



R.E.D. FACTS

Triphenyltin Hydroxide

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 0099, triphenyltin hydroxide (TPTH).

Use Profile

TPTH is a non-systemic foliar fungicide used to control early and late blight on potatoes; leaf spot on sugar beets; and scab, brown leaf spot and other diseases on pecans. It is only registered for use on these three crops. There are no residential, public health or other non-food uses of TPTH.

TPTH comes in liquid and wettable powder (in water soluble packaging) formulations, and its use is restricted to certified applicators. TPTH is applied by ground equipment, chemigation, airblast spray, and aircraft. TPTH labels require mechanical transfer for liquids, and a closed mixing/loading system for aerial applications. Handlers are required to wear coveralls, waterproof gloves, chemical resistant footwear, protective eyewear, chemical resistant headgear for overhead exposure, and chemical resistant apron when cleaning equipment, mixing, or

loading. These protective measures may be reduced or modified as specified by the Worker Protection Standard (WPS) when closed systems or enclosed cabs are used.

Regulatory History

TPTH was first registered as a pesticide in the U.S. in 1971. EPA issued a Registration Standard for TPTH in September, 1984 (PB85248797) that classified TPTH as a restricted use pesticide (RUP) due to acute and developmental toxicity concerns; imposed label warnings regarding developmental toxicity and potential adverse ecological effects; established a 24-hour reentry period; required additional data; and announced the Agency's intent to initiate a Special Review of TPTH. In January 1985, the Agency issued a Position Document (PD 1) initiating the Special Review of TPTH, based on potential developmental toxicity risks to mixers, loaders and applicators. In 1988, EPA issued a Data Call-In for studies on immunotoxicity, reproductive and inhalation toxicity, and carcinogenicity. EPA also issued a Reregistration Standard Update in 1992 to require additional data for reregistration purposes. In March 1992, TPTH was classified as a B₂ carcinogen (probable human carcinogen).

Currently, there are 16 TPTH products registered to four companies. There are also 10 Special Local Needs (or FIFRA section 24(c) registrations) for products containing TPTH.

Human Health Toxicity Assessment

In studies using laboratory animals, TPTH generally has been shown to have high acute oral, dermal and inhalation toxicity. It is an irritant to the eye and is not a skin sensitizer. Toxicity Categories, which range from 1 (most toxic) to 4 (least toxic), were II (oral), II (dermal), and I (inhalation).

TPTH belongs to a class of chemicals (organotins) known to be immunotoxic. TPTH is considered to be a developmental toxicant, although it is not considered to have mutagenic/genetic toxicity properties. It is carcinogenic both in the rat (inducing pituitary and testicular tumors) and in the mouse (inducing liver tumors), and is classified as a B₂, possible human carcinogen by all routes of exposure (oral, dermal and inhalation).

Dietary Exposure

People may be exposed to residues of TPTH through the diet. Tolerances or maximum residue limits have been established for TPTH (please see 40 CFR 180.236). EPA has reassessed the TPTH tolerances and found that most are acceptable, one must be reassigned, and new tolerances must be established for sugar beet tops and livestock commodities.

Currently there are no Codex Maximum Residue Limits (MRLs) established for residues of TPTH in/on plant or animal commodities.

EPA has assessed the dietary risk posed by TPTH.

For females 13+ years old, the population of concern for **acute dietary risk** assessment, exposure from all current TPTH tolerances represents less than 35% of the acute PAD (population adjusted dose, or the acute Reference Dose (RfD), the amount believed not to cause adverse effects from one day consumption, adjusted to reflect a 3x FQPA Safety Factor). The exposure level of the most highly exposed subgroup, females 20+ years old, not nursing or pregnant, represents 34% of the acute PAD. Therefore, it appears that acute dietary risk is not of concern.

