

# Active Ingredients Eligible for Minimum Risk Pesticide Use: Overview of the Profiles





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## Purpose

The New York State Integrated Pest Management (NYS IPM) Program at Cornell University, with support from the New York State Department of Environmental Conservation (NYS DEC), has produced profiles of the 31 active ingredients allowed in pesticides that are exempted from the federal pesticide product registration of the United States Environmental Protection Agency (EPA). These pesticides are termed “minimum-risk pesticides” by the EPA and are also known as ‘25(b)’ pesticides, because of the section of the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA) giving EPA the authority to grant exemptions (see <https://www.epa.gov/minimum-risk-pesticides/conditions-minimum-risk-pesticides>). The EPA has determined that the risk to the public and the environment is sufficiently low as to not require all the data and review necessary for registration. Thus, there are often data gaps for these substances compared to the active ingredients in registered pesticides. These profiles identify available data for the physical and chemical properties, human health information, environmental effects information, efficacy, and standards and regulations that apply to the substance. The profiles are intended to help officials, practitioners, and the public to better understand the potential risks and benefits of the active ingredients in minimum-risk pesticides. State pesticide regulators have the authority to require registration of some or all pesticide products exempt from federal registration; and many states do register them.

The profiles are informational only and any mention of a pesticide product should not be construed as an endorsement by Cornell University, NYS IPM, or NYS DEC.

## Minimum-Risk Pesticides

The statutory basis in FIFRA [PL 92-516, §25(b) (1972)] was codified and amended as 7 USC 136w(b). The EPA first proposed exempting certain pesticide products from registration based on criteria established

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This overview document references profiles of 31 active ingredients eligible for exemption from pesticide registration when used in a Minimum Risk Pesticide in accordance with the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA) section 25b. These profiles were developed by the New York State Integrated Pest Management Program at Cornell University, for the New York State Department of Environmental Conservation. The authors are solely responsible for its content. Mention of specific uses are for informational purposes only, and are not to be construed as recommendations. Brand name products are referred to for identification purposes only, and are not endorsements.

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through rulemaking in 1994 [59 *Federal Register* 47289 (1994)]. The agency then developed criteria to add other active ingredients and make provisions for non-active or 'inert' ingredients. EPA undertook this process of exempting certain pesticides from registration to encourage the adoption of lower-risk pesticide products (Andersen et al. 1996). During the rulemaking process, public comment was invited on the factors for exemption, what pesticide formulations would qualify for exemption, risks posed by the proposed active ingredients, and whether any additional active ingredients might qualify for exemption.

In publishing the final regulation, the EPA considered the following factors when considering what active ingredients would be eligible for exempt products:

1. whether the active ingredient is widely available to the general public for other uses;
2. if it is a common food or constituent of a common food;
3. if it has a nontoxic mode of action;
4. if it is Generally Recognized As Safe (GRAS) by the Food and Drug Administration (FDA) [when used in food];
5. if there is no information showing significant adverse human health or environmental effects on any population;
6. if its use pattern would result in significant exposure, and
7. if it is likely to persist in the environment [61 *Federal Register* 8876 (1996)].

In order to be exempt from the requirement of registration as a pesticide, a product must meet the following conditions (US EPA 2016):

1. The product's active ingredients must only be those that are listed in 40 CFR 152.25(f)(1).
2. The product's inert ingredients may only be those that have been classified by EPA as either Listed in 40 CFR 152.25(f)(2), are commonly consumed food commodities, animal feed items, and edible fats and oils as described in 40 CFR 180.950(a), (b), and (c); and certain chemical substances listed under 40 CFR 180.950(e).
3. All of the ingredients (both active and inert) must be listed on the label. The active ingredient(s) must be listed by label display name and percentage by weight. Each inert ingredient must be listed by label display name.
4. The product must not bear claims either to control or mitigate organisms that pose a threat to human health, or insects or rodents carrying specific diseases.
5. The name of the producer or the company for whom the product was produced and the company's contact information must be displayed prominently on the product label.
6. The label cannot include any false or misleading statements.

To clarify the eligibility and requirements for exemption, EPA proposed revisions to the regulation at the end of 2012 (US EPA 2012). These proposed revisions were amended after public notice and rulemaking, and took effect on February 26, 2016 (US EPA 2015d), with a full compliance date of February 26, 2019. The revisions more precisely identify the eligible active ingredients, disaggregating previously broader categories. Even though 41 active ingredients are now identified, no new substances were added and the clarification can be interpreted as a narrowing of the scope of eligible active ingredients. However, our profiles are arranged by the 31 active ingredients originally identified by the EPA in 1996. The revisions also codify the inert ingredient list to be consistent with other reforms the EPA is undertaking with formulated products that have both active and non-active substances. In the interest of transparency and accountability, manufacturers as well as vendors now need to be identified on the product labels.

Table 1 summarizes the uses of these minimum risk pesticide active ingredients in two particular categories: usage in organic production under the United States Department of Agriculture’s National Organic Program (USDA Organic), and permissible use in food products. None of the 31 active ingredients have a tolerance established for residual contamination of food, animal feed, and other agricultural commodities, but many are explicitly exempt from the requirement of a tolerance. Many 25(b) substances are also either a commonly consumed food or GRAS food additives.

