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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 152

[EPA-HQ-OPP-2010-0305; FRL-9339-1]

RIN 2070-AJ79

Pesticides; Revisions to Minimum Risk Exemption

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: EPA is proposing to more clearly describe the active and inert ingredients permitted in products eligible for the exemption from regulation for minimum risk pesticides. EPA is proposing to reorganize these lists with a focus on clarity and transparency by adding specific chemical identifiers. The identifiers would make it clearer to manufacturers; the public; and Federal, state, and tribal inspectors which ingredients are permitted in minimum risk pesticide products. EPA is also proposing to modify the label requirements in the exemption to require the use of specific common chemical names in lists of ingredients on minimum risk pesticide product labels, and to require producer contact information on the label. Once final, these proposed changes would maintain the availability of minimum risk pesticide products while providing more consistent information for consumers, clearer regulations for producers, and easier identification by states, tribes and EPA as to whether a product is in compliance with the exemption.

DATES: Comments must be received on or before [**INSERT DATE 90 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER**].

ADDRESSES: Submit your comments, identified by docket identification (ID) number

EPA-HQ-OPP-2010-0305, by one of the following methods:

• *Federal eRulemaking Portal*: *http://www.regulations.gov*. Follow the online instructions for submitting comments. Do not submit electronically any information you consider to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute.

• *Mail:* OPP Docket, Environmental Protection Agency Docket Center (EPA/DC) (28221T), 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001. In addition, please mail a copy of your comments on the information collection provisions to the Office of Information and Regulatory Affairs, Office of Management and Budget, ATTN: Desk Officer for EPA, 725 17th St., NW., Washington, DC 20503.

• *Hand Delivery:* To make special arrangements for hand delivery or delivery of boxed information, please follow the instructions at *http://www.epa.gov/dockets/contacts.htm*.

Additional instructions on commenting or visiting the docket, along with more information about dockets generally, is available at *http://www.epa.gov/dockets*.

FOR FURTHER INFORMATION CONTACT: Ryne Yarger, Field and External Affairs Division (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; e-mail address: *yarger.ryne@epa.gov.*

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

You may be potentially affected by this action if you manufacture, distribute, sell, or use minimum risk pesticide products. Minimum risk pesticide products are exempt from Federal regulation, 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 44220); outdoor power equipment stores (NAICS code 444210); and supermarkets (NAICS code 445110).

• Users of minimum risk pesticides, 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 day care services (NAICS code 624410). Many of these companies also manufacture minimum risk pesticide products.

B. 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., sections 3 and 25.

C. What Action is the Agency Taking?

EPA is proposing to more clearly describe the active and inert ingredients permitted in products eligible for the exemption from regulation for minimum risk pesticides (40 CFR 152.25(f)). EPA is proposing to reorganize these lists by adding specific chemical identifiers. The identifiers would make it clearer to manufacturers; the public; and Federal, state, and tribal inspectors the specific ingredients that are permitted in minimum risk pesticide products. EPA is also proposing to modify the label requirements in the exemption to require the use of specific common chemical names in lists of ingredients on minimum risk pesticide product labels, and to require producer contact information on the label.

D. Why is EPA Taking this Action?

The primary goal of this proposal is to clarify the conditions of exemption for minimum risk pesticides by making clearer the specific ingredients that are permitted in minimum risk pesticide products. EPA has exempted from the requirement of registration certain pesticide products if they are composed of specified ingredients and labeled according to EPA’s regulations in 40 CFR 152.25(f). EPA created the exemption for minimum risk pesticides to eliminate the need to expend significant resources to regulate products that were deemed to be of minimum risk to human health and the environment. In addition, exempting such products freed Agency resources to focus on evaluating formulations whose toxicity was less well characterized or of

higher toxicity. The existing regulatory structure, however, leads to confusion as to which ingredients are exempt under 40 CFR 152.25(f), and how they should be labeled on products.

The proposed revisions to the exemption would clarify the specific ingredients that are permitted, specify how they should be presented on a label, and provide consumers with contact information for the manufacturer of the products. EPA's intention is to restructure the exemption with a focus on clarity and transparency for the ingredient lists. Once final, these proposed changes would provide more consistent information for consumers, clearer regulations for producers, and easier identification by states, tribes and EPA as to whether a product is in compliance with the exemption.

II. Background

A. The Minimum Risk Pesticide Exemption

Under FIFRA section 25(b)(2), EPA may exempt from the requirements of FIFRA any pesticide that is "of a character unnecessary to be subject to [FIFRA]." Pursuant to this authority, in March 1996, EPA promulgated 40 CFR 152.25(g), which exempted from FIFRA any pesticide product consisting solely of specified ingredients that EPA judged to pose minimum risk to humans and the environment (61 FR 8876, March 6, 1996) (FRL-4984-8). This provision was later redesignated as 40 CFR 152.25(f) (66 FR 64759, December 14, 2001) (FRL-6752-1).

Unlike registered pesticides, sale and distribution of products exempted under 40 CFR 152.25(f) do not require that the products be registered with EPA, payment of registration fees, or reporting of production to EPA. To meet the criteria for the minimum risk exemption, a pesticide must:

- Contain only specified active and inert ingredients.
- List active ingredients on the label by name and percent weight in the formula.
- List inert ingredients on the label by name.
- 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.
- Not include false or misleading labeling statements, specified in 40 CFR 156.10(a)(5)(i) through (viii). These include false or misleading statements about product composition, effectiveness, comparison to other products, endorsement by the Federal Government, or label disclaimers.

Restrictions on which ingredients may be used in minimum risk pesticide products are key aspects of the exemption, since the properties of these specific ingredients are the reason EPA exempted minimum risk pesticide products from FIFRA regulatory requirements. As stated in the notice of proposed rulemaking for the minimum risk exemption, "EPA believes regulation of these substances is not necessary to prevent unreasonable adverse effects on man or the environment, and these substances are not of a character necessary to be subject to FIFRA in order to carry out its purposes" (Ref. 1).

1. *Active ingredients.* Active ingredients for minimum risk pesticide products are listed in 40 CFR 152.25(f)(1); no new active ingredients have been added since 1996.

2. *Inert ingredients.* Inert ingredients for minimum risk pesticide products were originally listed in List 4A, referenced at 40 CFR 152.25(f)(2). The 4A Inert Ingredient List was created on November 22, 1989 (54 FR 48314) (FRL-3667-6). List 4A

ingredients were described as minimal risk, or "substances for which there is no information to indicate that there is a basis for concern" (Ref. 2). On September 28, 1994, EPA added new chemicals to List 4A by publishing an updated list in the **Federal Register** (Ref. 3). The exemption for minimum risk pesticides referred to this list, as it appeared in the **Federal Register** in September 1994.

Since 1994, EPA has updated the list of inert ingredients permitted in minimum risk pesticide products. In 2002, EPA proposed (in January) and finalized (in May) a consolidated set of tolerance exemptions for minimum risk chemicals under section 408 of the Federal Food, Drug and Cosmetic Act (FFDCA), 21 U.S.C. 346a. These changes primarily allowed a set of commonly consumed foods to be included in minimum risk pesticides with food uses (Ref. 4). Some commonly consumed foods (such as peanuts, tree nuts, milk, soybeans, eggs, fish, crustacean, and wheat) were excluded due to their known allergenic properties. EPA proposed and finalized these changes as part of the tolerance reassessment requirements of the Food Quality Protection Act of 1996, which amended FFDCA. In the 2002 proposal, EPA explained that commonly consumed foods could be considered minimum risk, since "it is unlikely that a commonly consumed food commodity could be used to control a pest via a toxic mode of action" and that foods are generally recognized as safe (Ref. 2). The 2002 final rule explained that, with some exceptions, all commonly consumed food items and all animal feed items would be considered minimum risk pesticide chemicals and would be located in the newly established 40 CFR 180.950. The 2002 final rule did not amend the FIFRA minimum risk exemption in 40 CFR 152.25(f). In 2004, EPA updated List 4A to specifically list the substances in the 2002 rulemaking (Ref. 5).

