



Pesticide
Fact Sheet

Name of Chemical: Thiacloprid
Reason for Issuance: Conditional Registration
Date Issued: September 26, 2003

1. DESCRIPTION OF CHEMICAL

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| Generic Name: | [3-[(6-chloro-3-pyridinyl)methyl]-2-thiazolidinylidene]cyanamide |
| Common Name: | Thiacloprid |
| Trade Name: | Calypso; YRC-2894 |
| EPA PC Code: | 014019 |
| Chemical Abstracts Service (CAS) Number: | 111988-49-9 |
| Year of Initial Registration: | 2003 |
| Pesticide Type: | Insecticide |
| Chemical Class: | Chloronicotinoid |
| Function/Mode of Action of Active Ingredient: | Disruption of the nervous system by acting as an inhibitor at nicotinic acetylcholine receptors |
| U.S. Producer: | Bayer CropScience |
| Classification of End-Use Product: | The product is not a restricted use pesticide. |

2. DESCRIPTION OF USE PATTERN AND FORMULATIONS

The Agency has issued a conditional registration for thiacloprid as an outdoor non-residential, food/feed use on the agricultural crops cotton and pome fruits for control of a variety of sucking insects. The primary target pests for thiacloprid on cotton are aphids and whiteflies; Psylla, codling moth and plum Curculio are the primary pests on pome fruits. The two formulated products consist of a flowable concentrate at 40.4% and a wettable granular (WG) at 70%. Both formulated products are diluted in water and applied by ground or air as a full coverage foliar spray to cotton and pome fruits. They may also be applied as a concentrate foliar spray to pome fruits. The maximum single application rates are 0.25 lb. active ingredient per acre (a.i./A) for pome fruits and 0.09375 lb. a.i./A for cotton. The maximum seasonal application rates are 0.50 lb a.i./A for pome fruits and 0.28 lb a.i./A for cotton.

3. SUMMARY OF SCIENCE FINDINGS

I. Chemical Characteristics of Technical Thiacloprid

| | |
|---|---|
| Color | Yellowish |
| Physical State | Crystal powder |
| Odor | Odorless |
| Stability to normal and elevated temperatures, metals, and metal ions | Stable to elevated temperatures; stable in presence of metal and metal ions |
| Oxidation/reduction | Unaffected by reducing agents |
| Storage Stability | Stable for 2 weeks at 50°C |
| pH | 7.40 at 20°C |
| Melting Point | 136 °C |
| Relative density | 1.46 g at 20°C |
| Dissociation constants in water | No basic or acidic properties in aqueous solutions |
| Partition coefficient(n-octanol/water) | $K_{ow} = 18.0$; $\log P_{ow} = 1.26$ @ 20°C |
| Water solubility; column elution method; shake flask method | In water = 185ug/L at 20°C |
| Vapor pressure | 23×10^{-12} hPa at 20°C; 8×10^{-12} hPa at 25°C |

II. Toxicological Characteristics

A. Acute Toxicity Profile of Technical Thiocloprid and Formulated Products

| Study | Technical Product | | Formulated Product 40.4% Flowable | | Formulated Product 70% WG | |
|----------------------------------|--|----------------------|--|----------------------|---|----------------------|
| | Results | Toxicity Category | Results | Toxicity Category | Results | Toxicity Category |
| Acute oral toxicity; rat; LD50 | 621 mg/kg in males; 396 mg/kg in females. | II | 500-2000 mg/kg in males; 200-500 mg/kg in females. | II | 296 mg/kg in males; 274 mg/kg in females. (285 combined) | II |
| Acute dermal toxicity; rat, LD50 | 2000 mg/kg in males and females. | III | > 4000 mg/kg in males and females. | III | > 2000 mg/kg in males and females. | III |
| Acute inhalation; rat LC50 | > 0.481 mg/L in males and females. | III | > 1.535 mg/L in males; 0.690-1.535 mg/L in females. | III | > 2.5 mg/L in males and females. | IV |
| Primary eye irritation | Minimal effects. | IV | No effects observed. | IV | Minimal effects. | IV |
| Primary dermal irritation | Not a skin irritant. | IV | Minimal effects. | IV | Minimal effects. | IV |
| Dermal sensitization | Non-sensitizer. | Negative | Non-sensitizer. | Negative | Non-sensitizer. | Negative |

