Dated: June 2, 1997.

Linda A. Travers,

Director, Information Resources and Services Divisions, Office of Pesticide Programs.

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ENVIRONMENTAL PROTECTION AGENCY

[PF–738; FRL–5721–6]

Notice of Filing of Pesticide Petitions

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: This notice announces the initial filing of pesticide petitions proposing the establishment of regulations for residues of certain pesticide chemicals in or on various agricultural commodities.

DATES: Comments, identified by the docket control number PF–738, must be received on or before July 14, 1997.

ADDRESSES: By mail submit written comments to: Public Response and Program Resources Branch, Field Operations Divison (7505C), Office of Pesticides Programs, Environmental Protection Agency, 401 M St., SW., 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 following the instructions under ''SUPPLEMENTARY INFORMATION.'' No confidential business information should be submitted through e-mail.

Information submitted as a comment 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: The Product Manager (PM 90), Biopesticides and Pollution Prevention Division, (7501W), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460, listed in the table below:

Name	Location	Phone No.	E-mail address
Linda Hollis	5th Floor 5-J, CS#1, 2800 Crystal Drive, Arlington, VA.	703–308–8733	hollis.linda@epamail.epa.gov
Sheryl Reilly	5th Floor 5–W31, do.	703–308–8265	reilly.sheryl@epamail.epa.gov

SUPPLEMENTARY INFORMATION: EPA has received pesticide petitions as follows proposing the establishment and/or amendment of regulations for residues of certain pesticide chemicals in or on various raw agricultural commodities under section 408 of the Federal Food, Drug, and Comestic Act (FFDCA), 21 U.S.C. 346a. EPA has determined that these petitions contain 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.

The official record for this notice, as well as the public version, has been established for this notice of filing under docket control number PF–738 (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 official record is located at the address in ''ADDRESSES''.

Electronic comments can be sent directly to EPA at:

opp-docket@epamail.epa.gov

Electronic comments must be submitted as an ASCII file avoiding the use of special characters and any form of encryption. Comment and data will also be accepted on disks in Wordperfect 5.1 file format or ASCII file format. All comments and data in electronic form must be identified by the docket control number PF–738 and appropriate petition number. Electronic comments on this notice may be filed online at many Federal Depository Libraries.

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

List of Subjects

Environmental protection, Agricultural commodities, Food additives, Feed additives, Pesticides and pests, Reporting and recordkeeping requirements.

Dated: May 29, 1997.

Janet L. Andersen,

Director, Biopesticides and Pollution Prevention Division, Office of Pesticide Programs.

Summaries of Petitions

Below summaries of the pesticide petitions are printed. The summaries of the petitions were prepared by the petitioners. 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.

1. W. Neudorff GmbH KG Petition Summary:

PP 7F4804

EPA has received a pesticide petition (PP 7F4804) from W. Neudorff GmbH KG (''Neudorff''), c/o Walter G. Talarek, 1008 Riva Ridge Drive, Great Falls, VA 22066, proposing pursuant to section 408(d) of the Federal Food, Drug and Cosmetic Act, 21 U.S.C. section 346a(d), to amend 40 CFR Part 180 by establishing an exemption from the requirement for a tolerance for residues of the mollusicide iron phosphate when used in accordance with good agricultural practice as an active ingredient in pesticide formulations applied to growing crops.

A. Proposed Use Practices

1. *Recommended amount, frequency, method and time of application of pesticide chemical.* The amount, frequency, method and time of application of the pesticide are described in detail on the label of ''NEU 1165M Slug and Snail Bait''. This label was submitted to EPA as part of Neudorff's application for registration, EPA File Symbol 67702–G. However, in

summary, the bait should be scattered by hand or with a granular spreader at the rate of 1 pound (lb.) per 1,000 square feet to the surface of damp soil. The bait can be applied either prior to or after infestation by slugs or snails. Evening is the best time to apply the bait. The bait should be reapplied as it is consumed or at least every two weeks.

