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Prevention, Pesticides
And Toxic Substances
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EPA R.E.D. FACTS

Thiophanate-Methyl

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. To implement provisions of the Food Quality Protection Act 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 the safety standard of the FQPA and 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 2680, thiophanate-methyl (TM) and its primary metabolite carbendazim (methyl 2-benzimidazole carbamate) or MBC.

Use Profile

TM is a systemic fungicide used on a variety of tree, vine, and root crops, as well as on canola and wheat. Residential homeowners may use TM on lawns and ornamentals. MBC is registered as a systemic fungicide in paints in residential settings, but has no registered food uses in the US, nor import tolerances. TM formulations include dust, granular, wettable powder, water-dispersible granular, and flowable concentrate. TM may be applied with aerial, chemigation or ground equipment (broadcast, band, or soil drench); as a dip treatment for cut flowers, rose budwood, or nursery stock; and as a seed treatment for peanuts and potato pieces. Handheld equipment may be used on turf and ornamentals. The majority of the crops are treated with postemergent broadcast applications.

Regulatory History

TM was first registered as a pesticide in the U.S. in 1973 for use as a fungicide. EPA issued a Registration Standard for TM in March, 1996.

Subsequent Data Call-Ins (DCIs) were issued in 1991, 1995, and 1996 for TM. There are Section 3 registrations, Section 18 emergency exemptions, and Section 24(c) Special Local Needs registrations concurrently registered under FIFRA.

Human Health Assessment

Toxicity

TM generally has been shown to have low acute oral/dermal/inhalation toxicity (toxicity categories III/IV). TM is not an irritant to the skin and only a slight occular irritant (toxicity category IV) and is a skin sensitizer. MBC generally has been shown to also have low acute oral/dermal/inhalation toxicity (toxicity categories III/IV). MBC is only a slight irritant to skin (toxicity category IV) and minimal to no irritation (toxicity category III) and is not a skin sensitizer.

The liver and thyroid are the primary target organs of TM and MBC in several species following subchronic or chronic dietary exposure. The testes is also a known target organ of MBC. TM is classified as "likely to be carcinogenic to humans based on dose-dependent increases in liver tumors in male and female mice. MBC is classified as a possible human carcinogen based on hepatocellular tumors in female mice. Developmental toxicity based on decreased fetal body weight and increases in skeletal variations was observed in the fetuses of rabbits exposed to TM. MBC was associated with adverse reproductive effects in rats.

Dietary Exposure (Food and Water)

People may be exposed to residues of TM or MBC through the diet. Tolerances or maximum residue limits have been established for almond, apple, apricot, banana, bean, blueberry, canola seed, cattle, celery, cherry, cucumber, egg, goat, grape, hog, horse, melon, milk, nectarine, onion, pecan, peach, peanut, pistachio, pear, plum, potato, poultry, pumpkin, sheep, soybean, squash, strawberry, sugar beet, and wheat.

EPA has assessed the dietary risk posed by TM and MBC.

For the overall U.S. population and all subgroups as measured by the Population Adjusted Dose (PAD), all acute and chronic food risks are below the EPA's level of concern for all population subgroups for both TM and MBC. The lifetime cancer risk estimates range are generally below the EPA's level of concern.

Occupational and Residential Exposure

Based on current use patterns, occupational handlers (mixer/loader/applicators) can become exposed while mixing, loading and applying TM formulations (e.g., dry flowables, dusts, granular, liquid flowables, and wettable powders) to a variety of agricultural crops, turf and ornamental plants. Handlers are not expected to be exposed to MBC, because MBC is formed during the environmental degradation of TM. Workers can also become exposed to TM

and MBC residues from treated foliage from re-entering treated fields, orchards, nurseries, greenhouses, or golf courses. Some potential re-entry exposure or postapplication scenarios of concern include: scouting, irrigation, harvesting, pruning, transplanting, thinning, and handling treated seed and seed pieces.

