

telephone: (703) 305-5454. Office locations: 11th floor, Crystal Mall #2, 1921 Jefferson Davis Highway, Arlington, VA; e-mail smoot.cameo@epa.gov.

SUPPLEMENTARY INFORMATION:

I. Does this Action Apply to Me?

This action is directed to the public in general and to persons interested in the availability of public information regarding inert or "other" ingredients in pesticide products regulated under FIFRA.

The Inert Disclosure Stakeholder Workgroup was established to advise the U. S. Environmental Protection Agency, through the Pesticide Program Dialogue Committee (PPDC), on potential measures to increase the availability to the public of information about inert ingredients (also called "other ingredients") under FIFRA. Among the factors the workgroup has been asked to consider in preparing its recommendations are: Existing law regarding inert ingredients and Confidential Business Information (CBI); current Agency processes and policies for disseminating inert ingredient information to the public, including procedures for the protection of CBI; informational needs for a variety of stakeholders; and business reasons for limiting the disclosure of inert ingredient information.

The Inert Disclosure Stakeholder Workgroup is composed of participants from the following sectors: environmental/public interest and consumer groups; industry and pesticide users; Federal, State and local governments; the general public; academia and public health organizations.

The Inert Disclosure Stakeholder Workgroup meeting is open to the public. Written public statements are also welcome and should be submitted to the Office of Pesticide Programs' administrative docket OPP-00727. Any person who wishes to file a written statement can do so before or after the conference call. These statements will become part of the permanent file and will be provided to the workgroup members for their information. If you have any questions about the workgroup, consult the person listed under **FOR FURTHER INFORMATION CONTACT**.

II. How Can I Get Additional Information Including Copies of this Document and Other Related Documents?

1. *Electronically.* You may obtain electronic copies of this document, and

certain other related documents that might be available electronically, from the EPA Internet Home Page at <http://www.epa.gov/>. To access this document, on the Home Page select "Laws and Regulations," "Regulations and Proposed Rules," and then look up the entry for this document under the **"Federal Register"**—Environmental Documents." You can also go directly to the **Federal Register** listings at <http://www.epa.gov/fedrgstr/>.

For general background information about the Inert Disclosure Stakeholder Workgroup, its mission and a list of its members, go to <http://www.epa.gov/pesticides/ppdc/inert/>.

2. *In person.* The Agency has established an administrative record for this workgroup under docket control number OPP-00727. The administrative record consists of the workgroup documents including discussion papers, meeting agenda, as well as comments submitted to the workgroup by members of the public. This administrative record includes the documents that are physically located in the docket, as well as the documents that are referenced in those documents.

The public version of the administrative record, which includes printed, paper versions of any electronic comments that may be submitted during an applicable comment period, is available for inspection in the Public Information and Records Integrity Branch (PIRIB), Rm. 119, Crystal Mall #2, 1921 Jefferson Davis Hwy., Arlington, VA, from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The PIRIB telephone number is (703) 305-5805.

III. How and to Whom Do I Submit Comments?

You may submit comments through the mail, in person, or electronically. To ensure proper receipt by EPA, it is imperative that you identify docket control number OPP-00727 in the subject line on the first page of your correspondence.

1. *By mail.* Submit your comments to: Public Information and Records Integrity Branch (PIRIB), Information Resources and Services Division (7502C), Office of Pesticide Programs (OPP), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460.

2. *In person or by courier.* Deliver your comments to: Public Information and Records Integrity Branch (PIRIB), Information Resources and Services Division (7502C), Office of Pesticide Programs (OPP), Environmental Protection Agency, Rm. 119, Crystal Mall #2, 1921 Jefferson Davis Hwy.,

Arlington, VA. The PIRIB is open from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The PIRIB telephone number is (703) 305-5805.

3. *Electronically.* You may submit your comments and/or data electronically by e-mail to: "opp-docket@epa.gov," or you can submit a computer disk as described in Units III. 1. and 2. Do not submit any information electronically that you consider to be CBI. Avoid the use of special characters and any form of encryption. Electronic submissions will be accepted in WordPerfect 6.1/8.0 or ASCII file format. All comments in electronic form must be identified by docket control number OPP-00727. Electronic comments may also be filed online at many Federal Depository Libraries.

