

US EPA ARCHIVE DOCUMENT

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 Oxide

Company Name Carroll Company

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

Type Formulation Liquid concentrate

<u>Active Ingredient(s):</u>	<u>%</u>
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: Lethen 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	0/30	0/30	0/30	0/30	0/30
		(01-03-85)**		(01-11-85)		(12-27-84)
	0/30	0/30	0/30	0/30	0/30	0/30
		(01-07-85)		(01-29-85)		(01-08-85)
	0/30	0/30				
	(01-09-85)					
75303 (06-01-77)	0/30	0/30	0/30	0/30	0/30	0/30
		(12-31-84)		(01-14-85)		(12-28-84)
	0/30	0/30	0/30	0/30	0/30	0/30
	(01-04-85)		(01-21-85)		(02-05-85)	
75304 (10-25-77)	0/30	0/30	0/30	0/30	0/30	0/30
		(01-02-85)		(01-23-85)		(01-08-85)
	0/30	0/30	0/30	0/30	0/30	0/30
		(01-10-85)		(01-31-85)		(02-13-85)
	0/30	0/30				
		(01-15-85)				
	0/30	0/30				
	(01-17-85)					
	0/30	0/30				
	(01-25-85)					

*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 Oxide

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 ($\frac{1}{2}$ 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 ($\frac{1}{2}$ 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. Castillo'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 6560-60-M

