

in "ADDRESSES" at the beginning of this document.

List of Subjects

Environmental protection, Administrative practice and procedure, Agricultural commodities, Pesticides and pests, Reporting and recordkeeping requirements.

Dated: February 7, 1997.

Donald R. Stubbs,

Acting Director, Registration Division, Office of Pesticide Programs.

[FR Doc. 97-3645 Filed 2-11-97; 8:45 am]

BILLING CODE 6560-50-F

[PF-694; FRL-5583-9]

Nayfa Industries Inc.; Pesticide Tolerance Petition Filing

AGENCY: Environmental Protection Agency (EPA)

ACTION: Notice of filing.

SUMMARY: This notice announces the filing of a pesticide petition proposing an exemption from the requirement of a tolerance for residues of propionic acid in or on sugarbeet, potatoes and sweet potatoes. This notice includes a summary of the petition prepared by the petitioner Nayfa Industries Inc.

DATES: Comments, identified by the docket control number [PF-694], must be received on or before, March 14, 1997.

ADDRESSES: By mail, submit written comments to Public Response and Program Resources Branch, Field Operations Division (7506C), Office of Pesticide Programs, Environmental Protection Agency, 401 M Street, SW., Washington, DC 20460. In person, bring comments to Rm. 1132, CM #2, 1921 Jefferson Davis Highway, Arlington, VA 22202. Comments and data may also be submitted electronically by sending electronic mail (e-mail) to: opp-docket@epamail.epa.gov. Electronic comments on this notice may be filed online at many Federal Depository Libraries. Additional information on electronic submissions can be found below this document.

Information submitted as comments concerning this document may be claimed confidential by marking any part or all of that information as "Confidential Business Information" (CBI). CBI should not be submitted through e-mail. Information marked as CBI will not be disclosed except in accordance with procedures set forth in 40 CFR part 2. A copy of the comment that does not contain CBI must be submitted for inclusion in the public

record. Information not marked confidential may be disclosed publicly by EPA without prior notice. All written comments will be available for public inspection in Rm. 1132 at the address given above, from 8 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays.

FOR FURTHER INFORMATION CONTACT:

Cynthia Giles-Parker, Product Manager (PM) 22, Registration Division, (7505C), Office of Pesticide Programs, Environmental Protection Agency, 401 M. St., SW., Washington, DC. Office location, telephone number and e-mail address: Rm. 229, CM#2, 1921 Jefferson Davis Highway, Arlington, VA 703-305-7740. e-mail: giles-parker.cynthia@epamail.epa.gov.

SUPPLEMENTARY INFORMATION: EPA has received a pesticide petition (PP) 6F4770 from Nayfa Industries, Inc., c/o 1625 K St., NW., Suite 501, Washington, DC 20006, proposing pursuant to section 408(d) of the Federal Food, Drug and Cosmetic Act, 21 U.S.C. section 346(d), to amend 40 CFR part 180 by an exemption from the requirement of a tolerance for residues of the herbicide propionic acid in or on the raw agricultural commodities sugarbeets, potatoes and sweet potatoes. EPA has determined that the 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.

As required by section 408(d) of the FFDCFA, as recently amended by the Food Quality Protection Act, Nayfa Industries, Inc. included in the petition a summary of the petition and authorization for the summary to be published in the Federal Register in a notice of receipt of the petition. The summary represents the views of Nayfa Industries, Inc. EPA is in the process of evaluating the petition. As required by section 408(d)(3) EPA is including the summary as a part of this notice of filing. EPA has made minor edits to the summary for the purpose of clarity.

I. Petition Summary

A. Residue Chemistry

Propionic acid is currently exempt from the requirement of a tolerance (40 CFR 180.1023), when used as a fungicide for postharvest application to prevent fungal growth. The raw agricultural commodities include oat, corn, barley, wheat, rice and sorghum grains, hay, alfalfa, clover, cottonseed, timothy, vetch, sudan grass, rye grass,

peanuts, orchard grass, lespedeza, fescue, brome grass, lupines, soybeans, Bermuda grass and bluegrass, cowpea, peanut, peavine and soybean hays, livestock and poultry drinking water, storage areas for silage and grain, and poultry litter.

The formula statements dated January 4, 1991 are acceptable and have been included in this file. It is understood that the use of methylene chloride in this formulation is no longer consistent with the terms of its registration.

