



ENVIRONMENTAL PROTECTION AGENCY

[EPA-HQ-OPP-2017-0720; FRL-10008-07]

Pesticide Registration Review; Draft Human Health and Ecological Risk Assessments for Several Pesticides for Several Isothiazolinones; Notice of Availability

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: This notice announces the availability of EPA's draft human health and ecological risk assessments for the registration review of Methylisothiazolinone/Chloromethylisothiazolinone (MIT/CMIT), Octhiline (OIT), Benzisothiazolin-3-one, 3(2H)-Isothiazolone (BIT), 1,2-Benzisothiazol-3(2H)-one, 2-butyl (BBIT), and 3(2H)-isothiazolone, 4,5-dichloro-2-octyl- (DCOIT).

DATES: Comments must be received on or before [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*].

ADDRESSES: Submit your comments, to the docket identification (ID) number for the specific pesticide of interest provided in the Table in Unit IV, by one of the following methods:

- *Federal eRulemaking Portal:* <http://www.regulations.gov>. Follow the online instructions for submitting comments. Do not submit electronically any information you consider to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute.

- *Mail:* OPP Docket, Environmental Protection Agency Docket Center (EPA/DC), (28221T), 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001.

• *Hand Delivery*: To make special arrangements for hand delivery or delivery of boxed information, please follow the instructions at <http://www.epa.gov/dockets/contacts.html>.

Additional instructions on commenting or visiting the docket, along with more information about dockets generally, are available at <http://www.epa.gov/dockets>.

FOR FURTHER INFORMATION CONTACT: *For pesticide specific information contact:* The Chemical Review Manager for the pesticide of interest identified in the Table in Unit IV.

For general questions on the registration review program, contact: Richard Fehir, Antimicrobials Division (7510P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; telephone number: (703) 347-8101; email address: fehir.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 Chemical Review Manager identified in the Table in Unit IV.

B. What Should I Consider as I Prepare My Comments for EPA?

1. *Submitting CBI.* Do not submit this information to EPA through regulations.gov or email. Clearly mark the part or all of the information that you claim to be CBI. For CBI information in a disk or CD-ROM that you mail to EPA, mark the outside of the disk or CD-ROM as CBI and then identify electronically within the disk or CD-ROM the specific information that is claimed as CBI. In addition to one complete version of the comment that includes information claimed as CBI, a copy of the comment that does not contain the information claimed as CBI must be submitted for inclusion in the public docket. Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2.

2. *Tips for preparing your comments.* When preparing and submitting your comments, see the commenting tips at <http://www.epa.gov/dockets/comments.html>.

3. *Environmental justice.* EPA seeks to achieve environmental justice, the fair treatment and meaningful involvement of any group, including minority and/or low income populations, in the development, implementation, and enforcement of environmental laws, regulations, and policies. To help address potential environmental justice issues, the Agency seeks information on any groups or segments of the population who, as a result of their location, cultural practices, or other factors, may have atypical or disproportionately high and adverse human health impacts or environmental effects from exposure to the pesticides discussed in this document, compared to the general population.

II. Background

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, the pesticide can perform its intended function without unreasonable adverse effects on human health or the environment. As part of the registration review process, the Agency has completed comprehensive draft human health and/or ecological risk assessments for all pesticides listed in the Table in Unit IV. After reviewing comments received during the public comment period, EPA may issue a revised risk assessment, explain any changes to the draft risk assessment, and respond to comments and may request public input on risk mitigation before completing a proposed registration review decision for the pesticides listed in the Table in Unit IV. 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.

III. Authority

EPA is conducting its registration review of the chemicals listed in the Table in Unit IV pursuant to section 3(g) of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) and the Procedural Regulations for Registration Review at 40 CFR part 155, subpart C. Section 3(g) of FIFRA provides, among other things, that the registrations of pesticides are to be reviewed every 15 years. Under FIFRA, a pesticide product may be registered or remain registered only if it meets the statutory standard for registration given in FIFRA section 3(c)(5) (7 U.S.C. 136a(c)(5)). When used in accordance with widespread and commonly recognized practice, the pesticide product must perform its intended function without unreasonable adverse effects on the environment; that is,

without any unreasonable risk to man or the environment, or a human dietary risk from residues that result from the use of a pesticide in or on food.

IV. What Action is the Agency Taking?

Pursuant to 40 CFR 155.58, this notice announces the availability of EPA's human health and ecological risk assessments for the pesticides shown in the following table and opens a 60-day public comment period on the risk assessments.

