

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:* 264-TNL. *Applicant:* Bayer CropScience, 2 T.W. Alexander Drive, Research Triangle Park, NC 27709. *Product Name:* SCALA Brand SC Pyrimethanil Fungicide. Fungicide. *Active ingredient:* Pyrimethanil at 37.4%. *Proposed classification/Use:* None. For control of plant diseases on tree nuts, bulb vegetables, grapes, stone fruits (except cherries) pome fruits, tuberous and corm vegetables, strawberries, and tomatoes.

2. *File Symbol:* 264-TNU. *Applicant:* Bayer CropScience. *Product Name:* PYRIMETHANIL Technical. Fungicide. *Active ingredient:* Pyrimethanil at 98.5%. *Proposed classification/Use:* None. For formulation of fungicides only.

3. *File Symbol:* 43813-EL. *Applicant:* Janssen Pharmaceutica, Inc., 1125 Trenton-Harbourton Road, Titusville, NJ 08560-0200. *Product Name:* PH066. Fungicide. *Active ingredient:* Pyrimethanil at 37.4%. *Proposed classification/Use:* None. For postharvest use on citrus and pome fruit.

List of Subjects

Environmental protection, Pesticides and pest.

Dated: December 20, 2002.

Debra Edwards,

Acting Director, Registration Division, Office of Pesticide Programs.

[FR Doc. 03-8 Filed 1-2-03; 8:45 am]

BILLING CODE 6560-50-S

ENVIRONMENTAL PROTECTION AGENCY

[OPP-2002-0212; FRL-7283-4]

Imazethapyr; 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 imazethapyr in or on various food commodities.

DATES: Comments, identified by docket ID number OPP-2002-0212, must be received on or before February 3, 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: 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 affected by this action if you are an agricultural producer, food manufacturer, or pesticide manufacturer. Potentially affected categories and 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 the table could also be affected. The North American Industrial Classification System (NAICS) codes have been provided to assist you and others in determining whether or not this action might apply to certain entities. If you have 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-2002-0212. 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 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-2002-0212. 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-2002-0212. 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-2002-0212.

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-2002-0212. 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: December 20, 2002.

Debra Edwards,

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.

BASF Corporation

PP 1E6268

EPA has received a pesticide petition (PP 1E6268) from BASF Corporation, P.O. Box 400, Princeton, NJ 08543-0400 proposing pursuant to section 408(d) of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. 346a(d), to amend 40 CFR part 180 by establishing an import tolerance for the sum of the residues of the herbicide imazethapyr, 2-[4,5-dihydro-4-methyl-4-(1-methylethyl)-5-oxo-1H-imidazol-2-yl]-5-ethyl-3-pyridine-carboxylic acid) as its free acid or its ammonium salt (calculated as the acid), and its metabolite 2-[4,5-dihydro-4-methyl-4-(1-methylethyl-5-oxo-1H-imidazol-2-yl)]-5-(1-hydroxyethyl)-3-

pyridinecarboxylic acid in or on the raw agricultural commodity canola seed at 0.1 part 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 support granting of the petition. Additional data may be needed before EPA rules on the petition.

A. Residue Chemistry

1. *Plant metabolism.* The qualitative nature of the residues of imazethapyr in canola is adequately understood. Based on studies conducted on soybean, edible and forage legumes, corn and canola, parent imazethapyr and common metabolite CL 288511 are the only residues of concern for tolerance setting purposes.

2. *Analytical method.* Practical analytical methods for detecting and measuring imazethapyr residues of concern in canola are submitted to EPA with this petition. The analytical methods for canola seed are based on gas chromatography and capillary electrophoresis with limits of quantitation (LOQ) of 0.05 ppm. Measurement of imazethapyr residues in canola oil and meal are accomplished by gas chromatography with LOQ of 0.05 ppm. These validated methods are appropriate for the enforcement purposes of this petition.

3. *Magnitude of residues.* A total of 13 field trials were conducted with imazethapyr and its metabolite on canola in 1992, 1993, 1994, and 1999 at several different use rates and timing intervals to represent the use patterns, conditions and areas of use of this product in Canada. Apparent residues of imazethapyr (CL 263499) and metabolite CL 288511 in all canola seed samples were below the LOQ of 0.05 ppm regardless of rate or days after treatment sampled.

