6(f)(1)(C) of FIFRA requires that EPA provide a 180–day comment period on a request for voluntary termination of any minor agricultural use before granting the request, unless the registrants request a waiver of the comment period, or the Administrator determines that continued use of the pesticide would pose an unreasonable adverse effect on the environment. The registrant has requested that EPA waive the 180–day comment period. In light of this request, EPA is granting the request to waive the 180–day comment period.

The following Table 1 specifies the time frame for the immediate cancellation and phase-out of several uses as requested by BASF. Commodities legally treated will be allowed in the channels of trade past the last date of legal use in accordance with FFDCA section 408(l)(5).

TABLE 1. — TIME FRAME FOR USECANCELLATION AND PROPOSED EXISTING STOCKS PROVISION

Commodity	Date of Use Cancellation Request	Last Date for Sale and Distribution of Existing Stocks	Last Date for Legal Use
Onions	July 15, 2000	January 1, 2001	September 30, 2001
Raspberries	July 15, 2000	January 1, 2001	September 30, 2001
Ornamentals	July 15, 2000	July 15, 2001	September 1, 2001
Kiwi 24(c)	December 31, 2001*	December 31, 2002	November 30, 2003
Chicory 24(c)	December 31, 2001*	December 31, 2002	November 30, 2003
Lettuce	July 15, 2004	July 15, 2005	September 30, 2005
Succulent beans	July 15, 2004	July 15, 2005	September 30, 2005

*BASF will inform the State of California that it can no longer support the 24(c) registrations by this date.

III. What is the Agency's Authority for Taking this Action?

Section 6(f)(1) of FIFRA provides that a registrant of a pesticide product may at any time request that any of its pesticide registrations be canceled. FIFRA further provides that, before acting on the request, EPA must publish a notice of receipt of any such request in the **Federal Register**. Thereafter, the Administrator may approve such a request.

IV. Procedures for Withdrawal of Request

Registrants who choose to withdraw a request for cancellation must submit such withdrawal in writing to the person listed under **FOR FURTHER INFORMATION CONTACT,** postmarked before October 20, 2000. This written withdrawal of the request for cancellation will apply only to the applicable FIFRA section 6(f)(1) request listed in this notice. If the product(s) have been subject to a previous cancellation action, the effective date of cancellation and all other provisions of any earlier cancellation action are controlling. The withdrawal request must also include a commitment to pay any reregistration fees due, and to fulfill any applicable unsatisfied data requirements.

V. Proposed Existing Stocks Provision

Pursuant to section 6(f) of FIFRA, EPA proposes to grant the requests for voluntary amendment and cancellation during the appropriate time frames identified in Table 1. For purposes of the cancellation order that the Agency proposes to issue at the close of the comment period for this announcement, the term ''existing stocks'' will be defined, pursuant to EPA's existing stocks policy at (56 FR 29362, June 26, 1991) (FRL 3846–4), as those stocks of a registered pesticide product which are currently in the United States and which have been packaged, labeled, and released for shipment prior to the effective date of the amendment or cancellation. Any distribution, sale, or use of existing stocks after the effective date of the cancellation order that the Agency intends to issue that is not consistent with the terms of that order will be considered a violation of section 12(a)(2)(K) and/or 12(a)(1)(A) of FIFRA.

A. Distribution or Sale by Registrants

If the requested use deletions are approved, the distribution or sale of such stocks by registrants will not be lawful under FIFRA after the sale and distribution dates listed in Table 1, except for the purposes of returns and relabeling, shipping such stocks for export consistent with the requirements of section 17 of FIFRA, or for proper disposal.

B. Distribution, Sale and Use by Other Persons

If the requested use deletions are approved, retailers, distributors, and end-users may sell, distribute, or use products with previously approved labeling which have been released for shipment until such supplies are exhausted or the last legal use date presented in Table 1.

List of Subjects

Environmental protection, Agricultural commodities, Pesticides and pests.

Dated: September 7, 2000.

Lois Rossi,

Director, Special Review and Reregistration Division, Office of Pesticide Programs.

[FR Doc. 00–23941 Filed 9–19–00]

BILLING CODE 6560–50–S

ENVIRONMENTAL PROTECTION AGENCY

[PF–946; FRL–6588–8]

Notice of Filing a Pesticide Petition to Establish an Exemption from The Requirement of 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 to provide an exemption from the requirement of a tolerance for residues of a certain pesticide chemical in or on various food commodities.

