Docket Number EPA-HQ-OPP-2012-0162
www.regulations.gov

DEET (N,N-Diethyl-meta-toluamide)

Interim Registration Review Decision
Case Number 0002

September 2014

Approved by: Richard P Keigwin Jr

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Director
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Date: 9-15-2014

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Supporting documents for the DEET registration review case may be found in the docket EPA-HQ-OPP-2012-0162 at http://www.regulations.gov.

INTRODUCTION

This document is the Environmental Protection Agency's (EPA or the Agency) *Interim Registration Review Decision* for DEET and it discusses public comments received concerning the *Proposed Interim Registration Review Decision*. It is being issued pursuant to 40 CFR Sections 155.56 and 155.58. A registration review decision is the Agency's determination whether a pesticide meets, or does not meet, the standard for registration in the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA).

During the 60-day public comment period for the DEET *Proposed Interim Registration Review Decision*, which opened on June 4, 2014, and closed on August 4, 2014, the Agency received 3 submissions. Comments were submitted by the Center for Biological Diversity (CBD) and 2 anonymous public citizens. The comment from CBD agrees with the Agency's finding regarding endangered species. The anonymous public comments describe a personal reaction to DEET and request clarification about whether DEET is defined as a pesticide. The public comments did not result in changes to the Agency's DEET *Proposed Interim Registration Review Decision*. Public comments in their entirety are located in the docket, EPA-HQ-OPP-2012-0162.

DEET is a broad-spectrum insect repellent registered for use against biting flies, biting midges, black flies, chiggers, deer flies, fleas, gnats, horse flies, mosquitoes, no-see-ums, sand flies, stable flies, and ticks. DEET was developed by the United States (U.S.) Army in 1946 for use by military personnel in insect affected areas and was registered for use by the general public in 1957. DEET is currently registered for non-food and residential uses. There is also one registered product for use on horses. There are no registered food or agricultural uses. The Reregistration Eligibility Decision document (RED) for DEET was completed on April 13, 1998.[1] For further information about DEET, additional documents can be found in EPA's public docket (EPA-HQ-OPP-2012-0162) at www.regulations.gov.

STATUTORY AND REGULATORY AUTHORITY

The Food Quality Protection Act (FQPA) of 1996 mandated a registration review program. All pesticides distributed or sold in the U.S. generally must be registered by EPA, based on scientific data showing that they will not cause unreasonable risks to human health or the environment when used as directed on product labeling. The registration review program is intended to make sure that, as the ability to assess risk evolves and as policies and practices change, all registered pesticides continue to meet the statutory standard of no unreasonable adverse effects to human health or the environment. Changes in science, public policy, and pesticide use practices will occur over time. Through the registration review program, the Agency periodically reevaluates pesticides to make sure that as change occurs, products in the marketplace can be used safely. Information on this program is provided at www.epa.gov/oppsrrd1/registration_review/.

The Agency is implementing the registration review program pursuant to Section 3(g) of FIFRA, and will review each registered pesticide every 15 years to determine whether it

[1] Located at http://www.epa.gov/oppsrrd1/REDs/0002red.pdf

continues to meet the FIFRA standard for registration. The regulations governing registration review begin at 40 CFR 155.40. The Agency will consider benefits information and data as required by FIFRA. The public phase of registration review begins when the initial docket is opened for each case. The docket is the Agency's opportunity to state what it knows about the pesticide and what additional risk analyses and data or information it believes are needed to make a registration review decision.

DEET CHEMICAL FACTS

PC code	080301
Case Number	2
CAS Number	134-62-3
Year first registered	1957
Pesticide Type	Insect and acarid repellent
Chemical class	N, N-dialkylamides
Reregistration Eligibility Decision (RED)	September 1998
Tolerance Reassessment Eligibility Decision (TRED)	Not applicable. There are no registered DEET food/feed uses and no established tolerances for DEET.
Cumulative group	Not applicable. DEET has not been identified as a member of a cumulative group that shares a common mechanism of toxicity.
40 CFR Citation	There are no registered DEET food/feed uses and no established tolerances for DEET.
Dual-use	Conventional pesticidal uses only
Non-pesticidal uses	No non-pesticidal uses of DEET
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USE AND USAGE INFORMATION

Available data on DEET show that it accounted for the overwhelming majority of insect repellents used in the U.S. in 2005, 2009, and 2012 according to private market research surveys (Table 1.) About 30% of the U.S. population uses DEET annually as an insect repellent (EPA, 1998).

Table 1. DEET Usage in the U.S.

