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

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

MEMORANDUM

DATE: 3/24/97

SUBJECT: ID#97TX0011 & 97TX0012 SECTION 18 EXEMPTIONS FOR USE OF **TEBUFENOZIDE AND CHLORFENAPYR ON COTTON IN TEXAS.**

DP Barcode: D233125 & D233126	Caswell: 945 & NA
Trade Name: CONFIRM & PIRATE	Chem#: 129026 & 129093
Reg#: EPA 707-238 & EUP 241	Case#: 288355 & 288356
Class: Insecticides	40 CFR: 180.482 & NA

TO: A. Beard/R. Forrest, PM Team 41
ERMUS/RSB/RD (7505W)

FROM: W. Cutchin, S. Williams-Foy, W. Dykstra, C. Lewis
PIRAT/RCAB/HED (7509C)

THRU: Michael S. Metzger, Chief
RCAB/HED (7509C)

INTRODUCTION

The Texas Department of Agriculture is proposing specific exemptions for the use of tebufenozide and chlorfenapyr on cotton for control of army beetworm. These are repeat §18 requests for this use. The proposed programs will entail application of 225,000 gallons of Confirm 2F (450,000 lb ai) and 239,907 gallons of Pirate 3SC (720,000 lb ai) on 1.8 million acres throughout the State of Texas, during the period March 1 to September 30, 1997.

RECOMMENDATION

Occupational exposure and aggregate risk estimates do not exceed HED's level of concern. These Section 18 exemptions should not pose an unacceptable aggregate risk to infants and children.

Therefore, provided 1) **the Section 18 label for Confirm is modified to limit rotation only to Brassica and leafy vegetables, and 2) a 60-day plant-back interval for root crops and 30 days for all other crops is specified for Pirate,** HED has no objection to the issuance of these Section 18 exemptions for the use of tebufenozide and chlorfenapyr on cotton in the State of Texas. **Time-limited tolerances at the following levels should be established to support these Section 18 specific exemptions:**

Tebufenozide per se

cottonseed: 0.2 ppm
cotton meal: 0.5 ppm
cotton hulls: 0.8 ppm
cottonseed oil: 1.3 ppm
cotton gin byproducts: 4 ppm

Chlorfenapyr per se:

cottonseed: 0.5 ppm
cotton gin byproducts: 2.0 ppm
milk: 0.01 ppm
milk fat: 0.15 ppm
meat of cattle, goats, hogs, horses, and sheep: 0.01 ppm
fat of cattle, goats, hogs, horses, and sheep: 0.10 ppm
meat byproducts
of cattle, goats, hogs, horses and sheep: 0.3 ppm.

PIRAT also recommends that **the restriction prohibiting the feeding of treated cotton commodities should be removed from the Section 18 labels.** RD should ensure that the appropriate WPS statements appear on the Pirate Section 18 label.

RISK CHARACTERIZATION - Tebufenozide

Occupational Exposure Assessment

Since no short- or intermediate-term toxicological endpoints were identified by the Toxicology Endpoint Selection Committee (TES) for tebufenozide, an occupational risk assessment was not conducted. There are no anticipated risks for workers with this Section 18.

Acute Aggregate Risk Assessment

Since no acute endpoint was identified by the TES Committee for tebufenozide, an acute risk assessment was not conducted.

Chronic Aggregate Risk Assessment

The chronic dietary (food only) risk assessment used Theoretical Maximum Residue Contributions (TMRC) and 100% crop treated as the basis for the assessment. Therefore, the resulting exposure

estimates should be viewed as conservative; further refinement using anticipated residues and/or percent of crop-treated would result in lower dietary exposure estimates. For chronic dietary (food only) risk estimates, the population subgroup with the largest percentage of the RfD occupied is non-nursing infants < 1 year old at 61% of the RfD.

An assumption of 10% of the chronic aggregate risk was allocated to drinking water, as per OPP Interim Decision Logic (PR 97-1, 1/31/97). For tebufenozide, this estimate is considered conservative and protective of the public health.

According to the REFS File System, there are no indoor or outdoor residential uses registered for tebufenozide. Accordingly, non-dietary, non-occupational uses are not expected to contribute to the chronic aggregate risk for tebufenozide.

Using these conservative estimates, the sum total of the aggregate chronic risk estimates (food, water, residential indoor and outdoor) for tebufenozide for the population subgroup with the largest percentage of the RfD occupied, non-nursing infants < 1 year old, is 71%. In the best scientific judgment of HED, the tebufenozide aggregate chronic risk does not exceed our level of concern.

Short- and Intermediate-Term Aggregate Risk Assessment

Since there were no toxicity endpoints identified by the TES Committee for tebufenozide and no indoor/outdoor residential uses, no short- or intermediate-term risk assessment was required.

Cancer Aggregate Risk Assessment

The RfD Committee has determined that tebufenozide is Group E "no evidence of carcinogenicity for humans" chemical, so no cancer aggregate risk assessment was required.

Hazard Assessment - Tebufenozide

1. Non-Dietary Exposure Endpoint Selection

   a) Short-Term Dermal Risk. NOEL = 1000 mg/kg/day. Concerning short-term dermal toxicity, the TES (Toxicology Endpoint Selection) Committee (4/17/96) noted that in the 21-day dermal toxicity study in rats (MRID# 42991507) there was no systemic toxicity observed at 1000 mg/kg/day, the highest dose tested (HDT). The TES Committee stated that this risk assessment is not required.

   b) Intermediate-Term Risk. The TES Committee did not identify an intermediate-term toxicology endpoint.

Additionally, because there is no intermediate exposure scenario with this Section 18 request, a risk assessment is not required.

c) Chronic Risk. The TES Committee did not identify a chronic endpoint. Further, because there is no chronic exposure scenario associated with this Section 18 request, a chronic risk assessment is not required.

d) Cancer Risk. Tebufenozide has been classified as a Group E, "no evidence of carcinogenicity for humans", chemical by the HED RfD Committee (9/20/95).

e) Dermal Penetration. A dermal absorption factor is not required for the short- and intermediate-term occupational exposure risk assessments since a 21-day dermal toxicity study was used for these scenarios.

2. Dietary Exposure Endpoint Selection

a) Acute Risk. No acute dietary risk endpoint was identified by the TES Committee (4/17/96). This risk assessment is not required.

b) Chronic Risk. RfD = 0.018 mg/kg/day. The RfD was established based on a 1-year feeding study in dogs (MRID# 42931203) with a NOEL of 1.8 mg/kg/day and an uncertainty factor of 100. The LEL of 8.7 mg/kg/day was based on hematopoietic findings (decreased red blood cells, hematocrit, hemoglobin, increased heinz bodies, MCV, MCH, reticulocytes, and platelets).

c) Cancer Risk. Tebufenozide has been classified as a Group E, "no evidence of carcinogenicity for humans", chemical by the HED RfD Committee (9/20/95).

d) Risk to Infants and Children.

