

US EPA ARCHIVE DOCUMENT

(22 NOV 1988)



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
WASHINGTON, D.C. 20460

23 NOV 1988

OFFICE OF  
PESTICIDES AND TOXIC SUBSTANCES

MEMORANDUM

SUBJECT: PP# 8F3654

Tilt<sup>R</sup> (Propiconazole) In Or On Peanuts And Peanut Hulls/  
Hay. Evaluation Of Analytical Methodology And Residue  
Data.

MRID No(s): 406922-01 - 406922-06

DEB No(s): 4108

FROM: H. Fonouni, Ph.D., Chemist *H. E. Fonouni*  
Dietary Exposure Branch  
Health Effects Division (TS-769)

THRU: Charles L. Trichilo, Ph.D., Chief *CT*  
Dietary Exposure Branch  
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TO: L. Rossi, PM 21  
Fungicide/Herbicide Branch  
Registration Division (TS-767)

and

Toxicology Branch  
Health Effects Division (TS-769)

The petitioner, Ciba-Geigy Corporation proposes establishment of tolerances for the residues of the fungicide 1-([2-(2,4-dichlorophenyl)-4-propyl-1,3-dioxolan-2-yl]methyl)-1H-1,2,4-triazole and its metabolites determined as 2,4-dichlorobenzoic acid and expressed as parent compound in or on the following agricultural commodities (proposed tolerances in ppm are given in parenthesis):

|                          |        |
|--------------------------|--------|
| Section 40 CFR 180.434 - |        |
| Peanuts                  | (0.20) |
| Peanut Hulls             | (1.0)  |
| Peanut Hay               | (20.0) |

Permanent tolerances, in ppm, currently established include pecan, and barley, rice, rye, and wheat grain (0.1 each), bananas (0.2), meat and fat (0.1, each), liver and kidney (0.2, each), meat by products (except liver and kidney, 0.1), milk (0.05), and eggs (0.1). Established tolerances in or on animal feeds include barley, rye and wheat straw (1.5 ppm, each), and rice straw (3.0 ppm). Currently pending tolerances, expressed in ppm, for other agricultural commodities include celery (5.0), corn forage and fodder (10.0, each), corn grain (0.1), pineapples and pineapple fodder (0.1), legume vegetables (0.5), and legume vegetable foliage (5.0).

### CONCLUSIONS

1. Adequate information has been provided on the nature and composition of the fungicide.
2. The petitioner should revise the label to include statements prohibiting aerial application and grazing of livestock in the treated areas.
- 3a. The nature of the residues in peanuts is adequately delineated. The residues of concern are the parent fungicide 1-([2-(2,4-dichlorophenyl)-4-propyl-1,3-dioxolan-2-yl]methyl)-1H-1,2,4-triazole and its metabolites which are determined as 2,4-dichlorobenzoic acid.
- 3b. Although the previously submitted metabolism data were found to be adequate in conjunction with previous petitions which led to a negligible dietary exposure of livestock to residues of the fungicide and its metabolites, the currently proposed applications would result in considerably higher exposure levels. The petitioner should, therefore, conduct a metabolism study in lactating cows or goats using phenyl labelled <sup>14</sup>C-CGA-64250 to determine the nature of metabolites present, and provide an adequate material balance.
- 4a. Analytical methodologies provided are adequate for determination of known residues of 1-([2-(2,4-dichlorophenyl)-4-propyl-1,3-dioxolan-2-yl]methyl)-1H-1,2,4-triazole and its metabolites in the subject commodities. However, recovery data need to be submitted for peanut hay.
- 4b. We can not presently address the adequacy of previously submitted methodology for livestock products, until results from the study requested in 3b is evaluated. Should the livestock metabolism study lead to the detection of any

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new metabolite(s) of toxicological concern, additional enforcement method(s) may be required.

