

individually or cumulatively have a significant effect on the human environment. This rule involves the establishment of a safety zone for the New Year's Eve firework displays on the Main Branch of the Chicago River. It is categorically excluded from further review under paragraph 34(g) of Figure 2-1 of the Commandant Instruction. An environmental analysis checklist supporting this determination and a Categorical Exclusion Determination are available in the docket where indicated under **ADDRESSES**. We seek any comments or information that may lead to the discovery of a significant environmental impact from this rule.

#### G. Protest Activities

The Coast Guard respects the First Amendment rights of protesters. Protesters are asked to contact the person listed in the **FOR FURTHER INFORMATION CONTACT** section to coordinate protest activities so that your message can be received without jeopardizing the safety or security of people, places or vessels.

#### List of Subjects in 33 CFR Part 165

Harbors, Marine safety, Navigation (water), Reporting and recordkeeping requirements, Security measures, Waterways.

For the reasons discussed in the preamble, the Coast Guard amends 33 CFR part 165 as follows:

### PART 165—REGULATED NAVIGATION AREAS AND LIMITED ACCESS AREAS

■ 1. The authority citation for part 165 continues to read as follows:

**Authority:** 33 U.S.C. 1231; 50 U.S.C. 191; 33 CFR 1.05-1, 6.04-1, 6.04-6, and 160.5; Department of Homeland Security Delegation No. 0170.1.

■ 2. Add § 165.T09-1074 to read as follows:

#### § 165.T09-1074 Safety Zone; New Year's Eve Fireworks Display, Chicago River, Chicago, IL.

(a) *Location*. All waters of the the Main Branch of the Chicago River between the Michigan Avenue Highway Bridge and the west entrance of the Chicago Harbor Lock.

(b) *Enforcement Period*. This rule will be enforced from 11:30 p.m. on December 31, 2015 to 12:15 a.m. on January 1, 2016.

(c) *Regulations*. (1) In accordance with the general regulations in § 165.23 of this part, entry into, transiting, or anchoring within this safety zone is prohibited unless authorized by the Captain of the Port, Lake Michigan or a designated on-scene representative.

(2) This safety zone is closed to all vessel traffic, except as may be permitted by the Captain of the Port, Lake Michigan or a designated on-scene representative.

(3) The "on-scene representative" of the Captain of the Port, Lake Michigan is any Coast Guard commissioned, warrant or petty officer who has been designated by the Captain of the Port, Lake Michigan to act on his or her behalf.

(4) Vessel operators desiring to enter or operate within the safety zone shall contact the Captain of the Port, Lake Michigan or an on-scene representative to obtain permission to do so. The Captain of the Port, Lake Michigan or an on-scene representative may be contacted via VHF Channel 16. Vessel operators given permission to enter or operate in the safety zone must comply with all directions given to them by the Captain of the Port, Lake Michigan, or an on-scene representative.

Dated: December 11, 2015.

**A.B. Cocanour,**

*Captain, U. S. Coast Guard, Captain of the Port, Lake Michigan.*

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### ENVIRONMENTAL PROTECTION AGENCY

#### 40 CFR Part 152

[EPA-HQ-OPP-2010-0305; FRL-9934-44]

RIN 2070-AJ79

#### Pesticides; Revisions to Minimum Risk Exemption

**AGENCY:** Environmental Protection Agency (EPA).

**ACTION:** Final rule.

**SUMMARY:** EPA is revising its regulations to more clearly describe the active and inert ingredients that are permitted in products eligible for the minimum risk pesticide exemption. EPA is improving the clarity and transparency of the minimum risk exemption by codifying the inert ingredients list and by adding specific chemical identifiers, where available, for all eligible active and inert ingredients. These specific identifiers will make it easier for manufacturers, the public, and Federal, state, and tribal inspectors to determine the specific chemical substances that are permitted in minimum risk pesticide products. EPA is also modifying the labeling requirements in the exemption to require products to list ingredients on the label with a designated label display name and to provide the producer's

contact information on the product's label. These changes will provide more consistent information for consumers and clearer regulations for producers, and will simplify compliance determination by states, tribes, and EPA.

**DATES:** This final rule is effective February 26, 2016. The compliance date for the requirements to label ingredients with a label display name and to provide company contact information on the label is February 26, 2019.

**ADDRESSES:** The docket for this action, identified by docket identification (ID) number EPA-HQ-OPP-2010-0305, is available at <http://www.regulations.gov> or at the Office of Pesticide Programs Regulatory Public Docket (OPP Docket) in the Environmental Protection Agency Docket Center (EPA/DC), West William Jefferson Clinton Bldg., Rm. 3334, 1301 Constitution Ave. NW., Washington, DC 20460-0001. The Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Public Reading Room is (202) 566-1744, and the telephone number for the OPP Docket is (703) 305-5805. Please review the visitor instructions and additional information about the docket available at <http://www.epa.gov/dockets>.

**FOR FURTHER INFORMATION CONTACT:** Ryne Yarger, Field and External Affairs Divisions (7506P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave. NW., Washington, DC 20460-0001; telephone number: (703) 605-1193; fax number: (703) 305-5884; email address: [yarger.ryne@epa.gov](mailto:yarger.ryne@epa.gov).

#### SUPPLEMENTARY INFORMATION:

##### I. Executive Summary

##### A. Does this action apply to me?

You may be affected by this action if you manufacture, distribute, sell, or use minimum risk pesticide products. Minimum risk pesticide products are exempt from registration and other requirements under the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA), and are described in 40 CFR 152.25(f). The following list of North American Industrial Classification System (NAICS) codes is not intended to be exhaustive, but rather provides a guide to help readers determine whether this document applies to them. Potentially affected entities may include:

- Manufacturers of these products, which includes pesticide and other agricultural chemical manufacturers (NAICS codes 325320 and 325311), as well as other manufacturers in similar industries such as animal feed (NAICS

code 311119), cosmetics (NAICS code 325620), and soap and detergents (NAICS code 325611).

- Manufacturers who may also be distributors of these products, which includes farm supplies merchant wholesalers (NAICS code 424910), drug and druggists merchant wholesalers (NAICS code 424210), and motor vehicle supplies and new parts merchant wholesalers (NAICS code 423120).

- Retailers of minimum risk pesticide products (some of which may also be manufacturers), which includes nursery, garden center, and farm supply stores (NAICS code 444220), outdoor power equipment stores (NAICS code 444210), and supermarkets (NAICS code 445110).

- Users of minimum risk pesticide products, including the public in general, as well as exterminating and pest control services (NAICS code 561710), landscaping services (NAICS code 561730), sports and recreation institutions (NAICS code 611620), and child daycare services (NAICS code 624410). Many of these companies also manufacture minimum risk pesticide products.

#### B. What action is the agency taking?

EPA is revising its regulations to more clearly describe the active and inert ingredients permitted in products eligible for the minimum risk pesticide exemption (40 CFR 152.25(f)). EPA is doing this by codifying the inert ingredients list and reformatting the active and inert ingredients lists, adding specific chemical identifiers, where available, for each eligible active and inert ingredient. These identifiers, through the use of Chemical Abstracts Service Registry Numbers (CAS Nos.), will make it easier for manufacturers, the public, and Federal, state, and tribal inspectors to determine the specific chemical substances that are permitted in minimum risk pesticide products. EPA is also modifying the labeling requirements in the exemption to require the use of a designated label display name for each ingredient in the lists of ingredients on minimum risk pesticide product labels, and to require producers to provide contact information on their products' labels. EPA is finalizing most of the regulatory text that was proposed in the **Federal Register** of December 31, 2012 (Ref. 1), with changes based on the comments submitted to the Agency.

#### C. What is the agency's authority for taking this action?

This action is issued under the authority of the Federal Insecticide, Fungicide, and Rodenticide Act

(FIFRA), 7 U.S.C. 136 *et seq.*, particularly sections 3 and 25.

#### D. What are the incremental costs and benefits of the action?

EPA has determined that the total cost for industry to comply with the labeling requirements of this rulemaking is approximately \$800,000 under a 3-year implementation period as described in the Cost Analysis for this rulemaking (Ref. 2). EPA proposed a 2-year implementation period, but instead determined to use a 3-year implementation period based on public comments since 3 years would be the most sensitive to the smallest firms. The costs for industry to comply with this rulemaking are a result of meeting the new labeling requirements to list ingredients using a designated label display name and to list the company's contact information on the product's label. Since most companies update their labels every 3 years, EPA has determined that a rule implementation period of 3 years will allow most companies to meet the labeling requirements of the rule as part of their normal labeling practices and will therefore keep industry costs to a minimum.

Benefits of the rule include the improved clarity of the ingredient lists and the improved clarity and transparency of how minimum risk products are labeled. By providing specific chemical identifiers, such as the CAS Nos. for active and inert ingredients, manufacturers and Federal, state, and tribal inspectors will be able to easily determine whether a chemical substance can be used in a minimum risk product, *i.e.*, is eligible for the exemption. These regulatory changes improve compliance and enforcement of the exemption. Requiring ingredients to be listed on the label with common label display names will help inspectors to efficiently determine whether a product is in compliance with the exemption, and will also provide improved clarity and transparency for consumers who want more information about the ingredients used in a product. Additionally, requiring company contact information on labels will provide further transparency and accountability should an adverse event occur while using a product.

