



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

OFFICE OF  
PREVENTION, PESTICIDES AND  
TOXIC SUBSTANCES

**MEMORANDUM**

DATE: 1-MAR-2006

SUBJECT: ID# 06TX03. **Section 18 Specific Exemption for the Use of Triflumizole on Parsley, Dandelion, Swiss Chard, Collards, Kale, Kohlrabi, Mustard Greens, Chinese Napa Cabbage, Broccoli, Cilantro, and Turnip Greens in Texas.**  
DP#: 324956. Decision#: 363356. Chemical #: 128879. Trade Name: Procure® 50WS. 40 CFR §180.476. EPA Reg#: 400-431.

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**INTRODUCTION**

In accordance with 40 CFR 166.20, the Texas Department of Agriculture (TDA) proposes a Section 18 Specific Emergency Exemption for the use of triflumizole on parsley, dandelion, Swiss chard, collards, kale, kohlrabi, mustard greens, Chinese Napa cabbage, broccoli, cilantro, and turnip greens to control powdery mildew (*Erysiphe* spp.). This is the second year TDA has requested this Emergency Exemption. The proposed program will entail the application of approximately 2,418 pounds active ingredient (lb. a.i.; formulated as Procure 50WS) on a total of 6,450 acres of turnip greens (200 acres), broccoli (1000 acres), mustard greens (1800 acres), parsley (600 acres), dandelion (150 acres), Swiss chard (250 acres), kohlrabi (300 acres), Napa cabbage (150 acres), kale (500 acres), cilantro (300 acres), and collards (1,200 acres).

**NOTE:** Upon TDA’s request, HED recently reviewed Section 18 Emergency Exemptions for the use of triflumizole on parsley, dandelion, Swiss chard, collards, kale, kohlrabi, mustard greens, Napa cabbage, broccoli, cilantro (Memo, J. Tyler *et al.*; 1/28/05; D306463), and turnip greens (Memo, J. Tyler *et al.*; 5/26/05; D316789) to control Powdery Mildew. The following information from the HED risk assessment dated 1/28/05 can be applied directly to this action:

- Hazard Characterization (pp. 2-4).
- Toxicity Profile and Endpoint Selection summarized in Attachment 1 (p. 15-19).

The current risk assessment is warranted due the submission of new residue chemistry data and subsequent revision to the proposed time-limited tolerances on the aforementioned crops. This document contains only those aspects of the risk assessment which are affected by the change of tolerances.

**SUMMARY**

Triflumizole is an imidazole fungicide that inhibits ergosterol biosynthesis in fungi. Ergosterol is a sterol which is thought to function as a stabilizer for the membranes that make up the cell wall of fungi. Triflumizole is currently registered for use on apples, cherries, grapes, pears, strawberries, cucurbit vegetables, and filberts as well as ornamentals in greenhouses, shadehouses, nurseries (including Christmas tree/conifer plantations), and interiorscapes. There are currently no registered or proposed homeowner applicator uses. The proposed residential applications of triflumizole will be made by commercial applicators only.

**HED CONCLUSIONS/RECOMMENDATIONS**

**Provided the use directions for turnip greens is the same as the other proposed crops and the Section B is revised as specified below**, the toxicology, residue chemistry and occupational exposure databases are adequate to support the following time-limited tolerances for the combined residues of triflumizole and its metabolites containing the 4-chloro-2-trifluoromethylaniline moiety, calculated as the parent compound, in/on the following raw agricultural commodities (RACs):

Broccoli .....	1.0 ppm
Cabbage, Chinese, Napa .....	20 ppm
Collards .....	20 ppm
Coriander, leaves .....	20 ppm
Dandelion, leaves .....	7.0 ppm
Kale .....	20 ppm
Kohlrabi .....	20 ppm
Mustard, greens .....	20 ppm
Parsley, leaves .....	20 ppm
Swiss chard .....	7.0 ppm
Turnip, greens .....	20 ppm

**Section B should be amended to include the proposed use on turnip greens and a restriction against the use of triflumizole on dual purpose cultivars or varieties of turnip greens which produce a harvested root.**

## EXPOSURES AND RISKS

In examining aggregate exposure, the Food Quality Protection Act (FQPA) directs EPA to consider available information concerning exposures from pesticide residues in food and all other non-dietary, non-occupational exposures (*i.e.*, residential). The primary non-food sources of non-occupational exposure is drinking water (from both ground water and surface water). There are no uses that would result in residential exposure to children. In evaluating food exposures, EPA takes into account varying consumption patterns of major identifiable subgroups of consumers, including infants and children.

