

Guidance on "Absence of an Ingredient" Claims Associated with Federal Insecticide, Fungicide, and Rodenticide Act-Regulated Products

February 2024

I. PURPOSE

This guidance clarifies the status of "absence of an ingredient" claims associated with Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA)-regulated products. The discussion in this guidance is applicable to claims made on the labeling of both pesticides and devices because both types of products are subject to FIFRA's "misbranding" requirements. However, this guidance will largely focus on pesticide products.

The U.S. Environmental Protection Agency (EPA or Agency) is aware that the regulated community seeks clarity on whether and how "absence of an ingredient" claims¹ can be made lawfully on FIFRA-regulated products. In this guidance, EPA clarifies its current approach to "absence of an ingredient" claims on pesticide product labeling.

Besides this "Purpose" unit, the "Disclaimer" unit, and the "References" unit, this guidance includes four units. The first provides background information on the pesticide registration process, what information EPA considers during that process (e.g., whether a product would be misbranded because of false or misleading claims on the proposed labeling), and existing guidance on "absence of an ingredient" claims. The second clarifies EPA's approach to "absence of an ingredient" claims on EPA-registered pesticide product labeling. The third outlines the applicability of this guidance to minimum risk pesticide products. The fourth outlines the actions that may be taken by applicants and registrants who wish to modify their registrations or applications based on this guidance. It also notes that EPA expects to update various existing guidance documents that discuss "absence of an ingredient" claims.

II. BACKGROUND

Generally, before a pesticide may be sold or distributed in the United States, it must be registered with EPA under FIFRA.² When EPA registers a pesticide product, EPA reviews and approves labeling³ that provides directions to the user on how to handle and apply the product to avoid unreasonable adverse effects on human health and the environment,⁴ along with precautionary and other required statements. It is a violation of FIFRA to use any registered pesticide product in a manner inconsistent with its labeling.⁵ For a pesticide to meet the FIFRA registration standard, applicants for a registration must—among other things—demonstrate that the pesticide product's labeling is consistent with the requirements of FIFRA.⁶ These requirements include that the pesticide not be misbranded. A pesticide is misbranded if, among other things, "its labeling bears any statement, design, or graphic representation . . . [that] is false or misleading in any particular." In 40 C.F.R. § 156.10(a)(5), EPA provides several

¹ "Absence of an ingredient" claims include "[ingredient name]-free," "contains no/does not contain/does not include/made without [ingredient name]," "free from/of [ingredient name]," and "0% [ingredient name]."

² Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) § 3(a), 7 U.S.C. § 136a(a).

³ FIFRA § 2(p)(2), 7 U.S.C. § 136(p)(2) (defining "labeling").

⁴ FIFRA § 2(bb), 7 U.S.C. § 136(bb) (defining "unreasonable adverse effects on the environment").

⁵ FIFRA § 12(a)(2)(G), 7 U.S.C. § 136j(a)(2)(G); see also FIFRA § 2(ee), 7 U.S.C. § 136(ee) (defining "to use any registered pesticide in a manner inconsistent with its labeling").

⁶ See FIFRA § 3(c)(5)(B), 7 U.S.C. § 136a(c)(5)(B).

⁷ FIFRA § 2(q)(1)(A), 7 U.S.C. § 136(q)(1)(A); see also FIFRA § 12(a)(1)(E)-(F), 7 U.S.C. § 136j(a)(1)(E)-(F) (making it a violation of FIFRA to sell or distribute a regulated product that is misbranded).

examples of labeling statements or representations that constitute misbranding because they are false or misleading, including the following:

- (1) "false or misleading comparison[s] with other pesticides or devices";8
- (2) "true statement[s] used in such a way as to give a false or misleading impression to the purchaser";9
- (3) "[c]laims as to the safety of the pesticide or its ingredients . . . "; 10 and
- (4) "[n]on-numerical and/or comparative statements on the safety of the product "¹¹

In the early 2000s, EPA first provided guidance on "absence of an ingredient" claims and misbranding in Chapter 12 of the Label Review Manual. The current version of Chapter 12 of the Label Review Manual reflects a slight clarification of this guidance, made in 2013:

Claims about the *Absence* of an Ingredient: Statements or claims that express the absence of certain ingredients may be misleading statements prohibited by 40 CFR 156.10(a)(5). These claims are examples of a true statement used in such a way as to give a false or misleading impression to the purchaser. Even though a claim expressing the absence of an ingredient is true, it would generally be considered to be misleading because it falsely suggests to the purchaser that the product is less risky, better, or more desirable than a product containing the ingredient in question. Further, a product must not claim that it does not contain an ingredient if it never contained or was not likely to contain [the ingredient] in the first place. ¹³

EPA's most recent guidance on "absence of an ingredient" claims was in 2021:

Can a manufacturer advertise that their product does not contain a certain active ingredient (e.g., "DEET free")? LC21-1208; 10/14/21

Claims such as "free of [active ingredient]" or "contains no [active ingredient]" may constitute misbranding and may need to be removed. EPA is concerned that users might understand these types of statements to be safety claims. This could give users the impression that products without a certain active ingredient are

⁸ 40 C.F.R. § 156.10(a)(5)(iv).

