

developmental study based on maternal clinical signs and weight effects at the higher levels and an uncertainty factor of 100. The results of the acute dietary exposure analysis are below the EPA's level of concern.

#### RESULTS OF ACUTE DIETARY EXPOSURE ESTIMATES FOR CYMOXANIL

Population Group	99.9th Percentile of Exposure (mg/kg/day)	% aPAD
U.S. Population	0.001789	4.47
Non-Nursing (< 1 yr.)	0.000599	1.50
Children (1-6 yr.)	0.002096	5.24
Children (7- 12 yr.)	0.001936	4.84
Females (13+ nursing)	0.002287	5.72

b. *Chronic dietary exposure assessment.* The chronic dietary exposure assessment was estimated using the Dietary Exposure Evaluation Model (DEEM, Novigen Sciences, Inc., 1999 Version 6.74). The following table presents the results of an analysis for chronic exposure to cymoxanil in either TanosR 50DF or CurzateR 60DF. The chronic population adjusted dose (cPAD) of 0.041 mg/kg/day is based on a NOAEL of 4.08 mg/kg/day from the one-year rat feeding study and an uncertainty factor of 100. No sensitive subpopulations were identified. The results of the chronic dietary exposure analysis are below the EPA's level of concern.

#### RESULTS OF CHRONIC DIETARY ANALYSIS WITH CYMOXANIL

Population Group	Maximum Dietary Exposure (mg/kg/day)	% cPAD
U.S. Population	0.000063	0.2
Non-Nursing Infants (<1 yr.)	0.000016	0.1
Children (1-6 yr.)	0.000074	0.2
Children (7-12 yr.)	0.000068	0.2
Females (13+)	0.000074	0.2

ii. *Drinking water.* Surface water exposure was estimated using the Generic Expected Environmental Concentration (GENEEC) model. This

screening level model is used for determining upper bound concentrations of pesticides in surface water.

The acute drinking water level of concern(s) (DWLOCs) are 1.3 ppm for the U.S. population, and 0.38 ppm for children (1-6 years old), the most exposed population subgroup. The estimated environmental concentration (EECs) of cymoxanil in surface water is 8.15 parts per billion (ppb) derived from GENEEC does not exceed the acute DWLOC.

The chronic DWLOCs are 1.4 ppm for the U.S. population and 0.4 ppm for children (1-6 years old), the most sensitive subgroup. The GENEEC 56-day EECs of 0.37 ppb does not exceed the chronic DWLOC for cymoxanil in surface water.

Therefore, based on the above findings, the registrants conclude with reasonable certainty that residues of cymoxanil in drinking water do not contribute significantly to the aggregate chronic human health risk.

2. *Non-dietary exposure.* Cymoxanil products are not labeled for residential non-food uses, thereby eliminating the potential for residential exposure.

#### D. Cumulative Effects

EPA's consideration of a common mechanism of toxicity is not necessary at this time because there is no indication that toxic effects of cymoxanil should be cumulative with those of any other chemical compounds or with each other.

#### E. Safety Determination

1. *U.S. population.* For acute dietary exposure of cymoxanil, the estimated exposure is 0.000475 and 0.001789 at the 99th and 99.9th percentiles, which will utilize 1.19 and 4.47%, respectively, of the acute population adjusted dose (aPAD) for the overall U.S. population. The chronic dietary exposure for the overall U.S. population is estimated to be 0.000063 mg/kg/day, using 0.2% of the chronic population adjusted dose (cPAD). Based on the completeness and reliability of the toxicity data and the conservative exposure assessments, there is reasonable certainty that no harm will result from the aggregate exposure of residues of cymoxanil including all anticipated dietary exposure and all other non-occupational exposures.

2. *Infants and children.* For acute dietary exposure of cymoxanil, the aPAD for children 1-6 years old is 1.44 at the 99th percentile and 5.24 at the 99.9th percentile. For non-nursing infants (<1 yr.), the % aPAD is 0.46 at the 99th percentile and 1.50 at the

99.9th percentile. Chronic dietary exposure of cymoxanil for the most highly exposed children's subpopulations are: 0.000074 mg/kg/day for children 1-6 years old, and 0.000068 mg/kg/day for children 7-12 years old, representing 0.2% of the cPAD for each subpopulation. Exposure for all infant subpopulations was negligible.

In addition, there are no residential uses of cymoxanil; therefore, it is extremely unlikely that drinking water will be contaminated.