1) Developmental Studies

Rat - In the developmental toxicity study (MRIDs #424362-24 and -25) in rats, the maternal (systemic) NOEL was 250 mg/kg/day. The LOEL was 1000 mg/kg/day based on decreased body weight and food consumption. The developmental (pup) NOEL was >1000 mg/kg/day (HDT).

Rabbit - In the developmental toxicity study (MRIDs #424362-26 and -27) in rabbits, the maternal and developmental NOELs were >1000 mg/kg/day (HDT).

2) Reproductive Studies

Rat - In the multigeneration reproductive toxicity study (MRID# 42931207) in rats, the parental (systemic) NOEL was 0.85 mg/kg/day. Splenic pigmentation changes and extramedullary hematopoiesis occurred at the LOEL of 12.1 mg/kg/day (♂, ♀; F_0, F_1). In addition to these effects, decreased body weight gain and food consumption occurred at 171.1 mg/kg/day. The reproductive/developmental (pup) NOEL was 12.1 mg/kg/day and the LOEL was 171.1 mg/kg/day, based on a slight increase in both generations (F_0 and F_1) and in the number of pregnant females that either did not deliver or had difficulty and had to be sacrificed (F_1). Additionally at the LOEL, in F_1 dams, the length of gestation increased and implantation sites decreased significantly. Finally, the number of pups per litter decreased on Lactation Day (LD) 4 to 90% of the controls for the F_1 and on LD's 0 and 4 to 80% for the second generation.

Occupational Exposure - Tebufenozide

Based on the TES Committee recommendations, no worker exposure risk assessment for tebufenozide is required.

Dietary Exposure - Tebufenozide

1a. The metabolism of tebufenozide in/on plants is adequately understood. The residue of concern is the parent compound, tebufenozide *per se* as specified in 40 CFR 180.482.

1b. The metabolism of tebufenozide in animals is not adequately understood. However, for the purpose of this Section 18 exemption only, PIRAT considers the residue of concern to be the parent compound, tebufenozide *per se*.

2a. The Rohm and Haas Analytical Method TR 34-93-119 (HPLC/UV), described in PP# 5G4460 (MRID# 435048-02), should be adequate to determine residues of tebufenozide *per se* in/on cotton commodities of this Section 18.

2b. There are no analytical methods available to detect secondary residues of tebufenozide in animal commodities.

3a. Residues of tebufenozide are not expected to exceed **0.2 ppm in/on cottonseed, 0.5 ppm in cotton meal, 0.8 ppm in cotton hulls, and 1.3 ppm in cottonseed oil** for this proposed use. Time-limited tolerances should be established at these levels. A data summary on undelinted cottonseed was previously submitted by the registrant Rohm and Haas. Residue levels were calculated on cottonseed processed commodities using maximum theoretical concentration factors (94MS0008, DP Barcode: D205084, CBTS#: 13966, D. Davis, 7/15/94).

3b. No data have been submitted to date for tebufenozide on cotton gin byproducts. A search of the tolerance index system (TIS) 2/26/97, indicated two chemicals for which tolerances are established both on cotton gin byproducts and cottonseed. One use is for an at-planting use of the chemical imidacloprid. The other cottonseed/cotton gin byproducts tolerance pair, 6 ppm and 100 ppm respectively, was established for a preharvest desiccant use of the chemical glyphosate. Since this preharvest use would be a worst case scenario, the tebufenozide residues on cotton gin byproducts will be estimated based on the concentration factor from that use, 16.6x (100/6). Therefore, the **residue of tebufenozide on cotton gin byproducts will be 4 ppm** (0.2 ppm x 16.6 = 3.3 ppm, rounded to 4). **A time-limited tolerance should be established at 4 ppm on cotton gin byproducts.**

3c. There are cottonseed animal feed items. However, **the residue levels in animal commodities potentially resulting from feeding of these commodities would most likely be undetectable.** For the purposes of this Section 18 registration only, PIRAT will not recommend for time-limited **tolerances for tebufenozide** on animal commodities. Since PIRAT does not expect detectable residues in animals from tebufenozide treated cotton feed items, **the restriction prohibiting the feeding of these items should be removed from the Confirm Section 18 label.** See Additional Information below for more detail.

4. There are currently no rotational crop data for tebufenozide. CBTS has accepted a label restriction in lieu of data for the experimental use permit (EUP). Treated areas may be rotated only to *Brassica* (cole) and leafy vegetables (PP#5G4460, DP Barcode: D211092, D211442, CBTS#: 14986, 15022, D. Davis, 3/37/95). **The Confirm Section 18 label should be modified to incorporate this crop restriction.**

5. No Codex, Canadian, or Mexican Maximum Residue Limits (MRLs) exist. Therefore, there are no compatibility issues with respect to the MRLs and U.S. tolerances.

6. Acute Dietary Risk. Since there are no acute dietary exposure endpoints of concern for tebufenozide, no acute risk assessment was performed.

7. Chronic Dietary Risk. The existing tebufenozide tolerances plus proposed Section 18 use result in a Theoretical Maximum Residue Contribution (TMRC) that is equivalent to the following percentages of the RfD:

U.S. Population	28%
Nursing Infants	**37%**
Non-Nursing Infants (<1 year old)	**61%**

Children (1-6 years old)	**50%**
Children (7-12 years old)	**37%**

The subgroups listed above are: (1) the U.S. population (48 states); and (2) those for infants and children.

8. Dietary Cancer Risk. Based on the HED RfD Committee's classification of tebufenozide as a Group E chemical 'not likely to cause cancer in humans,' a dietary cancer risk assessment is not required.

Exposure from Water - Tebufenozide

Submitted environmental fate studies suggest the chemical is moderately persistent to persistent and mobile; thus, tebufenozide could potentially leach to groundwater and runoff to surface water under certain environmental conditions (W. Effland, ERCB, 9/26/95). There is no established Maximum Contaminant Level (MCL) for residues of tebufenozide in drinking water. No drinking water Health Advisories have been issued for tebufenozide. There is no entry for tebufenozide in the "Pesticides in Groundwater Database (EPA 734-12-92-001, September 1992).

HED does not have data available to perform a quantitative drinking water risk assessment for tebufenozide at this time. Although the lack of detectable residues found in the available groundwater monitoring data suggest that water contamination due to tebufenozide use may be unlikely, it has not been determined whether these data are adequately representative of sites at which it would be likely to be found. Since tebufenozide data indicate the potential for soil mobility, leaching, and slow degradation, water risks will be assumed to account for 10% of the total allowable chronic and acute risk until further data are provided (in accordance with OPP Interim Decision Logic, PR 97-1, 1/31/97). Based on analysis of water monitoring data for a large number of pesticides with varying soil mobility characteristics, environmental stabilities, physical/chemical properties, and toxicities, the assumption of 10% of the total acute and chronic risk allocated to drinking water is considered conservative and protective of the public health.

Non-Dietary Non-occupational Exposure - Tebufenozide

According to a search of the Reference Files System (REFS) on 03/07/97, tebufenozide is not currently registered for any residential uses; therefore no residential exposure is anticipated.

