

TABLE 4.—INTERMEDIATE-TERM AGGREGATE DRINKING WATER ASSESSMENT

Population Subgroup	NOAEL/MOE Mg/ Kg/Day	Aggregate Ex- posure Mg/ Kg/Day	Maximum Water Exposure mg/kg/day	SCI-GROW (ppb)	FIRST (ppb)	DWLOC (ppb)
Toddlers (1 to 3) ¹	0.307	0.217	2.852	0.94	6.24	42,785

¹ Assume 70kg bodyweight

The estimated average concentration of dinotefuran in surface water is 6.24 ppb. This value is less than the DWLOC for dinotefuran as a contribution to intermediate-term aggregate exposure (42,785 ppb). Therefore, taking into account the proposed uses, it can be concluded with reasonable certainty that residues of dinotefuran in residential environments and in food and drinking water will not result in unacceptable levels of human health risk.

D. Cumulative Effects

The potential for cumulative effects of dinotefuran and other substances that have a common mechanism of toxicity has also been considered. Dinotefuran belongs to a pesticide chemical class known as the neonicotinoids and subclass nitroguanadines. There is no reliable information to indicate that toxic effects produced by dinotefuran would be cumulative with those of any other chemical including another pesticide. Therefore, Mitsui believes it is appropriate to consider only the potential risks of dinotefuran in an aggregate risk assessment.

E. Safety Determinations

1. *U.S. population.* Using the chronic exposure assumptions and the proposed RfD described above, the dietary exposure to dinotefuran for the U.S. population (48 states, all seasons) was calculated to be 0.32% of the RfD of 1.27 mg/kg/day. The resulting DWLOC, 44,306 ppb, is much greater than the estimated average concentration of dinotefuran in surface water, 6.24 ppb. Therefore, taking into account the proposed uses, it can be concluded with reasonable certainty that residues of dinotefuran in residential environments and in food and drinking water will not result in unacceptable levels of human health risk.

2. *Infants and children.* FFDCA section 407 provides that EPA shall apply an additional safety factor for infants and children to account for prenatal and postnatal toxicity and the completeness of the data base. Only when there is no indication of increased sensitivity of infants and children and when the data base is complete, may the extra safety factor be removed. In the

case of dinotefuran, the toxicology data base is complete. There is no indication of increased sensitivity in the data base overall, and specifically, there is no indication of increased sensitivity in the developmental and multi-generation reproductive toxicity studies. Therefore, Mitsui concludes that there is no need for an additional safety factor; the RfD of 1.27 mg/kg/day and sub-chronic NOAEL of 307 mg/kg/day are protective of infants and children.

Using the chronic exposure assumptions and the proposed RfD described above, the dietary exposure to dinotefuran for infants and children (1 to 6 years) was calculated to be 0.57% of the reference dose of 1.27 mg/kg bwt/day. The resulting DWLOC for non-nursing infants, 12,666 ppb, is much greater than the estimated average concentration of dinotefuran in surface water, 6.24 ppb.

Using the intermediate-term exposure assumptions and the proposed NOAEL described above, the intermediate-term aggregate exposure to dinotefuran for the toddlers (1 to 3 years) resulted in an MOE of 1,410. The resulting DWLOC, 42,785 ppb, is much greater than the estimated average concentration of dinotefuran in surface water, 6.24 ppb. Therefore, taking into account the proposed uses, it can be concluded with reasonable certainty that residues of dinotefuran in residential environments and in food and drinking water will not result in unacceptable levels of human health risk.

F. International Tolerances

No codex maximum residue levels have been established for residues of dinotefuran on any crops at this time.

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ENVIRONMENTAL PROTECTION AGENCY

[OPP-2003-0226; FRL-7315-2]

Copper Hydroxide; Notice of Filing of 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 ID number OPP-2003-0226, must be received on or before August 1, 2003.

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

FOR FURTHER INFORMATION CONTACT: Kathryn Boyle, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; telephone number: (703) 305-6304; e-mail address: boyle.kathryn@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 code 111)
- Animal production (NAICS code 112)
- Food manufacturing (NAICS code 311)
- Pesticide manufacturing (NAICS code 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 identification (ID) number OPP-2003-0226. The official public docket consists of the documents specifically referenced in this action, any public comments received, and other information related to this action. Although a part of the official docket, the public docket does not include Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. The official public docket is the collection of materials that is available for public viewing at the Public Information and Records Integrity Branch (PIRIB), Rm. 119, Crystal Mall #2, 1921 Jefferson Davis Hwy., Arlington, VA. This docket facility is open from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The docket telephone number is (703) 305-5805.

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

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

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

Although not all docket materials may be available electronically, you may still access any of the publicly available docket materials through the docket facility identified in Unit I.B. EPA intends to work towards providing electronic access to all of the publicly available docket materials through EPA's electronic public docket.

