

# Overview of the Benfluralin Risk Assessment

February 11, 2003

## *Introduction*

This document summarizes EPA's human health and ecological risk findings and conclusions for the pesticide benfluralin, as presented fully in the documents "Benfluralin: Human Health Risk Assessment (Revised)," dated October 30, 2003 and, "Benfluralin: EFED's Response to 30-Day Error Comment," dated October 22, 2003. The purpose of this summary is to assist the reader by identifying the key features and conclusions reached in the assessments. References to relevant sections in the complete documents are provided to allow the reader to find the place in these assessments where a more detailed explanation is provided. This summary was developed in response to comments and requests from the public which indicated that the risk assessments were difficult to understand, that they were too lengthy, and that it was not easy to compare the assessments for different chemicals due to the use of different formats.

These benfluralin risk assessments and additional supporting documents are posted on EPA's Internet website (<http://www.epa.gov/pesticides/>) and are available in the Pesticide Docket for public viewing. Meetings with stakeholders will be held to discuss the risk assessments and solicit input on risk mitigation strategies, if needed. This feedback will be used to complete the Reregistration Eligibility Decision (RED) document, which will include the resulting risk management decisions. The Agency plans to conduct a close-out conference call with interested stakeholders to describe the regulatory decisions to be presented in the RED.

Risks summarized in this document are those that result only from the use of benfluralin. The Food Quality Protection Act (FQPA) requires that 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 reason for consideration of other substances is due to the possibility that low-level exposures to multiple chemical substances that cause a common toxic effect by a common toxic mechanism could lead to the same adverse health effect as would a higher level of exposure to any of the substances individually. Unlike other pesticides for which EPA has followed a cumulative risk approach based on a common mechanism of toxicity, EPA has not made a common mechanism of toxicity finding for benfluralin and any other substances and benfluralin does not appear to produce a toxic metabolite produced by other substances. For the purposes of this action, therefore, EPA has not assumed that benfluralin has a common mechanism of toxicity with other substances. For information regarding EPA's efforts to determine which chemicals have a common mechanism of toxicity and to evaluate the cumulative effects of such chemicals, see the policy statements released by EPA's Office of Pesticide Programs concerning common mechanism determinations

and procedures for cumulating effects from substances found to have a common mechanism on EPA's website at <http://www.epa.gov/pesticides/cumulative/>.

## ***Use Profile***

- **Herbicide/insecticide:** Benfluralin is a growth inhibitor (mitotic disruptor) registered for use primarily to control grasses (including johnsongrass seedlings), chickweed, lambsquarters, purslane, knotweed, clover, pigweed, and plantain. It is used as a herbicide on a single food crop (pre-plant on lettuce), feed crops (pre-plant on alfalfa, clover, trefoil), non-bearing fruit and nut trees, non-bearing berries, non-bearing vineyards, turf, ornamentals, rights of way, fence rows/hedgerows, and Christmas tree plantations. In addition, benfluralin is registered as an insecticide for controlling *Poa annua* decline disease in turf. Benfluralin is also known as benefin and N-Butyl-N-ethyl-alpha-alpha-phi-tri-fluoro-2,6-dinitro-p-toluidine.
- **Tolerances:** There are tolerances for benfluralin on alfalfa, birdsfoot trefoil, clover, and lettuce. A tolerance for peanuts will be proposed for revocation by the Agency.
- **Formulations:** Formulated as dust, emulsifiable concentrate, granular, soluble concentrate/liquid, and water dispersible granules (dry flowable). Benfluralin is commonly formulated with chlorpyrifos, diazinon, oryzalin, oxadiazon, trifluralin, or metolachlor.
- **Method of Application:** Band treatment, broadcast, golf course treatment, soil incorporated treatment, and spray, with ground, or overhead sprinkler irrigation systems.
- **Use Rates:** Maximum agricultural 1.2 - 3.0 lb ai/A; Maximum non-agricultural 1.48 - 6.0 lb ai/A.
- **Annual Poundage:** Total of approximately 1,200,000 lbs active ingredient applied per year, divided in the following sectors: lawn care operator (430,000 - 830,000 lbs), landscape (85,000 - 170,000 lbs), other turf (100,000 - 200,000 lbs), alfalfa (47,000 - 112,000 lbs), and lettuce (42,000 - 79,000 lbs).
- **Registrants:** Dow AgroSciences LLC (formerly DowElanco) and Loveland Products, (formerly Platte Chemical Company).

