

US EPA ARCHIVE DOCUMENT



R.E.D. FACTS

* *Bacillus thuringiensis* *

Pesticide Reregistration

All pesticides sold or distributed in the United States must be registered by EPA, based on scientific studies showing that they can be used without posing unreasonable risks to people or the environment. Because of advances in scientific knowledge, the law requires that pesticides which were first registered before November 1, 1984, be reregistered to ensure that they meet today's more stringent standards.

In evaluating pesticides for reregistration, EPA obtains and reviews a complete set of studies from pesticide producers, describing the human health and environmental effects of each pesticide. The Agency develops any mitigation measures or regulatory controls needed to effectively reduce each pesticide's risks. EPA then reregisters pesticides that can be used without posing unreasonable risks to human health or the environment.

When a pesticide is eligible for reregistration, EPA explains the basis for its decision in a Reregistration Eligibility Decision (RED) document. This fact sheet summarizes the information in the RED document for reregistration case 0247, *Bacillus thuringiensis*.

Use Profile

Bacillus thuringiensis is a group of similar bacteria that act as insecticides which are used on growing agricultural crops, harvested crops in storage, ornamentals, bodies of water, and around the home to control various groups of insects, depending on the particular toxins, known as delta-endotoxins, produced by the specific isolate of *Bacillus thuringiensis*.

Formulations include Water Dispersible Granule, Dry Flowable, Aqueous Suspension, Granule, Technical Powder, Dust, Wettable Powder, Emulsifiable Suspension, Aqueous Flowable, Bait, and Oil Flowable.

Bacillus thuringiensis is applied by hand sprayer, water treatment by aerial or ground equipment, soil application by drip or overhead irrigation systems, foliar application by aerial; conventional ground or hand-held equipment and center-pivot irrigation systems, and sprayer or sprinkler cans.

Use practice limitations include Restricted Entry Intervals (REIs) of 4-48 hours for agricultural uses; direct water application is not to be applied

directly to treated, finished drinking water reservoirs or drinking water receptacles; certain terrestrial uses are limited to terrestrial use only due to potential aquatic hazard.

Regulatory History

Bacillus thuringiensis was first registered as a pesticide in the U.S. in 1961. EPA issued a Registration Standard for *Bacillus thuringiensis* in December, 1988 (#540/RS-89-023). An associated Data Call-In (DCI) required additional product analysis, toxicology, and nontarget organism data.

Currently, approximately 180 *Bacillus thuringiensis* products are registered under 15 EPA product code numbers. Two of the product codes no longer have active products.

Isolates of *Bacillus thuringiensis* were originally grouped as registrations under the following subspecies names, each with an EPA product code number: *Bacillus thuringiensis* subspecies *kurstaki*, *Bacillus thuringiensis* subspecies *israelensis*, *Bacillus thuringiensis* subspecies *aizawai* and *Bacillus thuringiensis* subspecies *tenebrionis*. Each isolate is now assigned its own product code number and, as part of the reregistration process, the original registrations will be given new product numbers.

Human Health Assessment

Toxicity/Pathogenicity

To date, no known mammalian health effects have been demonstrated in any infectivity/pathogenicity study. Some strains of *Bacillus thuringiensis* have the potential to produce various toxins that may exhibit toxic symptoms in mammals, however the manufacturing process includes monitoring to prevent these toxins from appearing in products.

Dietary Exposure

An exemption from the requirements for a tolerance is currently established for *Bacillus thuringiensis* in or on beeswax and honey and all other raw agricultural commodities when it is applied either to growing crops, or when it is applied after harvest in accordance with good agricultural practices (40 CFR §180.1011). In addition, there is a tolerance exemption (40 CFR 180.1001(c)) for *Bacillus thuringiensis* fermentations solids and/or solubles. The absence of any toxicological/pathogenicity concerns for oral mammalian exposures to *Bacillus thuringiensis* warrants continuation of these exemptions as long as the proper quality control procedures are performed.

