

TABLE 1.—REGISTRATIONS WITH REQUESTED AMENDMENTS—Continued

Company	Reg. No.	Product	SLNs
	10163–95 10163–138 10163–139 10163–180	85% Technical 35% Wettable Powder 35% Wettable Powder 50% PVA (Water Soluble Bags)	..... ..... ..... .....
Micro-Flo Corporation .....	51036–76 51036–130 51036–164	22.2% Emulsifiable Concentrate 35% Wettable Powder 50% Water Dispensable Granules	..... ..... AZ99000500
Platte Chemical Company .....	34704–691	22.2% Emulsifiable Concentrate	.....

TABLE 2.—REGISTRATIONS WITH CANCELLATION REQUESTS

Company	Reg. No.	Product	SLNs
Micro-Flo Corporation .....	*51036–76 51036–205 51036–207	22.2% Emulsifiable Concentrate 50% Wettable Powder 22.2% Emulsifiable Concentrate	TX89001100 ..... .....

<sup>a</sup> Note that EPA Reg. No. 51036–76 is not being canceled; rather SLN TX89001100 is being canceled.

#### *B. What is the Agency's Authority for Taking this Action?*

In the December 3, 1999, FR Notice, EPA requested public comment on the voluntary cancellation and use deletion requests, and provided a 30-day comment period. The registrants requested that the Administrator waive the 180-day period provided under FIFRA section 6(f)(1)(C). No public comments were submitted to the docket in response to EPA's request for comments.

#### **III. Cancellation Order**

Pursuant to section 6(f) of FIFRA, EPA is approving the requested use deletions and the requested registration cancellations. Accordingly, the Agency orders that the registrations identified in Table 1 above are hereby amended to delete use on cotton in Louisiana and east of the Mississippi River, and on sugarcane, ornamentals (except for nursery stocks), Christmas trees, shade trees, and forest trees. The Agency also orders that the registrations identified in Table 2 are hereby canceled. Any distribution, sale, or use of existing stocks of the products identified in Tables 1 and 2 above in a manner inconsistent with the terms of this Order or the Existing Stock Provisions in Unit IV of this **Federal Register** Notice will be considered a violation of section 12(a)(2)(K) of FIFRA and/or section 12(a)(1)(A) of FIFRA.

#### **IV. Existing Stocks Provisions**

For purposes of this Order, the term "existing stocks" is defined, pursuant to EPA's existing stocks policy (56 FR 29362, June 26, 1991), 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.

#### *A. Distribution or Sale by Registrants*

Unless existing stocks of products identified in Table 1 above have been relabeled in a manner consistent with the Agreement, the distribution or sale of such stocks by registrants is not lawful under FIFRA after April 19, 2000, 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. The distribution or sale of existing stocks of products identified in Table 2 above by registrants is not lawful under FIFRA after April 19, 2000, except for the purposes of shipping such stocks for export consistent with the requirements of section 17 of FIFRA or for proper disposal.

#### *B. Distribution or Sale by Other Persons*

Unless existing stocks of products identified in Table 1 above have been relabeled in a manner consistent with the Agreement, the distribution or sale of such stocks by persons other than registrants is not lawful under FIFRA after April 19, 2000, 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. The distribution or sale of existing stocks of products identified in Table 2 by persons other than registrants is not lawful under FIFRA after April 19, 2000, except for the purposes of shipping such stocks for export

consistent with the requirements of section 17 of FIFRA or for proper disposal.

#### *C. Use of Existing Stocks*

The use of existing stocks of products identified in Tables 1 and 2 above on cotton in Louisiana and east of the Mississippi River, and on sugarcane, ornamentals (except nursery stock), Christmas trees, shade trees, and forest trees will be lawful under FIFRA until such stocks are depleted provided that the use is in accordance with either the directions for use contained in the Agreement or the existing labeling of that product.

#### **List of Subjects**

Environmental protection, pesticides and pests.

Dated: April 10, 2000.

