



R.E.D. FACTS

Pesticide Reregistration

Methylisothiazolinone

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. The Agency develops any mitigation measures or regulatory controls needed to effectively reduce each pesticide's risks. EPA then reregisters pesticides that 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 3092, methylisothiazolinone. The Reregistration Eligibility Decision covers the two active ingredients 5-chloro-2-methyl-3(2H)-isothiazolone and 2-methyl-3(2H)-isothiazolone. These two active ingredients occur together in the currently registered products in approximately a 3:1 ratio, respectively, and are commonly referred to as methylisothiazolinone.

Use Profile

Methylisothiazolinone is used to control slime-forming bacteria, fungi, and algae in pulp/paper mills, cooling water systems, oil field operations, industrial process waters, and air washer systems and is incorporated into adhesives, coatings, fuels, metal working fluids, resin emulsions, paints, and various other speciality industrial products as a preservative. It is also used to control the growth of mold, mildew, and sapstain on wood products. Formulations include soluble concentrated liquids and soluble concentrated solids. Products containing methylisothiazolinone are added to systems and industrial products using manual pouring and metered pumping methods, dip tanks and sprayers. Use practice limitations include National Pollutant Discharge Elimination System (NPDES) license restrictions.

Regulatory History

Methylisothiazolinone was first registered in the U.S. in 1977 as an antimicrobial with various uses. There are currently 85 products registered including one technical product.

In 1987 the Agency issued the Antimicrobial Data Call-In Notice to registrants with pesticides containing methylisothiazolinone to obtain additional chronic and subchronic toxicity data. A Phase 4 Data Call-In was issued on November 3, 1992, requiring additional toxicity and environmental fate data.

Human Health Assessment

Toxicity

In studies using laboratory animals, methylisothiazolinone has been shown to be of moderate acute toxicity by the oral and inhalation routes. It is highly acutely toxic when applied dermally or to the eye and is considered to be corrosive.

In subchronic studies, the most significant toxicological effect was microscopic lesions in the nasal turbinates from inhalation exposure. Developmental and chronic feeding/carcinogenicity studies in rats resulted in no significant effects and the Agency classified methylisothiazolinone as a Group D chemical, not classifiable as to human carcinogenicity. Results from mutagenicity studies were equivocal.

Dietary Exposure

Tolerances or residue limits are established for methylisothiazolinone in adhesives, paper, and paper products which may contact food. These uses are regulated by the U.S. Food and Drug Administration (FDA). There are no other registered food uses of methylisothiazolinone.

Occupational and Residential Exposure

Based on current use patterns, handlers may be exposed to methylisothiazolinone during and after normal use of the liquid and solid soluble concentrate formulations. Persons in residential settings may be exposed to products containing methylisothiazolinone. Therefore, an exposure assessment was conducted based on the toxicological endpoint of the respiratory effect from the subchronic inhalation study.

The open-pouring application of methylisothiazolinone is considered the worst-case inhalation exposure scenario for applicators. The worst-case scenario for persons exposed to methylisothiazolinone-treated products is the paint application use.

Although exposures to workers in areas where products containing methylisothiazolinone have recently been applied are expected, EPA believes that these post-application exposures would be significantly less than those for handlers applying the pesticide.

There are no methylisothiazolinone products labeled for homeowner use. Exposures to homeowners may occur from products, such as adhesives, paints or paper products, treated with methylisothiazolinone. Again, the Agency believes that these exposures would be minimal.

Human Risk Assessment

Methylisothiazolinone is moderately to highly acutely toxic in oral, dermal, eye irritation, dermal irritation, and inhalation acute toxicity studies.

The use of methylisothiazolinone in the manufacture of paper, paperboard, and adhesives which may contact food is regulated by FDA. There are no other registered food uses.

The Agency concluded that the risks of short-term and intermediate-term occupational exposure to pesticide handlers are acceptable. Margins of Exposure (MOEs) for all uses were above 100. An MOE of less than 100 is of concern to the Agency. Short-term risks of corrosivity can be adequately managed through the use of personal protective equipment (PPE) and monitoring, as necessary. The Agency further believes risks from secondary occupational exposures, residential exposures, and post-application exposures are comparatively less and also acceptable. However, protective measures are being imposed including additional product specific PPE (when appropriate), and baseline PPE.

Environmental Assessment

Environmental Fate

Of the two chemicals (5 -chloro-2-methyl-3(2H)-isothiazolone and 2-methyl-3(2H)-isothiazolone) that compose methylisothiazolinone, only 5 -chloro-2-methyl-3(2H)-isothiazolone was susceptible to hydrolysis and only at alkaline pH. 5-Chloro-2-methyl-3(2H)-isothiazolone was very mobile in most soils. The degradation profile observed in an aqueous availability study is similar to that observed in the hydrolysis studies.