- 5a. Adequate field residue data have been provided for the subject commodities and processed peanut fractions including soapstock, presscake, and crude/refined oils.
- 5b. Storage stability data should be provided for peanut hay. In addition, the petitioner should provide adequate explanation for the reported increase in residues of the fungicide/metabolites on nut meat which occurs as a result of storage.
- 5c. Although residue data on livestock products have been provided in conjunction with other petitions, until the results from the requested metabolism study, 3b, are evaluated DEB can not comment on the adequacy of available data.
- 6a. The petitioner has proposed tolerances of 0.20, 1.0, and 20.0 ppm for residues of 1-([2-(2,4-dichlorophenyl)-4-propyl-1,3-dioxolan-2-yl]methyl)-1H-1,2,4-triazole and its metabolites determined as 2,4-dichlorobenzoic acid in or on peanuts, peanut hulls, and hay, respectively. The proposed tolerances adequately cover the expected residues in or on the subject commodities. TOX considerations permitting, DEB would assent to establishing the proposed tolerances in or on peanuts and peanut hulls. However, the acceptability of the proposed tolerance in or on peanut hay is contingent upon submission of adequate recovery and storage stability data on the subject feed as requested in 4a and 5b, respectively. Since the maximum residues in or on peanut soapstock and presscake exceed the residues in comparable nut meat, DEB recommends feed additive tolerances of 0.40 ppm (each) be proposed for these processed commodities.
- 6b. We can not presently address the adequacy of established tolerances on meat, fat, liver, kidney, meat by products, and milk until the issues raised in 3b, 4b, and 5c are resolved.
7. An International Residue Limit Status form is included in the review. Since there is no Codex step 6 or above on the subject commodities, the compatibility issue is not relevant to the proposed tolerances. However, it should be noted that, the Agency's approach for determination of residues of propiconazole differs from that of Codex. While residues are determined and expressed as propiconazole by FAO/WHO, the Agency determines the combined residues of 1-([2-(2,4-dichlorophenyl)-4-propyl-1,3-

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dioxolan-2-yl)methyl)-1H-1,2,4-triazole and its metabolites containing 2,4-dichlorobenzoic acid and, expresses the residues as the parent fungicide.

#### RECOMMENDATIONS

As a result of aforementioned conclusions; 2, 3b, 4a, 4b, 5c, 6a, 5b, and 6b; we recommend against establishing the proposed tolerances on the subject commodities. It should be noted that, a labeling restriction prohibiting the feed use of peanut hay would eliminate the need for the ruminant metabolism study (3b), recovery data (4a), and storage stability data (5b).

#### DETAILED CONSIDERATIONS

##### Manufacture and Formulation

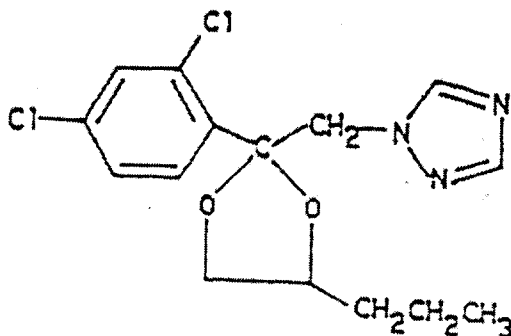
Adequate information has been provided on this topic in conjunction with pp# 1G2530 and pp# 4F3007 (memorandums of 1/7/1982 and 5/15/1984 by J. Worthington and A. Smith, respectively). Recently, additional information was reportedly provided on a proposed modification in the manufacturing process (MRID Nos. 405837-01 to 405837-03). However, review of this information is currently under the purview of the Registration Division. The formulated product, Tilt<sup>R</sup> 3.6E, containing 3.6 lbs ai/gallon is produced from a technical chemical having 88% active ingredient. The impurities present are not expected to result in a residue problem. The formulation has a composition of 41.8% active and 58.2% inert ingredients. The inert ingredients in the product have been cleared under Section 40 CFR 180.1001.

Chemical Name: 1-([2-(2,4-dichlorophenyl)-4-propyl-1,3-dioxolan-2-yl)methyl)-1H-1,2,4-triazole

Company Codes for the Active Ingredient: CGA-64250

Common Name: Propiconazole (Pending ISO)

Structural Formula:



Proposed Use

Tilt<sup>R</sup> fungicide is to be used for control of certain infections including late and early leaf spots. Late leaf spot (cercosporidium) in Al, Fl, GA and TX, and early leaf spot (cerco-spora) in VA, NC and OK are controlled, respectively, by applying 4 and 2.5 oz of the active ingredient in a minimum of 20 gallons of water per acre per application. The fungicide is to be applied by using ground equipments, 35-40 days after planting or on the appearance of the infection. The applications are to continue every 10-14 days and 14 days for late and early leaf spots, respectively. No more than four applications are permitted per season for control of late leaf spot where as upto six applications are permitted for early leaf spot. A preharvest interval (PHI) of 14 days has been proposed for peanuts. The green vines are not to be fed to livestock.