Total Aggregate Risk - Tebufenozide

Acute Aggregate Risk

Since no acute endpoint was identified for tebufenozide, an acute

risk assessment was not conducted.

Short- and Intermediate-Term Aggregate Risk

Since there were no toxicity endpoints identified for tebufenozide, no short- or intermediate-term risk assessment was conducted.

Chronic Aggregate Risk

The aggregate chronic risk is equal to the sum of the chronic risk from food + water + residential uses. Because there are no indoor or outdoor residential uses for tebufenozide, HED has concluded that a chronic residential exposure scenario does not exist. Accordingly, none of the chronic aggregate risk has been allocated to residential uses as per Interim Decision Logic (PR 97-1, 1/31/97). Therefore, the aggregate chronic risk for tebufenozide is equivalent to the following percentages of the RfD:

Subpopulation	% Food	% Water	Total
U.S. Population	28%	10%	38%
Nursing Infant	**37%**	**10%**	**47%**
Non-Nursing Infants (<1 yr)	**61%**	**10%**	**71%**
Children (1-6 yr)	**50%**	**10%**	**60%**
Children (7-12 yr)	**37%**	**10%**	**47%**

Cancer Aggregate Risk

Since the HED RfD committee has determined that "no evidence of carcinogenicity for humans" exists for tebufenozide, no cancer aggregate risk assessment was conducted.

Determination of Safety for Infants and Children - Tebufenozide

Based on current toxicological data requirements, the data base for tebufenozide relative to pre- and post-natal toxicity is complete.

PIRAT notes that the developmental NOELs of >1000 mg/kg/day (HDT) from the rat and rabbit developmental toxicity studies demonstrate that there is no developmental (prenatal) toxicity present for tebufenozide. Additionally, these developmental NOELs are greater than 500-fold higher than the NOEL of 1.8 mg/kg/day from the 1-year feeding study in dogs which was the basis of the RfD.

In the reproductive toxicity study in rats, the reproductive/ developmental NOEL (12.1 mg/kg/day) is 14-fold higher than the parental NOEL (0.85 mg/kg/day) and indicates that post-natal toxicity in the reproductive studies occurs only in the presence of significant parental toxicity. These developmental and reproductive studies indicate that tebufenozide does not have additional sensitivity for infants and children in comparison to other exposed groups.

Cumulative Exposure - Tebufenozide

Section 408(b)(2)(D)(v) of the FQPA requires that, when considering whether to establish, modify, or revoke a tolerance, the Agency consider "available information" concerning the cumulative effects of a particular pesticide's residues and "other substances that have a common mechanism of toxicity." The Agency believes that "available information" in this context might include not only toxicity, chemistry, and exposure data, but also scientific policies and methodologies for understanding common mechanisms of toxicity and conducting cumulative risk assessments. For most pesticides, although the Agency has some information in its files that may turn out to be helpful in eventually determining whether a pesticide shares a common mechanism of toxicity with any other substances, EPA does not at this time have the methodologies to resolve the complex scientific issues concerning common mechanism of toxicity in a meaningful way. EPA has begun a pilot process to study this issue further through the examination of particular classes of pesticides. The Agency hopes that the results of this pilot process will increase the Agency's scientific understanding of this question such that EPA will be able to develop and apply scientific principles for better determining which chemicals have a common mechanism of toxicity and evaluating the cumulative effects of such chemicals. The Agency anticipates, however, that even as its understanding of the science of common mechanisms increases, decisions on specific classes of chemicals will be heavily dependent on chemical-specific data, much of which may not be presently available.

Although at present the Agency does not know how to apply the information in its files concerning common mechanism issues to most risk assessments, there are pesticides as to which the common mechanism issues can be resolved. These pesticides include pesticides that are toxicologically dissimilar to existing chemical substances (in which case the Agency can conclude that it is unlikely that a pesticide shares a common mechanism of activity with other substances) and pesticides that produce a common toxic metabolite.

EPA does not have, at this time, available data to determine whether tebufenozide has a common mechanism of toxicity with other substances or how to include this pesticide in a cumulative risk assessment. Unlike other pesticides for which EPA has followed a cumulative risk approach based on a common mechanism of toxicity, tebufenozide does not appear to produce a toxic metabolite produced by other substances. For the purposes of this tolerance action, therefore, EPA has not assumed that tebufenozide has a common mechanism of toxicity with other substances.

RISK CHARACTERIZATION - Chlorfenapyr

Occupational Exposure Assessment

The occupational exposure assessment was conducted using PHED (Pesticide Handlers Exposure Database). Additional refinement is not possible in the absence of actual exposure data. Given the large Margin of Exposures (MOE) calculated, PIRAT does not believe that this Section 18 use poses an unacceptable risk to workers.

The TES Committee does not consider workers to be at risk from inhalation exposure due to the low toxicity of the chemical. Consequently, an inhalation component has not been included in the estimates of exposure for workers.

Acute Aggregate Risk Assessment

The acute dietary (food only) risk assessment used TMRCs as a basis for the assessment. The resulting high-end exposure estimate of 0.015 mg/kg/day, which results in a dietary (food only) MOE of 3000 for infants < 1 year old, the most highly exposed subgroup, should be viewed as a conservative risk estimate; further refinement using anticipated residue values and percent crop-treated data in conjunction with Monte Carlo analysis would result in a lower acute dietary exposure estimate.

The chemical behavior of chlorfenapyr has been determined to present surface water concerns. The agricultural field model PRZM 2 and the water quality model EXAMS were used by EPA's Environmental Fate and Effects Division (EFED) to calculate Tier II Estimated Environmental Concentrations (EEC's) to estimate the upper bounds of the exposure to chlorfenapyr from surface water. The chlorfenapyr acute exposure from drinking water was 11 μg/L, corresponding to 0.0011 mg/kg/day for children and 0.0003 mg/kg/day for adults.

To determine aggregate acute dietary and drinking water risk, an MOE approach is used where the total acute exposure from the diet and drinking water is compared to the acute dietary endpoint of concern, the NOEL of 45 mg/kg/day. An aggregate acute dietary and drinking water MOE greater than 1000 is considered appropriate for chlorfenapyr. The most highly exposed subgroup for chlorfenapyr is infants < 1 year old, with a combined dietary and drinking water exposure at 0.0153 mg/kg/day, yielding an MOE of 2900.

In the best scientific judgment of HED, the aggregate acute risk (food and water) from the currently registered uses and this Section 18 use of chlorfenapyr does not exceed our level of concern.

Chronic Aggregate Risk Assessment

The chronic dietary (food only) risk assessment used TMRCs to calculate the chlorfenapyr chronic risk. Therefore, the resulting exposure estimates should be viewed as conservative; further refinement using anticipated residues and/or percent of crop-

treated would result in lower dietary exposure estimates. For chronic dietary (food only) risk estimates, the population subgroup with the largest percentage of the RfD occupied is non-nursing infants less than 1 year old at 76% of the RfD.

