

offered for sale together with the class I or class II substance.

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BILLING CODE 6560-50-P

40 CFR Part 180

[PP 4F4344/R2207; FRL-5350-7]

RIN 2070-AB78

Sethoxydim; Pesticide Tolerance

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 commodities (RACs) corn, field, grain at 0.5 parts per million (ppm); corn, fodder at 2.5 ppm; and corn forage at 2.0 ppm. These tolerances replace current entries for field corn, grain; corn, fodder; and corn, forage. BASF Corporation requested these tolerances in a petition submitted to EPA pursuant to Federal Food, Drug, and Cosmetic Act (FFDCA).

EFFECTIVE DATE: February 29, 1996.

ADDRESSES: Written objections and hearing requests, identified by the docket control number, [PP 4F4344/R2207], may be submitted to: Hearing Clerk (1900), Environmental Protection Agency, Rm M3708, 401 M St., SW., Washington, DC 20460. Fees accompanying objections shall be labeled "Tolerance Petition Fees" and forwarded to EPA Headquarters Accounting Office Branch, OPP (Tolerance Fees), P.O. Box 360277M, Pittsburgh, PA 15251. 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 request to: Rm 1132, CM #2, 1921 Jefferson Davis Hwy., Arlington, VA.

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.gov. Copies of objections and hearing request must

submitted as an ACSII 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 Word Perfect 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 [4F4344/R2207]. 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, 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, telephone number, and e-mail address: Rm. 241, CM #2, 1921 Jefferson Davis Hwy., Arlington, VA, (703) 305-6027; e-mail: taylor.robert@epamail.epa.gov.

SUPPLEMENTARY INFORMATION: On August 17, 1995 (60 FR 42884), EPA issued a notice in the Federal Register announcing that BASF Corporation, P.O. Box 13528, Research Triangle Park, NC 27709-3528, had submitted a pesticide petition (PP 4F4344) to EPA proposing to amend 40 CFR part 180 pursuant to section 408(d) of the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. 346a(d), establishing regulations to permit 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 commodities (RACs) corn, grain at 0.5 part per million (ppm); corn, fodder at 2.5 ppm; corn, forage at 2.0 ppm, and corn, silage at 2.0 ppm.

No comments were received in response to this notice of filing.

The petitioner subsequently amended the petition by submitting a revised section F deleting the proposed tolerance for corn silage. Because this is a deletion of a previously proposed tolerance, no longer in Table 2 of the Residue Chemistry Guidelines, there is no potential risk to humans. Therefore an additional period of public comment is not necessary.

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 place 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 NOEL (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 (no-observed effect level) 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. A maximum tolerated dose (MTD) was not achieved for females in this study. A determination of the need for an additional study will be made once the replacement chronic feeding/carcinogenicity study in rats is evaluated.

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. A chronic feeding/carcinogenic study with rats was submitted to supplement the above study. Rats in this study were 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 NOEL of 55.9/71.8 mg/kg/day (males/females). A new study is necessary to replace both this study and the one discussed above.

7. A developmental toxicity study in rats fed dosages of 0, 50, 180, 650, and 1,000 mg/kg/day with a maternal NOEL 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 NOEL of 180 mg/kg/day and a developmental LEL of 650 mg/kg/day (21-22% 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% 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 2-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; sethoxydim 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%; an *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 (>101 ug/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% excreted into urine and 20.1% 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 existing tolerances for the overall U. S. population is 0.032767 mg/kg bwt/day or 35% of the RfD. The current action will increase the TMRC by 0.000134 mg/kg bwt/day. These tolerances and previously established tolerances utilize a total of 37 percent of the RfD 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 63.5% and 74% of the ADI, assuming that residue levels are at the established tolerances and that 100% of the crop is treated. [These studies are also referenced in an EPA proposed rule on sethoxydim published elsewhere in this issue of the Federal Register.]