Propionic acid naturally occurs in animals and in dairy products in small amounts. It is Generally Recognized As Safe (GRAS) [21 CFR 184.1081], by FDA for use in food. Propionic Acid is exempt from the requirement of a tolerance when applied (as an inert ingredient) to growing crops or to raw agricultural commodities after harvest as described in 40 CFR 180.1001(c).

Nayfa Industries, Inc. requested Residue Chemistry Data Waivers: All the residue chemistry data requirements covered under 40 CFR part 158 (Guideline Series 171) which covers nature of residues in plants and animals; residue analytical methods for plants and animals; storage stability; magnitude of residues in sugarbeets, potatoes, and sweet potatoes and their processed products, meat, milk, poultry and eggs. The bases for waivers are prior clearances for propionic acid by EPA and FDA. The Agency has determined that propionic acid as an active ingredient in registered products may be used for both human food and animal feed.

B. Toxicological Profile

1. *Acute toxicity.* Acute oral: > 2 g/kg (Category III); acute dermal: > 2 g/kg (Category III); acute inhalation: > 0.5 through 5 mg/L (Category III); eye irritation: corrosive (Category I); dermal irritation: corrosive (Category I); skin sensitization: not available and Nayfa believes this data requirement should be waived.

Contact with concentrated solutions of propionic acid may cause local damage to skin, eye, or mucosa. Tissue necrosis was caused by 10 mg/24 hr with propionic acid in a rabbit skin irritation test, but the same quantity of propionic acid as a 10 percent solution in acetone had little effect. The acid has been called moderately toxic for rabbits but corrosive for guinea pigs in skin irritation tests. Rats survived an eight hour exposure to concentrated vapor of propionic acid.

2. *Genotoxicity.* Propionic acid gave negative results in mutagenicity assays in 5 strains of *Salmonella typhimurium*

and one of *Saccharomyces cerevisiae*, with and without activation.

Additional data on calcium and sodium propionate indicate that:

a. Calcium propionate tested in three strains of *S. typhimurium* and one strain of *S. cerevisiae*, with several activation systems, gave negative results.

b. Sodium propionate showed higher incidence of abnormalities in developing chick embryos only at the highest level (10 mg/egg) by air cell administration, not in yolk treatment; however, 5 and 10 mg/egg levels had increased mortality.

3. *Reproductive and developmental toxicity.* Based on the available data:

a. No maternal or fetal effects were seen upon feeding calcium propionate to pregnant animals at rates up to 300 mg/kg/day for rats and mice, or up to 400 mg/kg/day for hamsters and rabbits.

b. No teratogenicity was found in developing chick embryos when up to 100 mg/kg calcium propionate was injected into the yolk or air cell, although there was increased mortality at 5 and 10 mg/kg.

4. *Subchronic toxicity.* Data on calcium and sodium propionate were used to assess subchronic toxicity of propionic acid. When rats were fed calcium or sodium propionate at 1 percent of the diet (equivalent to about 750 mg/kg/day of propionic acid) for 4 weeks followed by 3 percent (equivalent to about 1,200 mg/kg/day propionic acid) for 3 weeks, they had no changes in weight gain compared to controls. Rats fed 5 percent propionic acid in the diet (about 5,000 mg/kg body weight) for 110 days developed lesions of the forestomach.

Propionic acid was given in the feed to dogs at 220, 735, or 2,066 mg/kg/day (3,000, 10,000, and 30,000 ppm) for 90 days. The high dose dogs showed reduced food consumption, increased incidence of epithelial hyperplasia in the esophagus, and increased nitrite in the urine. These effects were no longer present in dogs held for a 6 week recovery period. A limited study with calcium propionate in dogs for 90 days showed vomiting and diarrhea in animals fed 2,523 mg/kg/day (43,500 ppm).

Addition of sodium propionate to the diet of chicks and young rats accentuated the growth depression seen when their diet was deficient in vitamin B12. Body weight gain in young lambs was not affected by 5,600 mg/kg/day of sodium propionate in the diet for 50 days.

When an adult male human was fed 6.0 g/day sodium propionate, the only effect noted was slightly alkaline urine.

5. *Chronic toxicity.* Twenty male rats per group were fed 0.4 or 4.0 percent propionic acid in the diet for 2 years. The high dose animals had hyperplasia and hyperplastic ulcers in the forestomach. (The rat forestomach has no counterpart in human anatomy).

Data on calcium and sodium propionate indicate that rats fed bread containing sodium propionate (4,000 mg/kg/day) for a year showed no adverse effects, nor did rats fed a similar diet for 32 weeks, other than an initial depression of growth.

