parameters and micropathological findings of the urinary bladder (females). The mutagenic potential of KWG 4168 N-oxide was studied *in vitro* in bacteria and mammalian cells. It did not cause mutations *in vitro* in the Ames assay, the V–79–HPRT gene mutation assay, or produce clastogenicity in the chromosome aberration assay with or without metabolic activation.

8. *Endocrine disruption*. The toxicology data base for Spiroxamine is current and complete. Studies in this data base include evaluation of the potential effects on reproduction and development, and an evaluation of the pathology of the endocrine organs following short- or long-term exposure. These studies revealed no primary endocrine effects due to Spiroxamine.

C. Aggregate Exposure

1. *Dietary exposure*. An aggregate risk assessment was conducted for all pending uses (grape, hop (domestic and imported) and banana (imported)) to assess the potential acute and chronic dietary exposure resulting from applications of Spiroxamine to these crops. Novigen Sciences, Inc.'s Dietary Exposure Evaluation Model (DEEM®) was used to estimate the chronic and acute dietary exposure.

For the acute dietary analysis, the proposed acute reference dose (aRfD) of 0.1 mg/kg/day was used. This aRfD is based on NOELs of 10 mg/kg from an acute oral toxicity and an acute neurotoxicity screening study and applying a 100–fold uncertainty factor.

For the chronic dietary analysis, the proposed chronic reference dose (cRfD) of 0.02 mg/kg/day was used. This cRfD is based on a parental toxicity NOEL of 2.13 mg/kg/day from the two-generation reproduction study and the application of a 100–fold uncertainty factor.

Results from the acute and chronic dietary exposure analyses described below demonstrate a reasonable certainty that no harm to the overall U.S. population or any population subgroup will result from the use of Spiroxamine on grape, hop and banana.

i. *Food*. An acute, Tier 1 dietary (food) risk assessment was conducted using the highest residue values and 100% crop treated. The estimated percent of the aRfD for the overall U.S. population (all seasons) at the 95 percentile is 8.5%. The most highly exposed population subgroup, non-nursing infants, had an exposure equal to 33.3% of the aRfD at the 95 percentile. These exposure estimates in are within EPA's criteria of acceptability.

A chronic, Tier 1 dietary (food) risk assessment was conducted using average residue values and 100% crop treated. The estimated percent of the cRfD for the overall U.S. population (all seasons) is 9.1%. For the most highly exposed population subgroup, children 1 to 6) years old, the exposure consumed 30.6% of the cRfD. These exposure estimates are within EPA's criteria of acceptability.

ii. *Drinking water*. No monitoring data are available for residues of Spiroxamine in ground water, and EPA has established no health advisory levels or maximum contaminant levels for residues of Spiroxamine in drinking water.

Studies show low to no soil mobility for Spiroxamine and its primary metabolites. In addition, field studies show that Spiroxamine and its degradates do not leach below the 6–inch depth level, and show very low potential to leach into ground water. Therefore, it can be concluded with reasonable certainty that no harm will result from acute or chronic aggregate exposure to Spiroxamine residues in drinking water.

2. *Non-dietary exposure*. Spiroxamine is not registered nor are registrations pending for uses that would result in non-dietary exposure.

D. Cumulative Effects

Spiroxamine belongs to a new class of chemistry know as spiroketalamines. Therefore, for this tolerance petition, it is assumed that Spiroxamine does not have a common mechanism of toxicity with other substances and only the potential risks of Spiroxamine in its aggregate exposure are considered.

E. Safety Determination

1. *U.S. population*. Based on the above aggregate food exposure estimates for the overall U.S. population (8.5% of the aRfD and 9.1% of the cRfD), the low potential for Spiroxamine and its degradates to leach into ground water, and the completeness of the toxicity data base, there is reasonable certainty that no harm to the U.S. population will result from aggregate exposure to Spiroxamine.

2. *Infants and children*. In assessing the potential for additional sensitivity of infants and children to residues of Spiroxamine, data from developmental toxicity studies in mice, rats, rabbits and a two-generation reproduction study in the rat are considered. The developmental toxicity studies are designed to evaluate adverse effects on the developing organism resulting from maternal pesticide exposure during gestation. Reproduction studies provide information relating to effects from exposure to the pesticide on the reproductive capability of mating animals and data on systemic toxicity.

