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

MAR 9 1988

OFFICE OF  
PESTICIDES AND TOXIC SUBSTANCES

MEMORANDUM

SUBJECT: PP#7F3530: Imazalil In Or On Melons, Citrus and Sweet  
Corn. Evaluation of Analytical Methods and Residue  
Data. (MRID #401764-1, #402049-1, #402049-2; RCB #2524  
and #2740)

FROM: W. T. Chin, Chemist *W. T. Chin*  
Tolerance Petition Section III  
Residue Chemistry Branch  
Hazard Evaluation Division (TS-769)

THRU: Philip V. Errico, Section Head *JG for*  
Tolerance Petition Section III  
Residue Chemistry Branch  
Hazard Evaluation Division (TS-769)

TO: Henry M. Jacoby, PM #21  
Herbicide-Fungicide Branch  
Registration Division (TS-767)

and

Toxicology Branch  
Hazard Evaluation Division (TS-769)

The petitioner, Janssen Pharmaceutica, is proposing tolerances for fungicide imazalil, [1-[2-(2,4-dichlorophenyl)-2-(2-propenyloxy)-ethyl]-1H-imidazole], and its metabolite, [1-(2,4-dichlorophenyl)-2-(1H-imidazole-1-yl)ethanol] (T-824 or R-14821) in or on the following agricultural commodities:

1. Melons (whole at 5.0 ppm; pulp at 0.7 ppm)
2. Citrus (whole and peel at 10.0 ppm; pulp at 0.2 ppm)
3. Sweet corn (kernels and cobs, and forage at 0.05 ppm)
4. Liver of cattle, goats, hogs, horses and sheep at 1.5 ppm
5. Milk, meat, fat and meat by-products (except liver) of cattle, goats, hogs, horses and sheep at 0.02 ppm

ppm); milk, meat, fat and meat by-products (except liver) of cattle, goats, hogs, horses and sheep at 0.01 ppm; and liver of cattle, goats, hogs, horses and sheep at 0.5 ppm. A food additive tolerance for imazalil on citrus pulp (dried) at 25 ppm has been established under 21 CFR 561.429.

There are temporary tolerances for fruiting vegetables and cucurbit vegetables (PP#4G3017) and stone fruits (PP#6G3308) and a pending petition for pome fruits (PP#4F3096).

There is no Registration Standard for imazalil at this time.

### CONCLUSIONS

1. The petitioner is requested to submit a revised Section 8 with the following modifications or clarifications:
  - (a) Add the following restriction to both the Fungaflor® 500EC and Fungaflor® 68EC labels: "Treat melons with a single application only."
  - (b) In Exhibit #2 entitled "A Typical Protocol for Melon Test" (MRID #401764-01), only the "spray" procedure was given; nothing is mentioned about dip treatment. The petitioner should submit the protocol used for the dip treatment.
  - (c) Examples are needed of EPA approved "dyes" that may be used for sweet corn seed treatment on the label of Fecundal® 10EC.
  - (d) Restrict the temperature of treatment solutions to not more than 30°C.
  - (e) Submit updated Confidential Statements of Formula using EPA Form 8570-4 (Rev. 2-85) for both Fungaflor® 68EC and Fecundal® 10EC in which all inerts should be listed by their chemical names.
- 2a. The fate of imazalil in or on melons, sweet corn and citrus is adequately understood for purposes of post-harvest and seed treatment uses.
- 2b. RCB has tentatively concluded that the metabolism of imazalil in animals (excluding poultry) is adequately understood.
3. The methods submitted are considered adequate for residue analysis. However, for enforcement purposes, adequate methods for the determination of imazalil residues in/on melons and sweet corn need to be developed. Any proposed enforcement method must be subjected to a successful method trial by COB.