**Table 1: Uses of Active Ingredients Eligible for use in Minimum Risk Pesticides**

Active Ingredient	Uses and Applications	USDA Organic	Food Use
Castor oil	Insecticide, Rodenticide	Yes	Yes
Cedarwood oil <sup>1</sup>	Insecticide, Nematicide	Yes	No
Cinnamon and cinnamon oil	Fungicide, Insecticide	Yes	Yes
Citric acid	Fungicide, Herbicide	Yes	Yes
Citronella and citronella oil	Insecticide	Yes	No <sup>4</sup>
Cloves and clove oil	Fungicide, Herbicide, Insecticide	Yes	Yes
Corn gluten meal	Herbicide	Yes	Yes
Corn oil	Insecticide	Yes	Yes
Cottonseed oil	Insecticide	Yes	Yes
Dried blood	Vertebrate repellent	Yes	No
Eugenol	Insecticide	Yes <sup>2</sup>	No <sup>4</sup>
Garlic and garlic oil	Fungicide, Insecticide	Yes	Yes
Geraniol	Insecticide	Yes	Yes
Geranium oil	Insecticide	Yes	No <sup>4</sup>
Lauryl sulfate	Insecticide	No	Yes
Lemongrass oil	Insecticide	Yes	No <sup>4</sup>
Linseed oil	Fungicide, Insecticide	Yes	Yes
Malic Acid	Fungicide	Yes <sup>2</sup>	No <sup>4</sup>
Mint and mint oil <sup>3</sup>	Fungicide, Insecticide	Yes	Yes
Peppermint and peppermint oil	Fungicide, Insecticide, Vertebrate repellent	Yes	Yes
2-Phenethyl propionate	Insecticide	No	No <sup>4</sup>
Potassium sorbate	Fungicide	No	Yes
Putrescent whole egg solids	Vertebrate repellent	Yes	Yes

Active Ingredient	Uses and Applications	USDA Organic	Food Use
Rosemary and rosemary oil	Fungicide, Insecticide	Yes	Yes
Sesame and sesame oil	Insecticide, Nematicide	Yes	Yes
Sodium chloride	Fungicide, Herbicide	Yes	Yes
Sodium lauryl sulfate	Insecticide	No	Yes
Soybean oil	Insecticide	Yes	Yes
Thyme and Thyme oil	Fungicide, Acaricide, Insecticide	Yes	Yes
White pepper	Vertebrate repellent	Yes	Yes
Zinc	Algicide	No <sup>5</sup>	No

<sup>1</sup>Limited to Virginia, Texas and Chinese cedarwood oil beginning in 2015.

<sup>2</sup>Must be from a non-synthetic source for organic status with the NOP.

<sup>3</sup>Limited to corn mint and spearmint beginning in 2015.

<sup>4</sup>Generally Recognized As Safe (GRAS) as a food additive by FDA, but not exempt from the requirement of an EPA food Tolerance.

<sup>5</sup>Structural use as roofing material is outside the scope of the NOP.

Ingredients that are not exempt from the requirement of a tolerance, and are not considered commonly consumed foods, are permitted to be used only where the use and application is not expected to result in residues in food. Therefore, dried blood, cedarwood oil, citronella and citronella oil, eugenol, geranium oil, 2-phenethyl propionate, and zinc metal strips are not permitted for food uses (US EPA 2015c). All 25(b)-eligible active ingredients are permitted for non-food uses. Most minimum risk pesticides are allowed for organic production under the NOP. However, products containing the active ingredients lauryl sulfate, sodium lauryl sulfate, potassium sorbate, and 2-phenethyl propionate, do not comply with the organic standards. Zinc metal strips used to prevent algal growth on roofs appear to be outside the scope of the organic standards.

Eligible active ingredients can be placed in broader categories by their chemical structures and specific functions. The largest single category is **essential oils** and their plant sources and derivatives. Essential oils are the volatile secondary metabolites found in plants that provide documented insect repellent, allelopathic, and fungistatic properties. These consist mostly of terpenoids, but may include aliphatic and aromatic esters, phenolics, and substituted benzene hydrocarbons. Many essential oils identified as phytoalexins—substances in plant tissue that are produced in response to parasitic organism damage to inhibit the organism's growth. Essential oils eligible for exemption as active ingredients in pesticides include cedarwood, citronella, cloves, geranium, mint, peppermint, rosemary, and thyme. Also included in this category are the essential oil derivatives eugenol and geraniol.

The next important category is **vegetable oils** and their plant sources. These are oils obtained from seeds, bulbs, or other plant parts. They are distinguished from essential oils in that they are more stable and do not have the aromatic properties found in essential oils. This category includes corn, cottonseed, linseed, and soybean oils. Castor, sesame, and garlic oil are also categorized as vegetable oils, even though they all contain secondary metabolites. These metabolites have a different mode of action that is explained more fully in the substances' individual profiles. Related to these vegetable oils are **plant by-products**. These include corn gluten meal, sesame by-products, and garlic.



Three profiled substances are used almost exclusively as **deer repellents**: dried blood, putrescent whole egg solids, and white pepper. White pepper is used in some insecticides for its synergistic properties, but this volume of use is relatively small compared with its use in deer repellents.

Citric acid and malic acid are **carboxylic acids** that may be plant- or fermentation-derived, and are common substances found in nature. Malic acid may also be synthesized. A few **synthetic** substances also appear on the 25(b) eligible list, including potassium sorbate, lauryl sulfate, sodium lauryl sulfate, and 2-phenethyl propionate. Rounding out the list are **sodium chloride** or common table salt, and **zinc** in the form of metal strips used to prevent algal growth on rooftops.

Note that a product is not necessarily a 25(b) minimum-risk pesticide just because it contains one or more ingredients listed in Table 1. To be a minimum-risk pesticide, it must meet ALL of the requirements listed earlier. For example, a product that contains citric acid plus an active ingredient NOT found in Table 1 would be subject to federal pesticide product registration requirements. (See <http://www2.epa.gov/minimum-risk-pesticides/conditions-minimum-risk-pesticides> for more information on the requirements.)

