

**§ 180.1139 Sodium 5-nitroguaiacolate; exemption from the requirement of a tolerance.**

The biochemical sodium 5-nitroguaiacolate is exempted from the requirement of a tolerance when used as a plant regulator in end-use products at a concentration of 0.1% by weight and applied at an application rate of 20 grams of active ingredient per acre (20 g ai/A) or less per application, in or on the raw agricultural commodities cottonseed, cotton gin byproducts, rice, rice straw, soybeans, and soybean forage and hay.

**§ 180.1140 Sodium o-nitrophenolate; exemption from the requirement of a tolerance.**

The biochemical sodium o-nitrophenolate is exempted from the requirement of a tolerance when used as a plant regulator in end-use products at a concentration of 0.2% by weight and applied at an application rate of 20 grams of active ingredient per acre (20 g ai/A) or less per application, in or on the raw agricultural commodities cottonseed, cotton gin byproducts, rice, rice straw, soybeans, and soybean forage and hay.

**§ 180.1141 Sodium p-nitrophenolate; exemption from the requirement of a tolerance.**

The biochemical sodium p-nitrophenolate is exempted from the requirement of a tolerance when used as a plant regulator in end-use products at a concentration of 0.3% by weight and applied at an application rate of 20 grams of active ingredient per acre (20 g ai/A) or less per application, in or on the raw agricultural commodities cottonseed, cotton gin by-products, rice, rice straw, soybeans and soybean forage and hay.

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**40 CFR Parts 180 and 186**

[PP 2F4041, FAP 2H5621/R2103; FRL-4931-2]

RIN 2070-AB78

**Pesticide Tolerance and Feed Additive Regulation for Sethoxydim**

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

**ACTION:** Final rule.

**SUMMARY:** This document establishes a pesticide tolerance for the combined residues of the herbicide sethoxydim, 2-[1-ethoxyimino) butyl]-5-[2-(ethylthio)propyl]-3-hydroxy-2-cyclohexene-1-one), and its metabolites

containing the 2-cyclohexene-1-one moiety (calculated as the herbicide) in or on the raw agricultural commodity (RAC) canola/rapeseed at 35.0 parts per million (ppm) and a feed additive regulation in or on animal feed commodity canola/rapeseed meal at 40 ppm. BASF Corp. requested these regulations to establish maximum permissible levels for residues of the pesticide in or on the commodities.

**EFFECTIVE DATE:** This regulation becomes effective January 20, 1995.

**ADDRESSES:** Written objections and hearing requests, identified by the document control number, [PP 2F4041, FAP 2H5261/R2103], may be submitted to: Hearing Clerk (1900), Environmental Protection Agency, Rm. M3708, 401 M St., SW., Washington, DC 20460. A copy of objections and hearing request 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 request 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 36277M, Pittsburgh, PA 15251.

**FOR FURTHER INFORMATION CONTACT:** By mail, Robert J. Taylor, Product Manager (PM 25), Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. Office location and telephone number: Rm. 245, CM #2, 1921 Jefferson Davis Hwy., Arlington, VA 22202, (703) 305-6800.

**SUPPLEMENTARY INFORMATION:** EPA issued a notice, published in the **Federal Register** of March 11, 1992 (57 FR 8658), which announced that BASF Corp., P.O. Box 13528, Research Triangle Park, NC 27709-3528, had submitted pesticide petition (PP) 2F4041. EPA issued a notice, published in the **Federal Register** of June 10, 1992 (57 FR 24646) that the company had submitted feed additive petition (FAP) 2H5621. PP 2F4041 requests that the Administrator, pursuant to section 408(d) of the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. 346a(d), amend 40 CFR part 180 by establishing a tolerance for the combined residues of the herbicide sethoxydim, 2-[1-ethoxyimino)butyl]-5-[2-(ethylthio)propyl]-3-hydroxy-2-

