8-16-93

Chemical Code: 122804

Date Out: 8/16/93

ENVIRONMENTAL FATE AND GROUND WATER BRANCH

Review Action

To: Mr. George LaRocca
Registration Division (H7505C)

From: Paul L. Zubkoff, Chemist
Environmental Assessment / Surface Water
Environmental Fate & Ground Water Branch/EFED (H7507C)

Paul L. Zubkoff 8/9/93

Thru: Henry Nelson, Section Chief H Nelson
Environmental Assessment / Surface Water
Environmental Fate & Ground Water Branch/EFED (H7507C)

Thru: Henry Jacoby, Chief Henry Jacoby 8/16/93
Environmental Fate & Ground Water Branch/EFED (H7507C)

Attached, please find the EFGWB review of...

DP Barcode:	D179965		
Common Name:	Avermectin B_1	Trade name:	Agri-Mek® 0.15 EC, Avid®, Affirm®, Vertimec®, Avomec®, Zephyr®
Company Name:	Merck & Co., Inc.		
ID #:	EFGWB 92-1111 S419252		
Purpose:	Review of Public Materials submitted by Merck & Co. in support of their voluntary product restrictions and assessment that aquatic exposure due to potential runoff of Avermectin B_1 is less than that previously estimated.		

Type Product:	Action Code:	EFGWB #(s):	Review Time:
Insecticide / Miticide		92-1111	days

STATUS OF STUDIES IN THIS PACKAGE:

Guideline	MRID	Status[1]
167-1* Field Runoff [* Proposed]		

Waiver Request for release of mesocosm study on basis of risk mitigation measures including geographic restrictions and reduction of quantities and frequency of applications

STATUS OF DATA REQUIREMENTS:

	Status[2]
	A

[1] Study Status Codes:
[2] Data Requirement Status Codes:

A=Acceptable U=Upgradeable C=Ancillary I=Invalid.
S=Satisfied P=Partially satisfied N=Not satisfied R=Reserved.

1. Chemical

Common Name:	**avermectin B_1**
Trade Name:	AGRI-MEK®; AVID® O.15 EC; Abamectin; MK-936
Chemical Name:	**5-O-demethyl-25-de-(1-methylpropyl)-25-(1-methylethyl) avermectin A_{1a}**
Chemical Family:	Avermectin
Formulation:	EC (Emulsifiable Concentration) 1 gallon = 0.15 pounds of Avermectin B_1

Physical / Chemical Properties Merck Index (1989): 2978

Molecular Formula:	$C_{45}H_{68}O_{14}$	Mol. Weight:	**829.97**	
Molecular Formula:	$C_{47}H_{70}O_{14}$	Mol. Weight:	**858.56**	**(R = CH_3)**
Molecular Formula:	$C_{48}H_{72}O_{14}$	Mol. Weight:	**872.58**	**(R = C_2H_5)**

Physical State:	odorless, off-white to yellow crystals from methanol
Melting Point:	150-5° C (dec)
Boiling Point:	83-84° C
Density (4°-20° C)	1.116-1.118 g ml^{-1}
Vapor Pressure:	1.5 x 10^{-9} torr (20°)
Solubility$_{water}$ (20°C):	5-10 ppb (= μg/L)

2. Test Material

Product Name:	**Agri-Mek® 0.15 EC** (May 14, 1993) 1.9% Avermectin B_1 active ingredient per gallon * 1 gallon contains 0.15 pound Avermectin B_1
Purity:	Avermectin B_1 [A mixture of avermectins containing ≥ 80% avermectin B_{1a} and ≤ 20 % avermectin B_{1b}
Active Ingredient:	**avermectin B_{1a}**

3. Study / Action Type

FIFRA Waiver Request for Continuing Mesocosm Study

4. Study Identification

Runoff Potential of Abamectin When Used by Ground Boom Application Equipment in Row Crops: Strawberries, Tomatoes, Celery and Head Lettuce
Florida
Western Region (California, Arizona and Texas)

5. **Reviewed By**

Paul L. Zubkoff, Ph.D., Chemist
Environmental Assessment / Surface Water Section
Environmental Fate & Ground Water Branch

6. **Approved By:**

Henry Nelson, Ph.D., Head
Environmental Assessment / Surface Water Section
Environmental Fate & Ground Water Branch

Approved By:

Henry Jacoby, Chief
Environmental Fate & Ground Water Branch
Environmental Fate & Effects Division

7. Conclusions

With respect to voluntary use restrictions placed on avermectin B_1 through proposed product labeling (May 14, 1993) and public materials submitted to the Agency for Western Region and Florida, EFGWB concurs that with such restrictions, Avermectin B_1 may be used without causing excessive loadings by runoff to bodies of water.

