

U.S. ENVIRONMENTAL PROTECTION AGENCY

# Repellency Awareness Guidance

For Skin-Applied Insect Repellent Producers  
Office of Pesticide Programs

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## Table of Contents

Guidance Summary.....	3
I. Introduction .....	4
II. Background .....	4
III. Applicability – Products for Which This Graphic is Intended .....	5
IV. Non-binding Nature of This Guidance .....	6
V. Recommended Criteria .....	6
A. Type of Product.....	6
B. Pest Claims that the Graphic Represents.....	6
C. Complete Protection Time (CPT) .....	8
D. Minimum Duration of CPT Represented by the Graphic .....	9
VI. Implementation – How to Obtain the Graphic .....	9
A. Registration Applications.....	9
B. Claims of Confidentiality .....	11
C. Data Citation and Compensation.....	11
D. Human Research Ethics Considerations .....	11
E. Where to Send the Application.....	12
F. Review and Determination .....	12
VII. Use of the Graphic on a Product Label and in Marketing Materials.....	12
A. Repellency Awareness Graphic Design.....	13
B. Label Language Relating to the Repellency Awareness Graphic .....	14
C. Other Labeling, Marketing, and Related Materials.....	16
D. Writing and Speaking About the Repellency Awareness Graphic and Effort.....	16
E. Use of the Graphic without EPA Review of Data.....	16
F. Terms of Use for the Repellency Awareness Graphic.....	17
VIII. Paperwork Reduction Act Notice .....	18
IX. Information Contact.....	18

## Guidance Summary

**The purpose of the repellency awareness graphic** is to enhance public health information for skin-applied insect repellent products by improving the prominence and clarity of product effectiveness claims on labels.

The Environmental Protection Agency (EPA) repellency awareness graphic is **voluntary and intended for** registrants of new and existing skin-applied insect repellent products that are subject to the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA). Applications to add the repellency awareness graphic to a product label will be subject to the Pesticide Registration Improvement Extension Act (PRIA 3).

The agency intends that registrants use the repellency awareness graphic to communicate the duration of repellent efficacy of a product against **mosquitoes and/or ticks**. Any other arthropods listed on the label are not included as part of this effort and should be supported by separate efficacy data.

**Data Generation**, if needed, should follow guidance in EPA's Office of Chemical Safety and Pollution Prevention (OCSPP) Harmonized Test Guideline 810.3700 and undergo human research ethics review.

**For mosquitoes**, median complete protection times (CPTs) should be calculated from results of product performance field studies at two distinct habitats where predominant mosquito species differ. The mosquito claim should be calculated using the most conservative (*i.e.*, lowest) CPT from all available field studies. The most conservative CPT should be a minimum of two hours in order for a mosquito efficacy claim to be made in the repellency awareness graphic.

**For ticks**, CPTs should be calculated from results of tests on three tick species suggested in this guidance. The tick claim should be calculated using the most conservative (*i.e.*, lowest) CPT from all available tick species tested. The most conservative CPT should be a minimum of two hours in order for a tick efficacy claim to be made in the repellency awareness graphic.

## I. Introduction

This document presents the U.S. Environmental Protection Agency's (EPA or the agency) guidance to industry for participation in the repellency awareness effort for one or more pesticide products. This effort is limited to pesticide products subject to FIFRA labeled for application to skin for the purpose of repelling mosquitoes and/or ticks. This guidance provides specific information regarding how applicants for new registrations or registrants of currently registered products can apply to EPA for approval to add a graphical claim to the product label. The graphic is a standardized design intended to clearly communicate to consumers the product's effective repellency in number of hours against mosquitoes and/or ticks when the product is used as directed on the label. EPA undertakes efforts such as this in order to improve and clarify pesticide product labeling for consumers and to promote public health protection. Although seeking approval to add this graphic to a pesticide product label is voluntary and this guidance creates no enforcement authority in and of itself, the inclusion of this graphic, or some variation of this graphic, on a pesticide product label without engaging the agency as recommended in this guidance may be "false or misleading" under 40 CFR sections 156.10(a)(5) and 152.25(f)(3)(iii) and therefore constitute "misbranding" under section 2(q)(1)(A) of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) and an unlawful act under FIFRA section 12(a)(1)(F), and in the case of pesticide products registered under section 3 of FIFRA may also constitute an unlawful act under FIFRA section 12(a)(1)(B).

EPA developed this guidance document to help those who are interested in the repellency awareness graphic to understand the types of efficacy data to provide to EPA in order for EPA to approve the addition of the graphical claim to the label. It conveys what the agency considers to be credible information and sound science needed to support use of the repellency awareness graphic. This guidance document also describes the process for providing such information to EPA and gives recommendations relating to the placement of the repellency awareness graphic on the product label.

