to be commensurate with the level of risk, extent of use, complexity of issues, and degree of public concern associated with each pesticide. Due to its uses, risks, and other factors, DDVP is being reviewed through the full 6-Phase public participation process.

All comments should be submitted using the methods in Unit I. of the **SUPPLEMENTARY INFORMATION**, and must be received by EPA on or before the closing date. Comments and proposals will become part of the Agency Docket for DDVP. Comments received after the close of the comment period will be marked ''late.'' EPA is not required to consider these late comments.

After considering comments received on the ecological risk assessment, and those on the the human health risk assessment due to be released for public comment shortly, EPA will develop and issue the DDVP IRED. The decisions presented in the IRED be supplemented by further risk mitigation measures when EPA considers its cumulative assessment of the organophosphate pesticides.

B. What is the Agency's Authority for Taking this Action?

Section 4(g)(2) of FIFRA as amended directs that, after submission of all data concerning a pesticide active ingredient, ''the Administrator shall determine whether pesticides containing such active ingredient are eligible for reregistration,'' before calling in product specific data on individual end-use products and either reregistering products or takingother ''appropriate regulatory action.''

Section 408(q) of the FFDCA, 21 U.S.C. 346a(q), requires EPA to review tolerances and exemptions for pesticide residues in effect as of August 2, 1996, to determine whether the tolerance or exemption meets the requirements of section 408(b)(2) or (c)(2) of FFDCA. This review is to be completed by August 3, 2006.

List of Subjects

Environmental protection, Pesticides and pests.

Dated: June 17, 2005.

Debra Edwards,

Director, Special Review and Reregistration Division, Office of Pesticide Programs.

[FR Doc. 05–12952 Filed 6–29–05; 8:45 am]

BILLING CODE 6560–50–S

ENVIRONMENTAL PROTECTION AGENCY

[OPP–2005–0141; FRL–7719–4]

2-amino-4,5-dihydro-6-methyl-4-propyl-s-triazolo(1,5-alpha)pyrimidin-5-one (PP796); Notice of Filing a Pesticide Petition to Amend the Existing Tolerance Exemption

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: This notice announces the initial filing of a pesticide petition by Syngenta Crop Protection, Inc. proposing to amend the established exemption from the requirement of a tolerance under 40 CFR 180.1065 for 2-amino-4,5-dihydro-6-methyl-4-propyl-s-triazolo(1,5-alpha)pyrimidin-5-one, which is also known as PP796, by increasing the amount that can be used to not more than 0.3 percent in formulation of paraquat dichloride.

DATES: Comments, identified by docket identification (ID) number OPP–2005–0141, must be received on or before August 1, 2005.

ADDRESSES: Comments may be submitted electronically, by mail, or through hand delivery/courier. Follow the detailed instructions as provided in Unit I. of the **SUPPLEMENTARY INFORMATION**.

FOR FURTHER INFORMATION CONTACT: Karen Angulo, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001; telephone number: (703) 306–0404; e-mail address: *angulo.karen@epa.gov*.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

You may be potentially affected by this action if you an agricultural producer, food manufacturer, or pesticide manufacturer. Potentially affected entities may include, but are not limited to:

- Crop production (NAICS 111)
- Animal production (NAICS 112)
- Food manufacturing (NAICS 311)
- Pesticide manufacturing (NAICS 32532)

This listing is not intended to be exhaustive, but rather provides a guide for readers regarding entities likely to be affected by this action. Other types of entities not listed in this unit could also be affected. The North American Industrial Classification System (NAICS) codes have been provided to assist you and others in determining whether this action might apply to certain entities. If you have any questions regarding the applicability of this action to a particular entity, consult the person listed under **FOR FURTHER INFORMATION CONTACT**.

