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ENVIRONMENTAL PROTECTION AGENCY

[EPA-HQ-OPP-2014-0651; FRL-9916-79]

Registration Review Final and Interim Decisions; Notice of Availability

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: This notice announces the availability of EPA's final registration review decisions.

Registration review is EPA's periodic review of pesticide registrations to ensure that each pesticide continues to satisfy the statutory standard for registration, that is, that the pesticide can perform its intended function without causing unreasonable adverse effects on human health or the environment. Through this program, EPA is ensuring that each pesticide's registration is based on current scientific and other knowledge, including its effects on human health and the environment.

FOR FURTHER INFORMATION CONTACT: *For pesticide specific information, contact:* The Chemical Review Manager for the pesticide of interest identified in the table in Unit II.A.

For general information on the registration review program, contact: Richard Dumas, Pesticide Re-Evaluation Division (7508P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; telephone number: (703) 308-8015; email address: dumas.richard@epa.gov.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

This action is directed to the public in general, and may be of interest to a wide range of stakeholders including environmental, human health, farm worker, and agricultural advocates; the chemical industry; pesticide users; and members of the public interested in the sale, distribution, or use of pesticides. Since others also may be interested, the Agency has not attempted to describe all the specific entities that may be affected by this action. If you have any questions regarding the applicability of this action to a particular entity, consult the pesticide specific contact person listed under **FOR FURTHER INFORMATION CONTACT**.

B. How Can I Get Copies of this Document and Other Related Information?

The docket for this action, identified by docket identification (ID) number EPA-HQ-OPP-2014-0651, is available at <http://www.regulations.gov> or at the Office of Pesticide Programs Regulatory Public Docket (OPP Docket) in the Environmental Protection Agency Docket Center (EPA/DC), West William Jefferson Clinton Bldg., Rm. 3334, 1301 Constitution Ave., NW., Washington, DC 20460-0001. The Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Public Reading Room is (202) 566-1744, and the telephone number for the OPP Docket is (703) 305-5805. Please review the visitor instructions and additional information about the docket available at <http://www.epa.gov/dockets>.

II. Background

A. What Action is the Agency Taking?

Pursuant to 40 CFR 155.58(c), this notice announces the availability of EPA's final registration review decision for dioctyl sodium sulfosuccinate (Case 4029), polybutene resins (Case 4076), and undecylenic acid (Case 4095) and interim decisions for ancymidol (Case 3017), DEET (Case 0002), denatonium saccharide (Case 7625), and metofluthrin (Case 7445).

In addition to the final and interim registration review decision document, the registration review dockets for ancymidol, DEET, denatonium saccharide, dioctyl sodium sulfosuccinate, metofluthrin, polybutene resins, and undecylenic acid also include other relevant documents related to the registration review of these cases. The proposed registration review decisions or interim decisions were posted to the respective dockets and the public was invited to submit any comments or new information. EPA is addressing the comments or information received during the 60-day comment period in the discussion for each pesticide listed in this document, see Unit II. for the discussions.

Table--Registration Review Final and Interim Decisions

Registration Review Case Name and Number	Pesticide Docket ID Number	Chemical Review Manager, Telephone Number, Email Address
Ancymidol (Case 3017)	EPA-HQ-OPP-2011-0482	Christina Scheltema (703) 308-2201 <i>scheltema.christina@epa.gov</i>
DEET (<i>N,N</i> -diethyl-meta-toulamide) (Case 0002)	EPA-HQ-OPP-2012-0162	Susan Bartow (703) 603-0065 <i>bartow.susan@epa.gov</i>
Denatonium saccharide (Case 7625)	EPA-HQ-OPP-2008-0441	Cathryn Britton (703) 308-0136 <i>britton.cathryn@epa.gov</i>
Dioctyl sodium sulfosuccinate (Case 4029)	EPA-HQ-OPP-2010-1006	Garland Waleko (703) 308-8049 <i>waleko.garland@epa.gov</i>
Metofluthrin (Case 7445)	EPA-HQ-OPP-2012-0105	Veronica Dutch (703) 308-8585

		<i>dutch.veronica@epa.gov</i>
Polybutene resins (Case 4076)	EPA-HQ-OPP-2009-0649	Joel Wolf (703) 347-0228 <i>wolf.joel@epa.gov</i>
Undecylenic acid (Case 4095)	EPA-HQ-OPP-2011-0910	Garland Waleko (703) 308-8049 <i>waleko.garland@epa.gov</i>

