



Brian Leahy
Director

Department of Pesticide Regulation



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California Notice 2018-04

NOTICE OF INITIATION OF HUMAN HEALTH RISK ASSESSMENT FOR THE ACTIVE INGREDIENTS **β -CYFLUTHRIN, CYFLUTHRIN**

This notice informs stakeholders that the Department of Pesticide Regulation (DPR) is initiating the human health risk assessment process for registered pesticide products containing the active ingredients β -cyfluthrin and/or cyfluthrin. β -cyfluthrin and cyfluthrin are synthetic pyrethroids. β -cyfluthrin is an isomeric enriched form of cyfluthrin.

BACKGROUND

Food and Agricultural Code (FAC) sections 13121-13130 require DPR to review the toxicology database of all registered 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 endeavor to eliminate from use in California any pesticide that endangers the agricultural or nonagricultural environment.

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 the active ingredient(s) undergoing risk assessment result in a significant adverse effect to human health action must be taken to mitigate the adverse effect(s).

BASIS FOR RISK ASSESSMENT INITIATION

DPR identified β -cyfluthrin and cyfluthrin as having potential adverse health effects in studies of sufficient quality to allow risk characterization. Specifically, DPR is initiating the human health risk assessment process for the active ingredients β -cyfluthrin and cyfluthrin for the following:

1. DPR has concerns regarding toxicity in animal studies:
 - Neurotoxicity from acute, subchronic, and chronic exposures (e.g., sensory irritation, tremors, behavioral changes, altered gait, respiratory apnea, etc.)
 - Developmental effects from prenatal exposures (e.g., malformations and tremors)
2. As required by FAC section 12825.5, registrants of β -cyfluthrin and cyfluthrin products notify DPR of potential adverse effects. DPR staff reviewed potential adverse effects submitted from 2008 – 2016. Nearly all alleged human adverse effects were classified “minor” or “minimal.” There were five human deaths reported from 2008 – 2016. Although these incidents are typically self-reported by the public and are not confirmed to be attributed to actual β -cyfluthrin or cyfluthrin use or exposure, they indicate a potential for human exposure and suggest that further investigation of these compounds is warranted.



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 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 United States 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.

REQUEST FOR RELEVANT β -CYFLUTHRIN AND CYFLUTHRIN DATA

As part of the problem formulation phase, DPR is seeking data and information on all registered uses of β -cyfluthrin and cyfluthrin that are relevant to the risk assessment.

DPR particularly welcomes input from those who sell or use β -cyfluthrin and/or cyfluthrin on:

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

DPR'S PESTICIDE DATA INDEX

To view the studies DPR currently has on file for β -cyfluthrin and cyfluthrin, you may search DPR's pesticide data index at <<http://apps.cdpr.ca.gov/ereglib/>>. A summary of toxicology data for β -cyfluthrin/cyfluthrin is available at <<http://www.cdpr.ca.gov/docs/risk/toxsums/pdfs/2223.pdf>>.

If you have information or data that you believe are relevant to this risk assessment, please submit it to DPR by **March 23, 2018**. Please address all submissions to:

Risk Assessment – (Cyfluthrin and β -Cyfluthrin)
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 β -cyfluthrin and cyfluthrin human health risk assessment to the Pesticide Registration and Evaluation Committee (PREC) on February 16, 2018. More information regarding the PREC can be found on DPR's Web site at <http://cdpr.ca.gov/docs/dept/prec/precmenu.htm>.

Please address all questions and comments regarding this notice to Ms. Ann Hanger, Senior Environmental Scientist (Supervisory), at 916-324-3535 or by e-mail at Ann.Hanger@cdpr.ca.gov.

Original signed by Ann M. Prichard

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

January 17, 2018

Date

cc: Ms. Ann Hanger, Senior Environmental Scientist (Supervisory)