reasonable expectation that there would be an additional incremental aggregate dietary contribution of clomazone through groundwater or surface water.

2. *Non-dietary exposure*. Clomazone is only registered for use on food crops. Since the proposed use on sugarcane is consistent with existing registrations, there will be no non-dietary, non-occupational exposure.

D. Cumulative Effects

Clomazone is an isoxazolidinone herbicide. No other registered chemical exists in this class of chemistry. Therefore, given clomazone s unique chemistry low acute toxicity, the absence of genotoxic, oncogenic, developmental or reproductive effects, and low exposure potential (see Sections A and C), the expression of cumulative human health effects with clomazone and other natural or synthetic pesticides is not anticipated.

E. Safety Determination

1. *U.S. population*. Using the conservative exposure assumptions described above, based on the completeness and reliability of the toxicology data, it is concluded that aggregate exposure due to existing registered uses, and pending uses, of clomazone will utilize less than 1% of the RfD for the U.S. population. Additionally, an analysis concluded that aggregate exposure to clomazone adding sugarcane at a 0.05 ppm tolerance level will utilize 0.04 percent of the RfD for the U.S. population. EPA generally has no concern for exposures below 100% of the RfD because the RfD represents the level at or below which daily aggregate dietary exposure over a lifetime will not pose appreciable risks to human health. It is concluded that there is a reasonable certainty that no harm will result from aggregate exposure to residues of clomazone, including all anticipated dietary exposure.

2. *Infants and children*. Based on the current toxicological data requirements, the database relative to pre- and post-natal effects for children is complete (See Section B.3). Further, for clomazone, the NOAEL in the two year feeding study which was used to calculate the RfD (0.043 mg/kg/day) is already lower than the NOAELs from the reproductive and developmental studies by a factor of more than 10–fold. Therefore, it can be concluded that no additional uncertainty factors are warranted and that the RfD at 0.043 mg/kg/day is appropriate for assessing aggregate risk to infants, children as well as adults.

Using the conservative exposure assumptions described above, FMC has concluded that the percent of the RfD that will be utilized by aggregate exposure to residues of clomazone in/on sugarcane for non-nursing infants (<1 year old), the population subgroup most sensitive, is 0.114 and the percent of the RfD that will be utilized by the children (1–6 years old) population subgroup is 0.086. The percent of the RfD utilized for infants and children for sugarcane plus all other current and pending (i.e., rice, tanier, cassava and arracacha) clomazone tolerances is 0.872 and 0.510 respectively.

Based on the above information, FMC has concluded that there is a reasonable certainty that no harm will result to infants, children or adults from dietary food consumption exposure to clomazone residues from either sugarcane sourced foods alone or sugarcane sourced foods plus all other clomazone treated human dietary food sources.

F. International Tolerances

There are Codex residue limits for residues of clomazone in or on oilseed rape, potatoes, tobacco, soybeans, rice, cottonseed, sugarcane and peas.

[FR DOC. 01–7644 Filed 3–27–01; 8:45 am]

BILLING CODE 6560–S

ENVIRONMENTAL PROTECTION AGENCY

[PF–1004; FRL–6769–9]

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 control number PF–1004, must be received on or before April 27, 2001.

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–000 in the subject line on the first page of your response.

FOR FURTHER INFORMATION CONTACT: By mail: Cynthia Giles-Parker, Registration Support Branch, Registration Division (7505W), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460; telephone number: (703) 305–7740; e-mail address: giles-parker.cynthia@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 Proposed Rule,'' 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–1004. 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–1004 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, 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–1004. 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: March 12, 2001.

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 petitioners. 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.

K-I Chemical U.S.A. Inc. (K-I Chemical)

0F06127

EPA has received a pesticide petition (0F06127) from K–I Chemical U.S.A. Inc. (K-I Chemical), 11 Martine Avenue, 9th floor, White Plains, New York 10606, 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 calcium 3-oxido-5-oxo-4-propionylcyclohex-3-enecarboxylate (prohexadione calcium) in or on the raw agricultural commodities grass forage at 0.1, grass hay at 0.1, grass straw at 1.2 and grass seed screenings at 3.5 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*. The metabolism in plants (peanuts and apples) is adequately understood.

2. *Analytical method*. The proposed analytical method involves homogenization, extraction, filtration, partition and cleanup, methylation and analysis by a gas chromatography system with a mass selective detector. The limit of quantitation is 0.05 ppm.