B. Product Identity/Chemistry

1. *Identity of the pesticide and corresponding residues.* The active ingredient is iron phosphate, also known as ferric orthophosphate; ferric phosphate; Fe(+3) phosphate; iron (III) phosphate; and phosphoric acid, and iron (3+) salt (1:1), which has a CAS #10045–86–0. Iron phosphate is practically insoluble in water and would only degrade through the metabolism of microorganisms in the soil and via the chemistry of plant root exudates which would utilize the degradates for plant growth. In certain soil types, iron phosphate may produce iron oxides and hydroxides that are no different from those normally found in soils, and which give soils their brown and red colors. Although some bacteria can reduce Iron (III) to the more mobile Iron (II), reoxidation and reprecipitation to Fe (III) oxides and hydroxides will rapidly immobilize any free Fe (II) that may form.

2. *Magnitude of the residue anticipated at the time of harvest and method used to determine the residue.* A waiver has been requested for these data requirements based on iron phosphate's (1) known low toxicity and risks, (2) natural occurrence and abundance in the environment, (3) widespread use as human nutrient and dietary supplements and in infant formula, (4) FDA generally recognized as safe (''GRAS'') status, (5) unique, non-toxic mode of action, (6) data available in the open literature, and (7) the fact that any degradates or metabolites of iron phosphate would be identical to those formed in nature, thus indicating that they should pose no unreasonable risks.

There are other factors which indicate that residues of iron phosphate are unlikely to occur, or if they do occur they are unlikely to be at levels of concern to human health. Iron phosphate from the Slug and Snail Bait most likely would not occur in plants, because it needs to be biodegraded via microbial action or plant root exudates before plants can utilize it. Furthermore, the use pattern for the Slug and Snail bait, where the product is not applied directly to plants but around them, and the facts that iron phosphate is insoluble in water and readily adsorbs to soils, would limit the availability of the chemical to plants. Last, even if residues of the chemical were to occur on plants, this chemical contains substances which are essential animal and plant nutrients, and there are chemical and physical factors which limit their availability in humans and growing plants.

3. *Statement of why an analytical method for detecting and measuring the levels of the pesticide residue are not needed.* Neudorff has not proposed an analytical method, because iron residue levels harmful to plants and animals are highly unlikely to occur when its Slug and Snail Bait product is applied according to label directions. Iron phosphate is an FDA-approved GRAS direct and indirect food additive which is not expected to present any significant adverse health effects to humans. Moreover, this chemical contains certain substances which are essential animal and plant nutrients, and there are chemical and physical factors which limit their availability in humans and growing plants. Furthermore, toxic levels of iron in plants induce an imbalance with other metals which causes plant dwarfing, stunted roots and decreased growth and yields, which effects appear before significant iron buildup occurs, and consequently acts as a warning which prevents excess application of iron compounds to plants. In addition, given the use pattern for the Slug and Snail Bait, where the product is not applied directly to plants but around them, and the fact that iron phosphate is insoluble in water and readily adsorbs to soils, there is unlikely to be significant amounts of residue in or on treated crops. Last, iron phosphate from the bait most likely would not occur in plants because it needs to be biodegraded via microbial action or plant root exudates before plants can utilize it.

C. Mammalian Toxicological Profile

1. *Acute toxicity.* The iron salts are of low acute toxicity through oral, dermal and inhalation routes of exposure. Results of studies conducted on the end-use product for which Neudorff has applied for registration confirm that this chemical has low acute toxicities. Iron phosphate is insoluble in water. Because of this, it is not as bioavailable as other iron salts, and it is not readily absorbed from the gastrointestinal tract into the systemic circulation. Consequently, it may be concluded that iron phosphate will have lower acute toxicities than the water-soluble iron salts.

2. *Genotoxicity, reproductive and developmental toxicity, subchronic toxicity, and chronic toxicity.* There is adequate information available from literature sources to characterize the toxicity of the iron salts (iron phosphate is an iron salt). Literature sources show that the iron salts have known low toxicities and risks and occur naturally and abundantly in the environment. Iron is recognized as an essential mineral nutrient for humans and all other vertebrate animals. It is a component of hemoglobin and myoglobin molecules, being the central atom in the heme portion of the molecule. The hemoglobin in red blood cells transports oxygen from the lungs to body cells and returns waste carbon dioxide from the cells to the lungs. The myoblobin in red muscle tissue transports oxygen into the tissues for energy storage. Iron also is a component of certain metabolic enzymes. Iron in the body that is not in use in these molecules is stored in the spleen, bone marrow and liver. Increased requirements for iron occur during the growth period and pregnacy and with excessive menses and other instances of blood loss. The average diet contains 10 to 15 mg a day, adequate for most people. Lack of sufficient iron causes fatigue and paleness and eventually leads to some form of anemia. With increases in iron beyond the physiologic limits, most of it is excreted in the feces, but small amounts may accumulate. Some iron may be excreted via the bile. In cases of overload, iron is excreted in the urine, and the presence of high urinary iron concentrations is indicative of excessive iron. Normally, significant quantities of iron are excreted by loss of epithelial cells of the gastrointestinal tract.