In 2006, EPA classified additional substances as minimum risk for purposes of tolerance exemptions under 40 CFR 180.950(e). The proposed rule also clarified that EPA was shifting existing tolerance exemptions for the inert ingredients that appear on List 4A from that list to 40 CFR 180.950(e) (Ref. 6).

Since 2006, EPA has been responding to stakeholder input and revising the web page that lists inert ingredients eligible for use in minimum risk pesticide products. Among these updates, this web page was revised on March 3, 2009, to include a common chemical name for many of the chemicals and to clearly delineate the food and non-food use status of the chemical substances.

The list was most recently re-formatted on December 20, 2010, to provide a more easily understood format for the chemicals listed. The list is available on the Agency's website at http://www.epa.gov/opprd001/inerts/section25b_inerts.pdf (Ref. 7).

3. *Labeling requirements.* Labeling requirements are also a key component of the exemption. While EPA does not review these products, and therefore a label review is not conducted, in order to maintain exempt status, an exempt product's label must meet certain criteria. The methods for displaying active and inert ingredient information are detailed in the exemption: Labels must include percentage (by weight) of active ingredients and list all inert ingredients.

The regulations for displaying ingredients on minimum risk pesticide product labels differ from the regulations for registered products. Since exempt products are not registered with EPA and manufacturers submit no information to the Agency, listing product ingredients provides important information to the public, and to enforcement officials who must determine whether or not a product complies with the exemption.

B. EPA's Initial Expectations for the Exemption

EPA had several expectations regarding this exemption:

- Reduction of burden on the Agency and manufacturers of minimum risk pesticides.
- Facilitate the development of more low-risk methods of pest control.
- No significant environmental use of these substances as pesticides.
- Uncomplicated enforcement.

Though some of these expectations were met, the lack of clarity regarding ingredients has produced significant enforcement difficulties. For example, the way active ingredients are currently listed in the exemption is vague, and inspectors are confronted with the need to determine whether certain product ingredients as they are listed on product labels, such as cedar leaf oil or cedar wood oil, are exempt under the more general terminology used in 40 CFR 152.25(f), which lists only "cedar oil." EPA has attempted to provide clarity by updating its website explaining minimum risk pesticide products; however, feedback from stakeholders indicated this was not sufficient to address the problems described in the next unit.

C. Reactions from and Challenges for States

1. *State registration practices.* Though minimum risk pesticide products are exempt from Federal regulation, most states regulate these products in some manner. In 2010, approximately 37 states and the District of Columbia required products that are exempt from Federal regulation under 40 CFR 152.25(f) to have a state-registration. In some ways, this is similar to many states' registration processes for federally registered pesticides, which also must be approved in each state in which they are sold or used.

However, a state's registration of a federally registered pesticide usually relies heavily on the previous Federal review of the product's toxicity, use patterns, and label. In contrast, given that minimum risk pesticides are largely exempt from Federal regulation under FIFRA, the numerous states that do regulate these products review and examine the products using criteria that vary from state to state. In some states, manufacturers of minimum risk pesticide products are only required to pay a registration fee; in others, there is a label review, which can include a review of the ingredients used in the product; and a few require Material Safety Data Sheets and data on product efficacy.

Though some states have more detailed registration processes for minimum risk pesticide products, and some states do not register these products at all, the exemption created significant enforcement concerns for all states since it created a category of legal but federally unregistered products. Instead of being able to rely on a Federal determination of whether a pesticide product was complying with relevant regulations, each state's enforcement authority had to make those decisions. To do this, each state had to become familiar with all active and inert ingredients permitted under the Federal exemption in order to determine whether a pesticide product lacking an EPA registration number was lawfully exempt from Federal regulation.

Inspectors have found it difficult to determine whether seemingly exempt products were complying with the exemption. One of the most common minimum risk pesticide product issues encountered by inspectors and enforcement case developers are products that claim the 40 CFR 152.25(f) exemption, but contain active or inert ingredients whose status as an ingredient that may be used in minimum risk pesticide products is not readily apparent from the name of the ingredient as listed on the label.

Since ingredients may be listed on the label with one of numerous chemical, common, or Latin names, determining whether an ingredient on a pesticide product label is the same substance referred to by the active or inert ingredient lists is a time consuming task.

The lack of clarity in which ingredients are permitted in minimum risk pesticide products makes it difficult for companies to determine whether a specific formulation is within the exemption. The lack of consistency in how those ingredients are displayed on the product labels by the various manufacturers has led to inefficiencies in enforcement of the exemption. As discussed in Unit IV., by creating a situation in which enforcement officials cannot swiftly examine an unregistered pesticide product label and then determine if the ingredients listed on the label are eligible for use in minimum risk pesticide products creates slowdowns in developing enforcement cases.

2. *Early negative response.* States' frustration with the exemption developed quickly. In 1998, less than 2 years after the exemption took effect, the Association of American Pesticide Control Officials (AAPCO) surveyed its members regarding 40 CFR 152.25(f) (Ref. 8). Overall, respondents indicated that the 1996 exemption has had a negative effect on their agencies or their states, and that ingredient or labeling issues are a major concern. Responses to selected questions from the survey are shown in Table 1.

Table 1.—Responses to Selected Questions in the 1998 AAPCO Survey

Response	Total No. of States	Percent of All States + Territories in AAPCO (53)	No. of States Registering Exempt Products in 1998	Percent of States at that Time Registering Exempt Products (36)
Have problems with companies submitting labels for 25(b) products that contain active ingredients not on the list	11	21%	9	25%

Have a system for determining changes in List 4A (inert ingredients)	7	13%	5	14%
Have seen exempt products that fail to list inert ingredients on the label as required	21	40%	18	50%

3. *Continuing enforcement challenges.* States' experience with 40 CFR 152.25(f) indicate that the exemption from regulation is not working as intended and, instead, has resulted in numerous inefficiencies. Under the exemption as it is currently written, inspectors have difficulty determining on-site whether a product is legally exempt from regulation or if it is an illegal product. If the pesticide's exemption status is not clear, the inspector collects evidence documenting sale/distribution (photos, sales records, etc.) and follows-up with EPA. This creates a noticeable resource burden for the states and EPA.

In 2006, in response to a petition from the Consumer Specialty Products Association, several states submitted comments that described their difficulties enforcing the terms of the exemption for minimum risk pesticide products. For example, the comment from Colorado stated:

> In Colorado this results in numerous cases of enforcement actions requiring Colorado retailers to remove unregistered products from their shelves. We issue about 90 Cease and Desist Orders per year to retailers selling unregistered pesticides that claim to be 25(b) exempt. (Ref. 9)

A similar comment was received from California:

> Although well intended, rather than relieving the States of ever increasing regulatory workload, the proliferation of minimum risk pesticides now available in the marketplace has resulted in the opposite effect. In California, recent data indicates that approximately 20% of the routine marketplace inspections include some type of additional follow up having to be performed to determine compliance status for 25(b) minimum risk pesticides. (Ref. 10)

Many of these burdens and inefficiencies resulted from confusion created by ambiguities in the list of ingredients permitted for use in pesticide products exempt from

Federal regulation. Several lists must be consulted to determine if a product's ingredients are permitted, and, often, ingredients on product labels may - legitimately - use chemical names different from those that appear on the ingredient lists. Chemicals often have multiple names. However, inspectors and consumers may be unfamiliar with alternative chemical names, resulting in confusion over whether the product complies with the exemption. For example, as Colorado stated in its comment on the 2006 petition:

> There is also continuing confusion among applicants, extension educators, state regulators and even regional EPA staff on which ingredients are or are not allowed, and what statements can or cannot be on labels for 25(B) products. Even after 10 years, we frequently see applications for products with ingredients that are not allowed. (Ref. 9).