DATES: Comments, identified by docket control number PF–946, must be received on or before October 20, 2000.

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–946 in the subject line on the first page of your response.

FOR FURTHER INFORMATION CONTACT: By mail: Marshall Swindell, Antimicrobial Division (7510C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460; telephone number: (703) 308–6341; e-mail address: swindell.marshall@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	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'' 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–946. 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–946 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–946. 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 to

provide an exemption from the requirement of a tolerance for residues of a certain pesticide chemical in or on various food commodities under section 408 of the Federal Food, Drug, and Comestic 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: September 5, 2000.

Frank Sanders,

Director, Antimicrobial 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.

3M

0F6124

EPA has received a pesticide petition (0F6124) from 3M, St. Paul, MN 55144-1000, 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 to establish an exemption from the requirement of a tolerance in raw agricultural commodities and food for residues of zinc 2-pyridinethiol-oxide, used as a preservative in sponges (zinc-chitosan modified cellulose sponges). EPA has determined that the petition contains data or information regarding the elements set forth in section 408(d)(2) of the FFDCA. EPA has completed a preliminary evaluation of the aggregate exposure and risk in reviewing an assessment provided by 3M. EPA's findings have been made part of this notice, with attribution. However, EPA has not completed its evaluation of the sufficiency of the submitted data at this time or whether the data support granting of the petition. Additional data may be needed before EPA rules on the petition.

A. Residue Chemistry

1. *Sample extract preparation*. The amount of zinc pyrithione that can be extracted from a 3M sponge in typical use was determined as a preliminary step in estimating exposure and risk. The mean level of zinc pyrithione bound into the 3M sponge is 0.35% on a dry weight basis. New sponges measuring 114 x 71 x 20 millimeters (mm) were removed from their packages and rinsed a total of 10 times by completely saturating the sponges under running 43 °C tap water with hand wringing between saturations. Samples were then filled with tap water one final time and passed through a zero clearance wringer with rubber rolls having a Shore gage A hardness of 20–25. These preconditioning rinses were carried out to insure removal of softening agents from the sponge manufacturing process and to bring all samples to an equal final moisture content.

Each preconditioned sponge was placed in a separate pint size ziplock polyethylene plastic bag. Fifty milliliters (mL) of extraction solution were added and the bag sealed. Extraction solutions were deionized water and dilute solutions of dishwashing detergent. Three sponges were tested for each set of extraction conditions. Each bag was thoroughly agitated by repeated hand squeezing to insure uniform distribution of the extraction liquid throughout the sponge sample. For elevated temperatures, samples were then placed in an agitated temperature controlled water bath for an extraction period of 10 minutes. Room temperature samples were placed on the lab bench in a horizontal position for 10 minutes.

Following the 10 minute extraction period, the extraction liquid was recovered by hand squeezing liquid from the sponge back into its sample bag. The recovered liquid was then transferred into a clean 125 mL high density polyethylene sample bottle with screw top lids. The bottle was sealed until the sample was analyzed.

2. *Analysis of extracts*. Extract samples were analyzed for zinc ion using a Thermo Jarrell Ash model 61 E inductively coupled plasma (ICP) atomic emission spectrometer.

Each extract sample was transferred to a beaker and weighed to the nearest milligram (mg). The beaker was then placed on a hot plate and carefully evaporated to dryness. Then 2–3 mL of concentrated sulfuric acid was added to the beaker to digest any organic material in the sample. Concentrated nitric acid was added dropwise to oxidize any resulting charred organic matter. The acid solution was carefully transferred to a 50 mL volumetric flask and the beaker washed several times with deionized water which was added to the flask. The solution was diluted to the mark with deionized water and analyzed directly for zinc ion. Fresh zinc standards were prepared in the same acid matrix as the samples.

Although the analysis measures only zinc ion, it is assumed that the full zinc pyrithione moiety is removed from the sponge by the extraction solution. The zinc ion forms a coordination complex with the cellulose, as shown above, thereby binding the pyrithione anion into the cellulose structure. Loss of a zinc cation (2+) is, therefore, necessarily accompanied by loss of two pyrithione anions (1 −).