B. Subchronic and Chronic Toxicity Profile of Technical Thiocloprid

| Guideline No. | Study Type | Results |
|---------------|------------------------------------|---|
| 870.3100 | 90-Day oral toxicity rodents | NOAEL = Rats: males, 7.3 mg/kg/day; females, 7.6 mg/kg/day. Mice: females, 27.3 mg/kg/day; males 102.6 milligram/kilogram/day (mg/kg/day). LOAEL = Rats: males, 28.6 mg/kg/day; females, 35.6 mg/kg/day based on decreased body weight throughout treatment. Mice: females, 27.2 mg/kg/day based on adrenal X-zone changes; males, 542.4 mg/kg/day based on liver effects (weight and hypertrophy). |
| 870.3150 | 90-Day oral toxicity in nonrodents | NOAEL = males. 8.5, females, 8.9 mg/kg/day. LOAEL ~ 34.9 mg/kg/day based on [mainly liver enzyme changes, thyroid hormone level (T4) and binding capacity changes and prostatic weight change and prostatic hypertrophy. |

| Guideline No. | Study Type | Results |
|----------------------------------|---|---|
| 870.4300 | Combined chronic feeding/carcinogenicity rats | NOAEL = Males, 1.2 mg/kg/day ; females, 1.6 mg/kg/day. LOAEL = Males, 2.5 mg/kg/day based on liver toxicity (hepatocellular hypertrophy and cytoplasmic change and increased enzyme activity), thyroid follicular epithelial hypertrophy; females, 3.3 mg/kg/day based on ocular toxicity (retinal atrophy). Evidence of carcinogenicity based on increased incidence of thyroid follicular cell adenomas in males and possibly also in females and increased incidence of uterine tumors (adenocarcinomas). |
| 870.4200 | Carcinogenicity mice | NOAEL = Males, 5.7 mg/kg/day; females: 10.9 mg/kg/day. LOAEL = Males, 234.1 mg/kg/day; females, 475.3 mg/kg/day. Based on liver toxicity and microscopic lymph node changes in both sexes, and increased X-zone vacuolization of the adrenal glands in female mice. Evidence of carcinogenicity based on increased incidence of ovarian luteomas. |
| 870.5100 870.5300 | Gene Mutation | Negative in a battery of tests. |
| 870.5375 870.5395 870.5500 | Cytogenetics | Negative in battery of tests. |
| 870.5550 | Other Effects | Negative. |
| 870.6200a | Acute neurotoxicity screening battery | NOAEL = Males, 11 mg/kg bodyweight (bw); females, 3.1 mg/kg/day. LOAEL = Males, 22 mg/kg bw based on FOB observations of slight tremors and ptosis of the eyelids on the day of treatment; females, 11 mg/kg/day based on reductions in motor and locomotor activity. |
| 870.6200b | Subchronic neurotoxicity screening battery | NOAEL = Males, 24.2 mg/kg/day; females, 27.9 mg/kg/day. LOAEL = Males, 101 mg/kg/day; females, 115 mg/kg/day. Based on decreased body weight gains and food consumption in both sexes and decreased hindlimb grip strength in males. |
| 870.6300 | Developmental neurotoxicity | Maternal NOAEL = 4.4 mg/kg/day. LOAEL = 25.6 mg/kg/day based on decreased body weight gain and food consumption during early gestation (gestation day 0-6). Offspring NOAEL = 4.4 mg/kg/day (tentative offspring) LOAEL = 25.6 mg/kg/day (tentative offspring) based on decreased pre-weaning and post-weaning body weights in both sexes and delayed sexual maturation in the males, and altered performance in passive avoidance testing. |