Western Region (California, Arizona, Texas)

Tomatoes, Strawberries / Lettuce and Celery
Application of avermectin B_1 is made by ground boom and does not exceed label concentrations, application rates, frequency of applications and maximum amounts of per season. These voluntary restrictions preclude applications of Avermectin B_1 by aerial spraying and thereby reduce the potential to contaminate nearby bodies of water directly by drift immediately following such aerial application.

Florida

Tomatoes, Strawberries / Lettuce and Celery
Application of avermectin B_1 is made by ground boom and does not exceed label concentrations, application rates, frequency of applications and maximum amounts of per season. These voluntary restrictions preclude applications of Avermectin B_1 by aerial spraying; thus, potential to contaminate nearby bodies of water (canals, ponds, lakes, coastal waters) directly by drift immediately following such aerial application is

obviated. In addition, the low grade (usually <~ 1%) and the high affinity of avermectin B_1 to bind to soils and the low precipitation during the growing period are factors which reduce the likelihood that runoff occurs.

Other Geographic Locations and Crops

Information for other geographic locations and crops mentioned in the November 20 ,1992 letter were not included with this review:

Cotton
Citrus
Strawberries, Lettuce, Celery
Idaho, Michigan, new York, Pennsylvania, Utah
Pears
California, Oregon, Washington
Other Minor Use Crops (23 states) Almonds & Walnuts
Pears, Hops, Tomatoes, Celery, Lettuce, Strawberries, Melons, Peppers

8. Recommendations

No specific recommendations concerning tomatoes, strawberries, lettuce and celery in the Western Region (California, Arizona and Texas) and Florida.

9. Discussion - Reviewer's Comments

9.1. Reviewer's Comments - Background

9.2. Reviewer's Comments and Interpretations of Items Submitted to Agency

9.2.1. Western Region
Runoff Potential of Abamectin When Used by Ground Boom Application Equipment on Row Crops - Strawberries, Tomatoes, Celery and Head Lettuce

9.2.2. Florida
Runoff Potential of Abamectin When Used by Ground Boom Application Equipment on Row Crops - Strawberries, Tomatoes, Celery and Head Lettuce

9.3. Reviewer's Simulation

Simulation the Environmental Fate of Avermectin B_1 in an Aquatic Ecosystem (Pond-Stream-Stream) with EXAMS II July 1990
EFGWB / SWS Report 90-05-003 Paul L. Zubkoff

Avermectin B_1

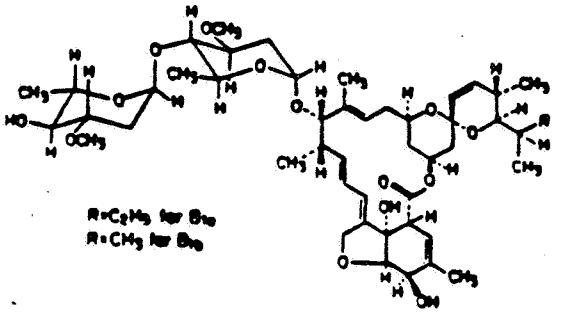
CAS 65195-55-3
SHA 122804

Synonyms: Abamectin; Avermectin B_1; C-076; MK-936

Avermectin B_1 = Abamectin
Avermectin B_1 contains at least 80% of Avermectin B_1 and not more than 20% avermectin B_{1b}

Trade names: Affirm®; Avid®; Agri-Mek®; Vertimec®; Avomec®; Zephyr

Structure:



$R = C_2H_5$ for B_{1a}
$R = CH_3$ for B_{1b}

Avermectin B_1 $C_{48}H_{72}O_{14}$ **Molecular Weight = 872**
Component a: $R_{25} = C_2H_5$

Avermectin B_{1b} $C_{47}H_{70}O_{14}$ **Molecular Weight = 858**
Component b: $R_{25} = CH_3$

W.C. Campbell, Ed. 1989.
Ivermectin and Abamectin, 363 pp. Springer-Verlag NY
1991 Farm Chemicals Handbook C4. Meister Publishing Co. Willoughby, Ohio
The Merck Index, 11th Edition. 1989. 1 Merck & Co. Rahway, N.J.