3. *Magnitude of residues*. The mean level of zinc pyrithione found using deionized water at 65 °C was 9.4 parts per million (ppm). In dish detergent solutions at the same temperature, mean levels were 12.4 ppm (0.1% detergent) and 26.8 ppm (1% detergent). For comparison purposes, certain samples were put through the sample preparation and extraction process three times. The amount of zinc pyrithione recovered was comparable in all three cycles. For ''worst case'' risk assessment purposes, the upper bound (95% probability) of highest mean value found for detergent extract solutions at 65 °C is used, i.e., ~30 parts per million (ppm). This extract solution contains 1% by weight dish detergent. A level of 0.1% or less is normally used for dishwashing.

The solubility of zinc pyrithione in water is known to increase with increasing detergent concentration. It has a very low solubility in pure water (15 to 20 ppm) but its solubility increases by complex formation with organic amines to near 300 ppm in very concentrated detergent such as shampoo base.

B. Toxicological Profile

In January 1996, EPA published its Reregistration Eligibility Decision (RED) for Sodium Omadine in which no observed adverse effect levels (NOAELs) and a reference dose (RfD) are formally selected. Sodium and zinc pyrithione have very similar toxicology profiles. The pyrithione anion is the biologically active moiety in either active ingredient. The pertinent toxicology endpoints are described below for zinc pyrithione

when studies on this test material are available. Otherwise endpoints were used from studies where sodium pyrithione was the test material. EPA, in its risk assessment for the 3M product, calculated RfD, given below, by applying various safety factors to the NOAELs.

1. *Acute toxicity*. Acute oral LD_{50} (rat) = 269 milligrams/kilograms (mg/kg) (male/female) for sodium pyrithione and 630 mg/kg (males) and 460 mg/kg (females) for zinc pyrithione. Acute dermal LD_{50} (rabbit) > 2,000 mg/kg for both sodium and zinc pyrithione. Acute inhalation LD_{50} (rat) = 0.61 milligram/liter (mg/L) (4–hour) for sodium pyrithione and > 0.61 mg/L for zinc pyrithione. Sodium pyrithione is a mild irritant to skin and eyes, and it is not a sensitizer. Zinc pyrithione is corrosive to skin and eyes, and it is not a sensitizer.

2. *Genotoxicty*. *In vitro* and *in vivo* tests indicate that sodium and zinc pyrithione are not genotoxic.

3. *Reproductive and developmental toxicity*. Technical grade zinc pyrithione active ingredient was administered by gavage at doses of 0, 7.5 and 15 mg/kg to Charles River albino rats. Maternal body weight gain depression was observed. A lowest observed adverse effect level (LOAEL) of 7.5 mg/kg was found. There was an increased incidence of skeletal abnormalities at the maternally toxic high dose level (15 mg/kg). In a separate study using sodium pyrithione, NOAEL = 5 mg/kg/day.

In a study using 30 pregnant Sprague-Dawley rats per group, zinc pyrithione was administered by oral gavage on days 6–15 of gestation at 0, 0.75, 3, and 15 mg/kg/day. One dam died on gestation day 16. Developmental toxicity was observed as an increase in postimplantation loss at mid and high dose levels. The high dose group was significantly different than controls ($p \leq 0.01$). An increase in early resorptions (3.6%/dam) was observed with whole litter resorption occurring in 3 high dose dams. In the 15 mg/kg/day group, the number of live fetuses per litter was significantly reduced ($p \leq 0.05$), mean fetal weights were reduced (16%), and gravid uterine weights were reduced (16%; $p \leq 0.01$) when compared to controls.

A significant number of fetuses were found to have external, visceral, or skeletal malformations at the 15 mg/kg/day group: digit anomalies at $p \leq 0.05$; dilated renal pelvis at $p \leq 0.05$; and a verbal/rib anomaly at $p \leq 0.01$. Dose-related fused ribs were observed at 3.0 and 15 mg/kg/day levels. The maternal toxicity NOAEL for the study was 0.75 mg/kg/day, based on excessive salivation during the dosing period, and the developmental toxicity NOAEL was 0.75 mg/kg/day based on increased incidences of fused ribs.

Another study used 20 white New Zealand rabbits per groups and oral gavage doses of 0, 0.5, 1.5, and 3.0 mg/kg/day of zinc pyrithione on gestation days 6–18. A significant decrease in body weight ($p \leq 0.01$) was observed for mid and high-dose groups, but the absolute body weight changes were small. Five high-dose does and one mid-dose doe had total resorption. One high-dose doe aborted on day 27. No statistically significant differences were observed in anomalies for treated groups compared to controls. The maternal/developmental NOAEL was 0.5 mg/kg/day.