| Guideline No. | Study Type | Results |
|---------------|---------------------------------|--|
| 870.7485 | Metabolism and pharmacokinetics | Thiacloprid is rapidly absorbed and is rapidly excreted after the following metabolic processes, with little remaining in the tissues. The metabolic processes were summarized as: 1) hydroxylation of the thiazolidine ring and subsequent glucuronidation (as shown by metabolite PIZ 1270), 2) hydroxylation of the cyanamide moiety (metabolite KNO 1891), 3) opening of the thiazolidine ring (e.g., metabolites KNO2672, PIZ1297F/WAK 6935), 4) formation of an oxazole ring (metabolite PIZ 1253), 5) oxidation and subsequent methylation of the thiazolidine ring (e.g., PIZ 1297E and PIZ 1269X), and 6) oxidative cleavage of the methylene bridge (PIZ 1243). Only minor gender-related quantitative differences in metabolite profiles were observed. |
| 870.7600 | Dermal penetration | A 5% dermal absorption value is appropriate for estimating the risk resulting from dermal exposure to Thiacloprid formulated as a 40.4% liquid formulation (SC 480). This 5% value is also appropriate for other liquid thiacloprid formulations that are similar to the SC 480 liquid formulation product tested and for aqueous dilutions of most thiacloprid formulations. |

III. Toxicological Endpoints

| Summary of Toxicological Dose and Endpoints for Thiacloprid for Use in Human Health Risk Assessment | | | |
|---|---|---|---|
| Exposure Scenario | Dose Used in Risk Assessment, UF | Special FQPA SF and Level of Concern for Risk Assessment | Study and Toxicological Effects |
| Acute Dietary (all population groups) | NOAEL = 3.1 mg/kg UF = 300 Acute RfD = 0.01 mg/kg | FQPA SF = 1 aPAD = acute RfD FQPA SF = 0.01 mg/kg | Acute neurotoxicity in rats. LOAEL = 11 mg/kg/day based on decreased motor activity in females. |
| Chronic Dietary (All populations) | NOAEL= 1.2 mg/kg/day UF = 300 Chronic RfD = 0.004 mg/kg/day | FQPA SF = 1 cPAD = chronic RfD FQPA SF = 0.004 mg/kg/day | Chronic feeding in rats. LOAEL = 2.5 mg/kg/day based on hepatic hypertrophy and cytoplasmic change and thyroid hypertrophy and retinal degeneration. |
| Incidental Oral - All Durations. | NOAEL= 1.2 mg/kg/day | Occupational = N/A | Chronic feeding in rats. LOAEL = 2.5 mg/kg/day based on hepatic hypertrophy and cytoplasmic change and thyroid hypertrophy. |
| Dermal- All Durations. | Oral study NOAEL= 1.2 mg/kg/day (dermal absorption rate = 5%) | Occupational LOC for MOE= 100 | Chronic feeding in rats. LOAEL = 2.5 mg/kg/day based on hepatic hypertrophy and cytoplasmic change and thyroid hypertrophy. |

| Summary of Toxicological Dose and Endpoints for Thiocloprid for Use in Human Health Risk Assessment | | | |
|--|--|--|---|
| Exposure Scenario | Dose Used in Risk Assessment, UF | Special FQPA SF and Level of Concern for Risk Assessment | Study and Toxicological Effects |
| Inhalation - <i>All Durations.</i> | NOAEL = 0.542 mg/kg/day | Occupational LOC for MOE = 100 | 28 day inhalation study in rats. LOAEL = 4.93 mg/kg/day based on liver hypertrophy increased N-DEM. |
| Cancer (oral, dermal, inhalation) | $Q_1^* \text{ (mg/kg/day)}^{-1} = 4.06 \times 10^{-2}$ | Classified as a "likely" human carcinogen based on thyroid tumors and uterine tumors in rats and ovary tumors in mice. | |

^a 3X database uncertainty factor for lack of morphological measurements in the low- and mid-dose groups in the developmental neurotoxicity study.