## ***Human Health Risk Assessment***

### ***Acute Dietary Risk (Food)***

(For a complete discussion, see section 3.0 of the Human Health Risk Assessment)

Acute dietary risk is calculated considering what is eaten in one day and maximum, or high-end residue values in food. A risk estimate that is less than 100% of the acute Population Adjusted Dose (acute PAD) (the dose at which an individual could be exposed on any given day and no adverse health effects would be expected) does not exceed the Agency's risk concern.

The acute dietary risk (food) has not been assessed for benfluralin because an appropriate endpoint attributable to single dose was not identified. Thus, an acute aPAD was not established.

### ***Chronic Dietary Risk (Food)***

(For a complete discussion, see section 3.0 of the Human Health Risk Assessment)

Chronic dietary risk is calculated by using the average consumption values for food and average residue values for those foods over a 70-year lifetime. A risk estimate that is less than 100% of the chronic PAD (the dose at which an individual could be exposed over the course of a lifetime and not expect an adverse health effect) does not exceed the Agency's level of concern.

The chronic dietary risk (food) for benfluralin does not exceed the Agency's level of concern (i.e., less than 100% of the chronic PAD is utilized).

- The toxicological endpoint is increased incidence of histologic lesions of the kidney as seen at the lowest observed adverse effect level (LOAEL) of 5.4 mg/kg/day (males) in the chronic toxicity/carcinogenicity feeding study in rats. The no observed adverse effect level (NOAEL) in this study is 0.5 mg/kg/day.
- The 10X FQPA safety factor was reduced to 1X based on a complete toxicological database that indicates no increased susceptibility to infants and children and no residual uncertainty.
- The chronic PAD is calculated to be 0.005 mg/kg/day derived from a NOAEL of 0.5 mg/kg/day and an Uncertainty Factor of 100 that includes 10X for interspecies extrapolation, 10X for intraspecies variation, and 1X for FQPA.
- An upper-bound (tier 1) chronic dietary risk assessment was conducted for benfluralin. The residue estimate for lettuce, the only direct food use for benfluralin, is based on the level set for tolerance (0.05 ppm). Also, an assumption is made that 100% of the US lettuce crop is treated with benfluralin. (Approximately 23% of the lettuce crop is

actually treated with benfluralin). Estimated chronic dietary risks for all population subgroups are less than 1% of the benfluralin chronic PAD (0.005 mg/kg/day) and do not indicate a concern for dietary exposure from food.

### ***Drinking Water Dietary Risk***

Drinking water exposure to pesticides can occur through groundwater and surface water contamination. EPA considers both acute (one day) and chronic (lifetime) drinking water risks and uses either modeling or actual monitoring data, if available, to estimate those risks. To determine the maximum allowable contribution from water allowed in the diet, EPA first looks at how much of the overall allowable risk is contributed by food and then determines a “drinking water level of comparison” (DWLOC) to ascertain whether modeled or monitored concentration levels exceed this level.

The Agency uses the DWLOC calculation to estimate risk associated with exposure from pesticides in drinking water. The DWLOCs represent the maximum contribution to the human diet (in ppb or ug/L) that may be attributed to residues of a pesticide in drinking water after dietary exposure is subtracted from the aPAD or the cPAD. Risks from drinking water are assessed by comparing the DWLOCs to the estimated environmental concentrations (EECs) in surface water and groundwater. EECs less than the DWLOC are not of concern. Drinking water modeling is considered to be an unrefined assessment and generally provides high-end estimates. The drinking water risks estimated for benfluralin do not exceed the Agency’s level of concern.

