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 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 your estimate.
5. Provide specific examples to illustrate your concerns.
6. Offer alternatives.
7. Make sure to submit your comments by the comment period deadline identified.
8. To ensure proper receipt by EPA, identify the appropriate docket ID number in the subject line on the first page of your response. It would also be helpful if you provided the name, date, and **Federal Register** citation related to your comments.

II. Background

A. What Action is the Agency Taking?

EPA is releasing for public comment its human health and environmental fate and effects risk assessment(s), and related documents for halohydantoins, and encouraging the public to suggest risk management ideas or proposals.

The halohydantoin antimicrobial chemicals are registered for use in indoor food, indoor non-food, indoor residential, aquatic non-food residential, aquatic food, aquatic non-food, and aquatic non-food industrial sites for control of bacteria, fungi, and algal slimes. EPA developed the risk assessment(s) and preliminary risk reduction options for halohydantoins through a modified version of its public process for making pesticide reregistration eligibility and tolerance reassessment decisions. Through these programs, EPA is ensuring that pesticides meet current standards under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), the Federal Food, Drug, and Cosmetic Act (FFDCA), as amended by the Food Quality Protection Act of 1996 (FQPA), and the Pesticide Registration Improvement Act of 2003 (PRIA).

EPA is providing an opportunity, through this notice, for interested parties to provide written comments and input on the Agency's risk assessment(s) for halohydantoins. Such comments and input could address, for example, the availability of additional data to further refine the risk assessments, or could address the Agency's risk assessment methodologies and assumptions as applied to this specific pesticide.

EPA seeks to achieve environmental justice, the fair treatment and meaningful involvement of all people, regardless of race, color, national origin, or income, in the development, implementation, and enforcement of environmental laws, regulations, and policies. To help address potential environmental justice issues, the Agency seeks information on any groups or segments of the population who, as a result of their location, cultural practices, or other factors, may have atypical, unusually high exposure to halohydantoins, compared to the general population.

All comments should be submitted using the methods in Unit I.C. and must be received by EPA on or before the closing date. Comments will become part of the Agency record for halohydantoins.

EPA is applying the principles of public participation to all pesticides undergoing reregistration and tolerance reassessment. In conducting these programs, the Agency is tailoring its public participation process to be commensurate with the level of risk, extent of use, complexity of the issues, and degree of public concern associated with each pesticide. For halohydantoins, a modified, four-phase process with one comment period and ample opportunity for public consultation seems appropriate in view of its refined risk assessment(s), limited use, small number of users, few complex issues, few affected stakeholders, and/or other factors. However, if as a result of comments received during this comment period EPA finds that additional issues warranting further discussion are raised, the Agency may lengthen the process and include a second comment period, as needed. EPA plans to issue the Haloydantoin RED as a final document for public comment.

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 taking other ''appropriate regulatory action.''

List of Subjects

Environmental protection, Pesticides and pests.

Dated: September 9, 2004.

Frank Sanders,

Director, Antimicrobials Division, Office of Pesticide Programs.

[FR Doc. 04–20911 Filed 9–15–04; 1:46 pm]

BILLING CODE 6560–50–S

ENVIRONMENTAL PROTECTION AGENCY

[OPP–2004–0285; FRL–7675–9]

1,2-Ethanediamine, N, N, N', N'-tetramethyl-, polymer with 1, 1'-oxybis 2-chloroethane; 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–2004–0285, must be received on or before October 18, 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: Bipin Gandhi, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001; telephone number: (703) 308–8380; e-mail address:*gandhi.bipin@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 ID number OPP–2004–0285. 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 South 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 on 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–2004–0285. 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–2004–0285. 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–2004–0285.

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 South Bell St., Arlington, VA, Attention: Docket ID number OPP–2004–0285. 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: September 1, 2004.

Donald R. Stubbs,

Acting 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 Buckman Laboratories International, Inc., 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. 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.

Buckman Laboratories International, Inc.

