



R.E.D. FACTS

1,3,5-Triethylhexahydro-s-triazine

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.

Under the Food Quality Protection Act of 1996, EPA must consider the increased susceptibility of infants and children to pesticide residues in food, as well as aggregate exposure of the public to pesticide residues from all sources, and the cumulative effects of pesticides and other compounds with a common mechanism of toxicity in establishing and reassessing tolerances.

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 met the safety standard of 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 3147, 1,3,5-triethylhexahydro-s-triazine.

Use Profile

1,3,5-Triethylhexahydro-s-triazine, or triethylhexahydrotriazine is an antimicrobial used as an industrial preservative treatment to control slime-forming bacteria and fungi in adhesives, fuels, oil storage tanks, metal-working cutting fluids, paints, slurries, rubber products, and industrial processing chemicals. Formulations include liquid soluble concentrates. Triethylhexahydrotriazine is added to industrial products using open-pouring or metering pump methods.

Regulatory History

Triethylhexahydrotriazine was first registered for use as a microbiocide and bacteriostat in the U.S. in 1967. In 1987 the Agency issued the Antimicrobial Data Call-In Notice to obtain additional data for this and other antimicrobial chemicals. Another Data Call-In Notice was issued in September 1992 requiring additional toxicity and ecological effects data in support of reregistration. Currently, two triethylhexahydrotriazine products are eligible for reregistration.

Human Health Assessment

Toxicity

In studies using laboratory animals, triethylhexahydrotriazine has been shown to be somewhat acutely toxic via the oral and inhalation routes and has been placed in Toxicity Category II (the second highest of four categories) for these effects. Because of its corrosivity, acute dermal toxicity and primary eye and skin irritation studies were waived, and triethylhexahydrotriazine has been placed in Toxicity Category I (the highest of four categories) for these effects.

In a dermal sensitization study with guinea pigs, triethylhexahydrotriazine was not a skin sensitizer. As for mutagenicity, although in vitro mutagenicity data indicate that it is mutagenic, negative in vivo data suggest that triethylhexahydrotriazine lacks mutagenic potential.

For short-term (1-7 days) and intermediate-term (1 week-several months) occupational and residential risk assessments, the Agency has chosen the 75 mg/kg/day NOEL (for both maternal and developmental toxicity) from a rat developmental toxicity study. In a sub-chronic dermal study in rats, no systemic effects were observed at any dose level. Consistent with current data requirements for non-food use chemicals, no chronic toxicity data have been required for triethylhexahydrotriazine. Even though chronic occupational exposure is possible with the use of triethylhexahydrotriazine, chronic testing for cancer and other long term effects is not required since EPA does not believe that chronic exposure would result in a risk of concern.

Dietary Exposure

Current uses of triethylhexahydrotriazine do not include any food or feed uses. Therefore dietary exposure is not anticipated and no dietary risk assessments have been conducted.

Occupational and Residential Exposure

Based on current use patterns, EPA has determined that there is a potential for exposure of mixers, loaders, applicators, and other handlers to triethylhexahydrotriazine and its break-down product, formaldehyde, during and after normal use of the pesticide in both occupational and residential settings. EPA conducted assessments for dermal exposure only. The Agency believes that inhalation exposure may also be a significant component of overall exposure to triethylhexahydrotriazine because of its high vapor pressure, particularly when triethylhexahydrotriazine-containing

paint is used. At this time, however, EPA has no data with which to conduct an inhalation exposure and risk assessment. Thus, the Agency is requiring handler and post-application inhalation exposure data.

Human Risk Assessment

As mentioned previously, triethylhexahydrotriazine is so corrosive that the dermal acute toxicity and primary skin and eye irritation studies were waived. The Agency expects that concentrated triethyl-hexahydrotriazine products may pose significant handler risk due to this corrosivity. The Agency is addressing these risks through the establishment of PPE requirements that are to be included on the labeling of all end-use products that are classified as toxicity category I or II for skin or eye irritation potential.

EPA is generally not concerned with occupational and residential risk if MOEs (margins of exposure) are greater than 100. For triethyl-hexahydrotriazine, all of the primary application (occupational) dermal MOEs are greater than 100; they range from approximately 2,100 for exposure in wet-end additives/industrial processing chemicals using a pump metering system, to approximately 21,000 for open-pour operations during paint, adhesive, and rubber manufacturing and in uses for fuels/oil storage tank bottom water. For secondary exposure, such as applying paint containing triethylhexahydrotriazine, dermal MOEs range from greater than 300 for occupational workers to greater than 1600 for residential applicators.

EPA has also considered the potential hazard of exposure to formaldehyde, a degradate of triethylhexahydrotriazine. The Occupational Safety and Health Administration (OSHA) has a comprehensive workplace standard for formaldehyde to protect workers in occupational settings. Residential and other non-occupational exposure to formaldehyde is expected to be very low. However, the Agency will require confirmatory exposure data that includes monitoring for formaldehyde during and after application.

