United States Environmental Protection Agency | Prevention, Pesticides And Toxic Substances (7508C) | EPA-738-F99-012 November, 1999

R.E.D. FACTS

TFM

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. The decisions for TFM and Niclosamide were combined into one publication because the use patterns are very similar and the compounds are often used together. This fact sheet summarizes the information in the RED document for reregistration case 3082, 3-trifluoromethyl-4-nitrophenol (TFM, Lamprecid®).

Use Profile

TFM is a lampricide used to control sea lamprey larvae in tributaries to the Great Lakes, the Finger Lakes and Lake Champlain.

Formulations include a liquid concentrate and a solid bar. The liquid formulation is applied by metered pump from the back of a boat or by backpack sprayer. The solid bar is placed in the water and allowed to dissolve slowly.

Regulatory History

TFM was first registered as a pesticide in the U.S. in 1964 by the U.S. Department of Agriculture (USDA), the Agency's predecessor for pesticide regulation under FIFRA. Currently, two TFM products are registered with EPA.

Human Health Assessment

Toxicity

In animal studies with rats, TFM has an acute oral LD_{50} value of 141 mg/kg (Toxicity Category II). The acute dermal toxicity is minimal, as indicated by a LD_{50} > 2000 mg/kg (Toxicity Category III). It produced slight skin irritation (Toxicity Category IV) and caused eye irritation which was cleared within seven days after application (Toxicity Category III). TFM is not a skin sensitizer. The acute inhalation data are not available, but based on the low vapor pressure of TFM, inhalation is not expected to be a major pathway of exposure.

TFM showed no evidence of causing developmental toxicity, carcinogenicity, mutagenicity or of increased tumor incidence.

Dietary Exposure

People are unlikely to be exposed to residues of TFM through the diet due to: the low amount of compound used, the United States Fish and Wildlife Service restrictions against removing irrigation and drinking water from streams during treatment, and the rapid dissipation of residues in fish and water. Tolerances have not have been established and are not required for TFM.

Occupational and Residential Exposure

Based on current use patterns, handlers (mixers, loaders, and applicators) may be exposed to TFM during and after normal use of the liquid concentrate formulation. Dermal exposure was considered to be the most relevant route of exposure.

Human Risk Assessment

The use of TFM is not expected to pose risk to the general population since exposure from food, water, and other non-occupational contact is negligible.

Risk to TFM handlers is not of concern since margins of exposure are at acceptable levels when the protective clothing required by current labeling was included in the calculations. PPE requirements are complimented by routine industrial hygiene and medical monitoring programs for workers who handle and apply TFM.

FQPA Considerations

There are no dietary exposures for TFM; therefore FQPA does not affect these regulatory decisions.

Environmental Assessment

TFM is applied to freshwater tributaries and is therefore expected to have little impact on terrestrial plants and animals. Applications are designed to have minimal effects on fish, but other aquatic animals are expected to be impacted.

Environmental Fate

- TFM is chemically and biologically very stable.
- There is conflicting evidence on whether TFM photodegrades in water.
- TFM remains toxic for long periods (>80 days) in aqueous systems; however, toxicity decreases in sediment-water systems over time.
- TFM was converted to reduced-TFM with a half-life of less than one week under both aerobic and anaerobic aquatic metabolism conditions, but this conversion was reversible.
- The tendency for TFM to bind to sediments is not strong, readily reversed, and is pH dependent with binding decreasing as pH increases.
- Based on rainbow trout studies, TFM is not expected to accumulate in fish.
- In the environment, the sorption and degradation of TFM by sediments is expected to occur primarily in the lakes and not in the tributary streams. TFM is expected to remain in solution in the lake system and persist for long periods of time.

Ecological Effects

- Avian acute-**nontoxic** (>5, 000 ppm)
- Mammalian acute-**moderately toxic** (>141 to 160 mg/kg)
- Mammalian chronic (>5,000 mg/kg)
- Fish (freshwater acute)- **slightly to highly toxic** (0.60 to 37 mg/L)
- Invertebrates (freshwater) acute- **slightly to moderately toxic** (3.8 to 22.3 mg/L)
- Aquatic plants- **toxic** (1.2 to > 15 mg/L)

Environmental Risk Characterization

TFM is both chemically and biologically stable and is expected to remain toxic for long periods of time. However, mitigation of its effects at the treatment site is likely to occur as a result of the flushing action of the stream/river.

Predicted treatment concentrations for specific locations, based on physico-chemical data or in-stream toxicity tests, are intended to result in a concentration greater than the $LC_{99.9}$ for sea lamprey while being substantially less than the LC_{25} for brown trout. This improves treatment effectiveness for sea

lampreys, yet minimizes the effect on nontarget species. At the predicted treatment levels, acute high risk, acute restricted use, and endangered species levels of concern are exceeded for aquatic animals. Although TFM is likely to have an immediate effect on the aquatic community, the data suggest that most organisms recover quickly and the treatment area community structure returns to pre-treatment conditions within weeks or months. This recovery is site specific and may take much longer in certain environments. Certain species may be significantly impacted, most notably the indigenous lamprey species that may populate treatment areas. In general, however, native lamprey species have tended to populate the upper reaches of tributary streams, whereas the sea lamprey is more likely to inhabit lower reaches of the stream. Thus, nontarget species that may have been affected in the treatment area are repopulated through downstream migration from untreated areas. Furthermore, retreatment of the stream will not occur for at least 3 to 5 years. Additionally, a genuine effort is made to document where sensitive populations reside, and steps are undertaken to avoid treatments at concentrations known to be toxic to these organisms. The long-term effects remain uncertain to more sensitive species, such as indigenous lampreys, and to aquatic communities downstream from the treatment sites where chronic effects may be more likely.

