(1) *Toxicity criteria.* (i) Evidence of potentially significant adverse effects have been observed in any applicable toxicity studies.

(ii) Scientifically sound epidemiological or poisoning incident data with a clear cause-effect relationship indicating that adverse health effects may have resulted from exposure to the pesticide.

(2) *Exposure criteria.* (i) Dermal exposure may occur during product use.

(ii) Respiratory exposure may occur during product use.

(c) *Key.* R = Required; CR = Conditionally required; TEP = Typical end-use product.

(d) *Antimicrobial applicator exposure data requirements table.* The following table shows the data requirements for applicator exposure. The test notes appear in paragraph (e) of this section.

TABLE—ANTIMICROBIAL APPLICATOR EXPOSURE DATA REQUIREMENTS

Guideline No.	Data requirements	Use sites		Test substance	Test note No.
		Occupational	Residential		
875.1100	Dermal exposure	R	R	TEP	1, 2, 3, 4
875.1200					
875.1300	Inhalation exposure	R	R	TEP	1, 2, 3, 4
875.1400					
875.1500	Biological monitoring	CR	CR	TEP	1, 2, 3
875.1600	Data reporting and calculations	R	R	TEP	5
875.1700	Product use information	R	R	TEP	

(e) *Test notes.* The following test notes apply to the data requirements in the table to paragraph (d) of this section:

1. Prior to initiation of the study, protocols involving intentional exposure of human subjects must be submitted for review by EPA and then the Human Studies Review Board (HSRB) according to 40 CFR 26.1125. Examples of proposed human study research can be found in various reviews provided by the Human Studies Review Board (*http://www.epa.gov/osa/hsrb/index.htm*).

2. Biological monitoring data may be submitted in addition to, or in lieu of, dermal and inhalation passive dosimetry exposure data, provided the human pharmacokinetics of the pesticide or metabolite/analog compounds (*i.e.*, whichever method is selected as an indicator of body burden or internal dose) allow for the back calculation to the total internal dose.

3. For products with both indoor and outdoor uses, and similar conditions of use, data are generally required for the indoor applications only. However, data for outdoor uses are required if the Agency expects outdoor uses to result in greater exposure than indoor uses (e.g., higher use rates and application frequency, or longer exposure duration, or application methods/equipment create potential for increased dermal or inhalation exposure in outdoor versus indoor use sites). In certain cases, when a pesticide may be used both indoors and outdoors under dissimilar conditions of use, the Agency may require submission of applicator exposure data for both use patterns.

4. EPA will consider waiving this data requirement for antimicrobials applied via closed loading systems if the antimicrobial has a low vapor pressure.

5. Data reporting and calculations are required only if handler exposure data are required.

§ 158.2270 Post-application exposure.

(a) *General.* Subpart B of this part and § 158.2201 describe how to use the table in paragraph (d) of this section to determine the post-application exposure data requirements for antimicrobial pesticide products. The data generated during these studies are used to determine the quantity of pesticide to which people may be exposed after application. Notes that apply to an individual test, including specific conditions, qualifications, or exceptions to the designated test, are listed in paragraph (e) of this section.

(1) Post-application exposure data are required when certain toxicity criteria are met and the human activities associated with the pesticide's use pattern can lead to potential adverse exposures.

(2) The Agency may accept surrogate exposure data estimations and/or modeling estimations from other sources to satisfy exposure data requirements. The surrogate data must meet the basic quality assurance, quality control, good laboratory practice, and other scientific requirements set by EPA. To be acceptable, the Agency must find that the surrogate exposure data estimations have adequate information to address the applicable exposure data requirements and contain adequate monitoring events of acceptable quality. The data must reflect the specific use prescribed on the label and the activity of concern, including formulation type, application methods and rates, type of activity, and other pertinent information.

(b) *Criteria for testing.* Post-application exposure data described in the table to paragraph (d) of this section are required based on toxicity and exposure criteria. Data are required if at least one of the toxicity criteria in paragraph (b)(1) of this section, and at least one of the exposure criteria in paragraph (b)(2) of this section are met.

(1) *Toxicity criteria.* (i) Evidence of potentially significant adverse effects have been observed in any applicable toxicity studies.

(ii) Scientifically sound epidemiological or poisoning incident data with a clear cause-effect relationship indicating that adverse health effects may have resulted from exposure to the pesticide.

(2) *Exposure criteria*—(i) *Outdoor uses.* (A) Occupational human post-application or bystander exposure to residues of antimicrobial pesticides could occur as the result of, but is not limited to, worker reentry into treatment sites, clean-up and equipment maintenance tasks, handling wood preservative-treated wood, or other work-related activity.

(B) Residential human post-application or bystander exposure to residues of antimicrobial pesticides could occur following the application of antimicrobial pesticides to outdoor areas and spaces at residential sites, such as, but not limited to homes, daycare centers, and other public buildings.

