5-3-85

TECHNICAL SUPPORT SECTION EFFICACY REVIEW - I

Disinfectants Branch

IN 03-21-85 OUT 05-02-85

Dennis G. Guse 5/3/85

Reviewed By Dennis G. Guse Date 05-02-85

EPA Reg. No. or File Symbol 4313-51

EPA Petition or EUP No. None

Date Division Received 03-12-85

Type Product Hospital Disinfectant

Data Accession No(s). 257176

Product Manager 32 (Castillo)

Product Name Super Ocide

Company Name Carroll Company

Submission Purpose Resubmission for amendment (revised use-dilution) with efficacy data

Type Formulation Liquid concentrate

Active Ingredient(s):	%
Isopropanol	13.50
Potassium o-benzyl-p-chlorophenate	10.10
Potassium o-phenylphenate	4.90
Potassium p-tert-amylphenate	2.50
Tetrasodium ethylenediaminetetraacetate	0.39

200.0 Introduction

200.1 Use(s)

"One-step" cleaner-disinfectant, fungicide (pathogenic fungi), and tuberculocide for floors, walls, woodwork, and equipment in hospitals, clinics, veterinary hospitals, rest homes, athletic departments, and industrial plants (last accepted label dated 08-15-77).

The pending amendment is for a revision in the recommended use-dilution from 1 oz/gal to ½ oz/gal.

200.2 Background

The amendment for a revised use-dilution was originally received 07-24-79 and subsequently resubmitted 09-11-84. The submissions were found to be deficient in reviews by TSS (Efficacy), DB, RD, dated 02-07-80 and 10-25-84, and the deficiencies were transmitted to the registrant with Mr. Castillo's letters of 03-07-80 and 12-20-84.

The current re-submission consists of additional efficacy data in response to the previous data deficiencies. The labeling deficiencies are not addressed in the current submission.

201.0 Data Summary

201.1 Brief Description of Tests

Reports on germicidal efficacy by Ronald D. Creamer and William R. Bryant, Carroll Company, Garland, TX 75041, dated from 12-27-84 to 02-13-85 (Accession No. 257176).

201.2 Test Summaries

a. Method: AOAC Use-Dilution

b. Modifications: None reported.

c. Samples: Super Ocide, Lots #75302, 75303, and 75304. Preparation dates and test dates are provided under Results.

d. Dilution: 1/256.

e. Exposure: 10 minutes at 20C (per method).

f. Test Organisms: Staphylococcus aureus ATCC 6538 (phenol resistance ranging from less than 1:60 to 1:65), Salmonella choleraesuis ATCC 10708 (phenol resistance ranging from less than 1:90 to 1:95), and Pseudomonas aeruginosa ATCC 15442 (phenol resistance ranging from 1:80 to 1:85).

g. Subculture Medium/Neutralizer: Letheen broth for primary and secondary subculturing (to insure neutralization).

h. Incubation: 48 hours at 37C (per method).

i. Results:

Test Lot #	No. Positive/Total Carriers					
	Staphylococcus aureus		Salmonella choleraesuis		Pseudomonas aeruginosa	
	Primary	Secondary	Primary	Secondary	Primary	Secondary
75302 (02-14-77)*	0/30 (01-03-85)**	0/30	0/30 (01-11-85)	0/30	0/30 (12-27-84)	0/30
	0/30 (01-07-85)	0/30	0/30 (01-29-85)	0/30	0/30 (01-08-85)	0/30
	0/30 (01-09-85)	0/30				
75303 (06-01-77)	0/30 (12-31-84)	0/30	0/30 (01-14-85)	0/30	0/30 (12-28-84)	0/30
	0/30 (01-04-85)	0/30	0/30 (01-21-85)	0/30	0/30 (02-05-85)	0/30
75304 (10-25-77)	0/30 (01-02-85)	0/30	0/30 (01-23-85)	0/30	0/30 (01-08-85)	0/30
	0/30 (01-10-85)	0/30	0/30 (01-31-85)	0/30	0/30 (02-13-85)	0/30
	0/30 (01-15-85)	0/30				
	0/30 (01-17-85)	0/30				
	0/30 (01-25-85)	0/30				

*Preparation date ** Test date

j. Conclusions: No failures reported vs. the three test bacteria at the revised use-dilution of 1/256 under the test conditions. The data are adequate to support effectiveness of the product as a hospital disinfectant vs. S. aureus, S. choleraesuis, and P. aeruginosa on pre-cleaned, hard, non-porous surfaces that are thoroughly wet by the solution for at least 10 minutes in a single application.

