Commodity	Parts per million
Barley, grain	0.05
Barley, hay	0.05
Barley, straw	0.05
Wheat, forage	0.05
Wheat, grain	0.05
Wheat, hay	0.05
Wheat, straw	0.05

(b) *Section 18 emergency exemptions.* [Reserved]

(c) *Tolerances with regional registrations.* [Reserved]

(d) *Indirect or inadvertent residues.* [Reserved]

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[OPP–2002–0233; FRL–7198–8]

Pseudozyma flocculosa strain PF-A22 UL; Exemption from the Requirement of a Tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes an exemption from the requirement of a tolerance for residues of the *Pseudozyma flocculosa* strain PF-A22 UL in or on all food commodities. Plant Products Co. Ltd., submitted a petition to EPA under the Federal Food, Drug, and Cosmetic Act, as amended by the Food Quality Protection Act of 1996, requesting an exemption from the requirement of a tolerance. This regulation eliminates the need to establish a maximum permissible level for residues of *Pseudozyma flocculosa* strain PF-A22 UL.

DATES: This regulation is effective September 27, 2002. Objections and requests for hearings, identified by docket ID number OPP–2002–0233, must be received on or before November 26, 2002.

ADDRESSES: Written objections and hearing requests may be submitted by mail, electronically, or in person. Please follow the detailed instructions for each method as provided in Unit IX. of the **SUPPLEMENTARY INFORMATION.** To ensure proper receipt by EPA, your objections and hearing requests must identify docket ID number OPP–2002–0233 in the subject line on the first page of your response.

FOR FURTHER INFORMATION CONTACT: By mail: Sharlene R. Matten, c/o Product Manager (PM) 90, Biopesticides and Pollution Prevention Division (7511C), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460; telephone number: (703) 605–0514; e-mail address: matten.sharlene@epa.gov.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

You may be affected by this action if you are an agricultural producer, food manufacturer, or pesticide manufacturer. Potentially affected categories and entities may include, but are not limited to:

Categories	NAICS codes	Examples of potentially affected entities
Industry	111 112 311 32532	Crop production Animal production Food manufacturing Pesticide manufacturing

This listing is not intended to be exhaustive, but rather provides a guide for readers regarding entities likely to be affected by this action. Other types of entities not listed in the table could also be affected. The North American Industrial Classification System (NAICS) codes have been provided to assist you and others in determining whether or not this action might apply to certain entities. If you have questions regarding the applicability of this action to a particular entity, consult the person listed under **FOR FURTHER INFORMATION CONTACT.**

B. How Can I Get Additional Information, Including Copies of this Document and Other Related Documents?

1. *Electronically.* You may obtain electronic copies of this document, and certain other related documents that might be available electronically, from the EPA Internet Home Page at http://www.epa.gov/. To access this document, on the Home Page select ''Laws and Regulations,'' ''Regulations and Proposed Rules,'' and then look up the entry for this document under the ''**Federal Register**—Environmental Documents.'' You can also go directly to the **Federal Register** listings at http://www.epa.gov/fedrgstr/. A frequently updated electronic version of 40 CFR part 180 is available at http://www.access.gpo.gov/nara/cfr/cfrhtml_00/Title_40/40cfr180_00.html, a beta site currently under development. To access the OPPTS Harmonized Guidelines referenced in this document, go directly to the guidelines at http://www.epa.gov/opptsfrs/home/guidelin.htm.

2. *In person.* The Agency has established an official record for this action under docket ID number OPP–2002–0233. The official record consists of the documents specifically referenced in this action, and other information related to this action, including any information claimed as Confidential Business Information (CBI). This official record includes the documents that are physically located in the docket, as well as the documents that are referenced in those documents. The public version of the official record does not include any information claimed as CBI. The public version of the official record, which includes printed, paper versions of any electronic comments submitted during an applicable comment period is available for inspection in the Public Information and Records Integrity Branch (PIRIB), Rm. 119, Crystal Mall #2, 1921 Jefferson Davis Hwy., Arlington, VA, from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The PIRIB telephone number is (703) 305–5805.

II. Background and Statutory Findings

In the **Federal Register** of August 30, 2000 (65 FR 52749) (FRL–6739–8), EPA issued a notice pursuant to section 408 of the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. 346a(d), as amended by the Food Quality Protection Act (FQPA) (Public Law 104–170), announcing the filing of a pesticide tolerance petition (PP 0F6136) by Plant Products Co. Ltd., f314 Orenda Rd., Brampton, Ontario, Canada L6T 1G1. This notice included a summary of the petition prepared by the petitioner Plant Products Co. Ltd. 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 *Pseudozyma flocculosa* strain PF-A22 UL in or on all food commodities.

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 tolerance 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.