Other Considerations

Because triethylhexahydrotriazine currently has no food uses and no tolerances have been established, the specific determinations outlined in the Food Quality Protection Act of 1996 are not required for this chemical. Nevertheless, EPA believes that consideration of available data relating to the special sensitivity of infants and children, as well as the potential for aggregate exposures and cumulative effects is prudent for triethylhexahydrotriazine because children and other individuals could be exposed to this compound in non-occupational settings.

Nothing in the available toxicity data base indicates special susceptibility of infants and children to triethylhexahydrotriazine and,

therefore, the Agency has concluded that an additional uncertainty factor for estimating risk to young organisms is not warranted.

All products containing triethylhexahydrotriazine have primarily indoor, non-food uses. Based on the available exposure information and current use patterns, EPA does not anticipate exposure to residues of triethylhexahydrotriazine in food or drinking water. Thus, the only non-occupational exposure to triethylhexahydrotriazine would be from uses in and around the home. Among these, applying paint would yield the greatest potential exposure. Because the dermal MOE for this reasonable worst case exposure is high (> 1600), EPA believes that aggregate exposures from other sources of triethylhexahydrotriazine in the home are not likely to be of concern.

The Agency has not yet made a determination regarding the common mode/mechanism of toxicity of triethylhexahydrotriazine and whether it is appropriate to consider exposure from triethyl-hexahydrotriazine with other compounds in order to address potential cumulative effects. However, based on the high dermal MOE for homeowner applicators, the lack of food uses, the unlikelihood of residues in drinking water, and the low concentration in paint, the Agency believes that the contribution of triethylhexahydrotriazine exposure to the risks of other chemicals with a common mode/mechanism of toxicity is likely to be minimal.

Environmental Assessment

Environmental Fate

EPA requires only a hydrolysis study to characterize the environmental fate of triethylhexahydrotriazine, due to its current use patterns. EPA does not have a hydrolysis study for this active ingredient, but, based on the behavior of structurally related chemicals, the expected reaction products are formaldehyde and ethylamine. However, the effect of different pHs on the rate of hydrolytic degradation is not known. Since the data requirement is not fulfilled, EPA is requiring confirmatory hydrolysis data on the rate of hydrolysis of triethylhexahydrotriazine at pH 5, 7, and 9, and the reaction products must be identified.

Ecological Effects

Triethylhexahydrotriazine is slightly to moderately toxic to birds on an acute basis and practically non-toxic on a subacute basis. It demonstrates slight toxicity to both cold and warm freshwater fish, and is slightly toxic to freshwater invertebrates on an acute basis.

Ecological Effects Risk Assessment

The Agency requires only a limited number of ecotoxicology and environmental fate studies for microbiocides with primarily indoor use patterns. While the hazard to aquatic organisms from triethylhexahydrotriazine has been characterized, a quantitative risk assessment has not been conducted. The risks to aquatic environments are regulated under the National Pollutant Discharge Elimination System

(NPDES) permitting program of the Agency's Office of Water. EPA does not anticipate any exposure of concern to fish or wildlife, providing that all triethylhexahydrotriazine products are handled and applied as specified in the product labeling, and discharges to the environment comply with all federal disposal laws and the NPDES program.

Risk Mitigation

To lessen the potential risks posed by triethylhexahydrotriazine and products treated with triethylhexahydrotriazine, EPA is requiring the following risk mitigation measures.

- EPA requires that handlers using occupational-use products wear long-sleeve shirts, long pants, shoes, and socks as minimum work attire. Further handler safety requirements for products containing triethylhexahydrotriazine will be determined based on the acute toxicity characteristics of the end-use product.
- EPA is requiring the use of meter pumps or other automatic dispensing equipment for triethylhexahydrotriazine use in wet-end additives and industrial processing chemicals.
- For use in paint, rubber products, industrial adhesives, or fuel/oil storage tank bottoms, EPA is requiring that the vats to which the triethylhexahydrotriazine is added must be closed and equipped with mechanical vents to the outdoors.
- EPA is requiring NPDES permits for discharge of triethylhexahydrotriazine effluent.

Additional Data Required

To confirm its regulatory conclusions on triethylhexahydrotriazine, EPA is requiring additional generic data to assess hydrolysis. Additionally, the Agency will require exposure data from paint applications by brush, roller, and sprayer, as well as post application monitoring data to determine exposure to residents or occupants of areas that have been painted. These post application data will include monitoring for degradates. Because much of the exposure data needed for triethylhexahydrotriazine is generic in nature and will also be required for other antimicrobial chemicals with similar characteristics and uses, EPA is developing a generic exposure DCI for antimicrobials. Triethylhexahydrotriazine registrants will receive the generic antimicrobial exposure DCI at the same time as registrants of other antimicrobial chemicals with similar uses.