Comments:

The petitioner should revise the label to include statements prohibiting aerial application and grazing of livestock in the treated areas.

Nature of The Residues

## I. Plants

The metabolism of CGA-64250 has been studied in peanuts, wheat, and grapes (pp# 4F3007, memorandum of 5/15/1984 by A. Smith). A myriad of metabolites resulting from beta-oxidation of n-propyl side chain, reductive deketalization of dioxolane ring, and cleavage of the alkyl bridge between phenyl and triazole ring systems have been reported (Figure 1).

Comments:

DEB considers the nature of metabolism of CGA-64250 in peanuts adequately understood. The major known metabolites in peanut stalks are the parent, alkanol, and four beta-hydroxy compounds (cis/trans, D/L). These metabolites constitute 72-79% of the total radioactive residues (TRR) in the mature stalk of greenhouse grown peanuts. The data provided for peanut kernels are consistent with selective translocation of triazole containing metabolites to kernels. For example, the residues found in kernels were found to be 0.33 and 0.05 ppm, respectively, for triazole and phenyl labelled <sup>14</sup>C-CGA-64250 treated peanuts. The triazole containing metabolites including the aminoacid conjugate 1,2,4-triazole-1-alanine constituted 74%

of TRR in kernels. Analogous results have been observed in field grown peanuts.

## II. Animals

The metabolism of CGA-64250 in lactating goats and rats has been reported (pp# 4F3007, memorandum of 5/15/1984 by A. Smith). The major metabolites, analogous to the plant metabolism, arise from oxidation of the alkyl side chain, dioxolane ring opening, and cleavage of the alkyl bridge between the phenyl and triazole ring systems. A scheme representing the metabolism of CGA-64250 in goats is provided in Figure 2.

### Comments:

On evaluation of the information/data provided on metabolism of the fungicide in lactating goats, it was noted that the petitioner has accounted for less than 21% of the residues of toxicological concern in livestock commodities (tissue, milk) using triazole labelled  $^{14}\text{C}$ -CGA-64250 as well as phenyl and triazole labelled  $^{14}\text{C}$ -CGA-64251. The latter product is a homolog of the former containing an ethyl side chain instead of a propyl group (EPA Accession No. 072214). Although the submitted data were found to be adequate in conjunction with previous petitions which led to negligible dietary intakes of the fungicide and its metabolites by livestock, the current petition is expected to result in a maximum dietary intake of 16 ppm in cattle. This value, reflecting a worse-case exposure level, was calculated based on the established/pending tolerances for the fungicide/metabolites, and maximum contribution of various feed items to the cattle diet (Table II, Pesticide Assessment Guidelines, Subdivision O). The petitioner should conduct a metabolism study in lactating cows or goats using phenyl labelled  $^{14}\text{C}$ -CGA-64250 to determine the nature of metabolites present, and provide an adequate material balance. A revision of tolerance expression might be required, if new metabolites of toxicological concern are detected in animal commodities.

### Analytical Methodologies

#### I. Plants

The method provided, AG-454, is similar to method AG-454A which was submitted in conjunction with other petitions (pp# 4F3007, 4F3074, 4E3026; memorandum of 5/28/1987 by S. Malak). The latter method has undergone successful method trial by the Agency and is to be sent to FDA for publication in PAM II. Method AG-454 involves extraction of samples with concentrated ammonium

