EPA

Pesticide Update

EPA's Office of Chemical Safety and Pollution Prevention

EPA Announces Interim Decisions on Chlorothalonil, Thiophanate-methyl, and Carbendazim

The U.S. Environmental Protection Agency (EPA) is releasing interim decisions (ID) for three pesticides with wide-ranging fungal and antimicrobial properties. Chlorothalonil, thiophanate-methyl (TM), and carbendazim (MBC) all have long histories of use with low potential for resistance, making them highly beneficial for growers of various crops and other antimicrobial applications. These IDs address any risks from these pesticides, providing necessary mitigations to protect both human health and the environment. These IDs reflect updates to the risk mitigation approaches contained in the Proposed Interim Decisions (PID) as a result of public comments, including reducing risks to children, workers and critical species habitat.

Chlorothalonil

Chlorothalonil is a fungicide and antimicrobial with a broad range of uses, including conventional food (e.g., potatoes, peanuts, tomatoes, herbs, berries, wheat, and fruit and nut trees), non-food (e.g., non-residential turf, sod, golf courses, ornamental plants and shrubs, and Christmas trees), and antimicrobial (e.g., building products, adhesives, concrete blocks and surfaces, paints, plaster, metals, and lumber). Chlorothalonil has been used for nearly 60 years with no known pest resistance.

As a part of the registration review process, draft human health and ecological risk assessments were conducted that identified several risks of concern. For human health, both acute and chronic risks driven by drinking water exposure were identified. Acute exposure in laboratory studies demonstrated potential for developmental effects in pregnant individuals and chronic exposure in laboratory studies demonstrated potential for adverse kidney effects. For some of the antimicrobial uses of chlorothalonil, there are also potential inhalation risks for workers handling chlorothalonil during the manufacturing of treated products. Inhalation exposure to chlorothalonil could result in difficulty breathing due to respiratory irritation. Acute and chronic ecological risks of concern were identified for birds, mammals, fish, amphibians, aquatic invertebrates, and aquatic non-vascular plants. For antimicrobial uses, ecological risks of concern were identified from use of chlorothalonil in the papermaking process and chlorothalonil-treated exterior paints.

EPA could not accurately assess the risks to pollinator species because of a lack of data; therefore, the agency is developing a Data Call-In for additional pollinator data to fully evaluate risks to non-target terrestrial invertebrates, especially invertebrate pollinators.

To address the human health and ecological risks identified from the use of chlorothalonil, as well as feedback from the public comment period, EPA identified necessary mitigation measures that will be included in the fungicide's label language including label standardization, reduction in maximum annual application rates, buffers to all conservation and aquatic areas, and prohibiting application to soils that are saturated with water. To address dietary risks resulting from drinking water exposure via groundwater contamination, lower maximum application rates were identified for areas where soils are vulnerable to chlorothalonil leaching into groundwater. To address the risks of concern identified for the antimicrobial uses of chlorothalonil, EPA has determined that new personal protective equipment (PPE) and respirator fit-testing measures are necessary for occupational handlers. Additionally, EPA determined it is necessary to restrict chlorothalonil's use to the dry end of the papermaking process.

In 2011, the National Marine Fisheries Service (NMFS) released a partial Biological Opinion (BiOp) specific to listed Pacific salmon and steelhead species for various pesticides, including chlorothalonil. With this ID, EPA is implementing modifications to the Reasonable and Prudent Alternatives (RPAs) described in the 2011 NMFS BiOp. These modified RPAs reflect the nationwide mitigation measures already proposed in the PID as well as updates to NMFS' approach to reducing pesticide exposure since the original RPAs of the 2011 NMFS BiOp. In addition to the label-wide mitigation measures described above, EPA is requiring a rainfall restriction for applications of chlorothalonil made within the listed salmonid and steelhead ranges and designated critical habitat. Geographically specific mitigation measures will be implemented using the Agency's Bulletins Live! Two system.