3. *Magnitude of residues*. Twelve grass grown for seed trials were conducted with prohexadione calcium in the major cool season grass seed-growing regions of the United States (Nebraska, Minnesota, Montana, Idaho, Oregon and Washington) to determine the magnitude of prohexadione calcium residues in/on grass forage, straw, hay and seed screenings. Grass grown for seed plots received one foliar application of prohexadione calcium at the target rate of 0.5 pounds active ingredient per acre (lb ai/A). The application was applied approximately 35 days prior to the anticipated seed harvest date. All sprays were applied in combination with a locally-available, non-silicone spray adjuvant. Prohexadione calcium residues ranged from <0.05 to 3.38 ppm in seed screenings, <0.05 to 1.04 ppm in straw, <0.05 to 0.06 ppm in forage, and <0.05 to 0.08 ppm in hay. Control samples did not exhibit resides above the limit of quantitation (LOQ) of 0.05 ppm.

B. Toxicological Profile

1. *Acute toxicity*. Based on available acute toxicity data prohexadione calcium does not pose any acute toxicity risks. The acute toxicity studies place technical prohexadione calcium and its formulated end-use products in acute toxicity category III for acute dermal; and in acute toxicity category IV for acute oral, acute inhalation, eye irritation, and skin irritation and the technical material is not a skin sensitizer.

2. *Genotoxicity*. Ames Test (1 Study; point mutation): Negative; *in vitro* V79 Cells CH/HGPRT Locus Mammalian Cell Mutation Assay (1 Study; point mutation): Negative; *in vitro* CHO Cytogenetic Assay (1 Study; Chromosome Damage): Negative; *in vivo* Mouse Micronucleus (1 Study; Chromosome Damage): Negative; *in vivo* Rat Bone Marrow Cytogenetic Assay (1 Study; Chromosomal Damage): Negative; Rec Assay (1 Study; DNA damage and repair): Negative; *in vitro* Rat Hepatocyte (1 Study; DNA damage and repair): Negative

Prohexadione calcium has been tested in a total of 7 genetic toxicology assays consisting of *in vitro* and *in vivo* studies. Based on the results described above, it can be stated in summary that prohexadione calcium did not show any mutagenic activity when tested under the conditions of the studies mentioned above. Therefore, prohexadione calcium does not pose a mutagenic hazard to humans.

3. *Reproductive and developmental toxicity*. The reproductive and developmental toxicity of prohexadione calcium was investigated in a 2–generation rat reproduction study as well as in rat and rabbit teratology studies. The 2–generation rat reproduction study was conducted at dose levels of 0, 500, 5,000 and 50,000 ppm. There were no adverse effects on reproduction parameters seen even at the dose level of 50,000 ppm (5164 mg/kg bw for males and 5,600 mg/kg bw for females). The No Observed Adverse Effect Level (NOAEL) for parental systemic toxicity was 500 ppm (48 mg/kg bw for males and 51 mg/kg bw for females) and the NOAEL for developmental toxicity was 5,000 ppm (270 mg/kg bw for females). Stomach lesions were observed at ≤5,000 ppm. Two mid-dose males and two males and one female of the high-dose from the F_0 died. Body weight and food consumption changes and slight transient reduction in offspring growth were noted at 50,000 ppm. No impairment of reproductive function was observed at any of the dose levels tested.

The reproductive and developmental studies are summarized below. A developmental study was conducted via oral gavage in rats at dose levels of 0, 100, 300, and the 1,000 highest dose tested (HDT) mg/kg bw. The No Observed Adverse Effect Level (NOAEL) for developmental and maternal toxicity was 1,000 mg/kg bw, HDT. This was based on the fact that there were no signs of maternal toxicity, fetotoxicity or teratogenic effects.

A developmental study was conducted via oral gavage in rabbits at dose levels of 0, 40, 200, and 750 (HDT) mg/kg bw. The NOAEL for development toxicity was 40 mg/kg bw and the NOAEL for maternal toxicity was 40 mg/kg bw based on the following findings. Toxicity in the form of maternal mortality with values 16/20 and 4/20 was excessive in the mid- and high-dose group, respectively. Fetal deaths also occurred. Dose levels believed to exceed MTD; NOAELs for maternal and developmental effects are not considered reliable and useful for risk characterization. No teratogenic effects were noted in this study.

i. *Teratogenicity*. Prohexadione calcium had no teratogenic potential at dose levels as high as 1,000 mg/kg bw in the rat and 350 mg/kg bw in the rabbit. The NOAEL for maternal toxicity in the teratogenicity studies is 100 mg/kg bw (rabbit) and 1,000 mg/kg bw (rat), and the NOAEL for fetotoxicity in the teratogenicity studies is 350 mg/kg bw (rabbit) and 1000 mg/kg bw (rat).