PP 4E6841

EPA has received a pesticide petition PP 4E6841 from Buckman Laboratories International, Inc., 1256 North McLean Blvd., Memphis, TN 38108, proposing, pursuant to section 408(d) of the FFDCA, 21 U.S.C. 346a(d), to amend 40 CFR 180.920 to establish an exemption from the requirement of a tolerance for 1,2-ethanediamine, N, N, N', N'-tetramethyl-, polymer with 1, 1'-oxybis[2-chloroethane] (CAS Reg. No. 31075–24–8) in or on raw agricultural commodities when used as an inert ingredient in or on growing crops. 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

Buckman is petitioning that the inert ingredient, 1,2-ethanediamine, N, N, N', N'-tetramethyl-, polymer with 1, 1'-oxybis[2-chloroethane], be exempt from the requirement of a tolerance because the chemical meets all but one of the criteria that define a low risk polymer under 40 CFR 723.250(e). For this reason, neither plant metabolism data, residue data, nor an analytical method to determine residues of 1,2-ethanediamine, N, N, N', N'-tetramethyl-

, polymer with 1, 1'-oxybis[2-chloroethane] in raw agricultural commodities (RACs) are required.

B. Toxicological Profile

In the case of certain substances that are defined as ''polymers,'' the Agency has established a set of criteria that identify categories of polymers that present low risk. These criteria, described in 40 CFR 723.250, identify polymers that are typically not readily absorbed, and are relatively unreactive and stable compounds in comparison to other chemical substances. These properties generally limit a polymer's ability to cause adverse effects. In addition, these criteria exclude polymers about which little is known. The Agency believes that polymers that meet the criteria in 40 CFR 723.250 will present minimal or no risk to human health.

1,2-Ethanediamine, N, N, N', N'-tetramethyl-, polymer with 1, 1'-oxybis[2-chloroethane] meets all but one of the exemption criteria in 40 CFR 723.250. That one exception is that 1,2-ethanediamine, N, N, N', N'-tetramethyl-, polymer with 1, 1'-oxybis[2-chloroethane] is a cationic polymer. Cationic polymers are excluded because of their typically inherent aquatic toxicity; however, 1,2-ethanediamine, N, N, N', N'-tetramethyl-, polymer with 1, 1'-oxybis[2-chloroethane] does not behave like a typical cationic polymer in the field. Environmental fate and toxicity data for 1,2-ethanediamine, N, N, N', N'-tetramethyl-, polymer with 1, 1'-oxybis[2-chloroethane] demonstrate that under natural conditions 1,2-ethanediamine, N, N, N', N'-tetramethyl-, polymer with 1, 1'-oxybis[2-chloroethane] binds tightly to organic material and, as a result, aquatic toxicity under field conditions is very low. For this reason, 1,2-ethanediamine, N, N, N', N'-tetramethyl-, polymer with 1, 1'-oxybis[2-chloroethane] should not be excluded on the basis that it is cationic because data are available that show that aquatic toxicity under field conditions is very low.

In all other respects, as listed below, 1,2-ethanediamine, N, N, N', N'-tetramethyl-, polymer with 1, 1'-oxybis[2-chloroethane] meets the polymer exemption criteria described in 40 CFR 723.250(d):

1. 1,2-Ethanediamine, N, N, N', N'-tetramethyl-, polymer with 1, 1'-oxybis[2-chloroethane] contains as an integral part of its composition the atomic elements carbon, hydrogen, oxygen, nitrogen and chloride ion.

2. 1,2-Ethanediamine, N, N, N', N'-tetramethyl-, polymer with 1, 1'-oxybis[2-chloroethane] does not contain as an integral part of its composition, except as impurities, any element other than those listed in 40 CFR 723.250 (d)(2)(ii).

3. 1,2-Ethanediamine, N, N, N', N'-tetramethyl-, polymer with 1, 1'-oxybis[2-chloroethane] is neither designed nor can it be reasonably anticipated to substantially degrade, decompose, or depolymerize.

