Naphthalene Acetic Acid, Its Salts, Ester and Acetamide R.E.D. FACTS

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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 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 that describe 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 ensures they can be used without posing unreasonable risks to human health and 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 the naphthalene acetate pesticides, Naphthalene Acetic Acid, Its Salts, Ester, and Acetamide, reregistration case number 0379.

Regulatory History

The first naphthalene acetate end-use product (with naphthalene acetamide as the active ingredient), Rootone Brand Rooting Hormone with Fungicide, was registered in 1952. Its labeled use was to stimulate root growth of cuttings of a number of ornamental plants, vines and shrubs, deciduous trees, and evergreens. Seven more naphthalene acetates, including naphthalene acetic acid (NAA), were registered in the early to mid-1960s. There are six active ingredients currently registered as part of the naphthalene acetates case.

In August 1981, EPA published a Registration Standard for “Naphthaleneacetic Acid its, Salts, Ester, and Acetamide.” This document described the uses and established the data requirements to reregister the six supported naphthalene acetates. Tolerances were established for NAA in/on apples, pears, quinces, olives, and pineapples (as the sodium salt); for the ethyl ester of NAA in/on apples, pears, and olives; and for naphthaleneacetamide in/on apples and pears. Data Call-ins (DCIs) were

issued in October and November 1990 and October 1995. The 1990 DCIs mainly restated data requirements of the Registration Standard. The 1995 DCI required data to discern post-application (reentry) occupational and residential exposure.

Use Sites and Patterns

Use Sites

Apples, pears, citrus, olives, and cherries.
Non-bearing fruit and nut trees, ornamental plants, and shade trees.
Residential uses to stimulate root growth (root dips and soil drench) and to control sprouts and sucker growth on non-bearing fruit and ornamental trees.

Use Patterns

- Apples and pears represent approximately 95% of the total active ingredient used annually with all other registered use sites accounting for the remaining 5% of use.

Approximately 20,000 lbs of the naphthalene acetate active ingredients are applied annually in the U.S.

Health Effects

Naphthalene acetates show low acute toxicity, are not mutagenic, and are not expected to be carcinogenic. In laboratory animal studies, the most common effect (acute or short-term) from high exposure to the naphthalene acetates is reduced body weight gain. High exposure chronic effects in animal studies include: vomiting, stomach lesions, and slight sinusoidal histiocytosis in the livers of males. No metabolites (break down substances) of toxicological concern have been identified.

Ecological Effects

- Based on the limited data set available, EPA believes that the toxicity of naphthalene acetates is low to mammals, birds, aquatic organisms, and non-endangered, non-target plants.
- Risks to terrestrial insects cannot be quantified, but the available data do not suggest a substantial potential for adverse effects.

The potential for effects to listed plants from the use of naphthalene acetates on olive trees has been refined to a very small geographic area. However, a species specific assessment for that area has not been completed.

Risk Summary

- The acute and chronic dietary exposure estimates for naphthalene acetates are significantly below EPA's level of concern for all supported commodities.
- High-end estimates of pesticide concentrations in drinking water (from surface or ground water) sources are low and do not pose risks of concern.
- For the highest residential exposure scenario to naphthalene acetates, estimated dermal and inhalation exposure are low and do not pose risks of concern.
- The acute and chronic aggregate risk assessments for naphthalene acetates include exposure from food and drinking water only. Both acute and chronic aggregate risks are not of concern; residential exposures are not aggregated because the toxicity endpoints selected for the dietary routes of exposure and those selected for residential exposures of the naphthalene acetates are not based on common effects.

- Using screening level exposure parameters, all but one occupational handler scenario results in MOEs above the target Margin of Exposure (MOE of 100), and are not of concern using baseline personal protective equipment (PPE). For the one handler scenario of potential concern, when using refined exposure parameters reflecting crop specific use patterns, the MOEs are above 100 and no longer of concern.
- Two occupational post-application reentry exposure scenarios were assessed for the naphthalene acetates. The MOEs for the two post-application exposure scenarios are well above the target MOE of 100 on the day of application and, therefore, not of risk concern.
- No measures are needed to mitigate risk to non-target species and non-endangered, non-target plants.
- Through the Agency's screening-level ecological risk assessment, the potential for effects to listed plants from the use of naphthalene acetates on olive trees has been refined to a very small geographic area. However, a species specific assessment for that area has not been completed. Until such time as that assessment is completed, the Agency cannot draw any definitive conclusions regarding whether the naphthalene acetates have effects on listed plants that may be in the vicinity of olive trees grown in in certain counties in California.

Regulatory Conclusion

The Agency has determined that the naphthalene acetates are eligible for reregistration provided that: (i) current data gaps and additional data needs are addressed and (ii) the label changes outlined in this document are adopted. Accordingly, should a registrant fail to implement any of the label changes or other measures identified in this document, the Agency may take further regulatory action for the naphthalene acetates.

For More Information

Electronic copies of the NAA RED Amendment and all supporting documents are available in public docket EPA-HQ-OPP-2006-0507 located online in the Federal Docket Management System (FDMS) at http://www.regulations.gov.
An electronic copy of the NAA RED Amendment is also available on EPA's pesticide reregistration status website at: http://www.epa.gov/pesticides/reregistration/status_page_n.html.

For more information about EPA's pesticide reregistration program, the NAA RED, or reregistration of individual products containing naphthalene acetates, please contact the Special Review and Reregistration Division (7508P), Office of Pesticide Programs, 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 am Pacific Time, or 9:30 am to 7:30 pm Eastern Standard Time, seven days a week. The NPIC internet address is http://npic.orst.edu.

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