As currently written, it is difficult and time-consuming for state regulators and producers to determine which ingredients are allowed in products claiming the exemption. As a result, marketplace inspections are hobbled, and discovery of non-compliant products is delayed. As California stated in its comment on the 2006 petition:

> The increased workload generated by unregulated 25(b) pesticides impacts other vital regulatory duties, such as worker protection inspections, and product registration (Ref. 10).

This encourages a proliferation of illegal products, or products that do not meet the Federal exemption criteria for ingredients, labeling, or other conditions.

The burden on the states is clear: Identifying which minimum risk pesticide products are compliant with the exemption requires significant state resources for inspection, yet when products are found to be violating the Federal exemption, states in many cases cannot precisely identify the problem or take action without significant guidance and assistance from EPA, which must interpret the ingredient lists and other criteria in the exemption to determine whether a product is compliant.

III. Need for this Rulemaking

More than a decade of experience with 40 CFR 152.25(f) on the Federal and state levels has indicated that there is confusion over permitted ingredients. This lack of clarity has created a significant burden for enforcement of the exemption. Confusion over permitted ingredients may also result in public hazards due to the proliferation of unregistered pesticide products that do not comply with the ingredient restrictions in the exemption. As part of a survey of compliance with the exemption, EPA conducted an analysis of labels of products sold as minimum risk personal insect repellents (also referred to as skin-applied repellents), relying in part on information provided by the Nielsen Company. Personal insect repellent products are estimated to make up approximately 14% of products registered by states that make their registration databases publicly available. EPA found that nearly half (47%) of the minimum risk personal insect repellent products contained ingredients not permitted under 152.25(f) (Ref. 11). This finding is based on:

- Identification of 135 personal insect repellent products claiming to be exempt, or that were not registered with EPA. These products were identified through state registration lists, nationwide sales data compiled by the Nielsen Company, and internet searches.

- Examination of publicly available labels of these personal insect repellent products. Labels were not available for 26 products (or 19% of all identified).

- Comparison of any stated ingredients with those on the active and inert ingredient lists specified in or referenced by the exemption. Forty-five products, or 33% of all identified, seemed to list only permitted ingredients; 64 products, or 47%, listed

ingredients not permitted under the exemption.

The data are likely an underestimate of the non-compliance rate with the ingredient criteria of the exemption. These underestimations result from a lack of information available on these products, and the sources used to identify these products are not comprehensive of the entire universe of minimum risk personal insect repellents, which are not registered in all states and which may not be sold in the major retailers tracked by the Nielsen Company nor sold online. Furthermore, the compliance rate for skin-applied insect repellents may not be representative of all minimum risk pesticide products. EPA has not examined the other products with respect to compliance, since labels from other minimum risk pesticide products representative of the national marketplace could not be located.

Lack of compliance with the requirements of the exemption may result from producers' uncertainty about which ingredients are permitted, or inspectors' inability to develop enforcement cases to remove non-compliant products from the marketplace in a timely manner. Currently, it may not be clear to companies which specific ingredients are permitted for minimum risk pesticides exempt from regulation, since the terminology describing the ingredients is difficult to understand. Additionally, product labels often use unfamiliar terms for permitted ingredients, which creates confusion for state and Federal inspectors who are not familiar with all possible names for these chemicals. For example, some products use Latin names for some ingredients, such as a product that listed some of its inert ingredients as Glycine Soja Oil, Cymbopogon Nardus Oil, and Pimenta Acris Leaf Oil, which most inspectors and members of the public would not recognize as soybean oil, citronella oil, and bay leaf oil, respectively. Inspectors have

reported the difficulty of determining the legality of some minimum risk pesticide products during field inspections.

The actions proposed today will provide greater specificity and clarity concerning the inert and active ingredients that can be used in exempted products, and specify the exact chemical terms that must be displayed on product labels. This will aid in resolving many of the issues surrounding non-compliance, as well as providing clearer information to consumers of these products without adversely affecting the availability of minimum risk pesticide products. Providing accurate and clear information to the public will assist users in making good choices regarding their use of pesticides. EPA believes that these beneficial label changes cannot be achieved through non-regulatory means.

IV. What EPA Considered

EPA considered the following options for addressing the issues described previously related to the minimum risk exemption:

Item 1: Revising the exemption to redesign the format of the active ingredient list.

Item 2: Revising the exemption to codify the inert ingredient list into the CFR.

Item 3: Revising the exemption to require the use of a common chemical name on the label.

Item 4: Revising the exemption to require a label statement that signals exempt status.

Item 5: Publishing guidance on how an exempt label should look.

Items 1 and 2 would provide clarity regarding the ingredients and, to some extent, promote states' abilities to enforce the exemption while continuing the availability of

minimum risk pesticide products.

Item 3 would not only significantly increase the clarity of the ingredients in a product claiming to be a minimum risk pesticide, but also augment visibility of that product's compliance with the exemption. Though companies would need to modify product labels to comply with the changes, the costs expended would be minimal and this would not impede the continued availability of minimum risk pesticides.

When considering Item 4, EPA believes that Item 4 is unlikely to provide any significant benefit to consumers from having a statement, a disclaimer, which signals exempt status on the product label. EPA's analysis of information from open literature and survey results indicates that in general most people do not read, understand, or believe a disclaimer. This means that a label disclaimer is unlikely to change consumer behavior or influence a purchasing decision. For a label statement to be effective, the purchaser must first read the label and notice the disclaimer, and then read the disclaimer, understand the disclaimer, believe the disclaimer, and choose to act on the disclaimer (Ref. 12). Potentially, there could be a slight benefit from such a statement for enforcement, as state inspectors could use this statement as part of their determination of a product's status under the exemption. However, as other pieces of label information may provide more useful information to consumers and enforcement, EPA chose to focus on making those modifications to the exemption.

Item 5 would assist manufacturers with complying with the minimum risk exemption. EPA plans to update its website on minimum risk pesticides (Ref. 13) to provide this guidance, including label formats, directions for use, and ways to display ingredient lists. Any clarifications communicated through this kind of guidance,

however, would not be considered requirements for compliance with the exemption, and would not aid in efficient enforcement of the exemption. For this reason, merely providing guidance to manufacturers is not sufficient to address the exemption's issues related to enforcement difficulties and current lack of clarity. EPA intends to provide guidance by updating the sections of its website explaining the minimum risk exemption, but this would be independent of rulemaking.

Additional issues regarding the minimum risk exemption have been raised by states, with states expressing interest in:

Item 6: Revising the exemption to require directions for use on minimum risk pesticide products.

Item 7: Revising the exemption to require company name and contact information.

Item 6 would provide consumers with directions for safe use of the product. Though many products already include directions on how to apply the product, some do not, and even for minimum risk pesticides there is a theoretical potential for injury or environmental hazard from improper use of the products. However, assessing the risk of certain uses of minimum risk pesticides already determined to be minimum risk is outside the scope of this rulemaking, which only proposes to clarify the terms of the original exemption. Additionally, EPA was not able to create a requirement for directions for use that would be both broad enough to apply to all potential categories of products, yet specific enough to be enforced fairly and effectively. For these reasons, EPA chose to focus on other aspects of minimum risk pesticide product labeling and on the ingredient lists. EPA will continue to seek ways to provide guidance on improving directions for

use on minimum risk pesticide products.