## Guide to the Profiles

A profile has been prepared for each of the original 31 minimum-risk-eligible pesticide active ingredients. Profiles include the identity and a brief summary and background of the substance, physical and chemical properties, human health information, environmental effects information, efficacy, standards and regulations, and literature cited. A glossary of technical terms used in the profiles is included in Appendix A.

Each document begins with a **summary section** that includes the label display name as it appears in 40 CFR 152(f)(1), Table 1, its other names, and its Chemical Abstract Service (CAS) number. The EPA's Pesticide Classification (PC) code is given, along with other descriptors from their pesticide active ingredient database (US EPA Office of Pesticides and Toxic Substances 2016). To aid readers in identifying the substance, other codes used to identify the substance, such as the California Department of Pesticide Registration (CDPR) chemical code (CDPR 2016), the Beilstein Reference Number (BRN), Flavor and Extract Manufacturers Association Code (FEMA), and the International Numbering System (INS) are given. Basic information on the chemical and physical properties, synonyms, discoveries, first syntheses, and summaries of uses was obtained from the Merck Index (Merck 2015) and the chemical structure database Chempider (Royal Society of Chemistry 2015).

Besides noting its main target pests, pesticidal use information for each substance may include specific uses in crops and food, its uses against structural pests or as an antimicrobial. Here and throughout most of each profile, each substance's information is presented as a technical grade active ingredient (TGAI) unless stated otherwise. Sometimes information is presented as a generic substance outside the context of pesticide use, or as one ingredient in a formulated product. Also, in cases where the substance contains components that are isolated and found to be biologically active, information on those active constituents is also presented. The pesticidal uses are later covered in greater depth in the efficacy section.

Efficacy data on formulated minimum risk products is reported when available. While the exemption means that the EPA does not review efficacy data, regulations still outlaw any false or misleading label claims, including those related to the efficacy of the product [40 CFR 152.25(f)(3)(iv) and 40 CFR 156.10(a)

(5)(ii)]. Data showing the efficacy of exempt pesticide products and specific active ingredients eligible for exemption are often difficult to find. Therefore, we included data from pesticide formulations made with eligible active ingredients that are registered or have unknown 25(b) status if we deemed the reference helpful and not misleading to the reader. For example, when used as pesticides, many of the substances are combined with other ingredients and formulated into products to improve performance. These co-formulants are not always reported, and in such cases some may be ineligible as inert ingredients in exempt formulations. In some instances, multiple active ingredients eligible for exemption are used in combination.

Some studies involved registered pesticide products and were conducted prior to the establishment of the regulatory exemption. Also, studies conducted outside the US are not under EPA's jurisdiction, so their use may be subject to a different set of regulatory requirements, and their potential 25(b) status has not been determined. The EPA status, or lack of knowledge of that status, is reported. As a general rule, pesticides that were registered and had active ingredients that were not eligible for exemption in addition to 25(b) eligible active ingredients were not included.

The summary also includes a safety overview that briefly states the basis for EPA's determination of minimum risk for that substance. In some cases, this was found in the EPA's most recent work plan for the substance or a Reregistration Eligibility Decision document (when available). Areas of concern identified by EPA with respect to human health, effects on non-target organisms, and environmental fate are also reported here. The later sections on human health and environmental effects information, as well as standards and regulations, cover product safety in greater depth.

The **Background** section includes a brief description of the sources, manufacturing processes, history of use, and regulatory history of the substance. Consulted references include Milne 2004, Gwynn 2014, Kegley et al. 2014, and US EPA 2015a. In most cases, primary sources were retrieved, verified, and cited directly. The scope of the review for the profile is also given. Some exemptions are for a family of substances, particularly in the case of the various essential oils. Sources specific to essential oils were searched for relevant data and studies (Baser and Buchbauer 2009; Khan and Abourashed 2010). The background provides general information on the substance profiled, including its standard of identity or constituent components.

Each profile has a table that summarizes the **Chemical and Physical Properties** of the substance. Properties may include chemical composition or molecular structure, physical state at standard temperature and pressure, color, specific gravity, density, solubility, vapor pressure, melting point, boiling point, pH, octanol/water partition coefficient, viscosity, miscibility, flammability, storage stability, corrosion characteristics, soil half-life, water half-life, and persistence. Where data was missing for a substance, characteristics of the main active constituent were included. For example, with cinnamon and cinnamon oil, the properties of the main active constituent cinnamaldehyde was used when the data for cinnamon or cinnamon oil could not be found. EPA data is reported when available. Other sources consulted include the Pubchem database (US NLM 2016) and the combined chemical dictionary and natural products database (ChemNetBase 2015).

Sources used for the general background and chemical and physical properties include the EPA's Pesticide Active Ingredient Database (US EPA Office of Pesticides and Toxic Substances 2016), the Merck Index (Merck 2015), the US National Institute of Health's Hazardous Substances Database (HSDB) (HSDB 2015),

the American Chemical Service's SciFinder database (ACS 2017), and the Royal Chemical Society's Chemspider (Royal Society of Chemistry 2015). If a data search of other specific sources was unsuccessful, the values were reported as 'Not Found'. Sources of every data value were reported and where possible, the original sources were reviewed and cited. Where primary sources were not readily accessible, secondary sources were cited. Where empirical data was unavailable, environmental fate estimates from the Estimation Programs Interface (EPI 2012) suite of models were reported.