## II. Background

### A. Summary of the Proposed Rule

EPA published a notice of proposed rulemaking (NPRM) in the **Federal Register** of December 31, 2012 (77 FR 76979) (FRL-9339-1) (Ref. 1) proposing to revise the regulations in 40 CFR

152.25(f) that created an exemption from FIFRA requirements for minimum risk pesticide products. The primary goal of the proposed revisions was to clarify the conditions of exemption for minimum risk pesticides by clearly specifying the chemical substances permitted in minimum risk pesticide products. EPA's proposed revisions clarified the specific active and inert ingredients permitted in minimum risk pesticide products, specified how the ingredients should be presented on the label, and provided consumers with the manufacturer's contact information on the product's label. EPA's intent with the proposed revisions was to clarify the terms of the original exemption and to provide additional clarity and transparency concerning the ingredients that are currently used in exempted products. As described in the proposal, no ingredients were intended to be added or removed from the lists.

### B. Public Comment on the Proposed Rule

EPA evaluated all comments received and developed a Response to Comments document, which is available in the docket at <http://www.regulations.gov> using Docket ID No. EPA-HQ-OPP-2010-0305 (Ref. 3). Only the key comments within the scope of the proposed rule and the Agency's responses to those comments are summarized here. For detailed responses, please see the Response to Comment document (Ref. 3).

1. *United States Pharmacopeia (USP) Specifications for 19 active ingredients.* Several commenters expressed concern that adding a USP specification for 19 active ingredients in the active ingredients table would go beyond the stated purpose of the proposal, which was to clarify the original active and inert ingredient lists. These commenters said that USP standards might ultimately result in the need to reformulate many products since technical grade active ingredients currently eligible would be removed from the exemption because the ingredients would be unlikely to meet the USP standards. These commenters said this change would create a new additional burden on minimum risk pesticide product manufacturers.

In response, for the final regulation, EPA has removed the USP specification for all of the active ingredients except for castor oil. EPA recognizes that the addition of USP specifications for the active ingredients identified would result in the removal of technical grade active ingredients that are currently eligible for the minimum risk exemption. Since this rulemaking is to

clarify the currently eligible active and inert ingredients and not to add or remove substances from the ingredients lists, EPA is not including the USP specification for 18 of the 19 active ingredients in the final regulatory text. EPA, however, has retained the specification for castor oil to say “United States Pharmacopeia (USP) standard or equivalent” since this specification was part of the original active ingredients list.

2. *Brackets in the label display name.* One commenter stated that requiring certain label display names to contain bracketed text fails to add additional clarity to consumers and inspectors and could create confusion. The commenter cited several inert ingredients with bracketed information in the label display name, such as vinegar (maximum 8% acetic acid in solution). The commenter recommended that the Agency remove the bracketed text included in the “Label Display Name” column, but continue to leave the bracketed information solely in the “Chemical Name” column since the bracketed text best serves as clarification for manufacturers to meet the requirements of the minimum risk exemption. The commenter suggested that keeping the information in the “Chemical Name” column and providing such information at state registration or upon request enables efficient monitoring of the exempted ingredients in a minimum risk pesticide, and allows for a more consumer-friendly label.

In response, EPA believes that the bracketed information provides important clarifying and safety information for manufacturers to meet the requirements of the exemption and for those states who review and register minimum risk pesticide products. This information ranges from safety limitations on certain inert ingredients such as vinegar (maximum 8% acetic acid in solution) to chemical formulas for inert ingredients such as calcite ( $\text{Ca}(\text{CO}_3)$ ). However, after examining the inert ingredients with bracketed information in the label display name, EPA agrees with the commenter that this information is not necessary to include on the label. The information provided within the brackets is more for manufacturers to correctly identify the specific inert ingredients and understand limitations on inert ingredients than it is to improve the clarity of the labels for consumers. EPA agrees that this information could potentially create confusion for consumers and may add more information than what consumers would want or need about an inert

ingredient. Therefore, EPA has removed the bracketed information from the “Label Display Name” column in the final regulatory text. EPA, however, will continue to provide the bracketed information for those inert ingredients in the “Chemical Name” column to help manufacturers comply with the minimum risk exemption’s requirements.

3. *Missing active ingredients.* Two commenters noted that common salt (sodium chloride) was missing from the proposed active ingredients table, while one of the commenters also noted that ground sesame plant was not listed in the active ingredients list.

In response, the deletion of sodium chloride and ground sesame plant from the exemption were inadvertent omissions in the proposed regulatory text. EPA did not intend for these ingredients to be removed from the exemption. EPA is restoring sodium chloride (CAS No. 7647–14–5) into the table of active ingredients, and is placing “includes ground sesame plant” into the specifications column for “sesame” in the final regulatory text.

4. *Inclusion of “spearmint oil” under the term “mint oil.”* Several commenters suggested that spearmint oil (CAS No. 8008–79–5) should be included under the definition of “mint oil” in the active ingredients table. The commenters stated that “mint oil” could include several varieties under the genus *Mentha*, and that spearmint oil has traditionally been accepted as an eligible active ingredient by the Agency. One commenter suggested that EPA needs to address the other oils that are broadly categorized as mint, while another commenter suggested that EPA should include specific notation or include all CAS numbers whenever multiple CAS numbers may be applicable.

In response, during the development of the proposal, EPA considered the historical use of the terms “mint” and “mint oil.” “Mint” is a broad term for the genus *Mentha*, and could represent a number of different mint or mint oils. However, in promulgating the minimum risk exemption, EPA did not intend the term “mint and mint oil” to include all oils from the genus *Mentha*. Peppermint and peppermint oil (derived from *Mentha piperita*), for example, was listed separately from “mint and mint oil” in the 1996 active ingredient list. When the minimum risk exemption was promulgated in 1996, “mint and mint oil” was intended to refer only to cornmint and cornmint oil (*Mentha arvensis*), since spearmint oil (*Mentha spicata*) at that time was a registered active ingredient. However, “mint and

mint oil” was written broadly so that spearmint oil could also be included under this term (Ref. 3).

EPA agrees with the commenters that spearmint oil has traditionally been accepted under the definition of “mint oil” and has been regarded as a minimum risk active ingredient by the Agency. Therefore, in addition to cornmint oil, EPA is including the CAS No. for spearmint oil (CAS No. 8008–79–5) in the active ingredients list. Additionally, since no other ingredients were intended to be included under “mint and mint oil” when the minimum risk exemption was written, EPA is also revising how cornmint, cornmint oil, spearmint, and spearmint oil are listed in the table. Instead of being identified under the general terms “mint” and “mint oil,” which has caused confusion in the past, these terms are being removed from the active ingredients list and are being replaced with separate listings for “cornmint,” “cornmint oil,” “spearmint,” and “spearmint oil.” EPA believes that this change will improve the clarity and transparency of the listings for these mints and mint oils, while also being more consistent with how the Agency lists these specific substances in other databases.

Since the purpose of this rulemaking is to clarify those ingredients that were intended to be exempt under the original exemption and not to add or remove ingredients, EPA is not reassessing the appropriateness of whether or not other mints or mint oils should be included under this rulemaking. If stakeholders have information that they believe supports the inclusion of other mints or mint oils, they can provide such information to EPA in a petition for evaluation. EPA will consider and respond to all such petitions.

5. *Use of CAS Nos. to identify eligible ingredients.* While several commenters expressed support for using CAS Nos. to identify eligible ingredients when available, one commenter stated that EPA’s assumption that CAS Nos. are unique chemical identifiers is not accurate for every ingredient. The commenter noted, for example, that many ingredients have multiple CAS Nos. that could apply, other ingredients have none, and many CAS Nos. are defined as broad general categories.

The commenter recommended that EPA add the Consumer Specialty Products Association’s Consumer Product Ingredients Dictionary (CSPA Dictionary) to the list of reference sources because the CSPA Dictionary Nomenclature Committee addresses the issues identified above. The commenter stated that the CSPA Dictionary

contains monographs developed by the Committee to establish consistent nomenclature for consumer product ingredients (including those in antimicrobial and pest management products) submitted for inclusion, and carefully defines each ingredient, including all CAS Nos. and other names the Committee finds for the ingredient, in addition to recommending a CSPA name that is judged to be best for consumer ingredient communication. The commenter suggested that including the CSPA Dictionary as a nomenclature option would further the stated goals of identifying the active ingredients by universally accepted names, since it includes all of the CAS Nos. and names where they are available and considered applicable.