Item 7 would provide a significant benefit to consumers, who may be unable to determine which company manufactured or distributed a minimum risk pesticide product. Although the labels of many products already provide this information, it does not appear on all minimum risk pesticide products. These changes would provide useful information without burdening manufacturers beyond the cost of changing their labels. Unlike directions for use, the requirements for company name and contact information (such as address and phone number) can be specified clearly in the proposed amendments to the exemption. Though this does not deal with ingredient clarity, EPA feels that in the interest of efficiency it is appropriate to propose this change at the same time, since it would provide a strong benefit to consumers with little added cost.

EPA determined that a combination of revisions and guidance would provide the best approach to the issues discussed previously. This combination is:

Item 1: Redesign the format of the active ingredient list.

Item 2: Codify the list of permitted inert ingredients.

Item 3: Require that common chemical names be used to describe active and inert ingredients on product labels.

Item 5: Provide guidance on how an exempt label should look.

Item 6: Require company name and address on product labels.

Items 1, 2, 3, and 6 are proposed in this rulemaking and are discussed in greater detail in Unit VII. Item 5 includes website changes that are in addition to the rulemaking proposed here, and is also outlined later in this document.

By clarifying the way ingredients are defined in the exemption and the way they

should be displayed on product labels, EPA will be able to protect public health while relieving product manufacturers of the burdens associated with regulation. Similarly, requiring contact information on product labels would provide important consumer information and greater producer accountability with minimal cost.

V. Proposal to Modify the Minimum Risk Exemption to Improve Clarity

A. Clarify the List of Active Ingredients

EPA proposes to replace the text in 40 CFR 152.25(f) specifying the active ingredients and their variations with a table that would show, for each permitted active ingredient:

- Label Display Name. This is the common chemical name that would be required to be used on labels of products that contain these ingredients.
- Chemical Name, as determined by Chemical Abstract Services (CAS).
- Specifications. Though this column would generally be empty, some substances listed in the exemption had specifications associated with them in the text of the exemption as published in 1996.
- CAS Registry Number (CAS No.). The Agency listed the CAS No. for each of the chemical substances listed in 40 CFR 152.25(f) where a CAS No., was available. A CAS No. is a unique numerical identifier that provides one of the most distinct, readily available, and universally accepted means of identifying chemical substances. Identifying chemicals permitted in minimum risk pesticides by CAS No. would assure manufacturers that they are purchasing and using the chemicals that can be used in minimum risk pesticide products. Only substances identified by the CAS No. listed would be permitted for use as active ingredients in minimum risk pesticide products. EPA

is only providing additional clarity concerning the ingredients that are currently used in exempted products: No ingredients are being added or removed from the list.

An example of this table is provided here, as Table 2.

Table 2.—Example of New Format for Active Ingredients

Label Display Name	Chemical Name	Specifications	CAS No.
Citric Acid	2-Hydroxypropane-1,2,3-tricarboxylic acid	USP	77-92-9
Citronella Oil	Citronella Oil	---	8000-29-1

In this document, EPA is not proposing to remove or add any active ingredients to the list. The current list is being clarified by using more precise chemical identifiers and nomenclature. For approximately 20 of the active ingredients in the proposed table, EPA is proposing to include the specification of USP (United States Pharmacopeia) standard in the Specifications column. USP standards are set for quality, purity, and identity, and usually provide information on chemical formula, chemical weight, CAS numbers, function, definition, packaging, storage, and labeling requirements. Information on the USP standards is included in the docket for this proposal.

State and Federal inspectors and interested members of the public would be able to easily match the name of the active ingredient on the label to the column in the table in 40 CFR 152.25(f)(1) that contains label display names. Linking the CAS No., the label display name, and the chemical name maintains the chemical identity specificity needed for enforcement, would provide the public and inspectors with understandable information, and would provide guidance for product manufacturers who may be unsure of the specific ingredients that their products can and cannot contain in order to comply with the minimum risk exemption.

B. Codify the Existing List of Inert Ingredients

As previously discussed, in Unit III.A.2., the minimum risk exemption in 40 CFR 152.25(f)(2) references a list of chemicals permitted to be used as inert ingredients that has been updated and currently is maintained on EPA's public website. To clarify which inert ingredients may be used in these products, EPA proposes to codify in the CFR a reference to sections detailing which chemicals may be used in addition to a reformatted version of the table that currently appears online.

The proposed changes to the section of the exemption dealing with inert ingredients would include references to 40 CFR 180.950(a), (b), and (c), which describe chemical substances exempt from the requirements of a tolerance and that may also be used as inert ingredients in minimum risk pesticides. The regulatory reference will provide the clarity needed for understanding which commonly consumed food commodities, animal feed items, and edible fats and oils can be used in exempted products. Additionally, EPA proposes to add a table that would contain the chemicals currently listed in 40 CFR 180.950(e) as well as those that appeared originally on List 4A. A version of this table currently appears online. Any duplicate listings would be removed.

EPA believes that adding these references and reformatting the table and placing it into the CFR will provide needed clarity, in as much as State inspectors, members of the public, or manufacturers of minimum risk pesticide products would be able to more quickly determine whether a given ingredient is a permitted inert ingredient for minimum risk pesticide products.

The columns of the table that would be codified would be:

- Label Display Name.
- Chemical Name, as determined by CAS.
- CAS No. (described previously).

An example of this table is listed, as Table 3.

Table 3.—Example of New Format for Permitted Inert Ingredients

Label Display Name	Chemical Name	CAS No.
Aluminum potassium sodium silicate	Silicic acid, aluminum potassium sodium salt	12736-96-8
Aluminum silicate	Silicic acid, aluminum salt	1335-30-4
Aluminum sodium silicate	Silicic acid, aluminum sodium salt	1344-00-9

Unlike the proposed table listing the active ingredients, the proposed table for the inert ingredients does not include a column outlining specifications, since none were outlined in the exemption. However, some of the substances have no tolerances or tolerance exemptions under FFDCA section 408 and thus have not been permitted for use in pesticides that may come in contact with foods, which are also known as food-use pesticides. For this reason, EPA is proposing that in addition to the proposed table listing inert ingredients, the text of the exemption be amended to indicate the address of an EPA website at which information can be found on which chemicals listed could be used in food-use pesticide products.

The FFDCA requires all active and inert ingredients that come into contact with food have an applicable tolerance or exemption from the tolerance requirement. EPA currently indicates on the minimum risk inert ingredient table that appears online (at *http://www.epa.gov/opprd001/inerts/section25b_inerts.pdf)* those chemicals that are exempt from the requirement of a tolerance, and thus could be used in pesticides that

come in contact with food. EPA proposes to maintain as guidance the online list that includes a column indicating which chemicals may be allowed as active or inert ingredients in pesticides that come in contact with food; there would also be a note indicating where the exemptions from the requirements of a tolerance are detailed in the CFR. This table could thus continue to serve as a quick guide to manufacturers, enforcement officials, and members of the public.

There are benefits to having all information about the minimum risk exemption consolidated in one location, and the CFR is a useful reference for many people interested in the exemption. Therefore, EPA proposes to add a reference to the address of the website that would contain the reformatted active and inert ingredient tables that include a "food use" and "non-food use" column. EPA would make clear that the information on the website is advisory and serves as guidance, and that the specific regulations should be consulted when seeking to learn about a chemical's exemption from the requirements of a tolerance. However, EPA believes that highlighting in the CFR where this guidance is available online would be helpful in explaining some of the more complicated aspects of the minimum risk exemption.

C. Require that Ingredient Lists Use a Label Display Name

Currently, the chemical names on exempted labels are derived from a variety of sources, which include CAS nomenclature, informal or lay terminology, and Latin plant name derivatives. This causes confusion for inspectors and the public, who may not be aware of the multiple names a single chemical may have. All stakeholders would benefit from the use of a common chemical name for ingredients listed on the product label. EPA proposes to revise 40 CFR 152.25(f)(3) to include the requirement that labels of exempt

products use the “label display name” in the ingredient listing, when a label display name is specified in the exemption.

