

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. Offer alternative ways to improve the registration activity.
7. Make sure to submit your comments by the deadline in this notice.
8. 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. Registration Applications

EPA received applications as follows to register pesticide products containing active ingredients not included in any previously registered products pursuant to the provision of section 3(c)(4) of FIFRA. Notice of receipt of these applications does not imply a decision by the Agency on the applications.

#### *Products Containing Active Ingredients Not Included in Any Previously Registered Products*

1. *File symbol:* 73512-E. *Applicant:* Interregional Research Project 4 (IR-4), Rutgers University, Technology Center of New Jersey, 681 U.S. Highway 1 South, North Brunswick, NJ 08902-3390 on behalf of Morse Enterprises Limited,

Inc., Brickell East, Floor Ten, 151 South East 15 Road, Miami, FL 33129. *Product name:* Yeast Hydrolysate Liquid. *Active ingredient:* Yeast extract hydrolysate from *Saccharomyces cerevisiae* at 2.5%. *Proposed classification/Use:* None. Manufacturing use product for management of plant diseases.

2. *File symbol:* 73512-R. *Applicant:* Interregional Research Project 4 (IR-4). *Product name:* KeyPlex 350. *Active ingredient:* Yeast Extract hydrolysate from *Saccharomyces cerevisiae* at 0.063%. *Proposed classification/Use:* None. For use in management of plant diseases.

#### List of Subjects

Environmental protection, Pesticides and pest.

Dated: July 28, 2003.

**Janet L. Andersen,**

*Director, Biopesticides and Pollution Prevention Division, Office of Pesticide Programs.*

[FR Doc. 03-19917 Filed 8-5-03; 8:45 am]

**BILLING CODE 6560-50-S**

## ENVIRONMENTAL PROTECTION AGENCY

[OPP-2003-0261; FRL-7320-4]

### Penoxsulam; 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-2003-0261, 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:**

Joanne Miller, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; telephone number: (703) 305-6224; e-mail address: [miller.joanne@epa.gov](mailto:miller.joanne@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 113)
- 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 identification (ID) number OPP-2003-0261. 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. 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-2003-0261. 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](mailto:opp-docket@epa.gov), Attention: Docket ID Number OPP-2003-0261. 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-2003-0261.

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-2003-0261. 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

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

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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 contain 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.

**Debra Edwards,**

*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 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.

#### **Dow AgroSciences LLC**

*PP 3F6542*

EPA has received a pesticide petition (3F6542) from Dow AgroSciences LLC, 9330 Zionsville Road, Indianapolis, IN 46268 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 2-(2,2-difluoroethoxy)-6-trifluoromethyl-N-(5,8-dimethoxy [1,2,4]triazolo-1,5c pyrimidin-2-yl) benzenesulfonamide, (penoxsulam, DE-638) in or on the raw agricultural commodity rice raw agricultural commodities (RACS) and rice processed products at 0.01 part per million (ppm) for rice grain, 0.05 ppm for rice straw, 0.01 ppm for rice hull, 0.01 ppm for rice bran, and 0.01 ppm for polished rice. 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 nature of residue study in rice, treated with <sup>14</sup>C-labeled DE-638 (2-position on the triazolopyrimidine ring or uniformly labeled in the phenyl ring) at 100 grams (g/ha), demonstrated that no significant residues (0.003–0.022 ppm) were found in mature straw and grain. The residues were fractionated by reversed-phase high performance liquid chromatography (HPLC) and consisted of DE-638, 5-OH DE-638 (identified by retention time), and two unidentified peaks. Each component was <0.01 µg/g (DE-638 equivalents). Based on the plant metabolism studies, the tolerance expression is the parent, penoxsulam.

Metabolism studies in livestock animals with <sup>14</sup>C-labeled DE-638 (2-position on the triazolopyrimidine ring or uniformly labeled in the phenyl ring) at a concentration equivalent to about 10 ppm in the diet indicated that approximately 99% of the administered dose was eliminated in the excreta. The low levels of residues (0.002–0.07 ppm) in fat and edible tissues, milk or eggs demonstrate that residues due to DE-

638 would not accumulate in the animals. Additionally, the dose levels in these studies are about 200 to 1,000 times higher than the theoretical maximum exposure in the animal diet of rice commodities treated with DE-638, therefore, livestock feeding studies are not considered necessary.

