of safety are expected to be considerable. Monsanto concludes that there is a reasonable certainty that no harm will result to the U.S. Population from aggregate exposure to sulfosulfuron residues.

2. *Infants and children*. In assessing the potential for additional sensitivity of infants and children to residues of sulfosulfuron, Monsanto considered data from developmental toxicity studies in the rat and rabbit and a two-generation reproduction study in rats. No developmental or reproductive effects were observed up to the highest dose tested in each of the three studies. The Observed NOEL's were 1,000 mg/kg/day, 1,000 mg/kg/day and 20,000 ppm, respectively. Using the same conservative assumptions that were made previously for the dietary exposure analysis for the U.S. General population, the percent of the RfD utilized by pre-adult sub-populations are: all infants-0.03%; nursing infants-0.005%; non-nursing infants-0.04%; children, 1-6 years-0.06%; children, 7-12 years-0.04%. Monsanto concludes that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to sulfosulfuron residues.

F. International Tolerances

There are currently no international (Codex) tolerances established for sulfosulfuron. Sulfosulfuron is currently registered on wheat in Switzerland, Poland, the Czech Republic, Slovakia and South Africa. Petitions for tolerances for sulfosulfuron in/on wheat have been submitted in Canada, Australia and the European Union. (Jim Tompkins)

[FR Doc. 97–32936 Filed 12–16–97; 8:45 am]
BILLING CODE 6560–50–F

ENVIRONMENTAL PROTECTION AGENCY

[PF–785; FRL–5760–5]

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 food commodities.

DATES: Comments, identified by the docket control number [PF–785], must be received on or before January 16, 1998.

ADDRESSES: By mail submit written comments to: Public Information and Records Integrity Branch, Information Resources and Services Division (7502C), 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 to: opp-docket@epamail.epa.gov. Follow 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: Amelia M. Acierto, Registrtion Division (7505W), Office of Pesticide Programs, U.S. Environmental Protection Agency, 401 M Street, S.W., Washington, D.C. 20460. Office location, telephone number and e-mail address: Rm. 4W60 4th floor, CS1, 2800 Crystal Drive, Arlington VA, (703)308-8377, e-mail: acierto.amelia@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 food 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 of filing, as well as the public version, has been established for this notice of filing under docket control number [PF–785] (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'' at the beginning of this document.

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 number [PF–785] and appropriate petition number. Electronic comments on notice may be filed online at many Federal Depository Libraries.

List of Subjects

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

Dated: December 4, 1997

Peter Caulkins,

Acting Director, Registration Division, Office of Pesticide Programs.

Summaries of Petitions

Petitioner summaries of the pesticide petitions are printed below as required by section 408(d)(3) of the FFDCA. The summaries of the petitions were prepared by the petitioners and represent the views of the petitioners. EPA is publishing the petition summaries verbatim without editing them 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.

1. Ecolab Inc.

PP 7E4922

EPA has received a pesticide petition (PP 7E4922) from Ecolab Inc., 370 N. Wabasha Street, St. Paul, Minnesota 55102, proposing pursuant to section 408(d) of the Federal Food, Drug and Cosmetic Act, 21 U.S.C. 346a(d), to amend 40 CFR 180.1001(c) to establish an exemption from the requirement of a tolerance for the residues of

hydroxyethylidine diphosphonic acid (HEDP) when used as an inert ingredient at levels of 0.9% in pesticide formulations applied to agricultural commodities after harvest.

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 the petition. Additional data may be needed before EPA rules on the petition.

A. Proposed Use Practices

HEDP is proposed for use as an inert ingredient in an antimicrobial treatment formulation contacting raw agricultural commodities.

1. *Acute toxicity*. The acute and chronic toxicity of HEDP have been tested extensively. Adverse effects are not expected when used in the proposed manner.

Pure HEDP exhibits low acute oral and dermal toxicity. The oral LD_{50} ranged from 1,340 to 3,130 milligrams/kilogram (mg/kg) (Toxicity Category III) and the dermal LD_{50} ranged from 7,940 to greater than 10,000 mg/kg (Toxicity Category IV). HEDP is moderately irritating to the skin (Toxicity Category III) and is corrosive to the eyes (Toxicity Category I).

2. *Genotoxicity*. No mutagenic activity was observed in microbial assays using five *Salmonella* strains or in a L5178Y TK mouse lymphoma cell point mutation assay, with and without mammalian microsomal activation. There are no significant genotoxicity concerns for HEDP.