D. Require Company Name and Contact Information

An additional revision to the exemption would require that producers of minimum risk pesticide products include their company’s name and contact information (address and telephone number) on the product label. In separate guidance, to be posted on EPA’s website on minimum risk pesticides, companies would be encouraged to also provide a phone number, mailing address, website, or email address on their minimum risk pesticide product labels.

Requiring a company name and contact information would provide valuable information to consumers with minimal cost. It would also provide state and Federal inspectors with important information that currently can be difficult to find. To provide additional clarity, if a company name appears on the label and that company is not the producer, EPA proposes that the text indicate that the product was “packed for” “distributed by” or “sold by” to show that the company selling the product is not the producer.

E. Estimated Costs Associated With These Proposed Changes

The potential costs incurred by manufacturers of minimum risk pesticide products to comply with these proposed changes are estimated to be minimal. The analysis summarized in this unit estimates the cost of label changes required by the proposed rule, as separate and distinct from (i.e., incremental to) routine label changes that producers already undertake. For greater detail, including the assumptions used for the cost analysis, see the “Cost and Small Business Analysis of Proposed Revisions to Minimum

Risk Exemption" (Ref. 14).

For Items 1 and 2 (Revising the exemption to redesign the format of the active ingredient list and revising the exemption to codify the inert ingredient list into the CFR), there are no costs to producers of exempt products. Since no ingredients are being added or removed from the list, manufacturers of currently exempted products should not need to change their product formulations.

For Items 3 and 7 (Revising the exemption to require the use of a common chemical name, and company name and contact information on the label), the cost is the cost of changing the label. To comply with the proposed changes for labeling requirements for minimum risk pesticide products, EPA expects that all products may need to be re-labeled in order to list ingredients by common chemical name. Some companies may also need to add their company name and contact information to product labels. The estimated costs associated with changing a label are summarized here.

Currently, EPA is aware of 216 companies producing 757 minimum risk pesticide products. EPA derived this information from publicly available lists of state registrations for minimum risk pesticides (Ref. 15), and AC Nielsen retail store scanner data (Ref. 16). As explained in the cost analysis, 192 parent companies were identified. Together, the 192 parent companies account for 541 minimum risk pesticide products, or about 79% percent of those identified by EPA.

Table 4 shows the distribution of firms by NAICS code. Most firms in the minimum risk pesticide industry belong to *Chemical Manufacturing* (NAICS code 325) and *Merchant Wholesalers, Nondurable Goods* (NAICS code 424). Forty-two firms are divided among 31 NAICS codes.

Table 4.— Producers of Minimum Risk Pesticides

3-Digit NAICS Code	NAICS Code Description	Number of Parent Firms
325	Chemical Manufacturing	72
339	Miscellaneous Manufacturing	8
423	Merchant Wholesalers, Durable Goods	11
424	Merchant Wholesalers, Nondurable Goods	32
444	Building Material and Garden Equipment and Supplies Dealers	7
541	Professional, Scientific, and Technical Services	7
561	Administrative and Support Services	13
Others		42
	Total with classification	**192**

The estimated cost of the proposed rule consists of a one-time change in the design of the label to comply with the proposed requirements. The estimated incremental cost of the proposed rule depends on the extent to which the change is separate and distinct from the routine label changes firms undertake on a regular basis. Firms routinely change their labels to update or "refresh" their product labels. This is an important factor that determines the magnitude of the cost of the rule since the expected cost of the label change will depend on the duration of the implementation period. A longer implementation period means that the new requirements could be incorporated into a routine or planned re-label.

Many products have more than one size or type of package. Each is referred to as a stock keeping unit (SKU). Each SKU would have to be relabeled to comply with the new requirements. Using an estimate of 1.53 SKUs per product, there are 1,158 products to be relabeled.

In its analysis, EPA has assumed that firms will routinely re-label every 3 years, although some firms may re-label more or less frequently. EPA also assumed that if the

changes occurred during a routine label update, then one-third of the label's artwork cost would be due to the new requirements. If the firm's routine relabeling cycle falls outside the rule compliance period (that is, if the rule requirements cannot be incorporated into the firm's routine labeling change), then the full cost of label change is due to the change in regulations.

The estimated costs of the rule under different rule compliance periods are shown in Table 5.

Table 5.—Relabeling Cost per SKU (Stock Keeping Unit) for Three Implementation Periods

Implementation Period	Average Cost Estimate
Immediate relabeling	$6,306
2-year implementation	$2,550
3-year implementation	$672

Using the average cost estimates from Table 5, EPA estimates the total potential industry cost in Table 6.

Table 6.— Industry Cost for Three Rule Implementation Periods

Industry Costs	Immediate	2 years	3 years
Total number of SKUs	1,158	1,158	1,158
Average cost per SKU label change (from Table 5)	$6,306	$2,550	$672
Total cost to industry	$7,300,282	$2,952,097	$778,005

Under an implementation period of 2 years, the estimated industry cost is about $3 million.

VI. Request for Comments

The Agency invites the public to provide its views and suggestions for changes on all the various proposals in this document. Specifically included within the Agency's request for comments are the following:

- The format of the ingredient lists (active and inert ingredients).
- The information in the new format of the ingredient lists (active and inert ingredients).
- The proposed reference to a website that contains a table formatted to include more information on exemptions from the requirement of a tolerance (which would indicate whether or not a substance can be in a pesticide used on or near food). Would this website provide the clarity some stakeholders seek?
- EPA's methodology for estimating the costs associated with the proposed label changes.
- The proposed timeframe (2 years from the effective date of the final rule) for complying with label changes.
- How will these changes impact state and local agencies?
- What are effective methods and venues for communicating these proposed changes to affected entities, and receiving their feedback?
- Because EPA's analysis was conducted with a subset of products, EPA was unable to determine if most minimum risk pesticide products for sale today comply with the requirements of the exemption, and it is unclear how specifying active and inert ingredients would affect the composition of products on the market. EPA expects that the only costs to industry will be re-labeling; however, the Agency is especially interested in learning of any products that would need to be reformulated as a result of these proposed changes.

Commenters are encouraged to present any data or information that should be considered by EPA during the development of the final rule. Please describe any

assumptions and provide any technical information used in preparing your comments. You should explain estimates in sufficient detail to allow for them to be reproduced for validation. EPA's underlying principle in developing the proposed revisions has been to strike an appropriate balance among:

- Clarifying the ingredients permitted for use in minimum risk pesticide products.
- Having revised labels with better information on the labels quickly.
- Minimizing the impacts on the affected industry.

VII. Reference List

The following is a listing of the documents that are specifically referenced in this proposed rule. The docket for this rulemaking, identified by docket ID number EPA-HQ-OPP–2010–0305, includes these documents and other information considered by EPA in developing this proposed rule. In some cases this may include 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 documents, please consult the person listed under **FOR FURTHER INFORMATION CONTACT**.

1. U.S. Environmental Protection Agency (EPA). Pesticides; Exemption of Certain Substances from Federal Insecticide, Fungicide, and Rodenticide Act Requirements; Proposed Rule. **Federal Register** (59 FR 47289, September 15, 1994) (FRL-4872-4). *https://federalregister.gov/a/94-22855.*

2. EPA. Pesticides; Tolerance Exemptions for Minimal Risk Active and Inert Ingredients; Proposed Rule. **Federal Register** (67 FR 1925, January 15, 2002) (FRL-6807-8). *https://federalregister.gov/a/02-699.*

3. EPA. Inert Ingredients in Pesticide Products; List of Minimal Risk Inerts;

Notice. **Federal Register** (September 28, 1994; FRL-4872-5). *http://www.gpo.gov/fdsys/pkg/FR-1994-06-23/html/94-15013.htm*.