A bioconcentration study on crayfish was conducted to determine the residues in edible tissues and estimate the bioconcentration factor. Crayfish (*Procambarus clarkii*) were exposed for 14 days to <sup>14</sup>C-DE-638 under flow-through conditions at an average exposure concentration of 494 µg/L ( $C_w$ ), equivalent to approximately 10x the initial estimated environmental concentration (EEC) based on the maximum application rate of 50 grams active ingredient/ha and one hectare rice paddy with 10 centimeters (cm) depth water.

Plateau of residues in crayfish occurred within 5 days following initiation of exposure with residues in edible tissues reaching an average steady-state concentration of 0.009 µg/g ( $C_f$ ). The bioconcentration factor ( $C_f/C_w$ ) was estimated to be <0.1 milligram per liter/gram (mg/L/g), indicating that penoxsulam has very low potential to bioconcentrate in edible tissues of crayfish. Based on the very low residues of <0.01 µg/g (method limit of detection (LOD) is 0.003 µg/g) in edible tissues of crayfish exposed to 10x the peak EEC, no tolerance in crayfish is required.

2. *Analytical method.* An analytical method has been developed and validated to determine the residues of penoxsulam in rice grain, straw, and processed products. The method was based on liquid chromatography with positive ion electrospray tandem mass spectrometry molecular size (LC/MS/MS) with LOD of 0.002 µg/g and limit of quantitation (LOQ) of 0.01 µg/g. The method has been successfully validated by an independent laboratory.

#### *B. Toxicological Profile*

1. *Acute toxicity.* The acute toxicity of penoxsulam is considered low. The acute oral and dermal LD<sub>50s</sub> were greater than 5,000 milligrams/kilogram (mg/kg), while the acute inhalation LC<sub>50</sub> was greater than the highest attainable aerosol concentration (3.50 mg/L). Only very slight, transient dermal irritation was seen, and mild eye irritation was noted. Penoxsulam was negative for skin sensitization in a Magnusson and Kligman maximization test involving intradermal injection of penoxsulam with an adjuvant.

2. *Genotoxicity.* Penoxsulam was negative for genotoxicity when tested in *in vitro* and *in vivo* systems.

3. *Reproductive and developmental toxicity.* Penoxsulam did not have any effect on reproductive parameters at dose levels that induced treatment-related effects in parental rats. At the highest dosage tested (HDT) (300 mg/kg/day), body weights and weight gains in both males and females were depressed, liver and/or kidney weights were increased, and histologic changes were noted in the liver (males) and kidneys (females). At 100 mg/kg/day, increased liver weights were recorded in males, with no histologic correlate, and histologic changes noted in the kidneys of females. Transient decreases in pup body weights were seen at the HDT, but dietary concentrations were targeted for adults and consumption of treated diets by the pups resulted in dose levels to the pups approximately 3-fold higher than in adults. A teratogenic potential was not demonstrated for penoxsulam in either rats or rabbits.

4. *Subchronic toxicity.* Dietary exposure to penoxsulam identified the liver and/or urinary tract (kidneys and bladder) as target organs in rats, mice, and dogs following a 4-week and 13-week administration. Effects on the liver were reflected in increased liver weights and hepatocellular hypertrophy, but these effects were not associated with increases in mixed function oxidase (MFO) enzyme activity. Effects noted in the kidneys included crystal deposition, most likely from precipitation of penoxsulam from the urine, with resultant irritation, inflammation, and hyperplasia of renal pelvic transitional epithelium. Other than the crystal deposition in the kidneys, all effects following subchronic exposure to rats appeared to be reversible. Very high doses were associated with significant decreases in body weight, weight gain, and feed consumption.