## II. Background

Mosquitoes and ticks can transmit infectious diseases, including West Nile virus, Lyme disease, and Eastern Equine Encephalitis. Using effective skin-applied insect repellent products and other preventative actions can discourage ticks, mosquitoes, and other biting insects from landing on you. EPA consumer research has shown that consumers believe product labels are unclear about product effectiveness, including the repellency time.<sup>1</sup> Consumers want clear and easy-to-find information on product labels that conveys the types of insects<sup>2</sup> repelled and the number of hours of protection against those insects.

Labeling of many skin-applied insect repellent products does not currently provide easy comparison among products when determining types of insects repelled and duration of

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<sup>1</sup> USEPA. 2012. Consumer Survey Results on Insect Repellent Labels.  
<http://www.epa.gov/pesticides/insect/repellent-consumer-survey.html>.

<sup>2</sup> The agency recognizes that ticks are arachnids rather than insects, but for simplicity will use the term "insects" for both mosquitoes and ticks in this document.

repellency. Thus, as part of EPA's efforts to protect public health and address consumer need for clear pesticide labeling, EPA's Office of Pesticide Programs (OPP) has developed the repellency awareness graphic. Much like the SPF (sun protection factor)<sup>3</sup> on labels of sunscreen products quickly conveys the amount of protection a sunscreen offers against UV-B, the repellency awareness graphic intends to make information on demonstrated duration of product efficacy more prominent and standardized on labels of skin-applied insect repellent products. Producers who wish to add the repellency awareness graphic to their label should consider this guidance before contacting EPA regarding use of the graphic.

Through the repellency awareness graphic and recommendations in this guidance, the agency intends to improve existing labels by clearly conveying to consumers the expected efficacy of skin-applied insect repellent products, when used as directed. The agency believes that this will help consumers make more informed choices in protecting themselves and family members against mosquitoes and ticks and the diseases they may carry.

The graphic is product-specific based on the efficacy data supporting the product. Producers of products subject to Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) registration requirements must submit to EPA an application for new or amended registration to use the repellency awareness graphic as described in section VI of this guidance document. These product applications will be subject to the Pesticide Registration Improvement Extension Act (PRIA 3).

### III. Applicability – Products for Which This Graphic is Intended

This voluntary graphic and guidance is for producers of new and existing skin-applied insect repellent products that are subject to FIFRA registration requirements. EPA is still considering the possible involvement of skin-applied insect repellent products that are exempt from FIFRA requirements. These products contain minimum risk pesticides and are referred to as “25(b) products,” in reference to section 25(b) of FIFRA, 7 U.S.C. § 136w(b). *See also*, 40 C.F.R. § 152.25(f) and [http://www.epa.gov/opp00001/biopesticides/regtools/25b\\_list.htm](http://www.epa.gov/opp00001/biopesticides/regtools/25b_list.htm). To the extent that producers of 25(b) products become involved, participation for such a product necessarily may differ from those products requiring registration prior to participation. The agency may recommend that information in addition to that outlined in this guidance be submitted by a 25(b) producer seeking to use the repellency awareness graphic. Additionally, since PRIA is an amendment to FIFRA, EPA cannot accept fees from 25(b) product manufacturers and give a decision date under PRIA with any request seeking to use the graphic unless the producer chooses to register their product. Therefore, at this time, EPA encourages producers of 25(b) products to apply to register their product under FIFRA if interested in the repellency awareness graphic.

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<sup>3</sup> The SPF program is administered by the Food and Drug Administration, and not EPA.

## IV. Non-binding Nature of This Guidance

This document provides EPA's general guidance to pesticide producers who may voluntarily request to add the repellency awareness graphic to their product labeling, as well as guidance to the public. This guidance is not binding on either EPA or any outside parties, and the EPA may depart from the guidance where circumstances warrant without prior notice. At places in this guidance, the agency uses the word "should." In this guidance, the use of the term "should" with regard to an action means that the action is recommended rather than mandatory. The procedures contained in this guidance are recommended for generating the data and information that are the subject of this guidance, but EPA recognizes that departures may be appropriate in specific situations. Producers seeking to use the repellency awareness graphic may propose alternative approaches to the recommendations in this guidance document, and the agency will evaluate them for appropriateness on a case-by-case basis.

## V. Recommended Criteria

The recommended criteria listed below intend to guide those interested in the repellency awareness graphic in identifying data to submit in connection with a request to add the repellency awareness graphic to a pesticide label. In conjunction with this guidance, applicants should refer to EPA's Office of Chemical Safety and Pollution Prevention (OCSPP) Harmonized Test Guidelines.<sup>4</sup> In particular, *Product Performance Test Guideline, OPPTS 810.3700: Insect Repellents to be Applied to Human Skin*<sup>5</sup> provides recommendations for the design and execution of repellent efficacy studies. The complete set of criteria described in those guidelines and this guidance document represent the quality and characteristics of efficacy studies and other information that EPA recommends companies provide to support their proposed repellency claims for the graphic.

