

However, the Agency concluded that no significant post-application exposure is anticipated from landscape ornamentals; therefore, no residential post-application assessment was conducted.

Bifenazate is currently registered for use on the following residential non-dietary sites: Commercial application to ornamental plants (including bedding plants, flowering plants, foliage plants, bulb crops, perennials, trees and shrubs; not turf) and all fruit trees which will not bear fruit for a minimum of 12 months. The registrant has proposed an amendment to the Floramite (EPA Reg. No. 400-508) label to permit application to home ornamental plants and fruit trees that will not bear fruit within 12 months by residents/homeowners. The risk assessment was conducted using the following residential exposure assumptions: EPA anticipates only short-term dermal and short-term inhalation exposure for the residential handler (applicator). The proposed formulation is appropriate for application via pump up sprayers, garden hose-end sprayers or similar homeowner pesticide devices. A larger area per day may be treated with a hose-end sprayer than with a pump up compressed air sprayer, which in turn results in possibly greater contact with the active ingredient per day. Therefore, exposure from a hose-end sprayer is assessed rather than that of a compressed air sprayer. For the treatment of shrubs and ornamentals, EPA assume 100 gallons of finish spray are applied per day. The unit exposure value for a residential handler using open pour mixing/loading for a garden hose-end sprayer is 11 mg/lb handled (dermal) and 0.013 mg/lb handled (inhalation). Exposures were calculated using the Agency's draft Residential Standard Operating Procedures.

The highest label rate of application is 8 fl oz product/100 gal water.

$2.0 \text{ lb ai/gal} \div 128 \text{ fl oz/gal} = 0.015625 \text{ lb ai/fl oz}$.

$(8 \text{ fl oz/100 gal})(100 \text{ gal/day})(0.015625 \text{ lb ai/fl oz}) = 0.125 \text{ lb ai/day}$

i. *Dermal Exposure Assessment and MOE.*

$((11.0 \text{ mg ai/lb handled})(0.125 \text{ lb ai handled/day})) \div 70 \text{ kg bw} = 0.019 \text{ mg/kg/day}$

$\text{MOE} = \text{NOAEL} \div \text{ADD} = 80 \text{ mg/kg/day} \div 0.019 \text{ mg/kg bw/day} = 4,200$

ii. *Inhalation Exposure Assessment and MOE.*

$((0.013 \text{ mg ai/lb handled})(0.125 \text{ lb ai handled/day})) \div 70 \text{ kg bw} = 0.0000232 \text{ mg/kg/day}$

$\text{MOE} = \text{NOAEL} \div \text{ADD} = 10 \text{ mg/kg/day} \div 0.0000232 \text{ mg/kg/day} = 430,000$

MOEs are combined for the dermal and inhalation routes of exposure since the short term toxicological effects are the same (reduced body weight gain and food consumption).

iii. *Combined MOE.*

$\text{combined MOE} = 1 \div ((1 \div \text{MOE}_{\text{dermal}}) + (1 \div \text{MOE}_{\text{inhalation}})) = 4,200$

An MOE of 100 is adequate to protect a residential handler under the circumstances described. The estimated MOE is > 100 therefore this use is not of concern.

4. Cumulative effects from substances with a common mechanism of toxicity. Section 408(b)(2)(D)(v) of the FFDCA requires that, when considering whether to establish, modify, or revoke a tolerance, the Agency consider available information concerning the cumulative effects of a particular pesticide's residues and other substances that have a common mechanism of toxicity.

EPA does not have, at this time, available data to determine whether bifenazate has a common mechanism of toxicity with other substances. Unlike other pesticides for which EPA has followed a cumulative risk approach based on a common mechanism of toxicity, EPA has not made a common mechanism of toxicity finding as to bifenazate and any other substances and bifenazate does not appear to produce a toxic metabolite produced by other substances. For the purposes of this tolerance action, therefore, EPA has not assumed that bifenazate has a common mechanism of toxicity with other substances. For information regarding EPA's efforts to determine which chemicals have a common mechanism of toxicity and to evaluate the cumulative effects of such chemicals, see the policy statements released by EPA's Office of Pesticide Programs concerning common mechanism determinations and procedures for cumulating effects from substances found to have a common mechanism on EPA's website at <http://www.epa.gov/pesticides/cumulative>.

D. *Safety Factor for Infants and Children*

1. *In general.* Section 408 of the FFDCA provides that EPA shall apply an additional tenfold margin of safety for infants and children in the case of threshold effects to account for prenatal and postnatal toxicity and the completeness of the data base on toxicity and exposure unless EPA determines that a different margin of safety will be safe for infants and children. Margins of safety are incorporated into EPA risk assessments either directly through use of a MOE analysis or through using uncertainty

(safety) factors in calculating a dose level that poses no appreciable risk to humans.

2. *Prenatal and postnatal sensitivity.* There is no indication of qualitative or quantitative increased susceptibility of rats and rabbits during in utero exposure or post-natal exposure based on developmental toxicity and reproductive toxicity studies performed with bifenazate.

3. *Conclusion.* There is a complete toxicity data base for bifenazate and exposure data are complete or are estimated based on data that reasonably accounts for potential exposures. EPA determined that the 10X SF to protect infants and children should be reduced to 1X for the following reasons:

Acceptable developmental toxicity studies in the rat and the rabbit are available, as is an acceptable 2-generation reproduction study in the rat and there is no indication of qualitative or quantitative increased susceptibility of rats and rabbits to *in utero* or postnatal exposure. A developmental neurotoxicity study is not required for bifenazate. The dietary (food and water) and non-dietary (residential) exposure assessments are not expected to underestimate the potential exposures for infants and children from the use of bifenazate.

E. *Aggregate Risks and Determination of Safety*

To estimate total aggregate exposure to a pesticide from food, drinking water, and residential uses, the Agency calculates DWLOCs which are used as a point of comparison against the model estimates of a pesticide's concentration in water (EECs). DWLOC values are not regulatory standards for drinking water. DWLOCs are theoretical upper limits on a pesticide's concentration in drinking water in light of total aggregate exposure to a pesticide in food and residential uses. In calculating a DWLOC, the Agency determines how much of the acceptable exposure (i.e., the PAD) is available for exposure through drinking water [e.g., allowable chronic water exposure (mg/kg/day) = cPAD - (average food + residential exposure)]. This allowable exposure through drinking water is used to calculate a DWLOC.

A DWLOC will vary depending on the toxic endpoint, drinking water consumption, and body weights. Default body weights and consumption values as used by the USEPA Office of Water are used to calculate DWLOCs: 2 liter (L)/70 kg (adult male), 2L/60 kg (adult female), and 1L/10 kg (child). Default body weights and drinking water consumption values vary on an individual basis. This variation will be