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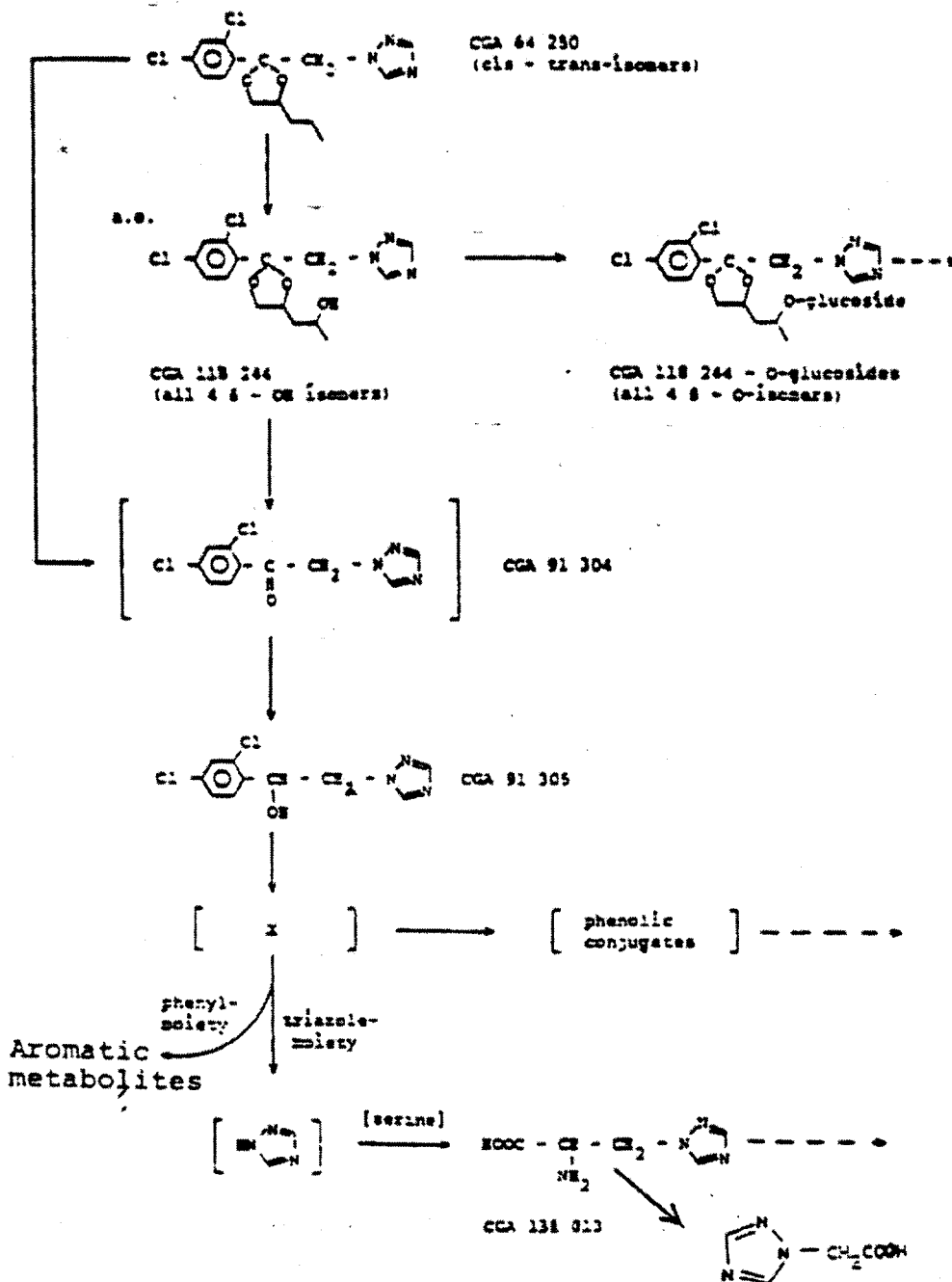


FIGURE 1. PROPOSED PATHWAYS FOR THE METABOLISM OF CGA-64250  
IN PLANTS INCLUDING PECANS

(Reproduced from pp# 4F3007)

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hydroxide/methanol (20%). After removing the solvent, the dried extract is dissolved in sodium hydroxide and oxidized using potassium permanganate. The latter step converts the fungicide and its metabolites containing the 2,4-dichlorophenyl moiety to 2,4-dichlorobenzoate. The mixture is acidified (HCl) and extracted with diethyl ether/hexane. After removing the solvent, the residue containing 2,4-dichlorobenzoic acid is esterified using diazomethane. The methyl ester is then purified by an acidic alumina Sep-pak<sup>R</sup> cartridge and analyzed by capillary gas chromatography using an electron capture detector.