The ''R.E.D. Facts on Iron Salts'', EPA–738–F–93–002 (February 1993), state that ''[i]ron salts are normally present in the environment. Iron is the fourth most abundant element and the second most abundant metal in the earth's crystal rocks. Iron occurs in a wide variety of minerals, and is present in foods naturally and through added ingredients. ''The iron salts are of low acute toxicity through oral, dermal and inhalation routes of exposure. They have been placed in Toxicity Category III for these effects. ... Other toxicity studies normally required for registration were not necessary to evaluate the risks of the iron salts. ''Further, the iron salts are generally recognized as safe (GRAS) by the Food and Drug Administration for use as a flavoring agent and nutrient supplement in foods (please see 40 CFR 180.2(a)).''

It should be noted that FDA has promulgated GRAS direct and indirect food additive regulations for ferric

phosphate, at 21 CFR sections 184.1301 and 182.5301, respectively. As a direct food additive, ferric phosphate may be used as a nutrient supplement and in infant formula in accordance with good manufacturing practice. As an indirect food additive, it may be used as a dietary supplement in accordance with good manufacturing practice. The Reregistration Eligibility Document (''RED'') on Iron Salts, EPA–738–S–93–001 (February 1993), indicates that the current toxicological database within the Agency and in the literature is adequate to support the reregistration eligibility of all iron sulfates.

Further, this document states that there are some unusual factors which indicate that specific studies to fulfill the usual data requirements are not necessary to regulate these substances as pesticides. The document goes on to list these factors as: (1) iron salts are normally present in the environment; (2) they may be present in foods naturally and as added ingredients; and (3) there is no reason to expect that usage in accordance with the label will present any hazard beyond that from ordinary exposure. By inference, this rationale for not requiring additional toxicological data for iron sulfates should be equally applicable to any other iron salt, such as iron phosphate.

D. Aggregate Exposure

1. *Dietary exposure. (a) Food* - There is no evidence of adverse health effects resulting from dietary exposure to insoluble iron salts, except in the case of massive intake disrupting the natural homeostatic mechanism controlling body level of iron. The risk from exposure to food containing iron phosphate is negligible due to its low toxicities, status as a food flavoring agent and a food nutrient supplement, and inherent function in the metabolic pathways of humans and animals.

(b) *Drinking water*. Iron phosphate is insoluble in water. As such, its biologic availability is limited. EPA has not established a maximum contaminant level or a maximum contaminant level goal for iron under the Safe Drinking Water Act. However, a secondary maximum contaminant level of 0.3 mg/L has been established. This level represents a level protective of aesthetic values, such as odor or appearance.

2. *Non-Dietary exposure*. Neudorff also is registering its Slug and Snail Bait for use on outdoor ornamentals and lawns. Therefore, applicators who apply this product to crops, ornamentals and lawns could be exposed. However, protective measures prescribed by the product's label are expected to be adequate to minimize exposure and protect applicators of this chemical. It also should be noted that the Iron Salts RED states that mixer/loader/applicator exposure to the iron sulfates is considered inconsequential, whether these substances are applied by spreaders, sprinkler cans or by hand and whether the product is granular or a soluble concentrate, because there is little concern from a toxicity perspective. Moreover, the document states that the risks from dietary and occupational exposures are considered to be negligible due to their low toxicities, status as food flavoring agents and food nutrient supplements, and inherent function in the metabolic pathways of humans and animals.

E. Cumulative Effects

Since Neudorff's Slug and Snail Bait is the first pesticide product containing iron phosphate being registered with EPA, there will not be exposures to this chemical through other pesticides. Although not widely used as a fertilizer, due to its insolubility in water, iron phosphate can be used as a fertilizer in acidic soils. Therefore, there is the possibility that in certain limited circumstances, there could be cumulative exposures to this chemical.

