January 17, 2002

MEMORANDUM

SUBJECT: Ziram Reregistration. Chemical No. 034805. Case No. 2180. Revised Ziram - Product and Residue Chemistry Chapters- DP Barcode D280352.

FROM: Gary Otakie, Chemist
Reregistration Branch 4
Health Effects Division (7509C)

THRU: Susan V. Hummel, Senior Scientist
Reregistration Branch 4
Health Effects Division (7509C)

TO: Sanjivani Diwan, Risk Assessor
Reregistration Branch 4
Health Effects Division (7509C)

and

Pat Dobak/Betty Shackleford
Reregistration Branch 3
Special Review and Reregistration Division (7508C)

The Product and Residue Chemistry Chapters for the Ziram RED were prepared by the Dynamac Corporation according to current Agency guidelines and the documents have undergone review by HED. The chapter was completed on 8/24/01. The revised chapters included with this submission incorporate applicable comments from the registrants' (Ziram Task Force) comment period. Revisions include water solubility as a data gap for the three techical products, incorporation of new blueberry field trial data as well as minor typograpical revisions.

Although there are some product chemistry data deficiencies, most of the remaining data deficiencies are for residue chemistry data. In brief, label amendments, plant and animal metabolism studies, analytical method data, storage stability data for plant and animal commodities, a ruminant feeding study, data on confined rotational crops, commercial processing data and field trial data are required.

cc: Chem F, Chron F. GOtakie
RDI:Team:6/21/01; HED ChemSAC: 08/02//01; SVH:01/17/02
GOtakie, Rm. 816D CM2, 305-6691, mail code 7509C

ZIRAM
PC Code 034805; Case 2180

Reregistration Eligibility Decision:
Product Chemistry Considerations

January 17, 2002

Contract No. 68-W-99-053

Submitted to:

U.S. Environmental Protection Agency
Arlington, VA

Submitted by:
Dynamac Corporation
The Dynamac Building
2275 Research Boulevard
Rockville, MD 20850-3268

ZIRAM

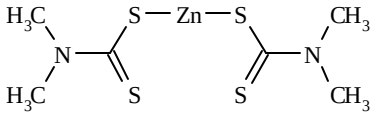
REREGISTRATION ELIGIBILITY DECISION:

PRODUCT CHEMISTRY CONSIDERATIONS

PC Code 034805; Case 2180

DESCRIPTION OF CHEMICAL

Ziram [zinc dimethyldithiocarbamate] is a fungicide registered for use on a variety of fruit, nut, and vegetable crops.



Empirical Formula:	$C_6H_{12}N_2S_4Zn$
Molecular Weight:	305.8
CAS Registry No.:	137-30-4
PC Code:	034805

IDENTIFICATION OF ACTIVE INGREDIENT

Ziram is a white powder with a melting point of 225.5-251 C, density of 1.7097 g/mL, vapor pressure of 1.8×10^{-5} Pa at 25 C, and octanol/water partition (log P_{ow}) of 1.65 at 20 C. Ziram is soluble in water at 65 ppm and is slightly soluble in diethyl ether and ethanol, moderately soluble in acetone, and

soluble in dilute alkali, carbon disulfide, and chloroform. Ziram is incompatible with copper and mercury compounds, but is the most stable of the metallic dithiocarbamates.

MANUFACTURING-USE PRODUCTS

A search of the Reference Files System (REFS) conducted 1/17/00 identified two registered manufacturing-use products (MPs) under PC Code 034805: the Elf Atochem North America Inc. 98% technical (T; EPA Reg. No. 4581-261) and UCB Chemicals Corporation 98% T (EPA Reg. No. 45728-14). In addition, R.T. Vanderbilt Company, Inc. produces three end-use products (96%, 51%, and 46% EPs; EPA Reg. Nos. 1965-79, 1965-87, and 1965-26, respectively) by an integrated formulation system. Because ziram is a List B chemical, only the Elf Atochem and UCB T/TGAIs, and the Vanderbilt TGAI are subject to a reregistration eligibility decision.

REGULATORY BACKGROUND

Ziram, a List B chemical and a dimethyldithiocarbamate salt, was the subject of a Phase 4 Review dated 4/24/91 by C. Olinger and S. Funk and a Data Call-In Notice (DCI) issued 10/1/91. Analysis for nitrosamines was required because ziram is a secondary alkylamine.

The current status of the product chemistry data requirements for the Elf Atochem and UCB T/TGAIs and the Vanderbilt TGAI is presented in the attached data summary tables. Refer to these tables for a listing of the outstanding product chemistry data requirements.

CONCLUSIONS

All pertinent data requirements are satisfied for the Elf Atochem 98% T/TGAI. Additional data are required for the UCB Chemicals 98% T/TGAI concerning product identity and composition, certified limits, and UV/visible absorption (OPPTS 830.1550, 1750, and 7050), and for the Vanderbilt TGAI concerning the production process, preliminary analysis, and UV/visible absorption (OPPTS 830.1620, 1700, and 7050). Provided that the registrants submit the data required in the attached data summary tables for the T/TGAIs, and either certify that the suppliers of beginning materials and the manufacturing processes for the ziram TGAIs have not changed since the last comprehensive product chemistry review or submit complete updated product chemistry data packages, HED has no objections to the reregistration of ziram with respect to product chemistry data requirements.

AGENCY MEMORANDA CITED IN THIS DOCUMENT

CBRS No(s).: 10777
DP Barcode(s) D183932

Subject:	Zinc Dimethyldithiocarbamate (Ziram) Reregistration. A List B Chemical (Case #2180; Chemical #034805): R.T. Vanderbilt Response to Dimethyldithiocarbamate Salts Phase 4 Review (dated 4/24/91) Product Chemistry Data Requirements Regarding Solubility (Guideline #63-8).
From:	F. Toghrol
To:	J. Ellenberger and L. Deluise
Dated:	11/19/92
MRID(s):	42503501

CBRS No(s).:	RD Memorandum
DP Barcode(s)	None
Subject:	Product Chemistry Review For End Use Products. EPA Reg. No. 45728-14.
From:	T. Aikens
To:	PM 23
Dated:	10/18/93
MRID(s):	41341001-41341003

CBRS No(s).:	RD Memorandum
DP Barcode(s)	None
Subject:	Product Chemistry Review. Chemical: Ziram 98%. Product Name: Thionic Ziram Technical.
From:	T. Aikens
To:	PM Team Reviewer
Dated:	6/14/94
MRID(s):	None

CBRS No(s).:	14773
DP Barcode(s)	D209865
Subject:	EPA Id. No. 34805-1965. Additional Nitrosamine Analyses of Vanderbilt's Ziram & SDDC.
From:	K. Dockter
To:	V. Dietrich/R. Kendall
Dated:	7/18/95
MRID(s):	43457101

CBRS No(s).:	15506
DP Barcode(s)	D214951
Subject:	Ziram Reregistration. Vanderbilt 4/21/95 Submission [62-1 Data: Nitrosamine Analysis]. Chemical 034805, Case 2180.
From:	K. Dockter
To:	P. Deschamp
Dated:	8/26/96
MRID(s):	42625001

CBRS No(s).: 16124
DP Barcode(s) D217249
Subject: Nitrosamine Analyses of Vanderbilt's Ziram; VANCIDE MZ-96; 1965-79. Rereg. Case 2180.
From: K. Dockter
To: P. Deschamp
Dated: 4/9/97
MRID(s): 43703001

CBRS No(s).: RD Memorandum
DP Barcode(s) D254027
Subject: Product Chemistry Review, TGAI; Reg./File Symbol No.: 4581-261; Product Name: Ziram Technical; Company: Elf Atochem North America Inc.
From: S. Mathur
To: C. Giles-Parker
Dated: 4/15/99
MRID(s): 446104401 and 44723301

CBRS No(s).: RD Memorandum
DP Barcode(s) D257625
Subject: Product Chemistry Review, Manufacturing-Use Product; Reg./File Symbol No.: 4581-261; Product Name: Ziram Technical, 98% Ziram; Company Name: Elf Atochem North America Inc.

From: S. Malak
To: C. Giles-Parker
Dated: 7/20/99
MRID(s): 44856801 and 44856802

DP Barcode(s) D276471
Subject: Product Chemistry Review of Blowbacks for the Vanderbilt TGAI.
From: G. Otakie
To: L. Parsons
Dated: 7/24/01
MRID(s): 40962201, 42555401, 42601401, 42609001, 42614801, and 43736301

PRODUCT CHEMISTRY CITATIONS

Bibliographic citations include only MRIDs containing data which fulfill data requirements.

References (cited):

00258212 Prochimie Internal, Inc. (1985) Ziram Task Force EPA Reg. No. 8236-4; Ziram Data-Call-In of July 20, 1984; Product Chemistry EPA Guidelines #63-8, 63-11. Unpublished study.

00259218 - PDMS citation unavailable

40348501 R.T. Vanderbilt Co., Inc. (1986) Vancide MZ-96 (...) Product Chemistry Data . Unpublished study. 18 p.

40419001 R. T. Vanderbilt Co., Inc. (1982) Vancide MZ-96: Product Chemistry. Unpublished compilation. 38 p.

40419002 R. T. Vanderbilt Co., Inc. (1987) Vancide MZ-96: Product Chemistry. Unpublished study. 7 p.

40962201 R.T. Vanderbilt Co., Inc. (1989) Vancide MZ-96: Discussion of Formation of Impurities. Unpublished study. 5 p

41341001 Larson, P. (1988) Compilation-Ziram Technical: Product Chemistry: Lab Project Number: Z80304. Unpublished study prepared by UCB Chemicals Corp. 40 p.

41341002 Larson, P. (1988) Compilation-Ziram Technical: Product Chemistry: Lab Project Number: Z80305. Unpublished study prepared by UCB Chemicals Corp. 21 p.

41341003 Larson, P. (1988) Compilation-Ziram Technical: Product Chemistry: Lab Project Number: Z80306. Unpublished study prepared by UCB Chemicals Corp. 31 p.

42503501 Flynn, F.; Gallagher, T. (1992) Solubility of Technical Grade Zinc Dimethyldithiocarbamate: [Product Chemistry]. Unpublished study prepared by R. T. Vanderbilt Co., Inc. 6 p.

42555401 Flynn, F. (1992) Supplement to MRID 40348501: Guideline Series 63--Physical and Chemical Characteristics. Unpublished study prepared by R.T. Vanderbilt Comp. Inc. 8 p.

42601401 Wells, D. (1992) Stability of Zinc Dimethyldithiocarbamate: Supplement to MRID 40348501: Lab Project Number: 92-10-4462. Unpublished study prepared by Springborn Labs, Inc. 51 p.

42609001 Flynn, F. (1992) Beginning Materials and Manufacturing Process (Vancide MZ-96): A Supplement. Unpublished study prepared by R.T. Vanderbilt Company, Inc. 14 p.

42614801 Flynn, F.; Gallagher, T. (1992) Supplemental to MRID 40419002: Analysis and Certification of Product Ingredients. Unpublished study prepared by R. T. Vanderbilt Co, Inc. 19 p.

43457101 Flynn, F. (1994) Nitrosamine Reduction of Zinc and Sodium Salts of Dimethyldithiocarbamate: Progress Report. Unpublished study prepared by R.T. Vanderbilt Co., Inc. 50 p.

43625001 Larson, J.; Harsy, S. (1995) Determination of Non-Polar Nitrosamines in Zinc Dimethyldithiocarbamate: Lab Project Number: HWI 6587-100A. Unpublished study prepared by Hazleton Wisconsin, Inc. 39 p.

43703001 Harsy, S. (1995) Determination of Non-Polar Nitrosamines in Vancide MZ-96: Lab Project Number: CHW 6587-102. Unpublished study prepared by Corning Hazleton, Inc. 36 p.

43736301 Flynn, F. (1995) Certification of Limits and Confidential Statement of Formula: Vancide MZ-96. Unpublished study prepared by R. T. Vanderbilt Co., Inc. 10 p.

44610401 Goodman, M. (1998) Ziram Integrated Manufacturing Process: Lab Project Number: QC0027R2/QTR. Unpublished study prepared by Elf Atochem North America. 20 p.

44723301 - PDMS citation unavailable

44856801 Flack, I. (1996) Ziram Physical and Chemical Properties: Lab Project Number: FCC150/953136: K95/2374: FCC150. Unpublished study prepared by Huntingdon Life Sciences. 165 p.

44856802 Beckwith, R. (1999) Preliminary Analysis of Ziram Manufacturing-Use Product: Lab Project Number: 1771-98-0165-AS-001: KP-98-53. Unpublished study prepared by Ricera, Inc. 104 p.

Case: 2180
Chemical No.: 034805

Case Name: Ziram
Registrant: Elf Atochem North America, Inc.
Product(s): 98% T (EPA Reg. No. 4581-261)

PRODUCT CHEMISTRY DATA SUMMARY

Guideline Number	Requirement	Are Data Requirements Fulfilled? [1]	MRID Number [2]
830.1550	Product identity and composition	Y	**44610401**, CSF 6/10/99 [3]
830.1600	Description of materials used to produce the product	Y	**44610401**
830.1620	Description of production process	Y	**44610401**
830.1670	Discussion of formation of impurities	Y	**44610401**
830.1700	Preliminary analysis	Y	44856802 [3]
830.1750	Certified limits	Y	CSF 6/10/99 [3]
830.1800	Enforcement analytical method	Y	44723301 [3]
830.6302	Color	Y	44856801 [3]
830.6303	Physical state	Y	44856801 [3]
830.6304	Odor	Y	44856801 [3]
830.6313	Stability to normal and elevated temperatures, metals, and metal ions	Y	44856801 [3]
830.7000	pH	Y	44856801 [3]
830.7050	UV/visible absorption	Y	44856801 [3]
830.7200	Melting point/melting range	Y	44856801 [3]
830.7220	Boiling point/boiling range	N/A [4]	
830.7300	Density/relative density/bulk density	Y	44856801 [3]
830.7370	Dissociation constants in water	Y	44856801 [3]
830.7550	Partition coefficient (n-octanol/water), shake flask method	Y	44856801 [3]
830.7840	Water solubility: Column elution method; shake flask method	N	44856801 [3]
830.7950	Vapor pressure	Y	44856801 [3]

[1] Y = Yes; N = No; N/A = Not Applicable. The database presented above was submitted in connection with amended registration to support a new producer/production process.

[2] **Bolded** references were reviewed under RD Memorandum D254027, 4/15/99, S. Mathur; and all other references were reviewed as noted.

[3] RD Memorandum, D257625, 7/20/99, S. Malak. Because of inconsitencies with reported water solubilty data from the three technicals and standard reference sources a new water solubility study must be conducted in accordance with OPPTS 830.7840 dated March 1998.

[4] Data are not required because the TGAI is a solid at room temperature.