4. 1,2-Ethanediamine, N, N, N', N'-tetramethyl-, polymer with 1, 1'-oxybis[2-chloroethane] is manufactured or imported from monomers and/or reactants that are already included on the TSCA Chemical Substance Inventory or manufactured under an applicable TSCA section 5 exemption.

5. 1,2-Ethanediamine, N, N, N', N'-tetramethyl-, polymer with 1, 1'-oxybis[2-chloroethane] is not a water-absorbing polymer with a number average MW greater than or equal to 10,000 daltons. The number average MW is about 2,000 and the MW is around 3,000–5,000 daltons.

Additionally, 1,2-ethanediamine, N, N, N', N'-tetramethyl-, polymer with 1, 1'-oxybis[2-chloroethane] meets as required the following criteria specified in 40 CFR 723.250(e):

6. 1,2-Ethanediamine, N, N, N', N'-tetramethyl-, polymer with 1, 1'-oxybis[2-chloroethane] has a number average MW of about 2,000, which is greater than 1,000 and less than 10,000 daltons. The polymer contains less than 10% oligomeric material below MW 1,000 and the polymer does not contain any reactive functional groups.

1,2-Ethanediamine, N, N, N', N'-tetramethyl-, polymer with 1, 1'-oxybis[2-chloroethane] has the same chemical composition as Busan 77, a pesticide active ingredient registered by Buckman for non-food antimicrobial uses. As a result, a complete set of mammalian toxicology studies have been submitted, and reviewed and evaluated by the Agency. A summary of the mammalian toxicology studies follows:

1. *Acute toxicity.* 1,2-Ethanediamine, N, N, N', N'-tetramethyl-, polymer with 1, 1'-oxybis[2-chloroethane] exhibits moderate to low acute toxicity. The rat acute oral LD_{50} is 1,951 milligrams/kilogram (mg/kg) for males and 2,587 mg/kg for females (Toxicity Category III). In the rabbit acute dermal toxicity study, the LD_{50} was demonstrated to be >2,000 mg/kg (Toxicity Category III). The rat acute inhalation toxicity study concluded that the LC_{50} is 2.9 milligrams/Liter (mg/L) for males and females combined (Toxicity Category IV).

1,2-Ethanediamine, N, N, N', N'-tetramethyl-, polymer with 1, 1'-oxybis[2-chloroethane] was slightly irritating (Toxicity Category III) in the primary eye irritation study in rabbits and minimally irritating (Toxicity Category IV) in the rabbit primary skin irritation study. 1,2-Ethanediamine, N, N, N', N'-tetramethyl-, polymer with 1, 1'-oxybis[2-chloroethane] is not a skin sensitizer.

2. *Genotoxicity.* Four mutagenicity studies have been conducted and none of them demonstrated any genotoxic potential to be associated with the test material. The Ames Salmonella assay was negative with and without metabolic activation. Unscheduled DNA synthesis in primary rat hepatocytes in cultures was negative at dose levels up to 1,500 mg/kg. The mouse micronucleus assay was negative at dose levels tested up to 2,000 mg/kg. The sex-linked recessive lethal assay was negative at all dose levels tested: 0.08, 0.3 or 0.8 mg/mL.

3. *Reproductive and developmental toxicity.* In a rat teratology study, no effects were observed when the dose was administered during organogenisis. Some toxic effects were observed at high dose levels when the dose was administered during early gestation, but no teratogenic effects were observed. The maternal systemic lowest observable effect level (LOEL) was <6,000 parts per million (ppm) (300 mg/kg/day) or less. The no observable effect level (NOEL) was less than 6,000 ppm (300 mg/kg/day). The reproductive LOEL was 12,000 ppm (600 mg/kg/day) based on decreased live pups. The NOEL was 6,000 ppm (300 mg/kg/day).