Uses:

1. Conditionally registered as miticide for use on citrus in Florida.
2. Conditionally registered as miticide for use on cotton in California.
3. Fully registered for use on ornamental plants in greenhouses and outdoor nurseries.
4. Fully registered for control of fire ants in non-cropland areas.

22

Avermectin B_1 CAS 65195-55-3 SHA 122804

Item 9.1. Letter to US EPA from MERCK & Co. (November 20, 1992)

To: Ms. Linda Fisher, Assistant Administrator, US EPA / OPTS, Washington DC
From: Richard A. Dybas, Executive Director, Agricultural Research & Development, Regulatory Affairs, Merck & Co., Inc., Rahway, NJ

Background / Summary:

9.1.1. Merck & Co. has reviewed the recommendations of the U.S. EPA Ecological Fate and Effects Task Force with respect to aquatic mesocosm studies and agree with the stated reasons and goals of making registration decisions based on adequate existing laboratory data and risk mitigating studies.

9.1.2. Merck & Co. requests the opportunity to discuss the need to complete a mesocosm study which is required as a condition for approval of registration of Avermectin B_1 (Agri-Mek®, Zephyr®). Avermectin B_1 is conditionally registered for use on citrus trees in Florida and cotton in California and fully registered for use in greenhouses and outdoor nurseries and for control of fire ants in non-cropland areas.

9.1.3. The conditions for Full §3 Registrations on cotton and citrus are dependent upon completion of field dissipation studies which are accepted by the Agency and conducting an aquatic mesocosm study with final report due to the Agency by October 31, 1994. The acclimation period for the mesocosm study is currently underway.

9.1.4. Avermectin B_1 is an efficacious miticide/insecticide with amendments pending for use on

celery (5/88)	strawberries (6/90)
pears (7/89)	lettuce (3/91)
tomatoes (10/88)	almonds & walnuts (3/91)

9.1.5. §18 Emergency Exemptions for Avermectin B_1 have been submitted by states since 1986:

pears CA, OR, WA 1986 - 1991 control of mites and pear psylla
more recently, ID, MI, NY, PA and UT have also submitted §18s
strawberries, lettuce, celery
other minor use crops (in 23 states)
pears, hops, tomatoes, celery, lettuce, strawberries, melons, peppers

23

9.1.6. Voluntary product use restrictions by product labeling to restrict product use to mitigate aquatic and terrestrial exposure to Avermectin B_1 and negate the need to conduct an aquatic mesocosm study:

9.1.6.1. Cotton (Zephyr®)

1. Reduce total seasonal application from 48 fl. oz / acre to 32 fl. oz. / acre
2. Restrict use east of the Mississippi River; implies use only west of the Mississippi
3. Use a 21-day retreatment interval
4. Inclusion of aquatic buffer zones of 25 yards for aerial applications and 10 yard for ground applications

9.1.6.2. Citrus (Agri-Mek®)

1. Reduce applications from 3 per season to 2 per season
   (A maximum of 40 fl.oz./ acre from 60 fl. oz. / acre)
2. Restrict aerial applications
3. Institute a 30-day retreatment interval
4. Inclusion of aquatic buffer zones of 25 yards for airblast applications.

All labeling as risk mitigation measures have been accepted except the inclusion of buffer zones.

9.1.6.3. Application Reductions for Pending Uses

1. Celery, Lettuce, Tomatoes
   Reduce from 160 to 48 fl. oz. / acre / season
2. Almonds, Walnuts, Pears
   1. Reduce from 60 to 40 fl. oz. / acre / season
   2. Restricted from aerial use
   3. Include 25 yard aquatic buffer zone for air blast applications

Merck & Co. state that aquatic exposure occurring from runoff following ground boom applications to vegetable crops and strawberries would be negligible and have submitted public documents in support of this contention. EFGWB concurs with Merck & Co.'s interpretation of these documents.

Merck & Co. also contend that buffer zones are and have been used as effective and acceptable means of reducing aquatic exposure through drift of pesticides for both §18 Emergency Exemptions and §24 Special Local Needs. However, documentation to support this contention are not available in this submission. The effectiveness of buffers zones remains to be resolved when appropriate information is available for review.

In summary, numerous proposals to mitigate potential adverse aquatic effects of

agricultural uses of Avermectin B_1 have been made to the Agency, including:

1. Geographic restrictions east of the Mississippi River
2. Reductions of amount applied (total per season)
3. Fewer applications and longer periods between applications.
4. Restriction of aerial spraying but not air blast applications.
5. Recommendation of aquatic buffer strips (10 yards for ground applications and 25 yards for airblast applications).

