

1. Available data demonstrate that oleyl alcohol is no more than slightly toxic to mammals, fish, and aquatic invertebrates.

2. Oleyl alcohol is found in fish oils and one of its uses is as a carrier for medicaments. Anticipated residues of oleyl alcohol at the proposed level of use are expected to be of little or no toxicological significance.

3. Oleyl alcohol is approved by the Food and Drug Administration for use as a component of paper and paperboard under 21 CFR 176.170, as defoaming agent under 21 CFR 176.210, and as a component of animal glue under 21 CFR 178.3120.

Based upon the above information and review of its use, the Agency does not believe that a potential for significant hazard exists when used in accordance with good agricultural practice. The Agency believes and that this ingredient is useful and a tolerance is not necessary to protect the public health. Therefore, EPA proposes that the exemption from the requirement of a tolerance 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 Federal Food, Drug, and Cosmetic Act.

Interested persons are invited to submit written comments on the proposed regulation. Comments must bear a notation indicating the document control number, [OPP-300384]. 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.

The Office of Management and Budget has exempted this rule from the requirements of section 3 of Executive Order 12866.

Pursuant to the requirements of the Regulatory Flexibility Act (Pub. L. 96-354 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: March 29, 1995.

James J. Jones,
Acting Director, Registration Division, Office of Pesticide Programs.

Therefore, it is proposed that 40 CFR part 180 be 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. Section 180.1001(c) is amended in the table therein by adding and alphabetically inserting the inert ingredient, to read as follows:

§ 180.1001 Exemptions from the requirements of a tolerance.

* * * * *
(c) * * *

| Inert ingredients | Limits | Uses |
|--------------------------------------------|-----------|-----------|
| * * * * * | * * * * * | * * * * * |
| Oleyl alcohol (CAS Reg. No 143-28-2) | 15% | Cosolvent |
| * * * * * | * * * * * | * * * * * |

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40 CFR Part 180
[PP 8F3671/P610; FRL-4945-3]
RIN 2070-AC18

Alachlor; Pesticide Tolerance

AGENCY: Environmental Protection Agency (EPA).
ACTION: Proposed rule.

SUMMARY: This document proposes to establish an increased tolerance for residues of the herbicide alachlor (2-chloro-2',6'-dimethyl-N-(methoxymethyl) acetanilide) and its metabolites in or on the raw agricultural commodity (RAC) sorghum forage at 2.0 parts per million (ppm). The Monsanto

Co. requested the establishment of this maximum permissible residue of the herbicide.

DATES: Comments, identified by the document control number [PP 8F3671/P610], must be received on or before May 12, 1995.

ADDRESSES: By mail, submit written comments 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 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 address given above, from 8 a.m. to 4 p.m., Monday through Friday, excluding legal holidays.

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. 241, CM #2, 1921 Jefferson Davis Hwy., Arlington, VA 22202, (703)-305-6800; e-mail: taylor.robert@epamail.epa.gov.

SUPPLEMENTARY INFORMATION: EPA issued a notice in the Federal Register of October 12, 1988 (53 FR 39785), that announced that the Monsanto Co., 1101 17th St., NW., Washington, DC 20036, proposed amending 40 CFR 180.249 by establishing a regulation under section 408 of the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. 346a, to permit the residues of the herbicide alachlor (2-chloro-2',6'-dimethyl-N-(methoxymethyl) acetanilide) and its metabolites in or on sorghum forage at 2.0 parts per million (ppm) (pesticide petition (PP) 8F3671). This increased tolerance was necessary because review of additional data submitted in response to reregistration indicated that the current tolerance of 1.0 for sorghum forage was not adequate and needed to be increased. EPA issued a notice in the Federal Register of March 23, 1989 (54 FR 12010), which announced that the Monsanto Co. proposed amending 40 CFR parts 185 and 186 by establishing a regulation under section 409 of the FFDCA, 21 U.S.C. 348, permitting residues of the herbicide alachlor in or on sorghum milling fractions at 0.5 ppm, sorghum milling fractions (except germ) at 0.3 ppm, and sorghum germ at 0.5 ppm (food/feed additive (FAP) 9H5576).

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

During the course of its review, the Agency determined that the food/feed additive tolerances for sorghum milling fractions and sorghum germ were not needed and that there is no current evidence of use of sorghum milling fractions as a human food and very limited evidence of use of sorghum milling fractions as livestock feed. The petitioner subsequently withdrew FAP No. 9H5576. Because it has been longer than 5 years since the original proposal, the tolerance of 2.0 ppm for sorghum forage is being proposed for 30 days following the date of publication in the Federal Register to allow for public comment.

The data submitted in the petition and other relevant material have been evaluated. The pesticide is considered useful for the purpose for which the tolerance is sought. The toxicological data listed below were considered in support of the proposed tolerance.

1. Several acute toxicology studies place technical alachlor in acute toxicity category IV for primary eye and dermal irritation and, acute toxicity category III for acute oral, dermal, and inhalation.