B. How Can I Get Copies of this Document and Other Related Information?

1. *Docket*. EPA has established an official public docket for this action under docket ID number OPP–2005–0141. The official public docket consists of the documents specifically referenced in this action, any public comments received, and other information related to this action. Although a part of the official docket, the public docket does not include Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. The official public docket is the collection of materials that is available for public viewing at the Public Information and Records Integrity Branch (PIRIB), Rm. 119, Crystal Mall #2, 1801 S. Bell St., Arlington, VA. This docket facility is open from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The docket telephone number is (703) 305–5805.

2. *Electronic access*. You may access this **Federal Register** document electronically through the EPA Internet under the ''**Federal Register**'' listings at *http://www.epa.gov/fedrgstr/*.

An electronic version of the public docket is available through EPA's electronic public docket and comment system, EPA Dockets. You may use EPA Dockets at *http://www.epa.gov/edocket/* to submit or view public comments, access the index listing of the contents of the official public docket, and to access those documents in the public docket that are available electronically. Although not all docket materials may be available electronically, you may still access any of the publicly available docket materials through the docket facility identified in Unit I.B.1. Once in the system, select ''search,'' then key in the appropriate docket ID number.

Certain types of information will not be placed in the EPA Dockets. Information claimed as CBI and other information whose disclosure is restricted by statute, which is not included in the official public docket, will not be available for public viewing in EPA's electronic public docket. EPA's policy is that copyrighted material will not be placed in EPA's electronic public docket but will be available only in printed, paper form in the official public docket. To the extent feasible, publicly available docket materials will be made

available in EPA's electronic public docket. When a document is selected from the index list in EPA Dockets, the system will identify whether the document is available for viewing in EPA's electronic public docket. Although not all docket materials may be available electronically, you may still access any of the publicly available docket materials through the docket facility identified in Unit I.B. EPA intends to work towards providing electronic access to all of the publicly available docket materials through EPA's electronic public docket.

For public commenters, it is important to note that EPA's policy is that public comments, whether submitted electronically or in paper, will be made available for public viewing in EPA's electronic public docket as EPA receives them and without change, unless the comment contains copyrighted material, CBI, or other information whose disclosure is restricted by statute. When EPA identifies a comment containing copyrighted material, EPA will provide a reference to that material in the version of the comment that is placed in EPA's electronic public docket. The entire printed comment, including the copyrighted material, will be available in the public docket.

Public comments submitted on computer disks that are mailed or delivered to the docket will be transferred to EPA's electronic public docket. Public comments that are mailed or delivered to the docket will be scanned and placed in EPA's electronic public docket. Where practical, physical objects will be photographed, and the photograph will be placed in EPA's electronic public docket along with a brief description written by the docket staff.

C. How and To Whom Do I Submit Comments?

You may submit comments electronically, by mail, or through hand delivery/courier. To ensure proper receipt by EPA, identify the appropriate docket ID number in the subject line on the first page of your comment. Please ensure that your comments are submitted within the specified comment period. Comments received after the close of the comment period will be marked ''late.'' EPA is not required to consider these late comments. If you wish to submit CBI or information that is otherwise protected by statute, please follow the instructions in Unit I.D. Do not use EPA Dockets or e-mail to submit CBI or information protected by statute.

1. *Electronically*. If you submit an electronic comment as prescribed in this unit, EPA recommends that you include your name, mailing address, and an e-mail address or other contact information in the body of your comment. Also include this contact information on the outside of any disk or CD ROM you submit, and in any cover letter accompanying the disk or CD ROM. This ensures that you can be identified as the submitter of the comment and allows EPA to contact you in case EPA cannot read your comment due to technical difficulties or needs further information on the substance of your comment. EPA's policy is that EPA will not edit your comment, and any identifying or contact information provided in the body of a comment will be included as part of the comment that is placed in the official public docket, and made available in EPA's electronic public docket. If EPA cannot read your comment due to technical difficulties and cannot contact you for clarification, EPA may not be able to consider your comment.