Based upon the above studies, EPA considers zinc pyrithione to be a frank developmental toxicant.

4. *Subchronic toxicity*. Technical grade zinc pyrithione was administered in the diet to 20 male and 20 female Charles River CD albino rats per dose group at 5, 25 and 125 ppm for up to 93 days. No mortality occurred at 5 or 25 ppm; significant mortality at 125 ppm (39 out of 40). Slight growth rate depression was observed in the 25 ppm group. No significant treatment-related biochemical or histopathological finding were made at 5 or 25 ppm. NOAEL = 25 ppm (~ 2.5 mg/kg/day).

Six Rhesus monkeys per dose group were administered a 1% suspension in gum tragacanth by gavage at does of 0.5, 2.0 and 8.0 mg/kg for 90 days. All animals appeared normal. Emesis was observed on days 1 and 2 in intermediate and high dose groups and not again throughout the study. No treatment-related gross or microscopic pathology was observed. There was a statistically significant decrease in the weights of uteri in high dose females.

Clinical signs, including hind limb weakness, motor incoordination and spinal kyphosus with muscle atrophy, were observed at the high dose in a neurotoxicity study in Charles River CD rats where zinc pyrithione was administered at 0 and 250 ppm for 9 or 14 days, followed by a 14- to 28-day recovery period. Clinical signs did not persist during the recovery period. Histopathology revealed dense granular axoplasmic deposits in the axons of sural and intramuscular lumbrical nerves. Normal muscle morphology was observed in the acutely affected rats. In a separate study using sodium pyrithione as a test material, neurotoxicity end points were as follows: lowest observed adverse effect level (LOAEL) = 2.0 mg/kg/day; NOAEL = 0.5 mg/kg/day.

Male and female Crl:CD(SD)BR rats were treated with zinc pyrithione using occluded dermal doses at 0, 20, 100, and, 1,000 mg/kg/day for 6 hours/day for 5/days/week for 13 weeks. Females in the high dose group exhibited decreased food consumption (91.6% of control), decreased body weight gain (48.9% of control), and decreased food efficiency (53.8% of control) for the period of treatment. The systemic NOAEL in females was 100 mg/kg/day and in males 1,000 mg/kg/day.

Groups of 15 male and 15 female Sprague-Dawley rats were tested in whole-body inhalation exposure chambers to zinc pyrithione aerosols at 0.005, 0.0025, or 0.01 mg/L/for 6 hours/day, 5 days/week for 13 weeks. One animal of each sex died at the 0.0025 mg/L/day level. Three males and four females died at the 0.01 mg/L/day exposure level. Decreased body weights, food consumption and food efficiency were observed at the highest dose. Significantly increased lung weights were noted at the mid and high dose. Mild inflammation of the interstitial tissue of the lung and medial hypertrophy of pulmonary arteries was found at the high dose. The systemic NOAEL was 0.005 mg/L/day.

5. *Chronic toxicity*. Zinc pyrithione was administered in the diet at doses of 0, 2, 5, 10, 25, and 50 ppm to groups of 10 male and 10 female albino rats for 2 years. There were no adverse effects on survival of the males. Decreased survival of the females in the 25 and 50 ppm dose groups and accelerated growth rate in females in lower dose groups were observed. Males in the 50 ppm group also were observed to have accelerated growth. No treatment-related biochemical or histopathological effects were noted. NOAEL = 10 ppm, or 0.5 mg/kg/day.

For sodium pyrithione, EPA has established in the RED a RfD of 0.005 mg/kg/day based upon a chronic rat study NOAEL of 0.5 mg/kg/day and an uncertainty factor of 100.

6. *Animal metabolism*. Three older animal metabolism studies are available for zinc pyrithione. In two studies radio labeled material is administered by intravenous injection and in one study oral dosing is used. In an intravenous study in Yorkshire pigs, ^{14}C-labeled sodium and zinc pyrithione are compared. For both compounds, urine appears to be the major route of excretion for the administered radio label. Significantly less radio label was recovered in the urine for the zinc salt than the sodium salt, as expected because the zinc salt has a very low

solubility in water. Presumably insoluble salt in the blood was captured and eliminated through the bile duct into the feces. In a study in which ^{14}C-zinc pyrithione or ^{65}Zn-zinc pyrithione were administered intravenously to rabbits, the animals were sacrificed at 6 hours after dosing and levels of radio label determined in urine, tissue and blood. The ^{14}C-labeled pyrithione was substantially excreted (75%) in the urine, but the ^{65}Zn remained relatively constant in the blood and tissue. The retention of zinc is expected because it readily forms coordination complexes with biochemical molecules and it is also an essential trace element in the diet, being present naturally in significant amounts in food, tissue and blood.