Case: 2180
Chemical No.: 034805

Case Name: Ziram
Registrant: UCB Chemicals Corporation
Product(s): 98% T (EPA Reg. No. 45728-14)

PRODUCT CHEMISTRY DATA SUMMARY

Guideline Number	Requirement	Are Data Requirements Fulfilled? [1]	MRID Number [2]
830.1550	Product identity and composition	N [3]	41341001 CSF 4/18/94 [4]
830.1600	Description of materials used to produce the product	Y	41341001
830.1620	Description of production process	Y	41341001
830.1670	Discussion of formation of impurities	Y	41341001
830.1700	Preliminary analysis	Y	41341002
830.1750	Certified limits	N [3]	41341002 CSF 4/18/94 [4]
830.1800	Enforcement analytical method	Y	41341002
830.6302	Color	Y	41341003
830.6303	Physical state		41341003
830.6304	Odor	Y	41341003
830.6313	Stability to normal and elevated temperatures, metals, and metal ions	Y	41341003
830.7000	pH	Y	41341003
830.7050	UV/visible absorption	N [5]	
830.7200	Melting point/melting range	Y	41341003
830.7220	Boiling point/boiling range	N/A [6]	
830.7300	Density/relative density/bulk density	Y	41341003
830.7370	Dissociation constants in water	Y	41341003
830.7550	Partition coefficient (n-octanol/water), shake flask method	Y	41341003
830.7840	Water solubility: Column elution method; shake flask method	N[7]	41341003[2]
830.7950	Vapor pressure	N/A	41341003

[1] Y = Yes; N = No; N/A = Not Applicable. The database presented above was submitted in support of registration of the 98% T as produced from another EPA-registered product which has since been canceled (7/24/96). Because the technical products were essentially the same, these data will remain applicable if the registrant confirms that the manufacturing process and location for the TGAI described in the above submissions have not changed and now apply to the 98% T. If the manufacturing process or technical source product has changed, additional product chemistry data may be required.

[2] All references were reviewed under RD Memorandum, 10/18/93, T. Aikens, unless otherwise noted.

[3] The technical source product listed on the CSF has been canceled. A revised CSF must be submitted listing the active ingredient and all impurities present at $0.1%, each with proposed nominal concentrations and certified limits as required.

[4] RD Memorandum, 6/14/94, T. Aiken.

[5] The OPPTS Series 830, Product Properties Test Guidelines require data pertaining to UV/visible absorption for the PAI.

[6] Data are not required because the TGAI is a solid at room temperature.

[7] Because of inconsitencies with reported water solubilty data from the three technicals and standard reference sources a new water solubility study must be conducted in accordance with OPPTS 830.7840 dated March 1998.

Case: 2180
Chemical No.: 034805

Case Name: Ziram
Registrant: R.T. Vanderbilt Company, Inc.
Product(s): 96% TGAI/EP (EPA Reg. No. 1965-79)

PRODUCT CHEMISTRY DATA SUMMARY

Guideline Number	Requirement	Are Data Requirements Fulfilled? [1]	MRID Number [2]
830.1550	Product identity and composition	N/A [3]	
830.1600	Description of materials used to produce the product	Y	**40419001**, 42609001
830.1620	Description of production process	N [4]	**40419001**, 42609001
830.1670	Discussion of formation of impurities	Y	40962201
830.1700	Preliminary analysis	N [5]	**40419002**, 42614801, 43457101 [6], 43625001 [7], 43703001 [8]
830.1750	Certified limits	N/A [3]	43736301
830.1800	Enforcement analytical method	N/A [3]	
830.6302	Color	Y	**40348501**
830.6303	Physical state	Y	**40348501**
830.6304	Odor	Y	**40348501**
830.6313	Stability to normal and elevated temperatures, metals, and metal ions	Y	**40348501**, 42601401
830.7000	pH	Y	**40348501**
830.7050	UV/visible absorption	N [9]	
830.7200	Melting point/melting range	Y	**40348501**
830.7220	Boiling point/boiling range	N/A [10]	
830.7300	Density/relative density/bulk density	Y	**40348501**, 42555401
830.7370	Dissociation constants in water	Y	**40348501**
830.7550	Partition coefficient (n-octanol/water), shake flask method	Y	**00258212**, **40348501**
830.7840	Water solubility: Column elution method; shake flask method	N[11]	42503501 [11]
830.7950	Vapor pressure	Y	00259218, **40348501**

[1] Y = Yes; N = No; N/A = Not Applicable.

[2] **Bolded** references were determined to be acceptable for Phase 5 review under the Phase 4 Review dated 4/24/91, by C. Olinger and S. Funk; underlined references were submitted in response to Phase 4 requirements and were reviewed under Ziram Reregistration dated 07/24/01, by G.Otakie; all other references were reviewed as noted.

[3] Data are not required for the TGAI.

[4] Information concerning the relative amounts of the starting materials, a description of the production equipment, and the duration of the process is required.

[5] The following are required: supporting validation data for the method used to analyze for an impurity group and a description of the analytical method used for another impurity. Additional data remain outstanding concerning nitrosamines.

[6] CBRS No. 14773, D209865, 7/18/95, K. Dockter.

[7] CBRS No. 15506, D214951, 8/26/96, K. Dockter.

[8] CBRS No. 16124, D217249, 4/9/97, K. Dockter.

[9] The OPPTS Series 830, Product Properties Test Guidelines require data pertaining to UV/visible absorption for the PAI.

[10] Data are not required because the TGAI is a solid at room temperature.

[11] CBRS No. 10777, D183932, 11/19/92, F. Toghrol. Because of inconsitencies with reported water solubilty data from the three technicals and standard reference sources a new water solubility study must be conducted in accordance with OPPTS 830.7840 dated March 1998.

ZIRAM
PC Code 034805; Case 2180

Reregistration Eligibility Decision: Residue Chemistry Considerations

January 17, 2002

Contract No. 68-W-99-053

Submitted to:
U.S. Environmental Protection Agency
Arlington, VA

Submitted by:
Dynamac Corporation
The Dynamac Building
2275 Research Boulevard
Rockville, MD 20850-3268

ZIRAM

REREGISTRATION ELIGIBILITY DECISION

RESIDUE CHEMISTRY CONSIDERATIONS

PC Code 034805; Case 2180

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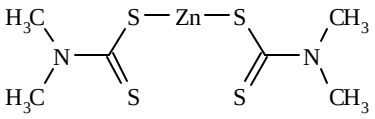
ZIRAM



REREGISTRATION ELIGIBILITY DECISION

RESIDUE CHEMISTRY CONSIDERATIONS

PC Code 034805; Case 2180

INTRODUCTION

Ziram is a fungicide registered for use on a variety of fruit, nut, and vegetable crops including almonds, apples, apricots, blackberries, blueberries, cherries, grapes, nectarines, peaches, pears, pecans, and tomatoes. The nonfood uses of ziram include ornamental plants.

The basic producers of ziram are the members of the Ziram Task Force (ZTF), consisting of Elf Atochem North America, Inc. and UCB Chemicals Corporation. Elf Atochem's end-use products are sold under the trade name Ziram 76DF Fungicide and UCB's end-use product is sold under the trade name Ziram Granuflo®. The ziram formulation class registered to the ZTF for food/feed uses is the dry flowable (DF). This formulation is typically applied as dormant, delayed dormant (prebloom), preharvest, and foliar treatments using ground or aerial equipment on food/feed crops.

REGULATORY BACKGROUND

Ziram is a List B reregistration pesticide. The Dimethyldithiocarbamate Salts Phase 4 Reviews for zinc dimethyldithiocarbamate were issued on 4/24/91 (C. Olinger) and a Zinc Dimethyldithiocarbamates Data-Call-In (DCI) Notice was issued 10/1/91. HED has conducted Phase 5 review of several residue chemistry studies that were submitted in response to the Phase 4 Reviews. This document presents the current Residue Chemistry Science Assessment with respect to the reregistration of ziram.

Tolerances have been established for residues of ziram (zinc dimethyldithiocarbamate; 40 CFR §180.116), calculated as zinc ethylenebisdithiocarbamate, in/on a wide variety of raw agricultural plant commodities. These tolerances are established at 7 ppm except those established for almonds and pecans which are set at 0.1 ppm each. No tolerances have been established for ziram residues in livestock and processed food/feed commodities. According to 40 CFR §180.3(d)(5), where a tolerance is established for more than one member of the class of dithiocarbamates (which includes

maneb, mancozeb, metiram, ferbam, thiram, zineb, ziram, and sodium dimethyldithiocarbamate) on the same raw agricultural commodity, the total amount of such pesticides shall not exceed the highest tolerance established for any one member of the class, calculated as zinc ethylenebisdithiocarbamate. The established permanent tolerances for plant commodities were established either on the basis of data acquired at the1950 Spray Residue Hearings (formerly §180.101) or on the basis of pesticide petitions presented under the procedure specified in the amendment to the Federal Food, Drug, and Cosmetic Act by Pub. L. 518, 83d Congress (68 Stat. 511). Although the nature of the residue in plants and animals is not adequately understood, the HED Metabolism Assessment Review Committee (MARC) has no objection to proceeding with the subject Ziram RED and with risk assessments, given that the current common moiety plant method would likely include the residues of toxicological concern (DP Barcodes D261844 and D261846, G. Otakie, 12/16/99).

The Pesticide Analytical Manual (PAM) Vol. II lists a colorimetric method, Method I, for the determination of dithiocarbamate residues in/on plant commodities. Additional methods (Methods II-IV and Method A), which are based on the decomposition of dithiocarbamates with release of carbon disulfide (CS_2), are also listed in PAM Vol. II. These methods are nonspecific for CS_2-generating compounds.

SUMMARY OF SCIENCE FINDINGS

GLN 860.1200: Directions for Use

According to a REFS search, conducted on 1/17/00, there are currently two active end-use products (EPs) registered to members of the ZTF under FIFRA Section 3 for use on food/feed crops. These EPs, including the associated Special Local Need (SLN) registrations under FIFRA Section 24 (c), are listed in Table A1.

Table A1. Ziram EPs with Food/Feed Uses Registered to the Ziram Task Force (with members consisting of Elf Atochem North America, Inc. and UCB Chemicals Corporation).

EPA Reg. No.	Label Acceptance Date	Formulation	Product Name
Elf Atochem North America, Inc.			
4581-140 [1]	12/10/99	76% DF	Ziram 76DF Fungicide
UCB Chemicals Corporation			
45728-12 [2]	7/7/98	76% DF	Ziram Granuflo®

[1] Including SLN Nos. IN960001, MI960002, MI990002, NJ980001, NY970004, OH960004, and PA960003.

[2] Including SLN No. WA920033.

A comprehensive summary of ziram food/feed use patterns, based on the product labels registered to the ZTF, is presented in Table A2. A tabular summary of the residue chemistry science assessments for reregistration of ziram is presented in Table B. The status of reregistration requirements for each guideline topic listed in Table B is based on the use patterns registered by the basic producers.

End use product formulators of ziram have additional types of formulations registered, wettable powders, and liquid flowables, and some labels have registered rates of application higher than those on the basic producer labels. The uses supported for reregistration are only those on the basic producer labels. Wettable powder formulations are supported as well, provided the application rates do not exceed those of the dry flowable formulation. Liquid flowable formulations are not supported by residue chemistry data. Label changes are required.

Label amendments are required to incorporate the parameters of use patterns reflected in the submitted field trials. For apples, cherries, nectarines, peaches, and pears, the labels must be modified to specifically define "eastern U.S." and "western U.S." For blueberries, the labels must be amended to include a maximum seasonal rate; this amendment must be supported by adequate field trial data. For cherries, the product label for EPA Reg. No. 45728-12 must be amended to change the 7-day PHI for CA to a 30-day PHI. There are no data available to support a 7-day PHI for cherries in CA. For grapes, the labels must be amended to reflect the use patterns of the submitted field trial data: multiple applications at up to 3.04 lb ai/A/application with a 21-day PHI and a maximum seasonal rate of 21.3 lb ai/A for states east of the Rocky Mountains and 15.2 lb ai/A for states west of Rocky Mountains; a restriction against use on Muscadine grapes must be added to the labels. For pears, the product label for EPA Reg. No. 4581-140 must be amended to state that pre-harvest spray applications with a 5-day PHI may only be made in the western U.S. (no data reflecting a 5-day PHI are available for the eastern U.S.). For tomatoes, the labels must be amended to reflect the use patterns of the submitted field trial data: multiple applications at up to 3.04 lb ai/A/application with a 7-day PHI and a maximum seasonal rate of 18.2 lb ai/A; use must be restricted to tomatoes grown east of the Rocky Mountains. In addition, the labels for tomatoes must specify the type of equipment to be used for application (i.e., ground or aerial) along with recommended spray volumes. The registrant should be aware that the Agency typically requires separate residue data for aerial applications of pesticides with spray volumes less than 2 gallons per acre.

For the purpose of generating this Residue Chemistry Science Chapter, HED examined the registered food/feed use patterns of the basic producer, ZTF, and reevaluated the available residue chemistry database for adequacy in supporting these use patterns. When end-use product DCIs are developed (e.g., at issuance of the RED), RD should require that all end-use product labels (e.g., MAI labels, SLNs, and products subject to the generic data exemption) be amended such that they are consistent with the basic producer labels.

The ZTF has stated that they will support use of ziram on almonds, apples, apricots, blackberries, cherries, nectarines, peaches, pears, and pecans, and that IR-4 is willing to support use of ziram on blueberries, grapes, and tomatoes (personal communication with L. Parson, 2/22/00). These are all the crops that are currently included on the labels of products registered to members of the ZTF. The ZTF has also stated that they would like to retain tolerances for Brassica vegetables, lettuce, and possibly strawberries for import purposes, and that IR-4 may be willing to support use of ziram on peppers. However, the ZTF does not currently have any registered uses on peppers, and no information describing the use patterns of ziram on Brassica vegetables, lettuce, or strawberries grown outside the U.S. for import to the U.S. has been submitted. These uses are not subject to reregistration and accordingly are not included in the dietary exposure assessment.

GLN 860.1300: Nature of the Residue - Plants

The reregistration requirements for plant metabolism are not fulfilled. The qualitative nature of ziram residues in plants is not adequately understood; metabolism studies with apples and grapes are have been reviewed (see MRIDs 43500001 and 44451401; DP Barcodes D210778 and D242544, G. Otakie, 7/24/01).

The ziram apple metabolism study is inadequate and cannot be upgraded. The specific radioactivity of the [^{14}C]ziram test substance was too low, at 0.25 µCi/mg (555 dpm/µg), to permit adequate characterization of residues, and the limits of detection for the radioassays were not reported. The registrant must submit a new apple metabolism study. Although inadequate, the apple metabolism study indicates that a major portion of the residue is surface residue captured in the solvent/water rinse at the lower PHIs, and these residues fall precipitously with longer PHIs. The registrant may want to consider a washing study with plain water as part of the new apple metabolism study, although this would be secondary to a commercial washing study using field treated residues. Although it is uncertain at this point if risk needs to be mitigated, it does appear that data on water washed fruits treated with ziram may be beneficial in future ziram dietary exposure assessments.

The ziram grape metabolism study is adequate. The study was conducted at approximately 1.3x the current maximum seasonal rate using [^{14}C]ziram and a 7-day PHI (note: currently, a 21-day PHI is being supported for grapes). The average total radioactive residue (TRR) level in/on mature grape samples was 6.312 ppm. Approximately 82-83% of TRR was recovered in surface rinses. Ziram (22.23% TRR) and its monomeric product, dimethyldithiocarbamate (DDC), and DDC-related compounds (37.77% TRR) together comprised ~60% of the TRR in surface rinse. The remainder of the rinse radioactivity was characterized as consisting of at least five unknown components totaling 21.69% of the TRR. In the rinsed grapes, 10.5% of TRR was characterized as sugars.

A third metabolism study on a leafy vegetable will be required if any uses in addition to those currently on the product labels are requested.

