

Dated: October 28, 2003.

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### Summary of Petition

The petitioner summary of the pesticide petition is printed below as required by FFDCA section 408(d)(3). The summary of the petition was prepared by W. F. Stoneman Company LLC 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.

### W.F. Stoneman Company LLC

PP 3F6737

EPA has received a pesticide petition 3F6737 from W.F. Stoneman Company LLC (on behalf of Propytha Biologischer Pflanzenschutz GmbH), 6307 Mourning Dove Drive, McFarland, Wisconsin 53558-9019, proposing pursuant to section 408(d) of the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. 346a(d), to amend 40 CFR part 180, to establish an exemption from the requirement of a tolerance for residues of the microbial pesticide *Paecilomyces lilacinus* strain 251 (*P. lilacinus*).

Pursuant to section 408(d)(2)(A)(i) of the FFDCA, as amended, W.F. Stoneman Company LLC (on behalf of Propytha Biologischer Pflanzenschutz GmbH) has submitted the following summary of information, data, and arguments in support of their pesticide petition. This summary was prepared by W.F. Stoneman Company LLC (on behalf of Propytha Biologischer Pflanzenschutz GmbH) 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

MeloCon™ WG. For purposes of marketing the product in the U.S.A., the name MeloCon™ WG was chosen and a registered trademark will be sought. The same active ingredient in the same or similar formulations is sold under other trade names in other countries of

the world including: Paecil, BioACT WG, and Nemachek.

*Proposed use practices.* MeloCon™ WG is a biological nematicide for the control of plant parasitic nematodes. The product is sold as water dispersible granules that are then mixed with water and applied as a soil spray, initially at a rate of 4 pounds per acre. Applications are made to soil before planting, to the soil of seedlings before transplanting, and as a post-plant soil drench.

### B. Product Identity/Chemistry

#### 1. Identity of the pesticide and corresponding residues.

- Product name. MeloCon™ WG
- Active ingredient. *Paecilomyces lilacinus* strain 251
- CAS No. Not applicable
- Color. Pink
- Physical state. Non-dusty, water dispersible granules
- Odor. Odorless
- Bulk density. 500–550 kg/cubic meter
- pH. Before storage, the pH of PBP-01001-I was 6.86 (mean of two replications). After storage at a temperature of 40°C for a period of 8 weeks, the pH of the product was 5.52 (mean of two replications).
- Mode of action. Control of plant-parasitic nematodes by *P. lilacinus* is basically achieved by parasitism and subsequent killing of eggs, juveniles and adult females of a range of nematode species. The infective units are spores and mycelia, enabling the fungus to parasitize the host epiphytically or as an endophyte, following penetration of cell walls.

*Historical Background.* Plant-parasitic nematodes infect a wide range of crops and cause reduction in yield and sometimes death of the crop plant. As early as 1877 parasitism of female nematodes of the species of *Heterodera schachtii* by a fungus was described, but it took several decades for researchers to discover that fungi play a major role as antagonists of parasitic nematodes. Numerous fungi are known to have nematophagous activity and to act by several mechanisms, including endoparasitic, predacious, and opportunistic parasitism. As opportunistic fungi, *P. lilacinus* and *Verticillium chlamydosporium* have been extensively studied as possible biocontrol agents.

In 1979, *P. lilacinus* was identified as an effective parasite of *Meloidogyne incognita* and *Globodera pallida* eggs on potatoes. Further study revealed that different strains of *P. lilacinus* differed considerably in their nematophagous potential. Efficient *P. lilacinus* strains have been registered as biocontrol

agents for plant-parasitic nematodes in the Philippines and South Africa, while registration is pending in Australia.

2. *Magnitude of residue at the time of harvest and method used to determine the residue—Analytical method.* An analytical method of residues is not applicable.

3. *A statement of why an analytical method for detecting and measuring the levels of the pesticide residue are not needed.* An analytic method for residues is not applicable. *Paecilomyces lilacinus* strain 251 is active in the soil, applied to the soil, and incorporated into the soil prior to planting, or drenched onto the soil surrounding plants very early in the growing season. It is not applied directly to the food commodity. Residues of the active ingredient in MeloCon™ WG are not expected on agricultural commodities.

In most of the crops envisaged for use of the active ingredient no deposit is likely to occur, since soil drench applications rule out a direct contact between the applied product and the fruit. This applies to all crops with above ground harvest, such as grapes, tomato, and tobacco. After harvest any remaining fungal spores on potato, celery and carrots will be exposed to unfavorable conditions (e.g. dryness), and are not likely to germinate and grow on the harvested crop.

Any potentially occurring residual deposits on these crops will not harm humans because the strain shows no toxicity in appropriate tests and any such residues will be very low due to the low environmental concentration in soil predicted from maximum field use of the active ingredient.

*P. lilacinus* is not able to enter plants and infest them. In fact, it enhances plant health and growth. As a *saprophytic fungus* it would use the resources of the plant host in case access was possible.

### C. Mammalian Toxicological Profile

MeloCon™ WG is the end use product of the active ingredient *P. lilacinus* strain 251. The active ingredient is in the end use product at a nominal concentration of 6% by weight (with a minimum concentration of 1 billion spores per gram). The active ingredient was tested for acute Toxicity/Pathogenicity through oral, dermal, IP injection, pulmonary, skin irritation, eye irritation, and skin sensitization. The results of these mammalian studies indicate no significant human health risks. The table below summarizes the results of the acute studies that were done.