5. *Chronic toxicity.* Chronic exposure in the dog indicated that the renal effects were not exacerbated with long-term exposure. Following long-term exposure in rats, the kidneys and urinary bladder were the primary target organs. Histologic changes seen at the end of 2 years of exposure consisted of inflammation and hyperplasia of the renal pelvic transitional epithelium, crystal deposition in the kidneys and urinary bladder, and hyperplasia of the mucosa of the urinary bladder. In the mouse, the liver was the primary target organ, and histologic changes consisted of hepatocellular hypertrophy. There were no treatment-related increases in tumors in either rats or mice. The incidence of mononuclear cell leukemia

(Fischer rat leukemia) was increased in all groups of treated male rats compared to the concurrent controls. However, the incidences in the treated groups were identical across a 50-fold increase in dosage, and well within the range of control values reported in the literature.

Using the Guidelines for Carcinogen Risk Assessment published September 24, 1986 (51 FR 33992), it is proposed that penoxsulam be classified as Group E for carcinogenicity (no evidence of carcinogenicity) based on the results of carcinogenicity studies in two species. Dow AgroSciences LLC believes there was no evidence of carcinogenicity in an 18-month mouse feeding study and a 24-month rat feeding study at all dosages tested.

6. *Animal metabolism.* Orally administered penoxsulam is rapidly absorbed, excreted and extensively metabolized in both male and female rats, thus, indicating that penoxsulam is not expected to accumulate in biological systems. The majority of the residue was associated with the parent, penoxsulam. Several metabolites were also observed but the vast majority were <1% of the administered dose. The major route of metabolism involves O-demethylation, producing the OH-Penoxsulam metabolite followed by conjugation.

7. *Metabolite toxicology.* A metabolism study with penoxsulam in rice revealed the presence of the parent, a desmethylation metabolite (5-OH-penoxsulam), and two other polar metabolites, which may represent conjugates of the desmethylated metabolite. The 5-OH-penoxsulam metabolite and its glucuronide and glutathione conjugates have also been identified in the plasma and liver of rats; therefore, plant metabolites are considered of little toxicological concern.

8. *Neurotoxicity.* Penoxsulam has been shown to have no neurotoxicologic potential based on acute and subchronic studies.

9. *Endocrine disruption.* Penoxsulam did not have any effects on endocrine organs or tissues in mice, rats or dogs in any of the studies conducted. There were no indications of effects on fetal development in either rats or rabbits, or on reproductive performance in rats. Based on the lack of any effects on the endocrine system, penoxsulam is not considered an endocrine disrupter.

#### C. Aggregate Exposure

*Dietary exposure.* Based on the rapid degradation of penoxsulam, no surface water or ground water contamination is expected. This agrees with EPA Tier I modeling carried out on penoxsulam. Therefore, drinking water will not be a

significant route of exposure. Dietary exposure is very low as previously mentioned. In addition, a rotational crop study showed no carryover of penoxsulam related residues in any representative test crop. There are no residential uses for this compound. As a result, the only potential for exposure is dietary, which is acceptable. Therefore, aggregation of exposures is not necessary.

#### D. Cumulative Effects

Currently, no methodologies are available to resolve the complex scientific issues concerning common mechanism of toxicity and cumulative exposure and risk. EPA has begun a pilot process to study this issue further through the examination of particular classes of pesticides. Thus, Dow AgroSciences LLC believes it is appropriate to consider only the potential risks of penoxsulam in its exposure assessment.

#### E. Safety Determination

1. *U.S. population.* Using the conservative exposure assumptions described above, and based on the completeness and reliability of the toxicity data, the aggregate exposure to penoxsulam, as determined under the guidance of the FQPA, will utilize no more than 0.1% of the RfD from the dietary exposure for all subgroups of the U.S. population. Generally and under the Food Quality Protection Act (FQPA), EPA has no concern for exposures below 100% of the reference dose (RfD) because the RfD represents the level at or below which daily dietary exposure over a lifetime will not pose appreciable risks to human health. Additionally, the calculated drinking water levels of concern (DWLOC) was substantially higher than the potential penoxsulam concentration in water. Therefore, there is a reasonable certainty that no harm will result to the general U.S. population from aggregate exposure to penoxsulam residues from proposed use.

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

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 identification (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](mailto: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)
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- 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.

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