**The Human Health Information** section includes data on the acute, sub-chronic and chronic toxicity of the substance. Acute toxicity results from exposure to a substance for less than 24 hours. Sub-chronic toxicity is measured by repeated exposures over a period of 1-3 months, and chronic toxicity results from exposures of more than three months (Klaassen et al. 2001). When available, values were reported for acute oral, dermal, and inhalation toxicity measured by the lethal dose for 50% of the test organisms (LD<sub>50</sub>) or the lethal concentration for 50% of the test organisms (LC<sub>50</sub>); eye and skin irritation; and skin sensitization—using EPA's Office of Chemical Safety and Pollution Prevention (OCSPP) guidelines (US EPA 2017). EPA's ACTor database was searched by common name, chemical name, and CAS number; and EPA data was reported when available (US EPA 2015a). If EPA data was not available, other sources were searched and referenced when appropriate. They included the Hazardous Substances Data Bank (HSDB 2015) which is part of the National Institute of Health's Toxnet dataset. Other significant sources were SciFinder (ACS 2017), and data from peer-reviewed journal articles.

Sub-chronic toxicity includes studies of the adverse effects of long-term or repeated exposure at doses that were not acutely toxic, mostly with animal models. Oral, dermal, and inhalation toxicity studies in rodents and non-rodents, as well as reproductive/developmental toxicity and fertility effects screening tests—with a narrative summary of relative risk—were also cited. Where EPA data is unavailable, ToxNet, HSDB and peer-reviewed studies were sometimes included. If none of those sources had data, those values were reported as 'Not Found'. If EPA reviews explicitly waived specific data requirements, the relevant agency documents were cited (US EPA 2015a). Not all sub-chronic toxicity tests follow OPPTS protocols.

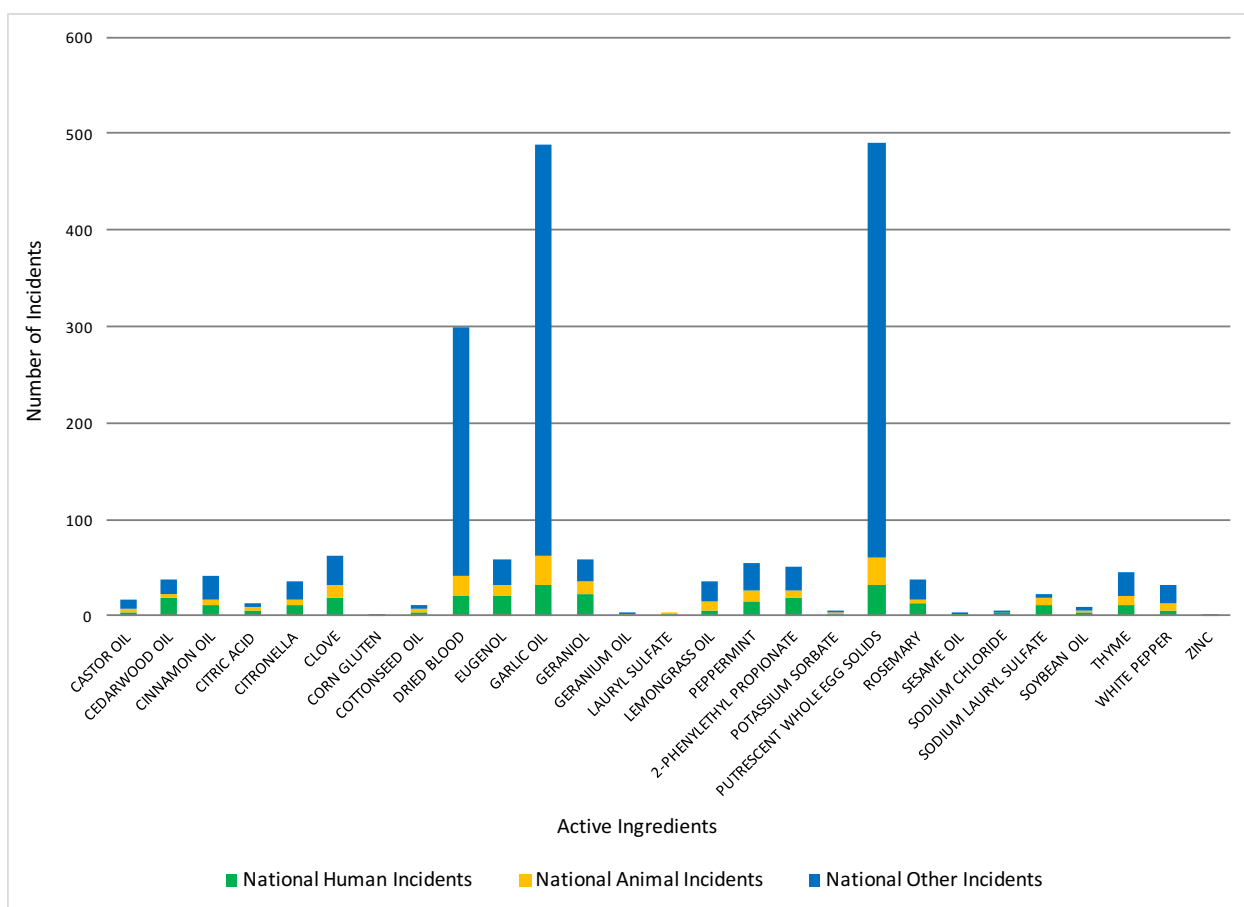
Chronic toxicity and carcinogenicity were reported with a narrative summary of relative risk, where appropriate. In most cases, chronic toxicity was reported when the substance was mutagenic based on a *Salmonella typhimurium* model (Ames et al. 1973; Ames et al. 1975). Additional data from ToxNet, HSDB, the International Agency for Research on Cancer (IARC) (IARC 2014), the EPA's Toxic Release Inventory (US EPA 2015b), or the California Proposition 65 list (Cal-EPA 2017) was presented when available. If EPA, IARC, or HSDB did not have data, then the values were reported as 'Not Found'. Note: none of the 31 substances have been identified as carcinogens by EPA, IARC, or California's Proposition 65 list.

