

submitted by the Virginia Department of Air Pollution Control on April 12, 1989.

(n) EPA approves as part of the Virginia State Implementation Plan the revised references to the documents listed in Appendix M, Sections II.A. and II.B. of the Virginia Regulations for the Control and Abatement of Air Pollution submitted by the Virginia Department of Air Pollution Control on February 12, 1993.

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40 CFR Part 180

[PP-8F3662/R1176; FRL-4178-2]

RIN 2070-AB78

Urea; Exemption From the Requirement of a Tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This document establishes a permanent exemption from the requirement of a tolerance for residues of the frost protectant urea in or on various agricultural commodities. Unocal Corp. requested this regulation pursuant to the Federal Food, Drug and Cosmetic Act.

EFFECTIVE DATE: This regulation becomes effective August 23, 1995.

ADDRESSES: Written objections and hearing requests, identified by the document control number, [PP 8F3662/R1176], may be submitted to: Hearing Clerk (1900), Environmental Protection Agency, Rm. M3708, 401 M St., SW., Washington, DC 20460. Fees accompanying objections and hearing requests 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 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.

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.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 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 [PP 8F3662/R1176]. 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: Cynthia Giles-Parker, Product Manager (PM) 22, Registration Division, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. Office location and telephone number: Rm. 229, CM #2, 1921 Jefferson Davis Hwy., Arlington, VA 22202, (703)-308-8323; e-mail: giles-parker.cynthia@epamail.epa.gov.

SUPPLEMENTARY INFORMATION: EPA issued a notice, published in the **Federal Register** of October 12, 1988 (53 FR 39784), which announced that the Unocal Corp., 3960 Industrial Blvd., Suite 600-B, West Sacramento, CA 95691, had submitted pesticide petition (PP) 8F3662 to EPA requesting that the Administrator, pursuant to section 408(d) of the Federal Food, Drug and Cosmetic Act (FFDCA), 21 U.S.C. 346a(d), establish an exemption from the requirement of a tolerance for the frost protectant urea in or on all raw agricultural products. The proposed exemption was subsequently editorially amended to specify the following crops on the label of the product proposed for registration under the Federal Insecticide, Fungicide, and Rodenticide Act, as amended: alfalfa, almonds, apples, apricots, artichokes, asparagus, avocados, beans, bell peppers, blackberries, blueberries, broccoli, brussels sprouts, boysenberries, caneberries, canola, cantaloupe, carrots, cauliflower, casaba, celery, cherries, chili peppers, chinese cabbage (bok choy, napa), cooking peppers, corn, cotton, crenshaw, cucumbers, figs, grapefruit, grapes, honeydew melon, hops, kiwifruit, kohlrabi, lemons, lentils, lettuce, limes, macadamia nuts, musk melon, nectarines, olives, onions, oranges, peaches, pears, peanuts, peas, persian melon, pistachios, plums, potatoes, pumpkin, prunes, radish, raspberries, rice, safflower, sorghum, spinach, spinach (New Zealand), squash (winter and summer), strawberries,

sugar beets, sunflower, sweet pepper, table beets, tangerines, tomatoes, walnuts, watermelon, and zucchini.

There were no comments or requests for referral to an advisory committee received in response to the proposed rule.

The toxicological data considered in support of the exemption from the requirement of a tolerance include an acute oral toxicity study in the rat, an acute dermal toxicity study in the rabbit, an acute inhalation toxicity study in the rat, a primary eye irritation study in the rabbit, a primary dermal irritation study in rabbits, and a dermal sensitization study in the guinea pig. These studies were performed on the end-use product, "Enfrost," with 42.9-percent urea. A review of these studies indicates that the frost protectant has a low toxicity to animals when administered via the oral, dermal, or inhalation routes of exposure (Toxicity Categories III and IV). The active ingredient, urea, has GRAS (Generally Recognized as Safe) status as a direct food additive under title 21 of the Code of Federal Regulations (CFR) under 40 CFR 184.1923. Urea is exempt from the requirement of a tolerance under 40 CFR 180.1001(c) as an inert ingredient in formulations applied to growing crops or crops after harvest. The amount to be used is similar to that permitted for the inert ingredient use. Urea is a normal constituent of animal tissues and body fluid. Humans excrete about 25 grams per day in the urine. Urea is a naturally occurring crop/plant constituent.

Acceptable daily intake (ADI) and maximum permissible intake (MPI) considerations are not relevant to this petition. No enforcement actions are expected. Therefore, the requirement for an analytical method for enforcement purposes is not applicable to this exemption request.

Urea is considered useful for the purpose for which the exemption from the requirement of a tolerance is sought. There are no regulatory actions pending against the registration of urea. Based on the information considered, the Agency concludes that establishment of a tolerance is not necessary to protect the public health, and therefore, the exemption from the requirement of a tolerance is established as set forth below.

The data submitted with the proposal and other relevant material have been evaluated and discussed in the proposed rule. Based on the data and information considered, the Agency concludes that the tolerance exemption will protect the public health. Therefore, the tolerance exemption is established 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 and/or request a hearing 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 such issues, 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 8F3662/R1176] (including any 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 document control number [PP 8F3662/R1176], 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 the paper record maintained at the address in "ADDRESSES" at the beginning of this document.

Under Executive Order 12866 (58 FR 51735, Oct. 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 obligations 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, Pesticides and pests, Reporting and recordkeeping requirements.

Dated: August 4, 1995.

Allen Jennings,

Acting Director, 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 subpart D, adding new § 180.1117, to read as follows:

§ 180.1117 Urea; exemption from the requirement of a tolerance.

An exemption from the requirement of a tolerance is established for residues of the frost protectant urea in or on the following raw agricultural commodities when used before harvest in the production of: alfalfa, almonds, apples, apricots, artichokes, asparagus, avocados, beans, bell peppers, blackberries, blueberries, broccoli, brussels sprouts, boysenberries, canberries, canola, cantaloupes, carrots, cauliflower, casaba, celery, cherries, chili peppers, chinese cabbage (bok choy, napa), cooking peppers, corn, cotton, crenshaw, cucumbers, figs, grapefruit, grapes, honeydew melon, hops, kiwifruit, kohlrabi, lemons, lentils, lettuce, limes, macadamia nuts, musk melon, nectarines, olives, onions, oranges, peaches, pears, peanuts, peas, persian melon, pistachios, plums, potatoes, pumpkin, prunes, radish, raspberries, rice, safflower, sorghum, spinach, spinach (New Zealand), squash (winter and summer), strawberries, sugar beets, sunflower, sweet pepper, table beets, tangerines, tomatoes, walnuts, watermelon, and zucchini.

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