4. EPA. Pesticides; Tolerance Exemptions for Minimal Risk Active and Inert Ingredients; Final Rule. **Federal Register** (67 FR 36534, May 24, 2002) (FRL- 6834-8); *http://federalregister.gov/a/02-12973*.

5. EPA. Office of Pesticide Programs (OPP). List 4A - Minimal Risk Inert Ingredients - By CAS Number. (August 2004). *http://www.epa.gov/opprd001/inerts/inerts_list4Acas.pdf.*

6. EPA. Pesticides: Minimal Risk Tolerance Exemptions; Proposed Rule. **Federal Register** (71 FR 4087, January 25, 2006) (FRL- 7754-8). *http://federalregister.gov/a/06-574.*

7. EPA. OPP. Inert Ingredients Eligible for FIFRA 25(b) Pesticide Products. (December 20, 2010). *http://www.epa.gov/opprd001/inerts/section25b_inerts.pdf.*

8. AAPCO. 25(b) Exempt Pesticides Survey. (1998). Accessible at: *http://aapco.ceris.purdue.edu/doc/surveys/25b_1srvy.html*. Survey results accessible at*: http://aapco.ceris.purdue.edu/doc/surveys/25b_1.html*.

9. Comment attachment by L. Quakenbush, Colorado Department of Agriculture. Docket ID No.: EPA-HQ-OPP-2006-0687. Document ID No.: EPA-HQ-OPP-2006-0687-0026.

10. Comment submitted by G. Farnsworth, Department of Pesticides Regulation (DPR). Docket ID No.: EPA-HQ-OPP-2006-0687. Document ID No.: EPA-HQ-OPP-2006-0687-0064.

11. EPA. OPP. EPA Analysis of Labeled Ingredients on Minimum Risk Insect

Repellent Products. (2009). Docket ID No.: EPA-HQ-OPP-2010-0305. Document ID No.: EPA- HQ-OPP-2010-0305-0010.

12. EPA. OPP. Review of Literature on Consumer Use of Label Statements and Findings Relevant to Planned Action on Minimum Risk Insect Repellents. (2009). Docket ID No.: EPA-HQ-OPP-2010-0305. Document ID No.: EPA-HQ-OPP-2010-0305-0011.

13. EPA. OPP. Minimum Risk Pesticides. *http://www.epa.gov/oppbppd1/biopesticides/regtools/25b_list.htm*.

14. EPA. OPP. Cost and Small Business Analysis of Proposed Revisions to Minimum Risk Exemption. (2012). Docket ID No.: EPA-HQ-OPP-2010-0305. Document ID No.: EPA-HQ-OPP-2010-0305-0012.

15. EPA. OPP. Minimum Risk Products Registered with States with Publicly Searchable Databases (AL, AK, AZ, CO, IA, LA, MS, NH, NC, OK, RI, SC, SD, and WA). (2010). Docket ID No.: EPA-HQ-OPP-2010-0305. Document ID No.: EPA-HQ-OPP-2010-0305-0013.

16. EPA. OPP. Products Located Through EPA Query of Nielson Company Scanner Data + Walmart Customer Panel Surveys. (2008). Docket ID No.: EPA-HQ-OPP-2010-0305. Document ID No.: EPA-HQ-OPP-2010-0305-0014.

17. EPA. OPP. Supporting Statement for an Information Collection Request (ICR): Labeling Change for Certain Minimum Risk Pesticides under FIFRA Section 25(b). (2012). Docket ID No.: EPA-HQ-OPP-2010-0305. Document ID No.: EPA-HQ-OPP-2010-0305-0015.

18. Small Entity Representative (SER) comments from 2009 SBREFA Panel, for

minimum risk insect repellents proposed rule. Docket ID No.: EPA-HQ-OPP-2010-0305. Document ID No.: EPA-HQ-OPP-2010-0305-0016.

VIII. FIFRA Review Requirements

Under FIFRA section 25(a), EPA submitted a draft of the proposed rule to the Secretary of the Department of Agriculture (USDA) and the appropriate Congressional Committees. Additionally, under FIFRA section 21(b), EPA submitted a draft of the proposed rule to the Secretary of the Department of Health and Human Services (HHS). No comments were received regarding this proposed rule. USDA waived its review of the draft proposed rule on December 19, 2011, and HHS waived its review of the draft proposed rule on February 2, 2012. Both USDA and HHS have retained the right to review a draft of the final rule.

Under FIFRA section 25(d), EPA submitted a draft of the proposed rule to the Scientific Advisory Panel (SAP). The SAP waived its scientific review of the proposed rule on January 4, 2012, because the proposed rule does not contain scientific issues that warrant review by the Panel.

IX. 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") under the terms of Executive Order 12866 (58 FR 51735, October 4, 1993) and was not therefore submitted to the Office of Management and Budget (OMB) for review under Executive Orders 12866 and 13563 (76 FR 3821, January 21, 2011).

B. Paperwork Reduction Act (PRA)

The information collection requirements in this proposed rule have been

submitted for approval to OMB under the PRA, 44 U.S.C. 3501 *et seq*. The Information Collection Request (ICR) document prepared by EPA has been assigned EPA ICR No. 2475.01; and OMB Control No. 2070-tbd, entitled "Labeling Change for Certain Minimum Risk Pesticides under FIFRA Section 25(b)".

The information collection requirements in this proposed rule consist of proposed changes to existing requirements that would involve the relabeling of products currently exempt under 40 CFR 152.25(f) in order to list chemical names in the format EPA proposes to require. The proposed change would be a one-time burden increase for existing products. The estimated annual respondent burden for this rule-related collection is estimated to be 5.5 hours per response, for a total one-time burden of 6,369 hours. Burden is defined at 5 CFR 1320.3(b).

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's regulations in 40 CFR are listed in 40 CFR part 9.

To comment on the Agency's need for this information, the accuracy of the provided burden estimates, and any suggested methods for minimizing respondent burden, EPA asks that you use the public docket established for this rule, i.e., Docket ID No. EPA-HQ-OPP-2010-0305. Submit any comments related to the ICR to EPA and OMB. For EPA, follow the instructions in the **ADDRESSES** section at the beginning of this document. For OMB, send comments to the following address: Office of Information and Regulatory Affairs, Office of Management and Budget, 725 17th Street, NW, Washington, DC 20503, Attention: Desk Office for EPA. Since OMB is required to make a decision concerning the ICR between 30 and 60 days after *[Insert date of*

*publication in the **Federal Register**]*, a comment to OMB is best assured of having its full effect if OMB receives it by [Insert date 30 days after publication in the **Federal Register**]. EPA will consider comments on the ICR as it develops the final rule, and will respond in the final rule to any OMB or public comments on the information collection requirements contained in this proposal.

C. Regulatory Flexibility Act (RFA)

The RFA, 5 U.S.C. 601 *et seq*., generally requires an agency to prepare a regulatory flexibility analysis of any rule subject to notice and comment rulemaking requirements under the Administrative Procedure Act, 5 U.S.C. 551-553, or any other statute unless the agency certifies that the rule will not have a significant economic impact on a substantial number of small entities. Small entities include small businesses, small organizations, and small governmental jurisdictions.

For purposes of assessing the impacts of this proposed rule on small entities, small entity is defined as:

1. A small business as defined by the Small Business Administration's (SBA) regulations at 13 CFR 121.201. As indicated in the Cost Analysis prepared for this proposed rule (Ref. 14), which is summarized in Unit V.E., most firms in the minimum risk pesticide industry are identified under NAICS code 325. A small business that manufactures pesticides and other agricultural chemicals as defined by NAICS code 325 has 500 or fewer employees based on the SBA standards.

