



Department of Pesticide Regulation



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MEMORANDUM

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SUBJECT: UPDATED POSSIBLE MITIGATION NEEDS FOR DELTAMETHRIN

Department of Pesticide Regulation (DPR) staff completed the risk characterization document (RCD) for deltamethrin in 2000. The acute no-observed-effect-level (NOEL) used in this study was based on sporadic effects reported during the first week of a subchronic study and the absorption rate determined in a rat metabolism study. The document presents an estimated NOEL of 0.006 mg/kg/day (0.1 mg/kg/day [lowest dog study dose divided by 10 to estimate the NOEL] times 60% absorption factor determined in a rat metabolism study) for possible regulatory purposes. The choice 0.006 mg/kg/day as the proposed regulatory end-point was not the consensus among the Department's toxicologists due to sensitivity issues, statistical vs. biological significance, dose-delivery selection, cross-species absorption extrapolation, etc. In the 1990's The U.S. EPA, World Health Organization and other regulatory agencies selected a NOEL of 1 mg/kg/day for deltamethrin regulatory purposes based on the weight-of-evidence from studies on multiple species.

In 2004, the DPR "Risk Management Directive for Deltamethrin and Tralomethrin" was released. This document states "*For these active ingredients, the toxicological hazard rests somewhere between 1mg/kg/day and 10 mg/kg/day. The risk characterization document*

adequately characterizes the hazard associated with these doses." In October 2014, DPR staff completed an addendum to the deltamethrin RCD to update the RCD to include deltamethrin products and uses registered since completion of the 2000 RCD. Since it has been almost 15 years since the completion of the DPR deltamethrin RCD, it might be prudent to perform an updated review of this RCD when resources permit. Many new toxicology studies, pesticide illness information, added uses and exposure changes have occurred since completion of the RCD.

The U.S. EPA Office of Pesticide Programs (OPP) is currently in the process of revising their deltamethrin risk assessment which is scheduled to be released during the spring of 2015 for public comment. In February 2010, OPP released a memorandum in support of registration review for deltamethrin containing toxicology end-points to be used for their risk assessment of deltamethrin. However, for dietary and non-occupational exposures, OPP is poised to apply a 10x FQPA safety factor for infants and children. Also, the Council for the Advancement of Pyrethroid Human Risk Assessment (CAPHRA) is under contract with U.S. EPA to



provide 21st Century Toxicology approaches for deltamethrin risk analysis by April 2015. CAPHRA is comprised of industry consultants, industry scientists and academicians tasked by U.S. EPA to look at the use of PBPK and *in vitro* models to reduce uncertainty factors used in pyrethroid risk assessments. CAPHRA is using deltamethrin as their first pyrethroid test-case. These results will most likely be used in the final U.S. EPA assessment decision for deltamethrin scheduled for release in 2016.

Below is a table of currently registered uses of deltamethrin that result in exposures of possible concern. Generally, a Margin of Exposure (MOE) of at least 100 is considered sufficiently protective of human health when no observable adverse effect levels for an adverse effect are derived from an animal study. These exposure scenarios include products used in a residential setting as dusts, granular formulations or applied with a paintbrush or in a flea collar.

Deltamethrin Risk Estimates for Agricultural Handlers, Non-Agricultural Handlers, Agricultural Reentry Exposure, Residential Handler, Residential Reentry Exposure and Flea Collar Exposure Scenarios with MOEs of less than 100.

EXPOSURE SCENARIO	1 mg/kg/day Dose MARGIN OF EXPOSURE
Agricultural Handler	
<i>Aerial Applications (Liquids)</i>	
Mixer/Loader	40
<i>High-Acre Aerial App. (Liquids)</i>	
Mixer/Loader	10
Applicator	60
<i>High-Acre Groundboom</i>	
Mixer/Loader	70
<i>Chemigation</i>	
Mixer/Loader	40
<i>High-Pressure Handwand</i>	
Mixer/Loader/Applicator	80
Non-Agricultural Handler	
<i>Right-Of-Way</i>	
Applicator	50
<i>High-Pressure Handwand</i>	
Mixer/Loader/Applicator	80
<i>Hand-Held Duster</i>	
Applicator	<10
<i>Paintbrush</i>	
Applicator	20

Agricultural Reentry	
Sweet Corn Hand-Harvesting	70
Residential Handler	
<i>Hand-Spread Granular</i>	
Applicator	<10
<i>Hand-Spread Duster</i>	
Applicator	<10
<i>Paintbrush</i>	
Applicator	60
<i>Flea Collar</i>	
Applicator	60
Residential Reentry	
Toddler	80
Post Application: Flea Collar	
Adult	30
Toddler	<10