amend 40 CFR part 180 to establish an exemption from the requirement of a tolerance for α-Butyl-ω-hydroxypoly(oxypropylene) block polymer with poly(oxyethylene) when used in a pesticide. 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

BASF Corporation is petitioning that α-Butyl-ω-hydroxypoly(oxypropylene) block polymer with poly(oxyethylene) be exempt from the requirement of a tolerance based upon the definition of a low risk polymer under 40 CFR 723.250(e). Consequently, BASF Corporation believes that the analytical method to determine residues, the residues present in plant material, and the magnitude of α-Butyl-ω-hydroxypoly(oxypropylene) block polymer with poly(oxyethylene) in raw agricultural commodities, is not relevant.

B. Toxicological Profile

- α-Butyl-ω-hydroxypoly(oxypropylene) block polymer with poly(oxyethylene) is a polymer as defined by 40 CFR 723.250(b). It is composed of at least three monomer units and one other reactant.
- α-Butyl-ω-hydroxypoly(oxypropylene) block polymer with poly(oxyethylene) consists of a simple weight majority of the polymer molecules. The monomer sequences form uninterrupted strings in the polymer and distribution of the molecular weight of the polymer is due largely to the number of monomer units in the individual molecules.
- α-Butyl-ω-hydroxypoly(oxypropylene) block polymer with poly(oxyethylene) consists of a number average molecular weight of 4,000 with 0% of its oligomeric material weighing below 500 daltons and 0% of its oligomeric material weighing less than 1,000 daltons.
- α-Butyl-ω-hydroxypoly(oxypropylene) block polymer with poly(oxyethylene) will not become cationic in an aquatic environment. It contains no moieties capable of obtaining a cationic charge.
- α-Butyl-ω-hydroxypoly(oxypropylene) block polymer with poly(oxyethylene) is composed of carbon, hydrogen, and oxygen; therefore, it meets the criteria of elemental composition. Namely it must be composed of at least two of the following elements (and no other elements than those listed): Carbon, hydrogen, nitrogen, oxygen, silicon, and sulfur.
- α-Butyl-ω-hydroxypoly(oxypropylene) block polymer with poly(oxyethylene) is not designed nor reasonably expected to degrade, decompose, or depolymerize under normal use conditions.
- α-Butyl-ω-hydroxypoly(oxypropylene) block polymer with poly(oxyethylene) is composed of molecules that are listed on the TSCA Inventory or manufactured under an applicable TSCA section 5 exemption.
- α-Butyl-ω-hydroxypoly(oxypropylene) block polymer with poly(oxyethylene) does not exceed the number average molecular weight of 10,000 and; therefore, is not subject to the water absorption limitation.

C. Aggregate Exposure

1. *Dietary exposure.* The physical-chemical characteristics of α-Butyl-ω-hydroxypoly(oxypropylene) block polymer with poly(oxyethylene) leads to the conclusion that there is a reasonable certainty of no harm from exposure to the polymer from food or drinking water nor from an aggregate exposure.

2. *Non-dietary exposure.* The physical-chemical characteristics of α-Butyl-ω-hydroxypoly(oxypropylene) block polymer with poly(oxyethylene) lead to the conclusion that there is a reasonable certainty of no harm from exposure to the polymer from non-dietary means.

D. Cumulative Effects

At this time there is no information to indicate that any toxic effects produced by α-Butyl-ω-hydroxypoly(oxypropylene) block polymer with poly(oxyethylene) would be cumulative with any other chemical. Given the compound's categorization as a low risk polymer, and its proposed use in pesticide formulations, there is no expectation of increased risk due to cumulative exposure.

E. Safety Determination

1. *U.S. population.* Based on the polymer's physical-chemical properties, and that it meets or exceeds the polymer exemption criteria at 40 CFR 723.250 for low-risk polymers, adverse effects are not expected.

2. *Infants and children.* Based on the polymer's physical-chemical properties, and that it meets or exceeds the polymer exemption criteria at 40 CFR 723.250 for low-risk polymers, adverse effects are not expected.

