RED Facts - Nitrapyrin

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EPA R.E.D. FACTS

Nitrapyrin

Pesticide Reregistration

All pesticides sold or distributed in the United States must be registered by EPA (the Agency), 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 registers pesticides that meet current 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 with the Reregistration Eligibility Decision (RED) document. This fact sheet summarizes the information in the RED document.

Use Profile

Nitrapyrin [2-chloro-6-(trichloromethyl) pyridine] is used as a nitrification inhibitor and soil bactericide, and as such, can prevent the loss of nitrogen from soil when used together with urea and nitrogen fertilizer. It is used on corn, sorghum, and wheat. There are no registered residential uses. Nitrapyrin is applied as a broadcast treatment, soil band treatment, soil incorporated broadcast treatment, top dressing treatment, soil injection, and soil sidedress. There are four products containing nitrapyrin (one technical and three end-use products). All end-use product formulations are emulsifiable concentrates.

Regulatory History

Nitrapyrin has been registered in the United States for use as a nitrification inhibitor since 1974.

EPA completed the reassessment for the 30 nitrapyrin tolerances on April 29, 2005. The Agency concluded that there is a reasonable certainty of no harm to any population subgroup from aggregate exposure to nitrapyrin from dietary (food and water) exposure and all other non-occupational sources for which there is reliable information. Some tolerances will be proposed for revocation and three new tolerances will be proposed for establishment.

Human Health Assessment

Toxicity

Nitrapyrin is considered to have low acute toxicity, with the exception of it being a Toxicity Category II eye irritant (Category I being the most severe). Nitrapyrin is placed in the following acute Toxicity Categories: oral III; dermal III; inhalation – cannot be classified; eye irritation II; and, dermal irritation IV. Nitrapyrin is classified as "likely to be a human carcinogen."

Dietary Risks

EPA determined that there is reasonable certainty that no harm to any population subgroup will result from aggregate exposure to nitrapyrin when considering dietary (food and water) exposure. An acute dietary assessment was not conducted, because no appropriate endpoint attributable to a single dose was identified. A chronic dietary assessment was conducted only for the major metabolite, 6-chlorpicolinic acid, because only 6-CPA residues have been detected in crops, and not residues of nitrapyrin. Chronic dietary exposure is expected to be less than 1% of the chronic Population Adjusted Dose (cPAD) for the general U.S. population and all population subgroups, and is therefore below the Agency's level of concern. A cancer dietary risk assessment was not conducted for nitrapyrin because exposure to nitrapyrin, per se, in the diet is negligible (zero) and the cancer endpoint is relevant only to nitrapyrin, per se, and not to 6-CPA.

The drinking water assessment for nitrapyrin and 6-CPA showed that all modeled surface water EECs (which are < 1.71 ppb) and ground water EECs (which are < 278.82 ppb) are less than the chronic DWLOCs (300 or greater) and therefore are not of concern.

Residential and Other Non-Occupational Risks

There are no registered residential uses for nitrapyrin and thus, residential exposure is not expected.

FQPA Considerations

The FQPA Safety Factor (as required by the Food Quality Protection Act of 1996) is intended to provide up to an additional 10-fold safety factor (10X), to protect for special sensitivity in infants and children to specific pesticide residues in food, drinking water, or residential exposures. EPA chose to waive the FQPA safety factor (i.e., reduce it to 1X) based on a conclusion of no increased susceptibility and no residual uncertainty.

EPA did not perform a cumulative risk assessment for nitrapyrin because unlike other pesticides for which EPA has followed a cumulative risk approach based on a common mechanism of toxicity, EPA has not made a common mechanism of toxicity finding for nitrapyrin and any other substances, and nitrapyrin does not appear to produce a toxic metabolite produced by other substances.

Worker Risks

Occupational workers can be exposed to a pesticide through mixing, loading, and/or applying a pesticide, or re-entering treated sites. Occupational handlers of nitrapyrin include the following: individuals who mix and load liquids for groundboom application and applicators who apply sprays via groundboom equipment. Non-cancer risks for all of these potentially exposed populations is measured by a Margin of Exposure (MOE), which determines how close the occupational exposure comes to a No Observed Adverse Effect Level (NOAEL), taken from an animal study. For nitrapyrin, MOEs greater than 100 do not exceed the Agency's level of concern. All short-term and intermediate-term MOEs are not of concern to the Agency when all handlers wear a long sleeved shirt, long pants, shoes plus socks, and chemical resistant gloves. Cancer risks to workers are also at acceptable levels when workers wear the same level of PPE. A postapplication assessment was not conducted for nitrapyrin because the expectation for postapplication exposures is low. This is because nitrapyrin is usually applied pre-plant, and is mechanically soil incorporated before plants mature. Nitrapyrin is a Toxicity Category II eye irritant and protective eye-wear is required for early re-entry post-application activities.

