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

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

MEMORANDUM

Date: November 29, 2004

SUBJECT: **Fluazifop-p-butyl**: REVISED Residential Exposure Assessment and Recommendations for the Tolerance Reassessment Eligibility Decision (TRED) Document

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The attached assessment shows the revised non-occupational (residential) exposure and risk estimates for fluazifop-p-butyl to support HED's tolerance reassessment eligibility decision (TRED) document.

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1.0 EXECUTIVE SUMMARY

This document supports the Tolerance Reassessment Eligibility Decision (TRED) document for fluazifop-p-butyl and addresses risks resulting from non-occupational (residential) exposures only. Occupational exposures will not be addressed in this document.

At this time, products containing fluazifop-p-butyl are intended for both occupational and non-occupational uses. Fluazifop-p-butyl is a selective herbicide used in the post-emergent control of grasses in agricultural, ornamental, residential and recreational (golf courses) settings. Fluazifop-p-butyl has several occupational uses that will not be addressed in this TRED. The fluazifop-p-butyl end-use products are formulated as liquid concentrates and ready-to-use liquids.

In residential settings, fluazifop-p-butyl is used on residential turfgrass, on broadleaf ornamentals, and for total grass weed control for lawn renovations, and around driveways, fence lines, sidewalks, and similar areas. The current maximum application rate for application to residential turfgrass and golf courses by lawn care operators (LCOs) is 0.09 pounds active ingredient per acre for selective weed control (Ornamec by PBI Gordon Corp, EPA Reg. No. 2217-728) and 0.98 pounds active ingredient per acre for lawn renovation (Grass and Weed Killer by Chemsico, EPA Reg. No. 9688-106). The maximum application rate for application to residential ornamentals is 0.44 pounds active ingredient per acre (0.01 pounds active ingredient per 1000 square feet). In addition, on November 26, 2003 Syngenta, the technical registrant for fluazifop-p-butyl, submitted a closure memo indicating the following application rates being supported for the technical reregistration: 0.075 lb ai/A for turf and 0.375 lb ai/A for non crops and ornamentals.

Short-term exposures (defined as exposures from 1 to 30 days in duration) may occur for residents applying fluazifop-p-butyl products and for residents exposed to fluazifop-p-butyl following applications in residential settings. Intermediate- and long-term exposures are not anticipated for residential handling or postapplication exposures. The HIARC document (June 15, 2004) selected two separate short-term endpoints of concern for fluazifop-p-butyl – one for females of childbearing age (2 mg/kg/day) and another for the general population, including infants and children (100 mg/kg/day). Since mitigating risks for one subpopulation and not for another is not considered feasible at this time, HED assessed short-term dermal and inhalation risks using the NOAEL of 2 mg/kg/day. The short-term dermal (noncancer) endpoint for fluazifop-p-butyl is from an oral study, therefore, a dermal absorption factor must be used. The HIARC report, dated June 15, 2004, states that a dermal absorption factor of 9 percent should be used to assess risks from low exposures and a dermal absorption factor of 2 percent should be used to assess risks from high exposures. For the purposes of this residential risk assessment, HED assumes that:

- the 9% dermal absorption factor is appropriate for assessing dermal exposure to residential handlers and for assessing postapplication dermal exposures during golfing or mowing residential lawns – all of which are considered representative of low exposure activities, and

- the 2% dermal absorption factor is appropriate for assessing high contact dermal exposure on residential lawns – which are considered more representative of high exposure activities.

The exposure and risk for residential handlers were assessed using the revised draft Standard Operating Procedures (SOPs) for Residential Exposure Assessment and the 2001 Recommended Revisions by the Science Advisory Council for Exposure (Policy #12). Exposures were estimated using surrogate unit exposure values from the Outdoor Residential Exposure Task Force (ORETF). Since ORETF does not include data for scenarios using ready-to-use spray bottle application, data from a proprietary study were used to estimate those exposures (MRID 447393-01). Estimated residential handler risks **do not exceed** HED's level of concern for any of the scenarios assessed.

Short-term postapplication exposures may occur following applications at residential sites. Residential exposures were estimated based on HED's 1997 draft Standard Operating Procedures for Residential Exposure Assessments and the 2001 Recommended Revisions by the Science Advisory Council for Exposure (Policy #12). Short-term risks estimated for postapplication exposure **do not exceed** HED's level of concern for any of the assessed scenarios.

High-contact dermal postapplication exposures for toddlers to fluazifop-p-butyl on treated turf have been combined with incidental oral postapplication exposures for toddlers, as these events are likely to coincide. Combined short-term postapplication risks to toddlers **do not exceed** HED's level of concern for any of the assessed scenarios.

2.0 BACKGROUND INFORMATION

2.1 Purpose

This document supports the Tolerance Reassessment Eligibility Decision (TRED) document for fluazifop-p-butyl and addresses risks resulting from non-occupational (residential) exposures only. Occupational exposures and risks are not addressed in this document.

2.2 Criteria for Conducting Exposure Assessments

An occupational and/or residential exposure assessment is required for an active ingredient if (1) certain toxicological criteria are triggered and (2) there is potential exposure to handlers (mixers, loaders, applicators, etc.) during use or to persons entering treated sites after application is complete. For fluazifop-p-butyl, both criteria are met.

2.3 Summary of Toxicity Concerns Related to Residential Exposures

Short-term Dermal and Inhalation (non-cancer)

The HIARC document (June 15, 2004) selected two separate short-term endpoints of concern for fluazifop-p-butyl – one for females of childbearing age and another for the general population, including infants and children. Short-term exposures are defined as exposures from 1 to 30 days in duration.

For females of childbearing age, the short-term (non-cancer) dermal and inhalation endpoint of concern for fluazifop-p-butyl is based on a NOAEL of **2 mg/kg/day** from a developmental toxicity study in rats. The NOAEL was based on fetal weight, hydroureter and delayed ossification. The HIARC states that these *in utero* effects are appropriate to assess dermal and inhalation risks for the population subgroup – females, ages 13 to 49 – from exposure to fluazifop-butyl. Since this short-term endpoint is from a developmental toxicity study, the adverse effects are considered to be female-specific and a body weight of 60 kilograms – the weight of an average female adult – is appropriate for the short-term dermal and inhalation risk assessment.

For the general population, including infants and children, the short-term (noncancer) dermal and inhalation endpoint of concern for fluazifop-p-butyl is based on a NOAEL of **100 mg/kg/day** from a developmental toxicity study in rats. The NOAEL was based on decreases in body weight gain in maternal animals during the dosing period at the LOAEL (300 mg/kg/day). The HIARC states that this endpoint is appropriate for the population subgroup – general population including infants and children. Since this short-term endpoint is from a developmental toxicity study, the adverse effects are considered to be female-specific and a body weight of 60 kilograms – the weight of an average female adult – is appropriate for the short-term dermal and inhalation risk assessment.

Since mitigating risks for one subpopulation and not for another is not considered feasible at this time, HED assessed short-term dermal and inhalation risks using the NOAEL of 2 mg/kg/day.

Intermediate-term Dermal and Inhalation (non-cancer)

The HIARC document (June 15, 2004) selected the same intermediate-term endpoint of concern for fluazifop-p-butyl for both dermal and inhalation routes of exposures. Intermediate-term exposures are defined as exposures from 31 days to 6 months. The intermediate-term dermal and inhalation risk assessment for fluazifop-p-butyl is based on a NOAEL of **0.74 mg/kg/day** from a two-generation reproduction study in rats. The NOAEL was based on decreased spleen, testes & epididymal weights in males and uterine & pituitary weights in females. Since the toxicological endpoint of concern is not sex-specific, a body weight of 70 kilograms – the weight of an average adult – is appropriate for the intermediate-term dermal and inhalation assessments. No intermediate-term exposures are expected for residential use-patterns, therefore, no intermediate-term risks were assessed.

Long-term (Chronic) Dermal and Inhalation (noncancer)

The same endpoint of concern was chosen for long-term dermal and inhalation exposures as was chosen for intermediate-term dermal and inhalation exposures. Long-term exposures are defined as exposures of greater than 6 months. No long-term exposures are expected for residential use-patterns, therefore, no long-term risks were assessed.

