

operators have continued to rely on the Gralin form to fulfill their SOA reporting and filing requirement under Section 111. Given that the Gralin form had been made available well in advance of the first day of the 60-day filing period in years past, operators had reasonably expected that it would be ready to use at or about the same time this year. However, through no fault of their own, the cable operators relying on Gralin did not have access to the revised Gralin form until August 6 this year, reducing to about three weeks the time they would have had to process and file their forms in the absence of a waiver. We recognize that complying with the existing deadline would be an arduous, and perhaps insurmountable task, for many cable operators particularly those who would have to file hundreds of forms during these last three weeks.

Further, as NCTA indicates, there are still minor problems with the Gralin software that have been discovered after its official release on August 6th. Cable operators should not be held accountable for matters beyond their control. The grant of the requested waiver will permit Gralin an additional amount of time to fix the problems with its software so that the SOA filings will be both accurate and complete.<sup>8</sup>

We also agree with NCTA when it states that additional time will help operators accurately complete their SOA filings, thus reducing the need to file supplemental or amended SOAs. It is evident that providing sufficient time so operators can make that single filing will alleviate burdens on the cable industry as well as the Copyright Office and produce more accurate filings. In this context, a waiver will serve the interest of the public because it will reduce unnecessary paperwork and further the efficient administration and processing of the incoming SOAs.

NCTA has also indicated that copyright owner groups would not oppose a thirty day extension of the filing deadline, and the Office has received confirmation from representatives of the copyright owner groups that this is the case. On this point, we note that the Office is waiving a procedural deadline and not a substantive royalty requirement. Cable operators will still be paying the royalties that are due under the Section 111 framework, albeit under a modified timeline. Thus, in light of the problems associated with providing forms and the lack of any opposition from those who

have a direct stake in the filing of the statements of account and the timely receipt of royalty payments, the Office perceives no reason to deny the request.

Finally, we note that waivers are rarely granted by the Office. However, the action taken today is necessary because of unique, extenuating circumstances.<sup>9</sup>

We hereby waive Section 201.17(c)(1) and extend the date for filing cable statements of account to September 29, 2010. Accordingly, interest will be assessed pursuant to Section 201.17(i)(4) for late payments made *after* September 29, 2010.

Dated: August 18, 2010

**Marybeth Peters,**

*Register of Copyrights,*

*U.S. Copyright Office.*

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**BILLING CODE 1410-30-S**

## ENVIRONMENTAL PROTECTION AGENCY

### 40 CFR Part 180

[EPA-HQ-OPP-2010-0429; FRL-8841-2]

#### Acetic Acid Ethenyl Ester, Polymer With Oxirane; Tolerance Exemption

**AGENCY:** Environmental Protection Agency (EPA).

**ACTION:** Final rule.

**SUMMARY:** This regulation establishes an exemption from the requirement of a tolerance for residues of acetic acid ethenyl ester, polymer with oxirane; when used as an inert ingredient in a pesticide chemical formulation under 40 CFR 180.960. BASF Corporation submitted a petition to EPA under the Federal Food, Drug, and Cosmetic Act (FFDCA), requesting an exemption from the requirement of a tolerance. This regulation eliminates the need to establish a maximum permissible level for residues of acetic acid ethenyl ester, polymer with oxirane on food or feed commodities.

**DATES:** This regulation is effective August 25, 2010. Objections and requests for hearings must be received on or before October 25, 2010, and must be filed in accordance with the instructions provided in 40 CFR part 178 (see also Unit I.C. of the **SUPPLEMENTARY INFORMATION**).

<sup>9</sup>See *Filing of Claims for DART Royalty Funds*, 68 FR 74481 (Dec. 24, 2003), citing *Northeast Cellular Telephone Company v. FCC*, 897 F.2d 1164, 1166 (D.C. Cir. 1990) (holding that a waiver of an agency's rules is "appropriate only if special circumstances warrant a deviation from the general rule and such deviation will serve the public interest.").

<sup>8</sup>Gralin has reported that the glitches in its software have led, in limited instances, to difficulties in reporting certain data points and printing of the SA3 form. The Office is currently working with Gralin to resolve these glitches.

**ADDRESSES:** EPA has established a docket for this action under docket identification (ID) number EPA-HQ-OPP-2010-0429. All documents in the docket are listed in the docket index available at <http://www.regulations.gov>. Although listed in the index, some information is not publicly available, e.g., Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the Internet and will be publicly available only in hard copy form. Publicly available docket materials are available in the electronic docket at <http://www.regulations.gov>, or, if only available in hard copy, at the OPP Regulatory Public Docket in Rm. S-4400, One Potomac Yard (South Bldg.), 2777 S. Crystal Dr., Arlington, VA. The Docket Facility is open from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The Docket Facility telephone number is (703) 305-5805.

