

micron particle size are generally not absorbed by inhalation.

3. The acrylate polymers and copolymers that are exempted are not cationic or are not anticipated to be converted (by degradation or decomposition) to a cationic state.

4. Acrylate and methacrylate are listed as high-concern reactive functional groups. Therefore, to meet the exemption criteria § 723.250 (e)(1)(ii)(C) the minimum permissible combined functional group equivalent weight is 5,000 daltons, when a number-average molecular weight (NAVG MW) of a polymer is greater than 1,000 and lower than 10,000 daltons. Additionally, in this range of molecular weight (greater than 1,000 and less than 10,000 daltons) the polymer must contain less than 10 percent oligomer content of molecular weight below 500 daltons and less than 25 percent oligomer content of molecular weight below 1,000 daltons.

5. The polymers with NAVG MW equal to or greater than 10,000 daltons (§ 723.250 (e)(2)), the polymer must contain less than 2 percent oligomer content of molecular weight below 500 daltons and must not exceed 5 percent oligomer content of molecular weight below 1,000 daltons. Water soluble polymers in this molecular weight range are excluded from exemption under § 723.250(d), with no restriction regarding the functional group.

6. For a polymer or polyester to meet the exemption criteria § 723.250 (e)(3), each feedstock, monomer or reactant in the chemical identity of the polymers at greater than 2 percent composition must be on the list. Excluded from this exemption would be biodegradable polyesters and highly water-absorbing polyester with NAVG MW greater than 10,000 daltons.

7. The acrylate polymers and copolymers must contain as an integral part of their composition at least two of the atomic elements carbon, hydrogen, nitrogen, oxygen, sulfur, or silicon (40 CFR § 723.250(d)(3)). A previous requirement in the 1984 rule stated that an eligible polymer contain at least 32 percent carbon. This requirement was deleted since cases reviewed to date contain less than 32 percent carbon, have either received low concern rating, or have been excluded for other reasons.

8. Certain other elements are permitted in the acrylate polymers and copolymers as an integral part of the polymers, except if present as impurities. The allowed elements (40 CFR § 723.250(d)(3)), in addition to the atomic elements carbon, hydrogen, nitrogen, oxygen, sulfur, silicon (C, H, N, O, S, Si) are: fluorine, chlorine, bromine, and iodine (F, Cl, Br, and I)

when covalently bonded to carbon, and monoatomic counterions such as chlorine, bromide, and iodide (Cl<sup>-</sup>, Br<sup>-</sup>, I<sup>-</sup>), sodium, magnesium, aluminum, potassium, and calcium (Na<sup>+</sup>, Mg<sup>2+</sup>, Al<sup>3+</sup>, K<sup>+</sup>, and Ca<sup>2+</sup>). Less than 0.2 percent weight total (in any combination) of the atomic elements lithium, boron, phosphorus, titanium, manganese, iron, nickel, copper, zinc, tin, and zirconium (Li, B, P, Ti, Mn, Fe, Ni, Cu, Zn, Sn, and Zr) are permitted. No other elements are permitted except as impurities.

9. The acrylate polymers and copolymers are not biopolymers, they are synthetic equivalents of a biopolymer, or derivatives or modifications of a biopolymer that is substantially intact. These polymers do not contain reactive functional groups that are anticipated to be converted to a cationic state.

10. The acrylate polymers and copolymers are not designated or reasonably anticipated to be substantially degraded, decomposed, or depolymerized. Based upon the above information and review of its use, EPA has found that when used in accordance with good agricultural practice, these inert ingredients are useful and a tolerance is not necessary to protect public health. Therefore, EPA proposes that the exemptions from the requirement of tolerance be established for acrylate polymers/copolymers used as inert ingredient for pesticide formulations.

## II. Filing of Objections

Any person adversely affected by this regulation may, within 30 days after publication of this document, file written objections and/or request a hearing with the Hearing Clerk and a copy submitted to the OPP docket for this rulemaking at the addresses given above.

## III. Regulatory Assessment Requirement

### A. Executive Order 12866

The Office of Management and Budget has exempted this notice from the requirement of section 3 of Executive Order 12866.

### B. Regulatory Flexibility Act

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).

Dated: February 7, 1996.