3. *Reproductive and developmental toxicity*. No reports were found in the open literature indicating that HEDP caused developmental or reproductive effects.

4. *Subchronic toxicity*. Subchronic studies were conducted in both rats and dogs. In these studies, rats were exposed to HEDP in the diet at concentrations up to 30,000 parts per million (ppm) and in dogs up to 10,000 ppm. Histopathological evaluations of tissues from the reproductive systems in male and female animals of both species did not demonstrate any lesions, morphological changes or weight variations. Although the functionality of the reproductive systems were not evaluated, there was no indication that the HEDP treatment affected these tissues.

In a 90–day feeding study, rats were fed diets containing 3,000, 10,000 or 30,000 ppm HEDP (disodium monohydrate salt). At 30,000 ppm average body weight gains of both males and females were reduced and absolute and relative liver weights of males were decreased. Increased erythrocyte counts (males), decreased hemoglobin concentration (both sexes), decreased hematocrit values (both sexes), and decreased leukocyte counts (females at 84–days only) were observed at 30,000 ppm. No other hematologic, urinalysis, or clinical chemistry parameter was affected. The no-observed-effect level (NOEL) was greater than 10,000 ppm.

The disodium monohydrate salt of HEDP was administered to beagle dogs at dietary concentrations of 1,000, 3,000, or 10,000 ppm for 90–days. No adverse hematologic, biochemical, or histopathologic effects were observed. The NOEL was 10,000 ppm.

The NOEL from both the rat and the dog studies was 10,000 ppm. Based on the data from these studies the daily intake of HEDP can be estimated. The estimated intake of HEDP by male and female rats at 10,000 ppm was 635 and 724 milligrams/kilogram/day (mg/kg/day), respectively. The estimated intake of HEDP by male and female dogs at 10,000 ppm was 278 and 385 mg/kg/day, respectively.

5. *Carcinogenicity*. Nothing in the available literature suggests that HEDP is known to be a carcinogen; thus, a discussion of aggregate excess lifetime cancer risk resulting from exposure to the chemical from residues in food and drinking water (ground and surface water) and from residential and other non-occupational source(s) is not applicable.

6. *Endocrine effects*. HEDP does not acts as an endocrine disrupter or possess intrinsic hormonal activity.

B. Aggregate Exposure

1. *Dietary exposure*—i. *Food*. There are no established U.S. food tolerances for HEDP. Because the compound has an affinity for water, residues are expected to drain away with wash water instead of ''sticking'' to the food items. Tests on broccoli and tomatoes indicate only trace amounts of HEDP remain on these food items that have contacted treated equipment. For broccoli (cut), an average of 0.78 ppb HEDP residues were found. An average of 0.09 ppb HEDP residues were found on tomatoes. While these data are not meant to be representative of all fruits and vegetables, it shows that any potential HEDP residues are not significant. Dietary exposure from the proposed use is possible; however, any residues that may remain are expected to be very minimal and, because of the low toxicity of the undiluted raw material, these residues would not be of toxicological concern.

ii. *Drinking water*. There should be no concern about the potential for transfer of HEDP residues to human drinking water because it does not interfere with routine removal of organics in laboratory semi-continuous activated sludge sewage treatment units. Because of the physical chemistry of this compound, it is unlikely that any States are conducting water monitoring programs for HEDP.

HEDP is proposed for use as an inert ingredient in a pesticide formulation used on fruits, vegetables, tree nuts, cereal grain, herbs, and spices. HEDP is classified as slow to intermediate in biodegradation to CO_2. Additionally, the biodegradation is accelerated by light. Data in the aforementioned reference indicates that 0.2 ppm HEDP solutions in a mineral medium biodegrade by 79% in 3–days when exposed to sunlight.

The maximum expected concentration of HEDP in waste water treatment streams from the use of the proposed pesticide product is 0.07 ppm. Furthermore, HEDP will biodegrade in waste water treatment plants and in the environment. Therefore, HEDP released from the use of the proposed pesticide product poses no threat to drinking water.

iii. *Non-dietary, non-occupational exposure*. The estimated non-occupational exposure to HEDP has been evaluated based on its proposed use pattern.

The compound, as an inert ingredient in a pesticide formulation in the form of a soluble concentrate/liquid, is used in industrial and commercial settings.

