DATA REQUIREMENTS

Applicants must determine the category and type to determine the applicable data requirements outlined below.

MANUFACTURING USE ONLY PRODUCTS (MUP)

Conventional Products	Acute Toxicology	40 CFR Part 158.500-158.510
	Chronic Toxicology	40 CFR Part 158.500-158.510; FAC §§13121-13135
	Product Chemistry	40 CFR Part 158.300-158.355
Antimicrobial Products	Acute Toxicology	40 CFR Part 158.2230
	Chronic Toxicology	40 CFR Part 158.2230; FAC §§13121-13135
	Product Chemistry	40 CFR Part 158.300-158.355
Biochemical Products	Acute Toxicology	40 CFR Part 158.2050
	Chronic Toxicology	40 CFR Part 158.2230; FAC §§13121-13135
	Product Chemistry	40 CFR Part 158.2030
Microbial Products	Acute Toxicology	40 CFR Part 158.2140
	Chronic Toxicology	40 CFR Part 158.2140; FAC §§13121-13135
	Product Chemistry	40 CFR Part 158.2120

END USE PRODUCTS

Conventional Products	Acute Toxicology	40 CFR Part 158.500-158.510
	Chronic Toxicology	40 CFR Part 158.500-158.510; FAC §§13121-13135
	Product Chemistry	40 CFR Part 158.300-158.355; 3 CCR §6188
	Environmental Fate	40 CFR Part 158.1300; FAC §13143 *(first agricultural use only)*
	Product Performance	40 CFR Part 158.400; 3 CCR §6186
	Phytotoxicity*	40 CFR Part 158.660, 158.1100; 3 CCR §6192
	Ecotoxicology*	40 CFR Part 158.630; 3 CCR §6187, §6192
	Human Exposure*	40 CFR Part 158.1000-158.1070; 3 CCR §6176, §6177, §6183
	Thermogravimetric Analysis	3 CCR §6191 *(liquid agricultural products)*

*if applicable

If the product contains agricultural uses, all the principal functioning agents must either be exempt from tolerance requirements for food and/or feed residues by U.S. EPA, on the U.S. Food and Drug Administration (FDA) list of chemicals Generally Recognized As Safe (GRAS), or allowed as food additives.

DATA REQUIREMENTS

END USE PRODUCTS *continued…*

Home and Garden Products	Acute Toxicology	40 CFR Part 158.500-158.510
	Chronic Toxicology	40 CFR Part 158.500-158.510; FAC §§13121-13135
	Product Chemistry	40 CFR Part 158.300-158.355
	Environmental Fate	40 CFR Part 158.1300 (*residential outdoor –limited)*
	Product Performance	40 CFR Part 158.400; 3 CCR §6186
	Phytotoxicity*	40 CFR Part 158.660; 3 CCR §6192
	Ecotoxicology*	40 CFR Part 158.630; 3 CCR §6187, §6192
*if applicable	Human Exposure*	40 CFR Part 158.1000-158.1070; 3 CCR §6176, §6177, §6183

If the product does not contain a new active ingredient, indoor exposure data may be required.

Microbial Products	Acute Toxicology	40 CFR Part 158.2140
	Chronic Toxicology	40 CFR Part 158.2140; FAC §§13121-13135
	Product Chemistry	40 CFR Part 158.2120
	Environmental Fate*	40 CFR Part 158.2150; FAC §13143
	Product Performance	40 CFR Part 158.2160; 3 CCR §6186
	Phytotoxicity*	40 CFR Part 158.2150; 3 CCR §6192
*if applicable	Ecotoxicology*	40 CFR Part 158.2150; 3 CCR §6187, §6192

Antimicrobial Products	Acute Toxicology	40 CFR Part 158.2230
	Chronic Toxicology	40 CFR Part 158.2230; FAC §§13121-13135
	Product Chemistry	40 CFR Part 158.300-158.355
	Environmental Fate*	40 CFR Part 158.2080; FAC §§13141-13152
	Product Performance	40 CFR Part 158.2220; 3 CCR §6186
	Phytotoxicity*	40 CFR Part 158.2250; 3 CCR §6192
	Ecotoxicology*	40 CFR Part 158.2240; 3 CCR §6187, §6192
	Human Exposure*	40 CFR Part 59.2260-158.2270; 3 CCR §6176, §6177, §6183

An antimicrobial product claiming to control germs but does not list specific organisms, must provide product performance (efficacy) data for bacteria, a fungi (e.g., trichophyton mentagrophytes), and a virus (one enveloped and one non-enveloped). An antimicrobial product claiming to control specific types of germs must provide product performance (efficacy) data for all organisms listed on the label.