F. Safety Determination

1. *U.S. population*. The metabolism of iron in man and growing plants is well understood and documented in the available literature. The use of iron phosphate as an active ingredient in slug and snail baits applied around and not on growing crops would not contribute significantly to the level of iron found naturally in the environment and to which man is exposed. Further, there is adequate information to show that there is no toxicological concern raised by the contribution of iron to growing crops, which is likely to result from the use of slug and snail baits containing iron, and consequently no tolerance should be required for the use of iron phosphate.

2. *Infants and children*. Increased requirements for iron occur during the growth period and pregnacy and with excessive menses and other instances of blood loss. The menstruating female requires about 21 ug/kg per day (about 1.4 mg). In the last two trimesters of pregnancy, requirements increase to about 80 µg/kg per day (5 to 6 mg), and there are similar requirements for the infant due to its rapid growth (Finch, 1976). During these periods, absorption of iron is greatly increased (Casarett and Doull's, 1991). Iron has been shown to cross the placenta and concentrate in the fetus. The concentration of iron in the fetus may serve a valuable physiologic purpose, inasmuch as it prevents anemia caused by rapid growth in the absence of sufficient supplies of iron in the mother's milk (Casarett and Doull's, 1980).

G. Existing Tolerances

1. *Existing tolerances or tolerance exemptions*. EPA has not established a tolerance or an exemption from the requirement for a tolerance for iron phosphate. However, EPA has established tolerance exemptions for other iron salts, i. e., iron sulfate and ferric chloride. See 40 CFR sections 180.1001(c) and (d).

2. *International tolerances*. No maximum residue level has been established for this substance by the Codex Alimentarius Commission. (Sheryl Reilly)

2. Plant Health Technologies Petition Summary:

PP 7G4817

EPA has received a pesticide petition (PP 7G4817) from Plant Health Technologies, P.O. Box 198, Lathrop, California 95330, proposing pursuant to section 408 (d) of the Federal Food, Drug and Cosmetic Act, 21 U.S.C. section 346a (d), to amend 40 CFR part 180 by establishing an exemption from the requirement of a tolerance for the residues of the biochemical pesticide, *Pantoea agglomerans* Strain C9–1, when applied in accordance with good agricultural practices in or on all raw agricultural commodities.

A. Proposed Use Practices

Pantoea agglomerans strain C9–1 is proposed for use to control Fire Blight (Erwinia amylovora) in apples and pears. Three to 6 applications will be made starting at 20 percent bloom through petal fall.

B. Product Identity/Chemistry

1. *Product name*. The product trade name is BlightBan C9–1. The active ingredient is the naturally occurring bacterium, P. agglomerans strain C9–1. Formulated product will contain 71 percent active ingredient and 29 percent inert ingredients.

2. *Magnitude of residue*. Plant Health Technologies believes that no residues are expected on the crop at the time of harvest. P. agglomerans colonizes the blossom and stigma and requires specific moisture and temperature conditions to grow. Strain C9–1 is not expected to colonize the fruit. This species occurs naturally in the environment and populations of indigenous P. agglomerans isolates may also be present in a variety of habitats.

3. Plant Health Technologies states that an analytical method is not needed because residues are not expected on crops at harvest.

C. Mammalian Toxicological Profile

Plant Health Technologies has submitted data in support of the exemption from tolerance for P. agglomerans Strain C9–1 to include: an acute oral toxicity in rats, an acute dermal toxicity/irritation study in rabbits; a primary eye irritation study in rabbits, an acute intratracheal toxicity/pathogenicity study in rats, and an acute intravenous toxicity/pathogenicity study in rats.

The results of these studies indicate that P. agglomerans Strain C9–1 has an acute oral toxicity greater than 5 grams/kilograms (g/kg) body weight in rats, an acute dermal toxicity greater than 2 g/kg body weight in rabbits, and causes slight to mild skin and eye irritation in rabbits. There was no evidence of toxicity or pathogenicity related to P. agglomerans Strain C9–1 in rats administered 1.63×108, 9.83×107, and 2.1×107 CFU by oral, intratracheal, or intravenous routes, respectively. Total clearance of the organism occurred rapidly in all cases.