The specific language in the tolerance exemption does not reflect current taxonomy designations for *Bacillus thuringiensis* isolates. In addition, it includes production testing requirements which will now be required under the product analysis data requirements in 40 CFR 158.740(a) and will apply to all registered isolates and all uses of *Bacillus thuringiensis*. To ensure that the production batch tests requirements do not lapse for any products, the Agency will repropose the tolerance exemptions following establishment of the new manufacturing process requirements as described in the Reregistration Eligibility Document.

Environmental Assessment

Toxicity and infectivity risks due to delta-endotoxin effects to nontarget avian, freshwater fish, freshwater aquatic invertebrates, estuarine and marine animals, arthropod predators/parasites, honey bees, annelids and mammalian wildlife will be minimal to nonexistent at the label use rates of registered *B. thuringiensis* active ingredients. However, other toxins which may be produced by *Bacillus thuringiensis* can produce adverse direct toxic effects on nontarget species. Despite the potential for immediate toxic effects on target, and possibly some nontarget, organisms, there is no evidence that *Bacillus thuringiensis* can cause epizootics in the field. therefore, the Agency has concluded that there will be no potential for adverse effects on nontarget organisms for *B. thuringiensis*-based products if the the presence of soluble, heat labile exotoxins and beta-exotoxin is minimized. However, the production process must be closely controlled and monitored or certified to assure these exotoxins are not present at levels that can cause significant adverse ecological effects.

Risk Mitigation

To lessen the potential for the production of various undesirable *Bacillus* exotoxins, EPA is requiring the following risk mitigation measures.

- N Production batch testing is required in order to detect undesirable toxins and to detect contamination by pathogenic bacteria.
- N If the organism is capable of producing beta-exotoxin, the registrant must ensure that none is present in the TGAI and that the product is not put in a medium, including formulated end use products that allows germination and/or growth at any time prior to use.
- N Each manufacturing process must be standardized and certified by a *Daphnia magna* test using a 10 day exposure period.

Additional Data Required

EPA is requiring the submission of a new manufacturing process as an additional generic study for *Bacillus thuringiensis* to confirm its regulatory assessments and conclusions.

The Agency also is requiring product-specific data including product chemistry and acute toxicity studies, a storage stability study, efficacy

studies for public health uses, revised Confidential Statements of Formula (CSFs), and revised labeling for reregistration.

Product Labeling Changes Required

All *Bacillus thuringiensis* end-use products must comply with EPA's current pesticide product labeling requirements and with the following. For a comprehensive list of labeling requirements, please see the *Bacillus thuringiensis* RED document.

Percent Active Ingredient: The percent active ingredient by weight for *Bacillus thuringiensis*-based products is required *in lieu* of potency determinations and a statement must be included "There is no direct relationship between intended activity (potency) and the Percent Active Ingredient by Weight."

Active Ingredients: The label must identify the active ingredient as *Bacillus thuringiensis* and all toxins and/or chemical substances that are present at levels that are known to contribute to the efficacy of the product against the target pest(s) must be listed on the label.

Personal Protective Equipment Requirements: A respiratory protection statement must appear on the label for different uses as follows:

Agricultural Use Products - The personal protective equipment (PPE) section must include the statement: "As a general precaution when exposed to potentially high concentrations of living microbial products such as this, all mixer/loaders and applicators must wear a dust/mist filtering respirator meeting NIOSH standards of at least N-95, R-95, or P-95."

Registrants may add the following engineering control statements to the PPE section if they so choose: "When handlers use closed systems, enclosed cabs, or aircraft in a manner that meets the requirements listed in the Worker Protection Standard (WPS) for agricultural pesticides [40 CFR 170.240(d)(4-6)], the handler PPE requirements may be reduced or modified as specified in the WPS."

PPE for early entry in the Agricultural Use Requirements box remains unaffected.