Dermal Absorption

The short- and intermediate-term dermal (noncancer) endpoints for fluazifop-p-butyl are both from oral studies, therefore, a dermal absorption factor must be used. The HIARC report, dated June 15, 2004, states that a dermal absorption factor of 9 percent should be used to assess risks from low exposures and a dermal absorption factor of 2 percent should be used to assess risks from high exposures. For the purposes of this residential risk assessment, HED assumes that:

- the 9% dermal absorption factor is appropriate for assessing dermal exposure to residential handlers and for assessing postapplication dermal exposures during golfing or mowing residential lawns – all of which are considered representative of low exposure activities, and
- the 2% dermal absorption factor is appropriate for assessing high contact dermal exposure on residential lawns – which are considered more representative of high exposure activities.

Non-cancer Level of Concern (LOC)

HED's level of concern for fluazifop-p-butyl exposures is 100 – a margin of exposure (MOE) less than 100 exceeds HED's level of concern for residential scenarios. The level of concern is based on 10X to account for interspecies extrapolation to humans from the animal test species and 10X to account for intraspecies sensitivity.

Aggregation

The dermal and inhalation margins of exposure were combined for the fluazifop-p-butyl risk assessment, because the toxicity endpoints for the dermal and inhalation routes of exposure are the same.

Cancer

The HIARC documents states that fluazifop-p-butyl is classified as not likely to be carcinogenic to humans, based on the lack of evidence of carcinogenicity in rats and hamsters.

Acute Toxicity

Fluazifop-p-butyl is classified as category III for acute oral, dermal, and inhalation toxicity. It is classified as category IV for eye irritation potential and skin irritation potential. Results were negative for dermal sensitization in guinea pigs.

Table 1. Acute Toxicity of Fluazifop-p-butyl			
Guideline No./ Study Type	MRID No.	Results	Toxicity Category
Fluazifp-P-butyl (PC 122809)			
870.1100 Acute oral toxicity/rats (PP005; 93.7% & 86.3%)	00162440 (1984)	LD50 = 3680 mg/kg for males rats LD50 = 2451 mg/kg for female rats	III III
870.1200 Acute dermal toxicity/rabbits (PP005; 93.7% & 86.3%)	00162440 (1984)	LD50 > 2000 mg/kg or >1.73 mL/kg	III for males and females
870.1300 Acute inhalation[a] toxicity/rats (PP005; 24.6%) CTL/P/3331	41917904 (1991)	LC50 > 1.7 mg/L	III
870.2400 Acute eye irritation/rabbit (PP005; 86.3%) CTL/P/856	00162441 (1983)	Mild irritation, cleared within 3 days	IV
870.2500 Acute dermal irritation/rabbit (PP005; 86.3%) CTL/P/856	00162441 (1983)	Slight irritation, cleared within 72 hours	IV
870.2600 Skin sensitization/GP (PP005; 99.6%) 80/ILK026/349	00162441 (1983)	No increased sensitization over controls in the Magnuuson-Kligmann Maximization Test	Not a skin sensitizer

[a] This study was conducted with a mixture of 24.6% fluazifop-p-butyl and 7.0% fenoxyprop-p-ethyl, however, the concentration fluazifop-p-butyl in the inhalation chamber was determined to be 1.7 mg/L. PPOO9 was used to indicate the technical grade of fluazifop-butyl. PPOO5 was used to indicate the technical grade of fluazifop-P-butyl.

Table 2. Summary of Toxicological Endpoints for Fluazifop-p-butyl			
Exposure Scenario	Dose Used in Risk Assessment, UF	Special FQPA SF* and Level of Concern for Risk Assessment	Study and Toxicological Effects
Acute Dietary (Females 13-49 years of age)	NOAEL = 50 mg/kg/day UF = 100 Acute RfD = 0.50 mg/kg	FQPA SF = 1X aPAD = acute RfD / FQPA SF = 0.50 mg/kg/	Developmental Toxicity in rats LOAEL = 200 mg/kg/day based on diaphragmatic hernia
Acute Dietary (General population including infants and children)	An appropriate endpoint attributable to a single dose was not identified in the available studies including the developmental toxicity studies.		
Chronic Dietary (All populations)	NOAEL= 0.74 mg/kg/day UF = 100 Chronic RfD = 0.008 mg/kg/day	FQPA SF = 1X cPAD = chronic RfD / FQPA SF = 0.0074 mg/kg/day	Two-Generation Reproduction in rats LOAEL = 5.8 mg/kg/day in males and 7.1 in females based on decreased spleen, testes & epididymal weights in males and uterine & pituitary weights in females

Table 2. Summary of Toxicological Endpoints for Fluazifop-p-butyl			
Exposure Scenario	Dose Used in Risk Assessment, UF	Special FQPA SF* and Level of Concern for Risk Assessment	Study and Toxicological Effects
Short-Term Incidental Oral (1-30 days)	Maternal NOAEL = 100 mg/kg/day	Residential LOC for MOE = 100 Occupational = NA	Developmental Toxicity Study in rats LOAEL = 300 mg/kg/day based on maternal body weight decrement during GD 7-16.
Intermediate-Term Incidental Oral (1- 6 months)	Parental/ Systemic NOAEL= 0.74 mg/kg/day	Residential LOC for MOE = 100 Occupational = NA	Two-Generation Reproduction in rats LOAEL = 5.8 mg/kg/day in males and 7.1 in females based on decreased spleen, testes & epididymal weights in males and uterine & pituitary weights in females
Short-Term Dermal[a] (1 to 30 days) (Females 13-49)	Developmental NOAEL= 2.0 mg/kg/day	Residential LOC for MOE = 100 Occupational LOC for MOE = 100	Developmental Toxicity Study in rats LOAEL = 5.0 mg/kg/day based on fetal weight, hydroureter and delayed ossification
Short-Term Dermal[a] (1 to 30 days) (General Population including Infants & children)	Maternal NOAEL= 100 mg/kg/day	Residential LOC for MOE = 100	Developmental Toxicity Study in rats LOAEL = 300 mg/kg/day based on maternal body weight decrements during GD 7-16.
Intermediate & Long-Term Dermal[a] (1 to >6 months)	Parental/ Systemic NOAEL= 0.74 mg/kg/day	Residential LOC for MOE = 100 Occupational LOC for MOE = 100	Two-Generation Reproduction in rats LOAEL = 5.8 mg/kg/day in males and 7.1 in females based on decreased spleen, testes & epididymal weights in males and uterine & pituitary weights in females
Short-Term Inhalation[b] (1 to 30 days) (Females 13-49)	Developmental NOAEL= 2.0 mg/kg/day	Residential LOC for MOE = 100 Occupational LOC for MOE = 100	Developmental Toxicity Study in rats LOAEL = 5.0 mg/kg/day based on fetal weight, hydroureter and delayed ossification
Short-Term Inhalation[b] (1 to 30 days) (General Population including Infants & children)	Maternal NOAEL= 100 mg/kg/day	Residential LOC for MOE = 100	Developmental Toxicity Study in rats LOAEL = 300 mg/kg/day based on maternal body weight decrements during GD 7-16.
Intermediate & Long-Term Inhalation[b] (1 to >6 months)	Parental/ Systemic NOAEL= 0.74 mg/kg/day	Residential LOC for MOE = 100 Occupational LOC for MOE = 100	Two-Generation Reproduction in rats LOAEL = 5.8 mg/kg/day in males and 7.1 in females based on decreased spleen, testes & epididymal weights in males and uterine & pituitary weights in females

Table 2. Summary of Toxicological Endpoints for Fluazifop-p-butyl			
Exposure Scenario	Dose Used in Risk Assessment, UF	Special FQPA SF* and Level of Concern for Risk Assessment	Study and Toxicological Effects
Cancer (oral, dermal, inhalation)	"Not likely to be carcinogenic to humans."		

[a] Use either 9% (low exposure scenario) or 2% (high exposure scenario) for route-to-route extrapolations.
[b] Absorption via the inhalation route is presumed to be equivalent to oral absorption.

2.4 FQPA Safety Factor

The HIARC document states that there is no need for a special FQPA safety factor (i.e., 1X), since there are no residual uncertainties for pre-and/or post-natal toxicity..

