

ENVIRONMENTAL PROTECTION AGENCY

[PF-843; FRL-6042-4]

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 food commodities.

DATES: Comments, identified by the docket control number PF-843, must be received on or before December 21, 1998.

ADDRESSES: By mail submit written comments to: Public Information and Records Integrity Branch, Information Resources and Services Division (7502C), 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: The product manager listed in the table below:

Product Manager	Office location/telephone number	Address
Edward Allen	Rm. 902W16, CM #2, 703-308-8699, e-mail: allen.edward@epamail.epa.gov.	1921 Jefferson Davis Hwy, Arlington, VA
Bipin Gandhi	Rm. 707A, CM #2, 703-308-8380, e-mail: gandhi.bipin@epamail.epa.gov.	Do.

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 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 of filing, as well as the public version, has been established for this notice of filing under docket control number [PF-843] (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 notice 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: November 12, 1998.

James Jones,

Director, Registration Division, Office of Pesticide Programs.

Summaries of Petitions

Petitioner summaries of the pesticide petitions are 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.

1. Agrium US Inc.

PP 8F5035

EPA has received a pesticide petition (PP 8F5035) from Agrium US Inc., 4582 S. St., Suite 1400, Denver, CO 80237, proposing pursuant to section 408(d) of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. 346a(d), to amend 40 CFR part 180 to establish an exemption from the requirement of a tolerance for *Pseudomonas chlororaphis* Strain 63-28 in or on the raw agricultural commodity greenhouse vegetable crops.

Pursuant to section 408(d)(2)(A)(i) of the FFDCA, as amended, Agrium US Inc. has submitted the following summary of information, data and arguments in support of their pesticide petition. This summary was prepared by Agrium US Inc. and EPA has not fully evaluated the merits of the petition. The summary may have been edited by EPA if the terminology used was unclear, the summary contained extraneous material, or the summary was not clear that it reflected the conclusion of the petitioner and not necessarily EPA.

A. Product Name and Proposed Use Practices

Pseudomonas chloroaphis Strain 63-28 will be incorporated into the end-use product, AtEze, as an active ingredient. AtEze is proposed for use on greenhouse vegetable crops for the suppression of two important soil-borne diseases *Rhizoctonia solani* and *Pythium spp.*

The product is applied as a soil drench treatment at a dilution rate of 1:500 using potable water. In addition,

the product may also be applied with drip irrigation systems in production greenhouses.

B. Product Identity/Chemistry

Identity of the pesticide and corresponding residues. *Pseudomonas chlororaphis* Strain 63-28 is a liquid suspension containing living cells at a concentration of 109 colony forming units (cfu)/mL of fermentation product. *Pseudomonas chlororaphis* Strain 63-28 is a plant-beneficial rhizobacterium that is a non-pathogenic, non-toxic, free-living organism which is naturally occurring in soils and water worldwide.

The association of *Pseudomonas chlororaphis* Strain 63-28 with plants is adequately understood for purposes of the tolerance exemption. This rhizosphere bacterium is one of the most commonly-occurring microorganisms in soils and on roots of many plants during growing seasons. Inocula of *P. chlororaphis* Strain 63-28 applied into natural soils do not persist for a long period of time, nor do they change soil microbial processes significantly, according to published literature. Several strains of *P. chlororaphis* Strain 63-28, when introduced at a concentration of approximately 106 cfu/g of root, fall below detection levels after 8-12 weeks. There is no indication that the bacterium can be translocated in great numbers within plants. An analytical method for residues is not applicable, since the petitioner has requested an exemption from the requirement of a tolerance.

C. Toxicological Profile

Acute toxicity. AtEze, the end-use formula containing 1.15% *Pseudomonas chlororaphis* Strain 63-28, has been studied for acute toxicity. The results of these studies indicate a Toxicity Category III or IV and poses no significant human health risks. The acute oral toxicity of *Pseudomonas chlororaphis* Strain 63-28 in rats is greater than 5,000 milligrams/kilogram (mg/kg) (5.50×10^{10} cfu-Toxicity Category IV). Acute dermal toxicity in rabbits is greater than 2,000 mg/kg (6.82×10^{10} cfu-Toxicity Category III). In an eye irritation study, each rabbit received a dose of 1.06×10^9 cfu viable bacteria. The highest primary irritation score observed during the study was 0.8 (out of a maximum score of 110), which was observed in a 24-hour scoring interval. No signs of ocular irritation were observed in any rabbit at the 48-hour scoring interval (Toxicity Category III). Agrium has not observed any incidents of hypersensitivity from personnel working with the product strain or the

product in laboratory, fermentation facilities, greenhouses, or field studies. There is no report in the literature to suggest that members of the species *Pseudomonas chlororaphis*, or closely related *Pseudomonads* cause any hypersensitive reaction in humans or animals.