Product Labeling Changes Required

All triethylhexahydrotriazine end-use products must comply with EPA's current pesticide product labeling requirements and with the following.

- **Minimum (Baseline) PPE/Engineering Control Requirements**
Any necessary PPE for each triethylhexahydrotriazine occupational end-use product will be established on the basis of the end-use product's acute toxicity category as specified in Section V of the RED

document. All end-use products will be required to specify the minimum work attire for all handlers.

The minimum handler work attire labeling requirement for occupational uses of triethylhexahydrotriazine end-use products is:

"Mixers, loaders, applicators and other handlers must wear:

- Long-sleeve shirt and long pants,
- Shoes plus socks."

If the end-use product is classified as toxicity category I or II for eye irritation potential or if data for this route of concern are waived due to corrosivity, add:

- Protective eyewear.

If the end-use product is classified as toxicity category I or II for acute dermal toxicity or skin irritation potential or data for either of these routes of concern are waived due to corrosivity, add:

- Chemical-resistant apron, and
- Chemical-resistant gloves*.

*For the glove statement, use the statement established for triethylhexahydrotriazine through the instructions in Supplement Three of PR Notice 93-7. In addition, for concentrated triethylhexahydrotriazine products, the corrosiveness and penetration of triethylhexahydrotriazine must be considered. Appropriate chemical-resistant materials must be listed on the product labeling.

If the end-use product is classified as toxicity category I or II for acute inhalation toxicity, a respirator requirement must be added. The type of respirator must be specified in the statement and is based on the acute toxicity category and the vapor pressure. EPA will assist registrants in determining the appropriate type of respirator during the end-use product phase of reregistration.

In addition to the minimum PPE specified above, the following specific PPE and engineering-control requirements must be added to labels containing the following uses.

When labeling contains uses for wet-end additives/industrial processing chemicals, add the following:

"For use in wet-end additives/industrial processing chemicals, meter pumps or other automatic dispensing equipment is required. Open pouring is prohibited."

When labeling contains uses for paint, rubber products, or industrial adhesives, or fuels/oil storage tank bottom water, add the following:

"For use in paint, rubber products, industrial adhesives, or fuels/oil storage tank bottom water, the vats to which triethylhexahydrotriazine is being added must be closed and equipped with mechanical vents to the outdoors."

Placement in Labeling

The personal protective equipment requirements must be placed on the end-use product labeling in the format and language specified above and must be placed in the "Hazards to Humans" section of the pesticide labeling.

Other Labeling Requirements - Products Intended for Occupational Use

The Agency is requiring the following labeling statements to be located on all end-use products containing triethylhexahydrotriazine that are intended primarily for occupational use. Additional handler safety requirements will be determined based on the acute toxicity characteristics of each end-use product.

Application Restrictions

"Do not use this product in a way that will contact workers or other persons."

"Do not apply this product as a spray."

User Safety Requirements

If gloves or protective eyewear are required PPE on the end-use product, add:

"Follow manufacturer's instructions for cleaning/maintaining PPE. If no such instructions are provided for washables, use detergent and hot water. Keep and wash PPE separately from other laundry."

User Safety Recommendations

"Users should wash hands before eating, drinking, chewing gum, using tobacco, or using the toilet."

"Users should remove clothing immediately if pesticide gets inside. Then wash thoroughly and put on clean clothing."

Registrants must add the following statements only if gloves are required PPE on the end-use product:

"Users should remove PPE immediately after handling this product. Wash the outside of gloves before removing. As soon as possible, wash thoroughly."

Regulatory Conclusion

The use of eligible triethylhexahydrotriazine products in accordance with labeling specified in this RED will not pose unreasonable adverse effects to humans or the environment. These products will be reregistered once the required confirmatory generic data, product specific data, revised Confidential Statements of Formula (CSFs), 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 triethylhexahydrotriazine 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 can be downloaded from the Pesticide Special Review and Reregistration Information System at 703-308-7224. They also are available on the Internet by using ftp on *FTP.EPA.GOV*, or using WWW (World Wide Web) on *WWW.EPA.GOV*.

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 triethylhexahydrotriazine RED document also will be available from the National Technical Information Service (NTIS), 5285 Port Royal Road, Springfield, VA 22161, telephone 703-487-4650.

For more information about EPA's pesticide reregistration program, the 1,3,5-triethylhexahydro-s-triazine RED, or reregistration of individual products containing triethylhexahydrotriazine, please contact the Special Review and Reregistration Division (7508W), 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 Pesticides Telecommunications Network (NPTN). Call toll-free 1-800-858-7378, between 9:30 am and 7:30 pm Eastern Standard Time, Monday through Friday.