In response, EPA has consistently provided the chemical names, as determined by the Chemical Abstracts Service, and CAS Nos., when available, for each of the eligible ingredients on the minimum risk inert ingredients list that has been provided on the Agency's Web site. EPA's experience with providing this information on the publicly-available inerts list has not shown to be problematic in the past. CAS Index Names and CAS Nos. are generally recognized as universal identifiers for chemicals, which helps to reduce confusion and improves clarity for the permitted ingredients. In fact, the use of these chemical names and CAS Nos. have benefitted state reviewers and formulators by providing the specific chemical identifiers needed to determine whether an inert ingredient is or is not permitted in minimum risk pesticide products. CAS Nos. are also required on Material Safety Data Sheets, which makes the CAS No. a useful tool for enforcement purposes. EPA believes that continuing this practice for the inert ingredient list and providing similar information in the active ingredients list will provide the specificity needed to help with compliance and enforcement of the exemption while maintaining consistency with Agency practices.

Regarding the use of the CSPA Dictionary as a reference option, the CSPA Dictionary is not a publicly-available information source, and individuals would have to purchase the dictionary in order to reference the information provided in it. Therefore, EPA believes that referencing the CSPA Dictionary would reduce transparency. While a Web page does offer access to publicly-available indices associated with the CSPA Dictionary, EPA does not believe that these indices alone offer improved transparency and clarity. EPA's intent in proposing the use of a

label display name was to provide a chemical name more understandable to many consumers, thus increasing transparency and consistency. Additionally, a standardized label display name provides the opportunity for state inspectors to become familiar with the name, thus decreasing label review timeframes. EPA believes that the CAS approach provides the most consistent and transparent way to provide information since this information is universally recognized and consistent with how the Agency has been identifying chemicals in the past.

*6. Codification of the inert ingredient list and the need for an efficient mechanism for adding or removing ingredients from the lists.* Several commenters expressed concerns about the codification of the inert ingredient list. Since the 1996 promulgation of the minimum risk exemption, the list has been held as a reference within 40 CFR 152.25(f)(2), updated periodically, and maintained on EPA's public Web site. The commenters questioned what codification would mean for getting ingredients added or removed from the list. These commenters understood that notice and comment rulemaking would be needed to make changes to the inert ingredients list once codified in 40 CFR 152.25(f). Accordingly, the commenters suggested that the rulemaking process would inadvertently create a barrier to adding new ingredients, as well as potentially slowing the Agency's ability to remove an ingredient should the need arise. The commenters questioned if an efficient mechanism could be developed so that additions or deletions from the list could be easily accomplished.

In response, for the final regulation, EPA believes that codifying the inert ingredient list in 40 CFR 152.25(f)(2) provides immediate benefits to all parties. An inert ingredient list directly in the regulations offers much needed clarity to Federal, state, and tribal inspectors and manufacturers. Having all of the ingredients codified also improves the efficiency of inspections because inspectors will not have to look through multiple sources to find the information they need.

EPA understands that stakeholders may want to add or remove ingredients from the ingredient lists for various reasons. EPA has been examining ways to make the process of adding or removing an ingredient from the exemption as streamlined as possible while meeting the requirements of notice and comment rulemaking. For example, EPA is considering developing guidance that would describe the process and types of information EPA may need for a stakeholder to request

the addition or removal of an ingredient from the lists. Any guidance that EPA may develop in the future for minimum risk pesticides would be available on EPA's Web site at <http://www2.epa.gov/minimum-risk-pesticides>.

EPA believes that codifying the inert ingredient list and revising both the active and inert ingredient lists as soon as possible via this final rule, even if the guidance is not yet available, is appropriate to provide the immediate benefits previously described. Companies may at any time petition the Agency to add or remove an ingredient from the active or inert ingredient lists under the Administrative Procedure Act, even in the absence of guidance. EPA cannot predict in advance what the response will be to any particular petition to amend the list of ingredients eligible for the exemption. If the Agency were to grant such a petition, the changes to the ingredient lists would be subject to notice and comment rulemaking.

*7. Proposed timeframe for implementation.* Most commenters indicated that the proposed 2-year compliance period was reasonable, although a few commenters supported a 3-year implementation period that would allow the smallest companies more time to complete the changes and sell existing stock at minimal cost.

In response, EPA has decided to use a 3-year compliance period instead of the proposed 2-year compliance period. EPA's Cost Analysis document (Ref. 2) indicated that the costs to change labels over a 2-year compliance period would cost the average small business \$14,634, or 0.5% of their gross revenue. However, a 3-year compliance period would be the most sensitive to the smallest firms, costing the average small business \$3,857, or 0.1% of their gross revenue. Based on estimates described in the Cost Analysis, companies typically change labels every 3 years, so costs to comply with the changes made in this rulemaking would be reduced by almost 75% when using a 3-year compliance period instead of a 2-year timeframe.

*8. Tolerance/tolerance exemptions for minimum risk pesticide ingredients.* One state commenter indicated that the most challenging issue for their state has been the lack of understanding about when residue tolerances or tolerance exemptions are required for products intended for use on food or feed sites. The commenter stated that they regularly encounter minimum risk products labeled for food/feed uses that do not comply with the tolerance requirements in 40 CFR part 180, and have been challenged over this issue by

several registrants. The commenter stated this problem is exacerbated by poor guidance, conflicting messages received by registrants from direct contacts within EPA, and inconsistent regulation among states regarding the issue. The commenter stated that the proposed revisions will do little to alleviate the problems associated with meeting the requirements for residue tolerances or exemptions from the tolerance requirement.

Another state commenter stated that better clarification is needed regarding allowed ingredients that do not have tolerance exemptions for residues that may end up on food or feed. The commenter stated that the current minimum risk exemption language makes no mention that exemption of a product is conditional on limitations on food use sites for products containing active and/or inert ingredients without tolerance exemptions. With the language provided in the proposed rule, the commenter stated that if EPA's intent is that minimum risk products must restrict labeled use sites based on the status of tolerance or tolerance exemptions of the ingredients, then the Agency should clearly state that as a requirement of the exemption. The commenter did not believe that referring minimum risk pesticide manufacturers to guidance with the suggestion that they consult tolerance information would be sufficient.

The commenter also stated that even if EPA amended the exemption to add label restrictions for food crop use sites as a condition of the exemption, this still would not be enough. The commenter argued that since these products are exempt from FIFRA, the prohibition in FIFRA on use of pesticides inconsistent with label directions would not apply. The commenter stated that while some states such as theirs are able to enforce minimum risk pesticide labels, EPA and the states cannot require the user to adhere to directions on labels for exempted products. The commenter also stated that the general reference to section 408 of the Federal Food, Drug, and Cosmetic Act (FFDCA) in the proposal is not sufficient authority for their state to deny registration applications or stop the distribution of a minimum risk exempt product that has food use sites but no tolerance exemption for one or more ingredients, and that the same is true for the guidance referenced in the proposed regulatory text. The commenter indicated that their state does not have the authority to enforce FFDCA. As a result, the commenter encouraged EPA to not include ingredients as allowable

active ingredients in minimum risk pesticides exempted from FIFRA if EPA does not have enough information to issue a broad tolerance exemption for use on food crops.

In response, this rule does not attempt to address when a tolerance or tolerance exemption may be required or to list existing tolerances or exemptions applicable to minimum risk pesticides. EPA understands that there can be confusion regarding whether a minimum risk pesticide ingredient is included in a pesticide tolerance or tolerance exemption, and regarding when a tolerance or tolerance exemption is necessary for use of a minimum risk pesticide product on food or feed. As noted in the NPRM, EPA proposed to address some of these issues by directing manufacturers to 40 CFR part 180 to find information about tolerance requirements. EPA is finalizing this change as proposed.

On its Web site, at <http://www2.epa.gov/minimum-risk-pesticides>, EPA recently provided additional guidance with clearer descriptions of where tolerance information can be found for those ingredients that are eligible for use on food or food-use sites. EPA believes the additional guidance will help manufacturers find the information they need to comply with pesticide tolerance requirements while alleviating some of the problems experienced by the commenter.

EPA is not attempting to enforce adherence to the labels of minimum risk pesticides, which as noted cannot be done for pesticides subject to 40 CFR 152.25(f). Rather, the Agency is assisting minimum risk pesticide producers in ensuring that the use directions on the product do not cause the label to be false or misleading. An exemption from FIFRA requirements under section 25(b) of the statute, including the minimum risk exemption at 40 CFR 152.25(f), cannot exempt pesticides from the requirements of a tolerance or tolerance exemption under FFDCA. Under FFDCA, any pesticide chemical residue to be used in or on foods in commerce in the United States must have either an established tolerance or tolerance exemption. When a minimum risk product explicitly states on its label that it can be used in or on food or food-use sites in commerce, but one or more of the ingredients does not have an established tolerance or tolerance exemption, the label is indicating that the product may be used in a way that would violate Federal law. Such a label is therefore false or misleading. One of the requirements for the exemption, contained in § 152.25(f)(3)(iii), is that

the product must not include any false and misleading labeling statements. A product bearing a label that is false and misleading would therefore not be eligible for the minimum risk exemption, and sale or distribution of that product would require FIFRA registration, including any needed label changes. If state law requires a pesticide to be compliant with FIFRA, the state can insist that the label not allow a food use without the necessary tolerance or tolerance exemption. This will help ensure that products labeled for food-uses are properly labeled, thus reducing the potential for improper use of the product.