2.5 Incident Reports

HED performed an analysis of poisoning incidents involving fluazifop-p-butyl (PC Code: 122805 and 122809) using the following data bases:

- OPP Incident Data System (IDS) - reports of incidents from various sources, including registrants, other federal and state health and environmental agencies and individual consumers, submitted to OPP since 1992. Reports submitted to the Incident Data System represent anecdotal reports or allegations only, unless otherwise stated. Typically no conclusions can be drawn implicating the pesticide as a cause of any of the reported health effects. Nevertheless, sometimes with enough cases and/or enough documentation risk mitigation measures may be suggested.
- Poison Control Centers - as the result of a data purchase by EPA, OPP received Poison Control Center data covering the years 1993 through 1998 for all pesticides. Most of the national Poison Control Centers (PCCs) participate in a national data collection system, the Toxic Exposure Surveillance System, which obtains data from about 65-70 centers at hospitals and universities. PCCs provide telephone consultation for individuals and health care providers on suspected poisonings involving drugs, household products, pesticides, etc.
- California Department of Pesticide Regulation - California has collected uniform data on suspected pesticide poisonings since 1982. Physicians are required, by statute, to report to their local health officer all occurrences of illness suspected of being related to exposure to pesticides. The majority of the incidents involve workers. Information on exposure (worker activity), type of illness (systemic, eye, skin, eye/skin and respiratory), likelihood of a causal relationship, and number of days off work and in the hospital are provided.
- National Pesticide Information Center (NPIC) - NPIC is a toll-free information service supported by OPP. A ranking of the top 200 active ingredients for which telephone calls were received during calendar years 1984-1991, inclusive, has been prepared. The total number of calls was tabulated for the following categories: human incidents, animal incidents, calls for information, and others.

Analysis of the OPP Incident Data System indicates that seventeen incidents were reported in which fluazifop-p-butyl was mentioned as a possible source. None of the incidents described provided strong evidence that fluazifop butyl was or was not causally related to the reported effects.

Analysis of Poison Control Center data covering the years 1993 through 1998 indicates that fluazifop-p-butyl incidents among non-occupational adults and older children appear about as likely to result in symptoms that require care as other pesticides. However, fluazifop-p-butyl exposures are less likely to result in major outcomes requiring hospitalization or intensive care. None of the cases required hospitalization or resulted in a life-threatening outcome. The overwhelming majority of symptomatic cases involved dermal or eye effects (irritation) and occasionally headache.

Analysis of California Department of Pesticide Regulation data collected since 1982 indicates that applicators and other handlers were associated with more incidents than any other category. These incidents included symptoms of eye irritation, contact dermatitis, nausea, headache, rash, and chemical conjunctivitis.

On the list of the top 200 chemicals about which the National Pesticide Information Center received telephone calls during 1984 through 1991, fluazifop-p-butyl was ranked 158th with 17 incidents in humans reported and 5 in animals (mostly pets).

HED concludes that relatively few incidents of illness or injury have been reported due to fluazifop-p-butyl and that the majority of incidents occurred among handlers who experienced skin or eye effects.

2.6 Summary of Physical and Chemical Properties of Fluazifop-p-butyl

See product chemistry chapter.

2.7 Summary of Use Pattern and Formulations

Fluazifop-p-butyl is formulated as an emulsifiable concentrate and ready-to-use liquid concentrate. It is registered for use in a variety of agricultural, occupational and residential scenarios. However, this assessment addresses risk resulting from non-occupational (residential) exposures only. Occupational exposures will not be addressed in this document. Fluazifop-p-butyl is registered for use by residential applicators, therefore, risks to residential handlers will be assessed as well as postapplication risks to residential populations. Table 3 summarizes the use-patterns that could impact nonoccupational (residential) populations.

Table 3. Summary of Maximum Application Rates for Fluazifop-p-butyl Uses in Residential Settings			
Target	Application Rate	Application Equipment	Area Treated Daily
Commercial Uses at Residential Sites			
Lawn replacement	0.005 lb ai/gal & 0.73 lb ai/A	Low pressure handwand	Not applicable to this assessment
		Backpack sprayer	
		Handgun	
Non-crop areas (including cemeteries, around buildings, parkways, roadsides, landscaped areas	0.38 lb ai/A	Low pressure handwand	
		Backpack sprayer	
		Handgun	
Turf (suppression/ control of weeds in Zoysia and Tall Fescue), including golf courses, around residential, commercial, public, and industrial buildings and areas, sports fields, parks [One label does not prohibit applications to home lawns.]	0.09 lb ai/A (Reg .# 2217-728) 0.075 lb ai/A (Reg. #100-1069)	Low pressure handwand	
		Backpack sprayer	
		Handgun	

Table 3. Summary of Maximum Application Rates for Fluazifop-p-butyl Uses in Residential Settings			
Target	Application Rate	Application Equipment	Area Treated Daily
Ornamentals, trees, shrubs, and groundcovers	0.01 lb ai/gal or 0.44 lb ai/A	Low pressure handwand	
		Handgun	
		Watering Can	
Residential (Homeowner) Uses			
Walks, drives, patios and fences, and lawn replacement	0.0056 lb ai/gallon or 0.98 lb ai/A (Reg. #9688-106) 0.075 lb ai/A (Reg.# 100-1069)	Low pressure handwand	5 gallons
		Hose-end sprayer	0.5 acre
		Watering can	5 gallons
In and around ornamentals and groundcover	0.0056 lb ai/gallon	Watering can	5 gallons
	0.04 lb ai/ gallon (ready-to-use)	Sprinkling Application	1 gallon
		Trigger-pump sprayer	1 gallon

3.0 RESIDENTIAL EXPOSURE AND RISKS

Residential handlers are involved in the entire pesticide application process (i.e., they do all functions related to a pesticide application event). The only significant difference between this category and the similar occupational category is that the individuals typically use less chemical on a daily basis and residents are assumed to wear attire consisting of short-sleeve shirt, short pants, shoes, and socks.

The fluazifop-p-butyl assessment reflects the Agency's current approaches for completing residential exposure assessments based on the guidance provided in the OPPTS Harmonized Guidelines, Series 875_Occupational and Residential Exposure Test Guidelines, Group B_Postapplication Exposure Monitoring Test Guidelines, the Draft: Standard Operating Procedures (SOPs) for Residential Exposure Assessment, and the Overview of Issues Related to the Standard Operating Procedures for Residential Exposure Assessment presented at the September 1999 meeting of the FIFRA Scientific Advisory Panel (SAP). The Agency is, however, currently in the process of revising its guidance for completing these types of assessments.

3.1 Residential Handler Exposures and Risks

3.1.1 Handler Exposure Scenarios

Scenarios are used to define risks based on the *U.S. EPA Guidelines For Exposure Assessment* (U.S. EPA; Federal Register Volume 57, Number 104; May 29, 1992). Assessing exposures and risks resulting from residential uses is very similar to assessing occupational exposures and risks, with the following exceptions:

- Residential handler exposure scenarios are considered to be short-term only, due to the infrequent use patterns associated with homeowner products.

- A tiered approach for personal protection using increasing levels of PPE is not used in residential handler risk assessments. Homeowner handler assessments are based on the assumption that individuals are wearing shorts, short-sleeved shirts, socks, and shoes.

- Homeowner handlers are expected to complete all tasks associated with the use of a pesticide product including mixing/loading, if needed, as well as the application.

- Label use-rates and use-information specific to residential products serve as the basis for the risk calculations.

- Area/volumes of spray or chemical used in the risk assessment are based on HED's guidance specific to residential use-patterns.

It has been determined that exposure to pesticide handlers is likely during the residential use of fluazifop-p-butyl in a variety of outdoor environments, including on lawns, walks, drives and ornamentals. The anticipated use patterns and current labeling indicate several residential handler exposure scenarios based on the types of equipment and techniques that can potentially be used to make fluazifop-p-butyl applications. The quantitative exposure/risk assessment developed for residential handlers is based on these scenarios.

Mixer/Loader/Applicators:
(1) Liquid Concentrate: Low Pressure Handwand (ORETF data)
(2) Liquid Concentrate: Hose-end Sprayer (ORETF data)
(3) Liquid Concentrate: Watering Can (ORETF hose-end sprayer data)
(4) RTU Formulations: Sprinkling Application (ORETF hose-end sprayer data)
(5) RTU Formulations: Trigger-pump Sprayer (proprietary data)

Note: the ready-to-use formulation has two options for application – use as a trigger-pump sprayer and use by sprinkling the liquid directly from the container. Therefore, two different exposure scenarios are assessed.

3.1.2 Data and Assumptions For Handler Exposure Scenarios

A series of assumptions and exposure factors served as the basis for completing the residential handler risk assessments. Each assumption and factor is detailed below. In addition to these factors, unit exposure values were used to calculate risk estimates. Mostly, the unit exposure values were taken from the Outdoor Residential Exposure Task Force (ORETF) studies, however, one proprietary study was used.