Occupational handler exposure assessments are completed by EPA using a baseline exposure scenario and, if required, increasing levels of mitigation (PPE and engineering controls) to achieve an adequate margin of exposure (MOE). For the case of TM, the level of is 100. Many scenarios are at acceptable levels of risk with the addition of a single layer of PPE (which includes chemical resistant gloves). However, mixing/loading wettable powder formulations for aerial/chemigation application requires the use of engineering controls (i.e., water soluble bags) to reach an acceptable risk level. Based on the cancer risk estimates, all handler risk estimates were in the acceptable range at below 1×10^{-4} and most were below 3×10^{-6} when adding either protective equipment or engineering controls.

For occupational postapplication activities, EPA calculates the number of days that must elapse after pesticide application until residues dissipate and risk (either non-cancer or cancer) to a worker falls below the target risk level. To address potential postapplication cancer risks to TM, the Agency has to adjust some of the REIs.

Residential handlers can apply TM formulated products to lawn and ornamentals. Residential risk mitigation for lawn and ornamental products was implemented before publication of this RED. MOEs and cancer risks are not of concern using the new label rates proposed. Therefore, no further risk mitigation is necessary.

Residential handlers may become exposed to MBC in paints, adhesives, and caulks. For the three painting scenarios assessed, all short-term dermal risks exceeded EPA's level of concern (i.e., MOEs<1,000) for residential handlers, with dermal MOEs ranging from 620-750. Mitigation to reduce the concentration of MBC in indoor paints is required to reduce the dermal exposure. Inhalation risk exposure for painters were initially of concern for airless sprayer. However, using the latest registrant submitted inhalation study indicate that MOEs are below EPA's level of concern (i.e., MOEs>1,000). It should be noted however that the Agency will include label amendments to reduce the concentration of MBC in paint based on dermal MOE which exceed the Agency's level of concern (i.e, MOEs<1,000). All residential cancer risk estimates for residential handlers were less than 1×10^{-6} and therefore not of concern. Postapplication risks (dermal and inhalation) were all below EPA's level of concern.

For residential postapplication to TM, two short-term MOEs for children playing on treated turf were less than 300 and therefore, exceed EPA's level of concern (MOEs range from 31 to 250) for hand to mouth activities and incidental granular ingestion based on a screening level assessment. Dermal MOEs are acceptable, however. The aggregate MOE for children based on combined dermal

and oral exposures are also below 300 (total MOE= 170 for treated turf). Application rates to turf are being reduced to address these risks.

Human Risk Assessment

TM and MBC are of low acute toxicity, but cause liver and thyroid effects in animal studies and has been classified as a probable human carcinogen. MBC has also been shown to cause adverse testicular effects. However, dietary exposure to TM residues in food and water is extremely low as is the cancer risk posed to the general population.

Of greater concern is the risk posed to pesticide workers, particularly mixers/loaders/applicators, and field workers who come into contact with treated foliage/crops/lawns/turf/etc. following application of this pesticide. Exposure and risk to workers will be mitigated by the use of PPE required by the WPS, supplemented by mitigation measures as required by this RED.

For post-application reentry, workers will be required to observe a 3-day Restricted Entry Intervals (REIs) for almonds and peanuts; 2-day REIs for apples, cherries, peaches, nectarines, apricots, and plums/prunes; 24-hour REIs for strawberries, blueberries, wheat, celery, cucurbits, soybeans, and green beans and 12-hour REIs for woody ornamentals.

FQPA Considerations

As part of the FQPA tolerance reassessment process, EPA assessed the risks associated with this pesticide. EPA has determined that risk from dietary exposure to TM is within it own "risk cup". An aggregate assessment was conducted for exposures through food, drinking water, and residential uses. The Agency has determined that the human health risks from these combined exposures are within acceptable levels. In other words, EPA has concluded that the tolerances for TM meet the FQPA safety standards. In reaching this determination, EPA has considered the available information on the special sensitivity of infants and children, as well as the chronic and acute food exposure.

Some of the tolerance limits will change because recent residue data may indicate that either a lower or higher value for the tolerance is needed. In addition, some tolerances have been revoked because they were either no longer a regulated commodity or significant livestock feed item, some of the tolerances were voluntarily canceled, some of the registered products used to establish tolerances were canceled and some of the older tolerances have been reassigned into a group tolerance.

