Dated: May 22, 1997.

Elizabeth Cotsworth,

Acting Director, Office of Solid Waste.

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Parts 180 and 185

[OPP–300475; FRL–5600–6]

(S)-Hydroprene Biochemical Pest Control Agent; Pesticide Tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed Rule.

SUMMARY: EPA proposes to expand the tolerance for residues of hydroprene, [(*S*)-(Ethyl (2*E*,4*E*,7*S*)-3,7,11-trimethyl-2,4-dodecadienoate)], an insect growth regulator, on all food items in food-handling establishments to include perimeters and pantries, and warehouses to the list of permissible food storage sites and ultra low volume (ULV) fogging as a permissible treatment method under certain precautions and conditions. The Agency also proposes permitting the use of point source device treatments providing those devices do not come into direct contact with food preparation surfaces and are kept a minimum distance of 3 feet from exposed foods. The Agency is also proposing to restrict the tolerance expression to residues of [(*S*)-(Ethyl (2*E*,4*E*,7*S*)-3,7,11-trimethyl-2,4-dodecadienoate)], the *S*-racemer of hydroprene since the *R*-racemer is no longer being supported in reregistration. This regulation is proposed by the EPA at its own initiative.

DATES: Comments identified by the docket control number [OPP–300475] must be received on or before July 7, 1997.

ADDRESSES: Submit written comments by mail to: Public Information and Records Integrity Branch, Information Resources and Services Division (7506C), Office of Pesticide Programs, U.S. Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. In person, bring comments to: Public Docket, Room 1132, Crystal Mall #2, 1921 Jefferson Davis Highway, Arlington, VA 22202. 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). Information so marked 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 will be included in the public docket by EPA without prior notice.

Comments and data may also be submitted electronically by following the instructions under Unit IV of this document. No Confidential Business Information (CBI) should be submitted through e-mail.

FOR FURTHER INFORMATION CONTACT: By mail: Diana Horne, c/o Product Manager (PM) 90, Biopesticides and Pollution Prevention Division (7501W) Office of Pesticide Programs, Environmental Protection Agency, 401 M St. SW., Washington, DC 20460. Office location, telephone number and e-mail address: Room 5-W38, 5th Floor, CS#1, 2800 Crystal Drive, Arlington, VA 22202 (703) 308-8367; horne.diana@epamail.epa.gov.

SUPPLEMENTARY INFORMATION: EPA proposes to amend 40 CFR parts 180 and 185 by removing § 185.3625 and adding § 180.501, and by adding perimeters, pantries and warehouses to the list of permissible food storage sites and ultra low volume (ULV) fogging as a permissible treatment method under certain precautions and conditions. The Agency is also permitting the use of point source device treatments providing those devices do not come into direct contact with food preparation surfaces and must be kept a minimum distance of 3 feet from exposed foods. The Agency is also proposing to restrict the tolerance expression to residues of [(*S*)-(Ethyl (2*E*,4*E*,7*S*)-3,7,11-trimethyl-2,4-dodecadienoate)], the *S*-racemer of hydroprene. The *R*-racemer is being removed from the tolerance expression since Sandoz Agro Inc., the manufacturer, is supporting only the reregistration of (*S*)-hydroprene and no longer manufacturers the R/S hydroprene racemic mixture.

I. Background and Statutory Authority

In the **Federal Register** of August 12, 1992 (57 FR 36005), EPA promulgated a final rule which established a tolerance under sections 408 and 409 of the Federal Food, Drug and Cosmetic Act, 21 U.S.C. 346a and 348, specifying a tolerance for (*R*)-hydroprene and (*S*)-hydroprene racemic mixture residues of the insect growth regulator in or on food commodities exposed during spot or crack and crevice treatment of food handling establishments at 0.2 ppm. This was in response to a pesticide tolerance petition (9H5573) filed by Zoecon Corporation.

The Food Quality Protection Act of 1996 (FQPA) (Pub. L. 104-170) was signed into law August 3, 1996. FQPA amends both the Federal Food, Drug and Cosmetic Act (FFDCA), 21 U.S.C. 301 et seq., and the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), 7 U.S.C, 136 at seq. The FQPA amendments went into effect immediately. Among other things, FQPA amends FFDCA to bring all EPA pesticide tolerance-setting activities under a new section 408 with a new safety standard and new procedures.