i. *EPA Dockets*. Your use of EPA's electronic public docket to submit comments to EPA electronically is EPA's preferred method for receiving comments. Go directly to EPA Dockets at *http://www.epa.gov/edocket/*, and follow the online instructions for submitting comments. Once in the system, select ''search,'' and then key in docket ID number OPP–2005–0141. The system is an ''anonymous access'' system, which means EPA will not know your identity, e-mail address, or other contact information unless you provide it in the body of your comment.

ii. *E-mail*. Comments may be sent by e-mail to opp-docket@epa.gov, Attention: Docket ID Number OPP–2005–0141. In contrast to EPA's electronic public docket, EPA's e-mail system is not an ''anonymous access'' system. If you send an e-mail comment directly to the docket without going through EPA's electronic public docket, EPA's e-mail system automatically captures your e-mail address. E-mail addresses that are automatically captured by EPA's e-mail system are included as part of the comment that is placed in the official public docket, and made available in EPA's electronic public docket.

iii. *Disk or CD ROM*. You may submit comments on a disk or CD ROM that you mail to the mailing address identified in Unit I.C.2. These electronic submissions will be accepted in WordPerfect or ASCII file format. Avoid the use of special characters and any form of encryption.

2. *By mail*. Send your comments to: Public Information and Records Integrity Branch (PIRIB) (7502C), Office of Pesticide Programs (OPP), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001, Attention: Docket ID Number OPP–2005–0141.

3. *By hand delivery or courier*. Deliver your comments to: Public Information and Records Integrity Branch (PIRIB), Office of Pesticide Programs (OPP), Environmental Protection Agency, Rm. 119, Crystal Mall #2, 1801 S. Bell St., Arlington, VA, Attention: Docket ID Number OPP–2005–0141. 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 assignedto this action in the subject line on the first page of your response. You may also provide thename, 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: June 22, 2005.

Lois Rossi,

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.

Syngenta Crop Protection, Inc.

PP 5E6929

EPA has received a pesticide petition (5E6929) from Syngenta Crop Protection, P.O Box 18300, Greensboro, NC 27419–8300 proposing, pursuant to section 408 of the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. 346a, to amend the established exemption from the requirement of a tolerance under 40 CFR 180.1065 for 2-amino-4,5-dihydro-6-methyl-4-propyl-s-triazolo(1,5-alpha)pyrimidin-5-one (CAS No. 27277–00–5). 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. 2-amino-4,5-dihydro-6-methyl-4-propyl-s-triazolo(1,5-alpha)pyrimidin-5-one is also known as ''PP796,'' and shall be referred to as such in this document for ease of reading.

A. Residue Chemistry

1. *Plant metabolism.* Plant metabolism studies are generally not required for exemption from tolerance of an inert ingredient. The plant metabolism of PP796 has not been investigated. Since this inert is only utilized as an emetic in paraquat dichloride end use products that are utilized for non-selective weed control, plant residues of PP796 are expected to be non-detectable.

2. *Analytical method.* Analytical methods are generally not required for exemption from a tolerance of an inert ingredient. Methods have been developed and could be provided if requested. The requested use is not expected to result in detectable residues.

3. *Magnitude of residues.* Potential residues of PP796 in raw and or processed agricultural commodities as a result of the use of paraquat dichloride formulations containing up to 0.3 % w/w of this substance are expected to be minimal. The maximum concentration of PP796 (0.3% w/w) in paraquat dichloride formulations is much lower than the concentration of the co-formulated active ingredient (paraquat dichloride). Based on data presented in the Reregistration Eligibility Decision (RED) on paraquat dichloride, and on the expected relative concentrations of paraquat and PP796 on agricultural commodities would be approximately 110 times lower than paraquat dichloride (assuming the maximum of 0.3% w/w emetic in a technical containing 33.0% paraquat ion).