The chemical behavior of chlorfenapyr has been determined to present surface water concerns. The agricultural field model PRZM 2 and the water quality model EXAMS were used by EPA's Environmental Fate and Effects Division (EFED) to calculate Tier II Estimated Environmental Concentrations (EEC's) to estimate the upper bounds of the exposure to chlorfenapyr from surface water. The chlorfenapyr chronic exposure from drinking water to children was calculated to be 30% of the RfD and the exposure for the general U.S. population to be 10% of the RfD.

Since there are no indoor/outdoor residential uses, HED has concluded that a chronic residential exposure scenario does not exist for chlorfenapyr.

Although the aggregate chronic risk for the population subgroup with the largest percentage of the chlorfenapyr RfD occupied exceeds 100% of the RfD (non-nursing infants at 106%), the estimate is conservative and would be lower if anticipated residue and percent crop-treated data were used. In the best scientific judgment of HED, the chlorfenapyr aggregate chronic risk does not exceed our level of concern.

Short- and Intermediate-Term Aggregate Risk Assessment

Since there are no indoor/outdoor residential uses, HED has concluded that a short- or intermediate-term exposure scenario does not exist for chlorfenapyr. Accordingly, no short- or intermediate-term aggregate risk assessment was conducted.

Cancer Aggregate Risk Assessment

Based on the Cancer Peer Review Committee (CPRC) classification of this chemical, Group D (not classifiable as to human carcinogenicity), dietary cancer risk assessment is not required.

Hazard Assessment - Chlorfenapyr

1. Non-Dietary Exposure Endpoint Selection

   a) Short- and Intermediate-Term Risk.

      Dermal Exposure: For short-term MOE calculations, the TES Committee recommended use of a 28-day dermal toxicity study (MRID# 43492831) in rabbits. The NOEL was 100 mg/kg/day. The LEL of 400 mg/kg/day was based on increased serum cholesterol, increased relative liver weights, and unspecified histological lesions. An MOE of

1000 is required because thwe TESC determined that an additional modifying factor of 10 is appropriate.

Inhalation Exposure (for short- or intermediate-endpoints): As determined by the TES Committee, this endpoint was based on the combined LC_{50} of 1.9 mg/L. Chlorfenapyr is placed in Toxicity Category III. Therefore, risk via the inhalation route is not a concern at this time.

b) Chronic Risk. Chronic MOE calculations were not performed since there is no chronic exposure scenario for this Section 18 use.

c) Cancer Risk. The HED CRPC met on September 25, 1996 to discuss chlorfenapyr. Chlorfenapyr was classified as a Group D (not classifiable as to human carcinogenicity) chemical.

d) Dermal Penetration. A dermal absorption factor is not required for the short- and intermediate-term occupational exposure risk assessments since a 21-day dermal toxicity study was used for these scenarios.

2. Dietary Exposure Endpoint Selection

a) Acute Risk. 45 mg/kg/day. For acute dietary risk assessment, the TES Committee recommended use of an acute neurotoxicity study (MRID# 43492829) in rats. The NOEL was 45 mg/kg/day. The LEL of 90 mg/kg/day was based on lethargy of the rats on the day of treatment. An MOE of 1000 is required for all subgroups. An additional modifying factor of 10 was applied because the neurotoxicity study was considered to be supplemental, but upgradeable to acceptable if adequate historical control data are provided.

b) Chronic Risk. The HED RfD Peer Review Committee (October 25, 1996) has established an RfD of 0.003 mg/kg/day, with a total uncertainty factor (UF) of 1000, for chlorfenapyr. The uncertainty factor of 1000 contains an additional modifying factor (MF) of 10 due to uncertainties regarding neurological risks in infants and children. These neurological findings were observed in a combined toxicity/oncogenicity study (MRID# 43492838) in mice which included central nervous system lesions and scabbing of the skin (males).

c) Cancer Risk. The HED CPRC met on September 25, 1996 to discuss chlorfenapyr. Chlorfenapyr was classified as a Group D (not classifiable as to human carcinogenicity) chemical.

d) Risk to Infants and Children

1) Developmental Toxicity Studies

Rat - From the developmental toxicity study (MRID# 42770221/42884202) in rats, the maternal (systemic) NOEL was 25 mg/kg/day. The LEL of 75 mg/kg/day was based on decreased body weight gain, decreased relative feed intake, and decreased water consumption. The developmental (pup) NOEL was $\geq$ 225 mg/kg/day (HDT).

Rabbit - From the developmental toxicity study (MRID# 42770222) in rabbits, the maternal (systemic) NOEL was 5 mg/kg/day. The LEL of 15 mg/kg/day was based on decreased body weight gain. The reproductive/ developmental NOEL was $\geq$ 30 mg/kg/day (HDT).

2) Reproductive Toxicity Studies

Rat - From the multigeneration reproductive toxicity study (MRID# 434292836) in the rat, the maternal (systemic) NOEL was 5 mg/kg/day. The LEL of 22 mg/kg/day was based on decreased body weight gain (pre-mating). The reproductive/developmental NOEL was 5 mg/kg/day. The LEL of 22 mg/kg/day was based on decreased weight gain during lactation.

Occupational Exposure - Chlorfenapyr

1. Acute data for this formulation were not provided to PIRAT. No determination can be made as to whether the work clothing and personal protective equipment (PPE) appearing on the label are in compliance with the Worker Protection Standard (WPS). The Pirate Insecticide-Miticide label (EPA Reg. No. 241-EUP-126) requires applicators and handlers to wear: coveralls over short-sleeved shirt and short pants, chemical-resistant gloves, chemical-resistant footwear plus socks, chemical-resistant headgear for overhead exposure, and chemical-resistant apron when cleaning equipment, mixing, or loading. RD should ensure that the appropriate WPS statements appear on the label.

2. Acute data for the technical are available. The restricted entry interval (REI) of 12 hours appearing on the label is in compliance with the WPS.

3. Occupational exposure assumptions and estimates of exposure are summarized in Tables 1 and 2, respectively. PIRAT has conducted the estimates of exposure with workers wearing a single layer of clothing plus gloves. Pilots are not expected to wear gloves.

The TES Committee does not consider workers to be at risk from inhalation exposure due to the low toxicity of the chemical. Consequently, an inhalation component has not been included in the estimates of exposure for workers.

Dietary Exposure - Chlorfenapyr

1a. The nature of the residue of chlorfenapyr in plants is adequately understood. The residue of concern is parent compound only.

1b. The nature of the residue of chlorfenapyr in ruminants is adequately understood. The HED Metabolism Committee (6/20/96) determined that, for ruminant commodities, the chlorfenapyr tolerance expression should be in terms of parent only. For chlorfenapyr dietary risk assessments on ruminant commodities (excluding meat byproducts), residues of parent only will be used. However, chlorfenapyr dietary risk assessments on ruminant meat byproducts should include the two metabolites CL 303,268, and CL 325,195 as well as the parent (CL 303,630). The ruminant meat byproduct risk assessment will use a factor (i.e. ratio parent plus metabolites/parent) multiplied by the parent-based tolerance determined from the residue levels of the three moieties in the ruminant metabolism studies.

