

depending on the cotton variety and its vigor, vary from 0.03 - 0.38 grams BPO1/A.

The maximum application level for BPO1 on cotton is 0.75 gram/acre/year, with an average of 0.2 g/acre/year. For row crops (e.g., corn, soybeans), the maximum application will be less than 2 g/acre/application and less than 20 g/acre/year. This tolerance exemption petition is for use of *Bacillus cereus* BPO1 up to 20 g/acre/year. There is a 30-day pre-harvest interval (PHI). Livestock should not be fed or permitted to graze on BPO1-treated cotton forage.

B. Product Identity/Chemistry

1. *Identity of the pesticide and corresponding residues.* The ATCC classification of Micro Flo's *Bacillus cereus* BPO1 is 55675. Only residues of BPO1 would be present, and these residues are indistinguishable from naturally-occurring *Bacillus cereus* without using specific genetic testing procedures for differentiating them.

2. *Magnitude of the residue anticipated at the time of harvest and the method used to determine the residue.* No magnitude of residue (MOR) studies have been conducted on BPO1 as total application rates are exceedingly low (Cotton: average, 0.2 g BPO1/acre/year; maximum, 0.75 g/acre/year; Other major row crops [e.g., soybeans, corn]: <20 g BPO1/acre/year) and it is toxicologically innocuous. The Pre-Harvest Interval (PHI) is currently 30 days. *Bacillus cereus* is indigenous and widespread throughout the United States and the rest of the world.

3. *Statement regarding the lack of need for an analytical method for detecting and measuring the levels of the pesticide residue.* As indicated above, the naturally-occurring population of *B. cereus* may make it impossible to distinguish between natural and introduced microbial populations without utilizing genetic differentiation techniques and therefore to establish and enforce tolerances for BPO1. In addition, the PHI is currently 30 days.

C. Mammalian Toxicity Profile

Acute mammalian toxicity studies via oral, dermal, inhalation, eye, intratracheal and intravenous routes were conducted with *Bacillus cereus* BPO1. No pathogenicity was observed. BPO1 was also tested for enterotoxin production; none was detected.

In a blood agar hemolysis assay conducted with BPO1, weak alpha hemolysis was observed. Based on the results of the above studies, subchronic, reproductive, teratology, chronic and

mutagenicity studies were not deemed necessary.

D. Aggregate Exposure

1. *Dietary exposure—*a. *Food.* *Bacillus cereus* BPO1 is currently pending registration for use on cotton at rates up to 0.75 g/A/year. Micro Flo Co. will, however, be evaluating BPO1 for future registration for use on other row crops (e.g., soybeans, corn) at rates less than 20 g/A/year. Considering the extremely low application rates, ubiquitous nature and natural occurrence of *Bacillus cereus*, the potential dietary exposure to BPO1 is minuscule.

b. *Drinking water.* *Bacillus cereus* BPO1 is prohibited on the label from direct application to water, although possible spray drift may contact drinking water. Again, considering the extremely low application rates, non-toxic mode of action, ubiquitous nature and natural occurrence of *Bacillus cereus*, the potential drinking water exposure to BPO1 is minuscule.

2. *Non-dietary exposure.* There is no anticipated non-dietary exposure to *Bacillus cereus* BPO1. Contact with naturally-occurring populations of *B. cereus* is common throughout the world. Residue exposure through contact with cotton seeds/oil and clothing produced from BPO1-treated cotton has been theoretically considered; residues are unlikely to be present after the delinting/cleaning process.

E. Cumulative Effects

Although there are other currently registered *Bacillus* products, some of which hold tolerance exemptions, their modes of action are unlike BPO1. Specifically, the other products typically produce enterotoxin which, when the bacteria producing it is consumed by insect pests, causes the pest to die. BPO1 does not produce enterotoxin, but instead appears to enable the target plant to more readily and efficiently uptake and utilize growth nutrients. BPO1 is a true growth regulator and to our knowledge does not have classic pesticidal activity. Maximum anticipated application rates are 0.75 g/A/year (cotton) and <20 g/A/year (major row crops including soybeans and corn). Based on the above, it is therefore felt that BPO1 should not be considered similar to existing *Bacillus* products.