⁹ 40 C.F.R. § 156.10(a)(5)(vii).

¹⁰ 40 C.F.R. § 156.10(a)(5)(ix).

¹¹ 40 C.F.R. § 156.10(a)(5)(x).

¹² Label Review Manual, Third Edition (2003) ("Claims about the <u>Absence</u> of an Ingredient: Statements or claims that express the absence of certain ingredients are misleading statements prohibited by 40 CFR 156.10(a)(5)(i) and/or 40 CFR 156.10(a)(5)(viii). These claims are examples of a true statement used in such a way as to give a false and misleading impression to the purchaser. Even though a claim expressing the absence of an ingredient is true, it would generally be considered to be misleading because if [sic] it falsely suggests to the purchaser that the product is less risky, better, or more desirable than a product containing the ingredient in question. Further, a product must not claim that it does not contain an ingredient if it never contained the substance in the first place.").

¹³ Label Review Manual (2021), at 12-3, https://www.epa.gov/sites/default/files/2021-02/documents/full-lrm 2-22-21.pdf.

safe or safer than products with the active ingredient, which may be false or misleading. Safety claims are considered false or misleading statements that constitute misbranding under 40 CFR 156.10(a)(5)(ix) and (x). Misleading comparative claims about the safety of the product versus other products also constitute misbranding under 40 CFR 156.10(a)(5)(iv) and (vii). These claims are therefore disallowable under FIFRA sections 2(q)(1)(A) and 12(a)(1)(E).

Consumers can readily determine if a pesticide product contains an active ingredient (e.g., DEET) by reviewing the active ingredients listed on the front panel of the label in accordance with 40 CFR 156.10(g). Because all active ingredients must be listed, the absence of an active ingredient in the ingredient statement would indicate it is not in the product.¹⁴

While the guidance referenced above indicates that "absence of an ingredient" labeling claims in general may be misleading statements that constitute misbranding, EPA has in some cases considered specific types of "absence of an ingredient" claims on labeling to be consistent with the requirements of FIFRA. For example, consistent with 40 C.F.R. § 152.46(a) and section II.K.3. of Pesticide Registration Notice 98-10, EPA currently permits a "fragrance free" claim to be added to labeling by notification provided that the product is odorless or nearly odorless and contains no odor-masking ingredient such as a perfume. Similarly, EPA has considered statements pertaining to the absence of chlorofluorocarbon and other ozone-depleting substances in aerosol pesticide product labeling to be consistent with the requirements of FIFRA. Additionally, EPA has approved pesticide registrations on a case-by-case basis with labeling that contains a variety of other "absence of an ingredient" claims (e.g., "DEET Free," "bleach free," and "contains no phosphates") since the 1970s.

Based on the Agency's further consideration of these labeling claims, EPA believes that clarifying its guidance on "absence of an ingredient" claims on FIFRA-regulated product labeling is warranted.

III. GUIDANCE ON MAKING "ABSENCE OF AN INGREDIENT" CLAIMS ON EPA-REGISTERED PESTICIDE PRODUCT LABELING

A. Clarification of Guidance

As stated in the current version of Chapter 12 of EPA's Label Review Manual, "[s]tatements or claims that express the absence of certain ingredients may be misleading statements prohibited

¹⁴ Pesticide Labeling Questions & Answers, https://www.epa.gov/pesticide-labeling-questions-qu

¹⁵ Pesticide Registration Notice (PRN) 98-10, at 6, https://www.epa.gov/sites/default/files/2014-04/documents/pr98-10.pdf. EPA has also piloted approving "dye-free," "fragrance-free," and "dye and fragrance free" on antimicrobial pesticide product labeling when applicants or registrants provided the appropriate supporting data/information. See Pesticide Label Statements: Pilot Program to Help Promote Environmental Sustainability, https://www.epa.gov/pesticide-labels/pesticide-label-statements-pilot-program-help-promote-environmental-sustainability (last updated May 16, 2023).

¹⁶ PRN 92-2, https://www.epa.gov/sites/default/files/2014-04/documents/prn-92-2.pdf.

by 40 CFR 156.10(a)(5)."¹⁷ Both EPA's Label Review Manual and additional guidance on EPA's website¹⁸ detail why these types of claims may be considered false or misleading, pointing primarily to concerns that "absence of an ingredient" claims could give users the impression that products without a certain ingredient are safe or safer, less risky, better, or more desirable than products containing that ingredient.¹⁹ For example, if an "absence of an ingredient" claim could lead users to believe that a product is safe for humans and the environment such that the directions, precautionary statements, and other required statements on the labeling can be disregarded, then EPA would consider the claim to be misleading. As another example, all EPA-registered pesticides are determined by the Agency to meet the same FIFRA registration standard of no unreasonable adverse effects on the environment.²⁰ If an "absence of an ingredient" claim could lead users to believe that an EPA-registered pesticide product containing that ingredient does not meet the FIFRA registration standard, then EPA would consider the claim to be misleading.