Limit of Detection: 0.5 picograms (0.05 ppm).

Standard Curves:

Standard curves have been provided for various commodities.

Chromatograms:

Representative chromatograms have been provided for the standards, untreated controls, fortified, and treated samples of various commodities.

Recoveries:

The average recoveries for untreated samples of peanut commodities fortified with CGA-64250 are presented in Table I.

Table I. Average Recoveries For CGA-64250

| <u>Peanut Commodity</u> | <u>Average Recoveries<sup>1</sup></u> |
|-------------------------|---------------------------------------|
| Nut Meats               | 105 ± 15<br>N = 12                    |
| Foliage                 | 99 ± 14<br>N = 16                     |
| Hulls (Shells)          | 104 ± 13                              |

1. Average percent recoveries were obtained for fortifications of 0.05-0.50, 0.10-10.0, and 0.05-0.50 ppm for peanut nutmeat, foliage, and hulls, respectively.

In addition recovery data have been provided for various peanut fractions using method AG-454A. The values for peanut hulls, kernels, presscake (expelled), presscake (solvent extracted), crude oil (expelled), crude oil (solvent extracted), and soap stock were found to be 107, 93, 109, 86, 108, 124 and 107%, respectively. The combined average percent recovery for various fractions is 104 ± 25 (N = 11).

Method AG-454 has been validated by analysis of mature soybeans, soybean stalks and corn stalks treated with phenyl labelled

<sup>14</sup>C-CGA-64250. Percent recovery for soybeans, soybean stalks, and corn stalks were found to be 80, 81, and 115%, respectively.

Comments:

The petitioner should provide recovery data for peanut hay.

II. Animals

Although analytical methodology has been provided in conjunction with other petitions (pp# 4F3007, 4F3074, 4E3026; memorandum of 5/28/1987 by S. Malak), DEB can not presently address the adequacy of previously submitted methodology for livestock products until results from the study requested in section II, Nature of the Residues, is evaluated. Should the new metabolism study lead to the detection of any new metabolite(s) of toxicological concern, additional enforcement method(s) may be required.

Magnitude Of The Residues

I. Plants

Sample History:

Field studies were conducted in the major growing regions including AL, FL, GA, VA, OK, NC, and TX using a variety of peanuts typical to each region. Foliar applications were made using standard ground application techniques. The fungicide, Tilt<sup>R</sup> 3.6E, was generally applied at a rate of 50 or 100 g ai/A. The treatment began about 60-90 days after planting and continued periodically at 5-22 day intervals. A maximum of four applications were made. Chlorothalonil as well as the fungicide was applied to the plants. Following the harvest, the samples were frozen and shipped in dry ice to the petitioner. The collected samples were not trimmed or washed. Removal of surface dirt was accomplished by shaking the commodities. The samples were frozen at -15 degree C for 11-22 months prior to extraction. Samples were prepared according to the Pesticide Analytical Manual, Vol. 1, Section 141, and extracted within eight hours after removal from the freezer. The maximum lapse period between extraction and analysis was found by DEB to be four months.

Comments:

Since the maximum lapse period between extraction and analysis of some samples is about four months, the petitioner should provide information on conditions under which the extracted samples were stored.

Storage Stability:

The information/data provided on the storage stability of various peanut commodities are presented in Table II.

Table II. Storage Stability of CGA-64250 and Its Metabolite in Field Treated Peanuts.

| <u>Commodity</u> | <u>Residues (ppm)<sup>1</sup></u> |                      | <u>Percent Change</u> |
|------------------|-----------------------------------|----------------------|-----------------------|
|                  | <u>After Harvest</u>              | <u>After Storage</u> |                       |
| Nut Meat         | 0.15 (<0.05)                      | 0.50 (0.05)          | 333 (100)             |
| Shells           | 1.3 (0.23)                        | 1.3 (0.11)           | 100 (-48)             |
| Fodder           | 8.3 (0.15)                        | 8.1 (0.09)           | 98 (-60)              |

1. The treated commodities were analyzed after the harvest, and following storage at 5 degrees F for 25 months, they were reanalyzed. The values were obtained from an application rate of 0.155 lbs. ai/A. Values reported in parenthesis are for untreated controls. Analytical method AG-356 was utilized for analysis of the samples. The data were obtained from report No. ABR-83086.