### A. Type of Product

This effort is intended for skin-applied insect repellents (*i.e.*, a product intended to repel insects when applied directly to human skin) labeled for use against mosquitoes and/or ticks. Repellents making claims to repel pests exclusive of mosquitoes or ticks; repellents intended for application to animals or fabric, foliar or general surface sprays; and products intended as spatial repellents (*e.g.*, coils and candles) are not included at this time.

### B. Pest Claims that the Graphic Represents

The repellency awareness graphic is intended to be used to communicate the duration of repellent efficacy of a product against mosquitoes and/or ticks. There are three possible claims that may be represented on the graphic: efficacy against mosquitoes only, against ticks only, or against both.

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<sup>4</sup> USEPA. Harmonized Test Guidelines. Home page. <http://www.epa.gov/ocspp/pubs/frs/home/guidelin.htm>.

<sup>5</sup> USEPA. 2010. Product Performance Test Guidelines. OPPTS 810.3700: Insect Repellents to be Applied to Human Skin. EPA 712-C-10-001. [http://www.epa.gov/ocspp/pubs/frs/publications/Test\\_Guidelines/series810.htm](http://www.epa.gov/ocspp/pubs/frs/publications/Test_Guidelines/series810.htm).

## Examples of Repellency Awareness Graphics

**Mosquitoes:**

For mosquitoes, EPA current practice is to only approve a general mosquito claim (*i.e.*, a claim to repel all mosquitoes and not a specific mosquito species) on labels of registered skin-applied insect repellent products. EPA will continue this practice in the repellency awareness effort. Protection against one mosquito species is impractical, and consumers may encounter many different species of mosquitoes in a given area. The mosquito symbol in the graphic will convey a generalized mosquito claim, and data to support a general mosquito claim should be submitted or cited in an application to use the mosquito symbol in the repellency awareness graphic.

Field testing at two distinct habitats where predominant mosquito species differ and preferably cover three different genera is recommended as support for a mosquito efficacy claim for skin-applied insect repellent products. EPA's policy is to request efficacy data that mimics, to the extent possible, actual use conditions, in order to provide the best possible indication of protection time for a typical consumer under environmental conditions. More information on generating data to support a general mosquito claim can be found in Product Performance Test Guideline, OPPTS 810.3700.<sup>6</sup>

**Ticks:**

For ticks, the agency has historically approved both a general taxonomic tick claim and claims against a single species of tick, *e.g.*, deer tick, (in the absence of a general taxonomic claim) as text claims on labels. However, the tick symbol in the graphic will convey a generalized tick, and the use of the graphic in the absence of data to support a generalized claim against ticks could be misleading. Therefore, data to support a general tick claim should be submitted or cited in an application to use the tick symbol in the repellency awareness graphic.

EPA recommends that studies from three representative tick species be submitted to support a tick claim for the repellency awareness graphic. In many cases, there are large differences in duration of repellency between different tick species. The representative test species recommended to support a generalized claim against ticks are intended to ensure an estimate of repellency duration against the most common disease-bearing tick species.

The representative test species EPA recommends to support a generalized claim against ticks are as follows:

<sup>6</sup> [http://www.epa.gov/ocspp/pubs/frs/publications/Test\\_Guidelines/series810.htm](http://www.epa.gov/ocspp/pubs/frs/publications/Test_Guidelines/series810.htm).

- Blacklegged tick (commonly known as deer tick; *Ixodes scapularis*), and
- Lone star tick (*Amblyomma americanum*), and
- American dog tick (*Dermacentor variabilis*).

These tick species are not only commonly occurring and widespread but are the primary vectors of several important tick borne diseases. The blacklegged tick is the primary vector of Lyme disease, babesiosis, and anaplasmosis. The lone star tick transmits diseases including ehrlichiosis, STARI (Southern tick associated rash illness), tularemia, and possibly Rocky Mountain spotted fever. The American dog tick is a primary vector of Rocky Mountain spotted fever and also transmits tularemia.

Information on conducting tick studies can be found in Product Performance Test Guideline, OPPTS 810.3700. However, that guideline reflects the historic practice of allowing claims against a single species of tick. Therefore, this repellency awareness guidance should be consulted regarding representative test species to support a general tick claim in the repellency awareness graphic.