2. A small governmental jurisdiction that is a government of a city, county, town, school district, or special district with a population of less than 50,000. This proposed rule is not expected to impact any governmental jurisdictions.

3. A small organization that is any not-for-profit enterprise which is independently owned and operated and is not dominant in its field. This proposed rule is not expected to impact any not-for-profit entities.

After considering the economic impacts of this final rule on small entities, I certify that this action will not have a significant economic impact on a substantial number of small entities. The factual basis for the Agency's determination is presented in the small entity impact analysis prepared as part of the Cost Analysis for this proposed rule (Ref. 14) that is summarized in Unit V.E., and a copy of which is available in the docket at *http://www.regulations.gov*. The following is a brief summary of the factual basis for this certification.

EPA has determined that this rulemaking does not impact any small governmental jurisdictions or any small non-for-profit enterprise because these entities are rarely producers of pesticide products. As such, EPA assessed the impacts on small businesses.

EPA determined that for the minimum risk pesticide industry, there are 97 small firms (out of the total 192), accounting for approximately 51% of the industry. EPA estimated the impacts on small firms in two ways. The first analysis estimated the impacts of the proposed rule on small firms by measuring the cost of the rule as a percent of the average small business annual revenue. These average small business impacts are presented in Table 6.

Table 6.—Small Business Impacts Based on Average Revenues

Rule Implementation Period	Average Cost Per SKU	Average Cost Per Firm	Impact (% of Gross Revenue)
Immediate	$6,306	$36,189	1.3%
With 2 years to change labels	$2,550	$14,634	0.5%
With 3 years to change labels	$672	$3,857	0.1%

However, this average revenues analysis may not account for the realities of very

small firms. To account for the impacts on very small firms, i.e., those with sales of less than $500K, EPA performed a refined analysis that divided each individual firm's relabeling cost by that firm's sales revenue. Additionally, a lower labeling cost was assumed for very small firms. These impacts are presented in Table 7.

Table 7.—Small Business Impacts – Refined Analysis

Rule Implementation Period	**Impact (% of Annual Gross Revenue)**	
	≥ 1%	**≥ 3%**
Immediate	64% (62)	21% (21)
With 2 years to change labels	27% (26)	9% (9)
With 3 years to change labels	7% (7)	0% (0)

With a 2-year compliance period, 26 small firms (or 27% of all small firms) are likely to experience an economic impact of 1% or more of gross sales, and nine small firms (9% of all small firms) may incur impacts greater than or equal to 3% of gross sales. The selection of the 2-year compliance period was also based on information obtained in 2009, from a group of small manufacturers of minimum risk insect repellents. These small manufacturers, in comments submitted to EPA, indicated that they would need 2 years to re-label their products to avoid significant costs (Ref. 18). By providing a 2-year transition period (2 years from the effective date of the final rule), most companies would be able to incorporate the changes proposed in this document into their regularly planned label updates, and sell any products with older labels, thus reducing the cost and burden of the proposed changes to the exemption.

EPA is particularly interested in receiving comment from small businesses as to the benefits, costs and impacts of this proposed rule. Any comments should be submitted to the Agency in the manner specified under **ADDRESSES**.

D. Unfunded Mandates Reform Act (UMRA)

Title II of UMRA, 2 U.S.C. 1531-1538, establishes requirements for Federal agencies, unless otherwise prohibited by law, to assess the effects of their regulatory actions on State, local, and tribal governments and the private sector. This proposed rule does not contain a Federal mandate that may result in expenditures of $100 million or more for State, local and tribal governments, in the aggregate, or for the private sector in any 1 year. This proposed rule is unlikely to affect State, local, and tribal governments at all, because no minimum risk pesticide products have been found to be produced by any state, local, or tribal governments. As summarized previously, under an implementation period of 2 years, the estimated industry total costs for the one-time relabeling proposed in this rule is about $3 million.

Thus, this proposed rule is not subject to the requirements of UMRA sections 202 or 205. This rule is also not subject to the requirements of UMRA section 203, because it contains no regulatory requirements that might significantly or uniquely affect small governments.

E. Executive Order 13132: Federalism

This rule does not have federalism implications because 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, as specified in Executive Order 13132 (64 FR 43255, August 10, 1999). As indicated previously, there are no known instances where a state or local government is currently the producer of a minimum risk pesticide currently exempt from regulation. Thus, Executive Order 13132 does not apply to this action.

In the spirit of Executive Order 13132 and consistent with EPA policy to promote

communication between EPA, and state and local governments, EPA did consult with representatives of state and local governments in developing this action. These consultations were conducted during the September 2010 meeting of the State- FIFRA Issues Research and Evaluation Group (SFIREG), two meetings of the Pesticide Regulatory Education Program (PREP) (July 2010 and April 2011) and a separate telephone conference with state pesticide regulators held on February 16, 2010.

Although these proposed changes would not have substantial direct effects on the states, they may indirectly affect states in two ways. First, the states that register minimum risk pesticide products may determine that they need to re-evaluate those registrations, since companies selling products claiming to be exempt from EPA registration would have to adopt the new label requirements, and demonstrate that compliance to any states in which they register. However, since most states that register minimum risk products require a new registration every year, little or no extra burden on state pesticide registration services is anticipated as a result of the changes at the Federal level. Second, there may be an improvement in the efficiency of state pesticide inspections, since the proposed changes would make it easier and faster for inspectors to identify which unregistered pesticide products contain ingredients that comply with the minimum risk exemption. This would positively affect all states, including those that do not register minimum risk pesticide products.

EPA specifically solicits comment on this proposed rule from state and local officials.

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

This proposed rule does not have tribal implications because it will not have

substantial direct effects on Indian Tribes, will not significantly or uniquely affect the communities of Indian Tribal governments, and does not involve or impose any requirements that affect Indian Tribes, as specified in Executive Order 13175 (65 FR 67249, November 9, 2000). As indicated previously, there are no known instances where a tribal government is currently the producer of a minimum risk pesticide currently exempt from regulation. Thus, Executive Order 13175 does not apply to this proposed rule. EPA specifically solicits comment on this proposed rule from tribal officials.

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

EPA interprets Executive Order 13045 (62 FR 19885, April 23, 1997), as applying only to those regulatory actions that concern health or safety risks, such that the analysis required under section 5-501 of the Executive Order has the potential to influence the regulation. This action is not subject to Executive Order 13045, because it is not an "economically significant regulatory action" as defined in Executive Order 12866, and because the Agency does not have reason to believe the environmental health or safety risks addressed by this action present a disproportionate risk to children. This proposed rule does not involve an environmental standard that is intended to have a negatively disproportionate effect on children. To the contrary, this proposed rule is intended to provide added protection to children by requiring clearer and more transparent information on the labels of exempted pesticide products.

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

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

I. National Technology Transfer and Advancement Act (NTTAA)

Section 12(d) of NTTAA, 15 U.S.C. 272 note, directs EPA to use voluntary consensus standards in its regulatory activities unless to do so would be inconsistent with applicable law or otherwise impractical. Voluntary consensus standards are technical standards (e.g., materials specifications, test methods, sampling procedures, and business practices) that are developed or adopted by voluntary consensus standards bodies. NTTAA directs EPA to provide Congress, through OMB, explanations when the Agency decides not to use available and applicable voluntary consensus standards. This action does not involve any technical standards. Therefore, EPA did not consider the use of any voluntary consensus standards. EPA invites comment on its conclusion regarding the applicability of voluntary consensus standards to this rulemaking.

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

Executive Order 12898 (59 FR 7629, February 16, 1994) establishes the Federal executive policy on environmental justice. Its main provision directs Federal agencies, to the greatest extent practicable and permitted by law, to make environmental justice part of their mission by identifying and addressing, as appropriate, disproportionately high and adverse human health or environmental effects of their programs, policies, and activities on minority populations and low-income populations in the United States.