F. International Tolerances

There are no Codex maximum residue limits established for α-Butyl-ω-hydroxypoly(oxypropylene) block polymer with poly(oxyethylene) in or on crops or commodities at this time.

[FR Doc. 05–10848 Filed 5–31–05; 8:45 am]

BILLING CODE 6560–50–S

ENVIRONMENTAL PROTECTION AGENCY

[OPP–2005–0114; FRL–7711–8]

Hexythiazox; Notice of Filing a Pesticide Petition to Establish a Tolerance for a Certain Pesticide Chemical in or on Food

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

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

DATES: Comments, identified by docket identification (ID) number OPP–2005–0114, must be received on or before July 1, 2005.

ADDRESSES: Comments may be submitted electronically, by mail, or through hand delivery/courier. Follow the detailed instructions as provided in Unit I. of the **SUPPLEMENTARY INFORMATION**.

FOR FURTHER INFORMATION CONTACT: Bonaventure Akinlosotu, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001; telephone number: (703) 605–0653; e-mail address: *akinlosotu.bonaventure@epa.gov*.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

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

- Crop production (NAICS 111)
- Animal production (NAICS 112)
- Food manufacturing (NAICS 311)
- Pesticide manufacturing (NAICS 32532)

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 this unit could also be affected. The North American Industrial Classification System (NAICS) codes have been provided to assist you and others in determining whether this action might apply to certain entities. If you have any 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 Copies of this Document and Other Related Information?

1. *Docket*. EPA has established an official public docket for this action under docket ID number OPP–2005–0114. The official public docket consists of the documents specifically referenced in this action, any public comments received, and other information related to this action. Although a part of the official docket, the public docket does not include Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. The official public docket is the collection of materials that is available for public viewing at the Public Information and Records Integrity Branch (PIRIB), Rm. 119, Crystal Mall #2, 1801S. Bell St., Arlington, VA. This docket facility is open from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The docket telephone number is (703) 305–5805.

2. *Electronic access*. You may access this **Federal Register** document electronically through the EPA Internet under the ''**Federal Register**'' listings at *http://www.epa.gov/fedrgstr/*.

An electronic version of the public docket is available through EPA's electronic public docket and comment system, EPA Dockets. You may use EPA Dockets at *http://www.epa.gov/edocket/* to submit or view public comments, access the index listing of the contents of the official public docket, and to access those documents in the public docket that are available electronically. Although not all docket materials may be available electronically, you may still access any of the publicly available docket materials through the docket facility identified in Unit I.B.1. Once in the system, select ''search,'' then key in the appropriate docket ID number.

Certain types of information will not be placed in the EPA Dockets. Information claimed as CBI and other information whose disclosure is restricted by statute, which is not included in the official public docket, will not be available for public viewing in EPA's electronic public docket. EPA's policy is that copyrighted material will not be placed in EPA's electronic public docket but will be available only in printed, paper form in the official public docket. To the extent feasible, publicly available docket materials will be made available in EPA's electronic public docket. When a document is selected from the index list in EPA Dockets, the system will identify whether the document is available for viewing in EPA's electronic public docket. Although not all docket materials may be available electronically, you may still access any of the publicly available docket materials through the docket facility identified in Unit I.B. EPA intends to work towards providing electronic access to all of the publicly available docket materials through EPA's electronic public docket.

For public commenters, it is important to note that EPA's policy is that public comments, whether submitted electronically or in paper, will be made available for public viewing in EPA's electronic public docket as EPA receives them and without change, unless the comment contains copyrighted material, CBI, or other information whose disclosure is restricted by statute. When EPA identifies a comment containing copyrighted material, EPA will provide a reference to that material in the version of the comment that is placed in EPA's electronic public docket. The entire printed comment, including the copyrighted material, will be available in the public docket.

