United States Environmental Protection Agency | Prevention, Pesticides And Toxic Substances (7508C) | EPA-738-F-98-019 December 1998

R.E.D. FACTS

METHOMYL

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. The Agency develops any mitigation measures or regulatory controls needed to effectively reduce each pesticide's risks. EPA then reregisters pesticides that 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 0028, methomyl, S-methyl N-((methylcarbamoyl)oxy) thioacetimidate.

Use Profile

Methomyl acts as an insecticide against Lepidopterous, suppresses Coleopterous and some Hemipterous insect pests. Methomyl acts as an ovicide against cotton bollworms and budworms. Methomyl is registered on a wide variety of sites including field, vegetable, and orchard crops; turf (sod farms only); livestock quarters; commercial premises; and refuse containers. There are currently 85 tolerances for methomyl. Application types for methomyl include aircraft (fixed-wing and helicopter), high and low volume ground sprayer, ultra low volume sprayer, granule applicator, bait box, brush duster, glove, and shaker can. Methomyl is formulated as a wettable powder, soluble concentrate/liquid, bait/solid, dust, granular, and solid. There are no homeowner uses of methomyl.

Regulatory History

Methomyl was first registered in the United States in October, 1968 for use as an insecticide. E.I. du Pont de Nemours and Company Inc., is the current manufacturer of methomyl. A Registration Standard was issued in April, 1989.

There are 15 methomyl products registered, along with 23 Special Local Needs registrations (SLNs). All methomyl products, except the 1% bait formulations, are classified as restricted use pesticides.

Human Health Assessment

Toxicity

In acute toxicity testing, methomyl places in Toxicity Category I (the highest toxicity category out of four) via the oral route and in eye irritation studies. Methomyl places in Toxicity Category II via the inhalation route. For acute dermal effects methomyl is in Toxicity Category III. For acute skin irritation, methomyl produced no irritation (Category IV).

The Agency has classified methomyl as a Group E, not likely to be carcinogenic to humans via relevant routes of exposure based on the results of the chronic toxicity and carcinogenicity studies conducted with methomyl which showed no evidence of carcinogenicity.

In determining whether to retain, reduce, or remove the 10x FQPA safety factor for infants and children, EPA uses a weight of evidence approach taking into account the completeness and adequacy of the toxicity data base, the nature and severity of the effects observed in pre- and post-natal studies, and exposure. Although the available data provided no indication of increased sensitivity of rats or rabbits to *in utero* and/or postnatal exposure to methomyl, data gaps exist for the acute and subchronic neurotoxicity studies. These studies would have yielded cholinesterase inhibition and field observation behavior data, as well as histopathology of the central and peripheral nervous system which are not presently available for evaluation. The Agency determined that the 10x safety factor to account for increased sensitivity of infants and children should be reduced from 10x to 3x.

The Agency has determined that methomyl is a degradate of thiodicarb, which is a registered pesticide. Therefore, methomyl residues resulting from applications of both thiodicarb and methomyl have been considered in an aggregate risk assessment and compared to appropriate toxicological endpoints for methomyl.

Dietary Exposure and Risk

The RfD for methomyl was calculated to be 0.008 mg/kg/day from a two-year feeding study in dogs with a NOEL of 2.5 mg/kg/day for males and females. The LOEL was 10 mg/kg/day based on histopathological effects in the kidney. An uncertainty factor (UF) of 100 was applied to account for intraspecies variability and interspecies extrapolation together with a safety factor of 3x for FQPA, based on the lack of acute and subchronic neurotoxicity studies (data gaps).

Acute dietary exposure estimates for methomyl alone were compared to the methomyl maternal NOEL of 6 mg/kg/day from a rabbit developmental study based on deaths in dams on days 1-3 after dosing at 16 mg/kg/day. An uncertainty factor (UF) of 100 was applied to account for intraspecies variability and interspecies extrapolation. For calculating the Margin of Exposure (MOE) for methomyl, the FQPA safety factor to account for any special sensitivity to infants and children has been reduced from 10x to 3x to account for the lack of acute and subchronic neurotoxicity studies. Therefore, a MOE of at least 300 is considered acceptable. The acute Monte Carlo dietary analysis for methomyl alone indicates that there are adequate margins of exposure for the U.S. population, children 1 to 6 years old and infants.

