

The IR-4 Process (cont'd)

**Using crop grouping,
compiling field/lab data into
final reports, submitting
petitions to EPA, securing
the final label**

????????

How do we get from:

All Data Received:



Labeled Use

Crop Grouping

Used to facilitate the establishment of pesticide MRLs for a large number of crops **based on residue data from selected representative crops**

- The representative commodity of a Crop Group is based on factors such that the representative commodity is likely to:
 - Contain the highest pesticide residue
 - Be major in terms of production and/or consumption
 - Be similar in morphology, growth habit, pest problems and edible portion to the related commodities of the group or subgroup

Example

- Residue Studies Are Conducted On:
 - A standard size tomato and a cultivar of small tomato
 - bell pepper and one cultivar of chili pepper
- Obtain tolerances on...

High production & consumption



Higher residues



High production & consumption



Higher residues



Look at all of Those Uses!!

8-10. FRUITING VEGETABLE GROUP

Tomato, standard size,
and one cultivar of small
tomato; bell pepper and
one cultivar of small
nonbell pepper

African eggplant; bush
tomato; bell pepper;
cocona; currant tomato;
eggplant; garden
huckleberry; goji berry;
groundcherry; martynia;
naranjilla; okra; pea
eggplant; pepino; nonbell
pepper; roselle; scarlet
eggplant; sunberry;
tomatillo; tomato; tree
tomato; cultivars,
varieties, and/or hybrids
of these



Crop Grouping Matters

Impact of Crop Grouping on Food Use Clearances

1 residue
study =
1 new use

Without Crop
Grouping
Prior to 1983

1 residue
study
 ≥ 5 new
uses

With Current
U.S. Crop
Grouping
Scheme

1 residue
study
 ≥ 10 new
uses

With Future
Crop
Grouping
Scheme





Crop Grouping Timeline

Crop Group	# new commodities	Submitted to EPA	PMRA Publication	US Federal Register	Codex, Adopted
Bulb vegetable Crop Group 3-07	6 → 26	2005	2009	2007	2017
Berries and small fruit Crop Group 13-07	8 → 45	2005	2009	2007	2012
New Edible fungi Crop Group 21	0 → 21	2005	2009	2007	2017
Fruiting Vegetable (except cucurbits) Crop Group 8-10	6 → 21	2005	2010	2010	2017
Oilseed Crop Group 20	0 → 32	2006	2010	2010	2018
Citrus fruit Crop Group 10-10	12 → 28	2006	2009	2010	2012
Pome fruit Crop Group 11-10	7 → 12	2006	2010	2010	2012
Stone fruit Crop Group 12-12	11 → 2	2007	2010	2012	2012
Tree nuts Crop Group 14-12	12 → 32	2008	2011	2012	2018



Crop Grouping Timeline

Crop Group	# new commodities	Submitted to EPA	PMRA Publication	US Federal Register	Codex, Adopted
Tropical/Subtrop. Edible peel, Crop Group 23	0 → 108	2010	2015	2016	2012
Tropical/Subtrop. Inedible peel, Crop Group 24	0 → 104	2010	2015	2016	2012
Leafy Vegetables Crop Group 4-16	27 → 107	2011	2014	2016	2017
Stalk, Stem and Leaf Petiole Crop Group 22	7 → 17	2011	2014	2016	2017
Brassica Head & Stem Vegetable Crop Group 5-16	17 → 5	2011	2014	2016	2017