List of Subjects

Environmental protection, Pesticides, Inerts, PPDC.

Dated: June 26, 2001.

Anne E. Lindsay,
Acting Director, Office of Pesticide Programs.
[FR Doc. 01-16958 Filed 7-5-01; 8:45 am]

BILLING CODE 6560-50-S

ENVIRONMENTAL PROTECTION AGENCY

[PF-1027; FRL-6784-9]

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 control number PF-1027, must be received on or before August 6, 2001.

ADDRESSES: Comments may be submitted by mail, electronically, or in person. Please follow the detailed instructions for each method as provided in Unit I.C. of the

SUPPLEMENTARY INFORMATION. To ensure proper receipt by EPA, it is imperative that you identify docket control number PF-1027 in the subject line on the first page of your response.

FOR FURTHER INFORMATION CONTACT: By mail: Shaja R. Brothers, Registration Division (7505W), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW.,

Washington, DC 20460; telephone number: (703) 308-3194; e-mail address: brothers.shaja@epa.gov.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

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

Categories	NAICS codes	Examples of potentially affected entities
Industry	111 112 311 32532	Crop production Animal production Food manufacturing Pesticide manufacturing

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 the table could also be affected. The North American Industrial Classification System (NAICS) codes have been provided to assist you and others in determining whether or not this action might apply to certain entities. If you have 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 Additional Information, Including Copies of this Document and Other Related Documents?

1. **Electronically.** You may obtain electronic copies of this document, and certain other related documents that might be available electronically, from the EPA Internet Home Page at <http://www.epa.gov/>. To access this document, on the Home Page select "Laws and Regulations," "Regulations and Proposed Rules," and then look up the entry for this document under the **Federal Register—Environmental Documents.**" You can also go directly to the **Federal Register** listings at <http://www.epa.gov/fedrgstr/>.

2. **In person.** The Agency has established an official record for this action under docket control number PF-1027. The official record consists of the documents specifically referenced in this action, any public comments received during an applicable comment period, and other information related to this action, including any information claimed as confidential business information (CBI). This official record

includes the documents that are physically located in the docket, as well as the documents that are referenced in those documents. The public version of the official record does not include any information claimed as CBI. The public version of the official record, which includes printed, paper versions of any electronic comments submitted during an applicable comment period, is available for inspection in the Public Information and Records Integrity Branch (PIRIB), Rm. 119, Crystal Mall #2, 1921 Jefferson Davis Highway, Arlington, VA, from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The PIRIB telephone number is (703) 305-5805.

C. How and to Whom Do I Submit Comments?

You may submit comments through the mail, in person, or electronically. To ensure proper receipt by EPA, it is imperative that you identify docket control number PF-1027 in the subject line on the first page of your response.

1. **By mail.** Submit your comments to: Public Information and Records Integrity Branch (PIRIB), Information Resources and Services Division (7502C), Office of Pesticide Programs (OPP), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460.

2. **In person or by courier.** Deliver your comments to: Public Information and Records Integrity Branch (PIRIB), Information Resources and Services Division (7502C), Office of Pesticide Programs (OPP), Environmental Protection Agency, Rm. 119, Crystal Mall #2, 1921 Jefferson Davis Highway, Arlington, VA. The PIRIB is open from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The PIRIB telephone number is (703) 305-5805.

3. **Electronically.** You may submit your comments electronically by e-mail to: opp-docket@epa.gov, or you can submit a computer disk as described above. Do not submit any information electronically that you consider to be CBI. Avoid the use of special characters and any form of encryption. Electronic submissions will be accepted in Wordperfect 6.1/8.0 or ASCII file format. All comments in electronic form must be identified by docket control number PF-1027. Electronic comments may also be filed online at many Federal Depository Libraries.

D. How Should I Handle CBI That I Want to Submit to the Agency?

Do not submit any information electronically that you consider to be CBI. You may claim information that

you submit to EPA in response to this document as CBI by marking any part or all of that information as 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 version of the official record.

Information not marked confidential will be included in the public version of the official record without prior notice. If you have any questions about CBI or the procedures for claiming CBI, please consult the person identified 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 control 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 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 20, 2001.