UF = uncertainty factor, FQPA SF = Special FQPA safety factor, NOAEL = no observed adverse effect level, LOAEL = lowest observed adverse effect level, PAD = population adjusted dose (a = acute, c = chronic) RfD = reference dose, MOE = margin of exposure, LOC = level of concern, NA = Not Applicable.

FQPA SAFETY FACTOR (SF): In evaluating whether to retain the 10X SF to protect infants and children, the following factors were considered: (a) there are no special concerns regarding pre- or post-natal toxicity exposure, (b) the exposure databases (dietary food and drinking water) are complete and/or employ conservative assumptions, (c) there is no residential exposure, (d) the risk assessments cover or approximate all the metabolites and degradates of concern, and (e) the assessments do not underestimate the potential risk for infants and children. However, an FQPA data base uncertainty factor of 3X is retained for the lack of morphometric assessments for the low- and mid-dose group animals in the developmental neurotoxicity study (DNT). A 3X factor was judged to be adequate because the dose selected for overall risk assessments is already based on the most sensitive end points for acute (i.e. clinical signs indicative of neurotoxicity) and chronic (i.e. liver and thyroid effects) dietary and non-dietary exposure scenarios, and the available data indicate that the full characterization of brain morphometrics from the DNT study would not be expected to lower the dose used for risk assessments by more than 3-fold. The 3X database uncertainty factor was applied across all aggregate risk assessments.

IV. Human Exposure/Risk Assessment

A. Dietary

1. Food

Acute and Chronic (non cancer): The acute dietary exposure estimates are below the Agency's level of concern (< 100% aPAD) at the 99.9th exposure percentile for the general U.S. population (20% of the aPAD) and for all other population subgroups. The most highly exposed population subgroup is "all infants," at 51% of the aPAD. The chronic dietary exposure estimates are also below the Agency's level of concern for the general U.S. population (< 1.0% of the cPAD) and for all other population subgroups. The most highly exposed population subgroup is "all infants," at 4.4% of the cPAD.

Cancer: For risk management purposes, EPA considers a cancer risk to be greater than negligible when it exceeds the range of 1 in 1 million (1×10^{-6}). EPA has generally treated cancer risks up to 3 in 1 million (3×10^{-6}) as within the range of 1 in 1 million. The lifetime cancer risk estimate for the U.S. General Population is 1.3×10^{-6} , based upon a Q1* of 4.06×10^{-2} .

2. Drinking Water: The residues of concern for purposes of the drinking water risk assessment are the parent and the degradate, YRC 2894-amide. For surface water, the acute (peak), chronic (annual average) and cancer (36 year average) Estimated Environmental Concentrations (EEC)s are 10.2 parts per billion (ppb), 2.36 ppb and 1.52 ppb, respectively. The ground water EEC is 0.06 ppb.

3. Aggregate (Food and Drinking Water): Human health aggregate risk assessments were conducted for: acute aggregate exposure (food + drinking water), chronic aggregate exposure (food + drinking water) and cancer aggregate exposure (food + drinking water). There are no proposed residential uses, so short-term, intermediate- and long-term aggregate risk assessments, which are specifically used to assess residential exposure, were not performed.

Acute: The acute aggregate risk associated with the proposed use of thiacloprid does not exceed the Agency's level of concern for the general U.S. population or any population subgroups. The subpopulation with the greatest exposure is all infants, where the surface water EEC is 10.2 ppb compared to a Drinking Water Level of Comparison (DWLOC) of 49 ppb.

Chronic (non-cancer): The chronic aggregate risk associated with the proposed use of thiacloprid does not exceed the Agency's level of concern for the general U.S. population or any population subgroups. The subpopulations with the greatest exposure is all infants and children 3-5 years old. For both population subgroups, the DWLOC is estimated at 38 ppb, while the surface water EEC is 2.36 ppb.