Pseudozyma flocculosa was isolated in 1986 from the leaves of red clover, *Trifolium pratense*, infected with powdery mildew, *Erysiphe polygoni*, by researchers at Agriculture and Agri-Food Canada, Harrow, Ontario. Initially, this organism was erroneously identified as a new ascomycetous yeast with an anamorphic state in the broad genus *Sporothrix* and a teleomorphic state in the genus *Stephanoascus*. In 1995, its taxon was changed to *P. flocculosa* following ribosomal DNA analysis. The genus *Pseudozyma* contains other smut-like anamorphs, including *P. rugulosa* (formerly *Sporothrix rugulosa*). *P. flocculosa* is a phyllosphere epiphyte and hyperparasite of primarily powdery mildew but has been isolated in association with other leaf-surface molds. It is widely distributed in North America (Canada and USA) and in Europe on aerial plant surfaces in field or greenhouse agricultural ecosystems.

P. flocculosa antagonizes a number of different powdery mildew fungi (*Sphaerotheca pannosa var. rosae, Sphaerotheca fulginea, Erysiphe graminis var. tritici* and *Erysiphe polygoni*) on many different plants in greenhouse and field environments when the relative humidity is greater or equal to 70%. This fungus is a necrotroph mycoparasite that kills susceptible target host cells upon contact or in close proximity. Rapid death and collapse of host cells without penetration is brought about by the secretion of three fungitoxic unsaturated C-17 fatty acids (9-heptadecenoic acid, 6-methyl-9-heptadecenoic acid and 4-methyl-7,11-heptadecadienoic acid) and an acyclic norterpene (2, 6, 10, 14, 18-pentamethyl-2, 6, 8, 10, 12, 14, 17-nonadecaheptene-1,19-diol). The fungitoxins disrupt susceptible plasma membranes and cytoplasmic organelles within 30 minutes of exposure. The inhibitory response includes a loss of proteins and electrolytes. After 24 hours, the host cells rapidly collapse and die as a result of the activity of the fungitoxins on the host cell's membranes and lipids. Sensitivity to the unsaturated C-17 free fatty acids is related to a high degree of unsaturation of phospholipid fatty acids and a low proportion of sterols.

P. flocculosa strain PF-A22 UL was considered of low toxicity and no pathogenicity based on the results of the Tier I toxicology studies. Tier II and Tier III studies were not required because the results from the Tier I studies were sufficient to satisfy guideline requirements. On the basis of the studies submitted, it was considered a Toxicity Category III pesticide for acute oral effects due to the amount dosed only, and Toxicity Category IV for dermal and primary dermal irritation health effects. These and additional toxicology studies are summarized below and in more detail in the Product Monograph for *Pseudozyma flocculosa* strain PF-A22 UL which is found in the OPP docket number OPP–2002–0233.

1. *Acute oral toxicity/pathogenicity study (OPPTS 885.3050) (Master Record Identification (MRID) numbers 451152–04 and 453634–01).* No signs of toxicity or pathogenicity were noted when Sporodex WP, a wettable powder formulation containing 2.0% (weight/weight) *P. flocculosa* strain PF-A22 UL was administered to rats via the oral route.

In an acute oral toxicity study, groups of fasted 6-7 week old Fisher 344 rats (12/sex) were administered a single oral dose of Sporodex WP in USP sterile water for injection at doses of 5.8×10^8 colony-forming units (CFU) per animal for males and 5.6×10^8 CFU per animal for females. An equal number of animals were dosed with heat-killed test substance and four animals/sex served as untreated controls. The animals were then observed for a period of up to 21 days with interim scheduled sacrifices. No effect on body weight gain and no apparent signs of treatment-related toxicity, infectivity or pathogenicity were observed in any of the treated animals during the study period. Clearance of the test organism occurred by, or prior to, post-treatment day 7. Based on the results of this study, Sporodex L and its active ingredient, *P. flocculosa*, is not considered toxic or pathogenic to male or female Fisher 344 rats.

2. *Acute pulmonary toxicity/pathogenicity study (OPPTS 885.3150) (MRID numbers 451152–06 and 453634–01).* The potential toxicity and pathogenicity of *P. flocculosa* was tested by observing the effects following a single intratracheal instillation of 3.2×10^7 CFU of the test organism (TS) to each of 12 male and 12 female CD rats. An equal number of animals were treated with heat-killed test substance (KTS) and four animals/sex served as untreated controls. Animals were observed for up to 14 days with interim scheduled sacrifices.

A total of 15 rats (3/8 male and 2/8 female TS-dosed rats and 6/8 male and 4/8 female KTS-dosed rats) died on days 2 and 3. Laboured respiration, rough hair coat, ocular discharge and nasal discharge were observed in both TS- and KTS-dosed rats. Hunched posture and lethargy were also observed in one female and one male TS-dosed rat, respectively. The presence or absence of clinical symptoms were not indicative of spontaneous deaths.

Due to the large number of spontaneous deaths and a number of missed data collections, data for evaluating effects on body weights, food consumption and relative organ weight were limited. At the end of the 14–day long study, administration of *P. flocculosa* did not have a statistically significant effect on body weight. Analyses of daily food consumption and relative organ weights were skewed as they were either not determined or did not include animals that died prior to their scheduled sacrifice dates.

