those activities involve different exposure potentials. To ensure that workers are adequately protected, that one REI will usually be based on the activity that involves the highest level of exposure. This approach is favored because users and employers are more likely to understand and comply with clear labels. Also, establishing multiple activity-based REIs for crops could cause confusion and compromise compliance with and enforcement of worker protection regulations. However, when the consideration of risks and benefits indicate that a single REI is unworkable, EPA will consider granting exceptions. For most propargite uses, a single crop-specific REI is being proposed in the RED because no critical activity was identified that warranted establishing an exception. During the 60–day comment period for this RED, however, EPA will accept further comments from growers regarding needs for additional REI exceptions for specific post-application activities, and will add such exceptions where needed if there are adequate margins of exposure (MOEs) and/or benefits associated with such activities warrant such an exception. To assist the Agency in making its risk/benefit finding on a specific exception request, the following benefits-related information is most useful.

1. Identify the crop(s) and provide a description of the specific production task(s) for which the exception is requested. Explain why the task is critical during the REI. As specifically as possible, describe how the task is performed including timing within the growing season, equipment and/or PPE used in performing the task, nature of the contact with treated surfaces, and duration for performing the task including the number of hours per days and number of days.

2. Explain why the critical tasks cannot be performed prior to application or after the REI has expired. Include detailed information on the critical pest(s), the timing of the application, and the impact of modifying the pesticide application to conform to the REI.

3. Describe the geographic area for which the exception or prohibition is requested. If the exception request is limited to a specific geographic area, describe why the circumstances of exposure or economic impact resulting from the prohibition of routine hand tasks during the REI are unique to the geographic area named in the exception.

4. Explain, for each requested crop/task combination, why alternative practices would not be technically or financially viable. Such alternative practices might include rescheduling the pesticide application or hand labor activity; using non-chemical pest control alternatives; using an alternative to hand labor tasks, such as machine cultivation; or substituting a pesticide with a shorter REI. This information should include estimates or data on per acre revenue, and cost of production for the crop area for which the exception is requested. These estimates or data should include: The current situation, the situation if the exception is not granted, the situation if the exception is granted, and specific information on the individual factors which cause differences in revenues and cost among the three situations.

5. Provide documentation or a description of the safety and feasibility of such an exception, including, but not limited to, the period of time required daily per worker to perform the hand labor activity, any suggested methods of reducing the worker's exposure, and any other mitigating factors, such as the availability of mechanical devices that would reduce the workers' contact with the treated surfaces.

B. What is the Agency's Authority for Taking this Action?

The legal authority for this RED falls under FIFRA, as amended in 1988 and 1996. Section 4(g)(2)(A) of FIFRA directs that, after submission of all data concerning a pesticide active ingredient, ''the Administrator shall determine whether pesticides containing such active ingredient are eligible for reregistration,'' before calling in product-specific data on individual end-use products, and either reregistering products or taking ''other appropriate regulatory action.''

List of Subjects

Environmental protection.

Dated: April 5, 2002.

Lois Rossi,

Director, Special Review and Reregistration Division, Office of Pesticide Programs.

[FR Doc. 02–9501 Filed 4–17–02 8:45 am]

BILLING CODE 6560–50–S

ENVIRONMENTAL PROTECTION AGENCY

[PF–1081; FRL–6831–2]

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

DATES: Comments, identified by docket control number PF–1081, must be received on or before May 20, 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 PF–1081 in the subject line on the first page of your response.

FOR FURTHER INFORMATION CONTACT: By mail: Mary L. Waller, Fungicide Branch, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460; telephone number: (703) 308–9354; e-mail address: waller.mary@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'' 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 PF–1081. 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 PF–1081 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 PF–1081. 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 identified 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 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 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: April 2, 2002

Robert A. Forrest

Acting 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 Safe Materials, Inc. and represents the views of Safe Materials, Inc. EPA is publishing the petition summary verbatim without editing it 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.

Safe Materials, Inc.