New section 408(b)(2)(A)(i) allows EPA to establish a tolerance (the legal limit for a pesticide chemical residue in or on a food) only if EPA determines that the tolerance is ''safe.'' Section 408(b)(2)(A)(ii) defines ''safe'' to mean that ''there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures and all other exposures for which there is reliable information.'' This includes exposure through drinking water, but does not include occupational exposure. Section 408(b)(2)(C) requires EPA to give special consideration to exposure of infants and children to the pesticide chemical residue in establishing a tolerance and to ''ensure that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to the pesticide chemical residue....'' Section 408(b)(2)(D) specifies factors EPA is to consider in establishing a tolerance. Section 408(b)(3) requires EPA to determine that there is a practical method for detecting and measuring levels of the pesticide chemical residue in or on food and that the tolerance be set at a level at or above the limit of detection of the designated method. Section 408(b)(4) requires EPA to determine whether a maximum residue level has been established for the pesticide chemical by the Codex Alimentarius Commission. If so, and EPA does not propose to adopt that level, EPA must publish for public comment a notice explaining the reasons for departing from the Codex level. Section 408 governs EPA's establishment of exemptions from the requirement for a tolerance using the same safety standard as section 408(B)(2)(A) and incorporating the provisions of section 408(b)(2)(C) and (D). Section 408(e) gives EPA general authority to establish tolerances and exemptions from the requirement for a tolerance through notice and comment rulemaking procedures upon EPA's initiative.

New section 408(c)(2)(A)(i) allows EPA to establish an exemption from the

requirement of a tolerance only if EPA determines that the exemption is ''safe.'' Section 408(c)(2)(A)(ii) defines ''safe'' to mean that ''there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures and all other exposures for which there is reliable information.'' This includes exposure through drinking water, but does not include occupational exposure. Section 408(c)(2)(B) requires EPA to give special consideration to exposure of infants and children to the pesticide chemical residue in establishing an exemption and to ''ensure that there is a reasonable certainty, that no harm will result to infants and children from aggregate exposure to the pesticide chemical residue ... '' and specifies factors EPA is to consider in establishing an exemption. Section 408(c)(3)(B) provides for circumstances when no need exists for a practical method for detecting and measuring levels of pesticide chemical residue in or on food.

II. Risk Assessment and Statutory Findings

Consistent with section 408(b)(2)(A), EPA has reviewed the available scientific data and other relevant information in support of this action. The scientific data submitted in previous petitions and other relevant material have been evaluated including toxicological and residue chemistry data. EPA has assessed the toxicology data base for (*S*)-hydroprene and has sufficient data to assess its hazards and to make a determination on aggregate exposure.

A. Use Practices

1. *Use practices.* The biochemical pest control agent (*S*)-hydroprene is presently used on walls, floors, ceilings, attics, basements, or crawlspaces of apartment buildings, bakeries, bottling facilities, breweries, boiler rooms, cafeterias, candy plants, grocery stores, day care centers, hospitals, residential homes, office buildings, kitchens, laboratories, cereal processing facilities, manufacturing plants, mausoleums, meat and produce canneries, nursing homes, restaurants, schools, locker rooms, stores, taverns, warehouses, as well as various modes of transporation such as aircraft, buses, trucks, trailers, rail cars, and marine vessels. It is also applied in food handling establishments where food is held, prepared, processed or served including areas where food is received, prepared, packaged and stored, as well as enclosed food processing systems (mills, dairies, etc.) in spot and crack and crevices, and small food storage areas. This proposal would expand the permissible food storage sites to include warehouses, pantries and perimeters and also ultra low volume (ULV) fogging as a permissible treatment method.

2. *Application rates.* For general surface applications, one ounce of product is applied to 1,500 square feet surface area (0.0015 gram active ingredient/square foot) for surface spray/paint brush, spot and crack crevice preparations. The product may be applied every 4 months by spray/paint brush, hand pressurized or power operated sprayers, foggers, mechanical misting sprayers, aerosol generators, Ultra Low Volume (ULV) misters, or thermal foggers. For fogging, space spray/mist applications, 1 ounce product/12,000 cubic feet (0.2 gram active ingredient/1,000 cubic feet). Emissions from bait stations are at the rate of 0.001 gram active ingredient/square feet over a 3–month period.

