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II. What Action is the Agency Taking?

EPA has received a pesticide petition as follows proposing the establishment and/or amendment of regulations for residues of a certain pesticide chemical in or on various food commodities under section 408 of the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. 346a. EPA has determined that this petition contains data or information regarding the elements set forth in FFDCA section 408(d)(2); however, EPA has not fully evaluated the sufficiency of the submitted data at this time or whether the data support granting of the petition. Additional data may be needed before EPA rules on the petition.

List of Subjects

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

Dated: July 28, 2003.

Janet L. Andersen,

Director, Biopesticides and Pollution Prevention Division, Office of Pesticide Programs.

Summary of Petition

The petitioner's summary of the pesticide petition is printed below as required by FFDCA section 408(d)(3). The summary of the petition was 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

Morse Enterprises Limited

PP 2E6383

EPA has received a pesticide petition (PP 2E6383) from Interregional Research Project Number 4 (IR-4), Technology Centre of New Jersey, Rutgers University, 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 part 180 to establish an exemption from the requirement of a tolerance for the biochemical pesticide yeast extract hydrolysate from *Saccharomyces*

cerevisiae in or on all food commodities.

Pursuant to section 408(d)(2)(A)(i) of the FFDCA, as amended, Morse Enterprises Limited has submitted the following summary of information, data, and arguments in support of their pesticide petition. This summary was prepared by Morse Enterprises Limited and EPA has not fully evaluated the merits of the pesticide petition. The summary may have been edited by EPA if the terminology used was unclear, the summary contained extraneous material, or the summary unintentionally made the reader conclude that the findings reflected EPA's position and not the position of the petitioner.

A. Product Name and Proposed Use Practices

Yeast extract hydrolysate from *Saccharomyces cerevisiae*, the active ingredient, is mixed with micronutrients to formulate the end use product known as KeyPlex 350. KeyPlex 350 is applied at 1 to 3 quarts per acre as a foliar spray. Applications are generally repeated at 14 to 21-day intervals. KeyPlex 350 aids in the prevention of certain plant diseases, such as post-bloom fruit drop and greasy spot diseases of citrus, and bacterial leaf spot disease of tomatoes.

B. Product Identity/Chemistry

1. *Identity of the pesticide and corresponding residues.* Yeast extract hydrolysate from *Saccharomyces cerevisiae* is mixed with micronutrients to formulate the end use product known as KeyPlex 350. KeyPlex 350 contains 0.063% yeast extract hydrolysate from *Saccharomyces cerevisiae* in combination with a micronutrient fertilizer. KeyPlex 350 is the end use product. Hereinafter the term "yeast extract hydrolysate" is used to mean yeast extract hydrolysate from *Saccharomyces cerevisiae*.

2. *Magnitude of residue at the time of harvest and method used to determine the residue.* This section is not applicable, as this notice proposes an exemption from the requirement of a tolerance.

3. *A statement of why an analytical method for detecting and measuring the levels of the pesticide residue are not needed.* An analytical method for residues is not applicable, as this notice proposes an exemption from the requirements of a tolerance.

C. Mammalian Toxicological Profile

1. *Acute toxicity.* An acute oral toxicity study (OPPTS Harmonized Guideline 870.1100) conducted in rats

with the end use product KeyPlex 350 containing 0.063% yeast extract hydrolysate showed that KeyPlex 350 at 5,000 milligrams/kilogram (mg/kg) is not toxic to rats. Furthermore, no test material-related lesions were revealed on the macroscopic necropsy examinations conducted at termination of the test.

2. *A primary dermal irritation study.* (OPPTS Harmonized Guideline 870.2500) conducted in rabbits with the end use product KeyPlex 350 showed that KeyPlex 350 only caused mild or very slight irritation to the skin of 1 of 6 rabbits.

3. *A primary eye irritation study.* (OPPTS Harmonized Guideline 870.2400) conducted in rabbits with the end use product KeyPlex 350 showed that KeyPlex 350 was only moderately irritating. Conjunctiva was noticed in all rabbits 1-hour after treatment; all symptoms cleared by 72 hours post-treatment.

Yeast extracts are considered generally recognized as safe (GRAS) and are approved by the Food and Drug Administration (FDA) as direct food additives (21 CFR 184.1983). Yeast extracts are used as a flavor improver in hundreds of foods at 0.1% to 2% in the final consumed product. The other ingredients in KeyPlex 350 are already approved as inert materials or are common fertilizer ingredients.

D. Aggregate Exposure

1. *Dietary exposure—i. Food.* The potential dietary exposure of the general public to yeast extract hydrolysate residues resulting from the use of KeyPlex 350 on food crops is not expected to be significant. The public is exposed to yeast extract through its use as a direct food additive.

ii. *Drinking water.* It is not anticipated that residues of yeast extract hydrolysate will occur in drinking water due to its low application rate.

2. *Non-dietary exposure.* There may be non-dietary exposure to yeast extract hydrolysate from non-pesticidal uses of yeast extracts, but significantly increased non-dietary exposure and non-occupational exposure from yeast extract hydrolysate when used as a pesticide is not expected.

E. Cumulative Exposure

Because of the lack of toxicity of an 0.063% solution of yeast extract hydrolysate and because of the fact that yeast extracts are already present in the diet at 0.1% to 2% in hundreds of food products, no cumulative mode of exposure is expected for yeast hydrolysate and other substances having a common mode of action.