polymers that present low risk. These criteria (described in 40 CFR 723.250) identify polymers that are relatively unreactive and stable 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. EPA believes that polymers meeting the criteria noted below will present minimal or no risk.

2-Propenoic acid, 2-methyl-, polymer with ethyl 2-propenoate and methyl 2-methyl-2-propenoate, ammonium salt (CAS Reg. No. 55989–05–4) conforms to the definition of polymer given in 40 CFR 723.250(b) and meets the following criteria that are used to identify low risk polymers:

1. 2-Propenoic acid, 2-methyl-, polymer with ethyl 2-propenoate and methyl 2-methyl-2-propenoate, ammonium salt is not a cationic polymer, nor is it reasonably anticipated to become a cationic polymer in a natural aquatic environment.

2. 2-Propenoic acid, 2-methyl-, polymer with ethyl 2-propenoate and methyl 2-methyl-2-propenoate, ammonium salt contains as an integral part of its composition the atomic elements carbon, hydrogen, oxygen, and nitrogen.

3. 2-Propenoic acid, 2-methyl-, polymer with ethyl 2-propenoate and methyl 2-methyl-2-propenoate, ammonium salt does not contain as an integral part of its composition, except as impurities, any elements other than those listed in 40 CFR 723.250(d)(2)(ii).

4. 2-Propenoic acid, 2-methyl-, polymer with ethyl 2-propenoate and methyl 2-methyl-2-propenoate, ammonium salt copolymer is not designed, nor is it reasonably anticipated to substantially degrade, decompose, or depolymerize.

5. 2-Propenoic acid, 2-methyl-, polymer with ethyl 2-propenoate and methyl 2-methyl-2-propenoate, ammonium salt is not manufactured or imported from monomers and/or other reactants that are not already included on the Toxic Substance Control Act (TSCA) Chemical Substance Inventory or manufactured under an applicable TSCA section 5 exemption.

6. 2-Propenoic acid, 2-methyl-, polymer with ethyl 2-propenoate and methyl 2-methyl-2-propenoate, ammonium salt is not a water-absorbing polymer.

7. 2-Propenoic acid, 2-methyl-, polymer with ethyl 2-propenoate and methyl 2-methyl-2-propenoate, ammonium salt does not contain any group as reactive functional groups.

8. The minimum number-average molecular weight of the 2-propenoic acid, 2-methyl-, polymer with ethyl 2-propenoate and methyl 2-methyl-2-propenoate is listed as 18,914 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.

9. The 2-propenoic acid, 2-methyl-, polymer with ethyl 2-propenoate and methyl 2-methyl-2-propenoate has a number-average molecular weight of 18,914 and contains less than 10% oligomeric material below molecular weight 500 and less than 25% oligomeric material below 1,000 molecular weight.

In addition, 2-propenoic acid, 2-methyl-, polymer with ethyl 2-propenoate and methyl 2-methyl-2-propenoate is acceptable for use, with limitations, under 21 CFR for contact with food as a component in adhesives (21 CFR 175.105), coatings (21 CFR 175.300), and paper and paperboard (21 CFR 176.170). The ammonium hydroxide utilized to form the ammonium salt is listed in 21 CFR 184.1139 under the section, ''Direct food substances affirmed as generally recognized as safe.''

C. Aggregate Exposure

1. *Dietary exposure.* Exposure to 2-propenoic acid, 2-methyl-, polymer with ethyl 2-propenoate and methyl 2-methyl-2-propenoate, ammonium salt may occur through dietary (e.g., food wrapping containing copolymer) and non-occupational (e.g., printed articles) sources. The chemical characteristics of 2-propenoic acid, 2-methyl-, polymer with ethyl 2-propenoate and methyl 2-methyl-2-propenoate, ammonium salt lead to the conclusion that there is a reasonable certainty of no harm from aggregate exposure to the polymer.

2. *Non-dietary exposure.* 2-propenoic acid, 2-methyl-, polymer with ethyl 2-propenoate and methyl 2-methyl-2-propenoate, ammonium salt formulations have been in commerce since the mid 1970's. The copolymer is ubiquitous in our every day environment and as it is commonly used in flexographic printing inks and coatings, such as on newspapers, corrugated boxes (e.g., pizza boxes), and disposable drinking cups.

Given the existing widespread and historic use of 2-propenoic acid, 2-methyl-, polymer with ethyl 2-propenoate and methyl 2-methyl-2-propenoate, ammonium salt, any additional exposure resulting from the approval of the copolymer as an inert ingredient in pesticide formulations for use on growing crops or to raw agricultural commodities after harvest should not be of concern.

D. Cumulative Effects

At this time there is no information to indicate that any toxic effects produced by 2-propenoic acid, 2-methyl-, polymer with ethyl 2-propenoate and methyl 2-methyl-2-propenoate, ammonium salt would be cumulative with those of any other chemical. Given the compound's categorization as a ''low risk polymer'' (40 CFR 723.250) and its proposed use as an inert ingredient in pesticide formulations, there is no reasonable expectation of increased risk due to cumulative exposure.

E. Safety Determination

1. *U.S. population.* 2-Propenoic acid, 2-methyl-, polymer with ethyl 2-propenoate and methyl 2-methyl-2-propenoate, ammonium salt formulations have been in commerce since the mid 1970's. The copolymer is ubiquitous in our every day environment and as it is commonly used in flexographic printing inks and coatings, with no known adverse effects.

F. International Tolerances

There are no CODEX Maximum Residue Limits established for 2-Propenoic acid, 2-methyl-,polymer with ethyl 2-propenoate and methyl 2-methyl-2-propenoate, ammonium salt in/on any crop commodities at this time.