An additional teratology study in the same strain of rabbits was conducted at dose levels of 0, 30, 75, and 150 mg/kg bw. The NOAEL for development toxicity was 150 mg/kg bw and the NOAEL for maternal toxicity was 30 mg/kg bw based on the following findings. One low-, two mid-, and three high-dose animals died prior to day 29, however, at the high dose group one died of gavage error and another pneumonia, and the reason for the other deaths could not be determined. No teratogenic or fetoxtoxic effects were noted in this study.

ii. *Oral teratology study*. An oral range-finding gavage teratology study in the same strain of rabbits (5 animals/dose level) was conducted in another independent laboratory. The dose levels selected were 0, 20, 100, 250, 500, and 1,000 mg/kg bw. This range finding study was conducted with a limited number of animals and a limited scope of examination. Based on these results the dose levels selected for the main study at this independent laboratory were 0, 30, 100, and 350 mg/kg bw. The NOAEL for development toxicity was 350 mg/kg bw and the NOAEL for maternal toxicity was 100 mg/kg bw based on the following findings. At the 350 mg/kg bw dose group transient body weight decreases and two abortions were observed. No teratogenic or fetotoxic effects were noted in this study.

iii. *Conclusions from teratology studies*. More than one definitive rabbit teratology study was conducted because issues associated with exceeding the maximum tolerated dose (MTD) in the first study and spurious deaths, apparently not compound-related, in the second study confounded the determination of a NOAEL for maternal toxicity. There were no signs of teratogenic or fetotoxic effects in any study other than the first definitive study in which maternal deaths above the MTD apparently occurred. It is BASF's and K–1 Chemicals' opinion based on a thorough review of the teratology studies that the following overall NOAELs can be derived for the teratology studies:

a. *NOAEL maternal toxicity*. 100 mg/kg body weight (rabbit) and 1,000 mg/kg body weight (rat).

b. *NOAEL prenatal toxicity*. 350 mg/kg body weight (rabbit) and 1,000 mg/kg body weight (rat).

The overall NOAEL of 100 mg/kg bw for maternal toxicity in rabbits is based on the last rabbit study, and is based on

reduction of body weight gain and food intake at dose levels of 250 mg/kg body weight onwards. The NOAEL of 350 mg/kg bw for fetotoxic effects in the rabbit is also based on a reduction in body weight gain. Based on the overall study results, it is concluded that there are no developmental effects of concern.

Based on preliminary discussions with EPA concerning the rabbit teratology studies, EPA concluded that the definitive NOAEL for maternal toxicity considering all of the studies ranges from 30 to 100 mg/kg/bw. Agency scientists further stated that they needed to review the studies in detail to ultimately determine the definitive NOAEL for maternal toxicity. This uncertainty associated with maternal toxicity in the rabbit teratology studies does not impact risk considerations since the risk assessment is based on a lower NOAEL (20 mg/kg bw) in the chronic dog study.

4. *Subchronic toxicity*. The subchronic toxicity of prohexadione calcium was investigated in 90–day feeding studies with rats, mice and dogs. In all these studies, prohexadione calcium displayed low toxicity. Prohexadione calcium showed no signs of neurotoxicity in a 90–day neurotoxicity rat study. Additionally, the results seen in four week feeding range-finding studies for rats and dogs were similar to the findings observed in the 90–day studies in the same animals.

5. *Chronic toxicity*. Based on review of the available data, the Reference Dose (RfD) for prohexadione calcium will be based on a 1–year feeding study in dogs with a threshold No Adverse Effect Level (NOAEL) of 20 mg/kg/day. Using an uncertainty factor of 100, the RfD is calculated to be 0.2 mg/kg/day. The following are summaries of studies submitted to EPA.

Prohexadione calcium was administered to Beagle dogs at dietary concentrations of 0, 20, 200, and 1,000 mg/kg bw for 12 months. Slight changes were observed for hematological and clinical chemical parameters and dilated basophilic renal tubules (without histopathological concurrence) at dose levels greater than 200 mg/kg bw. The NOAEL was 20 mg/kg bw for the males and female dogs.