- **Acute water risk:** No appropriate endpoint from a single dose has been identified. Thus, acute exposure from drinking water is not of concern.
- **Chronic water risk:** The EEC estimates for benfluralin and degradates (surface water 0.17 - 3.5 ppb; groundwater 0.009 - 0.07 ppb) are less than the estimated DWLOC (50 ppb for children; >100 ppb for adults), and a conclusion can be drawn that no adverse toxicological effect will occur due to chronic exposure from food and drinking water.
- The Agency calculated estimated environmental concentrations (EECs) for benfluralin in surface water based on PRZM-EXAMS modeling. This model estimates an upper end potential concentration in surface water.
- Ground water modeling was performed using the Tier 1 model SCI-GROW version 2.2.
- Surface water monitoring was performed for parent benfluralin by United States Geographical Survey (USGS) under the National Water Quality Assessment Program (NAWQA). Surface water sites, agriculturally-impacted streams, urban streams, and “integrated” streams were monitored. Benfluralin was detected less than 5% of the time, with a range of detections ranging from 0.5 to 3.4%. Therefore, the 95<sup>th</sup> percentile

concentration in each case is “below detection limit”(0.002 ppb). The concentrations detected by USGS are in the same range as predicted by the PRZM-EXAMS for chronic concentrations for the major uses (alfalfa, turf) or slightly lower. This is consistent with the somewhat conservative assumptions used in the modeling.

- USGS NAWQA ground water data shows that parent benfluralin has been detected in only a handful wells in nine states (CA, FL, MD, MO, MT, NJ, PA, TX, and VT). The highest reported concentration was 0.006 ppb. This is a factor of 10 less than the predicted SCI-GROW screening model concentration.
- Degradate B12 (2,6-dinitro-4-trifluoromethyl-phenol) was found at a relatively high level of 0.133 ppm in an aerobic soil study, and fate data indicate that B12 is more mobile than parent benfluralin, and has a higher potential to leach to ground water than parent. On this basis, degradate B12 is also considered in the drinking water assessment.
- Trifluoroacetic acid ( $\text{CF}_3\text{COOH}$ ) was observed as the major degradate in the confined rotational crop study. Trifluoroacetic acid is expected to be very stable in the environment, and thought to accumulate in lakes and reservoirs. The Agency has requested confirmatory data with a limited rotational field trial study with analysis for trifluoroacetic acid.
- Drinking water modeling is based on parent benfluralin. The assumptions used in the modeling are sufficiently conservative to account for parent benfluralin and its degradates.

### ***Dermal and Inhalation Toxicity***

The following endpoints were used to determine residential, aggregate, and occupational risk.

#### **Dermal Toxicity**

- Benfluralin is likely to cause skin sensitization effects, but in a 21-day dermal toxicity study in rabbits no systemic toxicity was seen; therefore an endpoint for dermal risk assessment was not identified. Non-systemic effects in the rabbit study included a variety of localized skin effects which are believed to be the result of sensitization.

#### **Inhalation Toxicity**

- The short-term inhalation endpoint is based on decreased maternal body weight gain over a 13 day dosing period as seen at the LOAEL of 225 mg/kg/day in a short-term oral study in rabbits. The NOAEL in this study was 100 mg/kg/day.
- The intermediate-term inhalation endpoint is based on Hyaline droplet formation in the kidneys of adult males, progressive chronic nephropathy in adult males and females, and pup weight decrement as seen at the LOAEL of 68.1 mg/kg/day in a two-generation rat

reproduction study. NOAEL in this study was 7.2 mg/kg/day.

## ***Residential Risk***

(For a complete discussion, see section 4.4 of the Human Health Risk Assessment)

Benfluralin products are marketed for homeowner use on residential lawns and for landscape ornamentals. Benfluralin-containing products are also marketed for use by professional applicators on residential turf, on golf courses, on other turf such as recreational/commercial areas, and on ornamental plantings. Based on these uses, benfluralin is assessed for the residential applicator (handler) and for children's post-application exposure that may occur from contact with treated turf.

### ***Residential Applicator (Handler)***

Risk to the residential applicator (handler) does not exceed the Agency's level of concern in that all MOEs are above 100. MOEs range from 22,000 - 11,000,000.