For the general U.S. population and four subgroups, exposure from all current TPTH tolerances represent less than 5% of the chronic PAD (population adjusted dose, or the chronic Reference Dose (RfD), the amount believed not to cause adverse effects if consumed daily over a 70-year lifetime, adjusted to reflect a 10x FQPA Safety Factor). The exposure level of the U.S. population, including infants and children, represents 2% of the chronic PAD. Therefore, it appears that **chronic non-cancer dietary risk** is minimal.

For the general U.S. population, however, it appears **chronic cancer dietary risk** is a concern. For the U.S. population, based on exposure from all current TPTH tolerances, the chronic cancer dietary risk estimate is 1.0×10^{-6} from food alone (generally, cancer dietary risk estimates that include food *and* drinking water exposures less than 1.0×10^{-6} are not of concern). However, the cancer dietary risk estimate is primarily driven by sugar beet tops (the main feed item of the three registered crop uses), and the resulting residues found in meat and milk. Since there is a feeding restriction on TPTH products, the dietary risk assessment is likely to overestimate actual exposure from sugar beet tops.

Based on the Agency's modeling estimates, potential exposure to TPTH residues in drinking water derived from surface water (through spray drift or run-off) results in aggregate dietary risk (food and drinking water exposures) that exceeds the Agency's levels of concern for both chronic non-cancer and chronic cancer dietary risk.

Occupational and Residential Exposure

There are no residential or other non-occupational uses of TPTH currently registered, so only occupational exposures were assessed. Based on current use patterns, handlers (mixers, loaders, and applicators) may be exposed to TPTH during and after normal use. Since 1985, the TPTH labels have been modified to include engineering controls (mechanical transfer systems for mixing/loading liquid formulations, closed systems for aerial applications, and water soluble packaging) and personal protective equipment (respirators and chemical resistant protective clothing).

Despite these protective measures, margins of exposure (MOEs) and cancer risk estimates remain unacceptable, primarily for mixers/loaders of the wettable powder formulation (in water soluble bags), and pecan harvesters who reenter treated fields.

Human Risk Assessment

TPTH generally is of high acute toxicity, causes developmental effects in animal studies and has been classified as a Group B₂, probable human carcinogen. Only three food crop uses (pecans, potatoes, sugar beets) are registered. Non-cancer dietary risk from exposure to TPTH residues in foods is low. However, the cancer risk posed to the general population may pose concerns, especially when aggregated with surface water source drinking water exposures; modeling estimates of TPTH concentrations in surface water exceed Drinking Water Levels of Concern (DWLOCs). Because of TPTH's soil binding qualities, however, and buffer zones implemented to mitigate ecological risks (discussed below), EPA does not believe TPTH residues will concentrate in water at levels of dietary concern. The Agency is calling in additional fate data to verify its conclusion; based on these studies, EPA will determine whether water monitoring is warranted. In addition, since there is an enforceable feeding restriction on TPTH labels against feeding sugar beet tops to livestock, it is likely that the Agency's estimates of dietary exposure from sugar beet tops overestimate potential risk.

Of greater concern is the risk posed to TPTH handlers, particularly mixers/loaders/applicators, and field workers who come into contact with treated crops following application of this pesticide. Exposure and risk to workers will be mitigated by the use of personal protective equipment (PPE) required by the Worker Protection Standard (WPS) and prior measures as a result of TPTH Special Review negotiations, supplemented by closed cab application as required by this RED. Post-application reentry workers on pecan fields will be required to observe a 30-day pre-harvest interval.

Based on this assessment, the wettable powder formulation poses unreasonable risk. However, the results of the Agency's occupational (non-cancer and cancer) risk assessment for this formulation are not consistent with the Agency's experience that water soluble packaging results in exposures comparable to the use of other engineering controls such as closed mixing/loading systems for liquid formulations. The Agency believes that the significant discrepancy observed between exposure from liquid formulations in closed systems and water soluble bags for this chemical are due to the failure of the TPTH water soluble bag study to replicate actual use patterns (acres treated) on all three registered crop sites. Therefore, to support this formulation and to refine the risk estimates for wettable powder in water soluble bags for groundboom and aerial/chemigation application on the larger acreages representative of actual use, the Agency will call in a new,

confirmatory exposure study on the wettable powder formulation. The Agency believes that a new worker exposure study based on a larger treated acreage will demonstrate that the MOEs for the water soluble bag formulation are acceptable.

