

for inspection and copying upon request by an employee of EPA or any entity designated by EPA, such as a State, another political subdivision or a Tribe. You must keep the following records:

(1) The name and EPA registration number of the pesticide product.

(2) A description of the nonrefillable container(s) in which the pesticide product is distributed or sold.

(3) At least one of the following records to document compliance with the requirement for closures in §165.25(d) for each nonrefillable container used to distribute or sell the pesticide product that must comply with §165.25(d):

(i) A letter or document from the container supplier that describes the closure.

(ii) A specification about the closure in the contract between the registrant or applicant and the container supplier.

(iii) A copy of EPA’s approval of any non-standard closure.

(4) At least one of the following records pertaining to the container dispensing capability requirements in §165.25(e) for each nonrefillable container used to distribute or sell the pesticide product that must comply with §165.25(e):

(i) Test data or documentation demonstrating that the nonrefillable container meets the standards in §165.25(e) when it contains the pesticide product.

(ii) Test data or documentation demonstrating that a different nonrefillable container meets the standards in §165.25(e) when it contains the pesticide product or even a different pesticide product and a written explanation of why such data or documentation demonstrates that the container meets the standards in §165.25(e) for the pesticide product.

(5) At least one of the following records pertaining to the nonrefillable container residue removal requirement in §165.25(f) if the pesticide product is a flowable concentrate or if EPA specifically requests the records on a case by case basis:

(i) Test data showing that the non-refillable container and pesticide formulation meet the standard in §165.25(f) .

(ii) Test data showing that a different nonrefillable container with the same or a different pesticide formulation meets the standard in §165.25(f), together with a written explanation of why such data demonstrate that the nonrefillable container and pesticide formulation meet the standard in §165.25(f).

§§ 165.28–165.39 [Reserved]

Subpart C—Refillable Container Standards: Container Design

§ 165.40 General provisions.

(a) *What is the purpose of the regulations in this subpart?* The regulations in this subpart establish design and construction requirements for refillable containers used for the distribution or sale of some pesticide products.

(b) *Do I have to comply with the regulations in this subpart?* (1) You must comply with all of the regulations in this subpart if you are a registrant who distributes or sells a pesticide product in refillable containers. If your pesticide product is subject to the regulations in this subpart as set out in §165.43, your pesticide product must be distributed or sold in a refillable container that meets the standards of these regulations. This includes your pesticide products that are repackaged according to subpart D of this part.

(2) You must comply with the regulations in §165.45(f) for stationary pesticide containers if you are a refiller of a pesticide product and you are not the registrant of the pesticide product. If the pesticide product is subject to the regulations in this subpart as set out in §165.43, the stationary pesticide containers used to distribute or sell the product must meet the standards of §165.45(f).

(c) *When do I have to comply?* As of August 16, 2011, all pesticide products distributed or sold by you in refillable containers must be distributed or sold in compliance with these regulations.

§ 165.43 Scope of pesticide products included.

(a) *Are manufacturing use products subject to the regulations in this subpart?* No, the regulations in this subpart do

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not apply to manufacturing use products, as defined in §158.153(h) of this chapter.

(b) *Are plant-incorporated protectants subject to the regulations in this subpart?* No, the regulations in this subpart do not apply to plant-incorporated protectants, as defined in §174.3 of this chapter.

(c) *Which “antimicrobial” pesticide products are not subject to the regulations in this subpart?* The regulations in this subpart do not apply to a pesticide product if it satisfies all of the following conditions:

(1) The pesticide product meets one of the following two criteria:

(i) The pesticide product is an antimicrobial pesticide as defined in FIFRA section 2(mm); or

(ii) The pesticide product: (A) Is intended to: disinfect, sanitize, reduce or mitigate growth or development of microbiological organisms; or protect inanimate objects, industrial processes or systems, surfaces, water, or other chemical substances from contamination, fouling, or deterioration caused by bacteria, viruses, fungi, protozoa, algae, or slime; and

(B) In the intended use is subject to a tolerance under section 408 of the Federal Food, Drug, and Cosmetic Act or a food additive regulation under section 409 of such Act.

(2) The labeling of the pesticide product includes directions for use on a site in at least one of the following antimicrobial product use categories: food handling/storage establishments premises and equipment; commercial, institutional, and industrial premises and equipment; residential and public access premises; medical premises and equipment; human drinking water systems; materials preservatives; industrial processes and water systems; antifouling coatings; wood preservatives; or swimming pools.

(3) The pesticide product is not a hazardous waste as set out in part 261 of this chapter when the pesticide product is intended to be disposed.

(4) EPA has not specifically determined that the pesticide product must be subject to the regulations in this subpart to prevent an unreasonable adverse effect on the environment ac-

ording to the provisions of paragraph (e) of this section.