**Dietary Risks From Drinking Water:** The Environmental Fate and Effects Division (EFED) provided revised Tier 1 estimated drinking water concentrations (EDWCs) to include the degradates containing the 4-chloro-2-trifluoromethylaniline moiety (Memo, S. Ramasamy, 3/13/02). The EDWCs derived for total residues, namely parent and degradates containing the 4-chloro-2-trifluoromethyl aniline moiety, as Metabolism Assessment Review Committee (MARC) suggested, are based on certain assumptions in the absence of some fate studies for degradates (*i.e.*, mobility studies) and may be associated with uncertainties in the water assessment. Tier I models Screening Concentration in Ground Water (SCI-GROW) and FQPA Index Reservoir Screening Tool (FIRST) were used to derive the ground and surface water EDWCs, respectively. Application to cherries provided the highest exposure scenario (0.5 lb. a.i./A/application × 6 applications/year = 3.0 lb. a.i./A/year); therefore, the drinking water EDWCs were derived for cherries. The ground water EDWC was 0.12 ppb. The acute and chronic surface water EDWCs were 191 and 40 ppb, respectively.

**Dietary Risks from Food:** A triflumizole acute [separate assessment for general U.S. population (including infants and children) and females 13-49 years old] and chronic dietary exposure (general U.S. population and all population subgroups) assessments were conducted using the Dietary Exposure Evaluation Model - Food Commodity Intake Database™ (DEEM-FCID™; ver. 2.03) program which incorporates consumption data from USDA's Continuing Surveys of Food Intakes by Individuals (CSFII), 1994-1996 and 1998 (Memo, J. Tyler, D325681, 3/1/06). The 1994-96, 98 data are based on the reported consumption of more than 20,000 individuals over two non-consecutive survey days. Foods "as consumed" (*e.g.*, apple pie) are linked to EPA-defined food commodities (*e.g.* apples, peeled fruit - cooked; fresh or N/S; baked; or wheat flour - cooked; fresh or N/S, baked) using publicly available recipe translation files developed jointly by USDA/ARS and EPA. Consumption data are averaged for the entire U.S. population and within population subgroups for chronic exposure assessment, but are retained as individual consumption events for acute exposure assessment.

For chronic exposure and risk assessment, an estimate of the residue level in each food or food-form (*e.g.*, orange or orange juice) on the food commodity residue list is multiplied by the average daily consumption estimate for that food/food form. The resulting residue consumption estimate for each food/food form is summed with the residue consumption estimates for all other food/food forms on the commodity residue list to arrive at the total average estimated exposure. Exposure is expressed in mg/kg body weight/day and as a percent of the chronic population adjusted dose (cPAD). This procedure is performed for each population subgroup.

For acute exposure assessments, individual one-day food consumption data are used on an individual-by-individual basis. The reported consumption amounts of each food item can be multiplied by a residue point estimate and summed to obtain a total daily pesticide exposure for a deterministic (Tier 1 or Tier 2) exposure assessment, or “matched” in multiple random pairings with residue values and then summed in a probabilistic (Tier 3/4) assessment. The resulting distribution of exposures is expressed as a percentage of the acute population adjusted dose (aPAD) on both a user (*i.e.*, those who reported eating relevant commodities/food forms) and a per-capita (*i.e.*, those who reported eating the relevant commodities as well as those who did not) basis. In accordance with HED policy, per capita exposure and risk are reported for all tiers of analysis. However, for Tiers 1 and 2, significant differences in user vs. per capita exposure and risk are identified and noted in the risk assessment.

HED’s level of concern is when the exposure is greater than 100% of the PAD. That is, estimated exposures above this level are of concern, while estimated exposures at or below this level are not of concern. The DEEM-FCID™ analysis estimates the dietary exposure of the U.S. population and 26 population subgroups. The results reported in Table 1 are for the U.S. Population, all infants (<1 year old), children 1-2, children 3-5, children 6-12, youth 13-19, females 13-49, males 20-49, and adults 50+ years.