HEDP use in homes does not occur.

The potential for significant non-occupational non-dietary exposure under the use proposed in this petition to the general population (including infants and children) is unlikely. HEDP is proposed in this petition to be used only at commercial establishments (including farms) and is not to be used in or around the home.

iv. *Environmental fate and ecological effects*. HEDP is classified as slow to intermediate in biodegradation to CO_2. Additionally, the biodegradation is accelerated by light. Data in the aforementioned reference indicates that 0.2 ppm HEDP solutions in a mineral medium biodegrade by 79% in 3–days when exposed to sunlight. Degradation of HEDP has been shown in several test soils at rates similar to biodegradable linear alkybenzenesulfonate. Complexes of HEDP with copper (II) and iron (III) rapidly photodegrade in aqueous solution under irradiation from a mercury arc lamp in the laboratory.

Environmental effects data on HEDP (including Daphnia magna, Midge Larvae, Grass Shrimp, Oyster Shell Deposition, Bluegill Sunfish, Rainbow Trout, Channel Catfish, and Sheepshead Minnow) show HEDP is classified as practically non-toxic, with the exception of oysters, in which it is classified as being slightly toxic. The maximum expected concentration of HEDP in waste water treatment streams from the use of the proposed pesticide product is 0.07 ppm. This value is three orders of magnitude below the lowest toxic concentration listed above (oysters). Furthermore, HEDP will biodegrade in waste water treatment plants and in the environment. Therefore, HEDP released from the use of the proposed pesticide product poses no threat to aqueous organisms present in the environment.

C. Cumulative Effects

Review of EPA's list of inert ingredients found no similar approved inert ingredients or compounds with similar structures.

The list of currently registered active ingredients from the National Pesticide Information Retrieval System (NPIRS) was reviewed for compounds similar to HEDP. The ethylene-releasing growth regulator ethephon (chemical name 2-chloroethylphosphonate) is somewhat similar in that a two-carbon fragment is the organic component of a phosphonic acid. However, HEDP contains two phosphonic acid groups attached to the same carbon and contains no chlorine. Ethephon, on the other hand, contains a single phosphonic moiety but has a chlorine attached at the 2-position of the ethyl group. Further, the mode of action of ethephon is to release ethylene by rapidly decomposing with loss of the chlorine and the phosphonate; this pathway is not available for HEDP. Thus, combining exposures to HEDP with this compound is not appropriate.

D. Safety Determination

1. *U.S. population*. Tests conducted by Ecolab Inc. indicate very low residues of HEDP are expected to remain on treated commodities (whether raw agricultural commodities or processed); thus, exposure to the U.S. general population including infants and children would be very minimal as a result of the proposed use.

In testing for Ecolab using tomatoes and broccoli the HEDP residue on these vegetables was generally below 1 ppb. Assuming that a normal adult weighing 70 kg ingests approximately 2,000 g of food a day, and that all the food ingested is fruits and vegetables that contain a 1 ppb residue of HEDP, the daily intake of HEDP would be estimated at 0.000027 mg/kg/day.

Comparing the daily intake of HEDP under these worst case situations with the lowest NOEL for HEDP in the subchronic animal studies (278 mg/kg/day) provides a margin of exposure of approximately 10,000,000. Clearly this larger margin of exposure demonstrates the lack of concern about the presence of the minute residues of HEDP on food.

Dietary exposure to HEDP is possible; however, any residues that may remain are expected to be very minimal and, because of the low toxicity of the undiluted raw material, these residues would not be of toxicological concern.

Therefore, exposure of this inert ingredient (from the use proposed in this petition) to the U.S. general population would not pose a health risk.

2. *Infants and children*. HEDP should not pose a health risk to the U.S. population subgroup of infants and children.

Tests conducted by Ecolab Inc. indicate very low residues of HEDP are expected to remain on treated commodities (whether raw agricultural commodities or processed); thus, exposure to the U.S. general population including infants and children would be very minimal as a result of the proposed use. Dietary exposure to HEDP is possible; however, any residues that may remain are expected to be very minimal and, because of the low toxicity of the undiluted raw material, these residues would not be of toxicological concern.

Therefore, exposure of this inert ingredient (from the use proposed in this petition) should not pose a health risk to the U.S. population subgroup of infants and children.

