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Title 40: Protection of Environment

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PART 166—EXEMPTION OF FEDERAL AND STATE AGENCIES FOR USE OF PESTICIDES UNDER EMERGENCY CONDITIONS

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Authority: 7 U.S.C. 136–136y.

Source: 51 FR 1902, Jan. 15, 1986, unless otherwise noted.

Subpart A—General Provisions

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§ 166.1 Purpose and organization.

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- (a) *Purpose and scope.* Section 18 of the Act authorizes the Administrator to exempt State and Federal agencies from any provision of the Act, if he determines that emergency conditions exist which require an exemption. The regulations in this part establish procedures whereby the Administrator may exempt a Federal or State agency from the provisions of the Act which regulate the manner in which a pesticide is made available for use or is used.
- (b) *Organization*. (1) The provisions in subpart A of this part describe the four types of emergency exemptions authorized by the Agency and define terms used in this part.
- (2) Subpart B of this part establishes procedures and criteria for specific, quarantine, and public health exemptions.
- (3) Subpart C of this part establishes procedures and criteria for crisis exemptions.

§ 166.2 Types of exemptions.

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There are four types of emergency exemptions which may be authorized: specific, quarantine, public health, and crisis exemptions.

- (a) Specific exemption. A specific exemption may be authorized in an emergency condition to avert:
- (1) A significant economic loss; or
- (2) A significant risk to:
- (i) Endangered species,
- (ii) Threatened species,
- (iii) Beneficial organisms, or
- (iv) The environment.

- (b) Quarantine exemption. A quarantine exemption may be authorized in an emergency condition to control the introduction or spread of any pest that is an invasive species, or is otherwise new to or not theretofore known to be widely prevalent or distributed within and throughout the United States and its territories.
- (c) *Public health exemption.* A public health exemption may be authorized in an emergency condition to control a pest that will cause a significant risk to human health.
- (d) *Crisis exemption.* A crisis exemption may be utilized in an emergency condition when the time from discovery of the emergency to the time when the pesticide use is needed is insufficient to allow for the authorization of a specific, quarantine, or public health exemption.

[51 FR 1902, Jan. 15, 1986, as amended at 71 FR 4510, Jan. 27, 2006]

§ 166.3 Definitions.

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Terms used in this part shall have the meanings established by the Federal Insecticide, Fungicide, and Rodenticide Act. In addition, as used in this part, the following terms shall also apply:

- (a) The term *the Act* means the Federal Insecticide, Fungicide, and Rodenticide Act, as amended, 7 U.S.C. 136 *et seg*.
- (b) The terms the Agency and EPA mean the U.S. Environmental Protection Agency.
- (c) The term *beneficial organism* means any pollinating insect, or any pest predator, parasite, pathogen or other biological control agent which functions naturally or as part of an integrated pest management program to control another pest.
- (d) The term *emergency condition* means an urgent, non-routine situation that requires the use of a pesticide(s) and shall be deemed to exist when:
- (1) No effective pesticides are available under the Act that have labeled uses registered for control of the pest under the conditions of the emergency; and
- (2) No economically or environmentally feasible alternative practices which provide adequate control are available; and
- (3) The situation:
- (i) Involves the introduction or dissemination of an invasive species or a pest new to or not theretofore known to be widely prevalent or distributed within or throughout the United States and its territories; or
- (ii) Will present significant risks to human health; or
- (iii) Will present significant risks to threatened or endangered species, beneficial organisms, or the environment; or
- (iv) Will cause significant economic loss due to:
- (A) An outbreak or an expected outbreak of a pest; or

- (B) A change in plant growth or development caused by unusual environmental conditions where such change can be rectified by the use of a pesticide(s).
- (e) The term *first food use* refers to the use of a pesticide on a food or in a manner which otherwise would be expected to result in residues in a food, if no tolerance or exemption from the requirement of a tolerance for residues of the pesticide on any food has been established for the pesticide under section 408(b)(2) and (c)(2) of the Federal Food, Drug, and Cosmetic Act.
- (f) The term *food* means any article used for food or drink for man or animals.
- (g) The term *new chemical* means an active ingredient not contained in any currently registered pesticide.
- (h) The term *significant economic loss* means that, compared to the situation without the pest emergency and despite the best efforts of the affected persons, the emergency conditions at the specific use site identified in the application are reasonably expected to cause losses meeting any of the following criteria:
- (1) For pest activity that primarily affects the current crop or other output, one or more of the following:
- (i) Yield loss greater than or equal to 20%;
- (ii) Economic loss, including revenue losses and cost increases, greater than or equal to 20% of gross revenues;
- (iii) Economic loss, including revenue losses and cost increases, greater than or equal to 50% of net revenues;
- (2) For any pest activity where EPA determines that the criteria in paragraph (h)(1) would not adequately describe the expected loss, substantial loss or impairment of capital assets, or a loss that would affect the long-term financial viability expected from the productive activity.
- (i) The term *Special Review* refers to any interim administrative review of the risks and benefits of the use of a pesticide conducted pursuant to the provisions of EPA's Rebuttable Presumption Against Registration rules, 40 CFR 162.11(a), or any subsequent version of those rules.
- (j) The term *unreasonable adverse effects on the environment* means any unreasonable risk to man or the environment, taking into account the economic, social, and environmental costs and benefits of the use of any pesticide.
- (k) The term *invasive species* means, with respect to a particular ecosystem, any species that is not native to that ecosystem, and whose introduction does or is likely to cause economic or environmental harm or harm to human health.
- (I) The term *IR-4 program* means the Interregional Research Project No. 4, a cooperative effort of the state land grant universities, the U.S. Department of Agriculture and EPA, to address the chronic shortage of pest control options for minor crops, which are generally of too small an acreage to provide economic incentive for registration by the crop protection industry.

[51 FR 1902, Jan. 15, 1986, as amended at 71 FR 4510, Jan. 27, 2006]

§ 166.7 User notification; advertising.

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- (a) A State or Federal agency that obtains an exemption may notify eligible users of the availability of the exempted pesticide(s) through user groups, retail dealers, and other means. Notification may include distributing copies of the section 18 approval letter, labeling, or other information to eligible persons.
- (b) As set forth more fully in §168.22 of this chapter, EPA interprets FIFRA sections 12(a)(1) (A) and (B) as making it unlawful for any person who distributes, sells, offers for sale, holds for sale, ships, delivers for shipment, or receives and (having so received) delivers or offers to deliver any pesticide, to advertise the pesticide for any use authorized by an emergency exemption, except for advertisements that are placed in media that address only persons in the geographical area to which the exemption applies, state the name and address of one or more retail dealers where users may buy the pesticide, and contain a prominent notice of the limitations on use under the emergency exemption. EPA may withdraw an exemption if the use of the pesticide covered by the exemption is advertised unlawfully.

[54 FR 1125, Jan. 11, 1989]

Subpart B—Specific, Quarantine, and Public Health Exemptions

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§ 166.20 Application for a specific, quarantine, or public health exemption.

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- (a) General information required in an application for a specific, quarantine or public health exemption. An application must be submitted in writing by the head of the Federal or State agency, the Governor of the State involved, or their official designee. If a designee has been delegated authority to request exemptions, written authorization of such delegation must accompany the request or be on file with the Agency. In addition, the application must contain all applicable information specified in paragraphs (a) (1) through (11) of this section.
- (1) *Identity of contact persons*. (i) Unless otherwise specified, the person who submits the application will be considered the contact person for all matters relating to administration of the emergency exemption.
- (ii) Requests should identify by name and telephone number one or more qualified experts who may be contacted in case any questions arise concerning the application.
- (2) Description of the pesticide. The application shall contain a description of the pesticide(s) proposed for use under the exemption. Such information shall include:
- (i) For a federally registered pesticide product:
- (A) A copy of the label(s) if a specific product(s) is/are requested; or the formulation(s) requested if a specific product is not requested; and
- (B) A copy of any additional labeling proposed for the emergency exemption; or
- (ii) For any other pesticide products:
- (A) A confidential statement of formula or reference to one already submitted to the Agency; and
- (B) Complete labeling to be used in connection with the proposed exemption use.
- (3) Description of the proposed use. The application shall identify all of the following:

- (i) Sites to be treated, including their locations within the State;
- (ii) The method of application;
- (iii) The rate of application in terms of active ingredient and product;
- (iv) The maximum number of applications;
- (v) The total acreage or other appropriate unit proposed to be treated;
- (vi) The total amount of pesticide proposed to be used in terms of both active ingredient and product;
- (vii) All applicable restrictions and requirements concerning the proposed use which may not appear on labeling;
- (viii) The duration of the proposed use; and
- (ix) Earliest possible harvest dates.
- (4) Alternative methods of control. The application shall contain:
- (i) A detailed explanation of why the pesticide(s) currently registered for the particular use proposed in the application is not available in adequate supplies and/or effective to the degree needed to control the emergency. If the applicant states that an available registered pesticide is ineffective for the given situation, the statement must be supported by field data which demonstrate ineffectiveness of registered pesticides, or, if such data are unavailable, statements by qualified agricultural experts, extension personnel, university personnel or other persons similarly qualified in the field of pest control; and
- (ii) A detailed explanation of why alternative practices, if available, either would not provide adequate control or would not be economically or environmentally feasible.
- (5) Effectiveness of proposed use. The application shall contain data, a discussion of field trials, or other evidence which provide the basis for the conclusion that the proposed pesticide treatment will be effective in dealing with the emergency.
- (6) Discussion of residues for food uses. If the proposed use is expected to result in residues of the pesticide in or on food, the application shall list the food likely to contain such residues and shall contain an estimate of the maximum amount of the residue likely to result from the proposed use, together with the information on which such estimates are based.
- (7) Discussion of risk information. The application shall address the potential risks to human health, endangered or threatened species, beneficial organisms, and the environment expected to result from the proposed use, together with references to data and other supporting information.
- (8) Coordination with other affected State or Federal agencies. If the proposed use of the pesticide is likely to be of concern to other Federal or State agencies, the application shall indicate that such agencies have been contacted prior to submission of the application, and any comments received from such agencies shall be submitted to EPA.
- (9) Acknowledgment by registrant. The application shall contain a statement by the registrants of all pesticide products proposed for use acknowledging that a request has been made to the Agency for use of the pesticide under this section. This acknowledgment shall include a statement of support for the requested use, including the expected availability of adequate quantities of the requested product under the use scenario proposed by

the applicant(s); and the status of the registration in regard to the requested use including appropriate petition numbers, or of the registrant's intentions regarding the registration of the use.