Although the nature of the residue in plants is not adequately understood, the HED MARC has no objection to proceeding with the subject Ziram RED and with risk assessments given that the current common moiety plant method would likely include the residues of toxicological concern (D261844 and D261846, G. Otakie, 12/16/99).

GLN 860.1300: Nature of the Residue - Livestock

The reregistration requirements for livestock metabolism are partially fulfilled. The qualitative nature of the residue in ruminant milk is adequately understood; however, the nature of the residue in ruminant tissues is not adequately understood since radioactive residues in tissues (most notably liver) were inadequately characterized; (see MRID 42839201; DP Barcode D193238, G. Otakie, 7/21/01). This study may be upgraded if sufficient tissue samples are available to allow further residue characterization and identification, and if the results of additional analytical work can be validated by adequate storage stability data. Otherwise a new goat metabolism study is required.

In the ruminant metabolism study, lactating goats were orally dosed with [^{14}C]ziram at an average dietary level of 304 ppm for 6 days; this level represents 76x the maximum theoretical dietary burden for dairy cattle (35x for beef cattle). The TRR (expressed in ziram equivalents) were <0.03-1.851 ppm in milk, 22.026 and 27.964 ppm in liver, 2.874 and 3.412 ppm in kidney, 0.477 and 0.812 ppm in muscle, and 0.160 and 0.200 ppm in fat. The registrant demonstrated the incorporation of radioactivity into lactose and milk protein (casein), and the data indicate that [^{14}C]lactose and [^{14}C]protein accounted for 29.7% and 36.5% of milk TRR, respectively. No parent or metabolites were identified in milk or any tissue. No analyses of muscle or fat extracts, other than radioactivity determinations, were conducted.

The requirement for a poultry metabolism study has been waived because the registrant does not intend to support uses on any crops with poultry feed items.

Although the nature of the residue in livestock is not adequately understood, the HED MARC has no objection to proceeding with the subject Ziram RED and with risk assessments, given that the current common moiety method would likely include the residues of toxicological concern (DP Barcodes D261844 and D261846, G. Otakie, 12/16/99).

GLN 860.1340: Residue Analytical Methods

Methods for determination of residues in/on plant commodities: Methodology available for tolerance enforcement does not distinguish among any of the fungicides in the dimethyldithiocarbamate salts group. If new metabolites (which require regulation) are found in the plant metabolism studies, then analytical method(s) may be developed for them. Any regulatory methods submitted will require an independent laboratory validation.

The Pesticide Analytical Manual Volume II (PAM II) lists the following methods for the determination of dithiocarbamates (ferbam, thiram, ziram, maneb, mancozeb, metiram, and zineb).

I.	Cullen, T. E., Anal. Chem, **36**, 221 (1964).
II	Pease, H. L., JAOAC, 40, 1113 (1957).
III	Keppel, G. E., JAOAC, 2, 162 (1969); 54, 529 (1971).
IV	Heuermann, R. F., JAOAC, 40, 264 (1957)
A	McKinley, W. P., and Magarvey, S. A., JAOAC, 43, 717 (1960)

The Keppel method is used most often by the enforcement agencies. The crop samples are cut into wedge shaped pieces and subsampled. The analysis must proceed promptly after cutting the crop samples. Dithiocarbamate residues in crops are decomposed by refluxing the crop with boiling dilute acid (HCl) with a reducing agent, stannous chloride. Evolved CS_2 is carried by gas stream through a sodium hydroxide trap to remove H_2S and other volatile interferences. It reacts in a second trap with a color reagent (copper acetate and diethanolamine) to form a yellow complex, the cupric salt of N,N-bis(2-hydroxyethyl) dithiocarbamic acid, which is measured spectrophotometrically. The amount of dithiocarbamate, is calculated as zineb, from the amount of CS_2 found, by the following equation:

$$\text{: g zineb} = \text{: g } CS_2 \times \frac{\text{Formula weight of zineb}}{2 \times \text{Formula weight of } CS_2}$$

The stated limit of detection (LOD) for Method I is 0.5-4.0 ppm. The stated limit of quantitation for Method III (Keppel method) is 0.02 ppm.

Adequate residue analytical methods are available for ziram data collection. Samples of raw agricultural and processed commodities from recent field trials and processing studies were analyzed for ziram residues using a headspace GC method with flame photometric detection (FPD; Morse Laboratories SOP# Method 7, Revision #3 and Method ZTF-88AM-001). These methods are similar to the enforcement method in that residues are converted to CS_2 prior to analysis. Based on acceptable recoveries from method validation including concurrent analysis of fortified control samples, the method is adequate for data collection. The GC/FPD method was adequately radiovalidated using samples from the grape metabolism study.

Methods for determination of residues in livestock commodities: Residue analytical methods for the determination of ziram residues of concern in livestock commodities are not available because tolerances for livestock commodities have not been established. If the requested ruminant feeding study suggests that tolerances in milk and edible tissues of ruminants are needed, the registrant will be required to develop enforcement and data-collection methods capable of determining ziram residues of concern. Any regulatory methods submitted will require successful radiovalidation and independent laboratory validation as per OPPTS 860.1340. The requirement for a confirmatory analytical method suitable for livestock commodities is reserved pending the outcome of the ruminant metabolism study.

The requirements for radiovalidation of the current plant enforcement method using samples from the goat metabolism study are partially fulfilled. Analysis of milk and tissue samples using an enforcement method (PAM, Vol. II, Method III) indicated nondetectable levels (<1.0 ppm) of dithiocarbamates in milk, kidney, fat, and muscle. Dithiocarbamates were detected in liver samples at - 2.3 ppm (- 10% of TRR). However, radioanalysis of the liver sample for $[^{14}C]CS_2$ indicated much lower levels of dithiocarbamates (0.4 ppm). The adequacy of the radiovalidation study will be assessed when all livestock metabolism data requirements have been fulfilled.

GLN 860.1360: Multiresidue Methods

The Phase 4 Reviews reported that recovery of zinc dimethyldithiocarbamate through any of the FDA multiresidue protocols is highly unlikely. The 10/99 PESTDATA database (PAM, Vol. I, Appendix I) does not contain any information for ziram.

GLN 860.1380: Storage Stability Data

Raw agricultural and processed commodities: The reregistration requirements for storage stability data are not fulfilled. Adequate storage stability data are available to support the submitted crop field trial and processing studies used for tolerance reassessment. However, additional storage stability data are required to support the outstanding field trial studies.

Storage stability studies have been submitted for almond nutmeat and hulls, apples, grapes, and peaches. The results of these studies are summarized below.

Almond, nutmeat: Storage stability studies demonstrated that residues of ziram declined 10% and 12% in/on almond nutmeats stored at -20 C for 3 and 6 months, respectively; field trial samples of treated almond nutmeats were stored frozen for 5-6.5 months prior to residue analysis. These data may be used to support pecan field trial data; samples of treated pecans were stored frozen for 3-5 months prior to residue analysis.

Almond, hull: Storage stability studies demonstrated that residues of ziram declined 25% in/on almond hulls stored at -20 C for 3 months; field trial samples of treated hulls at application rates up to 1.2X were stored frozen for 3-6.5 months prior to residue analysis. No data for longer storage periods were reported.

Apple: Storage stability studies demonstrated that residues of ziram declined 13% and 30% in/on apples stored at -20 C for 1 and 3 months, respectively. However, a recent additional storage stability data (DP Barcode D224367, 6/21/01, G. Otakie) indicate that fortified residues of ziram are stable in/on apple homogenates for up to 4 months during storage at -20 C. Based on the inconsistency in

apple storage stability data a 30% degradation after 3 months of frozen storage is assumed. Apple field trial samples were stored frozen for 1-3 months prior to analysis. These data may be used to support pear field trial data; samples of treated pears were stored frozen for 1-3 months prior to analysis.

Storage stability data for blueberry and apple processed commodities are not required because samples were analyzed within 1.5 months of collection.

Grape: Storage stability studies demonstrated that residues of ziram declined 40% in/on grapes stored frozen for 30 weeks; field trial samples were stored frozen for 9-30 weeks prior to analysis. Storage stability data indicated that residues of ziram were stable in grape juice for 9 weeks of frozen storage; grape juice samples from the processing study were stored frozen for up to 9 weeks prior to analysis. No storage stability data are needed for raisins as these samples were analyzed within one month of collection.

Peach: Storage stability studies demonstrated that residues of ziram declined 30% and 40% in/on peaches stored at -20 C for 3 and 4 months, respectively; after 6 months of storage, residues had declined 50%. Field trial samples of treated peaches were stored frozen for 2-4 months prior to residue analysis. These data may be used to support apricot, cherry, and nectarine field trial data; samples of treated apricots, cherries, and nectarines were stored frozen for 4, 3-5, and 2-3 months, respectively, prior to analysis.

Livestock commodities: The storage stability of ziram residues of concern in livestock commodities has not been investigated. Storage stability data are required to support storage conditions and intervals of milk and edible tissue samples collected from the goat metabolism and the requested ruminant feeding studies unless samples are analyzed within 30 days of collection.

GLN 860.1500: Crop Field Trials

The reregistration requirements for magnitude of the residue in/on the following raw agricultural commodities (RACs) will be considered fulfilled pending label revisions and/or tolerance adjustments: almond (nutmeat and hulls), apples, apricots, cherries, nectarines, peaches, pears, and pecan. Overall, adequate field trial data depicting ziram residues following treatments according to the maximum registered use patterns of representative formulations that are being supported have been submitted for the RACs listed above. Refer to "Tolerance Reassessment Summary" section for recommendations with respect to established tolerance levels.

The reregistration requirements for magnitude of the residue in/on the following RACs have not been fulfilled: blackberry, strawberry and grape. No field trial data have been submitted for blackberries or strawberries. The available data for grapes are summarized below.

The ZTF has stated that they would like to retain tolerances for Brassica vegetables, lettuce, and possibly strawberries for import purposes, and that IR-4 may be willing to support use of ziram on peppers (personal communication with L. Parson, 2/22/00). The ZTF does not currently have any registered uses on peppers. No information describing the use patterns of ziram on Brassica vegetables, lettuce, or strawberries grown outside the U.S. for import to the U.S. has been submitted. In addition, no crop field trial data for any Brassica vegetable, or for lettuce, peppers, or strawberries have been submitted. To retain the tolerances for Brassica vegetables, lettuce, and strawberries for import purposes, field residue data must be submitted reflecting the maximum use patterns for representative ziram formulations on these crops to be exported to the U.S. Because the ZTF has not provided any use pattern data or indicated in which countries ziram is used or intended to be used on these crops for export, the Agency cannot make specific recommendations concerning the number and locations of the foreign field trials to be conducted. In general, trials must be conducted in all countries in which ziram is sold or intended to be sold. All countries which represent at least 5% of the U.S. imports, and all major growing areas within each country should be represented. Substitution of data from one country to another is acceptable if the registrant can demonstrate similar climatic conditions and cultural practices. The Agency is in the process of developing guidance on the conduct of crop field trials to support import tolerances. It is recommended that the registrant(s) submit a protocol before generating field trial data for these commodities.

For purposes of reregistration, if IR-4 intends to support ziram uses on peppers, then data are required depicting residues of ziram in/on peppers following application of a representative DF formulation according to the maximum proposed use patterns. The number of field trials and geographic locations of trial sites should be in compliance with the current guidance.

Neither the ZTF nor IR-4 has expressed an interest in supporting ziram uses on the following commodities: bean, succulent and seed; beet, garden; boysenberry; carrot; celery; cranberry; cucumber; dewberry; eggplant; gooseberry; huckleberry; loganberry; melon; onion, dry bulb; peanut; pea, succulent and seed; pumpkin; quince; radish; raspberry; rutabaga; spinach; squash, summer; turnip; and youngberry. Unless the ZTF or IR-4 submit supporting data for these crops, or for Brassica vegetables (broccoli, Brussels sprouts, cabbage, cauliflower, collards, kale, and kohlrabi), lettuce, peppers, or strawberries, the established tolerances for the respective RACs should be revoked.

A summary of the available residue data which support the maximum registered use patterns of the ZTF are listed below by commodity.

Almond, nutmeat: Adequate field trial data for almond, nutmeat have been submitted and evaluated. An almond field study (MRIDs 92045006 and 41153106) indicates that uncorrected residues of ziram were nondetectable (<0.05 ppm) in/on almond nutmeat (30 samples) harvested 125-176 days following four applications of either the WDG or WP formulation at 6.08 lb ai/A/application (total rate = 24.32 lb ai/A; 1x maximum seasonal rate). Correcting for 12% decline during storage yields a residue value of <0.06 ppm.

Almond, hulls: Adequate field trial data for almond hulls have been submitted and evaluated. An almond field study (MRIDs 92045006 and 41153106) indicates that uncorrected residues of ziram were 0.05-13.8 ppm in/on almond hulls (30 samples) harvested 125-176 days following four applications of either the WDG or WP formulation at 6.08 lb ai/A/application (total rate = 24.32 lb ai/A; 1x maximum seasonal rate).

Storage stability studies demonstrated a 25% decrease after 3 months of frozen storage (field trial samples of treated hulls were stored frozen for 3-6.5 months prior to residue analysis). No data for longer storage periods were reported. If the highest residue value (13.8 ppm) resulting from the maximum use pattern for the WDG and WP formulations is corrected for at least a 25% loss expected during frozen storage, then the corrected residue value would be 18.4 ppm.

Apple: Adequate field trial data for apples have been submitted and evaluated. An apple field study (MRIDs 92045005 and 41229802) indicates that residues of ziram were 0.764-3.81 ppm in/on apples (4 samples grown in the eastern U.S.) harvested 14 days following seven applications of either the WDG or WP formulation at 6.08 lb ai/A/application (total rate = 42.56 lb ai/A; 1x maximum seasonal rate for eastern states). In the same study residues of ziram were 3.29-4.83 ppm in/on apples (4 samples grown in the western U.S.) harvested 14 days following four applications of the WDG formulation at 6.08 lb ai/A/application (total rate = 24.32 lb ai/A; 1x maximum seasonal rate for western states). In the same study residues of ziram were 0.726 and 0.321 ppm in/on apples (2 samples grown in the western U.S.) harvested 5 and 21 days following four applications of the WDG formulation at 6.08 lb ai/A/application (total rate = 24.32 lb ai/A; 1x maximum seasonal rate for western states).
Three samples from these studies bore residues exceeding the 7-ppm tolerance: one sample in IL at 7.09 ppm and two samples in CA at 8.11 and 8.44 ppm. The high residue in the IL trial was attributed to the fact that samples received eight applications of the WDG formulation instead of seven; however, the sample was collected at a 21-day PHI and the established PHI is 14 days. The high residues in the CA trial were attributed to the fact that samples were collected at a 5-day PHI.

In another apple field study (MRID 43282501), field trial data indicate that residues of ziram were 0.197-0.304 ppm in/on apples (3 samples grown in the eastern U.S.) harvested 14 days following seven applications of the WDG formulation at 6.08 lb ai/A/application (total rate = 42.56 lb ai/A; 1x maximum seasonal rate for eastern states). A total of 13 geographically representative field trials are available.

Correcting the highest residue value (4.83 ppm) for a 13% loss expected during frozen storage (sample was stored for 1 month prior to analysis) yields a value of 5.6 ppm.