Cancer: Cancer aggregate risk is calculated for the general U.S. population only. For this population, the calculated DWLOC of 1.5 ppb is the same as the calculated EEC of 1.5 ppb.

$$\text{DWLOC} = \frac{[3 \times 10^{-6}/Q_1^* - \text{average food exposure (mg/kg/day)] * bwt * 1000 \text{ug/mg}}{\text{Water consumption (liter/day)}}$$

$$\text{DWLOC (U.S. Pop.)} = 1.5 \text{ ug/L.}$$

Since the surface water EEC for cancer is 1.5 ug/L, the estimated aggregate cancer risk is equal to 3×10^{-6} . The dietary risk is based on residue data derived from the average of field trials. It is not unusual in the Agency's experience for field trial data to be an order of magnitude above actual monitoring. Since this will be the first registration for thiacloprid, actual monitoring data are not yet available. It is likely that the actual risk contribution from food will be much lower than current data indicate. Thus, EPA does not expect that the general population would be exposed to levels that would exceed a negligible cancer risk over a lifetime.

4. Cumulative Thiacloprid does produce 6-CNA, a metabolite also produced by another registered chloronicotinoid pesticide. However, the limiting toxic endpoints used in this assessment for thiacloprid are not based upon the toxicity of 6-CNA. For the purposes of this tolerance action, therefore, EPA has not assumed that thiacloprid has a common mechanism of toxicity with other substances.

B. Occupational Exposure/Risk Assessment

1. Handler

Short and Intermediate Term: None of the identified handler scenarios for either of the two formulated products were found to be of concern (all meet or exceed a Margin of Exposure (MOE) of 100), with the use of Level 1 Personal Protective Equipment (PPE) (a single layer work clothing and gloves).

Cancer: With baseline Personal Protective Equipment (PPE) (long pants, long-sleeved shirt and shoes plus socks), cancer risks estimated for handler activities were 3.5×10^{-5} to 1×10^{-6} for apples/pears and 4×10^{-4} to 2.8×10^{-7} for cotton. However, exposure calculations were based on a screening assessment which included a number of conservative assumptions. Thiacloprid was assumed to be applied at the maximum rate, to the maximum acreage of cotton, and with no dissipation assumed (because thiacloprid is a new active ingredient, typical application rate data are not available, so the maximum application rate was used to calculate cancer risk). In addition, the label requires additional PPE (waterproof gloves) that would further reduce handler exposure.

2. Agricultural Workers - Post-Application

Short and Intermediate Term: Post-application short and intermediate-term exposures are not of concern for any of the agricultural activities for any of the treated crops on the day of application (all MOE's exceed 100 at day zero).

Cancer: The cancer probabilities on the day of application were estimated using the cancer endpoint at the maximum labeling application rate. Cancer risks ranged from 2.2×10^{-7}

to 1.6×10^{-5} at 0 days REI. The risks for all the scenarios are very conservative, however, and likely can be refined once information about typical application rates becomes available. The risks were assessed based upon a combination of very conservative assumptions: thiacloprid was applied at the maximum rate, to the maximum acreage of cotton, exposure for 30 days, exposure over 30 years and with no dissipation assumed. Lacking an estimate for residue dissipation over the work interval, one needs to assume that the worker travels directly from one treated field to another so that the highest residue value is always found.

V. Environmental Fate

Degradation/Dissipation; Soil: The main route for dissipation of Thiacloprid in soil is through microbial degradation (from 0.6 to 3.8 days half-life). It is stable in anaerobic aquatic conditions (half life of over 1 year), and degrades under aerobic aquatic conditions with a half life of 10-63 days. The only two major degradates (greater than 10% of applied radioactivity) were YRC 2894 amide which is the metabolite of concern in drinking water and YRC 2894 sulfonic acid. In an aerobic soil system, the calculated DT50 for the amide and the sulfonic acid metabolites were from 32-142 days and 12 - 73 days, respectively. There are no toxicological concerns with the YRC 2894 amide metabolite.

Field: The submitted field studies showed that thiacloprid degrades with a half life range from 2.4 to 27.4 days, and major metabolites were YRC 2894 Amide and YRC 2894 sulfonic acid. The major route of dissipation under terrestrial field conditions was transformation.