- (10) Description of proposed enforcement program. Prior to approval, the applicant shall provide an explanation of the authority of the applicant or related State or Federal agencies for ensuring that use of the pesticide under the proposed exemption would comply with any special requirements imposed by the Agency and a description of the program and procedures for assuring such compliance.
- (11) Repeated uses. Applications for the use of a pesticide at a site for which the applicant has previously been exempted under section 18 shall contain an interim report summarizing the results of the specific, quarantine, or public health exemption previously issued, if the application is submitted prior to the time the final report for the previous exemption is due. The interim report shall contain that information specified in §166.32 to the extent available at the time the application is made.
- (b) *Information required for a specific exemption.* An application for a specific exemption shall provide all of the following information, as appropriate, concerning the nature of the emergency:
- (1) The scientific and common name of the pest or pest complex;
- (2) A discussion of the events which brought about the emergency condition;
- (3) A discussion of the anticipated risks to endangered or threatened species, beneficial organisms, or the environment that would be remedied by the proposed use of the pesticide; and
- (4) A discussion of the anticipated significant economic loss, together with data and other information supporting the discussion, that addresses one or more of the following, as appropriate:
- (i) Yield or utilized yield reasonably anticipated in the absence of the emergency and expected losses in quantity due to the emergency;
- (ii) The information in paragraph (b)(4)(i) of this section plus prices reasonably anticipated in the absence of the emergency and changes in prices and/or production costs due to the emergency;
- (iii) The information in paragraph (b)(4)(ii) of this section plus operating costs reasonably anticipated in the absence of the emergency;
- (iv) Any other information explaining the economic consequences of the emergency.
- (5) Re-certification of an emergency condition. Applicants for specific exemptions may submit re-certification applications relying on previously submitted information to satisfy the information requirements of paragraphs (a)(1) through (a)(10) of this section, and of paragraphs (b)(1) through (b)(4) of this section, where all of the following conditions are met:
- (i) An exemption was granted for the same pesticide at the same site to the same applicant the previous year;
- (ii) The emergency condition could reasonably be expected to continue for longer than 1 year;
- (iii) EPA has not declared the use ineligible for re-certification:
- (iv) The use is not subject to public notice pursuant to §166.24(a)(1) through (a)(6);
- (v) The applicant certifies that all of the following are true:

- (A) The emergency condition described in the preceding year's application continues to exist;
- (B) Except as expressly identified, all information submitted in the preceding year's application is still accurate;
- (C) Except as expressly identified, the proposed conditions of use are identical to the conditions of use EPA approved for the preceding year;
- (D) Any conditions or limitations on the eligibility for re-certification identified in the preceding year's notice of approval of the emergency exemption have been satisfied;
- (E) The applicant is not aware of any alternative chemical or non-chemical practice that may offer a meaningful level of pest control, or has provided documentation that each such known practice does not provide adequate control or is not economically or environmentally feasible.
- (c) *Information required for a quarantine exemption.* An application for a quarantine exemption shall provide all of the following information concerning the nature of the emergency:
- (1) The scientific and common name of pest;
- (2) The origin of pest and the means of its introduction or spread if known; and
- (3) The anticipated impact of not controlling the pest.
- (d) *Information required for a public health exemption.* An application for a public health exemption shall provide all the following information concerning the nature of the emergency:
- (1) The scientific and common name of the pest to be controlled and, if the pest is a vector, a description of the disease it is expected to transmit;
- (2) A discussion of the magnitude of the health problems which are expected to occur without the pesticide use; and
- (3) Discussion of the availability of medical treatment for the health problem.
- [51 FR 1902, Jan. 15, 1986, as amended at 58 FR 34203, June 23, 1993; 71 FR 4511, Jan. 27, 2006]

§ 166.22 Consultation with the Secretary of Agriculture and Governors of the States.

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The Agency, in determining whether or not such emergency conditions exist, shall consult with the Secretary of Agriculture and the Governor of any State concerned if they request such determination.

§ 166.24 Public notice of receipt of application and opportunity for public comment.

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- (a) *Publication requirement*. The Administrator shall issue a notice of receipt in theFederal Registerfor a specific, quarantine, or public health exemption and request public comment when any one of the following criteria is met:
- (1) The application proposes use of a new chemical;

- (2) The application proposes the first food use of an active ingredient;
- (3) The application proposes any use of a pesticide if the pesticide has been subject to a suspension notice under section 6(c) of the Act;
- (4) The application proposes use of a pesticide which:
- (i) Was the subject of a notice under section 6(b) of the Act and was subsequently cancelled, and
- (ii) Is intended for a use that poses a risk similar to the risk posed by any use of the pesticide which was the subject of the notice under section 6(b);
- (5) The application proposes use of a pesticide which:
- (i) Contains an active ingredient which is or has been the subject of a Special Review, and
- (ii) Is intended for a use that could pose a risk similar to the risk posed by any use of the pesticide which is or has been the subject of the Special Review;
- (6) The application proposes use of a pesticide which:
- (i) Was voluntarily canceled under section 6(f) of the Act, and
- (ii) Is intended for a use that poses a risk similar to the risk posed by any use of the pesticide which was voluntarily canceled under section 6(f);
- (7) The application proposes use of a pesticide for a specific or public health exemption, if:
- (i) An emergency exemption has been requested or approved for that use in any 3 previous years, or any 5 previous years if the use is supported by the IR-4 program, and
- (ii) A complete application for registration of that use and/or a petition for tolerance for residues in or on the commodity has not been submitted to the Agency; or
- (8) The Administrator determines that publication of notice is appropriate.
- (b) *Contents*. The notice of receipt of an application for an emergency exemption shall contain the following information:
- (1) The name of the applicant:
- (2) The name of the active ingredient requested for use, including, if available, the common name and the Chemical Abstracts Service (CAS) number;
- (3) The total amount of product or active ingredient proposed for use:
- (4) The geographical location where treatment is proposed:
- (5) The proposed number of acres or other appropriate units proposed to be treated;
- (6) A summary of the applicant's description of the emergency conditions including the pest and the site or crop to be treated:

- (7) A description of the major conditions of use of the pesticide as proposed by the applicant:
- (8) If the pesticide proposed for use meets the criteria of paragraph (a) (3), (4), or (5) of this section, an identification of the types of risks that were the basis for EPA's regulatory action; and
- (9) The name, telephone number, and address of a person in the Agency who can provide further information.
- (c) Length of comment period. Normally, a notice of receipt shall give the public 15 days in which to file comments on the application. The Administrator may shorten or eliminate the comment period if he determines that the time available for a decision on the application requires it and shall state reasons for such action in a notice in theFederal Register. The Administrator may extend the comment period if additional time for comment is requested and such an extension would not interfere with a timely decision on the application.

[51 FR 1902, Jan. 15, 1986, as amended at 71 FR 4511, Jan. 27, 2006]

§ 166.25 Agency review.

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- (a) General. The Agency will review all requests as expeditiously as possible, making every attempt to respond to requests prior to the time when the proposed use is needed. The Agency will review the application and other available data necessary to make a determination with respect to all of the following:
- (1) Whether an emergency condition exists or will exist;
- (2) The Agency's ability and intention to establish a time-limited tolerance(s) or exemption(s) from the requirement of a tolerance for any pesticide residues resulting from the authorized use, identifying the level of permissible residues in or on food or feed resulting from the proposed use;
- (3) The anticipated benefits to be derived from the proposed use; and
- (4) The potential risks to human health, endangered or threatened species, beneficial organisms, and the environment from the proposed use.
- (b) *Criteria for approval.* The Administrator may authorize a specific, public health, or quarantine exemption, based on the information available to the Agency, after:
- (1) He determines that:
- (i) An emergency condition exists;
- (ii) The use of the pesticide under the exemption will not cause unreasonable adverse effects on the environment;
- (iii) Registration of the pesticide use for which the exemption is requested has not been suspended under section 6(c) of the Act or cancelled following a notice under section 6(b) of the Act, unless the use is authorized in accordance with the provisions of §§164.130 through 164.133 of this chapter;
- (2) Giving due consideration to:
- (i) Whether the pesticide is reasonably likely to be used in compliance with the requirements imposed by the Agency under the exemption; and

(ii) The progress which has been made toward registration of the proposed use, if a repeated specific or public health exemption is sought. It shall be presumed that if a complete application for registration of a use, which has been under a specific or public health exemption for any 3 previous years, or any 5 previous years if the use is supported for registration by the IR-4 program, has not been submitted, reasonable progress towards registration has not been made.