B. Toxicological Profile

1. *Acute toxicity.* Acute oral toxicity has been evaluated in rats. Groups of 5 male and 5 female rats received single oral doses of 100, 150 and 200 mg/kg/body weight of PP796. Moderate signs of toxicity were seen at 100 mg/kg, but all animals recovered by day 7. Marked signs of toxicity were seen at both 150 and 200 mg/kg, with 9/10 animals dosed with 150 mg/kg, and 8/10 animals dosed with 200 mg/kg, being found dead or killed in extremis at day 2. All surviving animals had recovered by day 10. Clinical sign of toxicity included decreased activity, salivation, upward curvature of the spine, increased breathing rate, ptosis and stains around the mouth and nose. With no significant findings at post mortem, the median lethal dose is estimated as being between 100 and 150 mg/kg/body weight.

Acute dermal toxicity has been evaluated in rats. 2,000 mg/kg body weight of PP796 was applied to the skin of 5 male and 5 female rats for 24 hours, washed off, and the animals observed for signs of toxicity for 14 days. Other than an observation of slight erythema seen in one male rat on day 2, no signs of dermal irritation were noted. There were no mortalities, and with no macroscopic effects at post mortem, the acute dermal median lethal dose is considered to be > 2,000 mg/kg/day.

Skin irritation was evaluated in rats. PP796 caused slight irritation to rat skin and some evidence of dermal toxicity following repeated occluded application. Signs of irritation were evident after the 4th application when all animals developed erythema. In addition, all animals looked thin after the 5th application, one was subdued and another was hunched. One animal was found dead on the last day of the study (after a total dose of 0.6 mg/kg). Histopathological examination of the skin and selected major organs confirmed the irritant effect. With no obvious signs of chemical toxicity, the only systemic effects were severe involution of the thymus and spleen.

Eye irritation was evaluated on rabbits. Instillation of PP796 into the eyes of rabbits caused moderate initial pain and slight irritation. Treated eyes were examined at 1-2 hours and at 1-,2-,3-,4-, and 7- days post instillation. Although no corneal damage was noted, transient iridial and conjuctival reations were observed. With all signs of irritation clearing by day 2, PP796 is considered a slight eye irritant.

Skin sensitization potential was evaluated in guinea pigs. It has tested negative in a Stevens Ear/Flank test in guinea pigs and as such is not considered to be a strong skin sensitizer.

2. *Genotoxicity.* PP796 is non-mutagenic. It has tested negative in *Salmonella* Ames tests, both in the presence and absence of metabolic activation (Arochlor induced liver S9 fraction) with each of 5 tester strains (TA98, TA100, TA1535 and TA1538).

3.*Reproductive and developmental toxicity.* Developmental toxicity was evaluated in rabbits and rats. Tests on pregnant animals during organogenesis

showed no deformities in either rat or rabbit offspring, but at high doses in rabbit, PP796 was toxic to the dam resulting in spontaneous abortions.

i. *Rabbits*. Groups of 12 female rabbits were orally dosed days 6-18 of pregnancy with 0, 0.25, 0.75 and 1.25 mg/kg PP796. Half of the animals in each group were killed by day 28 and the fetuses removed. The dams were examined for signs of toxicity and macroscopic abnormalities. The fetuses were examined for soft tissue abnormalities before subsequent processing for skeletal examination. The remaining rabbits were allowed to litter and rear their offspring to 4 weeks post partum.

Dosing with 1.25 and 0.75 mg/kg caused an increase in the number of reabsorptions. No reabsorptions were seen at the 0.25 mg/kg level. Two rabbits receiving 1.25 mg/kg aborted day 20, and another one when killed day 29, had 6 reabsorptions and no viable fetuses. Of those receiving 0.75 mg/kg, one died day 18 (having 8 fetuses in utero) and another littered. The two higher dose levels also produced anorexia. Fewer offspring survived to 28 days of rabbits treated with 0.75 mg/kg. Only a small number of deformities were detected, including the presence of extra ribs, a common finding in this strain of rabbit.

PP796 induces vomiting in dogs at high doses. Although rabbits can not vomit, the high doses in this study resulted in poor appetite/anorexia.

