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List of Subjects

Environmental protection, Agricultural commodities, Feed additives, Food additives, Pesticides and pests, Reporting and recordkeeping requirements.

Dated: July 28, 2003.

Debra Edwards,

Director, Registration Division, Office of Pesticide Programs.

Summary of Petitions

The petitioner summary of the pesticide petitions are printed below as required by FFDCA section 408(d)(3). The summary of the petitions were prepared by the petitioner and represents the view of the petitioner. The petition summary announces the availability of a description of the analytical methods available to EPA for the detection and measurement of the pesticide chemical residues or an explanation of why no such method is needed.

Interregional Research Project Number 4 (IR-4)

PP 2E6507 and PP 2E6510

EPA has received pesticide petitions (PP 2E6507 and PP 2E6510) from IR-4, 681 U.S. Highway #1 South, North Brunswick, NJ 08902-3390 proposing, pursuant to section 408(d) of FFDCA, 21 U.S.C. 346a(d), to amend 40 CFR 180.414 by establishing tolerances for residues of cyromazine, (N-cyclopropyl-1,3,5-triazine-2,4,6-triamine) in or on the following raw agricultural commodities: Leek; onion, green; onion, potato; onion, tree; onion, welsh; and shallot, fresh leaves at 3.0 parts per million (ppm) (2E6507), garlic, bulb; garlic great-headed, bulb; onion, dry bulb; rakkyo, bulb; and shallot, bulb at 0.2 ppm (2E6507), vegetable brassica, leafy, group 5, except broccoli at 10 ppm (2E6510), broccoli at 1.0 ppm, turnip, greens; cabbage, abyssinian; cabbage, seakale; and hanover salad, leaves at 10 ppm, and kidney of cattle, goats, hogs, horses, and sheep at 0.2 ppm, and meat byproducts of cattle, goats, hogs, horses, and sheep at 0.05 ppm (2E6510). IR-4 also proposed that tolerances for residues of cyromazine in or on dry bulb onion at 2.0 ppm and green onion at 0.1 ppm established under 40 CFR 180.414(a) and Chinese cabbage and Chinese mustard at 3.0 ppm established under 40 CFR

180.414(c) be deleted when the proposed tolerances are established. Chinese cabbage and Chinese mustard are included in the Brassica leafy vegetable group. EPA has determined that the petitions contain data or information regarding the elements set forth in section 408(d)(2) of the FFDCA; however, EPA has not fully evaluated the sufficiency of the submitted data at this time or whether the data support granting of the petitions. Additional data may be needed before EPA rules on the petitions. This summary has been prepared by the Syngenta Crop Protection Incorporated.

A. Residue Chemistry

1. *Plant metabolism.* The metabolism of cyromazine in plants is adequately understood for the purposes of these tolerances.

2. *Analytical method.* Methods AG-408 and AG-417 as listed in the Food and Drug Administration's Pesticide Analytical Manual (PAM), Vol-II are adequate to enforce the proposed tolerances.

3. *Magnitude of residues.* Residue field tests were conducted in typical growing regions for Brassica and bulb vegetables and turnip tops. The data collected support the proposed tolerances of 10.0 ppm for Brassica leafy vegetables, 10.0 ppm for turnip tops and 3.0 ppm for bulb vegetables.

B. Toxicological Profile

1. *Acute.* A rat acute oral toxicity study with a lethal dose (LD)₅₀ of approximately 3,387 milligrams/kilogram (mg/kg) (toxicity category III; moderately toxic). A rat acute dermal toxicity study with a LD₅₀ greater than 3,100 mg/kg (toxicity category III; moderately toxic). A rat acute inhalation study with a lethal concentration (LC)₅₀ greater than 2.9 mg/kg (toxicity category IV; slightly toxic). A primary eye irritation study in the rabbit that showed no eye irritation. A primary dermal irritation study in the rabbit that showed mild irritation (toxicity category IV). A dermal sensitization study in the guinea pig that showed no sensitization.

2. *Genotoxicity.* Studies on gene mutation and other genotoxic effects showed no evidence of point mutation in an Ames test; no indication of mutagenic effects in a dominant lethal test; and no evidence of mutagenic effects in a nucleus anomaly test in Chinese hamsters.

3. *Reproductive and developmental toxicity.* In a rat developmental toxicity study, the maternal no observed adverse effect level (NOAEL) was 100 mg/kg/day. The maternal lowest observed

adverse effect level (LOAEL) was 300 mg/kg based on decreased body weight gain and clinical observations. The developmental NOAEL was 300 ppm. The developmental LOAEL was 600 mg/kg based upon an increase of minor skeletal variation.

In a rabbit developmental toxicity study, the maternal NOAEL was 10 mg/kg. The maternal LOAEL was 30 mg/kg based upon decreased body weight gain and food consumption. The developmental NOAEL/LOAEL was greater than or equal to 60 mg/kg.

In a multi-generation study in rats, the systemic NOAEL was 30 ppm (1.5 mg/kg). The systemic LOAEL was 1,000 ppm (50 mg/kg) based upon decreased body weights associated with decreased food consumption. The developmental/offspring systemic NOAEL was 1,000 ppm. The developmental/offspring systemic LOAEL was 3,000 ppm (150 mg/kg) based upon decreased body weight at birth through weaning. There were no effects on reproductive parameters at the highest dose tested (HDT) (3,000 ppm).

4. *Subchronic toxicity.* In a 6-month feeding study in dogs, the NOAEL was 30 ppm (0.75 mg/kg). The LOAEL was 300 ppm (7.5 mg/kg) based upon decreased hematocrit and decreased hemoglobin. Groups of male and female beagle dogs (4/sex/dose) were fed diets containing cyromazine at 0, 30, 300, or 3,000 ppm (0, 0.75, 7.5, or 75 mg/kg/day, respectively) for 6-months. No treatment-related effects were observed in survival, clinical signs or body weight parameters. Pronounced effects on hematologic parameters were manifested as decreases in hematocrit and hemoglobin levels at 300 and 3,000 ppm.

5. *Chronic toxicity.* In a 24-month feeding study in rats the NOAEL for the study was 30 ppm (1.5 mg/kg/day). The LOAEL was 300 ppm (15.0 mg/kg) based on decreased body weight. In a 24-month mouse chronic feeding carcinogenicity study the NOAEL was 50 ppm (7.5 mg/kg/day). The LOAEL was 1,000 ppm (150.0 mg/kg) based upon decreased body weight. There was no evidence of carcinogenicity at 3,000 ppm (450 mg/kg). In a 24-month rat chronic feeding carcinogenicity study the NOAEL was greater than 3,000 ppm (150 mg/kg) (HDT). There was no evidence of carcinogenicity at 3,000 ppm.

Cancer Peer Review Committee determined that there is no evidence of carcinogenicity in studies in either the mouse or rat. Based upon this determination it can be concluded that cyromazine does not pose a cancer risk.