PP 2F6362

EPA has received a pesticide petition (2F6362) from Safe Materials, Inc., P.O. Box 1065, Valdosta, GA 31603–1065 proposing, pursuant to section 408(d) of FFDCA, 21 U.S.C. 346a(d), to amend 40 CFR part 180 to establish an exemption from the requirement of a tolerance, in or on the raw agricultural commodity cotton seed. 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 **Federal Register** of July 7, 1995 (60 FR 35396) (FRL–4957–9), announced the reclassification of a number of inert ingredients from List 3 to List 4B (minimal risk). EPA included alpha-sec-alkyl($C_{11–15}$)-omega-hydroxypoly(oxyethylene) among those substances on List 4B indicating:

- ''On behalf of the Office of Pesticide Programs, these substances were reviewed by the Structure Activity Team of EPA's Office of Pollution Prevention and Toxics, with each judged to be of low concern for potential human health, and/or environmental effects.''
- ''These inert ingredients were evaluated by the Office of Pesticide Program's inert review group, and determined to be of minimal risk.''
- ''A list of these inert ingredients proposed for reclassification was provided to EPA's Office of Water and to the FDA's Center for Food Safety and Applied Nutrition for comment; no adverse comments were received.''

Additionally, EPA has already exempted from the requirements of a tolerance under 40 CFR 180.1001(c) the residues of alpha-sec-alkyl($C_{11–15}$)-omega-hydroxypoly(oxyethylene) for use in pesticide formulations applied to growing crops, or to raw agricultural commodities after harvest.

The addition of alpha-sec-alkyl($C_{11–15}$)-omega-hydroxypoly(oxyethylene) to the list of substances considered exempt from the requirement of a tolerance when used as an active ingredient, would merely acknowledge the fact, that this product is safe to humans and the environment.

As alpha-sec-alkyl($C_{11–15}$)-omega-hydroxypoly(oxyethylene), contains as an integral part of it's composition the atomic elements, carbon, hydrogen, and oxygen, it is not expected to be degraded into any metabolites of toxicological concern. This nonionic surfactant would be expected to biodegrade ultimately and completely into carbon dioxide and water.

The metabolism of 4-n-nonylphenol (4-NP), a metabolite of alpha-sec-alkyl($C_{11–15}$)-omega-hydroxypoly(oxyethylene), has been investigated. The metabolism was examined in cell cultures of wheat, according to a standard method. Four major radioactively labeled fractions, were detected and isolated. They were shown to be 4-(hydroxy)- and 4-(dihydroxy) nonylphenols, which were glucosylated at the phenolic OH-group and further glucosylated, glucuronidated, and acylated with acetic acid or malonic acid. These results confirm and extend the findings of a trial investigating p-tert-octyphenol in barley plants. Hexaethoxylated p-tert-octylphenol was also reduced to monohydroxylated and glycosylated metabolites. It is proposed that, alpha-sec-alkyl($C_{11–15}$)-omega-hydroxypoly(oxyethylene), would also be metabolized in the same manner.

2. *Analytical method.* Alpha-sec-alkyl($C_{11–15}$)-omega-hydroxypoly(oxyethylene), and its metabolites, can be extracted from crop matrices by blending with methylene chloride. After blending, the extract is filtered, volume reduced, excess solvent is evaporated using nitrogen. The organic residue is then analyzed by using a high performance liquid chromotography (HPLC) equipped with a ultraviolet (UV) detector.

3. *Magnitude of residues.* EPA has already exempted from the requirements of a tolerance under 40 CFR 180.1001(c) the residues of alpha-sec-alkyl($C_{11–15}$)-omega-hydroxypoly(oxyethylene), when used as an inert ingredient in pesticide formulations that may be applied to growing crops, or raw agricultural commodities after harvest. As Safe Materials, Inc. is requesting an exemption from the requirement of a tolerance, the magnitude of residues in cotton seed was not quantified.