In the regulatory text of the proposal, EPA stated in § 152.25(f)(1) that "all listed active ingredients may be used in non-food use products," but products intended to be used "on food and animal feed can only include active ingredients with applicable tolerances or tolerance exemptions in part 180" to comply with FFDCA. During development of the proposal, EPA considered adding tolerance information into the reformatted ingredients tables in 40 CFR 152.25(f) for reference purposes. However, EPA did not include this information because tolerances or tolerance exemptions can change frequently, meaning that any tolerance information in § 152.25(f) would also have to be revised via rulemaking, possibly leading to errors in the regulation.

To improve the clarity of the information about tolerances in the regulatory text, EPA is revising the explanatory text about tolerances in § 152.25(f)(1) for active ingredients, and is adding similar explanatory text for inert ingredients in § 152.25(f)(2). As specified in the final regulatory text, EPA is using its Web site to provide additional guidance on where tolerance information can be found. As needed, information on the Web site can be easily changed and can direct people where to find the tolerance information they need to comply with FFDCA. EPA believes that these approaches will make it clearer that manufacturers should review the tolerance information in 40 CFR part 180 before labeling their product for food uses to prevent their labels from potentially being false or misleading.

### *C. Other Modifications to the Regulatory Text*

While responding to the comments regarding mint oil, EPA realized that additional clarity would be helpful for the descriptions of cedar oil in the active ingredients table. "Cedar oil" is a non-specific term, and the proposal

listed three separate CAS Nos. for it. While each CAS No. is associated with a specific type of cedar oil, the type of cedar oil was not indicated in the label display name or the chemical name. EPA is revising the label display names from "Cedar oil" to "Cedarwood oil" to improve clarity and the chemical names to more clearly reflect the differences among the three CAS Nos. for cedarwood oil. These revisions will also improve the clarity and transparency of the eligible ingredients for manufacturers and inspectors. This does not change the list of ingredients eligible for the exemption or impose any additional requirements on producers of minimum risk pesticides containing one of these ingredients. The chemical name changes for the three cedarwood oil ingredients are, as follows:

- CAS No. 85085-29-6 will have the chemical name, "Cedarwood oil (China)."
- CAS No. 68990-83-0 will have the chemical name, "Cedarwood oil (Texas)."
- CAS No. 8000-27-9 will have the chemical name, "Cedarwood oil (Virginia)."

Additionally, EPA determined to finalize only the first sentence of proposed § 152.25(f)(3)(v). EPA believes that a description of the information available on EPA's Web site is not needed in regulatory text. Since this is not a condition of the exemption, EPA is finalizing the first sentence of proposed § 152.25(f)(3)(v) in a new § 152.25(f)(4) to be entitled "Providing guidance."

Because these changes do not modify the list of eligible ingredients for the exemption or otherwise affect the scope of the exemption, EPA has determined that notice and comment are unnecessary in accordance with the good cause exemption contained in 5 U.S.C. 553(b)(B) of the Administrative Procedure Act.

### III. The Final Rule

With the exception of the modifications discussed in Unit II.B. and II.C., EPA is finalizing the rule in essentially the same form as the proposed rule. The final rule continues to do the following:

- Redesign the format of the active ingredients list,
- Codify the list of permitted inert ingredients,
- Provide specific chemical identifiers, through the use of CAS Nos., for each eligible active and inert ingredient when available,
- Require that a common "label display name" for each ingredient be

used when listing ingredients on a product's label, and

- Require company name and contact information on product labels.

EPA recently updated its guidance on minimum risk pesticides online at <http://www2.epa.gov/minimum-risk-pesticides>. This Web site now includes guidance on pesticide tolerances for minimum risk ingredients and provides alternative formats of the active and inert ingredient lists that may be more suitable for some users. Shortly after the effective date of this final rule, EPA intends to include additional guidance, as needed, such as labeling guidance for minimum risk pesticides and how to request additional ingredients to be added or removed from the minimum risk exemption.

### IV. References

As indicated under **ADDRESSES**, a docket has been established for this final rule under docket ID number EPA-HQ-OPP-2010-0305. The following is a listing of the documents that are specifically referenced in this action. The docket includes these documents and other information considered by EPA, including documents that are referenced within the documents that are included in the docket, even if the referenced document is not physically located in the docket. For assistance in locating these other documents, please consult the person listed under **FOR FURTHER INFORMATION CONTACT**.

1. U.S. EPA. Pesticides; Revisions to Minimum Risk Exemption; Proposed Rule. **Federal Register** December 31, 2012 (77 FR 76979) (FRL-9339-1).
2. U.S. EPA. Office of Pesticide Programs (OPP). Cost and Small Business Analysis of Revisions to Minimum Risk Exemption (2014).
3. U.S. EPA, (OPP). Response to Public Comments on the Proposed Rule: "Pesticides; Revisions to Minimum Risk Exemption." (2014).
4. U.S. EPA, (OPP). Decision Memorandum: Mint Oil (2008).
5. U.S. EPA, (OPP). Supporting Statement for an Information Collection Request (ICR): Labeling Change for Certain Minimum Risk Pesticides under FIFRA Section 25(b). EPA ICR No. 2475.02; OMB Control No. 2070-0187 (2015).

### V. FIFRA Review Requirements

In accordance with FIFRA sections 21 and 25(a), the Agency submitted a draft of this final rule to the appropriate Congressional Committees, the Secretary of the Department of Agriculture (USDA), and the Secretary of the Department of Health and Human Services (HHS). HHS waived its review of this rule on June 19, 2015. On June 18, 2015, USDA reviewed this rule, and

did not have any comments related to policy. USDA provided a technical comment, which EPA has reviewed and accepted.

Under FIFRA section 25(d), EPA also submitted a draft of this final rule to the FIFRA Scientific Advisory Panel (SAP). The SAP waived its scientific review of the final rule on June 24, 2015, because the final rule does not contain scientific issues that warrant review by the Panel.

### VI. Statutory and Executive Order Reviews

#### A. Executive Order 12866: Regulatory Planning and Review and Executive Order 13563: Improving Regulation and Regulatory Review

This action is not a significant regulatory action and was therefore not submitted to the Office of Management and Budget (OMB) for review under Executive Orders 12866, October 4, 1993 (58 FR 51735) and 13563, January 21, 2011 (76 FR 3821).

#### B. Paperwork Reduction Act (PRA)

The information collection activities in this rule have been submitted to OMB for approval under the PRA, 44 U.S.C. 3501 *et seq.* The Information Collection Request (ICR), identified by EPA ICR No. 2475.02 (Ref. 5), is available in the docket for this rule, and it is briefly summarized here.

The information collection activities in this rule consist of changes to existing requirements that involve the one-time relabeling of products currently exempt under 40 CFR 152.25(f) in order to list chemical names in the format required by EPA and to include the producer's contact information. The ICR accounts for the burden for a one time label change which provides important regulatory information for the Federal, state, and tribal authorities that regulate minimum risk pesticide products.

**Respondent's obligation to respond:** Required to obtain or retain a benefit (40 CFR 152.25(f)).

**Estimated number of respondents:** 216.

**Frequency of response:** One-time for each product needing a label change.

**Total estimated burden:** 2,123 hours (per year). Burden is defined at 5 CFR 1320.3(b).

**Total estimated cost:** \$198,811.23 (per year). There are no capital or operation and maintenance costs.

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 OMB control numbers for EPA regulations in 40 CFR

are listed in 40 CFR part 9. When OMB approves this ICR, the Agency will announce that approval in the **Federal Register** and publish a technical amendment to 40 CFR part 9 to display the OMB control number for the approved information collection activities contained in this final rule.

### C. Regulatory Flexibility Act (RFA)

I certify that this action will not have a significant economic impact on a substantial number of small entities under the RFA, 5 U.S.C. 601 *et seq.* The small entities subject to the requirements of this action are small businesses who manufacture minimum risk pesticide products. No small governmental jurisdictions or not-for-profit enterprises are known to produce minimum risk pesticide products. The Agency has determined that there are approximately 97 small firms (out of a total of 192), accounting for approximately 51% of the industry. These small firms may experience an impact of 0.1% of gross revenue given a 3-year compliance period. To account for the impacts on very small firms, *i.e.*, those with sales less than \$500K, EPA performed a refined analysis that divided each individual firm's relabeling cost by that firm's sales revenue. With a 3-year compliance period, 7 small firms (or approximately 7% of all small firms) are likely to experience an economic impact of 1% or more of gross sales, while no small firms will incur impacts greater than or equal to 3% of gross sales. Details of this analysis are presented in the analysis for this rule (Ref. 2).

