section 408(b)(2)(D), EPA has reviewed the available scientific data and other relevant information in support of this action. Based on the information and data considered, the Agency has determined that use of this pesticide as a SAR inducer will not pose a dietary risk under reasonably foreseeable circumstances.

Accordingly, EPA concludes that, in amending 40 CFR part 180, to establish the exemptions as proposed, there is a reasonable certainty that no harm to the general population, including infants and children, will result from aggregate exposure to the pesticide chemical residues of the subject active ingredient, when used as a SAR inducer. The safety of infants and children is supported by oral toxicity data indicating that, for the subject active ingredient, the doses must exceed 5,000 mg/kg before toxicity occurs.

F. Endocrine Disruption

The Agency has no information that suggests silicates will have an effect on the immune or endocrine system. Given the widespread presence of natural silicates such effects are highly unlikely.

G. International Tolerances

There are no CODEX, national or international, tolerance exemptions established for the subject active ingredient at this time.

[FR Doc. 05–14864 Filed 7–26–05; 8:45 am]

BILLING CODE 6560–50–S

ENVIRONMENTAL PROTECTION AGENCY

[OPP–2005–0207; FRL–7727–8]

Orthosulfamuron; 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–2005–0207, must be received on or before August 26, 2005.

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: Jim Tompkins, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001; telephone number: (703) 305–5697; e-mail address: *Tompkins.Jim@epa.gov*.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

You may be potentially affected by this action if you 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–2005–0207. 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, 1801 S. Bell St., 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 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–2005–0207. 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–2005–0207. 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–2005–0207.

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, 1801 S. Bell St., Arlington, VA, Attention: Docket ID Number OPP–2005–0207. 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 recordkeeping requirements.

Dated: July 18, 2005.

Donald R. Stubbs,

Acting Director, Registration Division, Office of Pesticide Programs.

Summary of Petition

The petitioner 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.

ISAGRO S.p.A.

PP 5F 6957

EPA has received a pesticide petition (5F 6957) from ISAGRO S.p.A.,Centro Uffici S. Siro — Fabbricato D — ALA 3, Via Caldera, 21, 20153 Milano, Italy 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 for residues of orthosulfamuron in or on the raw agricultural commodity rice, grain and rice, straw at 0.05 parts per million (ppm). 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 metabolism*. In plants, the metabolism of orthosulfamuron is adequately understood for the purposes of establishing the proposed tolerances. Trace levels of parent orthosulfamuron were the predominant residue. In addition, several identified metabolites were found at very low concentrations. All residues (parent and metabolites) found in the plant metabolism studies were also found in the animal metabolism studies. Based on the available metabolism data, parent orthosulfamuron is proposed to be considered as the residue of concern in plant matrices.

2. *Analytical method*. In plants, the residue of concern, parent orthosulfamuron, can be determined using High Pressure Liquid Chromatography (HPLC) with a Mass Spectrometer (MS) detector. The proposed limit of detection (LOD) and limit of quantitation (LOQ) for the method are 0.03 ppm and 0.05 ppm, respectively.

3. *Magnitude of residues*. For rice, a total of twenty residue trials were conducted to evaluate the magnitude of the residues of orthosulfamuron. Of the twenty trials, fourteen were conducted using the 50WDG (water dispersible granule) formulation and six were conducted using the 50WP (wettable powder) formulation. In all trials, the rice was treated with orthosulfamuron at a rate of 75 grams of active ingredient (a.i.) per hectare, which is equivalent to 0.067 pounds of a.i. per acre. No orthosulfamuron residues above the limit of detection of 0.02 ppm were found in any rice grain or straw sample treated with either the WDG or WP formulations. The rice processing study conducted at the exaggerated rate of 3X showed no detectable residues and therefore indicated no concentration in any processed rice commodities (polished rice, hulls, and bran).

B. Toxicological Profile

1. *Acute toxicity*. The acute oral LD_{50} was > 5,000 milligrams/kilogram body weight (mg/kg bw) for both male and female rats. The acute dermal LD_{50} was > 5,000 mg/kg bw for both male and female rats. The 4–hour inhalation LC_{50} was estimated to be greater than the highest technically achievable gravimetrically determined aerosol concentration of 2.19 mg per liter for male and female rats. Orthosulfamuron was non-irritating to rabbit skin, slightly irritating to rabbit eyes, and did not cause skin sensitization in guinea pigs.