- Homeowners (or others) may be exposed to benfluralin while treating their lawns, before seasonal weed emergence, at a rate up to 2 lbs. ai/acre.
- The assessment for residential handlers is based on the following scenarios:
  - Granular formulation: loading/applying with bellygrinder spreader
  - Granular formulation: loading/applying with push-type spreader
  - Granular formulation: loading/applying with shaker can
- The following area treated estimates are used: 1) 0.5 acres for lawn and ornamental treatments with a bellygrinder spreader or push-type spreader; and 2) 1,000 square feet for ornamental treatments using a shaker can. Homeowners are also assumed to complete all elements of an application (mix/load/apply) without use of protective equipment (wearing shorts and short-sleeved shirts).
- The residential handler assessment is based only on inhalation exposure because no appropriate dermal endpoint for risk assessment was identified.
- Benfluralin-specific data to assess the above exposure scenarios were not available. Exposure estimates for these scenarios are developed using the Pesticide Handlers Exposure Database (PHED, Version 1.1 August 1998), and data from the Outdoor Residential Task Force (ORETF).

### ***Residential Postapplication***

The MOEs for each residential post-application exposure scenario (2,200 - 670,000) are well

above 100 and therefore are considered to be adequately protective.

- The scenarios chosen for post application risk assessment (exposure to children following residential turf use), represent the likely upper-end of possible exposures.
- Because systemic toxicity was not observed in a dermal toxicity study, and since post-application inhalation exposure is expected to be negligible, the only risk assessed is the possible oral exposure of small children from treated turf or from treated soil (i.e., soil ingestion, and hand-/object-to-mouth).
- The assessment for residential post-application risk is based on the following scenarios:
  - Hand-to-mouth activity from treated turf (i.e., those residues that end up in the mouth from a child touching turf and then putting their hands in their mouth).
  - Object-to-mouth activity from treated turf (i.e., those residues that end up in the mouth from a child mouthing a handful of treated turf).
  - Soil ingestion activity.
  - Ingestion of benfluralin granules from treated turf. (Since this is considered an acute exposure, this assessment is not needed because an endpoint for acute oral risk was not identified).
- The Total Oral MOE for post-application exposure to a child from all three turf scenarios is 1800, well above 100, and is thereby considered to be adequately protective.

### ***Dermal Sensitization***

The Agency is concerned about dermal sensitization reactions in adults and children due to benfluralin exposure in residential settings. At present, the Agency has no method for determining a quantitative endpoint for skin sensitization and, therefore, has no means of quantitatively assessing the risk resulting from benfluralin's sensitization potential. Also, data on the sensitization potential of benfluralin end-use products is inconclusive regarding whether or not sensitization reactions will occur from exposure to the formulated products.

- In a modified Buchler topical patch test in Guinea pigs with technical benfluralin at 5% in 95% ethanol, seven of twelve Guinea pigs responded with a typical delayed hypersensitivity reaction. At 48 hours nine of twelve exhibited slight to moderate erythema (abnormal redness of the skin), and eight of twelve exhibited very slight to slight edema (swelling due to accumulation of fluid).
- Formulated products showed no evidence of sensitization in Beuhler's assays, when tested concentrations ranged from 19.1% to 60% benfluralin. The lack of sensitization possibly occurred because the tests on the formulations were conducted with water as a vehicle, and/or benfluralin in the formulated product was not of sufficient concentration,

did not penetrate the skin, or material in the formulation interfered with the test. However, it is noted that skin lesions found in the 21-day rabbit dermal study, were with the technical grade and a water vehicle. Therefore potential skin sensitization of products containing benfluralin is not eliminated.

- Based on the incident reports received in the OPP Incident Data System, at Poison Control Centers, and at California Department of Pesticide Regulation, relatively few incidents of potential sensitization have been reported due to benfluralin use.

## ***Aggregate Risk***

(For a complete discussion, see section 5.0 of the Human Health Risk Assessment)

Aggregate risk looks at the combined risk from exposure through food, drinking water, and residential uses of a pesticide. Generally, all risks from these exposures must occupy less than 100 percent of the PAD to be below the Agency's level of concern.

For aggregate risk, EPA considers the combined exposures from food and residential sources and calculates a DWLOC (as described above in the drinking water section) which represents the maximum allowable exposure through drinking water after considering the food and residential exposures. If the water estimated environmental concentrations (EECs) are less than the DWLOCs, EPA does not have concern for aggregate exposure.

For benfluralin, there is not acute toxicological endpoint, and no intermediate term or chronic residential exposure scenarios are expected. Therefore, the aggregate exposure scenarios are short-term (food, water, and residential) and chronic (food and water only).