Waivers have been requested for acute oral toxicity/pathogenicity, and acute pulmonary toxicity/pathogenicity toxicity, genotoxicity, reproductive and developmental toxicity, subchronic toxicity, chronic toxicity, and acute toxicity to nontarget species based on AtEze's ubiquity in nature, favorable toxicological profile in that *Pseudomonas chlororaphis* Strain 63-28 has never been reported as a pathogen of humans or any type of animals, other published research and toxicology studies, and inconsequential exposure resulting from label-directed uses.

D. Aggregate Exposure

1. **Dietary exposure—Food.** The estimate of aggregate exposure to *P. chlororaphis* Strain 63-28 contained in AtEze through food intake is based on potential dispersal of the bacterial to edible portions of greenhouse vegetables and on a theoretical maximum residue contribution (TMRC) to diet. The TMRC considers a maximum level of residue consumed daily if each greenhouse vegetable crop is treated with the product. According to the research data on greenhouse tomato, residual populations of the product bacterium on fruits will be less than 10 cfu /g. It is likely that residue levels on greenhouse cucumber or pepper will be similar with the same product use pattern. A very liberal estimation of daily consumption of all greenhouse vegetables is used for calculation of the TMRC. With 2 kg/day, the TMRC value would be no more than 400 cfu/kg body weight for a person weighing 50 kg. Suppose the person had the same daily intake for a life time (80 years), the accumulative amount would still be only 1.2×10^7 cfu/kg body weight, which is less than 1% of the amount used in the oral toxicity test. With the large overestimate of human dietary exposure through food, the total amount is still well below levels used, and demonstrated safe in the acute oral toxicity study. The chronic toxicity information has not been established. However, a potential residue level is so low on food crops that natural populations of the bacterium may surpass it. Therefore, a chronic toxic impact is not expected.

2. **Dietary exposure—Drinking water.** There is no maximum contaminant level established for *Pseudomonas chlororaphis* Strain 63-28 in drinking

water, nor it is listed for drinking water monitoring under the Safe Drinking Water Act. The risk of contaminating well water by applied bacteria is very low because the product is used in greenhouses and the recommended amount of drench application severely limits leaching. It is expected that human exposure through drinking water is negligible. This bacterium exists in abundance in natural surface water such as ponds, lakes or streams.

3. **Non-dietary exposure.** AtEze is labeled for uses on commercial greenhouse crops only. Based on the study of persistence on several greenhouse crops, residue populations of the bacterium on the roots and in the growth medium will be negligibly low by the time of crop sales. Since the product is not found in or on fruits, and the general public has limited exposure to production greenhouses or plant growth media, the estimated non-occupational exposure to the general population is minuscule. Occupational exposure will be mitigated by the use of proper personal protective equipment and clothing.

E. Cumulative Exposure

The product strain belongs to the bacterial genus of *Pseudomonas*. Although other registered *pseudomonads* may have similar modes of action in suppressing plant diseases, there is no information available to suggest that these organisms exhibit a similar toxicity profile in the mammalian system that would be cumulative with *P. chlororaphis* Strain 63-28. Thus, consideration of a common mechanism of toxicity is not appropriate at this time. Agrium is considering only the potential risks of *P. chlororaphis* 63-28 in its aggregate exposure assessment.

F. Safety Determination

1. **U.S. population.** Based on the physical and chemical characteristics, low use rates, no evidence of any acute toxicity, lack of other toxicological concerns and a liberal estimation of exposure, Agrium believes that there is a reasonable certainty of no harm to the U.S. population in general from aggregate exposure to AtEze residue from all anticipated dietary and non-dietary exposures.

2. **Infants and children.** A developmental toxicity study was not conducted. Based on the observation that no adverse effect was found in acute toxicological studies, very low residue if any, limited exposure, and on the lack of reported concerns in the literature, Agrium believes that the product is of minimal risk.

G. Effects on the Immune and Endocrine Systems

Endocrine disruptors. Agrum has no information to suggest that *P. chlororaphis* Strain 63-28 will have an effect on the immune and endocrine systems. Furthermore, EPA is not requiring information on endocrine effects of this microbial pesticide at this time; Congress is allowing 3 years after August 3, 1996, to implement a screening program with respect to endocrine effects.