Daniel M. Barolo,

*Director, Office of Pesticide Programs.*

Therefore, 40 CFR part 180 is 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. By adding new § 180.1162 to subpart D to read as follows:

### § 180.1162 Acrylate Polymers and Copolymers; exemption from the requirement of a tolerance.

(a) Acrylate polymers and copolymers are exempt from the requirement of a tolerance when used as inert ingredients in pesticidal formulations applied to growing, raw agricultural commodities. This tolerance exemption covers the acrylate polymers/copolymers that are intrinsically safe and already listed in TSCA inventory or will meet the polymer tolerance exemption from requirements of premanufacturing notification under 40 CFR 723.250. Polymers exempted can be used as dispensers, resins, fibers, and beads, as long as the fibers, beads and resins particle sizes are greater than 10 microns and insoluble in water. This exemption pertains to the acrylate polymers/copolymers used as inert ingredients for sprayable and dispenser pesticide formulations that are applied on food crops. Any acrylate polymers/copolymers used for encapsulating material must be cleared as an inert ingredient when used in pesticide formulation applied on food crops.

(b) For the purposes of this exemption, acrylate polymers/copolymers used as inert ingredients in an end-use formulation must meet the definition for a polymer as given in 40 CFR 723.250(b), are not automatically excluded by 40 CFR 723.250(d), and meet the tolerance exemption criteria in 40 CFR 723.250(e)(1), 40 CFR 723.250 (e)(2) or 40 CFR 723.250(e)(3). Therefore, acrylate polymers and copolymers that are already listed in the TSCA inventory or will meet the polymer tolerance exemption under 40 CFR 723.250 as amended on March 29, 1995 are covered by this exemption.

[FR Doc. 96-3858 Filed 2-20-96; 8:45]

BILLING CODE 6560-50-F

**40 CFR Part 180**

[PP 5F4476/R2203; FRL-5350-6]

RIN 2070-AB78

**Hexythiazox; Pesticide Tolerance****AGENCY:** Environmental Protection Agency (EPA).**ACTION:** Final Rule.

**SUMMARY:** This document establishes a tolerance for the combined residues of the acaricide hexythiazox, trans-5-(4-chlorophenyl)-N-cyclohexyl-4-methyl-2-oxothiazolidine-3-carboxamide and its metabolites containing the (4-chlorophenyl)-4-methyl-2-oxo-3-thiazolidine moiety (expressed as parts per million of the parent compound), in or on the raw agricultural commodity apples. Gowan Company requested this regulation to establish a maximum permissible level for residues of the acaricide pursuant to the Federal Food, Drug, and Cosmetic Act (FFDCA).

**EFFECTIVE DATE:** This regulation becomes effective February 21, 1996.

**ADDRESSES:** Written objections and hearing requests, identified by the docket control number [PP 5F4476/R2203], may be submitted to: Hearing Clerk (1900), Environmental Protection Agency, Rm. M3708, 401 M St., SW., Washington, DC 20460. A copy of any objections and hearing requests filed with the Hearing Clerk should be identified by the docket control number and submitted 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 copy of objections and hearing requests to: Rm. 1132, CM #2, 1921 Jefferson Davis Highway, Arlington, VA. Fees accompanying objections shall be labeled "Tolerance Petition Fees" and forwarded to EPA Headquarters Accounting Operations Branch, OPP (Tolerance Fees), P.O. Box 360277M, Pittsburgh, PA 15251.

A copy of objections and hearing requests filed with the Hearing Clerk may also be submitted electronically by sending electronic mail (e-mail) to: opp-docket@epamail.epa.gov. Copies of objections and hearing requests must be submitted as an ASCII file avoiding the use of special characters and any form of encryption. Copies of objections and hearing requests will also be accepted on disks in WordPerfect in 5.1 file format or ASCII file format. All copies of objections and hearing requests in electronic form must be identified by the docket number [PP 5F4476/R2203].

No Confidential Business Information (CBI) should be submitted through e-mail. Electronic copies of objections and hearing requests on this rule may be filed online at many Federal Depository Libraries. Additional information on electronic submissions can be found below in this document.

**FOR FURTHER INFORMATION CONTACT:** By mail: George LaRocca, Product Manager (PM) 13, 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: Rm. 204, CM #2, 1921 Jefferson Davis Highway, Arlington, VA, (703) 305-6100; e-mail: larocca.george@epamail.epa.gov.