Short-term (up to 30 days) and chronic (one year or more) oral exposure (food + water + incidental) and inhalation exposure (residential handlers) are the intervals assessed for the aggregate assessment. Intermediate and chronic residential exposures to benfluralin are not expected and therefore not included in the aggregate assessment.

<b>Short-Term DWLOC Calculations</b>			
<b>Population Subgroup</b>	<b>Groundwater EEC (µg/L)</b>	<b>Surface Water EEC (µg/L)</b>	<b>DWLOC Short Term (µg/L)</b>
Children	Range of 0.009 - 0.07	Range of 0.17 - 3.5	>100
Females	Range of 0.009 - 0.07	Range of 0.17 - 3.5	>100



Males	Range of 0.009 - 0.07	Range of 0.17 - 3.5	>100
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The estimated environmental concentration (EEC) estimates for benfluralin and degradates are less than the estimated drinking water level of concern (DWLOC). EPA concludes that no adverse toxicological effect will occur due to aggregate short-term exposure.

Chronic DWLOC Calculations			
Population Subgroup	Groundwater EEC (µg/L)	Surface Water EEC (µg/L)	DWLOC Chronic (µg/L)
Children	Range of 0.009 - 0.07	Range of 0.17 - 3.5	50
Females	Range of 0.009 - 0.07	Range of 0.17 - 3.5	>100
Males	Range of 0.009 - 0.07	Range of 0.17 - 3.5	>100

The EEC estimates for benfluralin and degradates are less than the estimated DWLOC, and EPA concludes that no adverse toxicological effect will occur due to aggregate chronic exposure.

## ***Occupational Risk***

(For a complete discussion, see section 7.0 of the Human Health Risk Assessment)

Workers can be exposed to a pesticide through mixing, loading, or applying the pesticide, and reentering a treated site. Worker risk is measured by a Margin of Exposure (MOE) which determines how close the occupational exposure comes to the NOAEL taken from animal studies. Generally, MOEs that are greater than 100 do not exceed the Agency's level of concern.

Based on currently registered benfluralin use sites, formulations, and types of equipment commonly used for mixing, loading, and application, EPA has identified 13 major occupational handler scenarios. Short and intermediate term inhalation MOEs for all 13 scenarios are greater than 100 at the baseline level of protection (i.e., no respirator). Short-term MOEs range from 4,000 to 900,000, and intermediate-term MOEs range from 290 to 65,000.

- Benfluralin MOEs are calculated using the inhalation NOAEL of 100 mg/kg/day for short-term assessment or 7.2 mg/kg/day for intermediate-term assessment. Since no

dermal endpoint was identified, only inhalation risk was assessed.

- For benfluralin users the Agency's level of concern MOE is 100 for both short- and intermediate-term exposure) based on the standard uncertainty factors of 10X for interspecies extrapolation and 10X for intraspecies variability. Long-term worker exposure is not expected for benfluralin.
- The occupational exposure scenarios are based on the use sites, formulations (dry flowable and granular), and various equipment (groundboom, tractor/ATV-drawn spreader, low pressure handwand sprayer, backpack sprayer, low pressure/high volume turf/handgun sprayer, pump-feed backpack spreader, gravity-feed backpack spreader, bellygrinder spreader, push-type spreader, bucket and spoon, and shaker can) that may be used for benfluralin applications.
- Chemical-specific data to assess the exposure scenarios were not available. Analyses were completed using acceptable surrogate exposure data for the scenarios assessed. Several handler assessments were completed using data from the Pesticide Handler Exposure Database (ver. 1.1). Some handler assessments were completed using data from the Outdoor Residential Exposure Task Force (ORETF).

### ***Occupational Postapplication Exposures and Risk***

Benfluralin uses are varied because it is used in agriculture, on ornamentals, and on turf (lawns, golf courses). As a result, a wide array of individuals can potentially be exposed by working in areas that have been previously treated. However, since no dermal endpoint has been identified for systemic toxicity and inhalation exposure to reentry workers is expected to be negligible, no occupational post-application exposure risk assessment is required.

For workers entering a treated site, Restricted Entry Intervals (REIs) are calculated to determine the minimum length of time required before workers or others are allowed to re-enter. Reentry Intervals (REIs) for agricultural uses of benfluralin are 12 hours.

### ***Skin Sensitization Concerns for Occupational Exposure***

The Agency is concerned about dermal sensitization reactions in persons occupationally exposed to benfluralin.