cyclohexene-1-one) and its metabolites containing the 2-cyclohexene-1-one moiety (calculated as the herbicide) in or on the raw agricultural commodity (RAC) canola/rapeseed at 35.0 parts per million. FAP 2H5621 requests that the Administrator, pursuant to section 409(e) of the FFDCA (21 U.S.C. 348(e)), amend 40 CFR part 186 by establishing a feed additive regulation for combined residues of the herbicide sethoxydim, 2-[1-ethoxyimino)butyl]-5-[2-(ethylthio)propyl]-3-hydroxy-2-cyclohexene-1-one), and its metabolites containing the 2-cyclohexene-1-one moiety (calculated as the herbicide) in or on animal feed commodity canola/rapeseed meal at 40 ppm.

No comments were received in response to these notices of filing.

The scientific data submitted in the petitions and other relevant material have been evaluated. The toxicological data considered in support of the proposed tolerances include:

1. Several acute toxicology studies placing technical sethoxydim in acute toxicity category IV for primary eye and dermal irritation and acute toxicity category III for acute oral, dermal, and inhalation. The dermal sensitization-guinea pig study was waived because no sensitization was seen in guinea pigs dosed with the end-use product Poast (18% a.i.).

2. A 21-day dermal study with rabbits fed dosages of 0, 40, 200, and 1,000 mg/kg/day with a NOAEL (no-observed-adverse-effect level) of greater than 1,000 mg/kg/day (limit dose).

3. A 1-year feeding study with dogs fed dosages (based on consumption) of 0, 8.86/9.41, 17.5/19.9, and 110/129 mg/kg/day (males/females) with a NOEL of 8.86/9.41 mg/kg/day (males/females) based on equivocal anemia in males and females at 17.5/19.9 mg/kg/day, respectively.

4. A 2-year chronic feeding/carcinogenicity study with mice fed dosages of 0, 6, 18, 54, and 162 mg/kg/day with no carcinogenic effects observed under the conditions of the study at dose levels up to and including 162 mg/kg/day (highest dose tested [HDT]) and a systemic NOEL of 18 mg/kg/day.

5. A 2-year chronic feeding/carcinogenic study with rats fed dosages of 0, 2, 6, and 18 mg/kg/day (HDT) with no carcinogenic effects observed under the conditions of the study at dosage levels up to and including 18 mg/kg/day (HDT) and a systemic NOEL greater than or equal to 18 mg/kg/day (HDT). This study was reviewed under current guidelines and was found to be unacceptable because the doses used

were insufficient to induce a toxic response and a maximum tolerated dose (MTD) was not achieved. This study must be repeated.

6. In a second supplemental chronic feeding/carcinogenic study with rats fed dosages of 0, 18.2/23.0, and 55.9/71.8 mg/kg/day (males/females) with no carcinogenic effects observed under the conditions of the study at dose levels up to and including 55.9/71.8 mg/kg/day (HDT) (males/females) and a systemic NOEL greater than or equal to 55.9/71.8 mg/kg/day (males/females). The doses used were insufficient to induce a toxic response and failed to achieve an MTD or define a Lowest Effect Level (LEL). Slight decreases in body weights in the final quarter of the study, although not biologically significant, can support a free-standing NOAEL of 55.9/71.8 mg/kg/day (males/females).

7. A developmental toxicity study in rats fed dosages of 0, 50, 180, 650, and 1,000 mg/kg/day with a maternal NOAEL of 180 mg/kg/day and a maternal LEL of 650 mg/kg/day (irregular gait, decreased activity, excessive salivation, and anogenital staining); and a developmental NOAEL of 180 mg/kg/day and a developmental LEL of 650 mg/kg/day (21 to 22 percent decrease in fetal weights, filamentous tail and lack of tail due to the absence of sacral and/or caudal vertebrae, and delayed ossification in the hyoids, vertebral centrum and/or transverse processes, sternbrae and/or metatarsals, and pubes).