In addition storage stability data have been provided for samples of commodities obtained from plants treated with higher application rates.

Comments:

1. The petitioner should provide adequate explanation for the reported increase (300%) in residues of the fungicide/metabolites in/on nut meat which occurs as a result of storage.
2. Storage stability data should be provided for peanut hay.

## Residue Data:

DEB has used the submitted data tabulating the detected residues versus preharvest intervals for each commodity, and has determined the maximum and average residues for the subject commodities; refer to Tables III-V. The results and conclusions are discussed below.

Table III. Residues of CGA-64250 and Its Metabolites in Peanut Nut Meats.

| PHI (D) | Residues (ppm) <sup>1, 2, 3</sup> |   |
|---------|-----------------------------------|---|
|         | Range                             | Average   |
| 5       | <0.05-0.06<br>(0.05)              | 0.06<br>(0.05)  |
| 7       | <0.05-0.07<br>(0.05-0.15)         | 0.07<br>(0.09)  |
| 13      | <0.05-0.10<br>(0.06-0.10)         | 0.06<br>(0.08)  |
| 14      | <0.05-0.07<br>(0.08)              | 0.06<br>(0.08)  |
| 20      | <0.05-0.08<br>(0.05-0.12)         | 0.06<br>(0.08)  |
| 21      | <0.05-0.08<br>(0.12)              | 0.06<br>(0.12)  |
| 22      | <0.05-0.07<br>(0.07)              | 0.06<br>(0.07)  |
| 5-22    | <0.05-0.10<br>(0.05-0.15)         | 0.06, N=36<br>(0.08, N=12)<br>0.07, N=48 <sup>4</sup> |

1. Values reported in parenthesis were obtained from plants which were treated with a total of 400 g ai/A (2X). The data have not been corrected for controls or recovery, and for the purpose of averaging, values reported as <0.05 were considered as 0.05. The value reported for untreated controls is <0.05 ppm.

2. Residue values were obtained from field studies conducted in the major peanut producing regions including AL, FL, GA, VA, NC, and OK.

3. Residue data were also obtained from field studies conducted in TX involving an application rate of 563 g ai/A, the values reported is 0.06 ppm. Additional data has been provided from field studies conducted in OK.

4. The value represents combined averages for the two application rates (1X and 2X).

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Table IV. Residues of CGA-64250 and Its Metabolites in Peanut Shells (Hulls).

| PHI (D) | Residues (ppm) <sup>1, 2, 3</sup> |   |
|---------|-----------------------------------|---|
|         | Range                             | Average   |
| 5       | 0.07-0.09<br>(0.10)               | 0.10<br>(0.10)  |
| 7       | 0.10-0.30<br>(0.17-0.33)          | 0.18<br>(0.25)  |
| 13      | 0.10-0.21<br>(0.20-0.35)          | 0.16<br>(0.28)  |
| 14      | 0.12-0.28<br>(0.14-0.31)          | 0.19<br>(0.22)  |
| 20      | 0.13-0.16<br>(0.21-0.48)          | 0.14<br>(0.34)  |
| 21      | 0.10-0.52<br>(0.24)               | 0.27<br>(0.24)  |
| 22      | 0.21-0.26<br>(0.26)               | 0.24<br>(0.26)  |
| 5-22    | 0.10-0.52<br>(0.14-0.48)          | 0.19, N=36<br>(0.25, N=12)<br>0.21, N=48 <sup>4</sup> |

1. Values reported in parenthesis were obtained from plants which were treated with a total of 400 g ai/A (2X). The data have not been corrected for controls or recovery. The values reported for untreated controls are <0.05-0.06 ppm.

2. Residue data were obtained from field studies conducted in the major peanut producing regions including AL, FL, GA, VA, NC, and OK.

3. Residue data were also obtained from field studies conducted in TX using an application rate of 563 g ai/A, the value reported is 0.13 ppm (PHI = 14). Additional data have been provided from field studies conducted in OK.