### C. Complete Protection Time (CPT)

#### Determination of CPT:

The duration of the CPT for the graphic is determined through statistical analysis of the supporting efficacy data. The CPT is the time from application of a repellent to test subjects until efficacy failure as demonstrated by the supporting data. Failure is a landing event for a mosquito or a crossing event for a tick confirmed within 30 minutes by a second similar event. As stated in the Product Performance Test Guideline, OPPTS 810.3700, EPA currently uses the median CPT with its 95 percent confidence limits, calculated using Kaplan-Meier estimation analysis, as the summary measure of CPT to support an efficacy claim. The agency will continue this practice for applicants of the repellency awareness graphic.

#### Multiple data sets:

Data from multiple field locations (*i.e.*, for mosquitoes) or multiple species (*i.e.*, for ticks) are recommended to support general claims against each of these pest groups so that multiple data sets, each with a calculated CPT, will be available to inform the mosquito and/or tick claims made in the repellency awareness graphic. These CPTs are often different. The most conservative (*i.e.*, shortest) CPT from each of the pest group data sets should be used to represent the claim(s) shown in the repellency awareness graphic. EPA believes that this will more reliably inform consumers about the general duration of protection provided against each pest group, and thus may better inform a person how to protect themselves from being bitten and potentially exposed to vector-borne diseases.

#### Rounding:

The number of hours of protection appearing on the repellency awareness graphic should be expressed as a whole number. If the most conservative calculated CPT is not a whole number,



EPA recommends rounding down to the nearest whole number. For example, three hours and 45 minutes would be listed on the label as three hours.

#### **D. Minimum Duration of CPT Represented by the Graphic**

The minimum duration of CPT expressed by the repellency awareness graphic for a product is the fewest number of hours of repellency (*i.e.*, shortest protection time) that the graphic will convey. As described in section V.C., CPT will be based on agency assessment of the submitted efficacy data and statistical treatment of those data. Inherent variability in product effectiveness results from the interactions of factors such as differences in human behavior, host physiology and attractiveness, variable susceptibility of pests to a product, and environmental conditions. On this basis, EPA supports two hours as the credible minimum protection time for use of the graphic.

### **VI. Implementation – How to Obtain the Graphic**

Prior to contacting EPA concerning the repellency awareness graphic, EPA encourages applicants to review all guidance and materials related to this effort. The applicant should begin the application process only after the applicant has determined that the graphic is appropriate for its product and has identified the information that may be needed to be considered for the graphic. Information about the process for obtaining this graphic is provided in the following subsections.

#### **A. Registration Applications**

This voluntary effort is intended for skin-applied insect repellent products registered under FIFRA, and EPA views the repellency awareness graphic and the data used to support its claims as part of a registered product's approved registration, labeling, and claims. Accordingly, the addition of any graphic to a product's labeling, including the repellency awareness graphic, must be requested through an application for new or amended registration under FIFRA, as amended by the Pesticide Registration Improvement Extension Act (PRIA 3). Any information or data pertaining to the graphic must be submitted as part of the registration application package.

The process for submitting information to EPA for a registration application package will follow existing policies and procedures. Before making a regulatory decision on the registration application package that includes the graphic, EPA will review all submitted data, analyses, and proposed labeling to verify that the product meets both appropriate registration requirements and expectations for using the repellency awareness graphic.

##### **1. Data Items**

Regulations and guidance for registering or amending a registration are contained in 40 CFR parts 152, 156, 158, and in guidance, such as pesticide registration notices.<sup>7</sup> Companies seeking to use the voluntary repellency awareness graphic, which could ultimately involve changes to

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<sup>7</sup> [http://www.epa.gov/PR\\_Notices/](http://www.epa.gov/PR_Notices/)

pesticide product labels previously approved by EPA, must submit any information, data, analyses, and proposed labeling according to these regulations and with these guidelines in mind.

EPA has assembled an online Pesticide Registration Kit<sup>8</sup> which contains the pertinent forms and information needed to register or amend a registered pesticide product. In addition, the following items should be included in an application to add the repellency awareness graphic:

- The information, data, and analyses recommended in Chapter V of this guidance.
- A proposed master label following the recommended label language guidance found in Chapter VII, section B of this guidance, titled “Label Language Relating to the Repellency Awareness Graphic.”
- A list of distributor products, if any, associated with the pesticide product.
- EPA recommends that applicants also submit a cover letter with their submission, stating the general purpose of the submission and identifying each item in the submission package. The cover letter should indicate that the applicant is requesting to participate in the voluntary repellency awareness effort. The letter should also clearly state the pest claim(s) wanted on their graphic (*i.e.*, tick only, mosquito only, or both).

