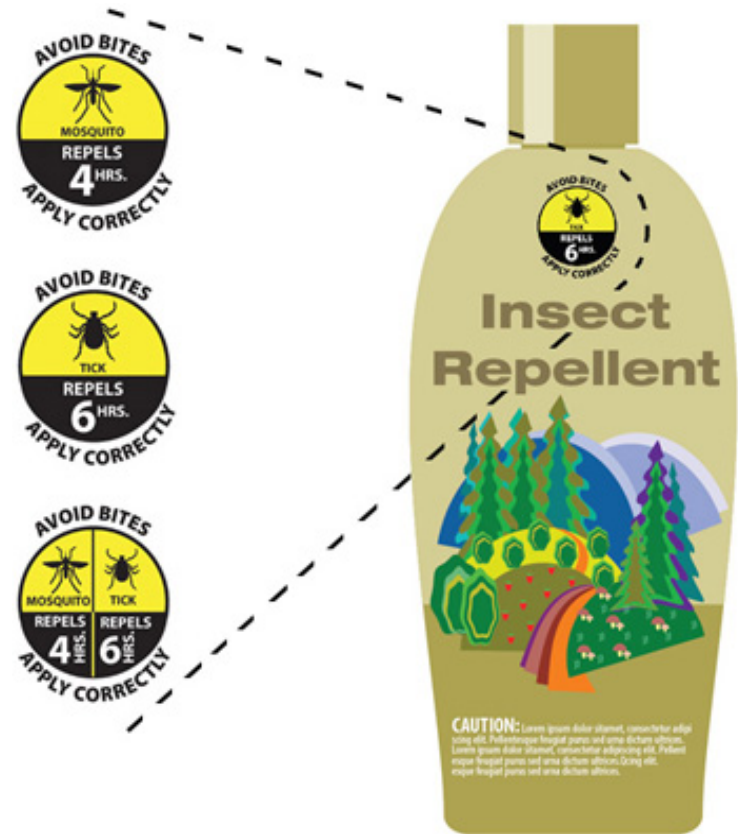
Informational Presentation for
EPA's Human Studies Review Board
April 9, 2014

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What is the Repellency Awareness Graphic?

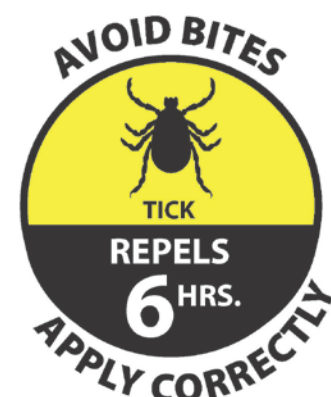
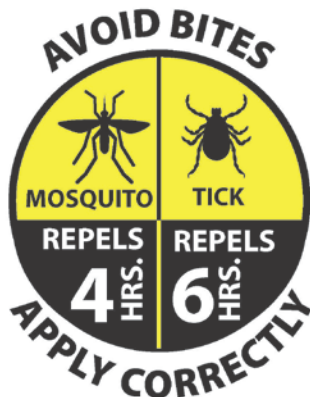
A voluntary EPA effort to:

- encourage standardized product labeling of skin-applied insect repellents through use of a graphic, and
- clearly communicate to consumers the estimated number of hours mosquitoes and/or ticks are repelled by a product when used as directed

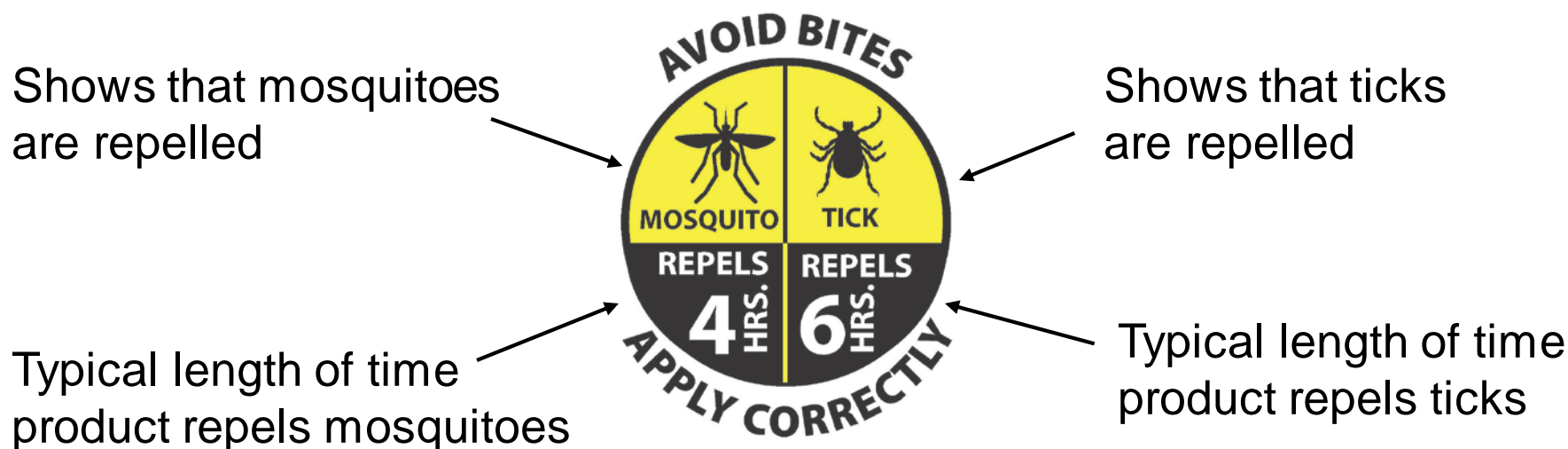


Graphic

- Three versions of the graphic will be available to voluntarily use on a product label
 - A graphic with mosquito and tick information together
 - Or graphics with only mosquito information or only tick information



How Will It Work?



- For skin-applied insect repellents only
- Graphical claim will be part of the product's approved registration and labeling
- Companies must voluntarily apply – through new or amended registration application

How Will It Work?

- Producers submit/cite data with the following qualities:
 - Following current test guidelines or using an equivalent standard
 - Using multiple studies to inform the label claim for the pest group
 - Ticks: specific representative test species
 - Mosquitoes: two field studies
- Data will undergo consistent analysis:
 - Median will be used to calculate Complete Protection Time (CPT)
 - EPA will develop criteria for determining the number(s) shown in the repellency awareness graphic
 - E.g., how to deal with multiple data sets, how to round a number, minimum CPT needed to use the graphic

Why Is This Effort Important?

- Assists public health protection
 - Improves consumers' knowledge about how to protect themselves against vector borne disease, like West Nile virus and Lyme disease
- Represents a more rigorous standard of data generation and analysis
 - Increases EPA's and consumers' confidence in the efficacy claims on labels
- Provides consistency
- Enhances public health information and improves the clarity of pesticide product labeling



Relevance to the HSRB

- Current guidelines for testing the efficacy of skin-applied repellents recommend intentional exposure studies with human subjects, which are subject to HSRB review
- EPA published guidance regarding the repellency awareness graphic and invited public comment last November
- If companies want to use the graphic, they may need to conduct new repellent efficacy studies
- Possibility of a fairly large work load for EPA and HSRB
- Some public comments expressed interest in exploring ways to streamline the HSRB review process

Next Steps

- Public comment period ended on March 6, 2014
- EPA is reviewing comments and encouraging companies interested in the graphic to contact us
- We could hear later this year from companies wanting to move forward to conduct research to obtain the repellency awareness graphic