EPA's Label Review Manual also states that a product should not claim that it does not contain an ingredient if it never contained or was not likely to contain the ingredient in the first place, indicating that an "absence of an ingredient" claim may be misleading if a product could not reasonably be expected to contain the ingredient. This guidance generally aligns with the Federal Trade Commission's 2012 Guides for the Use of Environmental Marketing Claims ("Green Guides"), which states the following: "A truthful claim that a product, package, or service is free of, or does not contain or use, a substance may nevertheless be deceptive if . . . the substance has not been associated with the product category." The Green Guides are designed to help marketers avoid making environmental marketing claims that are unfair or deceptive, and they include guidance regarding "free-of" and other claims about the environmental attributes of a product. ²³

There may be situations, however, where an "absence of an ingredient" claim may not be considered false or misleading by EPA. For example, an "absence of an ingredient" claim could be narrowly stated for purposes other than conveying information about the safety of the product for humans or the environment (e.g., with the use of an appropriate qualifying statement²⁴ that is prominently displayed and adjacent to the claim), so that the potential to

¹⁷ Label Review Manual (2021), at 12-3, https://www.epa.gov/sites/default/files/2021-02/documents/full-lrm 2-22-21.pdf.

¹⁸ Pesticide Labeling Questions & Answers, https://www.epa.gov/pesticide-labeling-questions-qu

¹⁹ See 40 C.F.R. § 156.10(a)(5)(iv), (vii), (ix), and (x).

²⁰ See FIFRA § 2(bb), 7 U.S.C. § 136(bb); and FIFRA § 3(c)(5), 7 U.S.C. § 136a(c)(5).

²¹ Label Review Manual (2021), at 12-3, https://www.epa.gov/sites/default/files/2021-02/documents/full-lrm 2-22-21.pdf.

²² 16 C.F.R. § 260.9(b)(2); see also Guides for the Use of Environmental Marketing Claims ("Green Guides") (2012), https://www.ftc.gov/sites/default/files/attachments/press-releases/ftc-issues-revised-greenguides.pdf.

²³ See 16 C.F.R. §§ 260.1 and 260.9.

²⁴ When associated with an "absence of an ingredient" claim, a qualifying statement would mitigate against the claim being viewed as a safety claim by consumers. See Unit III.D. of this document for an example of a qualifying statement for an "absence of DEET" claim.

mislead users is limited. Additionally, data/information demonstrating that an "absence of an ingredient" claim would not be misleading to users could be provided to EPA by an applicant or registrant proposing to make such a claim. For example, a consumer survey could show that an "absence of an ingredient" claim helps users better understand whether a product contains an ingredient that may cause damage to items (e.g., clothing) when applied, rather than misleading users as to the safety of the product for humans or the environment. In other situations, EPA may determine that the minimal potential of a specific "absence of an ingredient" claim to mislead consumers may be outweighed by the benefit to consumers and the regulated community in making EPA's guidance consistent with that of other regulatory entities.²⁵

In conclusion, EPA reviews "absence of an ingredient" claims on pesticide product labeling on a case-by-case basis, based on FIFRA and its implementing regulations and, as appropriate, guided by the principles above. For specific "absence of an ingredient" claims commonly proposed by applicants and registrants, EPA offers further guidance below.

B. Claims Related to Absence of Sodium Hypochlorite (Bleach)

EPA understands that many consumers are interested in products that contain bleach or that do not contain bleach for certain uses. Bleach has many purposes, including cleaning, whitening, sanitizing, and disinfecting. Some consumers may want to use products containing bleach when sanitizing and disinfecting hard, non-porous surfaces or for sanitizing laundry. Other consumers may want to use products that do not contain bleach to avoid causing damage to surfaces or laundry. Because bleach can cause damage or discoloration to surfaces, including that of clothing and other fabrics or textiles, EPA believes that "absence of bleach" claims are generally not false or misleading when used to help consumers make informed choices about purchasing antimicrobial surface sanitizer, surface disinfectant, and laundry sanitizer products.

EPA also believes that "absence of bleach" claims may help consumers better understand product chemistries by using more common terminology. Although pesticide product labels are required to bear an ingredient statement identifying each active ingredient in the product, 26 bleach is identified by its chemical name (sodium hypochlorite), and consumers may not be aware that an ingredient statement that lists sodium hypochlorite means that the pesticide product contains bleach. There are also other ingredients that break down into free available chlorine, such as hypochlorous acid. Consumers may not realize that these other chemistries are also bleaching agents. Therefore, EPA believes that "absence of bleach" claims are generally not false or misleading when used to help inform consumers, using common terminology, that a product does not contain bleach or bleaching agents.

In these situations, EPA generally would not consider "absence of bleach" claims,²⁷ even when used by themselves without a qualifying statement, to be misleading on labeling for

²⁵ See, e.g., PRN 92-2, at 2, https://www.epa.gov/sites/default/files/2014-04/documents/prn-92-2.pdf.