- See the "*Dermal Sensitization*" section of this document.

## Ecological Risk

To estimate potential ecological risk, EPA integrates the results of exposure and ecotoxicity studies using the quotient method. Risk quotients (RQs) are calculated by dividing exposure estimates by ecotoxicity values, both acute and chronic, for various wildlife species. RQs are then compared to levels of concern (LOCs). Generally, the higher the RQ, the greater the potential risk. Risk characterization provides further information on the likelihood of adverse effects occurring by considering the fate of the chemical in the environment, communities and species potentially at risk, their spatial and temporal distributions, and the nature of the effects observed in studies.

### *Environmental Fate and Transport*

Parent benfluralin is not expected to leach into groundwater, as it is immobile in soil. However, it has 26 identified degradates that are expected to be mobile in soil and may contaminate water. Benfluralin is expected to be bioaccumulative.

- Data indicate that the fastest fate process for benfluralin is aqueous photolysis, with a half-life of 9.9 hours. Benfluralin is stable to hydrolysis and is metabolized relatively slowly in soil. The upper 90<sup>th</sup> percentile on the mean half-life from 6 studies was 65 days, and the range of half-lives was 20 to 86 days, with a mean of 49 days.
- Benfluralin is a semi-volatile compound. Volatilization may be a major fate process for non-soil-incorporated uses, such as turf, but may also occur in incorporated uses to a lesser extent.
- Benfluralin has at least 26 identified degradates. In fate studies, nine of the degradates are estimated to exceed 10% of the applied parent concentration. Based on structure-activity analysis, the degradates are all expected to be more mobile in soil, more soluble in water, and equally or less volatile than the parent. Thus, they may have a greater tendency to remain in water than the parent. In the long term, the degradate trifluoroacetic acid is expected to be the ultimate water contaminate.
- Based on its measured bioaccumulation factor in the whole fish, parent benfluralin is considered to be bioaccumulative. Its half-lives in terrestrial field dissipation studies (22, 62, 79 days) indicate that benfluralin is borderline persistent in soil, where a half-life of 60 days or greater is considered persistent. The short estimated half-life of benfluralin in air (less than half a day), however, indicates that it may not be persistent in air (where a half-life of >2 days is considered persistent).

### *Nontarget Terrestrial Animal Risk*

There is cause for concern about reproductive and chronic effects in birds and small mammals from labeled uses of benfluralin.

- Risks to wildlife are expected to be greater from granular formulations than from spray formulations. Spray formulations are incorporated into the soil before planting or at the time of planting because of the volatile nature of benfluralin. Granules on the surface are more exposed than the spray formulations, and use sites with granular formulations tend to have higher amounts of active ingredient than soil-incorporated spray sites. Therefore, it is reasonable to assume that benfluralin exposure to wildlife would be greater from the granular formulations than from the spray formulations. Granular formulations have been assessed to determine risk to nontarget terrestrial animals.
- Acute risk of concern to non-endangered and to endangered species of birds and small mammals is unlikely, as the LC50 and LD50 endpoints were “greater than” values with no mortalities seen at the highest dose of 4360 mg/kg.
- There is the potential for concern about reproductive effects in birds and small mammals from labeled uses of benfluralin. However, there are currently no approved models for determining chronic exposure from granular formulations, so the Agency is unable to quantify this risk.
- Based on some qualitative assumptions, the Agency predicts that there is potential for chronic risk to birds and small mammals. The chronic levels of concern (LOC) are potentially exceeded for birds and small mammals feeding on food items when benfluralin is inadvertently sprayed at the edges of alfalfa and lettuce fields.
- Birds that eat fish may potentially be at risk. Modeled calculations indicate that there may be a potential for reproductive effects in birds that consume fish containing benfluralin residues. However, there is uncertainty in this prediction due to inadequate data.

### ***Nontarget Aquatic Animal Risk***

The potential for reproductive effects is a concern for nontarget aquatic animals.

