

otherwise interfering with an action taken or planned by another agency; (3) materially altering the budgetary impacts of entitlement, grants, user fees, or loan programs; or (4) raising novel legal or policy issues arising out of legal mandates, the President's priorities, or the principles set forth in this Executive Order.

Pursuant to the terms of this Executive Order, EPA has determined that this rule is not "significant" and is therefore not subject to OMB review.

Pursuant to the requirements of the Regulatory Flexibility Act (Pub. L. 96-354, 94 Stat. 1164, 5 U.S.C. 601-612), the Administrator has determined that regulations establishing new tolerances or raising tolerance levels or establishing exemptions from tolerance requirements do not have a significant economic impact on a substantial number of small entities. A certification statement to this effect was published in the **Federal Register** of May 4, 1981 (46 FR 24950).

List of Subjects in 40 CFR Part 180

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

Dated: March 8, 1995.

Stephen L. Johnson,

Director, Registration Division, Office of Pesticide Programs.

Therefore, it is proposed that 40 CFR part 180 be amended as follows:

PART 180—[AMENDED]

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

Authority: 21 U.S.C. 346a and 371.

2. In § 180.447, by adding new paragraph (d), to read as follows:

§ 180.447 Imazethapyr, ammonium salt; tolerance for residues.

* * * * *

(d) Tolerances with regional registration, as defined in § 180.1(n) of this chapter, are established for the sum of residues of the herbicide imazethapyr, 2-[4,5-dihydro-4-methyl-4-(1-methylethyl)-5-oxo-1H-imidazol-2-yl]-5-ethyl-3-pyridine carboxylic acid, as its ammonium salt, and its metabolite, 2-[4,5-dihydro-4-methyl-4-(1-methylethyl)-5-oxo-1H-imidazol-2-yl]-5-(1-hydroxyethyl)-3-pyridine carboxylic acid, both free and conjugated, in or on the following raw agricultural commodities:

Commodity	Parts per million
Endive (escarole)	0.1
Lettuce (head and leaf)	0.1

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BILLING CODE 6560-50-F

40 CFR Part 180

[OPP-300380; FRL-4936-4]

RIN 2070-AC18

Acetic Acid Ethenyl Ester, Polymer with Ethenol and (α)-2-Propenyl-(ω)-Hydroxypoly(Oxy-1,2-Ethanediy); Tolerance Exemption

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: This document proposes to establish an exemption from the requirement of a tolerance for residues of acetic acid ethenyl ester, polymer with ethenol and (α)-2-propenyl-(ω)-hydroxypoly(oxy-1,2-ethanediy) (CAS Reg. No. 137091-12-4), when used as an inert ingredient (component of water-soluble film) in pesticide formulations applied to growing crops only under 40 CFR 180.1001(d). Japan Technical Information Center, Inc., requested this proposed regulation on behalf of Nippon Gohsei (U.S.A.) Co., Ltd.

DATES: Written comments, identified by the document control number, [OPP-300380], must be received on or before April 21, 1995.

ADDRESSES: By mail, submit written comments to Public Response and Program Resources Branch, Field Operations Division (7506C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. In person, bring comments to: Rm. 1132, CM #2, 1921 Jefferson Davis Hwy., 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. All written comments will be available for public inspection in Rm. 1132 at the address given above, from 8 a.m. to 4 p.m.,

Monday through Friday, excluding legal holidays.

FOR FURTHER INFORMATION CONTACT:

Kerry Leifer, Registration Support Branch, Registration Division (7505W), Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. Office location and telephone number: 2800 Crystal Drive, North Tower, 6th Floor, Arlington, VA 22202, (703) 308-8323.

SUPPLEMENTARY INFORMATION: Japan Information Center, Inc., 775 South 23rd St., Arlington, VA 22202, on behalf of Nippon Gohsei (U.S.A.) Co., Ltd., submitted pesticide petition (PP) 4EO4403 to EPA requesting that the Administrator, pursuant to section 408(e) of the Federal Food Drug, and Cosmetic Act (FFDCA) (21 U.S.C. 346a(e)), propose to amend 40 CFR 180.1001(d) by establishing an exemption from the requirement of a tolerance for residues of acetic acid ethenyl ester, polymer with ethenol and (α)-2-propenyl-(ω)-hydroxypoly(oxy-1,2-ethanediy) (CAS Reg. No. 137091-12-4), when used as an inert ingredient (component of water-soluble film) in pesticide formulations applied to growing crops only under 40 CFR 180.1001(d).