In addition, for workers, cancer risk estimates are in the 10^{-5} to 10^{-6} range, taking into account certain personal protective equipment and engineering controls. Under EPA's Non-Dietary Cancer Risk Policy, the Agency considers risks of 10^{-6} or lower not to be of concern and carefully examines risks in the range of 10^{-4} to 10^{-6} to seek ways of reducing risks prior to reregistration. For most worker scenarios, cancer risks cannot be feasibly mitigated to 10^{-6} short of cancellation. Based on a benefits assessment conducted for the TPTH Special Review the Agency has determined that TPTH's continuing role as a resistance management tool for pecans, potatoes and sugar beets warrants continued availability of the fungicide, and that TPTH has benefits that outweigh the risks from use. In addition, reductions in the total amount of TPTH that can be used in a given season (implemented to mitigate ecological risks) will ensure that worker exposures will not increase beyond current levels.

FQPA Considerations

Tolerances with amendments and changes specified in the RED document meet the FQPA safety standard for the general population. EPA's water modeling indicates potential dietary concerns from residues in drinking water (surface water source). However, because of TPTH's soil binding qualities, and buffer zones that will be required on TPTH labels, the Agency does not believe TPTH will reach water at levels of dietary concern. The Agency is requiring additional data to verify its conclusion; based on these studies, EPA will determine whether water monitoring is required.

Aggregate risk assessment for TPTH considered risks from TPTH treated food and residues in drinking water (based on modeling). There are no residential uses of TPTH registered, so only dietary (food and drinking water) risk was assessed.

For risk assessment purposes, the Agency has not assumed that TPTH has a common mechanism of toxicity with any other chemical(s).

Environmental Assessment Environmental Fate

Data submitted for reregistration show that TPTH binds strongly to soil, is stable to photolysis, and resistant to photo degradation and hydrolysis. Because of its soil binding qualities, TPTH is not expected to leach to groundwater. However, TPTH could reach surface water through spray drift and run-off, where the fate of the TPTH parent compound and its degradates are uncertain, as data is lacking on important fate qualities of these metabolites. The registrants will submit aerobic and anaerobic aquatic metabolism studies, a field dissipation study, an aerobic soil

metabolism study, and batch equilibrium studies so that the Agency can better evaluate the fate of TPTH and its degradates in soil and water. In addition, buffer zones from water bodies will minimize the opportunity for spray drift and run-off into water.

Ecological Effects

TPTH is moderately toxic to avian and mammalian species and exceeds acute and chronic LOCs. For a single application of TPTH, acute avian LOCs were exceeded for endangered species for all crops. The avian chronic level of concern is exceeded at all registered maximum application rates.

For multiple broadcast applications of liquid products, mammalian acute levels of concern are not exceeded at maximum application rates for any crop. However, the mammalian chronic LOC is exceeded at all registered maximum application rates for all food uses.

TPTH is very highly toxic to freshwater and marine/estuarine organisms. Exposure assessments were conducted using Tier II level modeling with PRZM/EXAMS. The RQs calculated from the modeling results show that acute and chronic LOCs for freshwater fish are exceeded.

High acute and chronic LOCs for freshwater invertebrates are exceeded for the pecan use pattern. Also, acute restricted use, endangered species and chronic LOCs for freshwater invertebrates were exceeded for the potato and sugar beet use patterns.

High acute risk LOCs for estuarine/marine fish are exceeded for the pecan use pattern. Also, endangered species LOCs for estuarine/marine fish were exceeded for the potato and sugar beet use patterns. High acute, restricted use and endangered species LOCs for estuarine/marine invertebrates are exceeded for all use patterns.