For a detailed description of the registration process, please review the Pesticide Registration Manual (Blue Book).<sup>9</sup> All questions regarding pesticide registration procedures and specific registration actions should be directed to the appropriate regulatory contact listed at <http://www.epa.gov/pesticides/regulating/contacts.htm>. Applicants who wish to submit data for the repellency awareness graphic that differ from what is recommended in this guidance are encouraged to contact the ombudsperson from the appropriate registering division to verify that the data will satisfy expectations for the graphic.

## 2. PRIA Fees

As amended by PRIA 3, section 33 of FIFRA, among other things, establishes a registration service fee system for certain types of pesticide applications and creates a schedule of decision review times for applications covered by the service fee system. Under this system, each individual category corresponds to a certain registration service fee and decision review period. The goal is to create a more predictable evaluation process for affected pesticide decisions, coupling the collection of individual fees with specific decision review periods. The fees and decision review periods may change between fiscal years, and fees are periodically increased as prescribed by statute.

PRIA 3 applications are subject to fees based upon the type of application. Actions are categorized first by type of chemical (*i.e.*, conventional, antimicrobial, or biopesticide chemical product), and next by the type of action (*e.g.*, new active ingredient (nonfood use), new food use, new registration of an old product, label amendment requiring data submission, etc.). Because the graphic must become an approved part of the product’s registration and labeling and will require some level of review by EPA, the applicant must comply with any fee requirements established under PRIA 3 in addition to the registration requirements referenced in section

<sup>8</sup> <http://www.epa.gov/pesticides/registrationkit/>

<sup>9</sup> <http://www.epa.gov/pesticides/bluebook/>

VI(A)(1) of this guidance document. EPA will follow all existing policies and procedures associated with PRIA 3 applications.

EPA recommends that applicants contact the appropriate regulatory contact for their chemical, listed at <http://www.epa.gov/pesticides/regulating/contacts.htm>, to determine which PRIA 3 code and fee matches their product's application. For additional information about PRIA 3, please visit <http://www.epa.gov/pesticides/fees/>.

## B. Claims of Confidentiality

Any information claimed to be Confidential Business Information (CBI) will be handled in accordance with FIFRA Section 10 and the associated CBI regulations contained in 40 CFR Part 2, Subpart B. EPA recommends that applicants review the guidance in Pesticide Registration Notice (PRN) 2011-3<sup>10</sup> for information on how to assert this claim.

## C. Data Citation and Compensation

Existing policies and procedures regarding data citation and compensation apply to the submission of data when applying to add the repellency awareness graphic to a label. These requirements and applicable forms are fully discussed in Chapter 10 of the Pesticide Registration Manual (Blue Book).<sup>11</sup> For further reference, see [FIFRA section 3\(c\)\(1\)\(F\)](#) and the paragraphs on implementing regulations protecting data submitters' rights in [40 CFR Part 152 Subpart E](#).

For applicants that choose to rely on existing data to support the addition of the graphic on their product's labeling, EPA recommends that applicants use the selective method of support as described in 40 CFR Part 152, Subpart E. EPA believes that using specific individual efficacy studies rather than citing all studies will benefit both the applicant's ability to calculate repellency time and the agency's review of the application. EPA will consider each submission based on its own merits. Applicants are encouraged to contact the appropriate chemical manager for the product to discuss which method of citation might be more appropriate in any given situation.

## D. Human Research Ethics Considerations

New research testing the efficacy of a skin-applied insect repellent, conducted for the purpose of obtaining the repellency awareness graphic as described in this guidance, is subject to the requirements set forth in EPA's rules for the protection of human subjects of research, 40 CFR Part 26, subparts K through Q. This type of research would involve intentional exposure of human subjects to the test repellent, and therefore review of the protocol by an Institutional Review Board (IRB), by EPA, and by EPA's Human Studies Review Board (HSRB) is required before study initiation. *See* 40 CFR § 26.1109, § 26.1125, and § 26.1601. A more thorough

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<sup>10</sup> [http://www.epa.gov/PR\\_Notices/pr2011-3.pdf](http://www.epa.gov/PR_Notices/pr2011-3.pdf)

<sup>11</sup> <http://www.epa.gov/pesticides/bluebook/chapter10.html>

discussion of these requirements can be found in the Product Performance Test Guideline, OPPTS 810.3700.<sup>12</sup>

If existing efficacy data are submitted or cited for the purpose of obtaining the repellency awareness graphic, EPA will review the data for ethical acceptability unless the ethics of the study has previously been reviewed by EPA. The data submitter is subject to the requirements at 40 CFR § 26.1303 to provide information about the ethical conduct of the research. Studies that involve intentional exposure of children or pregnant or nursing women will not be considered by EPA, per 40 CFR § 26.1703.

## E. Where to Send the Application

Applicants should see PRN 2006-1<sup>13</sup> for guidance on transmitting information to OPP.