4. The petitioner should be advised that it is not necessary to propose a tolerance for residues of imazalil and its metabolite T-428 in or on "finisher pulp" of citrus fruit at 0.2 ppm as it is covered by the 10.0 ppm tolerance established under 40 CFR 180.413 for the raw agricultural commodity citrus fruit; and the residues in/on citrus pulp (dried) are covered by the 25 ppm tolerance established under 21 CFR 561.429.
5. RCB concludes that it would be appropriate to raise the tolerance in or on sweet corn (kernels and cobs, and forage) from the proposed 0.05 ppm to 0.2 ppm.
6. RCB has no objections to the proposed tolerances for imazalil and its metabolite T-428 in milk, meat, fat and meat by-products (except liver) of cattle, goats, hogs, horses and sheep at 0.02 ppm; and liver of cattle, goats, hogs, horses and sheep at 1.5 ppm. These proposals are RCB's recommendations suggested in connection with PP#4F3096 as indicated in W. T. Chin's 7/31/86, 9/2/86 and 10/1/87 memos.
7. The International Residue Limit Status sheet is attached. There are Codex limits of 5 ppm of the parent only on melons (except watermelons) and citrus fruits, and Canadian limit of 5 ppm of the parent on citrus fruit. Therefore, RCB cannot harmonize the U. S. and Codex and Canadian tolerances. RCB defers to TOX on this respect.

#### RECOMMENDATIONS

1. RCB recommends against the tolerances proposed for imazalil and its metabolite T-428 in or on melons (whole at 5.0 ppm; pulp at 0.7 ppm) because of the reasons identified in Conclusion 1.
2. RCB recommends against the tolerances proposed for imazalil and its metabolite T-428 in or on citrus (whole and peel at 10.0 ppm; pulp at 0.2 ppm) because of the reason identified in Conclusion 4.
3. RCB recommends against the tolerances proposed for imazalil and its metabolite T-428 in or on sweet corn (kernels and cobs, and forage at 0.05 ppm) because of the reason specified in Conclusion 5.
4. RCB recommends for the tolerances proposed for imazalil and its metabolite T-428 in milk, meat, fat and meat by-products (except liver) of cattle, goats, hogs, horses and sheep at 0.02 ppm and in liver of cattle, goats, hogs, horses and sheep at 1.5 ppm, because of the reason identified in Conclusion 6.

DETAILED CONSIDERATIONS

Manufacturing Process

The manufacturing process has been submitted and reviewed in detail in connections with PP#8E2100 (see M. Nelson's 3/12/79 memo) and PP#4G3017 (see L. Cheng's 8/13/84 memo). The specification for the technical product is stated to be >97.5% pure. RCB anticipates no residue problems from the low levels of impurities.

Formulations

There are three formulations recommended in this petition as summarized in Table 1:

Table 1. Formulations of Imazalil for the Current Petition

Formulation	EPA Reg. Number	a.i.% (w/w)	lb a.i. per gal	Proposed Use	
				Commodity	Application
Fungaflor® 500EC	43813-6	44.6	4.17	melons	dip/drench/wax
Fungaflor® 68EC	43813-1	68.0	6.77	melons	dip/drench/wax
Fecundal® 10EC	43813-3	10.0	0.86	sweet corn	seed treatment

On one of the three labels submitted, the terms "Fungaflor®" and "Fungaflor® 68EC" are used to specify the same formulation (EPA Reg. No. 43813-1). For consistency, the petitioner is advised to use only "Fungaflor® 68EC" on the label.

An adequate Confidential Statement of Formula for Fungaflor® 500EC was submitted in the amendment of 4/3/87 in connection with PP#4F 3096/4H5437. All of the inerts have been cleared for use under §180.1001.

However, the petitioner is requested to submit updated Confidential Statements of Formula using EPA Form 8570-4 (Rev. 2-85) for both Fungaflor® 68EC and Fecundal® 10EC in which all inerts should be listed by their chemical names.

Proposed Uses

Both Fungaflor® 500EC and Fungaflor® 68EC are proposed for post-harvest control of Fusarium, Diaporthe, Diplodia, Alternaria and Cladosporium on melons. Fecundal® 10EC is for control of seedborne Penicillium on sweet corn. The proposed dosages are summarized in Table 2.

Table 2. Proposed Dosages of Imazalil Formulations

Formulation	Commodity	Dosage
Fungaflor® 500EC	Melons	<u>In dips and drenchers:</u> 26.0 fl. oz./100 gal water (1,000 ppm ai)
		<u>In wax:</u> 51.1 fl. oz./100 gal melon wax (2,000 ppm ai)
Fungaflor® 68EC	Melons	<u>In dips and drenchers:</u> 16.0 fl. oz./100 gal water (1,000 ppm ai)
		<u>In wax:</u> 32.0 fl. oz./100 gal melon wax (2,000 ppm ai)
Fecundal® 10EC	Sweet corn	<u>For seed treatment:</u> 1.5 fl. oz./100 lbs seed (100 ppm ai)

The labels submitted also specify:

1. In Dips and Drenchers: Do not treat for over one minute. Dip or drench solutions should be maintained at room temperature during treatment. For best results, treat soon after harvest.
2. In Wax: Spray a sufficient amount of the diluted mixture to wet the melons, but do not spray in excess. After dilution of the formulations in wax, stir thoroughly for at least 15 minutes with an electric mixing device at 1,500 RPM.