Based on the completeness and reliability of the toxicity database, the lack of toxicological endpoints of special concern, the lack of any indication that children are more sensitive than adults to cymoxanil, and the conservative exposure assessment, the registrants believe there is a reasonable certainty that no harm will result to infants and children from the aggregate exposure of residues of cymoxanil, including all anticipated dietary exposure and all other non-occupational exposures. Accordingly, there is no need to apply an additional safety factor for infants and children.

#### F. International Tolerances

No international tolerances currently exist for cymoxanil.

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### ENVIRONMENTAL PROTECTION AGENCY

[PF-1031; FRL-6790-1]

#### Notice of Filing a Pesticide Petition to Establish a Tolerance for a Certain Pesticide Chemical in or on Food

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

**SUMMARY:** This notice announces the initial filing of a pesticide petition proposing the establishment of regulations for residues of a certain pesticide chemical in or on various food commodities.

**DATES:** Comments, identified by docket control number PF-1031, must be received on or before September 4, 2001.

**ADDRESSES:** Comments may be submitted by mail, electronically, or in person. Please follow the detailed instructions for each method as provided in Unit I.C. of the

**SUPPLEMENTARY INFORMATION.** To ensure proper receipt by EPA, it is imperative that you identify docket control number PF-1031 in the subject line on the first page of your response.

**FOR FURTHER INFORMATION CONTACT:** By mail: Mary L. Waller, Registration Support Branch, Registration Division (7505W), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460; telephone number: (703) 308-9354; e-mail address: waller.mary@epa.gov.

**SUPPLEMENTARY INFORMATION:**

**I. General Information**

*A. Does this Action Apply to Me?*

You may be affected by this action if you are an agricultural producer, food manufacturer or pesticide manufacturer. Potentially affected categories and entities may include, but are not limited to:

Categories	NAICS codes	Examples of potentially affected entities
Industry	111	Crop production
	112	
	311	Animal production
	32532	Food manufacturing Pesticide manufacturing

This listing is not intended to be exhaustive, but rather provides a guide for readers regarding entities likely to be affected by this action. Other types of entities not listed in the table could also be affected. The North American Industrial Classification System (NAICS) codes have been provided to assist you and others in determining whether or not this action might apply to certain entities. If you have questions regarding the applicability of this action to a particular entity, consult the person listed under **FOR FURTHER INFORMATION CONTACT**.

*B. How Can I Get Additional Information, Including Copies of this Document and Other Related Documents?*

1. *Electronically.* You may obtain electronic copies of this document, and certain other related documents that might be available electronically, from the EPA Internet Home Page at <http://www.epa.gov/>. To access this document, on the Home Page select "Laws and Regulations" "Regulation and Proposed Rules," and then look up the entry for this document under the "**Federal Register**—Environmental Documents." You can also go directly to the **Federal Register** listings at <http://www.epa.gov/fedrgstr/>.

2. *In person.* The Agency has established an official record for this action under docket control number PF-1031. The official record consists of the

documents specifically referenced in this action, any public comments received during an applicable comment period, and other information related to this action, including any information claimed as confidential business information (CBI). This official record includes the documents that are physically located in the docket, as well as the documents that are referenced in those documents. The public version of the official record does not include any information claimed as CBI. The public version of the official record, which includes printed, paper versions of any electronic comments submitted during an applicable comment period, is available for inspection in the Public Information and Records Integrity Branch (PIRIB), Rm. 119, Crystal Mall #2, 1921 Jefferson Davis Highway, Arlington, VA, from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The PIRIB telephone number is (703) 305-5805.

*C. How and to Whom Do I Submit Comments?*

You may submit comments through the mail, in person, or electronically. To ensure proper receipt by EPA, it is imperative that you identify docket control number PF-1031 in the subject line on the first page of your response.

1. *By mail.* Submit your comments to: Public Information and Records Integrity Branch (PIRIB), Information Resources and Services Division (7502C), Office of Pesticide Programs (OPP), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460.

2. *In person or by courier.* Deliver your comments to: Public Information and Records Integrity Branch (PIRIB), Information Resources and Services Division (7502C), Office of Pesticide Programs (OPP), Environmental Protection Agency, Rm. 119, Crystal Mall #2, 1921 Jefferson Davis Highway, Arlington, VA. The PIRIB is open from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The PIRIB telephone number is (703) 305-5805.