The 24–month Fisher 344 rat chronic/carcinogenic feeding study was conducted at dose levels of 0, 400, 2,000, 10,000, and 20,000 ppm with 80 male and 80 female animals per dose group. After 26, 52, and 78 weeks, 10 animals were sacrificed (satellite groups). The remaining animals were autopsied after 104 weeks of diet administration. The NOAEL for chronic toxicity was 2,000 ppm for males (93.9 mg/kg bw) and 2,000 ppm for females (114 mg/kg bw). The following effects were observed in the 10,000 and 20, 000 ppm groups:

i. Decreased body weights were observed in both male and female rats at the 20,000 ppm dose level;

ii. Clinical chemical effects (i.e., lower potassium, bilirubin, and glucose levels) were observed in male and female rats at the 20,000 ppm dose level, in the 10,000 ppm dose level, reduced glucose levels were only seen in the males, and increased albumin/globulin ratios, sodium, chloride and calcium levels were observed only in the females;

iii. Increased urine volumes and lower specific gravity were observed in the mid-high and high-dose groups for both male and female rats;

iv. Minor changes in organ weights were noted for animals of the high dose group only, which consisted of increased relative liver, adrenal and kidney weights, the latter also absolute in females only, at week 26; at the end of the study decreased liver weights and increased relative brain and testis weights were noted and these changes were considered to be associated with the decreased body weights;

v. Macroscopic findings revealed an increase of pituitary nodules in the high dose group for both male and female rats which was not confirmed histopathologically and submucosal ectopic tissue in the glandular stomach was found in both male and female rats in the highest dose levels that was confirmed by histopathology which showed an increase of squamous cell hyperplasia in males and of basal cell hyperplasia in the forestomach;

vi. A higher incidence of cellular hyperplasia was observed in the thyroid in the mid-high and high dose levels for male and female rats; and

vii. No increased incidence of neoplasms occurred at any dose levels tested in this study.

In the 24–month B6C3F1 mouse feeding study, conducted at dose levels of 0, 400, 2,000, 20,000, and 40,000 ppm with interim sacrifices at 52 and 78 weeks, prohexadione calcium was negative for oncogenicity. The NOAEL for chronic toxicity was 2,000 ppm for males (279 mg/kg bw) and 2,000 ppm for females (351 mg/kg bw). The following effects were observed in the 20,000 and 40,000 ppm groups:

i. Statistically significant decreases in body weights were observed in male mice at the 20,000 ppm dose level and in female mice at the 40,000 ppm dose level;

ii. A variety of changes in hematological parameters were noted in the respective investigations at weeks 52, 78, and 104, however, most of the changes were not dose related or consistent over time;

iii. Increased absolute and/or relative heart, brain, testes, liver, ovary, and kidney weights were observed in the mid-high and highest dose groups with a slight progression of severity to the highest dose group;

iv. A higher incidence of splenomegaly was observed only in the male mice of the highest dose group;

v. Histopathological examinations revealed an ectopic proliferation of the mucosal and glandular epithelium in the submucosal layer of the glandular stomach in male and female mice in the highest dose group tested, these changes were assessed to represent heteroplastic, ectopic proliferative changes accompanied by lumen dilatation and cytological degeneration;

vi. A higher incidence of hyperkeratosis of the forestomach was observed in both male and female mice and hyperplasia of the squamous epithelium of the forestomach of female male mice was observed in the highest dose group tested;

vii. Vacuolic changes in the exocrine pancreas of the high dose female were observed; and

viii. No increased incidence of neoplasms occurred at any dose levels tested in this study.

a. *Threshold effects*. Based on review of the available chronic toxicity data, K–I Chemical believes EPA will establish the Reference Dose(RfD) for prohexadione calcium at 0.20 mg/kg/day. This RfD for prohexadione calcium is based on the 1–year feeding study in dogs with a threshold NOEL of 20 mg/kg/day in male and female dogs. Using an uncertainty factor of 100, the RfD is calculated to be 0.20 mg/kg/day. Based on the acute toxicity data K–I Chemical believes that prohexadione calcium does not pose any dietary risks.

b. *Non-threshold effects*. Based on EPA Proposed Guidelines For Carcinogen Risk Assessment, K–I Chemical believes that prohexadione calcium will be classified as ''Not Likely a Human Carcinogen''. Under the current assessment method K–I Chemical believes that EPA will classify prohexadione calcium as Group E, no evidence of carcinogenicity based on studies in two species. There was no evidence of carcinogenicity in mice and rat 24–month feeding studies at the dosage levels tested. The doses tested were adequate for identifying a cancer risk.

