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II. Background and Statutory Findings

In the **Federal Register** of November 21, 2001 (66 FR 58481) (FRL-6802-2), EPA issued a notice pursuant to section 408(d)(3) of the FFDCA, 21 U.S.C. 346a(d)(3), announcing the filing of a pesticide tolerance petition (PP 1F6316) by Platte Chemical Company, 419 18th Street, Greeley, CO 80632. As required by section 408(d)(2)(A)(i)(I), this notice included a summary of the petition prepared by the petitioner Platte Chemical Company. There were no comments received in response to the notice of filing.

The petition requested that 40 CFR part 180 be amended by establishing an exemption from the requirement of a tolerance for residues of diallyl sulfides.

III. Risk Assessment

New section 408(c)(2)(A)(i) of the FFDCA allows EPA to establish an exemption from the requirement for a tolerance (the legal limit for a pesticide chemical residue in or on a food) only if EPA determines that the exemption is "safe." Section 408(c)(2)(A)(ii) defines "safe" to mean that "there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures and all other exposures for which there is reliable information." This includes exposure through drinking water and in residential settings, but does not include occupational exposure. Section 408(b)(2)(C) requires EPA to give special consideration to exposure of infants and children to the pesticide chemical residue in establishing a tolerance and to "ensure that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to the pesticide chemical residue. . . ." Additionally, section 408(b)(2)(D) requires that 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 performs a number of analyses to determine the risks from aggregate exposure to pesticide residues. First, EPA determines the toxicity of pesticides. Second, EPA examines exposure to the pesticide through food, drinking water, and through other exposures that occur as a result of pesticide use in residential settings.

IV. Toxicological Profile

Consistent with section 408(b)(2)(D) of FFDCA, EPA has reviewed the available scientific data and other relevant information in support of this action and considered its validity, completeness, and reliability and the relationship of this information to human risk. EPA has also considered available information concerning the variability of the sensitivities of major identifiable subgroups of consumers, including infants and children.

DADs are a composition of diallyl sulfides that includes diallyl monosulfide, diallyl disulfide, diallyl trisulfide, and diallyl pentasulfide. They are naturally occurring compounds found in *Allium* crops, including onion and garlic and are partially responsible for the distinctive odor of garlic. The end-use product, Alli-Up is proposed for use as a soil fumigant solution for the control of white rot (*Sclerotium cepivorum*) in garlic, leeks, onions, and shallots. It contains 90% of DADs in a liquid formulation (8.3 lbs of active ingredient per gallon). Application is recommended for any field that shows evidence or has a history of white rot infestations. When applied to infected soils in conjunction with a rotational crop, DADs will mimic the presence of an *Allium* crop, which will in turn stimulate the germination of white rot spores (*sclerotia*). The germinated spores will subsequently perish since no host crop is present. The product is applied through conventional soil fumigation equipment such as an enclosed shanking system.

Toxicity studies submitted in support of the tolerance exemption petition, and the Agency reviews are compiled in the public docket established for this action under the docket ID number OPP-2003-0134.

1. *Acute oral toxicity* (OPPTS Harmonized Guideline 870.1100; 152-10; Master Record Identification Number (MRID) 45422907). Five male and 5 female rats were dosed with 200, 600, and 1,000 milligram/kilogram (mg/kg) and 10 of each were dosed with 5,000 mg/kg. The acute oral LD₅₀ was

determined at 346 mg/kg. Treated rats displayed a number of abnormalities including breathing abnormalities, wobbly gait, decreased defecation, decreased activity, and pilo-erection. The abnormalities are attributed to hemolytic anemia as it is experienced by rodents when feeding on materials rich on sulfur and derived from onion and garlic.

2. *Acute dermal toxicity* (OPPTS Harmonized Guideline 870.1200; 152-11; MRID 45422908). Five male and 5 female rats were dosed with 1,500, 1,750, and 2,000 mg/kg, observed daily and weighed weekly. The acute dermal LD₅₀ of DADs in male rats was determined to be 1,826 mg/kg, in female 2,009 mg/kg, and in sexes combined 1,967 mg/kg, or a Toxicity Category II.

3. *Primary eye irritation* (OPPTS Harmonized Guideline 870.2400; 152-13; MRID 45422909). Six rabbits were administered DADs in the right eye with the left eye serving as an untreated control. Exposure of the test article produced corneal opacity in 3/6 test eyes at the 1 or 24-hour scoring interval. Conjunctivitis was noted in 6/6 test eyes at the 1-hour testing interval. The conjunctival irritation resolved completely in all animals by study day 14. Under the conditions of the test, DADs are considered a moderate eye irritant, and Toxicity Category III for eye irritation.

4. *Primary dermal irritation* (OPPTS Harmonized Guideline 870.2500; 152-14; MRID 45422910). These compound are Toxicity Category II for dermal irritation. Severe skin reactions of the rabbits exposed, with evident erythema grade 2 and 1 at 1 hour post-exposure were observed.

5. *Dermal sensitization* (OPPTS Harmonized Guideline 870.2600; 152-15; MRID 45422911). A dermal sensitization potential test for DADs was evaluated using guinea pigs. DADs were found to be contact dermal sensitizers in guinea pigs, in accordance with the Buehler test.

6. *Mutagenicity* (OPPTS Harmonized Guideline 870.5195; MRID 45422912). A *Salmonella*/mammalian-microsome reverse mutation assay (Ames Test) was done using DADs. The assay evaluated the test article for its ability to induce reverse mutations at the histidine locus in the genome of specific *Salmonella typhimurium* tester strains in both the presence and absence of an exogenous metabolic activation system of mammalian microsomal enzymes derived from Aroclor™ induced rat liver. The results of the assay indicate that under the conditions of the study, DADs did not cause a positive increase in the number of histidine revertants per