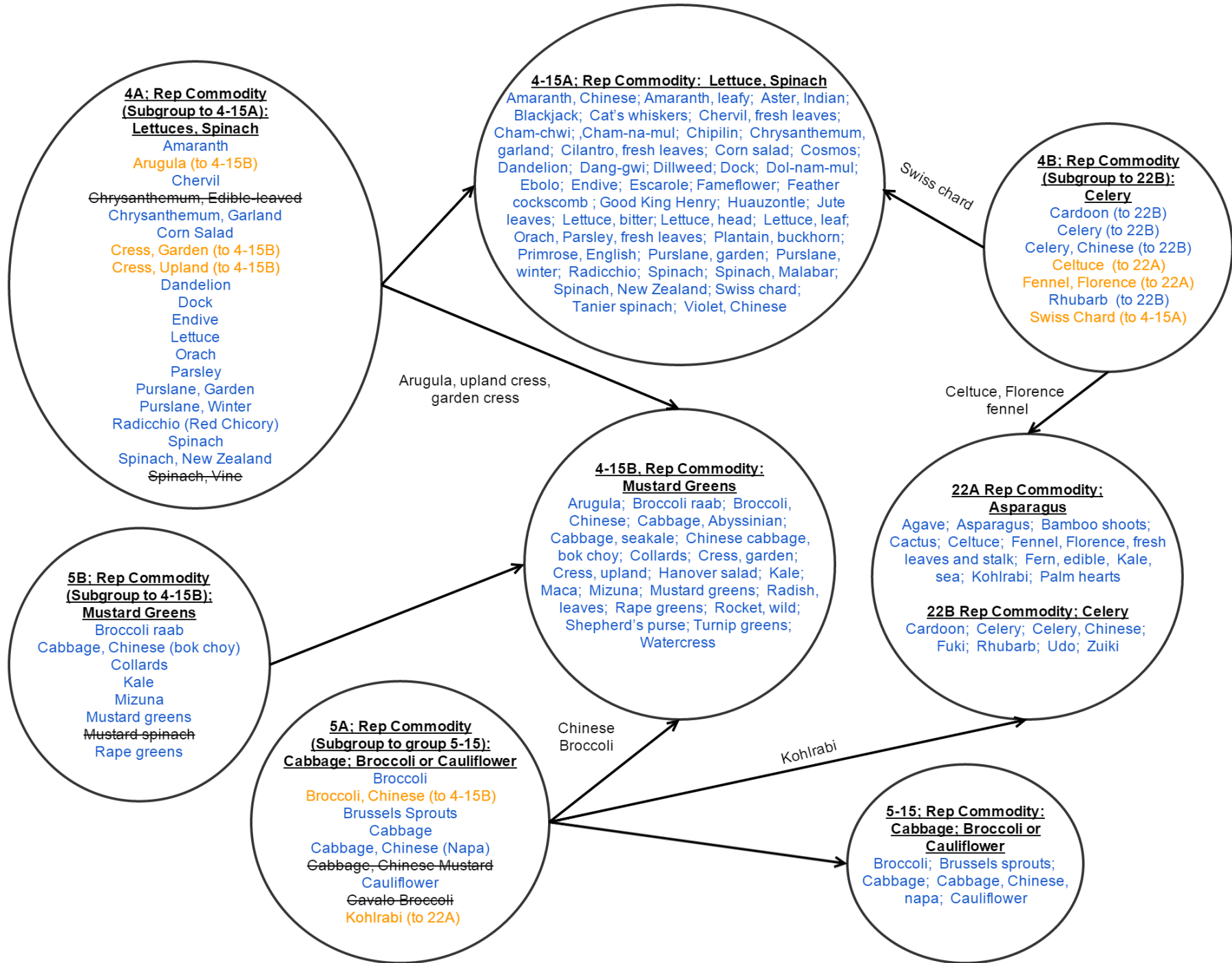
Crop Grouping Timeline

Crop Group	# new commodities	Submitted to EPA	PMRA Publication	US Federal Register	Codex, Adopted	
Herbs and Spices Crop Group 19	68 → ~300 herbs, ~175 Spices	2009		Herb Group 25 (2020)	2018	
				Spice Group 26 (2020)		
Root & Tuber Vegetable Crop Group 1	36 → 100	2012			2017	
Leaves of Root and Tuber Vegetables Group 2	18 → 41	2013			2017	
Legume Vegetables Crop Group 6	14 → 22	2013			2017	
Foliage of Legume Veg Crop Group 7	14 → 22	2013			(2020)	
Cucurbit Vegetable Crop Group 9	12 → 45	2014			2017	
Cereal Grains Crop Groups 15	14 → 35	2015			2017	
Forage, Fodder and Straw of Cereal Grains Crop Group 16	14 → 35	2015			(2020)	



Crop Grouping Timeline

Crop Group	# new commodities	Submitted to EPA	PMRA Publication	US Federal Register	Codex, Adopted
Grass Forage, Fodder, and Hay Crop Group 17	Any grass, Poaceae (Gramineae) family (either green or cured) except sugarcane and those included in the cereal grains group (2 subgroups)	Nov. 3, 2015			(2020)
Nongrass Animal Feeds (Forage, Fodder, Straw and Hay) Crop Group 18	11 → 103	March 15, 2016			(2020)



Codex 13A Leafy Greens

4-15A: Rep Commodity: Lettuce, Spinach

Amaranth, Chinese; Amaranth, leafy; Aster, Indian; Blackjack; Cat's whiskers; Chervil, fresh leaves; Cham-chwi; Cham-na-mul; Chipilin; Chrysanthemum, garland; Cilantro, fresh leaves; Corn salad; Cosmos; Dandelion; Dang-gwi; Dillweed; Dock; Dol-nam-mul; Ebolo; Endive; Escarole; Flameflower; Feather cockscomb; Good King Henry; Huauzontle; Jute leaves; Lettuce, bitter; Lettuce, head; Lettuce, leaf; Orach, Parsley, fresh leaves; Plantain, buckhorn; Primrose, English; Purslane, garden; Purslane, winter; Radicchio; Spinach; Spinach, Malabar; Spinach, New Zealand; Swiss chard; Tanier spinach; Violet, Chinese

4B: Rep Commodity (Subgroup to 22B): Celery

Cardoon (to 22B)
Celery (to 22B)
Celery, Chinese (to 22B)
Celtuce (to 22A)
Fennel, Florence (to 22A)
Rhubarb (to 22B)
Swiss Chard (to 4-15A)

Swiss chard

Celtuce, Florence fennel

Arugula, upland cress, garden cress

Codex 13B Brassica leafy veg.

4-15B, Rep Commodity: Mustard Greens

Arugula; Broccoli raab; Broccoli, Chinese; Cabbage, Abyssinian; Cabbage, seakale; Chinese cabbage, bok choy; Collards; Cress, garden; Cress, upland; Hanover salad; Kale; Maca; Mizuna; Mustard greens; Radish, leaves; Rape greens; Rocket, wild; Shepherd's purse; Turnip greens; Watercress

Codex 17B Young shoots

22A Rep Commodity: Asparagus

Agave; Asparagus; Bamboo shoots; Cactus; Celtuce; Fennel, Florence, fresh leaves and stalk; Fern, edible; Kale, sea; Kohlrabi; Palm hearts

22B Rep Commodity: Celery

Cardoon; Celery; Celery, Chinese; Fuki; Rhubarb; Udo; Zuiki

Codex 17A Stem & petioles

Kohlrabi

5-15: Rep Commodity: Cabbage; Broccoli or Cauliflower

Broccoli; Brussels sprouts; Cabbage; Cabbage, Chinese, napa; Cauliflower

Codex Group 10 Brassica veg.

4A: Rep Commodity (Subgroup to 4-15A): Lettuces, Spinach

Amaranth
Arugula (to 4-15B)
Chervil
Chrysanthemum, Edible-leaved
Chrysanthemum, Garland
Corn Salad
Cress, Garden (to 4-15B)
Cress, Upland (to 4-15B)
Dandelion
Dock
Endive
Lettuce
Orach
Parsley
Purslane, Garden
Purslane, Winter
Radicchio (Red Chicory)
Spinach
Spinach, New Zealand
Spinach, Vine

5B: Rep Commodity (Subgroup to 4-15B): Mustard Greens

Broccoli raab
Cabbage, Chinese (bok choy)
Collards
Kale
Mizuna
Mustard greens
Mustard spinach
Rape greens

5A: Rep Commodity (Subgroup to group 5-15): Cabbage; Broccoli or Cauliflower

Broccoli
Broccoli, Chinese (to 4-15B)
Brussels Sprouts
Cabbage
Cabbage, Chinese (Napa)
Cabbage, Chinese Mustard
Cauliflower
Cavalo-Broccoli
Kohlrabi (to 22A)