F. Safety Determination

1. *U. S. population.* Since: (a) the maximum currently sought use rate is 0.75 g BPO1/A/year for use on cotton (and 20 g/A/year on other row crops for which registration applications have not been submitted), (b) the associated

anticipated minute residue levels are extremely unlikely to add appreciably to the natural, indigenous background levels of *Bacillus cereus*, (c) BPO1 does not produce enterotoxin, and (d) the toxicity/pathogenicity/infectivity studies show virtually no negative effects, BPO1 should be considered safe when used on raw agricultural commodities and meets the reasonable certainty of no harm requirement.

2. *Infants and children.* As previously discussed, based on the minuscule quantities of BPO1 used, its lack of toxicity and pathogenicity, and its mode of action, it is exceedingly improbable that infants or children would be at greater risk to BPO1 exposure than would adults. BPO1 should be considered safe when used on raw agricultural commodities and meets the reasonable certainty of no harm requirement.

3. *Endocrine effects.* There is no evidence that BPO1 has endocrine disrupter effects individually or in combination with any other chemical. It is unlikely to be an endocrine disrupter or to have a synergistic endocrine effect in combination with other chemicals.

G. Existing Tolerances

1. *Existing U.S. tolerances or exemptions from the requirement of a tolerance.* There are no current tolerances or tolerance exemptions for *Bacillus cereus* strain BPO1.

2. *International tolerances or exemptions from the requirement of a tolerance.* There are no Codex Maximum Residue Levels or tolerance exemptions for *Bacillus cereus* strain BPO1.

[FR Doc. 97-16358 Filed 6-24-97; 8:45 am]

BILLING CODE 6560-50-F

ENVIRONMENTAL PROTECTION AGENCY

[PF-737; FRL-5719-7]

Notice of Filing of Pesticide Petitions

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: This notice announces the initial filing a pesticide petition proposing the establishment of regulations for residues of certain pesticide chemicals in or on various food commodities.

DATES: Comments, identified by the docket control number PF-737, must be received on or before July 25, 1997.

ADDRESSES: By mail submit written comments to: Public Information and

Records Integrity Branch, Information Resources and Services Division, (7506C), Office of Pesticides Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. In person bring comments to: Rm. 1132, CM #2, 1921 Jefferson Davis Highway, Arlington, VA.

Comments and data may also be submitted electronically by following the instructions under "SUPPLEMENTARY INFORMATION." No confidential business information should be submitted through e-mail.

Information submitted as a comment concerning this document may be claimed confidential by marking any part or all of that information as "Confidential Business Information" (CBI). CBI should not be submitted through e-mail. Information marked as CBI will not be disclosed except in accordance with procedures set forth in 40 CFR part 2. A copy of the comment 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. All written comments will be available for public inspection in Rm. 1132 at the address given above, from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays.

FOR FURTHER INFORMATION CONTACT: By mail: Rita Kumar, Product Manager(PM)90, Biopesticides and Pollution Prevention Division, Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. Office location, telephone number and e-mail address: 5th Floor, CS1, 2800 Cystal Drive, Arlington, VA 703-308-8291, e-mail: kumar.rita@epamail.epa.gov.

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

The official record for this notice of filing, as well as the public version, has been established for this notice of filing under docket control number [PF-737] (including comments and data submitted electronically as described

below). A public version of this record, including printed, paper versions of electronic comments, which does not include any information claimed as CBI, is available for inspection from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The official record is located at the address in "ADDRESSES" at the beginning of this document.

Electronic comments can be sent directly to EPA at: opp-docket@epamail.epa.gov

Electronic comments must be submitted as an ASCII file avoiding the use of special characters and any form of encryption. Comment and data will also be accepted on disks in Wordperfect 5.1 file format or ASCII file format. All comments and data in electronic form must be identified by the docket number (insert docket number) and appropriate petition number. Electronic comments on this proposed rule may be filed online at many Federal Depository Libraries.

List of Subjects

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

Dated: June 17, 1997.

Janet L. Andersen,

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

Summaries of Petitions

Petitioner summary of the pesticide petition is printed below as required by section 408(d)(3) of the FFDCA. The summaries of the petitions were prepared by the petitioners and represent the views of the petitioners. EPA is publishing the petition summaries verbatim without editing them in any way. 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.

Micro Flo Company

PP 2E04064

The purpose of this submission is to summarize the information provided by Micro Flo Company to the EPA in support of the proposed change in beginning materials for the inert Cucurbitacin in the manufacturing process of Slam/Adios (EPA Reg. No. 51036-185) and Adios AG (EPA Reg.

No. 51036-204). This amendment in the existing exemption is submitted pursuant to section 408 of the FFDCA.