DATA REQUIREMENTS

END USE PRODUCTS *continued…*

Biochemical Products	Acute Toxicology	40 CFR Part 158.2050
	Chronic Toxicology	40 CFR Part 158.2050; FAC §§13121-13135
	Product Chemistry	40 CFR Part 158.2030
	Environmental Fate*	40 CFR Part 158.2060; FAC §§13141-13152
	Product Performance	40 CFR Part 158.2070; 3 CCR §6186
	Phytotoxicity*	40 CFR Part 158.1100, §158.2060; 3 CCR §6192
	Ecotoxicology*	40 CFR Part 158.2060; 3 CCR §6187, §6192
*if applicable	Human Exposure*	40 CFR Part 158.2050; 3 CCR §6176, §6177, §6183

ADJUVANT PRODUCTS

Adjuvants do not require federal registration and are only subject to California data requirements.

Manufacturing Use Only Products	Acute Toxicology	3 CCR §6179
	Product Chemistry	3 CCR §6192

End Use Products	Acute Toxicology	3 CCR §6179
	Product Chemistry	3 CCR §6192
	Product Performance	3 CCR §6186
*if applicable	Phytotoxicity*	3 CCR §6192

Water Modifiers (including pH Control Buffers): Applicants must provide data to support label recommended rates or pH levels by demonstrating how much product is required. All buffers, pH adjusters, and water conditioners must show the pH readings from a titration starting below and continuing beyond the label rates suggested. The data must be in table format and may be accompanied by a graph for visual representation. Data conducted in the presence of hard water may be required.

MINIMUM RISK PESTICIDE (SECTION 25B)

Minimum risk pesticides requiring registration are considered as an end use product and in general, require the following:

Minimum Risk Pesticide Products	Acute Toxicology	3 CCR §6192
	Chronic Toxicology	FAC §§13121-13135
	Product Chemistry	3 CCR §6192
	Product Performance	3 CCR §6186
	Phytotoxicity*	3 CCR §6192
*if applicable	Ecotoxicology*	3 CCR §6192

Environmental fate data is typically not required.

DATA REQUIREMENTS

STRUCTURAL PEST CONTROL DEVICES

Applicants must support all structural pest control devices with safety and product performance (efficacy) data. Applicants must also submit structural integrity data including a wood damage study generated using the device. There are currently no test guidelines for devices. Applicants must identify any hazard(s) to applicators, bystanders, or animals associated with the use of the device. Information, data, or studies supporting how consumers mitigate the identified safety hazards should be included.

ASSEMBLY BILL (AB) 1011

The 2005 passage of Assembly Bill (AB) 1011 removed a requirement that had essentially forced DPR to be the arbiter of business disputes over use of scientific data to support new registrations. Such disputes could delay registration actions for years. The bill created a California data-protection and cost-sharing system similar to the federal system. AB 1011 did not change any of DPR's comprehensive requirements for health, safety, and environmental data. However, with its passage, DPR could consider all data on file, regardless of the source. Data-generating companies could no longer keep competitors out of the California market by refusing to grant a letter of authorization when many small companies could not afford to produce the required data themselves. The legislation also authorized DPR to use previous evaluations of pesticide products when evaluating new registrations and label amendments.

Under AB 1011, the registrant may reference an existing product(s) registration in California to satisfy any or all of the data requirements. The reference must include a detailed discussion why the reference product(s) based on items such as the active ingredient, use rate (equivalency based on active ingredient), signal word, precautionary statement, use sites, and pests should be used to satisfy the data requirements.