Based on the above, aggregate food exposure estimates for the most highly exposed population subgroups, i.e., non-nursing infants and children (1–6 years old), consumed 33.3% and 30.6% of the aRfD and cRfD, respectively. This, in combination with the low potential for Spiroxamine and its degradates to leach into ground water, and on the completeness of the toxicity data base, there is reasonable certainty that no harm to infants and children will result from aggregate exposure to Spiroxamine.

F. International Tolerances

There are no established Codex, Canadian or Mexican MRLs for Spiroxamine.

[FR Doc. E3–00489 Filed 12–8–03; 8:45 am]

BILLING CODE 6560–50–S

ENVIRONMENTAL PROTECTION AGENCY

[OPP–2003–0362; FRL–7335–5]

Alkyl (C_{10}–C_{16}) Polyglycosides; 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 ID number OPP–2003–0362, must be received on or before January 9, 2004.

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: James Parker, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001; telephone number: (703) 308–0731; e-mail address:*parker.james@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 code 111)
- Animal production (NAICS code 112)
- Food manufacturing (NAICS code 311)
- Pesticide manufacturing (NAICS code 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–2003–0362. 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, 1921 Jefferson Davis Hwy., 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 on 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–2003–0362. 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–2003–0362. 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–2003–0362.

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, 1921 Jefferson Davis Hwy., Arlington, VA, Attention: Docket ID number OPP–2003–0362. 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: November 21, 2003.

Susan Lewis,

Acting Director, Registration Division, Office of Pesticide Programs.

Summary of Petition

The petitioner's 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 Cognis Corporation and represents the view of the petitioner. The summary may have been edited by the EPA if the terminology used was unclear, the summary contained extraneous material, or the summary unintentionally made the reader conclude that the findings reflected EPA's position and not the position 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.

Cognis Corporation

PP 4E4332

EPA has received a pesticide petition (PP 4E4332) from Cognis Corporation, 4900 Este Avenue, Cincinnati, OH 45232 proposing, pursuant to section 408(d) of the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. 346a(d), to amend 40 CFR part 180, by establishing a tolerance exemption for residues of alkyl (C_{10}–C_{16}) polyglycosides (CAS Reg. No. 110615-47-9) when used as an inert ingredient in a pesticide product. 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 metabolis.* No plant metabolism studies have been submitted in support of this petition since an exemption from tolerance is being requested. In addition, alkyl ($C_{10–16}$) polyglycosides are expected to rapidly degrade to sugars and fatty alcohols in treated plants.

2. *Analytical method.* Since the petitioner has requested a tolerance exemption, a residue analytical method for alkyl ($C_{10–16}$) polyglycosides in food crops is not required.

3. *Magnitude of residues.* Due to the very low toxicity exhibited by the alkyl polyglycosides, in either acute or sub-chronic studies, and the rapid metabolism of these substances to sugars and fatty alcohols, no field residue studies were conducted.

B. Toxicological Profile

1. *Acute toxicity.* Based on acute studies conducted with alkyl ($C_{12–14}$) polyglycosides, the acute toxicity of alkyl ($C_{10–16}$) polyglycosides is expected to be of a very low order. The acute oral LD_{50} for alkyl ($C_{12–14}$) polyglycosides is

greater than 5 gram/kilogram (g/kg) body weight and the acute dermal LD_{50} is greater than 2 g/kg body weight. Concentrations of less than 30% alkyl ($C_{12–14}$) polyglycosides are non-irritating to skin. Alkyl ($C_{12–14}$) polyglycosides are not dermal sensitizers.

2. *Genotoxicty.* Based on studies conducted with alkyl ($C_{12–14}$) polyglycosides, alkyl ($C_{10–16}$) polyglycosides are considered non-mutagenic. In the bacterial gene mutation study (Ames test), alkyl ($C_{12–14}$) polyglycosides did not cause an increase in revertants, compared to controls, with or without metabolic activation. In the *in-vitro* cytogenetic study, alkyl ($C_{12–14}$) polyglycosides did not cause an increase in chromosomal aberrations, compared to controls, with or without metabolic activation.

3. *Reproductive and developmental toxicity.* In a developmental toxicity study, test animals were treated with alkyl ($C_{12–14}$) polyglycosides, by gavage, on days 6 through 15 of gestation at doses of 0, 100, 300 and 1,000 mg/kg body weight. There were no maternal or fetal effects noted in any of the test groups. Based on this study, both the maternal and developmental no observed effect level (NOEL) for alkyl ($C_{12–14}$) polyglycosides is greater than 1,000 milligrams/kilogram (mg/kg) body weight.