3. Seed Treatment for Sweet Corn: For ready mix treaters, Fecundal® 10EC may be applied directly to the seed. For slurry treaters, Fecundal® 10EC may be diluted with water to insure adequate coverage. Do not use treated seed for food, feed or oil purposes. Do not graze or feed foliage from treated area of livestock. All seed treated with this product must be adequately dyed. Any dye added to treated seed must be cleared for use under 40 CFR 180.1001.

The petitioner is requested to submit a revised Section B with the following modifications or clarifications:

1. Add the following restriction to both the Fungaflor® 500EC and Fungaflor® 68EC labels: "Treat melons with a single application only".
2. Clarify the discrepancy: The labels for melon treatments, indicate that no wax will be involved during dip and drench treatments. However, Pennwalt's residue data (MRID #401764-1) indicate that both "dip" and "spray" treatments were conducted using the same mixture containing Deccozil : wax : water = 1 : 10 : 100 (v/v) (see Residue Data Section below).
3. In Exhibit #2 entitled "A Typical Protocol for Melon Test" (MRID #401764-01), only the "spray" procedure is given and nothing is mentioned about dip treatment. The petitioner should submit the protocol used for the dip treatment.
4. Examples are needed of EPA approved "dyes" for sweet corn seed treatment on the label of Fecundal® 10EC.

#### Nature of the Residue in Plants

No new plant metabolism studies are submitted in this petition. Degradation studies have been performed using tritium-labeled imazalil in bananas, citrus and barley seedlings, as briefed below:

#### In Banana

A metabolism study of H<sup>3</sup>-imazalil in banana plants was submitted and reviewed in detail in connection with PP#8E2100 (see M. Neson's 3/12/79 memo). Briefly: The majority of radioactivity applied to banana leaves remained on the upper leaf surface. Translocation was minimal. Approximately 75-85% of the activity was methanol extractable, 4-7%

was extractable by Soxhlet, and 7-17% was unextractable. The extractable radioactivity was divided between imazalil (15-20%) and its metabolite R-14821 (15-25%). The balance of the radioactivity was due to a large number of uncharacterized minor metabolites.

#### In Barley

A 3-week barley seedling test with H<sup>3</sup>-imazalil was submitted and reviewed in detail in connection with PP#2F2651 (see Bradley's 6/28/82 memo). Briefly: Barley seeds treated with H<sup>3</sup>-imazalil were germinated on agar in petri dishes or grown for three weeks in soil or perlite. Radioactivity was found in all parts of the seedlings with the highest concentration in seed coat and roots. Leafy parts contained smaller concentrations. The total radioactivity did not diminish between the first and third week. Imazalil (3-22%) and a small amount of T-428 were identified by TLC. Much of the radioactivity which was not extracted was considered to be "bound" residues. RCB has concluded that imazalil is translocated to the growing plant from the seed treatment use and that the parent compound is also metabolized to the R-14821 metabolite in plants.

#### In Oranges

Several studies on oranges with post-harvest dip treatments with imazalil formulations have been submitted and reviewed in detail in connections with PP#8G2082 (see Rathman's 1/18/79 memo) and PP# OF2331 (see Bradley's 8/4/80 memo). Briefly: Translocation of residue from peel to pulp occurred (20%) mainly when oranges are stored at room temperature for 14 weeks. When stored under normal storage conditions up to 12 weeks, the original concentration (ca. 2 ppm) remained in the orange peel (95%), and consisted chiefly of imazalil and its metabolite T-428. The metabolite increased from about 5 to 20% with corresponding decreases in the parent compound over the 12-week storage period. The petitioner has presented the metabolism pattern schematically as shown in Figure 1.