8. A developmental toxicity study in rabbits fed doses of 0, 80, 160, 320, and 400 mg/kg/day with a maternal NOEL of 320 mg/kg/day and a maternal lowest observable effect level (LOEL) of 400 mg/kg/day (37 percent reduction in body weight gain without significant differences in group mean body weights, and decreased food consumption during dosing); and a developmental NOEL greater than 400 mg/kg/day (HDT).

9. A two-generation reproduction study with rats fed dosage levels of 0, 150, 600, and 3,000 ppm (approximately 0, 7.5, 30, and 150 mg/kg/day) with no reproductive effects observed at 3,000 ppm (approximately 150 mg/kg/day) (HDT). However, the Agency considers this study usable for regulatory purposes and has established a free-standing NOEL of 3,000 ppm (approximately 150 mg/kg/day).

10. Mutagenicity studies included: Ames Assays, which were negative for *Salmonella typhimurium* strains TA98, TA100, TA1535, and TA 1537, with and without metabolic activity; sethoxymim did not cause structural chromosomal aberrations at doses up to 5,000 mg/kg in Chinese hamster bone marrow cells

in vivo; a Host Mediated Assay (mouse) with *S. typhimurium* was negative at 2.5 grams/kg/day of chemical, and recombinant assays and forward mutations in *Bacillus subtilis*, *Escherichia coli*, and *S. typhimurium* were all negative at concentrations of greater than or equal to 100%; a in vitro Unscheduled DNA Synthesis Assay in Primary Rat Hepatocytes had a negative response for DNA repair (UDS) in primary rat hepatocyte cultures exposed up to insoluble (greater than 101 micrograms per milliliter (mL)) and cytotoxic (507 ug/mL) doses.

11. In a rat metabolism study, excretion was extremely rapid and tissue accumulation was negligible, assuming DMSO vehicle does not affect excretion or storage of NP-55 (78 percent excreted into urine and 20.1 percent excreted in feces).

The reference dose (RfD), based on a NOEL of 8.86 mg/kg bwt/day in the 1-year feeding study in dogs and an uncertainty factor of 100, was calculated to be 0.09 mg/kg bwt/day. The theoretical maximum residue contribution (TMRC) for the overall U.S. population is 0.031961 mg/kg bwt/day or 35.9% of the RfD for existing tolerances for the overall use population. The current action will increase the TMRC by 0.000380 mg/kg bwt/day. These tolerances and previously established tolerances utilize a total of 35.9 percent of the ADI for the overall U.S. population. For U.S. subgroup populations, nonnursing infants and children aged 1 to 6, the current action and previously established tolerances utilize, respectively, a total of 61.8 percent and 72.6 percent of the ADI, assuming that residue levels are at the established tolerances and that 100 percent of the crop is treated.

Desirable data lacking based on review of data under current guidelines include a carcinogenicity in mice study and a chronic feeding/carcinogenicity in rats study. Because the current studies, although unacceptable by current guidelines, provide useful information and these tolerances utilize 3 percent of the RfD, the Agency believes there is little risk from establishment of these tolerances. Any additional tolerance proposals will be considered on a case-by-case basis.

The pesticide is useful for the purposes for which these tolerances are sought and capable of achieving the intended physical or technical effect. The nature of the residue is adequately understood, and adequate analytical methods (gas chromatography using sulfur-specific flame photometric detection) are available for enforcement

purposes. The method is listed in the Pesticide Analytical Manual, Volume II (PAM II), as Method I.

There are currently no actions pending against the registration of this chemical. Any secondary residues occurring in meat, fat, meat byproducts and milk of cattle, goats, hogs, horses and sheep will be covered by existing tolerances. There are no residues expected to occur in poultry meat, meat byproducts, fat, or eggs from these tolerances.

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, and the establishment of a feed additive regulation by amending 40 CFR part 185 will be safe. Therefore, they are established as set forth below.