At necropsy, liver lesions and lesions and enlargement of the lung and spleen were observed in both TS- and KTS-dosed rats. Confluent dark areas were also seen in the kidneys of a single male TS-dosed rat. These necropsy findings were considered consistent with the

method of dosing and the body's normal immunological response to a foreign substance.

Pseudozyma flocculosa was detected in the lungs and lymph nodes and the stomach and small intestine of TS-dosed animals only. Counts in these tissues were below the limit of detection by day 7.

Based on this study, *P. flocculosa* is toxic, but not infective or pathogenic, at the dose administered when introduced by the intratracheal route to male and female CD rats. This acute pulmonary study, however, was originally classified as unacceptable due to major deficiencies in the collected data and a possible dosing error, as indicated by the presence of the microbial pest control agent (MPCA) in the stomach and small intestines on the day of dosing. However, there was relevant pathogenicity information that indicated clearance of the MPCA. Thus, this study is considered to be supplemental because it provides acceptable information regarding infectivity/pathogenicity; however, this study does not differentiate the cause of certain mortalities in the TS and KTS treatments. A confirmatory acute pulmonary toxicity/pathogenicity study using the technical grade of the active ingredient (TGAI) and testing of the sterile filtrate from the production culture will therefore be required to provide this additional information as a condition of registration.

3. *Acute pulmonary range-finding study (OPPTS 885.3150) (MRID numbers 451152–07 and 453634–01).* In order to determine whether the test substance (in both its viable and non-viable forms), *P. flocculosa*, was the cause of the deaths, a subsequent acute pulmonary range-finding toxicity study was conducted. In this range-finding study, groups of young adult CD rats (5/sex/dose level) were exposed by the intratracheal route to *P. flocculosa* (4.2×10^7 CFU/mL) in ASTM Type 1 water at doses of 4.2×10^7, 3.4×10^7, 6.8×10^6 and 3.4×10^6 CFU/animal. Animals were then observed for 14 days. There were no mortalities and all animals gained weight during the study. Rough hair coat occurred in a dose-dependent manner with all 5 animals/sex exhibiting this symptom at the highest dose of 4.2×10^7 CFU/animal. One female dosed with 4.2×10^7 CFU experienced tremors, closed eyes and rough hair coat. *Pseudozyma flocculosa* was classified as being of slight toxicity (EPA Toxicity Category IV) based on adverse effects observed in some test animals.

This acute pulmonary study was considered supplemental. According to USEPA OPPTS 885.3150, the minimum dose is 10^8 units of the MPCA per test animal. The maximum dose level used in this study, however, was only 4.2×10^7 CFU/animal. Furthermore, infectivity was not addressed; however, the acute pulmonary toxicity/pathogenicity study did address infectivity sufficiently. Consequently, this study does not satisfy the guideline requirement for an acute pulmonary study (OPPTS 885.3150) in the rat. EPA, in considering the two studies together, believes that there are sufficient data with which to determine the toxicity and pathogenicity of *Pseudozyma flocculosa*. As any potential inhalation risk that is raised by these studies is primarily a worker risk, EPA is requiring that a respirator be worn by workers to limit any inhalation exposures. In addition, a Restricted-Entry Interval (REI) of 4 hours is required for early entry (post-application) workers or other persons entering treated greenhouses. Finally, a confirmatory acute pulmonary toxicity/pathogenicity study using the TGAI and testing of the sterile filtrate from the production culture will be required as a condition of registration.

4. *Intraperitoneal toxicity/infectivity study (OPPTS 885.3200) (MRID numbers 451152–08 and 453634–01).* In an acute intraperitoneal toxicity/infectivity study, groups of young adult CD rats (4/sex/scheduled sacrifice date) were exposed by the intraperitoneal route to an undiluted suspension of *P. flocculosa* (TS) at a dose of 3.5×10^7 CFU/animal (in 1.0 mL). Animals were then observed for up to 14 days. An equal number of young adult CD rats were similarly injected with heat-killed test substance (KTS). An undosed naive control (NC) group consisting of 4 rats/sex was also included in the study. Cage side observation for clinical symptoms was performed daily and animal body weights and food consumption were monitored.

No unscheduled deaths occurred. Designated animals from the TS and KTS groups were sacrificed on days 0, 7, and 14 and gross necropsies were performed. The NC group of animals was sacrificed and necropsied at the end of the 14–day study. Infectivity and clearance were assessed by quantitatively recovering the MPCA from the blood, lungs and lymph nodes, spleen, kidneys, liver, heart, stomach and small intestine, peritoneal fluid, caecum and brain.