In all degradation studies, tritiated water was not found. A study also was conducted to show the stability and non-exchangeability of the H<sup>3</sup>-label. RCB has considered the fate of imazalil in citrus and in other plants to be essentially the same: (1) limited translocation or penetration of imazalil take place from the dermal layer; (2) imazalil and its metabolite T-428 are the major residues; and (3) with increased degradation and storage, conjugation and binding may take place.



## Nature of the Residue in Animals

### Goat

No new animal metabolism studies are submitted in this petition. A tritiated imazalil metabolism study in a lactating goat was submitted and reviewed in detail in connection with PP#OF2331 and its amendment (see L. Bradley's 8/4/80 and 4/21/82 memos). Briefly: One goat was medicated orally with 0.5 mg (ca. 80 ppm/day) twice a day for three and half days. Twenty-four hours after the last dose, the goat was sacrificed for analyses.

At the time of sacrifice, >96% of the total administered dose had been eliminated in urine (67%), feces (26%), milk (0.9%) and cage washings (3.8%). Radioactivity in milk plateaued after the third dose. Tissue levels were 0.03 ppm in fat and muscle, 0.26 ppm in kidneys and 1.36 ppm in liver. The basic metabolites identified in urine and feces are imazalil and the metabolite R-14821.

Identification of metabolites from liver homogenates showed 44% of radioactivity in M1 through M6 metabolites, 18% of the activity in 10 acidic compounds and 39% of the activity in 15 hydrophilic compounds. Tritiated water was less than 0.2%. The metabolism data in the goat and the tentative pathway for the degradation of imazalil are supported by studies performed for Econazole and Miconazole (antifungal drugs). The two drugs and imazalil share a common metabolite, T-428. The petitioner has submitted a metabolism pathway as shown by Figure 2.

The characterized residue in animals consists of the parent compound and five metabolites. The tolerance for animal tissues includes imazalil and its two imidazole-containing metabolites, T-428 and R42243. Toxicology Branch has concluded that additional characterization and/or regulation are not required. RCB has tentatively concluded that the metabolism of imazalil in animals (excluding poultry) is adequately understood.

### Analytical Methods

The following four methods are submitted in this petition:

1. A Gas-Liquid Chromatographic Method For Determining Total Regulable Residues of Imazalil in Citrus Fruit and Citrus By-products (Serial No. R-23-979/30, June/1982)

A method trial for this method has been successfully conducted for imazalil and T-428 in citrus fruit, citrus by-products, bovine tissue and milk in connection with PP#OF2331. Briefly: Imazalil



Imazalil and T-428 residues in samples are first acid (HCl) extracted, followed by neutralization with sodium hydroxide, and extraction into heptane - isoamyl alcohol. After derivatization to form the trimethylsilyl derivative, quantitation is done by a gas chromatograph equipped with an electron capture detector. The detectability of this method is 0.05 ppm for both imazalil and T-428.

2. Gas-Liquid Chromatographic Method For Determining Total Regulable Residues of Imazalil in Seeds, Foliage and Straw From Cereals and Cotton (Serial No. R-23-979/40, March/1983)

This method is essentially the same as the above method with minor modifications and was used for the determination of imazalil and T-428 residues to support the current petition for sweet corn. Although this method is considered adequate for generating residue data to support petitions, it is not adequate for enforcement purposes because untreated commodities are used as blanks for constructing standard curves (see §171-4(b)(5) of Pesticide Assessment Guidelines, 10/1/82). Therefore, the petitioner has to develop an adequate enforcement method.

3. Determination of Imazalil Residue On Melons (Method #432, Nov./85)

This is a new method used for generating residue data to support the current tolerance proposal for melons. Briefly: Imazalil residue is extracted by ethyl acetate from an alkaline (NaOH) sample of fruit slurry. The extract is partially purified and imazalil is quantitated directly by a GC equipped with an electron capture detector. The detectability of this method is 0.05 ppm. Recoveries of 84.1% and 101% were reported at 1.0 and 0.1 ppm fortifications, respectively. Samples of the calculations and chromatograms are adequate. RCB considers this method adequate for residue analysis of melon samples submitted in this petition.

4. Determination of Imazalil in Water and Wax (Method #509A)

This method is for routine analysis of imazalil in water and wax solutions. A known amount of sample solution is extracted with methanol. After filtration and evaporation to dryness, imazalil residue is dissolved in ethyl acetate and determined with a gas chromatograph equipped with an electron capture detector. RCB considers this method adequate to generate residue data for this petition. No method trial is needed for this method.