[51 FR 1902, Jan. 15, 1986, as amended at 71 FR 4511, Jan. 27, 2006]

§ 166.28 Duration of exemption.

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- (a) Specific or public health exemptions. EPA shall allow use of a pesticide under a specific or public health exemption for as long a period as is reasonably expected to be necessary but in no case for longer than 1 year.
- (b) Quarantine exemption. EPA shall allow use of a pesticide under a quarantine exemption for as long a period as is deemed necessary but in no case for longer than 3 years. Quarantine exemptions may be renewed. Interim reports containing the information specified in §166.32(b) to the extent available shall be filed annually.

§ 166.30 Notice of Agency decision.

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- (a) *Notification of applicants.* The Agency shall notify an applicant of its decision to approve or deny an application request for an emergency exemption in a timely manner.
- (1) *Incomplete applications*. The Agency may discontinue the processing of any application that does not address all of the requirements of §166.20 until such time the additional information is submitted by the applicant.
- (2) Complete applications—(i) Denials. The Agency shall provide the specific reasons and rationale for denying the exemption request. If the denial is based on a specific information gap, the decision shall be reconsidered in a timely manner when the information gap is filled.
- (ii) *Approvals.* The Agency *shall* provide the specific terms and conditions under which the exempted pesticide may be used.
- (b) Federal Register publication. (1) At least quarterly, the Administrator shall issue a notice in the Federal Registerannouncing all approvals of specific, quarantine, and public health exemptions. The notice shall contain all of the following:
- (i) The name of the applicant;
- (ii) The pesticide authorized for use;
- (iii) The crop or site to be treated; and
- (iv) The name, address, and telephone number of a person in the Agency who can provide further information.
- (2) In addition, if EPA has issued a Notice of Receipt of an application for an exemption, it will issue a notice of its final decision and the reasons for that decision.

§ 166.32 Reporting and recordkeeping requirements for specific, quarantine, and public health exemptions.

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- (a) *Unexpected adverse effects information*. Any unexpected adverse effects resulting from the use of a pesticide under a specific, guarantine, or public health exemption must be immediately reported to the Agency.
- (b) Interim and final reports. A final report summarizing the results of pesticide use under any specific, quarantine, or public health exemption must be submitted to the Agency within 6 months from the expiration of the exemption unless otherwise specified by the Agency. For quarantine exemptions granted for longer than 1 year, interim reports must be submitted annually. When an application for renewal of the exemption is submitted before the expiration of the exemption or before submission of the final report, an interim report must be submitted with the application. The information in interim and final reports shall include all of the following:
- (1) Total acreage, amount of commodity or other unit treated and the total quantity of the pesticide used;
- (2) A discussion of the effectiveness of the pesticide in dealing with the emergency condition;
- (3) A description of any unexpected adverse effects which resulted from use of the pesticide under the exemption;
- (4) The results of any monitoring required and/or carried out under the exemption;
- (5) A discussion of any enforcement actions taken in connection with the exemption;
- (6) Method(s) of disposition of a food crop, if required to be destroyed under an exemption; and
- (7) Any other information requested by the Administrator.
- (c) *Records*. Records for all treatments involving the first food use of a pesticide will be maintained by the agency to which the emergency exemption was granted for a minimum of 2 years following the date of expiration of the exemption. On request by the Agency these records shall be made available to the Administrator. Records will include all of the following:
- (1) Locations where the pesticide was applied;
- (2) Dates of application (range); and
- (3) Total quantity of the pesticide used.

[51 FR 1902, Jan. 15, 1986, as amended at 58 FR 34203, June 23, 1993; 71 FR 4512, Jan. 27, 2006]

§ 166.34 EPA review of information obtained in connection with emergency exemptions.

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EPA shall review information submitted in connection with emergency exemptions and, when applicable, use it in connection with other regulatory decisions under the Act.

§ 166.35 Revocation or modification of exemptions.

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- (a) *Grounds*. The Administrator may revoke or modify the terms or conditions of a specific, quarantine, or public health exemption if he determines one of the following:
- (1) An emergency no longer exists;
- (2) Use of the pesticide under the exemption may cause unreasonable adverse effects on the environment;
- (3) The pesticide authorized under the exemption is not effective at controlling the pest or conditions causing the emergency; or
- (4) The terms and conditions established by the exemption and these regulations are not being complied with.
- (b) *Implementation*. The revocation or modification becomes effective as soon as the Administrator notifies the State or Federal agency which submitted the application. Upon notification, the applicant is required immediately to take all necessary steps to assure that further use complies with the terms and conditions of any modification or, if the exemption has been revoked, to stop further use.

Subpart C—Crisis Exemptions

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§ 166.40 Authorization.

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The head of a Federal or State agency, the Governor of a State, or their official designee, may issue a crisis exemption in situations involving an unpredictable emergency situation when:

- (a) An unpredictable emergency condition exists;
- (b) The time element with respect to the application of the pesticide is critical, and there is not sufficient time either to request a specific, quarantine, or public health exemption or, if such a request has been submitted, for EPA to complete review of the request; and
- (c) EPA has provided verbal confirmation that, for food uses, a tolerance or exemption from the requirement of a tolerance can be established in a timely manner, responsive to the projected timeframe of use of the chemical and harvest of the commodity, and that, for any use, the Agency has no other objection.

[51 FR 1902, Jan. 15, 1986, as amended at 71 FR 4512, Jan. 27, 2006]

§ 166.41 Limitations.

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The crisis provisions may not be utilized to authorize a pesticide use if any of the following has occurred:

- (a) EPA has informed the head of the Federal or State agency, the Governor, or their official designee, not to issue such an exemption;
- (b) The pesticide use has been suspended under section 6(c) of the Act;

- (c) The pesticide use has been cancelled following a notice issued under section 6(b) of the Act;
- (d) The pesticide contains a new chemical; or
- (e) The application proposes the first food use of a pesticide.

§ 166.43 Notice to EPA and registrants or basic manufacturers.

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- (a) *Timing of notice.* (1) The State or Federal Agency issuing the crisis exemption must notify the Administrator in advance of utilization of the crisis provisions.
- (2) The State or Federal agency issuing the crisis exemption shall notify the registrant(s) or, if appropriate, the basic manufacturer(s) of the pesticide(s) being used under the crisis exemption at the same time notice is given to EPA or as soon thereafter as possible.
- (b) Contents of notice. Information required to be provided in notices shall include all of the following:
- (1) The name of the product and active ingredient authorized for use, along with the common name and CAS number if available, including a copy of the EPA registered label and use directions appropriate to the authorized use:
- (2) The site on which the pesticide is to be used or is being used;
- (3) The use pattern;
- (4) The date on which the pesticide use is to begin and the date when the use will end;
- (5) An estimate of the level of residues of the pesticide expected to result from use under the crisis exemption;
- (6) Earliest anticipated harvest date of the treated commodity;
- (7) Description of the emergency situation; and
- (8) Any other pertinent information available at the time.
- [51 FR 1902, Jan. 15, 1986, as amended at 58 FR 34203, June 23, 1993; 71 FR 4512, Jan. 27, 2006]

§ 166.45 Duration of crisis exemption.

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A crisis exemption may be authorized for:

- (a) Only as long as is necessary to control the pest or conditions causing the emergency; and
- (b) No longer than 15 days, unless an application requesting a specific, quarantine, or public health exemption for this use has been submitted to the Agency.

§ 166.49 Public notice of crisis exemptions.

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- (a) *Periodic notices*. At least quarterly, the Administrator shall issue a notice in theFederal Registerannouncing issuance of crisis exemptions. The notice shall contain all of the following:
- (1) The name of the applicant;
- (2) The pesticide authorized for use;
- (3) The crop or site to be treated; and
- (4) The name, address, and telephone number of a person in the Agency who can provide further information.
- (b) Annual reports. Annually, the Agency shall issue a notice in the Federal Registerthat shall summarize:
- (1) The number of crisis exemptions declared; and
- (2) The number of crisis exemptions revoked.

[51 FR 1902, Jan. 15, 1986, as amended at 71 FR 4512, Jan. 27, 2006]

§ 166.50 Reporting and recordkeeping requirements for crisis exemption.

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- (a) Adverse effects information. Any adverse effects resulting from the use of a pesticide under a crisis exemption must be immediately reported to the Agency.
- (b) Final reports. (1) A report summarizing the results of treatment under a crisis exemption will be required to be submitted to the Agency within 3 months following the last date of treatment. If a specific, quarantine, or public health exemption has been approved while the crisis exemption is in effect, however, the crisis exemption report may be incorporated into the specific, quarantine, or public health exemption final report required under §166.32(b) and submitted at the time it is due.
- (2) Information to be included in the crisis exemption report includes the same information as required in §166.32(b) and an explanation as to why there was a need to utilize the crisis provisions.
- (c) *Records*. Records will be maintained for a minimum of 2 years following the date of expiration of the exemption. On request by the Agency, these records shall be made available to the Administrator. Records will include all of the following:
- (1) Location where the pesticide was applied;
- (2) Dates of application (range); and
- (3) Total quantity of the pesticide used.

