ENVIRONMENTAL PROTECTION AGENCY

[PF–936; FRL–6554–3]

Notice of Filing a Pesticide Petition to Establish a Tolerance for Certain Pesticide Chemicals in or on Food

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: This notice announces the amendment of a pesticide petition (PP7E4920), proposing the establishment of regulations for residues of a certain pesticide chemical in or on various food commodities.

DATES: Comments, identified by docket control number PF–936, must be received on or before May 19, 2000.

ADDRESSES: Comments may be submitted by mail, electronically, or in person. Please follow the detailed instructions for each method as provided in Unit I.C. of the **SUPPLEMENTARY INFORMATION.** To ensure proper receipt by EPA, it is imperative that you identify docket control number PF–936 in the subject line on the first page of your response.

FOR FURTHER INFORMATION CONTACT: By mail: Treva C. Alston, Registration Support Branch, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, Ariel Rios Bldg., 1200 Pennsylvania Ave., NW., Washington, DC 20460; telephone number: (703) 308–8373; e-mail address: alston.treva@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:

Categories	NAICS codes	Examples of potentially affected entities
Industry	111 112 311 32532	Crop production Animal production Food manufacturing Pesticide manufacturing

This listing is not intended to be exhaustive, but rather provides a guide for readers regarding entities likely to be affected by this action. Other types of entities not listed in 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 Additional Information, Including Copies of this Document and Other Related Documents?

1. *Electronically.* You may obtain electronic copies of this document, and certain other related documents that might be available electronically, from the EPA Internet Home Page at http://www.epa.gov/. To access this document, on the Home Page select ''Laws and Regulations'' and then look up the entry for this document under the ''**Federal Register**—Environmental Documents.'' You can also go directly to the **Federal Register** listings at http://www.epa.gov/fedrgstr/.

2. *In person.* The Agency has established an official record for this action under docket control number PF–936. The official record consists of the documents specifically referenced in this action, any public comments received during an applicable comment period, and other information related to this action, including any information claimed as confidential business information (CBI). This official record includes the documents that are physically located in the docket, as well as the documents that are referenced in those documents. The public version of the official record does not include any information claimed as CBI. The public version of the official record, which includes printed, paper versions of any electronic comments submitted during an applicable comment period, is available for inspection in the Public Information and Records Integrity Branch (PIRIB), Rm. 119, Crystal Mall #2, 1921 Jefferson Davis Highway, Arlington, VA, from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The PIRIB telephone number is (703) 305–5805.

C. How and to Whom Do I Submit Comments?

You may submit comments through the mail, in person, or electronically. To ensure proper receipt by EPA, it is imperative that you identify docket control number PF–936 in the subject line on the first page of your response.

1. *By mail.* Submit your comments to: Public Information and Records Integrity Branch (PIRIB), Information Resources and Services Division (7502C), Office of Pesticide Programs (OPP), Environmental Protection Agency, Ariel Rios Bldg., 1200 Pennsylvania Ave., NW., Washington, DC 20460.

2. *In person or by courier.* Deliver your comments to: Public Information and Records Integrity Branch (PIRIB), Information Resources and Services Division (7502C), Office of Pesticide Programs (OPP), Environmental Protection Agency, Rm. 119, Crystal Mall #2, 1921 Jefferson Davis Highway, Arlington, VA. The PIRIB is open from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The PIRIB telephone number is (703) 305–5805.

3. *Electronically.* You may submit your comments electronically by e-mail to: *''opp-docket@epa.gov*,'' or you can submit a computer disk as described above. Do not submit any information electronically that you consider to be CBI. Avoid the use of special characters and any form of encryption. Electronic submissions will be accepted in Wordperfect 6.1/8.0 or ASCII file format. All comments in electronic form must be identified by docket control number PF–936. Electronic comments may also be filed online at many Federal Depository Libraries.