B. Toxicological Profile

1. *Acute toxicity.* The acute rat oral LD_{50} was 2,910 milligrams/kilogram (mg/kg) male and 971 mg/kg female. The acute rat dermal LD_{50} was 2,730 mg/kg male and <3,000 mg/kg for female. The 4–hour rat inhalation LC_{50} was 1.06 milligrams per liter (mg/L) for both male and female. Alpha-sec-alkyl($C_{11–15}$)-omega-hydroxypoly(oxyethylene), was slightly irritating to rabbit skin and caused corneal involvement. Based on these results, alpha-sec-alkyl($C_{11–15}$)-omega-hydroxypoly(oxyethylene) would be classified as EPA Category III, for inhalation toxicity and dermal toxicity, EPA Category IV, for oral toxicity and dermal irritation, and EPA Category I, for eye irritation. Alpha-sec-alkyl($C_{11–15}$)-omega-hydroxypoly(oxyethylene), was not a sensitizer to the skin.

2. *Genotoxicty.* The Ames test for mutagenicity of nonoxynol-9, a structurally similar product, was negative.

3. *Reproductive and developmental toxicity.* The broad range of structurally similar products, which are presently approved for use in pesticide formulations, and adjuvants have not been reported to cause reproductive or developmental toxicity. In a 3–month study with rats, dietary administration of alkyl-omega-hydroxypoly(oxyethylene) (100% $C_{11–15}$) at dose levels of 62.5, 125, 250 or 500 mg/kg/day resulted in statistically significant decreases in mean body weight gain, in both males and females at doses above 125 mg/kg/day. Females exhibited significant decreases in mean food consumption. Treatment had no effect on survival, clinical signs, organ weights, and weight gain. A no observed adverse effect level (NOAEL) of 62.5 mg/kg and a lowest observed adverse effect level (LOAEL) of 125 mg/kg was established.

In a 3–month study with rats, dietary administration at 82, 154 and 354 mg/kg/day caused no adverse effects on survival, clinical signs, organ weights, hematology, or gross and histopathology at any dose level. Based upon decrease in body weight gain, a NOAEL of 154 mg/kg/day and a LOAEL of 354 mg/kg/day was established.

A two-generation rat reproductive study to determine reproductive toxicity of octylphenol, a structurally similar product was conducted. Five groups of rats were administered octylphenol at dose levels of 0, 0.2, 20, 200, and 2,000 parts per million (ppm). Effects were observed only at 2,000 ppm, including decreased body weights in adults, and during the latter portion of lactation in offspring and minor body weight-related delays in acquisition of vaginal opening and preputial separation. No effects on reproductive parameters, testes, prostate, or ovary weights or morphology, on sperm counts, motility, morphology or production, or on estrous cyclicity were observed. The NOAELs for systemic and postnatal toxicity were 200 ppm and at or above 2,000 ppm for reproductive toxicity.

4. *Subchronic toxicity.* Para-nonylphenol is used to produce nonylphenol ethoxylates (a class of nonionic surfactants), a subgroup of alkylphenol ethoxylates to which alkyl-omega-hydroxypoly(oxyethylene) (100% $C_{11–15}$) belongs. The primary biodegradation of alkylphenol ethoxylates is the hydrolytic removal of ethoxylate groups. This step is relatively rapid, and results in the intermediate nonylphenol. Thus, it is widely

accepted that tests with para-nonylphenol represent the alkylphenol ethoxylates.

In a 90–day rat feeding study, para-nonylphenol was administered to four groups of rats at dietary concentrations of 0, 15, 50, and 150, mg/kg/day. There were 25 rats/sex/group in the control and high dose groups and 15 rats/sex/group in the low and mid-dose groups. Ten of the 25 rats/sex in the control and high-dose groups were designated as recovery animals and were maintained on control diets for 4 weeks after completion of the 90–day exposure period to assess the reversibility of any effects which might be observed. In-life effects, were limited to small decreases in body weight and food consumption in the 150 mg/kg dose group. Post-mortem measurements at week 14 indicated a dose-related kidney weight increase in males and a decrease in renal haline globules/droplets in males from the high dose group. The kidney weights showed complete recovery following the 4–week post-dosing recovery period. Due to the small magnitude of the changes, (i.e., all weights were within or near laboratory historical control values), and the lack of correlating clinical or histopathological changes, the kidney weight alterations were not considered toxicologically significant. The biological significance of reduced hyaline in the kidneys of male rats from the high dose group is uncertain. Renal tubular hyaline is associated with the rat-specific protein, alpha-2u-globulin, and therefore, this finding was not considered toxicologically relevant to humans. No other effects attributable to para-nonylphenol were observed. Based upon the minor findings for the high dose group, the NOAEL in this study is considered to be 50 mg/kg/day and the LOAEL is 150 mg/kg/day.