Active Ingredient	**2005**	**2009**	**2011**
	Million lb	**Million lb**	**Million lb**
DEET	7.7	6.8	9.2

Source: Kline & Company, 2006, 2010, and 2012

The use of insect repellents such as DEET is intended to provide certain public health benefits. Application of DEET insect repellents to the skin and clothing is intended to help prevent bites from mosquitoes, ticks and other biting insects that may vector diseases such as Lyme disease, West Nile virus, malaria, yellow fever, dengue fever, and encephalitis. Please see the *BEAD Chemical Profile for Registration Review: DEET (080301)* in the registration review docket for more details.

Summary of Use	Broad-spectrum insect repellant registered for use on the human body, clothing, and on horses to repel biting flies, biting midges, black flies, chiggers, deer flies, fleas, gnats, horse flies, mosquitoes, no-see-ums, sand flies, stable flies, and ticks.
Use Sites	DEET is registered for use on horses (animal treatment); and human skin, hair, clothing, footwear, shoes and headgear (hats).
Summary of Usage	DEET accounts for the overwhelming majority of insect repellents used in the United States; approximately 30% of the U.S. population uses DEET annually as an insect repellent.
Formulation Type(s)	Formulations include microencapsulated, pressurized spray (aerosol), impregnated materials (e.g., towelettes, roll on), and ready-to-use solution (non-aerosol pump sprays, liquids, creams, lotions, and foams). A number of DEET products are also formulated with sunscreen.
Application Method(s)	DEET is generally applied using aerosol sprays, non-aerosol sprays, creams, lotions, roll-ons, foams, and towelettes.
Technical Registrant(s)	Clairant Corporation (8340) and Vertellus Performance Materials, Inc. (51147)
No. of Registrations	122 active registrations
Restricted Use	No

RECENT ACTIONS

There are no recent actions for DEET.

SCIENTIFIC ASSESSMENTS

A summary of the Agency's human health and environmental fate and ecological risk assessments, *DEET (N,N-Diethyl-meta-toluamide) – Revised Human Health Risk Assessment in Support of Registration Review* (February 27, 2014) and *Registration Review – Ecological Risk, Environmental Fate, and Endangered Species Assessment for N,N-Diethyl-meta-toluamide (DEET)* (August 2, 2012), is presented below. For the detailed risk assessments, see the DEET public docket (EPA-HQ-OPP-2012-0162) accessed at www.regulations.gov.

A. Human Health Assessment

Hazard Characterization and Risk

The toxicological database is considered adequate for characterizing hazard and assessing risk from DEET. No additional studies are anticipated to be needed for registration review.

Dietary Exposure Assessment

There are no registered food/feed uses and existing use patterns are not expected to contaminate surface or ground water; thus, a dietary exposure assessment was not conducted.

Food Tolerances

There are no U.S. tolerances established for DEET because DEET is not registered for any food/feed uses.

Residential and Occupational Exposure

DEET is registered for use as an insect repellent, and for use on clothing or directly on the skin. There are also registered DEET-impregnated products, such as tablecloths. DEET products are available in multiple formulations, including aerosol sprays, creams, lotions, and in multiple concentrations. Exposures to DEET may occur from deliberate application to the skin and clothing of individuals. Human exposure from the repellent-use can be on the order of days or weeks or longer, depending on the individual user's activity pattern and geographic area. Exposure is expected to be of short- and intermediate-term exposure duration; however, long-term exposures are possible for some individuals in some climates.

Insect repellents are used by/on people of all ages. Adults are assumed to experience both dermal and inhalation handler exposures, as well as post-application dermal and, potentially, inhalation exposure. Adults are assumed to apply repellents to themselves or to others. Additionally, for aerosol repellents, individuals on whom the products are being applied can experience indirect inhalation exposure during the application. For children, post-application exposure consists of dermal, (potentially) inhalation, and hand-to-mouth exposure. An exposure assessment was previously prepared to support the DEET Registration Eligibility Decision (RED). Since no endpoints have been identified for DEET, a quantitative exposure and risk assessment for DEET products, including a residential exposure and risk assessment, is not anticipated to be needed at this time. There is no occupational exposure associated with DEET; therefore, an occupational risk assessment was not conducted (*DEET (N,N-Diethyl-meta-toluamide) – Revised Human Health Risk Assessment in Support of Registration Review* (February 27, 2014)).

Human Health Incidents

The Office of Pesticide Programs (OPP) Incident Data System (IDS) was used to retrieve pesticide incident data on DEET. The IDS records incidents in one of two modules: Main IDS and Aggregate IDS. Main IDS contains incidents resulting in higher severity outcomes and provides more detail with regard to case specifics. Aggregate IDS contains incidents resulting in less severe human incidents (minor, unknown, or no effects outcomes). For the Main IDS, from January 1, 2007 to February 22, 2012, there were 387 exposures reported for single chemical only in the database (382 exposure classified as resulting in a moderate severity, 4 classified as major severity and 1 classified as an undetermined severity). In the Aggregate IDS, from January 1, 2007 to February 22, 2012, there were 2,769 reported incidents involving DEET. DEET is not included in the Agricultural Health Study (AHS).