## F. Review and Determination

Once a complete application has been received, OPP will conduct a review of the application. This will include the following:

1. A review of any information and data submitted or cited for the purposes of the action.
2. A review of the applicant-submitted statistical analysis to determine the repellency time.
3. Confirmation that the formulation identified on the pesticide Confidential Statement of Formula (CSF) is substantially similar in composition (ingredients and percentages) to the formulation tested in the efficacy study.
4. A review of the entire product labeling.

Once the application has been reviewed, the agency will process the application and notify the applicant of the decision according to current agency practices.

## VII. Use of the Graphic on a Product Label and in Marketing Materials

This chapter provides recommendations for how the graphic should be displayed on a product label, including size, color, and location, and on other labeling information related to the graphic. EPA also provides advice in this chapter on how to describe the graphic in marketing materials.

Use of the repellency awareness graphic is voluntary, and the recommendations set forth in this guidance regarding how an applicant proposes to display the graphic are non-binding and will be considered by the agency on a case-by-case basis. However, once a registrant's label is amended to include the repellency awareness graphic and efficacy claim, that graphic and claim will become part of the labeling of the product, and all applicable requirements of FIFRA and other pesticide laws and regulations will then apply to the graphic and claim as part of the label approved by EPA under FIFRA.

<sup>12</sup> [http://www.epa.gov/ocsp/pubs/frs/publications/Test\\_Guidelines/series810.htm](http://www.epa.gov/ocsp/pubs/frs/publications/Test_Guidelines/series810.htm)

<sup>13</sup> [http://www.epa.gov/PR\\_Notices/pr2006-1.pdf](http://www.epa.gov/PR_Notices/pr2006-1.pdf)

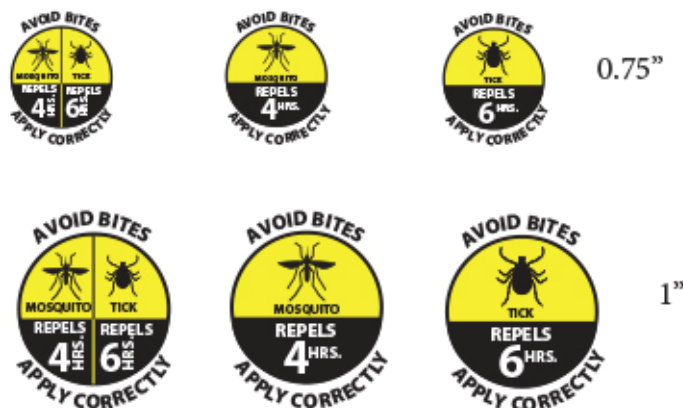
## A. Repellency Awareness Graphic Design

The repellency awareness graphic may be used on product packaging and labeling as long as the product continues to meet the criteria for efficacy.

### 1. Elements of the Repellency Awareness Graphic

For product labels approved to bear the repellency awareness graphic, EPA recommends that the labeling contain the following elements:

- Repellency awareness graphic should be prominently displayed on the front panel of the product label.
- Repellency awareness graphic size should be between 0.75 and 1 inch in diameter. The Repellency awareness graphic may be resized as long as it stays between 0.75 and 1 inch in diameter, but the proportions of the graphic should be maintained.



- The number of hours listed on the repellency awareness graphic is the duration verified by the agency and is not lesser or greater than what the data supports.
- The repellency awareness graphic should remain intact and unchanged (*e.g.*, no embellishments, using portions of the graphic, omitting wording encircling the graphic).
- The phrase “For more information on the repellency awareness graphic, see <http://www2.epa.gov/insect-repellents>” should appear separate from the graphic but on the product label. The URL provided here will become active by the end of 2013.
- EPA recommends the phrase “This graphic represents typical repellency time(s)” appear on the product label in relation to the graphic.

### 2. Repellency Awareness Graphic Orientation

There should be a minimum clear space “safe area” of at least 0.125 inches around the graphic. No other elements should be placed within this space surrounding the graphic. For legibility, it is recommended that the graphic not be reproduced in print smaller in width than 0.75 inches. Lettering of the repellency awareness graphic should be legible if used on the internet.



0.125" safe area

### 3. Repellency Awareness Graphic Color Palette

To ensure successful public recognition of the repellency awareness graphic, EPA recommends a uniform color palette for the graphic. The graphic should have yellow, black, and white as its colors.

#### Color Palette

##### RGB

Black: R 35 G 31 B 32

Yellow: R 246 G 238 B 49

White: R 255 G 255 B 255

##### CMYK

Black: C 70 M 67 Y 64 K 74

Yellow: C 7 M 0 Y 90 K 0

White: C 0 M 0 Y 0 K 0

### 4. Distribution of the Graphic to Successful Applicants

Upon successful processing of an application, EPA will notify the applicant of the decision according to current agency practices and provide instructions to successful applicants on how to retrieve the graphic.