In conclusion, PP796, is not teratogenic to rabbits, producing maternal toxicity at 1.25 and 0.75 mg/kg and only minimal fetal toxicity. The No Observable Effect Level (NOEL) = 0.25 mg/kg/day.

ii. *Rats*. Groups of 20 female rats were orally dosed days 6-15 of pregnancy with 0, 0.25 and 1.25 mg/kg of PP796. Half the rats were killed one day prior to parturition and the fetuses examined for soft tissue changes before being processed for skeletal examination. The remaining rats were allowed to litter and rear their offspring to weaning.

PP796 had no significant effect on stillbirths, reabsorption rates, litter size or mean offspring weight. There was however evidence of anorexia and a reduction in body weight gain in top dose females. Skeletal and soft tissue changes were within normal limits for the strain of rat. In conclusion, PP796 was not teratogenic to the rat and had little effect on pregnancy, littering or weaning. The NOEL = 0.25 mg/kg/day.

4. *Subchronic toxicity*.Subchronic toxicity was evaluated on rats and dogs.

i. *Rats*. 10 male and 10 female rats were orally dosed with 0, 0.25, or 1.25 mg/kg PP796 daily for 3 months. In this study 15 male and 15 female rats were similarly exposed to 5 mg/kg. At the end of the 3-month dosing period, 5 male and 5 female rats previously exposed to 5 mg/kg PP796 were maintained without treatment for a further 12 weeks to assess reversibility. There was a slight reduction in body weight gain in top dose male rats. Many top dose and a few mid dose rats salivated after dosing the first few weeks of treatment, but thereafter salivated before dosing. There were no treatment related effects on haematology (haemoglobin, packed cell volume, total white cell count, differential white cell count, platelets and mean cell haemoglobin) or on urine analysis. In terms of clinical chemistry, no treatment related effects were observed in AST, ICD or total protein. Slightly elevated levels of alkaline phosphatase were seen in male and female rats treated with 5 mg/kg PP796 on day 22. By day 36, the levels were statistically significantly different from the controls (Males $P<0.05$; females $P<0.001$), but by day 85, had returned to normal. Significantly increased serum urea levels were noted in female rats exposed to 5 mg/kg PP796 day 36 ($P< 0.001$) and day 85 ($P< 0.01$). Slightly increased serum urea levels were noted in male rats day 3 only ($P< 0.05$). At study termination (and termination of the recovery animals) there were no effects on organ weights and no histological changes attributable to treatment.

ii. *Dogs*. In this study 4 male and 4 female beagles were orally dosed with capsules containing 0, 0.15, 0.5, or 1.5 mg/kg PP796 daily for 3 months. From these animals 1 male and 1 female top dose animals were maintained on study for a further 6 weeks after dosing to assess recovery.

After the 5th week of treatment, many top dose animals salivated profusely before dosing. One male from the same group refused to eat days 9 and 10 of treatment. Vomiting occurred sporadically in 6 top dose and 3 mid-dose animals from day 9 onwards. One female top dose dog that was sick on several occasions and passed blood in its feces was found to have an ileo-caecal intussusception at post-mortem - a relatively common abnormality in this strain of dog. Examination of this animal's bone marrow smear showed megaloblastic hyperplasia - a finding consistent with poor intestinal absorption due to the ileo-caecal ulceration. Weight gains were similar in both control and treated males, while top dose females lost weight sporadically. There were no treatment related effects on haematology, urine analysis, clinical chemistry or clinical pharmacology. Analysis of serum level concentrations showed PP796 to be well absorbed via the oral route.

At study termination (and termination of the recovery animals) there were no effects on organ weights. Macroscopically, many of the animals (both control and treated) were observed to have reddish areas in the lungs. These patches of pneumonia or nodules of inflammatory cells were attributed to the presence of nematodes caused by the animals not having been treated with anti-helminthics prior to the start of dosing. One additional top-dose female had a small cystadenoma in the thyroid.

Other than a similar nematode-related bronchopneumonia, no pathological changes attributable to PP796 were noted in the recovery animals.

