mating animals and on various parameters associated with the well being of offspring. FFDCA section 408 provides that EPA may apply an additional safety factor (SF) for infants and children in the case of threshold effects to account for prenatal and postnatal toxicity and the completeness of the data base. Based on the current toxicological data requirements, the data base for penoxsulam relative to prenatal and postnatal effects for children is complete. Overall, penoxsulam had no effect on reproduction or embryo-fetal development at any dosage tested. No quantitative or qualitative susceptibility was seen following prenatal and postnatal exposures. In a rabbit developmental toxicity study, effects on *in-utero* survival were observed only at a dose level where clear maternal toxicity was seen. In a 2–generation reproductive toxicity study in rats, no effects on reproductive performance were observed and effects on neonatal growth were seen only at a dose level where parental toxicity was seen. In addition, the no observed adverse effect level (NOAEL) in the chronic rat study (5 mg/kg/day), used to calculate the chronic RfD (0.05 mg/kg/day), is already lower than the acute NOAEL from the rabbit developmental study (25 mg/kg/day). Therefore, an additional FQPA uncertainty factor (UF) is not needed and the RfD at 0.05 mg/kg/day is appropriate for assessing risk to infants and children. Using the conservative exposure assumptions previously described, the percent RfD utilized by the potential exposure to residues of penoxsulam on rice is <0.1% for non-nursing infants, the population subgroup predicted to be potentially the most highly exposed. Risk for developmental toxicity from acute exposure to penoxsulam was evaluated for pregnant females (13+ years old). The high-end margin of exposure value of >300,000 (0.03% of acute RfD) is well above the acceptable 100. Therefore, based on the completeness and reliability of the toxicity data and the conservative exposure assessment, Dow AgroSciences LLC concludes with reasonable certainty that no harm will result to infants and children, females 13+ years old and the prenatal development of infants from the aggregate exposure to penoxsulam residues.

F. International Tolerances

There are no Codex maximum residue levels established for residues of penoxsulam on/in rice and rice.

[FR Doc. 03–20015 Filed 8–5–03; 8:45

BILLING CODE 6560–50–S

ENVIRONMENTAL PROTECTION AGENCY

[OPP–2003–0152; FRL–7316–8]

Yeast Extract Hydrolysate from Saccharomyces Cerevisiae; 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 indentification (ID) number OPP–2003–0152, must be received on or before September 5, 2003.

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: Diana M. Horne, Biopesticides and Pollution Prevention Division (7511C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001; telephone number: (703) 308–8367; e-mail address: *horne.diana@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–2003–0152. 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 EPA's 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.1. 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–2003–0152. 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–2003–0152. 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–2003–0152.

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–2003–0152. 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 commodites 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 recordkeeping requirements.

Dated: July 28, 2003.

Janet L. Andersen,

Director, Biopesticides and Pollution Prevention 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 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.

Interregional Research Project Number 4

Morse Enterprises Limited

PP 2E6383

EPA has received a pesticide petition (PP 2E6383) from Interregional Research Project Number 4 (IR–4), Technology Centre of New Jersey, Rutgers University, 681 U.S. Highway #1 South, North Brunswick, NJ 08902–3390 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 for the biochemical pesticide yeast extract hydrolysate from *Saccharomyces cerevisiae* in or on all food commodities.

Pursuant to section 408(d)(2)(A)(i) of the FFDCA, as amended, Morse Enterprises Limited has submitted the following summary of information, data, and arguments in support of their pesticide petition. This summary was prepared by Morse Enterprises Limited and EPA has not fully evaluated the merits of the pesticide petition. The summary may have been edited by 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.

A. Product Name and Proposed Use Practices

Yeast extract hydrolysate from *Saccharomyces cerevisiae*, the active ingredient, is mixed with micronutrients to formulate the end use product known as KeyPlex 350. KeyPlex 350 is applied at 1 to 3 quarts per acre as a foliar spray. Applications are generally repeated at 14 to 21–day intervals. KeyPlex 350 aids in the prevention of certain plant diseases, such as post-bloom fruit drop and greasy spot diseases of citrus, and bacterial leaf spot disease of tomatoes.

B. Product Identity/Chemistry

1. *Identity of the pesticide and corresponding residues*. Yeast extract hydrolysate from *Saccharomyces cerevisiae* is mixed with micronutrients to formulate the end use product known as KeyPlex 350. KeyPlex 350 contains 0.063% yeast extract hydrolysate from *Saccharomyces cerevisiae* in combination with a micronutrient fertilizer. KeyPlex 350 is the end use product. Hereinafter the term ''yeast extract hydrolysate'' is used to mean yeast extract hydrolysate from *Saccharomyces cerevisiae*.