The exposure and risk to these nontarget species will be mitigated by reductions in the maximum seasonal use amounts currently allowed on TPTH labels. The registrants have agreed to reduce the maximum seasonal use rates on all three crop sites, which will reduce exposure to nontarget organisms. In addition, the addition of buffer zones to labels will protect aquatic species.

Risk Mitigation

Since the initiation of the TPTH Special Review in 1985, the registrants have voluntarily taken actions to reduce worker exposures to TPTH. These actions include deletion of TPTH use on carrots, peanuts and tobacco; requiring closed mixing/loading systems for aerial applications; requiring use of closed cab tractors by applicators of the flowable concentrate formulation; addition of protective clothing requirements to labels; adoption of mechanical transfer systems for liquid formulations; and packaging of the wettable powder in water soluble bags.

To lessen the risks to human health and the environment identified in the TPTH RED, EPA is requiring the following additional risk mitigation measures:

N The maximum seasonal use on pecans may not exceed 24 ounces ai/acre in areas and states that are west of Interstate 35 (e.g., Arizona, New Mexico, and some areas of Oklahoma and Texas). In all other areas and states (east of Interstate 35) the maximum seasonal use on pecans may not exceed 36 ounces ai/acre. High humidity east of Interstate 35 favors disease development in pecans, requiring higher seasonal use amounts.

N The maximum seasonal use on potatoes must be reduced to 9 ounces ai/acre in all states.

N The maximum seasonal use on sugar beets must be reduced to 8 ounces ai/acre in all states EXCEPT Minnesota, North Dakota, and Michigan.

N Labels will require a buffer zone of 100 feet from water bodies for ground applications, and a buffer zone of 300 feet from water bodies for aerial applications.

Additional Data Required

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

N 81-8: Acute neurotoxicity/rat

N 82-7: Subchronic neurotoxicity/rat

N Special Study: Developmental immunotoxicology neurotoxicity study

N 171-4: Independent laboratory validation (for animal method) and radio validation (plant and animal method)

N 171-4m: Multiresidue testing

N 171-4e: Storage stability

N 231 and 232: Dermal and inhalation exposure; wettable powder (in water soluble bags) formulation

N 72-4a: Fish early life stage toxicity test (sheepshead minnow)

N 72-4b: Aquatic invertebrate life cycle (mysid)

N 122-2: Aquatic plant growth

N 163-1: Sediment and soil absorption/desorption for parent and degradates

N 164-1: Field dissipation study

N 162-1: Aerobic soil metabolism

N 162-4: Aerobic aquatic metabolism

N 162-3: Anaerobic aquatic metabolism

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

N Applicators (ground and aerial) will be in enclosed cabs.

N The pre-harvest interval (PHI) for pecan use will be 30 days.

N The maximum seasonal use on pecans may not exceed 24 ounces ai/acre in areas and states that are west of Interstate 35 (e.g., Arizona, New Mexico, and some areas of Oklahoma and Texas). In all other areas and states (east of Interstate 35) the maximum seasonal use on pecans may not exceed 36 ounces ai/acre.

N The maximum seasonal use on potatoes must be reduced to 9 ounces ai/acre in all states.

N The maximum seasonal use on sugar beets must be reduced to 8 ounces ai/acre in all states EXCEPT Minnesota, North Dakota, and Michigan.

N A buffer zone of 100 feet from water bodies is required for ground applications.

N A buffer zone of 300 feet from water bodies is required for aerial applications.

Regulatory Conclusion

The use of currently registered products containing TPTH 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.

The registrants have agreed to amend labels reflecting worker and environmental risk mitigation measures for use in the 2000 growing season. However, full re-registration of products containing TPTH will not be completed until the required product-specific data and revised Confidential Statements of Formula are received and accepted by EPA.

For More Information

EPA is requesting public comments on the Reregistration Eligibility Decision (RED) document for TPTH during a 90-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/REDs>.

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

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

For more information about EPA's pesticide reregistration program, the TPTH RED, or reregistration of individual products containing TPTH, 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 (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. The NPTN internet address is ace.orst.edu/info/nptn.