

analysis modeling system (PRZM/EXAMS), and monitoring data. If monitoring data are not available then the models are used to predict potential residues in surface water and ground water. In the case of acetamiprid, monitoring data do not exist, therefore, GENECC and SCIGROW models were used to estimate a water residue. The calculated drinking water levels of comparison (DWLOC) for acute and chronic exposures for all adults and children greatly exceed the modeled acetamiprid water residues, drinking water estimated concentrations (DWECC). The acute DWLOC values are 3,360 ppb for adults and 940 parts per billion (ppb) for children. The worst case DWECC for acute scenarios is calculated to be 13.27 ppb using the GENECC surface water model. The chronic DWLOC values are 2,450 ppb for adults and 700 ppb for children. The DWECC for the worst case chronic scenario is 1.59 ppb (GENECC).

4. *Non-dietary exposure.* A ready to use, dilute formulation of acetamiprid is registered for insect control on outdoor ornamentals, vegetables and fruit trees. Based on surrogate exposure data obtained from a carbaryl study, the homeowner margin of exposure (MOE) was calculated to exceed ten million. Postapplication exposure resulting from contact with acetamiprid treated foliage resulted in an MOE in excess of 500,000.

D. Cumulative Effects

EPA and ILSI are developing the methodologies to resolve the complex scientific issues concerning common mechanism of toxicity and how to cumulate pesticides in a quantitative manner. A determination has not been made that acetamiprid has a common mechanism of toxicity with other substances. Acetamiprid does not appear to produce a common toxic metabolite with other substances. A cumulative risk assessment was, therefore, not performed for this analysis.

E. Safety Determination

1. *U.S. population.* Using the conservative assumptions described above, based on the completeness and reliability of the toxicity data, it is concluded that aggregate exposure to the proposed uses of acetamiprid will utilize at most 5.9% of the acute reference dose for the U.S. population, and is likely to be much less, as more realistic data and models are developed. EPA generally has no concern for exposures below 100% of the RfD because the RfD represents the level at or below which daily aggregate

exposure over a lifetime will not pose appreciable risks to human health. Drinking water levels of comparison based on this exposure are much greater than conservative estimated concentrations, and would be expected to be well below the 100% level, if they occur at all. Therefore, there is a reasonable certainty that no harm will occur to the U.S. population from aggregate exposure to acetamiprid.

2. *Infants and children.* In multi-generation reproduction and teratology studies, no adverse effects on reproduction were observed in either rats or rabbits. In the long term feeding studies in rats and mice there was no evidence of carcinogenicity. Acetamiprid was not mutagenic under the conditions of testing. Using the conservative exposure assumptions described in the exposure section above, the percent of the reference dose that will be used for short term aggregate exposure to residues of acetamiprid will be 15.4% for non-nursing infants (the most highly exposed sub-group). This value is based on dietary exposure alone as only children over 7 are expected to have residential post-application exposure for the proposed acetamiprid uses. As in the adult situation, drinking water levels of comparison are much higher than the worst case drinking water estimated concentrations and would be expected to use well below 100% of the RfD, if they occur at all. Therefore, there is a reasonable certainty that no harm will occur to infants and children from aggregate exposure to residues of acetamiprid.

F. International Tolerances

Acetamiprid is registered for use on food crops in several countries outside the United States (e.g., maximum residue levels (MRLs) are established in Canada and Japan).

[FR Doc. 04-17507 Filed 8-3-04; 8:45 am]

BILLING CODE 6560-50-S

ENVIRONMENTAL PROTECTION AGENCY

[OPP-2004-0207; FRL-7367-7]

Ethylene Glycol; 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-2004-0207, must be received on or before September 3, 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 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-2004-0207. 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/fedrgrstr/>.

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. 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-2004-0207. 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-2004-0207. 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-2004-0207.

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-2004-0207. 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: July 19, 2004.

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 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.