Data from the Office of Pesticide Program's Incident Data System (IDS) was also included when found in various EPA reports and work plans. One of the databases in the IDS, the National Pesticide Information Center (NPIC) database, was searched for poisonings that involve the active substance (NPIC 2016). Human health and animal exposure incidents reported to NPIC are displayed in Figure 1. The three 25(b)-eligible active ingredients that accounted for the greatest number of incidents—putrescent whole egg solids, dried blood, and garlic oil—were related to their use as vertebrate pest repellents, primarily for deer. These incidents were largely related to children or pets eating the repellents, causing nausea and other symptoms. Many of the eligible active ingredients can cause allergic reactions in sensitive individuals. At the other end of the spectrum, corn gluten meal and zinc had no incidents reported to NPIC over the 20-year period from April 1, 1996 to March 30, 2016.



Many reported incidents involved products with multiple active ingredients, some of which are not eligible for use in 25(b) products and may be the cause of the incident. Narrative information identifying the specific formulation and whether it was registered with EPA was not available in all cases. In some cases, the narrative identified the formulation as unregistered, and the statistics also include incidents that involved registered pesticides. Some of these registered formulations involved active or inert ingredients that were ineligible for use in 25(b) products, and the incident may have been related to exposure to those ineligible ingredients.

**Figure 1: Human Health Incidents and Animal Incidents Involving Pesticide Products Containing One or More 25(b)-eligible Active Ingredients as Reported to the National Pesticide Information Center April 1, 1996 to March 30, 2016**



The **Environmental Effects Information** section summarized the impact of the substance on non-target organisms, including acute toxicity on aquatic invertebrates, aquatic vertebrates, non-target avian species, non-target plants and non-target insects. Additional studies were included when the EPA identified data gaps with reference to the specified guidelines. Searches were conducted of bibliographic databases including Web of Science (Thomson-Reuters 2016), SciFinder (ACS 2017), and Google Scholar (Google 2016b). Keyword searches paired the substance name with clarifiers like ‘pollinators’ and ‘aquatic invertebrates’; if no data was found in EPA accessible documents or in searches for peer-reviewed sources using the databases cited above, then the values were reported as ‘Not Found’. EPA’s reports of incidents involving animals and environmental releases were searched and summarized (NPIC 2016). Reported incidents

that involved neither human health nor animal effects were assumed to be environmental in nature. These may have involved abandoned pesticides, spills, misapplications, and unknown exposures.

Next, the environmental fate, ecological exposure and environmental expression were summarized. The parameters include leaching; photodegradation in water, air, and soil; and ready biodegradability. EPA sources were given priority (US EPA 2015a; EPI 2012).

**Efficacy** is the next section. EPA sources were the first resource searched for public health claims, and verification if such claims were supported by agency review (US EPA 2015a). Applications involving indirect public health claims—including the control of mosquitos and ticks, or releases into an aquatic environment—were prioritized. While 25(b) products do not need to be registered with EPA, minimum risk pesticide labels cannot state or imply that the product can or will control or reduce rodent, insect or microbial pests in a way that reduces threat to human health. Neither can these labels mention any specific disease that an insect or rodent may be carrying. In order for product labels to make such public health claims, they must have efficacy data reviewed and approved by the agency, and be fully registered.

Thus, efficacy data involving registered pesticides may be included in the profiles.

The search for efficacy data in scientific literature included Web of Science (Thomson-Reuters 2016), SciFinder (ACS 2017), and Google Scholar (Google 2016b), and any patents that were granted—both in the US and internationally—claiming efficacy of formulations with active ingredients used in products that are exempt from registration (US PTO 2016; Google 2016a). Only patents in English were reviewed. Efficacy for the control of specific pests or specific uses and applications were reported. The reader should beware that patent claims are reviewed by examiners and are not considered peer reviewed. Applicants that make false or fraudulent claims can have their patents invalidated. In addition, pesticide products that are exempt from registration are barred from making any false or misleading claims of efficacy.

The profiles cite references involving technical grade active substances, registered pesticides with those substances declared as active ingredients, exempt formulations sold in the US, and formulations made and sold outside the US that are not subject to FIFRA. Some of these formulations, and experimental formulations used under laboratory conditions, may not be 25(b) exempt. Many efficacy studies involve multiple 25(b)-eligible active ingredients as well as non-active formulants—both of which may have possible synergistic effects. We have included these studies because they may be informative to those seeking information on 25(b)-eligible active ingredients, and it is sometimes difficult to determine from the reports whether the pesticide studied met 25(b) criteria. Summary information was provided to distinguish what was tested for efficacy. Thorough review of these products and formulations with multiple 25(b)-eligible active ingredients is beyond the scope of the project.

Finally, the substance's status under various regulations, laws and standards was summarized by looking at Titles 21 and 40 of the Code of Federal Regulations. Official EPA and FDA documents were also cited. The FDA and EPA have shared responsibilities for regulating pesticides in food. Status with FDA was one criterion that the EPA used to determine if a given active ingredient should qualify to be eligible for use in minimum risk pesticides, and whether the pesticide could be used on food crops. Specifically, every substance has a summary of its status with respect to tolerances for residues in food, feed, and other agricultural commodities and whether the FDA has declared the substance as Generally Recognized As Safe (GRAS) status as a food product [21 CFR 182, *inter alia*] or considers it a commonly consumed food. None

of the 31 active ingredients has a residue tolerance established, but many are explicitly exempt from the requirement of a tolerance. Such exemptions, listed in 40 CFR 180, are cited.