E. Analytical Method

Because this petition is for an exemption from the requirement of a tolerance, an enforcement method for HEDP is not needed. However, a spectrophotometric method to determine residues of HEDP has been submitted to the Agency .

F. International Tolerances

The petitioner understands that there are no current established Maximum Residue Levels for HEDP.

2. Wacker Silicones Corporation

PP 7E4794

EPA has received a pesticide petition (PP 7E4794) from Walker Silicones Corporation, on behalf of Wacker-Chemie, 3301 Sutton Road, Adrain, Michigan 49221-9397 proposing pursuant to section 408(d) of the Federal Food, Drug and Cosmetic Act, 21 U.S.C. 346a(d), to amend the exemption from the requirement of a tolerance established under 40 CFR 180.1001(c) for the residues of pentaerythritol stearates (CAS. No. 85116-93-4) from 25 ppm to 500 ppm.

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 the petition. Additional data may be needed before EPA rules on the petition.

A. Proposed Use Practices

As in the tolerance exemption established and published in the **Federal Register** on July 3, 1996 (61 FR 34741–34743) (FRL–5381–2), the proposed use of a pentaerythritol stearates which include pentaerythritol monostearate (CAS No. 78–23–9), pentaerythritol distearate (CAS No. 13081–97–5), pentaerythritol tristearate (CAS No. 28188–24–1), pentaerythritol tetrastearate (CAS No. 115–83–3) is limited to agricultural food use. This includes use on crops and seeds used to grow crops.

B. Toxicological Profile

A summary of the toxicology data is included in the proposed rule that was published in the **Federal Register** on April 17, 1996 (61 FR 16747–16749) (FRL–5355–7).

Pentaerythritol stearates are large, branched hydrocarbons. All carbon-carbon bonds are single bonds. Degradation is anticipated in the presence of enzymes. Hypothesized degradation products include free pentaerythritol and stearic acid (a natural product). The degradation products are likely to be polar and readily eliminated in urine.

1. *Acute toxicity*. The acute oral LD_{50} in rats was determined to be >2,000 mg/kg. This study demonstrates that the mixture of pentaerythritol stearates is practically non-toxic to mammals. Wacker Silicones Corporation and Wacker-Chemie are not aware of any data that suggest that pentaerythritol stearates pose any potentially greater acute risk to infants or children.

2. *Reproductive and developmental toxicity*. Wacker Silicones Corporation and Wacker-Chemie are not aware of any developmental or reproductive effects resulting from exposure to pentaerythritol stearates.

3. *Chronic toxicity*. Wacker Silicones Corporation and Wacker-Chemie are not aware of any effects resulting from chronic exposure to pentaerythritol

stearates. In addition, Wacker Silicones Corporation and Wacker-Chemie are not aware of any data that suggests that chronic exposure to pentaerythritol stearates, including during infancy and childhood, poses any potentially greater lifetime risk.

4. *Carcinogenicity*. Wacker Silicones Corporation and Wacker-Chemie are not aware of any oncogenic effects resulting from exposure to pentaerythritol stearates. In addition, Wacker Silicones Corporation and Wacker-Chemie are not aware of any data that suggests that chronic exposure to pentaerythritol stearates, including during infancy and childhood, poses any potentially greater lifetime cancer risk.

5. *Endocrine effects*. Pentaerythritol stearates are not structurally similar to any compounds with known endocrine effects. Wacker Silicones Corporation and Wacker-Chemie are not aware of any endocrine effects resulting from exposure to pentaerythritol stearates either individually or in combination with other substances.

C. Aggregate Exposure

Exposure to pentaerythritol stearates via both the diet and drinking water is anticipated to be negligible. Pentaerythritol stearates are ingredients in a product that Wacker-Chemie proposes to market in the United States exclusively as an inert ingredient in pesticide formulations that are used exclusively on crops and seeds used to grow crops.

1. *Dietary exposure— Food*. In its review on the previous exemption, EPA's Chemistry Branch determined that the maximum residue of pentaerythritol stearates in food/feed resulting from a single application of pentaerythritol stearates at 0.53 grams/acre (0.0012 lb/acre) would be 0.6 ppm assuming that (a) all the pentaerythritol stearates contained in the pesticide formulation applied to the crop are in the harvested commodity, (b) there is no loss of residue through weathering or volatilization, and (c) pentaerythritol stearates are used on low yield crops (2,000 lb/acre). Further assuming that (i) a maximum of 10 applications per season, (ii) all crops are treated at the proposed maximum seasonal rate, the maximum theoretical seasonal residues of pentaerythritol stearates would be 6 ppm.