2. *Genotoxicity*. Numerous mutagenicity studies were conducted with orthosulfamuron and no genotoxic effects were reported.

3. *Reproductive and developmental toxicity*. In a two generation reproduction study, rats were administered dietary concentrations of 0, 22.2, 88.6, and 354.5 mg per kilogram body weight (mg/kg bw) for males and 0, 25.6, 102.2, and 408.8 mg/kg bw for females. These dietary concentrations correspond to 0, 350/225, 1,400/900, and 5,600/3,600 ppm. The no observed effect level (NOEL) for effects in the P and F1 generation adults was considered to be 1,400/900 ppm based on increased liver and kidney weights and accompanying histopathological changes, while the NOEL for reproductive and developmental effects was considered to be 5,600/3,600 ppm based on the absence of reproductive and developmental effects, while the NOEL for pup behavior was considered to be 1400/900 ppm based on reduced locomotor activity in the F1 male offspring.

Developmental toxicity studies were conducted in female rats and rabbits. A developmental toxicity study was conducted in female rats with orthosulfamuron using dose levels administered by gavage of 0, 100, 300, and 1,000 mg/kg bw. The NOEL was established at 100 mg/kg bw for maternal toxicity based on decreased body weight gain and at 1,000 mg/kg bw based on the absence of fetal and developmental effects. In the developmental toxicity study conducted in female rabbits, the dose levels administered by gavage were 0, 25, 75, and 250 mg/kg bw. The NOEL for maternal toxicity is established at 250 mg/kg bw, while the NOEL for developmental effects is 75 mg/kg bw based on slight developmental changes.

Developmental toxicity studies showed no primary developmental toxicity and no teratogenic potential was evident.

4. *Subchronic toxicity*. 90–day feeding studies were conducted in rats and dogs. The rat study was conducted at dietary concentrations of 0, 19, 113, and 706 mg/kg bw and the dog study was conducted at 0, 150, 450, and 1,000 mg/kg bw. The NOELs were established at 113 mg/kg bw for the rat based on effects in the liver and at 150 mg/kg bw for the dog based on liver and hematological effects. In addition, a preliminary 90–day feeding study was conducted in mice at dietary concentrations of 0, 36, 187, and 865 mg/kg bw for males and 0, 47, 228, and 1,096 mk/kg bw for females. The NOEL for this study was 187 mg/kg bw for males and 228 mg/kg bw for females based on body weight gain depression.

5. *Chronic toxicity*. A two year combined rat chronic/oncogenicity study at dietary concentrations of 0, 1, 5, 500, and 1,000 mg/kg bw demonstrated a NOEL of 5 mg/kg bw based on increased thyroid, liver, and kidney toxicity. A 78–week mouse oncogenicity study conducted at dietary concentrations of 0, 100, 500, and 1,000 mg/kg bw demonstrated a NOEL of 100 mg/kg bw for males and 1,000 mg/kg bw for females. The NOEL of 100 mg/kg bw for males was based on liver effects. No evidence of oncogencity was observed in the rat or the mouse. A 52–week chronic toxicity study in dogs conducted at dietary levels of 0, 75, 300, and 1,000 mg/kg bw demonstrated a NOEL of 75 mg/kg bw based on increased liver toxicity.

6. *Animal metabolism*. The nature of the orthosulfamuron residue in animals is adequately understood. Orthosulfamuron is extensively

metabolized very quickly and eliminated from the body by fecal and urinary routes.

7. *Metabolite toxicology* . IR5878 is extensively metabolized and quickly cleared from the body. Low dose single administration was 5 mg/kg bw and high was 1,000 mg/kg bw, and repeated doses at low dose was 5 mg/kg bw. Single low and high dose, as well as repeated low dose excretion was mainly via feces. Radioactivity was almost completely excreted via urine by 24 hours post dose and via feces by 48 hours post dosing. Excretion patterns following the three dose administrations were not markedly different, and there was no difference due to sex. Metabolites included at least 9 compounds. Metabolic profiles were almost the same following single oral low and high administration, and repeated oral administration, although the amounts of some compounds were different especially between low and high doses. The metabolic profiles for males and females were the same. Identical metabolites were found both in urine and feces. The identity of metabolites found showed that IR5878 was metabolized mainly by O-demethylation yielding compound C_6, N-demethylation yielding compound C_5, O and N-demethylations yielding compound C_4 and hydrolytic cleavage of the sulfamoylurea linkage yielding compounds C_3, C_8 and C_9.