2. Adequate enforcement methodology is available to enforce the tolerance expression. A GC\ECD method by American Cyanamid, M 2216, is available in PP#3G4224 for chlorfenapyr residues in cottonseed (MRID# 427702-38). A meat and milk method has been submitted in conjunction with PP#5F4456 (MRID# 434928-57).

3a. **Residues of chlorfenapyr are not expected to exceed 0.5 ppm in/on cottonseed** as a result of this use. No concentration of parent residues (average level of 0.30 ppm in ginned cottonseed) occurred in crude/refined cottonseed oil or hulls. Therefore, separate tolerances for cottonseed processed commodities are not required (PP#5F4456, DP Barcode: D232519, D229102 & D225998, B. Madden, 3/6/97).

3b. Cotton gin byproduct field trial data have not been submitted. In the absence of these required data, PIRAT recommends a tolerance of **2.0 ppm of chlorfenapyr residues in/on cotton gin byproducts.** This level corresponds to that recommended in an earlier HED chlorfenapyr on cotton review (PP#5F4456, DP Barcode: D232519, D229102 & D225998, B. Madden, 3/6/97).

4a. Residues of chlorfenapyr in animal commodities are not expected to exceed (PP#5F4456, DP Barcode: D232519, D229102 & D225998, B. Madden, 3/6/97):

- **milk: 0.01 ppm**

milk fat: 0.15 ppm
meat of cattle, goats, hogs, horses, and sheep: 0.01 ppm
fat of cattle, goats, hogs, horses, and sheep: 0.10 ppm
meat byproducts
of cattle, goats, hogs, horses and sheep: 0.3 ppm.

Tolerances for poultry commodities are not required for this proposed cotton use (PP#5F4456, DP Barcode: D232519, D229102 & D225998, B. Madden, 3/6/97).

4b. Since there are cotton feed items and the cotton feed commodities are not always under the control of the grower, **the restriction prohibiting the feeding of these items should be removed from the Section 18 label.**

5. Do not plant root crops within 60 days of last application. For all other crops do not plant within 30 days of last application (PP5F4456, G. Otakie, 10/21/96). **The Pirate Section 18 label should be modified to incorporate these crop restrictions.**

6. No Codex, Canadian, or Mexican Maximum Residue Limits (MRLs) exist. Therefore, there are no compatibility issues with respect to Codex MRLs and U.S. tolerances.

7. Acute Dietary Risk. The acute dietary exposure endpoint of concern for chlorfenapyr is lethargy the day of dosing, which would affect all population subgroups. The acute analysis assumed tolerance level residues for all commodities. For all the population subgroups, the calculated MOE values are greater than 1125 based on high end exposures as follows (PP#5F4456, DP Barcode: D232519, D229102 & D225998, B. Madden, 3/6/97):

Subgroup	Exposure (mg/kg/day)	MOE
U.S. Population	0.005	9000
Infants (< 1 year)	**0.015**	**3000**
Children (1-6 year)	**0.01**	**4500**
Females (13+ years)	0.003	> 10000
Males (13+ years)	0.003	> 10000

8. Chronic Dietary Risk. Chronic dietary exposure estimates (DRES) for chlorfenapyr are summarized in the Appendix. The DRES analysis assumed tolerance level residues and 100% crop treated for all commodities. The proposed Section 18 use result in a Theoretical Maximum Residue Contribution (TMRC) that is equivalent to the following percentages of the RfD:

Subgroup	RfD%

U.S. Population (48 states)	23%
Nursing Infants	**15%**
Non-Nursing Infants (<1 year old)	**76%**
Children (1-6 years old)	**61%**
Children (7-12 years old)	**39%**

The subgroups listed above are: (1) the U.S. population (48 states); (2) those for infants and children (PP#5F4456, DP Barcode: D232519, D229102 & D225998, B. Madden, 3/6/97).

9. Dietary Cancer Risk. Based on the CPRC classification of this chemical as Group D (not classifiable as to human carcinogenicity), dietary cancer risk assessment is not required.

Exposure from Water - Chlorfenapyr

Based on review of environmental fate data (requirements listed under 40 CFR § 158.290) by EFED, chlorfenapyr is considered immobile and has a relatively high affinity for soil. The mobility characteristics exhibited by this compound are not those generally associated with compounds found in groundwater. However, the chemical behavior of chlorfenapyr does present surface water concerns. The agricultural field model PRZM 2 and the water quality model EXAMS were used by EPA's Environmental Fate and Effects Division (EFED) to calculate Tier II Estimated Environmental Concentrations (EEC's) to estimate the exposure of chlorfenapyr from surface water (S. Mostaghimi, 3/27/96). The values represent an upper bound estimate of the concentration in an edge-of-the-field pond with no outlet. The recommended values for drinking water exposure for use in human health risk assessment for surface water are 11 μg/L for acute drinking water exposure and 9 μg/L for chronic drinking water exposure. Using the following equations:

Adult Exposure = (chemical concentration in μg/L in consumed water) (10^{-3} mg/μg) (2 L/day) ÷ (70 kg body weight)

Children Exposure = (chemical concentration in μg/L in consumed water) (10^{-3} mg/μg) (1 L/day) ÷ (10 kg body weight)

%RfD = (Exposure from Water mg/kg/day) ÷ (RfD mg/kg/day) x 100

the chronic exposure from drinking water to children is calculated to be 30% of the RfD ((9μg/L x 10^{-3} mg/ug x 1 L/day ÷ 10 kg ÷ 0.003 mg/kg/day) x 100 = 30%), while the exposure for the general U.S. population would be 10% of the RfD (PP#5F4456, DP Barcode: D232519, D229102 & D225998, B. Madden, 3/6/97). Using the equations, the acute exposure from drinking water to children is calculated to be 0.0011 mg/kg/day (11μg/L x 10^{-3} mg/ug x 1 L/day ÷ 10 kg) and 0.0003 mg/kg/day for adults.

Non-Dietary Non-occupational Exposure - Chlorfenapyr

According to a search of REFS on 03/07/97, chlorfenapyr is not currently registered for any residential uses; therefore no residential exposure is anticipated.

Total Aggregate Risk - Chlorfenapyr

Acute Aggregate Risk

The acute aggregate risk assessment takes into account exposure from dietary food and water only. Based on the food dietary exposure finding and the recommended value for chlorfenapyr acute drinking water exposure, 11 µg/L (see Exposure from Water discussion above), an acute dietary (food only) MOE can be calculated (MOE = NOEL/Exposure). An aggregate acute dietary and drinking water MOE ≥ 1000 is considered appropriate for chlorfenapyr. Since the calculated MOEs are greater than 2900, the use of chlorfenapyr in/on cotton demonstrates no aggregate acute dietary and drinking water risk concern.