4. *Subchronic toxicity.* In a sub-chronic (90–day) feeding study, test animals were treated with alkyl ($C_{12–14}$) polyglycosides at doses of 0, 250, 500 and 1,000 mg/kg body weight. The only adverse effect observed in the study, in the mid (500 mg/kg) and high dose (1,000 mg/kg) groups, was reversible dose-dependent irritation and ulceration of the mucous membranes of the forestomach. Based on this study, the no observed adverse effect level (NOAEL) is 1,000 mg/kg body weight and the NOEL is 250 mg/kg/body.

5. *Animal metabolism.* Metabolism studies conducted in the mouse with closely related alkyl polyglycosides show that the -glycosidic bond of the alkyl polyglycosides is rapidly hydrolyzed in the intestine and liver. The degradates are sugars and long-chain alcohols, which then undergo carbohydrate and lipid metabolism.

6. *Metabolite toxicology.* The metabolites of alkyl ($C_{10–16}$) polyglycosides are glucose and fatty alcohols, neither of which present any toxicity concerns.

7. *Endocrine disruption.* There is no information from studies conducted by the Cognis Corporation nor from the published literature which associates the alkyl polyglycosides with endocrine disruption.

C. Aggregate Exposure

1. *Dietary exposure.* A dietary exposure assessment for alkyl (C*10–16*) polyglycosides has not been conducted because the alkyl polyglycosides, as a class of compounds, do not present any toxicological effects of concern. In addition, alkyl ($C_{10–16}$)polyglycosides are expected to be rapidly degraded to glucose and fatty alcohols.

i. *Food.* Crop levels of alkyl (C*10–16*) polyglycosides have not been determined since a tolerance exemption is being requested. Moreover, even if residues of alkyl ($C_{10–16}$) polyglycosides do occur on food crops these residues are of little concern since the alkyl polyglycosides are practically non-toxic.

ii. *Drinking water.* Minimal, if any, residues of alkyl ($C_{10–16}$) polyglycosides are expected to occur in drinking water since alkyl polyglycosides should be rapidly (and completely) biodegraded in soils.

2. *Non-dietary exposure.* Non-dietary (residential) exposure to alkyl ($C_{10–16}$) polyglycosides from the use of this substance as an inert ingredient in pesticide products is anticipated to be insignificant since only short-term exposure will be involved and dermal absorption through the skin is expected to be minimal.

D. Cumulative Effects

No cumulative adverse effects are expected from long-term exposure to alkyl ($C_{10–16}$) polyglycosides since the only affect observed in the safety studies conducted with the alkyl polyglycosides was localized irritation.

E. Safety Determination

1. *U.S. population.* The safety studies performed with the alkyl polyglycosides clearly demonstrate that this class of compounds are practically non-toxic. The only adverse effect observed in any of the studies conducted with the alkyl polyglycosides was localized, reversible irritation of the forestomach in the sub-chronic feeding study. Consequently, the use of the alkyl ($C_{10–16}$) polyglycosides as an inert ingredient in pesticidal formulations applied to growing crops is not anticipated to result in any adverse effects.

2. *Infants and children.* There is no evidence from the safety studies sponsored by Cognis, particularly the developmental toxicity study, nor from the published literature of any unique susceptibilities of infants and/or children to alkyl polyglycoside exposure. Based on the extremely low toxicity of the alkyl polyglycosides no adverse effects on infants and/or children from the use of alkyl ($C_{10–16}$) polyglycosides as an inert ingredient in pesticidal formulations applied to growing crops is anticipated.

F. International Tolerances

There are no approved CODEX maximum residue levels (MRLs) established for residues of alkyl ($C_{10–16}$) polyglycosides.

[FR Doc. 03–30522 Filed 12–9–03; 8:45 am]

BILLING CODE 6560–50–S

ENVIRONMENTAL PROTECTION AGENCY

[OPP–2003–0361; FRL–7336–2]

Bacillus thuringiensis Cry2Ab2 Protein and the Genetic Material Necessary for its Production in Cotton; Notice of Filing a Pesticide Petition to Amend a Tolerance Exemption 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 ID number OPP–2003–0361, must be received on or before January 9, 2004.

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: Leonard Cole, Biopesticides and Pollution Prevention Division (7511C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001; telephone number: (703) 305–5412; e-mail address: *cole.leonard@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)