9.2. Reviewer's Comments and Interpretations of Items Submitted to Agency

Item 9.2.1 Western Region
Runoff Potential of Abamectin When Used by Ground boom Application Equipment on Row Crops - Strawberries, Tomatoes, Celery and Head Lettuce

Merck & Co. contend that the runoff resulting from ground boom applications of Avermectin B_1 to strawberries and row crops (tomatoes, celery, head lettuce) according to label instructions would be less than that predicted by the model used by EEB based on the conditions of growing cotton in the [Mississippi] delta and Texas areas. EFGWB concurs with this contention, particularly for that region of west Texas beyond ~ 100° West Longitude.

Merck & Co. submitted public information that would support these differences as they apply to the **Registration of Avermectin B_1 on strawberries, tomatoes, celery and head lettuce in the Western Region of the United States.** Information on rainfall, ground slope, soil types and water tables in the major growing areas is submitted in 2 parts: Florida and Western (California, Texas and Arizona).

Strawberries

1. Geographic areas

CA Agricultural Statistics Service reports that CA's share of U.S strawberry production is 73.9%. Representative strawberry growing areas (with spray irrigation) accounting for 90% of California's production are in the Central and Southern Coastal Valley agricultural regions.

2. Typical Soil Types

Strawberries are grown, for the most part, on lighter soils (clay loam, loam, sandy loam, silty clay, fine sandy loam and loamy sand). Three typical soil types for each of the 5 growing areas were identified using Soil Surveys (USDA; CA Agricultural Extension Service).

3. Typical Slopes

Slopes identified from soil surveys ranged from 0-30% with majority in 0-9%. The higher slopes are in the Watsonville area with level (flat to 2%) slopes used predominantly in the other areas.

4. Rainfall

The Central and Southern Coastal Valleys may be classified as semi-arid to dessert regions during the growing and harvest seasons. Crops are grown with irrigation.

	Rainfall (in/y ave)			
Central Coastal Valleys	30 y	3 y	$3\ y^{hs}$	hs varies Apr-Nov
Watsonville	21.4	18.0	11.0	
Salinas	13.0	9.6	5.9	
Santa Maria	12.4	8.7	5.2	
Southern Coastal Valleys				hs varies Feb-Jun
Ventura	14.5	9.2	5.1	
Irvine	12.0	7.2	3.3	

$3y^{hs}$ = average rainfall during harvest season

5. Water Table Depth

The shallowest depths to water tables in the Ventura-Oxnard area (Southern Coastal Valley) are 2.5-5 feet and greater than 5-6 feet in the other areas.

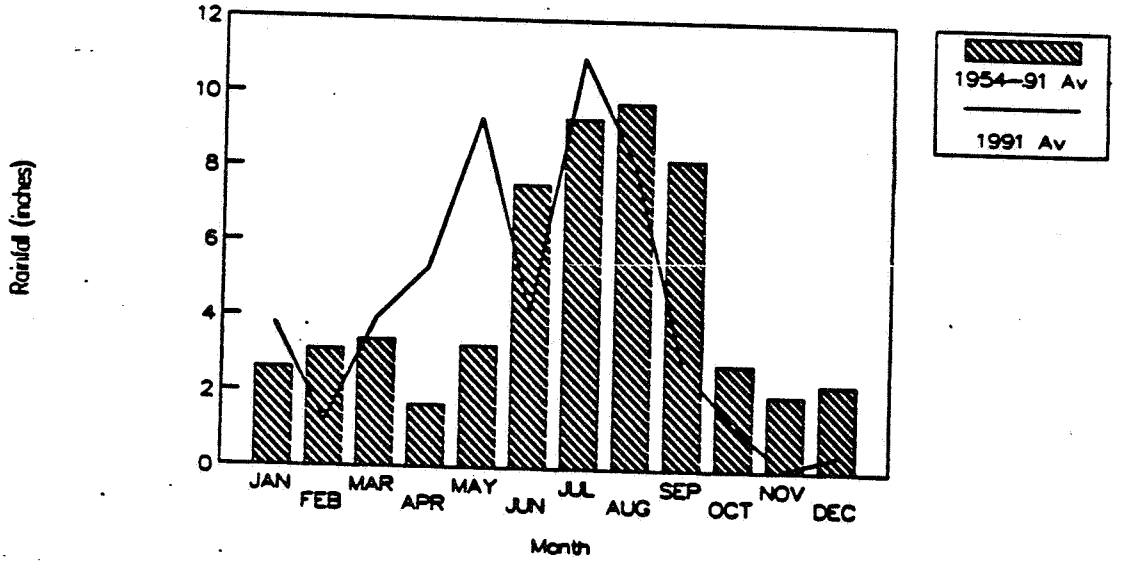
6. Major Aquatic Areas

The major aquatic areas indicated on soil maps are rivers, sloughs and creeks which, for the most part, are devoid of flowing waters. Lakes are identified as being on the fringes of growing areas.