Apricot: Adequate field trial data for apricots have been submitted and evaluated. Data from field trials (MRIDs 92055007 and 41153101) conducted in CA indicate that residues of ziram were below the established tolerance of 7 ppm in/on apricots harvested 30, 45, and 60 days following the last of 5

foliar applications of a representative WDG formulation at 4.56 lb ai/A/application for a total seasonal rate of 22.8 lb ai/A (~0.8x the maximum registered seasonal rate). Data from additional field trials (MRID 43282502) conducted in CA and WA indicate that residues of ziram were up to 11.1 ppm in/on apricots harvested 30 days following the last of 5 foliar applications of a representative WDG formulation at 6.08 lb ai/A/application for a total seasonal rate of 30.4 lb ai/A (1.0x the maximum registered seasonal rate). Correcting the highest residue value of 11.1 ppm for a 40% loss during storage yields a value of 18.5 ppm.

Blackberry: Although, no field trial data are currently available, IR-4 has conducted field trials but has not yet submitted report. The adequacy of the current tolerance cannot be assessed until data are submitted and reviewed.

Blueberry: Adequate field trial data for blueberries have been submitted and evaluated. Blueberry field trial data (MRIDs 45512001 and 45534501) indicate that maximum ziram residue in/on blueberry fruit after six foliar treatments of 3.17 lb a.i./A was 5.8 ppm at a 7 day PHI. The 7.0 ppm tolerance is adequate.

Cherry: Adequate field trial data for cherries have been submitted and evaluated. A cherry field study (MRIDs 92045008 and 41153103) indicates that residues of ziram were 1.58 and 1.69 ppm in/on cherries (2 samples grown in the eastern U.S.) harvested 14 days following eight applications of the WDG formulation at 4.56 lb ai/A/application (total rate = 36.48 lb ai/A; 1.2x maximum seasonal rate for eastern states). In the same study residues of ziram were 0.250-2.76 ppm in/on cherries (9 samples grown in the western U.S.) harvested 30 days following five applications of the WDG formulation at 4.56 lb ai/A/application (total rate = 22.8 lb ai/A; 1x maximum seasonal rate for western states). Correcting the highest residue value (2.76 ppm) for an expected 50% loss during storage yields a value of 5.5 ppm.

Grape: Additional field trial data are required for grapes. The data are expected to be submitted later this year. In brief, uncorrected ziram grape residues do not exceed the current 7.0 ppm tolerance level from the maximum proposed use of the DF or WDG formulation. Although residues on Muscadine grapes would exceed 7.0 ppm, the specimen label prohibits use on Muscadine grapes. Frozen storage stability data from a 30 week study indicated a ~40% reduction of ziram residue. Linear extrapolation would result in an estimated 13% loss for samples stored up to 10 weeks. New York samples were stored frozen up to 9 weeks while Michigan and Mississippi samples were stored up to 29 weeks before analysis.

The grape field trial data, reflecting the maximum proposed use pattern for the 76% DF or WDG formulation which IR-4 wishes to support, indicate that residues of ziram may occur at the established tolerance level of 7.0 ppm for grapes. Uncorrected residues of ziram ranged from 0.18 ppm to 5.69 ppm in/on grapes grown **east** of the Rocky Mountains and harvested 21 days following the last of seven or eight foliar applications of the ziram 76% DF or WDG formulation at 2.61-3.04 lb ai/A per

application (- 1x the maximum proposed single and seasonal rates) using ground equipment. If the highest residue value (5.69 ppm) resulting from the maximum use pattern for the DF or WDG formulation is corrected for a 13% loss expected from N.Y. samples during frozen storage, then the corrected residue value would be 6.54 ppm.

Uncorrected residues of ziram ranged from 0.363 ppm to 6.11 ppm in/on grapes grown **west** of the Rocky Mountains and harvested 21-22 days following the last of five foliar applications of the ziram 76% WDG formulation at 3.04-3.43 lb ai/A per application (- 1x the maximum proposed single and seasonal rates) using ground equipment. If the highest residue value (6.11 ppm) is corrected for a 13% loss expected during frozen storage, then the corrected residue value would be 7.0 ppm (however, averaging the two replicate field trial samples of 5.43 and 6.11 results in an average residue 5.77 ppm corrected for 13% loss would be 6.6 ppm.).

The registrant has stated that additional grape field trial data will be submitted from two field trials in New York and three in California. The adequacy of the current tolerance cannot be assessed until these data are submitted and reviewed.

Nectarine: Adequate field trial data for nectarines have been submitted and evaluated. A nectarine field study (MRIDs 92045009 and 41229801) indicates that the maximum residue of ziram was 2.31 ppm in/on nectarines (1 sample grown in the eastern U.S.) harvested 14 days following ten applications of the WDG formulation at 6.08 lb ai/A/application (total rate = 60.8 lb ai/A; 1.1x maximum seasonal rate for eastern states). In the same study residues of ziram were 0.080-0.395 ppm in/on nectarines (8 samples grown in the western U.S.) harvested 30 days following seven applications of the WDG formulation at 6.08 lb ai/A/application (total rate = 42.56 lb ai/A; 1x maximum seasonal rate for western states). Correcting the highest residue value (2.31 ppm) for an expected 30% loss during storage yields a value of 3.3 ppm. Residues of ziram were below the established 7 ppm tolerance in all the nectarine trials for ziram harvested at the proposed PHI's, 14 days in the Eastern States and 30 days in the Western states.

Peach: Adequate field trial data for peaches have been submitted and evaluated. A peach field study (MRIDs 92045010 and 41153104) indicates that residues of ziram ranged from 0.865 and 4.63 ppm in/on peaches (samples grown in the eastern U.S.) harvested 14 days following ten applications of the WDG formulation at 6.08 lb ai/A/application (total rate = 60.8 lb ai/A; 1.1x maximum seasonal rate for eastern states). In the same study residues of ziram were <0.05-1.450 ppm in/on peaches (13 samples grown in the western U.S.) harvested 30 days following seven applications of the WDG formulation at 6.08 lb ai/A/application (total rate = 42.56 lb ai/A; 1x maximum seasonal rate for western states). Correcting the highest residue value (4.63 ppm) for an expected 30% loss during storage (sample was stored 3 months prior to analysis) yields a value of 6.6 ppm.

Data were submitted for an additional field trial in GA (MRID 43282503). The WDG formulation was applied 6 times at 5.0 lb ai/A in a minimum of 25 gallons of water (total rate = 30.0 lb ai/A; 0.5x

maximum seasonal rate for eastern states). Residues on peaches at 7-day PHI were all above the 7 ppm tolerance. Residues on peaches harvested at the 21 day PHI were all below the 7 ppm tolerance. In an Agency review of these data, linear regression analysis was performed on all residue data. The analysis included a data set that was corrected for storage losses and one that was not corrected for losses. The analysis indicated that all residues (corrected and uncorrected) would be within tolerance at the 14-day PHI.

Pear: Adequate field trial data for pears have been submitted and evaluated. A pear field study (MRIDs 92045011 and 41153102) indicates that residues of ziram were 0.85-1.89 ppm in/on pears (4 samples grown in the eastern U.S.) harvested 14 days following seven applications of the WDG formulation at 6.08 lb ai/A/application (total rate = 42.56 lb ai/A; 1x maximum seasonal rate for eastern states). In the same study residues of ziram were 1.74-3.96 ppm in/on pears (5 samples grown in the western U.S.) harvested 5 days following four applications of the WDG formulation at 6.08 lb ai/A/application (total rate=24.32 lb ai/A; 1x maximum seasonal rate for western states). Correcting the highest residue value (3.96 ppm) for an expected 30% loss during storage yields a value of 5.7 ppm.

Pecan: Adequate field trial data for pecans have been submitted and evaluated. A pecan field study (MRIDs 92045012 and 41229803) indicates that residues of ziram were nondetectable (<0.05 ppm) in/on pecans (3 samples) harvested 51 or 57 days following eight applications of the WDG or WP formulation at 6.08 lb ai/A/application (total rate = 48.64 lb ai/A; 1x maximum seasonal rate). Correcting for 12% decline during storage yields a residue value of <0.06 ppm.

Strawberry: There are no field trial data available for strawberries. The adequacy of the current tolerance cannot be assessed until data are submitted and reviewed. It is noted that the Ziram Task Force has indicated that they do not intend to support strawberries. However, strawberries are on some end use products labels. It is HED policy to include all uses that are on labels.

Tomato: Adequate field trial data for tomatoes have been submitted and evaluated. In the latest submission in three field trials (MRID 45272901), residues of ziram were 0.179-1.89 ppm in/on 6 samples of tomatoes harvested 7-8 days (labeled PHI) after the last of five or six foliar applications of ziram (76% DF) at - 3 lb ai/A/application for a total of 15.94-18.03 lb ai/A (1x the maximum use rate). In the earlier five field trials (MRID 44898602 and 44898603), residues of ziram were <0.25-1.30 ppm in/on tomatoes (10 samples) harvested 6 or 7 days following the last of six foliar applications of a 76% DF formulation at 3.04 lb ai/A per application (- 1x the maximum use rate).

Together these studies indicate that the 7.0 ppm tolerance for ziram residues in/on tomatoes could be lowered. A 2 ppm tolerance with a regional registration should be established.

GLN 860.1520: Processed Food/Feed

The reregistration requirements for magnitude of the residue in the processed commodities of the following crops have been fulfilled: apple, grapes, and tomato. Refer to "Tolerance Reassessment Summary" section for recommendations with respect to the need for tolerances as a result of concentration of residues of ziram in processed commodities.

Neither the ZTF nor IR-4 has expressed an interest in supporting ziram uses on peanuts; therefore, processing data are no longer required for peanut commodities.

A summary of the available processing data is presented below.

Apple: Data from a processing study indicate that residues of ziram concentrated in wet pomace (average concentration factor of 1.4x) and dry pomace (average 1.8x) processed from whole apples that received seven foliar broadcast applications of the DF formulation at 5x the maximum registered single application rate. Ziram residues did not concentrate in apple juice (average reduction factor of 0.1x). The highest average field trial value (HAFT) from trials reflecting the maximum registered use pattern is 5.6 ppm (corrected). Based on this HAFT and the average concentration factor, the maximum expected residue is 7.6 ppm for wet apple pomace (tolerances on the processed commodity are not generally required if expected residues levels do not exceed 1.5x the tolerance in the raw agricultural commodity per OPPTS 860.1520). Since residues did not concentrate in apple juice, a tolerance for this commodity need not be proposed.

Grape: Data from a processing study indicate that residues of ziram concentrated in grape juice (average concentration factor of 2.2x) and raisins (2x) processed from fresh grapes bearing detectable ziram residues following multiple foliar treatments according to the use pattern the registrant wishes to support for states east and west of the Rocky Mountains. The maximum theoretical concentration factor for grape juice is 1.2X and accordingly this value will be used for the dietary exposure assessment. When adequate grape field trial data have been received, an appropriate tolerance level for raisins will be determined.

Tomato: Data from a processing study indicate that residues of ziram did not concentrate in tomato paste (average reduction factor of 0.5x) and puree (average 0.3x) processed from fresh tomatoes bearing detectable residues. Tolerances for residues of ziram in the processed commodities of tomatoes are not required.

Peach: A peach processing/washing study indicate a significant reduction in ziram residues occurred from the processing procedures utilized (e.g. hydrocooling and rinsing). A check by HED revealed that the subject peach processing procedures utilized in the study were typical of current commercial procedures. Accordingly, the study is adequate and indicates a minimum of 85% of ziram residues would likely be removed by commercial peach processing/washing procedures. Since the 85% reduction occurred on peaches processed after a 21 day PHI (the current PHI for peaches is 14 days) this is considered a conservative estimate for the current 14 day PHI. Ziram residue reduction from

processing of peaches from a 7 day PHI were higher at a 94% reduction, as would be expected since these residues were not as aged (degraded) as residues from peaches with the longer 21 day PHI.

Furthermore, based on the environmental fate profile for ziram, additional degradation of ziram residues in cold storage are likely to occur and accordingly the registrant is advised to include typical cold storage holding periods in any future ziram processing studies. Additional food processing studies representing current commercial procedures and including dissipation from representative cold storage intervals on apples, pears, grapes, nectarines, blueberries, and tomatoes are needed so a more accurate estimate of the reduction of ziram residues from processing procedures can be included in the dietary exposure assessment.

Ziram environmental fate parameters, indicate that ziram is not persistent in the environment, and include the following half life degradation data:

Hydrolysis pH 5, pH 7, pH 9	10 min, 17.7 hours,6.31 days
Photolysis in water	8.7 hours
" In soil	8.9 hours in exposed sample
In dark soil control	16.2 hours
Soil Metabolism-Aerobic	1.75 days
Soils Metabolism Anaerobic	14.1 days
Terrestrial Dissipation in soil surface layer	6.7 days in NC sand and 5.2 days in CA sandy loam

GLN 860.1480: Meat, Milk, Poultry, Eggs

The reregistration requirements for data depicting the magnitude of ziram residues of concern in livestock commodities remain outstanding. No tolerances have been established for ziram residues in livestock commodities, although tolerances need to be proposed for livestock feed items (i.e., almond hulls and wet apple pomace). The MARC *ad hoc* meeting on Ziram/Ferbam (DP Barcode D261844, G. Otakie, 12/16/99) concluded that for risk assessment purposes, secondary residues in livestock commodities may be estimated using the available ziram and ferbam goat metabolism studies. The qualitative nature of the residue in ruminant milk is adequately understood. The registrant demonstrated incorporation of radioactivity into lactose and milk protein (casein).

However, the qualitative nature of the residue in ruminant tissues is inadequately understood because the current study failed to sufficiently characterize and identify the majority of the total radioactive residues (TRR) in tissues. This study may be upgraded if sufficient tissue samples are available to allow further residue characterization and identification, and if the results of the additional analytical work can be validated by adequate storage stability data.

Two lactating goats were orally administered with [^{14}C]ziram (labeled at the dithio carbons, specific activity 13.9 mCi/mM, radiochemical purity - 95%, mixed with unlabeled ziram to a final specific activity of 5060 dpm/ : g), via gelatine capsules containing dextrose, once daily for 6 consecutive days at 500 mg/day. Based on an average feed intake of 1700 g/goat/day during the experimental period, the dose of 500 mg/day was equivalent to 304 ppm. This dose is equivalent to 36x the maximum theoretical dietary burden of 8.4 ppm/day, based on a diet consisting of 40% wet apple pomace [40% dry matter, 6 ppm revised tolerance, ca. 1.4x concentration factor (C. Swartz, CBRS No. 10628, DP Barcode D182885, 6/15/93)] .

The resulting TRR (expressed in ziram equivalents) were <0.03-1.851 ppm in milk, 22.026 and 27.964 ppm in liver, 2.874 and 3.412 ppm in kidney, 0.447 and 0.812 ppm in muscle, and 0.160 and 0.200 ppm in fat of the lactating goats. Analysis of milk and tissue samples using an enforcement method (PAM, Vol. II, Method III) indicated non-detectable levels (<1 ppm) of dithiocarbamates in milk, kidney, fat, and muscle. Dithiocarbamates were detected in liver samples at ca. 2.3 ppm (ca. 10% of TRR). However, radioanalysis of the liver sample for [^{14}C]CS_2 indicated much lower levels of dithiocarbamates (0.4 ppm). The discrepancy in residues detected in the liver is noted. Also, the fact that the registrant demonstrated incorporation of radioactivity into the natural products lactose and milk protein (casein) is not totally irrelevant to the likelihood of extractable dithiocarbamate residues in tissue. Based on these findings the likelihood of detectable dithiocarbamate residues in ruminant milk or tissues other than liver is considered unlikely based on the current approved ziram uses.