No adverse clinical signs were observed at any point of the study in any of the groups of rats. Body weight gain of TS-dosed male rats was significantly decreased while this group's food consumption was significantly increased compared to NC animals. There was no significant difference between KTS-dosed and NC animals in terms of body weight, body weight gain or food consumption. Upon necropsy of TS- and KTS-dosed animals, white nodules and higher relative spleen weights were observed and attributed to a normal immune response to a foreign substance. The detection of *P. flocculosa* in the peritoneal fluid lavage of TS-dosed male rats was consistent with the method of administration. Clearance of *P. flocculosa* from all other tissues and fluids occurred by day 7. No test substance was detected from any of the organs of the KTS-dosed or NC animals.

At the dose administered, *P. flocculosa* was slightly toxic but not pathogenic to male and female CD rats when introduced by the intraperitoneal route.

5. *Acute dermal toxicity/irritation study (OPPTS 885.3100) (MRID numbers 451152–09 and 453634–01).* In an acute dermal toxicity study, a single group of New Zealand White rabbits (5/sex) was dermally exposed to 1.2×10^7 CFU *P. flocculosa* (equivalent to approximately 0.82-0.90 g/kg bw for males and 0.80-0.91 g/kg bw for females), for 24 hours to an area equivalent to approximately 10% of the dorsal skin surface. Following exposure, the animals were observed for a period of 14 days.

No treatment-related signs of toxicity or skin irritation were observed in any animal during the 14–day observation period. At the dose administered, *P. flocculosa* was not considered toxic or irritating to the skin.

6. *Primary eye irritation study (OPPTS 870.2400) (MRID numbers 451152–10 and 453634–01).* Administration of 0.1 g of Sporodex WP to the eyes of rabbits resulted in slight conjunctival redness in 5/6 animals at the 1–hour scoring interval and in 2/6 rabbits at the 24–hour scoring interval. By the 48–hour scoring interval, all signs of ocular irritation had subsided. There were no other adverse clinical symptoms or mortalities during the 7–day observation period. The maximum irritation score (MIS) was 1.7 at the 1–hour scoring interval and the maximum average score (MAS) was 0.22 over the 24–, 48– and 72–hour scoring intervals. Based on the MAS, Sporodex WP was classified as minimally irritating.

7. *Subchronic, chronic toxicity and oncogenicity.* Survival, replication, infectivity, significant toxicity or persistence of the MPCA was not observed in the test animals treated in Tier I acute oral, pulmonary and intravenous toxicity/infectivity tests.

Consequently, higher tier tests involving subchronic and chronic testing, oncogenicity testing, mutagenicity and teratogenicity were not required based on the lack of concerns following analysis of Tier I test results. However, a genotoxicity computer search for *Pseudozyma flocculosa* was conducted. No reports of mammalian toxicity were found in standard biological, chemical and toxicological abstracts. The applicant included computer literature search results to a number of keywords such as *pseudozyma*; tilletiopsis, fate, non target, carcin, mutagen; toxic, pathogen, antibiotic, polyen; sporothrix, sporobolomyces, rhodotorula, phyllosphere yeast; carcinog and teratogen. The literature search covered *AGRICOLA*, Biological Abstracts, CAB Abstracts, CHEMTOX, RTEX and AGRIS databases from 1980 to 1999.

8. *Hypersensitivity (dermal sensitization) study (OPPTS 870.2600).* The applicant has also submitted an acceptable waiver rationale from conducting a dermal sensitization study based on the assumption that most microorganisms contain substances that could elicit a hypersensitivity response. *Pseudozyma flocculosa* is considered a potential sensitizing agent, therefore, the statement, ''POTENTIAL SENSITIZER'' is required on the principal display panels of the technical and end-use formulation labels. The use of personal protective equipment will also be required to mitigate against potential dermal sensitization in occupationally exposed workers/handlers.

9. *Reports of hypersensitivity incidents (OPPTS 885.3400).* Skin sensitizing studies are not considered substitutes for timely reports of hypersensitivity incidents subsequent to registration approval. No adverse effects have been noted among researchers who have worked closely with *P. flocculosa* strain PF-A22 UL for up to 10 years. The applicant will be expected to report any subsequent findings of hypersensitivity or other health incidents to workers, applicators, or bystanders exposed to the MPCA as a condition of registration. Incident reports are to include details such as a description of the MPCA and formulation, frequency, duration and routes of exposure to the material, clinical observations, and any other relevant information.

10. *Effects on the immune systems (OPPTS 880.3800, immune response).* The active ingredient, *P. flocculosa* strain PF-A22 UL, is not known to be a human pathogen nor an endocrine disrupter. The submitted toxicity/pathogenicity studies in the rodent indicate that, following several routes of exposure, the immune system is still intact and able to process and clear the active ingredient. Therefore, no adverse effects to the immune systems are known or expected. Based on this rationale, the registrant waiver request for OPPTS 880.3800 (Immune Response) was found to be acceptable.

V. Aggregate Exposures

A. Dietary Exposure

In examining aggregate exposure, FFDCA section 408 directs EPA to consider available information concerning exposures from the pesticide residue in food and all other non-occupational exposures, including drinking water from ground water or surface water and exposure through pesticide use in gardens, lawns, or buildings (residential and other indoor uses).