When ^{14}C-labeled zinc pyrithione was administered by the oral route to Sprague-Dawley rats, most of the radio labeled material (up to 84%) was excreted through the urine and the feces (up to 21%). Male rats appeared to metabolize and excrete zinc pyrithione more rapidly than female rats.

7. *Endocrine disruption.* There is no evidence to suggest that the active ingredient has an effect on any endocrine system. Developmental toxicity tests using both zinc and sodium pyrithione showed no evidence of maternal or fetal toxicity except at the limit dose. In a 2–generation reproduction study in Crl:CD(SD)BR rats in which sodium pyrithione was administered by gavage, a parental NOAEL of 0.5 mg/kg/day and a reproductive NOAEL of 1.5 mg/kg/day were established. At maternally toxic doses, a slightly decreased number of pups were born per litter in both generations, possibly as a consequence of reduced mating success due to hind limb atrophy.

C. Aggregate Exposure

The risk analysis for the use of 3M sponges includes estimates of total exposure to zinc and sodium pyrithione in all their uses registered by EPA or approved by FDA, not just sponges. The use of zinc pyrithione as a popular active ingredient in dandruff shampoos is of particular importance because it involves direct application to human skin. The analysis also includes four different sets of exposure assumptions:

A realistic adverse case exposure scenario.
A worst case exposure scenario.
A highly exaggerated worst case set of assumptions.
EPA's exposure assumptions.

Even the realistic adverse case assessment hugely overestimates exposure and can therefore, be considered to provide an absolute upper bound exposure estimate. The worst case and exaggerated worst case scenarios include a number of obviously even more unreasonable assumptions designed simply to test the sensitivity of the realistic adverse case numbers to changing assumptions.

Various routes of exposure that could result from use of the sponge are considered in the analyses, as follows:

Ingestion
Incidental residues in food from the use of the sponge in home kitchens.
Contaminated drinking water.
Use of sponges for teething for a lifetime (EPA's analysis only).

Per cutaneous absorption
Dermal contact with sponges and dishwater.

Exposure to sodium and zinc pyrithione that do not result from the use of the sponge but are included in the analyses are as follows:

Per cutaneous absorption

Dandruff shampoo.
Additive for plastics, adhesives, grouts, caulking, paints, yarns and fabrics.

All components of 3M's aggregate exposure analysis are summarized below and the methods and assumptions used in calculating the numbers are discussed in detail. In summary, huge margins of safety were found, as expected, when exposures were compared to the established NOELs and NOAELs.

In EPA's own analysis, dietary exposures were compared to the acute and chronic RfDs for zinc pyrithione. An acute RfD for zinc pyrithione was set at 0.005 mg/kg/day using an uncertainty factor (UF) of 100 and the lowest observed NOAEL of 0.5 mg/kg/day from a subchronic dietary exposure study described above. A chronic RfD of 0.0005 mg/kg/day was calculated using the NOAEL of 0.5 mg/kg/day from the developmental toxicity study in the rat described above and an UF of 1,000. The additional UF of 10 was included by EPA for protection of infants and children. The subchronic study was used, rather than available chronic dietary toxicity study in rats, because the chronic study was determined by EPA not to meet current guidelines. The Agency intends to ask for a new study. Although an acceptable chronic study is available for sodium pyrithione and a RfD of 0.005 mg/kg/day has been established for this sodium salt based on those data, EPA determined that sodium pyrithione cannot be used as a surrogate for assessing the risks posed by sponges containing the zinc salt.

1. *Dietary exposure.* Use of the 3M sponge by institutions is considered by EPA to be a food use of a pesticide, requiring a tolerance or exemption from a tolerance. In assessing aggregate risk, two incidental ways in which low level residues in food might originate have been considered. First, the worst case and exaggerated worst case assessments assume that all dishes used for service of food and beverages are hand washed (i.e., no dishwashers) in water with dish detergent using a 3M sponge. Furthermore, the dishes are never rinsed, thereby leaving a slight residue of zinc pyrithione on the surface of each dish that may become a component of food. The realistic adverse case assumes that the normal practice of rinsing dishes after washing is followed, thereby eliminating dishes as a source of residues in food.

