



R.E.D. FACTS

Boric Acid

Pesticide Reregistration

All pesticides sold or used 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 years ago 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 imposes any regulatory controls that are needed to effectively manage each pesticide's risks. EPA then reregisters pesticides that can be used without posing undue hazards to human health or the environment.

When a pesticide is eligible for reregistration, EPA announces this and explains why in a Reregistration Eligibility Decision (RED) document. This fact sheet summarizes the information in the RED document for boric acid and its sodium salts, which includes the seven active ingredients boric acid, sodium tetraborate decahydrate (borax decahydrate), sodium tetraborate pentahydrate (borax pentahydrate), sodium tetraborate (anhydrous borax), disodium octaborate tetrahydrate, disodium octaborate (anhydrous), and sodium metaborate.

Use Profile

Pesticide products containing boric acid and its sodium salts are registered in the U.S. for use as insecticides, fungicides and herbicides. As insecticides, some act as stomach poisons in ants, cockroaches, silverfish and termites, while others abrade the exoskeletons of insects. As herbicides, some cause desiccation or interrupt photosynthesis in plants, while others suppress algae in swimming pools and sewage systems. As fungicides, several are wood preservatives which control decay-producing fungi in lumber and timber products.

Boric acid and its sodium salts are used on several agricultural and many non-agricultural sites including residential, commercial, medical, veterinary, industrial, forestry and food/feed handling areas. They are marketed in many formulations including liquids, soluble and emulsifiable concentrates, granulars, powders, dusts, pellets, tablets, solids, paste, baits, and crystalline rods.

The quantities of boric acid and its sodium salts applied as pesticides are modest compared to amounts used for other, non-pesticidal purposes. Further, boric acid, borax and boron-containing salts are ubiquitous in the environment. Boron occurs naturally in water, fruits, vegetables and forage crops, and is an essential nutrient for plants as well as an essential element for many organisms.

Regulatory History

Boric acid was first registered as a pesticide in the U.S. in 1948. Currently, 189 pesticide products are registered which contain boric acid or one of its sodium salts as an active ingredient.

In February 1986, EPA issued two related documents dated November 1985, the "Boric Acid and Boron Containing Salts Registration Standard" (NTIS #PB87-101903), and a General Registration Standard entitled, "Guidance for the Registration and Reregistration of End-Use Pesticide Products Containing the Insecticidal Uses of Boric Acid." About 43 boric acid products, used indoors for cockroach and silverfish control, were reregistered under the General Registration Standard. Producers of those products need only submit current labels and Confidential Statements of Formula for the products to remain reregistered.

EPA has determined that, because they are of low toxicity and occur naturally, boric acid and its sodium salts should be exempted from the requirement of a tolerance (maximum residue limit) for all raw agricultural commodities. The Agency has established such exemptions and removed the previously established tolerances for residues of boric acid and certain derivatives in cotton seed and citrus fruits (please see 58 FR 44282); two other derivatives will be similarly exempted soon. Because boric acid is registered for crack and crevice use in food and feed handling establishments, the potential exists, though unlikely, for residues to occur in food. EPA therefore is establishing food and feed additive tolerances for boric acid and its sodium salts.

In developing this RED, the active ingredient sodium metaborate was added from another reregistration case. Also, this RED originally was to have included boric oxide as an active ingredient. However, since no registered products currently contain that active ingredient, it is not included.

Human Health Assessment

Human Toxicity

The toxicity of boric acid and its six sodium salts are expected to be similar. Information on the effects of these boron-related compounds in humans, supplemented by data from laboratory animal studies, were used by EPA to evaluate their toxicity.

Boric acid generally is of moderate acute toxicity, and has been placed in Toxicity Category III for most acute effects including oral and

dermal toxicity, and eye and skin irritation. Sodium tetraborate (anhydrous borax) products have been placed in Toxicity Category I indicating a high degree of acute toxicity for eye irritation effects.

A subchronic borax feeding study using dogs resulted in blood and metabolism disorders as well as effects to the testes, endocrine system, brain weight, and size ratios among various organs and glands.

In chronic oncogenicity studies using mice, rats and beagle dogs, boric acid and borax were found not to be carcinogenic; however, testicular effects and decreases in body weight resulted at high dose levels. EPA has classified boric acid as a "Group E" carcinogen, indicating that it shows "evidence of noncarcinogenicity" for humans.

In reproductive and developmental toxicity studies using rats, mice and rabbits, maternal liver and kidney effects and decreased weight gain as well as decreased fetal body weights were observed. In two studies, at the highest dose levels, no litters were produced. Prenatal mortality occurred at the highest dose levels in the rabbit study. Boric acid does not cause mutagenicity.

