

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

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-747] (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".

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 (PF-747) 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 19, 1997.

Kathleen D. Knox,

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

Summary of Petition

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

Monsanto Company

PP 7F4831

EPA has received a pesticide petition (PP 7F4831) from Monsanto Company of St. Louis Missouri. The petition proposes, pursuant to section 408 of the

Federal Food Drug and Cosmetic Act (FFDCA), 21 U.S.C. 346a, to amend 40 CFR part 180 to establish an exemption from the requirement of a tolerance for the plant-pesticide Coat Protein of Potato Virus Y and the genetic material necessary for its production in or on all raw agricultural commodities.

A. Proposed Use Practices

Recommended application method and rate(s), frequency of application, and timing of application. Monsanto states that the plant viral coat protein is produced within tissues of the engineered plant and is not to be applied externally. Appropriate cultural practices for growing seed with genetically engineered virus resistance will be determined by individual growers, such practices are for all other plant varieties. Accordingly, no special instructions for use will be necessary.

B. Product Identity/Chemistry

1. *Identity of the pesticide and corresponding residues.* Monsanto has determined that the sequence of the engineered viral coat protein expressed in transformed plants is identical to a viral coat protein found in nature.

2. *Magnitude of residue anticipated at the time of harvest and method used to determine the residue.* Monsanto states that the viral coat protein is expressed in plant tissues, and therefore, is not a residue in the same manner as a pesticide applied externally to growing crop plants. Monsanto does not expect any measurable residue of the engineered viral coat protein to remain on or in transformed raw agricultural commodities (RACs).

3. *A statement of why an analytical method for detecting and measuring the levels of the pesticide residue are not needed.* The ELISA (Enzyme-Linked Immunoabsorbent Assay) test can be used to determine expression levels of viral coat proteins in transformed plants, fruits and leaves if the level of expression is high enough for detection. In Monsanto's assay, the amount of viral coat protein expressed is below the limit of detection and between 10-100-fold lower than the levels found in natural infections of potato with PVY. However, because the Agency proposes to exempt all plant virus coat proteins from the requirement of a tolerance, Monsanto believes that an analytical method for detecting and measuring the levels of viral coat proteins in or on all RACs is not required for enforcement purposes.

C. Mammalian Toxicological Profile

Viral Coat Proteins are substances that viruses produce during a plant infection to encapsulate and protect

their genetic material. When the genetic material encoding the coat protein for a plant virus is introduced into a plant's genome, the plant is able to resist subsequent infections by that same virus as well as strains closely related to the donor virus. Virus-infected plants currently are and have always been a part of both the human and domestic animal food supply, and Monsanto agrees with EPA's finding, published in the **Federal Register** of November 23, 1994 (59 FR 60519-60535), that plant viruses are not known to be harmful to humans. All available data from the scientific literature indicates that plant viruses are not toxic to humans or other vertebrates. Additionally, plant viruses are unable to replicate in mammals or other vertebrates, eliminating the possibility of human infection. This has been shown by injections of purified whole virus into laboratory animals to develop antibodies for ELISA tests. More importantly, however, this tolerance exemption will apply to that portion of the viral genome coding for the whole coat protein and any subcomponent of the coat protein expressed in the plant. This component alone is incapable of forming infectious particles. Because whole intact plant viruses are not known to cause deleterious human health effects, Monsanto believes that it is reasonable to assume that a subunit of these viruses likewise will not cause adverse human health effects.

D. Aggregate Exposure

1. *Dietary exposure.—a. Food.*

Monsanto believes that the use of viral coat protein-mediated resistance will not result in any new dietary exposure to plant viruses. Entire infectious particles of Potato Virus Y, including the coat protein component, are found in the fruit, leaves and stems of most plants. Virus-infected food plants are and have always been a part of the human and domestic animal food supply. Such food plants and food derived from them have been consumed with no detectable or observed adverse effects to human health, including children and infants. Given this information, Monsanto believes that exposure via the human diet provides a direct and better method of establishing the lack of toxicity versus animal models of toxicity.

b. *Drinking water.* No measurable residues of coat proteins from engineered plant viruses are expected to be in the drinking water. Plant viruses are a natural component of the environment and are present in soil and water. Consequently, Monsanto believes that coat proteins produced as plant-

pesticides would represent a negligible addition to those existing in drinking water.

2. *Non-dietary exposure.* Monsanto believes that non-dietary exposure to engineered coat proteins will be minimal to non-existent because the coat protein is expressed only within the plant tissues.

E. Cumulative Exposure

Exposure through other pesticides and substances with the common mode of toxicity as this pesticide. Monsanto believes that due to the lack of toxicity/pathogenicity associated with plant viruses or plant viral coat proteins, cumulative effects with other pesticides and substances will be non-existent.

F. Safety Determination

1. *U.S. population.* There is no known toxicity associated with coat proteins from plant viruses. Consequently, a safety assessment is not needed for these proteins. Given the long history of mammalian consumption of the entire plant virus particle in foods, without any adverse human health effects, Monsanto reasonably believes that consumption of a noninfectious component of the PVY plant virus is safe. There are no known data that indicate aggregate exposure to plant viral coat proteins under normal conditions will result in harm to any person.

2. *Infants and children.* Viral coat proteins are ubiquitous in foods, including those foods consumed by infants and children. Moreover, there is no reason to believe that plant viral coat proteins are likely to occur in different amounts in foods, consumed by children and infants. Further, there is no scientific evidence that viral coat proteins used as plant-pesticides would have a different effect on children than on adults. Viral coat proteins are not toxic and, therefore, Monsanto believes with reasonable certainty that no harm will result to infants and children from aggregate exposure to coat proteins from plant viruses.

G. Existing Tolerances

No tolerance or exemption from tolerance has been previously granted for PVY coat protein.

H. International Tolerance

No international tolerance or exemption from tolerance has been previously granted for PVY coat protein. Monsanto Company concludes that plant viruses, including PVY coat proteins, are not harmful to humans, and that there is a reasonable certainty that no harm will result from aggregate exposure to Coat Protein of Potato Virus Y and the genetic material necessary for

its production, including all anticipated dietary exposures and all other non-occupational exposures. Accordingly, Monsanto believes that the PVY coat protein qualifies for an exemption from the requirement of a tolerance in or on all raw agricultural commodities.

[FR Doc. 97-16657 Filed 6-24-97; 8:45 am]

BILLING CODE 6560-50-F

ENVIRONMENTAL PROTECTION AGENCY

[PF-742; FRL-5723-2]

Notice of Filing of Pesticide Petitions

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

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

DATES: Comments, identified by the docket control number PF-742, must be received on or before July 25, 1997.

ADDRESSES: By mail submit written comments to: Public Response and Program Resources Branch, Field Operations Division (7505C), 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 pesticide petitions as follows proposing the establishment and/or amendment of regulations for residues of certain pesticide chemicals in or on various raw agricultural commodities under section 408 of the Federal Food, Drug, and Cosmetic 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, as well as the public version, has been established for this notice of filing under docket control number PF-742 (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.

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Authority: 21 U.S.C. 346a.

List of Subjects

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