The selection of the 3-year compliance period was based on information obtained in 2009 from a group of small manufacturers of minimum risk insect repellent products, as well as comments received during the public comment period for the proposed rule. EPA initially proposed a 2-year compliance period for companies to relabel their products since the companies indicated they needed at least 2 years in order to avoid significant costs (Ref. 2). This would allow most companies to incorporate the changes into their regularly planned label updates, and sell any products with older labels, thus reducing the cost and burden of the changes to the exemption. During the public comment period for the proposed rule, EPA received comments that expressed support for both the proposed 2-year compliance period and the longer 3-year compliance period. While several commenters felt that the 2-year period would provide sufficient time to comply with the new labeling requirements, some

commenters felt that a 3-year compliance period would benefit the smallest companies to incorporate the changes into regularly planned updates and to sell their existing stock, thus minimizing their costs and burden to comply with the new requirements. EPA is aware that most companies make regularly planned label updates every 3 years (Ref. 2). By going with a 3-year compliance period instead of the originally proposed 2-year timeframe, costs on industry would be reduced by almost 75% from the 2-year implementation period, thereby being more sensitive to the smallest of small firms.

### D. Unfunded Mandates Reform Act (UMRA)

This action does not contain an unfunded mandate of \$100 million or more as described in UMRA, 2 U.S.C. 1531–1538, and does not significantly or uniquely affect small governments. EPA has determined that this action imposes no enforceable duty on any state, local, or tribal governments because there are no known instances where such governments currently produce any pesticides such that they would be subject to this rulemaking. In addition, the potential costs for the private sector do not qualify as an unfunded mandate under UMRA.

### E. Executive Order 13132: Federalism

This action does not have federalism implications, as specified in Executive Order 13132, August 10, 1999 (64 FR 43255). It will not have substantial direct effects on the states, on the relationship between the national government and the states, or on the distribution of power and responsibilities among the various levels of government.

### F. Executive Order 13175: Consultation and Coordination With Indian Tribal Governments

This action does not have tribal implications as specified in Executive Order 13175, November 9, 2000 (65 FR 67249). There are no known instances where a tribal government is the producer of a minimum risk pesticide currently exempt from regulation. Thus, Executive Order 13175 does not apply to this action.

### G. Executive Order 13045: Protection of Children From Environmental Health Risks and Safety Risks

The EPA interprets Executive Order 13045, April 23, 1997 (62 FR 19885) as applying only to those regulatory actions that concern environmental health or safety risks that the EPA has

reason to believe may disproportionately affect children, per the definition of “covered regulatory action” in section 2–202 of the Executive Order. This action is not subject to Executive Order 13045 because it does not concern an environmental health risk or safety risk.

### H. Executive Order 13211: Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use

This action is not subject to Executive Order 13211, May 22, 2001 (66 FR 28355) because it is not a significant regulatory action under Executive Order 12866.

### I. National Technology Transfer and Advancement Act (NTTAA)

This rulemaking does not involve technical standards that would require the consideration of voluntary consensus standards pursuant to NTTAA section 12(d), 12(d) (15 U.S.C. 272 note).

### J. Executive Order 12898: Federal Actions To Address Environmental Justice in Minority Populations and Low-Income Populations

This action does not involve special consideration of environmental justice related issues as specified in Executive Order 12898, February 16, 1994 (59 FR 7629). EPA believes the human health or environmental risk addressed by this action will not have potential disproportionately high and adverse human health or environmental effects on minority, low-income, or indigenous populations because it does not affect the level of protection provided to human health or the environment. To the contrary, this action will increase the level of environmental protection for all affected populations without having disproportionately high and adverse human health or environmental effects on any population, including any minority or low-income population. This action only involves minimum risk pesticide products, and may have positive impacts for all communities, since the rule provides increased information for consumers considering the use of pesticides. This action, which will improve clarity on product labels, will enable all users regardless of economic status to become more informed about the pesticide substances they may be interested in using.

### VII. Congressional Review Act (CRA)

This action is subject to the CRA, 5 U.S.C. 801 *et seq.*, and the EPA will submit a rule report to each House of Congress and the Comptroller of the



United States. This action is not a “major rule” as defined by 5 U.S.C. 804(2).

#### List of Subjects in 40 CFR Part 152

Environmental protection, Administrative practice and procedure, Agricultural commodities, Pesticides and pests, Reporting and recordkeeping requirements.

Dated: December 16, 2015.

**Gina McCarthy,**  
Administrator.

Therefore, 40 CFR chapter I is amended as follows:

#### PART 152—[AMENDED]

■ 1. The authority citation for part 152 continues to read as follows:

**Authority:** 7 U.S.C. 136–136y; subpart U is also issued under 31 U.S.C. 9701.

■ 2. Amend § 152.25 by revising paragraph (f) to read as follows:

#### § 152.25 Exemptions for pesticides of a character not requiring FIFRA regulation.

\* \* \* \* \*

(f) *Minimum risk pesticides*—(1) *Exempted products.* Products containing the following active ingredients, alone or in combination with other substances listed in table 1

of this paragraph, are exempt from the requirements of FIFRA provided that all of the criteria of this section are met. All listed active ingredients may be used in non-food use products. Under section 408 of the Federal Food, Drug, and Cosmetic Act and EPA (FFDCA) implementing regulations at part 180 of this chapter, food and animal feed in commerce can bear pesticide residues only for those ingredients that have tolerances or tolerance exemptions in part 180 of this chapter. Such tolerances or exemptions may be found, for example, in §§ 180.950, 180.1071, 180.1087, 180.1233, and 180.1251 of this chapter.

TABLE 1—ACTIVE INGREDIENTS PERMITTED IN EXEMPTED MINIMUM RISK PESTICIDE PRODUCTS

Label display name	Chemical name	Specifications	CAS No.
Castor oil .....	Castor oil .....	United States Pharmacopeia (U.S.P.) or equivalent.	8001–79–4
Cedarwood oil .....	Cedarwood oil (China) .....		85085–29–6
Cedarwood oil .....	Cedarwood oil (Texas) .....		68990–83–0
Cedarwood oil .....	Cedarwood oil (Virginia) .....		8000–27–9
Cinnamon .....	Cinnamon .....		N/A
Cinnamon oil .....	Cinnamon oil .....		8015–91–6
Citric acid .....	2-Hydroxypropane-1,2,3-tricarboxylic acid .....		77–92–9
Citronella .....	Citronella .....		N/A
Citronella oil .....	Citronella oil .....		8000–29–1
Cloves .....	Cloves .....		N/A
Clove oil .....	Clove oil .....		8000–34–8
Corn gluten meal .....	Corn gluten meal .....		66071–96–3
Corn oil .....	Corn oil .....		8001–30–7
Cornmint .....	Cornmint .....		N/A
Cornmint oil .....	Cornmint oil .....		68917–18–0
Cottonseed oil .....	Cottonseed oil .....		8001–29–4
Dried blood .....	Dried blood .....		68991–49–9
Eugenol .....	4-Allyl-2-methoxyphenol .....		97–53–0
Garlic .....	Garlic .....		N/A
Garlic oil .....	Garlic oil .....		8000–78–0
Geraniol .....	(2E)-3,7-Dimethylocta-2,6-dien-1-ol .....		106–24–1
Geranium oil .....	Geranium oil .....		8000–46–2
Lauryl sulfate .....	Lauryl sulfate .....		151–41–7
Lemongrass oil .....	Lemongrass oil .....		8007–02–1
Linseed oil .....	Linseed oil .....		8001–26–1
Malic acid .....	2-Hydroxybutanedioic acid .....		6915–15–7
Peppermint .....	Peppermint .....		N/A
Peppermint oil .....	Peppermint oil .....		8006–90–4
2-Phenylethyl propionate .....	2-Phenylethyl propionate .....		122–70–3
Potassium sorbate .....	Potassium (2E,4E)-hexa-2,4-dienoate .....		24634–61–5
Putrescent whole egg solids ..	Putrescent whole egg solids .....		51609–52–0
Rosemary .....	Rosemary .....		N/A
Rosemary oil .....	Rosemary oil .....		8000–25–7
Sesame .....	Sesame .....	Includes ground sesame plant	N/A
Sesame oil .....	Sesame oil .....		8008–74–0
Sodium chloride .....	Sodium chloride .....		7647–14–5
Sodium lauryl sulfate .....	Sulfuric acid monododecyl ester, sodium salt .....		151–21–3
Soybean oil .....	Soybean oil .....		8001–22–7
Spearmint .....	Spearmint .....		N/A
Spearmint oil .....	Spearmint oil .....		8008–79–5
Thyme .....	Thyme .....		N/A
Thyme oil .....	Thyme oil .....		8007–46–3
White pepper .....	White pepper .....		N/A
Zinc .....	Zinc .....	Zinc metal strips (consisting solely of zinc metal and impurities).	7440–66–6

(2) *Permitted inert ingredients.* A pesticide product exempt under

paragraph (f)(1) of this section may only include the inert ingredients listed in

paragraphs (f)(2)(i) through (iv) of this section. All listed inert ingredients may



be used in non-food use products. Under FFDCA section 408 and EPA implementing regulations at part 180 of this chapter, food and animal feed in commerce can bear pesticide residues only for those ingredients that have tolerances or tolerance exemptions in

part 180 of this chapter. Such tolerances or exemptions may be found, for example, in §§ 180.910, 180.920, 180.930, 180.940, 180.950, and 180.1071 of this chapter.