Dietary Exposure

Tolerances were established for residues of boron resulting from the use of boric acid and its sodium salts on cottonseed (30 ppm) and citrus fruits, postharvest (8 ppm) (please see 40 CFR 180.271.) EPA's review of new toxicology studies raised no concerns. Further, boron occurs naturally in fruits and vegetables at much higher levels (200 to 300 ppm in red cabbage). Therefore, the Agency is exempting these compounds from the requirement of a tolerance and revoking the existing tolerances. EPA is establishing food/feed additive regulations to cover the use of boric acid salts for crack and crevice treatments at food and feed handling establishments (please see 58 FR 44282, and a soon-to-be-issued Federal Register notice).

Occupational and Residential Exposure

Boric acid and its sodium salts are applied both indoors and outdoors, in residential, commercial, medical, veterinary and industrial areas, in food handling establishments, in swimming pools and sewage systems, in lakes, ponds and reservoirs, and in treating wood. Depending on the use site, boric acid may be applied using aircraft, a spreader, airblower, power duster, squeeze applicator, aerosol can or knife/spatula. The potential for dermal and inhalation exposure exists among applicators and people reentering treated areas.

As a prudent measure to reduce any potential risks to handlers, EPA is requiring that all products containing boric acid and its sodium salts (except products for residential use) bear personal protective equipment (PPE) requirements. These must consist of at least the use of a long-sleeved shirt, long pants, shoes, socks and chemical-resistant gloves.

If end-use product labeling already bears PPE requirements that are more protective than these items, the more protective requirements must be retained.

The Worker Protection Standard (WPS) for Agricultural Pesticides (40 CFR 156 and 170) established an interim restricted-entry interval (REI) of 12 hours for boric acid and its sodium salts. EPA is retaining this REI for uses within the scope of the WPS, as a prudent risk mitigation measure to protect workers. During the REI, workers may enter treated areas only under the few narrow exceptions allowed in the WPS.

Human Risk Assessment

Dietary risk is not a concern with boric acid and its sodium salts since no direct food uses are registered and tolerances have been revoked. Applicators and others in treatment areas may be exposed to boric acid and its sodium salts during or after application. However, there is no reasonable expectation that these pesticide uses may constitute a hazard or risk to people involved in, or near to, handling or application activities. Proper care and adhering to label directions and precautions should reduce exposure and any associated risk.

Environmental Assessment

Environmental Fate

No new environmental fate data are required for reregistration of boric acid and its sodium salts because only relatively small amounts of boric acid are used as pesticides, and significant amounts of boron are present naturally in soil and water. Surface soil contains relatively high levels of boron. Boron salts occur naturally in low concentrations in most unpolluted waterways (both surface water and seawater). In some areas, boron occurs in surface waters in concentrations that have been shown to be toxic to commercially important plants.

Ecological Effects

Available studies indicate that technical boric acid is practically nontoxic to birds, fish and aquatic invertebrates, and relatively nontoxic to beneficial insects. The boric acid rights-of-way herbicide use pattern poses a potential risk to aquatic invertebrates, including some that are endangered. However, risk probably is mitigated by the practice of limiting treatment to small strips of land, thereby limiting the amount of contaminated runoff into adjacent aquatic environments.

Boric acid's noncrop herbicidal use also may harm endangered or threatened plants. EPA is requiring three phytotoxicity studies (seed germination, seedling emergence and vegetative vigor) to assess these risks. EPA is deferring endangered species labeling requirements until the Agency publishes the Endangered Species Protection Program plan and guidance for registrants. Labeling will refer users to county bulletins for area-specific use limitations.

Ecological Effects Risk Assessment

EPA's concerns regarding risks to birds, fish and wildlife species are minimal. Boric acid's limited outdoor use patterns, low toxicity, and natural presence in terrestrial and aquatic environments are mitigating factors for any potential risk to nontarget organisms.

Additional Data Required

EPA is requiring three phytotoxicity studies to further assess the risks of boric acid and its sodium salts to non-target plants and endangered plant species. However, these studies are not part of the target data base and do not affect the reregistration eligibility of boric acid and related active ingredients. The Agency also is requiring product-specific data including product chemistry, acute toxicity and efficacy studies, revised Confidential Statements of Formula, and revised product labeling for reregistration.

EPA already has reregistered all 43 boric acid products covered by the General Registration Standard. For these products, only current labeling and Confidential Statement of Formulas must be submitted to ensure that they still meet the criteria set forth in that document.