TECHNICAL SUPPORT SECTION EFFICACY REVIEW - II

Disinfectants Branch

EPA Reg. No. or File Symbol 4313-51

Date Division Received 03-12-85

Data Accession No(s). 257176

Product Manager No. 32 (Castillo)

Product Name Super Ocide

Company Name Carroll Company

202.0 Recommendations

202.1 Efficacy Supported by the Data

a. The additional submitted data/information are adequate to support effectiveness of the product as a hospital disinfectant vs. Staphylococcus aureus, Salmonella choleraesuis, and Pseudomonas aeruginosa at a use-dilution of 1/256 (½ ounce per gallon of water) on pre-cleaned, hard, non-porous surfaces that are thoroughly wet by the solution for a contact time of at least 10 minutes.

b. The previously submitted data were adequate to support effectiveness of the product as a fungicide against pathogenic fungi (Trichophyton mentagrophytes) and as a tuberculocide (Mycobacterium tuberculosis) at a use-dilution of 1/256 (½ ounce per gallon of water) on pre-cleaned, hard, non-porous surfaces that are thoroughly wet by the solution for a contact time of at least 10 minutes.

202.2 Efficacy Not Supported by the Data

None of the submitted data were developed in the presence of organic soil (5% blood serum) in order to support effectiveness of the product as a "one-step" cleaner-disinfectant. Therefore, the directions for use must specify pre-cleaning of surfaces prior to application of the product as a disinfectant. This was pointed out in the previous reviews of the amendment for this product which accompanied Mr. Castillo's letters of March 7, 1980, and December 20, 1984.

203.0 Labeling

The labeling comments in the previous review which accompanied Mr. Cast llo's letter of December 20, 1984, are still applicable, i.e.:

a. In the absence of data to support efficacy of the product as a "one-step" cleaner-disinfectant in the presence of moderate organic soil, the directions for use must be revised to specify pre-cleaning of surfaces prior to application of the product as a disinfectant, e.g., "Before disinfecting, thoroughly pre-clean surfaces". Delete the phrase "in one operation" from "Where a need exists to clean and disinfect thoroughly in one operation".

b. The directions for use must be expanded to specify treatment of hard, non-porous surfaces, i.e., ". . . for general hospital use on hard, non-porous surfaces such as floors, walls, woodwork, and equipment . . .".

c. The isopropanol and tetra sodium ethylenediaminetetraacetate in this product should be considered as inert ingredients in the ingredient statement. Refer to the notice in the Federal Register, Vol. 47, No. 126, Wednesday, June 30, 1982, pp. 28377-28380 (attached).

Dated: June 23, 1982.
Anne M. Gorsuch,
Administrator.

PART 52—APPROVAL AND PROMULGATION OF IMPLEMENTATION PLANS

Title 40 of the Code of Federal Regulations, Chapter I, Part 52 is Amended As follows:

Subpart KK—OHIO

Section 52.1881(a) (4) and (8) is revised as follows:

§ 52.1881 Control Strategy: Sulfur Dioxide.

(a) * * *

(4) Approval—USEPA approves the sulfur dioxide emission limits for the following counties: * * * Lucas County (except Gulf Oil Company, Coulton Chemical Company, Phillips Chemical Company and Sun Oil Company) * * * * * * * * *

(8) No action—USEPA is neither approving nor disapproving the emission limitations for the following counties or sources pending further review: * * * Lucas County (Gulf Oil Company, Coulton Chemical Company, Phillips Chemical Company and Sun Oil Company) * * *

[FR Doc. 82-17642 Filed 6-29-82; 8:45 am]
BILLING CODE 6560-50-M

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40 CFR Part 162

[PH-FRL 2113-5; OPP 30055]

Designation of Certain Antimicrobial Pesticide Ingredients as Inert Rather Than Active

AGENCY: Environmental Protection Agency (EPA).