3. *Electronically.* You may submit your comments electronically by e-mail to: [opp-docket@epa.gov](mailto:opp-docket@epa.gov), or you can submit a computer disk as described above. Do not submit any information electronically that you consider to be CBI. Avoid the use of special characters and any form of encryption. Electronic submissions will be accepted in Wordperfect 6.1/8.0 or ASCII file format. All comments in electronic form must be identified by docket control number PF-1031. Electronic comments

may also be filed online at many Federal Depository Libraries.

*D. How Should I Handle CBI That I Want to Submit to the Agency?*

Do not submit any information electronically that you consider to be CBI. You may claim information that you submit to EPA in response to this document as CBI by marking any part or all of that information as CBI. Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2. In addition to one complete version of the comment that includes any information claimed as CBI, a copy of the comment that does not contain the information claimed as CBI must be submitted for inclusion in the public version of the official record. Information not marked confidential will be included in the public version of the official record without prior notice. If you have any questions about CBI or the procedures for claiming CBI, please consult the person identified under **FOR FURTHER INFORMATION CONTACT**.

*E. What Should I Consider as I Prepare My Comments for EPA?*

You may find the following suggestions helpful for preparing your comments:

1. Explain your views as clearly as possible.
2. Describe any assumptions that you used.
3. Provide copies of any technical information and/or data you used that support your views.
4. If you estimate potential burden or costs, explain how you arrived at the estimate that you provide.
5. Provide specific examples to illustrate your concerns.
6. Make sure to submit your comments by the deadline in this notice.
7. To ensure proper receipt by EPA, be sure to identify the docket control number assigned to this action in the subject line on the first page of your response. You may also provide the name, date, and **Federal Register** citation.

**II. What Action is the Agency Taking?**

EPA has received a pesticide petition as follows proposing the establishment and/or amendment of regulations for residues of a certain pesticide chemical in or on various food commodities under section 408 of the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. 346a. EPA has determined that this petition contains data or information regarding the elements set

forth in section 408(d)(2); however, EPA has not fully evaluated the sufficiency of the submitted data at this time or whether the data support granting of the petition. Additional data may be needed before EPA rules on the petition.

#### List of Subjects

Environmental protection, Agricultural commodities, Feed additives, Food additives, Pesticides and pests, Reporting and recordkeeping requirements.

Dated: June 20, 2001.

#### Peter Caulkins,

Acting Director, Registration Division, Office of Pesticide Programs.

#### Summary of Petitions

The petitioner summary of the pesticide petition is printed below as required by section 408(d)(3) of the FFDCA. The summary of the petition was prepared by the petitioner and represents the view of the petitioners. EPA is publishing the petition summary verbatim without editing it in any way. The petition summary announces the availability of a description of the analytical methods available to EPA for the detection and measurement of the pesticide chemical residues or an explanation of why no such method is needed.

#### Uniroyal Chemical Company

PP 1F6297, 0F6077, and 8F4938

EPA has received pesticide petitions (1F6297, 0F6077, and 8F4938) from Uniroyal Chemical Company, 74 Amity Rd., Bethany, CT 06525 proposing, pursuant to section 408(d) of the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. 346a(d), to amend 40 CFR part 180 by establishing tolerances for residues of [[1-(4-chloro-2-(trifluoromethyl) phenyl)imino]-2-propoxyethyl -1H-Imidazole]] in or on the raw agricultural commodities strawberries at 2.0 parts per million (ppm) [1F6297], the cucurbit crop group at 0.5 ppm [0F6077] and cherries at 2.0 ppm [8F4938]. EPA has determined that the petitions contain data or information regarding the elements set forth in section 408(d)(2) of the FFDCA; however, EPA has not fully evaluated the sufficiency of the submitted data at this time or whether the data supports granting of the petitions. Additional data may be needed before EPA rules on the petitions.

#### A. Residue Chemistry

1. *Plant metabolism.* In crops, the metabolism of <sup>14</sup>C-Phenyl triflumizole was investigated in cucumber, pears, grapes and apples. The major

metabolites were: N-(4-chloro-2-trifluoromethylphenyl)-n-propoxyacetamidine (FM-6-1), N-(4-chloro-2-trifluoromethylphenyl)-n-propoxyacetanilide (FD-1-1) and the free or conjugated products of N-(4-chloro-2-trifluoromethylphenyl)-hydroxyacetamidine (the O-dealkylation product of FM-6-1), N-(4-chloro-2-trifluoromethylphenyl)-hydroxyacetanilide (FD-2-1) and the triflumizole aniline (FA-1-1).