Public comments submitted on computer disks that are mailed or delivered to the docket will be transferred to EPA's electronic public docket. Public comments that are mailed or delivered to the docket will be scanned and placed in EPA's electronic public docket. Where practical, physical objects will be photographed, and the photograph will be placed in EPA's electronic public docket along with a brief description written by the docket staff.

C. How and To Whom Do I Submit Comments?

You may submit comments electronically, by mail, or through hand delivery/courier. To ensure proper receipt by EPA, identify the appropriate docket ID number in the subject line on the first page of your comment. Please ensure that your comments are submitted within the specified comment period. Comments received after the close of the comment period will be marked ''late.'' EPA is not required to consider these late comments. If you wish to submit CBI or information that is otherwise protected by statute, please follow the instructions in Unit I.D. Do not use EPA Dockets or e-mail to submit CBI or information protected by statute.

1. *Electronically*. If you submit an electronic comment as prescribed in this unit, EPA recommends that you include your name, mailing address, and an e-mail address or other contact information in the body of your comment. Also include this contact information on the outside of any disk or CD ROM you submit, and in any cover letter accompanying the disk or CD ROM. This ensures that you can be identified as the submitter of the comment and allows EPA to contact you in case EPA cannot read your comment due to technical difficulties or needs further information on the substance of your comment. EPA's policy is that EPA will not edit your comment, and any identifying or contact information provided in the body of a comment will be included as part of the comment that is placed in the official public docket, and made available in EPA's electronic public docket. If EPA cannot read your comment due to technical difficulties and cannot contact you for clarification, EPA may not be able to consider your comment.

i. *EPA Dockets*. Your use of EPA's electronic public docket to submit comments to EPA electronically is EPA's preferred method for receiving comments. Go directly to EPA Dockets at *http://www.epa.gov/edocket/*, and follow the online instructions for submitting comments. Once in the system, select ''search,'' and then key in docket ID number OPP–2005–0114. The system is an ''anonymous access'' system, which means EPA will not know your identity, e-mail address, or other contact information unless you provide it in the body of your comment.

ii. *E-mail*. Comments may be sent by e-mail to opp-docket@epa.gov, Attention: Docket ID Number OPP–2005–0114. In contrast to EPA's electronic public docket, EPA's e-mail system is not an ''anonymous access'' system. If you send an e-mail comment directly to the docket without going through EPA's electronic public docket, EPA's e-mail system automatically captures your e-mail address. E-mail addresses that are automatically captured by EPA's e-mail system are included as part of the comment that is placed in the official public docket, and made available in EPA's electronic public docket.

iii. *Disk or CD ROM*. You may submit comments on a disk or CD ROM that you mail to the mailing address

identified in Unit I.C.2. These electronic submissions will be accepted in WordPerfect or ASCII file format. Avoid the use of special characters and any form of encryption.

2. *By mail.* Send your comments to: Public Information and Records Integrity Branch (PIRIB) (7502C), Office of Pesticide Programs (OPP), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001, Attention: Docket ID Number OPP–2005–0114.

3. *By hand delivery or courier.* Deliver your comments to: Public Information and Records Integrity Branch (PIRIB), Office of Pesticide Programs (OPP), Environmental Protection Agency, Rm. 119, Crystal Mall #2, 1801 S. Bell St., Arlington, VA, Attention: Docket ID Number OPP–2005–0114. Such deliveries are only accepted during the docket's normal hours of operation as identified in Unit I.B.1.

D. How Should I Submit CBI to the Agency?

Do not submit information that you consider to be CBI electronically through EPA's electronic public docket or by e-mail. You may claim information that you submit to EPA as CBI by marking any part or all of that information as CBI (if you submit CBI on disk or CD ROM, mark the outside of the disk or CD ROM as CBI and then identify electronically within the disk or CD ROM the specific information that is 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 docket and EPA's electronic public docket. If you submit the copy that does not contain CBI on disk or CD ROM, mark the outside of the disk or CD ROM clearly that it does not contain CBI. Information not marked as CBI will be included in the public docket and EPA's electronic public docket 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 ID 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 a pesticide petition as follows proposing the establishment and/or amendment of regulations for residues of a 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 FFDCA 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 record keeping requirements.