²⁶ FIFRA § 2(n) and 2(q)(2)(A), 7 U.S.C. § 136(n) and 136(q)(2)(A); 40 C.F.R. § 156.10(g).

²⁷ "Absence of bleach" claims include "bleach-free," "contains no/does not contain/does not include/made without bleach," "free from/of bleach," and "0% bleach." Such claims do not include "absence of chlorine" claims or "absence of" claims for other chlorinated chemistries.

antimicrobial surface sanitizer, surface disinfectant, or laundry sanitizer products that do not contain bleach or bleaching agents.

However, EPA views "absence of bleach" claims differently on labeling for pesticide products containing chlorinated chemistries, e.g., hypochlorous acid. The main premise of these chemistries is that when added to a solution, they break down into free available chlorine, which performs the pesticidal activity. Therefore, EPA believes "absence of bleach" claims generally would be false or misleading on labeling for the following pesticide products that break down into free available chlorine, because these products contain bleach or a bleaching agent:

- (1) Products containing sodium hypochlorite (bleach) (CAS Reg. No. 7681-52-9)
- (2) Products containing hypochlorous acid (CAS Reg. No. 7790-92-3)
- (3) Products containing hypochlorite compounds other than sodium hypochlorite (bleach):
 - Calcium hypochlorite (CAS Reg. No. 7778-54-3)
 - Lithium hypochlorite (CAS Reg. No. 13840-33-0)
 - Potassium hypochlorite (CAS Reg. No. 7778-66-7)
- (4) Products containing sodium chlorite (CAS Reg. No. 7758-19-2) or chlorine dioxide (CAS Reg. No. 10049-04-4)²⁸
- (5) Products containing chlorinated isocyanurate compounds:
 - Sodium dichloroisocyanurate (CAS Reg. No. 2893-78-9)
 - Trichloroisocyanuric acid (CAS Reg. No. 87-90-1)
 - Sodium dichloroisocyanurate dihydrate (CAS Reg. No. 51580-86-0)
- (6) Products containing halohydantoin compounds, which release chlorine in water solutions:
 - 1,3-dichloro-5,5-dimethylhydantoin (CAS Reg. No. 118-52-5)
 - 1-bromo-3-chloro-5,5-dimethylhydantoin (CAS Reg. No. 16079-88-2)
 - 1,3-dichloro-5-ethyl-5-methylhydantoin (CAS Reg. No. 89415-87-2)
 - 1,3-dibromo-5,5-dimethylhydantoin (CAS Reg. No. 77-48-5)
- (7) Products containing sodium bromide (CAS Reg. No. 7647-15-6)

EPA also views "absence of bleach" claims differently on labeling for pesticide products that are not antimicrobial surface disinfectants, surface sanitizers, or laundry sanitizers, even if such products do not contain bleach or bleaching agents. For example, "absence of bleach" claims

²⁸ Chlorine and chlorine dioxide are two different chemistries, but chlorine dioxide is used as a bleaching agent.

on labeling for antimicrobial materials preservative products, ²⁹ which are not antimicrobial surface disinfectant, surface sanitizer, or laundry sanitizer products, would generally be considered misleading. Even though such claims may be true, antimicrobial materials preservative products generally would never contain bleach or bleaching agents in the first place. ³⁰

C. Claims Related to Absence of Phosphates

Phosphates, such as sodium tripolyphosphate (CAS Reg. No. 7758-29-4) and tripotassium phosphate (CAS Reg. No. 7778-53-2), can be added both to cleaning products that are not regulated by EPA because they are not intended for a pesticidal purpose ³¹ and to antimicrobial laundry sanitizer products that are regulated by EPA under FIFRA. ³² The purpose of adding phosphates to both types of products is typically to help reduce the formation of soap scum. If this is the purpose of phosphates rather than a pesticidal purpose, the phosphates would be considered inert (other) ingredients when used in EPA-registered antimicrobial laundry sanitizer products. ³³ Although EPA may require the name of any inert ingredients to be listed in the ingredient statement on the label if the Agency determines that such ingredients may pose a hazard to humans or the environment, ³⁴ or registrants and applicants may voluntarily identify inert ingredients on the labels of their products, these ingredients generally are not required to be disclosed on pesticide product labels. ³⁵ Thus, a consumer purchasing an EPA-registered antimicrobial laundry sanitizer product would typically not be able to discern from the ingredient statement on the label alone if the product contained phosphates as inert ingredients.

Further, actions taken by states and localities to limit phosphate use is consistent with EPA's initiative to combat nutrient pollution in United States waterbodies³⁶ and strongly suggest there is public interest and expectation that cleaning products, including antimicrobial laundry sanitizer products that can function both as cleaners and pesticides, declare phosphate content. For example, some states and localities have banned or restricted phosphates in cleaning products, while at least one state also requires a statement such as "no phosphate" to appear on the wrappers or containers of household cleaning products that contain no phosphorus or trace quantities of phosphorus.³⁷ Therefore, EPA generally would not consider "absence of phosphates" claims, even when used by themselves without a qualifying statement, to be

²⁹ See Pesticide Registration Manual: Chapter 4 – Additional Considerations for Antimicrobial Products, https://www.epa.gov/pesticide-registration/pesticide-registration-manual-chapter-4-additional-considerations#use (describing materials preservatives).