Peter Caulkins,

Acting Director, Registration Division, Office of Pesticide Programs.

Summary of Petition

The petitioner summary of the pesticide petition is printed below as required by section 408(d)(3) of the FFDCA. The summary of the petition was prepared by the petitioner and represents the view of the petitioners. EPA is publishing the petition summary verbatim without editing it in any way. 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.

Interregional Research Project Number 4 (IR-4)**1E6224 and 1E6233**

EPA has received pesticide petitions 1E6224 from the Interregional Research Project Number 4 (IR-4), 681 US Highway #1 South, North Brunswick, NJ 08902-3390 and 1E6233 from the Taipai Economic and Cultural Representative Office, 4301 Connecticut Ave., NW., Suite 420, Washington, DC 20008 proposing, pursuant to section 408(d) of the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. 346a(d), to amend 40 CFR part 180.503 by establishing tolerances for residues of the fungicide, cymoxanil, 2-cyano-N-(ethylamino)carbonyl-2-(methoxyimino)acetamide in or on the following raw agricultural commodities (RACs): PP 1E6224 proposes to establish a tolerance on hops at 1.0 part per million (ppm). PP 1E6233 proposes to establish a tolerance on imported lychee at 1.0 ppm. This notice includes a summary of the petitions prepared by DuPont Agricultural Products, PO Box 80038, Wilmington, DE 19880-003. EPA

has determined that the petitions contain 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 petitions. Additional data may be needed before EPA rules on the petitions.

A. Residue Chemistry

1. Plant metabolism. The plant metabolism of cymoxanil is adequately understood in the crops of potatoes, tomatoes, and lettuce.

2. Analytical method. An analytical enforcement method is available for determining cymoxanil in plant residues using HPLC with UV detection.

3. Magnitude of residues. The magnitude of residues are adequately understood for lychee and hops.

B. Toxicological Profile

1. Acute toxicity. A battery of acute toxicity tests on technical cymoxanil and its Toxicity Categories are as follows:

Study Type	Species	Results	Toxicity Category
Oral LD ⁵⁰	Rat	960 mg/kg	Category III
Dermal LD ⁵⁰	Rabbit	≤2000 mg/kg	Category III
Inhalation LC ⁵⁰	Rat	5.06 mg/L	Category IV
Eye irritation	Rabbit	Slight Irritant	Category IV
Dermal irritation	Rabbit	Not an Irritant	Category IV
Dermal sensitization	Guinea pig	Not a sensitizer	

An acute neurotoxicity study was not required with cymoxanil; no short term or subchronic studies have been observed.

2. Genotoxicity. Cymoxanil was tested in a battery of assays to evaluate genotoxicity and chromosome aberrations; the results are as follows:

Study	Test Organisms	Results
Bacterial gene mutation	<i>Salmonella typhimurium</i>	Negative
Mammalian gene mutation <i>in vitro</i>	CHO/HGPRT	Negative
Mammalian chromosome aberrations <i>in vitro</i>	CHO	Positive

Study	Test Organisms	Results
Mammalian chromosome aberrations <i>in vivo</i>	Mouse micro-nucleus	Negative
Unscheduled DNA synthesis <i>in vitro</i>	Primary rat hepatocytes	Negative
Unscheduled DNA synthesis <i>in vivo</i> and Spermatocytes	Primary rat hepatocytes	Negative

Based on the weight-of-evidence, cymoxanil is not considered to be genotoxic or clastogenic.

3. Reproductive and developmental toxicity. The results of a series of studies showed no indication of reproductive or developmental hazards associated with cymoxanil.

In a 2-generation cymoxanil rat reproduction study, the NOAEL for both parents and offspring was approximately 7 milligrams/kilogram/day, based on decreased body weight, weight gain and food consumption in adults and decreased pup weight in offspring at 32 mg/kg/day. There were no reproductive or fertility effects. Since offspring effects occurred only in the presence of maternal toxicity, it is considered a secondary effect to the health effects on the dam.

The developmental studies conducted in rats demonstrated a NOAEL of 10 mg/kg/day, and a LOAEL of 25 mg/kg/day for both adult and developmental effects. Maternal effects in rats included decreased weight, weight gain, and food consumption. Developmental effects were increases in fetal variations, which were the result of generalized delays in ossification, and overall malformations, although malformations detected were not dose related.