Overall, there were a large number of incidents reported involving DEET; however, the number of incidents is relatively small when compared to the number of users. Most of the incidents reported to IDS involving DEET were classified as minor severity. Minor severity

means that a person alleged or exhibited some symptoms, but they were minimally traumatic, the symptoms resolved rapidly and usually involved skin, eye or respiratory irritation. Several high severity outcomes are reported in the IDS database. It is important to note, however, that there are a large number of users of DEET (approximately 104 million, based on the estimated use rate in 1984-1989[2]) and the number of incidents is relatively small in comparison. It also is unclear if there is a connection between DEET use and the incidents or if it is a coincidence. While incident information can be an important source of feedback to the Agency, reports of adverse health effects allegedly due to a specific pesticide exposure (i.e., an "incident") are largely self-reported and therefore, generally speaking, neither exposure to a pesticide or reported symptom (or the connection between the two) is validated or otherwise confirmed. Typically, causation cannot be determined based on incident data (*Revised DEET: Review of Human Incidents* (June 19, 2012) and *DEET (N,N-Diethyl-meta-toluamide) – Revised Human Health Risk Assessment in Support of Registration Review* (February 27, 2014)).

B. Environmental Assessment

Environmental Fate and Exposure

DEET is relatively stable, highly hygroscopic and sensitive to light. It is expected to be moderately mobile in the soil column. In surface waters and soil, DEET is expected to degrade at a moderate to rapid rate (the half-life of DEET is measured in days to weeks). The small amounts of DEET retained in air are subject to rapid photo-oxidation via hydroxy radical-mediated degradation with an estimated half-life between 10 to 15 hours. The bioaccumulation potential of DEET is low; it is neither a persistent, bioaccumulative toxicant nor a persistent organic pollutant.

Based on the use characteristics and environmental fate properties of DEET, runoff, spray drift, leaching, and atmospheric deposition are unlikely to result in aquatic or terrestrial exposures to non-target plants and organisms.

Ecological Risk Characterization

The results of risk estimation for aquatic organisms indicate that registered uses of DEET will not result in level of concern (LOC) exceedances for acute risk to fish and invertebrates. Chronic risk quotients (RQs) were not calculated; however, given the large margin of safety observed for acute effects based on the most conservative exposure scenario, it is unlikely that chronic RQs would approach LOCs. Risks for aquatic plants are expected to be lower than LOCs, given the mode of action of DEET and the large margin of safety demonstrated for other aquatic organisms.

Exposure in terrestrial habitats would be limited to human skin, clothing, and shoes, as well as horse skin and hair of horses that received DEET applications. Products formulated as lotions or impregnated wipes are applied directly to human skin. Many other product labels specify recommended spray distances of less than 10 inches from the intended application sites (human skin, clothing, and shoes, as well as horse skin and hair). The amount of DEET resulting

[2] Veltri, J.C., Osimitz, T.G., Bradford, D.C., and Page, B.C. 1994. Retrospective analysis of calls to Poison Control Centers resulting from exposure to the insect repellent N,N-diethyl-m-toluamide (DEET) from 1985-1989. Clinical Toxicology, 32(1):1-16.

from human or horse application in the terrestrial environment (air, ground, plants, or non-treated animals) is inconsequential. As there is no complete exposure pathway under the currently registered uses, the Agency expects negligible risk to terrestrial organisms.

Threatened and Endangered Species

There is no reasonable expectation for any registered use of DEET to cause direct or indirect adverse effects to threatened and endangered species. No adverse modification of critical habitat is expected from the use of DEET. There are no aquatic LOC exceedances based on low environmental exposure and low toxicity to aquatic organisms. Conclusions regarding terrestrial organisms and plants are based on the lack of a complete exposure pathway. As discussed above, exposure is expected to be limited to human skin, clothing, and horses. Exposure to listed species is not expected because they would not likely come in direct contact with humans or domestic horses (i.e., the registered use sites). Therefore, EPA has made a "no effect" determination under the Endangered Species Act (ESA) for all listed species and designated critical habitat for such species, and has therefore concluded that consultation with the Fish and Wildlife Service and the National Marine Fisheries Service under ESA section 7(a)(2) is not required (*Registration Review – Ecological Risk, Environmental Fate, and Endangered Species Assessment for N,N-Diethyl-meta-toluamide (DEET)* (August 2, 2012)).