D. How Should I Handle CBI That I Want to Submit to the Agency?

Do not submit any information electronically that you consider to be CBI. You may claim information that you submit to EPA in response to this document as CBI by marking any part or all of that information as 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 version of the official record. Information not marked confidential will be included in the public version of the official record without prior notice. If you have any questions about CBI or the procedures for claiming CBI, please consult the person identified 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 control 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 Comestic Act (FFDCA), 21 U.S.C. 346a. EPA has determined that this petition contains data or information regarding the elements set forth in 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: April 10, 2000.

James Jones,

Director, Registration Division, Office of Pesticide Programs.

Summary of Petition

The petitioner summary of the pesticide petition is printed below as required by section 408(d)(3) of the FFDCA. The summary of the petition was prepared by the petitioner and represents the view of the petitioner. EPA is publishing the petition summary verbatim without editing it in any way. 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.

Novartis Crop Protection, Inc.

7E4920

Amended Pesticide Petition

On April 15, 1998, EPA published a notice that it had received a pesticide petition (7E4920) from Novartis Crop Protection, Inc., P.O. Box 18300, Greensboro, NC 27419, proposing tolerances for the herbicide safener cloquintocet-mexyl acetic acid, (5-chloro-8-quinolinyl)oxy-,1-methylhexylester; CGA-185072) in or on raw agricultural commodities (RACs) of wheat. EPA has received an amendment to PP 7E4920 from Novartis Crop Protection, Inc., 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 to increase, as requested by EPA, the original proposed tolerances; thereby establishing tolerances for the combined residues of cloquintocet-mexyl and its acid metabolite, CGA-153433 (5-chloro-8-quinolinyl)oxy-acetic acid), in or on the RACs wheat, grain at 0.1 part per million (ppm); wheat, forage at 0.1 ppm; wheat, hay at 0.1 ppm; and wheat, straw at 0.1 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 metabolism of cloquintocet-mexyl in wheat has been investigated. Total residues in all crop samples are low. Metabolism involves primarily rapid hydrolysis of the parent to the resulting acid followed by conjugation.

2. *Analytical method*. Novartis has submitted practical analytical methods for the determination of cloquintocet-mexyl and its major plant metabolite CGA-153433 in wheat RACs. Cloquintocet-mexyl is extracted from crops with acetonitrile, cleaned up by solvent partition and solid phase extraction and determined by column switching high performance liquid chromotography (HPLC) with ultra violet (UV) detection. CGA-153433 is extracted from crops with an acetone-buffer (pH=3) solution, cleaned up by solvent partition and solid phase extraction, and determined by HPLC with UV detection. The limits of quantification (LOQ) for the methods are 0.02 ppm for cloquintocet-mexyl in forage and grain, 0.05 ppm for cloquintocet-mexyl in straw, and 0.05 ppm for CGA-153433 in forage, straw and grain.

3. *Magnitude of residues*. Both Canadian and United States spring wheat residue trials were conducted. Twelve residue trials were conducted from 1989–1992 in the major spring wheat growing areas of Manitoba, Alberta, and Saskatchewan, which share compatible crop zones with the major spring wheat growing areas of the United States (MT, ND, SD, MN). Nine trials were conducted in 1989–91 with a tank mix of clodinafop-propargyl active ingredient (a.i.) and the cloquintocet-mexyl safener as separate EC formulations and three trials in 1992 were conducted with clodinafop-propargyl and the cloquintocet-mexyl safener as a pre-pack EC formulation. All trials had a single post-emergence application of CGA-185072 at a rate of 20 gram active ingredient/hectacre (g a.i./ha). In 1998, an additional six spring wheat trials were conducted in the major growing areas of the United States. In these trials, cloquintocet-mexyl was applied as a safener in conjunction with clodinafop-propargyl as a 240EC formulation. The rate of cloquintocet-mexyl applied was 17 g a.i./ha as a single application. Samples of 30-day forage and hay, and mature straw and grain treated 60 days prior to harvest were taken for analysis. Grain treated at an exaggerated rate in one trial was processed under simulated commercial processing conditions. At pre-harvest intervals (PHIs) of 55–97 days, no detectable residues of cloquintocet-mexyl or its metabolite CGA-153433 were found in mature grain or straw from these trials. Separate decline studies three on green forage showed no detectable residues of cloquintocet-mexyl or CGA-153433 at 3 days after application. Freezer storage stability studies indicated reasonable stability of both analytes for a period of 1 year, with cloquintocet-mexyl declining to 83% in grain and 67% in straw after 2 years, while CGA-153433 was stable for at least 2 years.