D. Aggregate Exposure

Dietary and non-dietary exposure: For the purpose of assessing the potential dietary exposure under this tolerance exemption, it was considered that P. agglomerans strain C9–1 would not be present in raw agricultural commodities. Strain C9–1 is applied at blossom, before fruit development, and several months before harvest. C9–1 does not readily colonize the fruit. Plant Health Technolgies states that because strain C9–1 is a plant colonizing microorganism and will not be used in residential, home garden, or lawn care situations, other potential sources of dietary and non-dietary exposure to the general population such as drinking water and non-occupational exposures are not expected to be significant.

E. Cumulative Effects

The potential for cumulative effects of P. agglomerans strain C9–1 was also considered. C9–1 inhibits pest microorganisms from becoming established by out-competing the pests for space and nutrients, and through the production of herbicolin antibiotics. Applying strain C9–1 in relatively high doses to developing (uncolonized) apple and pear blossoms, confers a competitive advantage to strain C9–1, enabling the isolate to colonize specific plant surfaces before the pest microorganism has an opportunity to become established. While many microorganisms thrive in specific habitats due to competitive displacement, Plant Health Technologies believes that there is no reasonable basis to expect that P. agglomerans strain C9–1 exhibits a particular mechanism of toxicity in common with other pesticides and chemical substances. Moreover, aggregate exposure of humans to strain C9–1 is negligible. Therefore, PHT concludes that any effects attributable to P. agglomerans strain C9–1 would not be cumulative with those of any other substances. Thus, PHT believes it is appropriate to consider only the potential risks of P. agglomerans in the aggregate exposure assessment.

F. Safety Determination

1. *Population in general.* As a species, Pantoea agglomerans is ubiquitous, having been isolated from plants, animals, soil and water. Scientists have worked with biocontrol isolates belonging to the Pantoea agglomerans complex for over 50 years with no reported adverse effects. There is no evidence of toxicity or pathogenicity related to P. agglomerans Strain C9–1 by oral, intratracheal or intravenous routes. Based on this, and the lack of exposure to humans, Plant Health Technologies believes that the aggregate exposure to P. agglomerans strain C9–1 over a lifetime will not pose appreciable risks to human health. Thus, PHT concludes that there is a reasonable certainty that no harm will result from aggregate exposure to Pantoea agglomerans strain C9–1 residues and that exempting P. agglomerans strain C9–1 from the requirement of a tolerance is safe.

2. *Infants and children.* The toxicity, pathogenicity, and exposure data are sufficiently complete to adequately address the potential for additional sensitivity of infants and children to residues of P. agglomerans. Due to the lack of adverse effects and negligible exposure, Plant Health Technologies concludes with reasonable certainty, that no harm will result to infants and children from aggregate exposure to P. agglomerans.

G. Existing Tolerances

No tolerances or exemptions for tolerance have been issued in the United States or internationally for this microorganism. (Linda Hollis)

3. Tenneco Packaging Petition Summary:

PP 7F4818

A. Proposed Use Practices

Tenneco Packaging, 1603 Orrington Ave., Evanston, IL., 60201, has requested EPA to exempt methyl salicylate from the requirement of a tolerance in or on agricultural commodities under section 408 of the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. 346a, when used as a insect repellent in food packaging and animal feed packaging materials alone or in conjunction with inert components which conform to the requirements of regulations issued by the Food and Drug Administration under section 409 of the Federal Food, Drug, and Comestic Act (FFDCA).

B. Product Identity/Chemistry

Methyl salicylate (CAS Registry Number 119–36–8) is the primary chemical component of a naturally occurring fragrant oil, oil of wintergreen. Petitioner has stated that, if present at all, residues of methyl salicylate that may be found in foods in contact with treated packaging materials will be minimal and considerably below the levels expected in existing GRAS uses of the active ingredient as a direct food flavoring ingredient.

C. Toxicological Profile

The toxicity of methyl salicylate has been extensively studied in animal bioassays of acute, subchronic, and chronic duration. Studies include assessments of the mutagenicity, teratogenicity, and reproductive effects of methyl salicylate.