H. International Tolerances

There are no CODEX tolerances or international tolerance exemptions issued for *P. chlororaphis* Strain 63-28 at this time. (Edward Allen)

2. Rohm and Haas Company

PP 8E4952

EPA has received a pesticide petition (PP 8E4952) from Rohm and Haas Company, 100 Independence Mall West, Philadelphia, PA 19106-2399, proposing pursuant to section 408(d) of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. 346a(d), to amend 40 CFR part 180 to establish an exemption from the requirement of a tolerance for Alkyl (C12-C20) Methacrylate copolymer when used in accordance with good agricultural practices as inert ingredient in pesticide formulations applied to growing crops in or on the raw agricultural commodity after harvest or to animals at parts per million (ppm). EPA has determined that the petition contains data or information regarding the elements set forth in section 408(d)(2) of the FFDC; 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.

A. Toxicological Profile (Low-Risk Criteria for Polymers)

In the case of certain chemical substances that are defined as "polymers", the Agency has established a set of criteria which identify categories of polymers that present low risk. These criteria (described in 40 CFR 723.250) identify polymers that are relatively unreactive and stable compounds compared to other chemical substances as well as polymers that typically are not readily absorbed. These properties generally limit a polymer's ability to cause adverse effects. In addition, these criteria exclude polymers about which little is known. The Agency believes that polymers meeting the criteria noted above will present minimal or no risk. Alkyl (C12-C20) Methacrylate

copolymers conform to the definition of a polymer given in 40 CFR 723.250 (b) and meet the following criteria that are used to identify low risk polymers.

1. Alkyl (C12-C20) Methacrylate copolymer is not a cationic polymer, nor is it capable of becoming a cationic polymer in the natural aquatic environment.

2. Alkyl (C12-C20) Methacrylate copolymer contains as an integral part of its composition the atomic elements carbon, hydrogen, oxygen and less than 0.10% sulfur.

3. Alkyl (C12-C20) Methacrylate copolymer does not contain as an integral part of its composition, except as impurities, any element other than those listed in 40 CFR 723.250 (d)(2)(iii).

4. Alkyl (C12-C20) Methacrylate copolymer is not designed, nor is it reasonably anticipated to substantially degrade, decompose or depolymerize.

5. Alkyl (C12-C20) Methacrylate copolymer is not manufactured or imported from monomers and/or other reactants that are not already included on the TSCA Chemical Substance Inventory or manufactured under an applicable TSCA section 5 exemption.

6. Alkyl (C12-C20) Methacrylate copolymer is not a water absorbing polymer with a number average molecular weight greater than or equal to 10,000 daltons.

7. The minimum number-average molecular weight of Alkyl (C12-C20) Methacrylate copolymer is 50,000 daltons. Substances with molecular weights greater than 400 generally are not absorbed through the intact skin, and substances with molecular weights greater than 1,000 generally are not absorbed through the intact gastrointestinal (GI) tract. Chemicals not absorbed through the skin or GI tract generally are incapable of eliciting a toxic response.

8. Alkyl (C12-C20) Methacrylate copolymer has a minimum number average molecular weight of 50,000 and contains less than 2% oligomeric material below molecular weight 500 and less than 5% oligomeric material below 1,000 molecular weight.

9. Alkyl (C12-C20) Methacrylate copolymer does contain aliphatic ester groups as reactive functional groups. However, these reactive groups are not intended or reasonably anticipated to undergo further reactions under usual environmental conditions.

10. There are no evidence that Alkyl (C12-C20) Methacrylate copolymer is an endocrine disrupter, where as substances with molecular weights greater than 400 generally are not absorbed through the intact skin, and

substances with molecular weights greater than 1,000 generally are not absorbed through the intact gastrointestinal (GI) tract. Chemicals not absorbed through the skin or GI tract generally are incapable of eliciting a toxic response.

B. Aggregate Exposure

1. **Dietary.** Alkyl (C12-C20) Methacrylate copolymer is not absorbed through the intact gastrointestinal tract and is considered incapable of eliciting a toxic response.

2. **Water.** Based upon the aqueous insolubility of Alkyl (C12-C20) Methacrylate copolymer, there is no reason to expect human exposure to residues in drinking water.

3. **Non-dietary.** Typical use of Alkyl (C12-C20) Methacrylate copolymer is in the oil industry as a wax and viscosity modifier at very low use rates. In these uses the primary exposure rate would be dermal, however, Alkyl (C12-C20) Methacrylate copolymer with a molecular weight significantly greater than 400 is not absorbed through the intact skin.