B. Product Identity/Residue Chemistry

1. Plant metabolism. (*S*)-hydroprene is not applied to living plants or food and therefore plant metabolism studies have been waived. The currently regulated residues are the racemic components of hydroprene, namely [(*R*)-(Ethyl (2*E*,4*E*,)-3,7,11-trimethyl-2,4— dodecadienoate)], and [(*S*)-(Ethyl (2*E*,4*E*,)-3,7,11-trimethyl-2,4-dodecadienoate)] at 0.2 ppm. EPA proposes to keep the current tolerance limit of 0.2 ppm but to limit the regulated residue to [(*S*)-(Ethyl (2*E*,4*E*,7E)-3,7,11-trimethyl-2,4-dodecadienoate)]. The *R*-racemer is being removed from the tolerance expression since Sandoz Agro Inc., the manufacturer, is supporting only the reregistration of (*S*)-hydroprene and no longer manufacturers the R/S hydroprene racemer mixture.

2. *Analytical method.* The Agency has reviewed scientific data submitted by Zoecon Corporation and has determined that there is a practical analytical method for detecting and measuring levels of (*S*-)hydroprene in or on food with a limit of detection that allows monitoring of food with residues at or above the levels set in these tolerances. This method, Method No. 307, is an analytical method—Gas chromatography/Flame Ionization Detector and Mass Specific Detector/Selected Ion Monitoring (GC/FID and MD/SIM) with a limit of detection of 0.01 ppm for most foods and 0.02 ppm for butter. The method will be published in PAM II under Pesticide Reg. 40 CFR 185.3625. EPA has provided information on this method to the Food and Drug Administration. The method is available to anyone who is interested in pesticide residue enforcement from: By mail, Calvin Furlow, Public Information and Records Integrity Branch, Information Resoruces and Services Division (7506C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. Office location and telephone number: Crystal Mall #2, Rm. 1128, 1921 Jefferson Davis Highway, Arlington, VA 22202, (703) 305–5805.

3. *Magnitude of residues.* The Agency has also reviewed data for use of (*S*)-hydroprene as a diluted spray for partial area treatment of large food manufacturing/warehousing facilities. Residue studies of food commodities exposed under simulated warehouse pantry conditions for 24 hours indicate that the established tolerance of 0.2 ppm will not be exceeded as long as label directions are followed. Residue studies of food commodities exposed as a result of partial area treatments of large food handling/warehousing facilities indicated that food commodities exposed for up to 8 hours will not exceed the established tolerance of 0.2 ppm. Residues resulting from ULV fogging were also below the established tolerance of 0.2 ppm.

Also reviewed were exposure studies from the use of point source devices. Submitted residue studies indicated that bait and/or stations may be used in food handling establishments during food processing without exceeding the established tolerance of 0.2 ppm under the following conditions. The bait stations must not come into direct contact with food preparation surfaces and must be a minimum of 3 feet or more away from the exposed food.

C. Toxicological Profile

The toxicological findings include reviews/reassessments of a rat chronic toxicity study, rat carcinogenicity study, rat reproductive study, rat and rabbit developmental toxicity studies as well as an Agency assessment of the reference dose (RfD). The test material for all but one of the toxicology tests involved (*S*)-hydroprene which is known to be the more biologically active hydroprene racemer. An *R,S*-hydroprene racemic mixture was the test material in the rabbit developmental study.

1. *Acute toxicity.* Based on the available acute toxicity data, EPA has determined the (*S*)-hydroprene does not pose any acute dietary risks. The following mammalian toxicity studies have been conducted in support of the tolerance exemption for residues of technical (*S*)-hydroprene except for the

acute inhalation test and the skin sensitizing test.

Acute Toxicity Tests	Results	Rating
(*S*)-hydroprene technical unless otherwise stated.		
Acute Oral	LD_{50} > 5,000 mg/kg/day	Toxicity Category IV
Acute Dermal	LD_{50} > 5,000 mg/kg/day, abraded skin	Toxicity Category III
Acute Inhalation.	LC_{50} > 5.2 mg/L (actual) [65.7% formulation]	Toxicity Category III
Primary Dermal Irritation (Rat).	Mild irritation at 0 and 24 hours	Toxicity Category IV
Primary Eye Irritation (Rabbit).	Conjunctival irritation only after 24 hours	Toxicity Category IV
Dermal Sensitization (Guinea Pig).	Sensitizing agent [65.7% formulation]	Toxicity Category IV

2. *Genotoxicity.* There is no evidence for the Agency to believe that (*S*)-hydroprene, a biochemical, has genotoxic potential. Test results were negative for the following mutagenicity tests: unscheduled DNA synthesis in rat hepatocyte, micronucleus assay in mice, *in vivo* cytogenicity in rat bone marrow cells, and the Ames assay.