[FR Doc. 02–12976 Filed 5– 22–02; 8:45 am]

BILLING CODE 6560–50–S

ENVIRONMENTAL PROTECTION AGENCY

[OPP–2002–0038; FRL–6835–9]

Notice of Filing Pesticide Petitions to Establish a Tolerance for Certain Pesticide Chemicals in or on Food

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 docket control number OPP–2002–0038, must be received on or before June 24, 2002.

ADDRESSES: Comments may be submitted by mail, electronically, or in person. Please follow the detailed instructions for each method as provided in Unit I.C. of the **SUPPLEMENTARY INFORMATION.** To ensure proper receipt by EPA, it is imperative that you identify docket control number OPP–2002–0038 in the subject line on the first page of your response.

FOR FURTHER INFORMATION CONTACT: By mail: Thomas C. Harris, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency , 1200 Pennsylvania Ave., NW., Washington, DC 20460; telephone number: (703) 308–9423; e-mail address: harris.thomas@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/.

2. *In person.* The Agency has established an official record for this action under docket control number OPP2002–0038. The official record consists of the documents specifically referenced in this action, any public comments received during an applicable comment period, 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 Highway, 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.

C. How and to Whom Do I Submit Comments?

You may submit comments through the mail, in person, or electronically. To ensure proper receipt by EPA, it is imperative that you identify docket control number OPP–2002–0038 in the subject line on the first page of your response.

1. *By mail.* Submit your comments to: Public Information and Records Integrity Branch (PIRIB), Information Resources and Services Division (7502C), Office of Pesticide Programs (OPP), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460.

2. *In person or by courier.* Deliver your comments to: Public Information and Records Integrity Branch (PIRIB), Information Resources and Services Division (7502C), Office of Pesticide Programs (OPP), Environmental Protection Agency, Rm. 119, Crystal Mall #2, 1921 Jefferson Davis Highway, Arlington, VA. The PIRIB is open from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The PIRIB telephone number is (703) 305–5805.

3. *Electronically.* You may submit your comments electronically by e-mail to: opp-docket@epa.gov, or you can submit a computer disk as described above. Do not submit any information electronically that you consider to be CBI. Avoid the use of special characters and any form of encryption. Electronic submissions will be accepted in Wordperfect 6.1/8.0 or ASCII file format. All comments in electronic form must be identified by docket control number OPP–2002–0038. Electronic comments may also be filed online at many Federal Depository Libraries.

D. How Should I Handle CBI That I Want to Submit to the Agency?

Do not submit any information electronically that you consider to be CBI. You may claim information that you submit to EPA in response to this document as CBI 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. In addition to one complete version of the comment that includes any information claimed as CBI, a copy of the comment that does not contain the information claimed as CBI must be submitted for inclusion in the public version of the official record. Information not marked confidential will be included in the public version of the official record without prior notice. If you have any questions about CBI or the procedures for claiming CBI, please consult the person listed under **FOR FURTHER INFORMATION CONTACT.**

E. What Should I Consider as I Prepare My Comments for EPA?

You may find the following suggestions helpful for preparing your comments:

1. Explain your views as clearly as possible.

2. Describe any assumptions that you used.

3. Provide copies of any technical information and/or data you used that support your views.

4. If you estimate potential burden or costs, explain how you arrived at the estimate that you provide.

5. Provide specific examples to illustrate your concerns.

6. Make sure to submit your comments by the deadline in this notice.

7. To ensure proper receipt by EPA, be sure to identify the docket control number assigned to this action in the subject line on the first page of your response. You may also provide the name, date, and **Federal Register** citation.

II. What Action is the Agency Taking?

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 support granting of the petition. Additional data may be needed before EPA rules on the petition.

List of Subjects

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

Dated: May 6, 2002.

Debra Edwards,

Acting 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 Federal Food, Drug, and Cosmetic Act (FFDCA). The summaries of the petitions were prepared by Sankyo Company, Ltd., and represent the views of the Sankyo Company. 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.

Sankyo Company, Ltd.

PP 0F6134 and 1F6317

EPA has received pesticide petitions (0F6134 and 1F6317) from Sankyo Company, Ltd., c/o Rockwell Enterprises, Inc., 1720 Savannah Drive NE, Rio Rancho, NM 87124–5700 proposing, pursuant to section 408(d) of the FFDCA, 21 U.S.C. 346a(d), to amend 40 CFR part 180 by establishing a tolerance for residues of milbemectin (a mixture of milbemycins containing greater than or equal to 70% milbemycin A_4 [(6R, 25R)- 5-O-demethyl-28-deoxy-6, 28-epoxy-25-ethyl-milbemycin B] and less than or equal to 30% milbemycin A_3 [(6R, 25R)-5-O-demethyl-28-deoxy-6, 28-epoxy-25-methyl-milbemycin B]) in or on the raw agricultural commodities citrus crop group at 0.02 parts per million (ppm); citrus pulp, dried at 0.2 ppm; citrus oil at 0.1 ppm; cotton, undelinted seed at 0.02 ppm (CA only); cotton gin by-products at 0.08 ppm (CA only); pome fruit crop group at 0.02 ppm; apple pomace, wet at 0.15 ppm; stone fruit crop group at 0.03 ppm (CA only); strawberry at 0.04 ppm; tree nut crop group at 0.02 ppm; and almond hulls at 0.2 ppm. EPA has determined that the petition contains data or information regarding the elements set forth in section 408(d)(2) of the FFDCA; however, EPA has not fully evaluated the sufficiency of the submitted data at this time or whether the data support granting of the petition. Additional data may be needed before EPA rules on the petition.

A. Residue Chemistry

1. *Plant metabolism.* The metabolism of milbemectin in apples, oranges and strawberries has been studied. The parent molecules (Milbemycin A_3 and Milbemycin A_4) are the only metabolites found at significant levels in plant metabolism studies or in field residue studies under conditions of use, and are the only expected metabolites of toxicological concern in plants. The photolytic metabolites of milbemectin (8,9Z-$M.A_3$ and 8,9Z-$M.A_4$) were not found at toxicologically significant levels in these metabolism studies or in field residue studies limit of quantitation (LOQ) (Method LOQ = 0.01 ppm), but were included as part of the tolerance expression at the request of EPA.

