

CARBARYL IRED FACTS [Revised 10/22/04]

Action and Rationale

EPA has assessed the risks of carbaryl and, on June 30, 2003, reached an Interim Reregistration Eligibility Decision (IRED) for this carbamate pesticide. A revised IRED document is being released for public comment on October 27, 2004. A letter from EPA to registrants dated October 22, 2004 precedes the IRED document and explains the revisions made.

Although all uses may not meet the current safety standard and some uses may pose unreasonable risks to human health and the environment, these effects can be mitigated by the measures identified in the Carbaryl IRED. Provided that these risk mitigation measures are adopted, aggregate risks for carbaryl alone will be within acceptable levels and the pesticide will be eligible for reregistration once EPA considers the cumulative risks of the carbamates.

Carbaryl is one of the most widely used broad-spectrum insecticides in agriculture, professional turf management and ornamental production, and residential pet, lawn, and garden markets. Although dietary (food and drinking water) exposures are not of concern, carbaryl does pose risks of concern from uses in and around the home. With mitigation measures discussed in the IRED document, carbaryl will fit into its own "risk cup" and will not pose significant aggregate risk concerns. Carbaryl also poses risks of concern to occupational handlers who mix, load, and apply the pesticide in agricultural sites, and to workers who may be exposed upon re-entering treated agricultural areas. Carbaryl poses ecological risks, particularly to honey bees and aquatic invertebrates. With mitigation measures, these occupational and ecological risks also will not be of concern for reregistration.

EPA's next step under the Food Quality Protection Act of 1996 (FQPA) is to consider the cumulative effects of the carbamate pesticides, which have a common mechanism of toxicity. The interim decision on carbaryl will not be final until carbamate risks have been considered. The carbamate cumulative assessment may result in further risk mitigation measures for carbaryl.

EPA is reviewing the carbamate pesticides to determine whether they meet current health and safety standards. Older carbamates require decisions about their eligibility for reregistration under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA). Carbamates with food, drinking water, residential, and any other non-occupational exposures must also be reassessed to make sure they meet the Federal Food, Drug, and Cosmetic Act (FFDCA) safety standard brought about by FQPA.

The carbaryl decision was made through EPA's public participation process, which increases transparency and maximizes stakeholder involvement in the Agency's development of risk assessments and risk management decisions. EPA worked extensively with numerous affected parties to reach the decisions presented in the Carbaryl IRED document.

Uses

- The insecticide carbaryl, also known by the trade name Sevin, is registered for use on over 400 sites, including agriculture, professional turf management and ornamental production, and residential settings. Carbaryl also is registered for use as a mosquito adulticide. Washington State also has a Special Local Needs registration to control burrowing shimp in oyster beds.
- Carbaryl is used on many agricultural sites including fruit and nut tree, fruit and vegetable, and grain crops. More than 140 tolerances are established for carbaryl. Crops with the greatest amount (most pounds) of annual carbaryl use include apples, pecans, grapes, alfalfa, oranges, and corn. Crops with the highest percent of acres treated include asparagus, okra, cranberries, apples, blueberries, sweet cherries, pumpkins, and strawberries.
- Carbaryl is used by homeowners in residential settings for lawn care, gardening (vegetables and ornamentals), and pet care (pet collars, powders, and dips, in kennels, and on pet sleeping quarters).
- Carbaryl also is used by nursery, landscape, and golf course industries on turf, annuals, perennials, and shrubs.
- A total of approximately 3.9 million pounds of carbaryl active ingredient are sold annually in the U.S.; about half is used in agriculture and half in non-agricultural settings (per 1998 data). The amount of carbaryl usage in agriculture has declined from an average of 1.9 million pounds of active ingredient per year from 1992 through 2001, to 1 to 1.5 million pounds of active ingredient in 2001.

Human Health Effects

- A member of the n-methylcarbamate class of pesticides, carbaryl can cause cholinesterase inhibition in humans; that is, it can overstimulate the nervous system causing nausea, dizziness, confusion, and at high exposures, respiratory paralysis, and death. Carbaryl is a reversible inhibitor of acetylcholinesterase.
- Carbaryl is classified as a likely human carcinogen based on vascular tumors in mice. However, non-cancer risks are seen as the primary risk driver for almost all use scenarios.