***Acute Dietary Exposure Estimates:*** Acute dietary exposure assessments were conducted for the general U.S. population (including infants and children) and females 13-49 years old using tolerance level residues and 100% crop treated (CT) information for all registered and proposed uses). Drinking water was incorporated directly in the dietary assessment using the acute (peak) concentration for surface water generated by the FIRST model. These assessments conclude that the acute dietary exposure estimates (95<sup>th</sup> percentile) are below HED’s level of concern (<100% aPAD) for the general U.S. population (9.3% aPAD) and all population subgroups (children 1-2 years old at 25% aPAD and females 13-49 years old at 17% aPAD).

***Chronic Dietary Exposure Estimates:*** A refined, chronic dietary exposure assessment was performed for the general U.S. population and various population subgroups using anticipated residues (ARs) from average field trial residues for apple, grape, pear, cherry, cucurbit, strawberry, and milk commodities; registered and proposed tolerance for all other commodities; % CT information for apples, grapes and pear commodities; and 100% CT information for all other uses). Drinking water was incorporated directly into the dietary assessment using the chronic (annual average) concentration for surface water generated by the FIRST model. This assessment concludes that the chronic dietary exposure estimates are below HED’s level of concern [<100% chronic Population Adjusted Dose (cPAD)] for the general U.S. population (17% cPAD) and all population subgroups. The most highly exposed population subgroup is children 1-2 years old at 31% cPAD.

Table 1. Summary of Dietary Exposure and Risk for Triflumizole.

Population Subgroup	Acute Dietary <sup>1</sup>		Chronic Dietary <sup>2</sup>	
	Dietary Exposure (mg/kg/day)	% aPAD	Dietary Exposure (mg/kg/day)	% cPAD
U.S. Population (total)	0.023178	9.3	0.002612	17
All Infants (< 1 year old)	0.052501	21	0.003613	24
Children 1-2 years old	<b>0.062221</b>	<b>25</b>	<b>0.004590</b>	<b>31</b>
Children 3-5 years old	0.044932	18	0.004345	29
Children 6-12 years old	0.024485	9.8	0.002715	18
Youth 13-19 years old	0.015096	6.0	0.002269	15
Adults 20-49 years old	0.016551	6.6	0.002236	15
Adults 50+ years old	0.017857	7.1	0.002747	18
Females 13-49 years old	<b>0.016984</b>	<b>17</b>	0.002194	15

1. Acute dietary endpoints of 0.25 mg/kg/day and 0.1 mg/kg/day applies to the general U.S. population (including infants and children) and females 13-49 years old, respectively.

2. Chronic dietary endpoint of 0.015 mg/kg/day applies to the general U.S. population and all population subgroups.

**Aggregate Risk Assessment:** Aggregate risk assessments were performed for acute and chronic aggregate exposure (food + drinking water). Short-, intermediate- and long-term aggregate risk assessments were not performed because, there are no registered or proposed residential uses for triflumizole. A cancer aggregate risk assessment was not performed because triflumizole is not carcinogenic. All potential exposure pathways were assessed in the aggregate risk assessment.

**Acute Aggregate Risk Assessment (Food and Drinking Water):** The acute aggregate risk assessment takes into account exposure estimates from dietary consumption of triflumizole (food and drinking water). The acute dietary exposure estimates are below HED's level of concern (<100% aPAD) at the 95<sup>th</sup> exposure percentile for the general U.S. population and all other population subgroups (see Table 1). Therefore, the acute aggregate risk associated with the proposed use of triflumizole does not exceed HED's level of concern for the general U.S. population or any population subgroups.

**Chronic Aggregate Risk Assessment (Food and Drinking Water):** The chronic aggregate risk assessment takes into account average exposure estimates from dietary consumption of triflumizole (food and drinking water). The chronic dietary exposure estimates are below HED's level of concern (<100% cPAD) for the general U.S. population and all population subgroups (see Table 1). Therefore, the chronic aggregate risk associated with the proposed use of triflumizole does not exceed HED's level of concern for the general U.S. population or any population subgroups.

**Occupational Exposure and Risk Assessment:** See Attachment 1 for a summary of the proposed use pattern. The label requires applicators and other handlers to wear long-sleeved shirt, long pants, shoes plus socks, and chemical-resistant gloves made of any waterproof material.