EPA has determined that this proposed rule will not have disproportionately high and adverse human health or environmental effects on minority or low-income populations, because it is expected to increase the level of environmental protection for all affected populations without having any disproportionately high and adverse human health or environmental effects on any population, including any minority or low-income

population. This proposed rule only impacts minimum risk pesticide products, and, once final, may have positive impacts for all communities, since the rule provides increased information for consumers considering the use of pesticides. This proposed action, which would improve clarity on product labels, will enable all users, regardless of economic status, to become more informed about the substances they may be interested in using as pesticides.

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 13, 2012.

Lisa Jackson,

Administrator.

Therefore, it is proposed that 40 CFR chapter I be 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. Section 152.25 is amended 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) Products containing the following active ingredients are exempt from the requirements of FIFRA, alone or in combination with other substances listed in this paragraph, 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 implementing regulations at part 180 of this chapter, products intended for use on food or animal feed can only include active ingredients with applicable tolerances or tolerance exemptions in part 180 of this chapter. Such tolerances or exemptions may be found, for example, in §§ 180.950, 180.1071, 180.1233, and 180.1251 of this chapter.

Label Display Name	Chemical Name	Specifications	CAS Reg. No.
Castor oil	Castor oil	United States Pharmacopeia (USP) standard	8001-79-4
Cedar oil	Cedar oil	---	8000-27-9
Cedar oil	Cedar oil	---	68990-83-0
Cedar oil	Cedar oil	---	85085-29-6
Cinnamon	Food: N/A	---	Food: N/A
Cinnamon oil	Cinnamon oil	USP	8015-91-6
Citric acid	2-Hydroxypropane-1,2,3-tricarboxylic acid	USP	77-92-9

Citronella	N/A	---	N/A
Citronella oil	Citronella oil	---	8000-29-1
Cloves	Food: N/A	---	Food: N/A
Clove oil	Clove oil	USP	8000-34-8
Corn gluten meal	Corn gluten	---	66071-96-3
Corn oil	Corn oil	USP	8001-30-7
Cottonseed oil	Cottonseed oil	USP	8001-29-4
Dried blood	N/A	---	68991-49-9
Eugenol	4-Allyl-2-methoxyphenol	USP	97-53-0
Garlic	Food: N/A	---	Food: N/A
Garlic oil	Garlic oil	USP	8000-78-0
Geraniol	(2E)-3,7-Dimethylocta-2,6-dien-1-Ol	USP	106-24-1
Geranium oil	Geranium oil	USP	8000-46-2
Lauryl sulfate	Lauryl sulfate	---	151-41-7
Lemongrass oil	Lemongrass oil	USP	8007-02-1
Linseed oil	Linseed oil	---	8001-26-1
Malic acid	2-Hydroxybutanedioic acid	USP	6915-15-7
Mint	Food: N/A	---	Food: N/A
Mint oil	Mint oil	USP	68917-18-0
Peppermint	Food: N/A	---	Food: N/A
Peppermint oil	Peppermint oil	USP	8006-90-4
2-Phenylethyl propionate	2-Phenylethyl propionate	---	122-70-3
Potassium sorbate	Potassium (2E,4E)-hexa-2,4-Dienoate	USP	24634-61-5
Putrescent whole egg solids	Putrescent whole egg solids	---	51609-52-0
Rosemary	Food: N/A	---	Food: N/A
Rosemary oil	Rosemary oil	USP	8000-25-7
Sesame	Food: N/A	---	Food: N/A
Sesame oil	Sesame oil	---	8008-74-0
Sodium lauryl sulfate	Sulfuric acid monododecyl ester, sodium salt	USP	151-21-3
Soybean oil	Soybean oil	USP	8001-22-7
Thyme	Food: N/A	---	Food: N/A
Thyme oil	Thyme oil	USP	8007-46-3
White pepper	Food: N/A	---	Food: 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.

(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.

Label Display Name	Chemical Name	CAS Reg. 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 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 (1:1:1)	Silicic acid (H4 SiO4), 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
Attapulgite-type clay	Attapulgite-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 (Ca(CO3))	Calcite (Ca(CO3))	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 (Ca3 O(SiO4))	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 carbox ymethyl ether, sodium salt	Cellulose, mixture with cellulose carboxymethyl ether, sodium salt	51395-75-6

Cellulose, pulp	Cellulose, pulp	65996-61-4
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	Disodium sulfate decahydrate	7727-73-3
Diatomaceous earth	Kieselguhr; Diatomite	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
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 (as depolymd. animal collagen)	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	Glyceryl distearate	1323-83-7
Glyceryl monomyristate	Tetradecanoic acid, monoester with 1,2,3-propanetriol	27214-38-6
Glyceryl monooctanoate	Octanoic acid, monoester with 1,2,3-propanetriol	26402-26-6
Glyceryl monooleate	9-Octadecenoic acid (9Z)-, monoester with 1,2,3-propanetriol	25496-72-4
Glyceryl monostearate	Octadecanoic acid, monoester with 1,2,3-propanetriol	31566-31-1
Glyceryl stearate	Octadecanoic acid, ester with 1,2,3-propanetriol	11099-07-3
Granite	Granite	N/A
Graphite	Graphite	7782-42-5
Guar gum	Guar gum	9000-30-0
Gum Arabic	Gum arabic	9000-01-5
Gum tragacanth	Gum tragacanth	9000-65-1
Gypsum	Gypsum	13397-24-5
Hematite (Fe2O3)	Hematite (Fe2O3)	1317-60-8
Humic acid	Humic acid	1415-93-6

Hydrogenated cottonseed oil	Hydrogenated cottonseed oil	68334-00-9
Hydrogenated rapeseed oil	Hydrogenated rapeseed oil	84681-71-0
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 (Fe2 MgO4)	12068-86-9
Ferric oxide	Iron oxide (Fe2 O3)	1309-37-1
Iron oxide (Fe2 O3), hydrate	Iron oxide (Fe2 O3), hydrate	12259-21-1
Iron oxide (Fe3 O4)	Iron oxide (Fe3 O4)	1317-61-9
Ferric oxide	Iron oxide (FeO)	1345-25-1
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 (chemical) 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 (Mg3 O(Si2 O5)2), 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 (Mg2 Si3 O8)	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 (U.S.P.)	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
Oils, almond	Oils, almond	8007-69-0
Oils, wheat	Oils, wheat	68917-73-7
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
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 sulfate	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 (crystalline free)	Silica, amorphous, fumed (crystalline free)	112945-52-5
Silica, amorphous, precipitate and gel	Silica, amorphous, precipitate and gel	7699-41-4
Silica (crystalline free)	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 (H2 SiO3), magnesium salt (1:1)	Silicic acid (H2 SiO3), 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
Tetragylceryl 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 (maximum 8% acetic acid in solution)	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
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
Whey	Whey	92129-90-3
White mineral oil (petroleum)	White mineral oil (petroleum)	8042-47-5
Wintergreen oil	Wintergreen oil	68917-75-9
Wollastonite	Wollastonite (Ca(SiO3))	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. It must also list all inert ingredients by the label display name listed in the table 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 * * *," "Distributed by * * *, or "Sold by * * *" 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 phone 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 § 156.10(a)(5)(i) through (viii).

(v) Guidance on minimum risk pesticides is available at *http://www.epa.gov/oppbppd1/biopesticides/regtools/25b_list.htm* (or successor web pages at *http://www.epa.gov*). This advisory information includes guidance on label formats, explanation of when exemptions from the requirements of a tolerance should be consulted, and tables in alternative formats that may be suitable for some users.

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