Storage Stability Study

No storage stability data were submitted in this petition. However, the storage stability data on bananas submitted as an amendment of 11/1/81 in connection with PP#8E2100 indicated that about the same

levels of imazalil residues were detected at the beginning and the end of a 19-day storage period (see M. Nelson's 4/29/82 memo). A tritium-labeled study on oranges (MRID #099287) indicated non-detectable levels of metabolite T-824 on a whole fruit basis after three weeks of storage. Likewise, a <sup>14</sup>C-labeled study on apples (MRID #261892) indicated that detectable residues of metabolite T824 at 0.05 ppm level did not become apparent until after four months of controlled temperature storage. Since the shelf-life of melons from time of harvest is approximately two weeks, RCB expects no significant changes of imazalil during the two weeks shelf time for melons.

Residue Data for Melons

A report entitled "Use of Deccoziil-EC-289 On Melons (PP#4G3017, EPA Reg. No. 2792-EUP-1" (MRID #401764-01) was submitted by the Pennwalt Corp. Deccoziil-EC289 containing 22.2% Imazalil was used for three field tests in 1985 season in Texas and California and six tests in 1986 in Texas, Arizona, South Carolina and California. According to Exhibit #2 entitled "A Typical Protocol for Melon Test" submitted in the current final report, a well mixed solution of Deccoziil : wax : water = 1 : 10 : 100 (v/v) was used as a spray on cleaned melons with standard or routine procedures at room temperature. Residue data submitted on treated melons are summarized in Tables 3 and 4 below:

Table 3. Imazalil Residue In/On Treated Melons (By spray)

Test No.	a.i. in Tank (ppm)	Imazalil Residue (ppm)		
		Peel	Pulp	Total*
86-1	1953	1.73	0.19	0.58
		1.63	0.42	0.73
		1.48	0.30	0.56
		2.07	0.23	0.71
86-2	2515	8.72	0.15	2.06
		8.57	0.15	2.16
		5.99	0.23	1.76
		7.74	0.67	2.34
86-3	1928	1.72	0.26	0.09
		1.25	0.08	0.37
		1.39	0.05	0.38
		1.05	0.08	0.32
86-4	1205	6.85	0.23	1.70
		6.52	0.23	1.70
		1.24	0.10	0.39
		1.88	0.08	0.47
86-5	2180	2.69	0.04	0.72
		2.67	0.12	0.76
		0.21	0.03	0.07
		0.37	0.00	0.09

Table 4. Imazalil Residue In/On Treated Melons (By dip and spray)

Test No.	a.i. in Tank (ppm)	Imazalil Residue (ppm)		
		Peel	Pulp	Total*
86-7	2,000 (spray)	2.82	----	0.85
86-8	2,000 (spray)	0.54	0.04	0.17
		1.38	0.04	0.34
86-9	2,000 (dip)	15.87	1.07	5.49
		17.48	0.31	4.64
86-10	2,000 (dip)	34.30	1.90	7.70
		19.20	0.60	4.70
		23.90	0.90	6.20
86-10A	1,000 (dip)	12.50	0.10	2.50
		9.50	0.00	2.40
	2,000 (dip)	12.10	0.00	2.70
		16.70	0.05	3.90

The residue data shown in Tables 3 and 4 reflect the proposed use of Fungaflor® 500EC and Fungaflor® 68EC on melons in wax treatment at room temperature as proposed. Most imazalil residue is concentrated on melon peel. The total imazalil residue levels are less than the proposed tolerance, 10 ppm.