3. *Reproductive toxicity.* Originally, the Agency determined a parental toxicity no observed effect level (NOEL) of 300 ppm, lowest observed effect level (LOEL) at 1,500 ppm, a reproductive toxicity NOEL of 300 ppm and LOEL of 1,500 ppm (June 8, 1995 memo RfD/QA Peer Review Committee). The Agency has now determined that the parental toxicity NOEL is 1,500 ppm and the LOEL is 7,500 ppm for the rat reproductive toxicity study. The conclusion is based on a review of additional data indicating that: (a) Parental weight gain reductions of the low (300 ppm) and middle-dose (1,500 ppm) groups were sporadic and were not considered to be of biological significance; this is supported by the view of an FDA pathologist, (b) the mean parental body weight gains of the 7,500 ppm group males and females decreased more than 10% throughout the growth phase, when compared to the controls and appeared to be treatment-related, (c) body weight reductions of F1 generation males and females were inconsistent and did not exceed 10%; therefore body weight gains of F1 generation progeny could not be used to establish toxicological endpoints for setting the LOEL, (d) food efficiency of F1 generation and mean body weights of pups at birth were not affected by the treatment, (e) body weight gain reduction in pups of F1 and F2 were significantly reduced on days 14 and 21 at 7500 ppm when compared to controls, and (f) reduced conception rates in the F0 at the low- and high-dose levels were not treatment-related.

4. *Developmental Toxicity.* Following a reevaluation of the submitted data, the Agency has altered its earlier conclusion characterizing the post-implantation loss observed in the rabbit developmental toxicity study as developmental toxicity. As a result, the Agency is revising the developmental toxicity NOEL from 30 mg/kg/day to 90 mg/kg/day, the highest dose tested in rabbits. The observed developmental toxicity effects were maternal weight loss at the highest dose tested, 90 mg/kg/day. While the test material involved a mixture of R,*S*-hydroprene racemers, there were no adverse signs of development toxicity at the highest dosage levels.

5. *Subchronic toxicity.* A 3–month feeding study in rats resulted in a determination of lowest effect level (LEL) = 250 mg/kg/day and NOEL = 50 mg/kg/day. Vacuolated ovarian luteal cells were observed in females as were microscopic findings of homogeneous cytoplasm in male and in female hepatocytes. In a 28-day feeding study in rats, the LEL was 500 mg/kg/day and NOEL = 250 mg/kg/day. Observed was an increase in the kidney to brain weight ration and an increase in absolute kidney weight.

6. *Chronic toxicity.* In a previous review of the chronic toxicity phase of the rat study, the overall NOEL was considered to be 100 ppm (4.62 mg/kg/day in females), the lowest dose tested and was based on the observance of cytoplasmic vacuolization in the ovaries. However, the Agency now concludes that the cytoplasmic vacuolization observed in the ovaries is a result of cellular overload of inert endogenous products synthesized from hydroprene metabolites and thus constitutes no toxicological significance. This explanation is supported by an FDA pathologist (June 8, 1995 memo RfD/QA Peer Review Committee).

As a result of this finding (toxicological insignificance of the ovarian changes), the NOEL and LOEL are now 1,000 and 10,000 ppm, respectively, instead of 100 and 1,000 ppm. The NOEL and LOEL are based on reduced body weight gains in males and females, pancreatic arteritis in males, and increased incidence of syncytial macrophage aggregated in cervical lymph nodes and deep cholesterol clefts and cortical fatty vacuolization in the adrenals in females.

With respect to carcinogenicity, EPA used its Guidelines for Carcinogen Risk Assessment published September 24, 1986 (51 FR 33992). EPA has classified (*S*)-hydroprene as a Group ''D'' compound - not classifiable as to human carcinogenicity. In a previous review of the carcinogenicity phase of the rat study, the Agency noted that the incidence of thyroid follicular cell adenomas appeared to be increased in males of the highest dose group but never classified the compound with regard to its human carcinogenicity potential. The Agency, in a reconsideration of the findings, including the absence of a carcinogenicity study involving a second species, and the equivocal nature of the findings from the rat study, has now concluded that the data set presented is only suggestive of a carcinogenic response. *S*-hydroprene, therefore, should be classified as a ''Group D'' compound - not classifiable as to human carcinogenicity. The conclusion, as drawn from the rat study, is based on the following: (i) there was no increase in the incidence of carcinomas; the incidence of carcinomas in male groups were 6, 6, 2, 0 and 8%, respectively, in control group 1, control group 2, 100 ppm, 1,000 ppm and 10,000 ppm groups, (ii) there was no treatment-related increase in precancerous histopathological changes such as hyperplasia, (iii) the compound was not associated with a positive mutagenic response in several bioassay systems, (iv) the compound is not structurally related to any known carcinogen, and (v) the compound is a structural analog to methoprene, a pesticidal compound that has been adequately tested and did not demonstrate mutagenic or carcinogenic properties and has been found to be extensively metabolized via beta oxidation and, almost totally incorporated into components of the tricarboxylic acid cycle.