In rabbits, no evidence of developmental toxicity was observed. The maternal toxicity NOEL and LOEL were determined to be 45 mg/kg/day and 125 mg/kg/day the highest dose tested, respectively. The NOEL and LOEL were the same for developmental toxicity. In the two-generation rat reproduction study, body weight and food consumption changes were noted in the mid-dose (12,000 ppm) and high-dose (18,000 ppm) dose animals. The mid-dose and high-dose groups showed a reduction in the number of live pups in both generations and showed some evidence of kidney mineralization. The NOEL for parental in-life and pathology data was less than 6,000 ppm in the diet. The NOEL for reproductive effects was 6,000 ppm (300 mg/kg/day) in the diet.

4. *Subchronic toxicity.* The systemic NOEL was 3,000 ppm (221 mg/kg/day) in the diet in a 90–day rat study. The LOEL was 10,000 ppm (752 mg/kg/day). Dose dependent mineralization of the kidney tubules was observed and at 40,000 ppm (3,685 mg/kg/day),

inflammation of the choroid plexus occurred. In a 90-day dermal study in rabbits, the NOEL for systemic toxicity was greater than 1,000 mg/kg/day (highest dose tested). The NOEL for dermal irritation (localized) was 10 mg/kg/day and the LOEL was 100 mg/kg/day.

5. *Chronic toxicity*. In a 52–week dog study, the NOEL was 10,000 ppm (250 mg/kg/day) and the LOEL was 20,000 ppm (500 mg/kg/day) in males. In females, the NOEL was 10,000 ppm (250 mg/kg/day) and the LOEL was 40,000 ppm (1,000 mg/kg/day). There was a dose-related decrease in body weight gain and in changes in some clinical chemistry/hematology parameters. The only histology findings were thickening of the wall of the GI tract in the high dose group (40,000 ppm) and changes in sperm growth/maturation in some of the mid (20,000 ppm) and high dose (40,000 ppm) males.

In a 2–year combined chronic toxicity and carcinogenicity study in rats, body weight and food consumption values were generally lower with increasing dose. Survival increased with dose. There were some dose-related effects in several clinical chemistry/hematology parameters. Histological exams showed mineralization in the brains of high dose animals and a possible increase in thyroid C-cell adenomas in females given 6,000 (300 mg/kg/day) and 18,000 ppm (900 mg/kg/day). This product is not considered a carcinogen. The NOEL for systemic toxicity was determined to be 2,000 ppm (100 mg/kg/day).

In a 78–week oncogenicity study in mice, dietary administration produced reduced body weight gains in both males and females. Kidney cysts were observed in the high dose animals. There was no evidence of any oncogenic (cancer) activity that would be considered treatment related. The systemic NOEL could not be established but the LOEL was determined to be less than 600 mg/kg/day (4,000 ppm). 1,2-Ethanediamine, N, N, N', N'-tetramethyl-, polymer with 1, 1'-oxybis[2-chloroethane] was found not to be carcinogenic in mice at doses up to 2,400 mg/kg/day (16,000 ppm) in the diet.

6. *Animal metabolism*. In a rat metabolism study, test animals were dosed with ^{14}C-labeled 1,2-ethanediamine, N, N, N', N'-tetramethyl-, polymer with 1, 1'-oxybis[2-chloroethane] at oral or intravenous doses of 10 mg/kg, an oral dose of 1,000 mg/kg or at repeated oral doses (14 daily doses) of unlabeled 1,2-ethanediamine, N, N, N', N'-tetramethyl-, polymer with 1, 1'-oxybis[2-chloroethane] at 10 mg/kg followed by administration of a single oral dose of labeled 1,2-ethanediamine, N, N, N', N'-tetramethyl-, polymer with 1, 1'-oxybis[2-chloroethane] at 10 mg/kg. Expired $^{14}CO_2$ was not detected.

In the intravenous dose group, the major routes of excretion of radioactivity were via the urine and feces. Over a 7–day period, approximately half (52–55%) of the test compound administered was excreted in the urine (38–44%) and feces (11–14%) from the animals.

