United States Environmental Protection Agency | Prevention, Pesticides And Toxic Substances (7508W) | EPA-738-F-95-035 April 1996

# R.E.D. FACTS

# Trifluralin

## 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 0179, trifluralin.

## Use Profile

Trifluralin is a preemergent herbicide used to control annual grasses and broadleaf weeds on a variety of food crops and is also currently registered for non-food uses, including residential use sites. The herbicide is formulated as a liquid, emulsifiable concentrate, granular, flowable concentrate, impregnated material, soluble concentrate/liquid, soluble concentrate/solid, and water dispersible granules (dry flowable). Trifluralin is typically applied at the dormant, semi-dormant, preplant, pre-transplant, postplant, preemergence, postemergence, layby, or postharvest stage as a soil-incorporated treatment. It can be applied by aerial equipment, tractor-drawn groundbooms, tractor-drawn granular spreaders, push-type spreaders, "whirly-bird" spreaders, and commercial granular turf spreaders.

## Regulatory History

Trifluralin was first registered in the United States in 1963 as a selective preemergent herbicide. A Registration Standard for trifluralin was issued in April 1987 (NTIS# PB87-201935) and a Data Call-In (DCI) for reentry protection data and mixer/loader/applicator exposure monitoring data for trifluralin products used on turf was issued in March 1995.

EPA initiated a Special Review of trifluralin in August, 1979 because it was found to contain N-nitroso-di-n-propylamine (NDPA or nitrosamine) at levels that met or exceeded the Agency's oncogenic risk criterion. In concluding the Special Review in 1982, EPA required registrants to achieve a 0.5 ppm upper limit for nitrosamines in their technical products. As part of the reregistration eligibility decision on trifluralin, the Agency is requiring that all technical and manufacturing-use registrants submit nitrosamine analysis data to confirm that levels remain at or below the 0.5 ppm limit.

## Human Health Assessment

### Toxicity

Trifluralin technical is classified under Toxicity Category IV (practically non-toxic) for acute oral toxicity and dermal irritation, and Toxicity Category III (slightly toxic) for acute dermal toxicity, acute inhalation toxicity and eye irritation potential. Trifluralin is also classified as a dermal sensitizer.

Trifluralin has been classified as a Group C, possible human carcinogen by the OPP Carcinogenicity Peer Review Committee on April 4, 1986. Limited evidence of carcinogenicity exists in male and female rats based on an increase in combined malignant and benign urinary bladder tumors in females, renal pelvis carcinomas in male rats, and thyroid gland follicular cell tumors in males.

### Dietary Exposure

People may be exposed to residues of trifluralin through the diet. Tolerances or maximum residue limits have been established for residues of trifluralin in many food and feed crops (40 CFR 180.207). EPA has reassessed the trifluralin tolerances and found that some are acceptable, while others must be revoked because of refinements in established crop group tolerances and where no registered uses exist. Tolerances that are revoked because of refinements in crop groups must be replaced with new tolerances for the new crop groupings. The tolerance for residues of trifluralin in/on wheat straw, barley straw, and barley hay should be increased to 0.1 ppm.

Processing studies show that residues of trifluralin concentrate in peppermint oil and spearmint oil. New processing data are required on a confirmatory basis for both peppermint and spearmint oils to determine the actual amount of trifluralin that concentrates in both commodities. Available processing data are sufficient, however, to determine that trifluralin residues in ready-to-eat foods prepared from the mint oils will not exceed existing raw agricultural commodity tolerances. Therefore, the existing tolerance is sufficient to cover the residue levels of trifluralin in food containing mint oil, and a food additive regulation under Section 409 of the Federal Food, Drug, and Cosmetic Act is not necessary.

EPA has assessed the dietary risk posed by trifluralin. The Anticipated Residue Concentration (ARC) for the overall U.S. population represents 1% of the Reference Dose (RfD), or amount believed not to cause adverse effects if consumed daily over a 70-year lifetime. The most highly exposed subgroup, non-nursing infants less than one year old, has an ARC which represents 2% of the RfD. This low fraction of the allowable RfD is considered to be an acceptable dietary exposure risk.

### Occupational and Residential Exposure

Based on current use patterns, handlers (mixers, loaders, and applicators) may be exposed to trifluralin during and after applications in agricultural and other use sites. The occupational/residential cancer exposure risk assessment for all uses indicates a level of risk that does not exceed $10^{-5}$ for occupational handlers or $10^{-7}$ for residential handlers, levels considered reasonable by the Agency.

### Human Risk Assessment

Trifluralin generally is of low acute toxicity, but has been classified as a Group C, possible human carcinogen. Many food crop uses are registered, however, dietary exposure to trifluralin residues in food is at a low level, as is the cancer risk posed to the general population.