2. *Analytical method.* An adequate analytical method high performance liquid chromotography using ultra-violet detection (HPLC with UV fluorescence detection at 460 nm) is available for enforcement purposes. The parent compounds, milbemycin A_3 and milbemycin A_4, and their respective 8,9Z metabolites are converted to common moieties by derivatization before analysis. A successful Independent Laboratory Validation has been submitted.

3. *Magnitude of residues*—i *Cotton.* A total of 3 individual trials were conducted in California during the 1999 and 2000 crop season. Due to the limited geographical distribution of the crop residue trials for this crop grouping, a geographical restriction of California only is being requested. Applications were made at 1X the maximum labeled rate of 2 applications of 0.0192 lb. active ingredient/acre (a.i./acre) per crop season. Analyzed samples of undelinted cotton seed were < 0.01 ppm for both total $M.A_3$ ($M.A_3$ + 8,9Z-$M.A_3$) and total $M.A_4$ ($M.A_4$ + 8,9Z-$M.A_4$). Based on analysis of the findings, the expected maximum residue levels in undelinted cotton seed is 0.02 ppm (0.01 ppm total $M.A_3$ ($M.A_3$ + 8,9Z-$M.A_3$) + 0.01 ppm total $M.A_4$ ($M.A_4$ + 8,9Z-$M.A_4$)). Analyzed samples of cotton gin by-products were < 10 to 22.8 µg a.i./kg (0.023 ppm) of total $M.A_3$ ($M.A_3$ + 8,9Z- $M.A_3$) and < 10 to 54.9 µg a.i./kg (0.055 ppm) of total $M.A_4$ ($M.A_4$ + 8,9Z-$M.A_4$). Based on analysis of the findings, the expected maximum residue levels in cotton gin by-products is 0.08 ppm total milbemectin ($M.A_3$ + 8,9Z-$M.A_3$) + ($M.A_4$ + 8,9Z-$M.A_4$).

ii. *Strawberries.* A total of 8 individual field trials were conducted over a period of two crop seasons (1997, 1998) in 6 states. Number, type and location of trials were in accordance with those specified by Guideline OPPTS 860.1500, Table 1. Applications were made at 1X (3 trials), 1.5X (1 trial) and 2X (4 trials) the maximum labeled rate of 4 applications of 0.019 lb. ai/acre, or 0.076 lb. ai/acre per crop season. After applying a correction factor of 0.5X to 0.75X where appropriate to the mean residue levels found in the samples, total residues of milbemectin (total $M.A_3$ + total $M.A_4$) in strawberries fell within a range of 0.012 ppm to 0.035 ppm. The method LOQ was 0.01 ppm each for total $M.A_3$ ($M.A_3$ + 8,9Z-$M.A_3$) and total $M.A_4$ ($M.A_4$ + 8,9Z-$M.A_4$). The photolytic metabolites of milbemectin (8,9Z-$M.A_3$ and 8,9Z-$M.A_4$) were not present in any samples where a separate analysis was conducted (LOQ = 0.01 ppm). Based on these findings, the expected maximum residue levels in strawberries is 0.04 ppm total milbemectin ($M.A_3$ + 8,9Z-$M.A_3$) + ($M.A_4$ + 8,9Z-$M.A_4$).

iii. Citrus Crop Group: The representative crops for this grouping as specified by 40 CFR 180.41 are sweet oranges, lemons and grapefruit.

a. *Oranges.* A total of 12 individual field trials were conducted over a period of two crop seasons (1997, 1998) in the states of California, Florida and Texas. Number, type and location of trials were in accordance with those specified by Guideline OPPTS 860.1500, Table 2. Applications were made at 1X (5 trials), 1.3X (3 trials) and 2X (4 trials) the maximum labeled rate of 3 applications of 0.024 lb. ai/acre, or 0.072 lb. ai/acre per crop season. All analyzed samples of the raw agricultural commodities (RAC) were less than the method LOQ of 0.01 ppm each for total $M.A_3$ ($M.A_3$ + 8,9Z-$M.A_3$) and total $M.A_4$ ($M.A_4$ + 8,9Z-$M.A_4$). Based on these findings, the expected maximum residue levels in oranges is 0.02 ppm ((0.01 ppm total $M.A_3$ ($M.A_3$ + 8,9Z-$M.A_3$) + 0.01 ppm total $M.A_4$ ($M.A_4$ + 8,9Z-$M.A_4$)).

b. *Grapefruit.* A total of 6 individual field trials were conducted over a period of two crop seasons (1997, 1998) in the states of California, Florida and Texas. Number, type and location of trials were in accordance with those specified by Guideline OPPTS 860.1500, Table 2. Applications were made at 1X (3 trials), 1.3X (2 trials) and 2X (1 trial) the maximum labeled rate of 3 applications of 0.024 lb. ai/acre, or 0.072 lb. ai/acre per crop season. All analyzed samples of the RAC were less than the method LOQ of 0.01 ppm each for total $M.A_3$ ($M.A_3$ + 8,9Z-$M.A_3$) and total $M.A_4$ ($M.A_4$ + 8,9Z-$M.A_4$). Based on these findings, the expected maximum residue levels in grapefruit is 0.02 ppm ((0.01 ppm total $M.A_3$ ($M.A_3$ + 8,9Z-$M.A_3$) + 0.01 ppm total $M.A_4$ ($M.A_4$ + 8,9Z-$M.A_4$)).

