United States Environmental Protection Agency Office of Prevention, Pesticides And Toxic Substances (H-7508W) EPA-738-R-95-029 September, 1995

Nuranone

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 Document, or RED. This fact sheet summarizes the information in the RED for *nuranone*.

Use Profile *Nuranone* is the sex pheromone of the female Japanese beetle, *Popillia japonica* (Newman), and is used as a lure for male Japanese beetles in conjunction with a floral lure to attract female Japanese beetles.

Terrestrial Non-Food Crop:

- ¤ Agricultural Crops/Soils and Vegetables
- Orchards and Deciduous Fruit Trees
- ¤ Grapes

Terrestrial Non-Food + Outdoor Residential:

- ¤ Ornamental and/or Shade Trees
- ¤ Ornamental Herbaceous Plants
- ¤ Ornamental Nonflowering Plants
- ¤ Ornamental Woody Shrubs and Vines

Formulation is as impregnated material, 1-1.5 mg nuranone/dispenser.

Equipment: package applicator (trap)

Timing: Summer (when foliage is present)

Usage Less than 500 pounds used annually.

Use limitations: None.

Methods and Maximum Rates of Application:

As an attractant, package traps are placed to allow a maximum application rate of 3.53×10^{-5} pounds active ingredient per acre or 2.204×10^{-7} pounds active ingredient per one foot interval.

Regulatory History History Wiranone was first registered in the United States in 1979. A Data Call-In was issued in September, 1993. There are currently five nuranone products with an active registration. Because nuranone is an insect pheromone, and is used in a trap, the Agency granted reduced data requirements appropriate for a biochemical pesticide, for the original registration. Data on product chemistry and toxicology were received in response to a Data Call-In. The Agency has since waived the requirment for the remaining generic studies.

Human Health
AssessmentToxicityAdequate mammalian toxicology data on nuranone are available for
uses of nuranone in a trap, and will support a Reregistration Eligibility
Decision (RED).

Dietary Exposure

Since there are no food uses of nuranone, dietary exposure is not expected.

Occupational and Residential Exposure

Human exposure is limited to the inhalation route since the product is only available in the controlled-release dispenser. Exposure will be limited if label instructions are followed. The release rate from the trap is comparable to the release from the female Japanese beetle in the environment at peak pest infestations. Based on low exposure and lack of significant toxicological concerns by the inhalation route, occupational exposure studies are not triggered. The studies submitted for inhalation toxicology on the technical grade active ingredient used a dosage that resulted in a rating of Toxicology Category III. Based on a release rate of 0.005 mg/hr from the end-use product, the Agency has placed inhalation toxicity in Toxicology Category IV (>20 mg/L).

Human Risk Assessment

Applicator Exposure

The only route of exposure is inhalation, but risk characterization is inappropriate at this time because of the low exposure, the categorization of inhalation risk as Toxicology Category IV, and the lack of incident reports since 1979. Therefore no additional information and/or toxicology data are required.

Environmental Assessment

Ecological Toxicity Data

Effects to nontarget organisms are not expected because of the specific mode of action of nuranone as a Japanese beetle pheromone. Because nuranone is enclosed in a plastic dispenser within the trap, no exposure to birds, fish, or aquatic organisms is expected. Pheromones in traps are exempted from FIFRA regulation under 40 CFR §152.25 (b), and therefore the data requirements for ecological toxicity testing have been waived..

Environmental Fate

Environmental fate Tier II studies for biochemicals are not imposed unless adverse effects are observed in Tier I Environmental Expression testing with fish and wildlife. The Agency will not impose any environmental fate requirements for reregistration of the current registered products containing nuranone in dispensers.

Exposure and Risk Characterization

Effects to nontarget organisms are not expected because nuranone is specific only for Japanese beetles. Nuranone has a non-toxic mode of action, and with lack of exposure to non-target organisms, no unreasonable adverse effects are expected.

Additional Data Required

The generic data base supporting the reregistration of nuranone for the above eligible uses has been reviewed and determined to be substantially complete. Therefore, there are no further generic data requirements being imposed at this time.

Product Labeling Changes Required

The labels of all registered pesticide products containing nuranone must comply with EPA's current pesticide labeling requirements. In addition:

Use Sites - Those labels that have no use sites specified are only conditionally eligible for reregistration until new labels are submitted with use sites listed.

Application Rate - All labels must give a specific maximum application rate.

Non-Food Use - In conformity with nuranone's non-food use, labels should read, "Do not contaminate water, food, or feed by storage or disposal."

Regulatory Conclusion

Based on the reviews of the generic data for the active ingredient nuranone, the Agency has sufficient information on the health effects of nuranone and on its potential for causing adverse effects in fish and wildlife and the environment. The Agency has determined that nuranone products, labeled and used as specified in this Reregistration Eligibility Decision, will not pose unreasonable risks or adverse effects to humans or the environment. Therefore, the Agency concludes that for products containing nuranone in traps, all uses are eligible for reregistration.

For More Information

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

Following the comment period, the nuranone, RED 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 the nuranone RED or about EPA's pesticide reregistration program, and for information about reregistration of individual products containing this active ingredient, please contact the Biopesticides and Pollution Prevention Division (7501W), OPP, US EPA, Washington, DC 20460, telephone 703-308-8712.