2. *Analytical method.* The analytical method is suitable for analyzing crops for residues of triflumizole and its aniline containing metabolites at the proposed tolerance levels. The analytical method has been independently validated. Residue levels of triflumizole are converted to FA-1-1 by acidic and alkaline reflux, followed by distillation. Residues are then extracted and subjected to SPE purification. Detection and quantitation are conducted by a gas chromatography equipped with nitrogen phosphorus detector, electron capture detector or mass spectrometry detection. The limit of quantitation of the method has been determined at 0.05 parts per million (ppm) for cucurbits and cherries, and 0.02 ppm for strawberries. The enforcement methodology has been submitted to the Food & Drug Administration (FDA) for publication in the Pesticide Analytical Manual, Vol. II (PAM II).

3. *Magnitude of residues.* Eight field trials in strawberries were conducted in commercial growing areas of the United States. The analytical data show that the mean measured residue in/on strawberries was 0.859 ppm. The highest residue data was 2.0 ppm. Crop field trial residue data from 0-day pre-harvest interval studies were conducted on cucumbers, muskmelon, and squash (cucurbits). In these trials, residues ranged from 0.06 to 0.39 ppm. Field trials were carried out on cherries in five states. In these trials the residues of triflumizole and its aniline containing metabolites ranged from 0.4 to 1.5 ppm. These data support the proposed tolerances for triflumizole. There are no processed commodities or feed commodities associated with these crops.

#### B. Toxicological Profile

1. *Acute toxicity.* The database includes the following studies: a rat acute oral study with a LD<sub>50</sub> of 1.42 g/kg; a rabbit acute dermal study with a LD<sub>50</sub> >5 g/kg; a rat acute inhalation study with a LC<sub>50</sub> >3.2 mg/l; a rabbit primary ocular irritation study which showed mild irritation; a rabbit primary dermal irritation study which showed

no irritation; a guinea pig dermal sensitization study which showed slight dermal sensitization potential.

2. *Genotoxicity.* Triflumizole was negative in all genotoxicity assays including: Ames assay in *S. typhimurium*, gene conversion assay in yeast strain D4, REC assay in *B. subtilis*, unscheduled DNA synthesis (UDS) assay in cultured rat hepatocytes, chromosome aberration assay in cultured Chinese hamster ovary (CHO) cells and a mouse micronucleus assay.

3. *Reproductive and developmental toxicity.* In a developmental toxicity study, triflumizole was administered by oral gavage to pregnant female Sprague Dawley rats at dosage levels of 0, 10, 35 or 120 mg/kg/day. Maternal toxicity, as evidenced by a substantial reduction in body weight (bwt) gain, was seen at 35 and 120 mg/kg/day. At these dosage levels there was a decrease in fetal viability in the form of late resorptions. There were no teratogenic effects. The no observed adverse effect level (NOAEL) for maternal and developmental toxicity was 10 mg/kg/day. Triflumizole was also administered by oral gavage to pregnant female New Zealand White rabbits at dosage levels of 0, 5, 25, or 50 mg/kg/day. At a dose level of 50 mg/kg/day there was a reduction in bwt gain in kits. There were no developmental or teratogenic effects. The NOAEL for maternal toxicity was 25 mg/kg/day and the NOAEL for developmental toxicity was greater than 50 mg/kg/day.

The reproduction toxicity of triflumizole was evaluated in a rat reproduction study, conducted on three generations, at dietary concentrations of 0, 30, 70 and 170 ppm. Fertility was not affected by treatment. There was an increase in placental weight in the F1b, F2b and F3b litters and a statistically significant increase in gestation length in the high dose group at the F1a and F3a mating intervals. The NOAEL for systemic parental toxicity was greater than 170 ppm and the NOAEL for developmental effects was 70 ppm based upon effects seen in litters of both studies at the high dose level, including increased incidences of hydronephrosis and space between the body wall and organs. The NOAEL for reproductive effects was 70 ppm (3.5 mg/kg/day) based on increased gestation length observed at the high dose level at 2 of 6 mating intervals.

4. *Subchronic toxicity.* To assess sub-acute dermal toxicity, triflumizole was applied to the backs of male and female Sprague Dawley rats for three weeks. High dose female rats exposed to 1,000 mg/kg/day exhibited mild fatty vacuolation in the liver, which was

within the range of normal biological variation. Therefore, the NOAEL for sub-acute dermal toxicity in rats was greater than 1,000 mg/kg/day.