B. Toxicological Profile

1. *Acute toxicity*. The acute oral and dermal LD_{50} values for cloquintocet-mexyl are greater than 2,000 milligrams/kilograms (mg/kg) for rats of both sexes, respectively. Its acute inhalation LC_{50} in the rat is greater than 0.935 milligram/liter (mg/L), the highest attainable concentration. Cloquintocet-mexyl is slightly irritating to the eyes, minimally irritating to the skin of rabbits, but was found to be sensitizing to the skin of the guinea pig. This technical will carry the EPA signal word ''Caution.''

2. *Genotoxicity*. The mutagenic potential of cloquintocet-mexyl was investigated in six independent studies covering different end points in eukaryotes and prokaryotes *in vivo* and *in vitro*. These tests included: Ames reverse mutation with *Salmonella typhimurium* and Chinese hamster V79 cells *in vitro*; chromosomal aberrations using human lymphocytes *in vitro* and the mouse micronucleus test *in vivo*; and DNA repair using rat hepatocytes and human fibroblasts *in vitro*. Cloquintocet-mexyl was found to be negative in all these tests and, therefore, is considered devoid of any genotoxic potential at the levels of specific genes, chromosomes or DNA primary structure.

3. *Reproductive and developmental toxicity*. Dietary administration of cloquintocet-mexyl over 2 generations at levels as high as 10,000 part per million (ppm) did not affect mating performance, fertility, or litter sizes, but a slightly reduced body weight development of adults and pups was noted at this level. The target organ was the kidney in adults and pups. The treatment had no effect on reproductive organs. The no observed adverse effect level (NOAEL) for toxicity to the offspring and parental toxicity was 5,000 ppm, corresponding to a mean daily intake of 370 to 422 mg/kg/day of cloquintocet-mexyl. The reproductive NOAEL was > 10,000 ppm (722 mg/kg/day).

In a developmental toxicity study in rats, the highest dose level of 400 mg/kg bwt day resulted in reduced body weight gain of the dams and signs of retarded fetal development. No teratogenic activity of the test article was detected. The NOAEL for dams and fetuses was 100 mg/kg bwt day.

In a developmental toxicity study in rabbits, mortality was observed in dams at dose levels of 300 mg/kg. No teratogenic effects were noted. Fetuses showed signs of slightly retarded development. The NOAEL for both dams and fetuses was 60 mg/kg bwt day. EPA's Hazard Identification Assessment Review Committee (HIARC) suggested the maternal NOAEL was 60 mg/kg, but the developmental toxicity NOAEL is > 300 mg/kg/day.

4. *Subchronic toxicity*. In a 90-day study, rats fed 6,000 ppm exhibited reduced body weight gain and one male died with acute nephritis and inflamed urinary bladder. Reduced liver and kidney weights were observed in males fed 1,000 and 6,000 and in females fed 6,000 ppm. Target organs were identified to be kidney and urinary bladder. The NOAEL was 150 ppm (9.66 mg/kg in males and 10.2 mg/kg in females). EPA's HIARC concluded that the NOAEL in females was 6,000 ppm (407 mg/kg/day).

In a 90-day study in beagle dogs, a level of 40,000 ppm resulted in deterioration of general condition so that the feeding level was reduced in a stepwise fashion to 15,000 ppm. Anemia was noted at 15,000 and 1,000 ppm. The NOAEL of 100 ppm was equivalent to a mean daily intake of 2.9 mg/kg in males and females.

5. *Chronic toxicity*. In a 12-month feeding study in dogs, 15,000 ppm resulted in inappetence and body weight loss. As a result, this feeding level was adjusted to 10,000 ppm after 2 weeks. Animals fed this level exhibited anemia and an elevation in blood urea levels. The kidney was considered the target organ. The NOAEL of 1,500 ppm was equivalent to a mean daily intake of 43.2 mg/kg in males and 44.8 mg/kg in females.