7. *Reference dose.* As a result of the recent findings, the Agency is revising the RfD from 0.05 mg/kg/day to 0.1 mg/kg/day based on the chronic toxicity in rats. Previously, in a February 2, 1994 meeting of the RfD/QA Peer Review Committee, the Agency tentatively based the RfD for this chemical on the two-generation reproduction study in rats with a NOEL of 15 mg/kg/day for parental and reproductive toxicity (June

8, 1995 memo RfD/QA Peer Review Committee). Parental and reproductive toxicity manifested as increased liver weight and increased incidence of cytoplasmic vacuolization of the ovaries in the F1 were observed at 75 mg/kg/day and higher dose levels. The rat chronic toxicity study was considered as a co-critical study with a NOEL of 4.62 mg/kg/day and a lowest effect level of 45.7 mg/kg/day. Similar effects were observed in this study. Although the chronic toxicity study in rats demonstrated a slightly lower NOEL than the reproductive toxicity study, the Agency considered the findings of the reproductive study to be more reliable. An uncertainty factor (UF) of 100 was used to account for inter-species extrapolation and intra-species variability. An additional UF of 3 was used to account for the lack of chronic toxicity data on a non-rodent species. On this basis, the RfD was calculated to be 0.05 mg/kg/day.

However, as a result of an April 20, 1995 reassessment meeting, the Agency has now determined that the RfD should be based on the chronic toxicity study in rats with a NOEL of 1,000 (36.2 and 45.7 mg/kg/day for males and females, respectively) (June 8, 1995 memo RfD/QA Peer Review Committee). Significantly decreased cumulative body weight gains in males (18%) and females (20.6%) during growth phase (0 to 80 weeks), syncytial macrophage aggregates in cervical lymph nodes, deep cholesterol clefts and cortical fatty vacuolization in the adrenals of females and pancreatic arteritis in males were observed at the next higher dose level of 10,000 ppm (377 and 485 mg/kg/day for males and females, respectively). A UF of 100 was used to account for inter-species extrapolation and intra-species variability. An additional UF of 3 was used to account for the lack of toxicity data on a non-rodent species.

On the basis of the forementioned studies, the RfD is calculated to be 0.1 mg/kg/day.

8. *Animal metabolism.* A rat metabolism study using a mixture of 2*E*/4*E* and 2Z/4*E* isomers was submitted. About 13% is retained in the carcasses of both males and female rats. Hydroprene concentration in the plasma peaked at 5 to 7 hours. Elimination was biphasic. The half-life of the second phase took place 2 to 10 days after dosing. In a 54 hour period, the highest residues were found after 6 hours, with highest levels found in the liver, fat and adrenal glands. The Agency has now classified (*S*)-hydroprene as a biochemical and therefore, metabolism data are normally not required by the Agency due to the non-toxic mode of action.

9. *Metabolite toxicology.* No metabolites have been identified for (*S*)-hydroprene. No metabolite toxicity studies are required for this pesticide which is presently classified as a biochemical.

D. Aggregate Exposure

In examining aggregate exposure, FQPA directs EPA to consider available information concerning all routes of exposures from the pesticide residue in the diet, including drinking water, and all other non-occupational exposures. The primary non dietary routes of exposures are exposure through pesticide use in gardens, lawns, or buildings (residential and other indoor uses).

1. *Dietary exposure*— a. *Food.* As indicated in earlier in this document, reviewed data indicate that (*S*)-hydroprene residue levels are below the tolerance level under worse-case scenarios.

b. *Drinking water.* Because the use pattern for (*S*)-hydroprene involves only indoor uses, EPA does not anticipate any exposure to result from residues of (*S*)-hydroprene in drinking water. Furthermore, the chemical is not readily water-soluble.