Dated: May 23, 2005.

Lois Rossi,

Director, Registration Division, Office of Pesticide Programs.

Summary of Petition

The petitioner summary of the pesticide petition is printed below as required by FFDCA section 408(d)(3). The summary of the petition was prepared by the petitioner and represents the view 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.

Gowan Company

PP 3F6569

EPA has received a pesticide petition (PP) 3F6569 from Gowan Company, 370 S. Main Street, Yuma, AZ 85365 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 hexythiazox: (*trans*-5- (4-chlorophenyl)-N-cyclohexyl-4-methyl-2-oxothiazolidine-3-carboxamide) and its metabolites containing the (4-chlorophenyl)-4-methyl-2-oxothiazolidine moiety expressed as parts per million (ppm) of the parent compound in or on grapes at 1.0 ppm, raisins at 4.0 ppm, citrus at 0.5 ppm, and citrus oil at 2.0 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 supports granting of the petition. Additional data may be needed before EPA rules on the petition.

A. Residue Chemistry

1. *Plant metabolism.* The metabolism of hexythiazox as well as the nature of the residues in plants is adequately understood for purposes of this tolerance. Metabolism studies were conducted in four crops, viz.; pears, grapes, oranges and apples. The major residue component is unmetabolized parent. The metabolites are hydroxylcyclohexyl and ketocyclohexyl analogs of hexythiazox and the amide formed by loss of the cyclohexyl ring. Parent hexythiazox and its metabolites are converted to a common moiety for residue analysis.

2. *Analytical method.* A practical analytical method, high pressure liquid chromatography with an Ultraviolet (UV) detector, which detects and measures residues of hexythiazox and its metabolites as a common moiety, is available for enforcement purposes with a limit of detection that allows monitoring of food with residues at or above the levels set in this tolerance.

3. *Magnitude of residues.* Residue and processing studies on grapes and citrus were conducted to support the proposed use. The number of trials conducted is sufficient to satisfy requirements for national registration for grapes and regional registration (CA, AZ, TX) for citrus.

B. Toxicological Profile

1. *Acute toxicity.* A battery of acute toxicity studies places technical grade hexythiazox in Toxicity Category IV for acute oral lethal dose $_{50}$ (LD_{50}) > 5,000 milligram/kilograms (mg/kg)), Category III for dermal LD_{50} > 5,000 mg/kg), Category III for inhalation lethal concentration (LC_{50}) (LC_{50} > 2.0 mg/Liter(L)), Category III for primary eye

irritation (mild irritation, reddened conjunctiva), Category IV for dermal irritation (non irritant). Hexythiazox is a non-sensitizer.

2. *Genotoxicty*. The following genotoxicity studies were all negative: Ames gene mutation, CHO gene mutation, CHO chromosome aberration, mouse micronucleus and rat hepatocyte unscheduled DNA synthesis.

3. *Reproductive and developmental toxicity*. In a developmental toxicity study in rats, the maternal No-Observed-Adverse-Effect-Level (NOAEL) was 240 mg/kg/day and the maternal Lowest-Observed-Adverse-Effect-Level (LOAEL) was 720 mg/kg/day based on increased ovarian weights and decreased bone ossification.

In a developmental toxicity study in rabbits, the maternal NOAEL was 1,080 mg/kg/day highest dose tested (HDT); the maternal LOAEL was not determined. The developmental NOAEL was 1,080 mg/kg/day (HDT); the developmental LOAEL was not determined. In a 2–generation reproduction study in rats, the parental NOAEL was 35 mg/kg/day and the parental LOAEL was 200 mg/kg/day based on decreased body weight gain, decreased food consumption and efficiency, and increased liver, kidney and ovarian weights. The reproductive NOAEL was 35 mg/kg/day and the reproductive LOAEL was 200 mg/kg/day based on decreased pup body weight (bwt) during lactation, delayed hair growth and eye opening.