6. *Animal metabolism.* Propionic acid is rapidly absorbed from the mammalian gastro-intestinal tract. Propionic acid is a normal intermediary metabolite in the body. It is utilized by most organs and tissues, and can be metabolized to glucose, carbohydrates, amino acids, and lipids. It is produced in large quantities in ruminants. In non-ruminants, propionic acid is one of the metabolic products from the breakdown of several amino acids. Propionic acid is formed in the oxidation of fatty acids and from the side chain of cholesterol.

7. *Metabolite toxicology.* All the metabolites of propionic acid are naturally occurring and are utilized by humans and animals. Nayfa believes that the metabolite toxicity data requirements should be waived because these metabolites are not of toxicological concern.

C. *Aggregate Exposure*

1. *Dietary exposure.* Since propionic acid is utilized by most organs and tissues, and is metabolized to glucose, carbohydrates, amino acids and lipids when ingested by livestock and poultry, residues in meat, milk or poultry are considered to be negligible. Propionic acid or mixtures of methylene bispropionate and oxy (bismethylene) bispropionate are exempt from the requirements of a tolerance when used as a post-harvest fungicide on alfalfa, barley grain, Bermuda grass, bluegrass, brome grass, clover, corn grain, cowpea hay, fescue, lespedeza, lupines, oat grain, orchard grass, peanut hay, peavine hay, rye grass, sorghum grain, soybean hay, sudan grass, timothy, vetch, and wheat grain (40 CFR 180.1023). Propionic acid is also exempt from the requirement of a tolerance when applied (as an inert ingredient) to growing crops or to raw agricultural commodities after harvest as described in 40 CFR 180.1001(c). Propionic acid is Generally Recognized As Safe (GRAS) (21 CFR 184.1081), by FDA for use in food.

2. *Non-dietary exposure.* The only non-dietary exposure to propionic acid is the occupational exposure. Propionic

acid end-use products are sprayed on grain and forage at application rates ranging from 1 - 4 gallons of 85% - 100% a.i., depending on the moisture content of grain or forage, and type and length of storage desired. They are also applied to livestock and poultry drinking water and grain storage areas. Based on the use patterns, the potential exposure of applicators to propionic acid could be significant as well as to workers in the spray area. The potential for post-application exposure should be minimal (assuming the area is adequately ventilated).

Certain protective clothing is appropriate for propionic acid users due to eye and skin hazards. The Agency requires applicators to wear protective clothing if the products contain in excess of 63% propionic acid as active ingredient.

D. *Cumulative Effects*

1. *Environmental fate assessment.* Under anaerobic conditions propionic acid acts as a carbon source for various microbes and is metabolized to acetic acid, methane, carbon dioxide and water. The only incident reports concerning propionic acid were detections in the tissue of the mussel (*Mytilus Sdulis*) and in ground water as the result of the break-down of petroleum pollution. All environmental fate data requirements are waived for the currently registered uses based on the fact that propionic acid tends to be used as a carbon source by many microbes and is metabolized to carbon dioxide and water.

E. *Safety Determination*

1. *Human health assessment.*

a. *U.S. population.* Propionic acid is a normal component of metabolism in the human body and humans ordinarily consume propionic acid as a natural component of common foods and as an added ingredient. It is a natural component of butter and cheese, and may constitute as much as 1 percent of Swiss cheese. Dietary exposure from pesticidal use would be very low.

b. *Infants and children.* As noted above, propionic acid is produced by human body. The humans include not only adult population but also children and infants who receive propionic acid through common foods including those that contain this ingredient as a food additive. Additionally, children and infants consume dairy products such as butter and cheese which contain propionic acid. Therefore, dietary exposure from pesticidal use would be very minimal.

F. International Tolerances

There are no known international tolerances for residues of propionic acid in food or animal feed.

G. Tolerance Exemptions for Proposed Uses

The petitioner proposes new uses which include application of propionic acid to sugar beets, potatoes and sweet potatoes. The petitioner requests tolerance exemption for residues of propionic acid in or on sugar beets, potatoes and sweet potatoes. The petitioner also requests waivers for all tests for determining the residues including the analytical method.

The petitioner proposes tolerance exemption for propionic acid for its use on or in:

a. Sugarbeets (stored sugarbeets and seed sugarbeets, and also dried-pulp and dried-molasses intended for animal feed);

b. Potatoes (stored potatoes - marketable and frozen and stored seed potatoes, and also stored potatoes for animal feed); and,

c. Sweet potatoes (stored sweet potato and stored seed sweet potatoes).