2. *Non-dietary exposure.* With regard to non-dietary exposure, the current registrations for (*S*)-hydroprene permits its use in cafeterias, supermarkets, as well as kitchens in households. For general surface treatments, the sprays must be allowed to dry before ventilation is turned back on. Under these conditions, the risk from non-dietary exposure to the general population is, thus, expected to be negligible.

E. Cumulative Exposure to Substances with Common Mechanism of Toxicity

Section 408(b)(2)(D)(v) requires that, when considering whether to establish, modify, or revoke a tolerance, the Agency consider ''available information'' concerning the cumulative effects of a particular pesticide's residues and ''other substances that have a common mechanism of toxicity.'' The Agency believes that ''available information'' in this context might include not only toxicity, chemistry, and exposure data, but also scientific policies and methodologies for understanding common mechanisms of toxicity and conducting cumulative risk assessments. For most pesticides, although the Agency has some information in its files that may turn out to be helpful in eventually determining whether a pesticide shares a common mechanism of toxicity with any other substances, EPA does not at this time have the methodologies to resolve the complex scientific issues concerning common mechanism of toxicity in a meaningful way. EPA has begun a pilot process to study this issue further through the examination of particular classes of pesticides. The Agency hopes that the results of this pilot process will increase the Agency's scientific understanding of this question such that EPA will be able to develop and apply scientific principles for better determining which chemicals have a common mechanism of toxicity and evaluating the cumulative effects of such chemicals. The Agency anticipates, however, that even as its understanding of the science of common mechanisms increases, decisions on specific classes of chemicals will be heavily dependent on chemical specific data, much of which may not be presently available.

Although at present the Agency does not know how to apply the information in its files concerning common mechanism issues to most risk assessments, there are pesticides as to which the common mechanism issues can be resolved. These pesticides include pesticides that are toxicologically and structurally dissimilar to existing chemical substances (in which case the Agency can conclude that it is unlikely that a pesticide shares a common mechanism of activity with other substances) and pesticides that produce a common toxic metabolite (in which case common mechanism of activity will be assumed).

F. Safety Determinations

1. *U.S. population.* In general, using conservative exposure assumptions described earlier, and, based on the completeness and reliability of the toxicity data, EPA has concluded that aggregate exposure to (*S*)-hydroprene will utilize 6.8 percent of the RfD for the U.S. population. It should be noted that there will be no exposure issues for (*S*)-hydroprene residues in drinking water since this biochemical pesticide is not used outdoors. EPA generally has no concern for exposures below 100 percent of the RfD because the RfD represents the level at or below which daily aggregate dietary exposure over a lifetime will not pose appreciable risks to human health. EPA concludes that there is a reasonable certainty that no harm will result from aggregate exposure to *S*-hydroprene residues. There is no reason to believe that (*S*)-hydroprene possesses any immunotoxic or estrogenic properties at this time.

2. *Infants and children.* FFDCA section 408 provides that EPA shall

apply an additional tenfold margin of exposure (safety) for infants and children in the case of threshold effects to account for pre- and post-natal toxicity and the completeness of the database unless EPA determines that a different margin of exposure (safety) will be safe for infants and children. EPA believes that reliable data support using the standard margin of exposure (usually 100X for combined inter- and intra-species variability) and not the additional tenfold margin of exposure when EPA has a complete data base under existing guidelines and when the severity of the effect in infants or children or the potency or unusual toxic properties of a compound do not raise concerns regarding the adequacy of the standard margin of exposure.

In assessing the potential for additional sensitivity of infants and children to residues of (*S*)-hydroprene, EPA considered data from a 2-generation reproduction study in the rat and developmental toxicity studies in the rat and rabbit.

Reproduction studies provide information relating to effects from exposure to the pesticide on the reproductive capability of mating animals and data on systemic toxicity. As detailed in a previous paragraph in the toxicological profile section of this document, with regard to the reproductive toxicity potential for (*S*)-hydroprene, the Agency has concluded that the observed parental weight gain reductions of the low (300 ppm) and middle-dose (1,500 ppm) groups were sporadic and were not considered to be of biological significance. At the highest dose tested, 7,500 ppm, there were no reproductive toxicity effects other than a less than severe reduction in body weight gain in pups of F1 and F2 on days 14 and 21.