Note that products intended for use where food is grown, produced, or handled can only include active ingredients with applicable tolerances for residual contamination or tolerance exemptions established in 40 CFR 180. Where tolerances have not been set or exemptions granted, the EPA does not have sufficient information to know whether residues on food are safe (US EPA 2015d). Table 1 shows which 25(b)-eligible active ingredients are allowed for use on food crops.

A search was also conducted for Occupational Health and Safety Administration (OSHA) requirements, mostly through secondary references to the National Institute of Occupational Safety and Health (NIOSH) and product Material Safety Data Sheets (MSDSs). The substance's status as to whether the ingredient is allowed or prohibited by the USDA's National Organic Program (NOP) was also reported [7 CFR 205], and is summarized above in Table 1.

Most states require the registration of 25(b) exempt pesticides. Appendix B includes a table of the status of 25(b) products in the different states. As of January 2018, the following states do not require registration: California, Georgia, Hawaii, Massachusetts, Minnesota, Missouri, Nebraska, New Jersey, New York, North Dakota, and Texas. California exempts most 25(b) eligible products from registration, but requires some to be registered with additional labeling requirements. North Dakota gives manufacturers of minimum risk products the option either to register or to complete an exemption from registration application and pay the same fee as a registered pesticide. Delaware, Tennessee and Wisconsin require 25(b) exempt products to be registered, but no fee is required. Washington State also has additional labeling requirements for some pesticides exempt from registration.

References were compiled using the Chicago Manual of Style as a guide (Turabian 2013), with URLs to the references when readily available and open access. The hyperlinks to the URLs were active at the time they were accessed and may not be current.

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## Appendix A

### Glossary and Abbreviations

**Acaricide.** A pesticide that is used to manage mites or ticks.

**Acidulant.** A substance that lowers the pH of a solution or formulation.

**Active Ingredient.** Here is the definition from FIFRA: "(a) Active ingredient: The term "active ingredient" means—

1. in the case of a pesticide other than a plant regulator, defoliant, desiccant, or nitrogen stabilizer, an ingredient which will prevent, destroy, repel, or mitigate any pest;
2. in the case of a plant regulator, an ingredient which, through physiological action, will accelerate or retard the rate of growth or rate of maturation or otherwise alter the behavior of ornamental or crop plants or the product thereof;
3. in the case of a defoliant, an ingredient which will cause the leaves or foliage to drop from a plant;
4. in the case of a desiccant, an ingredient which will artificially accelerate the drying of plant tissue; and



5. in the case of a nitrogen stabilizer, an ingredient which will prevent or hinder the process of nitrification, denitrification, ammonia volatilization, or urease production through action affecting soil bacteria."

**Adjuvant.** A substance added to a pesticide or fertilizer to enhance its performance, increase its effectiveness, or improve its safety. Adjuvants may be used as carriers, emulsifiers, solvents, diluents, acidulants, spreaders, stickers, safeners, or synergists.

**Ames test.** A procedure used to determine the mutagenic properties and potential carcinogenicity of a substance through the exposure of various strains of *Salmonella typhimurium* bacteria and determining whether mutations have occurred as a result. Also known as the "**Salmonella/microsome test**".

**Carrier.** An adjuvant that is used to facilitate the ease of handling or uniformity of application of a material to its target.

**Chromosomal aberration.** Abnormalities found in the DNA structures of chromosomes.

**Clastogen.** A substance causing fragmentary damage of chromosomes. Such a substance is said to be "**clastogenic**" or to cause "**clastogenicity**".

**Cuticle.** (1) In insects, nematodes and other animals, a non-living tissue made of chitin or another polysaccharide that covers the living tissue. (2) In plants, a layer of wax that covers the epidermis of leaves and other aerial organs.

**DEC.** New York State Department of Environmental Conservation.

**Efficacy.** The ability of a pesticide to produce a desired effect on a target organism.

**Entomopathogen.** An organism or agent that causes disease in insects. Such a substance is called "**entomopathogenic**".

**EPA.** United States Environmental Protection Agency.

**Essential Oil.** Volatile secondary metabolites found in plants that are composed of terpenoids, phenolics, and other aromatic compounds.

**Ethereal** (chemistry). A concentrated hydrophobic liquid derived from plants.

**Excito-repellent.** A substance that an insect or other target organism actively avoids through movement in the opposite direction. Such a phenomenon is called "excito-repellency."

**FIFRA.** Federal Insecticide, Fungicide, and Rodenticide Act.

**Fungistat.** A substance that inhibits the growth of fungal organisms. Such a substance is called "**fungistatic**".

**Galling index.** A measure of the damage done to plant roots by nematodes or another pathogenic growth-inducing organism.

**Gavage.** Forced feeding.

**Herbicide.** A pesticide that is used to manage weeds.

**Herbistat.** A substance that inhibits the growth of plants.

**HSDB.** Hazardous Substances Database.

**Inert Ingredient.** An ingredient in a pesticide product that is not active.

**Insecticide.** A pesticide that is used to manage insects. May also be more broadly applied to pesticides used to control other invertebrates.

**LOAEL.** Lowest Observed Adverse Effect Level. In animal model toxicology experiments, the minimum amount of a substance that induces noticeable toxic reactions.

**Monoterpene.** A plant secondary metabolite with two isoprene ( $C_5$ ) units and the molecular formula  $C_{10}H_{16}$ .

**Mutagen.** A substance that causes organisms to mutate genetically.

**NOEL.** No Observed Effects Level. In animal model toxicology experiments, the lowest amount of a substance that does not induce any noticeable consequences.