In conclusion, PP796, when administered to rats and dogs at high doses produced no pathological changes, which could be attributed to treatment. The only effects being vomiting in dogs and elevated serum urea levels in female rats.

5.*Chronic toxicity*. Chronic toxicity was evaluated in mice. In this study 25 male and 25 female mice per group and controls were exposed to 5 and 20 ppm (1.25 and 5 mg/kg/day) PP796 in the diet for approximately 78 weeks. Although survival was good, statistically significant dose related reductions in body weight were evident at the high dose level. With no significant difference in the tumor incidence between control and treated animals, it may be concluded that PP796 is not carcinogenic to mice. The NOEL = 1.25 mg/kg/day.

6. *Animal metabolism*. PP796 is well absorbed following oral administration in the mouse, rat, guinea pig, and dog. With the exception of the rat, at least 70% of the administered dose was passed in the urine by 48 hours. The rat differs from the other species in passing a large proportion (43%) of the oral dose in the feces. It has been shown that biliary excretion is the major route in the rat and whole body autoradiography indicates that biliary excretion and reabsorption occurs in mice.

PP796 is extensively metabolized in all the above species, with the urine containing a metabolite in which the methyl group has been hydroxylated. In guinea pigs, it has been shown that serum and tissue levels of total radioactivity are steady over the period 0.25 to 4 hours after oral administration, with maximum levels at about 1 hour. The maximum serum level of PP796 is higher in guinea pigs (0.87 ug/ml) than in rats (0.17 ug/ml) or mice (0.06 ug/ml)

after an oral dose of 1 mg/kg. The mentioned metabolite is a minor component in the serum of all 3 species with 5, 4, and 7% of the total radioactivity in serum in the guinea pig, rat and mouse respectively.

Measurement of the concentration of PP796 in the serum of rats and dogs after prolonged dosing showed:

i. No difference in the levels between sexes.

ii. A linear dose - peak serum level response and a linear dose - area under the curve response in dogs throughout the range of doses tested (i.e. 0.15-1.5 mg/kg/day) with slopes of 0.26 ug/ml per 1 mg/kg dose and 1.18 ug.hr/ml per 1 mg/kg dose, respectively. Similar effects were noted in rats in the dose range up to 1.25 mg/kg with slopes of 0.11 ug/ml and 0.52 ug.hr/ml per 1 mg/kg dose, i.e. about half the response seen in dogs.

iii. A biological half-life of < 3 hours in the dog.

There was no evidence to suggest that serum concentration significantly increased or decreased after prolonged administration, hence PP796 is unlikely to be cumulative.

7. *Metabolite toxicology*. The toxicity of metabolites of PP796 has not been studied. Given the level of anticipated exposure and the available animal metabolism data, it is unlikely metabolites of this inert will be of concern.

8. *Endocrine disruption*. There is no evidence that PP796 has hormone disrupting activity.

C. Aggregate Exposure

1. *Dietary exposure*. The residues of PP796 on raw agricultural commodities, due to application in paraquat dichloride formulations, are expected to be negligible. This is due to the low concentration in end use formulations (< 0.2% w/w) and the use pattern for paraquat dichloride, a nonselective herbicide. In the 1997 RED for paraquat dichloride the Theoretical Maximum Residue Concentrations (TMRC) were calculated for the then existing tolerances for paraquat dichloride. Based on the conservative approach (Tier 1), the chronic exposure of the U.S. population, and of the most highly exposed population subgroup (non-nursing infants less than 1-year old), to paraquat was calculated to be 0.000442 and 0.001398 mg/kg body weight/day, respectively (pg. 55 of RED Paraquat Dichloride).