[51 FR 1902, Jan. 15, 1986, as amended at 58 FR 34203, June 23, 1993]

§ 166.53 EPA review of crisis exemption and revocation of authority.

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(a) *Review*. When a crisis exemption is about to be or has already been declared by a State or Federal agency, EPA will undertake an expedited review of the pesticide to determine if use of the pesticide may result

in such unreasonable health or environmental risks that the crisis authority should not be exercised or the crisis exemption should be revoked.

- (b) Revocation—(1) Individual crisis exemptions. A crisis exemption for the use of a specific pesticide may be revoked if the Administrator determines that:
- (i) There are insufficient data to determine the risks posed from the use;
- (ii) Such action is necessary to protect man or the environment; or
- (iii) The State or Federal agency is not complying with the requirements of this subpart C.
- (2) State or Federal agency authority. The Administrator may revoke the authority of a State or Federal agency to issue crisis exemptions for any pesticide if he determines that:
- (i) Such action is necessary to protect man or the environment; or
- (ii) The State or Federal agency is not complying with the requirements of this subpart C.
- (c) Reason for revocation. The Agency shall provide the specific reasons for revoking an agency's authority to issue a crisis exemption and for revoking an issued crisis exemption.

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http://www.epa.gov/pesticides/local/region9/lbam_guarantine.htm

EPA Quarantine Exemptions for Light Brown Apple Moth Pheromones

Current as of October 12, 2007

October 2007: A temporary restraining order issued by the California Superior Court, Monterey County, to halt the spraying of Checkmate OLR-F was based in part on the Court's uncertainty about the safety of one inert ingredient allegedly in the product. A communication from EPA to the Santa Cruz Sentinel presented an erroneous description of the ingredients in the product, and after additional review EPA has determined that Checkmate OLR-F does not in fact contain the ingredient cited by the Superior Court in its decision to issue a temporary restraining order. All of the actual ingredients of Checkmate OLR-F have been evaluated for safety and have been found to meet the Agency's requirements for the protection of human health and the environment.

EPA is responsible for the evaluation of pesticides to ensure that they will not have unreasonable

adverse effects on humans, the environment and non-target species. A pesticide cannot be legally used if it has not been registered by EPA's Office of Pesticide Programs in accordance with the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA). Pesticide registration is the process through which EPA examines the ingredients of a pesticide; the site or crop on which it is to be used; the amount, frequency and timing of its use; and storage and disposal practices. EPA also approves emergency exemptions (under Section 18 of FIFRA) for unregistered uses of pesticides for a limited time if EPA determines that emergency conditions exist and the request meets EPA safety requirements.

EPA has evaluated and approved four products for emergency use in a quarantine program for a new invasive pest to the continental United States, the Light Brown Apple Moth (LBAM). The EPA-approved quarantine products all contain moth pheromones designed to disrupt mating and thereby reduce populations of the pest.

Detection in the California Bay Area was confirmed in February 2007. More than 5,000 detections of the moth have been confirmed over an affected area encompassing 500,000 acres or more. LBAM has the potential to cause significant economic losses due to increased production costs and the possible loss of international and domestic markets. USDA estimates the impact on plant production costs may exceed \$100 million in the state of California. For questions about the Light Brown Apple Moth Eradication Project in California, call the California Department of Food and Agriculture Hotline at 1-800-491-1899.

The moth pheromone products, though artificially derived, are exact chemical replicas of the natural pheromones produced by the female LBAM to attract mates. The products impair males from finding female mates. Wide dispersal is key to product efficacy.

After a careful safety review, EPA has approved a hanging dispenser product and three additional products for ground and aerial application over wide areas where LBAM has been detected, including residential areas that harbor plant hosts for the new, invasive moth. The products are:

Product Name	Formulation Type
Checkmate OLR-F	Microencapsulated
Checkmate LBAM-F	Microencapsulated
Disrupt Micro-flake LBAM Mating Disruption	Flake
Isomate LBAM Plus Pheromone	Hanging Dispenser

EPA believes use of these pheromone products, including aerial application over residential areas, presents negligible risks to human health and the environment for the following reasons:

- The pheromone products approved by EPA for the quarantine program do not kill moths or other pests. Instead, the pheromones disrupt mating of the LBAM. Therefore, these products do not exhibit toxic characteristics more common to conventional pesticides. For more information see the <u>Lepidopteran Pheromones Fact Sheet</u>.
- 2. The pheromones in the quarantine products fall into the chemical class of Straight Chain Lepidopteran Pheromones (SCLPs). SCLPs encompass the majority of known pheromones produced by insects in the Order *Lepidoptera*, which includes moths and butterflies. Low mammalian/human toxicity for this class of chemicals is well documented. Data on this class regarding inhalation toxicity, toxicity from dermal (skin) exposure, and irritation from skin and eye exposure. The all resulted in "non-toxic" or "practically non-toxic" classifications. SCLPs also showed no evidence of mutagenicity (toxicity at the genetic level). Data submitted for structurally similar SCLP pheromones also identified no subchronic, chronic or developmental risks of concern. EPA considers the low toxicity of these pheromones to humans as well-established in

literature and through a long history of use. (See Refs 1, 2, 3, 4, 5).

- 3. EPA has also reviewed all the inert ingredients in the approved LBAM products. Based on their low toxicity, all inerts in the product formulations are cleared for use in products that come in contact with food. (40 CFR 180.910, 180.920, 180.930, and/or 180.960). The inert ingredients are present in the products to provide slow release of the micro-encapsulated or flaked pheromone to prolong its effectiveness in disrupting LBAM mating (See Refs 6, 7, 8, 9 for more information).
- 4. Other countries, such as Australia, where the LBAM is endemic, rely on the use of SCLPs. EPA is not aware of any adverse effects being reported as a result of these control programs. SCLPs are also registered in the U.S. for crop use to control other pests, with a similar track record for safe use. USEPA has received no reports of adverse effects to human health or environment associated with pheromone active ingredients registered for use in mating disruption.
- 5. In terms of exposure to the pheromones, pesticide applicators would be expected to receive the most exposure because they handle the concentrated product. However, even for the applicators, the expected level of exposure is not of concern. In addition, the product labels have standard precautionary information for handlers to follow. (see attached labels).
- 6. Residential and by-stander exposure is expected to be low due to the low application rate and the specific methods of application. EPA believes use of these pheromone products, including aerial application over residential areas, presents negligible risks to human health and the environment. Furthermore, there are no restrictions for re-entering treated residential or recreational areas.
- 7. LBAM and other SCLP pheromones naturally occur in the quarantine areas due to the presence of LBAM females and other Lepidopteran pests. Releasing the LBAM pheromone disrupts the mating cycle of the pest. These pheromone mating disrupters are very specific to targeted moth species, and are not expected to cause adverse effects or responses in humans or any other species, including the Monarch butterfly. SCLPs are biodegradable by enzyme systems in most living organisms and should present no problem to normal physiology.
- 8. EPA carefully evaluated the safety of the requested quarantine uses of these pheromone products and supports their use, and as noted previously, believes the risks to human health and the environment are negligible. In addition, the alternative approaches and controls to use of pheromones might include more traditional pesticides that would kill the pests rather than disrupt their mating cycle. Populations of threatened and endangered plant species could also be further impacted if this moth adapts to feeding on them as it has on many other plant hosts.

Background

EPA reviewed and approved use of these products as authorized by Section 18 of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), and under its own regulations at 40 CFR Part 166 (Ref 10).

Under these provisions, a state or other federal agency may apply for emergency use of a new pesticide or use pattern in order to help respond to an urgent new pest problem, such as the discovery of an invasive and damaging insect pest like LBAM. This program for release of pheromones in mating disruption is considered a "quarantine" emergency.

LBAM is native to Australia and is found in New Zealand, Ireland, the United Kingdom, and Hawaii. The pest destroys, stunts, or deforms young seedlings, spoils the appearance of ornamental plants, and

injures deciduous fruit-tree crops, citrus, and grapes.

References

- Guidance for Registration Requirements for Pheromones and Semiochemicals Used for Arthropod Pest Control. OECD Series on Pesticides. No. 12. Feb. 26, 2002 (25 pp, 77Kb, About PDF)
- Touhey, J.G. ca.1990. A review of the current bases for the United States Environmental Protection Agency's policies for the regulation of pheromones and other semiochemicals, together with a review of the available relevant data which may impact the assessment of risk for these classes of chemicals. Part No.1, Straight Chain Alcohols, Acetate Esters and Aldehydes. (Unpublished report, 474 pp.)
- 3. Amended SCLP Tolerance Exemption Final Rule published in the Federal Register 8/9/06
- 4. SCLP Tolerance Exemption Final Rule published in the Federal Register 8/9/95
- 5. The 1/26/94 Federal Register Document titled <u>Arthropod pheromones in Solid Matrix Dispensers:</u>
 Experimental Use Permit.
- 6. 40 CFR 180.910. <u>Inert Ingredients Used Pre- and Post-harvest; Exemptions from the Requirements of a Tolerance</u>
- 7. 40 CFR 180.920. <u>Inert Ingredients Used Pre-harvest; Exemptions from the Requirements of a Tolerance</u>
- 8. 40 CFR 180.930. <u>Inert Ingredients Applied to Animals; Exemptions from the Requirements of a Tolerance.</u>
- 9. 40 CFR 180.960. Polymers; Exemptions from the Requirements of a Tolerance.
- 10. 40 CFR 166. Exemption of Federal and State Agencies for Use of Pesticides Under Emergency Conditions.
- 11. California Department of Food and Agriculture EXIT Disclaimer Web site
- 12. National Pesticide Information Center Hotline: 1-800-858-7378

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Title 40: Protection of Environment

PART 180—TOLERANCES AND EXEMPTIONS FROM TOLERANCES FOR PESTICIDE CHEMICALS IN FOOD
Subpart D—Exemptions From Tolerances

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§ 180.910 Inert ingredients used pre- and post-harvest; exemptions from the requirement of a tolerance.