³⁰ See Label Review Manual (2021), at 12-3, https://www.epa.gov/sites/default/files/2021-02/documents/full-lrm 2-22-21.pdf.

³¹ See 40 C.F.R. § 152.10(a).

³² What's the difference between products that disinfect, sanitize, and clean surfaces?, https://www.epa.gov/coronavirus/whats-difference-between-products-disinfect-sanitize-and-clean-surfaces.
³³ See 40 C.F.R. § 152.3 (defining "inert ingredient").

³⁴ See 40 C.F.R. § 156.10(g)(7).

³⁵ See FIFRA § 2(n) and 2(q)(2)(A), 7 U.S.C. § 136(n) and 136(q)(2)(A); 40 C.F.R. § 156.10(g).

³⁶ EPA's Ongoing Efforts to Reduce Nutrient Pollution, https://www.epa.gov/nutrientpollution/epas-ongoing-efforts-reduce-nutrient-pollution.

³⁷ See 6 CRR-NY 659.4.

misleading on labeling for antimicrobial laundry sanitizer products that do not contain phosphates as inert ingredients.

D. Claims Related to Absence of N,N-Diethyl-meta-toluamide (DEET)

DEET (CAS Reg. No. 134-62-3) is the active ingredient in many EPA-registered insect repellent products. It has been in use in registered products since 1957, is widely used to repel biting pests such as mosquitoes and ticks, and is designed for direct application to human skin and clothing. EPA has performed numerous assessments of the approximately 600 pesticide products containing DEET that have been registered. 38 First, before these pesticide products were registered, EPA evaluated DEET, other constituent substances (including inert ingredients), and the proposed use patterns to ensure that, when the products are used according to directions, precautionary statements, and other required statements on the labeling, no unreasonable adverse effects on human health or the environment would occur. Additionally, as a part of reregistration,³⁹ EPA completed a review of DEET to ensure it met scientific and regulatory standards and published a Reregistration Eligibility Decision in 1998.⁴⁰ As a result of this comprehensive review, EPA concluded that the normal use of DEET does not present a health concern to the general population, including children. 41 Lastly, every 15 years and taking into account new scientific information that may be available, EPA is required to review registered pesticides to ensure they can carry out their intended function without unreasonable adverse effects on the environment. This process is known as "registration review."⁴² In 2014, EPA completed an interim review of DEET under registration review to ensure that it continues to meet the FIFRA registration standard based on current scientific knowledge. EPA did not identify risks of concern to human health or the environment.⁴³

Despite DEET being used for many years and its lack of risks of concern when used as directed on product labeling, EPA is aware that some members of the public have negative perceptions of DEET pertaining to its safety. 44,45 EPA also understands that "absence of DEET" claims may be used to aid consumers in making informed choices unrelated to perceptions about product

https://ordspub.epa.gov/ords/pesticides/f?p=113:6:::::P6 XCHEMICAL ID:2129.

³⁸ Chemical Name: Diethyl toluamide,

³⁹ Reregistration and Other Review Programs Predating Pesticide Registration Review, https://www.epa.gov/pesticide-reevaluation/reregistration-and-other-review-programs-predating-pesticide-registration.

 $^{^{}m 40}$ Reregistration Eligibility Decision – DEET,

https://www3.epa.gov/pesticides/chem_search/reg_actions/reregistration/red_PC-080301_1-Apr-98.pdf.

⁴¹ DEET, https://www.epa.gov/insect-repellents/deet.

⁴² See FIFRA § 3(g), 7 U.S.C. § 136a(g); see also Registration Review Process, https://www.epa.gov/pesticide-reevaluation/registration-review-process.

⁴³ DEET (N,N-Diethyl-meta-toluamide) – Interim Registration Review Decision (Case Number 0002) (2014), https://www.regulations.gov/document/EPA-HQ-OPP-2012-0162-0012.

⁴⁴ How Safe Is Deet? (2022), https://www.consumerreports.org/health/insect-repellent/how-safe-is-deet-insect-repellent-safety-a4952100929/.

⁴⁵ DEET repels bugs, worries consumers (2011), https://www.latimes.com/health/la-xpm-2011-jun-01-la-he-summer-health-deet-repellents-20110601-story.html.

safety related to human health or the environment (e.g., odor and potential damage to plastic, rubber, vinyl, and elastic on items like clothing and backpacks).⁴⁶

In light of the varying consumer perspectives about DEET and the potential use of "absence of DEET" claims for purposes other than conveying information about safety for humans or the environment, EPA generally would not consider "absence of DEET" claims to be misleading on labeling for EPA-registered insect repellents that are applied to human skin and clothing and that do not contain DEET, if such claims are followed by an asterisk and qualified with a prominently displayed statement like the following: "*Not a safety claim." The asterisk used after the claim, the asterisk used before the qualifying statement, and the qualifying statement itself should be prominent enough that the average consumer can easily find and read the qualifying statement. This should be accomplished by using the same font type/color for the asterisks and qualifying statement, using a type size for the asterisks and qualifying statement that is at least at least one half the type size of the claim, and placing the qualifying statement adjacent to the claim. Additionally, a more detailed qualifying statement could be placed elsewhere on the label, e.g., "The phrase "DEET free" should not be viewed as a statement on the safety of this product relative to any product containing DEET." EPA believes the qualifying statement is important to ensure that consumers are not misled, as there is a potential for the "absence of an ingredient" claim in this case to be used either for an improper comparative safety claim or for conveying other information about the product.

