

Dated: March 13, 2003.

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### Summary of Petitions

The petitioner summary of the pesticide petitions is printed below as required by FFDCA section 408(d)(3). The summary of the petitions was prepared by the petitioner and represent the views 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 (IR-4)

*PP 2E6369, 2E6455, and 2E6493*

EPA has received pesticide petitions (2E6369, 2E6455, and 2E6493) from the Interregional Research Project Number (IR-4), 681 U.S. Highway #1 South, North Brunswick, NJ 08902, proposing, pursuant to section 408(d) of the FFDCA, 21 U.S.C. 346a(d), to amend 40 CFR 180.511 by establishing tolerances for residues of buprofezin in or on the following raw agricultural commodities: Lychee, logan, spanish lime, rambutan, and pulasan at 0.3 parts per million (ppm) (2E6369); bean, snap, succulent at 0.02 ppm (2E6455); and pistachio at 0.05 ppm (2E6493). 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 Nichino American, Inc., Wilmington, DE 19808, the registrant.

#### A. Residue Chemistry

1. *Plant metabolism.* The metabolic profile of buprofezin has been elucidated in a wide range of crops, including tomatoes, lettuce, cotton, and citrus. In tomatoes, lettuce, and cotton unchanged buprofezin was the only significant residue. In citrus, besides buprofezin, the principal polar residue is a hexose conjugate of BF4 (buprofezin hydroxylated in the t-butyl group), which was resistant to enzyme hydrolysis. With acid hydrolysis of the polar fraction, BF26 was released, with minor amounts of BF9 and BF12. The same compounds were observed following acid hydrolysis of a standard of BF4, which clearly indicates that BF4 is the conjugated metabolite existing in

citrus. Although only limited metabolism was observed in lettuce and cotton, trace levels of BF4/BF26, BF9, and BF12 were observed indicating that the metabolic pathway does not differ with plant species.

2. *Analytical method.* Metabolism studies on lettuce and tomatoes have shown that the only significant residue in these crops is buprofezin. Development of the analytical method took place in parallel with the metabolism studies and the method was designed to quantify two metabolites (BF9 and BF12) in addition to the parent compound. This method was used for analysis of samples from the field trials on all crops except citrus, but for tolerance enforcement only the parent compound is considered.

3. *Magnitude of residues.* The magnitude of residues is adequately understood and supports the proposed tolerances.

#### B. Toxicological Profile

1. *Acute toxicity.* An assessment of toxic effects caused by buprofezin is discussed in Unit III.A. and Unit III.B. of the **Federal Register** dated September 5, 2001 (66 FR 46382) (FRL-6796-6).

2. *Animal metabolism.* The metabolism of buprofezin has been extensively studied in various species of animals and fish. Buprofezin has several groups that can metabolize in a variety of ways thus potentially producing a very large number of metabolites. Indeed extensive metabolism to many minor metabolites was observed in all the animal species. Metabolism in fish was, however, much more limited and clearly defined. Although not all metabolic intermediates have been detected in all the species, the major routes of metabolism have been identified in animals and fish and a consistent pattern is observed throughout these species. The proposed metabolic pathway was provided in the tolerance petition, PP 0F6087. For convenience, degradates are referred to by an internal code: BF 1 through 13. Corresponding chemical structures were provided in the tolerance petition, PP 0F6087.

3. *Endocrine disruption.* No special studies have been conducted to investigate the potential of buprofezin to induce estrogenic or other endocrine effects. The standard battery of required toxicity studies has been completed. These studies include an evaluation of the potential effects on reproduction and development and an evaluation of the pathology of the endocrine organs following repeated or long-term exposure. These studies are generally considered to be sufficient to detect any

endocrine effects. The only effect noted on endocrine organs was an increased incidence of follicular cell hypertrophy and C-cell hyperplasia of the thyroid gland in rats administered buprofezin at dietary concentrations of 2,000 ppm for 24 months. Buprofezin also caused mild to moderate hepatotoxic effects at this dietary concentration. Nichino America, Inc. believes that the effect on the thyroid most likely resulted from increased turnover of T3/T4 in the liver with a resultant rise in TSH secretion (due to the hepatotoxicity). The rat is known to be much more susceptible than humans to these effects due to the very rapid turnover of thyroxine in the blood in rats (12 hours versus about 5 to 9 days in humans). Therefore, the thyroid pathological changes which have been noted following administration of high doses of buprofezin are considered to be of minimal relevance to human risk assessment, particularly considering the low levels of buprofezin to which humans are likely to be exposed.

#### C. Aggregate Exposure

1. *Dietary exposure—i. Food.* Chronic dietary exposure was estimated using Dietary Exposure Evaluation Model (DEEM™) tolerance levels, and 100% crop treated, except for tomatoes with 40% of the crop treated. The chronic dietary exposure to the U.S. population (total) was estimated as 0.001229 milligrams/kilogram/body weight/day (mg/kg bwt/day), and was 37% of the estimated reference dose (RfD). Exposure to children ages 1 to 6, the highest exposed population subgroup, was 0.002393 mg/kg bwt/day (73% of the estimated RfD).

ii. *Drinking water.* The residue of concern in drinking water was determined to be buprofezin. The potential exposure of buprofezin in drinking water abstracted from surface water was assessed using a Tier 2, modeling approach. EPA's Pesticide Root Zone Model (PRZM) was used to generate potential runoff loads from a standardized agricultural field (10-hectare (ha)) to a standardized aquatic system (1-ha 2-meters (m) deep pond) following application of buprofezin to citrus (the maximum proposed use rate for all crops). Exposure Analysis Modeling Systems (EXAMS) was used to estimate the exposure concentration in surface water. The "once-in-10-year" exceedance probability corresponded to a concentration at 0.52 part per billion (ppb). This value refers to the 56-day average estimated concentration in a farm pond draining agricultural land and must be considered a gross overestimate of concentrations of buprofezin