**Lois A. Rossi,**

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

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**BILLING CODE 6560–50–F**

#### **ENVIRONMENTAL PROTECTION AGENCY**

[PF–923; FRL–6495–7]

#### **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 chemicals in or on various food commodities.

**DATES:** Comments, identified by docket control number PF-923, must be received on or before May 19, 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-923 in the subject line on the first page of your response.

**FOR FURTHER INFORMATION CONTACT:** By mail: Marshall Swindell, PM 33 Regulatory Management Branch I, Antimicrobials Division (7510C), Office of Pesticide Programs, Environmental Protection Agency, Ariel Rios Bldg., 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:

Cat-egories	NAICS codes	Examples of poten-tially affected entities
Industry	111 112 311 32532	Crop production. Animal production. Food manufacturing. Pesticide manufac-turing.

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-923. 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-923 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, Ariel Rios Bldg., 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](mailto: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-923. 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 supports 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: May 11, 2000.

**Frank Sanders,**

Director, Antimicrobials 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.

### Milliken Chemical

#### 8F5007

EPA has received a supplement to a pesticide petition (8F5007) from Milliken Chemical, P.O. Box 1927, Spartanburg, SC 29304-1927, 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 for silver sodium hydrogen zirconium phosphate, when used as an antimicrobial agent at levels up to 2% by weight, in or on polymers used for food-contact surfaces, for the following applications: containers, tubing, utensils, hardware, filters, appliances,

food preparation, or processing surfaces, food storage devices, coverings, film, packaging (other than food packaging regulated exclusively by the Food, and Drug Administration (FDA)), fabrics, equipment, conveyance, and transport items, and tools. EPA has determined that the petition contains data or information regarding the elements set forth in section 408(d)(2) of the FFDCA; however, EPA has not fully evaluated the sufficiency of the submitted data at this time, or whether the data supports granting of the petition. Additional data may be needed before EPA rules on the petition.

#### A. Residue Chemistry

1. *Plant metabolism.* Silver sodium hydrogen zirconium phosphate will not be used on growing plants. Plant metabolism studies are therefore not necessary.

2. *Analytical method.* Silver sodium hydrogen zirconium phosphate and its potential migration products, silver and zirconium, have been determined to be at such low levels that there is no need for an established method for quantitating levels of such residues in or on food.

3. *Magnitude of residues.* The proposed use of silver sodium hydrogen zirconium phosphate is at levels up to 2% by weight in or on substances such as polymers. Migration studies estimate the maximum amounts of silver and zirconium that might migrate from a polymer impregnated with silver sodium hydrogen zirconium phosphate are less than the limits of detection (i.e., 10 parts per billion (ppb) for silver, and 20 ppb for zirconium). The levels of anticipated residues of silver and zirconium that might migrate from contact substances into or onto food are expected to be negligible.

#### B. Toxicological Profile

1. *Acute toxicity.* The acute toxicity data for silver sodium hydrogen zirconium phosphate are the following: (i) The acute median lethal oral dose in rats is greater than 5 g/kg body weight (Toxicity Category IV); (ii) the acute median lethal dermal dose in rats is greater than 2 g/kg body weight (Toxicity Category III); (3) the acute inhalation median lethal concentration is greater than 5.18 milligram liter (mg/L) in rats with nose only exposure (Toxicity Category IV); (iv) eye irritation and opacity is reversible within 72 hours in rabbits (Toxicity Category III); (v) no dermal irritation is induced when applied at 0.5 g under occlusion to rabbits (Toxicity Category IV); and (vi) no evidence of dermal sensitization is produced in guinea pigs.

2. *Genotoxicity.* Mutagenicity tests for silver sodium hydrogen zirconium phosphate are negative in the *Ames Salmonella typhimurium*, and *Escherichia coli* (wp2 uvrA) assays with and without activation, and are negative in the forward mutation mouse lymphoma assay with and without activation. Silver sodium hydrogen zirconium phosphate shows no evidence for chromosome-damaging activity in the mouse micronucleus test.