Actual seasonal residues are anticipated to be several orders of magnitude lower than the 6 ppm calculated maximum residue for the following reasons:

(i) Only a portion of the pesticide spray is intercepted by edible plant parts.

(ii) Degradation of residues following application is anticipated.

(iii) Treated crops may be medium or high yield crops.

(iv) Crops generally received less than 10 applications per season.

(v) Only a small percentage of pesticide formulations will include pentaerythritol stearates as an inert ingredient.

Actual seasonal residues of pentaerythritol stearates are therefore anticipated to be negligible.

2. *Drinking water*. Exposure to pentaerythritol stearate via drinking water will be negligible. Pentaerythritol stearates have very low solubility in water (>0.1 mg/100 g water at 30° C). Solubility in organic solvents is also anticipated to be low due to the high molecular weight (403– 1201 amu) of the pentaerythritol stearates. The potential for pentaerythritol stearate contamination of ground water or surface water is therefore negligible. If residues did contaminate ground water or surface water, it is highly probable that the low solubility of pentaerythritol stearates in water and organic solvents would result in removal of the residues via standard drinking water purification techniques.

3. *Non-dietary, non-occupational exposure*. Pentaerythritol stearates are ingredients in a product that Wacker-Chemie proposes to market in the United States exclusively as an inert ingredient in pesticide formulations that are used exclusively on crops and seeds used to grow crops. No non-occupational exposure of the United States population to pentaerythritol stearates will result from the proposed use of pentaerythritol stearates.

D. Cumulative Effects

Pentaerythritol stearates do not have any known significant toxicological mechanism or mode of action. Therefore, there is no known significant cumulative risk associated with the proposed use of pentaerythritol stearates.

E. Safety Determination

1. *U.S. population*. Exposure to pentaerythritol stearates via both the diet and drinking water is anticipated to be negligible. Pentaerythritol stearates are ingredients in a product that Wacker-Chemie proposes to market in the United States exclusively as an inert ingredient in pesticide formulations that are used exclusively on crops and seeds used to grow crops. No non-occupational exposure of the United States population to pentaerythritol stearates will result from the proposed use of pentaerythritol stearates. Aggregate exposure to pentaerythritol stearates is therefore anticipated to be negligible.

2. *Infants and children*. Wacker Silicones Corporation and Wacker-Chemie are not aware of any data that suggest that pentaerythritol stearates pose any potential greater acute or chronic risk to infants or children.

F. International Tolerances

There are no Codex maximum residue levels (MRLs) or exemptions from MRLs for pentaerythritol stearates established for residues of pentaerythritol stearates.

[FR Doc. 97–32932 Filed 12–16–97; 8:45 am]

BILLING CODE 6560–50–F

ENVIRONMENTAL PROTECTION AGENCY

[OPP–50838; FRL–5761–5]

Issuance of an Experimental Use Permit

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: EPA has granted an experimental use permit to the following applicant. The permit is in accordance with, and subject to, the provisions of 40 CFR part l72, which defines EPA procedures with respect to the use of pesticides for experimental use purposes.

FOR FURTHER INFORMATION CONTACT: By mail: James Tompkins, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. Office location, telephone number, and e-mail address: 1921 Jefferson Davis Highway, Rm. 239, CM #2, Arlington, VA, 703–305–5697, e-mail: tompkins.james@epamail.epa.gov.

SUPPLEMENTARY INFORMATION: EPA has issued the following experimental use permit:

62719–EUP–1. Issuance. DowElanco, 9330 Zionsville Road, Indianapolis, IN 46268–1054. This experimental use permit allows the use of 7,000 pounds of the herbicide triclopyr on 1,950 aquatic acres to evaluate the control of various weeds. The program is authorized only in the States of Alabama, Arkansas, California, Florida, Georgia, Idaho, Illinois, Indiana, Kentucky, Louisiana, Maine, Massachusetts, Michigan, Minnesota, Mississippi, Missouri, New Jersey, North Carolina, Ohio, Oregon, Pennsylvania, South Carolina, Tennessee, Texas, Vermont, Virginia, Washington, and Wisconsin. The