7. Agricultural Practices

Although strawberries are perennial, in California they are planted annually from mid-August to early-September (Southern Coastal Valley) or mid-October (Central Coastal Valley) for high yields and best quality of fruit. Most strawberries are grown in light soils that are fumigated for disease and weed control. Beds are generally lined and drip irrigation is employed with a minimum of run-off occurring. Beds are covered with plastic mulch which retards weeds, helps maintain moisture and keeps berries above the soil. Hand weeding is common and no cover crops are grown.

Merck & Co. contend that runoff of Avermectin B_1 when used according to label directions for the 3 vegetables and strawberries would be negligible. In Florida, where annual rainfall is comparable to the delta area, these crops are grown only during months of lower rainfall (Fall/Winter/Spring) and would be less than that of the delta area. EFGWB concurs that the public information submitted by Merck & Co. indicates that the period of lowest precipitation (long term averages over 30 years for Dade County, 1961-90 and from Bradenton, 1954-91) are coincident with the growing season for strawberries (October - May). An excerpt of representative data from Bradenton (1954-91) from the *Bradenton GCREC Research Report BRA 1992-2* are depicted below:



Item 9.2.2. Florida

Runoff Potential of Abamectin When Used by Ground Boom Application Equipment on Row Crops - Strawberries, Tomatoes, Celery and Head Lettuce

Brief Summary of Key Factors in the Fate, Transport and Dissipation of Avermectin B_1

The following points have been identified as key factors in the fate, transport dissipation of Avermectin B_1 from Florida soils (Remick, Obreza, Geraldson, Mathews):

1. Partition Coefficient is high (K_{oc} or K_d) and thus Avermectin B_1 binds tightly to soils.

2. The soils are identified as sands and fine sands; an underlying hardpan may also exist.

3. The slope of the soils is often low, if not flat; if water accumulates or runs off from the field, it is drained to holding area for irrigation uses later.

4. The time of year for use of Avermectin B_1 coincides with the dry seasons. USDC NOAA Climatological Summaries are consistent with the vegetable growing periods as seasonally times of low rainfall.

5. Most vegetables are grown using bedded and plastic mulch culture practices, practices which may maintain warm, moist conditions (conditions which favor microbial growth and activity which may lead to the degradation of pesticides).

6. Irrigation waters are to be used in a manner in which runoff does not occur. Drip irrigation and sub-surface irrigation are often used because of the higher efficiency (compared to overhead spraying) in making water available to the plants.

7. The water table under vegetable plots is 12-24 inches below the surface, a condition which favors capillary rise of waters due to evaporation

R.D. Remick / Crop R&D Manager / DUDA / Belle Glade FL 33430-0208
T.A. Obreza / Soil Scientist U. Florida / Inst. Food & Ag. Sciences / Immokalee FL 33934
C.M. Geraldson, Professor U. Florida / Inst. Food & Ag. Sciences / Bradenton, FL 34203
C.H. Matthews, Jr. / Environmental & Pest Management Division
Florida fruit & Vegetable Association / Orlando FL 32814-0155

9.2.2.1. State Regulatory Impacts

In Florida, all farming operations are permitted for water use, consumption and discharge by one of 5 water management districts.

Consumptive permits are required for irrigation purposes. Consumptive permits further require that management practices are used so that runoff from the property does not occur after heavy rains; runoff is retained on the property in retention ponds or similar devices. Runoff from farm properties should not affect such large bodies of water as Lake Apopka and Lake Okeechobee.

9.2.2.2. Rainfall

Growing season for Florida vegetable production is confined to fall / winter / spring which coincides with dry weather. Heaviest rainfall in Florida occurs in June, July, August and September.

9.2.2.3. Cultural Practices

Tomatoes

Crop grown using raised, fumigated beds covered with plastic mulch; irrigation is either sub-surface or low volume seepage (drip) with small tubes running under the plastic. There is little or no overhead irrigation.