3. *Reproductive and developmental toxicity.* Doses up to 1,000 milligrams/kilograms/day (mg/kg/day) of silver sodium hydrogen zirconium phosphate showed no evidence for maternal toxicity and no statistically significant test material-related effects on the growth and development of offspring. Visceral and skeletal anomalies were proportional in fetuses from control and treated rats. The maternal (systemic) no observed adverse effect level (NOAEL) was 1,000 mg/kg/day, and the developmental (fetal) NOAEL was 1,000 mg/kg/day.

4. *Subchronic toxicity—i. Palatability study.* Doses up to 1,000 mg/kg/day of silver sodium hydrogen zirconium phosphate in the diet of male and female rats for 14 days caused no deaths, no abnormal clinical signs, no effects on body weights, and no palatability problems.

ii. *Ninety-day oral toxicity.* Male and female rats were administered silver sodium hydrogen zirconium phosphate in the diet for 13 weeks at concentrations up to 1,000 mg/kg/day. Increases in cholesterol in males and in alkaline phosphatase in females were observed but were not biologically significant. The NOAEL was 1,000 mg/kg/day, and the NOAEL was 30 mg/kg/day.

5. *Chronic toxicity.* No chronic exposure to silver sodium hydrogen zirconium phosphate is expected, therefore, no chronic toxicity studies are needed. Five chronic toxicity studies failed to show effects when silver was administered in the drinking water of rats.

6. *Carcinogenicity.* No chemical carcinogenicity is expected from silver sodium hydrogen zirconium phosphate. This is based on the absence of significant adverse toxicological effects in the subchronic study, and negative genotoxicity data. Negligible exposure to migrant silver is expected from the proposed uses of silver sodium hydrogen zirconium, based on migration studies. The levels of silver found in the normal human diet are greater than could potentially arise from migration. EPA classifies silver as a Group D carcinogen.

7. *Metabolite toxicology.* The principal migration products from silver sodium hydrogen zirconium phosphate are silver and zirconium. Silver has an EPA reference dose (RfD) of 0.005 mg/kg/day and does not occur normally in animal or human tissues. The major effect of excessive absorption of silver is local or generalized impregnation of the tissue with silver, a condition called argyria. Argyria is not associated with any adverse health effects. Silver is absorbed from the lungs and in small amounts from the gastrointestinal (GI) tract, and form complexes with albumin. The GI tract is the major route of excretion of silver (90 to 99% in 2 days).

Zirconium is extensive in the human diet with the daily uptake up to 125 mg. The toxicity level for this ubiquitous element is negligible. Zirconium is present and retained in high quantities in biological systems, but has not been associated with any specific metabolic function. The average body burden is 250 mg.

8. *Endocrine disruption.* Silver sodium hydrogen zirconium phosphate, silver, and zirconium are not chemically or structurally similar to natural hormones, and are not expected to disrupt, block, enhance, mimic, or otherwise interfere with normal endocrine system functions.

### C. Aggregate Exposure

1. *Dietary exposure.* Based on the toxicity data, an aggregate risk, or likelihood of the occurrence of an adverse health effect resulting from all routes of exposure to silver sodium hydrogen zirconium phosphate is not anticipated. Used in polymeric food contact substances, dietary exposures to migrant silver and zirconium are estimated in migration studies to be below 10 ppb for silver, and 20 ppb for zirconium. These levels are much less than in a normal human diet. For the migration studies, silver sodium hydrogen zirconium phosphate was embedded in a polymer, and migrant silver and zirconium were extracted into ethanol for quantitation by atomic absorption (silver) and UV/VIS absorption (zirconium). The Estimated Dietary Intakes (EDIs) that might be expected to enter the diet as a result of the proposed use of the silver sodium hydrogen zirconium phosphate were 12 µg/day (silver), and 24 µg/day (zirconium). These levels are not expected to induce toxicity.