2. *Magnitude of residue at the time of harvest and method used to determine the residue*. This section is not applicable, as this notice proposes an exemption from the requirement of a tolerance.

3. *A statement of why an analytical method for detecting and measuring the levels of the pesticide residue are not needed*. An analytical method for residues is not applicable, as this notice proposes an exemption from the requirements of a tolerance.

C. Mammalian Toxicological Profile

1. *Acute toxicity*. An acute oral toxicity study (OPPTS Harmonized Guideline 870.1100) conducted in rats with the end use product KeyPlex 350 containing 0.063% yeast extract hydrolysate showed that KeyPlex 350 at 5,000 milligrams/kilogram (mg/kg) is not toxic to rats. Furthermore, no test material-related lesions were revealed on the macroscopic necropsy examinations conducted at termination of the test.

2. *A primary dermal irritation study*. (OPPTS Harmonized Guideline 870.2500) conducted in rabbits with the end use product KeyPlex 350 showed that KeyPlex 350 only caused mild or very slight irritation to the skin of 1 of 6 rabbits.

3. *A primary eye irritation study*. (OPPTS Harmonized Guideline 870.2400) conducted in rabbits with the end use product KeyPlex 350 showed that KeyPlex 350 was only moderately irritating. Conjunctiva was noticed in all rabbits 1–hour after treatment; all symptoms cleared by 72 hours post-treatment.

Yeast extracts are considered generally recognized as safe (GRAS) and are approved by the Food and Drug Administration (FDA) as direct food additives (21 CFR 184.1983). Yeast extracts are used as a flavor improver in hundreds of foods at 0.1% to 2% in the final consumed product. The other ingredients in KeyPlex 350 are already approved as inert materials or are common fertilizer ingredients.

D. Aggregate Exposure

1. *Dietary exposure*—i. *Food*. The potential dietary exposure of the general public to yeast extract hydrolysate residues resulting from the use of KeyPlex 350 on food crops is not expected to be significant. The public is exposed to yeast extract through its use as a direct food additive.

ii. *Drinking water*. It is not anticipated that residues of yeast extract hydrolysate will occur in drinking water due to its low application rate.

2. *Non-dietary exposure*. There may be non-dietary exposure to yeast extract hydrolysate from non-pesticidal uses of yeast extracts, but significantly increased non-dietary exposure and non-occupational exposure from yeast extract hydrolysate when used as a pesticide is not expected.

E. Cumulative Exposure

Because of the lack of toxicity of an 0.063% solution of yeast extract hydrolysate and because of the fact that yeast extracts are already present in the diet at 0.1% to 2% in hundreds of food products, no cumulative mode of exposure is expected for yeast hydrolysate and other substances having a common mode of action.

F. Safety Determination

1. *U.S. population*. The use of products containing yeast extract hydrolysate, which lacks toxicity and is used in such low concentrations, is compatible with EPA's objectives to register reduced risk pesticides. Based on its lack of toxicity and the fact that yeast extracts are already present in the diet, there is reasonable certainty that no harm will result from aggregate exposure of the U.S. population, including infants and children, to residues of yeast extract hydrolysate. This includes all anticipated dietary exposures and all other exposures for which there is reliable information. Yeast extract hydrolysate is applied at low rates and with its lack of toxicity and its history of safe use, it does not pose a safety concern.

2. *Infants and children*. Based on the lack of toxicity of yeast extract hydrolysate, there is a reasonable certainty that no harm to children or adults will result from aggregate exposure to yeast hydrolysate. Exempting yeast extract hydrolysate from the requirement of a tolerance should pose no significant risk to humans.

G. Effects on the Immune and Endocrine Systems

Yeast extract hydrolysate is a naturally occurring biochemical. To date there is no evidence to suggest that yeast extract hydrolysate functions in a manner similar to any known hormone, or that it acts as an endocrine disruptor.

H. Existing Tolerances

There are no existing tolerances for yeast extract hydrolysate in the United States.

I. International Tolerances

There are no known approved Codex maximum residue levels established for residues of yeast extract hydrolysate.

[FR Doc. 03–19916 Filed 8–5–03; 8:45 am]

BILLING CODE 6560–50–S

ENVIRONMENTAL PROTECTION AGENCY

[OPP–2003–0240; FRL–7319–3]

Cyromazine; Notice of Filing of Pesticide Petitions 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 pesticide petitions 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–2003–0240, must be received on or before September 5, 2003.

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: Shaja R. Brothers, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001; telephone number: (703) 308–3194; e-mail address: *brothers.shaja@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:

- Industry (NAICS 111, 112, 311, 32532), e.g., Crop production, Animal production, Food manufacturing, and 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 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 identification (ID) number OPP–2003–0240. 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 in paper, will be made available for public viewing in EPA's electronic public docket as EPA receives them and