6. *Animal metabolism*. The metabolism in animals (goats and poultry) is adequately understood.

7. *Endocrine disruption*. No specific tests have been conducted with prohexadione calcium to determine whether the chemical may have an effect in humans that is similar to an effect produced by a naturally occurring estrogen or other endocrine effects. However, there were no significant findings in other relevant toxicity studies (i.e., subchronic and chronic toxicity, teratology and multi-generation reproductive studies) which would suggest that prohexadione calcium produces endocrine related effects.

C. Aggregate Exposure

1. *Dietary exposure*— i. *Food*. For purposes of assessing the potential dietary exposure, K–I Chemical has estimated aggregate exposure based on the Theoretical Maximum Residue Contribution (TMRC) from the proposed tolerances for prohexadione calcium in/on peanut nutmeat at 1.0 ppm and apples (pome fruit) at 3.0 ppm. A maximum residue level of 1.0 ppm was used for pears. The TMRC is a worse case estimate of dietary exposure since it is assumed that 100 percent of all crops for which tolerances are established are treated and that pesticide residues are always found at the tolerance levels. The TMRC from the proposed use of prohexadione calcium on peanuts, pears and apples is 0.002570 mg/kg bw/day and utilizes 1.28% of the RfD for the overall U.S. population. The exposure of the most highly exposed subgroup in the population, non-nursing infants (< 1 year old), is 0.025758 mg/kg bw/day and utilizes 12.88% of the RfD. K–I Chemical believes that the use of prohexadione calcium on grass grown for seed will not impact the TMRC.

Prohexadione calcium is currently registered for use on peanuts, apples and pears. Thus, dietary exposure to residues of prohexadione calcium in or on food will be limited to residues on peanuts, apples and pears. Apple pomace, peanut meal and hay are fed to animals; thus exposure of humans to residues in feed items might result if such residues carry through to meat, milk, poultry, or eggs. However, K–I Chemical has concluded that there is no reasonable expectation that measurable residues of prohexadione calcium will occur in meat, milk, poultry, or eggs from these registered uses but residues can be expected to be slightly above the limit of quantitation for kidney of cattle, goats, hogs, horses, and sheep. The Agency has established tolerances in or on the raw agricultural commodities peanuts at 1.0 ppm, peanut hay at 0.6 ppm, pome fruit at 3.0 ppm, kidney of cattle, goats, hogs, horses, and sheep, at 0.10 ppm and meat byproducts except kidney of cattle, goats, hogs, horses, and sheep at 0.05 ppm. The use of prohexadione calcium on grass grown for seed will require tolerances on grass forage, hay, straw and seed screenings, but will not require an increase in the tolerances for kidney or meat byproducts. Thus, K–I Chemical believes there will not be an increase in human dietary exposure to prohexadione calcium from this use.

The following table summarizes the mean dietary exposures and the percents of RfD occupied by these exposures.

SUMMARY: CHRONIC DIETARY EXPOSURE TO PROHEXADIONE CALCIUM.

Group	DRES(Dietary Risk Evaluation System) mg/kg bw/day	% RfD
U.S. Population	2.6	1.3
Nursing Infants (<1 Year Old)	19.3	9.7
Non-Nursing Infants (<1 Year Old)	25.8	12.9
Children 1–6 Years Old	8.7	4.4
Children 7–12 Years Old	3.5	1.8

ii. *Drinking water*. Other potential sources of exposure for the general population to prohexadione calcium are residues in drinking water and exposure from non-occupational sources. Based on studies submitted to EPA for assessment of environmental risk, K–I Chemical does not anticipate exposure to residues of prohexadione calcium in drinking water. There is no established Maximum Concentration Level (MCL) or Health Advisory Level (HAL) for prohexadione calcium under the Safe Drinking Water Act (SDWA).

2. *Non-dietary exposure*. K–I Chemical has not estimated non-occupational exposure to prohexadione calcium since the only pending registration is limited to commercial crop production. Prohexadione calcium products are not labeled for any residential uses, therefore eliminating the potential for residential exposure. Thus, potential for non-occupational exposure of the general population to prohexadione calcium is not present.

