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 ingredients	Limits	Uses
* * *	* *	* *
3,5-*Bis*(6-isocyanatohexyl)-2*H*-1,3,5-oxadiazine-2,4,6-(3*H*,5*H*)-trione, polymer with diethylenetriamine (CAS Reg. No. 87823-33-4); minimum number average molecular weight 1,000,000..	.....	Encapsulating agent
* * *	* *	* *

* * * * *

[FR Doc. 95–5652 Filed 3–7–95; 8:45 am]

BILLING CODE 6560–50–F

40 CFR Part 180

[PP 6F3392/R2105; FRL–4933–1]

RIN 2070–AB78

Pesticide Tolerance for Clofentezine

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This rule establishes a tolerance for residues of the insecticide clofentezine in or on the raw agricultural commodity apples. AgroEvo USA Corp. (formerly Nor-Am Chemical Co.) requested this regulation to establish a maximum permissible level for residues of the insecticide.

EFFECTIVE DATE: This regulation is effective February 22, 1995.

ADDRESSES: Written objections and hearing requests, identified by the document control number, [PP 6F3392/R2105], 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 document 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 Hwy., Arlington, VA 22202. 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.

FOR FURTHER INFORMATION CONTACT: By mail: Dennis H. Edwards, Product Manager (PM) 19, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. Office location and telephone number: Rm. 207, CM #2, 1921 Jefferson Davis Hwy., Arlington, VA 22202. (703)–305–3686.

SUPPLEMENTARY INFORMATION: EPA issued a notice, published in the **Federal Register** of June 4, 1986 (51 FR 20343), which announce that Nor-Am Chemical Co. of Little Falls Centre One, 2711 Centerville Rd., Wilmington, DE 19803, had sumitted a pesticide petition to EPA requesting that the Administrator, pursuant to section 408(d) of the Federal Food, Drug and Costmetic Act (FFDCA), 21 U.S.C. 346a(d), propose to amend 40 CFR 180.446 by establishing tolerances for residues of the insecticide clofentezine 3,b-bis(2-chlorophenyl)-1,2,4,5-tetrazine in or on the commodities apples at 0.05 part per million (ppm), meat at 0.05 ppm, meat byproducts at 0.05 ppm, milk at 0.01 ppm, and poultry and poultry byproducts at 0.05. A feed additive tolerance was proposed for dry apple pomace at 1.0 ppm.

Subsequent to the orginal notice of filing, EPA issued a notice, published **Federal Register** of May 27, 1992 (57 FR 22232), which announced that the Nor-Am Chemical Co. was amending pesticide petition 6F3392 by increasing the proposed tolerance in/on apples to 0.01 ppm, withdrawing the proposed feed additive tolerance, and withdrawing the petition for animal tolerances since they have already been established.

There were no comments or requests for referral to an advisory committee received in response to the notice of filings.

The scientific data submitted in the petition and other relevant material have been evaluated. The toxicological data considered in support of the tolerance include a 1-year dog feeding study with a no-observed-effect level (NOEL) of 50 ppm (1.25 mg/kg/day); a mouse carcinogenicity study which was negative at the doses tested, 50 ppm (7.5 mg/kg/day), 500 ppm (75 mg/kg/day), and 5,000 ppm (750 mg/kg/day); a multi-generation rat study with a NOEL of 400 ppm (20 mg/kg/day) (highest dose tested (HDT); a rat teratology study which was negative at 3,200 mg/kg/day (HDT) and had a developmental NOEL of 3,200 mg/kg/day; a rabbit teratology study which was negative at 3,000 mg/kg/day (HDT) also had a NOEL of 1,000 mg/kg/day for maternal toxicity (reduced litter and fetal body weights); and a 2-year rat chronic feeding/carcinogenicity study which showed an increase in the incidence of centrilobular hepatocyte hypertrophy and showed a statistically significant increase in thyroid follicular cell tumors in male rats at 400 ppm (20 mg/kg/day (HDT). Gene mutation, chromosomal aberrations, and diet DNA damage tests were negative for genetic toxicity.