Magic Table

CFR Citation	Chemical	Current Tolerances	Proposed Tolerances Agency will Accept under PRIA Code R175 for Crop Group Conversion or Assess during Registration Review	Notes
180.434	Propiconazole	Leaf petioles subgroup 4B (5.0 ppm)	Leaf Petiole Vegetable Subgroup 22B (5.0 ppm) Celtuce (5.0 ppm) Fennel, Florence (5.0 ppm) Swiss chard (5.0 ppm)	Celtuce, Florence fennel and Swiss chard were members of Leafy Vegetable Group 4 (subgroup 4B) so use directions for these commodities should be same as those for celery (subgroup 22B).
180.436	Cyfluthrin and the isomer beta-cyfluthrin	Brassica, head and stem, subgroup 5A (2.5 ppm) Brassica, leafy greens, subgroup 5B (7.0 ppm) Vegetable, leafy, except brassica, group 4 (6.0 ppm)	Leafy greens subgroup 4-16A (6.0 ppm) Brassica leafy greens subgroup 4-16B (7.0 ppm) Vegetable, Head and Stem Brassica, Group 5-16 (2.5 ppm) Leaf Petiole Vegetable Subgroup 22B (6.0 ppm) Celtuce (6.0 ppm) Fennel, Florence (6.0 ppm) Kohlrabi (2.5 ppm)	Celtuce and Florence fennel were members of Leafy Vegetable Group 4 (subgroup 4B) so use directions for these commodities should be same as those for celery (subgroup 22B). Kohlrabi was a member of Brassica leafy group 5 (subgroup 5A) so use directions for this commodity should be same as broccoli and cabbage (Group 5-16).
180.438	Lambda-cyhalothrin and an isomer gamma- cyhalothrin	Brassica, head and stem, subgroup 5A (0.4 ppm)	Vegetable, Head and Stem Brassica, Group 5-16 (0.4 ppm) Broccoli, Chinese (0.4 ppm) Kohlrabi (0.4 ppm)	Chinese broccoli and kohlrabi were members of Brassica head and stem subgroup 5A so use directions for these commodities should be same as broccoli and cabbage (Group 5-16).



Field Data Summaries and Final Report

- After all of the Field Data Books and Analytical Summary Report for the study arrive at IR-4 HQ, this information is summarized in Field Data Summaries and a Final Report.
- The final report is audited a number of times before it is signed.



FIELD DATA SUMMARY

Pesticide/Crop/Field ID No.: Fluopicolide / Basil (Field and GH) / 10121.10-NC03

Field Research Director (FRD): Roger B. Batts

Affiliation of FRD: NCSU IR-4 Field Research Center, Box 7523, NCSU Campus,
Raleigh, NC 27695-7523

Other Field None

Personnel:

TEST SUBSTANCE RECORDS (Separate page for each formulation or lot no.)			
Test Substance (Trade Name/Formulation): Presidio 4 SC			
Source: Valent U.S.A. Corporation			
Lot No.: V10C-15SC-2		Date Received: April 15, 2010	
		Expiration Date: March 18, 2011	
Spray Additives (Adjuvants) Used: Induce (non-ionic surfactant)			
Storage Location: Building 6A, 4012 Chi Rd., Raleigh, NC 27603			
Storage Temperature Range (from receipt of test substance to last application): 52 ° F to 106 ° F			
TRIAL SITE INFORMATION			
Test Site: Horticultural Crops Research Station-Clinton, 450 Faison Hwy, Clinton, NC 28328-9501 Sampson County			
Site Identifier: Field K12, Hort. Crops Research Station, Clinton, NC			
Soil Type/Texture: Sandy loam	% Sand: 75.3	% Silt: 17.6	% Clay: 6.9
	% OM: 1.7	Soil pH: 5.5	CEC: 2.8 meq/100 g
Crop Variety: Genovese		Field (Test Plot) Planting Date: April 16, 2010	
Row Width: Approximately 3.17 ft		Plant Spacing: Approximately 1 inch	
No. Rows <u>X</u> or Trees <u> </u> (check one)/plot: 6			
Control Plot Dimensions: 19 ft x 90 ft		Dimensions of Treated Plot: 19 ft x 90 ft	
Maintenance Fertilizers and Pesticides (applied during the year(s) of the field trial)			
6-6-18 fertilizer, 500 lbs/A, 4/9/10		Avaunt (indoxacarb), 3.5 oz/A + Manex (maneb), 1.8 qt/A, 5/27/10	
33-0-0 fertilizer, 200 lbs/A, 4/9/10		Thionex (endosulfan), 1.5 qt/A, 5/27/10	

Field Data Summary

Treatment 02, Application No.: 1 of 3 (Foliar)

Pesticide/Crop/Field ID No.: Fluopicolide / Basil (Field and GH) / 10121.10-NC03

APPLICATION RECORDS			
Application Date: June 8, 2010		Days From Last Application: NA ¹	
Application Equipment: Backpack, CO ₂ propellant, broadcast boom with 2 nozzles			
Type of Application: Foliar Broadcast			
Plot Length (feet): 90		Number of Passes: 6	
Number of Nozzles: 2		Spray Swath Width (feet): 3.2	
Nozzle Spacing (inches): 19		Screen Mesh: 50	
Nozzle Brand/Type/Size: TeeJet 11005 DG Flat Fan			
Equip. Calibration Date: June 8, 2010		Total Treated Area (ft ²): 1,710.0	
Boom Discharge Rate (mL/sec): 42.000		Total Pass Time (sec): 122.33	
Calculated Delivery of Spray Solution (GPA): 34.6			
Test Substance: Presidio 4 SC			
Formulation Conc.: 4 lbs ai / gal		Lot No.: V10C-15SC-2	
Tank Mix Amounts for Treatment:		02	
Carrier (Water) (mL):		6,976.2	
Formulated Product (mL):		6.3	
Adjuvant (mL):		17.5	
Total Mix Volume (mL):		7,000.0	
Actual Application Rate(s):			
Treatment No.	Protocol Rate (lb a.i./A)	Actual Rate (lb a.i./A)	% Dev. from Protocol Rate
01	0	NA	NA
02	0.125	0.1245	-0.4
Air Temperature:		84 ° F	
Wind Speed and Direction:		2 to 5 mph / W	
Crop Height:		6 to 15 inches	
Crop Growth Stage:		Vegetative	
Date of First Rain after App.:		June 10, 2010	
Amount of First Rain after App.:		0.32 inch	
Time after App. of First Rain:		2 days	
Date of First Irrigation after App.:		June 10, 2010	
Amount of First Irrigation after App.:		0.5 inch of overhead irrigation	
Time after App. of First Irrigation:		2 days	