Link to an amendment published at 71 FR 45421, August 9, 2006.

Residues of the following materials are exempted from the requirement of a tolerance when used in accordance with good agricultural practice as inert (or occasionally active) ingredients in pesticide formulations applied to growing crops or to raw agricultural commodities after harvest:

Inert ingredients	Limits	Uses
Acetic acid		Catalyst
Acetic anhydride		Solvent, cosolvent
Acetone		Do.
Alkanoic and alkenoic acids, mono- and diesters of α-hydro-ω-hydroxypoly (oxyethylene) with molecular weight (in amu) range of 200 to 6,000		Emulsifiers
Alkyl (C ₈ -C ₂₄) benzenesulfonic acid and its ammonium, calcium, magnesium, potassium, sodium, and zinc salts		Surfactants, related adjuvants of surfactants
$\alpha\text{-Alkyl}$ (C $_9\text{-C}_{18}\text{-}\omega\text{-hydroxypoly}(oxyethylene)$ with poly(oxyethylene) content of 2-30 moles		Solvent, cosolvent, surfactant, and related adjuvants of surfactants
α-(p -Alkylphenyl)-ω- hydroxypoly(oxyethylene) produced by the condensation of 1 mole of alkylphenol		Surfactants, related adjuvants of surfactants

(alkyl is a mixture of propylene tetramer and pentamer isomers and averages C ₁₃) with 6 moles of ethylene oxide		
α-Alkyl (C ₆ -C ₁₄)-ω- hydroxypoly(oxypropylene) block copolymer with polyoxyethylene; polyoxypropylene content is 1-3 moles; polyoxyethylene content is 4-12 moles; average molecular weight (in amu) is approximately 635		Do.
α-alkyl (C ₁₂ -C ₁₅)-ω-hydroxypoly (oxypropylene) poly (oxyethylene) copolymers (where the poly (oxypropylene) content is 3–60 moles and the poly (oxyethylene) content is 5–80 moles)	Not more than 20% of pesticide formulations	Surfactant
Alkyl (C ₈ -C ₁₈) sulfate and its ammonium, calcium, isopropylamine, magnesium, potassium, sodium, and zinc salts		Surfactants.
Aluminum hydroxide		Diluent, carrier
Aluminum oxide		Diluent
Aluminum stearate		Surfactant
Ammonium bicarbonate		Surfactant, suspending agent, dispersing agent
Ammonium carbamate		Synergist in aluminum phosphide formulations
Ammonium chloride		Intensifier when used with ammonium nitrate as a dessicant or defoliant. Fire suppressant in aluminum phosphide and magnesium phosphide formulations
Ammonium hydroxide		Solvent, cosolvent, neutralizer, solubilizing agent
Ammonium stearate		Surfactant
Ammonium sulfate		Solid diluent, carrier
Ammonium thiosulfate		Intensifier when used with

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Bicyclo[3.1.1]hept-2-ene, 2,6,6-trimethyl-, homopolymer (Alpha-pinene, homopolymer (ICAS Reg. No. 25766–18–1) Bicyclo[3.1.1]heptane, 6,6-dimethyl-2-methylene-, homopolymer (Beta-pinene, homopolymer) (CAS Reg. No. 25719–60–2) Bicyclo[3.1.1]hept-2-ene, 2,6,6-trimethyl-, polymer with 6,6-dimethyl-2-methylenebicyclo [3.1.1] heptane (Copolymer of alpha- and beta-pinene) (CAS Reg. No. 31393–98–3) 2-Bromo-2-nitro-1,3-propanediol (CAS Reg. No. 52–51–7) Butane n-Butanol (CAS Reg. No. 71–36–3) Butylated hydroxyanisole Butylated hydroxytoluene α-(p-tert-Butylphenyl)-ω-hydroxypoly (oxyethylene) mixture of dihydrogen phosphate esters and the corresponding ammonium calcium, magnesium, monoethanolamine, potassium, sodium, and zinc salts of the phosphate esters; the poly(oxyethylene) content averages 4-12 moles	Bentonite		Solid diluent, carrier
homopolymer (Alpha-pinene, homopolymer) (CAS Reg. No. 25766–18–1) adjuvants of surfactants Bicyclo[3.1.1]heptane, 6,6–dimethyl–2–methylene-, homopolymer (Beta-pinene, homopolymer) (CAS Reg. No. 25719–60–2) Surfactants, related adjuvants of surfactants Bicyclo[3.1.1]hept—2–ene, 2,6,6–trimethyl–, polymer with 6,6– dimethyl–2–methylenebicyclo [3.1.1] heptane (Copolymer of alpha- and beta-pinene) (CAS Reg. No. 31393–98–3) Surfactants, related adjuvants of surfactants 2-Bromo-2-nitro-1,3-propanediol (CAS Reg. No. 52–51–7) 0.04% or less by weight of the total pesticide formulation Butane Propellant n-Butanol (CAS Reg. No. 71–36–3) Solvent, cosolvent Butylated hydroxyanisole Antioxidant Butylated hydroxytoluene Do. α-(p-tert -Butylphenyl)-ω-hydroxypoly (oxyethylene) mixture of dihydrogen phosphate esters and the corresponding ammonium calcium, magnesium, monoethanolamine, potassium, sodium, and zinc salts of the phosphate esters; the poly(oxyethylene) content averages 4-12 moles Solid diluent carrier Calcareous shale Solid diluent carrier	Benzoic acid		
methylene—, homopolymer (Beta-pinene, homopolymer) (CAS Reg. No. 25719–60–2) Bicyclo[3.1.1]hept–2–ene, 2,6,6–trimethyl—, polymer with 6,6– dimethyl=2– methylenebicyclo [3.1.1] heptane (Copolymer of alpha- and beta-pinene) (CAS Reg. No. 31393–98–3) 2-Bromo-2-nitro-1,3-propanediol (CAS Reg. No. 52–51–7) Butane ### Propellant ### Propellant ### Propellant ### Do. ### Occupance of dipha- and beta-pinene) (CAS Reg. No. 71–36–3) ### Butane ### Propellant ### Do. ### Occupance of dipha- and beta-pinene) (CAS Reg. No. 71–36–3) ### Butane ### Butane ### Propellant ### Do. ### Occupance of dipha- and beta-pinene) (CAS Reg. No. 71–36–3) ### Butane ### Butane ### Propellant ### Do. ### Occupance of dipha- and beta-pinene) (CAS Reg. No. 71–36–3) ### Solvent, cosolvent ### Do. ### Occupance of dipha- and beta-pinene) (CAS Reg. No. 71–36–3) ### Solvent, cosolvent ### Do. ### Occupance of dipha- and beta-pinene) (CAS Reg. No. 71–36–3) ### Solvent, cosolvent ### Do. ### Occupance of dipha- and beta-pinene) (CAS Reg. No. 71–36–3) ### Solvent, cosolvent ### Do. ### Occupance of dipha- and beta-pinene) (CAS Reg. No. 71–36–3) ### Solvent, cosolvent ### Do. ### Occupance of dipha- and beta-pinene) (CAS Reg. No. 71–36–3) ### Solvent, cosolvent ### Do. ### Occupance of dipha- and beta-pinene) (CAS Reg. No. 71–36–3) ### Solvent, cosolvent ### Do. ### Occupance of dipha- and beta-pinene) (CAS Reg. No. 71–36–3) ### Solvent, cosolvent ### Do. ### Occupance of dipha- and beta-pinene) (CAS Reg. No. 71–36–3) ### Solvent, cosolvent ### Do. ### Occupance of dipha- and beta-pinene) (CAS Reg. No. 71–36–3) ### Solvent, cosolvent ### Do. ### Occupance of dipha- and beta-pinene) (CAS Reg. No. 71–36–3) ### Solvent, cosolvent ### Do. ### Occupance of dipha- and beta-pinene) (CAS Reg. No. 71–36–3) ### Occupance of dipha- and beta-pinene) (CAS Reg. No. 71–36–3) ### Occupance of dipha- and beta-pinene) (CAS Reg. No. 71–36–3) ### Occupance of dipha- and beta-pinene ### Occupance of dipha- and be	Bicyclo[3.1.1]hept–2–ene, 2,6,6–trimethyl–, homopolymer (Alpha-pinene, homopolymer)(CAS Reg. No. 25766–18–1)		adjuvants of
polymer with 6,6– dimethyl–2– methylenebicyclo [3.1.1] heptane (Copolymer of alpha- and beta-pinene) (CAS Reg. No. 31393–98–3) 2-Bromo-2-nitro-1,3-propanediol (CAS Reg. No. 52–51–7) Butane Propellant n-Butanol (CAS Reg. No. 71–36–3) Butylated hydroxyanisole Butylated hydroxytoluene α-(p-tert -Butylphenyl)-ω-hydroxypoly (oxyethylene) mixture of dihydrogen phosphate and monohydrogen phosphate esters and the corresponding ammonium calcium, magnesium, monoethanolamine, potassium, sodium, and zinc salts of the phosphate esters; the poly(oxyethylene) content averages 4-12 moles Calcareous shale 0.04% or less by weight of the total pesticide formulation Propellant Antioxidant Do. Surfactants related adjuvants of surfactants Solvent, cosolvent Surfactants related adjuvants of surfactants Solid diluent carrier	. , , ,		adjuvants of
Reg. No. 52–51–7) weight of the total pesticide formulation Butane Propellant n - Butanol (CAS Reg. No. 71–36–3) Solvent, cosolvent Butylated hydroxyanisole Antioxidant Butylated hydroxytoluene Do. α-(p-tert - Butylphenyl)-ω-hydroxypoly (oxyethylene) mixture of dihydrogen phosphate and monohydrogen phosphate esters and the corresponding ammonium calcium, magnesium, monoethanolamine, potassium, sodium, and zinc salts of the phosphate esters; the poly(oxyethylene) content averages 4-12 moles Solid diluent carrier	Bicyclo[3.1.1]hept–2–ene, 2,6,6–trimethyl–, polymer with 6,6– dimethyl–2– methylenebicyclo [3.1.1] heptane (Copolymer of alpha- and beta-pinene) (CAS Reg. No. 31393–98–3)		adjuvants of
n -Butanol (CAS Reg. No. 71–36–3) Solvent, cosolvent Butylated hydroxyanisole Antioxidant Butylated hydroxytoluene Do. α-(p-tert -Butylphenyl)-ω-hydroxypoly (oxyethylene) mixture of dihydrogen phosphate and monohydrogen phosphate esters and the corresponding ammonium calcium, magnesium, monoethanolamine, potassium, sodium, and zinc salts of the phosphate esters; the poly(oxyethylene) content averages 4-12 moles Solid diluent carrier	2-Bromo-2-nitro-1,3-propanediol (CAS Reg. No. 52–51–7)	weight of the total pesticide	In-can preservative
Butylated hydroxyanisole Butylated hydroxytoluene Do. α-(p-tert -Butylphenyl)-ω-hydroxypoly (oxyethylene) mixture of dihydrogen phosphate and monohydrogen phosphate esters and the corresponding ammonium calcium, magnesium, monoethanolamine, potassium, sodium, and zinc salts of the phosphate esters; the poly(oxyethylene) content averages 4-12 moles Calcareous shale Antioxidant Butylated hydroxyanisole Do. Surfactants related adjuvants of surfactants surfactants Surfactants Solid diluent carrier	Butane		Propellant
Butylated hydroxytoluene α-(p-tert -Butylphenyl)-ω-hydroxypoly (oxyethylene) mixture of dihydrogen phosphate and monohydrogen phosphate esters and the corresponding ammonium calcium, magnesium, monoethanolamine, potassium, sodium, and zinc salts of the phosphate esters; the poly(oxyethylene) content averages 4-12 moles Calcareous shale Do. Surfactants related adjuvants of surfactants surfactants Surfactants related adjuvants of surfactants	<i>n</i> -Butanol (CAS Reg. No. 71–36–3)		Solvent, cosolvent
α-(p-tert -Butylphenyl)-ω-hydroxypoly (oxyethylene) mixture of dihydrogen phosphate and monohydrogen phosphate esters and the corresponding ammonium calcium, magnesium, monoethanolamine, potassium, sodium, and zinc salts of the phosphate esters; the poly(oxyethylene) content averages 4-12 moles Calcareous shale Surfactants related adjuvants of surfactants surfactants Surfactants related adjuvants of surfactants	Butylated hydroxyanisole		Antioxidant
(oxyethylene) mixture of dihydrogen phosphate and monohydrogen phosphate esters and the corresponding ammonium calcium, magnesium, monoethanolamine, potassium, sodium, and zinc salts of the phosphate esters; the poly(oxyethylene) content averages 4-12 moles Calcareous shale adjuvants of surfactants surfactants Surfactants Solid diluent carrier	Butylated hydroxytoluene		Do.
	phosphate and monohydrogen phosphate esters and the corresponding ammonium calcium, magnesium, monoethanolamine, potassium, sodium, and zinc salts of the phosphate esters; the poly(oxyethylene)		adjuvants of
Calcite	Calcareous shale		Solid diluent carrier
Calcite Do.	Calcite		Do.