Ancymidol (Interim Decision). The registration review docket for ancymidol (EPA-HQ-OPP-2011-0482) opened in June 2011. EPA issued the Proposed Interim Registration Review Decision for ancymidol on June 4, 2014 and took comments for 60 days. The Agency received one comment from the Center for Biological Diversity, which supported the Proposed Interim Registration Review Decision. Therefore, EPA is issuing the Interim Registration Review Decision for ancymidol. Ancymidol is a plant growth regulator registered for treating container-grown herbaceous plants, ornamental woody shrubs, and bedding plants grown in greenhouses and in outdoor plant bedding areas. It is also registered for use as a seed treatment for ornamental plants, and treated seeds are used to start plants. Use of ancymidol is limited to nursery-grown ornamentals. There are no food, feed, or residential uses registered for ancymidol. No pesticide tolerances have been established. EPA conducted a qualitative assessment for both human health, and environmental fate, and ecological risks. No risks of concern were identified in the human health risk assessment. The environmental fate and ecological risk assessment indicated that there was no reasonable expectation for any registered use of ancymidol to cause direct or indirect adverse effects to threatened and endangered species or designated critical habitat. EPA made a “no effect” determination was all federally listed species and designated critical habitat. Ancymidol has not been evaluated under the endocrine disruptor screening

program (EDSP). Therefore, the Agency's final registration review decision is dependent upon the result of the evaluation of potential endocrine disruptor risk.

DEET (Interim Decision). EPA has completed an interim registration review decision for DEET (*N,N*-diethyl-meta-toulamide). The registration review docket for DEET opened in June 2014 (EPA-HQ-OPP-2012-0162). EPA issued a combined Work Plan and Proposed Interim Decision for DEET on June 4, 2014 and took comment for 60 days. The public comments received did not affect the Agency's interim decision. 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. It is currently registered for non-food uses and residential uses. It can be directly used on clothing, applied to the skin, and used on horses. EPA conducted a qualitative assessment for both human health and ecological risks. No risks of concern were identified. The ecological risk assessment made a "no effect" determination for federally listed species and designated critical habitat. DEET has not been evaluated under the EDSP. Therefore, the Agency's registration review decision is dependent upon the result of the evaluation of potential endocrine disruptor risk.

Denatonium saccharide (Interim Decision). EPA has completed an interim registration review decision for denatonium saccharide. The registration review docket for denatonium saccharide (EPA-HQ-OPP-2008-0441) opened in June 2008. EPA issued the proposed interim decision for denatonium saccharide on June 4, 2014 and took comment for 60 days. The Agency received one comment from the Center for Biological Diversity, which supported the Proposed Interim Registration Review Decision. Denatonium saccharide is a bittering agent in squirrel, vole, dog, and cat repellents used on outdoor surfaces and structures such as trees, fences, poles, decks, planters, siding, garbage cans, furniture, seeds, and bulbs. EPA conducted a

qualitative human health risk assessment and did not identify any risks of concern. The ecological risk assessment identified potential risks for birds and listed mammals. However, due to the number of conservative assumptions included in the assessment, there are no labeling changes at this time. The risk assessment for denatonium saccharide did not come to a conclusion of “no effect” to listed species. Therefore, consultation with the U.S. Fish and Wildlife Service (USFWS) on the potential risk of denatonium saccharide to listed species will be necessary. Denatonium saccharide has not been evaluated under the EDSP. Therefore, the Agency's final registration review decision is dependent upon the result of Section 7 Endangered Species consultation with the USFWS and the evaluation of potential endocrine disruptor risk.

Diocetyl sodium sulfosuccinate (Registration Review Decision). EPA has completed a registration review decision for dioctyl sodium sulfosuccinate (DSS). The registration review docket for DSS (EPA-HQ-OPP-2010-1006) opened in December 2010. EPA issued the proposed decision for DSS on June 4, 2014 and took comment for 60 days. The Agency received one comment from the Center for Biological Diversity, which supported the proposed registration review decision. DSS is registered as an insecticide and miticide in pet shampoos and spray products in combination with Undecylenic Acid (UDA). As a pesticidal active ingredient, there are no food uses and, thus, no tolerances are established. DSS is used as an active ingredient in over the counter stool-softener and laxative products for infants, children, and adults; it is also used in pharmaceutical, cosmetic, and food products. EPA has conducted a qualitative assessment for both human health and ecological risks, including listed species for DSS. The human health risk assessment did not identify any risks of concern for DSS. The ecological risk assessment made a “no effect” determination for federally listed species and designated critical habitat. Pursuant to section 408(p)(4) of the Federal Food, Drug, and Cosmetic Act (FFDCA), EPA has exempted DSS from the requirements of the EDSP in an Administrative Order entitled

“Exemption of Dioctyl Sodium Sulfosuccinate (DSS) and Undecylenic Acid (UDA) from the Requirements of the Endocrine Disruptor Screening Program” which is available in the registration review docket.

Metofluthrin (Interim Decision). EPA has completed an interim registration review decision for metofluthrin. The registration review docket for metofluthrin (EPA-HQ-OPP-2012-0105) opened in June 2013. EPA opened a 60-day comment period on the proposed interim decision for metofluthrin in June 2014. Three comments were received during that period. The Center for Biological Diversity commented that it agreed with the Agency’s proposed decision. Two other comments, from California Water Board representatives, expressed the view that metofluthrin should undergo a comprehensive ecological assessment, like the other pyrethroids. The commenters also expressed concern that metofluthrin (particularly the bed bug use and the tabletop mister) had the potential to contaminate urban waters. These comments have been addressed in a new response to comments document available on the docket. None of the comments resulted in changes to the interim decision. Metofluthrin is a Type 1 synthetic pyrethroid insect repellent and insecticide with products registered for use in residential and commercial areas, including barns, stables, and kennels. There are no registered food/feed uses. Metofluthrin has minimal potential for human health and ecological exposure. No risks of concern were identified. In addition, the Agency made a “no effect” determination for federally listed species and designated critical habitat. No additional data or changes to the affected registrations or their labeling are needed at this time. Metofluthrin has not been evaluated under the EDSP. Therefore, the Agency's final registration review decision will be dependent on evaluation of potential endocrine disruptor risk.