***Occupational Pesticide Handler Exposure:*** In this case, the most highly-exposed occupational pesticide handlers are likely to be a mixer loader using open pour of wettable powder and an applicator using open-cab groundboom equipment. Based upon the proposed use pattern, HED believes occupational pesticide handlers (*i.e.*, mixers, loaders, applicators) will have short-term (1-30 days) duration exposures. Intermediate-term exposures (1-6 months) are not expected. Treatment blocks are expected to be small in comparison to typical field crops such as corn, wheat, cotton or soybeans. Although multiple applications are possible, they are separated by 10-14 days. It is expected that private (*i.e.*, grower) applicators will treat the majority of acres needing treatment.

Private (*i.e.*, grower) applicators may perform all functions, that is, mix, load, and apply the material. The HED Science Advisory Council for Exposure (ExpoSAC) Standard Operating Procedure (SOP) Number 12 (29 March 2000) directs that although the same individual may perform all those tasks, they shall be assessed separately. "By separating the two job functions, (*i.e.*, mixing/loading from application) HED determines the most appropriate levels of personal protection equipment (PPE) for each aspect of the job without requiring an applicator to wear unnecessary PPE that may be required for mixer/loaders (*e.g.*, chemical-resistant gloves may only be necessary during the pouring of a liquid formulation)."

Chemical-specific data were not available with which to assess pesticide handler exposure. Therefore, surrogate data from studies in the Pesticide Handler Exposure Database (PHED) Version 1.1 (August 1998) SURROGATE EXPOSURE GUIDE were used to estimate mixer/loader and applicator exposure.

It is HED policy to assess handler exposure and risk using "baseline" PPE which is a single-layer of work clothing comprised of long-sleeved shirt, long pants, and shoes plus socks and to assess "baseline" **plus the use of protective gloves** or other PPE as might be necessary or appropriate. The Procure<sup>®</sup> 50WS label directs pesticide handlers to wear a long-sleeved shirt, long pants, chemical-resistant, waterproof gloves and shoes plus socks.

A margin of exposure (MOE)  $\geq 100$  is adequate to protect pesticide handlers. The MOE for inhalation and dermal routes of exposure are combined due to the same toxicological effect (*i.e.*, decreased body-weight gain in pups during lactation) being identified from the same multi-generation rat reproduction study. See Table 2 for a summary of estimated exposures and risks to occupational pesticide handlers.

**Table 2. Estimated Handler Exposure and Risk from the Use of Triflumizole on Leafy Green Vegetables.**

Unit Exposure <sup>1</sup> mg a.i./lb. handled	Application Rate <sup>2</sup> (lb. a.i./A)	Units Treated <sup>3</sup> Per Day	Average Daily Dose <sup>4</sup> (mg a.i./kg bw/day)	NOAEL <sup>5</sup> (mg a.i./kg bw/day)	MOE <sup>6</sup>
<i>Mixer/Loader - Wettable Powder - Open-pour</i>					
Dermal: No Glove 3.7 LC With Glove 0.17 MC Inhal. 0.043 MC	0.1875	200A	Dermal: No Glove 0.081 W Glove 0.0037 Inhal 0.0269	8.5	No Glove 79 W Glove 278
<i>Applicator - Ground-boom - Open Cab</i>					
Dermal: No Glove 0.014 HC With Glove 0.014 MC Inhal 0.00074 HC	0.1875	200 A	Dermal: No Glove 0.00031 W Glove 0.00031 Inhal 0.00046	8.5	No Glove 11,000 W Glove 11,039