Subgroup	Food Exposure (mg/kg/day)	Water Exposure (mg/kg/day)	MOE
US Population	0.005	0.0011	7400
Infants (< 1 year)	**0.015**	**0.0003**	**2900**
Children (1-6 years)	**0.01**	**0.0003**	**4400**
Females (13+ years)	0.003	0.0011	>10000
Males (13+ years)	0.003	0.0011	>10000

Short- and Intermediate-Term Aggregate Risk

Short- and intermediate-term aggregate risk estimates take into account exposure from chronic dietary food and water (considered to be a background exposure level) plus indoor and outdoor residential exposure. However, since there is no potential residential indoor/outdoor non-dietary non-occupational exposure scenarios for chlorfenapyr, an aggregate short- and intermediate-term risk assessment is not necessary. HED would has no short- and intermediate-term aggregate risk concerns.

Chronic Aggregate Risk

The aggregate chronic risk for chlorfenapyr is equal to the sum of the chronic risk from food + water + residential uses. Since there are no indoor or outdoor residential uses, HED has concluded that a chronic residential exposure scenario does not exist for indoor/outdoor residential uses. Accordingly, none of the chronic aggregate risk has been allocated to indoor/outdoor residential. Therefore, the aggregate chronic risk for chlorfenapyr is equivalent to the following percentages of the RfD:

Subpopulation	Food %	Water %	Total %RfD
U.S. Population (48 states)	23%	10%	33%
Nursing Infants	**15%**	**30%**	**45%**
Non-Nursing Infants (<1 year old)	**76%**	**30%**	**106%**
Children (1-6 years old)	**61%**	**30%**	**91%**
Children (7-12 years old)	**39%**	**30%**	**69%**

Although the aggregate chronic risk for the population subgroup with the largest percentage of the chlorfenapyr RfD occupied exceeds 100% of the RfD, non-nursing infants at 106%, the estimate is conservative and would be lower if anticipated residue and percent crop-treated data were used. In the best scientific judgment of HED, the chlorfenapyr aggregate chronic risk does not exceed our level of concern.

Cancer Aggregate Risk

Based on the CPRC classification of chlorfenapyr as Group D (not classifiable as to human carcinogenicity), dietary cancer risk assessment is not required.

Determination of Safety for Infants and Children - Chlorfenapyr

Based on current toxicological data requirements, the data base for chlorfenapyr relative to pre- and post-natal toxicity is complete.

PIRAT notes that the developmental toxicity NOELs of >225 mg/kg/day (HDT in rats) and >30 mg/kg/day (HDT in rabbits) demonstrate that there is no developmental (prenatal) toxicity present at levels which produce maternal effects. Additionally, these developmental NOELs are 75- and 10-fold higher in the rats and rabbits, respectively, than the NOEL of 1.8 mg/kg/day from the 1-year feeding study in dogs (the basis of the RfD).

In the reproductive toxicity study in the rat, the reproductive/developmental NOEL (5 mg/kg/day) is equal to the parental NOEL (5 mg/kg/day). Both the pup LEL and the parental LEL of 22 mg/kg/day were based on decreased body weight. This finding suggests that there is no special post-natal sensitivity present in the reproductive study and that young rats have the same sensitivity to chlorfenapyr as adult animals.

These developmental and reproductive toxicity studies indicate that infants and children have no special sensitivity to chlorfenapyr relative to other population subgroups. An additional safety factor for infants and children is not necessary for this proposed use.

Cumulative Exposure - Chlorfenapyr

Section 408(b)(2)(D)(v) of the FQPA requires that, when considering

whether to establish, modify, or revoke a tolerance, the Agency consider "available information" concerning the cumulative effects of a particular pesticide's residues and "other substances that have a common mechanism of toxicity." The Agency believes that "available information" in this context might include not only toxicity, chemistry, and exposure data, but also scientific policies and methodologies for understanding common mechanisms of toxicity and conducting cumulative risk assessments. For most pesticides, although the Agency has some information in its files that may turn out to be helpful in eventually determining whether a pesticide shares a common mechanism of toxicity with any other substances, EPA does not at this time have the methodologies to resolve the complex scientific issues concerning common mechanism of toxicity in a meaningful way. EPA has begun a pilot process to study this issue further through the examination of particular classes of pesticides. The Agency hopes that the results of this pilot process will increase the Agency's scientific understanding of this question such that EPA will be able to develop and apply scientific principles for better determining which chemicals have a common mechanism of toxicity and evaluating the cumulative effects of such chemicals. The Agency anticipates, however, that even as its understanding of the science of common mechanisms increases, decisions on specific classes of chemicals will be heavily dependent on chemical-specific data, much of which may not be presently available.

Although at present the Agency does not know how to apply the information in its files concerning common mechanism issues to most risk assessments, there are pesticides as to which the common mechanism issues can be resolved. These pesticides include pesticides that are toxicologically dissimilar to existing chemical substances (in which case the Agency can conclude that it is unlikely that a pesticide shares a common mechanism of activity with other substances) and pesticides that produce a common toxic metabolite.

EPA does not have, at this time, available data to determine whether chlorfenapyr has a common mechanism of toxicity with other substances or how to include this pesticide in a cumulative risk assessment. Unlike other pesticides for which EPA has followed a cumulative risk approach based on a common mechanism of toxicity, chlorfenapyr does not appear to produce a toxic metabolite produced by other substances. For the purposes of this tolerance action, therefore, EPA has not assumed that chlorfenapyr has a common mechanism of toxicity with other substances.

SUPPLEMENTAL INFORMATION

Occupational Exposure

Table 1. Chlorfenapyr Occupational Exposure Assumptions

PARAMETER	ASSUMPTION
Pesticide Handlers Exposure Database (PHED), Version 1.1: Mixer/loader from LIQ.OPN.MLOD (7/96); Groundboom Applicator from GBM.OPN.APPL (7/96): and Aerial Applicator from Best Available Surrogate Exposure Table (BASET, 7/25/96)	Mixer/Loader (liquid, open pour, single layer clothing plus gloves): Dermal = 22.9952 µg/lb ai handled (high confidence data).
	Applicator - Ground (groundboom, open cab, single layer clothing plus gloves): Dermal = 14.0180 µg/lb ai applied (medium confidence data).
	Applicator - Air (liquid formulations, enclosed cockpit, single layer clothing, no gloves): Dermal = 5.0 µg/lb ai applied (medium confidence data).
Percent Absorption	Dermal: NA (dermal Tox study)
Application Type	Ground and air
Minimum Finish Spray	Ground: 10 gal/A Air: 5 gal/A
Maximum Application Rate	0.2 lb ai/A
Maximum Applications Per Year	2
Duration of Occupational Exposure	Intermediate (one week to several months)
Acres Treated/Day (Y. NG,BEAD)	Ground: 111 acres Air: 409 acres
Average Farm Size (1992 Ag Census)	Based on Gaines county, TX 540 acres
Worker Weight	Dermal 70 kg (based on Tox endpoint)
Number of Farms Treated by PCO (Professional Chemical Operator)	Ground: 2 (OREB default value) Air: 10 (OREB default value)

Table 2. Chlorfenapyr Occupational Exposure and Risk Assessment[a]		
Worker	**Average Daily Dermal Dose[b] (ug/kg/day)**	**Short- & Intermediate-Term Dermal MOE[c]**
Ground Mixer/Loader	7.29	14,000
Ground Applicator	4.45	23,000
Aerial Mixer/Loader	26.9	3,700
Aerial Applicator	5.84	17,000

[a] MOEs are expressed to two significant figures.
[b] Average Daily Dose (ADD) Dermal = PHED unit exposure x % absorption x application rate x acres treated/day ÷ kg body weight.
[c] Short- & Intermediate-Term Occupational Exposure Dermal MOE = NOEL/ADD (where NOEL = 100 mg/kg/day).