Polybutene resins (Registration Review Decision). EPA has completed a registration review decision for polybutene resins. The registration review docket for polybutene resins (EPA-HQ-OPP-2009-0649) opened in June 2010. EPA issued the proposed decision for polybutene resins on June 4, 2014 and took comment for 60 days. The Agency received one comment from the Center for Biological Diversity, which supported the proposed registration review decision. Polybutene is a sticky polymer registered for use as a bird and small mammal repellent. It is used to prevent house sparrows, pigeons, and starlings from roosting inside and outside of buildings, as well as to prevent beavers from attacking trees and shrubs. There are no food/feed uses and, it is exempt from a tolerance requirement when used as a sticker agent in packaging of insect control products used on food crops. Polybutene is approved by the U.S. Food and Drug Administration (FDA) as an indirect food additive and is used as an ingredient in cosmetic products that are applied directly to the skin such as sun block or moisturizer, and that may be incidentally ingested, such as lipstick. EPA conducted a qualitative assessment for both human health and ecological risks. No risks of concern were identified in the human health risk assessment. The ecological risk assessment indicated that there was no reasonable expectation for any registered use of polybutene to cause direct or indirect adverse effects to threatened and endangered species. A “no effect” determination was made for all federally listed species and designated critical habitat. Pursuant to FFDCFA section 408(p)(4), EPA has exempted polybutene from the requirements of the EDSP in an Administrative Order (AO) entitled “Exemption of Polybutene from the Requirements of the Endocrine Disruptor Screening Program” which is available in the registration review docket.

Undecylenic acid (Registration Review Decision). EPA has completed a registration review decision for undecylenic acid (UDA). The registration review docket for UDA (EPA-HQ-OPP-2011-0910) opened in December 2011. EPA issued the proposed decision for UDA on June

4, 2014 and took comment for 60 days. The Agency received one comment from the Center for Biological Diversity, which supported the proposed registration review decision. UDA is registered as an insecticide and miticide in pet shampoos and spray products in combination with dioctyl sodium sulfosuccinate (DSS). As a pesticidal active ingredient, there are no food uses and, thus, no tolerances are established. UDA is approved by the FDA as an active ingredient in over the counter anti-fungal products, and it is also used as a flavoring agent. EPA has conducted a qualitative assessment for both human health and ecological risks, including listed species for UDA. The human health risk assessment did not identify any risks of concern for UDA. The ecological risk assessment made a “no effect” determination for federally listed species and designated critical habitat. Pursuant to FFDCa section 408(p)(4), EPA has exempted UDA from the requirements of the EDSP in an AO entitled “Exemption of Dioctyl Sodium Sulfosuccinate (DSS) and Undecylenic Acid (UDA) from the Requirements of the Endocrine Disruptor Screening Program” which is available in the registration review docket.

Pursuant to 40 CFR 155.57, a registration review decision is the Agency’s determination whether a pesticide meets, or does not meet, the standard for registration in FIFRA. EPA has considered Ancyamidol, DEET, Denatonium Saccharide, Dioctyl Sodium Sulfosuccinate, Metofluthrin, Polybutene Resins, and Undecylenic Acid in light of the FIFRA standard for registration. The Ancyamidol, DEET, Denatonium Saccharide, Dioctyl Sodium Sulfosuccinate, Metofluthrin, Polybutene Resins, and Undecylenic Acid Final or Interim Decision documents in the respective dockets describe the Agency’s rationale for issuing a registration review final or interim decision for these pesticides.

Pursuant to 40 CFR 155.58(c), the registration review case docket for Ancyamidol, DEET, Denatonium Saccharide, Dioctyl Sodium Sulfosuccinate, Metofluthrin, Polybutene Resins,

and Undecylenic Acid will remain open until all actions required in the final decision have been completed.

Background on the registration review program is provided at:

http://www.epa.gov/oppsrrd1/registration_review. Links to earlier documents related to the registration review of this pesticide are provided at: <http://www2.epa.gov/pesticide-reevaluation/individual-pesticides-registration-review>.

B. What is the Agency's Authority for Taking this Action?

Section 3(g) of FIFRA and 40 CFR part 155, subpart C, provide authority for this action.

Authority: 7 U.S.C. 136 *et seq.*

Dated: September 16, 2014.

Richard P. Keigwin, Jr.,

Director, Pesticide Re-Evaluation Division, Office of Pesticide Programs.

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