Triflumizole was fed to male and female Sprague Dawley rats for thirteen weeks at dietary concentrations of 0, 20, 200 and 2,000 ppm to assess sub-chronic toxicity. At a dosage level of 2,000 ppm there was a reduction in body weight gain, an increase in liver and kidney weights, lipid droplets in liver and a decrease in serum alkaline phosphatase in males and females. High dose females exhibited a reduction in red blood cell (RBC) and hemoglobin in blood. The NOAEL for sub-chronic toxicity in rats was 200 ppm (10 mg/kg/day).

5. *Chronic toxicity.* Triflumizole was fed to male and female Beagle dogs for one year at dietary concentrations of 0, 100, 300 and 1,000 ppm to assess chronic toxicity. At a dosage level of 1,000 ppm there was an increase in serum liver enzymes and a decrease in RBC concentration. The NOAEL for chronic toxicity in dogs was 300 ppm (7.5mg/kg/day).

Triflumizole was fed to male and female Sprague Dawley rats for two years at dietary concentrations of 0, 100, 400 and 1,600 ppm to assess chronic toxicity. At the high dose level there was a substantial reduction in body weight gain in males and females. At the mid and high dose levels there was an increase in liver weight. Ovary weight was increased in high dose female rats, and kidney weights were elevated in high dose animals. Alanine aminotransferase and lactose dehydrogenase was elevated in high dose males and females, respectively. High dose females had an increased incidence of ovarian follicular cysts, while high dose males exhibited pancreatic acinar cell atrophy. Fatty vacuolization of the liver was seen at all dose levels and hepatocytic hypertrophy was seen in high and mid-dose males and females. Female rats given 400 or 1,600 ppm had an increased incidence of basophilic foci/areas of hepatocytic alteration. Effects at 100 ppm were confined to hepatocytic fatty vacuolation and hypertrophy in females. These changes were less severe than those seen in rats given 400 or 1,600 ppm and were considered by the laboratory to be indicative of adaptive metabolic change. The dietary level of 100 ppm (5 mg/kg/day) is considered to be a NOAEL.

6. *Animal metabolism.* Triflumizole, [14C-Phenyl] 1-(1-((4-chloro-2-trifluoromethylphenyl)imino)-2-propoxyethyl)-1H-imidazole, was found to be rapidly absorbed and excreted in rats. Two days after oral dosing, 78%

was found to be excreted in the urine and 20% in the feces. No sex difference was noted. It appears that the loss of the imidazole ring was the basic step in the metabolic pathway of this fungicide in mammals. The elimination of the imidazole ring yielded initially N-(4-chloro-2-trifluoromethylphenyl)-n-propoxyacetamide (FM-6-1 and N-(4-chloro-2-trifluoromethylphenyl)-n-propoxyacetanilide (FD-1-1). Other hydroxylated metabolites identified (free, or as sulfate/glucuronide conjugates) included, among others, N-(4-chloro-2-trifluoromethylphenyl)-hydroxyacetamide (FM-8-1); 4-chloro-2-trifluoromethyl-hydroxyacetanilide (FD-2-1); and 4-chloro-2-trifluoromethyl-6-hydroxyaniline (FA-1-5).

7. *Metabolite toxicology.* Both plant and animals produce the same metabolites that were identified in the metabolism studies; therefore, the toxicity of the metabolites has essentially been evaluated in the rat toxicology studies.

8. *Endocrine disruption.* In the rat reproduction study there was an increase in placental weight in females at the high dose level of 170 ppm. There was also a biologically significant increase in gestation length in high dose F0 and F2 females (F1a and F3a intervals). The NOAEL for endocrine effects is 70 ppm (3.5 mg/kg/day).

#### C. Aggregate Exposure

1. *Dietary exposure—i. Food.* Tolerances have been established (40 CFR 180.476) for the combined residues of triflumizole, and its metabolites containing the 4-chloro-2-trifluoromethylaniline moiety, calculated as the parent compound, in or on apples, pears and grapes. Tolerances have also been established for the combined residues of triflumizole and 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 or on eggs, milk, meat, fat, and meat by-products of cattle, goats, hogs, horses, poultry and sheep.