c. *Lemons* A total of 5 individual field trials were conducted over a period of two crop seasons (1997, 1998) in the states of Arizona, California and Florida. Number, type and location of trials were in accordance with those specified by Guideline OPPTS 860.1500, Table 2. Applications were made at 1X (2 trials) and 2X (3 trials) the maximum labeled rate of 3 applications of 0.024 lb. ai/acre, or 0.072 lb. ai/acre per crop season. After applying a correction factor of 0.5X where appropriate to residue levels found in the samples, all analyzed samples of the RAC were less than the method LOQ of 0.01 ppm each for total $M.A_3$ ($M.A_3$ + 8,9Z-$M.A_3$) and total $M.A_4$ ($M.A_4$ + 8,9Z-$M.A_4$). Based on these findings, the expected maximum residue levels in lemons is 0.02 ppm ((0.01 ppm total $M.A_3$ ($M.A_3$ + 8,9Z-$M.A_3$) + 0.01 ppm total $M.A_4$ ($M.A_4$ + 8,9Z-$M.A_4$)).

d. *Processed oranges.* The study was comprised of a single trial located in east central Florida. The test substance was applied to the treated plot once at 60 days prior to normal maturity at 0.120 lb. ai/acre and an additional two times at 30 and 7 days prior to normal maturity at 0.240 lb. ai/acre, or 8.33X the maximum labeled rate. After processing, samples of orange juice, dried pulp and orange oil were analyzed for total $M.A_3$ and total $M.A_4$. Reported mean values for total milbemectin (total $M.A_3$ + total $M.A_4$) were as follows: RAC - 0.011 ppm, dry pulp - 0.107, juice - <0.01 ppm and oil - 0.0541 ppm. The method LOQ in each commodity was 0.01 ppm each for total $M.A_3$ ($M.A_3$ + 8,9Z-$M.A_3$) and total $M.A_4$ ($M.A_4$ + 8,9Z-$M.A_4$). The concentration factors were determined to be 9.7X for dry pulp and 4.9X for oil. Based on these findings, the expected maximum residue levels in dry citrus pulp is 0.20 ppm and in citrus oil is 0.10 ppm.

iv. *Pome Fruit Crop Group.* The representative crops for this grouping as specified by 40 CFR 180.41 are apples and pears.

a. *Apples.* A total of 12 validated individual field trials were conducted over a period of two crop seasons (1997, 1998) in the states of California, Colorado, Michigan, North Carolina, New York, Pennsylvania, and Washington. Number, type and location of trials were in accordance with those specified by Guideline OPPTS 860.1500, Table 2. Applications were made at 1X (2 trials) and 2X (10 trials) the maximum labeled rate of 2 applications of 0.024 lb. ai/acre, or 0.048 lb. ai/acre per crop season. After applying a correction factor of 0.5X where appropriate to residue levels found in the validated samples, all residues were less than or equal to the method LOQ of 0.01 ppm each for total $M.A_3$ ($M.A_3$ + 8,9Z-$M.A_3$, and total $M.A_4$ ($M.A_4$ + 8,9Z-$M.A_4$). Based on these findings, the expected maximum residue levels in apples is 0.02 ppm ((0.01 ppm total $M.A_3$ ($M.A_3$ + 8,9Z-$M.A_3$) + 0.01 ppm total $M.A_4$ ($M.A4$ + 8,9Z-$M.A_4$)).

b. *Pears.* A total of 6 individual field trials were conducted over a period of two crop seasons (1997, 1998) in the states of California, New York, Oregon and Washington. Number, type and location of trials were in accordance with those specified by Guideline OPPTS 860.1500, Table 2. Applications were made at 1X (3 trials) and 2X (3 trials) the maximum labeled rate of 2 applications of 0.024 lb. ai/acre, or 0.048 lb. ai/acre per crop season. After applying a correction factor of 0.5X where appropriate to residue levels found in the samples, all residues were less than or equal to the method LOQ of 0.01 ppm each for total $M.A_3$ ($M.A_3$ + 8,9Z- $M.A_3$) and total $M.A_4$ ($M.A_4$ + 8,9Z-$M.A_4$). Based on these findings, the expected maximum residue levels in pears is 0.02 ppm ((0.01 ppm total $M.A_3$ ($M.A_3$ + 8,9Z-$M.A_3$) + 0.01 ppm total $M.A_4$ ($M.A_4$ + 8,9Z-$M.A_4$)).

c. *Processed apples.* The study was comprised of a single trial located in eastern Washington. The test substance was applied to the treated plot twice at 28 and 7 days prior to normal maturity at 0.240 lb. ai/acre, or 10X the maximum labeled rate. After processing, samples of apple juice and wet pomace were analyzed for total $M.A_3$ and total $M.A_4$. Reported mean values for total milbemectin (total $M.A_3$ + total $M.A_4$) were as follows: RAC - 0.168 ppm, juice - < 0.01 ppm and wet pomace - 1.067 ppm. The method LOQ in each commodity was 0.01 ppm each for total $M.A_3$ ($M.A_3$ + 8,9Z-$M.A_3$) and total $M.A_4$ ($M.A_4$ + 8,9Z-$M.A_4$). The concentration factors were determined to be 6.4X for wet pomace and 0.06X for juice. Based on these findings, the expected maximum residue levels in wet apple pomace is 0.15 ppm. No residues in excess of the established tolerances in pome fruit juice, including apple juice, are expected.

v. *Stone Fruit Crop Group.* The representative crops for this grouping as specified by 40 CFR 180.41 are cherries, peaches and plums. Due to the limited geographical distribution of the crop residue trials for this crop grouping, a geographical restriction of California only is being requested.

a. *Cherries.* A total of 2 individual field trials were conducted during the 1999 crop season in the state of California. Applications were made at 1X the maximum labeled rate of 2 applications of 0.024 lb. ai/acre per crop season. Analyzed samples of the RAC were < 0.01 ppm for total $M.A_3$ ($M.A_3$ + 8,9Z-$M.A_3$) and < 0.01 to 0.0117 ppm total $M.A_4$ ($M.A_4$ + 8,9Z-$M.A_4$). Based on analysis of the findings, the expected maximum residue levels in cherries is 0.03 ppm ((0.01 ppm total $M.A_3$ ($M.A_3$ + 8,9Z-$M.A_3$) + 0.02 ppm total $M.A_4$ ($M.A_4$ + 8,9Z-$M.A_4$)).