However, a final decision on the need for a ruminant feeding study is reserved pending submission of a new goat metabolism study or the upgrading of the current study.

Poultry: As the registrant does not intend to support ziram uses on any crops with poultry feed items, a poultry feeding study is not required at this time.

Ruminant: Under the Phase 4 Reviews, the registrant requested a time extension to 7/15/91 to conduct a ruminant feeding study using ziram. For the required feeding study, ruminants should be dosed orally with parent only at 1x, 3x, and 10x the maximum expected dietary burden for a minimum of 28 days or until residues plateau in milk if they have not done so by 28 days. Animals should be sacrificed within 24 hours of receiving the final dose. Milk should be collected throughout the study, and samples of muscle, fat, liver, and kidney should be collected at sacrifice for analysis. In addition, these studies must be supported by data depicting the storage stability of residues in animal commodities.

Based upon the reassessed tolerances for ziram residues in/on animal feed items, the calculated maximum theoretical dietary burdens for beef and dairy cattle are presented below; there are no currently registered ziram uses on poultry or swine feed items.

Calculation of maximum dietary burdens of beef and dairy cattle for ziram.

Feed Commodity	% Dry Matter	% Diet	Reassessed Tolerance (ppm) [1]	Dietary Contribution (ppm) [2]
Beef Cattle				
Apple, wet pomace	40	40	6 for apples	8.4
TOTAL BURDEN				**8.4**
Dairy Cattle				
Apple, wet pomace	40	20	6 for apples	3.0
TOTAL BURDEN				**3.0**

[1] Reassessed tolerance from Table C.

[2] Contribution = [tolerance / % DM] X % diet X 1.4 (apple wet pomace concentration factor).

GLN 860.1400: Water, Fish, and Irrigated Crops

Ziram is presently not registered for direct use on water and aquatic food and feed crops; therefore, no residue chemistry data are required under these guideline topics.

GLN 860.1460: Food Handling

Ziram is presently not registered for use in food-handling establishments; therefore, no residue chemistry data are required under this guideline topic.

GLN 860.1850 and 860.1900: Confined/Field Accumulation in Rotational Crops

The reregistration requirements for confined/field accumulation in rotational crops have not been met. Based on EFED data summaries indicating the possible persistence of thiram and thiram oxide as ziram metabolites in water, a confined rotational crop study is required (see DP Barcodes D261844 and D261846, G. Otakie, 12/16/99).

GLN 171-5: Reduction of Residues

A peach hydrocooling/washing study, reflecting normal commercial practices indicate a significant reduction in ziram residues occurred from the processing procedures utilized (e.g. hydrocooling and rinsing). Accordingly, the study is adequate and indicates a minimum of 85% of ziram residues would likely be removed by commercial peach processing/washing procedures.
Furthermore, based on the environmental fate profile for ziram, additional degradation of ziram residues in cold storage are likely to occur and accordingly the registrant is advised to include typical cold

storage holding periods in any future ziram processing studies. Additional food processing studies representing current commercial procedures and including representative washing procedures, and dissipation from representative cold storage intervals on apples, pears, grapes, nectarines, blueberries, and tomatoes are needed so a more accurate estimate of the reduction of ziram residues from processing procedures can be included in the dietary exposure assessment. Processing studies on commercial dehydration of fruits (apples, pears, and nectarines) would be helpful in refining the dietary exposure to ziram.

Table A2. Food/Feed Use Patterns on EP Labels Subject to Reregistration for Ziram (Case 2180).

Site Application Timing Application Type Application Equipment	Formulation [EPA Reg. No.]	Maximum Single Application Rate, ai	Maximum Number of Applications Per Season	Maximum Seasonal Rate, ai	Preharvest Interval, Days	Use Directions and Limitations [1, 2, 3]
Almond						
Delayed dormant (prebloom) and foliar Ground or aerial	76% DF [4581-140]	6.08 lb/A (concentrate)	Not specified (NS)	24.3 lb/A	NS	Applications may be made at popcorn, full bloom, petal fall, or as needed. Applications may be made in a minimum of 10 gal/A. Applications later than 5 weeks after petal fall are prohibited.
	76% DF [45728-12]	6.08 lb/A (concentrate) 2.03 lb/100 gal (dilute)	NS	24.3 lb/A	NS	Applications may be made from prebloom through petal fall periods. Applications later than 5 weeks after petal fall are prohibited. Dilute application rates based on a finished spray of 300 gal/A.
Apple						
Delayed dormant (prebloom) and foliar Ground or aerial	76% DF [4581-140] [45728-12]	6.08 lb/A (concentrate) 1.52 lb/100 gal (dilute)	NS	42.6 lb/A for eastern U.S. 24.3 lb/A for western U.S.	14	Applications may be made from prebloom through cover sprays as needed. Dilute application rate based on a finished spray of 400 gal/A.
				24.3 lb/A	14	Use limited to Pacific Northwest only. Applications may be made in the first cover spray and in preharvest spray before fall rains begin. Dilute application rate based on a finished spray of 400 gal/A.
Delayed dormant (prebloom) and foliar Ground or aerial	76% DF [4581-140]	6.08 lb/A (concentrate) 1.52 lb/100 gal (dilute)	NS	24.3 lb/A	NS	Applications may be made as prebloom and calyx sprays. Dilute application rate based on a finished spray of 400 gal/A.

(continued; footnotes follow)

Table A2 *(continued)*.

Site Application Timing Application Type Application Equipment	Formulation [EPA Reg. No.]	Maximum Single Application Rate, ai	Maximum Number of Applications Per Season	Maximum Seasonal Rate, ai	Preharvest Interval, Days	Use Directions and Limitations [1, 2, 3]
Apple (continued)						
Delayed dormant (prebloom) and foliar Ground or aerial	76% DF [45728-12]	6.08 lb/A (concentrate) 1.52 lb/100 gal (dilute)	NS	24.3 lb/A	NS	Use limited to OR. Applications may be made as prebloom and calyx sprays. Dilute application rate based on a finished spray of 400 gal/A.
Apricot						
Delayed dormant (prebloom) and foliar Ground or aerial	76% DF [45728-12]	6.08 lb/A (concentrate) 2.03 lb/100 gal (dilute)	NS	30.4 lb/A	30	Applications may be made at prebloom, bloom, and petal fall through early cover sprays. Dilute application rate based on a finished spray of 300 gal/A.
	76% DF [4581-140]	4.56 lb/A (concentrate) 1.52 lb/100 gal (dilute)	NS	22.8 lb/A	30	Applications may be made at popcorn, full bloom, petal fall, and/or 5 weeks after petal, and in cover sprays as needed. Dilute application rate based on a finished spray of 300 gal/A.
Blackberry						
Foliar Ground or aerial	76% DF [4581-140] [45728-12]	2.28 lb/A (concentrate)	1	NS	NS	Use in CA is prohibited. A single application may be made between mid-June and early July.
Blueberry						
Foliar Ground or aerial	76% DF [4581-140] [45728-12]	2.28 lb/A (concentrate)	NS	NS	NS	Use in CA is prohibited. Applications may be made at loose bud scale stage and 7 days later. Application later than 3 weeks after bloom is prohibited.

(continued; footnotes follow)

Table A2 *(continued)*.

Site Application Timing Application Type Application Equipment	Formulation [EPA Reg. No.]	Maximum Single Application Rate, ai	Maximum Number of Applications Per Season	Maximum Seasonal Rate, ai	Preharvest Interval, Days	Use Directions and Limitations [1, 2, 3]
Blueberry (continued)						
Delayed dormant and foliar Ground or aerial	76% DF [MI990002] [NJ980001]	3.04 lb/A (concentrate)	NS	15.2 lb/A	14	Use limited to MI and NJ. Applications may be made beginning at bud break (green tip) or when conditions for disease development exist.
Cherry						
Delayed dormant (prebloom) and foliar Ground or aerial	76% DF [4581-140] [45728-12]	6.08 lb/A (concentrate) 2.03 lb/100 gal (dilute)	NS	30.4 lb/A	14	Use limited to eastern U.S. Applications may be made at prebloom through cover sprays as needed. Dilute application rate based on a finished spray of 300 gal/A.
Delayed dormant (prebloom) and foliar Ground or aerial	76% DF [4581-140]	4.56 lb/A (concentrate) 1.52 lb/100 gal (dilute)	NS	22.8 lb/A	30	Use limited to western U.S. Applications may be made at prebloom through cover sprays as needed. Dilute application rate based on a finished spray of 300 gal/A.
	76% DF [45728-12]	4.56 lb/A (concentrate) 1.52 lb/100 gal (dilute)	NS	22.8 lb/A	30	Use limited to western U.S. except CA. Applications may be made at prebloom, bloom, petal fall, and shuck stages, and approximately 2 weeks after shuck fall. Dilute application rate based on a finished spray of 300 gal/A.
Delayed dormant (prebloom) and foliar Ground or aerial	76% DF [45728-12]	3.8 lb/A (concentrate) 1.27 lb/100 gal (dilute)	NS	22.8 lb/A	7	Use limited to CA. Applications may be made at prebloom, bloom, petal fall, and shuck stages, and approximately 2 weeks after shuck fall. Dilute application rate based on a finished spray of 300 gal/A.

(continued; footnotes follow)

Table A2 *(continued)*.

Site Application Timing Application Type Application Equipment	Formulation [EPA Reg. No.]	Maximum Single Application Rate, ai	Maximum Number of Applications Per Season	Maximum Seasonal Rate, ai	Preharvest Interval, Days	Use Directions and Limitations [1, 2, 3]
Grape						
Foliar Ground or aerial	76% DF [4581-140] [45728-12] [IN960001] [MI960002] [NY970004] [OH960004] [PA960003]	3.04 lb/A (concentrate)	NS	21.3 lb/A	21	Use limited to eastern U.S. (east of the Rockies). Use on Muscadine grapes is prohibited for SLNs IN960001, MI960002, NY970004, OH960004, and PA960003. Applications may be made beginning when shoots are at least one inch long and continue at 7- to 14-day intervals or as necessary.
	76% DF [4581-140]	3.04 lb/A (concentrate)	NS	NS	NS	Use limited to western U.S. (west of the Rockies). Applications may be made beginning when shoots are 0.5 to 1.5 inches long and repeated at 7- to 10-day intervals as needed. Application after bloom is prohibited.
	76% DF [45728-12]	3.04 lb/A (concentrate)	NS	NS	NS	Use limited to western U.S. (west of the Rockies). Applications may be made before bud swell and repeated after blossoming but before fruit forms. Application after bloom is prohibited.

(continued; footnotes follow)

Table A2 *(continued)*.

Site Application Timing Application Type Application Equipment	Formulation [EPA Reg. No.]	Maximum Single Application Rate, ai	Maximum Number of Applications Per Season	Maximum Seasonal Rate, ai	Preharvest Interval, Days	Use Directions and Limitations [1, 2, 3]
Nectarine and Peach						
Delayed dormant (prebloom) and foliar Ground or aerial	76% DF [4581-140] [45728-12]	6.08 lb/A (concentrate) 2.03 lb/100 gal (dilute)	NS	54.8 lb/A	14	Use limited to eastern U.S. Applications may be made at prebloom through cover sprays as needed. Dilute application rate based on a finished spray of 300 gal/A.
	76% DF [4581-140]	6.08 lb/A (concentrate) 2.53 lb/100 gal (dilute)	NS	42.6 lb/A	30	Use limited to western U.S. Applications may be made at prebloom through cover sprays as needed. Dilute application rate based on a finished spray of 300 gal/A.
	76% DF [45728-12]	6.08 lb/A (concentrate) 2.03 lb/100 gal (dilute)	NS	42.6 lb/A	30	

(continued; footnotes follow)

Table A2 *(continued)*.

Site Application Timing Application Type Application Equipment	Formulation [EPA Reg. No.]	Maximum Single Application Rate, ai	Maximum Number of Applications Per Season	Maximum Seasonal Rate, ai	Preharvest Interval, Days	Use Directions and Limitations [1, 2, 3]
Nectarine and Peach (continued)						
Dormant Ground or aerial	76% DF [4581-140]	6.08 lb/A (concentrate) 2.03 lb/100 gal (dilute)	NS	NS	NS	Use limited to eastern U.S. Applications may be made after leaf drop and/or prior to bud swell. Dilute application rate based on a finished spray of 300 gal/A.
	76% DF [45728-12]	6.08 lb/A (concentrate) 2.03 lb/100 gal (dilute)	NS	54.8	NS	
	76% DF [4581-140]	7.6 lb/A (concentrate) 2.53 lb/100 gal (dilute)	NS	NS	NS	Use limited to western U.S. Applications may be made after leaf drop and/or prior to bud swell. Dilute application rate based on a finished spray of 300 gal/A.
Dormant Ground or aerial	76% DF [45728-12]	7.6 lb/A (concentrate) 2.53 lb/100 gal (dilute)	NS	42.6	NS	Use limited to western U.S. except CA. Applications may be made after leaf drop and/or prior to bud swell. Dilute application rate based on a finished spray of 300 gal/A.
	76% DF [45728-12]	6.08 lb/A (concentrate) 2.03 lb/100 gal (dilute)	NS	42.6	NS	Use limited to CA. Applications may be made after leaf drop and/or prior to bud swell. Dilute application rate based on a finished spray of 300 gal/A.

(continued; footnotes follow)

Table A2 *(continued)*.

Site Application Timing Application Type Application Equipment	Formulation [EPA Reg. No.]	Maximum Single Application Rate, ai	Maximum Number of Applications Per Season	Maximum Seasonal Rate, ai	Preharvest Interval, Days	Use Directions and Limitations [1, 2, 3]
Pear						
Delayed dormant (prebloom) and foliar Ground or aerial	76% DF [4581-140] [45728-12]	6.08 lb/A (concentrate) 1.52 lb/100 gal (dilute)	NS	42.6 lb/A for eastern U.S. 24.3 lb/A for western U.S.	14 for eastern U.S. 5 for western U.S.	Use in CA is prohibited. Applications may be made from prebloom through cover sprays as needed. Dilute application rate based on a finished spray of 400 gal/A.
				24.3 lb/A	5	Use limited to Pacific Northwest only. Applications may be made in the first cover spray and in preharvest spray before fall rains begin. Dilute application rate based on a finished spray of 400 gal/A.
Preharvest Ground or aerial	76% DF [4581-140]	6.08 lb/A (concentrate)	NS	24.3 lb/A	5	
	76% DF [45728-12]	6.08 lb/A (concentrate) 1.52 lb/100 gal (dilute)	NS	24.3 lb/A	5	Use limited to OR. Dilute application rate based on a finished spray of 400 gal/A.
	76% DF [WA920033]	6.08 lb/A (concentrate)	NS	NS	5	Use limited to WA. Concentrate ground applications may be made in a minimum of 40 gal/A and aerial applications may be made in a minimum of 10 gal/A. The label specifies that only one preharvest application during the late season use period is allowed.

(continued; footnotes follow)

Table A2 *(continued)*.