ACTION: Rule.

SUMMARY: The EPA Office of Pesticide Programs is amending 40 CFR Part 162 to set forth a policy regarding the classification of ingredients used in antimicrobial pesticides as inert rather than as active ingredients. The registrant of an affected product will not be required to adhere to this policy until the product is required to be reregistered. Until that time, no action on the part of any registrant to revise a label ingredient statement will be required. Voluntary label changes in accordance with the notice are accepted. Applicants for new registrations will be required to label their products in accordance with this notice.

EFFECTIVE DATE: This rule will not take effect before the end of 60 calendar days of continuous session of Congress after the date of publication of this rule. EPA will publish a notice of the effective date of this rule in a future Federal Register document. See Unit V for further information on effective date of this rule.

FOR FURTHER INFORMATION CONTACT: Reto Engler, Registration Division (TS-767C), Office of Pesticide Programs, Environmental Protection Agency, Rm. 246, CM#2, 1921 Jefferson Davis Highway, Arlington, VA 22202, (703-557-3661).

SUPPLEMENTARY INFORMATION:

I. Background and Purpose

Pesticide formulations generally are composed of one or more pesticidally active ingredients and other substances such as diluents, emulsifiers, fillers, solvents and buffers. The latter substances are considered inert. Statutory definitions of "active ingredient" and "inert ingredient" are provided in sections 2(a) and 2(m) of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), 7 U.S.C. 136 (a) and (m). Guidance for determining whether an ingredient should be considered pesticidally active is found in 40 CFR 162.6(b)(2)(i)(C). This section provides that the Agency will determine active ingredient status on the basis of factors such as: The ingredient's capability in and of itself to kill, destroy, repel, or mitigate pests; the presence of the ingredient in amounts sufficient to add materially to its effectiveness; and the ingredient's influence on the activity of the principal active ingredient.

In the past, particular ingredients have been classified as active in some products and as inert in other products. Often an ingredient was designated as active based upon the assertions of the applicant for registration, often with little or no data to support its "active" status. In addition, the term "active ingredient" has been interpreted and applied differently over the years by different EPA reviewers. As a result, there is a significant amount of inconsistency on labels of antimicrobial products with respect to classification of ingredients.

The classification of ingredients as "active" or "inert" has substantial importance to applicants for registration of pesticides. The EPA regulations and quidelines which specify the data required to support applications for registration normally require more testing of substances which are classified as pesticidally active. Pesticidally inert ingredients generally are not required to be tested unless there is particular concern about their properties. Ingredients which are pesticidally active, however, are meant to adversely affect some life forms, and so are subject to more extensive test requirements. Moreover, EPA's regulations which implement FIFRA section 3(c)(1)(D) (concerning data compensation and related matters) impose requirements with regard to data on "active" ingredients that do not apply to data on inert ingredients. Furthermore, these substances are not biologically active at the recommended use dilution.

Several pesticide companies and trade associations have petitioned EPA to treat certain chemical compounds as inert rather than as active ingredients for these very reasons. Because of this interest by pesticide producers and because these particular chemicals, when used in antimicrobial pesticides, generally do not have any pesticidal activity and in fact are inert, EPA has determined that certain chemical compounds should be regarded as inert rather than as active ingredients.

Accordingly, the Agency is announcing that it will be its policy to treat all the ingredients listed in this rule as "inert" when they appear in antimicrobial pesticide products, including sterilizer, disinfectant, sanitizer, and bacteriostatic formulation, unless the applicant or registrant presents evidence that such an ingredient is "active" under the criteria of 40 CFR 162.6(b)(2)(i)(C). If the Agency determines, based on substantial overall scientific evidence, that any listed chemical is active, it will further determine whether designation of the ingredient as active should be applicable to all products containing this chemical or to particular formulations. The listing may also be amended by adding percentages above which an ingredient will be deemed to be active.