4. *Subchronic toxicity*. In a 1–month feeding study in dogs, the NOAEL was 1.75 mg/kg/day and the LOAEL was 12.5 mg/kg/day, based on increased liver and adrenal weights.

5. *Chronic toxicity*. In a 1–year feeding study in dogs, the NOAEL was 2.5 mg/kg/day and the LOAEL was 12.5 mg/kg/day, based on increased alkaline phosphatase, increased adrenal and liver weights, and liver and adrenal lesions. In a carcinogenicity study in mice, the NOAEL was 36 mg/kg/day and the LOAEL was 215 mg/kg/day. Effects were decreased bwt in males and increased hepatocellular carcinomas and combined adenoma/carcinomas.

In a chronic feeding/carcinogenicity study in rats, the NOAEL (systemic) was 26 mg/kg/day and the LOAEL (systemic) was 180 mg/kg/day based on decreased bwt gain and increased liver weights in both sexes.

The chronic reference dose (RfD) for hexythiazox is based on the 1–year dog feeding study with a NOAEL of 2.5 mg/kg/day and an uncertainty factor of 100. The Agency has classified hexythiazox as a category C (possible human) carcinogen based on an increased incidence of hepatocellular carcinomas ($p = 0.028$) and combined adenomas/carcinomas ($p = 0.024$) in female mice at the highest dose tested (1,500 ppm) when compared to the controls as well as a significantly increased ($p < 0.001$) incidence of pre-neoplastic hepatic nodules in both males and females at the HDT. The decision supporting a category C classification was based primarily on the fact that only one species was affected and mutagenicity studies were negative. In classifying hexythiazox as a category C carcinogen, the Agency concluded that a quantitative estimate of the carcinogenic potential for humans should be calculated because of the increased incidence of liver tumors in the female mouse. A Q1* of 0.022 mg/kg/day^{-1} in human equivalents was published in the **Federal Register** of October 16, 1998 (63 FR 55540) (FRL–6035–2).

6. *Animal metabolism*. The metabolism of hexythiazox has been studied in goats, hens and rats. Metabolic pathways in the animal are similar to those in plants.

7. *Metabolite toxicology*. There are no metabolites of toxicological concern based on a differential metabolism between plants and animals.

8. *Endocrine disruption*. No specific tests have been conducted with hexythiazox to determine whether the chemical may have an effect in humans that is similar to an effect produced by a naturally occurring estrogen or other endocrine effects. However, there were no significant findings in other relevant toxicity tests, i.e., teratology and multi-generation reproduction studies, which would suggest that hexythiazox produces effects characteristic of the disruption of the estrogenic hormone.

C. Aggregate Exposure

1. *Dietary exposure from food*. Tolerances have been established (40 CFR 180.479) for residues of hexythiazox (*trans*-5- (4-chlorophenyl)-N-cyclohexyl-4-methyl-2-oxothiazolidine-3-carboxamide) and its metabolites containing the (4-chlorophenyl)-4-methyl-2-oxo-3-thiazolidine moiety in or on apples at 0.50 ppm; wet apple pomace at 0.80 ppm; pears at 0.30 ppm; stone fruits (except plums) at 1.0 ppm; plum, prune, fresh at 0.1 ppm; plum, prune, dried at 0.4 ppm; strawberries at 3.0 ppm; nut tree group at 0.30 ppm; pistachio at 0.30 ppm; almond hulls at 10 ppm; caneberry crop group at 2.0 ppm; dates at 1.0 ppm; hops at 2.0 ppm; milk at 0.02 ppm; fat of cattle, goats, horses, swine and sheep at 0.02 ppm; meat byproducts of cattle, goats, horses, swine and sheep at 0.02 ppm; cotton, undelinted seed (CA only), at 0.20 ppm; and cotton gin byproducts (CA only) at 3.0 ppm, and a tolerance of 0.1 ppm for greenhouse tomatoes is pending. Additional tolerances are being requested in this petition for grapes at 1.0 ppm, raisins at 4 ppm, citrus (CA, AZ, TX) at 0.5 ppm, and citrus oil at 2.0 ppm.