1. *Food.* The proposed food use pattern is likely to result in residues in or on food and feed. Residues of the microbial pesticide are likely to be removed from treated food by washing, peeling, cooking and processing. Even if residues are not removed, however, EPA believes that dietary exposure to the microbial agent will result in negligible to no risk to consumers. Although *Pseudozyma* species are ubiquitous in nature and have been isolated from a wide variety of plant surfaces including leaf litter, clover, maize and cucumber, no adverse effects from dietary exposure have been attributed to natural populations of *Pseudozyma flocculosa*. Furthermore, no adverse effects were observed at maximum hazard dose levels in the acute oral toxicity/pathogenicity study and there are no reports of known mammalian toxins being produced by the MPCA. Subchronic and chronic dietary exposure studies were not required because the Tier I acute oral study demonstrated a low level of toxicity and no pathogenicity potential for the active microorganism. Because of the low toxicity profile and low potential exposure of the MPCA expected for the proposed uses, there is no concern for chronic risks posed by dietary exposure for the general population or sensitive subpopulations, such as infants and children. In addition, an extensive literature search yielded no reports of mammalian toxins being produced by *P. flocculosa*. The fungitoxic unsaturated C-17 fatty acids and acyclic norterpene produced by the MPCA have not been reported to be toxic to mammals. Neither this organism nor its close relatives are listed among microbial contaminants of food. Therefore, EPA expects negligible to no dietary risk from exposure to naturally-occurring and isolated *P. flocculosa* strain PF-A22 UL residues.

2. *Drinking water exposure.* Although heavy rainfall likely carries *P. flocculosa* into neighboring aquatic environments, growth and survival of terrestrial fungi such as *P. flocculosa* is limited in such environments. Thus, it is not expected to proliferate in aquatic habitats following incidents of direct or indirect exposure (e.g., runoff from treated greenhouses). Moreover, *P. flocculosa* is not considered to pose a risk to humans from exposure to drinking water because of minimal to non-existent toxicity. Accordingly, drinking water is not specifically screened for *P. flocculosa* as a potential indicator of microbial contamination or as a direct pathogenic contaminant. Both percolation through soil and municipal treatment of drinking water would reduce the possibility of significant transfer of residues to drinking water. Therefore, the potential of exposure and risk via drinking water is likely to be minimal to non-existent for this MPCA.

B. Other Non-Occupational Exposure

The current label does not allow applications to turf, residential or recreational areas. Because the use sites are in greenhouses, exposure to the U.S. population including infants and children in school, residential and daycare facilities is likely to be minimal to non-existent. Consequently, the health risk posed by *P. flocculosa* strain PF A-22 UL from non-occupational dermal and inhalation exposures to the general public, including infants and children, is expected to be negligible to non-existent. Any concerns for potential inhalation risk is for occupational exposures, and as mentioned previously, will be mitigated by the requirement of a respirator and restriction of the reentry interval.

VI. Cumulative Effects

The Agency has considered available information on the cumulative effects of such residues and other substances that have a common mechanism of toxicity. These considerations included the cumulative effects on infants and children of such residues and other substances with a common mechanism of toxicity. EPA is not aware of any other bacteria or other substances, besides naturally-occurring strains of *Pseudozyma*, that share a common mechanism of toxicity with this active ingredient. Given the low toxicity and pathogenicity profile of *P. flocculosa*, even if there were any other substances with which *P. flocculosa* shared a

common mechanism of toxicity, no adverse cumulative effects are expected.

VII. Determination of Safety for U.S. Population, Infants and Children

Based on the toxicology data submitted and other relevant information in the Agency's files, there is reasonable certainty no harm will result from aggregate exposure of residues of *Pseudozyma flocculosa* strain PF-A22 UL to the U.S. population, including infants and children, under reasonably foreseeable circumstances when the microbial pesticide product is used as labeled. This includes all anticipated dietary exposures and all other exposures for which there is reliable information. The Agency has arrived at this conclusion based on data submitted demonstrating low toxicity at the maximum doses tested and a lack of information showing adverse effects from exposure to naturally occurring *P. flocculosa* as well as a consideration of the product as currently registered and labeled. As a result, EPA establishes an exemption from tolerance requirements pursuant to FFDCA 408(c) and (d) for residues of *Pseudozyma flocculosa* strain PF-A22 UL in or on all food commodities.

FFDCA section 408 provides that EPA shall apply an additional tenfold margin of exposure (safety) for infants and children in the case of threshold effects to account for prenatal and postnatal toxicity and the completeness of the data base unless EPA determines that a different margin of exposure (safety) will be safe for infants and children. Margins of exposure (safety) are often referred to as uncertainty (safety) factors. In this instance, based on all the available information, the Agency concludes that *P. flocculosa* strain PF-A22 UL is practically non-toxic to mammals, including infants and children. Thus, there are no threshold effects of concern and, as a result the provision requiring an additional margin of safety does not apply. Further, the provisions of consumption patterns, special susceptibility, and cumulative effects do not apply. As a result, EPA has not used a margin of exposure (safety) approach to assess the safety of *P. flocculosa* strain PF-A22 UL.