The inclusion of a chemical on the "inert" list should not be interpreted to mean that the Agency has determined that the substance is toxicologically insignificant. In fact, certain listed ingredients (Methanol, Petroleum distillates) must still be identified on the label because these ingredients, when used in certain formulations, may be more hazardous then the active ingredient contained in the product. The toxicological properties of any substance in a pesticide formulation are evaluated individually when they either contribute significantly to the toxicity of the formulated product or are expected to produce particular adverse effects of their own. The identification of an ingredient as "active" in the ingredients statement pertains only to its pesticidal activity. The Agency may, on a case-by-

case basis, require additional data on the hazards of that ingredient if its chemical properties, expected exposure level, and other pertinent information indicate the need for such data.

The efficacy of a public health-related antimicrobial pesticide formulation normally is evaluated without specifically determining the interactions of active and inert ingredients. However, if such an interaction is of singular importance, the Agency may require an ingredient to be designated as an active ingredient in a particular product or group of products of similar composition.

II. Affected Products

A. Currently Registered Antimicrobial Pesticide Products

FIFRA and the implementing regulations require that in order for a product not to be considered "misbranded", active and inert ingredients must be separately listed on the product label, although inert ingredients need not be specifically identified. See FIFRA sections 2(n), 2(q), (2)(a), and 12(a)(1)(E); 40 CFR 162.10 (g)(1). Since the labels of a number of already registered antimicrobial products list as "active" some ingredients that are presumed "inert" under the rule promulgated today, a transition mechanism is in order.

Registrants whose labels currently indicate a listed substance as an active rather than inert ingredient will not be required to revise their labels in accordance with the rule until they are required to apply for reregistration of their products. However, if registrants wish at this time to amend their labels in accordance with this policy, they should follow the procedures discussed under Unit III of this rule.

B. New Antimicrobial Pesticides

Applicants for new registrations will be required to label their products in accordance with this rule under the following procedure:

1. The confidential statement of formula (EPA Form 8570–4) must correctly identify all ingredients and their purpose in the formulation. Unless data have been presented to demonstrate otherwise, the listed ingredients must be identified as inert ingredients.

2. Ingredients listed in this Rule are to be included under the heading "Inert Ingredients" and their quantity in the total percentage of inerts. Specific inerts may be named in the label ingredients statements as long as they appear under the "Inert Ingredients" heading.

C. Pending Applications for Registration

Applications for new registration now pending will be reviewed and applicants will be notified routinely what they must do to comply with this policy.

III. Applications for Amended Registrations

Although current registrants will not be required to amend their labels in accordance with this policy until reregistration, those registrants who wish to amend their labels before reregistration are asked to submit the following information:

1. An application for amended registration (EPA Form 8570–11).

2. A revised confidential statement of formula (EPA Form 8570–4).

3. Two copies of draft labeling revising the ingredient statement as required. Final printed labeling may be submitted directly, but the registrant must assume responsibility for corrections if found deficient.

Applications should be submitted to the appropriate product manager in the Registration Division at the following address:

Product Manager (PM) ——— (team number), Registration Division (TS–767C), Office of Pesticide Programs, Environmental Protection Agency, 401 M. St., SW., Washington, D.C. 20460.

Applications to amend registrations by redesignating ingredients as inert under this rule will be treated by EPA as exempt from the data compensation requirements of FIFRA section 3(c)(1)(D), in accordance with 40 CFR 162.9–1(b), since no consideration of data will be necessary.

IV. Procedural Matters and Required Regulatory Reviews

A. Exemption From Notice-and-Comment Procedures

The Administrative Procedure Act, 5 U.S.C. 553, provides that notice-and-comment procedures need not be employed in issuing rules which merely state agency policy, and do not purport to bind courts or administrative tribunals. The rule announced today is a statement of Agency registration and enforcement policy. Applicants and registrants will be free to contest the validity of this policy as it applies to particular products in denial or cancellation proceedings under FIFRA section 6 or in enforcement proceedings under FIFRA section 14. Accordingly, the notice-and-comment rulemaking procedure is not required, and EPA has chosen not to employ it because of the delay that it would cause in promulgating the rule.