**SUPPLEMENTARY INFORMATION:** EPA issued a notice, published in the Federal Register of May 3 1995 (60 FR 21815), which announced that Gowan Company, P.O. Box 5569, Yuma, AZ 85366-5569, had submitted a pesticide petition (PP 5F4476) to EPA requesting the Administrator, pursuant to section 408(d) of the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. 346a(d), to establish a tolerance for the combined residues of the acaricide hexythiazox, trans-5-(4-chlorophenyl)-N-cyclohexyl-4-methyl-2-oxothiazolidine-3-carboxamide and its metabolites containing the (4-chlorophenyl)-4-methyl-2-oxo-3-thiazolidine moiety (expressed as parts per million of the parent compound), in or on the raw agricultural commodity apples at 0.05 parts per million (ppm). In a letter dated October 10, 1995, Gowan requested that the pesticide petition be amended by proposing a lower tolerance on apples at 0.02 ppm. No comments were received in response to the notice of filing.

The data submitted in support of this tolerance and other relevant material have been reviewed. The toxicological and metabolism data considered in support of this tolerance are discussed in detail in a related document published in the Federal Register of April 26, 1989 (54 FR 17947).

The Agency has classified hexythiazox as a class C (possible human) carcinogen based on a significantly increased incidence of hepatocellular carcinomas ( $p=0.028$ ), and adenomas/carcinomas combined ( $p=0.024$ ) in female mice at the highest dose tested (1,500 ppm) when compared to the controls as well as a significantly increased ( $p<0.001$ ) incidence of preneo-plastic hepatic nodules in both males and females at the highest dose tested (1,500 ppm). The decision supporting a Category C classification

(rather than a Category B) was based primarily on the fact that only one species was affected (mouse), mutagenicity assays did not support upgrading to a B classification, and structure-activity relationship of hexythiazox to other compounds supported a C classification. In classifying hexythiazox as a Category C carcinogen, the Agency concluded that a quantitative estimate of the carcinogenic potential for humans should be calculated because of the increased incidence of malignant liver tumors in the female mouse. Thus, a  $Q^{1*}$  of  $3.9 \times 10^{-2}$  (mg/kg/day)<sup>-1</sup> in human equivalents has been calculated.

A full review of the data indicates that although hexythiazox is a carcinogen in mice, the risks would be extremely small from the proposed use on apples. Estimated dietary carcinogenic risk to the general population based on the highly conservative assumption that all apples are treated with hexythiazox and would bear residues at the proposed tolerance level is estimated to be  $2 \times 10^{-6}$ . This is slightly higher than  $1 \times 10^{-6}$  a level which is generally considered of negligible risk concern by the Agency. The Agency believes that actual exposure and risk would be lower. The basis for this is that the risk estimate reflects a worst-case dietary exposure because it assumes that 100 percent of all apples consumed in the United States are treated with hexythiazox and that all quantities of the food consumed would bear residues levels as high as the proposed tolerance. In reality, the Agency knows that all apples would not be treated with this pesticide and expect that even apples receiving maximum treatment will have residues far below tolerance level. For example, in field trials conducted using application rates 10 times the label amount, residues in apples still did not exceed the tolerance level. Further, the maximum residue level in apple juice would be expected to be less than 50 percent of the residue level in whole fruit.

Based on an assessment of the cancer risks of the proposed use of hexythiazox, the Agency believes that the proposed use of hexythiazox on apples will pose an extremely small risk to humans.

A chronic dietary exposure/risk assessment has been performed for hexythiazox using a Reference Dose (RfD) of 0.025 mg/kg-bwt/day. The RfD was based on a NOEL of 2.5 mg/kg/day from a 1-year dog feeding study and a safety factor of 100. The endpoint effect of concern was hypertrophy of the adrenal cortex in both sexes, decreased red blood cell counts, hemoglobin content and hematocrit in males. The

analysis was performed using tolerance level residues and 100% crop treated information. The exposure for established tolerances and the current action is estimated at 0.000051 mg/kg-bwt/day and utilizes 0.2% of the RfD for the U.S. population. For non-nursing infants less than 1 year old (the subgroup population with the highest exposure level), the exposure for established tolerances and the current action is estimated at 0.000600 mg/kg-bwt/day and utilizes 2.4% of the RfD. Generally speaking, the Agency has no concern if dietary exposure is less than the RfD for all published and proposed tolerances.

The nature and metabolism of the chemical in plants and animals for the use is adequately understood. Since the petitioner has included the label restriction "Do not graze or feed livestock on cover crops growing in treated areas" and hexythiazox animal feeding studies indicate that there is no reasonable expectation of finite residue transfer to meat, milk, poultry and eggs, no secondary residues in meat or milk are expected. Adequate analytical methodology (gas liquid chromatography with an electron capture detector) is available for enforcement purposes. The enforcement methodology has been submitted to the Food and Drug Administration for publication in the *Pesticide Analytical Manual, Vol. II* (PAM II). Because of the long lead time for publication of the method in PAM II, the analytical methodology is being made available in the interim to anyone interested in pesticide enforcement when requested from Calvin Furlow, Public Response and Program Resource Branch, Field Operations Division (7506C), Office of Pesticide Programs, U.S. Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. Office location and telephone number: Rm. 1132, CM #2, 1921 Jefferson Davis Hwy., Arlington, VA, (703) 305-5232.

