

TABLE 4.—INTERMEDIATE-TERM AGGREGATE DRINKING WATER ASSESSMENT

Population Subgroup	NOAEL/MOE Mg/ Kg/Day	Aggregate Ex- posure Mg/ Kg/Day	Maximum Water Exposure mg/kg/day	SCI-GROW (ppb)	FIRST (ppb)	DWLOC (ppb)
Toddlers (1 to 3) ¹	0.307	0.217	2.852	0.94	6.24	42,785

¹ Assume 70kg bodyweight

The estimated average concentration of dinotefuran in surface water is 6.24 ppb. This value is less than the DWLOC for dinotefuran as a contribution to intermediate-term aggregate exposure (42,785 ppb). Therefore, taking into account the proposed uses, it can be concluded with reasonable certainty that residues of dinotefuran in residential environments and in food and drinking water will not result in unacceptable levels of human health risk.

D. Cumulative Effects

The potential for cumulative effects of dinotefuran and other substances that have a common mechanism of toxicity has also been considered. Dinotefuran belongs to a pesticide chemical class known as the neonicotinoids and subclass nitroguanadines. There is no reliable information to indicate that toxic effects produced by dinotefuran would be cumulative with those of any other chemical including another pesticide. Therefore, Mitsui believes it is appropriate to consider only the potential risks of dinotefuran in an aggregate risk assessment.

E. Safety Determinations

1. *U.S. population.* Using the chronic exposure assumptions and the proposed RfD described above, the dietary exposure to dinotefuran for the U.S. population (48 states, all seasons) was calculated to be 0.32% of the RfD of 1.27 mg/kg/day. The resulting DWLOC, 44,306 ppb, is much greater than the estimated average concentration of dinotefuran in surface water, 6.24 ppb. Therefore, taking into account the proposed uses, it can be concluded with reasonable certainty that residues of dinotefuran in residential environments and in food and drinking water will not result in unacceptable levels of human health risk.

2. *Infants and children.* FFDCA section 407 provides that EPA shall apply an additional safety factor for infants and children to account for prenatal and postnatal toxicity and the completeness of the data base. Only when there is no indication of increased sensitivity of infants and children and when the data base is complete, may the extra safety factor be removed. In the

case of dinotefuran, the toxicology data base is complete. There is no indication of increased sensitivity in the data base overall, and specifically, there is no indication of increased sensitivity in the developmental and multi-generation reproductive toxicity studies. Therefore, Mitsui concludes that there is no need for an additional safety factor; the RfD of 1.27 mg/kg/day and sub-chronic NOAEL of 307 mg/kg/day are protective of infants and children.

Using the chronic exposure assumptions and the proposed RfD described above, the dietary exposure to dinotefuran for infants and children (1 to 6 years) was calculated to be 0.57% of the reference dose of 1.27 mg/kg bwt/day. The resulting DWLOC for non-nursing infants, 12,666 ppb, is much greater than the estimated average concentration of dinotefuran in surface water, 6.24 ppb.

Using the intermediate-term exposure assumptions and the proposed NOAEL described above, the intermediate-term aggregate exposure to dinotefuran for the toddlers (1 to 3 years) resulted in an MOE of 1,410. The resulting DWLOC, 42,785 ppb, is much greater than the estimated average concentration of dinotefuran in surface water, 6.24 ppb. Therefore, taking into account the proposed uses, it can be concluded with reasonable certainty that residues of dinotefuran in residential environments and in food and drinking water will not result in unacceptable levels of human health risk.

F. International Tolerances

No codex maximum residue levels have been established for residues of dinotefuran on any crops at this time.

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ENVIRONMENTAL PROTECTION AGENCY

[OPP-2003-0226; FRL-7315-2]

Copper Hydroxide; Notice of Filing of a Pesticide Petition to Establish a Tolerance for a Certain Pesticide Chemical in or on Food

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: This notice announces the initial filing of a pesticide petition proposing the establishment of regulations for residues of a certain pesticide chemical in or on various food commodities.

DATES: Comments, identified by docket ID number OPP-2003-0226, must be received on or before August 1, 2003.

ADDRESSES: Comments may be submitted electronically, by mail, or through hand delivery/courier. Follow the detailed instructions as provided in Unit I. of the **SUPPLEMENTARY INFORMATION**.

FOR FURTHER INFORMATION CONTACT: Kathryn Boyle, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; telephone number: (703) 305-6304; e-mail address: boyle.kathryn@epa.gov.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

You may be potentially affected by this action if you are an agricultural producer, food manufacturer, or pesticide manufacturer. Potentially affected entities may include, but are not limited to:

- Crop production (NAICS code 111)
- Animal production (NAICS code 112)
- Food manufacturing (NAICS code 311)
- Pesticide manufacturing (NAICS code 32532)

This listing is not intended to be exhaustive, but rather provides a guide for readers regarding entities likely to be affected by this action. Other types of entities not listed in this unit could also be affected. The North American Industrial Classification System (NAICS) codes have been provided to assist you and others in determining whether this action might apply to certain entities. If you have any questions regarding the applicability of this action to a particular entity, consult the person listed under **FOR FURTHER INFORMATION CONTACT**.