B. Review Under Executive Order 12291

Under Executive Order 12291, EPA must judge whether a regulation is "major" and therefore subject to the requirement of a Regulatory Impact Analysis. This regulation is not "major" because it will not likely result in:

(1) An annual effect on the ecomomy of $100 million or more;

(2) A major increase in costs or prices for consumers, individual industries, Federal, State, or local government agencies, or geographic regions; or

(3) Significant adverse effects on competition, employment, investment, productivity, innovation, or on the ability of United States-based enterprises to compete with foreign-based enterprises in domestic or export markets.

This regulation was submitted to the Office of Management and Budget for review as required by Executive Order 12291

C. Review Under FIFRA Section 25

In accordance with FIFRA sec. 25, a draft of this rule was submitted to the FIFRA Scientific Advisory Panel (SAP), and subsequently to the U.S. Department of Agriculture. Copies were also supplied to the Committee on Agriculture of the House of Representatives and the Committee on Agriculture, Nutrition, and Forestry of the Senate.

The Scientific Advisory Panel waived its review on the grounds that the rule was administrative-legal in nature and devoid of substantive scientific issues. The Department of Agriculture and the respective Congressional Committees have concurred with this rule without further comment.

V. Further Information on Effective Date of This Rule

On December 17, 1980, the Federal Insecticide, Fungicide, and Rodenticide Act Extension Bill (Pub. L. 96–539) became law. This bill amended several sections of FIFRA, including sec. 25 on rulemaking. Section 4 of the Extension Act adds a new paragraph, sec. 25(e), to FIFRA which requires EPA to submit final regulations to Congress for review before the regulation becomes effective. Copies of this rule have been transmitted to appropriate offices in both House of Congress.

Under sec. 4 of the 1980 FIFRA Extension Act, this rule will not take effect before the end of 60 calendar days of continuous session of Congress after the date of publication of this rule. Since the actual length of this waiting period may be affected by Congressional action, it is not possible, at this time, to

specify a date on which this regulation will become effective. Therefore, at the appropriate time EPA will publish a notice announcing the end of the legislative review period and notify the public of the effective date of this regulation (sec. 3, as amended, Pub. L. 96–539 (7 U.S.C. 136)).

VI. List of Subjects in 40 CFR Part 162

Intergovernmental relations, Labeling, Packaging and containers, Pesticides and pests, Administrative practice and procedure.

Dated: June 14, 1982.

Anne M. Gorsuch,

Administrator.

PART 162—REGULATIONS FOR THE ENFORCEMENT OF THE FEDERAL INSECTICIDE, FUNGICIDE, AND RODENTICIDE ACT

Therefore, 40 CFR Part 162, Subchapter E, is amended by adding the following new § 162.60:

§ 162.60 Designation of certain ingredients of antimicrobial products as active or inert.

(a) The Agency has concluded that the ingredients listed in this section normally have no independent pesticidal activity when included in antimicrobial products, and thus normally are properly classified as inert ingredients of such products for purposes of sections 2(n), 2(q)(2)(A), and 12(a)(1)(E) of the Act and § 162.10(g)(1).

(b) Depending upon the formulation, the Agency may determine that an ingredient on the list is active in a particular product.

(c) If an applicant or registrant submits data to the Agency which demonstrates to the Agency's satisfaction that any such ingredient is pesticidally active under the criteria of § 162.6(b)(2)(i)(C), the ingredient may be listed as active on the product's label and statement of formula.

(d) Unless designated as an active ingredient in accordance with paragraph (b) or (c) of this section, the following ingredients, when used in antimicrobial products, are considered inert within the meaning of FIFRA section 2(m). The percentage of such ingredients shall be included on the label in the total percentage of inert ingredients. The confidential statement of formula must identify the inert ingredient and state its percentage.

