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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

WASHINGTON, D.C. 20460

OFFICE OF PREVENTION, PESTICIDES AND TOXIC SUBSTANCES

OPP OFFICIAL RECORD
HEALTH EFFECTS DIVISION
SCIENTIFIC DATA REVIEWS
EPA SERIES 361

MEMORANDUM

DATE: May 23, 2007

SUBJECT: Occupational and Residential Exposure Assessment for Use of Penoxsulam to Control Aquatic Weeds In and Around Slow-moving and Quiescent Bodies of Water and Broadleaf Weeds in Turfgrass, Residential Lawns, Golf Courses, Sport Fields and Sod Farms.

PC Code:	119031	Barcode:	339488
Chemical Class:	Herbicide		
Registration Nos.:	62719-LUA	Trade Names:	GF-443 SC SF
	62719-LUT		GF-907 37.5 g/l SC
	62719-LLN		Penoxsulam GR 0.04%
	62719-LUG		Penoxsulam GR 0.014%
	62719-LUI		Penoxsulam FERT 0.014%
	62719-LUO		Penoxsulam FERT 0.04%

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This document provides an occupational and residential exposure assessment for the use of herbicide penoxsulam to control weeds in aquatic areas, lawns, golf courses, sport fields and sod farms.

JUL 3 RECD, 2007

1.0 EXECUTIVE SUMMARY

This document provides an occupational and residential exposure assessment for the proposed use of penoxsulam in aquatic areas, residential lawns, golf courses, recreational sport fields, and sod farms to control aquatic and broadleaf weeds. Penoxsulam products are currently registered for weed control in dry- and water-seeded rice. The new proposed penoxsulam products are formulated as liquids and granules to be applied as broadcast or spot treatments. There are no restrictions on the use of treated water for recreational purposes, including swimming and fishing. Exposure is expected to be short- and intermediate-term in duration.

Hazard Characterization:

The toxicology database for penoxsulam is considered complete for the purpose of this assessment. Penoxsulam exhibited minimal acute toxicity via oral and dermal routes of exposure. It is minimally irritating to eye and skin (Toxicity Category IV) and was negative for dermal sensitization. An acute inhalation toxicity study in rats was classified as unacceptable/guideline due to a technical error during the study.

A NOAEL of 17.8 mg/kg/day was selected for assessing incidental oral and inhalation short- and intermediate-term exposure. The NOAEL is based on histological changes in the kidneys observed at the LOAEL was 49.4 mg/kg/day in a 13-week feeding study in dogs.

No dermal or systemic toxicity was seen at the limit dose in the dermal study; therefore, a short-term dermal endpoint was not selected. The same endpoint selected for both oral and inhalation exposure was selected for intermediate-term dermal exposure (NOAEL = 17.8 mg/kg/day).

On February 18, 2004, the Cancer Assessment Review Committee of the Health Effects Division of the Office of Pesticide Programs met to evaluate the carcinogenic potential of Penoxsulam. In accordance with the EPA Proposed Guidelines for Carcinogen Risk Assessment (July 1999), the Committee classified Penoxsulam as "Suggestive Evidence of Carcinogenicity, but Not Sufficient to Assess Human Carcinogenic Potential" and, therefore, quantification of human cancer risk is not required.

Residential (Non-Occupational) Exposure

The proposed use of penoxsulam is for control of aquatic,broadleaf weeds and vegetation in lakes, reservoirs, ponds and canals, residential lawns, golf courses, recreational sport fields, and sod farms ,which could result in potential oral, inhalation, and dermal exposure to adults and children using these treated areas. A total UF of 100 (10X for interspecies and 10X for intraspecies variations) has been applied to all residential risk assessments. Residential MOEs equal to or greater than 100 are not of concern to HED.

Handler

Based on information provided in the proposed aquatic use label, application of this

product is restricted to Dow AgroSciences-authorized applicators trained in Best Management Practices only. Therefore a residential handler exposure assessment was not required for aquatic uses. However, the proposed granular turf products can be applied by homeowners. HED's level of concern for non-cancer risks (i.e., Margins of Exposure (MOE)) for penoxsulam is 100 for residential exposure. Since a short-term dermal point was not selected, the only route of exposure to be addressed is inhalation. Residential handler inhalation MOEs were significantly greater than 100 and therefore not of concern to HED.

Postapplication

There is a potential for postapplication exposure from oral, inhalation and dermal routes of exposure while swimming in aquatic and or turf (lawns, golf courses, sports fields, and sod farms) treated sites. The duration of exposure is expected to be of short- and/or intermediate-term in duration.