IV. APPLICABILITY TO MINIMUM RISK PESTICIDE PRODUCTS

EPA has exempted from the requirements of FIFRA any minimum risk pesticide that meets the requirements of 40 C.F.R. § 152.25(f). This exemption includes a provision—40 C.F.R. § 152.25(f)(3)(iv)—that requires that the product "not include any false and misleading labeling statements, including those listed in [40 C.F.R. § 156.10(a)(5)(i)—(viii)]" to qualify for the exemption. Accordingly, to the extent that an "absence of an ingredient" claim is not false or misleading as discussed in Unit III., above, such a claim would not disqualify an otherwise qualified minimum risk pesticide from exemption under 40 C.F.R. § 152.25(f).

V. APPLICATION PROCESS AND FUTURE UPDATES

A. Application Process

The table below outlines actions that can be taken by applicants and registrants who wish to modify their applications or registrations based on this guidance. As stated above, EPA will review proposed "absence of an ingredient" claims on pesticide product labeling on a case-bycase basis, based on FIFRA and its implementing regulations and, as appropriate, guided by the principles outlined in this document.

EPA recommends that an applicant or registrant wishing to make an "absence of an ingredient" claim on their pesticide product labeling explain the purpose of the claim and how the claim is narrowly stated to limit the potential to mislead users about the safety of the product for humans or the environment (e.g., with the use of an appropriate qualifying statement that is prominently displayed and adjacent to the claim). To further support the "absence of an

⁴⁶ DEET Technical Fact Sheet (2008), http://npic.orst.edu/factsheets/archive/DEETtech.html.

ingredient" claim, the applicant or registrant may provide supporting data/information (e.g., consumer surveys) demonstrating that the claim would not be misleading to users. If a registrant wants to better understand whether to submit data/information to EPA as part of an application, they may contact the Agency before gathering the data/information.

If EPA determines that a proposed "absence of an ingredient" claim is not false or misleading because it is used for purposes other than conveying information about product safety for humans or the environment and is supported by data/information demonstrating that the claim would not be misleading to users and/or appropriately qualified to limit the potential to mislead users, then the claim would be approved.

SCENARIO	ACTION*
(1) Your product is currently registered with EPA;	
(2) You would like to amend your product's labeling based on this guidance; and	Submit a non-coded Pesticide Registration Improvement Act (PRIA) labeling amendment to EPA.
(3) You are not submitting data/information (e.g., consumer survey) for EPA's review.	, ,
(1) Your product is currently registered with EPA;	
(2) You would like to amend your product's labeling based on this guidance; and	Submit a PRIA labeling amendment to EPA.
(3) You are submitting data/information (e.g., consumer survey) for EPA's review.	
(1) Your product is not currently registered with EPA; and	Submit the appropriate PRIA application, typically in the
(2) You would like to propose product labeling based on this guidance.	new active ingredient, new use, or new product PRIA categories, to EPA. If you would like to include data/information (e.g., consumer survey) for EPA's review, provide the data/information with the initial application submitted to EPA.

^{*} For questions about the pesticide application submission process, please consult the appropriate chapters in EPA's Pesticide Registration Manual, a resource for companies and individuals who want to have their pesticide products registered for sale in the United States. 47

B. Future Updates

EPA expects to update the guidance on "absence of an ingredient" claims in Chapter 12 of the Label Review Manual and on the Pesticide Labeling Questions and Answers webpage to the extent necessary to align with the guidance presented in this document.

VI. DISCLAIMER

This document provides guidance and clarification to pesticide applicants and registrants. While the requirements in FIFRA and EPA's regulations are binding on EPA and pesticide applicants and registrants, this guidance is not binding on EPA, pesticide applicants and registrants, or the public. In the event of a conflict between the discussion in this guidance and FIFRA or EPA's regulations, this guidance would not be controlling. EPA may take action that differs from the

⁴⁷ Pesticide Registration Manual, https://www.epa.gov/pesticide-registration/pesticide-registration-manual.

recommendations in this guidance as appropriate. Likewise, interested persons are free to raise questions and objections about the substance of this guidance and the appropriateness of the application of this guidance to a particular situation and may propose alternatives to this guidance in any application to EPA.

VII. REFERENCES

Code of Federal Regulations. 2024a. Title 40, Chapter I, Subchapter E, Part 156, Subpart A, Section 156.10(a)(5) (False or misleading statements). Available at https://www.ecfr.gov/current/title-40/part-156/section-156.10#p-156.10(a)(5). Last accessed January 10, 2024.

