US EPA ARCHIVE DOCUMENT

United States Environmental Protection Agency | Prevention, Pesticides And Toxic Substances (7508C) | EPA-738-F-04-001 September 2003

R.E.D. FACTS

Sodium Acifluorfen (Blazer®)

US EPA ARCHIVE DOCUMENT

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. To implement provisions of the Food Quality Protection Act (FQPA) of 1996, EPA considers the special sensitivity of infants and children to pesticides, as well as aggregate exposure of the public to pesticide residues from all sources, and the cumulative effects of pesticides and other compounds with common mechanisms of toxicity. The Agency develops any mitigation measures or regulatory controls needed to effectively reduce each pesticide's risks. EPA then reregisters pesticides that meet current human health and safety standards and 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 2605, sodium acifluorfen.

Use Profile

Sodium acifluorfen is an herbicide for post-emergent weed control on agricultural crops and for residential spot treatment. Formulations include liquid, ready-to-use and soluble concentrate. Sodium acifluorfen is sometimes formulated or packaged with other herbicides, such as bentazon, imazaquin, sethoxydim, or glyphosate. Sodium acifluorfen is applied by aircraft, boom sprayer, and other ground equipment, and by hand held sprayer and trigger bottle.

Regulatory History

Sodium acifluorfen was first registered as a pesticide in the U.S. in 1980. There is no Registration Standard for sodium acifluorfen, but EPA issued three Data Call-Ins (DCIs) in June 1991, March 1995, and October 1995. Currently, 12 sodium acifluorfen products are registered, only one of which is registered for use in residential settings. The residential use product is labeled for application

by spot treatment only. Because this product is packaged in a ready-to-use spray trigger bottle, broadcast treatment is not expected to occur.

Human Health Assessment

Toxicity

Sodium acifluorfen generally has been shown to have low acute oral and dermal toxicity and practically no inhalation toxicity. It is a severe eye irritant and moderate skin irritant but is not a skin sensitizer. Toxicity Categories, which range from I (most toxic) to IV (least toxic), were Category I for acute eye irritation, Category II for skin irritation, Category III for acute oral and dermal toxicity, and Category IV for acute inhalation toxicity for sodium acifluorfen.

Toxicology studies in animals showed kidney effects following exposure to sodium acifluorfen. Because a rat developmental toxicity study showed fetal effects, the 10X FQPA Safety Factor was retained to account for special sensitivity to developing organisms. A confirmatory developmental neurotoxicity study is being required to provide additional information about susceptibility of developing organisms.

Sodium acifluorfen is associated with tumors in rodent studies, but is not genotoxic. In light of new information on the mechanism of tumor formation, EPA recently classified sodium acifluorfen as "likely to be carcinogenic to humans at high enough doses to cause the biochemical and histopathological changes in livers of rodents but unlikely to be carcinogenic at doses below those causing these changes." In other words, sodium acifluorfen is carcinogenic, but only above a certain threshold, at high doses.

Dietary Exposure and Risk

People may be exposed to residues of sodium acifluorfen through food or drinking water. EPA has assessed the dietary risk posed by sodium acifluorfen and found that dietary risk from food and drinking water is below the Agency's level of concern.

Acute and chronic dietary (food) risks are substantially less than 100% of the acute and chronic Population Adjusted Dose (aPAD and cPAD, respectively) for the general U.S. population and all population subgroups. This assessment incorporates the 10X FQPA Safety Factor to account for special sensitivity to infants and children. Because the chronic dietary risk assessment for non-cancer effects is also protective in terms of cancer effects, the chronic dietary risk from cancer is also below the Agency's level of concern.

People may also be exposed to acifluorfen, a degradate of sodium acifluorfen, in drinking water. Because acifluorfen can also be derived from the herbicide lactofen, the Agency conducted an aggregate drinking water assessment that includes acifluorfen from both sodium acifluorfen and lactofen.

EPA estimated drinking water concentrations of total acifluorfen in surface water and ground water using models. Estimated drinking water concentrations for acifluorfen in both surface and groundwater were all below the corresponding

US EPA ARCHIVE DOCUMENT

drinking water level of concern (DWLOC), the maximum concentration of acifluorfen in water that does not exceed EPA's risk concern.