Ecological Incidents

There are no reported incidents for aquatic organisms or plants. A review of the following databases was completed on May 29, 2012: Ecological Incident Information System (EIIS), Aggregate Incident Reports database, Avian Monitoring Information System (AIMS), and the Contaminant Exposure and Effects – Terrestrial Vertebrate (CEE-TV). One incident was listed in the EIIS database and one incident was listed in the Aggregate Incident Report database. No additional incidents for DEET were identified in the AIMS or the CEE-TV databases. For additional discussion of the reported ecological incidents, see the *Registration Review – Ecological Risk, Environmental Fate, and Endangered Species Assessment for N,N-Diethyl-meta-toluamide (DEET).*

C. Endocrine Disruptor Screening Program

As required by FIFRA and FFDCA, EPA reviews numerous studies to assess potential adverse outcomes from exposure to chemicals. Collectively, these studies include acute, subchronic and chronic toxicity, including assessments of carcinogenicity, neurotoxicity, developmental, reproductive, and general or systemic toxicity. These studies include endpoints which may be susceptible to endocrine influence, including effects on endocrine target organ histopathology, organ weights, estrus cyclicity, sexual maturation, fertility, pregnancy rates, reproductive loss, and sex ratios in offspring. For ecological hazard assessments, EPA evaluates acute tests and chronic studies that assess growth, developmental and reproductive effects in different taxonomic groups. As part of its most recent registration decision for DEET, EPA reviewed these data and determined that a qualitative toxicity assessment is appropriate for DEET. However, as required by FFDCA section 408(p), DEET is subject to the endocrine screening part of the Endocrine Disruptor Screening Program (EDSP).

EPA has developed the EDSP to determine whether certain substances (including pesticide active and other ingredients) may have an effect in humans or wildlife similar to an

effect produced by a "naturally occurring estrogen, or other such endocrine effects as the Administrator may designate." The EDSP employs a two-tiered approach to making the statutorily required determinations. Tier 1 consists of a battery of 11 screening assays to identify the potential of a chemical substance to interact with the estrogen, androgen, or thyroid (E, A, or T) hormonal systems. Chemicals that go through Tier 1 screening and are found to have the potential to interact with E, A, or T hormonal systems will proceed to the next stage of the EDSP where EPA will determine which, if any, of the Tier 2 tests are necessary based on the available data. Tier 2 testing is designed to identify any adverse endocrine-related effects caused by the substance, and establish a dose-response relationship between the dose and the E, A, or T effect.

Under FFDCA section 408(p), the Agency must screen all pesticide chemicals. Between October 2009 and February 2010, EPA issued test orders/data call-ins for the first group of 67 chemicals, which contains 58 pesticide active ingredients and 9 inert ingredients. A second list of chemicals identified for EDSP screening was published on June 14, 2013[3] and includes some pesticides scheduled for Registration Review and chemicals found in water. DEET was not included on either list. For further information on the status of the EDSP, the policies and procedures, the lists of chemicals, future lists, the test guidelines and the Tier 1 screening battery, please visit our website.[4]

In the interim, EPA is making no human health or environmental safety findings associated with the EDSP screening of DEET. Before completing this Registration Review, the Agency will make an EDSP FFDCA section 408(p) determination.

INTERIM REGISTRATION REVIEW DECISION

In accordance with 40 CFR Sections 155.56 and 155.58, the Agency is issuing this Interim Registration Review Decision. Except for the EDSP component of the DEET registration review case, the Agency has made the following interim decision: (1) no additional data are required at this time; and (2) no changes to the affected registrations or their labeling are needed at this time. EPA has not identified any risks of concern to human health. Currently registered uses of DEET are not expected to result in adverse effects for listed and non-listed species, or critical habitat. As such, EPA concludes "no effect" for listed species and no adverse modification of designated critical habitat for all currently registered uses of DEET.

NEXT STEPS AND TIMELINE

A final decision on the DEET registration review case will occur after an EDSP FFDCA section 408(p) determination has been made.

EPA created the following estimated timeline for the completion of the DEET Interim Registration Review Decision.

[3] See http://www.regulations.gov/#!documentDetail;D=EPA-HQ-OPPT-2009-0477-0074 for the final second list of chemicals.
[4] http://www.epa.gov/endo/

Registration Review for DEET – Interim Registration Review Timeline	
Activities	**Estimated Date**
Opening the Docket and Combined Work Plan, Summary Document, and Interim Registration Review Decision	
Open Public Docket and Public Comment Period for Combined Work Plan, Summary Document, and Proposed Interim Registration Review Decision	May 2014 – Completed
Close Public Comment Period	July 2014 – Completed
Interim Registration Review Decision and Begin Post-Decision Follow-up[5]	September 2014 – Completed
Total (months)	4

[5] A final decision on the DEET registration review case, in accordance with 40 CFR Section155.158, will occur after an EDSP FFDCA section 408(p) determination has been made.