B. Toxicological Profile

A complete, valid and reliable database of mammalian and genetic toxicology studies supports the proposed tolerance for imazethapyr on canola. This database was previously reviewed by EPA in support of the tolerance petitions and registration of imazethapyr on soybeans, legume vegetables, corn, alfalfa, and peanuts.

1. *Acute toxicity.* Imazethapyr technical is considered to be nontoxic (Toxicity Category IV) to the rat by the oral route of exposure. In an acute oral toxicity study in rats, the LD₅₀ value of imazethapyr technical was greater than 5,000 milligrams/kilogram body weight

(mg/kg bwt) for males and females. The results from an acute dermal toxicity study in rabbits indicate that imazethapyr is slightly toxic (Toxicity Category III) to rabbits by the dermal route of exposure. The dermal LD₅₀ value of imazethapyr technical was greater than 2,000 mg/kg bwt for both male and female rabbits. Imazethapyr technical is considered to be non-toxic (Toxicity Category IV) to the rat by the respiratory route of exposure. The 4-hour LC₅₀ value was greater than 3.27 milligram/liter (mg/L) (analytical) and greater than 4.21 mg/L (gravimetric) for both males and females.

Imazethapyr technical was shown to be non-irritating to rabbit skin (Toxicity Category IV) and mildly irritating to the rabbit eye (Toxicity Category III). Based on the results of a dermal sensitization study (Buehler), imazethapyr technical is not considered a sensitizer in guinea pigs.

2. *Genotoxicity.* Imazethapyr technical was tested in a battery of four *in vitro* and one *in vivo* genotoxicity assays measuring several different endpoints of potential genotoxicity. Collective results from these studies indicate that imazethapyr does not pose a mutagenic or genotoxic risk.

3. *Reproductive and developmental toxicity.* The developmental toxicity study in Sprague Dawley rats conducted with imazethapyr technical showed no evidence of developmental toxicity or teratogenic effects in fetuses. Thus, imazethapyr is neither a developmental toxicant nor a teratogen in the rat. The no observable adverse effect level (NOAEL) for maternal toxicity was 375 mg/kg bwt/day, based on clinical signs of toxicity in the dams (e.g., excessive salivation) at 1,125 mg/kg bwt/day. Imazethapyr technical did not exhibit developmental toxicity or teratogenic effects at maternal dosages up to and including 1,125 mg/kg bwt/day, the highest dose tested.

Results from a developmental toxicity study in New Zealand White rabbits with imazethapyr technical also indicated no evidence of developmental toxicity or teratogenicity. Thus, imazethapyr technical is neither a developmental toxicant nor a teratogen in the rabbit. The NOAEL for maternal toxicity was 300 mg/kg bwt/day, based on decreased food consumption and body weight gain, abortion, gastric ulceration and death at 1,000 mg/kg bwt/day, the next highest dose tested. The NOAEL for developmental toxicity and teratogenic effects was determined to be > 1,000 mg/kg bwt/day based on no developmental toxicity or fetal malformations associated with the administration of all doses.

The results from the 2-generation reproduction toxicity study in rats with imazethapyr technical support a NOAEL for reproductive toxicity of 10,000 ppm (equivalent to 800 mg/kg bwt/day). The NOAEL for non-reproductive parameters (i.e. decreased weanling body weights) is 5,000 ppm.

4. *Subchronic toxicity.* A short-term (21-day) dermal toxicity study in rabbits was conducted with imazethapyr technical. No dermal irritation or abnormal clinical signs were observed at dose levels up to and including 1,000 mg/kg bwt/day (highest dose tested), supporting a NOAEL for dermal irritation and systemic toxicity of 1,000 mg/kg bwt/day.

In a subchronic (13-week) dietary toxicity study in rats with imazethapyr technical, no signs of systemic toxicity were noted, supporting a NOAEL of 10,000 ppm the highest concentration tested (equivalent to 820 mg/kg bwt/day).

In a subchronic (13-week) dietary toxicity study in dogs with imazethapyr technical, no signs of systemic toxicity were noted, supporting a NOAEL of 10,000 ppm (equivalent to 250 mg/kg bwt/day), the highest concentration tested.

