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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 golbulin 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 sternebrae).
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).

10. A two-generation reproductive study with rats with a reproductive NOEL of 10 mg/kg/day and an LEL of 100 mg/kg/day and an LEL of 100 mg/kg/day (decreased pup weight in F_1, F_{2a}, and F_{2b} litters) and decreased pup survival at 250 mg/kg/day in F_{2b} litters; systemic NOEL of 10 mg/kg/day and LEL of 100 mg/kg/day (decreased body weight and body weight gains).

11. A chronic feeding/carcinogenicity study in rats with a negative carcinogenic potential and a systemic NOEL of 10 mg/kg/day and an LEL of 50 mg/kg/day (decreased food efficiency and weight gains in females).

12. A gene mutation assay with *Salmonella* strains TA1535, TA1537, TA1538, TA100, and TA98 with and without S–9 activation, negative.

13. A gene mutation (*in vitro*) CHO/HGPRT assay at cytotoxic doses (13.9 mM, without S–9 and 9.9 mM with S–9 activation), negative.

14. A structural chromosome aberration (mammalian cells in culture) cytogenetic assay in Chinese hamster ovary cells with CHO chromosomal aberrations with and without S–9 metabolic activation, positive.

15. A structural chromosome aberration (mammalian cells in culture) cytogenetic assay in rat bone marrow, negative.

16. An unscheduled DNA synthesis study with rats at doses of 1×10^5 to 30 mM, negative.

17. A rat metabolism study with a single dose, resulted in 97% of radioactivity excreted within 7 days (20 percent in feces and 77 percent in urine); the major metabolites were demethylated hydroxylated compounds.

As part of EPA's evaluation of potential human health risks, hexazinone has been the subject of two Peer Reviews by the Office of Pesticides' Carcinogenicity Peer Review Committee. The first Peer Review, dated October 10, 1991, indicated that based on the weight of evidence, hexazinone was classified as a Group C carcinogen, possible human carcinogen. The committee recommended that for the purposes of risk characterization, the EPA reference dose (RfD) approach should be used for quantification of human risk.

E. I. du Pont de Nemours & Co. questioned the finding of the first Peer Review and presented a reevaluation of the mouse carcinogenic study based on contemporary diagnostic nomenclature of the pathology of the neoplasium found. The pathologist classified the hepatocellular carcinomas and hyperplastic nodules as either hepatocellular carcinoma, hepatocellular adenoma, or a focus of cellular alteration (nonneoplastic). The Peer Review findings were based on a pathological diagnosis that classified all hyperplastic nodules as tumors/adenomas.

A second Peer Review dated May 11, 1994, was conducted based on the reclassification of the pathology. Based on another weight-of-evidence evaluation the Carcinogenicity Peer Review Committee determined that hexazinone should be recategorized as a Group D, not classifiable as to human carcinogenicity. That is, the evidence is inadequate and cannot be interpreted as showing either the presence or absence of a carcinogenic effect. Based on this conclusion, EPA determines that hexazinone does not induce cancer within the meaning of the Delaney Clause.

The Peer Review Committee considered the following facts regarding the toxicology data on hexazinone in a weight-of-evidence determination of carcinogenic potential:

1. Based on the registrant's submission of reevaluated liver sections, hexazinone feed in the diet of CD-1 male and female mice was not associated with any pairwise statistically significant increases in adenomas, carcinomas, or combined adenomas/carcinomas, when the controls were compared to the treated groups. Female mice had a statistically significant dose-related trend (P = 0.014) for combined hepatocellular adenoma/carcinoma, but the pairwise comparison of the high-dose group to control was not statistically significant. The incidence of combined hepatocellular adenomas/carcinomas (9%) in females at the highest dose exceeded the range of these tumors in historical controls (0-5%).

Male mice had a statistically significant increasing dose-related trend in foci of cellular alteration in the liver and also a significant increase (p = 0.004) in these nonneoplastic lesions in the pairwise comparison of the highest dose and the controls. The HDT, although very high, was not considered by the Committee to have been excessive for assessing the carcinogenic potential of hexazinone in mice.

2. Hexazinone fed in the diet to male and female Spragus-Dawley rats at doses up to 125 mg/kg/day was not associated with statistically significant increases of any neoplasms in either sex.

The dosing in this study was considered to be marginally adequate based on the lack of significant toxicity and enhanced survival.

3. Hexazinone was mutagenic both with and without S-9 activation in an *in vivo* assay for chromosomal aberrations in Chinese hamster ovary cells (almost at the level of a positive control without activation). The response in a Chinese hamster ovary (CHO) gene mutation assay with activation was equivocal. Hexazinone was negative in the *Salmonella* assay, in an *in vivo* cytogenetic assay, and in a UDS assay.