The registrant (Nor-AM) also submitted additional thyroid studies intended to show that there was an indirect mechanism for the follicular cell tumors associated with clofentezine's liver toxicity. The Agency has reviewed the data in accordance with criteria outlined in a draft document entitled, ''Thyroid Follicular Cell Carcinogenesis: Mechanistic and Science Policy Considerations,'' (December 15, 1987). While this document is still undergoing Agency review, and the assessment procedures set forth therein have not been adopted by the Agency, the draft does provide a useful framework in which to consider the issue. Although the additional thyroid function studies suggest the possibility of an indirect mechanism for follicular cell tumor induction that may be associated with clofentezine's liver toxicity, the Agency believes that

additional data are necessary to more completely define the mechanism of clofentezine's thyroid tumor induction in terms of the criteria listed in the above document. Based on the rat feeding/ carcinogenicity study, the Agency has classified clofentezine as a possible human carcinogen (Group C). The qualitative designation ''C'' refer to EPA's weight-of-evidence classification. The classification is based on the Agency's ''Guidelines for Carcinogenic Risk Assessment,'' published in the **Federal Register** of September 25, 1996 (51 FR 33992). The Agency believes a quantitative risk assessment based on the thyroid incidence is not approprate for the following reasons:

1. The increase tumor incidence was marginally increased above the control incidence only at the highest dose tested (20 mg/kg/day) in the chronic feeding study.
2. The increased incidence was observed only in male rats.
3. The thyroid tumor incidence in the chronic feeding study's highest dose group (20 percent) was slightly greater than the historical range provided by limited control group data (7.5 to 15 percent) from two other studies.
4. The additional thyroid function studies suggest the possibility of an indirect mechanism for follicular cell tumor induction that may be associated with clofentezine's liver toxicity.
5. The mouse was negative for carcinogency effects at all dose levels, i.e., 50, 500, 5,000 ppm (equivalent to 7.5, 75, 750 mg/kg/day, respectively).
6. There are no close structural analogs with carcinogenic concerns identified.
7. Clofentezine is not mutagenic in several acceptable studies.

The Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) Science Advisory Panel (SAP) also reviewed the weight-of-evidence consideration and classification of the carcinogenic potential of clofentezine. The SAP review included the additional thyroid studies submitted by Nor-Am that were available at that time. The SAP concluded that thyroid tumors in male rats from the chronic feeding/ carcinogenicity study with clofentezine did not provide adequate evidence of a potential carcinogenic hazard to humans and that the carcinogenic potential of clofentezine belongs to Group D (not classifiable as a human carcinogen).

The Panel's interpretation was based on observed increases in thyroid stimulation hormone (TSH) levels and the incidence of thyroid follicular cell hyperplasia which may be responses to decreases in blood levels of the circulating thyroid hormones (triiodothyroxine (T_3) and tetra-iodothyroxine (T_4) observed in clofentezine-treated rats. This sequence of reduced circulating thyroid hormones and increased TSH levels and follicular cell hyperplasia is known to lead to thyroid tumors in rats, and the Panel noted, ''Exposure to agents that cause this sequence in rats has not resulted in increased TSH, hyperplasia, and thyroid tumors in humans.'' Therefore, the Panel concluded that there was inadequate data for suggesting human carcinogenicity or a quantitative risk assessment.

Nor-Am has since submitted additional thyroid studies intended to show the mechanism of clofentezine's thyroid tumor induction. The Agency has reviewed these data, but as previously stated, the Agency continues to believe that additional data are needed to more completely define the mechanism of clofentezine's thyroid tumor induction and that the available data are not sufficient to change the classification of clofentezine from Category ''C'' to Category ''D.'' However, the Agency does agree with the SAP that a quantitative risk assessment is not appropriate.

The reference dose (RfD), based on the 1-year dog feeding/carcinogenic study with a NOEL of 1.25 mg/kg/bwt and 100-fold uncertainity factor, is calculated to be 0.013 mg/kg/bwt. The theoretical maximum residue contribution (TMRC) from published uses is 0.000591 mg/kg/bwt/day. This represents 4.54 percent of the RfD. The proposed tolerance contributes .000231 mg/kg/bwt/day. This represents 1.78 precent of the RfD. Dietary exposure from the existing uses and proposed uses will not exceed the reference dose for any subpopulation (including infants and children) based on the information available from EPA's Dietary Risk Evaluation System.

The nature of the residue is understood. An adequate analytical method, high-performance liquid chromatography (HPLC), is available for enforcement.

Also, in an editorial amendment to the clofentezine tolerances in 40 CFR 180.446, EPA is removing the sole entry in paragraph (a), for pears, and moving it to the table in paragraph (b). Paragraph (a) is redundant and is being removed and designated as ''reserved.''

There are currently no actions pending against the continued registration of this chemical.

