ENVIRONMENTAL PROTECTION AGENCY

[OPP–2004–0017; FRL–7343–4]

Potassium Dihydrogen Phosphate; Notice of Filing a Pesticide Petition to Establish a Tolerance for a Certain Pesticide Chemical in or on Food

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: This notice announces the initial filing of a pesticide petition proposing the establishment of regulations for residues of a certain pesticide chemical in or on various food commodities.

DATES: Comments, identified by docket identification (ID) number OPP–2004–0017, must be received on or before March 22, 2004.

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: Driss Benmhend, Biopesticides and Pollution Prevention Division (7511C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001; telephone number: (703) 308–9525; e-mail address: *benmhend.driss@epa.gov*.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

You may be potentially affected by this action if you are 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–2004–0017. The official public docket consists of the documents specifically referenced in this action, any public comments received, and other information related to this action. Although a part of the official docket, the public docket does not include Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. The official public docket is the collection of materials that is available for public viewing at the Public Information and Records Integrity Branch (PIRIB), Rm. 119, Crystal Mall #2, 1921 Jefferson Davis Hwy., Arlington, VA. This docket facility is open from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The docket telephone number is (703) 305–5805.

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

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

Certain types of information will not be placed in EPA's 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.1. 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–2004–0017. 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–2004–0017. 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–2004–0017.

3. *By hand delivery or courier*. Deliver your comments to: Public Information and Records Integrity Branch (PIRIB), Office of Pesticide Programs (OPP), Environmental Protection Agency, Rm. 119, Crystal Mall #2, 1921 Jefferson Davis Hwy., Arlington, VA, Attention: Docket ID Number OPP–2004–0017. Such deliveries are only accepted during the docket's normal hours of operation as identified in Unit I.B.1.

D. How Should I Submit CBI to the Agency?

Do not submit information that you consider to be CBI electronically through EPA's electronic public docket or by e-mail. You may claim information that you submit to EPA as CBI by marking any part or all of that information as CBI (if you submit CBI on disk or CD ROM, mark the outside of the disk or CD ROM as CBI and then identify electronically within the disk or CD ROM the specific information that is CBI). Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2.

In addition to one complete version of the comment that includes any information claimed as CBI, a copy of the comment that does not contain the information claimed as CBI must be submitted for inclusion in the public docket and EPA's electronic public docket. If you submit the copy that does not contain CBI on disk or CD ROM, mark the outside of the disk or CD ROM clearly that it does not contain CBI. Information not marked as CBI will be included in the public docket and EPA's electronic public docket without prior notice. If you have any questions about CBI or the procedures for claiming CBI, please consult the person listed under **FOR FURTHER INFORMATION CONTACT**.

E. What Should I Consider as I Prepare My Comments for EPA?

You may find the following suggestions helpful for preparing your comments:

1. Explain your views as clearly as possible.

2. Describe any assumptions that you used.

3. Provide copies of any technical information and/or data you used that support your views.

4. If you estimate potential burden or costs, explain how you arrived at the estimate that you provide.

5. Provide specific examples to illustrate your concerns.

6. Make sure to submit your comments by the deadline in this notice.

7. To ensure proper receipt by EPA, be sure to identify the docket ID number assigned to this action in the subject line on the first page of your response. You may also provide the name, date, and **Federal Register** citation.

II. What Action is the Agency Taking?

EPA has received a pesticide petition as follows proposing the establishment and/or amendment of regulations for residues of a certain pesticide chemical in or on various food commodities under section 408 of the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. 346a. EPA has determined that this petition contains data or information regarding the elements set forth in FFDCA section 408(d)(2); however, EPA has not fully evaluated the sufficiency of the submitted data at this time or whether the data support granting of the petition. Additional data may be needed before EPA rules on the petition.

List of Subjects

Environmental protection, Agricultural commodities, Feed additives, Food additives, Pesticides and pests, Reporting and recordkeeping requirements.

Dated: February 5, 2004.

Sheryl K. Reilly,

Acting Director, Biopesticides and Pollution Prevention Division, Office of Pesticide Programs.

Summary of Petition

The petitioner's 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.

Cal Agri Products, LLC

PP 3F6793

EPA has received a pesticide petition 3F6793 from Cal Agri Products, LLC, 10720 McCune Avenue, Los Angeles, CA 90034, proposing pursuant to section 408(d) of the FFDCA, 21 U.S.C. 346a(d), to amend 40 CFR part 180 to establish an amendment/expansion of an existing tolerance exemption for the biochemical pesticide potassium dihydrogen phosphate.

Pursuant to section 408(d)(2)(A)(i) of the FFDCA, as amended, Cal Agri Products, LLC has submitted the following summary of information, data, and arguments in support of their

pesticide petition. This summary was prepared by Cal Agri Products, LLC and EPA has not fully evaluated the merits of the pesticide petition. The summary may have been edited by EPA if the terminology used was unclear, the summary contained extraneous material, or the summary unintentionally made the reader conclude that the findings reflected EPA's position and not the position of the petitioner.