i. *Food.* Silver sodium hydrogen zirconium phosphate will be incorporated into polymeric food contact substances, will not be introduced intentionally into food, and

is not expected to induce acute or chronic toxicological concerns. The calculated RfD for silver sodium hydrogen zirconium phosphate is 0.003 mg/kg/day and is based on the subchronic toxicity (NOAEL=30 mg/kg/day) and accepted uncertainty factors that account for extrapolation from the subchronic NOAEL, extrapolation from animals to humans, variation among the human population, and a worst case modifying factor. EPA RfD for silver is 0.005 mg/kg/day.

ii. *Drinking water.* Silver sodium hydrogen zirconium phosphate will be incorporated into polymeric food contact substances and will not be introduced intentionally into the environment or the drinking water. If a drinking water exposure of 1 mg were assumed, the lifetime daily exposure level would be  $1.0 \times 10^{-6}$  mg/kg/day and would not cause toxic responses.

2. *Non-dietary exposure.* The proposed uses of silver sodium hydrogen zirconium phosphate are not expected to result in any significant non-dietary exposure for the general population.

### D. Cumulative Effects

The cumulative exposure assessment provides an estimate of the extent to which a defined population is exposed to two or more chemicals which share a common mechanism of toxicity by all relevant routes and from all relevant sources. There are no data to suggest that silver or zirconium are synergistic or antagonistic of each other, or of silver sodium hydrogen zirconium phosphate.

### E. Safety Determination

1. *U.S. population.* The toxicology data provided to establish an exemption from the requirement of a tolerance for silver sodium hydrogen zirconium phosphate demonstrate that this substance is of a very low order of toxicity. The EDIs for the silver and zirconium migrants from the pesticide chemical are 12 µg/day (4 ppb) for silver, and 24 µg/day (8 ppb) for zirconium. These exposure levels are not significant health or safety concerns. The RfD for silver sodium hydrogen zirconium phosphate is 0.003 mg/kg/day and is comparable to the RfD of 0.005 mg/kg/day for silver. For zirconium, neither an RfD nor an ADI have been established due to the absence of toxicological concern for this ubiquitous element. Zirconium is present at high levels in foods; the average daily intake is estimated to be 4.2 mg/kg/day. This level far exceeds the maximum contribution of zirconium anticipated from silver sodium

hydrogen zirconium phosphate in polymeric food-contact materials.

For drinking water, EPA has established a Secondary Maximum Contaminant Level (SMCL) for silver of 0.1 mg/L, and the FDA bottled drinking water standard is 50 µg/L. These standards far exceed the anticipated drinking water exposure levels of 0.039 µg/kg calculated for silver sodium hydrogen zirconium phosphate.

2. *Infants and children.* The potential for additional sensitivity of infants and children was assessed from a developmental toxicity study in rats. Doses up to 1,000 mg/kg/day elicited no maternal toxicity and no significant effects on the growth and development of offspring (fetal NOAEL = 1,000 mg/kg/day).

Based on migration data with silver sodium hydrogen zirconium phosphate, consumption patterns of infants and children (i.e., a 10 kg child consumes 1 kg of food), and the assumption that 80% of the diet comes into contact with polymeric packaging material containing the pesticide chemical, the expected dietary exposure to silver and zirconium are calculated as:

Silver:  $0.80 \times 5 \text{ ppb} = 4 \text{ ppb}$  (4 ppb of 1,000 g daily diet = 4 µg/person/day).

Zirconium:  $0.80 \times 10 \text{ ppb} = 8 \text{ ppb}$  (8 ppb of 1,000 g daily diet = 8 µg/person/day).

These exposure levels are not expected to cause toxicological responses.

There is no evidence that infants and children would: (1) consume disproportionately high levels of food containing residues of sodium hydrogen zirconium phosphate, silver or zirconium; (2) be more susceptible to silver sodium hydrogen zirconium phosphate, silver or zirconium; (3) be susceptible to growth and development defects or neurological effects induced by silver sodium hydrogen zirconium phosphate; or (4) experience harm from cumulative or aggregate exposures to silver sodium hydrogen zirconium phosphate or to silver and zirconium.

### F. International Tolerances

There are no international tolerances for silver sodium hydrogen zirconium phosphate. There are no U.S. EPA, CODEX (international), Canadian or Mexican tolerances for silver.

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