This change in beginning materials will require an amendment to the existing tolerance exemption (40 CFR 180.1001(d)) for buffalo gourd root powder and cucurbitacins.

40 CFR 180.1001(d) reads:

Inert Ingredients	Limits	Uses
Buffalo Gourd Root Powder (<i>Cucurbita Foetidissima</i> root powder).	No more than 2.5 lbs/acre/season (3.4 gm/acre/season of Cucurbitacin)	Gustatory stimulant

Cucurbitacins, found in plant of the Family Cucurbitaceae, act specifically on Diabrotic beetle (corn rootworm and cucumber beetles) as movement arrestants and compulsive feeding stimulants. These have been used in pesticide products Slam/Adios and Adios AG, which were developed to replace highly toxic corn rootworm and cucumber beetle insecticides. When used along with cucurbitacin in the formulation, a much smaller amount of the pesticide active ingredient carbaryl is needed to achieve efficacy against these pests.

MicroFlo Company's current source of cucurbitacin is buffalo gourd root powder. The Agency established an exemption from the requirement of a tolerance for residues of buffalo gourd root powder (57 FR 40128, September 2, 1992). Now MicroFlo Company proposes to add zucchini juice as an alternative sources of cucurbitacin, since production of buffalo gourd root powder is costly and unreliable.

Micro Flo Company believes that the submission and supporting data, together with the Agency's earlier findings and determinations, satisfies the Agency's requirement for the demonstrations, buffalo gourd root powder (*Cucurbita foetidissima* root powder) and zucchini juice (*Cucurbita pepo* juice).

Based upon the information presented, Micro Flo Company believes that when used in accordance with good agricultural practice, the ingredient zucchini juice is useful and a tolerance is not necessary to protect the public health.

Therefore, Micro Flo Company proposes amending the existing tolerance exemption by only adding zucchini juice to the "Inert Ingredients" list, no change in "Limits" or "Uses" is proposed.

Proposed Amendment to 40 CFR 180.1001 (d):

Inert Ingredients	Limits	Uses
Buffalo Gourd Root Powder (<i>Cucurbita Foetidissima</i> root powder); or, Zucchini Juice (<i>Cucurbita pepo</i> juice).	No more than 2.5 lbs/acre/season (3.4 gm/acre/season of Cucurbitacin)	Gustatory stimulant

A. Proposed Use Practices

1. Recommended application method and rate (s), frequency of application,

and timing of application. The formulation containing Zucchini Juice is to be applied according to good agricultural practice, by air or ground application method, when Diabrotic beetle populations reach the economic threshold and injury levels for the specific crop.

No change in the frequency of applications is proposed. The maximum number of applications will remain five (5) applications per crop growing season. The total amount of cucurbitacin will not exceed 3.4 gm/acre/season.

B. Product Identity And Chemistry

1. *Identity of the compound and corresponding residues.* The submitted product chemistry data for Zucchini Juice as an inert ingredient satisfy the requirements regarding product identity (151-10), beginning material and the manufacturing process (151-11), discussion of formation of unintentional ingredients (151-12), analysis of samples (151-13), certification of limits (151-15), analytical method (151-16), and physical / chemical properties (151-17). No additional data is required.

Name	EPA Shaunessy Number	Chemical identity	Composition
Buffalo Gourd Root Powder (<i>Cucurbita foetidissima</i> root powder).	128874 (Mar 90, Pesticide Data Submitters List)	Dry powder of plant derived from the cucurbit species <i>Cucurbita Foetidissima</i>	Root powder percent weight basis
Zucchini Juice Not Applicable		Juice Of Plant derived from the cucurbit species <i>Cucurbita pepo</i>	Fruit Juice Percent weight basis

The Product chemistries show similar nutritional profiles for each cucurbit species; and both cucurbit species are used as a food source for human consumption.

Component	Percent Weight Buffalo Gourd	Percent Weight Zucchini Juice Root Powder
Ash	8.44	4.85
Protein	15.4	3.78
Sugar ...	1.87	0.91
Moisture	10.0	66.7
Carbohydrate.	47.9	22.7
Fiber	18.0	1.2
Fat	0.25	0.77

2. *Magnitude of residue anticipated at the time of harvest and method used to determine the residue.* Based upon the proposed maximum number of applications, no residues are anticipated at harvest for Zucchini Juice (maximum 2.4375 pounds/acre/season); nor for Cucurbitacins (maximum 3.319875 grams/acre/season). Methods used to determine residues includes: high performance liquid chromatography (HPLC), mass spectrometry (MS), nuclear magnetic resonance spectra (NMRS), Rf values in normal phase thin layer chromatography (TLC), specific color reactions, and diabrotic beetle quantified feeding pattern bioassays.