#### B. Label Language Relating to the Repellency Awareness Graphic

##### 1. Label Language about Pests Represented in the Graphic

The label language of a product cannot conflict with information provided in the repellency awareness graphic. For example, any labeling statements about protection against ticks and/or mosquitoes can only relay information identical to or consistent with what is presented in the repellency awareness graphic (if used).

As stated in Section V.C., the most conservative (*i.e.*, shortest) CPT from each of the pest group data sets should be used to represent the claim(s) shown in the repellency awareness graphic. Specific species of a pest represented on the repellency awareness graphic may be listed on the label, but protection times for a species, if different than the time presented in the graphic, should not be listed. For example, if applying for a repellency awareness graphic that says that ticks are repelled for “X” hours, the label can state that the product repels deer ticks, also for X hours, but should not state for Y hours, even if deer tick data support that duration. It may confuse

consumers if the number of hours listed on the repellency awareness graphic differed from the number of hours listed protecting against a specific species of tick.

## 2. Label Language about Pests Not Represented in the Graphic

Efficacy claims for pests not represented in the repellency awareness graphic should not be placed or worded in such a way that implies a link to the repellency awareness effort, if granted and placed on the label. Additionally, if any pest not represented in the repellency awareness graphic has a repellency time less than that listed in the graphic, the repellency time for that pest should be indicated on the label. The graphic has the potential for causing generalizations of repellency for all pests claimed on the label, and indicating any pest repellency times lower than that on the repellency awareness graphic should avoid the label being misleading in that regard.

## 3. Vague Label Language about Efficacy of the Product

This repellency awareness effort aims to simplify and clarify efficacy statements on insect repellent product labeling. In keeping with this goal, the agency recommends that other efficacy-related labeling language that is vague or ineffective be removed, regardless of whether used in conjunction with the repellency awareness graphic or not. Language of this type that is recommended for removal includes the following:

- Phrases or statements containing poorly defined, inexact, or confusing descriptions such as:
  - Long lasting/strong/all day/effective protection against *[insert pest name(s)]*
  - Repels for hours
  - Provides protection hour after hour
  - Protects against severe conditions
- Efficacy statements containing information not related to efficacy:
  - Scented protection from *[insert pest name(s)]*
- Comparative efficacy claims such as:
  - As good as/safer than/better than *[insert competitor name(s)]*

## 4. Other Label Language Recommendations

The agency recommends that certain phrases appear on a product bearing the repellency awareness graphic, as outlined in Section VII.A.1. Labeling should not include additional statements about the repellency awareness graphic.

Regarding language not associated with the graphic itself but related to protecting public health against vector-borne disease, EPA recommends other label language enhancements that include the following:

- Clearly indicate the application method of the product so consumers can easily find how much product should be applied to get the protection indicated.
- Clearly distinguish if application method for children is different than for adults.
- Highlight the directions for use so consumers will be drawn to the information on how to apply the product correctly.
- Remove baseless claims, such as “sweat proof” or “waterproof,” unless explicitly approved for the product by the EPA.



## C. Other Labeling, Marketing, and Related Materials

### 1. Use of the Repellency Awareness Graphic on Labeling and Marketing Materials

The repellency awareness graphic may be used on manufacturer, distributor, or retailer brochures, advertisements, displays, or point-of-purchase materials, but should only be so used where clearly associated with a specific product to indicate that the product meets the efficacy criteria for the repellency awareness graphic. The repellency awareness graphic may also be used on manufacturer, distributor, or retailer Web sites, but should only be so used to clearly distinguish products that meet the efficacy criteria for the repellency awareness graphic, and in direct association with those products.

The repellency awareness graphic should not be used in a way that indicates or implies a connection with (1) products that are not repellency awareness graphic-labeled, (2) entire product lines, (3) company programs in general (*e.g.*, on a Web page that features several products, not all of which are labeled with the repellency awareness graphic), or (4) promotional materials on environmental/human health in general. In marketing materials, the graphic should only be used in association with and directly adjacent to a repellency awareness graphic-labeled product.

The repellency awareness graphic should not in any way be used to imply that EPA endorses the product or the labeled product's manufacturer, company, or producer. The repellency awareness graphic only recognizes that certain qualified products meet the efficacy criteria.

### 2. Other Materials

The repellency awareness graphic should not be used on materials outside of product labeling and marketing materials directly related to the repellency awareness graphic-labeled product. Other materials related to the product or its ingredients, such as Material Safety Data Sheets, should not display the repellency awareness graphic.

