

plate of any of the tester strains either in the presence or absence of the microsomal enzymes prepared from the Aroclor™ induced rat liver (S9). As a result, Diallyl disulfide, the main component of DADs, are not considered mutagenics.

Data Waivers were requested for the following studies:

Acute inhalation toxicity (OPPTS Harmonized Guideline 870.1300; 152–12).

Mammalian mutagenicity tests (OPPTS Harmonized Guideline 870.5195) except for an Ames test.

90-Day feeding (1 species) (OPPTS Harmonized Guideline 870.3100).

90-Day dermal (1 species) (OPPTS Harmonized Guideline 870.3250).

90-Day inhalation (1 species) (OPPTS Harmonized Guideline 870.3465).

Teratogenicity (1 species) (OPPTS Harmonized Guideline 870.3700).

Chronic exposure (OPPTS Harmonized Guideline 870.4100) (Tier III)

Oncogenicity (OPPTS Harmonized Guideline 870.4200) (Tier III)

DADs are naturally present in garlic and other *Allium* crops and in fields planted with these crops. In spite of the long history of garlic consumption and exposure to DADs by humans, no immunotoxic effects, such as induced dysfunction or inappropriate suppressive or stimulatory responses in components of the immune system of humans or test animals have been reported and are not expected from the exposure to DADs. As a result, the waiver requests listed above were approved.

V. Aggregate Exposures

In examining aggregate exposure, FFDCA section 408 directs EPA to consider available information concerning exposures from the pesticide residue in food and all other non-occupational exposures, including drinking water from ground water or surface water and exposure through pesticide use in gardens, lawns, or buildings (residential and other indoor uses).

A. Dietary Exposure

The product Alli-Up containing DADs is intended for agricultural use as a soil fumigant for the purpose of suppression of onion white rot (*Sclerotia cepivorum*). The presence of DADs in the soil will stimulate the pathogen to become active and seek out its host, an *Allium* sp., which is not present. The pathogen will then perish. DADs in the soil are then subject to microbial breakdown and adsorption to soil

particles. By the time the soil is prepared and ready for a new crop, most DADs have already dissipated. As a result, when new crops are planted, the likelihood of DADs residue present in the mature crop is considered low.

1. *Food*. From food and feed uses. As explained above, the presence of DADs residue in food is unlikely. Moreover, the primary source for human exposure to DADs would occur through the consumption of garlic, other *Allium* crops or garlic derived products. There have been no reports of adverse reactions to humans resulting from the consumption of *Allium* crops and derived products. The over-all toxicology profile of DADs suggests that the risk associated with acute exposures by the oral route would be low.

2. *Drinking water exposure*. Since Alli-Up will only be used as a soil fumigant, there is little if any, potential for drinking water exposure from pesticide drift in the surface water. Moreover, DADs in the soil are then subject to microbial breakdown and adsorption to soil particles and dissipation in the air. Therefore, the level of residues that might get into the ground water or surface water would most likely be negligible.

B. Other Non-Occupational Exposure

The potential for non-dietary exposure to DADs for the general population is unlikely because potential use sites are commercial agricultural. Since the material is shanked into the treated soil during commercial applications, any odor present would be similar to that of a commercial garlic field or to that arising from freshly cut or pressed garlic as found in a typical household kitchen. EPA is unaware of any reports of adverse reactions to humans resulting from *Allium* crops and derived products odor or consumption.

VI. Cumulative Effects

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 DADs have a common mechanism of toxicity with other substances or how to include this pesticide in a cumulative risk assessment. Unlike other pesticides for which EPA has followed a cumulative risk approach based on a common mechanism of toxicity, DADs

do not appear to produce a toxic metabolite produced by other substances. For the purposes of this tolerance action, therefore, EPA has not assumed that DADs have 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 final rule for Bifenthrin Pesticide Tolerances (62 FR 62961, November 26, 1997).

VII. 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*. Based on the lack of observed developmental toxicity, EPA has concluded there is reasonable certainty that no harm to infants, children, or adults will result from aggregate exposure to DADs residues. Exemption of DADs from the requirements of a tolerance should pose no significant risk to humans or the environment.

3. *Conclusion*. There is reasonable certainty that no harm will result from aggregate exposure to residues of diallyl sulfides to the U.S. population. This includes all anticipated dietary exposures and all other exposures for which there is reliable information. The Agency has arrived at this conclusion based on the low levels of toxicity, the long history of safe consumption of garlic and onions which naturally contain diallyl sulfides, and the lack of exposure. Levels of exposure resulting from use of diallyl sulfides would be significantly lower than those found in the U.S. population’s consumption of onion and garlic foods (raw, cooked and processed). Moreover, the Agency concludes that diallyl sulfides is non-toxic to humans, including infants and children. Thus, there is no threshold effects of concern and, as a result the provision requiring an additional margin of safety does not apply. Further, the provisions of consumption patterns,