4. The value represents combined averages for the two application rates (1X and 2X).

Table V. Residues of CGA-64250 and Its Metabolites in Peanut Hay.

| PHI (D) | Residues (ppm) <sup>1, 2, 3</sup> |                             |
|---------|-----------------------------------|-----------------------------|
|         | Range                             | Average                     |
| 5       | 2.90-3.00<br>(15.00)              | 2.95<br>(15.00)             |
| 7       | 0.90-15.90<br>(1.70-24.50)        | 5.60<br>(11.37)             |
| 13      | 1.20-6.20<br>(3.60-14.40)         | 3.00<br>(9.00)              |
| 14      | 2.20-14.90<br>(3.60-32.40)        | 7.71<br>(18.00)             |
| 20      | 1.40-13.40<br>(3.50-7.70)         | 4.98<br>(5.60)              |
| 21      | 2.90-14.90<br>(21.40)             | 8.73<br>(21.40)             |
| 22      | 0.76-2.49<br>(1.50)               | 1.62<br>(1.50)              |
| 5-22    | 0.76-15.90<br>(1.50-32.40)        | 5.86, N=36<br>(11.43, N=12) |

1. Values reported in parenthesis were obtained from plants which were treated with a total of 400 g ai/A (2X). The data have not been corrected for controls or recovery. The value reported for untreated controls are <0.05-1.10 ppm.

2. Residue data were obtained from field studies conducted in the major peanut producing regions including AL, FL, GA, VA, NC, and OK.

In addition, residue data have been provided on processed commodities including peanut soapstock and presscake (Table VI).

Table VI. Residues of CGA-64250 and Its Metabolites in Peanut Processed Commodities.<sup>1</sup>

| Application Rate (g ai/A) | Maximum Soapstock Residues (ppm) | Maximum Presscake Residues (ppm) | Maximum Nut Meat Residues |
|---------------------------|----------------------------------|----------------------------------|---------------------------|
| 200                       | 0.10                             | 0.08                             | <0.05                     |
| 400                       | 0.15                             | 0.16                             | 0.10                      |
| 563                       | <0.05                            | <0.05                            | 0.06                      |
| 563 + (340)               | <0.05                            | 0.10                             | 0.11                      |
| 1126 + (680)              | 0.12                             | 0.25                             | 0.19                      |

(Footnotes Continued)

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(Footnotes Table VI)

1. The residue data were obtained from field studies conducted in OK and TX. The values in parenthesis are total 2.5% granular treatments applied post-directed over the top.

Residue data have also been provided for crude/refined oils. The maximum residues reported for application rates of 200, 400 and 563, 563 + 340, and 1126 + 680 g ai/A were found to be <0.05, 0.05, and 0.11 ppm, respectively.

Comments:

1. Considering the expected statistical variability of the field residue data, residues of CGA-64250 and its metabolites do not vary significantly with preharvest intervals of 5-22 days for peanut commodities. Further, the residues do not vary with application rates (1X or 2X) for peanut nutmeat and shells. However, higher residues were found in hay as a result of 2X application rate.
2. The maximum and average residues (shown in parenthesis) of CGA-64250 and its metabolites, expressed in ppm, in or on peanut nutmeat, hulls, and shells were found to be 0.15 (0.07, N=48), 0.52 (0.21, N=48), and 15.9 (5.86, N=36), respectively.
3. The Maximum residues found in soapstock and presscake exceed the corresponding residues in nut meat in some trials. However, the maximum residues observed in crude/refined oils do not indicate concentration of residues in this processed commodity.

II. Animals

Although residue data have been provided on residues of CGA-64250 and its metabolites in livestock commodities in conjunction with previous petitions (pp# 4F3074, memorandum of 7/12/1984 by A. Smith ; pp# 4F3007, 4F3074, and 4E3026 memorandum of 5/14/1987 by S. Malak), until the results from the metabolism study, Magnitude of the Residues, are evaluated DEB can not comment on the adequacy of available data.

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Other Considerations - Proposed Tolerances

## I. Plant Commodities

The maximum residues reported together with proposed tolerances for various raw agricultural commodities, and the residues for processed commodities along with the DEB recommended tolerances appear in Tables VII and VIII, respectively.