5. *Chronic toxicity.* No long-term chronic toxicity studies are available for alkylphenol ethoxylates to which alkyl-omega-hydroxypoly(oxyethylene) (100% $C_{11–15}$) belongs, but an unpublished 2–year feeding study in rats and an 18–month dermal study in mice using primary alcohol ethoxylates are available. There were no treatment related effects.

Additionally, in its notice of July 7, 1995 (60 FR 35396) (FRL–4957–9) which moved alkyl-omega-hydroxypoly(oxyethylene) (100% $C_{11–15}$) from List 3 to List 4B (minimal risk), EPA stated:

- ''On behalf of the Office of Pesticide Programs, these substances were reviewed by the Structure Activity Team of the EPA's Office of Pollution Prevention and Toxics with each judged to be of low concern for potential human health and/or environmental effects.''
- ''These inert ingredients were evaluated by the Office of Pesticide Program's Inert Review Group and determined to be of minimal risk.''
- ''A list of these inert ingredients proposed for reclassification was provided to EPA's Office of Water and to the FDA's Center for Food Safety and Applied Nutrition for comment; no adverse comments were received.''

Safe Materials, Inc. believes, alkyl-omega-hydroxypoly(oxyethylene) (100% $C_{11–15}$), should be classified as a ''Not Likely'' carcinogen based upon lack of carcinogenicity in rats and mice. As alkyl-omega-hydroxypoly(oxyethylene) (100% $C_{11—15}$) has been federally approved for use in pesticide formulations applied to growing crops, or to raw agricultural commodities after harvest, this particular minute, additional use should be of little concern to the welfare of the U.S. population.

6. *Animal metabolism.* The absorption, distribution, metabolism and excretion of alkyl-omega-hydroxypoly(oxyethylene) (100% $C_{11–15}$) is well understood in mammals. Pharmacokinetic data indicate rapid metabolism and excretion of alkylphenols, which is consistent with the low toxicity of nonylphenol. Current research confirms, that single doses of nonylphenol (5 or 200 mg/kg) are rapidly excreted, and that nonylphenol does not accumulate in the tissues of rats. It has also been proven that the liver and kidney of female rats were able to clear nonoxynol labeled with ^{14}C in the ethylene oxide chain within 48 hours. Similarly, it has been shown that structurally related alkylphenol, octylphenol, was rapidly excreted (half-life of approximately 5 hours) by first-pass hepatic metabolism via glucuronide conjugation. Octylphenol toxicokinetics after repeated administration was investigated, in male Wistar rats receiving daily gavage administrations of 50 or 200 mg octylphenol/kg body weight for 14 consecutive days. Profiles of octylphenol blood concentration vs time determined on day 1 and day 14 were similar, indicating that repeated oral gavage administration did not lead to increased blood concentrations. Only doses which saturated the metabolic capacity of the liver, (<200 mg/kg/day for 14–days), resulted in measurable concentrations of octylphenol in the tissues (primarily the fat). Another group of rats received octylphenol via drinking water saturated with octylphenol (8 ppm) over a period of 28–days. Octylphenol was not detected in any blood sample from animals treated via drinking water.

7. *Endocrine disruption.* A two-generation rat reproductive study to determine reproductive toxicity of octylphenol, a structurally similar product, was conducted. Five groups of rats were administered octylphenol at dose levels of 0, 0.2, 20, 200, and 2,000 ppm. No effects in reproductive parameters, testes, prostate, or ovary weights or morphology, on sperm counts, motility, morphology, production, or on estrous cyclicity were observed. No estrogen-like effects were evident.