Product Labeling Changes Required

The labeling of all end-use products containing boric acid and its sodium salts must comply with EPA's current pesticide labeling requirements. In addition:

h Compliance with Worker Protection Standard (WPS) - Any product whose labeling permits use in the production of an agricultural plant on any farm, forest, nursery or greenhouse must comply with the labeling requirements of:

- PR Notice 93-7, "Labeling Revisions Required by the Worker Protection Standard (WPS)," and
- PR Notice 93-11, "Supplemental Guidance for PR Notice 93-7."

Unless specifically directed in the RED, all statements required by these two PR Notices must appear on product labeling exactly as instructed in the Notices. Labels must be revised by April 21, 1994, for products distributed or sold by the primary registrant or supplementally registered distributors, and by October 23, 1995, for products distributed or sold by anyone.

h Personal Protective Equipment (PPE) Requirements

Products NOT Primarily Intended for Home Use

The PPE requirement for handlers of all end-use products except those intended primarily for home use is:

"Applicators and other handlers must wear:

- Long-sleeved shirt and long pants
- Chemical-resistant or waterproof gloves*
- Shoes plus socks

* The glove statement is that established through the instructions in Supplement Three of PR Notice 93-7."

Registrants must compare the PPE requirements in this section with those on their product labeling, and retain the more protective PPE.

Products Primarily Intended for Home Use

No new PPE requirements need to be added. However, any PPE requirements on current product labeling must be retained.

¶ Entry Restrictions

Products NOT Primarily Intended for Home Use

¶ Uses Within the Scope of the WPS: A 12-hour restricted entry interval (REI) is required for all uses within the scope of the WPS, except on products intended primarily for home use. The PPE for early entry should be that required for applicators of boric acid and its sodium salts, except that the requirement for an apron or respirator is waived. Registrants should insert this REI and PPE into the standardized statements required by PR Notice 93-7.

- Sole Active Ingredient Products: Must be revised to adopt the entry restrictions set forth in this section, and any conflicting entry restrictions on current labeling must be removed.
- Multiple Active Ingredient Products: Registrants must compare the entry restrictions set forth in this section to the entry restrictions on their current labeling and retain those which are more protective. A specific time period in hours or days is considered more protective than "until sprays have dried" or "dusts have settled."

¶ Uses Not Within the Scope of the WPS: No new entry restrictions must be added. However, any entry restrictions on current product labeling must be retained.

Products Primarily Intended for Home Use

No new entry restrictions need to be added. However, any entry restrictions on current product labeling must be retained.

¶ Products Under the General Boric Acid Registration Standard

Labels must comply with the format labels issued with the Standard. Five copies of current labeling must be submitted.

¶ Products Not Under the General Registration Standard

Labels must bear the following Environmental Hazards statements, if appropriate:

b Terrestrial Food and Feed Use and Non-Crop Products

"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 disposing of equipment washwaters or rinsate."

b Indoor Use Products with Effluent

"Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans or other waters unless in accordance with the requirements of a National Pollutant Discharge Elimination System (NPDES) permit and the permitting authority has been notified in writing prior to discharge. Do not discharge effluent containing this product to sewer systems without previously notifying the sewage treatment plant authority. For guidance, contact your State Water Board or Regional Office of the EPA."

Labels with uses on carpets and floors to combat fleas, cockroaches, ants and silverfish must bear the following under Directions for Use:

b Use Restrictions

"Children and pets should not be in treatment area until after application is completed. Do not treat pets with this product. Avoid contamination of feed and foodstuff. Avoid contamination of ornamental plants."

b Carpets

"Apply to dry surfaces only. Apply directly on carpets where pets frequently traffic or sleep. Work powder deeply into fibers and mat with a broom or rug rake. Any powder visible after application must be brushed into carpet fibers or removed."

b Upholstery

"Remove loose cushions. Apply along creases and into corners and furniture wells. Do not apply product to exposed fabric. Any product visible after application must be removed."

**Regulatory
Conclusion**

The use of currently registered pesticide products containing boric acid and its sodium salts 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. These products will be reregistered once the required product-specific data, Confidential Statements of Formula and revised labeling are received and accepted by EPA.

Boric acid products that already have been reregistered under the General Registration Standard will remain reregistered as long as current labeling and Confidential Statements of Formula are submitted, and demonstrate that these products still meet the criteria set forth in the Standard.

Boric acid products which also contain other active ingredients will be reregistered only after the other active ingredients are determined to be eligible for reregistration.

**For More
Information**

EPA is requesting public comments on the Reregistration Eligibility Decision (RED) document for boric acid and its sodium salts 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.

Following the comment period, the boric acid RED document 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 boric acid and its sodium salts RED, or reregistration of individual products containing these active ingredients, please contact the Special Review and Reregistration Division (7508W), OPP, US EPA, Washington, DC 20460, telephone 703-308-8000.

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 8:00 am and 6:00 pm Central Time, Monday through Friday.