1. *Acute toxicity.* The acute oral LD_{50} for methyl salicylate in the rat ranges from 887–1,250 mg/kg. Acute dermal toxicity (LD_{50} dermal) has been reported to be 0.70 ml/kg (approx. 700 mg/kg) in guinea pigs, and > 5 g/kg in the rabbit.

2. *Skin and eye irritation.* Methyl salicylate has been reported to be a severe eye irritant. Methyl salicylate has been reported to produce mild dermal irritation in rabbits at a concentration of 1 percent. Moderate to severe irritation is produced in rabbits and guinea pigs at concentrations above 1 percent. Applied full strength to intact or abraded rabbit skin for 24 hours under occlusion, methyl salicylate was moderately irritating. However, tested at 8 percent in petrolatum, it produced no irritation after a 48 hour closed-patch test on human subjects.

3. *Mutagenicity.* No evidence for genotoxicity was observed in two studies with prokaryotic test systems;

no data on genotoxicity in mammalian test systems are available.

4. *Subchronic toxicity.* Studies of subchronic duration with administration by the oral route have been conducted in both rats and dogs. In rats, no adverse effects were seen at a dose of 0.1 percent in the diet. In dogs, doses ≤250 mg/kg/day did not result in any adverse effects, however, the liver appeared to be the target organ of toxicity at doses above this level. No toxicity was observed when rats were exposed to methyl salicylate via inhalation of saturated air (approx. 700 mg/m3) after twenty 7–hour exposures.

5. *Teratogenicity.* Methyl salicylate has been tested for teratogenic potential in hamsters, rats and mice by several different routes of administration. In hamsters, at dose levels of methyl salicylate which produced maternal toxicity, an increased incidence of neural tube defects was also observed. The no observed adverse effects level (NOAEL) for developmental effects in rats given methyl salicylate by the dermal route (assuming 100 percent absorption) was 180 mg/kg/day (the highest dose tested). In mice, the NOAEL for developmental effects in a continuous breeding study using oral administration was 100 mg/kg/day based on decreases in numbers of live pups per litter, percentage of live pups, and pup weight.

6. *Chronic Toxicity.* Toxicity resulting from chronic exposure has been evaluated in studies of two-years' duration as well as studies initially intended to evaluate multi-generational reproductive and developmental effects. In mice, the NOAEL for reproductive parameters and the other toxic endpoints examined has been reported as 250 mg/kg/day. When rats were exposed to methyl salicylate in the diet for two years, no adverse effects were noted at levels of 0.1 percent (approx. 50 mg/kg/day); pituitary lesions were increased in animals exposed to 0.5 percent (approx. 250 mg/kg/day). In dogs orally exposed to methyl salicylate for two years, no adverse effects were observed at 50 mg/kg/day; the LOAEL (liver effects) was reported as 150 mg/kg/day.

7. *Carcinogenicity.* No studies have been performed with the primary purpose of determining the oncogenicity of methyl salicylate; however, chronic exposure studies with two-year exposure durations that included extensive pathology did not indicate any increases in incidences of benign or malignant tumors.

8. *GRAS Assessment.* The Flavoring Extract Manufacturer's Association (FEMA) has determined GRAS levels of methyl salicylate and oil of wintergreen in foods and beverages as indicated in the table below.

FEMA GRAS LEVELS IN FOOD (PPM)

Food	Methyl Salicylate	Oil of Wintergreen
Beverages	59	56
Ice cream	27	44
Candy	840	260
Baked goods	54	1,500
Chewing gum	8,400	3,900
Syrups	200	

GRAS food levels in the Table are above both the maximum food residue concentration (approx. 16 ppm) and the maximum dietary exposure concentration (approx. 4.7 ppm) estimated by the Petitioner for the proposed use pattern for methyl salicylate. These estimates used highly conservative assumptions for migration of methyl salicylate from packaging and food consumption. Petitioner has shown that even under worst-case exposure conditions (i.e., assuming 30 percent of all food consumed is in contact with packaging containing methyl salicylate, and 100 percent of the methyl salicylate migrates to food) exposure to methyl salicylate from use in packaging materials would be less than that received by chewing one stick of chewing gum at the GRAS-approved level. Based on this comparison, use of methyl salicylate in food packaging materials should also be considered GRAS.