2. A 1-year feeding study with dogs fed dose levels of 0, 1, 3, and 10 milligrams/kilograms/day (mg/kg/day) with a no-observed effect level (NOEL) of 1.0 mg/kg/day based on hemosiderin

storage in kidney and spleen in males at 10 mg/kg.

3. A 2-year chronic feeding/carcinogenicity study in rats fed epichlorohydrin-free alachlor at dose levels of 0, 0.5, 2.5, and 15 mg/kg/day with a NOEL for nonneoplastic toxicity at 2.5 mg/kg/day based on ocular lesions and hepatotoxicity at 10 mg/kg/day. Carcinogenic effects included a nasal turbinate tumor in females at 2.5 mg/kg/day, significant increases in nasal turbinate tumors in both males and females at 15 mg/kg/day (highest dose tested (HDT)) and a significant increase in thymus lymphosarcomas and adrenal pheochromocytomas in high-dose females.

4. A second chronic feeding/carcinogenic study with rats fed alachlor, with epichlorohydrin, at dose levels of 0, 14, 42, and 126 mg/kg/day with a systemic NOEL of less than 14 mg/kg/day based on ocular lesions and hepatotoxicity at 14 mg/kg/day. Carcinogenic effects included increased number of nasal turbinate tumor in males and females at 42 mg/kg/day and mg/kg/day, an increase in stomach tumors in both sexes at 126 mg/kg/day, and an increase in thyroid follicular tumors in males at 126 mg/kg/day (HDT).

5. A special chronic feeding study in rats fed a dose level of 126 mg/kg/day. Ocular lesions, mainly, the uveal degeneration syndrome (UDS) occurred in 100% of the animals at the end of the study. This syndrome was irreversible once it began. Alachlor was a positive oncogen with increased nasal turbinate tumors, stomach tumors, and thyroid tumors.

6. An 18-month carcinogenicity study in mice fed dose levels of 0, 26, 78, and 260 mg/kg/day with carcinogenic effects (increased lung bronchiolaraveolar tumors in females at 260 mg/kg/day).

7. A three-generation reproduction study with rats fed dose levels of 0, 3, 10, 11, and 30 mg/kg/day with a reproductive NOEL of 10 mg/kg/day based on kidney effects in F2 and F3 pups at 30 mg/kg/day (HDT).

8. A developmental toxicity study in rats fed dose levels of 0, 50, 150, and 400 mg/kg/day with a developmental toxicity equal to a greater than 400 mg/kg/day with a fetotoxic NOEL of 150 mg/kg/day based on an increase in post-implantation loss and a slight decrease in mean number of viable fetuses at 400 mg/kg/day. The maternal toxicity NOEL for this study is 150 mg/kg/day based on soft stools, hair loss, anogenital staining, and death at 400 mg/kg/day.

9. A developmental toxicity study in rabbits fed doses of 50, 100, and 150 mg/kg/day with a developmental NOEL

greater than 150 mg/kg/day greater than 150 mg/kg/day. The maternal NOEL was 100 mg/kg/day based on reduced body weight gain.

10. Mutagenicity studies include several Ames Tests. Alachlor and its metabolites were negative in four Ames assays with *Salmonella* with and without S9 activation at 0.1 to 10 mg/plate. Two metabolites of alachlor were positive in an Ames test with and without S9 activation at 0.01 to 10 mg/plate. Bile from alachlor-treated rats did not induce a mutagenic response towards *Salmonella* strains TA98, TA100, TA1535, and TA1537. Other mutagenicity tests include DNA damage/repair in rat positive for UDS at the HDT = LD₅₀ at the 4 doses tested (50, 200, and 1,000 mg/kg)—weakly genotoxic; gene mutation in CHO/HGPRT—negative, and *in vivo* bone marrow chromosome aberration assay—negative.

Alachlor has been classified as a B₂ carcinogen—"Probable Human Carcinogen" by the Agency. Alachlor met all but one of the criteria specified for the B₂ classification. Alachlor produced an increased incidence of nasal turbinate tumors (mostly benign) at the mid and high doses, in both sexes, thyroid follicular tumors in male rats and malignant stomach tumors in male and female rats in Long-Evans rats in three different experiments at more than one dose level via dietary administration. Alachlor also produced a statistically significant increase in lung tumors in female CD-1 mice at two dose levels. In another experiment with Long-Evans rats, nasal turbinate tumors occurred only 5 to 6 months after exposure. The tumor incidence was as high at 50% and tumor site was unusual, i.e., not an increase of normal high background tumor type. A metabolite of alachlor was mutagenic in the Ames Test at 6 dose levels, and alachlor is structurally similar to acetochlor and metolachlor, two other known carcinogens. A detailed discussion of the Agency's classification of alachlor as a B₂ carcinogen was published in the Federal Register of December 31, 1987 (52 FR 49480). The publication was entitled "Alachlor, Notice of Intent to Cancel Registrations, Conclusion of Special Review."