b. *Peaches.* A total of 3 individual field trials were conducted during the 1999 crop season in the state of California. Applications were made at 1X the maximum labeled rate of 2 applications of 0.024 lb. ai/acre per crop season. All analyzed samples of the RAC were < 0.01 ppm for total $M.A_3$ ($M.A_3$ + 8,9Z-$M.A_3$) and < 0.01 to 0.0145 ppm total $M.A_4$ ($M.A_4$ + 8,9Z-$M.A_4$). Based on analysis of the findings, the expected maximum residue levels in peaches is 0.03 ppm ((0.01 ppm total $M.A_3$ ($M.A_3$ + 8,9Z-$M.A_3$) + 0.02 ppm total $M.A_4$ ($M.A_4$ + 8,9Z-$M.A_4$)).

c. *Plums.* A total of 5 individual field trials were conducted during the 1999 crop season in the state of California. Applications were made at 1X the maximum labeled rate of 2 applications of 0.024 lb. ai/acre per crop season. All analyzed samples of the RAC were < 0.01 ppm for both total $M.A_3$ ($M.A_3$ + 8,9Z-$M.A_3$) and total $M.A_4$ ($M.A_4$ + 8,9Z-$M.A_4$). Based on analysis of the findings, the expected maximum residue levels in plums is 0.02 ppm (0.01 ppm total $M.A_3$ (($M.A_3$ + 8,9Z-$M.A_3$) + 0.01 ppm total $M.A_4$ ($M.A_4$ + 8,9Z-$M.A_4$)).

d. *Prunes.* The study was comprised of a single trial located in California. Applications were made at 5X the maximum labeled rate as 2 applications of 0.12 lb. ai/acre, 21 and 14 days respectively before crop harvest. After processing, samples of prunes were analyzed for total $M.A_3$ and total $M.A_4$. The mean residue levels in plums were

< 0.01 ppm of total $M.A_3$ ($M.A_3$ + 8,9Z-$M.A_3$) and 0.0193 ppm total $M.A_4$ ($M.A_4$ + 8,9Z-$M.A_4$). The mean residue levels in the prunes were < 0.01 ppm of total $M.A_3$ ($M.A_3$ + 8,9Z-$M.A_3$) and 0.0179 ppm total $M.A_4$ ($M.A_4$ + 8,9Z-$M.A_4$). Based on analysis of the findings, no concentration of residues is expected in the processed commodity, prunes.

vi. *Tree Nut Crop Group.* The representative crops for this grouping as specified by 40 CFR 180.41 are almonds and pecans.

a. *Almonds.* A total of 5 individual field trials were conducted during the 1999 crop season in the state of California. Number, type and location of trials were in accordance with those specified by Guideline OPPTS 860.1500, Table 2. Applications were made at 1X the maximum labeled rate of 2 applications of 0.024 lb. ai/acre per crop season. Analyzed samples of the almond nut meat samples were < 0.01 ppm for both total $M.A_3$ ($M.A_3$ + 8,9Z-$M.A_3$) and total $M.A_4$ ($M.A_4$ + 8,9Z-$M.A_4$). In almond hull samples the residue levels were < 0.01 to 0.0388 ppm of total $M.A_3$ ($M.A_3$ + 8,9Z-$M.A_3$) and < 0.01 to 0.0911 ppm total $M.A_4$ ($M.A_4$ + 8,9Z-$M.A_4$). Based on analysis of the findings, the expected maximum residue level in almonds is 0.02 ppm ((0.01 ppm total $M.A_3$ ($M.A_3$ + 8,9Z-$M.A_3$) + 0.01 ppm total $M.A_4$ ($M.A_4$ + 8,9Z-$M.A_4$)) and the expected maximum residue level in almond hulls is 0.2 ppm ((0.05 ppm total $M.A_3$ ($M.A_3$ + 8,9Z-$M.A_3$) + 0.15 ppm total $M.A_4$ ($M.A_4$ + 8,9Z-$M.A_4$)).

b. *Pecans.* A total of 5 individual field trials were conducted during the 1999 crop season in the states of Arkansas, Georgia and Texas. Number, type and location of trials were in accordance with those specified by Guideline OPPTS 860.1500, Table 2. Applications were made at 1X the maximum labeled rate of 2 applications of 0.024 lb. ai/acre per crop season. Analyzed samples of the pecan meat samples were < 0.01 ppm for both total $M.A_3$ ($M.A_3$ + 8,9Z-$M.A_3$) and total $M.A_4$ ($M.A_4$ + 8,9Z-$M.A_4$). Based on analysis of the findings, the expected maximum residue levels in pecans is 0.02 ppm ((0.01 ppm total $M.A_3$ ($M.A_3$ + 8,9Z-$M.A_3$) + 0.01 ppm total $M.A_4$ ($M.A_4$ + 8,9Z-$M.A_4$)).

A metabolism study in goats was conducted using 14C-labeled milbemycin A_4. In this study it was determined that the primary route of elimination of milbemectin in the goat was the feces and urine. Only very low levels of total radioactive residues were found in meat or meat by-products, fat, and milk. Based on the total radioactive residue levels in meat, meat by-products and milk found in the goat metabolism study and analysis of the expected feeding levels from consumption of the feed commodities, the registrant has determined that finite residues in fed ruminants are not expected, therefore, no tolerances in meat or meat by-products, fat, and milk are required in accordance with 40 CFR 180.6.