Field trial residue values from the currently labeled raw agricultural commodities (apples, pears, grapes) and from the proposed cucurbit, cherry, filbert and strawberry uses were used to estimate dietary exposure (Dietary Exposure Evaluation Model (DEEM)<sup>TM</sup>, Novigen Sciences, Inc.). Tissue to feed ratios were used to calculate secondary residues for meat, milk, and egg products. Processing factors and percent

of crop treated were also factored into the estimates.

ii. *Drinking water.* Exposure to triflumizole or its degradates in drinking water is not anticipated, and is unlikely to occur. Triflumizole is not expected to contaminate ground water. Laboratory and field data have demonstrated that it degrades rapidly and that triflumizole and its metabolites do not leach, even in sandy soil. A Maximum Contaminant Level (MCL) for triflumizole has not been established by EPA. Ornamental and proposed residential uses are not expected to result in drinking water concerns. Most commercial uses on outdoor-grown plants would typically be only a spot treatment or on very limited acreage. Containerized ornamentals would mimic greenhouse production, as these plants are generally elevated off the ground, with some type of ground covering underneath. For residential areas, triflumizole would be used only by commercial applicators, and only as a spot treatment.

Tier I screen models generic expected environmental concentration (GENEEC) (surface water) and screening concentration in ground water (SCI-GRO) (ground water) were used to predict the estimated environmental concentration (EEC) of triflumizole from current and proposed food uses. For surface water, the theoretical acute EEC was 18 parts per billion (ppb) (peak concentration) and the chronic EEC (divided by 3 to account for the large overestimates inherent in the model) was 3 ppb. Theoretical acute and chronic ground water concentrations from the SCI-GRO modeling were <0.1 ppb.

2. *Non-dietary exposure.* The only source of non-dietary exposure to triflumizole for consideration under FQPA is in the proposed use of Terraguard 50W on institutional, recreational, and homeowner landscapes and other outdoor ornamentals. This registration could result in intermittent, low-level residential post-application exposures. Terraguard 50W is not available for application by homeowners and is not registered for use on turf. Only professional handlers would apply Terraguard 50W to any existing or proposed use sites. Treatment would be made to individual plants or specific sub-sections within labeled use sites, and only as needed for disease. The above use sites amount to minimal acreage in comparison with turf and other sources of residential exposure, and activities therein are of low duration and intensity.

Dislodgeable foliar residues (DFRs) can be estimated from existing data. A

recent study on Terraguard 50W DFRs on *Spathiphyllum* foliage showed significantly lower levels of triflumizole than would be predicted by current Agency SOP defaults, and an approximately complete dissipation within the minimum treatment interval of 30 days. From that study, potential residue levels were calculated based on the geometric means of regressed values that were adjusted to represent the maximum application rate of 1.0 lb ai/acre, and averaged over the duration of potential post-application exposure.

The DFR transfer coefficients, representing reentry into treated gardens, are EPA default assumptions (draft OPP/HED SOP for Residential

Exposure Assessment). Such defaults are considered by EPA to be very conservative and are considered to be screening-level assumptions. In addition, work by the Agricultural Reentry Task Force and others has shown far lower transfer coefficients for many relatively high-exposure activities, such as pruning, that may occur on residential landscapes. Contact with residential landscape foliage is assumed to occur incidentally or for short durations since typical Terraguard applications will be spot-treatments within small areas.

The toxicological assumptions in this assessment are also conservative, including (a) a default value of 100%

dermal absorption; (b) the acute endpoint of 3.5 mg/kg/day (see above) for short-term assessment; and (c) the sub-chronic endpoint of 3.5 mg/kg/day (see above) for intermediate-term assessment. Chronic assessment is not required since a yearly maximum of 3 applications, from which triflumizole is expected to dissipate within 30-days, should result in less than 90-days of potential exposure per year. The factors used in the assessment and resulting estimates of absorbed daily dose and margins of exposure (MOEs) are provided in the following table:

	Short-Term Assessment:		Intermediate Term Assessment:	
	Females 13–50	Infants/Children	Females 13–50	Infants/Children
Duration of Assessment (days)	7 days	7 days	90–days	90–days
DFR (–g/cm <sup>2</sup> )	0.345	0.345	0.0092	0.0092
Transfer Coefficient (cm <sup>2</sup> /hr)	1,000	5,000	1,000	5,000
Duration (hr/day)	0.083	0.033	0.083	0.033
bwt (kg)	60	10	60	10
Absorbed Daily Dose (mg/kg/day)	0.00477	0.00569	0.00013	0.00015
NOAEL (mg/kg/day)	3.5	3.5	3.5	3.5
Margin of Exposure (MOE):	733	615	27501	23057

The above calculations are based on appropriate DFR data from an ornamental crop, a complete toxicological profile, transfer coefficients understood to be conservative, and a very conservative assumption of 100% dermal absorption. The resulting MOEs, which are still well over 100, therefore indicate clearly that residential exposure following Terraguard 50W use on institutional, recreational, and homeowner landscapes, and other outdoor ornamentals, would pose a low potential risk and a reasonable certainty of no harm.