C. Cumulative Risk

There is data to support cumulative risk from Alkyl (C12-C20) Methacrylate copolymer, since polymers with molecular weights greater than 400 generally are not absorbed through the intact skin, and substances with molecular weights greater than 1,000 generally are not absorbed through the intact gastrointestinal (GI) tract. Chemicals not absorbed through the skin or GI tract generally are incapable of eliciting a toxic response. Therefore, there is no reasonable expectations of increased risk due to cumulative exposure.

D. Safety Determination

1. **U.S. population.** Alkyl (C12-C20) Methacrylate copolymer causes no safety concerns because it conforms to the definition of a low risk polymer given in 40 CFR 723.250 (b) and as such is considered incapable of eliciting a toxic response. Also, there are no additional pathways of exposure (non-occupational, drinking water, etc.) where there would be additional risk.

2. **Infants and children.** Alkyl (C12-C20) Methacrylate copolymer causes no additional concern to infants and children because it conforms to the definition of a low risk polymer given in 40 CFR 723.250 (b) and as such is considered incapable of eliciting a toxic response. Also there are no additional pathways of exposure (non-occupational, drinking water, etc.)

where infants and children would be at additional risk.

E. International Tolerances

Rohm and Haas is petitioning that Alkyl (C12-C20) Methacrylate copolymer be exempt from the requirement of a tolerance based upon the low risk polymer as per 40 CFR 723.250. Therefore, an analytical method to determine residues of Alkyl (C12-C20) Methacrylate copolymer in raw agricultural commodities has not been proposed.

We are not aware of any country requiring a tolerance for Alkyl (C12-C20) Methacrylate copolymer. Nor have there been any CODEX Maximum Residue Levels (MRL's) established for any food crops at this time. (Bipin Gandhi)

[FR Doc. 98-31068 Filed 11-19-98; 8:45 am]

BILLING CODE 6560-50-F

ENVIRONMENTAL PROTECTION AGENCY

[PF-846; FRL-6043-9]

BASF Corporation; Pesticide Tolerance Petition Filing

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 a certain pesticide chemical in or on various food commodities.

DATES: Comments, identified by the docket control number PF-846, must be received on or before December 21, 1998.

ADDRESSES: By mail submit written comments to: Information and Records Integrity Branch, Public Information and Services Division (7502C), Office of Pesticides Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. In person bring comments to: Rm. 119, CM #2, 1921 Jefferson Davis Highway, Arlington, VA.

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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. 119 at the address given above, from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays.

FOR FURTHER INFORMATION CONTACT:

Joanne I. Miller, Product Manager 23, Herbicide Branch, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW, Washington, DC 20460. Office location, telephone number, and e-mail address: Rm. 237, Crystal Mall #2, 1921 Jefferson Davis Highway, Arlington, VA 22202, (703) 305-6224; e-mail: miller.joanne@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 chemical in or on various food commodities under section 408 of the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. 346a. EPA has determined that this petition contains data or information regarding the elements set forth in 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-846] (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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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 5.1/6.1 file format or ASCII file format. All comments and data in electronic form must be identified by

the docket control number (PF-846) and appropriate petition number. Electronic comments on this notice 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: November 4, 1998.

James Jones,

Director, Registration Division, Office of Pesticide Programs.

Summary of Petition

The 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 represents the views of the petitioner. 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.

BASF Corporation

PP 6F 4604 and 4F 3041/FAP 4H5428

EPA has received pesticide petitions (PP 6F 4604 and 4F 3041/FAP 4H5428) from BASF Corporation, 26 Davis Drive, Research Triangle Park, P.O. Box 13528, NC 27709, proposing pursuant to section 408 (d) of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. 346a(d), to amend 40 CFR 180.227 by establishing and revising tolerances for residues of the herbicide dicamba (3,6-dichloro-o-anisic acid) and its two metabolites; 3,6-dichloro-5-hydroxy-o-anisic acid and 3,6-dichloro-2-hydroxybenzoic acid. The tolerances requested for residues in or on the following raw agricultural commodities are described as follows:

1. Revise tolerances for residues of dicamba (3,6-dichloro-o-anisic acid) and its metabolite 3,6-dichloro-5-hydroxy-o-anisic acid in or on: barley grain to 6 ppm, barley straw to 15 ppm; cottonseed to 3 ppm; wheat grain to 2 ppm, wheat straw to 30 ppm.

2. Establish new tolerances for residues of dicamba (3,6-dichloro-o-anisic acid) and its metabolite 3,6-dichloro-5-hydroxy-o-anisic acid in or on: barley hay at 2 ppm, corn, field, forage at 3 ppm; corn, field, stover at 3 ppm, corn, pop, stover at 3 ppm;