(i) *Commonly consumed food commodities*, as described in § 180.950(a) of this chapter.

(ii) *Animal feed items*, as described in § 180.950(b) of this chapter.

(iii) *Edible fats and oils*, as described in § 180.950(c) of this chapter.

(iv) *Specific chemical substances*, as listed in the following table.

TABLE 2—INERT INGREDIENTS PERMITTED IN MINIMUM RISK PESTICIDE PRODUCTS

Label display name	Chemical name	CAS No.
Acetyl tributyl citrate .....	Citric acid, 2-(acetyloxy)-, tributyl ester .....	77-90-7
Agar .....	Agar .....	9002-18-0
Almond hulls .....	Almond hulls .....	N/A
Almond oil .....	Oils, almond .....	8007-69-0
Almond shells .....	Almond shells .....	N/A
alpha-Cyclodextrin .....	alpha-Cyclodextrin .....	10016-20-3
Aluminatesilicate .....	Aluminatesilicate .....	1327-36-2
Aluminum magnesium silicate .....	Silicic acid, aluminum magnesium salt .....	1327-43-1
Aluminum potassium sodium silicate .....	Silicic acid, aluminum potassium sodium salt .....	12736-96-8
Aluminum silicate .....	Aluminum silicate .....	1335-30-4
Aluminum sodium silicate .....	Silicic acid, aluminum sodium salt .....	1344-00-9
Aluminum sodium silicate .....	Silicic acid (H <sub>4</sub> SiO <sub>4</sub> ), aluminum sodium salt (1:1:1) .....	12003-51-9
Ammonium benzoate .....	Benzoic acid, ammonium salt .....	1863-63-4
Ammonium stearate .....	Octadecanoic acid, ammonium salt .....	1002-89-7
Amylopectin, acid-hydrolyzed, 1-octenylbutanedioate. ....	Amylopectin, acid-hydrolyzed, 1-octenylbutanedioate .....	113894-85-2
Amylopectin, hydrogen 1-octadecenylbutanedioate. ....	Amylopectin, hydrogen 1-octadecenylbutanedioate .....	125109-81-1
Animal glue .....	Animal glue .....	N/A
Ascorbyl palmitate .....	Ascorbyl palmitate .....	137-66-6
Attapulgate-type clay .....	Attapulgate-type clay .....	12174-11-7
Beeswax .....	Beeswax .....	8012-89-3
Bentonite .....	Bentonite .....	1302-78-9
Bentonite, sodian .....	Bentonite, sodian .....	85049-30-5
beta-Cyclodextrin .....	beta-Cyclodextrin .....	7585-39-9
Bone meal .....	Bone meal .....	68409-75-6
Bran .....	Bran .....	N/A
Bread crumbs .....	Bread crumbs .....	N/A
(+)-Butyl lactate .....	Lactic acid, n-butyl ester, (S) .....	34451-19-9
Butyl lactate .....	Lactic acid, n-butyl ester .....	138-22-7
Butyl stearate .....	Octadecanoic acid, butyl ester .....	123-95-5
Calcareous shale .....	Calcareous shale .....	N/A
Calcite .....	Calcite (Ca(CO <sub>3</sub> )) .....	13397-26-7
Calcium acetate .....	Calcium acetate .....	62-54-4
Calcium acetate monohydrate .....	Acetic acid, calcium salt, monohydrate .....	5743-26-0
Calcium benzoate .....	Benzoic acid, calcium salt .....	2090-05-3
Calcium carbonate .....	Calcium carbonate .....	471-34-1
Calcium citrate .....	Citric acid, calcium salt .....	7693-13-2
Calcium octanoate .....	Calcium octanoate .....	6107-56-8
Calcium oxide silicate .....	Calcium oxide silicate (Ca <sub>3</sub> O(SiO <sub>4</sub> )) .....	12168-85-3
Calcium silicate .....	Silicic acid, calcium salt .....	1344-95-2
Calcium stearate .....	Octadecanoic acid, calcium salt .....	1592-23-0
Calcium sulfate .....	Calcium sulfate .....	7778-18-9
Calcium sulfate dihydrate .....	Calcium sulfate dihydrate .....	10101-41-4
Calcium sulfate hemihydrate .....	Calcium sulfate hemihydrate .....	10034-76-1
Canary seed .....	Canary seed .....	N/A
Carbon .....	Carbon .....	7440-44-0
Carbon dioxide .....	Carbon dioxide .....	124-38-9
Carboxymethyl cellulose .....	Cellulose, carboxymethyl ether .....	9000-11-7
Cardboard .....	Cardboard .....	N/A
Carnauba wax .....	Carnauba wax .....	8015-86-9
Carob gum .....	Locust bean gum .....	9000-40-2
Carrageenan .....	Carrageenan .....	9000-07-1
Caseins .....	Caseins .....	9000-71-9
Castor oil .....	Castor oil .....	8001-79-4
Castor oil, hydrogenated .....	Castor oil, hydrogenated .....	8001-78-3
Cat food .....	Cat food .....	N/A
Cellulose .....	Cellulose .....	9004-34-6
Cellulose acetate .....	Cellulose acetate .....	9004-35-7
Cellulose, mixture with cellulose carboxymethyl ether, sodium salt. ....	Cellulose, mixture with cellulose carboxymethyl ether, sodium salt .....	51395-75-6
Cellulose, pulp .....	Cellulose, pulp .....	65996-61-4

TABLE 2—INERT INGREDIENTS PERMITTED IN MINIMUM RISK PESTICIDE PRODUCTS—Continued

Label display name	Chemical name	CAS No.
Cellulose, regenerated	Cellulose, regenerated	68442–85–3
Cheese	Cheese	N/A
Chlorophyll a	Chlorophyll a	479–61–8
Chlorophyll b	Chlorophyll b	519–62–0
Citric acid	Citric acid	77–92–9
Citric acid, monohydrate	Citric acid, monohydrate	5949–29–1
Citrus meal	Citrus meal	N/A
Citrus pectin	Citrus pectin	9000–69–5
Citrus pulp	Citrus pulp	68514–76–1
Clam shells	Clam shells	N/A
Cocoa	Cocoa	8002–31–1
Cocoa shell flour	Cocoa shell flour	N/A
Cocoa shells	Cocoa shells	N/A
Cod-liver oil	Cod-liver oil	8001–69–2
Coffee grounds	Coffee grounds	68916–18–7
Cookies	Cookies	N/A
Cork	Cork	61789–98–8
Corn cobs	Corn cobs	N/A
Cotton	Cotton	N/A
Cottonseed meal	Cottonseed meal	68424–10–2
Cracked wheat	Cracked wheat	N/A
Decanoic acid, monoester with 1,2,3-propanetriol.	Decanoic acid, monoester with 1,2,3-propanetriol	26402–22–2
Dextrins	Dextrins	9004–53–9
Diglyceryl monooleate	9-Octadecenoic acid, ester with 1,2,3-propanetriol	49553–76–6
Diglyceryl monostearate	9-Octadecanoic acid, monoester with oxybis(propanediol)	12694–22–3
Dilaurin	Dodecanoic acid, diester with 1,2,3-propanetriol	27638–00–2
Dipalmitin	Hexadecanoic acid, diester with 1,2,3-propanetriol	26657–95–4
Dipotassium citrate	Citric acid, dipotassium salt	3609–96–9
Disodium citrate	Citric acid, disodium salt	144–33–2
Disodium sulfate decahydrate	Disodium sulfate decahydrate	7727–73–3
Diatomaceous earth	Kieselguhr; Diatomite (less than 1% crystalline silica)	61790–53–2
Dodecanoic acid, monoester with 1,2,3-propanetriol.	Dodecanoic acid, monoester with 1,2,3-propanetriol	27215–38–9
Dolomite	Dolomite	16389–88–1
Douglas fir bark	Douglas fir bark	N/A
Egg shells	Egg shells	N/A
Eggs	Eggs	N/A
(+)-Ethyl lactate	Lactic acid, ethyl ester, (S)	687–47–8
Ethyl lactate	Lactic acid, ethyl ester	97–64–3
Feldspar	Feldspar	68476–25–5
Ferric oxide	Iron oxide (Fe <sub>2</sub> O <sub>3</sub> )	1309–37–1
Ferrous oxide	Iron oxide (FeO)	1345–25–1
Fish meal	Fish meal	N/A
Fish oil	Fish oil	8016–13–5
Fuller's earth	Fuller's earth	8031–18–3
Fumaric acid	Fumaric acid	110–17–8
gamma-Cyclodextrin	gamma-Cyclodextrin	17465–86–0
Gelatins	Gelatins	9000–70–8
Gellan gum	Gellan gum	71010–52–1
Glue	Glue (as depolymd. animal collagen)	68476–37–9
Glycerin	1,2,3-Propanetriol	56–81–5
Glycerol monooleate	9-Octadecenoic acid (Z)-, 2,3-dihydroxypropyl ester	111–03–5
Glyceryl dicaprylate	Octanoic acid, diester with 1,2,3-propanetriol	36354–80–0
Glyceryl dimyristate	Tetradecanoic acid, diester with 1,2,3-propanetriol	53563–63–6
Glyceryl dioleate	9-Octadecenoic acid (9Z)-, diester with 1,2,3-propanetriol	25637–84–7
Glyceryl distearate	Octadecanoic acid, diester with 1,2,3-propanetriol	1323–83–7
Glyceryl monomyristate	Tetradecanoic acid, monoester with 1,2,3-propanetriol	27214–38–6
Glyceryl monooleate	Octanoic acid, monoester with 1,2,3-propanetriol	26402–26–6
Glyceryl monostearate	9-Octadecenoic acid (9Z)-, monoester with 1,2,3-propanetriol	25496–72–4
Glyceryl stearate	Octadecanoic acid, monoester with 1,2,3-propanetriol	31566–31–1
Granite	Octadecanoic acid, ester with 1,2,3-propanetriol	11099–07–3
Graphite	Granite	N/A
Guar gum	Graphite	7782–42–5
Gum Arabic	Guar gum	9000–30–0
Gum tragacanth	Gum arabic	9000–01–5
Gypsum	Gum tragacanth	9000–65–1
Hematite	Gypsum	13397–24–5
Humic acid	Hematite (Fe <sub>2</sub> O <sub>3</sub> )	1317–60–8
Hydrogenated cottonseed oil	Humic acid	1415–93–6
Hydrogenated rapeseed oil	Hydrogenated cottonseed oil	68334–00–9
	Hydrogenated rapeseed oil	84681–71–0