D. Aggregate Exposure

There is no established Maximum Contaminant Level (MCL) for residues of methyl salicylate in drinking water under the Safe Drinking Water Act.

The Petitioner is aware of five currently registered products containing methyl salicylate as an active ingredient. These products include two categories: *(1)* impregnated materials and pellets to be used as vertebrate repellents, and *(2)* disinfectants/ germicides registered for use in household, institutional, hospital, and eating establishment premises. Although these registered uses could potentially result in exposures to methyl salicylate, EPA did not require establishment of a tolerance (or an exemption from the requirement of a tolerance) for methyl salicylate as a condition for granting registrations for these products. Petitioner believes that anticipated dietary exposures from these registered products would be indirect (i.e., resulting from food contact with a treated surface) and therefore very low.

In addition to the anticipated dietary exposure to methyl salicylate from Petitioner's proposed use (i.e., food packaging materials) estimated in Section A.8., above, drinking water is the only reasonably anticipated additional exposure resulting from pesticidal uses of methyl salicylate. Based on its rapid environmental degradation, Petitioner does not anticipate the occurrence of pesticidal residues of methyl salicylate in drinking water and is not aware of any existing residues.

Therefore, the potential for non-occupational, non-dietary exposure to the general population as a result of pesticidal use of methyl salicylate in food packaging materials is not expected to be significant.

E. Cumulative Effects

The Petitioner has also considered the potential for cumulative toxicity effects of pesticidal uses of methyl salicylate and other pesticidal substances that may have a common mechanism of toxicity. Petitioner has concluded that consideration of a common mechanism of toxicity is not appropriate because there is no information available from the publicly available literature indicating that there are other pesticidal substances that operate via a mechanism of action common with methyl salicylate. Thus, Petitioner recommends that only the potential risks of methyl salicylate be considered in this request for an exemption from the requirement of a tolerance.

F. Safety

1. *U.S. population.* Methyl salicylate is the major component of a naturally occurring fragrant oil. The Flavor and Extract Manufacturer's Association (FEMA) has listed methyl salicylate on its GRAS list for use as a flavoring ingredient in foods and beverages. An FDA Advisory Review Panel has concluded that methyl salicylate is safe for use up to a concentration of 0.4 percent in the form of a rinse or mouthwash. The compound is extensively used in foods, beverages, pharmaceuticals, lotions and perfumes and has wide distribution in commerce with no reports of adverse outcomes associated with intended uses. The toxicity of the active ingredient (i.e., methyl salicylate) has been adequately and reliably characterized; it is summarized in this submission.

Based on this information, the Petitioner recommends that EPA conclude that there is reasonable certainty of no harm from aggregate exposures to pesticidal uses of methyl salicylate over a lifetime, and that no

significant human health risks will result from such exposures. Accordingly, Petitioner recommends that EPA determine that exempting methyl salicylate from the requirement of a tolerance is safe.

2. *Infants and children.* Petitioner believes that EPA has sufficient data to address the issue of the potential additional sensitivity of infants and children to pesticidal methyl salicylate residues. Petitioner points to the long history of use of this substance as a flavoring in foods, its GRAS status, and the data submitted to the Agency in support of this petition. Reproductive and developmental effects have been found in toxicology studies for methyl salicylate; however, these adverse effects occurred at exposure levels that were also maternally toxic or at exposure levels higher than those producing other adverse effects following chronic exposure. Petitioner believes that infants and children are not differentially sensitive to methyl salicylate either by virtue of increased toxicological susceptibility or increased potential exposures. Therefore, Petitioner requests that EPA conclude that there is a reasonable certainty that no harm will result to infants and children from aggregate exposures to pesticidal chemical residues of methyl salicylate.

3. *Endocrine effects.* Methyl salicylate has been studied in several tests of reproductive and developmental effects, including multigenerational studies. In addition, the pathology of endocrine-sensitive tissues and organs has been evaluated following repeated (i.e., subchronic) and long-term (i.e., chronic) exposures. These studies are sufficient to detect endocrine effects. No such effects were reported in any of these studies. Therefore, Petitioner concludes that pesticidal uses of methyl salicylate are unlikely to have an effect in humans that is similar to an effect produced by a naturally occurring estrogen or other endocrine effects.