Residential Exposure and Risk

Homeowners or residential handlers can be exposed to sodium acifluorfen by applying it as a spot treatment, or by entering or performing other activities in treated areas. Residential handlers include homeowner applicators performing spot treatment of weeds along driveways, sidewalks, patios, and trees.

For the homeowner use of sodium acifluorfen, EPA is concerned about any Margin of Exposure (MOE) less than 1000, which incorporates the FQPA safety factor to protect females age 13-50 years (childbearing age) and any unborn children. For the only potential exposure scenario, spot treatment with a ready-to-use trigger sprayer, EPA estimated an MOE of 18000, a safety margin large enough so that residential applicator risk is not of concern to the Agency. Furthermore, EPA has no concerns for post-application residential exposure because residential uses are limited to spot treatments, which do not include broadcast application to lawns; therefore, post-application exposure is expected to be negligible.

Occupational Exposure and Risk

Based on current use patterns, agricultural handlers (mixers, loaders, and applicators) may be exposed to sodium acifluorfen during and after normal use of liquid formulations in agricultural settings. EPA assessed occupational exposure to sodium acifluorfen using data from the Pesticide Handler Exposure Database (PHED) and proprietary data, including chemical-specific data submitted by the technical registrant for sodium acifluorfen. Occupational exposure to sodium acifluorfen is not of concern to the Agency for handlers using personal protective equipment (PPE) specified on the current labels. Post application exposures to agricultural workers re-entering treated areas for activities such as scouting, hand weeding, and irrigating is not of concern with the current restricted entry interval (REI) of 48 hours.

FQPA Considerations

FQPA requires that the Agency consider the available information on the special sensitivity of infants and children, as well as the aggregate exposure from food, drinking water, and residential use. The 10X FQPA Safety Factor was retained for sodium acifluorfen to account for potential sensitivity of females age 13-50 years (childbearing age) and any unborn children. For sodium acifluorfen, EPA has determined that the FQPA Safety Factor only applies to this population. An aggregate assessment was conducted to assess combined exposures from food, residential uses, and drinking water. Results of this aggregate assessment indicate that the human health risks from these combined exposures are not of concern; that is, combined risks from all exposures to sodium acifluorfen,

US EPA ARCHIVE DOCUMENT

US EPA ARCHIVE DOCUMENT

including acifluorfen derived from lactofen, fit within the individual pesticide's risk cup.

FQPA also requires the Agency to consider the "available information" concerning the cumulative effects of a particular pesticide's residues and "other substances that have a common mechanism of toxicity." The Agency does not have sufficient information at this time concerning common mechanism issues to determine whether or not sodium acifluorfen shares a common mechanism of toxicity with other substances, including other diphenyl ethers. Therefore, for the purposes of this risk assessment, the Agency has assumed that sodium acifluorfen does not share a common mechanism of toxicity with any other chemicals.

Sodium acifluorfen's primary environmental degradate is the acifluorfen anion, which is also a degradate of another herbicide, lactofen. Because lactofen will degrade to acifluorfen in the environment, the reregistration eligibility decision (RED) for sodium acifluorfen and the tolerance reassessment decision (TRED) for lactofen include assessments aggregating the potential exposure to acifluorfen from the use of both pesticides. This was done in addition to EPA's evaluation of the combined risk from dietary exposure to residues of sodium acifluorfen in food and water and residues resulting from residential use. EPA does not have a risk concern for total aggregate exposure to sodium acifluorfen residues from non-occupational exposure pathways. Therefore, EPA has determined that risk from exposure to sodium acifluorfen is within its own "risk cup." More detailed information can be found in the technical supporting documents for sodium acifluorfen referenced in the RED document.

