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:	•	Exemptions from the of a tolerance.	
Inert ingredients	Limits		Uses	
* * * * 3,5- <i>Bis</i> (6-isocyanatohexyl)-2 <i>H</i> -1,3,5-oxadiazine- (3 <i>H</i> ,5 <i>H</i> )-trione, polymer with diethylenetr (CAS Reg. No. 87823-33-4); minimum numb erage molecular weight 1,000,000	amine	* 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