Code of Federal Regulations. 2024b. Title 40, Chapter I, Subchapter E, Part 152, Subpart C, Section 152.46(a) (Changes permitted by notification). Available at https://www.ecfr.gov/current/title-40/part-152/section-152.46#p-152.46(a). Last accessed January 10, 2024.

Code of Federal Regulations. 2024c. Title 16, Chapter I, Subchapter B, Part 260, Section 260.1 (Purpose, scope, and structure of the guides). Available at https://www.ecfr.gov/current/title-16/chapter-l/subchapter-B/part-260/section-260.1. Last accessed January 11, 2024.

Code of Federal Regulations. 2024d. Title 16, Chapter I, Subchapter B, Part 260, Section 260.9 (Free-of claims). Available at https://www.ecfr.gov/current/title-16/chapter-l/subchapter-B/part-260/section-260.9. Last accessed January 11, 2024.

Code of Federal Regulations. 2024e. Title 40, Chapter I, Subchapter E, Part 152, Subpart A, Section 152.10(a). Available at https://www.ecfr.gov/current/title-40/part-152/section-152.10#p-152.10(a). Last accessed January 11, 2024.

Code of Federal Regulations. 2024f. Title 40, Chapter I, Subchapter E, Part 152, Subpart A, Section 152.3 (Definitions – Inert ingredient). Available at https://www.ecfr.gov/current/title-40/part-152/section-152.3#p-152.3(Inert%20ingredient). Last accessed January 11, 2024.

Code of Federal Regulations. 2024g. Title 40, Chapter I, Subchapter E, Part 156, Subpart A, Section 156.10(g) (Ingredient statement). Available at https://www.ecfr.gov/current/title-40/part-156/section-156.10#p-156.10(g). Last accessed January 11, 2024.

Code of Federal Regulations. 2024h. Title 40, Chapter I, Subchapter E, Part 152, Subpart B, Section 152.25(f) (Minimum risk pesticides). Available at https://www.ecfr.gov/current/title-40/part-152/section-152.25#p-152.25(f">https://www.ecfr.gov/current/title-40/part-152/section-152.25#p-152.25(f">https://www.ecfr.gov/current/title-40/part-152/section-152.25#p-152.25(f">https://www.ecfr.gov/current/title-40/part-152/section-152.25#p-152.25(f">https://www.ecfr.gov/current/title-40/part-152/section-152.25#p-152.25(f">https://www.ecfr.gov/current/title-40/part-152/section-152.25#p-152.25(f">https://www.ecfr.gov/current/title-40/part-152/section-152.25#p-152.25(f">https://www.ecfr.gov/current/title-40/part-152/section-152.25#p-152.25(f">https://www.ecfr.gov/current/title-40/part-152/section-152.25#p-152.25(f">https://www.ecfr.gov/current/title-40/part-152/section-152.25#p-152.25(f">https://www.ecfr.gov/current/title-40/part-152/section-152.25#p-152.25(f">https://www.ecfr.gov/current/title-40/part-152/section-152.25#p-152.25(f">https://www.ecfr.gov/current/title-40/part-152/section-152.25#p-152.25(f">https://www.ecfr.gov/current/title-40/part-152/section-152.25#p-152.25(f">https://www.ecfr.gov/current/title-40/part-152/section-152.25#p-152.25(f")

Consumer Reports. 2022. How Safe Is Deet? (updated July 30, 2022) (by Jeneen Interlandi and Catherine Roberts). Available at https://www.consumerreports.org/health/insect-repellent-safety-a4952100929/. Last accessed January 11, 2024.

EPA. 2023a. Pesticide Registration Manual (last updated on December 5, 2023). Available at https://www.epa.gov/pesticide-registration/pesticide-registration-manual. Last accessed January 11, 2024.

EPA. 2023b. EPA's Ongoing Efforts to Reduce Nutrient Pollution (last updated November 30, 2023). Available at https://www.epa.gov/nutrientpollution/epas-ongoing-efforts-reduce-nutrient-pollution. Last accessed January 17, 2024.

EPA. 2023c. What's the difference between products that disinfect, sanitize, and clean surfaces? (last updated on November 14, 2023). Available at https://www.epa.gov/coronavirus/whats-difference-between-products-disinfect-sanitize-and-clean-surfaces. Last accessed January 11, 2024.

EPA. 2023d. Registration Review Process (last updated on November 2, 2023). Available at https://www.epa.gov/pesticide-reevaluation/registration-review-process. Last accessed January 11, 2024.

EPA. 2023e. Pesticide Labeling Questions & Answers (last updated on October 4, 2023). See "Can a manufacturer advertise that their product does not contain a certain active ingredient (e.g., "DEET free")? LC21-1208; 10/14/21 under "1. Advertising Claims" available at https://www.epa.gov/pesticide-labels/pesticide-labeling-questions-answers#advertising. Last accessed January 11, 2024.