EPA has estimated the following dietary exposures from hexythiazox in food (**Federal Register** of September 29, 2000 (65 FR 58437) (FRL–6746–5).

i. *Acute exposure*. For acute dietary exposure of the general population including infants and children, a dose and endpoint attributable to a single exposure were not identified by the Agency from the available oral toxicity studies, including maternal toxicity in the developmental toxicity studies. An acute RfD of 2.4 mg/kg/day for females 13–50 years of age was identified from the rat developmental toxicology study based on delayed ossification. A conservative analysis was performed by the Agency using existing and recommended tolerance level residues and 100% crop treated (CT) information for all commodities. The acute dietary exposure estimate for the females 13–50 years old subgroup was 0.002617 mg/kg/day at the 95th percentile. The registrant has concluded that hexythiazox use on grapes and citrus will not significantly contribute to this dietary exposure.

ii. *Chronic exposure*. A partially refined deterministic analysis was performed by the Agency using anticipated residues (AR) levels for most crops and %CT or anticipated market share information for all crops. Dietary exposure estimates for the U.S. population and other representative subgroups were <0.00003 mg/kg/day. The registrant has concluded that hexythiazox use on grapes and citrus will not significantly contribute to this dietary exposure.

iii. *Cancer*. A partially refined deterministic carcinogenic risk estimate analysis was performed by the Agency using AR levels and %CT or anticipated market share information for all crops. The chronic dietary exposure estimate for the U.S. population was 0.000011 mg/kg/day. The registrant has concluded that hexythiazox use on grapes and citrus will not significantly contribute to this dietary exposure.

2. *Dietary exposure from drinking water*. Using the Generic expected environmental concentration (GENEEC) and Screening concentration in ground water (SCI-GROW) models, the Agency has calculated the estimated environmental concentrations (EECs) of hexythiazox to be 910.32 nanogram

(ng)/L for surface water and 1.47 ng/L for ground water. These estimates are based on a maximum application rate of 0.1875 lbs. active ingredient per acre.

3. *From non-dietary exposure*. The term ''residential exposure'' is used by the Agency to refer to non-occupational, non-dietary exposure (e.g., for lawn and garden pest control, indoor pest control, termiticides, and flea and tick control on pets). Hexythiazox is not registered for use on any sites that would result in residential exposure.

D. Cumulative Exposure

EPA has not determined whether hexythiazox has a common mechanism of toxicity with other substances or how to include this pesticide in a cumulative risk assessment. Unlike other pesticides for which EPA has followed a cumulative risk approach based on a common mechanism of toxicity, hexythiazox does not share a toxic metabolite with other substances. For the purposes of this tolerance action, therefore, the registrant has not assumed that hexythiazox has a common mechanism of toxicity with other substances. For purposes of this petition the potential risks of hexythiazox in its aggregate exposure will only be considered.

E. Safety Determination

1. *U.S. population*—i. *Acute risk*. Aggregate exposure risk includes exposure from food and water. For acute dietary exposure of the general population, a dose and endpoint attributable to a single exposure were not identified by the Agency from the available oral toxicity studies. For the relevant population subgroup of females 13+ years, the risk from acute ''food only'' exposure is less than 1% of the RfD, which is less than EPA's level of concern. The acute drinking water level of comparison (DWLOC) calculated for the relevant population subgroup of females 13+ years is 72,000 parts per billion (ppb). The calculated DWLOC is significantly higher than the drinking water EECs for ground water (0.0015 ppb) and surface water (0.910 ppb). EPA has concluded with reasonable certainty that residues of hexythiazox in drinking water do not contribute to the acute aggregate health risk.