Tolerance Reassessment

The tolerances for sodium acifluorfen meet the FQPA safety standards for the US population and sensitive populations, including infants and children. Therefore, EPA has reassessed the sodium acifluorfen tolerances and found that 1 tolerance should be increased and 3 tolerances remain the same. The Agency is not able to reassess the tolerance for strawberries until additional confirmatory data are submitted and reviewed. EPA has previously revoked 15 tolerances for livestock commodities because sodium acifluorfen does not concentrate in livestock tissues under the current conditions of use. Also, the current tolerance expression is appropriate and will not change. Because there are no maximum residue limits (MRLs) for sodium acifluorfen, there are no issues of compatibility of US tolerances with Codex MRLs.

Environmental Assessment

Environmental Fate

Sodium acifluorfen is persistent on soils and in aquatic environments and is relatively mobile. It is stable to hydrolysis and does not break down in sunlight. Off-target transport is expected to occur initially through drift and leaching, and later through erosion and runoff. Sodium acifluorfen exists in the anion (negatively charged) form in most agricultural soils. Several factors, including soil pH, soil organic carbon content, and soil iron content determine the extent to

US EPA ARCHIVE DOCUMENT

which acifluorfen adsorbs to soil particles. Therefore, the persistence and mobility of acifluorfen vary with different soil conditions. Because acifluorfen's fate properties showed that it might leach to groundwater, EPA required a small scale prospective ground water monitoring study, which was conducted on soybeans in the central sands of Wisconsin. Acifluorfen and two degradates were monitored; the parent only was detected at concentrations ranging from 1 to 46 ppb (average 7.33 ppb) in 56 out of 283 samples. However, a prospective groundwater study for the related herbicide lactofen showed no detections of acifluorfen.

Ecological Toxicity

Sodium acifluorfen is slightly toxic to fish and aquatic invertebrates and slightly toxic to aquatic plants. It is moderately to practically nontoxic to birds on an acute oral basis. Sodium acifluorfen is associated with reproductive effects in bobwhite quail but not in mallard ducks. Although no data are available on the toxicity of sodium acifluorfen to wild mammals, it is slightly toxic to rats in laboratory studies. No effects were seen in a rat reproductive toxicity study, but effects were seen in a rat developmental toxicity study.

There are no available data on the toxicity of sodium acifluorfen to honeybees; therefore, a honeybee acute toxicity study is required. Limited information is available about the toxicity of sodium acifluorfen to non-target terrestrial plants. However, because of the potential for adverse effects from spray drift, EPA is requiring several label amendments to limit the potential for drift. In addition, the EPA is requiring confirmatory plant toxicity data.

Sodium acifluorfen belongs to a class of compounds known to have a phototropic mode of action in plants and animals. To address the potential for increased toxicity in the presence of light, a confirmatory phototoxicity study is required for sodium acifluorfen.

Risks to Terrestrial and Aquatic Organisms

The Agency conducted a screening level ecological risk assessment to determine the potential impact of sodium acifluorfen use on non-target terrestrial and aquatic organisms. The Agency used modeling to evaluate ecological risks for sodium acifluorfen.

The Agency has minor concerns for chronic risk to birds that feed on short grasses with RQs slightly exceeding the Agency’s level of concern. In a refined assessment, which uses mean residues, RQs range from 0.15 to 1.8, which slightly exceed the level of concern of 1.0.

The Agency has no concerns for the impacts of sodium acifluorfen on mammalian species. In a worst case acute scenario, the acute RQ is less than 0.01 and not of concern. The chronic RQ for mammals is less than 0.05, which does not exceed the Agency’s level of concern for any registered use.

US EPA ARCHIVE DOCUMENT

The Agency has no concerns for the impacts of sodium acifluorfen on aquatic organisms. The risk assessment shows that the RQs for all aquatic species are less than 0.01, which is well below any of EPA's levels of concern.

The Agency's review of sodium acifluorfen resulted in a determination that sodium acifluorfen will have "no effect" on threatened and endangered aquatic organisms, mammals, and birds. Although chronic RQs for birds which eat short grass exceed the level of concern, the only listed endangered species that consumes short grass is the Hawaiian goose, which resides on golf courses in Hawaii. Because sodium acifluorfen is not used in or around this bird's habitat, the Agency concludes that there is "no effect" to endangered birds.