For the acute aggregate dietary risk assessment for food, for thiodicarb and methomyl combined, the acute methomyl (6 mg/kg/day) endpoint was used in the risk assessment and compared to residues of methomyl from thiodicarb application plus residues of methomyl from methomyl application. The results of the acute aggregate exposure analyses for food, for thiodicarb and methomyl show that there are adequate margins of exposure for the general U.S. population, children 1 to 6 years of age, and infants.

For the chronic dietary risk assessment for food, for methomyl alone, the RfD for methomyl was used in the risk assessment The DRES chronic analysis for methomyl alone indicates that chronic risk from exposure to methomyl from food sources is not of concern for the same population groups.

For the chronic aggregate dietary risk assessment for food, for thiodicarb and methomyl combined, the RfD for methomyl was used in the risk assessment and compared to residues of methomyl from thiodicarb application plus

residues of methomyl from methomyl application. The results of the chronic aggregate exposure analysis indicate that there are no chronic concerns associated with potential residues of methomyl on foods as the result of application of thiodicarb and methomyl.

The Agency has calculated drinking water levels of concern (DWLOCs) for methomyl. The maximum estimated concentrations of methomyl in surface and ground water are less than the Agency's levels of concern for methomyl in drinking water as a contribution to acute aggregate exposure. The estimated average concentrations of methomyl in surface and ground water are less than OPP's levels of concern for methomyl in drinking water as a contribution to chronic aggregate exposure.

Occupational Exposure and Risk

Handlers (mixers, loaders, and applicators) of methomyl may be exposed to methomyl during and after normal use of liquid, wettable powder, pastes, baits, and dusts formulations. For combined dermal and inhalation exposure, the Agency is requiring the use of additional personal protective equipment and/or the use of engineering controls (water soluble bags). The handler information for methomyl has been integrated with other considerations, including epidemiologic information and handler incident data in determining the required PPE.

The calculations of postapplication exposure and risk indicate that for certain crops, restricted-entry intervals (REIs) based on the short and intermediate term dermal toxicological endpoint should be considered. This information has been integrated with other considerations based on epidemiological information and incident data to determine the required REIs. The required REIs for apple, cotton, grapefruit, lemon, nectarine, oranges, tangelo, and tangerine is 3 days, for peaches 4 days, and for grapes 7 days. For other crops and sites, no additional postapplication mitigation is indicated based on the short and intermediate term dermal endpoint. For these other crops and sites the REI should be based on the acute toxicity of methomyl. Since methomyl is in acute toxicity category 1 for primary eye irritation, a 48 hour REI is indicated.

No data are available for estimating worker's dermal exposures to methomyl following applications of baits. However, EPA recognizes that dermal expo-

sures to methomyl following application of baits are likely to be significantly lower than would result from workers' contact with treated foliage. Therefore, EPA believes that dermal risk from bait applications would not exceed the risks estimated above for foliar contact in "low exposure" crops.

Postapplication risk assessments were not completed for dusts, pastes, and paintbrush applications of methomyl. Dust use scenarios were not assessed, but are believed to be similar to other postapplication agricultural scenarios (i.e., postapplication exposure assessments for sprays on various crops were used to assess risks from dusts). Pastes and paintbrush postapplication exposures are believed to have a low risk due to low potential for exposure (i.e., dermal contact with treated surfaces is likely minimal or nonexistent given the use pattern).

Environmental Assessment

Environmental Fate

Laboratory studies indicate that methomyl is moderately persistent and highly mobile. It is stable to hydrolysis at lower pH's (neutral to acidic) and degrades slowly in alkaline conditions. Methomyl photolyzes quickly in water but more slowly in soils. It is moderately stable to aerobic soil metabolism but degrades more rapidly under anaerobic conditions. In laboratory studies, methomyl does not readily adsorb to soil and has the potential to be very mobile. Field studies show varying dissipation rates of the chemical in soils. Dissipation rates were related primarily to differences in soil moisture content, which may affect the microbial activity, and rainfall/irrigation, which could influence leaching.

Methomyl has been detected in ground water in a prospective ground water monitoring study and in other reported incidences. While it may reach ground water under certain conditions, methomyl will not likely persist under many conditions. Methomyl can contaminate surface water as a result of spray drift during application or by runoff from treated sites. Methomyl would not be expected to persist in clear, shallow waters because of its susceptibility to photolysis. However, methomyl may persist in waters where sunlight penetration is limited (such as in deeper waters or waters with a significant sediment load or populations of organisms such as algae).