A. Product Name and Proposed Use Practices

Cal Agri Products, LLC has filed a petition for the extension of the existing exemption from the requirement of a tolerance for residues in or on growing crops and raw agricultural commodities for potassium dihydrogen phosphate (KDP), also known as monopotassium phosphate, to include uses as an active ingredient for insect control. KDP is a ubiquitous element in nature and is a common ingredient in many consumer and industrial products used worldwide. KDP is an important nutrient supplement for human health and a common ingredient in pharmaceuticals, food processing and manufacturing. KDP is categorized as a generally recognized as safe (GRAS) compound (21 CFR 182.1073), with minimal risks associated with acute and chronic human exposure when used in accordance with good manufacturing practices. In addition to food applications, KDP is also a common ingredient in many agricultural fertilizers and pesticides. Currently, KDP is registered as an active ingredient in three reduced-risk fungicides (EPA No. 70644–1, 70644–4 and 42519–24) and is exempt from the requirement of a food tolerance under 40 CFR 180.1193, when applied as fungicide in accordance with good agricultural practices. KDP is also exempt from the requirement of a food tolerance under 40 CFR 180.1001 (c) and (e) when used as an inert ingredient in pesticide formulations.

KDP is formulated as a pesticide active ingredient and has been shown to operate as an effective non-toxic control agent of a number of agriculturally important insect pests and pathogens. The pesticide formulation utilizing KDP operates through a non-toxic physical mode of action that effects the insects' protective coating making them vulnerable to disruption and desiccation from the KDP active ingredient. Use patterns for KDP will include foliar applications to food and non-food crops for the control of soft-bodied insects, such as aphids and whiteflies, and foliar pathogens, such as powdery mildew. Proposed uses will also include soil drenches for the control of soil dwelling pathogens. The pesticide formulation will be diluted with water for a use rate of 2,000 to 4,000 parts per million (ppm) (20 to 50 ppm of KDP). Use patterns will include application on agricultural food crops, ornamental and nursery crops grown in fields and greenhouses. Use of the pesticide formulation containing KDP as an active ingredient may be an effective substitute for some highly toxic pesticides (such as some organophosphates) that are currently used to control some of these same pests.

B. Product Identity/Chemistry

1. *Identity of the pesticide and corresponding residues*. Potassium dihydrogen phosphate (CAS No. 7778–77–0), also known as monopotassium phosphate, is a phosphate and potassium salt compound and described by the empirical formula KH_2PO_4. KDP is produced through the electrolysis of potassium chloride, which in turn, is reacted with phosphoric acid. KDP is an ingredient widely used in processing foods for animal and human consumption and in other consumer products including detergents, creams, lotions, foods, shampoos, and toothpaste. KDP is the active ingredient in three previously registered pesticides (EPA No. 70644–1, 70644–2 and 42519–24) applied for the control of powdery mildew.

2. *Magnitude of residue at the time of harvest and method used to determine the residue*. Residues of KDP are projected to be negligible because of the small amounts applied and the rapid absorption by plants and biodegradability of this compound.

3.*A statement of why an analytical method for detecting and measuring the levels of the pesticide residue are not needed*. KDP has been approved by the U.S. Food and Drug Administration (FDA) for use as a food additive and is categorized as a GRAS compound under 21 CFR 182.1073. Consumption of KDP in the typical diet and environmental exposure to KDP is far in excess of any residuals expected to be found on or in food crops from the use of KDP at the rates proposed as a fungicide or insecticide. EPA in granting an exemption from the requirement of a tolerance for KDP. EPA has determined that no harm will result from aggregate exposure to KDP when use as an active ingredient in fungicide formulations or an inert ingredient in other pesticide formulations. Therefore no analytic method for detecting residues of KDP is required.

C. Mammalian Toxicological Profile

KDP has been approved by the FDA for use as a food additive and is categorized as a GRAS compound under 21 CFR 182.1073. It is a common component of many consumer products in the United States and most industrial nations. In 1998, under the initiative of EPA, KDP was listed as exempt from the requirement of a food tolerance when used as a fungicide (40 CFR 180.1193) and additionally, is listed as exempt from the requirement of a food tolerance when used as an inert ingredient in pesticide formulations (40 CFR 180.1001 (c) and (e)). EPA concluded, based on the available scientific information coupled with a lack of reported adverse effects, that KDP does not pose an unreasonable risk to human health or the environment.

1. *Acute toxicity*. KDP has been extensively studied in animal and human studies in both short-term and long-term trials (sub-acute to chronic exposure). Studies have demonstrated an acute oral toxicity lethal dose $(LD)_{50}$ >500 milligrams/kilogram (mg/kg) in female rats, LD_{50} >5,000 mg/kg in male rats and LD_{50} >4,640 mg/kg for rats (toxicity category III) and an acute dermal toxicity lethal dose LD_{50} = 2,000 mg/kg for rabbits (toxicity category III). It has also been determined to be non-irritating to skin in rabbits (toxicity category IV) and a mild eye irritant (toxicity category III). Human experience with KDP has demonstrated that consumption of phosphorus from 30 mg/kg/day to a maximum of 70 mg/kg/day can be tolerated without adverse affect. The FDA recommended daily value of potassium intake is 3,500 mg/day.