Lifetime dietary administration of cloquintocet-mexyl to mice resulted in reduced body weights in both sexes at 5,000 ppm. Overall body weight gain was reduced by 17% to 22% in males and females, respectively, indicating the MTD was achieved or exceeded. Histopathological examination revealed chronic inflammation of the urinary bladder. There was no indication of any tumorigenic response due to treatment. The NOAEL of 1,000 ppm was equivalent to a mean daily dose of 111 mg/kg in males and 102 mg/kg in females.

Rats were fed a top feeding level of 2,000 ppm, based on the 90-day subchonic study, for a lifetime. This feeding level was well-tolerated, but produced hyperplasia of the thymus in males at the top dose and hyperplasia of the thyroid in females at 1,000 and 2,000 ppm. There was no increase in tumors of any type and the total number of tumor-bearing animals showed no dose-related trends. The NOAEL of 100 ppm was equivalent to a mean daily dose of 4.33 mg/kg in females. EPA's HIARC suggested that the NOAEL in male rats was 1,000 ppm (36.4 mg/kg/day).

6. *Carcinogenicity*. There is no evidence supporting any oncogenic potential associated with cloquincet-mexyl. EPA's HIARC classified cloquintocet-mexyl as a ''not likely'' human carcinogen according to the proposed guidelines for carcinogen risk assessment.

7. *Animal metabolism*. In rats, approximately 50% of an oral dose of cloquintocet-mexyl was rapidly absorbed through the gastrointestinal tract and excreted via urine and bile. The administered dose was excreted independent of sex and was essentially complete within 48 hours. Ninety-five percent of the excreted dose was associated with one metabolite, an acid residue of cloquintocet-mexyl, CGA-153433. Simultaneous administration of the cloquintocet-mexyl and clodinafop-propargyl did not alter the rate of excretion of cloquintocet-mexyl or its metabolite pattern.

8. *Metabolite toxicology*. At the present time there is no evidence which affords an association of the toxicity noted with the highest feeding levels of cloquintocet-mexyl with its primary metabolite, CGA-153433.

9. *Endocrine disruption*. A special study was conducted to investigate a histological finding of hyperplasia of thyroid gland epithelium noted in the female rat in the standard lifetime combined chronic toxicity and carcinogenicity study. This study was a 28-day oral gavage study with a 28-day recovery period at dose levels as high as 400 mg/kg/day or approximately 4,000 ppm. No effect was noted on the level of thyroid hormones at any of the treatment levels. Although a slight stimulation of the thyroid and an accompanying increase in pituitary basophilic cells were noted at the end of 28-days, these effects were reversible in the recovery period.

C. Aggregate Exposure

1. *Dietary exposure*. Cloquintocet-mexyl is intended as a safener for the postemergence herbicide, clodinafop-propargyl, used on wheat. The use rate for cloquintocet-mexyl is very low (formulated at a 1:4 ratio of safener to active ingredient and results from plant metabolism and residue studies show that residues are below the detection limit in wheat grain and other wheat fractions. The tolerance expression will include parent cloquintocet-methyl and the corresponding hydrolysis product, CGA-153433, and tolerances are being proposed at 0.1 ppm in wheat grain, forage, hay, and straw. No tolerances are proposed for secondary residues in animal commodities since residues would be far below the LOQ of existing analytical methodology.

i. *Food*. Chronic and acute dietary exposure analyses were conducted using the dietary exposure evaluation model (DEEM) from Novigen Sciences and the 1994–96 Continuing Survey of Food Intake by Individuals (CSFII). Chronic and acute tier one dietary assessments were made assuming tolerance-level residues and treatment of 100% of all planted wheat.