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Calcium carbonate		Do.
Calcium chloride		Stabilizer
Calcium phosphate		Solid diluent, carrier
Calcium hydroxide		Do.
Calcium hypochlorite		Sanitizing and bleaching agent
Calcium oxide		Solid diluent, carrier
Calcium salt of partially dimerized rosin, conforming to 21 CFR 172.210		Coating agent
Calcium silicate		Solid diluent, carrier
Calcium stearate		Do.
Carrageenan, conforming to 21 CFR 172.620	Minimum molecular weight (in amu): 100,000	Thickener
Cetyl alcohol (CAS Reg. No. 36653–82–4)	Not more than 5.0% of pesticide formulation	Evaporation retardant
Charcoal, activated	Meets specifications in the Food Chemical Codex	Carrier
Coconut shells		Solid diluent and carrier
Cod liver oil		Solvent, cosolvent
Croscarmellose sodium (CAS Reg. No. 74811–65–7)		Disintegrant, solid diluent, carrier, and thickener
Dialkyl (C ₈ -C ₁₈) dimethyl ammonium chloride	Not more than 0.2% in silica, hydrated silica	Flocculating agent in the manufacture of silica, hydrated silica for use as a solid diluent, carrier
Diatomite (diatomaceous earth)		Solid diluent carrier
Diethylene glycol abietate		Surfactants, related adjuvants of surfactants
1,1-Difluoroethane (CAS Reg. No. 75–37–6)	For aerosol pesticide formulations used for insect control in food-	Aerosol propellant

	and feed- handling establishments and animals	
trimethylquinolene	Not more than 0.02% of pesticide formulation	Antioxidant
Dimethyl ether (methane, oxybis-) (CAS Reg. No. 115–10–6)		Propellant
	Not more than 2.5% of pesticide formulation	Surfactants, related adjuvants of surfactants
α-(<i>o,p</i> -Dinonylphenyl)-ω-hydroxypoly (oxyethylene) mixture of dihydrogen phosphate and monohydrogen phosphate esters and the corresponding ammonium, calcium, magnesium, monoethanolamine, potassium, sodium, and zinc salts of the phosphate esters; the nonyl group is a propylene trimer isomer and the poly(oxyethylene) content averages 4-14 moles		Surfactants, related adjuvants of surfactants
α-(<i>o,p</i> -Dinonylphenyl)-ω-hydroxypoly (oxyethylene) produced by condensation of 1 mole of dinonylphenol (nonyl group is a propylene trimer isomer) with an average of 4-14 or 140-160 moles of ethylene oxide		Do.
Dipropylene glycol		Solvent, cosolvent
Disodium phosphate		Anticaking agent, conditioning agent
Disodium zinc ethylenediaminetetraacetate dihydride		Sequestrant
Dodecylbenzenesulfonic acid, amine salts		Release rate regulator in pheromone formulation
α-(p -Dodecylphenyl)-ω-hydroxypoly (oxyethylene) produced by the condensation of 1 mole of dodecylphenol (dodecyl group is a propylene tetramer isomer) with an average of 4-14 or 30-70 moles of ethylene oxide; if a blend of products is used, the average number of moles of ethylene oxide reacted to produce any product that is a component of the		Surfactants, related, adjuvants of surfactants

blend shall be in the range of 4-14 or 30-70		
Dolomite		Solid diluent, carrier
Epoxidized linseed oil		Surfactants, related adjuvants of surfactants
Epoxidized soybean oil		Do.
Ethyl acetate		Solvent, cosolvent
Ethyl alcohol		Do.
Ethyl esters of fatty acids derived from edible fats and oils		Solvent, cosolvent
Ethyl maltol (CAS Reg. No.4940–11–8)	Not more than 0.2 % of the pesticide formulation	Odor masking agent
Ethylene oxide adducts of 2,4,7,9- tetramethyl-5-decynediol, the ethylene oxide content averages 3.5, 10, or 30 moles		Surfactants, related adjuvants of surfactants
Ethylenediaminetetraacetic acid	3% of pesticide formulation	Sequestrant
Ethylenediaminetetraacetic acid, tetrasodium salt	5% of pesticide formulation	Sequestrant
2-Ethyl-1-hexanol	Not more than 2.5% of pesticide formulation	Solvent, adjuvant of surfactants
Fatty acids, conforming to 21 CFR 172.860		Binder, defoaming agent, lubricant
FD&C Blue No. 1	Not more than 0.2% of pesticide formulation	Dye
FD&C Red No. 40 (CAS Reg. No. 25956– 17–6) conforming to 21 CFR 74.340	Not to exceed 0.002% by weight of pesticide formulation	Dye, coloring agent
Ferric Citrate (CAS Reg. No. 2338-05-8)		Stabilizer
Ferric sulfate		Solid diluent, carrier
Furcelleran		Thickener
D-glucopyranose, oligomeric, C _{10–16} -alkyl glycosides (CAS Reg. No. 110615–47–9)		Surfactant