- Acute risk to freshwater fish and invertebrates is unquantifiable due to uncertainties in the toxicity data.
- However, the PRZM-EXAMS model predicts environmental concentrations that are above the endangered species LOC of 0.05 ppb for fish and aquatic invertebrates. Therefore, updated toxicity data for freshwater invertebrates is required.
- Chronic risk to freshwater fish: The potential for adverse reproductive effects to

freshwater fish appears likely because the No Observed Adverse Effect Concentrations (NOAECs) from the early life stage tests are low (1.9 ppb), and because modeled EECs are above 1.9 ppb for long periods of time (GA peaches, 60-day average EEC 2.3 ppb; FL citrus, 90-day average EEC 2.6 ppb; NC apples, 365-day EEC 2.6 ppb). Chronic risk to estuarine fish and invertebrates cannot be assessed due to lack of toxicity data.

- Chronic risk to aquatic invertebrates: The potential for adverse reproductive effects to aquatic invertebrates appears likely because the No Observed Adverse Effect Concentrations (NOAECs) from the early life stage test is low (15.5 ppb), and because GENEEC modeled aquatic EECs (21-day average of 22.5 ppb from single application and 37.2 ppb from two applications) are above this concentration.
- Chronic risk to estuarine fish and invertebrates from benfluralin exposure can not be assessed due to lack of toxicity data.
- The following data gaps have been identified in the risk characterization for aquatic/marine animals:
  - Acute toxicity of technical on bluegill and trout
  - Acute toxicity of technical on *Daphnia magna*
  - Acute toxicity of technical on oyster
  - Acute toxicity of technical on sheepshead minnow
  - Chronic toxicity of technical on sheepshead minnow
  - Chronic toxicity of technical on mysid shrimp

### ***Nontarget Plant Risk***

Because of inadequate data, there is much uncertainty in the non-target plant risk assessment.

- The plant toxicity studies were conducted with technical benfluralin. While these studies showed that the plant species tested were tolerant of technical benfluralin, the uncertainties from the use of a technical active ingredient on terrestrial plants, versus the formulated product, are great. Adjuvants are normally used with herbicides to enhance penetration of the chemical into the plant. It is for this reason that the Agency generally requests that terrestrial plant studies be done with formulated products that have the highest percentage of active ingredient.

### ***Endangered Species***

Based on this preliminary assessment, the Agency's level of concern for potential acute and chronic risk to endangered and threatened birds, mammals, fish, and aquatic invertebrates, is exceeded for the use of benfluralin on the sites listed below.

Use Sites where Endangered Species LOCs are Exceeded					
Granule					Spray
	Non-Agricultural Areas	Turf	Non-Bearing Vineyards, Fruit Trees, Nut Trees, and Berries	Christmas Tree Farms	Alfalfa, Lettuce
Acute Risk	freshwater fish, freshwater invertebrates, estuarine invertebrates	freshwater fish, freshwater invertebrates, estuarine invertebrates	freshwater fish, freshwater invertebrates, estuarine invertebrates		
Chronic Risk	freshwater fish, birds, mammals	birds, mammals	freshwater fish, birds, mammals	birds, mammals	birds, mammals

- The Agency has determined that acute risk to endangered species of birds and mammals are not likely, as the LC50 and LD50 endpoints were “greater than” values with no mortalities seen at the highest dose.

## Summary of Pending Data

### *Human Health Data Requirements*

- Toxicology: Subchronic inhalation study is required on a solution of benfluralin.
- Carcinogenicity: Another study on carcinogenicity in the male mouse is necessary. The Agency determined that the male mouse was not dosed sufficiently high to test the carcinogenic potential of benfluralin.
- Product Chemistry: UV/Visible absorption; 830.7050.
- Residue Chemistry: A limited rotational field trial study with analysis for trifluoroacetic acid.

### *Ecological and Environmental Fate Requirements*

- Wildlife and Aquatic Organisms: Avian Reproduction Quail, Acute Fish Toxicity Bluegill, Acute Toxicity Rainbow Trout, Acute Aquatic Invertebrate, Acute Estuarine/Marine Toxicity Fish, Acute Estuarine/Marine Toxicity Mollusk, Life Cycle Aquatic Invertebrate, Life Cycle Fish
- Plant Protection: Aquatic Plant Growth, Seed Germination/Seedling Emergence,

- Vegetative Vigor, Aquatic Plant Growth  
Environmental Fate Requirements: Aerobic Aquatic Metabolism, Droplet Size Spectrum,  
Drift Field Evaluation