Ecological Effects

Laboratory studies show that methomyl is highly toxic to birds and mammals on an acute oral basis but only slightly toxic to birds on a subacute dietary basis. Methomyl poses acute risks to birds and mammals that feed on short and tall grasses, broadleaf plants, and small insects. Methomyl is moderately to highly toxic to freshwater fish and moderately toxic to estuarine fish. In a chronic early life-stage study, methomyl significantly reduced fish larvae survival under flow through conditions.

The major concerns for non-target organisms are chronic risks to non-target mammalian and freshwater invertebrate organisms. Risks to aquatic invertebrates from exposure to methomyl are likely to occur wherever methomyl is used. Toxicity data suggest that aquatic invertebrates are much more sensitive to methomyl contamination than either fresh or salt water fish species. Accumulation of methomyl from repeated applications contributes to the chronic risks.

Ecological Effects Risk Assessment

EPA is generally concerned about the ecological effects to terrestrial wildlife and aquatic organisms posed by exposure to methomyl. The risk assessment for methomyl shows various levels of concern regarding avian risk and mammalian risk from multiple applications of methomyl at short intervals. In addition, most agricultural uses present acute and chronic risks of varying levels to endangered and nonendangered aquatic organisms. The major concerns for non-target organisms are the chronic risks posed by the use of methomyl to non-target mammalian and freshwater invertebrate organisms. With risk mitigation measures in place, the Agency considers these risks acceptable.

Risk Mitigation

To lessen ecological and potential water risks posed by methomyl, the Agency is requiring the following mitigation for methomyl containing products.

- Based on the environmental risk assessment for methomyl, the following advisories are required for methomyl: a labeling statement for potential ground water contamination, a labeling statement to minimize the potential for surface water contamination and labeling statements on manufac-

turing use products and end use products based on the toxicity to nontarget organisms. A bee hazard statement is also required.

- The registrant will reduce the highest seasonal use rates between 11 to 20 percent on eight crops. These crops are generally the crops for which most methomyl is sold.
- The registrant will reduce the single maximum per acre application rate of methomyl by 50% from 1.8 pounds to 0.9 pounds on peaches and commercial sod farms. No methomyl crop use will exceed a single application rate of 0.9 pounds of methomyl per acre.
- A statement supporting the use of an Integrated Pest Management (IPM) plan must be added to the labels.
- Buffer zones have been imposed that will reduce the potential risk to non-target aquatic organisms from spray drift during aerial or ground applications.

Additionally, there are risk mitigation measures required in the RED to protect mixers, loaders, applicators and workers, including water soluble bags, additional PPE and appropriate REIs. For a detailed list, refer to Chapter V. of the methomyl RED document.

Additional Data Required

The generic data base supporting the reregistration of methomyl for the above eligible uses has been reviewed and determined to be substantially complete. For methomyl, the following information is being required:

81-8 Acute neurotoxicity study - rat
82-7 Subchronic neurotoxicity study - rat
72-4(a) Estuarine/marine fish early life stage test
72-4(b) Estuarine/marine invertebrate life-cycle tests
860.1380 Storage Stability Data (formerly 171-4e)
860.1500 Magnitude of the Residue in Crop Plants (formerly 171-4k)
860.1850 Confined Accumulation in Rotational Crops (formerly 165-1)
830.7050 UV/Visible Absorption spectrum

Product Labeling Changes Required

All methomyl end-use products must comply with EPA's current pesticide product labeling requirements and with those labeling requirements

imposed in the Methomyl RED. For a comprehensive list of labeling requirements, please see Section V. of the Methomyl RED document.

Regulatory Conclusion

Based on the reviews of the generic data for the active ingredient methomyl, the Agency has sufficient information on the health effects of methomyl and on its potential for causing adverse effects in fish and wildlife and the environment. The Agency has determined that methomyl products, labeled and used as specified in the Reregistration Eligibility Decision, will not pose unreasonable risks to humans or the environment.

For More Information

EPA is requesting public comments on the Reregistration Eligibility Decision (RED) document for methomyl during a 60-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 Response and Program Resources Branch, Field Operations Division (7506C), 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.

Printed copies of the RED and fact sheet can be obtained from EPA's National Center for Environmental Publications and Information (EPA/NCEPI), PO Box 42419, Cincinnati, OH 45242-0419, telephone 513-489-8190, fax 513-489-8695.

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

For more information about EPA's pesticide reregistration program, the Methomyl RED, or reregistration of individual products containing methomyl, please 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 Telecommunications Network (NPTN). Call toll-free 1-800-858-7378, between 6:30 am and 4:30 pm Pacific Time, Monday through Sunday. The NPTN website is: ace.orst.edu/info/nptn/.