Glycerides, edible fats and oils derived from plants and animals, reaction products with sucrose (CAS Reg. Nos. 100403–38–1, 100403–41–6, 100403–39–2, 100403–40–5)		Emulsifier, dispersing agent
Glycerol mono-, di-, and triacetate		Solvent, cosolvent
Glyceryl monostearate		Emulsifier
Granite		Do.
Graphite		Solid diluent, carrier
Gum arabic (acacia)		Surfactant, suspending agent, dispersing agent
Gypsum		Solid diluent, carrier
Hexamethylenetetramine	For use in citrus washing solutions only at not more than 1%	Preservative
3-hexen-1-ol, (3Z)- (CAS Reg. No. 928-96- 1)	Not more than 0.4% of the pesticide formulation	Odorant, alerting agent
n-Hexyl alcohol (CAS Reg. No. 111–27–3)		Solvent, cosolvent
Hydrochloric acid		Solvent, neutralizer
Hydroxyethylidine diphosphonic acid (HEDP) (CAS Reg. No. 2809–21–4)	For use in antimicrobial pesticide formulations at not more than 1 percent	Stabilizer, chelator
Iron oxide		Solid diluent, carrier
Isopropyl myristate (CAS Reg. No. 110– 27–0)		Solvent
Kaolinite-type clay		Solid diluent, carrier
Lactic acid		Solvent
Lactic acid, 2-ethylhexyl ester (CAS Reg. No. 6283–86–9)		Solvent
Lactic acid, 2-ethylhexyl ester, (2S)- (CAS Reg. No. 186817–80–1)		Solvent
Lactic acid, n-propyl ester, (S); (CAS Reg. No. 53651–69–7)		Solvent
Lauryl alcohol		Surfactant

α-Lauryl-ω-hydroxypoly(oxyethylene), average molecular weight (in amu) of 600	Emulsifier
α-Lauryl-ω-hydroxypoly(oxyethylene) sulfate, sodium salt; the poly(oxyethylene) content is 3-4 moles	Surfactants, related adjuvants of surfactants
Lignin (CAS Reg. No. 9005–53–2)	Surfactant, related adjuvants of surfactants
Lignin, alkali (CAS Reg. No. 8068–05–1)	Do.
Lignin, alkali, oxidized, sodium salt (CAS Reg. No. 68201–23–0)	Do.
Lignin alkali reaction products with disodium sulfite and formaldehyde (CAS Reg. No. 105859–97–0)	Do.
Lignin alkali reaction products with formaldehyde and sodium bisulfite (CAS Reg. No. 68512–35–6)	Do.
Lignosulfonic acid (CAS Reg. No. 8062– 15–5)	Do.
Lignosulfonic acid, ammonium calcium salt (CAS Reg. No. 12710–04–2)	Do.
Lignosulfonic acid, ammonium magnesium salt (CAS Reg. No. 123175–37–1)	Do.
Lignosulfonic acid, ammonium salt (CAS Reg. No. 8061–53–8)	Do.
Lignosulfonic acid, ammonium sodium salt (CAS Reg. No. 166798–73–8)	Do.
Lignosulfonic acid, calcium magnesium salt (CAS Reg. No. 55598–86–2)	Do.
Lignosulfonic acid, calcium salt (CAS Reg. No. 8061–52–7)	Do.
Lignosulfonic acid, calcium sodium salt (CAS Reg. No. 37325–33–0)	Do.
Lignosulfonic acid, ethoxylated, sodium salt (CAS Reg. No. 68611–14–3)	Do.
Lignosulfonic acid, magnesium salt (CAS Reg. No. 8061–54–9)	Do.
Lignosulfonic acid, potassium salt (CAS Reg. No. 37314–65–1)	Do.
Lignosulfonic acid, sodium salt (CAS Reg. No. 8061–51–6)	Do.
Lignosulfonic acid, sodium salt, oxidized	Do.

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(CAS Reg. No. 68855–41–4)		
Lignosulfonic acid, sodium salt, polymer with formaldehyde and phenol (CAS Reg. No. 37207–89–9)		Do.
Lignosulfonic acid, sodium salt, sulfomethylated (CAS Reg. No. 68512–34–5)		Do.
Lignosulfonic acid, zinc salt (CAS Reg. No. 57866–49–6)		Do.
d-Limonene (CAS Reg. No. 5989–27–5)		Solvent, fragrance
Magnesium carbonate		Anticaking agent, conditioning agent
Magnesium chloride		Safener
Magnesium lime		Solid diluent, carrier
Magnesium oxide		Do.
Magnesium silicate		Do.
Magnesium stearate		Surfactant
Magnesium sulfate		Solid diluent, carrier, safener
Manganous oxide		Solid diluent, carrier
Methyl alcohol		Solvent
Methyl <i>n</i> -amyl ketone (CAS Reg. No. 110–43–0)		Solvent, cosolvent
Methylated silicones		Antifoaming agent
Methyl esters of fatty acids derived from edible fats and oils		Solvent, cosolvent
Methyl esters of higher fatty acids conforming to 21 CFR 573.640		Antidusting agent, surfactant
Methyl isobutyl ketone		Solvent
Mica		Solid diluent, carrier
Mineral oil, U.S.P., or conforming to 21 CFR 172.878 or 178.3620(a) (CAS Reg. No. 8012–95–1)		Diluent, carrier, and solvent
Monoammonium phosphate	No more than 3.75% by weight in formulation	Postharvest fumigation in formulation with aluminum phosphide
Mono- and diglycerides of C ₈ -C ₁₈ fatty acids		Surfactants, related adjuvants of

		surfactants
Montmorillonite-type clay		Solid diluent, carrier
Nonyl, decyl, and undecyl glycoside mixture with a mixture of nonyl, decyl, and undecyl oligosaccharides and related reaction products (primarily decanol and undecanol) produced as an aqueous-based liquid (50 to 65% solids) from the reaction of primary alcohols (containing 15 to 20% secondary alcohol isomers) in a ratio of 20% C ₉ , 40% C ₁₀ , and 40% C ₁₁ with carbohydrates (average glucose to alkyl chain ratio 1.3 to 1.8)		Surfactant.
α-(<i>p</i> -Nonylphenyl)-ω-hydroxypoly(oxyethylene) mixture of dihydrogen phosphate and monohydrogen phosphate esters and the corresponding ammonium, calcium, magnesium, monoethanolamine, potassium, sodium, and zinc salts of the phosphate esters; the nonyl group is a propylene trimer isomer and the poly(oxyethylene) content averages 4-14 moles or 30 moles		Surfactants, related adjuvants of surfactants
α-(<i>p</i> -Nonylphenyl)-ω-hydroxypoly(oxyethylene) produced by the condensation of 1 mole of nonylphenol (nonyl group is a propylene trimer isomer) with an average of 4-14 or 30-90 moles of ethylene oxide; if a blend of products is used, the average number of moles of ethylene oxide reacted to produce any product that is a component of the blend shall be in the range of 4-14 or 30-90		Do.
α-(p -Nonylphenyl)-ω- hydroxypoly(oxyethylene) sulfate, ammonium, calcium, magnesium, potassium, sodium, and zinc salts; the nonyl group is a propylene trimer isomer and the poly(oxyethylene) content averages 4 moles		Do.
,	Not more than 0.2% of the pesticide formulation	Odor masking agent
Octyl and decyl glucosides mixture with a mixture of octyl and decyloligosaccharides and related reaction products (primarily <i>n</i> -decanol) produced as an aqueous-based liquid (68-72% solids) from the reaction of		Surfactants, related adjuvants of surfactants

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straight chain alcohols ($C_8(45\%)$, $C_{10}(55\%)$) with anhydrous glucose		
Oleic acid		Diluent
Oleic acid diester of α-hydro-ω-hydroxypoly (oxyethylene); the poly(oxyethylene) having average molecular weight (in amu) 400		Surfactants, related adjuvants of surfactants
α-Oleoyl-ω-hydroxypoly(oxyethylene), average molecular weight (in amu) of 600		Emulsifier
Oleyl alcohol (CAS Reg. No. 143–28–2	15%	Cosolvent
Oxalic acid	No more oxalic acid should be used than is necessary to chelate calcium and in no case should more than 2 lb oxalic acid per acre be used	Calcium chelating hard water inhibitor
Palmitic acid		Diluent
Pentaerythritol ester of maleic anhydride modified wood rosin		Plasticizer
Petrolatum, conforming to 21 CFR 172.880		Coating agent
Petroleum hydrocarbons, light odorless conforming to 21 CFR 172.884		Solvent, diluent.
Petroleum hydrocarbons, synthetic isoparaffinic, conforming to 21 CFR 172.882		Do.
Petroleum naphtha, conforming to 21 CFR 172.250(d)		Component of coating agent
Petroleum wax, conforming to 21 CFR 172.886(d)		Coating agent
Phosphoric acid		Buffer
Polyethylene, conforming to 21 CFR 177.1520(c)		Binder, carrier, and coating agent
Polyethylene glycol[α-hydro-ω- hydroxypoly(oxyethylene)]; mean molecular weight (in amu) 194 to 9,500 conforms to 21 CFR 178.3750		Surfactants, related adjuvants of surfactants
Polyglycerol esters of fatty acids conforming to 21 CFR 172.854		Surfactants, related adjuvants of surfactants
Polyglyceryl phthalate ester of coconut oil		Do.

