

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.

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## 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)
- 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