Of greater concern is the carcinogenicity risk posed to trifluralin handlers, particularly mixers/loaders/applicators, and field workers who come into contact with treated areas. Exposure and risk to workers will be mitigated by the use of Personal Protective Equipment required by the Worker Protection Standard, including coveralls, chemical-resistant gloves, shoes, and socks. Post-application reentry workers will be required to observe a 12-hour Restricted Entry Interval.

## Environmental Assessment

### Environmental Fate

Trifluralin is moderately persistent and non-mobile in a microbially active soil environment. In general, high persistence and high mobility promote movement into ground water. Because annual average surface water concentrations are not likely to exceed the lifetime health advisory level (2 ug/L) and peak/short term averages are not likely to exceed 1 day and 10 day health advisory levels, exposure/risk from trifluralin in drinking water is expected to be minimal. Although trifluralin has no direct aquatic applications, contamination of surface water may occur by spray drift and under some circumstances, runoff.

### Ecological Effects

Trifluralin is practically non-toxic to birds and mammals on an acute basis. It does not pose acute risks of concern to terrestrial vertebrates, except to those which are endangered species. Also, two of four laboratory bird studies indicate chronic risk, as evidenced by egg shell cracking.

For aquatic animals (fish and invertebrates), trifluralin is considered moderately to highly toxic, and poses acute toxicity risks of concern to endangered species. In addition, laboratory and field studies suggest exposure-related abnormalities in vertebral development, at concentrations below those where acute effects are anticipated. Also, this assessment is based on trifluralin dissolved in the water column and does not take into account trifluralin adsorbed to sediment. Trifluralin adsorbed to sediment may pose a risk for fish species that forage by feeding from sediment, particularly since it has a moderate tendency to bioaccumulate. EPA will explore the need for further monitoring efforts or additional analyses with the registrants of technical trifluralin in order to obtain more refined characterization of the risk to fish.

While semi-aquatic plants exceed the "high risk" level of concern, EPA does not note concerns for effects on aquatic plants resulting from use of trifluralin. To control adverse effects resulting from aerial application of trifluralin, the Agency will require a spray drift advisory as precautionary labeling.

## Additional Data Required

EPA is requiring the following additional generic studies for trifluralin to confirm its regulatory assessments and conclusions: nitrosamine analysis data and peppermint oil and spearmint oil processing data. Residue chemistry data are also required for nongrass forage/fodder/straw/hay and dill uses because the Agency does not have enough information at this time to make an eligibility decision for trifluralin products labeled for those uses.

The Agency also is requiring product-specific data including product chemistry and acute toxicity studies, revised Confidential Statements of Formula (CSFs), and revised labeling for reregistration.

## Product Labeling Changes Required

All trifluralin end-use products must comply with EPA's pesticide product labeling requirements. A 12-hour restricted-entry interval (REI) is required for uses within the scope of the WPS on all trifluralin end-use products. Early-entry personal protective equipment (PPE) required for occupational uses within the scope of the WPS include coveralls, chemical-resistant gloves and socks plus shoes. Aquatic impact labeling is required for all trifluralin end-use products. For all trifluralin products that can be applied aerially, special spray drift prevention language is required.

## Regulatory Conclusion

The use of currently registered products containing trifluralin in accordance with approved labeling will not pose unreasonable risks or adverse effects to humans or the environment. EPA has determined that products containing trifluralin are eligible for reregistration **except** products labeled for use on nongrass forage/fodder/straw/hay and dill. EPA does not have enough information at this time to make an eligibility decision for

trifluralin products labeled for those uses. The Agency is requiring additional data in order to develop a more complete data base regarding these uses of trifluralin.

Before reregistering any trifluralin product, the Agency will review product specific data, Confidential Statements of Formula and revised labeling imposed by the RED. Once this information is accepted, the Agency will reregister trifluralin products bearing only eligible uses. After the Agency receives the data necessary to make a reregistration eligibility decision on nongrass forage/fodder/straw/hay and dill and the data show that these uses will not cause unreasonable adverse effects, the Agency will reregister products bearing these uses. Products which contain active ingredients in addition to trifluralin will be reregistered when all of their other active ingredients also are eligible for reregistration.

## For More Information

EPA is requesting public comments on the Reregistration Eligibility Decision (RED) document for trifluralin 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 gopher server, *GOPHER.EPA.GOV*, or using ftp on *FTP.EPA.GOV*, or using WWW (World Wide Web) on *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 trifluralin 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 trifluralin RED, or reregistration of individual products containing trifluralin, 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 9:30 am and 7:30 pm Eastern Standard Time, Monday through Friday.