(d) *Which requirements must an “antimicrobial” swimming pool product comply with if it is not exempt from these regulations?* An antimicrobial swimming pool product that is not exempt by paragraph (a), (b), or (c) of this section must comply with all of the regulations in this subpart except §165.45(d) regarding marking and §165.45(e) regarding openings. For the purposes of this subpart, an antimicrobial swimming pool product is a pesticide product that satisfies both of the following conditions:

(1) The pesticide product is intended to: disinfect, sanitize, reduce or mitigate growth or development of microbiological organisms; or protect inanimate objects, industrial processes or systems, surfaces, water, or other chemical substances from contamination, fouling, or deterioration caused by bacteria, viruses, fungi, protozoa, algae, or slime.

(2) The labeling of the pesticide product includes directions for use on only a site or sites in the antimicrobial product use category of swimming pools.

(e) *How will EPA determine if an “antimicrobial” pesticide product otherwise exempted must be subject to the regulations in this subpart to prevent an unreasonable adverse effect on the environment?* (1) EPA may determine that an antimicrobial pesticide product otherwise exempted by paragraph (c) of this section must be subject to the refillable container regulations in this subpart to prevent an unreasonable adverse effect on the environment if all of the following conditions exist:

(i) EPA obtains information, data or other evidence of a problem with the containers of a certain pesticide product or related group of products.

(ii) The information, data or other evidence is reliable and factual.

(iii) The problem causes or could reasonably be expected to cause an unreasonable adverse effect on the environment.

(iv) Complying with the container regulations could reasonably be expected to eliminate the problem.

(2) If EPA determines that an antimicrobial pesticide product otherwise

exempted by paragraph (c) of this section must be subject to the refillable container regulations in this subpart to prevent an unreasonable adverse effect on the environment, EPA may require, by rule, that the product be distributed or sold in refillable containers that comply with all or some of the requirements in this subpart. Alternatively, EPA may notify the applicant or registrant of its intent to make such a determination. After allowing the applicant or registrant a reasonable amount of time to reply, EPA may require, by notification and as a condition of registration, that the product be distributed or sold in refillable containers that comply with all or some of the requirements in this subpart. For the purpose of the previous sentence, 60 days would be a reasonable amount of time to reply, although EPA may, in its discretion, provide more time. EPA may deny registration or initiate cancellation proceedings if the registrant fails to comply with the refillable container regulations within the time frames established by EPA in the rule or in its notification.

(f) *What other pesticide products are subject to the regulations in this subpart?* The regulations in this subpart apply to all pesticide products other than manufacturing use products, plant-incorporated protectants, and antimicrobial products that are exempt by paragraph (c) of this section. Antimicrobial products covered under by paragraph (d) of this section are subject to the regulations indicated in that section.

(g) *What does "pesticide product" or "pesticide" mean in the rest of this subpart?* In §§165.43(h) through 165.47, the term "pesticide product" or "pesticide" refers only to a pesticide product or a pesticide that is subject to the regulations in this subpart as described in paragraphs (a) through (f) of this section.

(h) *Are there any other exceptions?* (1) The regulations in this subpart do not apply to transport vehicles that contain pesticide in pesticide-holding tanks that are an integral part of the transport vehicle and that are the primary containment for the pesticide.

(2) The regulations in this subpart do not apply to containers that hold pes-

ticides that are gaseous at atmospheric temperature and pressure.

§165.45 Refillable container standards.

(a) *What Department of Transportation (DOT) standards do my refillable containers have to meet under this part if my pesticide product is not a DOT hazardous material?* (1) A pesticide product that does not meet the definition of a hazardous material in 49 CFR 171.8 must be packaged in a refillable container that is designed, constructed, and marked to comply with the requirements of 49 CFR 173.24, 173.24a, 173.24b, 173.28, 173.155, 173.203, 173.213, 173.240(c), 173.240(d), 173.241(c), 173.241(d), part 178, and part 180 that are applicable to a Packing Group III material.

(2) A refiller is not required to comply with 49 CFR 173.28(b)(2) for pesticide products that are not DOT hazardous materials if the refillable container to be reused complies with the refillable container regulations in this subpart and the refilling is done in compliance with the repackaging regulations in subpart D of this part.

(b) *What DOT standards do my refillable containers have to meet under this part if my pesticide product is a DOT hazardous material?* (1) If your pesticide product meets the definition of a hazardous material in 49 CFR 171.8, the DOT requires your pesticide product to be packaged according to 49 CFR parts 171-180.

(2) For the purposes of these regulations, a pesticide product that meets the definition of a hazardous material in 49 CFR 171.8 must be packaged in a refillable container that is designed, constructed, and marked to comply with the requirements of 49 CFR parts 171-180.

(c) *What will EPA do if DOT proposes to change any of the cross-referenced regulations?* If the DOT proposes to change any of the regulations that are incorporated in paragraphs (a) and (b) of this section, EPA will provide notice of the proposed changes and an opportunity to comment in the FEDERAL REGISTER. Following notice and comment, EPA will take final action regarding whether or not to revise its rules, and the extent to which any such