Field Data Summary**Harvest No.: 1****Pesticide/Crop/Field ID No.: Fluopicolide / Basil (Field and GH) / 10121.10-NC03**

SAMPLE COLLECTION AND STORAGE: Fresh Basil Stems and Leaves		
Harvest Date: 6/21/10	Sampling Date: 6/21/10	PHI (Days): 1
Crop Fraction Sampled: Commercially mature basil stems and leaves		
Sampling Equipment: None; hand-picked		
Sampling Procedures: Untreated samples (A, B) were collected before treated samples (C, D). Uncontaminated gloves were worn and changed between samples. Using gloved hands stems and leaves were collected across all 6 plot rows and from all areas of the basil plants (high, low, sheltered, exposed). Each sample was collected from more than 12 areas of the plot. Stems and leaves were placed directly into pre-labeled sample bags. 3 feet of the length of row ends were not sampled. Less than 50% of the harvestable crop was sampled.		
Trimming, Cleaning, Cutting, Drying, Composting, etc: No modifications were made to the crop.		
Sample Handling between Field and Freezer (or Field and Shipment): Samples from the same plot were over-bagged together and placed into pre-labeled coolers ("check" or "treated") with large bags of wet ice. Then samples were transferred to the freezer in a covered trailer pulled by a pickup truck.		
Maximum Length of Time from Treated Sample Collection to Frozen Storage: 1 hour and 50 minutes (sample C)		
Freezer Temperature Range(s) (prior to shipment): -18 ° F to 14 ° F (NCSU IR-4 Field Research Center Freezer #1; samples A, B, C, D)		
Shipped (Please Check): Frozen <input checked="" type="checkbox"/> (Copies of the shipping papers were placed in plastic bags and put into each shipping box. Using gloved hands, the UTC samples were placed into Box #1 and sealed. After changing gloves, the treated samples were placed into Box #2 and sealed.)		
Shipped Via: ACDS Freezer Truck	Shipment Date: July 16, 2010	
METEOROLOGICAL INFORMATION		
Were the test plots irrigated?: Yes		
Type of Irrigation: Overhead irrigation		
Was the weather during this field trial normal for this test site? Yes		
Describe any unusual weather occurrences: None		
PHYTOTOXICITY, EFFICACY & YIELD		
Were any phytotoxic effects seen? No		
Describe the severity & symptoms of any phytotoxic effects: None recorded		
If efficacy/yield data were recorded, describe any differences between treatment(s) and controls: None recorded		

The Final Report

FLUOPICOLIDE: MAGNITUDE OF THE RESIDUE ON BASIL
(FIELD AND GREENHOUSE)

IR-4 PR No. 10121

Data Requirement

U.S. EPA OPPTS 860 Series Guidelines

Author

Kathryn Homa
IR-4 Project Headquarters
Rutgers, The State University of NJ
500 College Road East, Suite 201 W
Princeton, NJ 08540

Study Completed on

See page 7 for Study Director's signature

Performing Laboratories

See pages 5-6 for list of performing laboratories

Analytical Laboratory Identification Number

10121.10-CAR05

Field Identification Numbers

10121.10-FL05	10121.10-AZ*08
10121.10-NC03	10121.10-CA18
10121.10-SC*01	10121.11-MD08
10121.10-CA*19	10121.11-AR02

- Appendix 1 Field Data Summaries
- Appendix 2 Certificates of Analysis
- Appendix 3 Analytical Summary Report
- Appendix 4 Protocol, Amendments/Deviations



IR-4 Submission To EPA

- Submissions to EPA are made electronically to be reviewed by EPA to eventually obtain pesticide tolerance / labeled use
- Administrative Volume

EPA forms that are submitted with the petition

- Form 8570-1 Application for Pesticide
- **Form 8570-4 Confidential Statement of Formula**
- Form 8570-34 Certification with Respect to Citation of Data
- Form 8570-35 Data Matrix (EPA and public versions)
- **Form 8570-36 Physical/Chemical properties**
- **Form 8570-37 Self-Certification**
- Draft labeling – technical and end use
- Notice of Filing
- Letter of Authorization from chemical manufacturer
- Neurotoxicity and Immunotoxicity Data



Administrative Volume

VOLUME 1 – ADMINISTRATIVE VOLUME

TABLE OF CONTENTS

LETTER OF AUTHORIZATION

SECTION A: THE NAME, CHEMICAL IDENTITY, AND COMPOSITION OF ACEQUINOCYL

Section B: THE AMOUNT, FREQUENCY AND TIMING OF APPLICATION OF ACEQUINOCYL IN AVOCADO, DRIED SHELLLED BEANS, SUMMER SQUASH AND TEA PRODUCTION

SECTION C: FULL REPORT OF INVESTIGATIONS MADE WITH RESPECT TO THE SAFETY OF THE PESTICIDE CHEMICAL ACEQUINOCYL

SECTION D: THE RESULTS OF TESTS ON THE AMOUNT OF ACEQUINOCYL RESIDUES REMAINING IN OR ON AVOCADO, DRIED SHELLLED BEANS, SUMMER SQUASH AND TEA

SECTION E: PRACTICAL METHODS FOR REMOVING RESIDUES THAT EXCEED ANY PROPOSED TOLERANCE

SECTION F: PROPOSED TOLERANCE FOR THE PESTICIDE CHEMICAL ACEQUINOCYL USE IN OR ON AVOCADO, BEANS (DRIED SHELLLED) AND SUMMER SQUASH AND TEA

SECTION G: REASONABLE GROUNDS IN SUPPORT OF OUR PETITION FOR ACEQUINOCYL ON AVOCADO, BEANS (DRIED SHELLLED), SUMMER SQUASH AND TEA