The developmental toxicity studies are designed to evaluate adverse effects on the developing organism resulting from pesticide exposure during prenatal development to one or both parents. As discussed in the toxicology section, the Agency has set the developmental toxicity NOEL at 90 mg/kg/day, the highest dose tested in rabbits. There was no developmental effect on the pups observed at the highest dose tested in the study.

Based on the current toxicological data requirements, the database relative to pre- and post-natal effects for children is more than adequate for this biochemical pesticide. The data from the reproductive and developmental toxicity tests do not suggest additional sensitivity for infants and children. Therefore, EPA concludes that an additional uncertainty factor is not warranted for (*S*)-hydroprene. EPA concludes that reliable data support the use of a 300-fold uncertainty factor as providing an adequate margin of safety for infants and children. Using the conservative exposure assumptions described above, EPA has determined that the percent of the RfD that will be utilized by aggregate exposure to residues of (*S*)-hydroprene ranges from 6.9 percent for nursing infants less than 1 year old to, 20.9 percent for non-nursing infants less than 1 year old to 13.4 percent for children 7 to 12 years old. Therefore, based on the completeness and reliability of the toxicity data and the conservative exposure assessment, EPA concludes that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to (*S*)-hydroprene residues.

G. International Tolerances

There is no CODEX tolerance or any other international tolerance at this time.

H. Other Considerations

The Agency does not conduct acute dietary risk analyses for tolerances involving food handling establishments. It is the opinion of the Science Advisory Panel and the Agency that the calculations would result in a gross overestimation of acute dietary risk. In any case, there are no acute endpoints of concern for (*S*)-hydroprene.

The proposed tolerance amendment has been jointly reviewed per a Memorandum of Understanding between the California Environmental Protection Agency (CalEPA) and the Agency. CalEPA has also concluded that the proposed tolerance amendments present minimal toxicological concern.

I. Conclusion

Consistent with section 408(b)(2)(D), EPA has reviewed the available scientific data and other relevant information in support of this action. Based on the information and data considered, the Agency has determined that, in amending 40 CFR part 185, as proposed, there is reasonable certainty that no harm to the general population will result from aggregate exposure to the pesticide chemical residue.

IV. Public Docket

The official record for this rulemaking, as well as the public version, has been established for this rulemaking under docket control number [OPP–300475] (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 rulemaking record is located at the Virginia 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 [OPP–300475]. Electronic comments on this proposed rule may be filed online at many Federal Depository Libraries.

V. Regulatory Assessment Requirements

This action proposes to establish a tolerance under section 408 ofthe FFDCA. The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Order 12866, entitled Regulatory Planning and Review (58 FR 51735, October 4, 1993). In addition, this proposed rule does not contain any information collections subject to OMB approval under the Paperwork Reduction Act (PRA), 44 U.S.C. 3501 et seq., or impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act of 1995 (UMRA) (Pub. L. 104-4). Nor does it require any prior consultation as specified by Executive Order 12875, entitled Enhancing the Intergovernmental Partnership (58 FR 58093, October 28, 1993), or special considerations as required by Executive Order 12898, entitled Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations (59 FR 7629, February 16, 1994), or require special OMB review in accordance with Executive Order 13045, entitled Protection of Children from Environmental Health Risks and Safety Risks (62 FR 19885, April 23, 1997).

In addition, pursuant to the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 et seq.), the Agency previously assessed whether establishing tolerances, exemptions from tolerances, raising tolerance levels or expanding exemptions might adversely impact small entities and concluded, as a generic matter, that there is no adverse economic impact (46 FR 24950, May 4, 1981). In accordance

with Small Business Administration (SBA) policy, this determination will be provided to the Chief Counsel for Advocacy of the SBA upon request.

List of Subjects

40 CFR Part 180

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

40 CFR Part 185

Environmental protection, Food additives, Pesticides and pests.

Dated: May 22, 1997.

Janet L. Andersen,

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

Therefore, 40 CFR Chapter I is proposed to be amended as follows:

PART 180—[AMENDED]

In part 180:

a. The authority citation for part 180 continues to read as follows:

Authority: 21 U.S.C. 346a and 348.

b. Section 180.501 is added to read as follows:

§ 180.501 Hydroprene; tolerances for residues.