#### FOR FURTHER INFORMATION CONTACT:

Deirdre Sunderland, Registration Division (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; telephone number: (703) 603-0851; e-mail address: [sunderland.deirdre@epa.gov](mailto:sunderland.deirdre@epa.gov).

#### SUPPLEMENTARY INFORMATION:

##### I. General Information

###### A. Does this Action Apply to Me?

You may be potentially affected by this action if you are an agricultural producer, food manufacturer, or pesticide manufacturer. Potentially affected entities may include, but are not limited to:

- Crop production (NAICS code 111).
- Animal production (NAICS code 112).
- Food manufacturing (NAICS code 311).
- Pesticide manufacturing (NAICS code 32532).

This listing is not intended to be exhaustive, but rather provides a guide for readers regarding entities likely to be affected by this action. Other types of entities not listed in this unit could also be affected. The North American Industrial Classification System (NAICS) codes have been provided to assist you and others in determining whether this action might apply to certain entities. If you have any questions regarding the applicability of this action to a particular entity, consult the person listed under **FOR FURTHER INFORMATION CONTACT**.

### B. How Can I Get Electronic Access to Other Related Information?

You may access a frequently updated electronic version of 40 CFR part 180 through the Government Printing Office's e-CFR site at <http://www.gpoaccess.gov/ecfr>.

### C. Can I File an Objection or Hearing Request?

Under section 408(g) of FFDCA, 21 U.S.C. 346a, any person may file an objection to any aspect of this regulation and may also request a hearing on those objections. You must file your objection or request a hearing on this regulation in accordance with the instructions provided in 40 CFR part 178. To ensure proper receipt by EPA, you must identify docket ID number EPA-HQ-OPP-2010-0429 in the subject line on the first page of your submission. All objections and requests for a hearing must be in writing, and must be received by the Hearing Clerk on or before October 25, 2010. Addresses for mail and hand delivery of objections and hearing requests are provided in 40 CFR 178.25(b).

In addition to filing an objection or hearing request with the Hearing Clerk as described in 40 CFR part 178, please submit a copy of the filing that does not contain any CBI for inclusion in the public docket. Information not marked confidential pursuant to 40 CFR part 2 may be disclosed publicly by EPA without prior notice. Submit a copy of your non-CBI objection or hearing request, identified by docket ID number EPA-HQ-OPP-2010-0429, by one of the following methods.

- *Federal eRulemaking Portal:* <http://www.regulations.gov>. Follow the on-line instructions for submitting comments.

- *Mail:* Office of Pesticide Programs (OPP) Regulatory Public Docket (7502P), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001.

- *Delivery:* OPP Regulatory Public Docket (7502P), Environmental Protection Agency, Rm. S-4400, One Potomac Yard (South Bldg.), 2777 S. Crystal Dr., Arlington, VA. Deliveries are only accepted during the Docket Facility's normal hours of operation (8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays). Special arrangements should be made for deliveries of boxed information. The Docket Facility telephone number is (703) 305-5805.

## II. Background and Statutory Findings

In the **Federal Register** of June 23, 2010 (75 FR 35801) (FRL-8831-3), EPA issued a notice pursuant to section 408

of FFDCA, 21 U.S.C. 346a, announcing the receipt of a pesticide petition (PP 9E7660) filed by, BASF Corporation, 100 Campus Drive, Florham Park, NJ 07932. The petition requested that 40 CFR 180.960 be amended by establishing an exemption from the requirement of a tolerance for residues of acetic acid ethenyl ester, polymer with oxirane; (CAS No. 25820-49-9). That notice included a summary of the petition prepared by the petitioner and solicited comments on the petitioner's request. The Agency did not receive any comments.

Section 408(c)(2)(A)(i) of FFDCA allows EPA to establish an exemption from the requirement for a tolerance (the legal limit for a pesticide chemical residue in or on a food) only if EPA determines that the exemption is "safe." Section 408(c)(2)(A)(ii) of FFDCA 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 and use in residential settings, but does not include occupational exposure. Section 408(b)(2)(C) of FFDCA requires EPA to give special consideration to exposure of infants and children to the pesticide chemical residue in establishing an exemption from the requirement of 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. . ." and specifies factors EPA is to consider in establishing an exemption.