VIII. Other Considerations

A. Endocrine Disruptors

EPA does not have any information regarding endocrine effects of this microbial pesticide at this time. There is no evidence to suggest that use of *P. flocculosa* strain PF-A22 UL at the proposed concentrations will adversely affect the endocrine system. The active ingredient, *P. flocculosa* strain PF-A22 UL, is not known to be a human pathogen nor an endocrine disrupter. The submitted toxicity/pathogenicity studies in the rodent indicate that, following several routes of exposure, the immune system is still intact and able to process and clear the active ingredient. Therefore, no adverse effects to the endocrine systems are known or expected.

B. Analytical Method(s)

As part of the standard Quality Control measures, the Agency is requiring microbial assays and analytical methods to identify the active ingredient and potential contaminants. Analytical methods are available and sufficient to identify metabolites and contaminants within regulatory levels. All batches containing potential human pathogens are to be destroyed. The MPCA is identified using a combination of morphological traits, molecular techniques and biological activity.

The identification of *Pseudozyma* to the species level is done using a standard mycological approach. *Pseudozyma* species can be differentiated from morphologically similar species such as *Hyalodendron, Tilletiopsis, Sporobolomyces and Sporothrix*. The branching conidiophores of *Pseudozyma* can be confused with those produced by *Hyalodendron*; however, the whole cell hydrolysates of this filamentous basidiomycete contain xylose which is not found in *Pseudozyma. Tilletiopsis* and *Sporobolomyces*, other saprophytic wild yeasts on aerial plant surfaces, are different from *Pseudozyma* in that they produce spores that are forcibly discharged upon sporulation (ballistospores). Furthermore, *Tilletiopsis* species produce a fungus-degrading β-1,3 glucanase that is not produced by *Pseudozyma* species. The genus *Sporothrix* represents a group of anamorphic ascomycetous yeasts such as *Sporothrix schenckii* (type), an animal pathogen. Physiologically, *Pseudozyma* species differ greatly from *Sporothrix* species. Unlike the ascomycetous *Sporothrix* anamorphs, *P. flocculosa* shows positive reactions in Diazonium Blue B and urease tests typical of all basidiomycetous yeasts. Also, the major ubiquinone is Q-10 rather than Q-8 or Q-9 typical of the ascomycetes, *Saccharomycopsis* and *Stephanoascus*.

Strain PF-A22 UL can be differentiated from other strains of *P. flocculosa* using a DNA-based technique called multiplex polymerase chain reaction (multiplex PCR). The multiplex PCR system is essentially a cocktail of different primers which allows the rapid assessment of numerous DNA fragments in a single PCR amplification. The protocol is based on the amplification of two nuclear regions, (ITS and NS), and one mitochondrial region (ML). Those regions were found to be discriminant in the identification of *P. flocculosa* PF-A22 UL.

The integrity and consistency of the MPCA is ensured by two methods. The first method is a DNA-based PCR technique called random amplified microsatellites PCR (RAMS). Microsatellites are hypervariable non-coding regions of DNA within the genome that evolve more rapidly than coding DNA. The other method is a bioassay that measures biological activity. The biological activity of the MPCA is measured by the inhibition zone created when a susceptible organism is grown next to it. Given that the pest controlled, *Sphaerotheca* species, is an obligate biotroph, it cannot be used directly in this bioassay. Instead, a *Phomopsis* species is used because its sensitivity to *P. flocculosa's* fungitoxic secretions is similar.

C. Codex Maximum Residue Level

There are no Codex Maximum Residue Levels or exemption from tolerances for the microbial active ingredient *Pseudozyma flocculosa* strain PF-A22 UL.

IX. Objections and Hearing Requests

Under section 408(g) of the FFDCA, as amended by the FQPA, any person may file an objection to any aspect of this regulation and may also request a hearing on those objections. The EPA procedural regulations which govern the submission of objections and requests for hearings appear in 40 CFR part 178. Although the procedures in those regulations require some modification to reflect the amendments made to the FFDCA by the FQPA of 1996, EPA will continue to use those procedures, with appropriate adjustments, until the necessary modifications can be made. The new section 408(g) provides essentially the same process for persons to ''object'' to a regulation for an exemption from the requirement of a tolerance issued by EPA under new section 408(d), as was provided in the old FFDCA sections 408 and 409. However, the period for filing objections is now 60 days, rather than 30 days.

A. What Do I Need to Do to File an Objection or Request a Hearing?

You must file your objection or request a hearing on this regulation in accordance with the instructions provided in this unit and in 40 CFR part

178. To ensure proper receipt by EPA, you must identify docket ID number OPP–2002–0233 in the subject line on the first page of your submission. All requests must be in writing, and must be mailed or delivered to the Hearing Clerk on or before November 26, 2002.