Strawberries

Grown in manner similar to tomatoes: raised, plastic mulched beds with drip irrigation and limited overhead irrigation for protection from frost.

Celery

Celery is transplanted to 2-row beds on peat soils. Some overhead irrigation used immediately after transplanting. Most irrigation is sub-surface.

Lettuce

Lettuce is direct seeded in 2-row beds on peat soils. All irrigation is subsurface.

Land Preparation

Land preparation is laser leveled prior to planting: Tomatoes and strawberries are leveled to 0-0.5% slope; land for celery and lettuce is essentially flat.

Weed Control

Cultivation is not used for tomatoes and strawberries; plastic mulch provides weed control in the row and herbicides in the middles. Herbicides are used exclusively for celery and lettuce.

9.2.2.4. Geographic Crop Production Areas

Tomatoes

Production occurs throughout the state. Major production is in Palmetto/Ruskin, Southwest, East Coast and Dade County areas. production in the North has decreased while that in West (Gadsen County) is expanding.

Lettuce / Celery

Lettuce / celery production is confined to Everglade peat soils (Everglades, Belle Glade) and central (Zellwood) areas.

Strawberries

Approximately 90% of strawberry production is in the Hillsborough / Manatte County are in West Central Florida (Plant City).

9.2.2.5. Soil Types, Ground Slope, Water Table

Tomatoes / Strawberries

Typical soils for tomatoes and strawberries are spodosols with an organic hardpan usually at a depth of 18-24 inches (45-60 cm) below the surface. Representative soil types are:

Eaugallie fine sand	Myakka fine sand
Leon sand	Immokalee sand

Slopes range from nearly level to 2%.

Sub-surface water may be found below the hardpan. Water for potable purposes is usually found at depths of 100 feet or more (>30 meters).

Celery / Lettuce

Celery and lettuce are grown primarily on Everglades peat soils (~100% organic). Depth of this soil varies but rarely exceeds 3 feet (~1 meter). This soil type may be underlain by sand, sandy clay or limestone.

The water table varies but most wells are deeper than 100 feet (~30 meters).

9.2.2.6. Irrigation Scheduling and Management

Clark, G.A., G.N. Maynard, C.D. Stanley, G.J. Hochmuth, E.A. Hanlon & D.Z. Haman. 1990.
Irrigation scheduling and management of micro-irrigated tomatoes. 12pp. Circular 872. Florida Cooperative Extension Service / Institute of food and Agricultural Sciences. U. Florida.

The methodology for scheduling irrigation for tomato production on sandy soils in Florida is described, including:

crop water requirements, soil characteristics, limited irrigation zones, crop water budget and management of soil water.

The steps include:

1. Determine water requirements of the crop
2. Determine soil water holding characteristics
3. Realize limitations of the root zone of the crop and delivery capabilities of the irrigation system
4. Develop a water budget by analyzing crop water demands, storage amounts and rainfall and determine irrigation schedule to maintain soil water storage with allowable depletion for the crop
5. Use field checks of soil moisture levels to adjust irrigation schedules to conform to actual field conditions.

9.2.2.7 Water Requirements for Florida Vegetable Crops

Kovach, S.P. 1984.
Determination of water requirements for Florida Vegetable Crops. 8 pp. Circular 607. Florida Cooperative Extension Service / Institute of food and Agricultural Sciences. U. Florida.

Irrigation water management for optimizing water requirements of growing plants commercially without using excess water is described. Calculating the needs of the plants, soil holding capacity and the rates of utilization of water is described for various regions of Florida. The interactions of climate, plant, soil and cultural factors are described. Illustrative problems for calculating the needs of growing strawberries and watermelons are presented. A table of values for evapo-transpiration of a reference crop for 5 Florida regions (Northwest, North, Central, Southwest and Everglades-Lower East Coast) is provided.

9.2.2.8. Tomato Producton Guide for Florida

Hochmuth, G.J. (Ed.) 1988.
Tomato production guide for Florida. 22 pp.
Circular 98C. Florida Cooperative Extension Service / Institute of food and Agricultural Sciences. U. Florida.

Topics include chapters on tomato cutivars (standard and trial), cultural practices (soil preparation, mulches), windbreaks, fertilization, irrigation (seep, overhead, drip), liming, micronutrients, crop establishment, seeding, transplanting (bare roots, containerized) irrigation, staking, pest management (control of nematodes, disease, insects, weeds), harvesting (maturity, packing house operations, ripening initiation, storage).

10. Results

Not applicable

11. One-Liner

Not applicable

12. CBI

Not applicable