The second way in which residues in food might originate is from contact with counters that have been cleaned with dishwater containing trace levels of zinc pyrithione. A discussion of the assumptions used in assessing exposure from counters can be found below. Dietary exposure is assumed to occur also, for the purpose of aggregate exposure and risk assessment, through drinking water containing minute levels of zinc pyrithione originating from home dishwater effluent discharged to publicly owned water treatment systems. Again, the assumptions behind the assessment are discussed below.

EPA added a scenario in which children may become exposed to zinc pyrithione through chewing sponges while teething. Incidental ingestion exposures were calculated for infants using a formula for foreign object/matter non-dietary ingestion as set forth in EPA's Occupational and Residential Exposure Test Guidelines, Series 875, Part D—Exposure and Risk Assessment Calculations, Test Guideline No. 875.2900. Assuming children will teeth on sponges for a lifetime, EPA calculated that the margin of exposure (MOE) was acceptable.

For other dietary exposures, EPA assumed 3M's exaggerated worst case scenario.

i. *Food-incidental residues from dishes.* 3M's analysis begins by assuming that all dishes are washed by hand using a sponge and that the same amount of zinc pyrithione is extracted from the sponge by dishwater every time. The amounts assumed from the extraction study are 12.4 ppm (adverse and worst case) and 29.6 ppm (exaggerated worst case). The extraction study was designed to estimate the total amount of zinc pyrithione that might be extracted from a sponge during a single use. A 50 mL volume of extract was used for convenience. A mean extract

concentration of 12.4 ppm in 50 mL, used for the realistic adverse case and worst case analyses, results from vigorous extraction of the sponge with 50 ml of 0.1% dish detergent in water at 65 °C, much hotter than normal dishwater, thereby releasing 0.62 mg of zinc pyrithione. A 95% upper bound estimate for extraction with 1.0% dish detergent in water at 65 °C is used for the exaggerated worst case calculations, wherein 1.48 mg are released. Informal measurements of the amount of detergent necessary to make a quite sudsy dishwater demonstrate that less than 0.1% by weight is needed. The analysis also assumes that the average volume of water used each time a load of dishes are washed is 10 liters. Hence, a dilution factor of 200 is applied to the concentration of the original extract. If it were assumed that the entire volume of dish water has the same concentration of zinc pyrithione as the experimental extract, the amount in solution would substantially exceed the original active ingredient in the sponge.

For the worst case and exaggerated worst case analyses, it is assumed, based on gravimetric measurements, that 0.25 mL of dishwater, on the average, remains uniformly distributed over the surface of a drained but not rinsed plate or cup. It is also assumed that food or drink acquires the entire amount of residue from one side (50% of the surface area) of each plate or cup and that on an average each person uses a total of 12 plates and cups a day. For the realistic adverse case it is assumed that the plates and cups are rinsed free of dishwater, a normal practice, and therefore, have no residual zinc pyrithione to transfer to food.

a. *Incidental residues from counters and other surfaces.* It is assumed that the same dishwater is also used to wash counters and other surfaces that may come in contact with solid foods. A wet residue level of 1 mg/cm^2 is applied in the analysis, in keeping with the value used by FDA for the amount of non-rinsed sanitizing solutions remaining on cleaned dishes, cups and counters in, for example, a bar. Also borrowing from FDA, it is assumed that 1.55 g/cm^2 of food contacts the counter and that an individual consumes 3,000 g of food total per day, 50% of which is solids. These figures are used by FDA for assessments involving packaged food and drink products. An uncut apple or tomato placed on a counter, for example, might be expected to have a much higher weight to area value.