1. Unit Exposures are taken from "PHED SURROGATE EXPOSURE GUIDE", Estimates of Worker Exposure from PHED Version 1.1, August 1998. Dermal = Single-layer Work Clothing **No Gloves**; Single-layer Work Clothing **With Gloves**; Inhal. = Inhalation. Units = mg a.i./pound of active ingredient handled. Data Confidence: LC = Low Confidence, MC = Medium Confidence, HC = High Confidence.
2. Applic. Rate. = Taken from the Texas Section 18 request.
3. Units Treated are taken from "Standard Values for Daily Acres Treated in Agriculture"; SOP No. 9.1. ExpoSAC: Revised 5 July 2000.
4. Average Daily Dose = Unit Exposure \* Applic. Rate \* Units Treated \* absorption factor (3.5 % dermal; 100 % inhalation ÷ Body Weight (60 kg since NOAELs are identified from a developmental study with fetal effects).
5. NOAEL = No Observable Adverse Effect Level (8.5 mg a.i./kg bw/day for short-term dermal and short-term inhalation)
6. MOE = Margin of Exposure = No Observable Adverse Effect Level (NOAEL) ÷ ADD. Short-term dermal and short-term inhalation exposures are summed and divided into the NOAEL. The dermal and inhalation endpoints are the same and identified from the same study and have the same NOAELs.

A MOE of 100 is adequate to protect occupational pesticide handlers from short-term exposures to triflumizole. Therefore, these exposures do not exceed HED's level of concern.

**Post-application Exposure to Agricultural Workers:** There is a potential for agricultural workers to experience post-application exposures to pesticides during the course of typical agricultural activities. HED in conjunction with the Agricultural Re-entry Task Force (ARTF) has identified a number of post-application agricultural activities that may occur. HED has also identified transfer coefficients (TCs) expressed as cm<sup>2</sup>/hr which describe the amount of foliar dislodgeable pesticide residue that is available to be transferred to agricultural workers during the course of post-application agricultural activities.

There were no chemical-specific data with which to estimate post-application exposures of agricultural workers to dislodgeable residues of triflumizole. Therefore, theoretical estimates of exposure, based on surrogate studies, have been conducted. The ExpoSAC (SOP 003.1, Rev. 7 Aug. 2000, Regarding Agricultural Transfer Coefficients; Amended ExpoSAC Meeting notes - 13 Sept 01) lists a number of possible post-application agricultural activities relative to leafy vegetables that result in pesticide exposure to agricultural workers.

The highest TC identified for collards and leafy green vegetables is 2,500 cm<sup>2</sup>/hr for hand harvesting. For this assessment, HED uses the 2,500 cm<sup>2</sup>/hr TC as a Tier I, screening level figure.

The TCs used in this assessment are from an interim TC procedure developed by HED's ExpoSAC using proprietary data from the ARTF database (SOP #3.1). It is the intention of HED's ExpoSAC that this procedure will be periodically updated to incorporate additional information about agricultural practices in crops and new data on TCs. Much of this information will originate from exposure studies currently being conducted by the ARTF, from further analysis of studies already submitted to the Agency, and from studies in the published scientific literature.

Post-application worker exposure is estimated using the HED procedure that assumes 20% of the application rate is available as dislodgeable foliar residue on the day of treatment. HED expects that post-application agricultural exposures to scouts (*i.e.*, crop advisors) or workers involved in irrigation would typically be short-term. The total number of acres treated per day is comparatively small and treatment is not expected to be necessary at the same time for all acres on a given farm, therefore scouting after treatment will occur in short-term periods of time.

$PDR_t = DFR_t * CF1 * Tc * ET$  where:

$PDR_t$  = potential dose rate on day "t" (mg/day)

$DFR_t$  = dislodgeable foliar residue on day "t" ( $\mu\text{g}/\text{cm}^2$ )

CF1 = weight unit conversion factor to convert  $\mu\text{g}$  units in DFR value to mg for the daily dose (0.001 mg/ $\mu\text{g}$ )

TC = transfer coefficient ( $\text{cm}^2/\text{hr}$ ) (In this case 2,500  $\text{cm}^2/\text{hr}$ ; ExpoSAC SOP 003.1 Rev. 7 Aug. 2000; amended 13 Sept 01 ExpoSAC meeting Notes).