Assumptions and Factors: The assumptions and factors used in the risk calculations include:

- HED always considers the maximum application rates allowed by labels in its risk assessments. If additional information such as average or typical rates are available, these values also may be used to allow risk managers to make a more informed risk management decision. Average/typical application rates were not available for residential scenarios.

- Residential risk assessments are based on estimates of what homeowners would typically treat, such as the size of a lawn. The factors used for the fluazifop-p-butyl assessment were from the Health Effects Division Science Advisory Committee *Policy 12: Recommended Revisions To The Standard Operating Procedures For Residential Exposure Assessment* which was completed on February 22, 2001, and on professional judgement. The daily volumes handled and area treated used in each residential scenario are provided in Table 3.

- A 9 percent dermal absorption factor was used to assess residential handler exposures, since these exposures are considered representative of low exposure activities.

Residential Handler Exposure Studies: No chemical-specific data were submitted for use in the residential handler risk assessment. The unit exposure values that were used in this assessment were based on Outdoor Residential Exposure Task Force studies and one proprietary study. Summaries of the studies are below.

Homeowner Hand-held Sprayer (MRID 445185-01): Applications of Sevin Liquid® Carbaryl insecticide [RP-2 liquid (21%)] were made by volunteers to two young citrus trees and two shrubs in each replicate that was monitored in the study. The test field was located only in Florida. Twenty (20) replicates were monitored using hand held pump sprayers (low pressure handwands).

Each replicate opened the end-use product, added it to the hand held pump and then applied it to the trees and shrubs. After application to two trees and two shrubs, dosimeters were collected. Inhalation exposure was monitored with personal air sampling pumps with OVS tubes attached to the shirt collar in the breathing zone. Dermal exposure was assessed by extraction of carbaryl from inner and outer 100 percent

cotton dosimeters. The inner and outer dosimeters were segmented into: lower and upper arms, lower and upper legs, front and back torso. No gloves were worn, therefore, hand exposure was assessed with a 400 ml handwash with 0.01 percent Aerosol OT-75 sodium dioctyl sulfosuccinate (OTS). One hundred percent cotton handkerchiefs wetted with 25 ml OTS were used to wipe face and neck to determine exposure.

Field fortification recoveries for passive dosimeters averaged 88.3 percent for inner and 76.2 percent for outer dosimeters. Face and neck wipe fortifications average 82.5 percent. Handwash and inhalation OVS tube field fortification averaged >90 percent. Inner and outer dosimeter and face and neck wipe residues were adjusted for field fortification results. Handwash and inhalation residues were not adjusted.

Laboratory method validation for each matrix fell within the acceptable range of 70 to 120 percent. The limit of quantitation (LOQ) was 1.0 µg/sample for all media, except the inhalation monitors, where the LOQ was 0.01 µg/sample. The limit of detection (LOD) was 0.5 µg/sample for all media, except the inhalation monitors, where the LOQ was 0.005 µg/sample.

For use in reregistration documents, the dermal exposure was calculated by adding the values from the hand rinses, face/neck wipes to the outer dosimeter lower legs and lower arms plus the inner dosimeter front and rear torso, upper legs and upper arms. This accounts for the residential handler wearing short-sleeved shirt and short pants. The results for the low pressure handwand are summarized in Table 4 below.

Table 4: Unit Exposure Values Obtained From ORETF Homeowner Low Pressure Handwand Studies (MRID 445185-01)

Type	Dermal: Short Pants, Short Sleeves (mg ai/lb handled)	Inhalation (µg ai/lb handled)
Low Pressure Handwand	56	3.8
All unit exposure values are geometric means.		

ORETF Hose End Sprayer Study: A mixer/loader/applicator study was performed by the Outdoor Residential Exposure Task Force (ORETF) using Diazinon as a surrogate compound to determine "generic" exposures to individuals applying a pesticide to turf with a dial type hose end sprayer. Dermal and inhalation exposures were estimated using whole-body passive dosimeters and breathing-zone air samples on OVS tubes. Inhalation exposure was calculated using an assumed respiratory rate of 17 liters per minute for light work (NAFTA,1999), the actual sampling time for each individual, and the pump flow rate. All results were normalized for pounds active ingredient handled. A total of 30 replicates were monitored throughout the study. Diazinon (25% emulsifiable concentrate) was applied by homeowners to actual residential lawns at a site in Maryland. A target application rate of 4 pounds active ingredient was used for all replicates. Each replicate monitored the test subject treating 5,000 ft^2 of turf and handling a total of 0.5 lb ai/replicate. The exposure periods (mixing/loading/applying) averaged seventy-five minutes. Dermal exposure was measured using inner and outer whole body dosimeters,

hand washes, face/neck washes, and personal air monitoring devices. In general, concurrent lab spikes produced mean recoveries in the range of 87-103 percent. Adjustment for recoveries from field fortifications (79-104%) were performed on each dosimeter section or sample matrix for each study participant, using the mean recovery for the closest field spike level for each matrix and correcting the value to 100 percent. The unit exposures are presented below. [Note the data were found to be lognormally distributed. As a result, all exposures are geometric means.]

Table 5: Unit Exposures Obtained From ORETF Hose End Sprayer Studies (MRID 449722-01)

Type	Dermal: Short Pants, Short Sleeves (mg ai/lb handled)	Inhalation (µg ai/lb handled)
Hose-end (Mix-your-own)	11	17
All unit exposures are geometric means.		

Proprietary Trigger-Pump Sprayer Study (EPA MRID 410547-01): A total of 15 applicator events during residential applications using a hand-operated trigger pump sprayer, attached with an 18 inch hose to half gallon cans containing 0.95 percent propoxur, were completed in this study. The study was completed between October 26 and November 1, 1988 in the Kansas City, Missouri, metro area. Each person monitored in the study was a Bayer (the sponsor corporation) employee. Three employees were used to complete all replicates. In each replicate, "each applicator used a separate one-half gallon can of Raid for each house. The cap was removed from the top of the can and the hose sprayer was attached by inserting the dip tube into the can and tightening the screw cap. The sprayer was primed by pumping the trigger. The applicator treated the outside of the home in areas where pests were likely to be found, such as screens, door and window frames, foundation walls, patios, porches, stoops, and decks. When the application was completed, the hose sprayer was secured under the handle of the can." The data included in the study indicate that exposure durations ranged from 9 to 21 minutes per replicate and the amount of active ingredient handled ranged from 0.16 to 0.4 oz (i.e., 0.01 to 0.025 lb ai). Dermal (nonhand) exposure monitoring during each replicate was completed using gauze sponges held in "aluminized paper holders" with an open sampling surface area of 24.6 cm^2, while hand exposures were quantified with the handwash technique (2 - 200 mL aliquots of ethanol per hand for a total volume of 800 mL per person). Inhalation exposures were monitored using standard personal sampling pumps operating at 1 liter per minute with quartz microfiber filters. Samples were collected in this study to represent exposures when a person was wearing normal work clothing (i.e., long pants and long-sleeved shirts) and chemical-resistant gloves.

Analysis of propoxur residues was completed with high performance liquid chromatography, post-column derivatization, and fluorescence detection. The limits of quantification (LOQ) were 10 µg per sample for the handwash solutions, 0.1 µg/sample for the inhalation filters, and 0.03 µg/cm^2 for the dermal patch samples. Field and laboratory recovery data were generated for all media. This study was reviewed in September 1989 under EPA contract 68-02-4254 by Versar. The values used for

regulatory purposes have been excerpted from that review (including recovery results). Average laboratory recovery for all media ranged from 99.2 to 109 percent, while the coefficients of variation for each media were generally less than 5 (i.e., for the patches, the CV = 16.5). Patches and filters were fortified at 1 µg/sample, while hand rinses were fortified at either 200 or 1000 µg/sample. Average field recovery results ranged from 90.3 to 102.2 percent, while coefficients of variation also were generally less than 5 (i.e., inside patch CV= 6.9). Patches were fortified at levels from 1 to 50 µg/sample, hand rinses were fortified at 200 µg/sample, and filters were fortified at 0.2 µg/sample.