Swimmer Postapplication Exposure

A short-term dermal endpoint was not selected and inhalation exposure is expected to be negligible. Therefore, the short-term postapplication assessment for swimmers needs to address only oral exposure. The intermediate-term postapplication exposure assessment combined oral and dermal exposures and is protective for short-term exposure. Therefore, a short-term swimmer postapplication exposure assessment was not performed. The intermediate-term postapplication exposures for adults and children (6 years old) resulted in MOEs that were greater than the level of concern (MOE > 100) and therefore these risks are not of concern to HED. Intermediate-term oral and dermal exposures were assessed using the SWIMODEL from the Residential Standard Operating Procedures (SOPs).

Turf Postapplication Exposure

HED does anticipate short-term dermal exposure to individuals entering turf areas treated with penoxsulam; however, a short-term dermal exposure endpoint was not determined. An intermediate-term dermal exposure NOAEL of 17.8 mg/kg/day was selected; however, based on information from the proposed turf labels and a chemical specific turf transfer residue (TTR) study, intermediate-term dermal exposure is expected to be negligible. Therefore, a dermal postapplication exposure assessment was not performed. Since penoxsulam is applied outdoors inhalation postapplication exposure is also expected to be negligible.

HED's level of concern for risks (i.e., Margins of Exposure (MOE)) for penoxsulam is 100 for residential exposure. Oral (hand-to-mouth, object-to-mouth, and soil ingestions) MOEs were greater than 100. Residential exposure and risk resulting in MOEs greater than or equal to 100 are not of concern to HED.

There are four proposed penoxsulam turf products formulated as granules (Penoxsulam FERT 0.04%, Penoxsulam FERT 0.014%, Penoxsulam GR 0.014% and Penoxsulam GR 0.04%). Although there may be a potential for incidental ingestion of pesticide applied to lawns no acute dietary endpoint attributable to a single exposure was identified in the available toxicology studies on penoxsulam. Therefore, an episodic incidental ingestion of granules assessment could not be performed.

Residential Aggregate Exposure

When there are potential residential exposures to the pesticide, aggregate risk assessment must consider exposures from three major sources: oral, dermal and inhalation exposures. In the case of the proposed aquatic and turf scenarios, inhalation exposure is expected to be negligible; therefore, only oral and dermal exposures will be considered for purposes of this assessment.

HED used the SWIMODEL from the Residential Standard Operating Procedures (SOPs) to assess dermal and oral exposure to recreational swimmers. Parameters used in calculating exposure and risk are based on information for competitive swimmers both adult and children (6 years) in swimming pools which includes an exposure duration of 5 hours. Therefore, **HED considers the swimmer dermal and oral margins of exposure to be over estimates of the actual risk** (see characterization below) **and therefore does not recommend that these MOEs be used when aggregating risk.**

Residential exposure is considered to generally be short-term in duration; however, no short-term dermal endpoint was selected. An intermediate-term dermal endpoint was selected; however, intermediate-term dermal exposure is expected to be negligible. As a result, the only route of postapplication exposure for turf to be aggregated is oral (hand-to-mouth, object–to-mouth, and ingestions of soil). The aggregate margins of exposure for children were greater than the level of concern (Total MOE > 100) and therefore were not of concern to HED.

Occupational Exposure

Handler

Since a short-term dermal point was not selected, the only route of short-term exposure to be addressed for handlers is inhalation. All turf and aquatic handler short-term exposure scenarios resulted in MOEs greater than 100 and therefore are not of concern to HED.

Dermal and inhalation endpoints were selected for intermediate-term exposure. Since both endpoints were derived from the same study, toxicological effects were the same and therefore exposures could be combined to determine a total margin of exposure for intermediate-term aquatic handler scenarios only. All intermediate-term aquatic handler scenarios resulted in Total MOEs greater than HED's level of concern (MOE > 100) when occupational handlers wore single layer of clothing plus gloves. Based on information provided in the proposed turf labels; handler exposure is anticipated to only be short-term in duration. Therefore, neither a dermal nor inhalation intermediate-term handler exposure assessment was performed for turf uses.

Postapplication

In regard to aquatic scenarios, postapplication exposure is expected to occur to only non-occupational individuals swimming in treated areas. Therefore an occupational postapplication exposure assessment is not required for aquatic postapplication scenarios.