Environmental Assessment

Ecological Fate

Available data indicate that nitrapyrin hydrolyzes and photodegrades rapidly, and hence should not persist in most environments. It is shown to be mobile to moderately mobile in mineral soils, and also prone to volatilize from the application site, so it could leave application sites through leaching or volatilization. 6-CPA, the primary degradate of nitrapyrin, is mobile and degrades via hydroxylation (breaking the pyridine ring) and microbial mineralization.

Ecological Risks

When soil incorporation of nitrapyrin is delayed, there are risks of concern to small and medium birds and mammals. However, the Agency is requiring immediate

soil incorporation for all nitrapyrin products; therefore, no ecological risks of concern remain.

The screening level risk assessment for nitrapyrin resulted in no acute risks above EPA's level of concern to any listed species and no chronic risks above EPA's level of concern for any listed terrestrial organisms if nitrapyrin is incorporated immediately post-treatment. However, at this time, the Agency does not have chronic toxicity data for estuarine aquatic organisms. Therefore, EPA concludes that there is "no effect" from direct acute risks for any listed species and from direct chronic risks for any listed terrestrial species when nitrapyrin is soil incorporated immediately post-treatment. The EPA cannot, at this time, make a clear "no effect" finding for indirect effects or for direct chronic effects for listed estuarine organisms.

Risk Mitigation

Dietary Risk

For all supported commodities, the acute and chronic dietary exposure estimates (food and drinking water) are below the Agency's level of concern. Therefore, no risk mitigation measures are required to address exposure to from food and drinking water.

Occupational Risk

Currently, all nitrapyrin labels require all mixers, loaders, and applicators to wear protective eyewear. Although nitrapyrin is a Toxicity Category II eye irritant, exposures to mixers, loaders, and applicators are expected to be low, since nitrapyrin is applied directly to the soil and soil incorporated well before plants mature. Therefore, protective eyewear will be required for early re-entry workers only, and the re-entry interval of 24 hours will be maintained for nitrapyrin products.

Ecological Risk

EPA has concluded that there are no ecological risks of concern when nitrapyrin is soil incorporated immediately after application. Immediate soil incorporation will be required for all products; therefore, no ecological risks of concern remain.

Additional Data Required

The generic database supporting the reregistration of nitrapyrin has been reviewed and determined to be substantially complete. However, the following additional data requirements have been identified by the Agency as confirmatory and are listed below.

OPPTS GLN 835.3410	Soil Photolysis
OPPTS GLN 835.4300	Aerobic Aquatic Metabolism

OPPTS GLN 835.6100	Terrestrial Field Dissipation
OPPTS GLN 835.2120	Hydrolysis (6-CPA)
OPPTS GLN 835.2240	Aqueous Photolysis (6-CPA)
OPPTS GLN 835.4100	Aerobic Soil Metabolism (6-CPA)
OPPTS GLN 835.4300	Aerobic Aquatic Metabolism (6-CPA)
OPPTS GLN 835.1410	Laboratory volatilization (6-CPA)
OPPTS GLN 850.1350	Estuarine/marine invertebrates, life cycle
OPPTS GLN 850.1400	Estuarine/marine fish, early-life stage

Regulatory Conclusion

The use of currently registered products containing nitrapyrin in accordance with approved labeling will not pose unreasonable risks or adverse effects to humans or the environment if the risk mitigation measures and label changes outlined in the RED are implemented. 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 (CSFs), and revised labeling are received and accepted by EPA. Products that contain ingredients in addition to nitrapyrin will be reregistered when all of their other active ingredients also are reregistered.

For More Information

To obtain a copy of the nitrapyrin RED document, please contact the OPP Public Docket (7502C), US EPA, Ariel Rios Building, 1200 Pennsylvania Avenue, NW, Washington, DC 20460-0001, telephone: (703) 305-5805. Electronic copies of the nitrapyrin RED and all supporting documents are also available on the Agency's electronic docket at http://www.epa.gov/edocket.

For more information about EPA's pesticide reregistration program or the nitrapyrin RED, please contact the U.S. EPA, OPP, Special Review and Reregistration Division (7508C), 1200 Pennsylvania Avenue, NW, Washington, DC 20460, telephone (703) 308-8000.

For more 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 (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. The NPIC internet address is http://www/npic.orst.edu.