



Department of Pesticide Regulation



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MEMORANDUM

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DATE: November 15, 2015

SUBJECT: EVALUATION OF THE ACUTE DIETARY RISK OF A 0.010 PPM RESIDUE
OF HYDRAMETHYLNON ON A CHINESE CABBAGE SAMPLE FROM
MEXICO

The Worker Health and Safety Branch (WHS) is preparing a mitigation close-out for the active ingredient hydramethylnon (DPR Chem Code 2203). WHS requested that the Human Health Assessment Branch (HHA) conduct an evaluation of the acute dietary risk of a 0.010 ppm residue of hydramethylnon on a Chinese cabbage sample from Mexico. The produce sample was collected by the Food and Drug Administration (FDA). The WHS requested that HHA evaluate the acute dietary risk to hydramethylnon based on exposures not exceeding 3 mg/kg/day.

Hydramethylnon is an amidinohydrazone insecticide registered in the US for control of ants, termites, and cockroaches in pastures, rangelands, fruit and nut orchards (bait station only, non-food use), domestic dwellings and commercial establishments, and pineapple orchards (food use). There are currently three tolerances under 40CFR180.395: grass, forage, 2.0 ppm; grass, hay, 2.0 ppm; and pineapple, 0.05 ppm.

Hydramethylnon is undergoing registration review at U.S. EPA, and a human health scoping document was completed in 2012 (USEPA, 2012). U.S. EPA evaluated the human risk from dietary exposures to hydramethylnon in 2003 (USEPA, 2003). Acute food-only exposure for females 13-49 years occupied less than 1% of the acute Population Adjusted Dose (aPAD). The drinking water level of concern (DWLOC) was well above modeled estimated environmental concentrations (EECs) for surface water and groundwater. The main conclusion from these



assessments was that the exposure from food and drinking water to hydramethylnon would not result in harm.

As of November 2015, there are 35 products containing hydramethylnon registered in California for structural pest control. There are no products registered to control agricultural crop pests in California. DPR completed a risk characterization document (RCD) in 2004 (DPR, 2004) and performed a Tier 1 (unrefined) dietary exposure assessment in which the residue level on the only permitted food---pineapple---was set to the 0.05-ppm tolerance. Calculated MOEs for acute exposure ranged from 2,377 in nursing infants to 10,042 in females 13-19 years compared to a target MOE of 100, indicating no acute health risk.

The critical acute endpoint for dietary exposure assessment in the 2004 DPR RCD was a No-Observed Effect Level (NOEL) of 3 mg/kg for decreased body weight, clinical signs (perianal area and bloody nasal discharges), and reduced fertility at the Lowest Observed Effect Level (LOEL) of 30 mg/kg/day in a 5-day rat oral gavage study. The aRfD is 0.03 mg/kg based on total uncertainty factors of 100X, resulting in a target MOE of 100. This endpoint applies to the general population.

HHA calculated the threshold consumption for a 0.010 ppm residue on any commodity (see Attachment 1). The threshold consumption is the consumption rate at a given residue concentration that correlates with 100% of the acute toxicity reference dose (aRfD or aPAD). For the purposes of DPR's residue monitoring program, HHA considers 100 g/kg/day to be a reasonable daily maximum (acute) consumption rate. Ninety-fifth percentile consumption rates for most fresh produce are well below 100 g/kg/day. The threshold consumption rate for a 0.010 ppm hydramethylnon residue on any commodity, based on an aRfD of 0.03 mg/kg, is 3,000 g/kg, indicating no acute risk.

We also calculated acute risk values for a 0.010 ppm hydramethylnon residue on Chinese cabbage using consumption data from DEEM-FCID, v. 3.18, which uses survey data from NHANES, 2003-2008 (see Attachment 2). A large survey sample size (i.e., >100 user-days) provides an adequate representation of the consumption pattern of a given population subgroup for a particular commodity. For Chinese cabbage consumption, the exposure estimates were based on <100 user-days for every standard subpopulation, and therefore, may not be representative of actual consumption patterns. The subpopulation with the most user days is Non-Hispanic Other (61 user days, 95th percentile = 1.9 g/kg). The single highest consumption rate is 2.6 g/kg for a 17-year old male. Exposure to a 0.01 ppm hydramethylnon residue on Chinese cabbage based on a consumption rate of 2.6 g/kg would be 0.000026 mg/kg, or 0.1% of the aRfD (MOE = 115,385).

In conclusion, these results indicate no potential acute health risk to the consumers of this Chinese cabbage.

Sheryl Beauvais
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cc: Dr. Lisa Ross, Branch Chief, Worker Health and Safety Branch
Mr. Kevin Solari, Environmental Program Manager

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ATTACHMENT 1: Risk Calculator Using Acute Point of Departures and Consumption

ATTACHMENT 2: Threshold Consumption Calculator Using the Residue and Acute Reference Dose

| THRESHOLD CONSUMPTION CALCULATOR USING THE RESIDUE AND ACUTE REFERENCE DOSE | | |
|--|----------|---|
| HYDRAMETHYLNON / CHINESE CABBAGE | | |
| aRfD (mg/kg) = | 0.030000 | NOEL = 3 mg/kg for decreased body weight, clinical signs (perianal area and bloody nasal discharges), and reduced fertility in a 5-day rat oral gavage study (CDPR, 2004) |
| residue (ppm) | 0.010 | Enter measured residue level (ppm) from the PSAR |
| CONSUMPTION (g food/kg body wt) THAT WOULD RESULT IN EXPOSURE EQUIVALENT TO 100% OF THE aRfD | 3,000 | THRESHOLD CONSUMPTION (g/kg) |
| | | |

| RISK CALCULATOR USING aPoD AND CONSUMPTION | | |
|---|--------------|---|
| HYDRAMETHYLNON / CHINESE CABBAGE | | |
| aPoD (mg/kg) = | 3.000 | NOEL = 3 mg/kg for decreased body weight, clinical signs (perianal area and bloody nasal discharges), and reduced fertility in a 5-day rat oral gavage study (CDPR, 2004) |
| UFH (intraspecies) = | 10 | always 10X |
| UFA (interspecies) = | 10 | 10X if the PoD is derived from an animal study; 1X if the PoD is derived from a human study |
| UFDB (database) = | n/a | 1X - 10X depending on the age of the risk assessment that was the source of the PoD and any known data gaps |
| FQPA SF = | n/a | 1X - 10X depending on the degree of increased sensitivity to acute toxicity by infants & children and/or pregnant females (specify subpopulations to which it applies) |
| TARGET MOE = | 100 | |
| aRfD (mg/kg) = | 0.030000 | aPoD divided by Ufs |
| consumption (g/kg/day) | 2.628 | Single highest consumption rate for Chinese cabbage (M, 17 years) |
| measured residue (ppm) | 0.010 | Hydramethylnon |
| calculated exposure (mg/kg) | 0.000026 | residue (ppm) * consumption (kg/kg) |
| calculated MOE | 115,385 | aPoD divided by calculated exposure |
| %aRfD | 0.1% | Calculated exposure divided by aRfD/aPAD, formatted as % |
| | | |