5. *Chronic toxicity.* A 1-year dietary toxicity study was conducted with imazethapyr technical in Beagle dogs at dietary concentrations of 0, 1,000, 5,000, and 10,000 ppm. In this study, the NOAEL for systemic toxicity was 1,000 ppm (equivalent to 25 mg/kg bwt/day), based on slight anemia, i.e., decreased red cell parameters observed at 5,000 and 10,000 ppm concentrations. No treatment-related histopathological lesions were observed at any dietary concentration, including the highest concentration tested (10,000 ppm).

In a 2-year chronic dietary oncogenicity and toxicity study in rats conducted with imazethapyr technical, the NOAEL for oncogenicity and chronic systemic toxicity was 10,000 ppm (equivalent to 500 mg/kg bwt/day), the highest concentration tested. An 18-month chronic dietary oncogenicity and toxicity study in mice with imazethapyr technical supports a NOAEL for oncogenicity of 10,000 ppm, the highest concentration tested (equivalent to 1,500 mg/kg bwt/day), and a NOAEL for chronic systemic toxicity of 5,000 ppm (equivalent to 750 mg/kg bwt/day), based on decreased body weight gain in both sexes).

EPA has classified imazethapyr as negative for carcinogenicity (evidence of non-carcinogenicity for humans) based on the absence of treatment-related tumors in acceptable carcinogenicity studies in both rats and mice.

6. *Animal metabolism.* The rat, goat, and hen metabolism studies indicate that the qualitative nature of the residues of imazethapyr in animals is adequately understood.

In three rat metabolism studies conducted with radiolabeled imazethapyr technical, the major route of elimination of the herbicide was through rapid excretion in urine and to a much lesser extent in feces. In the first study, almost 100% of the administered material was recovered in excreta within 96 hours (89–95% in urine, 6–11% in feces). The major residue in urine and feces was parent compound. Approximately 2% of the dose was metabolized and excreted as the α -hydroxyethyl derivative of imazethapyr. In the second study, the test material was rapidly and completely eliminated unchanged in the urine within 72 hours of dosing. After 24 hours, 92.1% of radioactivity was excreted in the urine with 4.67% in the feces. There was no significant bioaccumulation of radioactivity in the tissues from this rat metabolism study (< 0.01 ppm after 24 hours). In the third study, four groups treated with radiolabeled imazethapyr readily excreted > 95% of the test material in the urine and feces within 48 hours. A high percentage (97–99%) of the test material was excreted in the urine as unchanged parent, the remainder as the α -hydroxyethyl derivative of imazethapyr. For all three studies, the major route of elimination of the herbicide in rats was through rapid excretion of unchanged parent compound in urine. It is clear that imazethapyr and its related residues do not accumulate in tissues and organs.

In the goat metabolism study, parent ^{14}C -imazethapyr was dosed to lactating goats at 0.25 ppm and 1.25 ppm. Results showed ^{14}C -residues of < 0.01 ppm in milk and < 0.05 ppm in leg muscle, loin muscle, blood, fat, liver and kidney. Laying hens dosed at 0.5 ppm and 2.5 ppm with ^{14}C -imazethapyr showed ^{14}C -residues of < 0.05 ppm in eggs and all tissues (blood, muscle, skin/fat, liver and kidney).

Additional animal metabolism studies have been conducted with CL 288511 (main metabolite in treated crops fed to livestock) in both laying hens and lactating goats. These studies have been repeated to support subsequent use extensions on crops used as livestock feed items which would theoretically result in a higher dosing of imazethapyr derived residues to livestock (i.e., corn, alfalfa). In these studies, lactating goats dosed at 42 ppm of ^{14}C -CL 288511 showed ^{14}C -residues of < 0.01 ppm in milk, leg muscle, loin muscle and omental fat. ^{14}C -Residues in blood were

mostly < 0.01 ppm but reached 0.01 ppm on two of the treatment days. ^{14}C -Residue levels in the liver and kidney were 0.02 and 0.09 ppm, respectively. Laying hens dosed at 10.2 ppm of ^{14}C -imazethapyr showed ^{14}C -residues of < 0.01 ppm in eggs and all tissues (blood, muscle, skin/fat, liver and kidney). ^{14}C -imazethapyr or ^{14}C -CL 288511 ingested by either laying hens or lactating goats was excreted within 48 hours of dosing. These studies indicate that parent imazethapyr and CL 288511-related residues do not accumulate in milk or edible tissues of the ruminant.