a. *Chronic*. Chronic exposure was compared to a reference dose (RfD) of 0.04 mg/kg/day which was derived from

a NOAEL of 4.3 mg/kg/day in a chronic toxicity/carcinogenicity study in female rats and a 100x uncertainty factor (UF). Exposure was calculated assuming that 100% of crop was treated and residues were at the proposed tolerance levels of 0.1 ppm for wheat grain and associated fractions. Exposure for the U.S. population was minimal with 0.4% of the RfD utilized and this result was the same for the U.S. population through all seasons and all ethnic groups. The most sensitive subpopulation was children (1–6 years old) with an exposure of 0.9% of the chronic RfD. These results are extremely conservative since tolerance values were used and are reflective of the maximum application rate and minimum PHI. In addition, it was assumed that all planted acres are treated. Therefore, there is more than a reasonable certainty of no harm resulting from exposure to residues of cloquintocet-mexyl.

b. *Acute*. Acute exposure was assessed for the female population (13+ years) only and was compared to an acute RfD of 1.0 mg/kg/day based on a NOAEL of 100 mg/kg/day from a developmental toxicity study in rats and a 100x UF. The resulting assessment revealed that exposures to all female subpopulations reported in the DEEM were between 0.03%–0.04% of the RfD at the 95th percentile of exposure. The 95th percentile is the appropriate percentile to consider since this assessment is based on tolerance-level residues and 100% of crop treated was assumed. Even at the 99.9th percentile of exposure, the results show that females (13–50 years old) utilize only 0.07% of the acute RfD. EPA's HIARC concluded that no acute dietary assessment was necessary for the general population because a suitable toxicological endpoint (resulting from a single dose exposure) was not identified in either the rat or rabbit developmental studies.

ii. *Drinking water*. Another potential route of exposure to residues of pesticides includes drinking water. Field and laboratory study results have demonstrated that cloquintocet-mexyl and its degradation products have minimal potential to reach surface or ground water. Thus, drinking water exposure to cloquintocet-mexyl and its degradation products was not included in the aggregate risk assessment. Also, since cloquintocet-mexyl is not intended for uses other than the agricultural use on wheat, there is no potential for non-occupational exposure.

The estimated exposures of cloquintocet-mexyl and its main environmental degradate were combined and the hazards for both compounds were based on the RfD values determined for cloquintocet-mexyl alone. The estimated water concentrations for cloquintocet-mexyl and the degradate were estimated, weighted and combined based on applications rates adjusted for the maximum concentration of the degradate present in the aerobic soil metabolism studies.

The GENEEC and SCI–GROW models respectively provided the estimated surface water and ground water concentrations. The estimated acute exposures from drinking surface and ground water were 0.04964 part per billion (ppb) and 0.006166 ppb, respectively. The females 13+ years sub-population was the only subgroup which was required for the acute exposure assessment. The acute exposures for females 13+ years were based on 1.0 mg/kg/day. Based on the 95th percentile acute dietary assessment, the females (13+/nursing) was the most exposed female sub-population at 3.71E-6 mg/kg/day. This resulted in an acute DWLOC of 30,000 ppb. Therefore, the estimated acute surface and ground water exposures for cloquintocet-mexyl and its degradate did not exceed the exposure allowed by the risk cup. The chronic dietary exposures for all sub-populations provided DWLOC values of 224 to 1,396 ppb. The estimated chronic exposures from drinking surface and ground water were 0.00316 ppb and 0.006166 ppb, respectively. Therefore, the estimated acute and chronic drinking water exposures of cloquintocet-mexyl and its degradate did not exceed the exposures allowed by the risk cup.

2. *Non-dietary exposure*. Exposure to cloquintocet-mexyl for the mixer/loader/ground-boom/aerial applicator and flagger was calculated using the pesticide handlers exposure data base. It was assumed that the product would be applied 6 days per year by ground-boom application to a maximum of 80 acres per day by the grower, 15 days per year by ground-boom application to a maximum of 80 acres per day by the commercial ground-boom applicator, and 15 days per year to a maximum of 350 acres per day by the aerial applicator, at a maximum use rate of 7.1 grams cloquintocet-mexyl per acre. For purposes of this assessment, it was assumed that an applicator would be wearing a long-sleeved shirt and long pants and the mixer/loader would, in addition, wear gloves. Daily doses were calculated for a 70 kg person assuming 100% dermal penetration. Short-term and intermediate-term dermal and inhalation risk assessments were performed. Doses and endpoints used for risk assessments were based on Agency determined toxicological endpoints recommended by the HIARC. The NOAEL of 200 mg/kg/day from the 28-day rat dermal toxicity study was used for short-term and intermediate-term dermal risk assessments. The NOAEL of 100 mg/kg/day from the developmental toxicity study in rats was used for short-term inhalation risk assessments. The NOAEL of 4.3 mg/kg/day from the 2-year chronic toxicity study in rats was used for intermediate-term risk assessments. Based on the use pattern, no long-term dermal or inhalation exposure is expected to occur and long-term risk assessments are not required.