The tolerances established by amending 40 CFR part 180 will be adequate to cover residues in or on apples. There are presently no actions pending against the continued registration of this chemical. Based on the information and data considered, the Agency has determined that the tolerance established by amending 40 CFR 180 would protect the public health. Therefore, it is proposed that the tolerance be established as set forth below.

Any person adversely affected by this regulation may, within 30 days after publication of this document in the Federal Register, file written objections and/or request a hearing with the

Hearing Clerk, at the address given above (40 CFR 178.20). A copy of the objections and/or hearing requests filed with the Hearing Clerk should be submitted to the OPP docket for this rulemaking. The objections submitted must specify the provisions of the regulation deemed objectionable and the grounds for the objections (40 CFR 178.25). Each objection must be accompanied by the fee prescribed by 40 CFR 180.33(i). If a hearing is requested, the objections must include a statement of the factual issue(s) on which a hearing is requested, the requestor's contentions on such issues, and a summary of any evidence relied upon by the objector (40 CFR 178.27). A request for a hearing will be granted if the Administrator determines that the material submitted shows the following: There is genuine and substantial issue of fact; there is a reasonable possibility that available evidence identified by the requestor would, if established, resolve one or more of such issues in favor of the requestor, taking into account uncontested claims or facts to the contrary; and resolution of the factual issue(s) in the manner sought by the requestor would be adequate to justify the action requested (40 CFR 178.32).

A record has been established for this rulemaking under docket number [PP 5F4476/R2203] (including comments and data submitted electronically as described below). A public version of this record, including printed, paper version of electronic comments, which does not include any information claimed as CBI, is available for inspection from 8 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The public record is located in Room 1132 of the Public Response and Program Resources Branch, Field Operations Division (7506C), Office of Pesticide Programs, Environmental Protection Agency, Crystall Mall #2, 1921 Jefferson Davis Highway, Arlington, VA.

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.

The official record for this rulemaking, as well as the public version, as described above will be kept in paper form. Accordingly, EPA will transfer all comments received electronically into printed, paper form as they are received and will place the paper copies in the official rulemaking record which will also include all comments submitted directly in writing. The official rulemaking record is the

paper record maintained at the address in "ADDRESSES" at the beginning of this document.

Under Executive Order 12866 (58 FR 51735, October 4, 1993), the Agency must determine whether the regulatory action is "significant" and therefore subject to all the requirements of the Executive Order (i.e., Regulatory Impact Analysis, review by the Office of Management and Budget (OMB)). Under section 3(f), the order defines "significant" as those actions likely to lead to a rule: (1) Having an annual effect on the economy of \$100 million or more, or adversely and materially affecting a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local or tribal governments or communities (also known as "economically significant"); (2) creating serious inconsistency or 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: February 8, 1996.

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

Therefore, 40 CFR part 180 continues to read as follows:

#### **PART 180—[AMENDED]**

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

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

2. By amending § 180.448 in the table therein and alphabetically inserting an entry for apples, to read as follows:

§ 180.448 **Hexythiazox; tolerances for residues.**

Commodity	Parts per million
Apples .....	0.02

[FR Doc. 96-3721 Filed 2-20-96; 8:45 am]  
BILLING CODE 6560-50-F

**40 CFR Part 282**

[FRL-5345-2]

**Underground Storage Tank Program; Approved State Program for Maine**

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

**ACTION:** Immediate final rule.

**SUMMARY:** The Resource Conservation and Recovery Act of 1976, as amended (RCRA), authorizes the Environmental Protection Agency (EPA) to grant approval to states to operate their underground storage tank programs in lieu of the federal program. 40 CFR part 282 codifies EPA's decision to approve state programs and incorporates by reference those provisions of the state statutes and regulations that will be subject to EPA's inspection and enforcement authorities under sections 3007, 7003, 9005, and 9006 of RCRA. This rule codifies in part 282 the prior approval of Maine's underground storage tank program and incorporates by reference appropriate provisions of state statutes and regulations.