Leaching: Both the parent and the drinking water metabolite of concern, YRC 2894 amide, have low-medium potential to leach to ground water. Though the other of the two major metabolites, sulfonic acid, is expected to be more persistent and mobile than the parent, its toxicity is likely to be much less than the parent due to its increased polarity and expected ease of excretion. In addition, the amide is a much larger percentage of the applied dose (74%) than is the sulfonic acid (19.7%). There are incomplete environmental fate data for YRC 2894 amide, so conservative assumptions were made about its fate based upon the fate of the parent.

Ground and Surface Water: The modeling predicts that both thiacloprid and its major degradate, YRC 2894 amide, will not be found in significant concentrations in groundwater. However, YRC 2894 sulfonic acid is expected to be more persistent and mobile, and, thus, a groundwater advisory will be required on the label. Because of limited mobility, thiacloprid is not likely to run off from the use site to contaminate surface water. However, thiacloprid has a high water solubility that results in the potential contamination of surface water following rainfall events.

VI. Ecological Effects

A. Aquatic organisms:

Fresh water: There is no concern for acute risk to freshwater fish and invertebrates nor for chronic risk to freshwater fish and invertebrates. In addition, environmental fate studies indicate that thiacloprid is not expected to exist in concentrations that will pose risk to freshwater aquatic organisms.

It is predicted that the degradates will pose minimal risk to freshwater organisms. Supplemental toxicity data were submitted for the metabolites of thiacloprid for freshwater organisms only. The test demonstrated that the LC₅₀ values were higher than the highest concentrations tested which also indicated that the degradates were slightly toxic to practically non-toxic to aquatic organisms.

Marine/Estuarine: There is no concern for acute or chronic risks to marine/estuarine fish. There is concern for risk to marine/estuarine invertebrate species, both acute (all the proposed uses) and chronic (for apple and cotton uses). This is because of the close proximity of the use sites to marine/estuarine habitats, the potential for thiacloprid to be washed off the use sites into these habitats after a rainfall event, the high toxicity (acute and potential for adverse reproductive effects to these species), and the Agency's risk quotients (RQ) predict that thiacloprid may contaminate surface water at concentrations that exceed the Agency's level of concern.

B. Terrestrial Organisms: There is no concern for birds on an acute oral basis or on a subacute basis. There is concern for chronic risks to birds for all the proposed uses. There is concern for acute risks to only the very smallest sized mammal species for all the proposed uses, and chronic risks to all small mammals for all the proposed uses.

C. Plants: Based on the submitted data, it is not expected that plant species will be adversely effected by the proposed uses.

D. Beneficial Insects: Based upon the results of core bee toxicity tests, it is predicted that thiacloprid will not adversely affect bees. In addition, thiacloprid toxicity is unlike other neonicotinoid insecticides (i.e.: imidacloprid, and clothianidin) which have demonstrated very high to high acute toxicity to bees.

4. SUMMARY OF REGULATORY POSITION AND RATIONALE

Based on the available data as described in this document, there is adequate information to support a registration decision under FIFRA section 3(c)(5) for the conditional registration of the pesticide products thiacloprid technical and the formulated product described in this document for use on cotton and pome fruits.

Cancer - Dietary (Food and Water): The estimated aggregate cancer risk is 3×10^{-6} . For risk management purposes, EPA considers a cancer risk to be greater than negligible when it

exceeds the range of 1 in 1 million. EPA has generally treated cancer risks up to 3 in 1 million as within the range of 1 in 1 million.

Furthermore, EPA believes that the lifetime exposure will be negligible for the following reasons:

(a) The cancer risk from the food uses alone is 1.3×10^{-6} . The dietary risk is based on residue data derived from the average of field trials. It is not unusual in the Agency's experience for field trial data to be an order of magnitude above actual monitoring. Since thiacloprid is a new chemical, actual monitoring data are not yet available. It is likely that the actual risk contribution from food will be much lower than current data indicate.

(b) Drinking water exposure estimates are based upon screening models that do not take into account mixing, dilution or treatment of raw water for distribution as drinking water.