Sumitomo Chemical Company

PP 4E6828

EPA has received a pesticide petition (4E6828) from Sumitomo Chemical Company, Limited, 5-33, Kitahara, 4-Chome, Chuo-Ku, Osaka 541, Japan, through their United States agent, 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 ethylene glycol when used as an encapsulating agent for pesticides being applied post-harvest as residual, and crack and crevice sprays in and around food and non-food areas of residential and non-residential structures, including food handling establishments, with no limit. 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

The primary method for determining ethylene glycol in biological samples is by gas (and high-resolution gas) high performance liquid chromatography (HPLC), or colorimetric determination. Gas chromatography (GC) is also employed to determine ethylene glycol concentrations in environmental samples such as air, water, food, drugs, or other substances. Methods for determining biomarkers of exposure to, and effects of, ethylene glycol are available for blood, tissue, and urine, as well as for the metabolic products (glycolic acid and oxalic acid) in blood and urine. The 1997 Agency for Toxic Substances and Disease Registry (ATSDR) report contains details of extraction and concentration methods for measuring these metabolites in humans. Methods for determining ethylene glycol in air, water, or aqueous solutions, foods, as well as foods stored in plastic containers from which leaching has occurred have been developed. Methods used to detect ethylene glycol in environmental samples are approved by EPA, National Institute of Occupational Safety and Health (NIOSH), Association of Official Analytical Chemists (AOAC) International, and American Public Health Association (APHA).

B. Toxicological Profile

1. *Acute toxicity.* ATSDR established an maximum residue level (MRL) (minimal risk level) of 0.5 parts per million (ppm) based on a no observed adverse effect level (NOAEL) of 197 ppm for acute inhalation exposure to ethylene glycol, and an MRL of 2.0 milligrams/kilogram/day (mg/kg/day) for acute oral exposure. The American Conference of Governmental Industrial Hygienists (ACGIH) recommends a maximum level of 50 ppm (125 milligrams/cubic meter (mg/m³)).

Dermal exposure to ethylene glycol causes minimum skin irritation or toxic effect. Eye contact with ethylene oxide may cause irritation.

2. *Genotoxicity.* Negative results for mutagenicity were obtained in the following assays: Mouse lymphoma, with and without activation; chromosomal aberrations and sister chromatid exchange in cultured chinese hamster ovary (CHO) cells (with and without activation); and for deoxyribonucleic acid (DNA) damage in rat hepatocytes. In *in vivo* genotoxicity studies, results have also been negative.

3. *Reproductive and developmental toxicity.* Literature on reproductive effects of ethylene glycol in humans could not be located.

Pregnant mice and rats fed ethylene glycol in their diet produced young with statistically significant increases in external and vertebral malformations, and the percentage of malformed live fetuses per litter was significantly increased. Decreased pup weights were observed, particularly in animals receiving higher doses. New Zealand White rabbits showed no adverse effects in similar tests.

4. *Subchronic toxicity.* A human study showed that inhalation of 7–19 ppm for 20–22 hours a day for 4 weeks did not cause adverse hematological or immune function effects. No studies were located describing neurological, reproductive, genotoxicity, or developmental effects in humans by all other routes of exposure. No subchronic dermal or oral human studies were found. No subchronic inhalation animal toxicity studies were located, but subchronic dermal and oral studies for inhalation exposure showed adverse effects similar to chronic exposure.

5. *Chronic toxicity.* The oral reference dose (RfD) for ethylene glycol is 2.0 mg/kg/day with an uncertainty factor (UF) of 100, based on the NOAEL of 200 mg/kg/day toxic effect in kidneys in rats. The oral RfD for ethylene glycol is 2.0 mg/kg/day with an UF of 100, based on the NOAEL of 200 mg/kg/day toxic effect in kidneys in rats. Rats and mice given ethylene glycol orally for 2 years, in separate studies, did not exhibit any carcinogenic effect. The Department of Health and Human Services (DHHS), the International Agency for Research on Cancer (IARC), and EPA have not classified ethylene glycol for carcinogenicity. Studies with people who used ethylene glycol did not show carcinogenic effects. However, rodents fed ethylene glycol in long-term feeding studies showed mortality.

6. *Animal metabolism.* Animal studies have shown that rats and dogs are more sensitive to ethylene glycol exposure than mice. Ethylene glycol ingestion causes metabolic acidosis and toxic calcium oxalate production in humans and other animals. The main toxic metabolites are glycolic acid, glyoxylic acid, and oxalic acid.