Desirable data lacking based on review of data under current guidelines include a repeat of the chronic feeding/carcinogenicity study in rats. Once the rat study is evaluated, a repeat of the mouse carcinogenicity study may be needed. Because the current studies, although unacceptable by current guidelines, provide useful information and these tolerances utilize less than 1% 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. Previously approved versions of the analytical method are listed in the *Pesticide Analytical Manual, Volume II* (PAM II), as Method I. The analytical methods for corn grain, fodder, and forage are revisions of the above method. Because of the long lead time from establishing these tolerances until publication, the enforcement methodology for corn grain, fodder, and forage are being made available in the interim to anyone interested in pesticide enforcement when requested by mail from: Calvin Furlow, Public Response Resources Branch, Field Operations

Division (7506C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. Office location and telephone number; Rm 1130 A, CM #2, 1921 Jefferson Davis Hwy., Arlington, VA, (703) 305-6027.

There are currently no actions pending against the registration of this chemical. Any expectation of residues occurring in eggs, milk, meat, fat or meat by-products of cattle, goats, hogs, horses, and sheep or poultry will be covered by existing tolerances.

Based on the information and data considered, the Agency has determined that the tolerances established by amending 40 CFR part 180 would protect the public health. Therefore, EPA is establishing the tolerances 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 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 each such issue, 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 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 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 4F4344/R2207] (including objections and hearing requests submitted electronically as described below). A public version of this record, including printed, paper versions 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, Crystal Mall #2, 1921 Jefferson Davis Highway, Arlington, VA.

Written objections and hearing requests, identified by the docket control number [PP 4F4344/R2207], may be submitted to the Hearing Clerk (1900), Environmental Protection Agency, Rm 3708, 401 M St., SW., Washington, DC 20460.

A copy of electronic objections and hearing requests filed with the Hearing Clerk can be sent directly to EPA at:

opp-docket@epamail.epa.gov

A copy of electronic objections and hearing requests filed with the Hearing Clerk 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 any objections and hearing requests 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 objections and hearing requests submitted directly in writing. The official rulemaking record is a 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 review by the Office of Management and Budget (OMB) and the requirements of the Executive Order. Under section 3(f), the order defines a "significant regulatory action" as an action that is likely to result in 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 referred to 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 the rights and obligation of recipients thereof; 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 the 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, Food additive, Pesticides and pests, Reporting and recordkeeping requirements.

Dated: February 20, 1996.

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 § 180.412(a), by revising the entries for corn, field, grain; corn fodder; and corn forage to read as follows.

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

(a) * * *

Commodity	Parts per million
* * *	
corn, field, grain	0.5
corn fodder	2.5
corn forage	2.0
* * *	
* * *	

[FR Doc. 96-4396 Filed 2-28-96; 8:45 am]

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40 CFR Part 180

[PP 5F4493/R2205; FRL-5351-5]

RIN 2070-AB78

Pesticide Tolerance for Glyphosate

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This rule establishes a tolerance for residues of the herbicide glyphosate [N-(phosphonomethyl)glycine] in or on the raw agricultural commodity (RAC) cotton gin byproducts at 100 parts per million (ppm). Monsanto Company requested this tolerance in a petition submitted to EPA pursuant to the Federal Food, Drug, and Cosmetic Act (FFDCA).

EFFECTIVE DATE: These regulations become effective February 29, 1996.

ADDRESSES: Written objection and hearing requests, identified by the docket number, [PP 5F4493/R2205], may be submitted to: Hearing Clerk (1900), Environmental Protection Agency, Rm. M3708, 401 M St., SW., Washington, DC 20460. 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 any objections and hearing request filed with the Hearing Clerk should be identified by the docket 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 a copy of objections and hearing requests to: Rm. 1132, CM #2, 1921 Jefferson Davis Hwy., Arlington, VA 22202. A copy of objections and hearing requests filed with the Hearing Clerk may also be submitted electronically by sending electronic mail (e-mail) to: oppdocket@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 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 5F4493/R2205]. 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