TABLE 2—INERT INGREDIENTS PERMITTED IN MINIMUM RISK PESTICIDE PRODUCTS—Continued

Label display name	Chemical name	CAS No.
Hydrogenated soybean oil .....	Hydrogenated soybean oil .....	8016–70–4
Hydroxyethyl cellulose .....	Cellulose, 2-hydroxyethyl ether .....	9004–62–0
Hydroxypropyl cellulose .....	Cellulose, 2-hydroxypropyl ether .....	9004–64–2
Hydroxypropyl methyl cellulose .....	Cellulose, 2-hydroxypropyl methyl ether .....	9004–65–3
Iron magnesium oxide .....	Iron magnesium oxide (Fe <sub>2</sub> MgO <sub>4</sub> ) .....	12068–86–9
Iron oxide, hydrate .....	Iron oxide (Fe <sub>2</sub> O <sub>3</sub> ), hydrate .....	12259–21–1
Iron oxide .....	Iron oxide (Fe <sub>3</sub> O <sub>4</sub> ) .....	1317–61–9
Isopropyl alcohol .....	2-Propanol .....	67–63–0
Isopropyl myristate .....	Isopropyl myristate .....	110–27–0
Kaolin .....	Kaolin .....	1332–58–7
Lactose .....	Lactose .....	63–42–3
Lactose monohydrate .....	Lactose monohydrate .....	64044–51–5
Lanolin .....	Lanolin .....	8006–54–0
Latex rubber .....	Latex rubber .....	N/A
Lauric acid .....	Lauric acid .....	143–07–7
Lecithins .....	Lecithins .....	8002–43–5
Licorice extract .....	Licorice extract .....	68916–91–6
Lime dolomitic .....	Lime (chemical) dolomitic .....	12001–27–3
Limestone .....	Limestone .....	1317–65–3
Linseed oil .....	Linseed oil .....	8001–26–1
Magnesium carbonate .....	Carbonic acid, magnesium salt (1:1) .....	546–93–0
Magnesium benzoate .....	Magnesium benzoate .....	553–70–8
Magnesium oxide .....	Magnesium oxide .....	1309–48–4
Magnesium oxide silicate .....	Magnesium oxide silicate (Mg <sub>3</sub> O(Si <sub>2</sub> O <sub>5</sub> ) <sub>2</sub> ), monohydrate .....	12207–97–5
Magnesium silicate .....	Magnesium silicate .....	1343–88–0
Magnesium silicate hydrate .....	Magnesium silicate hydrate .....	1343–90–4
Magnesium silicon oxide .....	Magnesium silicon oxide (Mg <sub>2</sub> Si <sub>3</sub> O <sub>8</sub> ) .....	14987–04–3
Magnesium stearate .....	Octadecanoic acid, magnesium salt .....	557–04–0
Magnesium sulfate .....	Magnesium sulfate .....	7487–88–9
Magnesium sulfate heptahydrate .....	Magnesium sulfate heptahydrate .....	10034–99–8
Malic acid .....	Malic acid .....	6915–15–7
Malt extract .....	Malt extract .....	8002–48–0
Malt flavor .....	Malt flavor .....	N/A
Maltodextrin .....	Maltodextrin .....	9050–36–6
Methylcellulose .....	Cellulose, methyl ether .....	9004–67–5
Mica .....	Mica .....	12003–38–2
Mica-group minerals .....	Mica-group minerals .....	12001–26–2
Milk .....	Milk .....	8049–98–7
Millet seed .....	Millet seed .....	N/A
Mineral oil .....	Mineral oil (U.S.P.) .....	8012–95–1
1-Monolaurin .....	Dodecanoic acid, 2,3-dihydroxypropyl ester .....	142–18–7
1-Monomyristin .....	Tetradecanoic acid, 2,3-dihydroxypropyl ester .....	589–68–4
Monomyristin .....	Decanoic acid, diester with 1,2,3-propanetriol .....	53998–07–1
Monopalmitin .....	Hexadecanoic acid, monoester with 1,2,3-propanetriol .....	26657–96–5
Monopotassium citrate .....	Citric acid, monopotassium salt .....	866–83–1
Monosodium citrate .....	Citric acid, monosodium salt .....	18996–35–5
Montmorillonite .....	Montmorillonite .....	1318–93–0
Myristic acid .....	Myristic acid .....	544–63–8
Nepheline syenite .....	Nepheline syenite .....	37244–96–5
Nitrogen .....	Nitrogen .....	7727–37–9
Nutria meat .....	Nutria meat .....	N/A
Nylon .....	Nylon .....	N/A
Octanoic acid, potassium salt .....	Octanoic acid, potassium salt .....	764–71–6
Octanoic acid, sodium salt .....	Octanoic acid, sodium salt .....	1984–06–1
Oleic acid .....	Oleic acid .....	112–80–1
Oyster shells .....	Oyster shells .....	N/A
Palm oil .....	Palm oil .....	8002–75–3
Palm oil, hydrogenated .....	Palm oil, hydrogenated .....	68514–74–9
Palmitic acid .....	Hexadecanoic acid .....	57–10–3
Paper .....	Paper .....	N/A
Paraffin wax .....	Paraffin wax .....	8002–74–2
Peanut butter .....	Peanut butter .....	N/A
Peanut shells .....	Peanut shells .....	N/A
Peanuts .....	Peanuts .....	N/A
Peat moss .....	Peat moss .....	N/A
Pectin .....	Pectin .....	9000–69–5
Perlite .....	Perlite .....	130885–09–5
Perlite, expanded .....	Perlite, expanded .....	93763–70–3
Plaster of paris .....	Plaster of paris .....	26499–65–0
Polyethylene .....	Polyethylene .....	9002–88–4
Polyglyceryl oleate .....	Polyglyceryl oleate .....	9007–48–1
Polyglyceryl stearate .....	Polyglyceryl stearate .....	9009–32–9