In the realistic adverse case, it is assumed that 50% of all solid food consumed by an individual comes into contact with a counter cleaned with dishwater as described above and that the food absorbs all the available zinc pyrithione residue. In the worst case and exaggerated worst case analyses, it is assumed that 100% of the solid food consumed by an individual has contact with a counter or other surface containing zinc pyrithione residues and absorbs all those residues.

b. *EPA analysis.* In terms of exposure, EPA assumed 3M's exaggerated worst case scenario and added to it the assumption that infants would use sponges for teething for a lifetime. Both acute and chronic dietary risks were calculated using somewhat different assumptions for body weights, consumption amounts, and lifetime exposure durations. The risk calculations were also broken down for the U.S. population, females 13 and older, and infants and children. The smallest margin of exposure (MOE), calculated by EPA was for chronic (lifetime) exposure to infants and children at 2,673, with the overall chronic MOE for the U.S. population calculated to be 138,121.

ii. *Drinking water.* A number of obvious worst case assumptions were made in estimating potential exposure to zinc pyrithione in drinking water from use of the 3M sponge. A figure of 157 gallons was used for the average water usage per person per day, and the average publicly owned treatment works (POTW) was assumed to treat 1.45 x 10^6 gallons per day and serve a population of 9,200 persons. It was assumed that every household hand washes all dishes (no dishwashers) and that every time dishes are washed a sponge is used. It is also assumed that each household does one load of dishes per person per day. The extraction levels used above for zinc pyrithione are applied in this analysis as well.

Other than in the amount of extract, the three cases analyzed differ in assumptions regarding which sponge is used and the amount of dilution of POTW effluent by receiving waters. In the realistic adverse case, it is assumed that 20% of the sponges used each day are new. This assumption means that sponges are replaced on the average every 5 days, rather than the 6 to 8 weeks normally found by consumer research. The replacement figure increases to 50% and 100% for the worst case and exaggerated worst case respectively. Used sponges are assumed to release minimal zinc pyrithione to dishwater. It is also assumed that 60%, 80% and 100% of all households use the 3M sponge in going from the realistic adverse case to the exaggerated worst case. The amount by weight of zinc pyrithione extracted from the sponge during each washing is calculated and assumed to be discharged to the POTW with each persons daily allotment of water. The POTW is assumed to remove none of the zinc pyrithione before the water effluent is discharged. The effluent is assumed to be diluted to a minimal degree by receiving waters and these same waters are assumed to be returned to the community as drinking water, with the level of zinc pyrithione conserved throughout the cycle. Furthermore, every individual is assumed to consume only tap water as a beverage (*i.e.*, no packaged drinks such as soda, milk, bottled water, prepackaged infant formula).

Using a different approach wherein a drinking water level of comparison (DWLOC) is calculated, EPA concluded without explanation that the concern for drinking water exposures should be higher than calculated by 3M. The DWLOC is the concentration of a pesticide in drinking water that would produce an unacceptable aggregate risk, considering all other food and non-occupational exposures. EPA calculated acute DWLOCs for the U.S. population, for females 13 and older, and for infants and children of 174 parts per billion (ppb), 174 ppb, and 50 ppb, respectively. Chronic DWLOCs were calculated to be 84 ppb, 84 ppb, and 20 ppb, respectively, for the same subpopulations. 3M calculated, as described above and summarized in Table 5, below zinc pyrithione levels of 0.03 to 1.25 ppb using extremely conservative assumptions. 3M's uppermost value comes from a scenario that uses the upper 95% probability bound leachate value for sponges extracted in high temperature water containing extreme levels of detergent. The scenario also assumes that 100% of the U.S. population uses a new sponge every time dishes are washed and that the wash water is recycled as drinking water with only a 2x dilution factor. If water usage is 157 gallons per individual per day, and dishwater were recycled directly, each sink of dishwater would need to be diluted by a factor of 100 or more to supply the requisite amount of water.

2. *Non-dietary exposure*—i. Dermal absorption from dishwashing. To estimate the potential dermal dose of zinc pyrithione associated with use of the sponge during dishwashing, it was assumed that an adult will immerse both hands and one-half of their forearms in dishwater for a total of 1–hour per day. Again the concentration of zinc pyrithione in the dishwater was varied from case-to-case, as described earlier. Dermal permeability and

absorbed amount were calculated using methods recommended by EPA.

ii. *Per cutaneous absorption from dandruff shampoo.* Information on the absorption of zinc pyrithione from the use of dandruff shampoos was obtained from FDA's docket supporting formal rulemaking leading to a monograph establishing conditions under which over-the-counter drug products for the control of dandruff, seborrheic dermatitis, and psoriasis are ''generally recognized as safe and effective.'' In a study involving 30 human subjects, a shampoo containing radio labeled zinc pyrithione (^{14}C in the 2- and 6-positions) was applied in both a sink shampoo procedure (head exposure only) and a shower shampoo (total body exposure). All wash water and towels, etc. were retained and biological samples of skin, hair, blood and urine collected for a period of ten days following application. Recovery of radio label was essentially 100%.