Any person adversely affected by this regulation may, within 30 days after the date of publication in the **Federal Register**, file written objections with the Hearing Clerk, Environmental Protection Agency, 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 objection. 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 intentions on each issue, and a summary of any evidence relied upon by the objector. 40 CFR 178.27. A request for hearing will be granted if the Administrator determines at the material submitted shows the following: There is a 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 aims 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, 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 of 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, or establishing or raising food additive regulations 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 and 186**

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

Dated: January 6, 1995.

**Stephen L. Johnson,**

*Director, Registration Division, Office of Pesticide Programs.*

Therefore, chapter I of title 40 of the Code of Federal Regulations is 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 § 180.412 by amending paragraph (a) in the table therein by adding and alphabetically inserting the entry for the raw agricultural commodity canola/rapeseed to read as follows:

**§ 180.412 2-[1-(Ethoxyimino)butyl]-5-[2-(ethylthio)propyl]-3-hydroxy-2-cyclohexene-1-one; tolerances for residues.**

(a) \* \* \*

Commodity	Parts per million
Canola/rapeseed .....	35.0

**PART 186—[AMENDED]**

2. In part 186:

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

**Authority:** 21 U.S.C. 348.

b. In § 186.2800 in the table therein by adding and alphabetically inserting the entry for canola/rapeseed, to read as follows:

**§ 186.2800 2-[1-(Ethoxyimino)butyl]-5-[2-(ethylthio)propyl]-3-hydroxy-2-cyclohexene-1-one.**

Food	Parts per million
Canola/rapeseed .....	40.0

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**FEDERAL EMERGENCY MANAGEMENT AGENCY**

**44 CFR Part 65**

[Docket No. FEMA-7121]

**Changes in Flood Elevation Determinations**

**AGENCY:** Federal Emergency Management Agency (FEMA).

**ACTION:** Interim rule.

**SUMMARY:** This interim rule lists communities where modification of the base (100-year) flood elevations is appropriate because of new scientific or technical data. New flood insurance premium rates will be calculated from the modified base (100-year) flood elevations for new buildings and their contents.

**DATES:** These modified base flood elevations are currently in effect on the dates listed in the table and revise the Flood Insurance Rate Map(s) in effect

prior to this determination for each listed community.

From the date of the second publication of these changes in a newspaper of local circulation, any person has ninety (90) days in which to request through the community that the Associate Director, Mitigation Directorate, reconsider the changes. The modified elevations may be changed during the 90-day period.

**ADDRESSES:** The modified base (100-year) flood elevations for each community are available for inspection at the office of the Chief Executive Officer of each community. The respective addresses are listed in the following table.

**FOR FURTHER INFORMATION CONTACT:** Michael K. Buckley, P.E., Chief, Hazard Identification Branch, Mitigation Directorate, 500 C Street, SW, Washington, DC 20472, (202) 646-2756.

**SUPPLEMENTARY INFORMATION:** The modified base (100-year) flood elevations are not listed for each community in this interim rule. However, the address of the Chief Executive Officer of the community where the modified base (100-year) flood elevation determinations are available for inspection is provided.

Any request for reconsideration must be based upon knowledge of changed conditions, or upon new scientific or technical data.

The modifications are made pursuant to Section 201 of the Flood Disaster Protection Act of 1973, 42 U.S.C. 4105, and are in accordance with the National Flood Insurance Act of 1968, 42 U.S.C. 4001 *et seq.*, and with 44 CFR Part 65.

For rating purposes, the currently effective community number is shown and must be used for all new policies and renewals.

The modified base (100-year) flood elevations are the basis for the floodplain management measures that the community is required to either adopt or to show evidence of being already in effect in order to qualify or to remain qualified for participation in the National Flood Insurance Program (NFIP).

These modified elevations, together with the floodplain management criteria required by 44 CFR 60.3, are the minimum that are required. They should not be construed to mean that the community must change any existing ordinances that are more stringent in their floodplain management requirements. The community may at any time enact stricter requirements of its own, or