Table -- Draft Risk Assessments Being Made Available for Public Comment

Registration Review Case Name and Number	Docket ID Number	Chemical Review Manager and Contact Information
MIT/CMIT Case 3092	EPA-HQ-OPP-2013-0605	Stephen Savage <i>savage.stephen@epa.gov</i> (703) 347-0345
OIT Case 2475	EPA-HQ-OPP-2014-0160	Stephen Savage <i>savage.stephen@epa.gov</i> (703) 347-0345
BIT Case 3026	EPA-HQ-OPP-2014-0159	Stephen Savage <i>savage.stephen@epa.gov</i> (703) 347-0345
BBIT Case 5017	EPA-HQ-OPP-2015-0736	Stephen Savage <i>savage.stephen@epa.gov</i> (703) 347-0345
DCOIT Case 5023	EPA-HQ-OPP-2014-0403	Stephen Savage <i>savage.stephen@epa.gov</i> (703) 347-0345

Pursuant to 40 CFR 155.53(c), EPA is providing an opportunity, through this notice of availability, for interested parties to provide comments and input concerning the Agency's draft human health and/or ecological risk assessments for the pesticides listed in the Table in Unit IV. The Agency will consider all comments received during the public comment period and make changes, as appropriate, to a draft human health and/or ecological risk assessment. For specific comments the Agency is soliciting, see Unit V of

this notice. EPA may then issue a revised risk assessment as part of the proposed interim decision (PID), explain any changes to the draft risk assessment, and respond to comments.

Information submission requirements. Anyone may submit data or information in response to this document. To be considered during a pesticide's registration review, the submitted data or information must meet the following requirements:

- To ensure that EPA will consider data or information submitted, interested persons must submit the data or information during the comment period. The Agency may, at its discretion, consider data or information submitted at a later date.
- The data or information submitted must be presented in a legible and useable form. For example, an English translation must accompany any material that is not in English and a written transcript must accompany any information submitted as an audiographic or videographic record. Written material may be submitted in paper or electronic form.
- Submitters must clearly identify the source of any submitted data or information.
- Submitters may request the Agency to reconsider data or information that the Agency rejected in a previous review. However, submitters must explain why they believe the Agency should reconsider the data or information in the pesticide's registration review.

As provided in 40 CFR 155.58, the registration review docket for each pesticide case will remain publicly accessible through the duration of the registration review process; that is, until all actions required in the final decision on the registration review case have been completed.

V. Request for Comment

The EPA specifically requests comment concerning the draft risk assessments in the following areas:

- The use of *in vitro* and the artificial neural network-based defined approach (DA) to determine points of departure used in the isothiazolinone draft risk assessments instead of using laboratory animal data to evaluate risks for dermal sensitization.
- The use of a 100-fold uncertainty factor (UF) for the *in vitro* points of departure and use of a 10-fold UF for the human study point of departure selected for the human health dermal assessment.

Additionally, EPA requests information that may help the Agency refine the draft risk assessments. For the human health risk assessment, EPA welcomes the following information:

- For the assessment of inhalation risk, the inhalation toxicity study for DCOIT has been bridged to assess hazard of both BIT and BBIT, which do not have inhalation toxicity data. While the no observed adverse effect level (NOAEC) value from the DCOIT study is conservative, refinement of the NOAEC through benchmark dosing is not possible. Due to the 32-fold difference between the NOAEC and lowest observed adverse effect level (LOAEC) values in the DCOIT study, the inhalation risks may be overestimated using the conservative, unrefined endpoint from DCOIT. Additional chemical-specific inhalation toxicity data using proper dose spacing to conduct benchmark dose analysis would help to refine the inhalation risk assessments for the isothiazolinones.

- Residue transfer data are not available at this time for textiles/clothing, plastics, and carpets and 100% of the application rate was assumed to transfer to children. Data currently being collected by the Antimicrobial Exposure Assessment Task Force (AEATF II) will potentially help to refine the human incidental oral and dermal exposures.

For the environmental risk assessments, EPA requests the following information:

- Degradation studies to show potential degradation in wastewater treatment facilities.
- More robust usage data on paper production, including information on how the compounds are used in paper production.

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

Dated: ____April 9, 2020._____

Anita Pease,

Director, Antimicrobials Division, Office of Pesticide Programs.

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