G. Analytical Method

Petitioner proposes that EPA establish this exemption from the requirement of a tolerance without any numerical limitation; therefore, analytical methods for residues of methyl salicylate would not be required for enforcement purposes. Petitioner is confident that, if present at all, residues of methyl salicylate that may be found in foods in contact with treated packaging materials will be minimal and considerably below the levels expected in existing GRAS uses of the active ingredient as a direct food flavoring ingredient. The Petitioner believes that an analytical method for the detection and measurement of methyl salicylate residues is not necessary to protect the public health or the environment. The natural occurrence of methyl salicylate in the environment (as oil of wintergreen), and its widespread use as a flavoring agent in the food supply preclude the need to quantify pesticidal methyl salicylate residues. Therefore, Petitioner has requested that EPA waive the requirement for an analytical method.

H. Existing Tolerances or Tolerance Exemptions

There are no known existing tolerances or tolerance exemptions for methyl salicylate; however, oil of wintergreen is exempt from the requirement of a tolerance when used in accordance with good agricultural practice as an inert (or occasionally active) ingredient in pesticide formulations applied to growing crops or to raw agricultural commodities (40 CFR 180.1001(c)).

I. Codex Maximum Residue Level

No known maximum residue limits (MRLs) have been established for methyl salicylate by the Codex Alimentarius Commission. (Sheryl Reilly)

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ENVIRONMENTAL PROTECTION AGENCY

[OPP–181047; FRL–5719–1]

Emergency Exemptions

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: EPA has granted specific exemptions for the control of various pests to three States listed below. There were eight crisis exemptions initiated by various States. These exemptions, issued during the months of January, February, and March 1997, are subject to application and timing restrictions and reporting requirements designed to protect the environment to the maximum extent possible. Information on these restrictions is available from the contact persons in EPA listed below.

DATES: See each specific and crisis exemption for its effective date.

FOR FURTHER INFORMATION CONTACT: See each emergency exemption for the name of the contact person. The following information applies to all contact persons: By mail: Registration Division (7505W), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. Office location and telephone number: 6th Floor, CS 1B1, 2800 Jefferson Davis Highway, Arlington, VA (703–308–8417); e-mail: group.ermus@epamail.epa.gov.

SUPPLEMENTARY INFORMATION: EPA has granted specific exemptions to the:

1. Arizona Department of Agriculture withdrew their specific exemption request for the use of chlorfenapyr on lettuce to control the beet armyworm on December 27, 1996. (Pat Cimino)

2. California Department of Pesticide Regulation for the use of propamocarb hydrochloride on potatoes to control late blight; February 11, 1997, to February 10, 1998. (Libby Pemberton)

3. Texas Department of Agriculture for the use of propamocarb hydrochloride on potatoes to control late blight; February 11, 1997, to February 10, 1998. (Libby Pemberton)

Crisis exemptions were initiated by the:

1. Alabama Department of Agriculture and Industries on March 28, 1997, for the use of norflurazon on bermudagrass hay meadows to control weeds. The need for this program is expected to last until September 15, 1997. (Libby Pemberton)

2. California Department of Pesticide Regulation on February 5, 1997, for the use of imidacloprid on cucurbits to control the whitefly. The need for this program is expected to last until February 5, 1998. (Andrea Beard)

3. California Department of Pesticide Regulation on February 3, 1997, for the use of propiconazole on almonds to control anthracnose. The need for this program is expected to last until June 1, 1997. (Olga Odiott)

4. Idaho Department of Agriculture on March 3, 1997, for the use of pendimethalin on mint to control kochia and redroot pigweed. The need for this program is expected to last until December 31, 1997. (Steve Schaible)

5. Louisiana Department of Agriculture and Forestry on March 7, 1997, for the use of norflurazon on bermudagrass to control grassy weeds. The need for this program is expected to last until September 15, 1997. (Libby Pemberton)

6. Oregon Department of Agriculture on March 3, 1997, for the use of pendimethalin on mint to control kochia and redroot pigweed. This program is expected to last until December 31, 1997. (Steve Schaible)

7. Texas Department of Agriculture on January 27, 1997, for the use of imidacloprid on cucurbits to control the whitefly. This program is expected to