Environmental Assessment

EPA's ecological risk assessment suggests that TM dose not pose a high acute risk to terrestrial or aquatic organisms. Acute high risk levels of concern (LOCs) are not exceeded for any registered uses except for use on golf course, which may present acute risk to small animals. Golf course uses of TM also appear

to generate acute concerns for endangered species.

TM is not stable or persistent in the environment, but transforms to MBC within a matter of days whether on foliage, in soil, or in water. Both photolysis and hydrolysis are important routes of degradation. MBC is persistent and mobile in the environment. Metabolism of MBC under aerobic and anaerobic conditions in both soil and water proceed at a very slow rate. Because of the rapid transformation of TM to MBC, MBC residue values were used in the TM chronic ecological risk assessment. EPA's ecological risk assessment suggests that TM/MBC is expected to pose a chronic risk to endangered birds, mammals, aquatic animals, and aquatic plants under most of the registered use scenarios. The acute risks to small mammals from golf course use and chronic risks to endangered species listed here are based on EPA's screening level assessment do not constitute "may affect" findings under the ESA.

Risk Mitigation

To mitigate human health risks of concern posed by TM, EPA is requiring the following risk mitigation measures:

- Reduce turf application rates in residential/public areas (e.g. parks, athletic fields, lawns) to 2.74 lbs ai/acre, maximum of 10.88 lbs ai/acre per year, 14 day retreatment interval.
- Reduce golf course turf application rates to 8.16 lbs ai/acre/application. 21.8 lbs ai/acre/year, 14 day retreatment interval for tees and greens.
- Reduce golf course turf application rates to 5.45 lbs ai/acre/year, except in Florida, which has a maximum annual rate of 2.72 lbs ai/acre on fairways.
- Require wettable powder formulations labeled for aerial/chemigation applications to be packaged in **water soluble bags**.
- Require wettable powder formulations <u>not</u> packaged in water soluble bags to specifically prohibit aerial/chemigation use.
- Require an **enclosed cab** for planters/operators while planting potato seed that has been treated with dust
- Require **double-layer PPE, chemical-resistant gloves, and a chemical-resistant apron** to be worn when applying dip treatment and mixing/loading/applying dip treatment.
- **Single-layer PPE (Baseline) and chemical-resistant gloves** must be worn when handlers are performing certain tasks (see section IV of the RED).
- **Single-layer PPE (Baseline)** must be worn by handlers during certain tasks (see section IV of the RED)
- The Agency has determined that significant risk reduction would occur by **reducing the maximum allowable rate on cut flowers to 0.5 lb ai/acre**. which is currently the typical rate at which TM is applied to cut flowers.
- For post-application reentry, workers will be required to observe a 3-day Restricted Entry Intervals (REIs) for almonds and peanuts; 2-day REIs for apples, cherries, peaches, nectarines, apricots, and plums/prunes; 24-hour

REIs for strawberries, blueberries, wheat, celery, cucurbits, soybeans, and green beans and 12-hour REIs for woody ornamentals.

- The maximum single application rate for ornamentals is 1.8 lb ai/acre for homeowners using spray products.
- Only granular formulations are now available to residents for broadcast lawn treatment. Use of liquid formulations for broadcast turf/lawn use is restricted to commercial pest control operators (PCOs).
- Product labels were revised to specifically prohibit belly grinder and hand application methods.
- PCO treatment of backyard fruit trees will be allowed only up to fruit set.
- As a result of ecological mitigation activities, application rates and applications per year have been reduced as follows: aerial application of grapes and apples 0.7 lb ai/acre and 4 applications per year; aerial application of soybeans 0.7 lb ai/acre and 2 applications per year; ground application of golf course fairways 5.45 lb ai/acre and 1 application per year; aerial application of potatoes 0.93 lb ai/acre and 3 allowable applications per year; and ground application of onions 1.4 lb ai/acre and 1 application per year.
- Reduce the concentration of MBC in paint from 0.5% to 0.35% based on dermal MOEs which exceed the Agency's level of concern (i.e, MOEs<1,000).