Ecological Effects

Methylisothiazolinone is moderately to practically non-toxic to birds, and moderately to highly toxic to freshwater and estuarine/marine organisms.

Ecological Effects Risk Assessment

While the hazard to aquatic organisms from methylisothiazolinone has been characterized, a quantitative risk assessment has not been conducted. The risks to aquatic environments from this use are regulated under the NPDES permitting program of EPA's Office of Water. The Agency currently requires that labels for all methylisothiazolinone products require that discharges to aquatic environments comply with an NPDES permit.

Risk Mitigation

To lessen the potential human health risks posed by methylisothiazolinone, EPA is requiring the following risk mitigation measures.

- (1) The Agency is establishing active-ingredient based minimum PPE for primary occupational handlers. Since all the MOEs generated are based on units of exposure from the Pesticide Handlers Exposure Database in which handlers wore chemical resistant gloves, long-sleeve shirts, long pants, and shoes plus socks, these PPE are required for occupational handlers of methylisothiazolinone products.
- (2) The acute dermal, inhalation and ocular toxicity of the end-use products will be used to determine appropriate protection from the corrosivity of methylisothiazolinone.

Additional Data Required

EPA has required additional generic information describing the hydrolysis of 5-chloro-2-methyl-3(2H)-isothiazolone at pH 9 to confirm its regulatory assessments and conclusions.

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

Product Labeling Changes Required

All methylisothiazolinone 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 methylisothiazolinone RED document.

Personal Protective (PPE) Requirements

- (1) EPA is establishing the following minimum, baseline PPE:
Mixers, loaders, and others exposed to methylisothiazolinone products must wear:
 - Long-sleeve shirt and long pants,
 - Chemical resistant gloves,
 - Shoes plus socks.
- (2) If the end-use product is classified as Toxicity Category I or II for eye irritation potential, add to the above PPE:
 - Protective eyewear
- (3) If the end-use product is classified as Toxicity Category I or II for acute dermal toxicity or skin irritation potential, add:
 - Chemical-resistant apron

-
- (4) If the end-use product is classified as Toxicity Category I or II for acute inhalation toxicity, add:

--Respirator (the type must be specified; EPA will assist registrants in determining appropriate respirators during product reregistration).

Labeling Clarifications

The following clarifications must be made on all end-use products labels, where applicable.

(1) Use Profile Clarifications

Registrants must specify on labeling of products containing methylisothiazolinone the complete directions for use for each use pattern: site of application, type of application, timing of application, equipment used for application, and the rate of application (dosage).

(2) Use on Pilings

Methylisothiazolinone is to be used only on terrestrial-use pilings not aquatic-use pilings. The phrase "terrestrial-use pilings" must be used when referring to any type of piling.

(3) Water Treatment Systems

All uses of products containing methylisothiazolinone in water treatment systems must clearly specify recirculating water treatment systems. The term "recirculating" must be added before all references to water treatment systems (e.g., water treatment, cooling towers, etc.).

(4) Clarification of Oil Drilling Mud Use

To clarify the intent of the oil recovery drilling muds/packer fluids use (as an aquatic or terrestrial non-food use pattern), the following statement must be added to the labels for terrestrial non-food oil drilling muds and packer fluids:

"For use in terrestrial wells only."

And the following statement must be added to the precautionary labeling:

"Do not apply in marine and/or estuarine oil fields."

The following statement must be added to the labels for aquatic non-food industrial oil drilling muds and packer fluids:

"For use in offshore wells only."

For use in both terrestrial and offshore oil drilling muds and packer fluids, the following statement must be added:

"This product may be used for terrestrial and off-shore oil drilling muds and packer fluids."

Other Labeling Requirements

The Agency is requiring the following labeling statements to be located on all end-use products containing methylisothiazolinone that are intended primarily for occupational use.

(1) Application Restrictions

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

(2) User Safety Requirements

"Discard clothing or other absorbent materials that have been drenched or heavily contaminated with this product's concentrate. Do not reuse them. Follow manufacturer's instructions for cleaning/maintaining PPE. If there are no such instructions for washables, use detergent and hot water. Keep and wash PPE separately from other laundry."

(3) 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."
- ! "Users should remove PPE immediately after handling this product. Wash the outside of gloves before removing. As soon as possible wash thoroughly."

(4) Skin Sensitizer Statement

"This product may cause skin sensitization reactions in some people."

Regulatory Conclusion

The use of currently registered products containing methylisothiazolinone in accordance with approved labeling and as described in the Reregistration Eligibility Decision Document will not pose unreasonable risks or adverse effects to humans or the environment. Therefore, all uses of these products are eligible for reregistration.

Methylisothiazolinone products will be reregistered once the required product-specific data, generic 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 methylisothiazolinone 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 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 methylisothiazolinone 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 methylisothiazolinone RED, or reregistration of individual products containing methylisothiazolinone, 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 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.