Risks

- Dietary Risks – Both acute and chronic (non-cancer and cancer) risks from food are below EPA's level of concern. Screening-level modeling estimates indicate that acute dietary risks from carbaryl residues in surface water sources of drinking water are above the Agency's level

of concern for children and the general population. Due to uncertainties and limitations of model predictions, and based on results of monitoring data, however, actual concentrations of carbaryl in drinking water derived from surface water are likely to be much lower than estimated. Further, EPA expects conventional drinking water treatment to significantly reduce concentrations of carbaryl in drinking water. Chronic (non-cancer and cancer) dietary risks from surface water sources, based on screening-level modeling estimates, are below the Agency's level of concern. Estimated concentrations of carbaryl in ground water sources of drinking water also are below the Agency's level of concern for acute and chronic (non-cancer and cancer) exposure.

- Residential Risks – EPA is concerned about exposures of homeowners using carbaryl lawn, garden, ornamental plant, and pet flea control products, as well as adults doing yard work and toddlers playing on treated lawns. To address the greatest residential handler risk concerns, the carbaryl registrant is voluntarily canceling all pet uses except flea collars. The registrant also has agreed to measures that will effectively mitigate other residential handler risks, such as changes in the amount of active ingredient, packaging, and size of residential use products. Residential post-application risks of concern also will be mitigated by canceling liquid and dust use on pets (allowing flea collars only), and canceling liquid broadcast use on lawns, pending the results of data being developed to refine these risks (spot treatments with liquid products may continue). **[Note: Bayer CropScience submitted data to refine risk estimates for residential lawn liquid broadcast applications. For a description of EPA's preliminary conclusions and ongoing review of this data, see EPA's letter to registrants, dated 10/22/04, at the front of the carbaryl IRED document.]** With these mitigation measures, residential risks will no longer be of concern to the Agency.
- Aggregate Risks – EPA assessed the aggregate risks of exposures to carbaryl through food, drinking water, and residential uses, excluding uses that are being canceled to mitigate risks. The Agency made an interim determination that the human health risks from these combined exposures are within acceptable limits. Although combined exposures appear to “fill” the aggregate risk cup, the drinking water exposure estimate is based on screening-level modeling; actual drinking water exposures are believed to be lower than estimated. Confirmatory data are required to verify the Agency's conclusion that carbaryl does “fit” within the aggregate risk cup.
- Occupational Risks – Carbaryl poses risks of concern to occupational handlers who mix, load, and apply the pesticide in agricultural sites, and to workers who are exposed upon re-entering treated agricultural areas. EPA evaluated 28 major occupational exposure scenarios which resulted in about 140 crop/rate/acreage risk calculations to assess dermal and inhalation exposures to carbaryl handlers. Although several scenarios exceeded the Agency's level of concern, these handler risk concerns can be mitigated by implementing various levels of personal protective equipment and engineering controls, in most cases.

EPA also evaluated post-application (reentry) risks to workers who enter areas previously treated with carbaryl. For workers involved in post-application activities, the Agency assessed risks at various time intervals after application, and then set restricted entry intervals (REIs) to ensure that workers wearing baseline protective clothing could safely reenter treated areas. Because reentry risks are of concern for many crops and scenarios at the currently labeled REI of 12 hours, the REI is being lengthened for many crops.

- Ecological Risks – Carbaryl is very highly toxic on an acute exposure basis to honey bees, estuarine/marine invertebrates, and other aquatic animals, including Atlantic salmon (see next paragraph which addresses endangered species). Based on a screening-level assessment, ecological risks for carbaryl are low and some are of concern. Mitigation measures will help address these risk concerns. In addition, oyster growers in Washington State who use carbaryl to control burrowing shrimp on oyster beds in tidal mudflats have agreed to phase out this use.
- Endangered Species – EPA consulted with the US Fish and Wildlife Service (FWS) in 1989 regarding carbaryl impacts on endangered species. As a result, FWS issued a formal Biological Opinion which identified reasonable and prudent measures and alternatives to mitigate effects of carbaryl use on endangered species. EPA currently is consulting with the National Marine Fisheries Service (NMFS) concerning carbaryl effects on endangered species of salmon and steelhead, and is engaged in a proactive conservation review with FWS and NMFS to determine best processes to assess pesticide impacts on endangered species.