TABLE 2—INERT INGREDIENTS PERMITTED IN MINIMUM RISK PESTICIDE PRODUCTS—Continued

Label display name	Chemical name	CAS No.
Potassium acetate	Acetic acid, potassium salt	127-08-2
Potassium aluminum silicate, anhydrous	Potassium aluminum silicate, anhydrous	1327-44-2
Potassium benzoate	Benzoic acid, potassium salt	582-25-2
Potassium bicarbonate	Carbonic acid, monopotassium salt	298-14-6
Potassium chloride	Potassium chloride	7447-40-7
Potassium citrate	Citric acid, potassium salt	7778-49-6
Potassium humate	Humic acids, potassium salts	68514-28-3
Potassium myristate	Tetradecanoic acid, potassium salt	13429-27-1
Potassium oleate	9-Octadecenoic acid (9Z)-, potassium salt	143-18-0
Potassium ricinoleate	9-Octadecenoic acid, 12-hydroxy-, monopotassium salt, (9Z, 12R)-	7492-30-0
Potassium sorbate	Sorbic acid, potassium salt	24634-61-5
Potassium stearate	Octadecanoic acid, potassium salt	593-29-3
Potassium sulfate	Potassium sulfate	7778-80-5
Potassium sulfite	Sulfuric acid, monopotassium salt	7646-93-7
1,2-Propylene carbonate	1,3-Dioxolan-2-one, 4-methyl-	108-32-7
Pumice	Pumice	1332-09-8
Red cabbage color	Red cabbage color (expressed from edible red cabbage heads via a pressing process using only acidified water).	N/A
Red cedar chips	Red cedar chips	N/A
Red dog flour	Red dog flour	N/A
Rubber	Rubber	9006-04-6
Sawdust	Sawdust	N/A
Shale	Shale	N/A
Silica, amorphous, fumed	Silica, amorphous, fumed (crystalline free)	112945-52-5
Silica, amorphous, precipitate and gel	Silica, amorphous, precipitate and gel	7699-41-4
Silica	Silica (crystalline free)	7631-86-9
Silica gel	Silica gel	63231-67-4
Silica gel, precipitated, crystalline-free	Silica gel, precipitated, crystalline-free	112926-00-8
Silica, hydrate	Silica, hydrate	10279-57-9
Silica, vitreous	Silica, vitreous	60676-86-0
Silicic acid, magnesium salt	Silicic acid (H <sub>2</sub> SiO <sub>3</sub> ), magnesium salt (1:1)	13776-74-4
Soap	Soap (The water soluble sodium or potassium salts of fatty acids produced by either the saponification of fats and oils, or the neutralization of fatty acid).	N/A
Soapbark	Quillaja saponin	1393-03-9
Soapstone	Soapstone	308076-02-0
Sodium acetate	Acetic acid, sodium salt	127-09-3
Sodium alginate	Sodium alginate	9005-38-3
Sodium benzoate	Benzoic acid, sodium salt	532-32-1
Sodium bicarbonate	Sodium bicarbonate	144-55-8
Sodium carboxymethyl cellulose	Cellulose, carboxymethyl ether, sodium salt	9004-32-4
Sodium chloride	Sodium chloride	7647-14-5
Sodium citrate	Sodium citrate	994-36-5
Sodium humate	Humic acids, sodium salts	68131-04-4
Sodium oleate	Sodium oleate	143-19-1
Sodium ricinoleate	9-Octadecenoic acid, 12-hydroxy-, monosodium salt, (9Z,12R)-	5323-95-5
Sodium stearate	Octadecanoic acid, sodium salt	822-16-2
Sodium sulfate	Sodium sulfate	7757-82-6
Sorbitol	D-glucitol	50-70-4
Soy protein	Soy protein	N/A
Soya lecithins	Lecithins, soya	8030-76-0
Soybean hulls	Soybean hulls	N/A
Soybean meal	Soybean meal	68308-36-1
Soybean, flour	Soybean, flour	68513-95-1
Stearic acid	Octadecanoic acid	57-11-4
Sulfur	Sulfur	7704-34-9
Syrups, hydrolyzed starch, hydrogenated	Syrups, hydrolyzed starch, hydrogenated	68425-17-2
Tetraglyceryl monooleate	9-Octadecenoic acid (9Z)-, monoester with tetraglycerol	71012-10-7
Tricalcium citrate	Citric acid, calcium salt (2:3)	813-94-5
Triethyl citrate	Citric acid, triethyl ester	77-93-0
Tripotassium citrate	Citric acid, tripotassium salt	866-84-2
Tripotassium citrate monohydrate	Citric acid, tripotassium salt, monohydrate	6100-05-6
Trisodium citrate	Citric acid, trisodium salt	68-04-2
Trisodium citrate dehydrate	Citric acid, trisodium salt, dehydrate	6132-04-3
Trisodium citrate pentahydrate	Citric acid, trisodium salt, pentahydrate	6858-44-2
Ultramarine blue	C.I. Pigment Blue 29	57455-37-5
Urea	Urea	57-13-6
Vanillin	Benzaldehyde, 4-hydroxy-3-methoxy-	121-33-5
Vermiculite	Vermiculite	1318-00-9
Vinegar	Vinegar (maximum 8% acetic acid in solution)	8028-52-2
Vitamin C	L-Ascorbic acid	50-81-7
Vitamin E	Vitamin E	1406-18-4
Walnut flour	Walnut flour	N/A

TABLE 2—INERT INGREDIENTS PERMITTED IN MINIMUM RISK PESTICIDE PRODUCTS—Continued

Label display name	Chemical name	CAS No.
Walnut shells .....	Walnut shells .....	N/A
Wheat .....	Wheat .....	N/A
Wheat flour .....	Wheat flour .....	N/A
Wheat germ oil .....	Wheat germ oil .....	8006–95–9
Wheat oil .....	Oils, wheat .....	68917–73–7
Whey .....	Whey .....	92129–90–3
White mineral oil .....	White mineral oil (petroleum) .....	8042–47–5
Wintergreen oil .....	Wintergreen oil .....	68917–75–9
Wollastonite .....	Wollastonite (CaSiO <sub>3</sub> ) .....	13983–17–0
Wool .....	Wool .....	N/A
Xanthan gum .....	Xanthan gum .....	11138–66–2
Yeast .....	Yeast .....	68876–77–7
Zeolites .....	Zeolites (excluding erionite (CAS Reg. No. 66733–21–9)) .....	1318–02–1
Zeolites, NaA .....	Zeolites, NaA .....	68989–22–0
Zinc iron oxide .....	Zinc iron oxide .....	12063–19–3
Zinc oxide .....	Zinc oxide (ZnO) .....	1314–13–2
Zinc stearate .....	Octadecanoic acid, zinc salt .....	557–05–1

(3) *Other conditions of exemption.* All of the following conditions must be met for products to be exempted under this section:

(i) Each product containing the substance must bear a label identifying the label display name and percentage (by weight) of each active ingredient as listed in table 1 in paragraph (f)(1) of this section. Each product must also list all inert ingredients by the label display name listed in table 2 in paragraph (f)(2)(iv) of this section.

(ii) The product must not bear claims either to control or mitigate microorganisms that pose a threat to human health, including but not limited to disease transmitting bacteria or viruses, or claims to control insects or rodents carrying specific diseases, including, but not limited to ticks that carry Lyme disease.

(iii) Company name and contact information.

(A) The name of the producer or the company for whom the product was produced must appear on the product label. If the company whose name appears on the label in accordance with this paragraph is not the producer, the company name must be qualified by appropriate wording such as “Packed for [insert name],” “Distributed by [insert name], or “Sold by [insert name]” to show that the name is not that of the producer.

(B) Contact information for the company specified in accordance with paragraph (f)(3)(iii)(A) of this section must appear on the product label including the street address plus ZIP code and the telephone number of the location at which the company may be reached.

(C) The company name and contact information must be displayed prominently on the product label.

(iv) The product must not include any false and misleading labeling statements, including those listed in 40 CFR 156.10(a)(5)(i) through (viii).

(4) *Providing guidance.* Guidance on minimum risk pesticides is available at <http://www2.epa.gov/minimum-risk-pesticides> or successor Web pages.

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## ENVIRONMENTAL PROTECTION AGENCY

### 40 CFR Part 180

[EPA–HQ–OPP–2013–0727; FRL–9933–41]

### Spinosad; Pesticide Tolerances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

**SUMMARY:** This regulation establishes tolerances for residues of spinosad in or on multiple commodities that are identified and discussed later in this document. In addition, this regulation removes a number of existing tolerances for residues of spinosad that are superseded by tolerances being established in this action. Interregional Research Project #4 (IR–4) requested these tolerances under the Federal Food, Drug, and Cosmetic Act (FFDCA).

**DATES:** This regulation is effective December 28, 2015. Objections and requests for hearings must be received on or before February 26, 2016, and must be filed in accordance with the instructions provided in 40 CFR part 178 (see also Unit I.C. of the **SUPPLEMENTARY INFORMATION**).

**ADDRESSES:** The docket for this action, identified by docket identification (ID) number EPA–HQ–OPP–2013–0727, is

available at <http://www.regulations.gov> or at the Office of Pesticide Programs Regulatory Public Docket (OPP Docket) in the Environmental Protection Agency Docket Center (EPA/DC), West William Jefferson Clinton Bldg., Rm. 3334, 1301 Constitution Ave., NW., Washington, DC 20460–0001. The Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Public Reading Room is (202) 566–1744, and the telephone number for the OPP Docket is (703) 305–5805. Please review the visitor instructions and additional information about the docket available at <http://www.epa.gov/dockets>.

### FOR FURTHER INFORMATION CONTACT:

Susan Lewis, Registration Division (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001; main telephone number: (703) 305–7090; email address: [RDFFRNotices@epa.gov](mailto:RDFFRNotices@epa.gov).

### SUPPLEMENTARY INFORMATION:

#### I. General Information

##### A. Does this action apply to me?

You may be potentially affected by this action if you are an agricultural producer, food manufacturer, or pesticide manufacturer. The following list of North American Industrial Classification System (NAICS) codes is not intended to be exhaustive, but rather provides a guide to help readers determine whether this document applies to them. Potentially affected entities may include:

- Crop production (NAICS code 111).
- Animal production (NAICS code 112).
- Food manufacturing (NAICS code 311).