In rabbits, several developmental toxicity studies were conducted. Based on the weight-of-evidence of all three studies, there was no unique sensitivity of perinatal animals to the effects of cymoxanil, nor any anomalies of the fetal nervous system at maternally toxic doses up to and including 32 mg/kg/day.

4. *Subchronic toxicity.* Subchronic (90-day) feeding studies were conducted with rats, mice, and dogs. In addition, the following subchronic feeding studies were conducted: a 90-day in rats to evaluate neurotoxicity and 28-day rats and mice to evaluate immunotoxicity. A 28-day dermal study was also conducted in rats.

In a subchronic toxicity/neurotoxicity study in rats with cymoxanil, the NOAEL of 47.6 mg/kg/day in males was based on decreased body weights, and minimal to mild testicular and epididymal effects at higher concentrations. In females, the NOAEL of 59.9 mg/kg/day was based on effects on body weight, weight gain, and food efficiency at higher levels.

The subchronic NOAEL for male mice administered cymoxanil was 8.25 mg/kg/day based on body weight and weight gain effects at 82.4 mg/kg/day and above. The NOAEL for females was 121 mg/kg/day based on increases in spleen and liver weights at 433 mg/kg/day and above.

For cymoxanil, dogs were the most sensitive species in subchronic studies. Reduced body weight gain and/or food consumption was observed at 3 mg/kg/day or greater in females and 5 mg/kg/day and above in males. Both sexes had RBC changes (decreased RBC counts, Hb, and/or Hct), increased incidence of ketonuria at the intermediate and high concentration, and changes in serum chemistry (decreases in various electrolytes and proteins) at the high dose. Males had testicular and epididymal effects at the highest concentration, 11 mg/kg/day (raised from 5 mg/kg/day at week 3); this was considered to be retardation of development due to markedly reduced body weight in this group. The NOAEL for males was 3 mg/kg/day. There was no NOAEL in female dogs in the 90-day study. Although a NOAEL was not established in the dog subchronic study, 3 mg/kg/day was found to be a NOAEL in a subsequent chronic study in dogs.

Subchronic (28-day) studies were conducted in rats and mice to evaluate the immunotoxicity potential of cymoxanil. Cymoxanil was not immunotoxic up to and including the highest dose tested (HDT) which was 1,600 ppm in rats (108 and 117 mg/kg/day in males and females, respectively),

1,200 ppm (218 mg/kg/day) in male mice, and 2,400 ppm (552 mg/kg/day) in female mice.

Cymoxanil was applied to the skin of rats 6-hours/day for 28 days at doses of 0, 50, 500, and 1,000 mg/kg/day. There were no effects at any dose tested. The 28-day dermal NOAEL was 1,000 mg/kg/day, the HDT.

5. *Chronic toxicity.* Chronic studies with cymoxanil were conducted on rats, mice, and dogs to determine carcinogenic potential and/or chronic toxicity of the compound. Effects generally similar to those observed in the 90-day studies were seen in the chronic studies; cymoxanil was not found to be carcinogenic.

The chronic NOAEL for cymoxanil in male rats was 4.08 mg/kg/day based on decreased body weight, weight gain, food efficiency, and non-neoplastic lesions in several organs including lung inflammation, spermatid degeneration, and retinal atrophy at 30.3 mg/kg/day or higher. In addition, male rats in the two highest groups displayed increased aggressiveness and hyperreactivity consistent with the compromised general health status (i.e. systemic toxicity) of those groups. In females, the NOAEL of 5.36 mg/kg/day was based on decreased body weight, weight gain, food efficiency, and non-neoplastic lesions in several organs including lungs, liver, intestines, mesenteric lymph nodes, sciatic nerve, and retina at 38.4 mg/kg/day or higher. Retinal atrophy and sciatic lesions are common spontaneous lesions associated with aging. These effects observed in cymoxanil test animals were considered aging-related effects. Spermatid degeneration occurs spontaneously in rats. While the incidence was increased in cymoxanil-treated rats, most were mild or minimal, and none were more than moderate. Thus, the effects are considered a mild exacerbation of a spontaneously occurring lesion.