Benefits

- Carbaryl controls a wide spectrum of insect pests across a wide range of use sites, both agricultural and non-agricultural. EPA reviewed carbaryl's use patterns on many sites, and used that information in forming a regulatory position and determining the mitigation measures necessary to address risks of concern. In particular, the Agency considered the benefits associated with the use of carbaryl on citrus, especially in Florida and California, and grapes to evaluate occupational and ecological risks.

Mitigation Measures

Residential

- Residential lawn care liquid broadcast applications will be voluntarily canceled pending the outcome of data that the registrant is voluntarily generating to refine post-application risks. *[See earlier NOTE concerning data submission by Bayer CropScience.]* Liquid broadcast use on sod farms, golf courses, commercial landscape areas, and cemeteries are not being cancelled.

- Home garden/ornamental dust products must be packaged in ready-to-use shaker can containers, with no more than 0.05 lbs. active ingredient per container.
- Certain uses and application methods will be canceled:
 - All pet uses (dusts and liquids) except collars;
 - Aerosol products for various uses;
 - Belly grinder applications of granular and bait products for lawns;
 - Hand applications of granular and bait products for ornamentals and gardens.

Occupational

To address handler risk concerns:

- Certain uses and application methods will be canceled:
 - Wheat use;
 - Pet uses (except pet collars);
 - Applications by hand, spoon, and bellygrinder;
- Maximum application rates are reduced for mosquito control, citrus, and asparagus.
- Aerial applications are prohibited for:
 - Wettable powder formulations;
 - Granular and bait formulations applied to corn (field, pop, and sweet), grain sorghum, alfalfa, rice, and sunflowers.
- Additional personal protective equipment (PPE) and engineering controls are to be used for aerial/chemigation and ground airblast applications, and for use of granular and bait, liquid, and wettable powder formulations.

To address post-application worker risk concerns:

- Current 12-hour restricted entry interval (REI) for carbaryl is being extended for most crop uses;
- Maximum application rates are reduced for citrus (including California citrus and Florida 24(c) registration), asparagus (including both pre-harvest and post-harvest applications), field corn, and stone fruit;
- For brassica crops, leafy vegetables, and table beets and turnips when harvested for greens, use is restricted for applications only within 30 days of crop emergence/ transplanting.

Ecological

- To address toxicity concerns for honey bees, all carbaryl products must carry a bee precaution statement in the Environmental Hazards section of all their labels, as follows:

“This product is highly toxic to bees exposed to direct treatment or residues on blooming crops or weeds. Do not apply this product or allow it to drift to blooming crops or weeds if bees are

visiting the treatment area.”

- Several mitigation measures required to address residential and occupational risks, described above, will also address risks to terrestrial and aquatic organisms, including:
 - Reducing maximum application rates for mosquito control, citrus, asparagus, field corn, and stone fruit;
 - Canceling use on wheat;
 - Prohibiting certain aerial applications;
 - Canceling liquid broadcast applications to home lawns pending EPA review of pharmacokinetic data to refine postapplication risk estimates. [*See earlier NOTE concerning data submission by Bayer CropScience.*]
- Oyster growers in Washington State who use carbaryl to control burrowing shrimp on oyster beds in tidal mudflats are phasing out this use per local agreements and independent of EPA.

Next Steps

- EPA is publishing a Federal Register notice announcing a 60-day public comment period on a revised carbaryl IRED. Revisions are explained in a letter to registrants dated October 22, 2004 at the beginning of the revised IRED document.
- Once EPA has considered the cumulative risks of the carbamate pesticides, the Agency will issue its final tolerance reassessment decision for carbaryl and may need to pursue further risk management measures. The Agency will propose revocation of 9 carbaryl tolerances now, will lower 31 tolerances, and will reassign 49 tolerances to conform with changes in commodity definitions. For all carbamates, including carbaryl, tolerances will not be raised and new tolerances will not be established until cumulative risks have been considered.