### III. Risk Assessment and Statutory Findings

EPA establishes exemptions from the requirement of a tolerance only in those cases where it can be shown that the risks from aggregate exposure to pesticide chemical residues under reasonably foreseeable circumstances will pose no appreciable risks to human health. In order to determine the risks from aggregate exposure to pesticide inert ingredients, the Agency considers the toxicity of the inert in conjunction with possible exposure to residues of the inert ingredient through food, drinking water, and through other exposures that occur as a result of pesticide use in residential settings. If EPA is able to determine that a finite tolerance is not necessary to ensure that there is a reasonable certainty that no harm will result from aggregate exposure to the inert ingredient, an

exemption from the requirement of a tolerance may be established.

Consistent with section 408(b)(2)(D) of FFDCA, EPA has reviewed the available scientific data and other relevant information in support of this action and considered its validity, completeness and reliability and the relationship of this information to human risk. EPA has also considered available information concerning the variability of the sensitivities of major identifiable subgroups of consumers, including infants and children. In the case of certain chemical substances that are defined as polymers, the Agency has established a set of criteria to identify categories of polymers expected to present minimal or no risk. The definition of a polymer is given in 40 CFR 723.250(b) and the exclusion criteria for identifying these low-risk polymers are described in 40 CFR 723.250(d). acetic acid ethenyl ester, polymer with oxirane conforms to the definition of a polymer given in 40 CFR 723.250(b) and meets the following criteria that are used to identify low-risk polymers.

1. The polymer is not a cationic polymer nor is it reasonably anticipated to become a cationic polymer in a natural aquatic environment.

2. The polymer does contain as an integral part of its composition the atomic elements carbon, hydrogen, and oxygen.

3. The polymer does not contain as an integral part of its composition, except as impurities, any element other than those listed in 40 CFR 723.250(d)(2)(ii).

4. The polymer is neither designed nor can it be reasonably anticipated to substantially degrade, decompose, or depolymerize.

5. The polymer is manufactured or imported from monomers and/or reactants that are already included on the TSCA Chemical Substance Inventory or manufactured under an applicable TSCA section 5 exemption.

6. The polymer is not a water absorbing polymer with a number average molecular weight (MW) greater than or equal to 10,000 daltons.

Additionally, the polymer also meets as required the following exemption criteria specified in 40 CFR 723.250(e).

7. The polymer's number average MW of 17,000 is greater than or equal to 10,000 daltons. The polymer contains less than 2% oligomeric material below MW 500 and less than 5% oligomeric material below MW 1,000.

Thus, acetic acid ethenyl ester, polymer with oxirane meets the criteria for a polymer to be considered low risk under 40 CFR 723.250. Based on its conformance to the criteria in this unit,

no mammalian toxicity is anticipated from dietary, inhalation, or dermal exposure to acetic acid ethenyl ester, polymer with oxirane.

#### IV. Aggregate Exposures

For the purposes of assessing potential exposure under this exemption, EPA considered that acetic acid ethenyl ester, polymer with oxirane could be present in all raw and processed agricultural commodities and drinking water, and that non-occupational non-dietary exposure was possible. The number average MW of acetic acid ethenyl ester, polymer with oxirane is 17,000 daltons. Generally, a polymer of this size would be poorly absorbed through the intact gastrointestinal tract or through intact human skin. Since acetic acid ethenyl ester, polymer with oxirane conform to the criteria that identify a low-risk polymer, there are no concerns for risks associated with any potential exposure scenarios that are reasonably foreseeable. The Agency has determined that a tolerance is not necessary to protect the public health.

#### V. Cumulative Effects From Substances With a Common Mechanism of Toxicity

Section 408(b)(2)(D)(v) of FFDCA 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."

EPA has not found acetic acid ethenyl ester, polymer with oxirane to share a common mechanism of toxicity with any other substances, and acetic acid ethenyl ester, polymer with oxirane does not appear to produce a toxic metabolite produced by other substances. For the purposes of this tolerance action, therefore, EPA has assumed that acetic acid ethenyl ester, polymer with oxirane does not have a common mechanism of toxicity with other substances. For information regarding EPA's efforts to determine which chemicals have a common mechanism of toxicity and to evaluate the cumulative effects of such chemicals, see EPA's website at <http://www.epa.gov/pesticides/cumulative>.

#### VI. Additional Safety Factor for the Protection of Infants and Children

Section 408(b)(2)(C) of FFDCA provides that EPA shall apply an additional tenfold margin of safety for infants and children in the case of threshold effects to account for prenatal and postnatal toxicity and the

completeness of the data base unless EPA concludes that a different margin of safety will be safe for infants and children. Due to the expected low toxicity of acetic acid ethenyl ester, polymer with oxirane, EPA has not used a safety factor analysis to assess the risk. For the same reasons the additional tenfold safety factor is unnecessary.