Site Application Timing Application Type Application Equipment	Formulation [EPA Reg. No.]	Maximum Single Application Rate, ai	Maximum Number of Applications Per Season	Maximum Seasonal Rate, ai	Preharvest Interval, Days	Use Directions and Limitations [1, 2, 3]
Pecan						
Foliar Ground or aerial	76% DF [4581-140]	6.08 lb/A (concentrate)	NS	48.6 lb/A	55	Applications may be made when leaves are 1/4- to ½-inch long. Applications may be repeated after pollination is complete for up to 5 cover sprays at 3-4 week intervals. Dilute application rate based on a finished spray of 300 gal/A.
	76% DF [45728-12]	6.08 lb/A (concentrate) 2.03 lb/100 gal (dilute)	NS	48.6 lb/A	55	
Tomato						
Foliar Ground or aerial	76% DF [4581-140] [45728-12]	3.04 lb/A (concentrate)	NS	18.2 lb/A	7	Use in CA is prohibited. Use on cherry tomatoes is prohibited. Applications may be made at first sign of infection and continue at 7- to 14-day intervals.

[1] The restricted entry interval (REI) for the 76% DF formulations (EPA Reg. Nos. 4581-140 and 45728-12) is 48 hours.

[2] Unless otherwise specified, concentrate ground applications may be made in a minimum of 20 gal/A and concentrate aerial applications may be made in a minimum of 10 gal/A.

[3] The grazing or feeding of cover crops from treated orchards is prohibited for the 76% DF formulations (EPA Reg. Nos. 4581-140 and 45728-12).

Table B. Residue Chemistry Science Assessments for Reregistration of Ziram.

GLN: Data Requirements	Current Tolerances, ppm [40 CFR §180.116]	Must Additional Data Be Submitted?	References [1]
860.1200: Directions for Use	N/A = Not Applicable	Yes [2]	See Tables A1 and A2.
860.1300: Plant Metabolism	N/A	Yes [3]	43500001 [4], 44451401 [4]
860.1300: Animal Metabolism	N/A	Yes [5]	42839201 [6]
860.1340: Residue Analytical Methods			
- Plant commodities	N/A	Yes [7]	**41229801**, **92045003**
- Animal commodities	N/A	Reserved [8]	
860.1360: Multiresidue Methods	N/A	No [9]	
860.1380: Storage Stability Data			
- Plant commodities	N/A	Yes [10]	**41153105**, **92045004**, 43949701 [11]
- Animal commodities	N/A	Yes [12]	
860.1500: Crop Field Trials			
Root and Tuber Vegetables Group			
- Beet, garden, root	7	No [13]	
- Carrot	7	No [13]	
- Radish, root	7	No [13]	
- Rutabaga	7	No [13]	
- Turnip, root	7	No [13]	

(continued; footnotes follow)

Table B *(continued)*.

GLN: Data Requirements	Current Tolerances, ppm [40 CFR §180.116]	Must Additional Data Be Submitted?	References [1]
Leaves of Root and Tuber Vegetables Group			
- Beet, garden, tops	7	No [13]	
- Radish, tops	7	No [13]	
- Turnip, tops	7	No [13]	
Bulb Vegetables (*Allium spp.*) Group			
- Onion, bulb	7	No [13]	
Leafy Vegetables (Except *Brassica* Vegetables) Group			
- Celery	7	No [13]	
- Lettuce, head	7	No [13]	
- Lettuce, leaf	7	No [13]	
- Spinach	7	No [13]	
Brassica (Cole) Leafy Vegetables Group			
- Broccoli	7	No [13]	
- Brussels sprouts	7	No [13]	
- Cabbage	7	No [13]	
- Cauliflower	7	No [13]	
- Collards	7	No [13]	
- Kale	7	No [13]	
- Kohlrabi	7	No [13]	

(continued; footnotes follow)

Table B *(continued)*.

GLN: Data Requirements	Current Tolerances, ppm [40 CFR §180.116]	Must Additional Data Be Submitted?	References [1]
Legume Vegetables (Succulent or Dried) Group			
- Bean, succulent and seed	7	No [13]	
- Pea, succulent and seed	7	No [13]	
Fruiting Vegetables (Except Cucurbits) Group			
- Eggplant	7	No [13]	
- Pepper	7	No [13]	
- Tomato	7	No [14]	44898601-44898603 [15]
Cucurbit Vegetables Group			
- Cucumber	7	No [13]	
- Melon	7	No [13]	
- Pumpkin	7	No [13]	
- Squash	7	No [13]	
Pome Fruits Group			
- Apple	7	No	**41229802** [16], 43282501 [16], **92045005** [16]
- Pear	7	No	**41153102** [16], **92045011** [16]
- Quince	7	No [13]	
Stone Fruits Group			
- Apricot	7	No	**41153101** [16], 43282502 [16], **92045007** [16]
- Cherry	7	No	**41153103** [16], **92045008** [16], 43520901 [17]
- Nectarine	7	No	**41229801** [16], **92045009** [16]

(continued; footnotes follow)

Table B *(continued)*.

GLN: Data Requirements	Current Tolerances, ppm [40 CFR §180.116]	Must Additional Data Be Submitted?	References [1]
- Peach	7	No	**41153104** [16], 43282503[16], **92045010** [16]
Berries Group			
- Blackberry	7	Yes [18]	
- Blueberry	7	No [19]	
- Boysenberry	7	No [13]	
- Dewberry	7	No [13]	
- Gooseberry	7	No [13]	
- Huckleberry	7	No [13]	
- Loganberry	7	No [13]	
- Raspberry	7	No [13]	
- Youngberry	7	No [13]	
Tree Nuts Group			
- Almond, nutmeat and hulls	0.1, almonds	No	**41153106** [16], **92045006** [16]
- Pecan	0.1	No	**41229803** [16], **92045012** [16]
Miscellaneous Commodities			
- Cranberry	7	No [13]	
- Grape	7	Yes [20]	44914101-44914103 [21]
- Peanut, nutmeat and hay	7, peanuts	No [13]	
- Strawberry	7	No [13]	

(continued; footnotes follow)

Table B *(continued)*.

GLN: Data Requirements	Current Tolerances, ppm [40 CFR §180.116]	Must Additional Data Be Submitted?	References [1]
860.1520: Processed Food/Feed			
- Apple	None established	No	42473601[22]
- Grape	None established	No	44914102-44914103 [21]
- Peanut	None established	No [13]	
- Tomato	None established	No	44898603 [15]
860.1480: Meat, Milk, Poultry, Eggs			
- Milk, Fat, Meat, and Meat Byproducts of Cattle, Goats, Hogs, Horses, and Sheep	None established	Yes [23]	
- Eggs and the Fat, Meat, and Meat Byproducts of Poultry	None established	No [24]	
860.1400: Water, Fish, and Irrigated Crops	None established	No	
860.1460: Food Handling	None established	No	
860.1850: Confined Rotational Crops	N/A	Yes [25]	
860.1900: Field Rotational Crops	None established	Reserved [25]	
171-5: Reduction of Residue	N/A	Yes[26]	42839201

1. **Bolded** references were reviewed in the Dimethyldithiocarbamate Salts Phase 4 Reviews for zinc dimethyldithiocarbamate (ziram; C. Olinger, 4/24/91). All other references were reviewed as noted.

2. Label amendments are required to incorporate the parameters of use patterns reflected in the submitted field trials. For apples, cherries, nectarines, peaches, and pears, the labels must be modified to specifically define "eastern U.S." and "western U.S." For cherries, the product label for EPA Reg. No. 45728-12 must be amended to change the 7-day PHI for CA to a 30-day PHI. There are no data available to support a 7-day PHI for cherries in CA.

   For blueberries, the labels must be amended to include a maximum seasonal rate; this amendment must be supported by adequate field trial data.

Table B *(continued)*.

For grapes, the labels must be amended to reflect the use patterns of the submitted field trial data: multiple applications at up to 3.04 lb ai/A/application with a 21-day PHI and a maximum seasonal rate of 21.3 lb ai/A for states east of the Rocky Mountains and 15.2 lb ai/A for states west of Rocky Mountains; a restriction against use on Muscadine grapes must be added to the labels.

For pears, the product label for EPA Reg. No. 4581-140 must be amended to state that pre-harvest spray applications with a 5-day PHI may only be made in the western U.S. (no data reflecting a 5-day PHI are available for the eastern U.S.).

For tomatoes, the labels must be amended to reflect the use patterns of the submitted field trial data: multiple applications at up to 3.04 lb ai/A/application with a 7-day PHI and a maximum seasonal rate of 18.2 lb ai/A; use must be restricted to tomatoes grown east of the Rocky Mountains. In addition, the labels must specify the type of equipment to be used for application (i.e., ground or aerial) along with recommended spray volumes. The registrant should be aware that the Agency typically requires separate residue data for aerial applications of pesticides with spray volumes less than 2 gallons per acre.

For the purpose of generating this Residue Chemistry Science Chapter, HED examined the registered food/feed use patterns of the basic producer, ZTF, and reevaluated the available residue chemistry database for adequacy in supporting these use patterns. When end-use product DCIs are developed (e.g., at issuance of the RED), RD should require that all end-use product labels (e.g., MAI labels, SLNs, and products subject to the generic data exemption) be amended such that they are consistent with the basic producer labels.

3. The apple metabolism study is inadequate and cannot be upgraded. The registrant must submit a new apple metabolism study. Although inadequate, the apple metabolism study indicates that a major portion of the residue is surface residue captured in the solvent/water rinse at the lower PHIs, and these residues fall precipitously with longer PHIs. The registrant may want to consider a washing study with plain water as part of the new apple metabolism study, particularly if low PHIs are desired. Although it is uncertain at this point if risk needs to be mitigated, it does appear that data on water washed fruits treated with ziram may be beneficial in future ziram dietary exposure assessments.

   A third metabolism study on a leafy vegetable will be required if any uses in addition to those currently on the product labels are supported.

4. DP Barcodes D210778 and D242544, 7/24/01, G. Otakie.

5. The reregistration requirements for animal metabolism are partially fulfilled. The qualitative nature of the residue in ruminant milk is adequately understood, however, the nature of the residue in ruminant tissues is not adequately understood since radioactive residues in tissues (most notably liver) were inadequately characterized; this goat metabolism study is currently under RRB4 secondary review (see DP Barcode D193238, G. Otakie, 6/21/01). This study may be upgraded if sufficient tissue samples are available to allow further residue characterization and identification, and if the results of additional analytical work can be validated by adequate storage stability data.

   The requirement for a poultry metabolism study has been waived because the registrant does not intend to support uses on any crops with poultry feed items.

6. DP Barcode D193238, G. Otakie, 6/21/01.

Table B *(continued)*.

7. If new metabolites (which require regulation) are found in the plant metabolism studies, then analytical method(s) must be developed for them. Any regulatory methods submitted will require an independent method validation.

8. If the requested ruminant feeding study suggests that tolerances in milk and edible tissues of ruminants are needed, the registrant will be required to develop enforcement and data collection method(s) capable of determining ziram residues of concern. Any regulatory method submitted will require successful radiovalidation and independent laboratory validation as per OPPTS 860.1340. The requirement for a specific, confirmatory analytical method suitable for animal products is reserved pending the outcome of the ruminant metabolism study.

9. The Phase 4 Reviews reported that recovery of zinc dimethyldithiocarbamate through any of the FDA multiresidue protocols is highly unlikely.

10. Adequate storage stability data to support the outstanding field trial studies must be submitted.

11. D224367, 6/21/01, G. Otakie.

12. There are no available storage stability data for ziram residues of concern in milk and livestock tissues. The goat metabolism and the requested ruminant feeding studies must be supported by acceptable storage stability data.

13. At this time no data is required due to the proposed revocation of the subject tolerances. Data are required if these proposed uses are being supported. The ZTF has stated that they would like to retain tolerances for Brassica vegetables, lettuce, and possibly strawberries for import purposes, and that IR-4 may be willing to support use of ziram on peppers (personal communication with L. Parson, 2/22/00). The ZTF does not currently have any registered used on peppers. No information describing the use patterns of ziram on Brassica vegetables, lettuce, or strawberries grown outside the U.S. for import to the U.S. has been submitted. In addition, no crop field trial data for any Brassica vegetable, or for lettuce, peppers, or strawberries have been submitted. To retain the tolerances for Brassica vegetables, lettuce, and strawberries for import purposes, field residue data must be submitted reflecting the maximum use patterns for representative ziram formulations on these crops to be exported to the U.S. Because the ZTF has not provided any use pattern data or indicated in which countries ziram is used or intended to be used on these crops for export, the Agency cannot make specific recommendations concerning the number and locations of the foreign field trials to be conducted. In general, trials must be conducted in all countries in which ziram is sold or intended to be sold. All countries which represent at least 5% of the U.S. imports, and all major growing areas within each country should be represented. Substitution of data from one country to another is acceptable if the registrant can demonstrate similar climatic conditions and cultural practices. The Agency is in the process of developing guidance on the conduct of crop field trials to support import tolerances. It is recommended that the registrant(s) submit a protocol before generating field trial data for these commodities.

    For purposes of reregistration, if IR-4 intends to support ziram uses on peppers, then data are required depicting residues of ziram in/on peppers following application of a representative DF formulation according to the maximum proposed use patterns. The number of field trials and geographic locations of trial sites should be in compliance with the current guidance.

    Neither the ZTF nor IR-4 has expressed an interest in supporting ziram uses on the following commodities: bean, succulent and seed; beet, garden; boysenberry; carrot; celery; cranberry; cucumber; dewberry; eggplant; gooseberry; huckleberry; loganberry; melon; onion, dry bulb; peanut; pea, succulent and seed; pumpkin; quince; radish; raspberry; rutabaga; spinach; squash, summer; turnip; and youngberry. Unless the

Table B *(continued)*.

ZTF or IR-4 submit supporting data for these crops, or for Brassica vegetables (broccoli, Brussels sprouts, cabbage, cauliflower, collards, kale, and kohlrabi), lettuce, peppers, or strawberries, the established tolerances for the respective RACs should be revoked.

14. DP Barcode D258972, 6/21/01, G. Otakie and DP Barcode D2271210, 7/26/01, G. Otakie.

15. DP Barcode D258972, 6/21/01, G. Otakie.

16. CBRS No. 13957, DP Barcode D205009, 4/4/95, C. Eiden.

17. CBRS No. 15065, 2/14/95, S. Hummel.

18. The ZTF has stated that they will support ziram use on blackberry and submit residue data late in 2001 (personal communication with L. Parsons, 7/24/01).

    The following are required: Data depicting residues of ziram in/on blackberry following application of the Elf Atochem or UCB 76% DF formulation (EPA Reg. Nos. 4581-140 and 45728-12) according to the maximum registered use patterns. The number of field trials and geographic locations of trial sites should be in compliance with the current guidance.

19. DP Barcode D279177, 1/17/02, T. Morton

20. Additional field trial data on grapes must be submitted; IR-4 has stated that data from five additional field trials will be submitted in 2001(personal communication with L. Parsons, 7/24/01).

21. DP Barcode D276470, 7/24/01, G. Otakie.

22. CBRS No. 10628, DP Barcode D182885, 6/15/93, C. Swartz.

23. A ruminant feeding study is required.

24. The registrant does not intend to support ziram uses on any crops with poultry feed items.

25. The reregistration requirements for confined/field accumulation in rotational crops have not been met. Based on EFED data summaries indicating that possible persistence of thiram and thiram oxide as ziram metabolites in water, a confined rotation study should be required (see DP Barcodes D261844 and D261846, G. Otakie, 12/16/99).