1. *Filing the request.* Your objection must specify the specific provisions in the regulation that you object to, and the grounds for the objections (40 CFR 178.25). If a hearing is requested, the objections must include a statement of the factual issues(s) on which a hearing is requested, the requestor's contentions on such issues, and a summary of any evidence relied upon by the objector (40 CFR 178.27). Information submitted in connection with an objection or hearing request may be claimed confidential by marking any part or all of that information as CBI. Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2. A copy of the information that does not contain CBI must be submitted for inclusion in the public record. Information not marked confidential may be disclosed publicly by EPA without prior notice.

Mail your written request to: Office of the Hearing Clerk (1900C), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460. You may also deliver your request to the Office of the Hearing Clerk in Rm. 104, Crystal Mall #2, 1921 Jefferson Davis Hwy., Arlington, VA. The Office of the Hearing Clerk is open from 8 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Office of the Hearing Clerk is (703) 603–0061.

2. *Tolerance fee payment.* If you file an objection or request a hearing, you must also pay the fee prescribed by 40 CFR 180.33(i) or request a waiver of that fee pursuant to 40 CFR 180.33(m). You must mail the fee to: EPA Headquarters Accounting Operations Branch, Office of Pesticide Programs, P.O. Box 360277M, Pittsburgh, PA 15251. Please identify the fee submission by labeling it ''Tolerance Petition Fees.''

EPA is authorized to waive any fee requirement ''when in the judgement of the Administrator such a waiver or refund is equitable and not contrary to the purpose of this subsection.'' For additional information regarding the waiver of these fees, you may contact James Tompkins by phone at (703) 305–5697, by e-mail at tompkins.jim@epa.gov, or by mailing a request for information to Mr. Tompkins at Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460.

If you would like to request a waiver of the tolerance objection fees, you must mail your request for such a waiver to: James Hollins, Information Resources and Services Division (7502C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460.

3. *Copies for the Docket.* In addition to filing an objection or hearing request with the Hearing Clerk as described in Unit IX.A., you should also send a copy of your request to the PIRIB for its inclusion in the official record that is described in Unit I.B.2. Mail your copies, identified by docket ID number OPP–2002–0233, to: Public Information and Records Integrity Branch, Information Resources and Services Division (7502C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460. In person or by courier, bring a copy to the location of the PIRIB described in Unit I.B.2. You may also send an electronic copy of your request via e-mail to: opp-docket@epa.gov. Please use an ASCII file format and avoid the use of special characters and any form of encryption. Copies of electronic objections and hearing requests will also be accepted on disks in WordPerfect 6.1/8.0 or ASCII file format. Do not include any CBI in your electronic copy. You may also submit an electronic copy of your request at many Federal Depository Libraries.

B. When Will the Agency Grant a Request for a Hearing?

A request for a hearing will be granted if the Administrator determines that the material submitted shows the following: There is a genuine and substantial issue of fact; there is a reasonable possibility that available evidence identified by the requestor would, if established resolve one or more of such issues in favor of the requestor, taking into account uncontested claims or facts to the contrary; and resolution of the factual issues(s) in the manner sought by the requestor would be adequate to justify the action requested (40 CFR 178.32).

X. Regulatory Assessment Requirements

This final rule establishes an exemption from the tolerance requirement under FFDCA section 408(d) in response to a petition submitted to the Agency. The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Order 12866, entitled *Regulatory Planning and Review* (58 FR 51735, October 4, 1993). Because this rule has been exempted from review under Executive Order 12866 due to its lack of significance, this rule is not subject to Executive Order 13211, *Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use* (66 FR 28355, May 22, 2001). This final rule does not contain any information collections subject to OMB approval under the Paperwork Reduction Act (PRA), 44 U.S.C. 3501 *et seq.*, or impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act of 1995 (UMRA) (Public Law 104–4). Nor does it require any special considerations under Executive Order 12898, entitled *Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations* (59 FR 7629, February 16, 1994); or OMB review or any Agency action under Executive Order 13045, entitled *Protection of Children from Environmental Health Risks and Safety Risks* (62 FR 19885, April 23, 1997). This action does not involve any technical standards that would require Agency consideration of voluntary consensus standards pursuant to section 12(d) of the National Technology Transfer and Advancement Act of 1995 (NTTAA), Public Law 104–113, section 12(d) (15 U.S.C. 272 note). Since tolerances and exemptions that are established on the basis of a petition under FFDCA section 408(d), such as the exemption in this final rule, do not require the issuance of a proposed rule, the requirements of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*) do not apply. In addition, the Agency has determined that this action will not have a substantial direct effect on States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government, as specified in Executive Order 13132, entitled *Federalism* (64 FR 43255, August 10, 1999). Executive Order 13132 requires EPA to develop an accountable process to ensure ''meaningful and timely input by State and local officials in the development of regulatory policies that have federalism implications.'' ''Policies that have federalism implications'' is defined in the Executive Order to include regulations that have ''substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government.'' This final rule directly regulates growers, food processors, food handlers and food