3. A statement of why an analytical method for detecting and measuring the levels of the residue are not needed. There are several highly accurate, reliable and reproducible analytical methods available for detecting and measuring the levels of the residue of zucchini juice and cucurbitacins. Please see Section B-2 above.

C. Mammalian Toxicological Profile

1. *Acute toxicity.* The subject studies were found to be acceptable and performed in accordance with the Subdivision M Guidelines. Comparative toxicology data shows a more favorable toxicological profile for the Zucchini Juice (*Cucurbita pepo* juice), as compared to the Buffalo Gourd Root Powder (*Cucurbita foetidissima* root powder), as a cucurbit source of cucurbitacins.

The acute mammalian toxicity studies indicate that the Zucchini Juice is practically non-toxic to mammals. The acute oral, acute dermal, acute inhalation, primary eye, and skin irritation are all toxicity category IV. No acute systemic toxicity, irritation or dermal sensitization was exhibited in the studies performed with the Zucchini Juice.

2. *Chronic toxicity.* The proposed inert biochemical pesticide ingredient Zucchini Juice and the associated component cucurbitacin do not meet the conditions of 40 CFR 158.690 (b): based on the results of Tier I toxicology studies, neither Tier II nor III toxicology data are required.

Given the small amounts used and rapid degradation of Zucchini Juice and associated cucurbitacins, no chronic effects are expected. Neither the Zucchini Juice and associated cucurbitacins, nor metabolites, are known to, or expected to have any effect on the immune or endocrine systems. Zucchini Juice in general, and associated cucurbitacins are not carcinogenic.

D. Aggregate Exposure

1. *Dietary exposure— a. Food.* The petitioner presents the following dietary risk data and assessment on potential crop residues of Zucchini Juice. In accordance with 40 CFR 180.34, these data are presented to establish, theoretically, the residues that would remain under conditions most likely to result in high residues on the commodity.

Assumptions, for the purpose of this maximum dietary risk - worst case scenario, (case crop - corn; the example can be extended to other crops) include that the Zucchini Juice and thus, the cucurbitacin, is applied at the maximum label rate, the maximum number of times, the day of harvest, and all of the material applied to the field is concentrated in the grain; with no loss of Zucchini Juice nor cucurbitacin due to any environmental, physical, chemical microbial or milling / processing degradation. This will result in 2.4375 pounds of Zucchini Juice and 0.0073125 pounds (3.319875 grams) of cucurbitacins per acre.

The national average grain yield for corn is 120 - 130 bushels per acre. At 56 pounds per bushel, for the purpose of the calculation, we will use the lower yield value of 6,720 pounds per acre. The maximum label rates allow for the application of 3.4 grams of cucurbitacin per acre. Assuming all of the cucurbitacin is concentrated in the grain, cucurbitacin levels would be 0.00051 grams cucurbitacin per pound of grain corn.

It has been established that the cucurbitacins found in Zucchini Juice are Cucurbitacin E and Cucurbitacin E Glycoside, at concentrations of 0.2 - 0.3

percent. The acute oral LD₅₀ values are: cucurbitacin E = 340 mg/kg; cucurbitacin E Glycoside = 40 mg/kg. For the purpose of the calculation, we will use the higher LD₅₀ value of 40 mg/kg.

Assuming 50 kg human being as the average weight, the amount of cucurbitacin required to reach the Acute Oral LD₅₀ is 2,000 mg (40 mg/kg × 50 kg). One pound of grain corn contains 0.51 milligrams cucurbitacin. This is 1/3922 of the amount of cucurbitacin a 50 kg person would have to ingest to reach the acute oral LD₅₀ level. Therefore, to ingest 2,000 mg of cucurbitacin, a 50 kg person would need to consume 3,922 pounds of corn at one sitting. Alternatively, to ingest 2,000 mg of cucurbitacin, a 50 kg person would need to consume 11,013 ears of corn at one sitting, given an average weight of grain in one ear of corn is 0.36 pounds.

b. *Drinking water.* Cucurbitacins are insoluble in water and transfer of the zucchini juice to drink water is highly unlikely. No leaching or groundwater contamination is expected to result from registered uses according to good agricultural practice. No uses are registered for application to bodies of water and none are being sought.