4. Hexazinone is structurally, but not chemically (lacks aromaticity), related to the 2-triazines, which are usually associated with mammary gland tumors in Sprague-Dawley rats (the same strain used in the hexazinone study). Phenobarbital was considered to be a closer analog, both structurally and chemically, but unlike hexazinone, phenobarbital has no known genotoxicity. Hexazinone may also be viewed as a pyrimidine analog, a property which is thought to be predictive of carcinogenicity.

The Reference Dose (RfD) is established at 0.05 mg/kg/day, based on a NOEL of 5.0 mg/kg/day in the 12-month dog-feeding study and an uncertainty factor of 100. The Anticipated Residue Contribution (ARC) from the current actions is estimated at 7.4×10^{-5} mg/kg of body weight/day for the general population and utilizes less than 15% of the RfD for the U.S. population. The ARC for the most exposed subgroups is 2.0×10^{-2} mg/kg/body weight/day for nonnursing infants (less than 1 year old) and 1.0×10^{-2} mg/kg/body weight/day for children (1 to 6 years old), or 40.0 and 20.0 percent of the RfD, respectively. No appreciable risk is expected from chronic dietary intake because the RfD is not exceeded for either the general population or any subgroup.

The nature of the residue is adequately understood for establishing these tolerances.

An adequate analytical method, gas chromatography with a nitrogen-phosphorus detector, is available for enforcement purposes.

The pesticide is considered useful for the purpose for which these tolerances are sought, and these tolerances will limit dietary exposure to this pesticidal chemical. There are currently no actions pending against the registration of this chemical.

Based on the information and data considered, the Agency has determined that the tolerances and food/feed additive regulations established by amending 40 CFR parts 180, 185, and 186 would protect the public health. Therefore, it is proposed that the tolerances and food/feed additive regulations 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, which contains any of the ingredients listed herein, may request within 30 days after 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, [FAP 4H5683/P600]. 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.

Under Executive Order 12866 (58 FR 51735, Oct. 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 Parts 180, 185, 186

Administrative practice and procedure, Agricultural commodities, Food additives, Feed additives, Pesticides and pests, Processed foods, Reporting and recordkeeping requirements.

Dated: March 9, 1995.

Daniel M. Barolo,

Director, Office of Pesticide Programs.

Therefore, it is proposed that 40 CFR parts 180, 185, and 186 be amended as follows:

PART 180—[AMENDED]

1. In part 180:

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

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

b. In § 180.396, the existing text is designated as paragraph (a), and the table therein is amended by removing the entry for sugarcane, and new paragraph (b) is added, to read as follows:

§ 180.396 Hexazinone; tolerances for residues.

(a) * * *

(b) A tolerance with regional registration, as defined in § 180.1(n) and which excludes use of hexazinone on sugarcane in Florida, is established for combined 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 the following raw agricultural commodity:

Commodity	Parts per million
Sugarcane	0.2

PART 185—[AMENDED]

2. In part 185:

a. The authority citation for part 185 continues to read as follows:

Authority: 21 U.S.C. 346a and 348.

b. By adding new § 185.3575, to read as follows:

§ 185.3575 Hexazinone; tolerances for residues.

A food additive tolerance with regional registration, as defined in § 180.1(n) and which excludes use of hexazinone on sugarcane in Florida, is established for combined 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 the following commodity:

Commodity	Parts per million
Sugarcane, molasses	0.5

PART 186—[AMENDED]

3. In part 186:

a. The authority citation for part 186 continues to read as follows:

Authority: 21 U.S.C. 348.

b. By adding new § 186.3575, to read as follows:

§ 186.3575 Hexazinone; tolerances for residues.

A feed additive tolerance with regional registration, as defined in § 180.1(n) and which excludes use of hexazinone on sugarcane in Florida, is established for combined 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 hexazinone) in or on the following feed commodity:

Commodity	Parts per million
Sugarcane, molasses	0.5

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DEPARTMENT OF TRANSPORTATION

Coast Guard

46 CFR Parts 4 and 5

[CGD 95–023]

Marine Safety Investigation Process Review

AGENCY: Coast Guard, DOT.

ACTION: Notice and request for comments.

SUMMARY: The Coast Guard conducts marine casualty investigations to determine the causes of casualties. The findings of an investigation may lead to proceedings for the suspension or revocation of a merchant mariner's license, certificate of registry, or document, the assessment of a civil penalty, or to criminal prosecution. The Coast Guard is reviewing its marine safety investigation process to identify possible improvements, and is seeking input from the public.