A formulation that contained the maximum proposed amount of PP796 (0.3% w/w) would contain 110 times more paraquat ion than PP796 (assuming a technical containing 33.0% w/w paraquat ion). Therefore, the theoretical chronic exposure can be estimated by dividing the paraquat exposure numbers by 110, resulting in 0.00000402 mg/kg body weight/day for the U.S. population and 0.0000127 mg/kg body weight/day for the most exposed population (non-nursing infants (<1 years old).

i. *Food*. Exposures to PP796 from food are expected to be negligible.

ii. *Drinking water*. Exposures to PP796 from drinking water are expected to be negligible due to the low concentration in the end-use products. There are no aquatic uses of products containing paraquat dichloride.

2. *Non-dietary exposure*. End use products containing paraquat dichloride are restricted use pesticides. There are no residential or homeowner uses. Non-dietary exposure is expected to be negligible.

D. Cumulative Effects

PP796 is only approved for use in paraquat dichloride formulations. There is no evidence for a common mechanism of toxicity with other substances. Therefore, there is no expectation that the use of PP796 as an inert ingredient in paraquat formulations (up to 0.3 % w/w) would contribute to any cumulative toxicity arising from exposure to other substances having a common mechanism of toxicity.

E. Safety Determination

1. *U.S. population*. Based on the toxicity data presented and the very low level of exposure, Syngenta Crop Protection, Inc. believes that there is reasonable certainty that no harm will result to the general U.S. population by increasing the emetic level in paraquat dichloride formulations. PP796 is included in paraquat dichloride formulations as an added safety factor as required by USEPA. The 1987 *Guidance for the Reregistration of Pesticide Products Containing Paraquat Dichloride as the Active Ingredient* states on page 27 that ''The Agency is continuing to require that an emetic cleared under 40 CFR 180.1001(b) and (c) be incorporated into all manufacturing use and end use products containing paraquat. Rationale: Based on the history of poisoning by accidental ingestion of paraquat and partial effectiveness of therapeutic treatment after exposure, the Agency determined that an emetic is needed in formulations to induce rapid vomiting thereby reducing absorption of paraquat.'' Syngenta Crop Protection, Inc. has developed a novel formulation which significantly improves acute oral toxicity of paraquat dichloride formulations in vomiting species. This novel formulation improvement is largely accomplished by adding a gelling agent which slows the movement of paraquat into the intestine where most absorption occurs. Improving human safety is the primary reason for this request, as the emetic level is being increased to ensure adequate absorption from the gel in the stomach.

2. *Infants and children*. Based on the toxicity data presented and the very low level of exposure, Syngenta Crop Protection, Inc. believes that there is reasonable certainty that no harm will result to infants and children by increasing the emetic level in paraquat formulations. PP796 is included in paraquat dichloride formulations as an added safety factor as required by U.S. EPA.

F. International Tolerances

Import tolerances are not required for this inert ingredient. It is listed as a requirement in FAO Specification 56.302/TK (2003). The FAO specification requires that ''An effective emetic, having the following characteristics, be incorporated into the technical. It must be rapidly absorbed (more rapidly than paraquat) and be quick acting. Emesis must occur in about half an hour in at least 50% of cases. It must be an effective (strong) stimulant of the emetic center of the brain, to produce effective emesis. The emetic effect should have a limited 'action period', of about two to three hours, to allow effective treatment of poisoning. It must act centrally on the emetic center in the brain. It must not be a gastric irritant because, as paraquat itself is an irritant, this could potentiate the toxicity of paraquat. It must be toxicologically acceptable. It must have a short half-life in the body (to comply with the need for a limited action period). It must be compatible with, and stable in, the paraquat formulation and not affect the herbicidal efficacy or occupational use of the product. To date, the only compound found to meet these requirements is 2-amino-4,5-dihydro-6-methyl-4-propyl-s-triazole-(1,5a)pyrimidin-5-one (PP796). PP796 must be present in the technical at not less than 0.8 g/l. The method for determination of PP796 content is available from the Plant Protection Officer, FAO Plant Production and Protection Division.''

[FR Doc. 05–12922 Filed 6–29–05; 8:45 am]

BILLING CODE 6560–50–S