Section D

SECTION D

THE RESULTS OF TESTS ON THE AMOUNT OF ACEQUINOCYL RESIDUES REMAINING IN OR ON AVOCADO, DRIED SHELLED BEANS, SUMMER SQUASH AND TEA

LIST OF STUDIES SUBMITTED WITH PETITION VOLUME NO. AND TITLE

- Volume 2: Acequinocyl: Magnitude of the Residue on Avocado
- Volume 3: Acequinocyl: Magnitude of the Residue on Beans (Dried Shelled)
- Volume 4: Acequinocyl: Magnitude of the Residue on Summer Squash
- Volume 5: Acequinocyl, Analytical Results, Crude Tea, 1995, Japan
- Volume 6: Acequinocyl, Analytical Results, Infusion, 1995, Japan
- Volume 7: Acequinocyl, Analytical Results, Crude Tea, 1996, Japan
- Volume 8: Acequinocyl, Analytical Results, Infusion, 1996, Japan

Note that while the acequinocyl, dried shelled bean was conducted with two applications at a 21 day interval with a PHI of 7 days, Section B and the proposed label include a 14 day interval between the two applications for dried shelled beans. This is comparable to the labeled use of succulent shelled beans with the same 7 day PHI.

While the existing tolerance for Bean, succulent, shelled is 0.30 ppm, a tolerance of 0.03 ppm is proposed for Bean, dry, seed (see Section F). Residues were only found in two of the eleven dried shelled bean trials. With the same PHI (7 days) as succulent shelled beans, shortening the interval from 21 to 14 days is unlikely to have an impact on residues in dried shelled beans.

Volumes 5, 6, 7 and 8 include translated analytical data from Japan used to establish a 40 ppm tolerance for acequinocyl in Japan (see following email). This submission for harmonization purposes also proposes a US tolerance of 40 ppm (See Section F).



Section F

SECTION F

PROPOSED TOLERANCE FOR THE PESTICIDE CHEMICAL ACEQUINOCYL USE IN OR ON AVOCADO, BEANS (DRIED SHELLED) AND SUMMER SQUASH AND TEA

AMENDS 40 CFR 180.599

The petitioner, IR-4, on behalf of the Agricultural Experiment Station of Florida (avocado), Texas and New York (dried shelled beans) and Texas, Oklahoma and Tennessee (summer squash) requests the establishment of a tolerance for residues of acequinocyl, including its metabolites and degradates, in or on the commodities in the table below. Compliance with the tolerance levels specified below is to be determined by measuring only the sum of acequinocyl [2-(acetyloxy)-3-dodecyl-1,4-naphthalenedione] and its metabolite, 2-dodecyl-3-hydroxy-1,4-naphthoquinone, calculated as the stoichiometric equivalent of acequinocyl, in or on the following commodities:

Commodity	Proposed Tolerance (ppm)
Avocado [residue study]	0.4
Bean, dry, seed [residue study]	0.03
Vegetable, cucurbit, group 9 [residue study]	0.2
Tea, plucked leaves [Japanese studies for import tolerance]	40
Cherry subgroup 12-12A [crop group expansion]	1.0
Fruit, citrus, group 10-10 [crop group conversion]	0.20
Fruit, pome, group 11-10 [crop group conversion]	0.40
Nut, tree, group 14-12 [crop group conversion]	0.02
Vegetable, fruiting, group 8-10 [crop group conversion]	0.70

The petitioner, IR-4, proposes, upon the approval of the aforementioned tolerances, to remove established tolerances for residues of acequinocyl, including its metabolites and degradates, in or on the commodities in the table below. Compliance with the tolerance levels specified below is to be determined by measuring only the sum of acequinocyl [2-(acetyloxy)-3-dodecyl-1,4-naphthalenedione] and its metabolite, 2-dodecyl-3-hydroxy-1,4-naphthoquinone, calculated as the stoichiometric equivalent of acequinocyl, in or on the following commodities:

Commodity	Proposed Tolerance (ppm)
Cucumber	0.15
Melon, subgroup 9A	0.15
Cherry, sweet	0.50
Cherry, tart	1.0
Fruit, citrus, group 10	0.20
Fruit, pome, group 11	0.40
Nut, tree, group 14	0.02
Pistachio	0.02
Vegetable, fruiting, group 8	0.70
Okra	0.70

Acequinocyl	Reset file	Select frame
Summer Squash		
United States		
0.3 lb ai/A, 2 applications, 1 day PHI		
Residues (mg/kg)	Acequinocyl	
0.033	Summer Squash	
0.159	United States	
0.048	0.3 lb ai/A, 2 applications, 1 day PHI	
0.062	Total number of data (n)	10
0.067	Percentage of censored data	0%
0.039	Number of non-censored data	10
0.067	Lowest residue	0.033
0.041	Highest residue	0.159
0.041	Median residue	0.049
0.050	Mean	0.061
	Standard deviation (SD)	0.037
	Correction factor for censoring (CF)	1.000
	<u>Proposed MRL estimate</u>	
	- Highest residue	0.159
	- Mean + 4 SD	0.207
	- CF x 3 Mean	0.182
	Unrounded MRL	<u>0.207</u>
	Rounded MRL	<u>0.2</u>

Conversions and Expansions

Action Code	Description	FY'20- FY'21 Fee	Decision Time (months)
R170	Additional food use (3) (4)	\$83,317	15

Action Code	Description	FY'20- FY'21 Fee	Decision Time (months)
R175	Additional food uses covered within a crop group resulting from the conversion of existing approved crop group(s) to one or more revised crop groups (3) (4)	\$69,431	10



Factors for IR-4 Public Interest Finding

Under the Pesticide Registration Improvement Extension Act (PRIA 4) (FIFRA Section 33(b)(7)(E)), the Administrator shall **exempt an application from the registration service fee** if the Administrator determines that the application meets both of the following criteria:

- (i) the application is solely associated with a tolerance petition submitted in connection with the Inter-Regional Project Number 4 (IR-4) as described in Section 2 of Public Law 89-106 (7 U.S.C. 450i(e)), and
- (ii) the exemption is in the **public interest**.