Thiophanate-methyl (TM) and Carbendazim (MBC)

TM is a fungicide registered for many agricultural use sites including fruit crops (pome, stone, citrus, grapes, strawberries), nut crops (almonds, pecans, pistachios), vegetables (cucurbits, potatoes, dried and succulent beans, and onions), soybeans, peanuts, canola, crambe, garlic, ginseng, coffee, sugar beet, wheat, and triticale. Seed treatment uses of TM include dried and succulent beans, peanuts, potatoes, soybeans, spinach, triticale, and wheat. TM is also registered for non-agricultural uses on turf and ornamentals. TM degrades rapidly to MBC, which is more stable and persistent than TM. MBC has one conventional use as a tree injection and is also an industrial biocide used in antimicrobial products as a fungicide for materials preservation (e.g., coatings, paints, adhesives, sealants, textiles, and plastics). Both TM and MBC are older, cost-effective active ingredients with low potential to develop resistance.

The draft human health and ecological risk assessments conducted as a part of the registration review process identified several risks of concern. For TM, dietary and aggregate cancer risks (based on the potential for liver tumors) were identified. Non-cancer risks (based on potential thyroid toxicity) and cancer risks were also identified for occupational handlers of TM in some scenarios. For MBC, non-cancer dietary risks were not of concern after considering the effects of the mitigation measures and refinements for uses of TM. EPA also reevaluated the carcinogenic potential of MBC which included new information submitted to support a proposed mode of action for liver tumors in mice. The re-evaluation resulted in a lower concern for potential carcinogenicity in humans,

reclassifying MBC as “Suggestive Evidence of Carcinogenic Potential.” For chemicals with this cancer classification, the chronic non-cancer risk estimates are protective of potential carcinogenicity in humans. Mitigation measures, however, are still needed to address non-cancer risks of concern. Additionally, risks were found to freshwater and estuarine/marine fish and invertebrates, birds, mammals, and terrestrial invertebrates.

EPA has developed measures to mitigate the risks of concern for conventional uses of TM and MBC. To mitigate risks from dietary exposure to TM and MBC in water, EPA is restricting soil applications and reducing application rates of TM. To mitigate risks to occupational handlers of TM, EPA has determined that additional PPE is needed for some scenarios to reduce risk for mixers, loaders, and applicators of TM. To address risks to ecological taxa, EPA is updating label statements and implementing spray drift management measures. The restriction of soil applications and reduction in application rates of TM are also expected to reduce risks to ecological taxa, as less TM is expected to enter the environment when compared with what is currently permitted on labels.

EPA updated some of the Federal Insecticide Fungicide Rodenticide Act Interim Ecological Mitigation measures after considering public comments on the Endangered Species Act Workplan Update and additional EPA and interagency review of the mitigation measures. For TM only, EPA is updating product label language for surface water protection and treated seed, the surface water runoff mitigation menu, and spray drift reduction buffers. For TM and conventional use of MBC, EPA is updating product label language for pollinator stewardship, ecological incident reporting, and endangered species protection requirements.

For antimicrobial uses of MBC, the use in Polyvinyl Chloride (PVC) applications will be removed from pesticide labeling to mitigate residential post-application risks to children 1 to 2 years old. Although the initial risk assessment found potential risk to children who might be exposed to vinyl flooring with MBC-treated PVC, during the public comment period on the risk assessment, the registrant indicated that MBC is only used on the adhesive on the back of the vinyl flooring and is not used on the top layers of vinyl flooring that would result in dermal exposures to residents who have MBC-treated floors, thus minimizing potential exposure. In subsequent discussion with the registrant to clarify the use on the label and ensure the potential risk was mitigated, the registrant decided to cancel the use. To mitigate inhalation and dermal risks to occupational handlers applying paint, EPA determined that rate reductions are needed for paint preservative uses. EPA also determined that application rate reductions are needed for caulks, plasters, sealants, and adhesives to mitigate inhalation and dermal risks for workers applying these treated materials. EPA also determined that closed loading for liquid formulations and closed loading or water-soluble packaging is needed for powder formulations of MBC as a materials preservative to mitigate inhalation and dermal risks to occupational handlers mixing MBC into materials. EPA has also determined that mitigation language is needed to clarify that MBC may only be used in the dry end of the pulp and paper process to mitigate risks to freshwater fish and invertebrates and aquatic non-vascular plants.

The IDs are available for review in dockets EPA-HQ-OPP-2017-0751 (Chlorothalonil) and EPA-HQ-OPP-2014-0004 (TM and MBC) at www.regulations.gov.