26. Additional food processing studies representing current commercial procedures and including representative washing procedures, and dissipation from representative cold storage intervals on apples, pears, grapes, nectarines, blueberries, and tomatoes are needed so a more accurate estimate of the reduction of ziram residues from processing procedures can be included in the dietary exposure assessment. Processing studies on commercial dehydration of fruits (apples, pears, and nectarines) would be helpful in refining the dietary exposure to ziram.

TOLERANCE REASSESSMENT SUMMARY

Tolerances for residues of ziram in/on raw agricultural commodities are currently expressed in terms of residues of ziram (zinc dimethyldithiocarbamate), calculated as zinc ethylenebisdithiocarbamate (zineb) [40 CFR §180.116]. Also, 40 CFR §180.3(d)(5) and 40 CFR §180.3(e)(3) which addresses tolerances on similar pesticides and specifically dithicarbamates states as follows:

"Where tolerances are established for more than one member of the class of dithiocarbamates listed in paragraph (e)(3) of this section on the same raw agricultural commodity, the total residue of such pesticides shall not exceed that permitted by the highest tolerance established for any one member of the class, calculated as zinc ethylenebisdithiocarbamate."

"The following pesticides are members of the class of dithiocarbamates:

A mixture of 5.2 parts by weight of ammoniates of [ethylenebis(dithiocarbamato)] zinc with 1 part by weight ethylenebis[dithiocarbamic acid] bimolecular and trimolecular cyclic anhydrosulfdes and disulfides {metiram; §180.217, §180.319}

2-Chloroallyl diethyldithiocarbamate {sulfallate, canceled}

Coordination product of zinc ion and maneb containing 20% manganese, 2.5 percent Zinc and 77.5 percent ethylenebisdithiocarbamate {mancozeb; §180.176, §180.319}

Ferbam {§180.114}

Maneb {§180.110}

Manganous dimethyldithiocarbamate {§180.161}

Sodium dimethyldithiocarbamate {§180.152}

Thiram {§180.132}

Zineb {§180.115, §180.319; canceled}

Ziram {§180.116}

The tolerances for ziram and the other dithiocarbamates are enforced by a common moiety method that determines carbon disulfide. The Agency is recommending that the tolerances for ziram and all other dithiocarbamates be changed to be expressed in terms of carbon disulfide. This recommended change in tolerance expression allows harmonization of US tolerances with Codex MRLs. This recommendation for a change in the tolerance expression should also apply to the other dithiocarbamate fungicides that are determined by the carbon disulfide common moiety method. This group includes ferbam, ziram, thiram, maneb, mancozeb, and metiram, which have current tolerances.

Consequently, in the interim, unless all the tolerances for dithiocarbamates can be changed simultaneously, it appears that in accordance with the above section it would be necessary to publish tolerances for ziram expressed as both zineb and carbon disulfide.

The listing of ziram tolerances under 40 CFR §180.116 should be subdivided into parts (a), (b), (c), and (d). Part (a) should be reserved for commodities with permanent tolerances, part (b) for Section

18 emergency exemptions, part (c) for tolerances with regional registrations, and part (d) for indirect or inadvertent residues.

Tolerances Listed Under 40 CFR §180.116:

Sufficient data have been submitted to reassess the established tolerances for the following commodities, **as defined**, pending label amendments for some crops: almonds, apples, apricots, blueberries, cherries, peaches, pears, and pecans. The tolerances for almonds, blueberries, peaches, and pecans are reassessed at the same level. The tolerances for apples, cherries, pears and tomatoes are reassessed at a decreased level, and the tolerance for apricots is reassessed at an increased level.

Insufficient data are available to ascertain the adequacy of the established tolerances for the following commodities, **as defined**: blackberries; grapes.

The tolerance for nectarines should be revoked as the tolerance for peaches is sufficient to address ziram residues in nectarines (40 CFR §180.1(h)). The tolerance for strawberries should be revoked since there are no field trial data supporting that tolerance.

Although, the ZTF has stated that they would like to retain tolerances for Brassica vegetables, lettuce, and possibly strawberries for import purposes, and that IR-4 may be willing to support use of ziram on peppers (the ZTF does not currently have any registered used on peppers). No information describing the use patterns of ziram on Brassica vegetables, lettuce, or strawberries grown outside the U.S. for import to the U.S. has been submitted and there are no crop field trial data available for these crops. Accordingly unless sufficient data are submitted these tolerances will be revoked. Neither the ZTF nor IR-4 has committed to support ziram uses on the remaining crops for which tolerances are established. Therefore, the established tolerances for the following commodities, **as defined**, should be revoked unless the registrants or IR-4 commit to submit supporting data: beans; beets (with and without tops) or beet greens alone; boysenberries; broccoli; Brussels sprouts; cabbage; carrot; cauliflower; celery; collards; cranberries; cucumber; dewberries; eggplants; gooseberries; kale; kohlrabi; lettuce; loganberries; melons; onions; peanuts; peas; peppers; pumpkin; quince; radishes (with or without tops) or radish tops; raspberries; rutabaga (with or without tops) or rutabaga tops; spinach; squash; strawberries; summer squash; turnip (with or without tops) or turnip tops; and youngberries.

Tolerances To Be Proposed Under 40 CFR §180.116:

A tolerance is required for almond hulls (the registrant has already proposed this tolerance; see below).

Per OPPTS 860.1520: when residues in the processed food (i.e. concentration factor times HAFT) are significantly above the LOQ, a separate tolerance will normally be needed if these residues are approximately 1.5x the tolerance for the raw agricultural commodity (or higher).

Accordingly, tolerances for grape juice and apple pomace are not required.(theoretical maximum for grape juice 1.2 X and wet apple pomace 1.4X per apple processing study) However an appropriate tolerance for raisins reflecting the 2X concentration factor will be determined after all the grape field trial data have been submitted and reviewed.

Pending Tolerance Petitions:

PP#5F4561: The ZTF has proposed a tolerance for residues of ziram in/on almond hulls at 20 ppm, and an increased tolerance for apricots at 20 ppm. The Agency will take action on the tolerance petition request when the reregistration eligibility decision document (RED) for ziram is issued (see D217787, 6/21/01, G. Otakie).

Table C. Tolerance Reassessment Summary for Ziram.

Commodity	Tolerance Listed Under 40 CFR (ppm zineb)	MRID(s) used for Tolerance Reassessment	Maximum Residue Value [1] (ppm ziram)	Reassessed Tolerance [2] (ppm zineb)	Comment *[Correct Commodity Definition]*
Tolerance Listed Under 40 CFR §180.116					
Almonds	0.1	92045006 41153106	<0.05/**<0.06**	0.1	[*Almond, nutmeat*]
Apples	7	92045005 41229802 43282501	4.83/**5.6**	6	[*Apple*]
Apricots	7	43282502	11.1/**18.5**	20 [3]	[*Apricot*]
Beans	7	Unless the registrant(s) or IR-4 submit supporting data for ziram use on beans and beets, the established tolerances should be revoked.		Revoke	
Beets (with and without tops) or beet greens alone	7			Revoke	
Blackberries	7	Additional data are required.		TBD [4]	[*Blackberry*]
Blueberries (huckleberries)	7	45512001 45534501	5.8	TBD	[*Blueberry*]
Boysenberries	7	Unless the registrant(s) or IR-4 submit supporting data for ziram use on boysenberry, broccoli, Brussels sprouts, cabbage, carrots, cauliflower, and celery, the established tolerances should be revoked.		Revoke	
Broccoli	7			Revoke	
Brussels sprouts	7			Revoke	
Cabbage	7			Revoke	
Carrots	7			Revoke	
Cauliflower	7			Revoke	
Celery	7			Revoke	
Cherries	7	92045008 41153103	2.76/**5.5**	6	[*Cherry, sweet*] [*Cherry, tart*]
Collards	7	Unless the registrant(s) or IR-4 submit supporting data for ziram use on collards, cranberry, cucumber, dewberry, eggplant, and gooseberries, the established tolerances should be revoked.		Revoke	
Cranberries	7			Revoke	
Cucumbers	7			Revoke	
Dewberries	7			Revoke	

(continued; footnotes follow)

Table C *(continued)*.

Commodity	Tolerance Listed Under 40 CFR (ppm zineb)	MRID(s) used for Tolerance Reassessment	Maximum Residue Value [1] (ppm ziram)	Reassessed Tolerance [2] (ppm zineb)	Comment *[Correct Commodity Definition]*
Eggplants	7			Revoke	
Gooseberries	7			Revoke	
Grapes	7	Additional data are required.		TBD	additional field trials pending
Kale	7	Unless the registrant(s) or IR-4 submit supporting data for ziram use on kale, kohlrabi, lettuce, loganberry, and melons, the established tolerances should be revoked.		Revoke	
Kohlrabi	7			Revoke	
Lettuce	7			Revoke	
Loganberries	7			Revoke	
Melons	7			Revoke	
Nectarines	7	92045009 41229801	2.31/**3.3**	Revoke	Residues in/on nectarines are covered by the tolerance for peaches.
Onions	7	Unless the registrant(s) or IR-4 submit supporting data for ziram use on onions the established tolerance should be revoked.		Revoke	
Peaches	7	92045010 41153104	4.63/**6.6**	7	[*Peach*]
Peanuts	7	Unless the registrant(s) or IR-4 submit supporting data for ziram use on peanuts the established tolerance should be revoked.		Revoke	
Pears	7	92045011 41153102	3.96/**5.7**	6	[*Pear*]
Peas	7	Unless the registrant(s) or IR-4 submit supporting data for ziram use on peas the established tolerance should be revoked.		Revoke	
Pecans	0.1	92045012 41229803	<0.05/<**0.06**	0.1	[*Pecan*]

(continued; footnotes follow)

Table C *(continued)*.

Commodity	Tolerance Listed Under 40 CFR (ppm zineb)	MRID(s) used for Tolerance Reassessment	Maximum Residue Value [1] (ppm ziram)	Reassessed Tolerance [2] (ppm zineb)	Comment *[Correct Commodity Definition]*
Peppers	7	Unless the registrant(s) or IR-4 submit supporting data for ziram use on peppers, pumpkin, quince, radish, raspberry, rutabaga, spinach, squash, strawberries, and summer squash, the established tolerances should be revoked.		Revoke	
Pumpkins	7			Revoke	
Quinces	7			Revoke	
Radishes (with or without tops) or radish tops	7			Revoke	
Raspberries	7			Revoke	
Rutabagas (with or without tops) or rutabaga tops	7			Revoke	
Spinach	7			Revoke	
Squash	7			Revoke	
Strawberries	7			Revoke	
Summer squash	7			Revoke	
Tomatoes	7	448986-01 thru -03, 45272901	1.89/**1.89**	2	Because the registrant wishes to restrict use of ziram to tomatoes grown east of the Rocky Mountains, a geographic restriction will be necessary for this tolerance. [*Tomato*]
Turnips (with or without tops) or turnip greens	7	Unless the registrant(s) or IR-4 submit supporting data for ziram use on turnips and youngberry, the established tolerances should be revoked.		Revoke	
Youngberries	7			Revoke	
Tolerance To Be Proposed Under 40 CFR §180.116					
Almond, hulls	None	92045006 41153106	13.8/**18.4**	20 [3]	

(continued; footnotes follow)

Table C *(continued)*.

Commodity	Tolerance Listed Under 40 CFR (ppm zineb)	MRID(s) used for Tolerance Reassessment	Maximum Residue Value [1] (ppm ziram)	Reassessed Tolerance [2] (ppm zineb)	Comment *[Correct Commodity Definition]*
Apple, pomace, wet	None	42473601	5.6 (HAFT) x 1.35 (average concentration factor) = 7.6	TBD	per OPPTS 860.1520 a Section 409 tolerance will normally not be required if those residues are approximately 1.5X the Section 408 tolerance
Grape, juice	None	44914102 44194103	Average concentration factor 2.2x	TBD	Since the theoretical concentration factor for grape juice is 1.2X a separate tolerance for grape juice is unlikely.
Grape, raisin	None	44914102 44194103	Average concentration factor 2x	TBD	Pending receipt of additional grape field trials a 14 ppm (2 x 7) raisin tolerance would be required.

[1] Maximum residue of treated RAC sample(s) following application of ziram formulation according to the maximum use patterns the registrant(s) wishes to support for reregistration. When two residue values are presented, the value in **bold** has been corrected for residue decline during storage.

[2] The reassessed tolerances are contingent upon the recommended label revisions outlined in Table B and are expressed as zineb.

[3] The ZTF has submitted a tolerance petition, PP#5F4561, for this tolerance.

[4] TBD = To be determined. Tolerance reassessment cannot be made at this time because additional data are required.

CODEX HARMONIZATION

There are no established or proposed Codex MRLs for ziram residues *per se*, however, Codex maximum residue limits for mancozeb, maneb, metiram, propineb, thiram and ziram are grouped under dithiocarbamates and are currently determined and expressed as carbon disulfide. Harmonization of the U.S. tolerances with Codex MRLs will require a change in the tolerance expression.

The CODEX residue definition for dithiocarbamates: Total dithiocarbamates, determined as CS_2, evolved during acid digestion and expressed as mg CS_2/kg. The MRLs apply to total residues from the use of any or each of the groups of dithicarbamates, ferbam & ziram; thiram; mancozeb, maneb, metiram, & zineb; propineb.

The tolerances for ziram are currently expressed as zineb (i.e. zinc ethylenebisdithiocarbamate). and are enforced by a common moiety method that determines carbon disulfide. The Agency is recommending that the tolerances for ziram and all other dithiocarbamates be changed to be expressed in terms of both zineb and carbon disulfide. This recommended change in tolerance expression allows harmonization of US tolerances with Codex MRLs. This recommendation for a change in the tolerance expression should also apply to the other dithiocarbamate fungicides that are determined by the carbon disulfide common moiety method. This includes ferbam, ziram, thiram, maneb, mancozeb, and metiram.

Also, 40 CFR §180.3(d)(5) which addresses tolerances on similar pesticides and specifically dithicarbamates states as follows:

(5) Where tolerances are established for more than one member of the class of dithiocarbamates listed in paragraph (e)(3) of this section on the same raw agricultural commodity, the total residue of such pesticides shall not exceed that permitted by the highest tolerance established for any one member of the class, calculated as zinc ethylenebisdithiocarbamate.

Since the above Section requires the use of zineb as the basis for calculating the tolerance levels, for all the dithiocarbamate tolerances, all the tolerances as well as 40 CFR §180.3(5) would need to be revised at the same time. Consequently, in the interim, it appears that in accordance with the above section it would be necessary to publish tolerances for ziram expressed as both zineb and carbon disulfide. As the ziram reregistration process proceeds and tolerances which are supported are finalized (additional numerical revisions and revocation of tolerances not supported are possible) 40 CFR §180.116 will require revision and at that time the tolerances could be expressed as CS_2 as well as zineb in accordance with 40 CFR §180.3(d)(5) and 40 CFR §180.3(e)(3) should be revised to remove reference to the canceled dithiocarbamates.

(*continued; footnotes follow*)

Table D. Codex MRLs for dithiocarbamates [1] and applicable U.S. tolerances for ziram. Recommendations are based on conclusions following reassessment of U.S. tolerances (see Table C).