Table 6: Unit Exposure Values Obtained From Propoxur Trigger Pump Sprayer Study (MRID 410547-01)

Type	Dermal (mg ai/lb handled)	Inhalation (µg ai/lb handled)
Trigger Pump Sprayer	13.5	123

3.1.3 Residential Handler Exposure and Non-Cancer Risk Estimates

Residential risk assessments must include the determination of an appropriate Food Quality Protection Act (FQPA) safety factor to be applied to the overall safety factor or level of concern. In the case of fluazifop-p-butyl, it was decided by the FQPA Safety Factor Committee that the factor should be 1X, based on the recently revised FQPA SFC standard operating procedures. Therefore, the overall uncertainty factor applied to fluazifop-p-butyl for residential handler risk assessments is 100, which is based on the FQPA safety factor of 1 along with the 10X for inter-species extrapolation, and the 10X for intra-species sensitivity.

Dermal and inhalation potential doses for handlers are calculated as follows:

$$\textit{Exposure Dose (mg/kg/day)} = \frac{UE \times AR \times A \times AB}{BW}$$

Where,

UE	=	unit exposure from ORETF or proprietary study data (mg/lb ai or µg/lb ai)
AR	=	maximum application rate (lb ai/acre or lb ai/gal)
A	=	maximum area treated (acres/day or gal/day)
AB	=	absorption value (dermal absorption = 9%; inhalation absorption = 100%)
BW	=	body weight (60 kg)

For handler short- term exposure, the margin of exposure (MOE) was calculated as follows:

$$\textit{Dermal MOE} = \frac{\textit{NOAEL (2 mg/kg/day)}}{\textit{Dermal Exposure Dose}}$$

$$\textit{Inhalation MOE} = \frac{\textit{NOAEL (2 mg/kg/day)}}{\textit{Inhalation Exposure Dose}}$$

$$MOE_{TOTAL} = \frac{1}{(1/\text{Dermal MOE}) + (1/\text{Inhalation MOE})}$$

Noncancer Risk Summary: All of the noncancer risk calculations for residential fluazifop-p-butyl handlers completed in this assessment are included in Table 7. The results of

the residential handler noncancer risk assessment indicate that none of the residential handler risks exceed HED's level of concern (i.e., MOEs are all greater than 100).

3.1.4 Residential Handler Exposure and Risk Estimates for Cancer

Residential handler cancer risks are not assessed, since no toxicological endpoint of concern for cancer was selected.

3.1.5 Summary of Risk Concerns and Data Gaps for Handlers

Noncancer risks (i.e., MOEs) associated with the residential handler scenarios do not exceed HED's uncertainty factor of 100.

HED has no data to assess exposures from applications using a sprinkling can. Therefore,
ORETF residential hose-end data were used in the assessment as a surrogate.

3.1.6 Recommendations For Refining Residential Handler Risk Assessment

In order to refine this residential risk assessment, more data on actual use patterns including rates, timing, and areas treated would better characterize fluazifop-p-butyl risks.

Table 7: Summary of Residential Handler Noncancer Risks from Fluazifop-p-butyl										
Exposure Scenario	Target	Application Rate[a]	Area Treated Daily[b]	Dermal Unit Exposure (mg/lb ai)	Inhalation Unit Exposure (mg/lb ai)	Dermal Dose[d] (mg/kg/day)	Inhalation Dose[e] (mg/kg/day)	MOE (HED's level of concern = 100)		
								Dermal[f]	Inhalation[g]	Dermal + Inhalation[h]
Mixer/Loader/Applicator										
Mixing/Loading/Applying Liquid Concentrates with Low Pressure Handwand (ORETF residential handheld pump sprayer data) (1)	Walks, drives, patios, and fences	0.0056 lb ai/gallon	5 gallons	56	0.0038	0.0024	0.0000018	850	1,100,000	850
Mixing/Loading/Applying Liquid Concentrates with Hose-End Sprayer (Residential ORETF data) (2)	Walks, drives, patios, and fences, lawn replacement	0.98 lb ai/acre	0.5 acre	11	0.017	0.0081	0.00014	250	14,000	240
		0.075 lb ai/acre	0.5 acre	11	0.017	0.00062	0.00001	3000	200,000	2900
Mixing/Loading/Applying Liquid Concentrates with a Watering Can (using ORETF residential hose-end data) (3)	Walks, drives, patios, and fences	0.0056 lb ai/gallon	5 gallons	11	0.017	0.00046	0.0000079	4300	250,000	4300
Loading/Applying Ready-To-Use Liquid with a Watering Can (using ORETF residential hose-end data) (4)	in around ornamentals and ground cover	0.04 lb ai/gallon	1 gallons	11	0.017	0.00066	0.000011	3000	180,000	3000
Applying Ready to Use Liquid via Trigger-Pump Sprayer (using proprietary data) (5)	in around ornamentals and ground cover	0.04 lb ai/gallon	1 gallons	13.5	0.123	0.00081	0.000082	2500	24,000	2200

Footnotes

a Application rates are the maximum application rates determined from EPA registered labels for fluazifop-p-butyl.

b Amount handled per day values are EPA estimates.

c Attire is short-sleeve shirt, short pants, and no gloves and no respirator.

d Dermal Dose = application rate x area treated x dermal unit exposure x %DA (.09 or 0.02) ÷ 60

e. Inhalation Dose = application rate x area treated x inhalation unit exposure ÷ 60

f. Dermal MOE = NOAEL (2 mg/kg/day) / dermal daily dose (mg/kg/day),

g. Inhalation MOE = NOAEL (2 mg/kg/day) / inhalation daily dose (mg/kg/day)

h $MOE_{TOTAL} = \frac{1}{(1/\text{Dermal MOE}) + (1/\text{Inhalation MOE})}$

3.2 Residential Postapplication Exposures and Risks

HED uses the term "postapplication" to describe exposures to individuals that occur as a result of being in an environment that has been previously treated with a pesticide. Fluazifop-p-butyl can be used in many areas that can be frequented by the general population including residential areas (e.g., home lawns). As a result, individuals can be exposed by entering these areas if they have been previously treated.

3.2.1 Residential Postapplication Exposure Scenarios

Individuals of varying ages can potentially be exposed to fluazifop-p-butyl when they are in areas that have been previously treated. Postapplication exposure scenarios were developed for each residential setting where fluazifop-p-butyl can be used.

HED relies on a standardized approach for completing residential risk assessments that is based on current fluazifop-p-butyl labels and guidance contained in the following five documents:

- ***Series 875, Residential and Residential Exposure Test Guidelines: Group B - Postapplication Exposure Monitoring Test Guidelines (V 5.4, Feb. 1998)*** This document provides general risk assessment guidance and criteria for analysis of residue dissipation data.

- ***Standard Operating Procedures For Residential Exposure Assessment (Dec. 1997)*** This document provides the overarching guidance for developing residential risk assessments including scenario development, algorithms, and values for inputs.

- ***Science Advisory Council For Exposure Policy 12 (Feb. 2001): Recommended Revisions To The Standard Operating Procedures (SOPs) For Residential Exposure Assessment*** This document provides additional, revised guidance for completing residential exposure assessments.

- ***Overview of Issues Related To The Standard Operating Procedures For Residential Exposure Assessment (August 1999 Presentation To The FIFRA SAP)*** This document provides rationale for Agency changes in SOPs.

When the guidance in current labels and these documents is considered, it is clear that HED should consider children of differing ages as well as adults in its assessments. It is also clear that different age groups should be considered in different situations. The populations that were considered in the assessment include:

- **Residential Adults:** these individuals are members of the general population that are exposed to chemicals by engaging in activities at their residences (e.g., in their lawns) and also in areas not limited to their residence (e.g., golf courses or parks) previously treated with a pesticide. These kinds of exposures are attributable to a

variety of activities and are usually addressed by HED in risk assessments by considering a representative activity as the basis for the exposure calculation.

- **Residential Children:** children are members of the general population that can also be exposed in their residences (e.g., on lawns and other residential turfgrass areas). These kinds of exposures are attributable to a variety of activities such as playing outside. Toddlers have been selected as the sentinel (representative) population for turf. Youth-aged children (ages 10 to 12) are considered the sentinel population for a golfing assessment, because it is likely that children of this age would play golf. Children are addressed by HED in risk assessments by considering representative activities for each age group in an exposure calculation.