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

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

C. How and to Whom do I Submit Comments?

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

1. *Electronically.* If you submit an electronic comment as prescribed in this unit, EPA recommends that you include your name, mailing address, and an e-mail address or other contact information in the body of your comment. Also include this contact information on the outside of any disk

or CD ROM you submit, and in any cover letter accompanying the disk or CD ROM. This ensures that you can be identified as the submitter of the comment and allows EPA to contact you in case EPA cannot read your comment due to technical difficulties or needs further information on the substance of your comment. EPA's policy is that EPA will not edit your comment, and any identifying or contact information provided in the body of a comment will be included as part of the comment that is placed in the official public docket, and made available in EPA's electronic public docket. If EPA cannot read your comment due to technical difficulties and cannot contact you for clarification, EPA may not be able to consider your comment.

i. *EPA Dockets.* Your use of EPA's electronic public docket to submit comments to EPA electronically is EPA's preferred method for receiving comments. Go directly to EPA Dockets at <http://www.epa.gov/edocket/>, and follow the online instructions for submitting comments. Once in the system, select "search," and then key in docket ID number OPP-2003-0226. 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-2003-0226. 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-2003-0226.

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-2003-0226. 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: June 23, 2003.

Debra Edwards,

Director, Registration 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 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.

Syngenta Crop Protection

PP 2E6471

EPA has received a pesticide petition (PP 2E6471) from Syngenta Crop Protection, P.O. Box 18300, Greensboro, North Carolina, 27419-8300 proposing, pursuant to section 408(d) of the FFDCA, 21 U.S.C. 346a(d), to amend 40 CFR part 180 to establish an exemption from the requirement of a tolerance for copper (II) hydroxide in or on raw agricultural commodities. EPA has determined that the petition contains data or information regarding the elements set forth in section 408(d)(2) of the FFDCA; however, EPA has not fully evaluated the sufficiency of the

submitted data at this time or whether the data support granting of the petition. Additional data may be needed before EPA rules on the petition.

A. Residue Chemistry

1. *Plant metabolism.* Copper hydroxide is exempt from the requirement of a tolerance (40 CFR 180.1021(b)) for use as a broad-spectrum foliar fungicide on growing crops. It is used at application rates greater than an order of magnitude higher than the proposed use as a formulation inert. As such, the metabolism and magnitude of the residue is well understood at application rates much higher than in the current petition.

2. *Analytical method.* Copper ions are released from copper hydroxide by solubilization in the presence of moisture. A method for copper is listed in the January 2002 Pesticide Analytical Volume II.

3. *Magnitude of residues.* Copper hydroxide is exempt from the requirement of a tolerance (CFR 180.1021(b)) for use as a broad-spectrum foliar fungicide on growing crops. It is used as a fungicide at application rates greater than an order of magnitude higher than the proposed use as a formulation inert. As such, the metabolism and magnitude of the residue is well understood at application rates much higher than in the current petition. Copper is naturally found at significant levels in many different types of foods.

B. Toxicological Profile

Copper hydroxide is a versatile and safe material which is used almost everywhere where copper is needed in chemistry. Copper hydroxide is used directly in the planting and ceramics industry, and in agriculture as a fungicide and bactericide. It is widely used as a manufacturing intermediate in numerous applications, for example to make copper compounds, for the production of pigments containing copper, in the manufacture of copper fibers, in galvanizing, metallurgy, pyrotechnics, and electronics, to name just a few applications. Copper ions are released from copper hydroxide by solubilization in the presence of moisture. Copper is ubiquitous in nature and is a necessary nutritional element for both animals (including humans), and plants. Copper is found naturally in the food we eat, in soils, in the water we drink, in the air we breathe and in our bodies. It is one of 26 elements found essential to life. The copper ion is present in the adult human body at levels of 70-150 milligrams (mg).

Due to its being used in small percentages in the proposed formulations, oral ingestion of quantifiable amounts of copper will not result from use of copper hydroxide as an inert. Copper compounds are irritating to the gastric mucosa. Ingestion of large amounts of copper results in prompt emesis. This protective reflex reduces the amount of copper ion available for absorption into the human body. Additionally, at high levels humans are also sensitive to the taste of copper. Because of this organoleptic property, oral ingestion would also serve to limit high doses. Only a small percentage of ingested copper is absorbed, and most of the absorbed copper is excreted. The copper ion occurs naturally in many foods and the metabolism of copper is well understood. There are several factors unique to copper which indicate that additional studies are not needed to regulate copper hydroxide as an inert in pesticide formulations. One of the foremost of these is the fact that copper is a required nutritional element for both plants and animals. It appears that more evidence is available to define the adverse effects of a deficiency in the diet than to show the toxic effects of an excess intake. In fact, no account has been found in the literature reviewed which describes a toxic effect to normal humans from ingestion of common foodstuffs containing copper. Because copper toxicity to man through the diet has been shown in normal persons, little is known about the minimum levels of dietary copper necessary to cause evidence of adverse effects. This situation is likely due, to an effective homeostatic mechanism that is involved in the dietary intake of copper and that protects man from excess body copper. This complex mechanism integrates absorption, retention, and excretion to stabilize the copper body burden. Given that copper is ubiquitous and is routinely consumed as part of the daily diet, it is unlikely that with current exposure patterns there would be any long-term adverse effects. The hydroxide ion is also ubiquitous in plants, animals including humans, and the environment. The use of copper hydroxide as an inert will not result in any increased burden on the environment or living organisms.