**NPIC.** National Pesticide Information Center.

**Pesticide.** Here is the FIFRA definition:

“The term “pesticide” means (1) any substance or mixture of substances intended for preventing, destroying, repelling, or mitigating any pest, (2) any substance or mixture of substances intended for use as a plant regulator, defoliant, or desiccant, and (3) any nitrogen stabilizer, except that the term “pesticide” shall not include any article that is a “new animal drug” within the meaning of section 321(w) [1] of title 21, that has been determined by the Secretary of Health and Human Services not to be a new animal drug by a regulation establishing conditions of use for the article, or that is an animal feed within the meaning of section 321(x) [1] of title 21 bearing or containing a new animal drug. The term “pesticide” does not include liquid chemical sterilant products (including any sterilant or subordinate disinfectant claims on such products) for use on a critical or semi-critical device, as defined in section 321 of title 21. For purposes of the preceding sentence, the term “critical device” includes any device which is introduced directly into the human body, either into or in contact with the bloodstream or normally sterile areas of the body and the term “semi-critical device” includes any device which contacts intact mucous membranes but which does not ordinarily penetrate the blood barrier or otherwise enter normally sterile areas of the body.”

**Phenol.** An aromatic organic compound with the molecular formula  $C_6H_5OH$ .

**Plant Regulator.** FIFRA Definition:

The term “plant regulator” means any substance or mixture of substances intended, through physiological action, for accelerating or retarding the rate of growth or rate of maturation, or for otherwise altering

the behavior of plants or the produce thereof, but shall not include substances to the extent that they are intended as plant nutrients, trace elements, nutritional chemicals, plant inoculants, and soil amendments. Also, the term “plant regulator” shall not be required to include any of such of those nutrient mixtures or soil amendments as are commonly known as vitamin-hormone horticultural products, intended for improvement, maintenance, survival, health, and propagation of plants, and as are not for pest destruction and are nontoxic, nonpoisonous in the undiluted packaged concentration.

**Polyphenol.** An chemical that is composed of three or more phenol structural units.

**Putrefaction.** The chemical breakdown of plant or animal material after death through the action of anaerobic bacteria. A substance produced by such a process is called “**putrescent**”.

**Saponification.** The chemical reaction of an oil and an alkali to produce soap. The fraction of oil that can be reacted by an alkali is called “**saponifiable**” and the unreacted fraction is called “**unsaponifiable**”.

**Sequestrant.** A substance that limits the reactivity of another substance or other substances, increases the stability of formulations or aggregates, and preserves molecular structure. Also used to refer to specific agents that chelate polyvalent metal ions.

**Stoma.** (Plural stomata). A pore or opening in the epidermis of plant tissue that is used for gas and vapor exchange with the atmosphere.

**Synergist.** A substance that, when used with another substance, will produce a greater total effect than the sum of their individual effects.

**Terpenoids.** A group of plant secondary metabolites based on four or more isoprene (C<sub>5</sub>) units and found in essential oils.

**Toxicant.** A substance that is poisonous.

**Virucide.** A substance that deactivates or destroys a virus.

**Virus.** A sub-microscopic infectious agent that can replicate only in living cells.

**Volatile.** Changing readily from liquid to vapor phase at standard temperature and pressure. The process by which a substance performs such a phase change is called “**volatilization**”.

**Weed.** Any plant that grows where it is not wanted.

## Appendix B

### Registration Status of FIFRA 25(b) Exempt Pesticides By State

State	Reg.1	Notes	Ann. Fees
Alabama	Yes	Has separate form for 25(b) product registration.	\$300 <sup>2</sup>
Alaska	Yes	Requires registration for 25(b) products.	\$90/ \$120 <sup>3</sup>
Arizona	Yes	Every product making pesticidal claims [including] 25(b) exempt must be registered.	\$110
Arkansas	Yes	Section 25(b) exempt products are registered in the same manner as other products.	\$250
California	No*	Additional label requirements apply to some AIs. See narrative for details.	\$1,150
Colorado	Yes	Requires registration form with inert ingredient information	\$160
Connecticut	Yes	Section 25(b) pesticides must be registered in Connecticut.	\$188
Delaware	Yes	No fee to register 25(b) products, but applicant must provide a registration form and label.	-0-
District of Columbia	Yes	Pesticides exempt from registration with the USEPA under FIFRA must register in DC.	\$250
Florida	Yes	Label must state the pesticide product is exempted by EPA.	\$350 <sup>2</sup>
Georgia	No	Products that meet EPA's criteria for 25(b) exemption are not required to be registered.	-0-
Hawaii	No	The Pesticides Branch does not require licensing for pesticides that are exempt under FIFRA Section 25(b).	-0-
Idaho	Yes	For 25(b) exempted products, a copy of the CSF must be included.	\$160
Illinois	No	No mention of 25(b) exemption in the state pesticide statute.	-0-
Indiana	Yes	Requires efficacy data for label claims and a statement of formula.	\$170
Iowa	Yes	Data may be requested.	\$250 <sup>5</sup>
Kansas	Yes	All minimum risk or 25(b) pesticides require registration.	\$210
Kentucky	Yes	No separate provision for 25(b). A 2012 survey said that efficacy data may be required.	\$250
Louisiana	Yes	LDAF requires all pesticides, including 25(b) to be registered.	\$400
Maine	Yes	All pesticide products, including FIFRA 25(b) minimum risk pesticides must be registered annually. CSF required beginning in 2013.	\$160
Maryland	Yes	All products making pesticidal claims, including those exempt under FIFRA 25(b), are required to register with the Maryland Department of Agriculture.	\$110
Massachusetts	No	Pesticides required to be registered by US EPA under FIFRA are required to be registered in Massachusetts.	-0-
Michigan	Yes	Michigan law requires all products that make a pesticidal claim, including those that EPA exempts under FIFRA 25(b), to be registered with the Michigan Department of Agriculture and Rural Development (MDARD).	\$370
Minnesota	No	Minnesota does not require registration of FIFRA 25(b) minimum risk pesticides.	-0-
Mississippi	Yes	All pesticides or pesticide products exempt from registration by EPA under Section 25b of FIFRA, or under other EPA policies and guidelines not exempt under Mississippi Law. Food uses must show proof that a food tolerance or exemption from food tolerance has been granted by EPA and FDA. Efficacy data and other proof may be required by request of the Bureau of Plant Industry.	\$100/ 200 <sup>6</sup>