## D. Writing and Speaking About the Repellency Awareness Graphic and Effort

Successful applicants may want to market their product that has the graphic (*e.g.*, explain what the graphic on the label means or how EPA's review process works). EPA recommends that successful applicants consult EPA's website on repellency awareness at <http://www2.epa.gov/insect-repellents><sup>14</sup> for key messages about the graphic and the effort as well as for the appropriate OPP contact for any questions.

## E. Use of the Graphic without EPA Review of Data

Pesticide products, whether registered under section 3 of FIFRA or exempted from the requirements of FIFRA per FIFRA § 25(b), may not include any "false or misleading" labeling statements (*see* 40 CFR § 156.10(a)(5) and 40 CFR § 152.25(f)(3)(iii)). The repellency

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<sup>14</sup> This URL will become active by the end of 2013.



awareness graphic is an indicator of the duration of effectiveness demonstrated to the agency for the pest group(s) represented. Although seeking approval to use the graphic is voluntary and this guidance creates no enforcement authority in and of itself, use of this graphic, or variation thereof, without engaging the agency as recommended in this guidance may be “false or misleading” under 40 CFR sections 156.10(a)(5) and 152.25(f)(3)(iii) and therefore constitute “misbranding” under section 2(q)(1)(A) of FIFRA and an unlawful act under FIFRA section 12(a)(1)(F), and in the case of pesticides products registered under section 3 of FIFRA may also constitute an unlawful act under FIFRA section 12(a)(1)(B).

## F. Terms of Use for the Repellency Awareness Graphic

For a detailed description of the registration process, please review the Pesticide Registration Manual (Blue Book).<sup>15</sup> All questions regarding pesticide registration procedures and specific registration actions should be directed to the appropriate ombudsperson or registration liaison listed at <http://www.epa.gov/pesticides/regulating/contacts.htm#product>.

### 1. Periodic Updates of the Graphic

In the possibility that the agency needs to update the process or criteria for the repellency awareness effort, which affects usage of the graphic, EPA will notify users of the graphic of the update, who should then, if appropriate, submit an amendment and change their label accordingly.

### 2. Product Alterations

If a product that has a previously-approved repellency awareness graphic changes its formulation in a way that is not substantially similar to the original basic Confidential Statement of Formula (CSF) approved for the product when the graphic was added or makes other alterations which could affect the efficacy of the product, the producer should follow existing policies and procedures for submitting information to EPA for an amendment to their product’s registration and at the same time make a new request to use the repellency awareness graphic based on data from the altered product.

### 3. Termination of Use

If EPA determines that a product that has previously been approved to use the repellency awareness graphic no longer qualifies for the repellency awareness graphic, the agency will so notify the producer. The Agency expects that existing stocks will be handled consistent with EPA’s established “existing stocks policy” at 56 FR 29362 (June 26, 1991), *as amended by* 61 FR 16632 (April 16, 1996), and 40 CFR § 152.130. The repellency awareness graphic should be eliminated from promotional materials. The producer should submit to the agency an application for a label amendment that contains a new master label without the repellency awareness graphic, and no new products should be produced with the repellency awareness graphic included on labeling.

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<sup>15</sup> <http://www.epa.gov/pesticides/bluebook/>

## VIII. Paperwork Reduction Act Notice

As stated previously, the repellency awareness graphic will become part of a product's labeling, and registrants should apply for use of the graphic through a new or amended registration application. Since registered products will be applying to use the graphic through existing processes, the information collection associated with the activities described in this document are already approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act (PRA), 44 U.S.C. § 3501, *et seq.*

The corresponding ICR document related to the information collection activities associated with the application for a new or amended pesticide registration has been approved under OMB Control No. 2070-0060 (EPA ICR No. 0277). The annual average reporting and recordkeeping burden for a registration applicant respondent is estimated at 14 to 840 hours, depending on the type of activity. A copy of the most recently approved version of EPA ICR No. 0277 is available under Docket ID No. EPA-HQ-OPP-2011-0886 at <http://www.regulations.gov>.

Under the PRA, "burden" means the total time, effort or financial resources expended by persons to generate, maintain, retain or disclose or provide information to or for a Federal agency. For this collection, it is the time reading the regulations, planning the necessary data collection activities, conducting tests, analyzing data, generating reports and completing other required paperwork, and storing, filing and maintaining the data.

Under the PRA, an agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. The appropriate OMB control number will appear on any collections of information pertaining to this guidance, including the pesticide application.

## IX. Information Contact

For further information, please contact Rose Kyprianou of the Field and External Affairs Division (7506P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW, Washington, DC 20460-0001; telephone number (703) 305-5354; fax number: (703) 305-5884; e-mail address: [kyprianou.rose@epa.gov](mailto:kyprianou.rose@epa.gov).