fatty acids		
Poly(methylene- <i>p-tert</i> -butylphenoxy)- poly(oxyethylene) ethanol; the poly(oxyethylene) content averages 4-12 moles		Coating agent
Poly(methylene- <i>p</i> -nonylphenoxy)poly (oxyethylene) ethanol; the poly(oxyethylene) content averages 4-12 moles		Coating agent
Poly(oxy-1,2-ethanediyl), α- (carboxymethyl)-ω-(nonylphenoxy) produced by the condensation of 1 mole of nonylphenol (nonyl group is a propylene trimer isomer) with an average of 4-14 or 30-90 moles of ethylene oxide. The molecular weight (in amu) ranges are 454- 894 and 1598-4238		Surfactant
Polyoxyethylene (20) sorbitan monostearate		Surfactants, related adjuvants of surfactants
bis(2-hydroxyethyl)amino]propyl]-ω- hydroxy,-ether with α-hydro-ω- hydroxypoly(oxy-1,2-ethanediyl) (1:2), mono-C ₁₂₋₁₆ alkyl ethers, (CAS Reg. No.	Not to exceed 15% in the formulated product; only for use with glyphosate	Surfactant
Polysorbate 65, conforming to 21 CFR 172.838		Emulsifier
Potassium aluminum silicate		Solid diluent, carrier
Potassium hydroxide		Neutralizer
Potassium phosphate		Buffer
Potassium sulfate		Solid diluent
Propane		Propellant
n-Propanol		Solvent, cosolvent
2-Propenoic acid, 2-methyl-, polymer with ethyl 2-propenoate and methyl 2-methyl-2-propenoate, ammonium salt (CAS Registration No. 55989–05–4), minimum number average molecular weight (in amu), 18,900.		Encapsulating agent, dispensers, resins, fibers and beads
Propylene glycol		Solvent, cosolvent.
Propylene glycol alginate (as defined in 21 CFR 172.858)		Defoaming agent
Propyl gallate		Antioxidant

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Propyl <i>p</i> -hydroxybenzoate	Preservative for formulations
Pyrophyllite	Solid diluent, carrier
Rhizobium inoculants (e.g. Sinorhizobium, Bradyrhizobium & Rhizobium)	All leguminous food commodities
Rosin, partially dimerized (as defined in 21 CFR 172.615)	Surfactants, related adjuvants of surfactants
Rosin, partially hydrogenated (as defined in 21 CFR 172.615)	Do.
Rosin, wood	Do.
Salts of fatty acids, conforming to 21 CFR 172.863	Binder, emulsifier, anticaking agent
Sand	Solid diluent, carrier
Secondary alkyl (C ₁₁ -C ₁₅) poly(oxyethylene) acetate, sodium salt; the ethylene oxide content averages 5 moles	Surfactant
Shellac, bleached; refined, food grade, arsenic and rosin-free	Coating agent
Soapstone	Solid diluent
Sodium acid pyrophosphate	Surfactant, suspending agent, dispersing agent, buffer
Sodium α-olefinsulfonate (sodium C ₁₄ -C ₁₆) (Olefin sulfonate)	Surfactants, related adjuvants of surfactants
Sodium aluminum silicate	Solid diluent, carrier
Sodium diisobutylnaphthalenesulfonate	Surfactants, related adjuvants of surfactants
Sodium dioctylsulfosuccinate	Do.
Sodium dodecylphenoxybenzenedisulfonate	Do.
Sodium hexametaphosphate	Surfactant, emulsifier, wetting agent, suspending agent, dispersing agent, buffer
Sodium hydroxide	Neutralizer
Sodium isopropylisohexylnaphthalenesulfonate	Surfactants, related adjuvants of

		surfactants
Sodium lauryl glyceryl ether sulfonate		Do.
Sodium metasilicate		Surfactants, emulsifiers, wetting agents, dispersing agents, buffer
Sodium monoalkyl and dialkyl (C ₈ -C ₁₆) phenoxybenzenedisulfonate mixtures containing not less than 70% of the monoalkylated product		Surfactants, related adjuvants of surfactants
Sodium mono- and dimethyl naphthalenesulfonates, molecular weight (in amu) 245-260		Do.
Sodium mono-, di-, and tributyl naphthalenesulfonates		Do.
Sodium mono-, di-, and triisopropyl naphthalenesulfonate		Do.
Sodium N -oleoyl- N -methyltaurine		Do.
Sodium salt of sulfated oleic acid		Surfactants, related adjuvants of surfactants
Sodium silicate		Surfactant, emulsifier, wetting agent, stabilizer, inhibitor
Sodium starch glycolate (CAS Reg. No. 9063–38–1)	Granular and tableted products only; not to exceed 8% of the formulated product	Disintegrant
Sodium sulfate		Solid diluent, carrier
Sodium sulfite		Stabilizer
Sodium tripolyphosphate		Buffer, surfactant, suspending agent, dispersing agent, anticaking agent, conditioning agent
Sorbic acid (CAS Reg. No. 110–44–1)		Preservative for formulations
Sorbitan fatty acid esters (fatty acids limited to C_{12} , C_{14} , C_{16} , and C_{18} containing minor amounts of associated fatty acids) and their		Surfactants, related adjuvants or surfactants.

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Expires May 24, 2005.	Surfactant
	Solvent, cosolvent
	Coating agent
	Diluent
	Emulsifier
е	Surfactants, related adjuvants of surfactants
	Adhesive
	Surfactant, related adjuvants of surfactants
Not to exceed 10% of the pesticide formulation; nonaerosol formulations only	pH Control agent
	Carrier, binder, and carrying agent
	Binder, carrier, and coating agent
	Solid diluent, carriers
	Surfactants, related adjuvants of surfactants
	Dye
	Surfactants, related adjuvants of surfactants
	Aerosol propellant
Expires February 9,	Solvent/cosolvent
	Not to exceed 10% of the pesticide formulation; non-aerosol formulations only

	2008	
α-[p -(1,1,3,3-Tetramethylbutyl)phenyl]-ω-hydroxypoly(oxyethylene) produced by the condensation of 1 mole of p -(1,1,3,3-tetramethylbutyl)phenol with a range of 1-14 or 30-70 moles of ethylene oxide: if a blend of products is used, the average range number of moles of ethylene oxide reacted to produce any product that is a component of the blend shall be in the range of 1-14 or 30-70		Surfactants, related adjuvants of surfactants
2,4,7,9-Tetramethyl-5-decyn-4, 7-diol	Not more than 2.5% of pesticide formulation	Surfactants, related adjuvants of surfactants
Tetrasodium pyrophosphate		Anticaking agent, conditioning agent
Thiosulfuric acid, disodium salt, anhydrous. (CAS Reg. No 7772–98–7)		Dechlorinator, reducing agent
Thiosulfuric acid, disodium salt, pentahydrate. (CAS Reg. No. 10102–17–7)		Do.
d-Alpha tocopherol (CAS Reg. No. 9-02-9	None	Safener
d-Alpha tocopheryl acetate (CAS Reg. No. 58–95–7)	None	Do.
dl-Alpha tocopherol (CAS Reg. No.10191– 41–0)	None	Do.
dl-Alpha tocopheryl acetate (CAS Reg. No. 7695–91–2)	None	Do.
Tricalcium phosphate		Surfactant, suspending agent, dispersing agent, anticaking agent, conditioning agent
Tridecylpoly(oxyethylene) acetate, sodium salt; where the ethylene oxide content averages 6-7 moles		Surfactants, related adjuvants of surfactants
Trisodium phosphate		Surfactant, emulsifier, wetting agent
Vermiculite		Solid diluent, carrier.
Vitamin E (CAS Reg. No. 1406–18–4)	None	Safener
Walnut shells		Leaching inhibitor, binder for water-

		dispersible aggregates, sticker and suspension stabilizer
Wintergreen oil		Attractant
Wood flour	Derived from wood free of chemical preservatives	Solid diluent and carrier
Xanthan gum-modified, produced by the reaction of xanthan gum and glyoxal (maximum 0.3% by weight)	Not more than 0.5% of pesticide formulation	Surfactant
Xylene meeting the specifications listed in 21 CFR 172.884(b)(4)	In pesticide formulations for grain storage only	Solvent, cosolvent
Zeolite (hydrated alkali aluminum silicate)		Solid diluent, carrier
Zinc oxide		Coating agent
Zinc sulfate (basic and monohydrate)		Do.
Zinc sulfate (basic and monohydrate)		Solid diluent, carrier

[69 FR 23117, Apr. 28, 2004, as amended at 69 FR 33578, June 16, 2004; 69 FR 34949, June 23, 2004; 69 FR 40786, July 7, 2004; 69 FR 47025, Aug. 4, 2004; 69 FR 58304, 58314, Sept. 30, 2004; 70 FR 28443, 28451, May 18, 2005; 70 FR 31364, June 1, 2005; 70 FR 37692, June 30, 2005; 70 FR 38786, July 6, 2005; 70 FR 43311, July 27, 2005; 70 FR 44496, Aug. 3, 2005; 70 FR 51628, Aug. 31, 2005; 70 FR 54286, Sept. 14, 2005; 70 FR 55296, Sept. 21, 2005; 70 FR 55733, Sept. 23, 2005; 70 FR 67910, Nov. 9, 2005; 71 FR 14414, Mar. 22, 2006; 71 FR 30810, May 31, 2006; 71 FR 43660, Aug. 2, 2006; 71 FR 45414, 45421, Aug. 9, 2006; 73 FR 9217, Feb. 20, 2008; 73 FR 17913, Apr. 2, 2008]

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