ET = Exposure Time (hrs) (8)

and

$DFR_t = AR * F * (1-D)^t * CF2 * CF3$  where:

AR = Application rate (lb. a.i./A) (0.1875 lb. a.i./A)

F = fraction of a.i. retained on foliage (unitless)

D = fraction of residue that dissipates daily (unitless)

t = post-application day on which exposure is being assessed

CF2 = weight unit conversion factor to convert the lbs a.i. in the application rate to  $\mu\text{g}$  for the DFR value ( $4.54 \times 10^8 \mu\text{g}/\text{lb.}$ )

CF3 = Area unit conversion factor to convert the surface area units ( $\text{ft}^2$ ) in the application rate to  $\text{cm}^2$  for the DFR value ( $1.08 \times 10^3 \text{ ft}^2/\text{cm}^2$  or  $2.47 \times 10^8 \text{ acre}/\text{cm}^2$  if the application rate is per acre).

$$\therefore DFR = 0.1875 \text{ lb. a.i./A} * 0.20 * (1-0)^0 * 4.54 \times 10^8 \mu\text{g a.i./lb.} * 2.47 \times 10^8 \text{ A}/\text{cm}^2 = 0.42 \mu\text{g}/\text{cm}^2$$

$$PDR = 0.42 \mu\text{g}/\text{cm}^2 * 0.001 \text{ mg}/\mu\text{g} * 2,500 \text{ cm}^2/\text{hr} * 8 \text{ hr}/\text{day} = 8.4 \text{ mg a.i./day} * 3.5 \% \text{ dermal absorption} \div 60 \text{ kg bw} = 0.0049 \text{ mg a.i./kg bw/day}$$

$$MOE = \text{NOAEL} \div PDR$$

$$\therefore 8.5 \text{ mg a.i./kg bw/day} \div 0.0049 \text{ mg a.i./kg bw/day} = 1,734.$$

A MOE of 100 is adequate to protect agricultural workers from post-application exposure to triflumizole. Therefore, this use does not exceed HED's level of concern.

**OTHER CONSIDERATIONS**

**Residue Chemistry:** Triflumizole is an imidazole fungicide that inhibits ergosterol biosynthesis in fungi. Ergosterol is a sterol which is thought to function as a stabilizer for the membranes that make up the cell wall of fungi. Permanent tolerances are established under 40 CFR §180.476(a) for the combined residues of triflumizole and its metabolites containing the 4-chloro-2-trifluoromethylaniline moiety, calculated as the parent compound, in/on apples, cherries, grapes, pears, strawberries, and cucurbit vegetables. In addition permanent tolerances for livestock commodities have been established under 40 CFR §180.476(b) for the combined residues of triflumizole, the metabolite 4-chloro-2-hydroxy-6-trifluoromethylaniline sulfate, and other metabolites containing the 4-chloro-2-trifluoromethylaniline moiety, calculated as the parent compound, in/on milk; eggs; meat, fat, and meat byproducts (mbyp) of cattle, goats, hogs, horses, and sheep; and in/on meat, and mbyp of poultry. A time-limited tolerance in conjunction with a Section 18 Emergency Exemption has been established under 40 CFR §180.476(a) for the combined residues of triflumizole and its metabolites containing the 4-chloro-2-trifluoromethylaniline moiety, calculated as the parent compound, in/on filberts.

**Summary of Proposed Uses:** See Table 3 and Attachment 1 for a summary of the proposed use pattern. The proposed label includes the following plantback intervals (PBIs): no restriction for labeled crops, 30 days for leafy vegetables, and 60 days for root vegetables. Rotation to all other crops is prohibited.

**Table 3. Summary of Directions for Use of Triflumizole (EC).**

Application Timing, Type, and Equipment	Formulation	Max. Single Appl. Rate (lb. a.i./A)	Max. No. Appl. per Season	Max. Seasonal Appl. Rate (lb. a.i./A)	RTI <sup>1</sup> (days)	PHI <sup>2</sup> (days)
Broccoli, Cilantro, Collards, Dandelion, Kale, Kohlrabi, Mustard Greens, Chinese Napa Cabbage, Parsley, Swiss Chard in Texas						
Groundboom	Procure <sup>®</sup> 50 WS Fungicide	0.19	2	0.38	10-14	1

<sup>1</sup> RTI = retreatment interval.