8. *Endocrine disruption*. Orthosulfamuron did not have any effects on endocrine organs or tissues except in the rat at very high doses. In addition, there were no indications of effects on fetal developmental in either rats or rabbits, or on reproductive performance in rats. Therefore, at doses likely to be encountered, orthosulfamuron is not likely to be an endocrine disruptor.

C. Aggregate Exposure

1. *Dietary exposure*. The chronic reference dose (cRfD) and the acute reference dose (aRfD) of 0.05 mg/kg bw and 1.65 mg/kg bw, respectively, were used to assess chronic and acute dietary exposure. ISAGRO has conducted Tier 1 chronic and acute risk assessments which indicate that the highest chronic and acute exposure estimates never exceed 0.13% and 0.01% (at the 95th percentile of exposure) for the chronic and acute RFDs, respectively.

i. *Food*. The chronic reference dose (cRfD) and the acute reference dose (aRfD) of 0.05 mg/kg bw and 1.65 mg/kg bw, respectively, were used to assess chronic and acute dietary exposure. ISAGRO has conducted Tier 1 chronic and acute risk assessments which indicate that the highest chronic and acute exposure estimates never exceed 0.13% and 0.01% (at the 95th percentile of exposure) for the chronic and acute RFDs, respectively.

ii. *Drinking water*. For drinking water, the FIRST model (FQPA Index Reservoir Screening Tool) was used to conservatively estimate concentrations of orthosulfamuron in surface water. The chronic and acute drinking water estimated concentrations (DWECs) estimated with the FIRST model were 0.35 ppb (chronic) and 4.8 ppb (acute). These compare very favorably to the lowest drinking water level of comparison (DWLOC) values of 500 ppb (chronic) and 16,498 ppb (acute).

2. *Non-dietary exposure*. Orthosulfamuron is currently not registered for use on any residential non-food site. Therefore, residential exposure to orthosulfamuron residues will be through dietary exposure only.

D. Cumulative Effects

There is no information currently available to indicate that toxic effects produced by orthosulfamuron are cumulative with those of any other compound.

E. Safety Determination

1. *U.S. population*. Based on the conservative exposure assumptions described above and on the completeness of the toxicology database, it can be concluded that total aggregate exposure from food and water to the U.S. population and all evaluated population subgroups from orthosulfamuron from all proposed uses will be well below the chronic and acute RfDs. EPA generally has no concerns for estimated exposures below 100% of the RfD, since the RfD represents the level at or below which daily aggregate exposure will not pose an appreciable risk to human health. Thus, ISAGRO believes it can be concluded that there is reasonable certainty that no harm will result from aggregate exposure to orthosulfamuron residues.

2. *Infants and children*. In assessing the potential for additional sensitivity of infants and children to residues of orthosulfamuron, the data from developmental toxicity studies in both the rat and rabbit and a two generation reproduction study in rats have been considered. The developmental toxicity studies evaluate potential adverse effects on the developing animal resulting from pesticide exposure to the mother during prenatal development. The reproduction study evaluates effects from exposure to the pesticide on the reproductive capability of mating animals through two generations, as well as any observed systemic toxicity.

Since none of the studies indicate the offspring to be more sensitive and all effects were secondary to severe maternal toxicity, ISAGRO believes that infants and children are protected and that an additional uncertainty factor for infants and children is not warranted.

F. International Tolerances

No CODEX maximum residue levels (MRL's) have been established for residues of orthosulfamuron on any crops at this time.

[FR Doc. 05–14606 Filed 7–26–05; 8:45 am]

BILLING CODE 6560–50–S

ENVIRONMENTAL PROTECTION AGENCY

[OPP–2005–0079; FRL–7706–4]

Notice of Availability Regarding Activity-Based Reentry Restrictions

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: To enhance transparency in the EPA's decision making, this notice announces the availability of its guidance, comments from interested parties, its response to stakeholder input, and several other documents related to the use of activity-based reentry restrictions. Based on consideration of the extensive stakeholder input, the EPA intends to continue with its case-by-case consideration in setting worker field reentry restrictions described in its 2001 guidance document.

FOR FURTHER INFORMATION CONTACT: Richard Dumas, Special Review and Reregistration Division (7508C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW, Washington, DC 20460–0001; telephone number: (703) 308–8015; fax number: (703) 308–8005; e-mail address: *dumas.richard@epa.gov*.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

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