A tolerance of 0.2 part per million is established for residues of hydroprene [(*S*)-(Ethyl (2*E*,4*E*,7*S*)-3,7,11 trimethyl-2,4-dodecadienoate)], (CAS Reg. NO. 65733–18–8)# on all food items in food-handing establishments in accordance with the following prescribed conditions:

(a) Application shall be limited to spot, crack and crevice, perimeter and ultra low volume (ULV) fogging treatment in food storage or food-handling establishments, including warehouses, food service, manufacturing, and processing establishments such as restaurants, cafeterias, supermarkets, bakeries, breweries, dairies, meat slaughtering and packing plants, and canneries where food and food products are held, processed, and served: Provided that the food is removed or covered prior to such use, and food-processing surfaces are covered during treatment or thoroughly cleaned before using, or in the case of point-source device treatments, devices must not come into direct contact with food preparation surfaces and must be in a minimum distance of 3 feet from exposed foods.

(b) To assure safe use of the insect growth regulator, the label and labeling shall conform to that registered by the U.S. Environmental Protection Agency, and it shall be used in accordance with such label and labeling.

PART 185—[AMENDED]

In part 185:

a. The authority citation for part 185 continues to read as follows:

Authority: 21 U.S.C. 346a and 348.

§ 185.3625 [Removed]

b. Section 185.3625 is removed.

[FR Doc. 97–14298 Filed 6–3–97; 8:45 am]

BILLING CODE 6560–50–F

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 300

[FRL–5830–9]

National Oil and Hazardous Substance Pollution Contingency Plan

National Priorities List

AGENCY: Environmental Protection Agency.

ACTION: Notice of intent to delete the Bayou Sorrel Superfund Site from the National Priorities List and request for comments.

SUMMARY: The Environmental Protection Agency (EPA) Region 6 announces its intent to delete the Bayou Sorrel Superfund Site (Site) from the National Priorities List (NPL) and requests public comment on this proposed action. The NPL, promulgated pursuant to Section 105 of the Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA) of 1980, as amended, constitutes Appendix B of 40 CFR Part 300 which is the National Oil and Hazardous Substances Pollution Contingency Plan (NCP). EPA and the State of Louisiana, through the Louisiana Department of Environmental Quality (LDEQ), have determined that the Site poses no significant threat to public health, welfare, or the environment and, therefore, further remedial measures pursuant to CERCLA are not appropriate.

DATES: The EPA will accept comments concerning its proposal to delete this Site from the NPL until July 7, 1997.

ADDRESSES: Comments may be mailed to: Mr. Verne McFarland, Community Relations Coordinator (6SF–P), U.S. Environmental Protection Agency, Region 6, 1445 Ross Avenue, Dallas, Texas 75202–2733, (214) 665–6617.

Information Repositories: Comprehensive information on the Site is available through the public docket which is available for viewing at the Bayou Sorrel Superfund Site information repositories at the following locations:

U.S. EPA Region 6 Library (12th Floor), 445 Ross Avenue, Dallas, Texas 75202–2733, (214) 665–6424 / 665–6427.

Louisiana Department of Environmental Quality, 290 Bluebonnet Road, Baton Rouge, Louisiana 70809, (504) 765–0487.

Police Jury of Iberville Parish, 10 Meriam, Plaquemine, LA 70765, (504) 687–5190.

Iberville Parish Library, 501 J. Gerald Berret Blvd., Plaquemine, LA 70765, (504) 687–2520.

FOR FURTHER INFORMATION CONTACT: Mr. Stephen L. Tzhone, Remedial Project Manager (6SF–LP), U.S. Environmental Protection Agency, Region 6, 1445 Ross Avenue, Dallas, Texas 75202–2733, (214) 665–8409.

SUPPLEMENTARY INFORMATION:

Table of Contents

I. Introduction

The Environmental Protection Agency (EPA) Region 6 announces its intent to delete the Bayou Sorrel Superfund Site (Site) from the National Priorities List (NPL), Appendix B of the National Oil and Hazardous Substances Pollution Contingency Plan (NCP), Code of Federal Regulations, Title 40 (40 CFR), Part 300, and request comments on the proposed deletion. The EPA identifies sites that appear to present a significant risk to public health, welfare, or the environment and maintains the NPL as the list of those sites. As described in section 300.425(e)(3) of the NCP, sites deleted from the NPL remain eligible for remedial actions in the unlikely event that conditions at the site warrant such action.

The EPA will accept comments concerning its intent to delete for thirty (30) days after publication of this document in the **Federal Register** and a newspaper of record.

Section II of this document explains the criteria for deleting sites from the NPL. Section III discusses procedures that EPA is using for this action. Section IV discusses the Bayou Sorrel. Superfund Site and how the Site meets the deletion criteria.