The *SOPs For Residential Exposure Assessment* define several scenarios that apply to uses specified in current labels. These scenarios served as the basis for the residential postapplication assessment along with the modifications to them and the additional data and approaches described above. HED used this guidance to define the exposure scenarios that essentially include dermal and nondietary ingestion exposure to toddlers on treated lawns, dermal exposure to youths on treated golf courses, and dermal exposure to adults on treated lawns and on treated golf courses. The SOPs and the associated scenarios are presented below:

- ***Dose from dermal exposure on treated turf:*** Postapplication dermal dose calculations for toddlers from playing on treated turf, for adults mowing and exercising on treated turf, and for youths and adults playing golf on treated golf courses;

- ***Dose from hand-to-mouth activity from treated turf:*** Postapplication dose calculations for toddlers from incidental nondietary ingestion of pesticide residues on treated turf from hand-to-mouth transfer (i.e., those residues that are swallowed when toddlers get pesticide residues on their hands from touching treated turf and then put their hands in their mouth);

- ***Dose from object-to-mouth activity from treated turf:*** Postapplication dose calculations for toddlers from incidental nondietary ingestion of pesticide residues on treated turf from object-to-mouth transfer (i.e., those residues that are swallowed when toddlers put treated turf in their mouths);

- ***Dose from soil ingestion activity from treated turf:*** Postapplication dose calculations for toddlers from incidental nondietary ingestion of pesticide residues from ingesting soil in a treated turf area (i.e., those soil residues that are swallowed when toddlers get pesticide residues on their hands from touching treated soil and then put their hands in their mouth).

The detailed residential postapplication calculations are presented in the appendix of this document.

3.2.2 Data and Assumptions for Residential Postapplication Exposure Scenarios

A series of assumptions and exposure factors served as the basis for completing the residential postapplication risk assessments. The assumptions and factors used in the risk calculations are consistent with current Agency policy for completing residential exposure assessments (i.e., *SOPs For Residential Exposure Assessment*). The values used in this assessment include:

- The body weight of an average adult female (60 kilograms) is used for assessing dermal risks to adults, since the toxicological endpoint of concern is female-specific.

- HED combines risks resulting from exposures to individual applications when it is likely they can occur simultaneously based on the use pattern and the behavior associated with the exposed population. For fluazifop-p-butyl, HED has combined risks (i.e., MOEs) for turf scenarios involving toddlers – dermal plus hand-to-mouth plus object-to-mouth plus soil ingestion.

- Exposures to adults and children on treated turf have been addressed using the latest HED standard operating procedures for this scenario including:
  - two separate application rates are assessed – the higher rate is for lawn renovation and the lower rate is for treatments to established lawns. The label directions for the lawn renovation use pattern indicate that the turf is not immediately killed following application, rather it takes up to 7 days for the treated turf to die. Therefore, it is feasible that adults and toddlers could contact the treated turf after application;
  - two separate dermal absorption values are used – 9% is used for assessing dermal exposures while golfing or while mowing a lawn, since these are representative of low exposure activities, whereas 2% is used for assessing dermal exposures from high contact lawn activities, since these are representative of high exposure activities.
  - 5 percent of the application rate has been used to calculate the day-zero TTR residue levels used for assessing risks from dermal and hand-to-mouth exposures, since fluazifop-p-butyl-specific turf transferable residue study data are not available;
  - 20 percent of the application rate has been used to calculate the day-zero residue levels used for assessing risks from object-to-mouth behaviors (a higher percent transfer has been used for object-to-mouth behaviors, because it involves a teething action believed to be more analogous to DFR/leaf wash sample collection where 20 percent is also used);
  - the transfer coefficients used are those presented during the 1999 Agency presentation before the FIFRA Science Advisory Panel that have been adopted in routine practice by HED;

- 3 year old toddlers are expected to weigh 15 kilograms (representing an average weight from years one to six);
- hand-to-mouth exposures are based on a frequency of 20 events/hour and a surface area per event of 20 cm^2, representing the palmar surfaces of three fingers;
- saliva extraction efficiency is 50 percent meaning that every time the hand goes in the mouth approximately ½ of the residues on the hand are removed;
- object-to-mouth exposures are based on a 25 cm^2 surface area;
- exposure durations for turfgrass scenarios are estimated to be 2 hours based on information in HED's *Exposure Factors Handbook*;
- soil residues are contained in the top centimeter and soil density is 0.67 mL/gram; and
- dermal, hand- and object-to-mouth, and soil ingestion are combined to represent an overall risk from exposure to turf.

- Postapplication residential risks are based on maximum application rates or values specified in the *SOPs For Residential Exposure Assessment*.

- The Jazzercize approach is the basis for the dermal transfer coefficients from turfgrass as described in HED's Series 875 guidelines, *SOPs For Residential Exposure Assessment*, and the 1999 FIFRA SAP Overview document.

3.2.3 Residential Postapplication Exposure and Noncancer Risk Estimates

Noncancer risks were calculated using the Margin of Exposure (MOE) approach, which is a ratio of the body burden to the toxicological endpoint of concern. Exposures were calculated by considering the potential sources of exposure (i.e., TTRs on lawns), then calculating dermal and nondietary ingestion exposures.

Nondietary Ingestion Exposure From Treated Turf: Nondietary ingestion exposure from treated turf were calculated using the following equations. These values were then used to calculate MOEs.

Estimating Turf Transferrable Residues and Dislodgeable Foliar Residues

To estimate turf transferrable residue (TTR) values and dislodgeable foliar residue (DFR) values when no chemical-specific TTR or DFR data are available, HED assumes that 5 percent of the turf application rate is available for transfer on day 0. Then HED converts the application rate (in pounds active ingredient per acre) to micrograms per square centimeter using conversion factors.

TTR = AR x F x CF2 x CF 3

where:

AR	=	application rate
F	=	fraction of ai available on turf
CF2	=	weight unit conversion factor to convert the lbs ai in the application rate to ug for TTR value (4.54E8 ug/lb)
CF3	=	area unit conversion factor to convert the surface are units (acres) in the application rate to cm2 for the TTR value (2.47E-8 acre/cm2)

Dermal Exposure from Treated Lawns (adult and toddler)

The approach used to calculate the dermal exposures that are attributable to exposure from contacting treated lawns is:

$$ADD = (TTR_0 * ET * TC * DA * CF1) / BW$$

Where:

ADD	=	average daily dose (mg/kg/day);
TTR_t	=	turf transferable residue on day "0" (µg/cm^2);
ET	=	exposure time (2 hr/day) for lawn and (4 hr.day) for golf;
TC	=	transfer coefficient (14,500 cm^2/hr for adults and 5,200 cm^2/hr for toddlers for high contact lawn activities; 500 cm2/hr for golf or mowing);
DA	=	dermal absorption factor (2% for high contact lawn activities (high exposure) and 9% for golfing or mowing (low exposure));
CF1	=	weight unit conversion factor to convert µg units to mg for the daily exposure (0.001 mg/µg); and
BW	=	body weight (60 kg for adults and 15 kg for toddlers).

Hand-to-mouth Transfer of Pesticide Residues on Lawns (toddler)

The approach used to calculate the nondietary ingestion exposures that are attributable to hand-to-mouth behavior on treated turf is:

$$ADD = (TTR_0 * SA * FQ * ET * SE * CF1) / BW$$

Where:

ADD	=	average daily dose (mg/kg/day);
TTR_t	=	turf transferable residue on day "0" (µg/cm^2);
SA	=	surface area of the hands (20 cm^2/event);
FQ	=	frequency of hand-to-mouth activity (20 events/hr);
ET	=	exposure time (2 hr/day);
SE	=	extraction by saliva (50%);
CF1	=	weight unit conversion factor to convert µg units in the DFR value to mg for the daily exposure (0.001 mg/µg); and
BW	=	body weight (15 kg).

Object-to-mouth Transfer of Pesticide Residues on Lawns (toddler)

The approach used to calculate exposures that are attributable to object-to-mouth behavior on treated turf that is represented by a child mouthing on a handful of turf is:

$$ADD = (TTR_0 * IgR * CF1) / BW$$

Where:

ADD	=	average daily dose (mg/kg/day);

TTR_t	=	turf transferable residue on day "0" (µg/cm^2);
IgR	=	ingestion rate of grass (25 cm^2/day);
CF1	=	weight unit conversion factor to convert the µg of residues on the grass to mg to provide units of mg/day (1E-3 mg/µg); and
BW	=	body weight (15 kg).