The feed commodities, dried citrus pulp, wet apple pomace and almond hulls, are not utilized as a poultry feed stuff. The feed commodity, cotton meal, is utilized as a poultry feed stuff at 20% of the diet. Since applications of milbemectin at 5X the labeled rate resulted in no detectable residues in cotton seed of total $M.A_3$ or $M.A_4$ at the LOQ of 0.01 ppm, no detectable residues are expected to occur in poultry tissues including meat, fat, meat by-products and eggs. Therefore, no tolerances are required under the provisions of 40CFR 180.6.

B. Toxicological Profile

1. *Acute toxicity.* The acute oral LD_{50} in rats was 762 mg/kg for males and 456 milligrams/kilogram (mg/kg) for females, the dermal LD_{50} of technical milbemectin is greater than 5,000 mg/kg, and the 4–hour acute inhalation LC_{50} in rats is 1.9 milligrams per liter (mg/L) in males and 2.8 mg/L in females. It is not a dermal irritant or sensitizer and is a mild eye irritant. In a 28–day dermal study in rabbits, the no observed effect level (NOEL) was 1,000 mg/kg/day, the highest dose tested. No effects on mortality, general or specific toxic effects, gross pathology, clinical signs or other measured parameters at 1,000 milligrams/kilogram/day (mg/kg/day). The gross necropsy and histopathological evaluation revealed no apparent compound-related effects.

2. *Genotoxicty.* The following genotoxicity tests were all negative: Ames gene mutation, CHL chromosome aberration, mouse lymphoma cell mutation and *in vivo* mouse bone marrow micronucleus.

3. *Reproductive and developmental toxicity.* No reproductive or teratologic effects were observed in any study with milbemectin. Maternal NOEL's of 20 and 50 milligrams/kilogram/day (mg/kg/day) were observed in rat and rabbit teratogenicity studies but no teratogenic effects were observed at the highest doses tested, 60 and 1,000 mg/kg/day respectively. In a rat reproduction study the NOEL for both parents and offspring was observed to be 200 ppm, equivalent to consumption up to 26.4 mg/kg/day for males and 27.0 mg/kg/day for females. There were no reproductive effects at the highest dose tested, 800 ppm.

4. *Subchronic toxicity.* A NOEL of 3 mg/kg/day was derived from the dog 90–day feeding study. The NOEL derived from the rat 90–day study was 375 ppm for males. No NOEL was determined for females, however the NOEL from the chronic rat study for females was 150 ppm, equivalent to 8.77 mg/kg/day. The NOEL derived from the dog subchronic study is therefore the lowest of those derived from the studies.

5. *Chronic toxicity.* A NOEL of 3 mg/kg/day was derived from the dog 12–month feeding study. The NOEL derived from the rat 24–month chronic and oncogenicity study was 150 ppm, equivalent to 6.81 mg/kg/day for males and 8.77 mg/kg/day for females. The NOEL derived from the 96–week mouse oncogenicity study was 200 ppm, equivalent to 18.9 mg/kg/day for males and 19.6 mg/kg/day for females. The NOEL derived from the dog chronic study is, therefore, the lowest of those derived from the chronic studies. Milbemectin did not produce an oncogenic effect in either the rat or mouse study.

6. *Neurotoxicity.* The NOEL for acute neurotoxicity is 20 mg/kg with no neuropathological effects were noted at a dose levels of 100 mg/kg/day in female and 500 mg/kg/day in males. No histopathological evidence of central or peripheral neuropathology was associated with a single oral gavage dose at 500 mg/kg/day (males) or 100 mg/kg/day (females). The NOEL for subchronic neurotoxicity is the highest dose tested, 750 ppm (equivalent to 59.357 mg/kg/day for males and 72.416 mg/kg/day for females), based on a 13–week rat dietary neurotoxicity study. None of the observations noted during the functional observation battery (FOB) were considered to be related to exposure to the test substance. There were no statistically significant or otherwise notable differences between the mean motor activity counts of the control and treated rats during weeks 4, 8, and 13. There was no macroscopic or microscopic evidence central or peripheral neurotoxicity associated with 13 weeks of dietary administration to rats.

7. *Animal metabolism.* In a rat metabolism study conducted in Japan, more than 98% of the applied dose was excreted within 7 days, mostly in the feces. Radioactivity in blood reached maximum levels within 3 hours, with a half-life of 7–8 hours. In tissues, maximum levels were reached in 6 hours in the intestines, followed by the liver, fat and stomach. Residues in rats underwent extensive oxidation. Metabolites identified were hydroxy-, epoxy- and dehydrogenated

milbemectins, followed by a number of polar metabolites. No metabolite exceeded 5% of the dose. Excretion, tissue distribution and metabolic profile after multiple day dosing was essentially the same as the single dose suggesting that none of the residues accumulate in any tissue.

In a more recent US study, no overt signs of toxicity were associated with 14C-M.A_4 following oral administration to male and female rats at 2.5 and 25 mg/kg. No significant gender-related differences were noted in the excretion, adsorption or distribution of 14C-M.A_4. In analysis of tissues other than the gastroentestinal (GI) tract, the highest concentrations of total radioactive residue (TRR) was found in the liver for both genders at all time points. The lowest concentrations were found in the brain, eyes, *uterus* and *testes* of males and/or females. Excretion of TRR was rapid with most excreted within 24 hours post dose. Total recovery of radioactivity in feces through 168 hours post dose was from 84.8% to 100% for the low dose, and 81.5% to 92.8% for the high dose. Biliary excretion played a significant role in elimination of 14C-M.A_4 in rats. Based on TRR in bile and urine, ca 47% of the dose was absorbed in both sexes at the low dose level, and 40% and 30% were absorbed in males and females respectively at the high dose. Based on pharmacokinetic parameters of TRR in plasma, 14C-M.A_4 reaches maximum concentrations at 2 to 3 hours post dose and is eliminated slowly in the high dose groups. The metabolic pathway of 14C-M.A_4 in rats consists mainly of primary metabolism by hydroxylation, with the major metabolite, 13-hydroxy-M.A_4, found in all plasma, liver and kidney samples. The unchanged parent compound was detected in the high dose group in all liver samples, except the 24–hour liver samples, all analyzed kidney samples and in the early time points of the plasma samples. It was also found in the 2–hour liver samples of the low dose group. A minor glucuronidation pathway was identified in the bile. Excretion, tissue distribution, and metabolic profiles were the same for single and multiple dosing suggesting that residues do not accumulate.