(ii) *Indoor uses.* (A) Occupational human post-application or bystander exposure to pesticide residues could occur following the application of the antimicrobial pesticide to indoor spaces or surfaces.

(B) Residential human post-application or bystander exposure to pesticide residues could occur following the application of the antimicrobial pesticide to indoor spaces or surfaces at residential sites, such as, but not limited to homes, daycare centers, hospitals, schools, and other public buildings.

(c) *Key.* R = Required; CR = Conditionally required; NR = Not required; TEP = Typical end-use product.

(d) *Antimicrobial post-application exposure data requirements table.* The following table shows the data requirements for post-application exposure. The test notes appear in paragraph (e) of this section.

TABLE—ANTIMICROBIAL POST-APPLICATION EXPOSURE DATA REQUIREMENTS

Guideline No.	Data requirement	Use sites		Test substance	Test note No.
		Occupational	Residential		
875.2200	Soil residue dissipation	CR	CR	TEP	2, 3
875.2300	Indoor surface residue dissipation	CR	R	TEP	3, 4, 5, 6
875.2400	Dermal exposure	CR	CR	TEP	1, 7, 8
875.2500	Inhalation exposure	CR	CR	TEP	1,7, 8, 9
875.2600	Biological monitoring	CR	CR	TEP	1, 8
875.2700	Product use information	R	R	TEP.	
875.2800	Description of human activity	R	R	TEP.	
875.2900	Data reporting and calculations	R	R	TEP	10

(e) *Test notes.* The following test notes apply to the data requirements in the table to paragraph (d) of this section:

1. Prior to initiation of the study, protocols involving intentional exposure of human subjects must be submitted for review by EPA and then the Human Studies Review Board (HSRB) according to 40 CFR 26.1125. Examples of proposed human study research can be found in various reviews provided by the Human Studies Review Board (HSRB) (*http://www.epa.gov/osa/hsrb/index.htm)*.

2. For residential wood preservative uses, data may be required if soil has the potential to be an important exposure pathway, and soil is in contact with or adjacent to treated wood, including but not limited to decks, play sets, and gazebos,

3. Protocols must be approved by the Agency prior to the initiation of the study.

4. For wood preservatives, data are required for treated wood surfaces where post-application contact with treated wood is anticipated.

5. For occupational uses, data are required if the pesticide may be applied to or around surfaces, and if the human activity data indicate that workers are likely to have post-application dermal contact with treated surfaces while participating in typical activities.

6. Data are required for residential use sites, schools, and daycare institutions. This includes but is not limited to the following: Residential and public access premises; material preservatives (including those used in residential products, including but not limited to clothing and plastic toys) and wood preservatives (when contact with treated wood is likely to occur).

7. Data are required for occupational and residential uses if the human activity data indicate the potential for post-application dermal and/or inhalation exposures while participating in typical activities and no acceptable modeling options are available.

8. Biological monitoring data may be submitted in addition to, or in lieu of, dermal and inhalation passive dosimetry exposure data provided the human pharmacokinetics of the pesticide or metabolite/analog compounds (*i.e.*, whichever method is selected as an indicator of body burden or internal dose) allow for a back-calculation to the total internal dose.

9. Data are required for occupational and residential uses if there is the potential for bystander exposure and the pesticide use could result in respirable and/or inhalable material (e.g., gas, vapor, aerosol, or particulates).

10. Data reporting and calculations are required only if post-application exposure data are required.

§ 158.2280 Environmental fate.

(a) *General.* Subpart B of this part and § 158.2201 describe how to use the table in paragraph (c) of this section to determine the environmental fate data requirements for antimicrobial pesticide products. Notes that apply to an individual test including specific conditions, qualifications, or exceptions are listed in paragraph (d) of this section.

(1) Environmental fate data are required to support the registrations of all end-use and manufacturing-use antimicrobial products.

(2) Data on transformation/degradation products or leachate residues of the parent compound are also required to support registration, if the transformation/degradation products or leachate residues meet one of the following criteria:

(i) More toxic, persistent, or bioaccumulative than the parent;

(ii) Have been shown to cause adverse effects in mammalian or aquatic reproductive studies; or

(iii) The moiety of concern (*i.e.*, functional group in the parent chemical molecule that imparts adverse effects) remains intact.

(3) For the purpose of determining data requirements, the all other use patterns category includes the following use patterns:

(i) Agricultural premises and equipment.

(ii) Food-handling/storage establishments, premises, and equipment.

(iii) Commercial, institutional and industrial premises and equipment.

(iv) Residential and public access premises.

(v) Medical premises and equipment.

(vi) Human drinking water systems.

(vii) Materials preservatives.

(viii) Swimming pools.

(b) *Key.* MP = Manufacturing use product; EP = End-use product; R = Required; CR = Conditionally required;