Dietary Exposure

Table 3. Tebufenozide Residue Consideration Summary Table		
Parameter	**Proposed Use**	**Residue Data**
Chemical	Tebufenozide	Tebufenozide
Formulation	Confirm 2F	Confirm 2F
Crop	Cotton	Cotton
Type Application	ground (>10 gpa) or aerial (>5 gpa)	Foliar
Number of Applications	2	4
Timing	Timing based on pest population and army beetworm life cycle.	Applications initiated to allow a minimum of four applications on a 10- to 14- day spray schedule with 0-, 7- and 14-day PHIs.
Rate/Application	0.125 lbs ai/A	0.125 and 0.250 lbs ai/A
Rate/Year or Season	0.25 lbs ai/A/season	0.5 and 1.0 lbs ai/A/season

Maximum Residue	N/A	0.18 ppm undelinted cottonseed
Restrictions	30-day PHI	None
Residue Data Source	N/A	94MS0008
Performing Lab	N/A	Rohm and Haas, and ABC Laboratories

Table 4. Chlorfenapyr Residue Consideration Summary Table

PARAMETER	PROPOSED USE	RESIDUE DATA
CHEMICAL	Chlorfenapyr	Chlorfenapyr
FORMULATION	Pirate 3 SC (EPA Reg. No. 241-EUP-126) (packaged as a suspension concentrate)	Alert 2 SC (EPA Reg. No. 241-EUP-136) (packaged as a suspension concentrate)
CROP	Cotton	Cotton
TYPE APPLICATION	Ground (≥10 gpa) or air (≥5 gpa)	Ground - broadcast spray
# APPLICATIONS	2	5
TIMING/PHI	Timing based on pest population and army beetworm life cycle. 21-day PHI.	Weekly applications. Discontinue 21 days before harvest.
RATE/APPLICATION	0.2 lbs ai/A	0.4 lbs ai/A
RATE/YEAR	0.4 lbs ai/A	2.0 lbs ai/A
MAXIMUM RESIDUE	N/A	0.32 ppm cottonseed. No detectable residues in processed commodities.
RESTRICTIONS	Do not plant rotational within 60 days of application.	Do not allow livestock to graze in treated fields.
RESIDUE DATA SOURCE	N/A	PP#3G4224, MRID# 427702-38
PERFORMING LAB	N/A	American Cyanamid Co.

SUPPLEMENTAL INFORMATION

Additional Information

Magnitude of the Residue - Animals - Tebufenozide

Undelinted cottonseed, cottonseed meal, hulls, and cotton gin byproducts are animal feed items (OPPTS 860.1100, Table 1, 7/31/96). The maximum theoretical dietary burden for tebufenozide treated cottonseed feed items is calculated as 1.2 ppm (see Table 5).

Radioactive residues in milk and animal commodities were found in a goat metabolism study. Goats were dosed with 50 ppm ^{14}C-tebufenozide (PP#4E4375, MRID #437066-01, CBTS #15817 and 15926, DP Barcode D216949 and D217246, D. Davis, 11/3/95). Three separate studies, using three different tebufenozide formulations each with different ring labels were conducted. Maximum total radioactive residues (TRR) of 2.9 ppm in liver, 0.2 ppm in kidney, 0.1 ppm in meat and meat by-products, 0.3 ppm in fat, and 0.2 ppm in milk, were found. No attempt was made to characterize the residues.

There are no established tolerances for the secondary residues of tebufenozide in animal commodities. Using the TRR data available from the goat metabolism study and extrapolating to the maximum theoretical dietary burden of 1.21 ppm, the following TRR levels could potentially be present in/on ruminant commodities:

fat: 0.01 ppm
liver: 0.1 ppm
meat: 0.005 ppm
meat byp (except liver): 0.005 ppm
milk: 0.005 ppm

However, PIRAT considers these residue levels to be highly unlikely. We note that these levels are based on extrapolation from a high dose level metabolism study (50 ppm) and are based on TRR levels. Additionally, the maximum theoretical ruminant dietary burden is based on the livestock diet being comprised of 80% cotton feedstuffs - a highly improbable situation. PIRAT concludes that residue levels in animal commodities resulting from this Section 18 use would be undetectable. PIRAT will not recommend for time-limited tolerances for tebufenozide on animal commodities for this use. Since PIRAT does not expect detectable residues in animals from tebufenozide treated cotton feed items, **the restriction prohibiting the feeding of these items should be removed from the Confirm Section 18 label.**

Table 5: Theoretical Maximum Dietary Burden of Tebufenozide Residues in Cottonseed Feedstuffs								
Commodity (tolerance and % dry matter)	Beef Cattle		Dairy Cattle		Poultry		Swine	
	Diet %	Burden (ppm)	Diet %	Burden (ppm)	Diet %	Burden (ppm)	Diet %	Burden (ppm)
undelinted cottonseed, (0.2 ppm, 88% DM)	25	0.06	25	0.06	NU	NA	NU	NA
cottonseed hulls, (0.8 ppm, 90% DM)	20	0.18	15	0.18	NU	NA	NU	NA
cottonseed meal (0.5 ppm, 89%DM)	15	0.08	15	0.08	20	0.1	15	0.08
cotton gin byproducts (4 ppm, 90% DM)	20	0.89	20	0.89	NU	NA	NU	NA

Theoretical Maximum Dietary Burden for cattle is calculated by multiplying the percent of diet times the proposed feedstuff tolerance and dividing the result by the percent dry matter (DM) for that feedstuff.
Theoretical Maximum Dietary Burden for poultry and swine is calculated by multiplying the percent of diet times the proposed feedstuff tolerance.
DM = dry matter; NU = not usually; NA = not applicable.