Inert ingredients are all ingredients that are not active ingredients as defined in 40 CFR 153.125, and include, but are not limited to, the following types of ingredients (except when they have a pesticidal efficacy of their own): solvents such as alcohols and hydrocarbons; surfactants such as polyoxyethylene polymers and fatty acids; carriers such as clay and diatomaceous earth; thickeners such as carrageenan and modified cellulose; wetting, spreading, and dispersing agents; propellants in aerosol dispensers; microencapsulating agents; and emulsifiers. The term "inert" is not intended to imply nontoxicity; the ingredient may or may not be chemically active.

The data submitted in the petition and other relevant material have been evaluated. As part of the EPA policy statement on inert ingredients published in the **Federal Register** of April 22, 1987 (52 FR 13305), the Agency set forth a list of studies which would generally be used to evaluate the risks posed by the presence of an inert ingredient in a pesticide formulation. However, where it can be determined without that data that the inert ingredient will present minimal or no risk, the Agency generally does not require some or all of the listed studies to rule on the proposed tolerance or exemption from the requirement of a tolerance for an

inert ingredient. The Agency has decided that no data, in addition to that described below, for acetic acid ethenyl ester, polymer with ethenol and (α)-2-propenyl-(ω)-hydroxypoly(oxy-1,2-ethanediyl) will need to be submitted. The rationale for this decision is described below.

In the case of certain chemical substances that are defined as "polymers," the Agency has established a set of criteria which identify categories of polymers that present low risk. These criteria (described in 40 CFR 723.250) identify polymers that are relatively unreactive and stable compared to other chemical substances as well as polymers that typically are not readily absorbed. These properties generally limit a polymer's ability to cause adverse effects. In addition, these criteria exclude polymers about which little is known. The Agency believes that polymers meeting the criteria noted above will present minimal or no risk. Acetic acid ethenyl ester, polymer with ethenol and (α)-2-propenyl-(ω)-hydroxypoly(oxy-1,2-ethanediyl) conforms to the definition of a polymer given in 40 CFR 723.250(b)(11) and meets the following criteria that are used to identify low-risk polymers.

1. The minimum number-average molecular weight of acetic acid ethenyl ester, polymer with ethenol and (α)-2-propenyl-(ω)-hydroxypoly(oxy-1,2-ethanediyl) is 15,000. Substances with molecular weights greater than 400 generally are not absorbed through the intact skin, and substances with molecular weights greater than 1,000 generally are not absorbed through the intact gastrointestinal tract. Chemicals not absorbed through skin or GI tract generally are incapable of eliciting a toxic response.

2. Acetic acid ethenyl ester, polymer with ethenol and (α)-2-propenyl-(ω)-hydroxypoly(oxy-1,2-ethanediyl) is not a cationic polymer, nor is it reasonably expected to become a cationic polymer in a natural aquatic environment.

3. Acetic acid ethenyl ester, polymer with ethenol and (α)-2-propenyl-(ω)-hydroxypoly(oxy-1,2-ethanediyl) does not contain less than 32.0 percent by weight of the atomic element carbon.

4. Acetic acid ethenyl ester, polymer with ethenol and (α)-2-propenyl-(ω)-hydroxypoly(oxy-1,2-ethanediyl) contains as an integral part of its composition the atomic elements carbon, hydrogen, nitrogen, and oxygen.

5. Acetic acid ethenyl ester, polymer with ethenol and (α)-2-propenyl-(ω)-hydroxypoly(oxy-1,2-ethanediyl) does not contain as an integral part of its composition, except as impurities, any elements other than those listed in 40 CFR 723.250(d)(3)(ii).

6. Acetic acid ethenyl ester, polymer with ethenol and (α)-2-propenyl-(ω)-hydroxypoly(oxy-1,2-ethanediyl) is not a biopolymer, a synthetic equivalent of a biopolymer, or a derivative or modification of a biopolymer that is substantially intact.

7. Acetic acid ethenyl ester, polymer with ethenol and (α)-2-propenyl-(ω)-hydroxypoly(oxy-1,2-ethanediyl) is not manufactured from reactants containing, other than impurities, halogen atoms or cyano groups.