ii. *Short- and intermediate-term risk*. Hexythiazox is not registered for use on any sites that would result in residential exposure. Therefore, the aggregate risk is the sum of the risk from food and water, which do not exceed the Agency's level of concern.

iii. *Chronic risk*. Aggregate chronic risk (non cancer) exposure from ''food only'' exposure utilizes less than 1% of the RfD for all population subgroups. The chronic DWLOC for hexythiazox exposure in drinking water is 870 ppb for the U.S. population and 250 ppb for infants and children. The calculated DWLOCs are significantly higher than the drinking water EECs for ground water (0.0015 ppb) and surface water (0.910 ppb). EPA has concluded with reasonable certainty that residues of hexythiazox in drinking water do not contribute to the chronic (non cancer) aggregate health risk.

iv. *Cancer risk*. The carcinogenic risk estimate (food only) for the general U.S. population $<5 \times 10^{-7}$. Thus, the carcinogenic dietary risk associated with the existing and proposed uses of hexythiazox does not exceed the level of concern for excess lifetime cancer risk (1×10^{-6}). The surface water and ground water EECs were used to compare against back calculated the DWLOC for aggregate risk assessments. For the carcinogenic risk scenario, EPA calculated a DWLOC of 1.2 ppb for the U.S. population. The EECs ground water and surface water (0.0015 ppb and 0.910 ppb, respectively) are less than EPA's calculated DWLOC. Therefore, EPA concluded that residues of hexythiazox in drinking water do not contribute significantly to the carcinogenic aggregate human health risk.

2. *Infants and children*. For acute dietary exposure of infants and children, a dose and endpoint attributable to a single exposure were not identified by the Agency from the available oral toxicity studies. The Agency has determined that the 10X-safety factor to protect infants and children should be removed and reduced to 1X. It is concluded that there is a reasonable certainty of no harm to infants and children from aggregate exposure to hexythiazox residues.

F. International Tolerances

National maximum residue levels (MRL) for hexythiazox on grapes have been established at 0.5 ppm in Germany, France, Italy, Spain, Austria, and Hungry, and at 0.05 ppm in Switzerland. MRLs for hexythiazox on citrus have been established at 2.0 ppm in Japan and Korea, at 1.0 ppm in Spain, at 0.5 ppm in Italy, at 1.0 ppm for peel and 0.01 ppm for pulp in Brazil, 0.2 ppm in France and 0.1 ppm in New Zealand.

[FR Doc. 05–10843 Filed 5–31–05; 8:45 am]

BILLING CODE 6560–50–S

ENVIRONMENTAL PROTECTION AGENCY

[OPP–2005–0135; FRL–7715–7]

Furilazole; Notice of Filing a Pesticide Petition to Establish a Tolerance for a Certain Pesticide Chemical in or on Food

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: This notice announces the initial filing of a pesticide petition (PP) by Monsanto Company proposing the establishment of regulations for residues of 3-dichloroacetyl-5-(2-furanyl)-2,2-dimethyloxazolidine (furilazole) (safener) in or on the raw agricultural commodities sorghum grain, forage, stover, flour, and bran at 0.01 parts per million.

DATES: Comments, identified by docket identification (ID) number OPP–2005–0135, must be received on or before July 1, 2005.

ADDRESSES: Comments may be submitted electronically, by mail, or through hand delivery/courier. Follow the detailed instructions as provided in Unit I. of the **SUPPLEMENTARY INFORMATION**.

FOR FURTHER INFORMATION CONTACT: Karen Angulo, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001; telephone number: (703) 306–0404; e-mail address: *angulo.karen@epa.gov*.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

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

- Crop production (NAICS 111)
- Animal production (NAICS 112)
- Food manufacturing (NAICS 311)
- Pesticide manufacturing (NAICS 32532)

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 this unit could also be affected. The North American Industrial Classification System (NAICS) codes have been provided to assist you and others in determining whether this action might apply to certain entities. If you have any