Large margins of exposure (MOE) exist for all occupational exposure scenarios. Short-term dermal exposure MOEs ranged from 6.4E+04 for the commercial open mixer-loader to 2.8E+06 for the commercial or grower groundboom enclosed-cab applicator. Intermediate-term dermal exposure MOEs ranged from 1.6E+06 for the commercial open mixer-loader to 1.7E+08 for the grower ground-boom enclosed-cab applicator. Short-term inhalation exposure MOEs ranged from 2.8E+06 for the commercial open mixer-loader to 1.3E+08 for the commercial or grower ground-boom enclosed-cab applicator. Intermediate-term inhalation exposure MOEs ranged from 3.0E+06 for the commercial open mixer-loader to 3.4E+08 for the grower ground-boom enclosed-cab applicator.

Although there are no residential uses of cloquintocet-mexyl, there is potential for residential exposure to spray drift resulting from aerial application. No standard operating procedure exists for performing this risk assessment; however, a very conservative risk assessment was performed assuming dermal exposure equal to total deposition to outside clothing for a flagger as well as inhalation exposure equivalent to a pesticide flagger, as reflected in PHED. A dermal absorption factor of 100% and offsite drift of 15% were assumed. The area assumed to be adjacent to the sensitive area was one acre. Large MOEs exist for this potential exposure scenario. Dermal exposure MOEs were 2.4E+07 for a 15 kg child and 1.1E+08 for a 70 kg adult. Inhalation MOEs were 1.8E+09 for a 15 kg child and 8.6E+09 for a 70 kg adult.

D. Cumulative Effects

Novartis has considered the potential for a cumulative exposure assessment for effects of cloquintocet-mexyl and other substances with the same mechanism of toxicity. It is concluded that such a determination would be

inappropriate at this time because of the unique role of cloquintocet-mexyl as a product-specific safener.

E. Safety Determination

1. *U.S. population.* Acute and chronic dietary exposure is minimal for cloquintocet-mexyl and corresponding hydrolysis product, CGA-153433. Both chronic and acute exposure estimates at the 95th percentile showed that less than 1.0% of the reference dose is utilized in all populations. These exposure estimates are extremely conservative and are based on tolerance-level residues and assume all planted acres are treated.

Exposure through the consumption of drinking water is minimal from both surface water and ground water model estimates and in all cases less than 1% of the risk cup is utilized. The estimated water concentrations are very conservative since conservative model parameters were assumed.

There are no residential uses of cloquintocet-mexyl that would result in non-dietary exposure. However, there is a remote possibility that spray drift resulting from aerial application could lead to residential exposure. Since exposure from spray drift would be an unlikely event, it is not appropriate to include non-dietary exposure into the aggregate assessment. Therefore, it is concluded that there is a more than a reasonable certainty that no harm will result from aggregate exposure to residues of cloquintocet-mexyl.

2. *Infants and children.* In assessing the potential for additional sensitivity of infants and children to residues of cloquintocet-mexyl, data from developmental toxicity studies in the rat and rabbit and a 2-generation reproduction study in the rat have been considered. The developmental toxicity studies are designed to evaluate adverse effects on the developing organism resulting from chemical exposure during prenatal development to one or both parents. Reproduction studies provide information relating to effects from exposure to a chemical on the reproductive capability of mating animals and data on systemic toxicity.