7. *Metabolite toxicology.* Ethylene glycol is absorbed from the digestive tract rapidly, depleting the water in the body and breaking down into three major metabolites; glycolic acid, glyoxylic acid, and oxalic acid that cause harmful crystalline deposits in the body. These metabolites are typically detected in urine. Ethylene glycol can be detected in the blood and serum soon after ingestion, but much less so after metabolic activity begins.

8. *Endocrine disruption.* Neither mice nor rats have exhibited endocrine effects after experimental exposure.

C. Aggregate Exposure

1. *Dietary exposure.* Oral consumption of ethylene glycol by humans is usually accidental, but has serious, sometimes fatal, toxicity. Oral consumption by animals attracted by the sweet odor is an important cause of veterinary emergencies. The oral dose of ethylene glycol required to cause death in humans is not well defined, but a lethal dose is estimated to be 1,330 mg/kg body weight.

i. *Food.* The migration of ethylene glycol from regenerated cellulose films containing triethylene glycol and polyethylene glycol as softening agents into food has been documented. It has also been found to migrate into food from pet (polyethylene terephthalate) plastic bottles used for packaging carbonated beverages. Ethylene oxide is a commonly used food disinfectant and preservative. After treatment with ethylene oxide, trace amounts of residual ethylene glycol may be retained in food. Potential exposure to minute amounts of ethylene glycol present in microencapsulated pesticides used in food and non-food areas of food handling establishments would not be of concern.

ii. *Drinking water.* EPA has established several drinking water Health Advisories for ethylene glycol. The (DWEL) Drinking Water Equivalent Level is 70 milligrams per liter for an adult. Ethylene glycol would only be present in drinking water by accidental release into reservoirs. However, biodegradation is an effective method of removing ethylene glycol from soil and water.

2. *Non-dietary exposure.* The most likely route of exposure to ethylene glycol is through dermal exposure; however, dermal exposure is not likely to lead to lethal toxic effects. Dermal exposure can occur occupationally in production facilities, and by handling liquid antifreeze, brake and other car and industrial fluids and solvents, inks in stamp pads, ballpoint pens, and in print shops. Inhalation of ethylene glycol mist may occur in industrial production, and there are trace amounts in cigarette smoke. Dermal and inhalation exposure may occur during airplane de-icing. Hazardous waste sites may also contain ethylene glycol until degradation occurs. Small amounts of ethylene glycol are also in pharmaceuticals (components of skin lotions, powders, and as a glycerin substitute).

D. Cumulative Effects

Humans and animals are exposed to significant levels of ethylene glycol by several routes of exposure. Available studies have not shown that cumulative effects are seen, due to the rapid biodegradation of ethylene glycol.

E. Safety Determination

1. *U.S. population.* Little information on quantitative levels in human tissues and body fluids, populations near hazardous waste sites, or those occupationally exposed to ethylene glycol is available. Most exposure to the general population is through dermal contact with products containing ethylene glycol during application or use, or by accidental or intentional oral ingestion. Workers involved in the manufacture or use of products containing high concentrations of ethylene glycol are at greater risk by this exposure than the general population, but no widespread reports of toxicity and deaths have been located.

2. *Infants and children.* As ethylene glycol is mainly used in antifreeze, hydraulic fluids and de-icing compounds, and other industrial and consumer products, children and infants would be exposed to it mostly by adult carelessness in use, disposal, and storage of products containing ethylene glycol.

F. International Tolerances

No listings found.
[FR Doc. 04–17506 Filed 8–3–04; 8:45 am]
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FEDERAL COMMUNICATIONS COMMISSION

[DA 04–2154]

The Consumer & Governmental Affairs Bureau Seeks Additional Information Regarding Certain Slamming Informal Complaints

AGENCY: Federal Communications Commission.

ACTION: Notice.

SUMMARY: In this document, the Consumer & Governmental Affairs Bureau seeks additional information for certain informal complaints regarding “slamming” (the unauthorized change of a subscriber’s selection of telephone exchange or telephone toll service).

DATES: Additional information regarding certain slamming informal complaints is due on or before August 16, 2004.

ADDRESSES: Federal Communications Commission, 445 12th Street, SW., Washington, DC 20554.