An average upper level systemic load of zinc pyrithione was calculated from the urinary output data to be 1 µg/kg/day. Absorption was greatest for subjects with seborrheic dermatitis, and the absorbed material was derived from solid zinc pyrithione deposited on the head, rather than from the soluble zinc pyrithione complexed with detergent in the commercial shampoo.

For this aggregate exposure analysis, in the realistic adverse case it was assumed that all persons have chronic dandruff and use a dandruff shampoo every day, absorbing the maximum dose of the active ingredient. In the worst case and exaggerated worst case, it is assumed that all persons have seborrheic dermatitis and use the dandruff shampoo every day for life (i.e., the treatment has no curative effect on the seborrheic dermatitis). It was also assumed that infants and small children do not use dandruff shampoo on a regular basis. Using these assumptions, exposure from use of zinc pyrithione in dandruff shampoo was found to be three orders of magnitude higher than exposure from all other uses of zinc pyrithione.

EPA assumed 3% dermal absorption of zinc pyrithione for non-dietary exposures. In contrast, for assessments involving dermal exposure to sodium pyrithione, the Agency has used an absorption value of 0.1% in risk assessments. In its assessment of aggregate risk for the sponge, EPA did not consider exposures through the use of dandruff shampoos containing zinc pyrithione.

D. Cumulative Effects

It is 3M's position that zinc pyrithione should not be expected to have any effects cumulative with any other substances. It is EPA's position that the Agency ''does not at this time have the methodology to resolve scientific issues concerning common mechanisms of toxicity.'' Hence, for the time being EPA has not assumed that zinc pyrithione has a common mechanism of toxicity with other substances.

E. Safety Determination

1. *U.S. population.* EPA has established an oral NOAEL for zinc pyrithione of 0.5 mg/kg/day based upon a chronic rat study. This value is confirmed in the NOAEL for a subchronic neurotoxicity study and a 2–generation reproduction study. Using a substantial number of high exposure assumptions, the absolute upper limit exposure to zinc pyrithione was calculated for all uses in the realistic adverse case presented above. When exposure to zinc pyrithione through daily lifetime use of dandruff shampoo is included, a minimum adult MOE of 128,000 was found, with total aggregate exposure at 7.81×10^{-4} mg/kg/day. The exposure from the assumed daily use of dandruff shampoo is huge compared to the aggregate adult exposure from use of zinc pyrithione in sponges. Total adult exposure (oral + dermal) not counting shampoo is 1.20×10^{-6} mg/kg/day. The maximum possible daily intake of zinc pyrithione for all uses other than shampoo was calculated to yield an aggregate adult MOE of over 400,000, assuming an individual does not routinely (i.e., daily) use dandruff shampoo (see Table 2).

2. *Infants and children.* Aggregate exposure to children was determined by adjusting the assumptions used for adults. The assessment was designed to examine exposure for non-nursing infants, the subpopulation that most often is calculated to have the highest exposure to pesticides in the diet in EPA's own assessments for most chemicals.

In this assessment, it was assumed that the dietary consumption of food and water by infants was 2.5 times more per kg of body weight than for adults. Because a large portion of an infant's diet is liquids, the additional assumption was made that a smaller portion of the diet for infants than adults would be exposed to counters and other surfaces washed with dishwater. Therefore, absorption of zinc pyrithione from washed surfaces would be expected to be less. Non-nursing infants are also not expected to wash dishes or use dandruff shampoo on a regular basis, eliminating these routes of exposure. Maximum possible aggregate dietary exposure for non-nursing infants is calculated to be 1.92×10^{-6} mg/kg/day, yielding an MOE of 260,000, far in excess of the 1,000 fold safety factor applied by EPA in its assessment to calculate an RfD. The use of sponges for teething for a lifetime, which EPA included in its assessments, was not considered.

F. International Tolerances

No international tolerances have been issued for the use of zinc pyrithione as a preservative in cellulose sponges.

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ENVIRONMENTAL PROTECTION AGENCY

[PF–974; FRL–6742–7]

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–974, must be received on or before October 20, 2000.

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–974 in the subject line on the first page of your response.

FOR FURTHER INFORMATION CONTACT: By mail: James Tompkins, Herbicide Branch, Registration Division (7505W), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460; telephone number: (703) 305–5697; e-mail address: tompkins.jim@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