In a 90–day rat feeding study, para-nonylphenol (primary breakdown product) was administered to four groups of rats at dietary concentrations of 0, 15, 50, and 150 milligram/kilogram/day (mg/kg/day). There were 25 rats/sex/group in the control and high dose groups and 15 rats/sex/group in the low and mid dose groups. Ten of the 25 rats/sex in the control and high dose groups were designated as recovery animals and were maintained on control diets for 4 weeks after completion of the 90–day exposure period to assess the reversibility of any effects which might be observed. Estrous cyclicity was monitored using vaginal cytology during week 8 of the study, and sperm count, motility and morphology were evaluated at termination. No changes were observed for estrous cycling, sperm evaluations, or effects on endocrine organs. Para-nonylphenol, therefore, did not manifest any estrogen-like activity as measured in these parameters at dietary concentrations as high as 150 mg/kg/day. Safe Materials, Inc., therefore, does not expect alkyl-omega-hydroxypoly(oxyethylene) (100% $C_{11–15}$) to exhibit any estrogen-like activity.

C. Aggregate Exposure

1. *Dietary exposure.* Alkyl-omega-hydroxypoly(oxyethylene) (100% $C_{11–15}$), is proposed as a nematicide and fungicide for use on cotton. EPA has exempted from the requirements of a tolerance under 40 CFR 180.1001(c) the residues of alpha-sec-alkyl($C_{11–15}$)-omega-hydroxypoly(oxyethylene) when used as an inert ingredient in pesticide formulations, that may be applied to growing crops or raw agricultural commodities after harvest. 21 CFR 173.315 permits use as a surface active agent for washing sugar beets prior to the slicing operation at a level not to exceed 3 ppm. 21 CFR 178.3400, allows use as an emulsifier and/or surface active agent in the manufacture of articles or components of articles

intended for use in producing, manufacturing, packing, processing, preparing, treating, packaging or holding food. 21 CFR 181.30 permits the use in the manufacture of paper and paperboard products for use in food packaging.

The **Federal Register**, of July 7, 1995 (60 FR 35396), announced the reclassification of a number of inert ingredients from List 3 to List 4B (minimal risk). EPA included alpha-sec-alkyl($C_{11–15}$)-omega-hydroxypoly(oxyethylene) among those substances on List 4B indicating:

- ''On behalf of the Office of Pesticide Programs, these substances were reviewed by the Structure Activity Team of EPA's Office of Pollution Prevention and Toxics, with each judged to be of low concern for potential human health and/or environmental effects.''
- ''These inert ingredients were evaluated by the Office of Pesticide Program's Inert Review Group and determined to be of minimal risk.''
- ''A list of these inert ingredients proposed for reclassification was provided to EPA's Office of Water and to the FDA's Center for Food Safety and Applied Nutrition for comment; no adverse comments were received.''

i. *Food.* As 61 companies currently have 135 different pesticide products approved by the EPA containing alpha-sec-alkyl($C_{11–15}$)-omega-hydroxypoly(oxyethylene) at varying concentrations approved for various use sites including food crops, we believe that the approval of this petition, adding the use of cotton would pose minimal additional risk to the U.S. population.

The addition of alpha-sec-alkyl($C_{11–15}$)-omega-hydroxypoly(oxyethylene) to the list of substances considered exempt, from the requirement of a tolerance when used as an active ingredient would merely acknowledge the fact that this product is safe to humans and the environment.

The addition of the expanded use on cotton is not expected to significantly increase the dietary exposure to this compound.

ii. *Drinking water.* The product has been shown to readily biodegrade and, therefore, is not likely to be present in potable water supplies. The standard wastewater treatment systems as they exist in the United States are able to treat surfactants effectively, and there is no evidence of accumulation of nonylphenol, or other structurally similar products in the aquatic environments.