2. *Non-dietary exposure such as lawn care, topical insect repellents, etc.* Registered uses are limited to agricultural crop production use.

E. Cumulative Exposure

Exposure through other pesticides and substances with the common mode of toxicity as this compound. Consideration of a common mode of toxicity is not appropriate given that the Zucchini Juice is practically non-toxic to mammals and no information indicates that toxic effects would be cumulative with any other compounds. Further, no other pesticides or substances are registered with this mode of toxicity.

F. Safety Determination

1. *U.S. population.* The fact that Zucchini Juice is practically non-toxic to mammals; that to ingest the Acute Oral LD₅₀ level of 2,000 mg of cucurbitacin, a 50 kg person would need to consume 3,922 pounds of corn at one sitting; that Aggregate Exposure and Cumulative Exposure pose little, if any, risk at all; and previous Agency actions granting a temporary exemption (55 FR 49700, November 30, 1990), and establishing a permanent exemption from the requirement of a tolerance (57 FR 40128, September 2, 1992), support an amendment to the existing tolerance exemption.

2. *Infants and children.* The use sites for the Zucchini Juice are all agricultural for control of Diabrotic beetle. Therefore, nondietary exposure to infants and children is not expected. The fact that Zucchini Juice is practically non-toxic to mammals; that to ingest the Acute Oral LD₅₀ level 40 mg of cucurbitacin, a 1 kg infant or child, would need to consume 78.44 pounds of corn at one sitting; and that Aggregate Exposure and Cumulative Exposure pose little, if any, risk at all; all provide reasonable certainty that no harm will result to infants and children from exposure to residue of Zucchini Juice.

G. Existing Tolerances

1. *Existing tolerance or tolerance exemptions for this compound.* Prior EPA findings of significant relevance to this petition include a temporary exemption from the requirements of a tolerance for residues of the kairimone, *Cucurbita foetidissima* root powder in or on the raw agricultural commodity field corn for control of adult corn rootworms (55 FR 49700, November 30, 1990).

In addition, the Agency established a permanent exemption from the requirement of a tolerance for residues of buffalo gourd root powder when used as an inert ingredient (gustatory stimulant) in pesticide formulations applied to growing crops only (57 FR 40128, September 2, 1992).

40 CFR 180.1001 (d) reads:

Inert Ingredients	Limits	Uses
Buffalo Gourd Root Powder (<i>Cucurbita Foetidissima</i> root powder).	No more than 2.5 lbs/acre/season (3.4 gm/acre/season of Cucurbitacin)	Gustatory stimulant

2. *International tolerances or tolerance exemptions.* No international tolerances of tolerance exemptions have been sought.

[FR Doc. 97-16509 Filed 6-24-97; 8:45 am]

BILLING CODE 6560-50-F

ENVIRONMENTAL PROTECTION AGENCY

[PF-747; FRL-5728-4]

Monsanto Company; Pesticide Tolerance Petition Filing

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: This notice announces the initial filing of a pesticide petition

proposing the establishment of regulations for residues of a certain pesticide chemical in or on various food commodities.

DATES: Comments, identified by the docket control number PF-747, must be received on or before July 25, 1997.

ADDRESSES: By mail submit written comments to: Information and Records Integrity Branch, Public Information and Services Division (7506C), Office of Pesticides Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. In person bring comments to: Rm. 1132, CM #2, 1921 Jefferson Davis Highway, Arlington, VA.

Comments and data may also be submitted electronically by following the instructions under "SUPPLEMENTARY INFORMATION." No confidential business information should be submitted through e-mail.

Information submitted as a comment concerning this document may be claimed confidential by marking any part or all of that information as "Confidential Business Information" (CBI). CBI should not be submitted through e-mail. Information marked as CBI will not be disclosed except in accordance with procedures set forth in 40 CFR part 2. A copy of the comment 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. All written comments will be available for public inspection in Rm. 1132 at the address given above, from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays.

FOR FURTHER INFORMATION CONTACT: By mail: Linda Hollis, Product Manager (PM) 90, Biopesticides and Pollution Prevention Division, (7501W), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. Office location and telephone number: Rm. 5th floor, CS1, 2800 Crystal Drive, Arlington, VA., 22202, (703) 308-8733; e-mail: hollis.linda@epamail.epa.gov.

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