#### VII. Determination of Safety

Based on the conformance to the criteria used to identify a low-risk polymer, EPA concludes that there is a reasonable certainty of no harm to the U.S. population, including infants and children, from aggregate exposure to residues of acetic acid ethenyl ester, polymer with oxirane.

#### VIII. Other Considerations

##### A. Analytical Enforcement Methodology

An analytical method is not required for enforcement purposes since the Agency is establishing an exemption from the requirement of a tolerance without any numerical limitation.

##### B. International Residue Limits

In making its tolerance decisions, EPA seeks to harmonize U.S. tolerances with international standards whenever possible, consistent with U.S. food safety standards and agricultural practices. EPA considers the international maximum residue limits (MRLs) established by the Codex Alimentarius Commission (Codex), as required by section 408(b)(4) of FFDCA. The Codex Alimentarius is a joint U.N. Food and Agriculture Organization/World Health Organization food standards program, and it is recognized as an international food safety standards-setting organization in trade agreements to which the United States is a party. EPA may establish a tolerance that is different from a Codex MRL; however, section 408(b)(4) of FFDCA requires that EPA explain the reasons for departing from the Codex level.

The Codex has not established a MRL for acetic acid ethenyl ester, polymer with oxirane.

#### IX. Conclusion

Accordingly, EPA finds that exempting residues of acetic acid ethenyl ester, polymer with oxirane from the requirement of a tolerance will be safe.

#### X. Statutory and Executive Order Reviews

This final rule establishes an exemption from the requirement of a tolerance under section 408(d) of FFDCA in response to a petition submitted to the Agency. The Office of

Management and Budget (OMB) has exempted these rules from review under Executive Order 12866, entitled *Regulatory Planning and Review* (58 FR 51735, October 4, 1993). Because this final rule has been exempted from review under Executive Order 12866, this final rule is not subject to Executive Order 13211, entitled *Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use* (66 FR 28355, May 22, 2001) or Executive Order 13045, entitled *Protection of Children from Environmental Health Risks and Safety Risks* (62 FR 19885, April 23, 1997). This final rule does not contain any information collections subject to OMB approval under the Paperwork Reduction Act (PRA), 44 U.S.C. 3501 *et seq.*, nor does it involve any technical standards that would require Agency consideration of voluntary consensus standards pursuant to section 12(d) of the National Technology Transfer and Advancement Act of 1995 (NTTAA), Public Law 104-113, section 12(d) (15 U.S.C. 272 note).

Since tolerances and exemptions that are established on the basis of a petition under section 408(d) of FFDCA, such as the exemption in this final rule, do not require the issuance of a proposed rule, the requirements of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*) do not apply.

This final rule directly regulates growers, food processors, food handlers, and food retailers, not States or tribes, nor does this action alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of section 408(n)(4) of FFDCA. As such, the Agency has determined that this action will not have a substantial direct effect on States or tribal governments, on the relationship between the national government and the States or tribal governments, or on the distribution of power and responsibilities among the various levels of government or between the Federal Government and Indian tribes, or otherwise have any unique impacts on local governments. Thus, the Agency has determined that Executive Order 13132, entitled *Federalism* (64 FR 43255, August 10, 1999) and Executive Order 13175, entitled *Consultation and Coordination with Indian Tribal Governments* (65 FR 67249, November 9, 2000) do not apply to this final rule. In addition, this final rule does not impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act of 1995 (UMRA) (Public Law 104-4).

Although this action does not require any special considerations under Executive Order 12898, entitled *Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations* (59 FR 7629, February 16, 1994), EPA seeks to achieve environmental justice, the fair treatment and meaningful involvement of any group, including minority and/or low-income populations, in the development, implementation, and enforcement of environmental laws, regulations, and policies. As such, to the extent that information is publicly available or was submitted in comments to EPA, the Agency considered whether groups or segments of the population, as a result of their location, cultural practices, or other factors, may have atypical or disproportionately high and adverse human health impacts or environmental effects from exposure to the pesticide discussed in this document, compared to the general population.

**XI. Congressional Review Act**

The Congressional Review Act, 5 U.S.C. 801 *et seq.*, generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report to each House of the Congress and to the Comptroller General of the United States. EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of this rule in the **Federal Register**. This rule is not a “major rule” as defined by 5 U.S.C. 804(2).