EPA. 2023f. DEET (last updated on September 25, 2023). Available at https://www.epa.gov/insect-repellents/deet. Last accessed January 11, 2024.

EPA. 2023g. Pesticide Registration Manual: Chapter 4 – Additional Considerations for Antimicrobial Products (last updated on July 11, 2023). See #7 (Materials Preservatives) under "Use Patterns" available at https://www.epa.gov/pesticide-registration/pesticide-registration-manual-chapter-4-additional-considerations#use. Last accessed January 11, 2024.

EPA. 2023h. Pesticide Label Statements: Pilot Program to Help Promote Environmental Sustainability (last updated on May 16, 2023). Available at https://www.epa.gov/pesticide-label-statements-pilot-program-help-promote-environmental-sustainability. Last accessed January 10, 2024.

EPA. 2023i. Reregistration and Other Review Programs Predating Pesticide Registration Review (last updated on January 25, 2023). Available at https://www.epa.gov/pesticide-registration. Last accessed January 11, 2024.

EPA. 2016. Pesticide Product and Label System (template updated on December 11, 2016). Search for products containing diethyl toluamide (DEET) available at https://ordspub.epa.gov/ords/pesticides/f?p=113:6::::P6 XCHEMICAL ID:2129. Last accessed January 11, 2024.

EPA. 2014. DEET (N,N-Diethyl-meta-toluamide) – Interim Registration Review Decision (Case Number 0002) (dated September 2014). Available at https://www.regulations.gov/document/EPA-HQ-OPP-2012-0162-0012. Last accessed January 11, 2024.

EPA. 2013. Label Review Manual – Chapter 12: Labeling Claims (revised November 2013). See page 4 of 13 available at https://www.epa.gov/sites/default/files/2017-10/documents/chap-12-nov-2013.pdf. Last accessed January 11, 2024.

EPA. 2003. Label Review Manual – 3rd Edition (EPA 735-B-03-001) (August 2003). See page 140 of 178 available at https://nepis.epa.gov/Exe/ZyPURL.cgi?Dockey=2000GY7M.txt. Last accessed January 10, 2024.

EPA. 1998a. Pesticide Registration Notice (PR) 98-10: Notifications, Non-Notifications and Minor Formulation Amendments (October 22, 1998). See page 7 of 23 available at https://www.epa.gov/sites/default/files/2014-04/documents/pr98-10.pdf. Last accessed January 10, 2024.

EPA. 1998b. Reregistration Eligibility Decision – DEET (EPA738-R-98-010) (September 1998). Available at

https://www3.epa.gov/pesticides/chem_search/reg_actions/reregistration/red_PC-080301_1-Apr-98.pdf. Last accessed January 11, 2024.

EPA. 1992. PR Notice 92-2: Permissible Label Claims Regarding Ozone Depleting Substances (February 10, 1992). Available at https://www.epa.gov/sites/default/files/2014-04/documents/prn-92-2.pdf. Last accessed January 11, 2024.

Federal Trade Commission. 2012. Guides for the Use of Environmental Marketing Claims ("Green Guides"). See "§ 260.9 Free-Of Claims" on pages 20 and 21 of 36 available at https://www.ftc.gov/sites/default/files/attachments/press-releases/ftc-issues-revised-greenguides/greenguides.pdf). Last accessed January 11, 2024.

Jackson D, Luukinen B, Buhl K, Stone D. 2008. *DEET Technical Fact Sheet*; National Pesticide Information Center, Oregon State University Extension Services (date reviewed: July 2008). Available at http://npic.orst.edu/factsheets/archive/DEETtech.html. Last accessed January 11, 2024.

Los Angeles Times. 2011. DEET repels bugs, worries consumers (dated June 1, 2011) (by Amanda Mascarelli, Healthkey). Available at https://www.latimes.com/health/la-xpm-2011-jun-01-la-he-summer-health-deet-repellents-20110601-story.html. Last accessed January 11, 2024.

New York Codes, Rules and Regulations. 2021. Official Compilation of Codes, Rules and Regulations of the State of New York, Title 6. Department of Environmental Conservation, Chapter X. Division of Water Resources, Subchapter A. General, Article 1. Miscellaneous Rules, Part 659. Household Cleansing Products (6 CRR-NY 659.4) (current through September 30, 2021). Available at

https://govt.westlaw.com/nycrr/Document/I4ecccf24cd1711dda432a117e6e0f345?viewType= FullText&originationContext=documenttoc&transitionType=CategoryPageItem&contextData=(sc.Default). Last accessed January 17, 2024.

U.S. Code. 2022. Title 7 – Agriculture, Chapter 6 – Insecticides and Environmental Pesticide Control, Subchapter II – Environmental Pesticide Control, Sections 135 – 136y (The Federal Insecticide, Fungicide, and Rodenticide Act). See pages 2–4, 8, 13, 19, 54, and 55 of 114 available at https://www.govinfo.gov/content/pkg/USCODE-2022-title7/pdf/USCODE-2022-title7-chap6-subchapII.pdf. Last accessed January 11, 2024.