Table VII. Maximum Residues and Proposed Tolerances for CGA-64250 and Its Metabolites in or on Peanut Commodities.

| <u>Commodity</u> | <u>Maximum Residues (ppm)<sup>1</sup></u> | <u>Proposed Tolerances (ppm)</u> |
|------------------|---|----------------------------------|
| Peanuts          | 0.15                                      | 0.20                             |
| Peanut, Hulls    | 0.52                                      | 1.0                              |
| Peanut, Hay      | 15.90                                     | 20.0                             |

1. The residue data from the field studies indicate invariability of residues in various commodities with preharvest intervals of 5-22 days; refer to Magnitude Of The Residues. A preharvest interval of 14 days has been proposed for peanuts.

Table VIII. Maximum Residues and Recommended Tolerances for CGA-64250 and Its Metabolites in or on Nut Meat and Peanut Processed Commodities.

| <u>Processed Commodity</u> | <u>Maximum Residues (ppm)<sup>1</sup></u> | <u>Recommended Tolerances (ppm)</u> |
|----------------------------|---|-------------------------------------|
| Nut Meat                   | <0.05                                     | -                                   |
| Presscake                  | 0.08                                      | 0.40                                |
| Soapstock                  | 0.10                                      | 0.40                                |

1. The residue data from the IX study conducted in OK. Additional data have been provided for exaggerated application rates, refer to Table VI.

Comments:

The proposed tolerances adequately cover the expected residues in or on the subject commodities. TOX considerations permitting, DEB would assent to establishing the proposed tolerances in or on peanuts and peanut hulls. However, the acceptability of the proposed tolerance in or on peanut hay is contingent upon submission of adequate

recovery data on the subject feed item.

Since the maximum residues in or on peanut soapstock and presscake exceed the residues in comparable nut meat, DEB recommends feed additive tolerances of 0.40 ppm (each) be proposed for these processed commodities. However, no food additive tolerances are required for peanut crude/refined oils, refer to Magnitude The Of Residues.

## II. Livestock Commodities

The established tolerances, expressed in ppm, for meat/fat, liver/kidney, meat by products (except liver and kidney), and milk are 0.1, 0.2, 0.1, and 0.05, respectively. At this time, DEB can make no conclusion as to the adequacy of existing tolerances, until the deficiency raised, Nature Of The Residues, is resolved. Should the metabolism study lead to the detection of any new metabolite(s) of toxicological significance, additional residue data and enforcement methodology may be required.

cc: Reading File, Circulation, Reviewer (H. Fonouni), pp# 8F3654, TAS, ISB/PMSD (E. Eldredge), FDA.

TS - 769:DEB:Reviewer(HF):CM#2,Rm803:557-7561:typist(hf): 11/17/1988.

RDI:Section Head:JHOnley:11/18/1988:Branch Senior Scientist: RLoranger:11/22/1988.

INTERNATIONAL RESIDUE LIMIT STATUS

*J. Lues*  
*11/17/88*

CHEMICAL Tilt<sup>®</sup> (CGA-64250 (propiconazole))

CODEX NO. 160

CODEX STATUS:

No Codex Proposal  
Step 6 or above 4

PROPOSED U.S. TOLERANCES:

Petition No. BF 3654

RCB Reviewer H. Fournier

Residue (if Step 8): \_\_\_\_\_

Propiconazole per se

Residue: CGA-64250 and its metabolites determined as 2,4-dichloro-6-bromo-3-oxo-1,4-dihydro-1,2,4-triazin-5(1H)-one

| Crop(s)      | Limit (mg/kg) |
|--------------|---------------|
| peanut       | 0.05          |
| peanut whole | 0.1           |

| Crop(s)      | Limit (mg/kg) |
|--------------|---------------|
| peanuts      | 0.20          |
| peanut hulls | 1.0           |
| peanut hay   | 20.0          |

CANADIAN LIMITS:

No Canadian limit

Residue: \_\_\_\_\_

MEXICAN LIMITS:

No Mexican limit

Residue: \_\_\_\_\_

| Crop(s) | Limit (mg/kg) |
|---------|---------------|
|---------|---------------|

| Crop(s) | Limit (mg/kg) |
|---------|---------------|
|---------|---------------|

NOTES:

*Currently these are proposals at step 2*

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