United States Environmental Protection Agency | Prevention, Pesticides And Toxic Substances (7508W) | EPA-738-F-95-010 APRIL 1998

R.E.D. FACTS

DEET

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. 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 0002, N,N-diethyl-meta-toluamide and other isomers (DEET).

Use Profile

N,N-diethyl-meta-toluamide (DEET) is an insect repellent used in households/domestic dwellings, on the human body and clothing being worn, on cats, dogs, horses and pet living/sleeping quarters. There are no food uses. It is used to control biting flies, biting midges, black flies, chiggers, deer flies, fleas, gnats, horse flies, mosquitoes, no-see-ums, sand flies, small flying insects, stable flies, and ticks. Formulations include liquids, pressurized liquids, ready-to-use formulations and impregnated material. DEET is applied by aerosol can, by hand, non-aerosol pump sprayer, package applicator, and pump spray bottle.

Regulatory History

DEET was first registered in the U.S. in 1957 after first being developed by the U.S. Army in 1946 for use by military personnel in insect-infested areas. A Registration Standard for DEET was issued in December, 1980 (PB81-207722), and a subsequent Data Call-In (DCI) for DEET (issued September, 1988) required additional animal and avian toxicity data.

Currently, 225 DEET products are registered. DEET products that are applied directly to the skin and/or clothing are available in numerous formula-

tion types (e.g. aerosol and non-aerosol sprays, creams, lotions, sticks, foams, and towelettes). Product concentrations range from ≈4% a.i. to 100% a.i.

Human Health Assessment

Toxicity

In studies using laboratory animals, DEET generally has been shown to be of low acute toxicity. It is slightly toxic by the eye, dermal and oral routes and has been placed in Toxicity Category III (the second lowest of four categories) for these effects.

[NOTE: For acute oral, dermal, ocular and inhalation toxicity:

Category I = very highly or highly toxic

Category II = moderately toxic

Category III = slightly toxic

Category IV = practically non-toxic]

Dietary Exposure

Because of its use pattern, people are not exposed to residues of DEET through the diet.

Occupational and Residential Exposure

Based on DEET's indoor/residential use pattern, handlers (mixers, loaders, and applicators) are not exposed to DEET.

Human Risk Assessment

DEET generally is of low acute toxicity, and, based on the available toxicological data, the Agency believes that the normal use of DEET does not present a health concern to the general U.S. population (the Agency's human risk assessment has identified no toxicologically significant effects in animal studies.) DEET has been classified as a Group D carcinogen (not classifiable as a human carcinogen.)

Although DEET's use has been implicated in seizures among children, the Agency believes that the incident data are insufficient to establish DEET as the cause of the reported effects. However, because of DEET's unusual use pattern (direct application to human skin and clothing) and its association with seizure incidents, the Agency believes it is prudent to require clear, common sense use directions and improved label warnings and restrictions on all DEET product labels.

Environmental Assessment

Environmental Fate

Because of its limited use pattern, the only environmental fate study required for DEET was hydrolysis. From that data, it was concluded that DEET is stable to hydrolysis at pH levels found in the environment.

Ecological Effects

Because DEET is only applied directly to the human body/clothing, cats, dogs, pet quarters and household/domestic dwellings, it is considered to be an "indoor residential" use. A limited set of toxicity data for indoor-use pesticides

is required to determine precautionary label statements and for assessing environmental hazards in case of spills. The available data characterize DEET as slightly toxic to birds, fish, and aquatic invertebrates and as practically nontoxic to mammals.

Ecological Effects Risk Assessment

Ecological risk assessments are not conducted for pesticides with exclusively indoor use patterns. Application of DEET to the human body/clothing, cats, dogs, pet quarters, and household/domestic dwellings, is not likely to adversely affect terrestrial wildlife or aquatic organisms.

Risk Mitigation

DEET is a personal insect repellent that is widely used among the U.S. population, including children, and is one of the few residential-use pesticides that is applied directly to the skin. Although the available toxicological data to not indicate a health concern under normal use conditions, DEET's use has been associated with possible adverse effects. For all of these reasons, the Agency believes it is prudent to require improved label warnings and product restrictions. A listing of the required labeling statements for DEET formulations is included in the RED, Section V. The Agency had deferred its decision on the combination DEET/sunscreen products until it has solicited the views of various governmental agencies and other groups. Sunscreen products are intended for frequent, generous use, and DEET products are intended for spare, infrequent use. The Agency is concerned that use of the combination products may promote greater use of DEET than is needed for pesticidal efficacy and thus pose unnecessary exposure to DEET. In addition, child-safety claims must be removed from all end-use product labels in order to be reregistered. Child-safety claims are misleading and irreconcilable with the intended use and pesticidal ingredients of DEET products. From the toxicological data reviewed by the Agency for DEET, and from DEET incident data, there appears to be no correlation between the percent active ingredient in the product and its safety. Therefore, the Agency does not believe that certain DEET formulations are inherently safer for children. DEET uses/formulations with labels that make cosmetic claims must be labeled such that label statements and use directions regarding insect repellency appear first and more prominently on the label.

Additional Data Required

EPA is not requiring additional generic studies for DEET to confirm its regulatory assessments and conclusions.

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

Product Labeling Changes Required

All DEET end-use products must comply with EPA's current pesticide product labeling requirements and with those labeling requirements imposed in

this RED. For a comprehensive list of labeling requirements, please see section V. of the DEET RED document.

1. All products must incorporate a series of 14 statements informing the consumer on the method of application, special precautions for children, and directions for medical attention.

2. For aerosol and pump spray formulations: labels must direct the consumer not to spray in enclosed areas, avoid direct spraying on the face and must be packaged in containers which will ensure the product will not be inadvertently sprayed in the eyes.

3. Other labeling requirements include: specifying percent active ingredient in terms of DEET; use of the term "first aid"; addition of a toll-free number for consumer support; requirement to use permanent labels; all cosmetic claims must be less prominent that the term "Insect repellent"; and all direct or indirect claims of child safety must be removed.

Regulatory Conclusion

With the exception of products/formulations that combine DEET and sunscreen, all uses/formulations of DEET are eligible for reregistration provided all labels are amended as specified in the RED. The use of currently registered products containing DEET 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 Agency will defer its decision regarding the reregistration eligibility of products/formulations that combine DEET and sunscreen until the Agency has solicited the views of various governmental agencies and other groups. Additionally, the Agency will not act on any pending registration applications under section 3 until that time.

DEET products will be reregistered once the required product-specific data, including efficacy data, revised Confidential Statements of Formula, and revised labeling are received and accepted by EPA. Products which contain active ingredients in addition to DEET will be reregistered when all of their other active ingredients also are eligible for reregistration.

For More Information

EPA is requesting public comments on the Reregistration Eligibility Decision (RED) document for DEET 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 on EPA's gopher

server, *GOPHER.EPA.GOV*, or 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 DEET 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 DEET RED, or reregistration of individual products containing DEET, 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.