Non-Agricultural Use Products not Used Around the Home - Either the PPE section or the precautionary statements of the Hazards to Humans and Domestic Animals section must include the statement: "As a general precaution when exposed to potentially high concentrations of living

microbial products such as this, all mixer/loaders and applicators not in enclosed cabs or aircraft must wear a dust/mist filtering respirator meeting NIOSH standards of at least N-95, R-95, or P-95."

Domestic (Home) Use Products - Either the PPE section or the precautionary statements of the Hazards to Humans and Domestic Animals section must include the statement: "As a general precaution when exposed to potentially high concentrations of living microbial products such as this, wear a dust particle mask when mixing or applying this product."

Environmental Hazard Statement: All commercially applied products with directions for outdoor terrestrial uses must have the following statements in the Environmental Hazards section: "Do not apply directly to water, or to areas where surface water is present or to intertidal areas below the mean high water mark. Do not contaminate water when cleaning equipment or disposing of equipment washwaters." This statement should be preceded by "For terrestrial uses," if the product has aquatic sites in addition to terrestrial, forestry (except aerial application) and/or domestic outdoor uses. This revised statement would then not apply to other general use patterns -- aquatic (e.g., mosquito larvicides or adulticides, aquatic herbicides, piscicides, slimicides, etc.), greenhouse and indoor uses. The "For terrestrial uses," qualifier is not allowed on products which allow aerial application to forests but which have no approved aquatic use sites.

For residential consumer products, the required statement is: "Do not apply directly to water. Do not contaminate water when disposing of equipment washwaters or rinsate."

For direct water application uses, the required statement is: "Do not apply directly to treated, finished drinking water reservoirs or drinking water receptacles."

Spray Drift Labeling: The following language must be placed on each product label that can be applied aerially: "Avoiding spray drift at the application site is the responsibility of the applicator. The interaction of many equipment-and-weather-related factors determine the potential for spray drift. The applicator and the grower are responsible for considering all these factors when making decisions."

**Regulatory
Conclusion**

The use of currently registered products containing *Bacillus thuringiensis* in accordance with approved labeling will not pose

unreasonable risks or adverse effects to humans or the environment. Therefore, all uses of these products are eligible for reregistration.

Bacillus thuringiensis products will be reregistered once the required confirmatory generic data, product-specific data, revised Confidential Statements of Formula, and revised labeling are received and accepted by EPA.

For More Information

EPA is requesting public comments on the Reregistration Eligibility Decision (RED) document for *Bacillus thuringiensis* during a 60-day time period, as announced in a Notice of Availability published in the Federal Register. To obtain a copy of the RED document or to submit written comments, please contact the Pesticide Docket, Public Response and Program Resources Branch, Field Operations Division (7506C), Office of Pesticide Programs (OPP), US EPA, Washington, DC 20460, telephone 703-305-5805.

Electronic copies of the RED and this fact sheet can be downloaded from the Pesticide Special Review and Reregistration Information System at 703-308-7224. They also are available on the Internet on EPA's web site at www.epa.gov.

Printed copies of the RED and fact sheet can be obtained from EPA's National Center for Environmental Publications and Information (EPA/NCEPI), PO Box 42419, Cincinnati, OH 45242-0419, telephone 513-489-8190, fax 513-489-8695.

Following the comment period, the *Bacillus thuringiensis* RED document also will be available from the National Technical Information Service (NTIS), 5285 Port Royal Road, Springfield, VA 22161, telephone 703-487-4650.

For more information about EPA's pesticide reregistration program, the *Bacillus thuringiensis* RED, or reregistration of individual products containing *Bacillus thuringiensis*, please contact the Biopesticides and Pollution Prevention Division (7511W), OPP, US EPA, Washington, DC 20460, telephone 703-308-8712.

For information about the health effects of pesticides, or for assistance in recognizing and managing pesticide poisoning symptoms, please contact the National Pesticides Telecommunications Network (NPTN). Call toll-free 1-800-858-7378, between 9:30 am and 7:30 pm Eastern Standard Time, Monday through Friday.