Incidental Ingestion of Soil from Pesticide-Treated Residential Areas (toddler)

The approach used to calculate exposures that are attributable to soil ingestion is:

$$ADD = (SR_0 * IgR * CF1) / BW$$

Where:

ADD	=	average daily dose (mg/kg/day);
SR_{0t}	=	soil residue on day "0" (7.4 µg/g at the 0.98 lb ai/A rate and 0.7 µg/g at the 0.09 lb ai/A rate);
IgR	=	ingestion rate of soil (100 mg/day);
CF1	=	weight unit conversion factor to convert the µg of residues on the soil to grams to provide units of mg/day (1E-6 g/µg); and
BW	=	body weight (15 kg).

and

$$SR_t = TTR_t * F * CF2$$

Where:

TTR_t	=	turf transferable residue on day "0" (µg/cm^2);
F	=	fraction of ai available in uppermost cm of soil (1 fraction/cm); and
CF2	=	volume to weight unit conversion factor to convert the volume units (cm^3) to weight units for the SR value (U.S. EPA, 1992) (0.67 cm^3/g soil).

Noncancer Risk Summary: All of the noncancer risk calculations for the various residential fluazifop-p-butyl postapplication assessments are included in the appendix.

HED has addressed residential postapplication exposures to fluazifop-p-butyl using the standard set of scenarios that are prescribed in current guidance. There are many issues associated with the development of these scenarios and, in general, residential exposure methods. Readers should refer to the guidance documents that are presented above for further information concerning the development of scenarios for residential exposure assessment purposes. HED's level of concern is 100 for short-term risks.

Risk Summary:

Adults

Table 8 presents the fluazifop-p-butyl postapplication MOE values calculated for adults after applications to golf courses, to established lawns and to lawns slated for renovation. All MOEs are ≥100 on the day of application.

Table 8. Adult Residential Risk Estimates for Postapplication Exposure to Fluazifop-p-butyl			
Exposure Scenario	Route of Exposure	Application Rate (lb ai/acre)	MOE at Day 0 (HED's level of concern = 100)
High Contact Lawn Activities	Dermal	0.98 (lawn renovation)	380
		0.09 (established turf)	4,200
		0.075 (turf)	5,000
Mowing Turf	Dermal	0.09 (established turf)	26,000
		0.075 (turf)	32,000
Golf Course	Dermal	0.09 (established turf)	13,000
		0.075 (turf)	16,000

Youth-aged children (10 to 12 years old)

Table 9 summarizes the postapplication MOE values calculated for youth following golf course applications of fluazifop-p-butyl. MOEs for youths were ≥100.

Table 9: Youth Residential Risk Estimates for Postapplication Exposure to Fluazifop-p-butyl			
Exposure Scenario	Route of Exposure	Application Rate (lb ai/acre)	MOE at Day 0 (HED's level of concern = 100)
Golf course	Dermal	0.09 (established turf)	8,600
		0.075	10,000

Toddler (3 year old)

Risks (MOEs) to toddlers were calculated for postapplication risks following the application of fluazifop-p-butyl to established home lawns and to lawns slated for renovation. Table 10 summarizes the risk assessment for toddlers. All MOEs are greater than HED's level of concern of 100 on day 0.

Table 10. Toddler Residential Postapplication Risk Estimates for Fluazifop-p-butyl			
Exposure Scenario	Route of Exposure	Application Rate (lb ai/acre)	MOE on Day 0 (HED's level of concern = 100)
Residential Turf (High Contact Activities)	Dermal	0.98 (lawn renovation)	260

		0.09 (established turf)	2,900
		0.075 (turf)	170,000
Hand to Mouth Activity on Turf	Oral	0.98 (lawn renovation)	6,800
		0.09 (established turf)	74,000
		0.075 (turf)	6,000,000
Object to Mouth Activity on Turf	Oral	0.98 (lawn renovation)	27,000
		0.09 (established turf)	300,000
		0.075 (turf)	360,000
Incidental Soil Ingestion	Oral	0.98 (lawn renovation)	2,000,000
		0.09 (established turf)	22,000,000
		0.075 (turf)	26,000,000

Combined Risk Assessment for Residential Scenarios

HED combines risk values resulting from separate postapplication exposure scenarios when it is likely they can occur simultaneously based on the use-pattern and the behavior associated with the exposed population. Table 11 presents a summary of the combined MOE estimates.

The combined risk assessment for exposures to toddlers following home lawn applications was calculated:

$$\textit{Combined MOE} = NOAEL/(ADD_{\textit{hand-to-mouth}} + ADD_{\textit{object-to-mouth}} + ADD_{\textit{incidental soil ingestion}} + ADD_{\textit{dermal}})$$

The results of the combined postapplication risk assessment for toddlers indicates that the combined risks to toddlers on day 0 following applications to established lawns and to lawns slated for renovation are greater than HED's level of concern of 100 (i.e., MOE = 630).

Table 11: Fluazifop-p-butyl Residential Scenarios for Combined Risk Estimates

Postapplication Exposure Scenario		Margins of Exposure (MOEs) (HED's level of concern = 100)	
		Short-Term MOE	Combined Non-Dietary Risk
Lawn Renovation (0.98 lb ai/A)			
Toddler Risks following spray applications to lawns	Hand to Mouth	6,800	250
	Object to Mouth	27,000	
	Incidental Soil Ingestion	2,000,000	
	High Contact Dermal	260	
Established Lawns (0.09 lb ai/A)			

Postapplication Exposure Scenario		Margins of Exposure (MOEs) (HED's level of concern = 100)	
		Short-Term MOE	Combined Non-Dietary Risk
Toddler Risks following spray applications to lawns	Hand to Mouth	74,000	2,800
	Object to Mouth	300,000	
	Incidental Soil Ingestion	22,000,000	
	High Contact Dermal	2,900	
Turf (0.075 lb ai/A)			
Toddler Risks following spray applications to lawns	Hand to Mouth	6,000,000	110,000
	Object to Mouth	360,000	
	Incidental Soil Ingestion	26,000,000	
	High Contact Dermal	170,000	

3.2.4 Residential Postapplication Exposure and Risk Estimates for Cancer

Residential postapplication cancer risks were not assessed for fluazifop-p-butyl, since no toxicological endpoint of concern was selected for cancer.

3.2.5 Summary of Residential Postapplication Risk Concerns and Data Gaps

HED considered a number of exposure scenarios for products that can be used in the residential environment representing different segments of the population including toddlers, youth-aged children, and adults. Short-term noncancer MOEs were calculated for all scenarios. Cancer risks were not calculated, since no toxicological endpoint for cancer was selected. In residential settings, HED does not use restricted-entry intervals or other mitigation approaches to limit postapplication exposures, because they are viewed as impractical and not enforceable. As such, risk estimates on the day of application are the key concern.

In the assessment for residential postapplication exposure and risk, HED has no postapplication risk concerns following the use of fluazifop-p-butyl in residential settings.

3.2.6 Recommendations For Refining Residential Postapplication Risk Assessment

In order to refine this residential assessment, data on actual use patterns including rates, timing, and the kinds of tasks performed are required to better characterize fluazifop-p-butyl risks.

3.3 Spray Drift from Agricultural Uses

HED has concerns for the potential for children's exposure in the home as a result of agricultural uses of fluazifop-p-butyl. Environmental concentrations of fluazifop-p-butyl in homes may result from spray drift, track-in, or from redistribution of residues brought home on the farm worker's clothing. Potential routes of exposure for children may include incidental ingestion and dermal contact with residues on carpets/hard surfaces. Further research into children's exposures resulting from agricultural uses of pesticides are being conducted by the Agency's Office of Research and Development through the STAR (Science to Achieve Results) grant program. The STAR program can be accessed at http://es.epa.gov/ncerqa/grants/ Modifications to this assessment shall be incorporated as updated guidance becomes available. This will include expanding the scope of the residential exposure assessments by developing guidance for characterizing exposures from other sources not addressed such as from spray drift and exposures to farm worker children.