For the purpose of risk characterization of alachlor, the use of the linearized multi-stage model, as recommended to EPA's Carcinogenic Risk Assessment Guidelines, was applied to the rat oncogenicity data discussed above. As a result, the cancer potency value for alachlor, known as the "Q*1", was calculated to be 8 X 10⁻² or 0.08 (mg/kg/day)⁻¹. Refer to the

document published in the Federal Register of December 31, 1987 (54 FR 49484) for details.

The reference dose (RfD) based on a NOEL of 1.0 mg/kg/day (1-year feeding study in dogs) and an uncertainty factor of 100 was calculated to be 0.01 mg/kg/day. The theoretical maximum residue contribution (TMRC) for the overall U. S. population from published and proposed uses recommended through reregistration is 0.000532 mg/kg/day or 5.3% of the RfD. For the most highly exposed subgroup, nonnursing infants less than 1 year old, the published and proposed use recommended through reregistration is 0.002184 mg/kg/day or 21.8% of the RfD. The current action of increasing the tolerance on sorghum forage to 2.0 does not contribute any additional TMRC or utilize additional RfD because sorghum forage is not a human food and current tolerances in livestock commodities will not be exceeded as a result of the proposed increase in the tolerance for sorghum forage.

Refinements in residue and percent-crop treated information were considered in calculating the Anticipated Residue Contribution (ARC) for the same population groups above. The ARC is considered the more accurate estimate of dietary exposure. These exposure estimates were then compared to the RfD for alachlor to get estimates of chronic dietary risk. The ARC for the overall U. S. population for published tolerances is 1.3×10^{-5} or 0.1% of the RfD. For the most highly exposed subgroup, nonnursing infants, the ARC is 5.4×10^{-5} or less than 1% of the RfD. The current action does not contribute additional ARC or utilize additional RfD. Other tolerances proposed by reregistration result in an ARC of 4.0×10^{-6} mg/kg/day or 0.04% of the RfD for the overall U.S. population and an ARC of 5.3×10^{-5} mg/kg/day or 0.5% of the RfD for nonnursing infants, less than 1 year old.

Based on a Q^*1 of 0.08 (mg/kg/day)⁻¹ the upper-bound cancer risk was calculated to be 1.4×10^{-6} and contributed through all published and proposed uses for alachlor. The current action for sorghum forage contributes no additional risks.

There are currently no regulations against the registration of this chemical for use on sorghum forage. Even though alachlor is classified as a probable human carcinogen, EPA believes the establishment of this tolerance will not pose an unreasonable risk to humans as a result of dietary exposure.

The pesticide is useful for the purposes for which tolerances are sought. The nature of the residues is

adequately understood for the purposes of establishing tolerances. Adequate analytical methods (high-pressure liquid chromatography and gas chromatography) are available for enforcement purposes (PAM II, Method III).

Based on the information considered by the Agency, the Agency has determined that when used in accordance with good agricultural practice, this ingredient is useful and that the tolerance established by amending 40 CFR part 180 would protect the public health. It is proposed, therefore, that the tolerance 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 Federal Food, Drug and Cosmetic Act.

Interested persons are invited to submit written comments on the proposed regulation. Comments must bear a notation indicating the document control number, [PP 8F3671/P610]. 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.

The Office of Management and Budget has exempted this rule from the requirements of section 3 of Executive Order 12866. 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: March 30, 1995.

Stephen L. Johnson,
Director, Registration Division, Office of Pesticide Programs.

Therefore, it is proposed that 40 CFR part 180 be 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 § 180.249, by amending the table therein by revising the entry for sorghum forage, to read as follows:

§ 180.249 Alachlor; tolerances for residues.

| Commodity | Parts per million |
|-----------------------|-------------------|
| * * * * * | |
| Sorghum, forage | 2.0 |
| * * * * * | |

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40 CFR Parts 180 and 186

[PP 8F3646 and FAP 8H5558/P611; FRL-4947-3]

RIN 2070-AC18

Sethoxydim; Pesticide Tolerance and Feed Additive Regulation

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: EPA proposes to increase the established pesticide tolerance for the combined residues of the herbicide sethoxydim (2-[1-(ethoxyimino)butyl]-5-[2-(ethylthio)propyl]-3-hydroxy-2-cyclohexen-1-one) and its metabolites containing the 2-cyclohexen-1-one moiety (calculated as the herbicide) in or on the raw agricultural commodity sugar beet roots to 1.0 part per million (ppm) and to increase the established feed additive regulation on the animal feed commodity sugarbeet molasses to 10.0 ppm. The BASF Corp. requested these regulations to establish the maximum permissible levels for residues of the pesticide in or on the above commodities.

DATES: Comments, identified by the document control number, [PP 8F3646 and FAP 8H5558/P611], must appear on or before May 12, 1995.

ADDRESSES: By mail, submit written comments to: Public Response and