Attachments: Tebufenozide Chronic DRES Analysis (3/5/97)

cc with Attachments: Cutchin, PIRAT, DRES (B. Steinwand), RCAB (K. Boyle)

cc without Attachments: Williams-Foy, Lewis, Dykstra, OREB (Chem File), Caswell File, TOXII Files, CBTS (Sect 18)

RDI: PIRAT: 3/18/97

CHEMICAL	STUDY TYPE	EFFECTS	REFERENCE DOSES	DATA GAPS/COMMENTS	STATUS
Tebufenozide Caswell #945 CAS No. 112410-23-8 A.I. CODE: 129026 CFR No.	1yr feeding- dog NOEL= 1.8000 mg/kg 50.00 ppm LEL= 8.7000 mg/kg 250.00 ppm ONCO: E (RfD/PR Committee)	Changes in hematology, clinical chemistry, abs. & rel. spleen wts; histo of bone, spleen & liver. No evidence of carcinogenicity in rats or mice.	ADI UF -->100 OPP RfD= 0.018000 EPA RfD= 0.000000	No data gaps. From dog study NOEL/LEL for females are 1.9 & 8.9 mg/kg-day, respectively.	RfD/PR reviewed 07/21/94

FOOD CODE	FOOD NAME	PETITION NUMBER	TOLERANCE (PPM) NEW	PENDING	PUBLISHED
03009AA	WALNUTS	4F4280			0.100000
04001AA	APPLES-FRESH	4E4375			1.000000
04001DA	APPLES-DRIED	4E4375			1.000000
04001JA	APPLES-JUICE	4E4375			1.000000
08048DA	PAPRIKA	97TX002		0.500000	
11003AA	PEPPERS,SWEET,GARDEN	97TX002		0.500000	
11003AB	CHILI PEPPERS	97TX002		0.500000	
11003AD	PEPPERS-OTHER	97TX002		0.500000	
11004AA	PIMIENTOS	97TX002		0.500000	
13002AA	CELERY	97TX001		5.000000	
13003AA	CHICORY (FRENCH OR BELGIAN ENDIVE)	97TX001		5.000000	
13005AA	BROCCOLI	97TX001		5.000000	
13006AA	BRUSSEL SPROUTS	97TX001		5.000000	
13007AA	CABBAGE-GREEN AND RED	97TX001		5.000000	
13008AA	CAULIFLOWER	97TX001		5.000000	
13009AA	COLLARDS	97TX001		5.000000	
13010AA	CABBAGE-CHINESE/CELERY, INC. BOK CHOY	97TX001		5.000000	
13011AA	KALE	97TX001		5.000000	
13012AA	KOHLRABI	97TX001		5.000000	
13013AA	LETTUCE-LEAFY VARIETIES	97TX001		5.000000	
13014AA	DANDELION	97TX001		5.000000	
13015AA	ENDIVE,CURLEY AND ESCAROLE	97TX001		5.000000	
13017AA	CRESS,GARDEN,FIELD	97TX001		5.000000	
13020AA	LETTUCE-UNSPECIFIED	97TX001		5.000000	
13021AA	MUSTARD GREENS	97TX001		5.000000	
13022AA	PARSLEY	97TX001		5.000000	
13023AA	RHUBARB	97TX001		5.000000	
13024AA	SPINACH	97TX001		5.000000	
13025AA	SWISS CHARD	97TX001		5.000000	
13026AA	TURNIPS-TOPS	97TX001		5.000000	
13039AA	CRESS,UPLAND	97TX001		5.000000	
13045AA	LETTUCE-HEAD VARIETIES	97TX001		5.000000	
25002SA	BEET SUGAR	97CA001		4.000000	
27003OA	COTTONSEED-OIL	97TX011	1.300000		
27003WA	COTTONSEED-MEAL	97TX011	0.500000		

CHEMICAL INFORMATION	STUDY TYPE	EFFECTS	REFERENCE DOSES	DATA GAPS/COMMENTS	STATUS
Tebufenozide Caswell #945 CAS No. 112410-23-8 A.I. CODE: 129026 CFR No.	1yr feeding- dog NOEL= 1.8000 mg/kg 50.00 ppm LEL= 8.7000 mg/kg 250.00 ppm ONCO: E (RfD/PR Committee)	Changes in hematology, clinical chemistry, abs. & rel. spleen wts; histo of bone, spleen & liver. No evidence of carcinogenicity in rats or mice.	ADI UF -->100 OPP RfD= 0.018000 EPA RfD= 0.000000	No data gaps. From dog study NOEL/LEL for females are 1.9 & 8.9 mg/kg-day, respectively.	RfD/PR reviewed 07/21/94

POPULATION SUBGROUP	TOTAL TMRC (MG/KG BODY WEIGHT/DAY) CURRENT TMRC*	NEW TMRC**	NEW TMRC AS PERCENT OF RFD	DIFFERENCE AS PERCENT OF RFD	EFFECT OF ANTICIPATED RESIDUES ARC	XRFD
U.S. POPULATION - 48 STATES	0.000791	0.004950	27.499950	23.103639		
U.S. POPULATION - SPRING SEASON	0.000640	0.004937	27.428967	23.874178		
U.S. POPULATION - SUMMER SEASON	0.000643	0.004723	26.241094	22.667711		
U.S. POPULATION - FALL SEASON	0.000950	0.005070	28.163928	22.885717		
U.S. POPULATION - WINTER SEASON	0.000932	0.005056	28.089856	22.910006		
NORTHEAST REGION	0.000999	0.005033	27.962006	22.409461		
NORTH CENTRAL REGION	0.000709	0.004669	25.938000	21.998283		
SOUTHERN REGION	0.000608	0.004852	26.957117	23.578711		
WESTERN REGION	0.000949	0.005402	30.010194	24.738128		
HISPANICS	0.000867	0.004333	24.073028	19.258378		
NON-HISPANIC WHITES	0.000823	0.004863	27.016183	22.441322		
NON-HISPANIC BLACKS	0.000542	0.005575	30.974128	27.962228		
NON-HISPANIC OTHERS	0.000846	0.006734	37.411222	32.712133		
NURSING INFANTS (< 1 YEAR OLD)	0.005978	0.006665	37.029894	3.818511		
NON-NURSING INFANTS (< 1 YEAR OLD)	0.008051	0.011045	61.362606	16.637050		
FEMALES (13+ YEARS, PREGNANT)	0.000485	0.003730	20.720561	18.024578		
FEMALES 13+ YEARS, NURSING	0.000617	0.005007	27.817328	24.392211		
CHILDREN (1-6 YEARS OLD)	0.002723	0.009023	50.126122	34.999572		
CHILDREN (7-12 YEARS OLD)	0.001062	0.006594	36.632428	30.733117		
MALES (13-19 YEARS OLD)	0.000491	0.004342	24.121278	21.393978		
FEMALES (13-19 YEARS OLD, NOT PREG. OR NURSING)	0.000496	0.004292	23.846400	21.089539		
MALES (20 YEARS AND OLDER)	0.000354	0.003827	21.260417	19.292094		
FEMALES (20 YEARS AND OLDER, NOT PREG. OR NURS)	0.000394	0.004300	23.890211	21.700128		

*Current TMRC does not include new or pending tolerances.
**New TMRC includes new, pending, and published tolerances.