In mice, the chronic NOAELs for cymoxanil were 4.19 and 5.83 mg/kg/day for males and females, respectively, based on changes in organ weights, gastrointestinal effects in females, and liver, testes and epididymal effects in males at the LOAEL. Similar to the rat, the testicular effects were considered an exacerbation of a spontaneous lesion that occurred in one-quarter of the control mice. The LOAELs were 42.0 and 58.1 mg/kg/day for males and females, respectively.

The chronic cymoxanil NOAEL for male dogs was 3.0 mg/kg/day based on a temporary decrease in body weight and food consumption, and lower RBC count, hemoglobin, and hematocrit at 5.7 mg/kg/day. In female dogs the only

finding was a transient effect on body weight, food consumption, and food efficiency at the HDT, 3.1 mg/kg/day, only during the first week of the study.

6. *Animal metabolism.* When administered by gavage to rats, cymoxanil was readily absorbed and eliminated. Absorption reached maximum concentrations in whole blood within 4 hours post-dosing. A rapid and almost complete elimination was observed in the urine and feces. The majority of radioactivity was recovered within 96 hours, mainly in urine but also in feces. Radioactivity in the tissues and carcass was less than 1%. In the urine and feces, the majority of the radioactivity was free and/or conjugated glycine. 2-Cyano-2-methoxyimino-acetic acid was also found in low levels in the urine and trace levels in the feces. Intact cymoxanil was less than 1% in feces and not detected urine. The metabolite profile in urine and feces was similar between sexes, among dose groups, and between dosing regimens.

7. *Metabolite toxicology.* There are no metabolites of toxicological significance to mammals.

8. *Endocrine disruption.* The probability of an endocrine effect due to agricultural uses of cymoxanil is negligible.

C. Aggregate Exposure

1. *Dietary exposure.* Cymoxanil is a fungicide currently registered in the United States for use on potatoes. In addition, tolerances have been approved for cymoxanil on imported tomatoes and grapes.

i. *Food.* The acute and chronic analysis conservatively assumed that 30% of cucurbits, fruiting vegetables, head lettuce, potatoes and imported grapes would be treated with cymoxanil and field trial residue data was used. As reflected in the 1994-1996 USDA CSFII data, neither hops nor lychee are consumed as part of the diet. Therefore, any increased exposure from the use of cymoxanil on hops and lychee would be negligible and would not significantly alter the acute and chronic dietary risk estimates provided. The analysis' show that adequate margins of safety exist for all population subgroups, and no effects would result from dietary exposure to cymoxanil.

a. *Acute dietary exposure assessment.* The acute dietary exposure assessment was estimated using Tier 3. The results of the acute dietary exposure analysis for cymoxanil are given in table below. The percentages of the acute population adjusted dose (aPAD) for cymoxanil were calculated based on an acute NOAEL of 4 mg/kg/day from the rabbit

developmental study based on maternal clinical signs and weight effects at the higher levels and an uncertainty factor of 100. The results of the acute dietary exposure analysis are below the EPA's level of concern.

RESULTS OF ACUTE DIETARY EXPOSURE ESTIMATES FOR CYMOXANIL

Population Group	99.9th Percentile of Exposure (mg/kg/day)	% aPAD
U.S. Population	0.001789	4.47
Non-Nursing (< 1 yr.)	0.000599	1.50
Children (1–6 yr.)	0.002096	5.24
Children (7–12 yr.)	0.001936	4.84
Females (13+ nursing)	0.002287	5.72

b. *Chronic dietary exposure assessment.* The chronic dietary exposure assessment was estimated using the Dietary Exposure Evaluation Model (DEEM, Novigen Sciences, Inc., 1999 Version 6.74). The following table presents the results of an analysis for chronic exposure to cymoxanil in either TanosR 50DF or CurzateR 60DF. The chronic population adjusted dose (cPAD) of 0.041 mg/kg/day is based on a NOAEL of 4.08 mg/kg/day from the one-year rat feeding study and an uncertainty factor of 100. No sensitive subpopulations were identified. The results of the chronic dietary exposure analysis are below the EPA's level of concern.