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
guidelines 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 than 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 economy 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	Substance	Uses
Acetone	Solvent	Potassium <i>N</i> -(4-nitroethyl)benzyl ethylenediamine	Emulsifier
Alkyl ¹ amino betaine (46 percent C ₁₂ , 24 percent C ₁₄ , 10 percent C ₁₆ , 8 percent C ₁₈ , 7 percent C ₂₀ , 5 percent C ₂₂)	Corrosion Inhibitor/Surfactant	Potassium phosphate, tribasic	Sequesterant
Alkyl monoethanolamide	Emulsifier	Potassium nonoate	Emulsifier
Aluminum chloride	Detergent	Potassium toluene sulfonate	Detergent
Aluminum hydroxybenzenesulfate sulfonate	Emulsifier	Potassium xylene sulfonate	Detergent
Aluminum powder	Filler	Propenol (propyl alcohol)	Solvent, except in tinctures or where sole or major active ingredient
Ammonium carbonate	Detergent	Soap	Detergent
Ammonium citrate	Sequesterant	Sodium acetate	Buffer
Ammonium lauryl sulfonate	Emulsifier	Sodium alkyl (100 percent C ₁₂)	Detergent
Ammonium oleate	Detergent/Emulsifier	Sodium bicarbonate	Detergent
Ammonium oxalate	Detergent	Sodium carbonate	Detergent
Amyl acetate	Diluent	Sodium chloride	Builder
Borax	Detergent	Sodium decylbenzene sulfonate	Detergent
Butyl alcohol, tertiary	Solvent/Odorant	Sodium diacetate	Sequesterant
Carbon	Carrier/Absorbent	Sodium dithionite	Chelate/Buffer
Castor oil	Emulsifier	Sodium diisopropylnaphthalene sulfonate	Detergent
Citric acid	Sequesterant	Sodium di (monoethanolamine) phosphate	Emulsifier
Diethanolamine dodecylbenzene sulfonate	Detergent	Sodium dodecylbenzene sulfonate (May be active as a sanitizer in dishwashing formulations)	Detergent
Dimethyl phthalate	Perfume	Sodium dodecyl diphenyl oxide sulfonate	Perfume
Disodium monoethanolamine phosphate	Emulsifier	Sodium glycolate	Sequesterant
Dodecyl benzene sulfonic acid	Detergent	Sodium laurate	Detergent
Essential oils	Perfume	Sodium <i>N</i> -lauroylsarcosinate	Detergent
Ethanol (ethyl alcohol)	Solvent, except in tinctures or where sole or major active ingredient	Sodium lauryl sulfate	Detergent
Ethanolamine	Emulsifier	Sodium metasilicate	Detergent
Ethanolamine dodecylbenzene sulfonate	Detergent	Sodium <i>N</i> -nonyl- <i>N</i> -oleoyl-taurate	Emulsifier
Ethoxylated lanolin	Ointment base	Sodium mono and dimethyl naphthalene sulfonate	Detergent
Ethylenediamine	Emulsifier	Sodium oleate	Emulsifier
Ethylenediaminetetraacetic acid (including all salts and derivatives)	Sequesterant	Sodium phosphate	Emulsifier/Buffer
Fumaric acid	Sequesterant	Sodium salt of Turkey Red Oil	Emulsifier
Gluconic acid	Buffer	Sodium sebacate	Detergent
Isocetyl phenoxypolyethoxy ethanol	Surfactant	Sodium sebacate	Detergent
Isopropanol (isopropyl alcohol)	Solvent, except in tinctures or where sole or major active ingredient	Sodium sulfate	Detergent
Isopropyl myristate	Solvent	Sodium sulfonated oleic acid	Emulsifier
Juniper tar	Odorant	Sodium thiosulfate	Builder
Lauryl alcohol	Detergent/Odorant	Sodium toluene sulfonate	Detergent
Lauryl methacrylate	Emulsifier	Sodium tripolyphosphate	Sequesterant
Limonene	Odorant/Perfume	Sodium xylene sulfonate	Detergent
Magnesium chloride	Builder	Tetrapotassium pyrophosphate	Sequesterant
Magnesium lauryl sulfate	Detergent	Tetrasodium pyrophosphate	Sequesterant
Magnesium silicate	Odor absorbent	Toluene sulfonic acid	Emulsifier
Menthol	Perfume	1,1,1-Trichloroethane	Diluent
Methanol (methyl alcohol)	Solvent, except in tinctures or where sole or major active ingredient	Triethanolamine	Emulsifier
Methyl ethyl ketone	Solvent	Triethanolamine dodecylbenzene sulfonate	Detergent
Methyl salicylate	Perfume/Odorant	Triethanolamine laurate	Emulsifier
Mineral oil, mineral seal oil, or white mineral oil	Lubricant	Triethanolamine lauryl sulfate	Emulsifier
Monoethanolamides of the fatty acids of coconut oil	Emulsifier	Triethanolamine myristate	Emulsifier
Monosodium phosphate	Emulsifier/Buffer	Trisopropanolamine	Emulsifier
Morpholine	Corrosion inhibitor	Trisopropylamine	Emulsifier
Nonylphenoxypolyethoxyethanol	Surfactant	Trisodium phosphate	Detergent
Octylphenol	Nonionic surfactant	Turkey red oil	Emulsifier
Oil of citronella	Perfume/Odorant	Undecylenic acid	Perfume
Oil of eucalyptus	Perfume	Xylene	Solvent
Oil of lemongrass	Perfume	Zirconium oxide	Oya
Oleic acid	Solvent		
Petroleum distillate, oils, hydrocarbons, also paraffinic hydrocarbons, alpha-fenic hydrocarbons, paraffinic oil	Lubricant/Solvent		
Polyoxyethylene sorbitol, mixed ether ester of	Emulsifier		
Polyvinylpyrrolidone	Emulsifier		
Potassium bisulfate	Builder		
Polyvinylpyrrolidone	Emulsifier		
Potassium disulfate	Builder		
Potassium carbonate	Detergent		
Potassium dodecylbenzenesulfonate	Alionic detergent		
Potassium laurate	Emulsifier		
Potassium myristate	Emulsifier		

(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 re-registration.

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

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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.

[FR Doc. 82-17355 Filed 6-29-82; 8:45 am] BILLING CODE 6560-50-M

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 (LD50) rat study; an acute oral lethal dose (LD50) 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 ADL. 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, spectrometrical 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 grounds 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), 66 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. 82-17311 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

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