#### D. Cumulative Effects

The potential for cumulative effects of triflumizole, an imidazole, and other substances that have a common mechanism of toxicity was considered. The mammalian toxicity of triflumizole is well defined. No reliable information exists to indicate that toxic effects produced by triflumizole would be cumulative with those of any other chemical compounds. Therefore, consideration of a common mechanism of toxicity with other compounds is not appropriate. Thus, only the potential risks of triflumizole are considered in the aggregate exposure assessment.

#### E. Safety Determination

1. *U.S. population*— i. *Short-term risk*. Based on the toxicology database,

the NOAEL of 3.5 mg/kg/day from the reproduction toxicity study, and available information on anticipated residues and percent crop treated, the acute dietary exposure was determined to be within the acceptable MOE of 100. Exposure to potential triflumizole residues in drinking water is not expected to significantly contribute to the overall exposure of females 13–50 years old and infants and children, as DWLOC's are substantially higher than modeled EEC's. Residential post application exposure would occur within an acceptable margin of safety. Based on these assessments, Uniroyal concludes that there is reasonable certainty of no harm to females (13–50 years old), infants, and children from short-term aggregate exposure to triflumizole residues.

ii. *Intermediate-term risk*. Based on the toxicology database, the RfD of 0.035 mg/kg/day from the reproduction study, and available information on anticipated residues and percent crop treated, the chronic dietary exposure was determined as 0.1% of the RfD for females (13–50 years old), and 0.4% for infants and children. These exposures do not exceed EPA's level of concern of >100% of the RfD. Exposure to potential triflumizole residues in drinking water is not expected to significantly contribute to the overall exposure of females 13–50 years old and infants and children, as DWLOC's are substantially

higher than modeled EEC's. Residential post application exposure would occur within an acceptable margin of safety. Based on these assessments, Uniroyal concludes that there is reasonable certainty of no harm to females (13–50 years old), infants, and children from intermediate-term aggregate exposure to triflumizole residues.

iii. *Chronic risk*. Based on the toxicology database, the reference dose (RfD) of 0.035 mg/kg/day from the reproduction study, and available information on anticipated residues and percent crop treated, the chronic dietary exposure was determined as 0.1% of the RfD for the U.S. population, and 0.4% for infants and children. These exposures do not exceed EPA's level of concern of >100% of the RfD. Exposure to potential triflumizole residues in drinking water is not expected to significantly contribute to the overall exposure of the U.S. population, infants, and children, as DWLOC's are substantially higher than modeled EEC's. Based on these assessments, Uniroyal concludes that there is reasonable certainty of no harm to the U.S. population, infants, and children from chronic aggregate exposure to triflumizole residues.

2. *Infants and children*. Triflumizole was evaluated in rat and rabbit developmental toxicity studies and a three generation rat reproduction study to assess the potential for additional

sensitivity to infants and children. No developmental toxicity was seen in the rabbit teratology study at doses up to 50 mg/kg/day. Maternal toxicity was seen at this dosage level. In the rat teratology study, there was an increase in late resorptions at doses of 35 and 120 mg/kg/day which was accompanied by maternal toxicity in the form of a substantial reduction in bwt. The NOAEL for maternal and developmental toxicity was 10 mg/kg/day. In the rat reproduction study, there was an increase in gestation length and an increased incidence of hydroureter and space between the body wall and organs at the high dose level of 170 ppm. The NOAEL for reproductive and developmental effects was 3.5 mg/kg/day. No additional safety factor is necessary as the data package is complete and the sensitivity to infants and children is adequately characterized.

#### F. International Tolerances

There are no Codex, Canadian or Mexican maximum residue limits established for triflumizole on strawberries, cucurbits or cherries.

[FR Doc. 01-16956 Filed 7-5-01; 8:45 am]

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## ENVIRONMENTAL PROTECTION AGENCY

[FRL-7006-9]

### Massachusetts Marine Sanitation Device Standard; Notice of Determination

On May 23, 2001, notice was published that the State of Massachusetts had petitioned the Regional Administrator, Environmental Protection Agency, to determine that adequate facilities for the safe and sanitary removal and treatment of sewage from all vessels are reasonably available for the Three Bay/Centerville Harbor Area in the Town of Barnstable, County of Barnstable, State of Massachusetts. The petition was filed pursuant to Section 312(f)(3) of Public Law 92-500, as amended by Public Laws 95-217 and 100-4, for the purpose of declaring these waters a "No Discharge Area" (NDA).