Substance	Uses
Acetone	Solvent.
Alkyl* amino betaine (46 percent C_{16}, 24 percent C_{18}, 10 percent C_{14}, 6 percent C_{12}, 7 percent C_{10}, 5 percent C_{8})	Corrosion inhibitor/Surfactant.
Alkyl monoethanolamide	Emulsifier.
Aluminum chloride	Detergent.
Aluminum hydroxybenzenesulfate sulfonate	Emulsifier.
Aluminum powder	Filler.
Ammonium carbonate	Detergent.
Ammonium citrate	Sequesterant.
Ammonium lauryl sulfonate	Emulsifier.
Ammonium oleate	Detergent/Emulsifier.
Ammonium oxalate	Detergent.
Amyl acetate	Diluent.
Borax	Detergent.
Butyl alcohol, tertiary	Solvent/Odorant.
Carbon	Carrier/Absorbent.
Castor oil	Emulsifier.
Citric acid	Sequesterant.
Diethanolamine dodecylbenzene sulfonate	Detergent.
Dimethyl phthalate	Perfume.
Disodium monoethanolamine phosphate	Emulsifier
Dodecyl benzene sulfonic acid	Detergent.
Essential oils	Perfume.
Ethanol (ethyl alcohol)	Solvent, except in tinctures or where sole or major active ingredient.
Ethanolamine	Emulsifier.
Ethanolamine dodecylbenzene sulfonate	Detergent.
Ethoxylated lanolin	Ointment base.
Ethylenediamine	Emulsifier.
Ethylenediaminetetraacetic acid (including all salts and derivatives)	Sequesterant.
Fumaric acid	Sequesterant.
Gluconic acid	Buffer.
Isooctyl phenoxy-polyethoxy ethanol	Surfactant.
Isopropanol (isopropyl alcohol)	Solvent, except in tinctures or where sole or major active ingredient.
Isopropyl myristate	Solvent.
Juniper tar	Odorant.
Lauryl alcohol	Detergent/Odorant.
Lauryl methacrylate	Emulsifier.
Limonene	Odorant/Perfume.
Magnesium chloride	Builder.
Magnesium lauryl sulfate	Detergent.
Magnesium silicate	Odor absorbent.
Menthol	Perfume.
Methanol (methyl alcohol)	Solvent, except in tinctures or where sole or major active ingredient.
Methyl ethyl ketone	Solvent.
Methyl salicylate	Perfume/Odorant.
Mineral oil, mineral seal oil, or white mineral oil	Lubricant.
Monoethanolamides of the fatty acids of coconut oil	Emulsifier.
Monosodium phosphate	Emulsifier/Buffer.
Morpholine	Corrosion inhibitor.
Nonylphenoxypolyethoxyethanol	Surfactant.
Octylphenol	Nonionic surfactant.
Oil of citronella	Perfume/Odorant.
Oil of eucalyptus	Perfume.
Oil of lemongrass	Perfume.
Oleic acid	Solvent.
Petroleum distillate, oils, hydrocarbons, also paraffinic hydrocarbons, aliphatic hydrocarbons, paraffinic oil	Lubricant/Solvent.
Polyoxyethylene sorbitol, mixed ether ester of	Emulsifier.
Polyvinylpyrrolidone	Emulsifier.
Potassium bisulfate	Builder.
Polyvinylpyrrolidone	Emulsifier.
Potassium bisulfate	Builder.
Potassium carbonate	Detergent.
Potassium dodecylbenzenesulfonate	Anionic detergent.
Potassium laurate	Emulsifier.
Potassium myristate	Emulsifier.
Potassium *N*-(*p*-(nitroethyl) benzyl) ethylenediamine	Emulsifier.
Potassium phosphate, tribasic	Sequesterant.
Potassium nonoleate	Emulsifier.
Potassium toluene sulfonate	Detergent.
Potassium xylene sulfonate	Detergent.
Propanol (propyl alcohol)	Solvent, except in tinctures or where sole or major active ingredient.
Soap	Detergent.
Sodium acetate	Buffer.
Sodium alkyl (100 percent C_{12})	Detergent.
Sodium bicarbonate	Detergent.
Sodium carbonate	Detergent.
Sodium chloride	Builder.
Sodium decylbenzene sulfonate	Detergent.
Sodium diacetate	Sequesterant.
Sodium dihydroxyethylglycine	Chelate/Buffer.
Sodium diisopropylnaphthalene sulfonate	Detergent.
Sodium di (monoethanolamine) phosphate	Emulsifier.
Sodium dodecylbenzene sulfonate (May be active as a sanitizer in dishwashing formulations)	Detergent.
Sodium dodecyl diphenyl oxide sulfonate	Perfume.
Sodium glycolate	Sequesterant.
Sodium laurate	Detergent.
Sodium *N*-lauroylsarcosinate	Detergent.
Sodium lauryl sulfate	Detergent.
Sodium metasilicate	Detergent.
Sodium *N*-methyl-*N* oleoyl-taurate	Emulsifier.
Sodium mono and dimethyl naphthalene sulfonate	Detergent.
Sodium oleate	Emulsifier.
Sodium phosphate	Emulsifier/Buffers.
Sodium salt of Turkey Red Oil	Emulsifier.
Sodium sesquicarbonate	Detergent.
Sodium silicate	Detergent.
Sodium sulfate	Detergent.
Sodium sulfonated oleic acid	Emulsifier.
Sodium thiosulfate	Builder.
Sodium toluene sulfonate	Detergent.
Sodium tripolyphosphate	Sequesterant.
Sodium xylene sulfonate	Detergent.
Tetrapotassium pyrophosphate	Sequesterant.
Tetrasodium pyrophosphate	Sequesterant.
Toluene sulfonic acid	Emulsifier.
1,1,1,-Trichloroethane	Diluent.
Triethanolamine	Emulsifier.
Triethanolamine dodecylbenzene sulfonate	Detergent.
Triethanolamine laurate	Emulsifier.
Triethanolamine lauryl sulfate	Emulsifier.
Triethanolamine myristate	Emulsifier.
Triisopropanolamine	Emulsifier.
Triisopropylamine	Emulsifier.
Trisodium phosphate	Detergent.
Turkey red oil	Emulsifier.
Undecylenic acid	Perfume.
Xylene	Solvent.
Zirconium oxide	Dye.