Another two reports entitled "Residues of Imazalil and Metabolite T-824 on Melons Following Post-harvest Application" were submitted by Janssen Pharmaceutica in this petition. Fungaflor® 500EC was used for dip and spray tests using cantaloupes, muskmelons and honeydew at 1,000 to 2,000 ppm with treating solutions maintained at 22°C and 57°C. Results are summarized in Tables 5 and 6 below:

Table 5. Residues of Imazalil and Metabolite T-824 In/On Melons (one minute dip at room temperature)

a.i. (ppm)	Temp. (°C)	Residue Determined (ppm)	
		Imazalil	T-824
1,000	57	15.41	ND
	57	18.97	--
1,500	57	0.85	<0.05
	22	0.44	<0.05
2,000	22	0.62	<0.05
	57	1.15	<0.05

Table 6. Residues of Imazalil and Metabolite T-824 In/On Melons

Melon	a.i. in Tank (ppm)	Imazalil			T-824 (ppm)		
		Peel	Pulp	Whole	Peel	Pulp	Whole
Cantaloupe (Cal.) (22°C)	500 (spray)	2.50	0.06	0.85	0.30	ND	0.11
	500 (dip)	9.19	0.06	2.73	0.23	ND	0.08
	1,000 (spray)	6.15	ND	1.71	0.17	ND	0.06
	1,000 (dip)	14.18	0.08	4.35	0.37	ND	0.12
	2,000 (spray)	14.96	0.09	3.57	0.26	ND	0.07
	2,000 (dip)	28.98	0.11	7.78	0.59	ND	0.16
Cantaloupe (Texas) (57°C)	1,000 (dip)	71.3	1.66	23.5	0.63	0.05	0.23
	2,000 (dip)	80.8	2.16	24.4	0.71	0.07	0.25
	1,000 (dip)*	18.5	0.35	6.77	0.61	0.07	0.26
Honeydew (Texas) (57°C)	1,000 (dip)*	7.10	0.15	2.33	0.09	ND	0.03

\* Five minutes dip, all other dips were one minute.

The residue data presented in Table 5 do not reflect the proposed use of Fungaflor® 500EC and Fungaflor® 68EC on melons in dip treatment as indicated on the proposed label. The label indicates that no wax should be added to the solutions. However, the residue data shown in Table 5 were generated from a mixture of DeccoZil : wax : water = 1 : 10 : 100 (v/v). If the petitioner intends to use this treating solution, it should be stated on the proposed labels.

Data shown in Tables 5 and 6 indicate again that higher residue levels were concentrated on melon peel. Melons treated with solutions maintained at room temperature (25°C) as proposed have a total residue less than 10 ppm, the proposed tolerance. However, melons treated with solutions at 57°C resulted in significantly higher residues. Therefore, the petitioner is requested to restrict the temperature of the treatment solutions to not more than 30°C. This should be specified on the revised Section B.

#### Residue Data for Citrus Fruit

No residue data are submitted in this petition to support the proposed tolerances for citrus fruit (whole and peel at 10.0 ppm and pulp at 0.2 ppm).

Under 40 CFR 180.413, tolerances have been established for imazalil and its metabolite R-14821 on citrus fruit at 10.0 ppm for post-harvest use only. The petitioner claims in Section G that "citrus

peel is a processed commodity of citrus used in marmalade and as a condiment in drinks. The dietary intake of imazalil is grossly overstated based on a whole fruit tolerance of 10.0 ppm. Metabolism, autoradiography and field study data clearly indicate markedly higher residues of imazalil and metabolite T-824 on the peel vs pulp. Dietary intake of imazalil on citrus should be calculated separately for peel and pulp based on appropriate food factors for each."

The term "pulp" used in the petitioner's above statement appears to mean "finisher pulp". For post-harvest treatment, residues mainly concentrated on fruit skin rather than in finisher pulp. The above statement is supported by the residue data submitted in connection with PP#OF2331/OH5254, as shown in Table 7.

Table 7. Imazalil Residues (ppm) in Treated Oranges and Lemons

Processing By-products	Orange		Lemon	
	X	2X	X	2X
Whole Fruit	1.30	3.50	0.76	2.11
SS Juice	0.04	0.10	0.10	0.31
Conc. Juice	-	-	0.61	1.54
Oil	6.30	15.70	0.47	1.73
Dried pulp & Peel	3.80	6.20	4.00	11.12
Finisher Pulp	0.05	0.10	0.09	0.40

However, the petitioner should be advised that it is not necessary to propose a tolerance for imazalil and its metabolite R-14821 in or on "finisher pulp" of citrus fruit at 0.2 ppm because it is covered by the 10.0 ppm tolerance established under 40 CFR 180.413 for the raw agricultural commodity citrus fruit; and the residues in/on citrus pulp (dried) are covered by the 25 ppm tolerance established under 21 CFR 561.429.