Additional Data Required

EPA is requiring the following additional generic studies for TM to confirm its regulatory assessments and conclusions:

Toxicology Data

TM:

OPPTS GLN 870.6200 - Rat Acute and Subchronic Neurotoxicity Screening Studies

OPPTS GLN 870.6300 - Developmental Neurotoxicity Study 'Reserved' pending the results of the above studies.

OPPTS GLN 870.3465 - 90-day Subchronic Inhalation Toxicity Test, Rat

MBC:

OPPTS GLN 870.3200 - Repeated Dose Dermal Toxicity Test (21 Day - rat)

OPPTS GLN 870.6300 - Developmental Neurotoxicity Study in rats

OPPTS GLN 870.3800 - 2-Generation Reproduction and Fertility Effects, Rat

Product Chemistry Data

OPPTS GLN 830.1620 - Starting Materials and Manufacturing Process

OPPTS GLN 830.1670 - Discussion of Formation of Impurities

OPPTS GLN 830.6313 - Stability

OPPTS GLN 830.7050 - UV/Visible Absorption

Residue Chemistry Data

OPPTS GLN 860.1200 - Directions for Use

OPPTS GLN 860.1340 - Residue Analytical Methods

OPPTS GLN 860.1360 - Multiresidue Method Testing

OPPTS GLN 860.1380 - Storage Stability Data

OPPTS GLN 860.1500 - Magnitude of the Residue in Plants

OPPTS GLN 860.1520 - Magnitude of the Residue in Processed Food/Feed

Occupational Exposure Data

Handlers:

OPPTS GLN 875.1100 - Dermal Exposure: Outdoor (Mixing/loading/applying WP/DF solution as a seedling or bulb treatment)

OPPTS GLN 875.1200 - Dermal Exposure: Indoor (Mixing/loading/applying wettable powder; greenhouse use)

OPPTS GLN 875.1300 - Inhalation Exposure: Outdoor (Mixing/loading/applying WP/DF solution as a seedling or bulb treatment)

OPPTS GLN 875.1400 - Inhalation Exposure: Indoor (Mixing/loading/applying wettable powder; greenhouse use)

Post-application Workers:

OPPTS GLN 875.2400 - Dermal Exposure - Handling treated seed & seedlings; sorting, packing crops; cultivating, transplanting in treated soil.

OPPTS GLN 875.2800 - Descriptions of human activity - Handling treated seed & seedlings; sorting, packing crops; cultivating, transplanting in treated soil.

The Agency also is requiring product-specific data including product chemistry and acute toxicity studies, revised Confidential Statements of Formula (CSFs), and revised labeling for reregistration.

Product Labeling Changes Required

All TM and MBC end-use products must comply with EPA's current pesticide product labeling requirements and with the following. For a comprehensive list of labeling requirements, please see the TM RED document.

Regulatory Conclusion

The use of currently registered products containing TM in accordance with approved labeling will not pose unreasonable risks or adverse effects to humans or the environment. Therefore, all uses of these products are eligible for reregistration. TM/MBC products will be reregistered once the required product-specific data, revised Confidential Statements of Formula, and revised labeling are received and accepted by EPA.

For More Information

EPA is requesting public comments on the Reregistration Eligibility Decision (RED) document for TM 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 Information and Records Integrity Branch, Information Resources and Services Division (7502C), 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/pesticides/reregistration/status.htm

Printed copies of the RED and fact sheet can be obtained from EPA's National Service Center for Environmental Publications (EPA/NSCEP), PO Box 42419, Cincinnati, OH 45242-2419, telephone 1-800-490-9198; fax 513-489-8695.

Following the comment period, the TM RED document also will be available from the National Technical Information Service (NTIS), 5285 Port Royal Road, Springfield, VA 22161, telephone 1-800-553-6847, or 703-605-6000.

For more information about EPA's pesticide reregistration program, the TM RED, or reregistration of individual products containing TM, 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 Information Center (NPIC). Call toll-free 1-800-858-7378, from 6:30 am to 4:30 pm Pacific Time, or 9:30 am to 7:30 pm Eastern Standard Time, seven days a week. Their internet address is http://npic.orst.edu.