8. *Metabolite toxicology.* There is no evidence that the metabolites of milbemectin as identified in either the plant, or animal metabolism studies are of any toxicological significance.

9. *Endocrine disruption.* There is no evidence from the developmental/chronic studies that milbemectin induces any estrogenic or other endocrine effects.

C. Aggregate Exposure

1. *Dietary exposure.* Milbemectin is not currently registered as a pesticide in the U.S. and no tolerances have been previously established for food or feed commodities. Analysis of dietary exposure for proposed tolerances was made using Novigen Sciences DEEM software Version 7.62 using the USDA Continuing Survey of Food Intakes by Individuals.

i. *Food.* Tolerances are proposed for the combined residues of the miticide/insecticide milbemectin (a mixture of milbemectins containing greater than or equal to 70% milbemycin A_4 [(6R, 25R)-5-O-demethyl-28-deoxy-6, 28-epoxy-25-ethyl-milbemycin B] and less than or equal to 30% milbemycin A_3 [(6R, 25R)-5-O-demethyl-28-deoxy-6, 28-epoxy-25-methyl- milbemycin B] and their 8,9-Z isomers (expressed as parts per million of the parent compound) in or on the following agricultural commodities: citrus crop group - 0.02 ppm, citrus pulp, dried - 0.20 ppm, citrus oil - 0.10 ppm, cotton, undelinted seed (CA only) - 0.02 ppm, cotton gin by-products (CA only) - 0.08 ppm, pome fruit crop group - 0.02 ppm, apple pomace, wet - 0.15 ppm, stone fruit crop group (CA only) - 0.03 ppm, strawberries - 0.04 ppm, tree nut crop group - 0.02 ppm and almond hulls - 0.20 ppm.

a. *Acute dietary risk analysis.* An acute reference dose (aRfD) of 0.20 mg/kg/day was used in a acute dietary risk analysis. The aRfD is based on oral no observed adverse effects levels (NOAEL's) of 20 mg/kg/day in the acute neurotoxicity and teratology studies in rats, divided by an uncertainty factor of 100 (interspecies safety factor = 10, intraspecies safety factor = 10). There was no evidence from the developmental or chronic studies that milbemectin induces any estrogenic or other endocrine effects. Therefore, the Food Quality Protection Act (FQPA) additional 10X uncertainty factor was not used. In the Tier 1 analysis it was assumed that all residues would be equal to the pending tolerances on cotton seed of 0.02 ppm, strawberries of 0.04 ppm, citrus, pome fruit, tree nuts of 0.02 ppm, and stone fruit of 0.03 ppm. It was assumed that 100% of the nation's acreage would be treated. Based on the review of data from the reproduction and teratology studies, no additional FQPA safety factor was applied to infants, since no additional toxicity to or sensitivity of the fetal or nursing infant test animals was seen during exposure to the test material. Based on this tier 1 analysis, the acute dietary exposure of all infants and nursing infants (<1 yr. old) would be only 0.58% at the 99.9th percentile of the proposed aRfD. The percentage of the proposed aRfD for the U.S. population and all other subgroups are below this amount.

b. *Chronic dietary risk analysis.* A reference dose(RfD) of 0.03 mg/kg/day was used in a chronic dietary risk analysis. The RfD is based on a NOEL of 3 mg/kg/day derived from the dog 90–day and 12–month feeding studies, the lowest of those derived from the chronic feeding studies. In view of the fact that no special sensitivity in offspring were observed in any test and that no reproductive or teratogenic effects were observed, an uncertainty factor of 100 (interspecies safety factor = 10, intraspecies safety factor = 10) was used for milbemectin. In the Tier 1 analysis it was assumed that all residues would be equal to the pending tolerances on cotton seed of 0.02 ppm, strawberries of 0.04 ppm, citrus, pome fruit, tree nuts of 0.02 ppm, and stone fruit of 0.03 ppm. It was assumed that 100% of the nation's acreage would be treated. Based on the review of data from the reproduction and teratology studies, no additional FQPA safety factor was applied to infants, since no additional toxicity to or sensitivity of the fetal or nursing infant test animals was seen during exposure to the test material. Based on this tier 1 analysis, the dietary exposure of non-nursing infants would be only 0.4% of the proposed RfD. The percentage of the proposed RfD for the U.S. population and all other subgroups are below this amount.

c. *Carcinogenic risk analysis.* Not applicable. Milbemectin did not produce an oncogenic effect in two animal feeding studies.

ii. *Drinking water.* A screening level drinking water assessment for milbemectin was conducted using a maximum use scenario. Potential drinking water concentrations were estimated using models generated by GENEEC (surface water) and SCIGROW (ground water). Input parameters for the use models were those which maximized concentrations in water.

Dietary exposures were modeled with DEEM version 7.62 using the USDA Continuing Survey of Food Intakes by Individuals. It was assumed that all residues would be equal to the pending tolerances on cotton seed of 0.02 ppm, strawberries of 0.04 ppm, citrus, pome fruit, tree nuts of 0.02 ppm, and stone fruit of 0.03 ppm. It was assumed that 100% of the nation's acreage would be treated. Both acute and chronic exposures were modeled. For the acute assessment, the 99.9th percentile of exposure was used. The most highly

exposed subpopulations representing children, adult males, and adult females were evaluated. There are no residential exposures to consider at this time.

a. *Acute exposure and risk.* An aRfD of 0.20 mg/kg/day was used in an acute dietary risk analysis. The aRfD is based on oral NOAEL's of 20 mg/kg/day in the acute neurotoxicity and teratology studies in rats, divided by an uncertainty factor of 100 (interspecies safety factor = 10, intraspecies safety factor = 10). There was no evidence from the developmental or chronic studies that milbemectin induces any estrogenic or other endocrine effects. Therefore, the FQPA additional 10X uncertainty factor was not used.