2. *Genotoxicity*. There is no evidence of genetoxicity from exposure to KDP. EPA in granting an exemption from tolerance for KDP when used as a fungicide, waived requirement of further testing to determine genotoxicity because of low mammalian toxicity and no reports of adverse effects.

3. *Reproductive and developmental toxicity.* There is no evidence of reproductive or developmental toxicity from exposure to KDP. EPA in granting an exemption from the requirement of a tolerance for KDP when used as a fungicide, waived requirement of further testing to determine reproductive and developmental toxicity because of low mammalian toxicity and no reports of adverse effects.

4. *Subchronic toxicity*. KDP disassociates into potassium and phosphorus ions which are both essential nutrients in mammals. EPA in

granting an exemption from tolerance for KDP when used as a fungicide, waived requirement of further testing to determine subchronic toxicity because of low mammalian toxicity and no reports of adverse effects.

5. *Chronic toxicity*. There is no evidence of chronic toxicity from exposure to KDP. EPA in granting an exemption from the requirement of a tolerance for KDP when used as a fungicide, waived requirement of further testing to determine chronic toxicity because of low mammalian toxicity and no reports of adverse effects.

6. *Animal metabolism*. KDP is a food grade material as established by the FDA under 21 CFR 182.1073. No adverse effects on animal metabolism have been reported in any of the animal studies reviewed.

7. *Metabolite toxicology*. KDP is a food grade material as established by the FDA 21 CFR 182.1073. None of the metabolites of KDP are known or suspected to be toxic.

8. *Endocrine disruption*. KDP does not belong to a class of chemicals known to have adverse effects on the endocrine system. No adverse effects were reported in any of the animal studies reviewed.

D. Aggregate Exposure

1. *Dietary exposure*—i. *Food*. KDP is a food grade material as established by the FDA under 21 CFR 182.1073 and is identified as a GRAS chemical compound. KDP is exempt from the requirement of establishing a tolerance under 40 CFR 180.1193 and 180.1001(c) and (e). Use of KDP as an insecticide (use rates between 20 and 50 ppm) is unlikely to enhance consumer exposure given its ubiquitous nature and rapid biodegradability.

ii. *Drinking water*. There is no expected human exposure to KDP in drinking water as most of it is absorbed when applied to plants.

2. *Non-dietary exposure*. KDP is commonly found in many foods and consumer products and is a ubiquitous element in nature and, as a result, there are numerous routes of non-dietary exposure. In view of the small amount of KDP used in the pesticide formulation, its rapid absorption by plants and the rapid biodegradability of KDP, it is unlikely to influence non-dietary exposure to infants, children, or other consumer groups.

E. Cumulative Exposure

The small amount of KDP used in the proposed pesticide formulation, its rapid absorption by plants and the rapid biodegradability of KDP, make it unlikely that KDP will influence the cumulative exposure to infants, children, or other consumer groups at the proposed use rates.

F. Safety Determination

1.*U.S. population*. Given KDP's low-risk profile and the history of its safe use in pesticides and fertilizers, there is every reason to believe that no additional risk to the U.S. population will result from aggregate exposure to KDP.

2. *Infants and children*. EPA, in granting an exemption from the requirement of a tolerance for KDP when used as a fungicide, has determined that in view of the lack of mammalian toxicity and the history of safe use there is no additional exposure or safety concerns for infants and children from the use of KDP as a pesticide.

G. Effects on the Immune and Endocrine Systems

There are no reports of any adverse effects to immune or endocrine systems in animal studies or to human populations. There is reasonable certainty that no adverse effects will result from the use of KDP as an insecticide.

H. Existing Tolerances

KDP is a food grade material as established by the FDA under 21 CFR 182.1073. KDP is exempt from the requirement of a tolerance under 40 CFR 180.1001(c) and (e) when used as an inert ingredient in pesticide formulations and under 40 CFR 180.1193 when used as a fungicide.

I. International Tolerances

There are no Codex tolerances established for KDP.

[FR Doc. 04–3718 Filed 2–19–04; 8:45 am]

BILLING CODE 6560–50–S

ENVIRONMENTAL PROTECTION AGENCY

[OPP–2004–0016; FRL–7343–3]

Ethoxy Dodecyl Phenol; Notice of Filing a Pesticide Petition to Establish a Tolerance for a Certain Pesticide Chemical in or on Food

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: This notice announces the initial filing of a pesticide petition proposing the establishment of regulations for residues of a certain pesticide chemical in or on various food commodities.

DATES: Comments, identified by docket identification (ID) number OPP–2004–0016, must be received on or before March 22, 2004.

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: Driss Benmhend, Biopesticides and Pollution Prevention Division (7511C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001; telephone number: (703) 308–9525; e-mail address: *benmhend.driss@epa.gov*.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

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

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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–2004–0016. 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