The maximum amount of propionic acid applied to these RACs during storage will be 6 lb/ton.

II. Administrative Matters

EPA invites interested persons to submit comments on this notice of filing. Comments must bear a notification indicating the document control number [PF-694]. All written comments filed in response to this petition will be available, in the Public Response and Program Resources Branch, at the address given above from 8:30 a.m. to 4 p.m., Monday through Friday, except legal holidays.

A record has been established for this notice under docket control number [PF-694] (including comments and data submitted electronically as described below). A public version of this record, including printed, paper versions of electronic comments, which does not include any information claimed as CBI, is available for inspection from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The public record is located in Rm. 1132 of the Public Response and Program Resources Branch, Field Operations Division (7506C), Office of Pesticide Programs, Environmental Protection Agency, Crystal Mall #2, 1921 Jefferson Davis Highway, Arlington, VA.

Electronic comments can be sent directly to EPA at:

opp-docket@epamail.epa.gov

Electronic comments must be submitted as ASCII file avoiding the use of special characters and any form of encryption.

The official record for this notice, as well as the public version, as described above will be kept in paper form. Accordingly, EPA will transfer all comments received electronically into printed, paper form as they are received and will place the paper copies in the official record which will also include all comments submitted directly in writing. The official record is the paper record maintained at the address in "ADDRESSES" at the beginning of this document.

Authority: 21 U.S.C. 346a.

List of Subjects

Environmental Protection, Administrative practice and procedure, Agricultural commodities, pesticides and pests, Reporting and recordkeeping requirements.

Dated: February 3, 1997.

Stephen L. Johnson,
Director, Registration Division, Office of
Pesticide Programs.

[FR Doc. 97-3227 Filed 2-11-97; 8:45 am]
BILLING CODE 6560-50-F

[PF-702; FRL-5586-3]

Valent U.S.A. Corporation; Pesticide Tolerance Petition Filing

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice of filing.

SUMMARY: This notice announces the filing of a pesticide petition proposing the establishment of a regulation for residues of the herbicide clethodim in or on tomato, alfalfa, dry bean, and peanut commodities. The summary of the petition was prepared by the petitioner, Valent U.S.A. Corporation (Valent).

DATES: Comments, identified by the docket control number [PF-702], must be received on or before, March 13, 1997.

ADDRESSES: By mail, submit written comments to Public Response and Program Resources Branch Field Operations Division (7506C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., S.W., Washington, DC 20460. In person, bring comments to Rm. 1132, CM #2, 1921 Jefferson Davis Highway, Arlington, VA. Comments and data may also be submitted electronically by sending electronic mail (e-mail) to: opp-

docket@epamail.epa.gov. Electronic comments on this notice may be filed online at many Federal Depository Libraries. Additional information on electronic submissions can be found in unit II. of this document.

Information submitted as comments concerning this document may be claimed confidential by marking any part or all of that information as "Confidential Business Information" (CBI). CBI should not be submitted through e-mail. Information marked as CBI will not be disclosed except in accordance with procedures set forth in 40 CFR part 2. A copy of the comment that does not contain CBI must be submitted for inclusion in the public record. Information not marked confidential may be disclosed publicly by EPA without prior notice. All written comments will be available for public inspection in Rm. 1132 at the address given above, from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays.

FOR FURTHER INFORMATION CONTACT: By mail: Joanne I. Miller, Product Manager (PM) 23; Registration Division (7505C), Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. Office location, telephone number, and e-mail address: Rm. 237, CM #2, 1921 Jefferson Davis Highway, Arlington, VA; (703) 305-6224; e-mail: miller.joanne@epamail.epa.gov.

SUPPLEMENTARY INFORMATION: EPA has received pesticide petitions (PP 5F4572 and PP 5F4440) from Valent U.S.A. Corporation, 1333 N. California Blvd., Walnut Creek, CA 94596 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 by establishing tolerances for residues of the herbicide clethodim in or on the following raw or processed agricultural commodities: tomatoes at 1.0 part per million (ppm); tomato puree at 2.0 ppm; tomato paste at 3.0 ppm; alfalfa forage at 6.0 ppm; alfalfa hay at 10.0 ppm; peanut nutmeat at 3.0 ppm; peanut hay at 3.0 ppm; peanut meal at 5.0 ppm; and dry bean seeds at 2.0 ppm. The proposed enforcement analytical method for these commodities is EPA-RM-26D-3, a high-performance liquid chromatography (HPLC) method. EPA has determined that the 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 petitions. Additional data may be needed before EPA rules on the petitions.