Codex		Reassessed U.S. Ziram Tolerance, ppm	Codex Comments
Commodity, As Defined	MRL [2] (mg/kg CS_2)		
Almond hulls	20	20	Source of data: maneb, ziram
Almonds	0.1 (*)	0.1	Source of data: maneb, ziram
Asparagus	0.1	--	Source of data: mancozeb
Banana	2	--	Source of data: mancozeb
Barley	1	--	Source of data: mancozeb
Barley straw and fodder, dry	25	--	Source of data: mancozeb, maneb
Cabbages, head	5	Revoke	Source of data: mancozeb, maneb
Carrot	1	Revoke	Source of data: mancozeb
Cherries	1	6	Source of data: thiram
Cos lettuce	10	Revoke	Source of data: maneb
Cranberry	5	Revoke	Source of data: mancozeb
Cucumber	2	Revoke	Source of data: mancozeb, maneb
Currants, black, red, white	10	--	Source of data: mancozeb, metiram
Edible offal (mammalian)	0.1	--	Source of data: mancozeb, metiram
Eggs	0.05 (*)	--	Source of data: mancozeb
Garlic	0.5	--	Source of data: mancozeb
Grapes	5	TBD	Source of data: mancozeb, metiram, maneb, propineb
Hops, dry	30	--	Source of data: metiram
Kale	15	Revoke	Source of data: mancozeb, maneb
Leek	0.5	--	Source of data: mancozeb
Lettuce, head	10	Revoke	Source of data: mancozeb, maneb, metiram
Maize fodder	2	--	Source of data: mancozeb
Mandarins	10	--	Source of data: mancozeb
Mango	2	--	Source of data: mancozeb
Meat (from mammals other than marine mammals)	0.05 (*)	--	Source of data: mancozeb, metiram

(*continued; footnotes follow*)

Codex		Reassessed U.S. Ziram Tolerance, ppm	Codex Comments
Commodity, As Defined	MRL [2] (mg/kg CS_2)		
Melons, except watermelon	0.5	Revoke	Source of data: mancozeb, propineb
Milks	0.05 (*)	--	Source of data: mancozeb, metiram
Onion, bulb	0.5	Revoke	Source of data: mancozeb, propineb
Oranges, sweet, sour	2	--	Source of data: mancozeb
Papaya	5	--	Source of data: mancozeb
Peanut	0.1 (*)	Revoke	Source of data: mancozeb
Peanut fodder	5	Revoke	Source of data: mancozeb
Pepper, sweet	1	Revoke	Source of data: mancozeb, maneb
Plums (including prunes)	1	--	Source of data: thiram
Pome fruits	5	6 for apples 6 for pears	Source of data: mancozeb, metiram, propineb, thiram, ziram
Potato	0.2	--	Source of data: mancozeb, maneb, metiram
Poultry meat	0.1	--	Source of data: mancozeb
Poultry, edible offal of	0.1	--	Source of data: mancozeb
Pumpkins	0.2	Revoke	Source of data: mancozeb
Spring onion	10	Revoke	Source of data: maneb
Squash, summer	1	Revoke	Source of data: mancozeb
Sugar beet	0.5	--	Source of data: mancozeb, maneb
Sugar beet leaves or tops	20	--	Source of data: mancozeb, maneb
Sweet corn (corn-on-the-cob)	0.1 (*)	--	Source of data: mancozeb
Tomato	5	TBD	Source of data: mancozeb, maneb, metiram, propineb
Watermelon	1	Revoke	Source of data: mancozeb, maneb
Wheat	1	--	Source of data: mancozeb, maneb, metiram

(*continued; footnotes follow*)

Codex		Reassessed U.S. Ziram Tolerance, ppm	Codex Comments
Commodity, As Defined	MRL [2] (mg/kg CS_2)		
Wheat straw and fodder, dry	25	--	Source of data: mancozeb, maneb, metiram
Winter squash	0.1	Revoke	Source of data: mancozeb

[1] Plant and animal commodities, maximum residue limits (MRLs), and source of data for residues of dithiocarbamates and ethylene thiourea (ETU) were obtained from a search conducted on 2/9/00 of the FAO STAT Database, Codex Alimentarius Pesticide Residues in Food (http://apps1.fao.org/servlet/org.fao.waicent.codex.PesticideServlet).

[2] All MRLs are at CXL step. An asterisk (*) signifies that the MRL was established at or about the limit of detection.

[3] Shaded rows indicate that one of the sources of data for the Codex MRL was ziram.

DIETARY EXPOSURE ASSESSMENT

The referenced 01/16/02 memo of T. Morton (Revised Anticipated Residue, Acute Chronic, and Cancer Dietary Exposure and Risk Analyses for the HED Human Health Risk Assessment.), summarizes estimated dietary exposure for ziram. In brief, estimated acute dietary exposure is above HED's level of concern for All Infants, Children (1-6 yrs), and females 13-50 years at the 99.9 th percentile, estimated chronic dietary risk is below HED's level of concern and estimated cancer risk is above HED's level of concern. The dietary exposure estimates used for the assessment are from RAC residue data from the ziram field trial data (together with % crop treated estimates and appropriate processing and reduction factors). Inclusion of a .15X reduction factor (i.e. 85% degradation of ziram residues) reflecting translation of data available from a peach washing/processing study (see 7/24/01 memo of G. Otakie) to other fruits and vegetable except berries and nuts significantly reduces the estimated ziram dietary exposure.

In addition to processing/washing, additional degradation of ziram residues from harvest to market appears likely. Environmental fate parameters for ziram include the following half life data:

Hydrolysis pH 5, pH 7, pH 9	10 min, 17.7 hours,6.31 days
Photolysis in water	8.7 hours
" In soil	8.9 hours in exposed sample
In dark soil control	16.2 hours
Soil Metabolism-Aerobic	1.75 days
Soils Metabolism Anaerobic	14.1 days
Terrestrial Dissipation in soil surface layer	6.7 days in NC sand and 5.2 days in CA sandy loam

Accordingly, additional ziram degradation in cold storage would likely occur and any future ziram processing studies should include data on dissipation from typical cold storage intervals.

The PDP data collection program also includes washing of the fruit as part of the protocol, however ziram residue data from the PDP program are not available. Since ziram is used as a late season fungicide and plant metabolism studies confirm that a majority of residues are surface residues it appears that a significant reduction in RAC residue levels are likely to occur from harvest to human consumption. The environmental fate profile also indicates that ziram is not expected to persistent in the environment. Additional food processing studies representing current commercial procedures and including dissipation from representative cold storage intervals on apples, pears, grapes, nectarines, blueberries, and tomatoes are needed so a more accurate estimate of reduction of ziram residues from processing procedures can be included in the dietary exposure assessment.

Furthermore, there are some limited RAC residue data available from the FDA Pesticide Monitoring

Program, reported as "EBDC, identity unknown." The analytical method used which includes conversion to and analysis of CS_2 residues would have also detected ziram residues as well as EBDC's, thiram etc., which include the dithiocarbamate chemical structure. Sample residue levels above the tolerance level would be confirmed for EBDC by conversion to ETU. In the absence of any other actual ziram residue data, these data should be noted since they do represent a potential worst case estimate of potential ziram residues in commerce for the period from 1992-1999. The primary objective of FDA's regulatory monitoring is the enforcement of pesticide tolerances in foods moving in interstate commerce. FDA officials make it clear that this program is not designed to resemble a probability-based sample of foods in interstate commerce and that the monitoring data are not designed for use in risk assessment.

Note these residues reported by FDA could have occurred from any of the dithiocarbamate fungicides and as such are possibly an over estimate of ziram residues. Furthermore, these FDA data do not include a sufficient number of samples to satisfy current HED SOPs for use of Anticipated Residues in Dietary Exposure Assessment (e.g. which require a minimum of 100 samples, geographically representative, etc.). Only FDA data from the United States for the three commodities with the largest number of samples (note: the other U.S. residue data for commodities included in the ziram dietary exposure assessment consisted of less than 100 samples) are summarized below. The limit of detection for the FDA residue data was approximately 0.006 ppm and samples were 20 pound composites.

For apples there were 11 negative samples from 1992, 21 samples from 1993 (20 negative and one at 1.92 ppm), 1 negative sample from 1994, 17 samples from 1995 (16 negative and 1 at 0.41 ppm), 9 negative samples from 1995, 13 samples from 1996 (11 negative, 1 at 0.2 and 1 at 0.38 ppm), and 11 samples from 1997 (7 negative and 4 ranging from 0.4-0.58 ppm). In brief, there were a total of 83 samples including 75 with no detectable residues (i.e. 90.4%) and 8 with residues from 0.2-0.58 ppm. The average/maximum percent crop treated estimate for ziram on apples is 14/25 %, respectively.

For peaches there was 1 negative sample from 1992, 2 negative samples from 1994, 36 negative samples from 1995, 3 negative samples from 1996, and 11 samples from 1997 (10 negative and 1 at 0.37 ppm).The average/maximum percent crop treated estimate for ziram on peaches is 10/20%, respectively. In brief, there were a total 53 peach samples including 52 with no detectable residues (i.e. 98.1%) and 1 with a residue of 0.37 ppm.

For tomatoes there was 1 negative sample from 1992, 10 samples from 1995 (nine negative and one at 0.31 ppm), 42 samples from 1996 (41 negative and one at 0.33 ppm), and 1 negative sample from 1997. The average/maximum percent crop treated estimate for ziram on tomatoes is 0/1%, respectively. In brief, there were a total of 58 tomato samples including 56 with no detectable residues (i.e. 96.6%) and two with residues of 0.31 and 0.33 ppm.

In conclusion, the peach washing/processing study, the environmental fate profile and the limited FDA monitoring data available when considered together do seem to indicate that ziram residue levels occurring in commerce are likely significantly lower than reported RAC field trial residues. Additional ziram processing studies accurately reflecting current commercial practices are needed to provide meaningful data on the fate of ziram in commerce and a basis to refine the current ziram dietary exposure estimates.

AGENCY MEMORANDA RELEVANT TO REREGISTRATION

CBRS No.:	10628
DP Barcode:	D182885
Subject:	Ziram (zinc dimethyldithiocarbamate). List B Reregistration Case No. 2180/Chemical ID No. 034805. Ziram Task Force Submission of an Apple Processing Study.
From:	C. Swartz
To:	K. Davis
Dated:	6/15/93
MRID(s):	42473601

CBRS No.:	15065
DP Barcode:	None
Subject:	Ziram (zinc dimethyldithiocarbamate). Chemical ID No. 034805. List B Reregistration Case No. 2180. Ziram Task Force Submission of 6(a)(2) data on Cherries.
From:	S. Hummel
To:	Files
Dated:	2/14/95
MRID(s):	43520901

CBRS No.:	13957
DP Barcode:	D205009
Subject:	Ziram (034805). Reregistration Case No. 2180. Additional Residue Field Trial Data on Apples, Peaches, and Apricots. Residue Data on Almond Hulls. Proposed Label Amendments.
From:	C. Eiden
To:	R. Kendall
Dated:	4/4/95
MRID(s):	43282501, 43282502, and 43282503

CBRS No.:	15121
DP Barcode:	D212368
Subject:	Ziram (034805). Reregistration Case No. 2180. Ziram Task Force Meeting Minutes for meeting of 1/12/95.
From:	S. Hummel
To:	R. Kendall/M. Wilhite
Dated:	4/4/95
MRID(s):	None

CBRS No.:	16197
DP Barcode:	D219292
Subject:	Ziram (034805). Reregistration Case No. 2180 (Dimethyl dithiocarbamates) Review of DCI
From:	S. Hummel
To:	R. Kendall
Dated:	9/25/95
MRID(s):	None

DP Barcodes:	D227396, D227397, D227402, and D227403
Subject:	ID# IN960001, KY960001, OH960004, PA960003 Section 24© Special Local Need Registration for Use of Ziram on Grapes in the States of Indiana, Kentucky, Ohio, and Pennsylvania.
From:	G. Herndon
To:	D. Morgan/J. Miller
Dated:	7/11/96
MRID(s):	None

DP Barcodes:	D261843 and D261845
Subject:	Ziram/Ferbam Plant and Animal Metabolism. Ad Hoc Metabolism Assessment Review Committee Meeting to be Held December 9, 1999.
From:	G. Otakie
To:	G. Kramer
Dated:	12/8/99
MRID(s):	None

DP Barcodes:	D261844 and D261846
Subject:	HED Metabolism Assessment Review Committee ad hoc Meeting of 12/09/99. Ziram/Ferbam Metabolism. Chemical Nos. 034805 and 034801.
From:	G. Otakie
To:	G. Kramer
Dated:	12/16/99
MRID(s):	None

DP Barcode:	D193238
Subject:	Ziram Reregistration. PC No. 03480. Case No. 2180. Nature of the Residue in Animals (Goat Metabolism).
From:	G. Otakie
To:	L. Parsons
Dated:	6/21/01
MRID(s):	42839201

DP Barcodes:	D210778 and D242544
Subject:	Ziram Reregistration. PC No. 03480. Case No. 2180. Nature of the Residue in Plants (Apple and Grape Metabolism Studies).
From:	G. Otakie
To:	L. Parsons
Dated:	7/26/01
MRID(s):	43500001 and 44451401

DP Barcode:	D224367
Subject:	Storage Stability in Apples for Both Ziram and Ferbam.
From:	G. Otakie
To:	L. Parsons
Dated:	6/21/01

MRID(s):	43949701

DP Barcode:	D217787
Subject:	Ziram: Magnitude in Almond Hulls/Apricots - Registrant's Proposed Change in Tolerance Levels.
From:	G. Otakie
To:	L. Parsons
Dated:	6/21/01
MRID(s):	None

DP Barcode:	D258972
Subject:	Magnitude of Ziram Residues in/on Tomatoes and Tomato Processed Commodities
From:	G. Otakie
To:	L. Parsons
Dated:	6/21/01
MRID(s):	44898601, 44898602, and 44898603

DP Barcode:	D276470
Subject:	Magnitude of Ziram Residues in/on Grapes and Processed Products
From:	G. Otakie
To:	L. Parsons
Dated:	7/26/01
MRID(s):	44914101, 44914102, and 44914103

DP Barcode:	D276038
Subject:	Peach Processing/Washing Study.
From:	G. Otakie
To:	L. Parsons
Dated:	7/26/01
MRID(s):	42839201

DP Barcode:	D2271210
Subject:	Ziram: Magnitude of Residue in Tomatoes.
From:	G. Otakie
To:	L. Parsons
Dated:	7/26/01
MRID(s):	45272901

DP Barcode:	D276471
Subject:	Review of Product Chemistry Blowbacks.
From:	G. Otakie
To:	L. Parsons
Dated:	7/26/01
MRID(s):	40962201, 42555401, 42601401, 42609001, 42614801 and 43736301.

DP Barcode:	D280195
Subject:	Revised Anticipated Residues, Acute Chronic, and Cancer Dietary Exposure and Risk Analyses for the HED Human Health Risk Assessment.
From:	T. Morton
To:	S. Diwan and P. Dobak
Dated:	1/16/02
MRID(s):	None

DP Barcode:	D279177
Subject:	Magnitude of the Residue of Ziram in/on Blueberries
From:	T. Morton
To:	P. Dobak
Dated:	1/17/02
MRID(s):	45512001 and 45534501

MASTER RECORD IDENTIFICATION NUMBERS

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