8. Acetic acid ethenyl ester, polymer with ethenol and (α)-2-propenyl-(ω)-hydroxypoly(oxy-1,2-ethanediyl) does not contain a reactive functional group that is intended or reasonably expected to undergo further reaction.

9. Acetic acid ethenyl ester, polymer with ethenol and (α)-2-propenyl-(ω)-hydroxypoly(oxy-1,2-ethanediyl) is neither designed nor reasonably expected to substantially degrade, decompose, or depolymerize.

Based on the information above and review of its use, EPA has found that, when used in accordance with good agricultural practice, this ingredient is useful, and a tolerance is not necessary to protect the public health. Therefore, EPA proposes that the exemption from the requirement of a tolerance be established as set forth below.

Any person who has registered or submitted an application for registration of a pesticide, under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) as amended, that contains any of the ingredients listed herein, may request within 30 days after the publication of this document in the **Federal Register** that this rulemaking proposal be referred to an Advisory

Committee in accordance with section 408(e) of the FFDCA.

Interested persons are invited to submit written comments on the proposed regulation. Comments must bear a notation indicating the document control number, [OPP-300380]. All written comments filed in response to this petition will be available in the Public Response and Program Resources Branch, at the address given above, from 8 a.m. to 4 p.m., Monday through Friday, except legal holidays.

The Office of Management and Budget has exempted this rule from the requirements of section 2 of Executive Order 12866.

Pursuant to the requirement of the Regulatory Flexibility Act (Pub. L. 96-354, 94 Stat. 1164, 5 U.S.C. 601-612), the Administrator has determined that regulations establishing new tolerances or raising tolerance levels or establishing exemptions from tolerance requirements do not have an economic impact on a substantial number of small entities. A certification statement to this effect was published in the **Federal Register** of May 4, 1981 (46 FR 24950).

List of Subject in 40 CFR Part 180

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

Dated: March 8, 1995.

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

Therefore, it is proposed that 40 CFR part 180 be amended as follows:

PART 180—[AMENDED]

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

Authority: 21 U.S.C. 346a and 371.

2. Section 180.1001(d) is amended in the table therein by adding and alphabetically inserting the inert ingredient, to read as follows:

§ 180.1001 Exemptions from the requirement of a tolerance.

* * * * *
(d) * * *

Inert ingredient	Limits	Uses
* * *	* * *	* * *
Acetic acid ethenyl ester, polymer with ethenol and (α)-2-propenyl-(ω)-hydroxypoly(oxy-1,2-ethanediyl) (CAS Reg. No. 137091-12-4); minimum number average molecular weight 15,000.	Component of water-soluble film.
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[FR Doc. 95-6933 Filed 3-21-95; 8:45 am]

BILLING CODE 6560-50-F

40 CFR Parts 180, 185, and 186

[FAP 4H5683/P600; FRL-4935-1]

RIN 2070-AC18

Hexazinone; Pesticide Tolerances and Food/Feed Additive Regulations

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: This document proposes to amend the current tolerance for residues of the herbicide hexazinone (3-cyclohexyl-6-(dimethylamino)-1-methyl-1,3,5-triazine-2,4-(1*H*,3*H*)-dione and its metabolites (calculated as hexazinone) in or on sugarcane at 0.2 part per million (ppm) by revoking the current tolerance and reestablishing the same tolerance with regional registration and tolerance as described by 40 CFR 180.1(n). EPA also proposes to establish food and feed additive regulations for residues of hexazinone and its metabolites (calculated as hexazinone) in sugarcane molasses at 0.5 ppm. E. I. du Pont de Nemours & Co., Inc., requested these proposed regulations.

DATES: Written comments, identified by the document control number [FAP 4H5683/P600], must be received on or before April 21, 1995.

ADDRESSES: By mail, submit written comments to: Public Response Section, Field Operations Division (7506C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. In person, bring comments to: Rm. 1132, CM #2, 1921 Jefferson Davis Hwy., 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 may be disclosed publicly by EPA without prior notice. All written comments will be available for public inspection in Rm. 1132 at the Virginia address given above, from 8 a.m. to 4 p.m., Monday through Friday, excluding legal holidays.

FOR FURTHER INFORMATION CONTACT: By mail: Joanne I. Miller, Product Manager (PM) 23, Registration Division (7505C), Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. Office location and telephone number: Rm. 237, CM #2, 1921 Jefferson Davis Hwy., Arlington, VA 22202, (703-305-7830).