In the single oral dose and repeated oral dose groups, most (88%–106%) of the test compound administered was excreted in the urine (3% of the dose) and feces (85–103% of the dose). In the oral dosed groups, the highest amount of residual radioactivity was found in kidneys, liver and spleen. The residues in the tissues including carcass were not more than 0.14%. This indicates that the potential for bioaccumulation of 1,2-ethanediamine, N, N, N', N'-tetramethyl-, polymer with 1, 1'-oxybis[2-chloroethane] is minimal after low single or repeated oral dose exposures. In the high (1,000 mg/kg) oral dose group, most (85%) of the dose was excreted in urine (14–17% of the dose) and feces (68–71%). Seven days after dosing, residues were low in all tissues except for the kidneys, liver and spleen in this group.

C. Aggregate Exposure

1,2-Ethanediamine, N, N, N', N'-tetramethyl-, polymer with 1, 1'-oxybis[2-chloroethane] is a polymer with a high molecular weight (3,000 – 5,000 daltons) that is not expected to be absorbed through the intact gastrointestinal (GI) tract or through intact human skin, therefore, it would not be capable of eliciting a toxic response. For this reason, health risks from potential exposure to 1,2-ethanediamine, N, N, N', N'-tetramethyl-, polymer with 1, 1'-oxybis[2-chloroethane] in food or drinking water as well as non-dietary exposure are expected to be negligible.

D. Cumulative Effects

Polymers with molecular weights greater than 400 generally are not absorbed through the intact skin and substances with molecular weights greater than 1,000 generally are not absorbed through the GI tract. Chemicals that are not absorbed through the skin or GI tract generally are incapable of eliciting a toxic response. 1,2-ethanediamine, N, N, N', N'-tetramethyl-, polymer with 1, 1'-oxybis[2-chloroethane] has a molecular weight of 3,000 - 5,000, therefore, there is no reasonable expectation of risk due to cumulative exposure.

E. Safety Determination

There are no safety concerns with 1,2-ethanediamine, N, N, N', N'-tetramethyl-, polymer with 1, 1'-oxybis[2-chloroethane] because it conforms to the definition of a low risk polymer given in 40 CFR 723.250 and is considered to be incapable of eliciting a toxic response because it is not expected to be absorbed through the intact skin or intact GI tract.

F. International Tolerances

Buckman is not aware of any country requiring a tolerance for 1,2-ethanediamine, N, N, N', N'-tetramethyl-, polymer with 1, 1'-oxybis[2-chloroethane], nor have there been any Codex maximum residue levels established for any food crops at this time.

[FR Doc. 04–20912 Filed 9–16–04; 8:45 am]

BILLING CODE 6560–50–S

ENVIRONMENTAL PROTECTION AGENCY

[FRL–7814–9]

Public Water System Supervision Program Revision for the State of Colorado

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: The State of Colorado has revised its Public Water System Supervision (PWSS) Primacy Program by adopting regulations for the Long Term One Enhanced Surface Water Treatment Rule (LT1), the Filter Backwash Recycling Rule (FBRR), the Lead and Copper Rule Minor Revisions (LCRMR), the Arsenic MCL Clarifications and updates to analytical methods that correspond to 40 CFR parts 141 and 142. Having determined that these revisions meet all pertinent requirements in the Safe Drinking Water Act (SDWA), 42 U.S.C. 300f *et seq.*, and EPA's implementing regulations at 40 CFR parts 141 and 142, the EPA approves them.

Today's approval action does not extend to public water systems in Indian Country as that term is defined in 18 U.S.C. 1151. Please see Supplementary Information, Item B.

DATES: Any member of the public is invited to submit written comments and/or request a public hearing on this determination by October 18, 2004. Please see **SUPPLEMENTARY INFORMATION**, Item C, for information on submitting comments and requesting a hearing. If no hearing is requested or granted, then this action shall become effective