No short-term dermal exposure endpoint was selected. Although an intermediate-term dermal endpoint was selected, intermediate-term dermal postapplication exposure is expected to be negligible based on information on the proposed turf labels and chemical

specific turf transfer residue studies. Therefore, a dermal postapplication exposure assessment for turf was not performed

The restricted entry interval is based on the acute toxicity of penoxsulam technical material which is classified as Categories IV. Acute toxicity Category IV chemicals require a 12 hour REI. Therefore, the 12-hour REI which appears on the product labels is adequate and in accordance with worker standard protection guidelines.

2.0 HAZARD CHARACTERIZATION

2.1 Hazard Profile

The toxicology database for penoxsulam is considered complete for the purpose of this assessment. Penoxsulam exhibited minimal acute toxicity via oral and dermal routes of exposure. It is minimally irritating to eye and skin (Toxicity Category IV) and was negative for dermal sensitization. An acute inhalation toxicity study in rats was classified as unacceptable/guideline due to a technical error during the study.

A NOAEL of 17.8 mg/kg/day was selected for assessing incidental oral and inhalation short- and intermediate-term exposure. The NOAEL is based on histological changes in the kidneys observed at the LOAEL of 49.4 mg/kg/day in a 13-week feeding study in dogs.

No dermal or systemic toxicity was seen at the limit dose in the dermal study; therefore, a short-term dermal endpoint was not selected. The same endpoint selected for both oral and inhalation exposure was selected for intermediate-term dermal exposure (NOAEL = 17.8 mg/kg/day).

On February 18, 2004, the Cancer Assessment Review Committee of the Health Effects Division of the Office of Pesticide Programs met to evaluate the carcinogenic potential of Penoxsulam. In accordance with the EPA Proposed Guidelines for Carcinogen Risk Assessment (July 1999), the Committee classified Penoxsulam as "Suggestive Evidence of Carcinogenicity, but Not Sufficient to Assess Human Carcinogenic Potential" and, therefore, quantification of human cancer risk is not required.

The acute toxicity categories for the penoxsulam technical material are summarized in Table 2.1. The doses and endpoints are summarized in Table 2.2. An MOE of 100 is adequate for oral, dermal and inhalation residential and occupational exposure risk assessments.

Table 2.1 Acute Toxicity of Penoxsulam

GDLN	Study Type	MRID	Results	Tox Category
870.1100	Acute Oral Rats	45830812	M: LD50 > 5000 mg/kg F: LD50 > 5000 mg/kg	IV
870.1200	Acute Dermal Rabbits	45830815	M: LD50 > 5000 mg/kg F: LD50 > 5000 mg/kg	IV
870.1300	Acute Inhalation Rats **UNACCEPTABLE**/ guideline	45830818	------	------
870.2400	Primary Eye Irritation Rabbits	45830820	Minimal irritation	IV
870.2500	Primary Skin Irritation Rabbits	45830823	Minimal irritation	IV
870.2600	Dermal Sensitization Guinea Pigs (Maximization)	45830826	Negative for dermal sensitization	N/A

Table 2.2: Summary of Toxicological Doses and Endpoints for Penoxsulam			
Exposure Scenario	**Dose Used in Risk Assessment, UF**	**FQPA SF* and Level of Concern for Risk Assessment**	**Study and Toxicological Effects**
Incidental Oral Short-Term (1 - 30 days) and Intermediate-Term (1-6 months)	NOAEL = 17.8 mg/kg/day	**Residential** LOC for MOE = 100 **Occupational** = NA	13-Week Feeding Study in Dogs. LOAEL = 49.4 mg/kg/day based on histopathologic changes in kidneys.
Dermal Short-Term (1 - 30 days)	None	Not applicable	No dermal, systemic, neuro or developmental toxicity concerns.
Dermal Intermediate-Term (1 - 6 months)	Oral study NOAEL= 17.8 mg/kg/day (dermal absorption rate = 50%)	**Residential** LOC for MOE = 100 **Occupational** LOC for MOE = 100	13-Week Feeding Study in Dogs. LOAEL = 49.4 mg/kg/day based on histopathologic changes in kidneys.
Dermal Long-Term (> 6 months)	Oral study NOAEL= 14.7 mg/kg/day (dermal absorption rate = 50%)	**Residential** LOC for MOE = 100 **Occupational** LOC for MOE = 100	1-Year Chronic Feeding Study in Dogs. LOAEL = 46.2 mg/kg/day based on multifocal hyperplasia of the pelvic epithelium of the kidney.
Inhalation Short-Term (1 - 30 days) and Intermediate-term (1-6 months)	Oral study NOAEL = 17.8 mg/kg/day (inhalation absorption rate = 100%)	**Residential** LOC for MOE = 100 **Occupational** LOC for MOE = 100	13-Week Feeding Study in Dogs. LOAEL = 49.4 mg/kg/day based on histopathologic changes in kidneys.
Inhalation Long-Term (> 6 months)	Oral study NOAEL= 14.7 mg/kg/day (inhalation absorption rate = 100%)	**Residential** LOC for MOE = 100 **Occupational** LOC for MOE = 100	1-Year Chronic Feeding Study in Dogs. LOAEL = 46.2 mg/kg/day based on multifocal hyperplasia of the pelvic epithelium of the kidney.
Cancer (oral, dermal, inhalation)	Penoxsulam was classified as "Suggestive Evidence of Carcinogenicity, but Not Sufficient to Assess Human Carcinogenic Potential" and, therefore, quantification of human cancer risk was not required		