Risk Mitigation

To lessen the risks posed by sodium acifluorfen, EPA is requiring the following risk mitigation measures:

Dietary Risk

- An approved labeled use for strawberries and use directions are required, to maintain the tolerance on strawberries (OPPTS 860.1200).
- A 100-day plant-back interval is necessary for all rotated crops except small grains, which require a 40-day plant-back interval.
- Groundwater label advisory must be maintained on all labels.
- Confirmatory data are required, including a developmental neurotoxicity study and determination of a lower level of quantification (LOQ) for the analytical method.

Residential Risk

- No label changes are necessary.

Occupational Risk

- No label changes are necessary.
- PPE can be reduced to baseline with chemical-resistant gloves for technical sodium acifluorfen. Additional PPE may be required on a product-specific basis.

Ecological Risk

- Label amendments to minimize the potential for spray drift are required.
- Confirmatory data are required, including Aquatic Phototoxicity (modified fish early life stage), Honey Bee Acute Contact, Vegetative Vigor, and Seedling Emergence studies.

Additional Data

EPA is requiring the following additional generic studies for sodium

US EPA ARCHIVE DOCUMENT

Required

acifluorfen to confirm its regulatory assessments and conclusions:

- UV/visible Absorption (OPPTS 830.7050)
- Fish Early Life Stage Toxicity Study (OPPTS 850.1400), modified for Aquatic Phototoxicity
- Honey Bee Acute Contact Study (OPPTS 850.3020)
- Directions for Use (on strawberries) (OPPTS 860.1200)
- Developmental Neurotoxicity Study in Rats (OPPTS 870.6300)

The Agency is also requiring data gaps from previous data call ins be fulfilled. These studies must be submitted to EPA in a timely manner. These include the following data gaps:

- Analytical Methods - Plants (OPPTS Guideline 885.2300) for rice straw, to include a lower LOQ.
- Seed Germination/Seedling Emergence (OPPTS 850.4100)
- Vegetative Vigor (OPPTS 850.4150)

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 sodium acifluorfen end-use products must comply with EPA's current pesticide product labeling requirements and with the following:

- An approved labeled use for strawberries and use directions are required, to maintain the tolerance on strawberries (OPPTS 860.1200).
- A 100-day plant-back interval is necessary for all rotated crops except small grains, which require a 40-day plant-back interval.
- Groundwater label advisory must be maintained on all labels.
- Label amendments to minimize the potential for spray drift are required.
- PPE can be reduced to baseline with chemical-resistant gloves for technical sodium acifluorfen.

For a comprehensive list of labeling requirements, please see Chapter V of the Sodium Acifluorfen RED document.

Regulatory Conclusion

The use of currently registered products containing sodium acifluorfen 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 confirmatory generic data, product specific data, CSFs, and revised labeling are received and accepted by EPA. Products which contain active ingredients in addition to sodium acifluorfen 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 sodium acifluorfen during a 30-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 Information and Records Integrity Branch, Information Resources and Services Division (7502C), Office of Pesticide Programs (OPP), US EPA, Washington, DC 20460, telephone, (703)305-5805.

Electronic copies of the RED and this fact sheet are available on the Internet. See http://www.epa.gov/REDs or http://www.epa.gov/edockets.

Printed copies of the RED and fact sheet can be obtained from EPA's National Service Center for Environmental Publications (EPA/NSCEP), PO Box 42419, Cincinnati, OH 45242-2419, telephone 1-800-490-9198; fax 513-489-8695.

Following the comment period, the Sodium Acifluorfen RED document also will be available from the National Technical Information Service (NTIS), 5285 Port Royal Road, Springfield, VA 22161, telephone 1-800-553-6847, or 703-605-6000.

For more information about EPA's pesticide reregistration program, the Sodium Acifluorfen RED, or reregistration of individual products containing sodium acifluorfen, contact the Special Review and Reregistration Division (7508C), 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 Pesticide Information Center (NPIC). Call toll-free 1-800-858-7378, from 6:30 am to 4:30 pm Pacific Time, or 9:30 am to 7:30 pm Eastern Standard Time, seven days a week. Their internet address is http://npic.orst.edu.

US EPA ARCHIVE DOCUMENT