<sup>2</sup> PHI = pre-harvest interval

**HED Conclusions:** The Section 18 label does not include the proposed turnip green use. **The Section B should be revised to include this use, as well as a restriction against the use of triflumizole on dual purpose cultivars or varieties of turnip greens which produce a harvested root. Provided these amendments are made, the application scenario is adequately described.**

**Nature of the Residue - Plants and Livestock:** The nature of the residue in fruit and fruiting vegetables is adequately understood based on acceptable metabolism data on apples, cucumbers, grapes, and pears. The results of metabolism studies were extensively discussed in connection with PP#5G3232 (Memo, N. Dodd, 7/3/85). HED concluded that the residues of concern in/on apples, pears, cucumbers and grapes include the parent compound, triflumizole and its metabolites (free and conjugates) containing the 4-chloro-2-trifluormethylaniline moiety (calculated as triflumizole). In a meeting on 2/26/02, HED MARC concluded that there was no need to revisit the residues of concern in primary crops (Memo, J. Tyler, 3/13/02; D280869). The MARC concurred with the current tolerance expression for plants as stated in 40 CFR §180.476.

There are no livestock feed items associated with the proposed uses; therefore, a discussion of potential transfer of secondary residues to livestock commodities is not relevant to the proposed uses.

**Storage Stability:** No storage stability data were submitted to support the current actions. Previously reviewed data indicate that triflumizole is stable for up to 10 months in frozen cucurbit vegetables (MRID 449713-01 thru -03; Memo, J. Tyler, 3/11/02; D271003) and strawberries (MRID 45375406; J. Tyler, 3/11/02; D274589) and up to ~12 months in frozen cherries (MRID 44438401; Memo, J. Tyler, 4/30/01; D242429) and apples and grapes (MRID 41131203; Memo, S. Malak, 1/25/90, DEB#s 5479 & 5480).

**Magnitude of the Residue - Plants:** TDA cited preliminary results of crop field trial studies performed on lettuce (head and leaf), Swiss chard, and mustard greens.

**Lettuce:** The Interregional Research Project No. 4 (IR-4) submitted the preliminary crop field trial data (field and greenhouse) on lettuce (head and leaf). Residues of triflumizole ranged from 2.0 ppm to 17 ppm in lettuce samples collected 0 days following a total of 4 applications at 0.25 lb. a.i./A/application [total application rate of 1.0 lb. a.i./A (~2.5x); 7-day RTI; 0-day PHI]. Residues were 4.6-11 ppm and 9.3-17 ppm in leaf lettuce field and greenhouse studies, respectively. Residues were 2.0-4.6 ppm in head lettuce. Preliminary residue decline data indicate that residue of triflumizole decline from 4.6 ppm at 0-day PHI to approximately 0.09 ppm at 14-day PHI.

**Swiss Chard:** IR-4 submitted the preliminary crop field trial data on Swiss chard. Residues of triflumizole ranged from 2.2 ppm to 9.2 ppm in Swiss chard (leaves and stems) samples collected 0 days following a total of 4 applications at 0.25 lb. a.i./A/application [total application rate of 1.0 lb. a.i./A (~2.5x); 7-day RTI; 0-day PHI].

**Mustard Greens:** TDA cited the results of a crop field trial study performed on mustard greens in several states in 2004. Residues of triflumizole were 1.36-17.9 ppm (average 6.83 ppm) in mustard green samples collected 1 day following the last of 4 applications at 0.25 lb. a.i./A/application [total application rate of 1.0 lb. a.i./A (~2.5x); 7-day RTI; 0-day PHI].

The available residue data show that residues of triflumizole are  $\leq 17.9$  ppm in lettuce (head and leaf), Swiss chard, and mustard greens when treated with a total of 1.0 lb. a.i./A/year (4 applications of 0.25 lb. a.i./A/application) with a RTI of 7 days and pre-harvest interval (PHI) of 1 day.

No residue data on broccoli were submitted with the current action. However, in support of a previous Section 18 Emergency Exemption request, HED has completed a preliminary review of a crop field trial study on broccoli (Memo, J. Tyler, 1/28/05; D306463; MRID# 46212403). Residues of triflumizole were 0.323 ppm, 0.864 ppm, and 0.926 ppm (average 0.704 ppm) in broccoli samples collected 1 day following the last of 5 applications of Procure<sup>®</sup> 50WS at 0.25 lb. a.i./A (total application rate of 2.5 lb. a.i./A (6.6x); 7-day RTI).

Residue data for mustard greens can be translated to turnip greens; however, the petitioner should add a restriction against the use of triflumizole on dual purpose cultivars or varieties which produce a harvested root.