Risk Mitigation

The use practices of TFM have been refined over the past several years in order to lower the impacts of these applications on non-target organisms and to lower occupational and non-occupational exposure to people. TFM is a Restricted Use Pesticide and its labels refer users to the US Fish and Wildlife Service's Manual for Pesticide Applications. Additional mitigation required by the Agency includes minor clarifications of label language. Aerial applications were prohibited on some of the current labels and will be prohibited on all new labels in order to lessen chances of nontarget human and other terrestrial animal exposures to these restricted use compounds.

Additional Data Required

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

Photodegradation in Water Guideline # 835-2240 (161-2)

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 TFM end-use products must comply with EPA's current pesticide product labeling requirements. Please see the attached labeling table for a comprehensive list of labeling requirements from the TFM RED document.

Regulatory Conclusion

The use of currently registered products containing TFM 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.

TFM 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 TFM during a 60-day time period, as announced in a Notice of Availability published in the Federal Register. The document is entitled Reregistration Eligibility Decision: 3-Trifluoro-Methyl-4-Nitro-Phenol CASE 3082 and Niclosamide CASE 2455. 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), PO Box 42419, Cincinnati, OH 45242-2419, telephone 1-800-490-9198; fax 513-489-8695.

Following the comment period, the TFM 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 TFM RED, or reregistration of individual products containing TFM, 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, 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 ace.orst.edu/info/nptn.

Table 14: Summary of Required Labeling Changes for TFM		
Description	**Required Labeling**	**Placement on Label**
End Use Products Intended for Occupational Use (Non-WPS))		
Restricted Use Pesticide is Triggered by Active Ingredient	"RESTRICTED USE PESTICIDE due to acute hazards to the eye, nontarget aquatic organisms, and to the need for hightly specialized applicator training." "Only for sale to and application by certified applicators of the U.S. Fish and Wildlife Service, Fisheries and Oceans Canada, and Provincial and State fish and game employees or persons under their direct supervision."	Top of Front Panel and enclosed in a box.
	"RESTRICTED USE PESTICIDE"	Immediately under the heading Directions for Use.
[1]PPE Requirements Established by the RED Based on the Active Ingredient.	"Personal Protective Equipment (PPE) Some materials that are chemical-resistant to this product are listed below. If you want more options, follow the instructions for category [insert A,B,C,D,E,F,G,or H] on an EPA chemical-resistance category selection chart." "Mixers, loaders, applicators and other handlers must wear: Long sleeved shirt and long pants Rubber boots and socks Chemical resistant gloves such as (registrant inserts correct glove type) Chemical Resistant aprons or coveralls Face shield."	Precautionary Statements: Hazards to Humans and Domestic Animals
User Safety Requirements	"Follow manufacturer's instructions for cleaning/maintaining PPE. If no such instructions for washable exist, use detergent and hot water. Keep and wash PPE separately from other laundry."	Precautionary Statements: Hazards to Humans and Domestic Animals immediately following the PPE requirements

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Description	**Required Labeling**	**Placement on Label**
User Safety Recommendations	"User Safety Recommendations" "Users should wash hands before eating, drinking, chewing gum, using tobacco, or using the toilet." "Users should remove clothing/PPE immediately if pesticide gets inside. Then wash thoroughly and put on clean clothing." "Users should remove PPE immediately after handling this product. Wash the outside of gloves before removing. As soon as possible, wash thoroughly and change into clean clothing."	Precautionary Statements under: Hazards to Humans and Domestic Animals immediately following Engineering Controls (Must be placed in a box.)
Environmental Hazards	"Environmental Hazards" "This chemical is toxic to fish and aquatic invertebrates. Nontarget aquatic organisms may be killed at rates recommended on this label." "Directions for Use must be strictly followed to minimize hazards to nontarget organisms. Do not contaminate water when cleaning equipment or disposing of equipment washwaters." "Local, State, and Provincial Fish and Game Agencies must be contacted before product is applied. Municipalities that use streams requiring treatment as potable water sources must be notified of the impending treatment at least 24 hours prior to application. Agricultural irrigators that use streams requiring treatment as a source of irrigation water must be notified of the impending treatment at least 24 hours prior to application. Agricultural irrigators must turn off their irrigation systems for a 24-hour period during and after treatment." "May not be used by unauthorized personnel."	Precautionary Statements under Environmental Hazards
Application Restrictions	"Do not apply this product in a way that will contact workers or other persons, either directly or through drift"	Directions for Use

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Description	**Required Labeling**	**Placement on Label**
Other Use/Application Restrictions	"Applicators must follow the instructions provided in the "Manual for Application of Lampricides in the U.S. Fish and Wildlife Service Sea Lamprey (*Petromyzon marinus*) Control Program" for correct rates of application. Prior to and during the application of this chemical, take all appropriate actions to notify public water users including notification actions specified in this manual."	Directions for Use under Application Instructions and/or General Precautions and Restrictions
Other Use/Application Restrictions	"Aerial applications of this product are prohibited."	Directions for Use under Application Instructions and/or General Precautions and Restrictions

[1]PPE that is established on the basis of Acute Toxicity of the end-use product must be compared to the active ingredient PPE in this document. The more protective PPE must be placed in the product labeling. For guidence on which PPE is considered more protective, see PR Notice 93-7.