Section 312(f)(3) states: After the effective date of the initial standards and regulations promulgated under this section, if any State determines that the protection and enhancement of the quality of some or all of the waters within such States require greater environmental protection, such State may completely prohibit the discharge from all vessels of any sewage, whether

treated or not, into such waters, except that no such prohibition shall apply until the Administrator determines that adequate facilities for the safe and sanitary removal and treatment of sewage from all vessels are reasonably available for such water to which such prohibition would apply.

The information submitted to me by the State of Massachusetts certified that there are two public pump-out facilities located within the proposed area to service vessels in Three Bay/Centerville Harbor Area.

There is a self service pumpout trailer unit located at the Oyster Harbor Marina, with a holding capacity of 250 gallons, and provides access for vessels up to 50 feet in length and a draft of 4 feet at mean low water. This facility is available daily from June 15 through September 15 from approximately 0800 to 1700 (8am to 5pm). The second pumpout facility is a pumpout boat operated by the Harbormasters Office, and docked at the Oyster Harbor Marina when not in use. The boat has a holding capacity of 300 gallons. The pumpout boat is available Wednesday through Sunday from 0930 to 1630 (9:30am-4:30pm) from Memorial Day to Thanksgiving. The pump-out boat is accessible by VHF marine radio via Channel 9 and by calling the Oyster Harbor Marine and Environmental Affairs Division (MEAD) in Barnstable at (508) 790-6273.

The waste from the pump-out boat is off loaded to the trailer unit then transported to the Barnstable Water Pollution Control Facility. The Barnstable Board of Health issues a waste permit for this disposal.

The town of Barnstable maintains public facilities at four locations, Loop Beach, Craigville Beach, Covells Beach and Dowse's Beach and are seasonal. In addition, the three marinas in the area provide on-shore toilet facilities for marina patrons and their guests.

The number of mooring permits indicate that 1,667 vessels reside within the Three Bay/Centerville Harbor Area and 1584 are identified as recreational and 83 are commercial vessels. The Three Bay/Centerville Harbor Area is primarily a "parking lot" harbor and 70% of the vessel population is under 25 feet in length, and therefore do not have any type of Marine Sanitation Device (MSD). There are a number of locations in the Three Bay/Centerville Harbor Area with public launching ramps, however, the size and condition of the ramps and the depth of the water limit use to vessels 25 feet and under. In addition to the vessels that reside in the Complex, there is a transient

population estimated at 110 vessels which have MSD's.

The resources of the Three Bay/Centerville Harbor Area are recreational and commercial. There are four public beaches, the Dead Neck Audubon Bird/Wildlife Refuge, and town conservation lands located within the area. The Three Bay/Centerville Harbor Area is also used by both recreational and commercial shell fishermen for the harvest of quahogs, soft-shell clams.

Therefore, based on an examination of the petition and its supporting information, which included a site visit by EPA New England staff, I have determined that adequate facilities for the safe and sanitary removal and treatment of sewage from all vessels are reasonably available for the areas covered under this petition. The area includes Cotuit Bay, West Bay, East Bay, and Squaw Island Marsh, north of a line drawn 500 feet south of their mouths at Nantucket Sound. The area also includes the following sub-embayments: North Bay, Prince Cove, Marstons Mills River South of Route 28, Scudder Bay South of Bumps River Road, Bumps River East of Bumps River Road, Centerville River West of Craigville Beach Road, and Halls Creek South of Craigville Beach Road. The proposed NDA encompasses approximately 2,150 surface acres in the Southwest corner in the Town of Barnstable. The area is roughly bounded by: 41° 36' 40.0" N by 70° 26' 41.1" W, 41° 37' 26.9" N by 70° 19' 05.4" W, 41° 38' 19.8" N by 70° 19' 21.9" W, and 41° 39' 03.2" N-70° 24' 53.8" W.

This determination is made pursuant to Section 312(f)(3) of Public Law 92-500, as amended by Public Laws 95-217 and 100-4.

Dated: June 22, 2001.

**Ira Leighton,**

*Acting Regional Administrator.*

[FR Doc. 01-16942 Filed 7-5-01; 8:45 am]

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## FEDERAL COMMUNICATIONS COMMISSION

[Report No. 2490]

### Petitions for Reconsideration Clarification of Action in Rulemaking Proceedings

June 29, 2001.

Petitions for Reconsideration Clarification have been filed in the Commission's rulemaking proceedings listed in this Public Notice and published pursuant to 47 CFR Section 1.429(e). The full text of these documents are available for viewing and