A risk assessment of nonylphenol and its ethoxylates (a degradation product of the proposed chemical, in U.S. river water and sediment was conducted. A survey of those river reaches most likely to contain nonylphenol and its ethoxylate residues was conducted based on a random sample of a subset of EPA River Reach File defined by certain selection criteria. Applying enhanced analytical techniques, little or no nonylphenol or nonylphenoethoxylate was found in river water at most locations: median 0.00008 milligrams per liter (mg/L), 95th percentile 0.00027 mg/L.

A study of nonylphenol polyethoxy carboxylate (NPEC) metabolites of nonionic surfactants in U.S. paper mill effluents, municipal sewage treatment plant effluents and river waters reported similar findings. Paper mill effluents typically contained less than 100 µg/L NPECs and NPEC concentrations in effluents from sewage treatment plants ranged from 140 to 270 micrograms/Liter (µg/L). Based upon animal metabolism studies, these low level concentrations in drinking water would be rapidly excreted by humans.

2. *Non-dietary exposure.* Alkyl-omega-hydroxypoly(oxyethylene) (100% $C_{11–15}$) and structurally, similar surfactants are widely used in various industry, institutional, and household applications. U.S. production exceeded 500 million pounds in 1990. Industrial uses (55% of total volume) included manufacture of plastics, textiles, paper and agricultural chemical products. Institutional applications (30% of total volume) include vehicle cleaning, commercial laundry products, and hard surface cleaners. Personal care products, contraceptives, cosmetics, and household laundry products account for the majority of household applications (15% of total volume).

Given the wide spread use of this group of compounds, the additional exposure resulting from granting this petition is not expected to significantly alter the risk profile.

D. Cumulative Effects

There is a wide range of structurally similar compounds that are used in many products to which the U.S. population is exposed. Safe Materials, Inc. is unaware of any cumulative effects occurring from such uses. Further, the use of the product that is subject to the tolerance exemption petition is not likely to significantly increase daily exposure to this class of compounds. Therefore, a cumulative risk assessment was not done for this chemical.

E. Safety Determination

1. *U.S. population.* In the **Federal Register** of July 7, 1995 (60 FR 35396), which moved alpha-sec-alkyl($C_{11–15}$)-omega-hydroxypoly(oxyethylene) from List 3 to List 4B (minimal risk) EPA stated:

- ''On behalf of the Office of Pesticide Programs, these substances were reviewed by the Structure Activity Team of EPA's Office of Pollution Prevention and Toxics, with each judged to be of low concern for potential human health and/or environmental effects.''
- ''These inert ingredients were evaluated by the Office of Pesticide Program's Inert Review Group and determined to be of minimal risk.''
- ''A list of these inert ingredients proposed for reclassification, was provided to EPA's Office of Water and to the FDA's Center for Food Safety and Applied Nutrition for comment; no adverse comments were received.''

Expansion of the uses of the product to cotton as an active ingredient, is not likely to significantly increase the U.S. population's exposure to the product and related compounds. Therefore, there is reasonable certainty that no harm to the U.S. population will result from the use described.

2. *Infants and children.* FFDCA section 408 provides that EPA shall apply an additional tenfold margin of safety, for infants and children in the case of threshold effects to account for prenatal and postnatal toxicity and the completeness of the data base, unless EPA concludes that a different margin of safety will be safe for infants and children. Margins of safety are incorporated into EPA risk assessments, either directly through the use of margin of exposure (MOE) analysis, or through using uncertainty (safety) factors in calculating a dose level that poses no appreciable risk to humans. There is no available data to indicate any additional sensitivity of infants and children to this product, or to other similar products, which have been in use for many years and for numerous uses. There are no data that suggest that there is a basis to require an additional margin of safety to be applied.

F. International Tolerances

There are no Codex Alimentarius Commission maximum residue levels established for residues of alpha-sec-alkyl($C_{11–15}$)-omega-hydroxypoly(oxyethylene).

[FR Doc. 02–9500 Filed 4–17–02; 8:45 am]

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