RESULTS OF CHRONIC DIETARY ANALYSIS WITH CYMOXANIL

Population Group	Maximum Dietary Exposure (mg/kg/day)	% cPAD
U.S. Population	0.000063	0.2
Non-Nursing Infants (<1 yr.)	0.000016	0.1
Children (1–6 yr.)	0.000074	0.2
Children (7–12 yr.)	0.000068	0.2
Females (13+)	0.000074	0.2

ii. *Drinking water.* Surface water exposure was estimated using the Generic Expected Environmental Concentration (GENEEC) model. This

screening level model is used for determining upper bound concentrations of pesticides in surface water.

The acute drinking water level of concern(s) (DWLOCs) are 1.3 ppm for the U.S. population, and 0.38 ppm for children (1–6 years old), the most exposed population subgroup. The estimated environmental concentration (EECs) of cymoxanil in surface water is 8.15 parts per billion (ppb) derived from GENECC does not exceed the acute DWLOC.

The chronic DWLOCs are 1.4 ppm for the U.S. population and 0.4 ppm for children (1–6 years old), the most sensitive subgroup. The GENECC 56-day EECs of 0.37 ppb does not exceed the chronic DWLOC for cymoxanil in surface water.

Therefore, based on the above findings, the registrants conclude with reasonable certainty that residues of cymoxanil in drinking water do not contribute significantly to the aggregate chronic human health risk.

2. *Non-dietary exposure.* Cymoxanil products are not labeled for residential non-food uses, thereby eliminating the potential for residential exposure.

D. Cumulative Effects

EPA's consideration of a common mechanism of toxicity is not necessary at this time because there is no indication that toxic effects of cymoxanil should be cumulative with those of any other chemical compounds or with each other.

E. Safety Determination

1. *U.S. population.* For acute dietary exposure of cymoxanil, the estimated exposure is 0.000475 and 0.001789 at the 99th and 99.9th percentiles, which will utilize 1.19 and 4.47%, respectively, of the acute population adjusted dose (aPAD) for the overall U.S. population. The chronic dietary exposure for the overall U.S. population is estimated to be 0.000063 mg/kg/day, using 0.2% of the chronic population adjusted dose (cPAD). Based on the completeness and reliability of the toxicity data and the conservative exposure assessments, there is reasonable certainty that no harm will result from the aggregate exposure of residues of cymoxanil including all anticipated dietary exposure and all other non-occupational exposures.

2. *Infants and children.* For acute dietary exposure of cymoxanil, the aPAD for children 1–6 years old is 1.44 at the 99th percentile and 5.24 at the 99.9th percentile. For non-nursing infants (<1 yr.), the % aPAD is 0.46 at the 99th percentile and 1.50 at the

99.9th percentile. Chronic dietary exposure of cymoxanil for the most highly exposed children's subpopulations are: 0.000074 mg/kg/day for children 1–6 years old, and 0.000068 mg/kg/day for children 7–12 years old, representing 0.2% of the cPAD for each subpopulation. Exposure for all infant subpopulations was negligible.

In addition, there are no residential uses of cymoxanil; therefore, it is extremely unlikely that drinking water will be contaminated.

Based on the completeness and reliability of the toxicity database, the lack of toxicological endpoints of special concern, the lack of any indication that children are more sensitive than adults to cymoxanil, and the conservative exposure assessment, the registrants believe there is a reasonable certainty that no harm will result to infants and children from the aggregate exposure of residues of cymoxanil, including all anticipated dietary exposure and all other non-occupational exposures. Accordingly, there is no need to apply an additional safety factor for infants and children.

F. International Tolerances

No international tolerances currently exist for cymoxanil.

[FR Doc. 01-16957 Filed 7-5-01; 8:45 am]
BILLING CODE 6560-50-S

ENVIRONMENTAL PROTECTION AGENCY

[PF-1031; FRL-6790-1]

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 control number PF-1031, must be received on or before September 4, 2001.

ADDRESSES: Comments may be submitted by mail, electronically, or in person. Please follow the detailed instructions for each method as provided in Unit I.C. of the

SUPPLEMENTARY INFORMATION. To ensure proper receipt by EPA, it is imperative that you identify docket control number PF-1031 in the subject line on the first page of your response.