Public Interest Presumption

An application will be presumed to be in the public interest if it is for a **biopesticide** or if the following criteria are met:

- the data submitted have been developed by IR-4; and
- the active ingredient, for which the data are developed, must have been already registered for use on a food commodity; and
- the active ingredient/crop combination has been pre-screened by EPA prior to the Food Use Workshop, and EPA has discussed any risk concerns that might hinder registration or the establishment of tolerances with IR-4; and
- the use is for:
 - a minor crop ($\leq 300,000$ acres) or a specialty crop¹, which the [2004 Specialty Crop Competitiveness Act](#) defines to include:
 - fruits;
 - vegetables;
 - tree nuts;
 - dried fruits; and
 - nursery crops (including floriculture); or
 - a major crop that is a representative commodity for a crop group/subgroup that is being submitted to establish tolerances for the minor uses/specialty crops in the crop group/subgroup, and where the accompanying label amendment adds at least one new minor use/specialty crop from that crop group to the label; or
 - control of a niche pest on a major crop (where the most likely number of acres treated is $\leq 300,000$ acres at the time the application is submitted); or
 - control of a public health pest on the [List of Pests of Significant Public Health Importance](#); or
 - control of a pest identified as critical by the federal government [National Plant Disease Recovery System \(NPDRS\)](#) as called for in [Homeland Security Presidential Directive # 9 \(HSPD-9\) \(PDF\)](#) (5 pp, 135.5 K, [About PDF](#)); or
 - control of a pest identified as critical by the USDA OPMP or [APHIS Plant Protection and Quarantine \(PPQ\) Program Pests](#); or
 - pesticide/crop combination associated with a Section 18 and there likely is insufficient economic incentive for the registrant to generate the data.

For other actions that do not meet the criteria listed above, EPA will determine if a fee exemption is warranted on a case-by-case basis using a weight-of-evidence approach considering the following factors:



Submission Letter

Ms. Barbara Madden
Minor Use Officer
US EPA OPP/Proc Desk (REGFEE)
Room S-4900
2777 S. Crystal Drive
Arlington, VA 22202


Dear Ms. Madden:

Submission of the IR-4 Acequinocyl studies on Avocado, Dried Shelled Beans and Summer Squash and Tea data from Japan

The IR-4 Project requests Reduced Risk classification for these uses.


RE: Acequinocyl
Kannemite 15 SC Miticide, EPA Reg. No. 66330-038

IR-4 Public Interest Finding:

- 
- (1) The avocado, dried shelled beans and summer squash data being submitted was developed by IR-4.
 - (2) The active ingredient, acequinocyl, is already registered on other food crops.
 - (3) The active ingredient/crop combinations of acequinocyl / avocado (PR # 09218); acequinocyl / dried shelled beans (PR # 08675) and acequinocyl / summer squash (PR # 08606) were pre-screened by the EPA because this IR-4 study were initiated after 2010.
 - (4) The uses on avocado, dried shelled beans and summer squash are for crops grown on less than 300,000 acres. Production of avocado in 2014 in the US was 61,300 acres (http://www.nass.usda.gov/Statistics_by_Subject/result.php?013E44DE-3990-3D98-8528-79441DAFFCB2§or=CROPS&group=FRUIT%20%26%20TREE%20NUTS&comm=AVOC DOS) and production of squash in 2014 was 34,530 acres (http://www.nass.usda.gov/Statistics_by_Subject/result.php?8AE5A049-20A8-3E87-A87A-E501C0EBC502§or=CROPS&group=VEGETABLES&comm=SQUASH) (USDA, National Agricultural Statistics Service, Quick Stats). While dried shelled beans are grown on >300,000 acres, dried shelled bean is one of the representative crops of Crop Subgroup 6C. Dried shelled pea and bean. Dried shelled beans are also defined as vegetables (2004 Specialty Crop Competitiveness Act) and mites are considered to be a niche pest occurring only in outbreaks caused by hot dry weather or the use of broad spectrum insecticides that kill natural enemies of mites (<https://nevegetable.org/crops/insect-control-1>).



Submission Letter



New Uses	Supporting Data	
Tolerance Requested	IR-4 PR Numbers	Source of New Tolerance
Avocado	09218	Avocado residue data
Bean, dry, seed	08675	Dried Shelled bean residue data
Vegetable, cucurbit, group 9	08608	Summer Squash residue data and cucumber tolerance
Tea, plucked leaves	11706	Residue data from Japan
Cherry subgroup 12-12A	11800	Crop group expansion from sweet cherry and tar cherry tolerances
Fruit, citrus, group 10-10	11801	Crop group conversion from Fruit, citrus, group 10 tolerance
Fruit, pome, group 11-10	11802	Crop group conversion from Fruit, pome, group 11 tolerance
Nut, tree, group 14-12	11803	Crop group conversion from Nut, tree, group 14 and pistachio tolerances
Vegetable, fruiting, group 8-10	11804	Crop group conversion from Vegetable, fruiting, group 8 and okra tolerances



The IR-4 Project requests Reduced Risk classification for these uses.

Fee Category: R-180 and R175

Registration Fee: \$66,124 (R-180) X 5 and \$66,124 (R-175) (See IR-4 exemption request below)

The undersigned, William Barney, Coordinator, Interregional Research Project No. 4, The State University of New Jersey, Princeton, New Jersey 08540, on behalf of the IR-4 Project and the Agricultural Experiment Station of the state of Florida (avocado), Texas and New York (dried shelled beans) and Texas, Oklahoma and Tennessee (summer squash), submits this petition pursuant to Section 408(e) of the Federal Food, Drug and Cosmetic Act, as amended, with respect to the pesticide chemical, acequinocyl, including its metabolites and degradates, in or on the commodities in the table below.



Submission Letter



Vol. #	Volume Title	PP No.
1	Petition (Administrative Volume) Supporting data for Acequinocyl Use in Avocado, Dried Shelled Beans, Summer Squash and Tea	---
2	Acequinocyl: Magnitude of the Residue on Avocado	49716701
3	Acequinocyl: Beans (Dried Shelled)	49716702
4	Acequinocyl: Summer Squash	49716703
5	Summary Report of Magnitude of the Residue Research of Acequinocyl on Tea	49716704

The entire submission is being made as an electronic submission only using EPA's e-submission XML format described in the e-Submission XML Guidance Document Version 1.2, dated July 21, 2008.