(e) This section shall apply to:

(1) Each application for registration of a new product which is approved on or after this section's effective date; and

(2) Each product already registered on the effective date of this section, except that no such product will be regarded by EPA as in violation of this section until reregistration.

(f) This section is a statement of Agency policy. It does not bind decision-makers in a formal adjudicatory proceeding under FIFRA section 3, 6, or

14. If this section becomes an issued in any such proceeding, the decision-makers in that proceeding will make an independent judgment whether to adhere to it or not.

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40 CFR Part 180

[PP 2E2594/R454; PH-FRL-2157-5]

Tolerances and Exemptions From Tolerances for Pesticide Chemicals in or on Raw Agricultural Commodities; Thiabendazole

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This rule establishes tolerances for residues of the fungicide thiabendazole in or on avocados and mangos. This regulation to establish the maximum permissible level for residues of thiabendazole in or on these raw agricultural commodities was requested by Merck and Company, Inc.

EFFECTIVE DATE: Effective on June 30, 1982.

ADDRESS: Written objections may be submitted to the: Hearing Clerk (A-110), Environmental Protection Agency, Rm. 3708, 401 M St., SW., Washington, DC 20460.

FOR FURTHER INFORMATION CONTACT: Henry M. Jacoby, Product Manager (PM)21, Registration Division (TS-767C), Office of Pesticide Programs, Environmental Protection Agency, Rm. 227, CM#2, 1921 Jefferson Davis Highway, Arlington, VA 22202, (703-557-1900).

SUPPLEMENTARY INFORMATION: EPA issued a notice published in the Federal Register of January 13, 1982 (47 FR 1408) which announced that Merck and Company, Inc., PO Box 2000, Rahway, NJ 07065, had filed a pesticide petition (PP 2E2594) with EPA. This petition proposed that 40 CFR 180.242 be amended by establishing tolerances for residues of the fungicide thiabendazole [2-(4-thiazolyl)benzimidazole] in or on the raw agricultural commodities avocados and mangos at 10.0 parts per million (ppm). No comments were received in response to this notice of filing.