**List of Subjects in 40 CFR Part 180**

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

Dated: August 13, 2010.

**Daniel J. Rosenblatt,**  
Acting Director, Registration Division, Office of Pesticide Programs.

■ Therefore, 40 CFR chapter I is amended as follows:

**PART 180—[AMENDED]**

- 1. The authority citation for part 180 continues to read as follows:  
**Authority:** 21 U.S.C. 321(q), 346a and 371.
- 2. In §180.960, in the table, add alphabetically the following polymer to read as follows:

**§ 180.960 Polymers; exemptions from the requirement of a tolerance.**

Polymer	CAS No.
* * *	* *
Acetic acid ethenyl ester, polymer with oxirane, minimum number average molecular weight (in amu), 17,000.	25820–49–9
* * *	* *

[FR Doc. 2010–21138 Filed 8–24–10; 8:45 am]  
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**DEPARTMENT OF THE INTERIOR**

**Fish and Wildlife Service**

**50 CFR Part 17**

[Docket No. FWS–R1–ES–2008–0084; 92220–1113–0000–C6]

RIN 1018–AW16

**Endangered and Threatened Wildlife and Plants; Removal of the Utah (Desert) Valvata Snail From the Federal List of Endangered and Threatened Wildlife**

**AGENCY:** Fish and Wildlife Service, Interior.

**ACTION:** Final rule.

**SUMMARY:** Under the authority of the Endangered Species Act of 1973, as amended (Act), we, the U.S. Fish and Wildlife Service (Service), are removing the Utah (desert) valvata snail (*Valvata utahensis*) from the Federal List of Endangered and Threatened Wildlife (List). Based on a thorough review of the best available scientific and commercial data, we determined that the Utah valvata snail is more widespread and occurs in a greater variety of habitats in the Snake River than known at the time of listing in 1992. We now know the Utah valvata snail is not limited to areas of cold-water springs or spring outflows; rather, it persists in a variety of aquatic habitats, including cold-water springs, spring creeks and tributaries, the mainstem Snake River and associated tributary stream habitats, and reservoirs influenced by dam operations. Given our current understanding of the species’ habitat requirements and threats, the species does not meet the definition of an endangered or threatened species under the Act. Therefore, we are removing the Utah valvata snail from the List, thereby removing all protections provided by the Act.

**DATES:** This effective date of this rule is September 24, 2010.

**ADDRESSES:** This final rule is available on the Internet at <http://www.regulations.gov> and at <http://www.fws.gov/idaho>. Comments and materials received, including supporting documentation used in preparing this rule, will be available for public inspection, by appointment, during normal business hours at the U.S. Fish and Wildlife Service, Idaho Fish and Wildlife Office, 1387 S. Vinnell Way, Room 368, Boise, ID 83709; by telephone.

**FOR FURTHER INFORMATION CONTACT:** Brian Kelly, State Supervisor, at the above address; by telephone 208–378–5243; or by fax at 208–378–5262 e-mail at: [fw1srbocomment@fws.gov](mailto:fw1srbocomment@fws.gov). Persons who use a telecommunications device for the deaf (TDD) may call the Federal Information Relay Service (FIRS) at 800–877–8339.

**SUPPLEMENTARY INFORMATION:**

**Background**

The Utah valvata snail (*Valvata utahensis*) was first recognized as a species in 1902, based on specimens collected from Utah Lake and Bear Lake, Utah (Walker 1902, p. 125). Its common name has since been changed by the American Fisheries Society to the “desert valvata” in the benchmark text for aquatic invertebrate nomenclature, *Common and Scientific Names of Aquatic Invertebrates from the United States and Canada* (Turgeon *et al.* 1998, p. 109), presumably due to the fact that it is no longer known to occur in Utah. However, because the species is currently listed in the Code of Federal Regulations as the Utah valvata snail, *Valvata utahensis* will be referred to as the Utah valvata snail throughout this final rule.

**Range**

The Utah valvata snail, or at least its closely related ancestors, has been described as ranging widely across the western United States and Canada as far back as the Jurassic Period, 199.6 ± 0.6 to 145.5 ± 4 million years ago (Taylor 1985a, p. 268). Fossils of the Utah valvata snail are known from Utah to California (Taylor 1985a, pp. 286–287). The Utah valvata snail was likely present in the ancestral Snake River as it flowed south from Idaho, through Nevada, and into northeastern California (Taylor 1985a, p. 303). The Snake River’s course changed to join the Columbia River Basin approximately 2 million years ago (Hershler and Liu 2004, pp. 927–928).