Although the application rates made at 2.5-6.6x the proposed application rate, the submitted data are adequate and support time-limited tolerances for the combined residues of triflumizole and its metabolites containing the 4-chloro-2-trifluoromethylaniline moiety, calculated as the parent compound, in/on the following RACs: parsley, leaves at 20 ppm; dandelion, leaves at 10 ppm; Swiss chard at 10 ppm; collards at 20 ppm; kale at 20 ppm; kohlrabi at 20 ppm; mustard greens at 20 ppm; cabbage, Chinese, Napa at 20 ppm; broccoli at 1.0 ppm; and coriander, leaves at 20 ppm.

**Magnitude of the Residue - Processed Food and Feed:** As there are no processed commodities associated with the proposed uses, a processing study is not required to support the current action.

**Magnitude of the Residue - Livestock:** As there are no livestock feed items associated with the proposed uses, data on residues of triflumizole in livestock tissues, milk and eggs are not required to support the current actions.

**Magnitude of the Residue - Rotational Crops:** Results of confined and limited field rotational crop studies were reviewed in the HED memoranda dated 3/11/02 (Memo, J. Tyler; D274589). HED concluded that the following PBIs are appropriate: no restriction for labeled crops, 30 days for leafy vegetables, and 60 days for root vegetables. Because quantifiable residues were found in wheat commodities at the longest **adequate** PBI tested (120 days), rotation to wheat and all other crops is not permitted. As mentioned previously, the proposed Section 18 label includes the following PBIs: no restriction for labeled crops, 30 days for leafy vegetables, and 60 days for root vegetables. Rotation to all other crops is prohibited.

**Analytical Enforcement Method - Plants and Livestock:** A gas chromatography (GC)/nitrogen-phosphorus detector (NPD) method has been deemed acceptable as a tolerance enforcement method in conjunction with a petition for use on apples, grapes, and pears, and has been forwarded to FDA for inclusion in the Pesticide Analytical Manual (PAM), Volume II as Method I (G. Kramer, 12/16/94). For the purposes of this petition, HED concludes that the current enforcement method is appropriate for enforcement of the tolerance associated with this petition.

There are no livestock feed items associated with the proposed uses; therefore, data collection and tolerance enforcement methods for livestock commodities are not required for the establishment of a tolerance for triflumizole residues in/on the proposed uses.

**Multiresidue Methods:** The Food and Drug Administration (FDA) PESTDATA database (PAM Volume I, Appendix I, 3rd edition, 1994) indicates that triflumizole is completely recovered (>80%) by Multiresidue Protocol D (PAM I Sections 232.4).

## Attachment 1

<b>Crop Site</b>	broccoli, cilantro, collards, dandelion, kale, kohlrabi, mustard greens, Napa cabbage, parsley, Swiss chard and turnip greens in Texas
<b>Pest</b>	powdery mildew <i>Erysiphe polygoni</i>
<b>a.i.</b>	triflumizole [1-[1-(4-chloro-2-(trifluoromethyl)phenyl)imino]-2-propoxyethyl]-1H-imidazole]
<b>Formulation</b>	Procure <sup>®</sup> 50 WS Fungicide, EPA Reg. No. 400 - 431, 50 % a.i. powder.
<b>Application Method</b>	groundboom
<b>Application Rate</b>	0.19 lb. a.i./A
<b>Application Number</b>	2
<b>Application Maximum</b>	0.38 lb. a.i./A/yr.
<b>Application Interval</b>	10-14 days (do not apply more than 2 sequential applications)
<b>PHI</b>	1 day
<b>Maximum acres treated</b>	6,450 possible
<b>Maximum a.i. used</b>	2,418 lb. a.i. if 6,450 acres are treated two times at 0.19 lb. a.i./A
<b>Manufacturer</b>	Gowan Company
<b>Rotational Crop Restrictions</b>	Not specified
<b>Restrictions</b>	<ul style="list-style-type: none"> <li>• No more than two sequential applications without at least one intervening application of an alternative registered fungicide for powdery mildew control is allowed.</li> <li>• Applications through any type of irrigation system is prohibited.</li> </ul>



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R124633

**Chemical:** Triflumizole

**PC Code:**

128879

**HED File Code:** 14000 Risk Reviews

**Memo Date:** 3/1/2006

**File ID:** DPD324956

**Accession #:** 412-06-0013

**HED Records Reference Center**

3/30/2006