



California Notice 2018-17

NOTICE OF INITIATION OF HUMAN HEALTH RISK ASSESSMENT FOR THE NEW ACTIVE INGREDIENT ALLYL ISOTHIOCYANATE (AITC)

The Department of Pesticide Regulation (DPR) is initiating the human health risk assessment process for the new pesticide active ingredient allyl isothiocyanate (AITC). Currently, AITC is not found in any registered pesticide products in California.

BACKGROUND

Food and Agricultural Code (FAC) sections 13121-13130 require DPR to review the toxicology database of pesticide active ingredients. FAC section 13134 requires DPR to assess dietary risks associated with the use of pesticides. In addition, FAC section 12824 requires DPR to conduct a thorough evaluation before a substance is registered as a pesticide for the first time.

During the risk assessment process, DPR evaluates the significance of any adverse effects to human health. If DPR decides that use of, or certain uses of, pesticide products containing a new active ingredient undergoing risk assessment may result in a significant adverse effect to human health that cannot be mitigated, DPR will deny registration of pesticide products containing the active ingredient.

BASIS FOR RISK ASSESSMENT INITIATION

In addition to DPR's policy of conducting risk assessments on new fumigant active ingredients before a registration decision, DPR is initiating the human health risk assessment process for the active ingredient AITC due to DPR concerns regarding toxicity in the following animal studies:

- a. reproductive effects
- b. genotoxicity, and
- c. oncogenicity

RISK ASSESSMENT PROCESS

The process begins with a problem formulation/scoping phase prior to drafting the Risk Characterization Document (RCD). During this phase, DPR risk managers and risk assessors will discuss the scope of the risk assessment for a specific pesticide. Information and data relevant to the pesticide are evaluated to determine the scope of the risk assessment. The information and data evaluated may include toxicology, pesticide use reports, pesticide sales, illness reports including adverse effects reports, primary uses of the pesticide, exposure scenarios identified on product labels, relevant U.S. Environmental Protection Agency risk assessments, important sources of uncertainty and variability in the data, potential exposure pathways, and mitigation options that could address these potential exposure pathways.

More information regarding DPR's human health risk assessment process can be found on DPR's Web site at <https://www.cdpr.ca.gov/docs/whs/active_ingredient/index.htm>.

REQUEST FOR RELEVANT AITC DATA

As a part of the problem formulation phase, DPR is seeking data and information on all proposed uses of AITC that are relevant to the risk assessment.

DPR particularly welcomes input regarding AITC on:

- Potential exposure scenarios for consideration and application procedures (use information, settings, rates, etc.)
- Possible mitigation options that might reduce potential exposure
- Additional data that may be needed to conduct the risk assessment
- Availability of feasible alternatives

DPR'S PESTICIDE DATA INDEX

To view studies DPR currently has on file for AITC, you may search DPR's pesticide data index at <<https://apps.cdpr.ca.gov/ereglib/>>.

If you have information or data that you believe are relevant to this risk assessment, please submit them to DPR by November 9, 2018. Please address all submissions to:

Risk Assessment -- AITC
Attn: Risk Assessment Coordinator
Pesticide Registration Branch
Department of Pesticide Regulation
1001 I Street, P.O. Box 4015
Sacramento, CA 95812-4015

NEXT STEPS

DPR intends to present a draft problem formulation document for the AITC human health risk assessment to the Pesticide Registration and Evaluation Committee (PREC) on November 16, 2018. To receive information regarding PREC meetings, please subscribe to the PREC electronic mailing list at <<https://www.cdpr.ca.gov/docs/dept/listserv/listdesc.htm>>.

Please address all questions and comments regarding this notice to Ms. Kara James, Environmental Scientist, at 916-324-3523 or by e-mail to <Kara.James@cdpr.ca.gov>.

Original signed by Ann M. Prichard

Ann M. Prichard, Chief
Pesticide Registration Branch
916-324-3931

October 2, 2018

Date

cc: Ms. Kara James, Environmental Scientist