7. *Metabolite toxicology.* Metabolism studies in soybean, peanut, corn, alfalfa, and canola indicate that the only significant metabolites are the α -hydroxyethyl derivative of imazethapyr, CL 288511 and its glucose conjugate CL 182704. The α -hydroxyethyl metabolite has also been identified in minor quantities in the previously submitted rat metabolism studies and in goat and hen metabolism studies. No additional toxicologically significant metabolites were detected in any of the plant or animal metabolism studies.

8. *Endocrine disruption.* Collective organ weight data and histopathological findings from the 2-generation rat reproductive study, as well as from the subchronic and chronic toxicity studies in three different animal species demonstrate no apparent estrogenic effects or treatment-related effects of imazethapyr on the endocrine system.

C. Aggregate Exposure

1. *Dietary exposure.* The potential dietary exposure to imazethapyr has been calculated from the proposed tolerance for use on rice and previously established tolerances for peanuts, legume vegetables, soybeans, alfalfa, endive, lettuce, and corn. This very conservative chronic dietary exposure estimate used the proposed tolerance of 0.5 ppm for rice, and tolerance values of 0.1 ppm for peanuts, 0.1 ppm for legume vegetables, 0.1 ppm for soybeans, 3.0 ppm for alfalfa, 0.1 ppm for endive (escarole), 0.1 ppm for lettuce, and 0.1 ppm for corn. In addition, these estimates assume that 100% of these crops contain imazethapyr residues. In support of this import tolerance petition, a proposed tolerance of 0.1 ppm for canola would not be expected to contribute significantly to this dietary risk assessment.

i. *Food.* Potential exposure to residues of imazethapyr in food will be restricted to intake of rice, peanuts, legume vegetables, soybeans, alfalfa (sprouts), endive, lettuce, and corn. Using the assumptions discussed above, the

Theoretical Maximum Residue Concentration (TMRC) values of imazethapyr were calculated for the U.S. general population and subgroups. Based on the tolerances given above, the TMRC values for each group are:

- 0.000419 mg/kg bwt/day for the general U.S. population;
- 0.001104 mg/kg bwt/day for all infants (< 1 year);
- 0.001298 mg/kg bwt/day for non-nursing infants;
- 0.000870 mg/kg bwt/day for children 1 to 6 years of age; and
- 0.000610 mg/kg bwt/day for children 7 to 12 years of age.

The TMRC values indicate that non-nursing infants are the most highly exposed population subgroup.

ii. *Drinking water.* As a screening-level assessment for aggregate exposure, EPA evaluates a Drinking Water Level of Comparison (DWLOC), which is the maximum concentration of a chemical in drinking water that would be acceptable in light of total aggregate exposure to that chemical. In 1990, EPA set the Reference Dose (RfD) for imazethapyr at 0.25 mg/kg bwt/day, based on the NOAEL from the 1-year dietary toxicity study in dogs of 25 mg/kg bwt/day and a 100-fold uncertainty factor. Based on the chronic RfD of 0.25 mg/kg bwt/day and EPA's default factors for body weight and drinking water consumption, the DWLOCs have been calculated to assess the potential dietary exposure from residues of imazethapyr in water. For the adult population, the chronic DWLOC was 8,735 parts per billion (ppb) and for children the DWLOC was estimated to be 2,491 ppb.

Chronic drinking water exposure analyses were calculated for imazethapyr using EPA screening models Screening Concentration in Ground Water (SCI-GROW) for ground water and Generic Expected Environmental Concentration (GENEEC) for surface water). The SCI-GROW value is 16.54 ppb and the calculated peak GENEEC value is 5.96 ppb by aerial application. For the U.S. adult population, the estimated exposures of imazethapyr residues in ground water and surface water are approximately 0.19% and 0.07%, respectively, of the DWLOC. The estimated exposures of children to imazethapyr residues in ground water and surface water are approximately 0.66%, and 0.24%, respectively, of the DWLOC. Therefore, the exposures to drinking water from imazethapyr use are negligible.

2. *Non-dietary exposure.* Imazethapyr products are not currently registered or requested to be registered for residential use; therefore the estimate of residential

exposure is not relevant to this tolerance petition.