SUPPLEMENTARY INFORMATION: E.I. du Pont de Nemours & Co., Inc., has requested a regional registration for the use of hexazinone end-use pesticide products for the use site, sugarcane. The company proposed that the use-site exclude the State of Florida, because the product is not efficacious in muck soils at dosages that would be economically viable to growers. The company has stated that the rate needed for weed control in the typically high organic soil of Florida used for the culture of sugarcane would exceed the maximum labelled dosage. In addition, the company also stated that the high rates would not be economically viable considering other less expensive, lower application rate products. Based on the information submitted, the company has proposed a geographically limited registration for use of hexazinone in sugarcane. In this case, the company contends that there is little likelihood for the use of hexazinone in the State of Florida and that its residue data are representative of all sugarcane-growing areas of the United States.

Published information on acres of sugarcane grown in the State of Florida on other than organic soils (Spodosols, Entisols, Mollisols) was 11.1% of a total of 464,191 acres in 1993 (Sugar Y Azucar 89:(1): 39-44). EPA has no data on potential residues of hexazinone when used in the culture of sugarcane commodities from studies with sugarcane cultured in the State of Florida. Residue chemistry data from a Florida study are required to allow the unrestricted use of hexazinone in the culture of sugarcane.

EPA issued a notice, published in the **Federal Register** of July 13, 1994 (59 FR 35179), which announced that E.I. Du Pont de Nemours & Co., Inc., had submitted food additive petition (FAP) 4H5683 to EPA requesting that the Administrator, pursuant to section 409 of the Federal Food, Drug and Cosmetic Act (FFDCA), 21 U.S.C. 346a(e), amend 40 CFR parts 185 and 186 by establishing tolerances for residues of the herbicide hexazinone (3-cyclohexyl-6-(dimethylamino)-1-methyl-1,3,5-triazine-2,4-(1*H*,3*H*)-dione) in or on sugarcane molasses at 5.0 ppm and sugarcane bagasse at 0.5 ppm. Sugarcane bagasse is not currently

considered a food or a feed commodity by EPA; therefore, the requested tolerance is not proposed to be established in this document.

There were no comments received in response to the notice of filing. The scientific data submitted with the petition and other relevant material have been evaluated. The toxicological and residue chemistry data considered in support of the proposed actions include the following:

1. Plant and animal metabolism studies.
2. Enforcement methodology for determining residues.
3. A 90-day feeding study with rats, with a NOEL of 50 mg/kg/day and an LEL of 150 mg/kg/day with the effect being decreased body weights in both sexes.
4. A 90-day feeding study with dogs, with a NOEL of 25 mg/kg/day, increase alkaline phosphatase, decreased albumin/globulin, and increased absolute and relative liver weights in both sexes.
5. A 21-day dermal study in rabbits, with a NOEL of 1,000 mg/kg/day, the highest dose tested (HDT).
6. A 12-month chronic feeding study with dogs, with a NOEL of 5.0 mg/kg/day and a lowest effect level (LEL) of 37.5 mg/kg/day with thinness in one male dog, increased alkaline phosphatase in males, decrease albumin and increased globulin in males, pale kidneys in one female, and increased incidence of hepatocellular vacuolation in males, and cytoplasmic inclusions and pigmented Kupffer cells in the livers of females.
7. A 24-month carcinogenicity study in mice that was equivocal for adenomas/carcinomas, with no statistical significance in pair-wise comparison between control and dosed animals; systemic NOEL of 30 mg/kg/day and systemic LEL of 375 mg/kg/day.
8. A developmental toxicity study with rats, with a maternal NOEL of 100 mg/kg/day and maternal LEL of 400 mg/kg/day; a developmental NOEL of 100 mg/kg/day and developmental LEL of 400 mg/kg/day (decreased fetal body weight, increased incidence of fetuses with no kidney papilla, and increased incidence of fetus with unossified sternbrae).
9. A developmental toxicity study in rabbits, with a maternal NOEL of 50 mg/kg/day and a maternal LEL of 125 mg/kg/day (decreased body weight gains, increased resorptions and increased clinical signs); and with a developmental NOEL of 50 mg/kg/day and a developmental LEL of 125 mg/kg/day (decreased body weight and delayed ossifications of extremities).