Enclosed in this submission as an electronic copy on CD are the Administrative Volume, ata Volume, Notice of Filing, the Letter of Authorization and the following documents:

For the technical product:

- EPA Form 8570-1 for acequinocyl technical (EPA Reg. No. 66330-39)
- EPA Form 8570-34 Certification with Respect to Citation of Data for acequinocyl technical (EPA Reg. No. 66330-39)
- EPA Form 8570-35 Data Matrix (EPA copy) for acequinocyl technical (EPA Reg. No. 66330-39)
- EPA Form 8570-35 Data Matrix (Public copy) for acequinocyl technical (EPA Reg. 66330-39)
- Acequinocyl technical label (EPA Reg. No. 66330-39)
- Acequinocyl technical label, shaded version (EPA Reg. No. 66330-39)



For the end use product:

- EPA Form 8570-1 Application for Pesticide for Kanemite® 15 SC Miticide (EPA Reg. No. 66330-38)
- EPA Form 8570-34 Certification with Respect to Citation of Data for Kanemite® 15 SC Miticide (EPA Reg. No. 66330-38)
- EPA Form 8570-27 Formulator's Exemption Statement for Kanemite® 15 SC Miticide (EPA Reg. No. 66330-38)
- EPA Form 8570-35 Data Matrix (EPA copy) for Kanemite® 15 SC Miticide (EPA Reg. No. 66330-38)
- EPA Form 8570-35 Data Matrix (Public copy) for Kanemite® 15 SC Miticide (EPA Reg. No. 66330-38)
- Kanemite® 15 SC Miticide label (EPA Reg. No. 66330-38)
- Supplemental Labeling Kanemite 15 SC Miticide label for use on Avocado (EPA Reg. No. 66330-38)
- Supplemental Labeling Kanemite 15 SC Miticide label for use on Dried Shelled Beans (EPA Reg. No. 66330-38)





Submission Letter



An immunotoxicity study for acequinocyl in mice (MRID 48660604) has been accepted and the data requirements considered fulfilled. The waiver request for 90-day inhalation, per the HASPOC memo dated 5/24/12 (DP 389992) has been accepted and no studies are required.

HED, using a weight of evidence approach considered all hazard and exposure data for acequinocyl and determined that a subchronic neurotoxicity study is not required and granted a waiver. Please see attached memoranda.



There are no Codex MRLs relevant to this submission. While both Canada and the US have 0.15 ppm tolerances on cucumber, the summer squash submission and subsequent proposed tolerance of 0.2 ppm for Vegetable, cucurbit, group 9 is a joint submission with Canada. Also included in the joint submission is the dried shelled bean study.

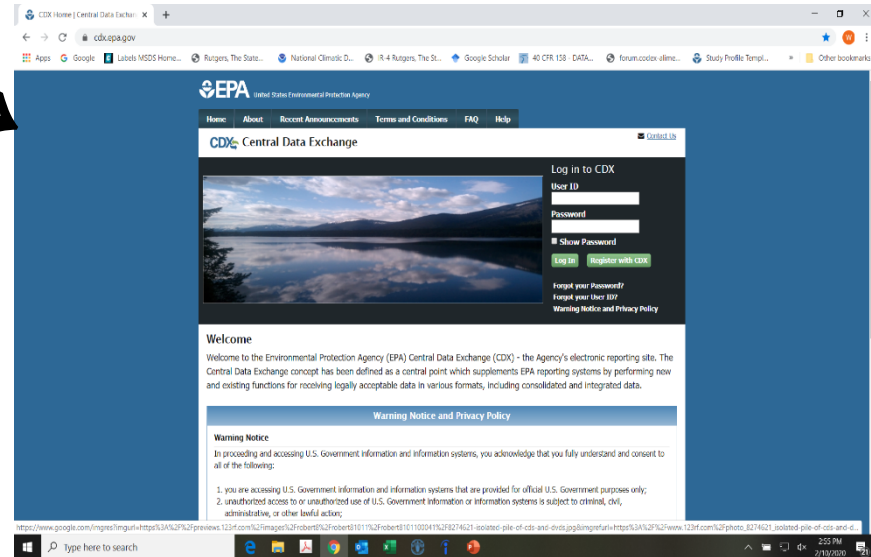
For questions pertaining to the 8570 forms, the labels and the notice of filing, please contact Dave Bolin, Regulatory Manager, Arysta LifeScience North America, Tel. No.: (919) 678-4917, dave.bolin@arysta.com. For questions concerning the transmittal letter, petition and / or final study report please contact William Barney, IR-4, Tel. No.: (732) 932-9575 ext. 4603; email: barney@aesop.rutgers.edu

Yours very truly,
Interregional Research Project No. 4
Petitioner

Per

William P. Barney, Coordinator,
Food, Crop Grouping Manager and Biopesticides
IR-4 Project Headquarters
Rutgers, The State University of New Jersey
500 College Road East, Suite 201 W
Princeton, NJ 08540

Evolution of Submissions



EPA Central Data Exchange

US EPA
Application Documents

cdxnodengn.epa.gov/cdx-opp-psp/action/edossierpackage/applicationDocuments?edossierPackage.id=IZAze7vJa-92ILDc0HHMAw%3D%3D&application.id=bBP070kqFDBMXye7VvEJ7g%3D%3D

Apps
Google
Labels MSDS Home...
Rutgers, The State...
National Climatic D...
IR-4 Rutgers, The St...
Google Scholar
40 CFR 158 - DATA...
forum.codex-alime...
Study Profile Templ...
Other bookmarks

Portal
Packages
Batch Uploads
Help
William Barney, Interregional Research Project No. 4 (Primary Submitter)

Oxalic Acid Dihydrate

- Package Info
- Package Documents
- Application(s): 2
 - Sec3-New-Oxalic Acid Dihydrate
 - Application Info
 - Application Documents
 - ToiPet-New-000001
 - Application Info
 - Application Documents

Click the 'Add' button to upload documents and enter data about the uploaded documents. Click 'Save' to save your changes. Different fields will display based on the chosen document type and sub type.