This pesticide is considered useful for the purposes for which the tolerances are sought and capable of achieving the intended physical or technical effect. Based on the information and data considered, the Agency has determined that the tolerances established by amending 40 CFR part 180 will protect the public health. Therefore, the tolerance is 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 to the regulation and may also request a hearing on those objections. Objections and hearing requests must be filed 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).

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 22, 1995.

Stephen L. Johnson,

Director, Registration Division, 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. In § 180.446, by removing paragraph (a) and designating it as ''reserved'' and by amending paragraph (b) by revising the table therein, to read as follows:

§ 180.446 Clofentezine; tolerances for residues.

(a) [Reserved]

(b) * * *

Commodity	Parts per million
Almonds, hulls	5.0
Almonds, nutmeat	0.5
Apples	0.01
Apricots	1.0
Cherries	1.0
Nectarines	1.0
Peaches	1.0
Pears	0.5
Walnuts	0.02

* * * * *

[FR Doc. 95–5651 Filed 3–7–95; 8:45 am]
BILLING CODE 6560–50–F

40 CFR Part 281

[FRL–5168–1]

Utah; Final Approval of State Underground Storage Tank Program

AGENCY: Environmental Protection Agency.

ACTION: Notice of final determination on State of Utah application for final approval.

SUMMARY: The State of Utah has applied for final approval of its underground storage tank program under Subtitle I of the Resource Conservation and Recovery Act (RCRA). The Environmental Protection Agency (EPA) has reviewed the Utah application and has reached a final determination that Utah's underground storage tank (UST) program satisfies all of the requirements necessary to qualify for final approval. Thus, EPA is granting final approval to the State to operate its program in lieu of the Federal program.

EFFECTIVE DATE: Final approval for Utah shall be effective at 1:00 pm Eastern Time on April 7, 1995.

FOR FURTHER INFORMATION CONTACT: Leslie Zawacki, Underground Storage Tank Program Section, U.S. EPA, Region 8, 8HWM–WM, 999 18th Street, Denver, Colorado 80202, phone: (303) 293–1665.

SUPPLEMENTARY INFORMATION:

A. Background

Section 9004 of the Resource Conservation and Recovery Act (RCRA) enables EPA to approve state underground storage tank programs to operate in the State in lieu of the Federal underground storage tank (UST) program. Program approval is granted by EPA if the Agency finds that the State program: (1) is ''no less stringent'' than the Federal program in all seven elements, and includes notification requirements of section 9004(a)(8), 42 U.S.C. 6991c(a)(8); and (2) provides for adequate enforcement of compliance with UST standards (section 9004(a), 42 U.S.C. 6991c(a)).

On September 20, 1993, Utah submitted an application for ''complete'' program approval which includes regulation of both petroleum and hazardous substance tanks. The State of Utah established authority through the Utah Solid and Hazardous Waste Act to implement an underground storage tank program in February 1986, and further developed its authority in the UST Act in February 1989. The State adopted the federal rules and developed some additional rules in February 1989.

On October 27, 1994, EPA published a tentative decision announcing its intent to grant Utah final approval. Further background on the tentative decision to grant approval appears at 59 FR 53955, October 27, 1994. Along with the tentative determination, EPA announced the availability of the application for public comment and provided notice that a public hearing would be provided if significant public interest was shown. EPA received no comments on the application and no request for a public hearing, therefore, a hearing was not held.

B. Decision

I conclude that Utah's application for final approval meets all of the statutory and regulatory requirements established by Subtitle I of RCRA. Accordingly, Utah is granted final approval to operate its underground storage tank program in lieu of the Federal program. Utah now has the responsibility for managing underground storage tank facilities within its borders and carrying out all aspects of the UST program except with regard to ''Indian Country,'' as defined in 18 U.S.C. 1151, where EPA will retain and otherwise exercise regulatory authority. Utah also has primary enforcement responsibility, although EPA retains the right to conduct inspections under section 9005 of RCRA 42 U.S.C. 6991d and to take enforcement actions under section 9006 of RCRA 42 U.S.C. 6991e.

Compliance With Executive Order 12866

The Office of Management and Budget has exempted this rule from the requirements of Section 6 of Executive Order 12866.

Certification Under the Regulatory Flexibility Act

Pursuant to the provisions of 5 U.S.C. 605(b), I hereby certify that this approval will not have a significant economic impact on a substantial number of small entities. The approval effectively suspends the applicability of certain Federal regulations in favor of Utah's program, thereby eliminating duplicative requirements for owners and operators of underground storage tanks in the State. It does not impose any new burdens on small entities. This rule, therefore, does not require a regulatory flexibility analysis.