D. Cumulative Effects

Imazethapyr is a member of the imidazolinone class of herbicides. Other compounds of this class are registered for use in the U.S. However, the herbicidal activity of the imidazolinones is due to the inhibition of acetohydroxyacid synthase (AHAS), an enzyme only found in plants. AHAS is part of the biosynthetic pathway leading to the formation of branched chain amino acids. Animals lack AHAS and this biosynthetic pathway. This lack of AHAS contributes to the low toxicity of the imidazolinone compounds in animals. BASF is aware of no information to indicate or suggest that imazethapyr has any toxic effects on mammals that would be cumulative with those of any other chemical. Therefore, for the purposes of this tolerance petition no assumption has been made with regard to cumulative exposure with other compounds having a common mode of action.

E. Safety Determination

1. *U.S. population.* The RfD represents the level at or below which daily aggregate exposure over a lifetime will not pose appreciable risks to human health. In 1990, EPA set the RfD for imazethapyr at 0.25 mg/kg bwt/day, based on the NOAEL from the 1-year dietary toxicity study in dogs of 25 mg/kg bwt/day and a 100-fold uncertainty factor. The chronic dietary exposure of 0.000419 mg/kg bwt/day for the general U.S. population will utilize only 0.2% of the RfD of 0.25 mg/kg bwt/day. EPA generally has no concern for exposures below 100% of the RfD. Due to the low toxicity of imazethapyr, an acute exposure dietary risk assessment is not warranted. The complete and reliable toxicity database, the low toxicity of the active ingredient, and the results of the chronic dietary exposure risk assessment support the conclusion that there is a "reasonable certainty of no harm" from the proposed use of imazethapyr on imidazolinone tolerant rice and canola.

2. *Infants and children.* The conservative dietary exposure estimates of all registered uses including the proposed tolerance for rice show exposures of 0.001104, 0.000440, 0.000870, and 0.000610 mg/kg bwt/day which will utilize 0.4, 0.2, 0.3, and 0.2% of the RfD for all infants (< 1 year), nursing infants, children 1-6 years, and children 7-12 years, respectively. The chronic dietary exposures for non-nursing infants, the most highly exposed subgroup, will utilize only

0.5% of the RfD. Results from the 2-generation reproduction study in rats and the developmental toxicity studies in rabbits and rats indicate no increased sensitivity to developing offspring when compared to parental toxicity. These results also indicate that imazethapyr is neither a developmental toxicant nor a teratogen in either the rat or rabbit. Therefore, an additional safety factor is not warranted, and the RfD of 0.25 mg/kg bwt/day, which utilizes a 100-fold safety factor is appropriate to ensure a reasonable certainty of no harm to infants and children.

F. International Tolerances

There are no Codex maximum residue levels established or proposed for residues of imazethapyr on canola.

[FR Doc. 03-7 Filed 1-2-03; 8:45 am]

BILLING CODE 6560-50-S

ENVIRONMENTAL PROTECTION AGENCY

[FRL-7435-5]

Proposed CERCLA Section 122(h) Administrative Agreement for Recovery of Past Costs for the Johnstown Landfill Site, Town of Johnstown, Fulton County, NY

AGENCY: Environmental Protection Agency.

ACTION: Notice; request for public comment.

SUMMARY: In accordance with section 122(i) of the Comprehensive Environmental Response, Compensation, and Liability Act of 1980, as amended ("CERCLA"), 42 U.S.C. 9622(i), notice is hereby given by the U.S. Environmental Protection Agency ("EPA"), Region II, of a proposed administrative agreement pursuant to section 122(h) of CERCLA, 42 U.S.C. 9622(h), for recovery of past response costs concerning the Johnstown Landfill Site ("Site") located in the Town of Johnstown, Fulton County, New York. The settlement requires the settling parties, the City of Johnstown, New York; Gloversville-Johnstown Joint Sewer Board; Milligan & Higgins, Division of Hudson Industries; Simco Leather Corporation; Johnstown Leather Corporation; Crescent Leather Finishing Co., Inc.; and Pearl Leather Finishers, Inc., to pay the sum total of \$202,125 in reimbursement of EPA's past response costs at the Site. The settlement includes a covenant not to sue the settling parties pursuant to section 107(a) of CERCLA, 42 U.S.C. 9607(a), in exchange for their payment of monies. For thirty (30) days following