The data submitted in the petition and other relevant material have been evaluated. The toxicological data considered in support of the tolerances included: An acute oral lethal dose (LD_{50}) rat study; an acute oral lethal dose (LD_{50}) mouse study; a 2-year rat feeding study with a no-observed-effect level (NOEL) of 10 mg/kg/day and with an negative oncogenic potential; a 2-year dog feeding study with a NOEL of 50 mg/kg/day; a mouse oncogenicity feeding study with a negative oncogenic potential; a rat teratology study that was negative at 80 mg/kg; a rabbit teratology study that was negative at 800 mg/kg; a mouse reproduction study with a NOEL of 150 mg/kg/day and a rat reproduction study with a NOEL of 20 mg/kg/day. Based on the 2-year rat feeding study, the (NOEL) is 10 mg/kg/day. Using a 100-fold safety factor, the allowable daily intake (ADI) is 0.10 mg/kg/day and the maximum permissible intake (MPI) is 6.0 mg/day for a 60-kg person. Presently established tolerances and these tolerances result in a maximum theoretical exposure of 1.658 mg/day for a 60-kg person and 27.63 percent of the ADI. Tolerances have previously been established for residues of thiabendazole in or on a variety of raw agricultural commodities (40 CFR 180.242). There are no regulatory actions pending against continued registration of the pesticide, and there are no other considerations involved in establishing the tolerances. The metabolism of thiabendazole is adequately understood, and an adequate analytical method, spectrotometrical analysis, is available for enforcement purposes.

Based on the information cited above, the Agency has determined that the establishment of tolerances of the fungicide thiabendazole in or on the raw agricultural commodities avocados and mangos will protect the public health. Therefore, the regulation is established by amending 40 CFR 180.242, as set forth below.

Any person adversely affected by this regulation may, on or before July 30, 1982, file written objections with the Hearing Clerk, at the address given above. Such objections should be submitted in quintuplicate and specify the provisions of the regulation deemed objectionable and the gounds for the objections. If a hearing is requested, the objections must state the issues for the hearing and the grounds for the objections. A hearing will be granted if the objections are supported by grounds legally sufficient to justify the relief sought.

The Office of Management and Budget has exempted this rule from the requirements of section 3 of Executive Order 12291.

Pursuant to the requirements of the Regulatory Flexibility Act (Pub. L. 96-534, 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).

Effective on: June 30, 1982.

(Sec. 408(d)(2), 68 Stat. 512 (21 U.S.C. 346a(d)(2))).

List of Subjects in 40 CFR Part 180

Administrative practice and procedure, Agricultural commodities, Pesticides and pests.

Dated: June 17, 1982.

James M. Conlon,
Acting Director, Office of Pesticide Programs.

PART 180—TOLERANCES AND EXEMPTIONS FROM TOLERANCES FOR PESTICIDE CHEMICALS IN OR ON RAW AGRICULTURAL COMMODITIES

Therefore, 40 CFR 180.242(a) is amended by adding and alphabetically inserting the raw agricultural commodities avocados and mangos to read as follows:

§ 180.242 Thiabendazole; tolerances for residues.

(a) * * *

Commodities	Parts per million
Avocados	10
Mangos	10

[FR Doc. 82-17511 Filed 6-29-82; 8:45 am]
BILLING CODE 6560-50-M

40 CFR Part 180

[PP OF2357/R451; PH-FRL 2159-3]

Tolerances and Exemptions From Tolerances for Pesticide Chemicals in or on Raw Agricultural Commodities; 2-Chloro-N-isopropylacetanilide

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule

SUMMARY: This rule establishes tolerances for the combined residues of the herbicide 2-chloro-*N*-isopropylacetanilide and its metabolites in or on the raw agricultural commodities sorghum fodder and forage. This regulation to establish the maximum permissible level for residues of the herbicide in or on the