Occupational, Handlers: With baseline PPE (long pants, long-sleeved shirt and shoes plus socks), cancer risks estimated for handler activities were 3.5×10^{-5} to 1×10^{-6} for apples/pears and 4×10^{-4} to 2.8×10^{-7} for cotton. However, exposure calculations were based on a screening assessment which included a number of conservative assumptions. Thiacloprid was assumed to be applied at the maximum rate, to the maximum acreage of cotton, and with no dissipation assumed (because thiacloprid is a new active ingredient, typical application rate data are not available, so the maximum application rate was used to calculate cancer risk). In addition, the label requires additional PPE (waterproof gloves) that would further reduce handler exposure.

Post-Application: Occupational post-application cancer risks were estimated to be in the 10^{-5} to 10^{-7} range. However, a combination of very conservative assumptions was used to estimate post-application occupational risks. These assumptions include 1) application of the insecticide at the maximum rate, 2) application to the maximum acreage of cotton, 3) no dissipation over the work interval, 4) exposure for 30 days a year, and 5) exposure for 35 years. Lacking an estimate for residue dissipation over the work interval, one needs to assume that the worker always travels directly from one treated field to another so that the highest residue value is always found. In addition, it is likely that the risk can be refined once information about typical application rates becomes available. Thus, EPA does not expect that workers would be exposed to levels greater than negligible over their lifetime with use of the PPE specified on the proposed label; i.e. coveralls, shoes, socks and gloves in addition to the implementation of a 12 hour REI.

Ecological Concerns: It is expected that the spray drift management labeling which appears on the product labeling will aid in the mitigation of the above identified risks to non-target species. The labeling includes a 100 foot buffer zone for aerial application when spraying in the vicinity of aquatic areas. It also includes drift management practices when spraying as a ground application in the vicinity of aquatic areas as well as drift management practices covering non-aquatic areas.

Labeling Restrictions: The following restrictions are addressed on the labeling for thiacloprid products:

Use restriction: Not for use or storage in or around residential sites.

Worker Protection Standard (WPS): The formulated products must be used only in accordance with the Worker Protection Standard (WPS) labeling and requirements (40 CFR part 170). The formulated product labeling includes the following WPS restrictions:

-a restricted entry interval of 12 hours,

-the standard WPS drift restriction of not applying in any way that will contact workers or other persons, either directly or through drift, and the statement that only protected workers may be in the area during application,

-the use of Personal Protective Equipment (PPE) by applicators and other handlers, consisting of long-sleeved shirt and long pants, socks, shoes and chemical resistant gloves made of waterproof material.

Pre-harvest Interval (PHI): 30 days for pome fruit and 14 days for cotton.

Crop Rotation (Plant Back Interval): Roots, tubers, and bulb vegetables whose tops are not used for feed may be rotated with cotton after a PBI of 30 days. Leafy vegetables may be rotated after a 6 month PBI. Vegetables other than those vegetables described above, wheat, and other grains may not be rotated for one year after application.

Drift management: The labeling bears various drift management practices, including a 100 foot buffer zone for aerial application when spraying in the vicinity of aquatic areas. Restrictions include buffer zone requirements, recommendations for aerial applications, information regarding droplet size, specific recommendations for airblast applications to tree crops, wind speed restrictions, and temperature inversion restrictions.

Ecological Hazard Statement: This chemical is very highly toxic to Marine/Estuarine invertebrates.

Surface Water Label Advisory: This product may contaminate water through run-off following rainfall events.

Groundwater Label Advisory: The degradate YRC 2894 sulfonic acid has properties and characteristics associated with chemicals detected in ground water. The use of this chemical in areas where soils are permeable, particularly where the water table is shallow, may result in groundwater contamination.

5. SUMMARY OF DATA GAPS

Submittal of the following data is being required as conditions of registration: bioaccumulation in fish; photodegradation in soil, limited field accumulation study in rotational crops, a confirmatory procedure (or confirmatory MS ions) for the livestock tissue analytical enforcement method, storage stability and corrosion characteristics for the proposed products, and batch analysis for the technical product as produced on a commercial scale.

6. CONTACT PERSON AT EPA

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