Residue Data for Sweet Corn

A report entitled "Residues of Imazalil and Metabolite T-824 on Sweet Corn Following Seed Treatment Application" was submitted with this petition. Fecundal® 10EC and FLO-PRO-INZ (flowable formulation from Gustafson Inc.) were evaluated as seed treatment on sweet corn at 1X (100 ppm), 2X and 4X levels in Florida, Minnesota, New Jersey and Idaho. Residue analysis of the raw agricultural commodities sweet corn (kernels on the cobs), forage (leaves and stalks) and cannery-waste (husks) were performed for both imazalil and metabolite T-824. Sampling time for leaves and stalks were between 40-46 days and at plant maturity.

Residue data submitted indicate that imazalil and metabolite T-824 are not detectable in all samples, except in the following two cases:

1. Sample F1165N (NJ), 1X, 0.10 ppm of imazalil was determined in/on sweet corn ears.
2. Sample F1144N (Idaho), 1X, 0.12 ppm of imazalil was determined in/on sweet corn husks.

RCB concludes that it would be appropriate to raise the tolerance in or on sweet corn (kernels and cobs, and forage) from the proposed 0.05 ppm to 0.2 ppm.

The cattle feed items are sweet corn and sweet corn forage. The tolerances proposed in this petition in meat, milk and liver which cover secondary residues resulting from the seed treatment are adequate for the proposed use on sweet corn.

#### Meat, Milk, Poultry and eggs

No residue data are submitted to support the proposed tolerances of imazalil in milk, meat, fat and meat by-products (except liver) of cattle, goats, hogs, horses and sheep at 0.02 ppm; and liver of cattle, goats, hogs, horses and sheep at 1.5 ppm. However, RCB has no objections to these proposals, as these proposals are RCB's recommendations suggested in connection with PP#4F3096 (see W. T. Chin's 7/31/86, 9/2/86 and 10/1/87 memos). This request should not have been proposed because it has already been covered by PP#4F3096.

#### Other Considerations The International

A Residue Limit Status sheet is attached. There are Codex limits of 5 ppm of the parent only on melons (except watermelons) and citrus fruits, and Canadian limit of 5 ppm of the parent on citrus fruit. Therefore, RCB cannot harmonize the U. S. and Codex and Canadian tolerances.

Attachments: International Residue Limit Status sheet

cc: R.F., S.F., circu., PM#21, PP#7F3530, W.T.Chin, TOX, EAB, EEP and PMSD-ISB.

RDI: P.V.Errico(3/4/88): R.D.Schmitt(3/4/88)  
TS-769: RCB: CM#2: RM812:557-4352: W.T.Chin,wc(3/4/88)

INTERNATIONAL RES. DUE LIMIT STATUS

CHEMICAL Imazalil

*J. Area*  
*10/24/87*

CODEX NO. 110

CODEX STATUS:

No Codex Proposal  
Step 6 or above

PROPOSED U.S. TOLERANCES:

Petition No. PP# 7 F3530

RCB Reviewer W. T. Chin

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

Residue: Imazalil + its metabolites T84

Imazalil

\_\_\_\_\_

<u>Crop(s)</u>	<u>Limit (mg/kg)</u>
Melons (except watermelons)	5
Citrus fruits	5

<u>Crop(s)</u>	<u>Limit (mg/kg)</u>
Melons (Whole)	5.0
Melons (pulp)	0.7
Sweet Corn (Ears and Cobs)	0.05
Sweet Corn Forage	0.05
Citrus (Whole)	10
Citrus (peel)	10
Citrus (pulp)	0.2
Milk, meat, fat + meat byproducts (except liver) of Cattle, goats, hogs, sheep and horses	0.02
Livers of Cattle, goats, hogs, horses + sheep	1.5

CANADIAN LIMITS:

No Canadian limit

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

Imazalil

MEXICAN LIMITS:

No Mexican limit

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

<u>Crop(s)</u>	<u>Limit (mg/kg)</u>
Citrus fruit	5

<u>Crop(s)</u>	<u>Limit (mg/kg)</u>
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NOTES:



13544



R132071

**Chemical:** Imazalil

**PC Code:**  
111901

**HED File Code:** 13000 Tox Reviews

**Memo Date:** 3/9/1988

**File ID:** 00000000

**Accession #:** 000-00-0108

**HED Records Reference Center**  
8/29/2006