D. Cumulative Effects

K–I Chemical is aware of only one other registered compound, trinexapac-ethyl 4- (cyclopropyl-a-hydroxymethylene)-3,5-dioxo-cyclohexanecarboxylic acid ethylester, that has a structure similar to prohexadione calcium. However, K–I Chemical has no information that would indicate that the two compounds have a common mechanism of toxicity. Furthermore, trinexapac is registered for use only on turf. Therefore, even if the compounds were considered similar there would be no cumulative dietary exposure issue because of the differences in use patterns. In summary, dietary exposure to prohexadione calcium should not result in cumulative toxicity with other known chemical compounds.

E. Safety Determination

1. *U.S. population*. Using the conservative exposure assumptions described above and based on the completeness and the reliability of the toxicity data, K–I Chemical has estimated that aggregate exposure to prohexadione calcium will utilize~1.3 % of the RfD for the U.S. population. K–I Chemical concludes that there is a reasonable certainty that no harm will result from the aggregate exposure to residues of prohexadione calcium, including anticipated dietary exposure and non-occupational exposures.

2. *Infants and children*—i. *Developmental toxicity in the rat*. A developmental study was conducted via oral gavage in rats with dosages of 0, 100, 300, and 1,000 (HDT) mg/kg/day with a No-Adverse-Effect Level (NOAEL) of 1,000 mg/kg/day the highest dose tested for developmental and maternal toxicity based on the fact that no effects were observed for any test parameter measured in this study. Therefore, these NOAEL values are significantly higher than the NOAEL from the 1–year feeding study in dogs used to establish the RfD.

ii. *Developmental toxicity in the rabbit*. A series of developmental studies were conducted via oral gavage in rabbits with dosages ranging from 0 to 750 mg/kg/day with a development toxicity NOAEL of 350 mg/kg/day and a maternal toxicity NOAEL of 100 mg/kg/day based on body weight gain reductions. These NOAEL values are higher than the NOAEL from the 1–year feeding study in dogs used to establish the RfD.

iii. *Reproductive toxicity*. A two–generation reproduction study with rats fed dosages of 0, 500, 5,000, and 50,000 mg/kg/day resulted in a reproductive NOAEL of 50,000 ppm (~5,300 mg/kg/bw/day), a developmental NOAEL of 5,000 ppm (270 mg/kg bw/day), and a maternal toxicity NOAEL of 500 ppm (~50 mg/kg bw/day). The developmental NOAEL was based on a slight, transient

reduction in offspring growth. The maternal NOAEL is similar and the reproductive NOAEL is significantly higher (above the limit dose of 1,000 mg/kg/day) than the NOAEL from the one–year feeding study in dogs used to establish the RfD.

iv. *Reference dose*. Since developmental and reproductive toxicity occurs at levels above the levels shown to exhibit parental toxicity and since these levels are significantly higher than those used to calculate the Reference Dose, K–I Chemical believes the Reference Dose of 0.20 mg/kg/day (20 mg/kg/day and an Uncertainty Factor of 100) is an appropriate measure of safety for infants and children.

Dietary exposure of the most highly exposed subgroup in the population, non-nursing infants (< 1 year old) is 0.025758 mg/kg bw/day. This accounts for 12.9 percent of the RfD. There are no residential uses of prohexadione calcium and contamination of drinking water is extremely unlikely. In addition, there were no significant findings in relevant toxicity studies (i.e., subchronic and chronic toxicity, teratology and multi-generation reproductive studies) which would suggest that prohexadione calcium produces endocrine related effects. Therefore, based on the completeness and reliability of the toxicity data and the conservative exposure assessment, K–I Chemical concludes that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to the residues of prohexadione calcium, including all anticipated dietary exposure and all other non-occupational exposures.

F. International Tolerances

A maximum residue level (MRL) has not been established for prohexadione calcium in peanuts, apples, pears or grass grown for seed by the Codex Alimentarius Commission.

[FR Doc. 01–7520 Filed 3–27–01; 8:45 am]

BILLING CODE 6560–50–S

ENVIRONMENTAL PROTECTION AGENCY

[PF–1011; FRL–6774–5]

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 control number PF–1011, must be received on or before April 27, 2001.

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–1011 in the subject line on the first page of your response.

FOR FURTHER INFORMATION CONTACT: By mail: Leonard Cole, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460; telephone number: (703) 305–5412; e-mail address: cole.leonard@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–1011. 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–1011 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, 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