FLUAZIFOP-P-BUTYL APPENDIX

POSTAPPLICATION EXPOSURE AND RISK CALCULATIONS

Appendix Table 1 - Oral Exposure from Hand-to-Mouth Activity on Fluazifop-p-butyl Treated Turf									
Exposure Scenario	Application Rate (lb ai/acre)	Percent active ingredient dislodgeable	Surface area (cm^2)	Hand to Mouth (events/hr)	Extraction by Saliva	Exposure Time	Body Weight (kg)	Average Daily Dose (mg/kg/day)	Oral MOE (HED's level of concern = 100)
Hand to Mouth (turf)	0.98	5%	20	20	50%	2	15	0.014652699	6,800
	0.09	5%	20	20	50%	2	15	0.001345656	74,000
	0.075	5%	20	20	50%	2	15	0.0000168	6,000,000

$$\text{Oral Dose (mg/kg/day)} = \frac{\text{AR (lb ai) x CF1 x CF2 x CF3 x F x SA (cm}^2\text{) x EXT x FQ(events/hr) x ET(hrs/day) x (0.001mg/µg)}}{\text{BW (kg)}}$$

Where:

Dose = oral dose on day of application (mg/kg/day)
AR = application rate (lb ai/A)
CF1 = conversion factor to convert µg to mg (1.00×10^{-3} µg/mg)
CF2 = weight unit conversion factor to convert the lbs ai in the application rate to µg for the soil residue value (4.54×10^{8} µg/lb)
CF3 = area unit conversion factor to convert the surface area units (acres) in the application rate to cm^2 for the SR value (2.47×10^{-8} acre/cm^2)
F = fraction of residue dislodgeable from wet hands (unitless)
SA = surface area of 1 to 3 fingers (cm^2)
EXT = extraction rate by saliva (unitless)
FQ = frequency of hand-to-mouth events (events/hour)
ET = exposure duration (hours/day)
BW = body weight (kg)

Assumptions:

SA - The surface area of 1 to 3 finger is 20 cm^2
FQ - The frequency of hand-to-mouth events is 20 events per hour
F - The fraction of residue dislodgeable from wet hands is 5%
EXT - The extraction rate by saliva is 50%.
ET - The time spent outdoors is 2 hours/day
MOE = NOAEL (100 mg/kg/day) ÷ Dermal Dose

Appendix Table 2 - Oral Exposure from Mouthing Fluazifop-p-butyl Treated Turf						
Exposure Scenario	Application Rate (lb ai/acre)	Percent Active Ingredient Dislodgeable	Surface Area (cm^2)	Body Weight (kg)	Average Daily Dose (mg/kg/day)	Oral MOE (HED's level of concern = 100)
Object (turf) to Mouth	0.98	20%	25	15	0.003663175	27,000
	0.09	20%	25	15	0.000336414	300,000
	0.075	20%	25	15	0.00028	360,000

$$\text{Oral Dose (mg/kg/day)} = \frac{\text{AR (lb ai) x CF1 x CF2 x CF3 x F x SA (cm}^2\text{)}}{\text{BW (kg)}}$$

Where:

Dose = oral dose on day of application (mg/kg/day)
AR = application rate (lb ai/A)
CF1 = conversion factor to convert µg to mg (1.00×10^{-3} µg/mg)
CF2 = weight unit conversion factor to convert the lbs ai in the application rate to µg for the soil residue value (4.54×10^{8} µg/lb)
CF3 = area unit conversion factor to convert the surface area units (acres) in the application rate to cm^2 for the SR value (2.47×10^{-8} acre/cm^2)
F = fraction of residue dislodgeable from wet hands (unitless)
SA = surface area of 1 to 3 fingers (cm^2/day)
BW = body weight (kg)
Oral MOE = NOAEL (100 mg/kg/day) ÷ Daily Dose

Assumptions:
SA - The surface area of 1 to 3 finger is 25 cm^2/day
F - The fraction of residue dislodgeable from wet hands is 20%

Appendix Table 3 - Oral Exposure from Incidental Soil Ingestion						
Exposure Scenario	Application Rate (lb ai/acre)	% of rate in uppermost 1 cm of soil	Body Weight (kg)	Ingestion Rate (IgR) (mg/day)	Average Daily Dose mg/kg/day	Oral MOE (HED's level of concern = 100)
Soil Ingestion	0.98	100%	15	100	0.0000491	2,000,000
	0.09	100%	15	100	0.0000045	22,000,000
	0.075	100%	15	100	0.0000038	26,000,000

$$\text{Oral Dose} = \frac{\text{AR (lb ai/A)} \times \text{F (1.0/cm)} \times \text{IgR(mg/day)} \times \text{CF1(4.54E-8µg/lb)} \times \text{CF2 (2.47E-8 A/cm}^2\text{)} \times \text{CF3 (0.67 cm}^3\text{/g)} \times \text{CF4 (1E-6 g/µg)}}{\text{BW (kg)}}$$

Where:

Dose = oral dose on day of application (mg/kg/day)
AR = application rate (lb ai/A)
F = fraction or residue retained on uppermost 1 cm of soil
IgR = ingestion rate of soil (mg/day)
CF1 = weight unit conversion factor to convert the lbs ai in the application rate to µg for the soil residue value (4.54×10^8 µg/lb)
CF2 = area unit conversion factor to convert the surface area units (acres) in the application rate to cm^2 for the SR value (2.47×10^{-8} acre/cm^2)
CF3 = volume to weight unit conversion factor to convert the volume units (cm^3) to weight units for the soil residue value (0.67 cm^3/g soil)
CF4 = weight unit conversion factor to convert the µg of residues on the soil to grams to provide units of mg/day (1E-6 g/µg)
BW = body weight (kg)
MOE = NOAEL (100 mg/kg/day) ÷ Daily Dose

Assumptions:
F - The fraction or residue retained on uppermost 1 cm of soil is 100 percent based on soil incorporation into top 1 cm of soil after application (1.0/cm)
IgR - The ingestion rate of soil is 100 mg/day

Appendix Table 4 - Dermal Exposure from Fluazifop-p-butyl Treated Turfgrass										
Exposure Scenario		Application Rate (lb ai/acre)	Hours of Exposure	Body Weight (kg)	Percent available	TTR (µg/cm^2) (normalized) DAT 0	Transfer Coefficient (cm^2/hr)	Dermal Absorption (%)	Absorbed Dermal Dose (mg/kg/day)	Dermal MOE (HED's level of concern = 100)
High Contact Lawn Activities	Adult	0.98 (lawn renovation)	2	60	5%	0.549	14,500	2	0.0053	380
		0.09 (established lawn)	2	60	5%	0.050	14,500	2	0.00049	4,100
		0.075 (turf)	2	60	5%	0.042	14,500	2	0.0004	5000
	Toddler	0.98 (lawn renovation)	2	15	5%	0.549	5,200	2	0.0076	260
		0.09 (established lawn)	2	15	5%	0.050	5,200	2	0.0007	2,900
		0.075 (turf)	2	15	5%	0.042	5,200	2	0.00058	170,000
Mowing Turf	Adult	0.09 (established lawn)	2	60	5%	0.050	500	9	0.000076	26,000
		0.075 (turf)	2	60	5%	0.042	500	9	0.000063	32,000
Golf Course	Adults	0.09 (established lawn)	4	60	5%	0.050	500	9	0.00015	13,000
		0.075 (turf)	4	60	5%	0.042	500	9	0.000126	16,000
	Youths (10-12 yrs)	0.09 (established lawn)	4	39	5%	0.050	500	9	0.00023	8,600
		0.075 (turf)	4	39	5%	0.042	500	9	0.000194	10,000

$$\text{Dermal Dose (mg/kg/day)} = \frac{\text{TTR (µg/cm}^2\text{) x 0.001 (mg/µg) x TC (cm}^2\text{/hr) x ET (hr/day) x DA (\%)}}{\text{BW (kg)}}$$

Where:

Dose = Dermal exposure at on day of application attributable for activity in a previously treated area (mg/kg/day)
TTR = Turf Transferable Residue on day of application (µg/cm^2)
TC = Transfer Coefficient;
ET = Exposure Time (hours);

DA = Dermal Absorption; and
BW = Body Weight (60 kg)

TTR ($\mu g/cm^2$) = AR (lb ai/acre) x CF1(4.54E-8µg/lb) x CF2 (2.47E-8 A/cm^2) x PA

Where:

AR = Application rate (lb ai/acre)
CF1 = weight unit conversion factor to convert the lbs ai in the application rate to µg for the soil residue value (4.54×10^8 µg/lb)
CF2 = area unit conversion factor to convert the surface area units (acres) in the application rate to cm^2 for the SR value (2.47×10^{-8} acre/cm^2)
PA = Percent available (%)

Assumptions:
TC - The assumed transfer coefficients (TCs) for adults and children performing short-term high contact activities on treated turf are 14,500 and 5,200, respectively. Golfing, mowing and other low contact activities were assumed to have a TC of 500 µg/cm^2.
ET - The exposure time for high contact activities on residential lawns is 2 hours. The exposure time for golfers is 4 hours. The exposure time for mowing is 2 hours.
DA - The dermal absorption for high contact lawn activities is 2 percent, since these are considered high exposure activities. The dermal absorption for mowing and golfing is 9 percent, since these are considered low exposure activities.