The estimated screening level water concentrations of milbemectin in surface and ground water are 0.813 µg/L (peak EEC from GENEEC) and 0.005 µg/L (from SCIGROW), respectively. The acute DWLOCs for milbemectin for the most susceptible populations were calculated to be 6,990.83 µg/L, 5,985.45 µg/L and 1,987.55 µg/L for males, 13–19 years; females, 13+ years, nursing; and all infants, respectively.

Since the screening level water concentrations were orders of magnitude less than the acute drinking water levels of concerns (DWLOC's), the Agency should have no concern about exposures from drinking water.

b. *Chronic exposure and risk.* A RfD of 0.03 mg/kg/day was used in a chronic dietary risk analysis. The RfD is based on NOAEL of 3 mg/kg/day derived from the dog 90–day and 12–month feeding studies, the lowest of those derived from the chronic feeding studies. In view of the fact that no special sensitivity in offspring were observed in any test and that no reproductive or teratogenic effects were observed, an uncertainty factor of 100 (interspecies safety factor = 10, intraspecies safety factor = 10) was used for milbemectin. Based on the review of data from the reproduction and teratology studies, no additional FQPA safety factor was applied to infants, since no additional toxicity to or sensitivity of the fetal or nursing infant test animals was seen during exposure to the test material.

The estimated screening level water concentrations of milbemectin in surface and ground water are 0.434 µg/L (56 day average EEC from GENEEC) and 0.005 µg/L (from SCIGROW), respectively. The chronic DWLOCs for milbemectin for the most susceptible populations were calculated to be 1,049.30 µg/L, 899.13 µg/L and 299.08 µg/L for males, 13–19 years; females, 13+ years, nursing; and non-nursing infants, respectively.

Since the screening level water concentrations were orders of magnitude less than the chronic DWLOC's, the Agency should have no concern about exposures from drinking water.

2. *Non-dietary exposure.* There are no current non-food uses for milbemectin registered under the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA), as amended. No non-dietary exposures are expected for the general public. Secondary exposure would not be expected since milbemectin is not expected to be taken up by plants from the soil. The low application rates and short soil half-life are not conductive to buildup in the environment.

D. Cumulative Effects

At this time, the Agency has not reviewed available information concerning the potentially cumulative effects of milbemectin and other substances that may have a common mechanism of toxicity. For purposes of this petition only, the Agency is considering only the potential risks of milbemectin in its aggregate exposure.

E. Safety Determination

1. *U.S. population..* As pointed out above in dietary exposure-food, the acute dietary exposure of all infants and non-nursing infants (<1 yr. old) would be only 0.58% at the 99.9th percentile of the proposed aRfD and the chronic dietary exposure of non-nursing infants would be only 0.4% of the proposed RfD. The percentages of aRfD and chronic RfD for the U.S. population and all other subgroups are below these amounts.

2. *Infants and children.* In assessing the potential for additional sensitivity of infants and children to residues of milbemectin, EPA considered data from developmental toxicity studies in the rat and rabbit and a 2–generation study in the rat. The developmental toxicity studies are designed to evaluate adverse effects on the developing organism resulting from pesticide exposure during prenatal development to one or both parents. Reproduction studies provide information relating to effects from exposure to the pesticide on the reproductive capability of mating animals and data on systemic toxicity. No developmental or reproductive effects have been observed in any study with milbemectin. The calculation of safety margins with respect to these segments of the population were taken into consideration in the tolerance method validation (TMRC) estimates with respect to the risk associated with the percentage of the reference dose being consumed. It is concluded that there is a reasonable certainty of no harm to infants and children from aggregate exposure to milbemectin residues.

F. International Tolerances

No Codex maximum residue levels have been established for residues of milbemectin. Milbemectin is not yet registered for use on any crop in Canada or Mexico. National maximum residue levels (MRL's) for milbemectin in Japan are as follows: Apple, Pear, Peach, Citrus, Melon, Watermelon, Cucumber, Eggplant, Adzuki-bean - 0.2 ppm, Strawberry, Cherry, Grape - 0.5 ppm, and Tea - 2 ppm. National MRL's for milbemectin in Taiwan are as follows: Small berry (Grape, Strawberry, Star fruit, etc.), Tree fruit (Pear, Apple, Cherry, Peach, Plum, etc.), Vegetables (Eggplant, Cucumber, Tomato, etc.), Melon (Watermelon, Muskmelon, etc.) - 0.2 ppm; Tea - 2 ppm. In general, where national MRL's differ from those proposed to EPA, they are associated with agricultural and regulatory practices that differ from those common in the U.S.

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ENVIRONMENTAL PROTECTION AGENCY

[FRL–7216–3]

Public Water System Supervision Program Revision for the State of South Carolina

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: Notice is hereby given that the State of South Carolina is revising its approved Public Water System Supervision Program. South Carolina has adopted drinking water regulations revising the interim enhanced surface water treatment rule and disinfection by-product rule. EPA has determined that the interim enhanced surface water treatment rule and disinfection by-product rule revisions meet all minimum federal requirements, and are no less stringent than the corresponding federal regulations. Therefore, EPA has tentatively decided to approve these State program revisions.

All interested parties may request a public hearing. A request for a public hearing must be submitted by June 24, 2002 to the Regional Administrator at the address shown below. Frivolous or insubstantial requests for a hearing may be denied by the Regional Administrator. However, if a substantial