C. Aggregate Exposure

1. *Dietary exposure.* Twelve Food and Drug Administration (FDA) total diet studies, conducted from mid 1982–1984, examined dietary intake of copper for age groups 14–16, 25–30, and 60–65 years. The copper intake ranged from 0.77 (14–16 year old females) to 1.24

mg/day (25–30 year old males). Use of copper hydroxide as an inert at rates at an order of magnitude lower than current pesticide rates will not result in any quantifiable increase in exposure to copper from dietary sources.

i. *Food.* The main source of copper for infants, children, and adults, regardless of age, is the diet. Copper is typically present in mineral rich foods like vegetables (potato, legumes (beans and peas)), nuts (peanuts and pecans), grains (wheat and rye), fruits (peach and raisins), and chocolate in levels ranging from 0.3 to 3.9 parts per million (ppm). A single day's diet may contain 10 mg or more of copper. The daily recommended allowance of copper for adults nutritional needs is 2 mg.

ii. *Drinking water.* Copper is a natural element found in the earth's crust. As a result, most of the world's surface water and ground water that is used for drinking purposes contains copper. Naturally occurring copper in drinking water is safe for human consumption, even in rare instances where it is at levels high enough to impart a metallic taste to the water. The Agency has set a maximum contaminant level for copper at 1.3 ppm. Use of copper hydroxide as an inert at rates at an order of magnitude lower than current pesticide rates will not result in any quantifiable increase in exposure to copper from drinking water.

2. *Non-dietary exposure.* Copper is a naturally occurring element present in the earth's crust, and it is therefore naturally occurring in soil, water and air. Soils would be considered copper deficient if they contain less than 2 ppm available copper in the context of plant health. Air concentrations of copper are relatively low. A study based on several thousand samples assembled by EPA's Environmental Monitoring Systems Laboratory showed copper levels ranging from 0.003 to 7.32 micrograms per cubic meter. Use of copper hydroxide as an inert at rates at an order of magnitude lower than current pesticide rates will not result in quantifiable increase in exposure to copper from non-dietary sources.

D. Cumulative Effects

Exposure to copper occurs over a lifetime from numerous sources and does not result in any known toxicity. Use of copper hydroxide as an inert will not result in quantifiable increase in cumulative exposure to copper.

E. Safety Determination

1. *U.S. population.* Copper is an essential trace element for which the National Academy of Sciences has issued a recommended daily allowance

of up to 3 mg/day for adults. Accordingly, there is reasonable certainty that no harm will result from aggregate exposure of the U.S. population to copper. The use of copper hydroxide as an inert in pesticide formulations will not result in any measurable increase in exposure to copper.

2. *Infants and children.* Copper is also a component of the diet of infants and children and also an essential element of their diet. The use of copper hydroxide as an inert in pesticide formulations will not result in any measurable increase in exposure of infants and children to copper.

F. International Tolerances

There does not appear to be any international tolerances for copper or copper hydroxide, and no CODEX maximum residue levels has been established for any food crops at this time.

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ENVIRONMENTAL PROTECTION AGENCY

[FRL–7521–6]

Public Water Supply Supervision Program Revision for the Commonwealth of Puerto Rico

AGENCY: Environmental Protection Agency.

ACTION: Notice of tentative approval and solicitation of request for a public hearing for Public Water Supply Supervision Program Revision for the Commonwealth of Puerto Rico

SUMMARY: Notice is hereby given that the Environmental Protection Agency (EPA) has determined to approve an application by the Commonwealth of Puerto Rico to revise its Public Water Supply Supervision Primacy Program to incorporate regulations no less stringent than the EPA's National Primary Drinking Water Regulations (NPDWR) for the following: Lead and Copper Rule Technical Correction; Final Rule, promulgated by EPA on June 30, 1994 (59 FR 33860), Synthetic Organic Chemicals and Inorganic Chemicals; Final Rule, promulgated by EPA on July 1, 1994 (59 FR 34320), Analytical Methods Technical Corrections; Final Rule, promulgated by EPA on December 5, 1994 (59 FR 62456), Analytical Methods Technical Corrections; Final Rule, promulgated by EPA on June 29, 1995 (60 FR 34083), Analytical Methods for Radionuclides Technical Corrections, promulgated by EPA on