**DATES:** This regulation shall be effective April 22, 1996, unless EPA publishes a prior Federal Register notice withdrawing this immediate final rule. All comments on the codification of Maine's underground storage tank program must be received by the close of business March 22, 1996. The incorporation by reference of certain publications listed in the regulations is approved by the Director of the Federal Register, as of April 22, 1996.

**ADDRESSES:** Comments may be mailed to the Docket Clerk (Docket No. UST 5-3), Underground Storage Tank Program, HPU-CAN7, U.S. EPA Region I, JFK Federal Building, Boston, MA 02203-2211. Comments received by EPA may be inspected in the public docket,

located in the Waste Management Division Record Center, 90 Canal St., Boston, MA 02203 from 9 a.m. to 4 p.m., Monday through Friday, excluding federal holidays.

**FOR FURTHER INFORMATION CONTACT:** Thomas Burns, Underground Storage Tank Program, HPU-CAN7, U.S. EPA Region I, JFK Federal Building, Boston, MA 02203-2211. Phone: (617) 573-9663.

**SUPPLEMENTARY INFORMATION:**

**Background**

Section 9004 of the Resource Conservation and Recovery Act of 1976, as amended (RCRA), 42 U.S.C. 6991c, allows the U.S. Environmental Protection Agency to approve state underground storage tank programs to operate in the state in lieu of the federal underground storage tank program. EPA published a Federal Register document announcing its decision to grant approval to Maine. (57 FR 36, February 24, 1992). Approval was effective on March 18, 1992.

EPA codifies its approval of State programs in 40 CFR part 282 and incorporates by reference therein the state statutes and regulations that will be subject to EPA's inspection and enforcement authorities under sections 3007, 7003, 9005, and 9006 of Subtitle I of RCRA, 42 U.S.C. 6927, 6973, 6991d and 6991e. Today's rulemaking codifies EPA's approval of the Maine underground storage tank program. This codification reflects the state program in effect at the time EPA granted Maine approval under section 9004(a), 42 U.S.C. 6991c(a) for its underground storage tank program. Notice and opportunity for comment were provided earlier on the Agency's decision to approve the Maine program, and EPA is not now reopening that decision nor requesting comment on it.

Codification provides clear notice to the public of the scope of the approved program in each state. Revisions to state underground storage tank programs are necessary when federal statutory or regulatory authority is modified. By codifying the approved Maine program and by amending the Code of Federal Regulations whenever a new or different set of requirements is approved in Maine, the status of federally approved requirements of the Maine program will be readily discernible. Only those provisions of the Maine underground storage tank program for which approval has been granted by EPA will be incorporated by reference for enforcement purposes.

To codify EPA's approval of Maine's underground storage tank program, EPA

has added § 282.69 to title 40 of the CFR. Section 282.69 incorporates by reference for enforcement purposes the State's statutes and regulations. Section 282.69 also references the Attorney General's Statement, Demonstration of Adequate Enforcement Procedures, the Program Description, and the Memorandum of Agreement, which are approved as part of the underground storage tank program under Subtitle I of RCRA.

The Agency retains the authority under Sections 9005 and 9006 of Subtitle I of RCRA, 42 U.S.C. 6991d and 6991e, and other applicable statutory and regulatory provisions to undertake inspections and enforcement actions in approved states. With respect to such an enforcement action, EPA will rely on federal sanctions, federal inspection authorities, and federal procedures rather than the state authorized analogs to these provisions. Therefore, the approved Maine enforcement authorities will not be incorporated by reference. Forty CFR § 282.69 lists those approved Maine authorities that would fall into this category.

The public also needs to be aware that some provisions of the Maine's underground storage tank program are not part of the federally approved state program. These are:

- Registration requirements for farm or residential tanks less than or equal to 1,100 gallons containing motor fuels for non-commercial use;
- Registration requirements for tanks used for storing heating oil for consumptive use on the premises; and
- Permanent closure requirements for tanks containing heating oil consumed on the premises where stored.

These non-approved provisions are not part of the RCRA Subtitle I program because they are "broader in scope" than Subtitle I of RCRA. See 40 CFR 281.12(a)(3)(ii). As a result, state provisions which are "broader in scope" than the federal program are not incorporated by reference for purposes of enforcement in part 282. Section 282.69 of the codification simply lists for reference and clarity the Maine statutory and regulatory provisions which are "broader in scope" than the federal program and which are not, therefore, part of the approved program being codified today. "Broader in scope" provisions cannot be enforced by EPA; the State, however, will continue to enforce such provisions.

**Certification Under the Regulatory Flexibility Act**

This rule codifies the decision already made (57 FR 36, February 24, 1992) to approve the Maine underground storage