Overview of the Profiles

State	Reg.1	Notes	Ann. Fees
Missouri	No	No reference made to registration or exemption from registration in the statute or regulations	-0-
Montana	Yes	Section 25(b) pesticides are considered minimum risk pesticides and are exempt from federal registration; however, they still require state registration in Montana.	\$233
Nebraska	No	Products which satisfy the requirements of the FIFRA 25(b) federal exemption are typically also considered exempt from Nebraska's registration requirements. Pesticide labels are required to be submitted for review and approval before distribution and sale in Nebraska.	-0-
Nevada	Yes	Minimum risk pesticides that are exempt from Federal registration under §25(b) of FIFRA must be registered with the Nevada Department of Agriculture prior to distribution in Nevada.	\$125
New Hampshire	Yes	Products ... covered under a federal exemption [FIFRA §25(b) must still be registered in New Hampshire.	\$160
New Jersey	No	Registration not required of any "minimum risk" pesticide exempted from regulation by US EPA under 40 CFR Part 152. NJDEP may regulate and require registration of any pesticide if conditions indicate the need.	-0-
New Mexico	Yes	While these products are exempt from registration with USEPA, the New Mexico Pest Control Act (NMPCA) requires registration of all pesticides distributed in the state of New Mexico.	\$100
New York	No	Currently, the DEC does not require registration of [25(b)] Minimum Risk Pesticide products, but they must conform to the USEPA exemption guidelines.	-0-
North Carolina	Yes	North Carolina DOES require registration of minimum risk pesticides (25(b) pesticides) that are exempt from federal registration.	\$150
North Dakota	No <sup>4</sup>	North Dakota gives registrants the option to apply for exemption and pay or to register pesticides that are exempted by USEPA. Both registered and exempt products must pay fees.	\$175 <sup>2</sup>
Ohio	Yes	For 25b Exempt products, the registrant must submit a completed application with a fee of \$150.00 per product. Labels must list all active ingredients by name and percentage. Labels must also list all inert ingredients by name.	\$150
Oklahoma	Yes	Every 25b pesticide product distributed, sold, or offered for sale in Oklahoma must be registered with the state's Dept. of Agriculture, Food, & Forestry.	\$210
Oregon	Yes	The Oregon Department of Agriculture (ODA), Pesticides Division requires registration of 25(b) Minimum Risk Pesticide products.	\$320
Pennsylvania	Yes	"Minimum Risk Pesticides" (known as 25(b)s) must be registered in Pennsylvania.	\$250
Rhode Island	Yes	All products including 25(b) products must be registered with the state of Rhode Island. Confidential statement of formula required.	\$200
South Carolina	Yes	Products that meet EPA's criteria for exemption [25b] are required to be registered. All procedures and fees are equal to regular products.	\$175
South Dakota	Yes	State law requires that all pesticide products sold in South Dakota be registered with the South Dakota Department of Agriculture. All 25(b) products must complete a Confidential Statement of Formula.	\$120 <sup>2</sup>
Tennessee	Yes	Products exempt under FIFRA 25-b do require registration, but no fee is required.	-0-
Texas	No	Pesticide products exempt from registration include minimum risk pesticides (25b list).	-0-



State	Reg.1	Notes	Ann. Fees
Utah	Yes	All 25(b) products are required to pay the annual registration fee.	\$195
Vermont	Yes	Pesticide products which are classified as minimum risk pesticides “25(b) federally exempt” need to be registered in Vermont.	\$175
Virginia	Yes	All pesticide products distributed, manufactured, sold or used in Virginia must be registered with the VDACS, including those which are exempt from federal registration under Section 25(b) of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA),	\$160
Washington	Yes	Minimum risk pesticides exempt from federal registration under Section 25(b) of FIFRA must be registered with WSDA prior to distribution in Washington State. A confidential statement of formula is required.	\$195 <sup>2</sup>
West Virginia	Yes	FIFRA Section 25(b) pesticides must be registered prior to their distribution, sale, offering for sale, transport and use in West Virginia.	\$150
Wisconsin	Yes	Label and an exempt pesticide registration form is required. No fees.	-0-
Wyoming	Yes	FIFRA 25B products are included in required registrations	\$90

<sup>1</sup>Yes if the state requires all 25(b) exempt products to be registered, No if all Federally exempt products are exempted by the state, No\* if some 25(b) products are exempt and the state requires some to be registered.

<sup>2</sup>Pro-rated annual cost of a multi-year fee.

<sup>3</sup>On-line/paper fees.

<sup>4</sup>Registration is optional; unregistered pesticides are subject to the same annual fee as registered pesticides.

<sup>5</sup>Minimum of \$250, with 0.2% of the gross sales in Iowa up to \$3,000 per product.

<sup>6</sup>In-state manufacturers are eligible for a \$100 rebate upon approval.

Information current as of January 2018. Please check with the state agency for current information.

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