retailers, not States. This action does not alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of FFDCA section 408(n)(4). For these same reasons, the Agency has determined that this rule does not have any ''tribal implications '' as described in Executive Order 13175, entitled *Consultation and Coordination with Indian Tribal Governments* (65 FR 67249, November 6, 2000). Executive Order 13175, requires EPA to develop an accountable process to ensure ''meaningful and timely input by tribal officials in the development of regulatory policies that have tribal implications.'' ''Policies that have tribal implications'' is defined in the Executive Order to include regulations that have ''substantial direct effects on one or more Indian tribes, on the relationship between the Federal Government and the Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes.'' This rule will not have substantial direct effects on tribal governments, on the relationship between the Federal Government and Indian tribes, or on the distribution of power and responsibilities between the Federal government and Indian tribes, as specified in Executive Order 13175. Thus, Executive Order 13175 does not apply to this rule.

XI. Submission to Congress and the Comptroller General

The Congressional Review Act, 5 U.S.C. 801 *et seq.*, as added by the Small Business Regulatory Enforcement Fairness Act of 1996, generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report, which includes a copy of the rule, to each House of the Congress and to the Comptroller General of the United States. EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of this final rule in the **Federal Register**. This final rule is not a ''major rule'' as defined by 5 U.S.C. 804(2).

List of Subjects in 40 CFR Part 180

Environmental protection, Administrative practice and procedure, Agricultural commodities, Pesticides and pests, Reporting and recordkeeping requirements.

Dated: September 19, 2002.

James Jones,

Acting Director, Office of Pesticide Programs.

Therefore, 40 CFR chapter I is amended as follows:

PART 180—[AMENDED]

1. The authority citation for part 180 continues to read as follows:

Authority: 21 U.S.C. 321(q), 346(a) and 374.

2. Section 180.1221 is added to subpart D to read as follows:

§ 180.1221 Pseudozyma flocculosa strain PF-A22 UL; exemption from the requirement of a tolerance.

An exemption from the requirement of a tolerance is established for residues of *Pseudozyma flocculosa* strain PF-A22 UL in or on all food commodities.

[FR Doc. 02–24651 Filed 9–26–02; 8:45 am]

BILLING CODE 6560–50–S

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[OPP–2002–0229; FRL–7196–8]

Fenamidone; Pesticide Tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes tolerances for residues of fenamidone, [4H-Imidazol-4-one, 3,5-dihydro-5-methyl-2-(methylthio)-5-phenyl-3-(phenylamino)-, (S)-], in or on lettuce, head at 15 ppm and lettuce, leaf at 20 ppm. Aventis CropScience requested these tolerances under the Federal Food, Drug, and Cosmetic Act, as amended by the Food Quality Protection Act of 1996. Subsequent to the filing of this petition, Bayer Corporation acquired Aventis CropScience to form Bayer CropScience. Therefore, the registrant is now Bayer CropScience.

DATES: This regulation is effective September 27, 2002. Objections and requests for hearings, identified by docket control number OPP–2002–0229, must be received on or before November 26, 2002.

ADDRESSES: Written objections and hearing requests may be submitted by mail, in person, or by courier. Please follow the detailed instructions for each method as provided in Unit VI. of the **SUPPLEMENTARY INFORMATION**. To ensure proper receipt by EPA, your objections and hearing requests must identify docket control number OPP–2002–0229 in the subject line on the first page of your response.

FOR FURTHER INFORMATION CONTACT: By mail: Cynthia Giles-Parker, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW.,Washington, DC 20460; telephone number: (703) 305–7740; e-mail address: giles-parker.cynthia@epa.gov.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

You may be affected by this action if you are an agricultural producer, food manufacturer, or pesticide manufacturer. Potentially affected categories and entities may include, but are not limited to:

Categories	NAICS codes	Examples of potentially affected entities
Industry	111 112 311 32532	Crop production Animal production Food manufacturing Pesticide manufacturing

This listing is not intended to be exhaustive, but rather provides a guide for readers regarding entities likely to be affected by this action. Other types of entities not listed in the table could also be affected. The North American Industrial Classification System (NAICS) codes have been provided to assist you and others in determining whether or not this action might apply to certain entities. If you have questions regarding the applicability of this action to a particular entity, consult the person listed under **FOR FURTHER INFORMATION CONTACT**.

B. How Can I Get Additional Information, Including Copies of this Document and Other Related Documents?

1. *Electronically.*You may obtain electronic copies of this document, and certain other related documents that might be available electronically, from the EPA Internet Home Page at http://www.epa.gov/. To access this document, on the Home Page select ''Laws and Regulations,'' ''Regulations and Proposed Rules,'' and then look up the entry for this document under the ''**Federal Register**—Environmental Documents.'' You can also go directly to the **Federal Register** listings at http://www.epa.gov/fedrgstr/. A frequently updated electronic version of 40 CFR part 180 is available at http://www.access.gpo.gov/nara/cfr/cfrhtml_00/Title_40/40cfr180_00.html, a