The highest dose level of 400 mg/kg/day in a developmental toxicity study in rats resulted in reduced body weight gain of the dams and signs of retarded fetal development. No teratogenic activity due to the test article was detected. The NOAEL for dams and fetuses was 100 mg/kg/day. Although mortality was observed in rabbit dams at the dose level of 300 mg/kg/day, no teratogenic effects were noted. The maternal NOAEL was 60 mg/kg/day, but the developmental NOAEL was > 300 mg/kg/day.

Dietary administration of cloquintocet-mexyl over 2-generations at levels as high as 10,000 ppm did not affect mating performance, fertility, or litter sizes in rats, but a slightly reduced body weight development of adults and pups was noted at this level. The target organ was kidney in adults and pups. The treatment had no effect on reproductive organs. The parental and developmental NOAEL was 5,000 ppm, corresponding to a mean daily intake of 370 to 422 mg/kg/day of cloquintocet-mexyl. The reproductive NOAEL was > 10,000 ppm (722 mg/kg/day). FFDCA section 408 provides that EPA may apply an additional safety factor 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 relative to prenatal and postnatal effects for children is complete. EPA's HIARC concluded that there was no concern for an increased susceptibility for cloquintocet-mexyl based on the reproduction study in rats and the developmental studies in rat and rabbit. Further, for cloquintocet-mexyl, the NOAEL of 4.3 mg/kg/day from the combined chronic/oncogenicity study in rats, which was used to calculate the RfD, is already lower than the developmental NOAEL of 100 mg/kg/day for the rat developmental toxicity study. Further, the developmental and parental NOAEL of 370 mg/kg/day from the cloquintocet-mexyl reproduction study is nearly 100 times greater than the NOAEL for the combined chronic/oncogenicity rat study. These data would indicate that there is no additional sensitivity of infants and children to cloquintocet-mexyl. Therefore, it is concluded that an additional UF is not warranted to protect the health of infants and children from the use of cloquintocet-mexyl.

Using conservative exposure assumptions, dietary exposure to the most sensitive subpopulation, children (1–6 years old), is 0.9% of the chronic reference dose (RfD). Chronic dietary exposure to infants (non-nursing, 1–6 years old) is 0.2% of the chronic RfD. EPA's HIARC concluded that no acute dietary assessment was necessary for the general population (infants and children) because a suitable toxicological endpoint (resulting from a single dose exposure) was not identified in either the rat or rabbit developmental studies.

Although not required, acute dietary exposure to infants and children was assessed. Acute exposures for all infants and children at the 95th percentile are less than 1.0% of the acute RfD (0.08% of the RfD for the most sensitive subpopulation, children 1–6 years). Exposures to drinking water for children (1–6 years old) and infants utilize less than 1% of the chronic and acute RfD values (worst-case surface water estimates). These results show that aggregate exposure to residues of cloquintocet-mexyl in the diet and drinking water is negligible. Based on the completeness and reliability of the toxicity data and the conservative nature of the exposure assumptions, it is concluded that there is a more than reasonable certainty that no harm will result to infants and children from exposure to residues of cloquintocet-mexyl.

F. International Tolerances

Cloquintocet-mexyl is used as a safener for the herbicide, clodinafop-propargyl. There are no Codex Alimentarius Commission (CODEX) maximum residue levels (MRLs) established for residues of cloquintocet-mexyl in or on RACs.

[FR Doc. 00–9796 Filed 4–18–00; 8:45 am]
BILLING CODE 6560–50–F

ENVIRONMENTAL PROTECTION AGENCY

[OPP–50868; FRL–6553–3]

Experimental Use Permit; Receipt of Application

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: This notice announces receipt of an application 67986–EUP–E from AgriPhi, Inc. requesting an experimental use permit (EUP) for the microbial bacteriophages. The Agency has determined that the application may be of regional and national significance. Therefore, in accordance with 40 CFR 172.11(a), the Agency is soliciting comments on this application.

DATES: Comments, identified by docket control number OPP–50868, must be received on or before May 19, 2000.

ADDRESSES: Comments and data may be submitted by mail, electronically, or in person. Please follow the detailed instructions for each method as provided in Unit I.C. of the **SUPPLEMENTARY INFORMATION**. To ensure proper receipt by EPA, it is imperative that you identify docket control number