Documents for the Application

Please submit application-level Document(s) in the following fields.

Total Submission Package File Count: 11, Total Submission Package File Size: 5.05 MB

Document Type	File Name	Document Date	CBI	MRID	Action(s)
8570-1: Pesticide Registration/Amendment Application	8570-1 Oxalic acid...		N		↶ ✖
8570-4: Confidential Statement of Formula	8570-4_0 Oxalic ac...		Y		↶ ✖
8570-34: Cert with Respect to Citations of Data	8570-34 Oxalic aci...		N		↶ ✖
8570-35: Data Matrix	8570-35 Oxalic aci...		Y		↶ ✖
8570-35: Data Matrix	8570-35 Oxalic aci...		N		↶ ✖
8570-36: Summary of the Phy/Chem Properties	8570-36 Oxalic aci...		N		↶ ✖
8570-37: Self-Cert Stmt for the Phy/Chem Properties	8570-37 Oxalic aci...		N		↶ ✖
Label-PDF	Oxalic Acid Dihydr...		N		↶ ✖
Label-PDF	Oxalic Acid Dihydr...		N		↶ ✖

Add

To add a new application-level Document, please click the 'Add' button.
To edit an existing application-level Document, please click the "Doc Type" in the above list.

Package Name
Oxalic Acid Dihydrate

Application Name
Sec3-New-Oxalic Acid Dihydrate

* Document Type
Please select an item ...

Save
Preview
Validate
Submit

CDX Links

Type here to search

8:38 AM
2/13/2020



Automated Email Milestone Tracking for PRIA Actions

PRIA requires EPA to inform registrant contacts when any of their PRIA submissions reach each of the seven defined tracking milestones.

- The seven milestones are:
 1. Application receipt date; receipt number assigned.
 2. PRIA category(ies) assigned; waiver decision, if applicable, completed; payment completed; 21-day screen timeframe expired; PRIA start date; PRIA due date; pre-decisional determination due date, if applicable.
 3. Contact information for PM assigned to your application; data sent into review.
 4. 45/90 technical screen timeframe expired.
 5. Actual last science review completion date.
 6. Pre-decisional determination date reached, if applicable.
 7. Regulatory decision completed.



Established Tolerances

Electronic Code of Federal Regulations
e-CFR data is current as of February 13, 2020

[Title 40](#) → [Chapter I](#) → [Subchapter E](#) → [Part 180](#) → [Subpart C](#) → §180.599

[Browse Previous](#) | [Browse Next](#)

Title 40: Protection of Environment

PART 180—TOLERANCES AND EXEMPTIONS FOR PESTICIDE CHEMICAL RESIDUES IN FOOD

Subpart C—Specific Tolerances

§180.599 Acequinocyl; tolerances for residues.

(a) *General.* Tolerances are established for residues of acequinocyl, including its metabolites and degradates, in or on the commodities in the table below. Compliance with the tolerance levels specified below is to be determined by measuring only the sum of acequinocyl [2-(acetyloxy)-3-dodecyl-1,4-naphthalenedione] and its metabolite, 2-dodecyl-3-hydroxy-1,4-naphthoquinone, calculated as the stoichiometric equivalent of acequinocyl, in or on the commodity.

Commodity	Parts per million
Fruit, pome, group 11-10	0.40
Fruit, small vine climbing, except fuzzy kiwifruit, subgroup 13-07F	1.6
Goat, fat	0.02
Goat, meat byproducts	0.02
Guava	0.90
Hop, dried cones	15
Horse, fat	0.02
Horse, meat byproducts	0.02
Nut, tree, group 14-12	0.02
Sheep, fat	0.02
Sheep, meat byproducts	0.02
Soybean, vegetable, succulent	0.25
Tea, plucked leaves ¹	40
Tropical and subtropical, small fruit, inedible peel, subgroup 24A	2.0
Vegetable, cucurbit, group 9	0.30
Vegetable, fruiting, group 8-10	0.70

¹There are no U.S. registrations as of January 18, 2017 for use on tea.



Label

GROUP	20B	INSECTICIDE
-------	-----	-------------

KANEMITE® 15 SC

Supplemental Label to Add **DIRECTIONS FOR USE** on **SUMMER SQUASH**.

This supplemental label expires , 2018 and must not be used or distributed after this date.

For Agricultural Use Only

INGREDIENTS: _____ ACTIVE
INGREDIENT:

% BY WT.

*Acequinocyl 15.8%
OTHER INGREDIENTS: 84.2%
TOTAL: 100.0%
*3-dodecyl-1, 4-dihydro-1, 4-dioxo-2-naphthyl-acetate.
Contains 1.25 lb ai/gal.

KEEP OUT OF REACH OF CHILDREN
CAUTION / PRECAUCIÓN

DIRECTIONS FOR USE

It is a violation of Federal Law to use this product in a manner inconsistent with its labeling.

THIS LABELING MUST BE IN THE POSSESSION OF THE USER AT THE TIME OF APPLICATION. READ THE LABEL AFFIXED TO THE CONTAINER FOR **KANEMITE 15 SC** BEFORE APPLYING. USE OF **KANEMITE 15 SC** ACCORDING TO THIS LABELING IS SUBJECT TO THE USE PRECAUTIONS AND LIMITATIONS IMPOSED BY THE LABEL AFFIXED TO THE CONTAINER FOR **KANEMITE 15 SC** (EPA Reg. No. 66330-38).

SUMMER SQUASH - CHAYOTE (FRUIT), CHINESE WAXGOURD, CUCUMBER, GHERKIN, EDIBLE GOURD, *MOMORDICA* SPP., PUMPKIN, SUMMER SQUASH AND WINTER SQUASH

PEST	USE RATE
Two spotted spider mite (<i>Tetranychus urticae</i>)	31 fl oz/A
Broad mite (<i>Polyphagotarsonamus latus</i>)	(0.3 lb ai/A)

Thank you - everyone!

- For all your Contributions to Make this happen!



Questions?