UF = uncertainty factor, FQPA SF = FQPA safety factor, NOAEL = no observed adverse effect level, LOAEL = lowest observed adverse effect level, MOE = margin of exposure, LOC = level of concern.

3.0 PROPOSED END USE PRODUCT AND USE PATTERNS

Penoxsulam is a member of the triazolopyrimidine sulfonamide chemistry family. Its mode of action in susceptible weeds is by inhibition of acetolactate synthase (ALS), an enzyme required for the biosynthesis of certain amino acids necessary for plant growth. Table 3 summarizes the proposed aquatic and turf uses of penoxsulam.

Table 3: Proposed Product and Use Pattern			
Formulation or Product	**Use Site**	**Application Rate**	**Comment**
GF-443 SC SF Herbicide 21.7% a.i. EPA Reg # 62719-LUA	Lakes, reservoirs, ponds, marshes, wetlands, bayouts, drainage ditches, non-irrigated canals and other slow moving or quiescent bodies of water including rivers and streams	**In water treatment**: 0.174 fl oz per acre-foot of water for each part per billion of final concentration of a.i. (4.1 lb ai/acre)	Maximum target concentration in any treated area is 150 ppb a.i. per growth cycle for in water treatment
		Foliar application: 2 to 5.6 fl oz/acre (0.03125 to 0.0875 lb ai/acre)	Apply to actively growing weeds only
	Turfgrass, residential lawns, golf courses, sport fields, and sod farms	0.08 to 0.24 pt/acre (0.02 to 0.06 lb ai/acre)	
GF-907 37.5 g/l SC Herbicide 3.68 % a.i. EPA Reg # 62719-LUT		0.5 to 1.5 pt/acre (0.02 to 0.06 lb ai/acre)	
Penoxsulam GR 0.04% granular EPA Reg # 62719-LLN		0.06 lb ai/acre 0.0014 lb ai/1000 ft^2	
Penoxsulam GR 0.014 granular EPA Reg # 62719-LUG		0.06 lb ai/acre 0.0014 lb ai/1000 ft^2	
Penoxsulam FERT 0.04% granule EPA Reg#62719-LUO		0.06 lb ai/acre 0.0014 lb ai/1000 ft^2	Do not apply more than 150 lb of penoxsulam Fert 0.04% (0.06 lb ai) per acre per application or more than 225 lb of product (0.09 lb ai) per acre per growing season
Penoxsulam FERT 0.014% granule EPA Reg#62719-LUI		0.06 lb ai/acre 0.0014 lb ai/1000 ft^2	

4.0 NON-OCCUPATIONAL/RESIDENTIAL EXPOSURE

4.1 Residential (Aquatic) Handler

The Agency uses the term "Handlers" to describe those individuals who are involved in the pesticide application process. Based on information in the proposed aquatic use labels, application is restricted to Dow AgroSciences-authorized applicators trained in Best Management Practices for use of this product only.

4.2 Residential (Aquatic) Postapplication

There is a potential for postapplication exposure from oral and dermal routes of exposure while swimming in aquatic sites treated with penoxsulam. The duration of exposure is expected to be of short- and/or intermediate-term in duration.

4.2.1 Postapplication Swimmer Exposure Scenario

4.2.1.1 Data and Assumptions

The following data, assumptions and calculations were used to assess post-application exposure as a result of recreational swimming in aquatic sites treated with penoxsulam.

Data and Assumptions:

- Since penoxsulam is to be applied outdoors and its vapor pressure is very low (7.2×10^{-16} mmHg) inhalation exposure is expected to be negligible. Therefore inhalation exposure is not of concern.
- Standard Operating Procedures (SOPs) for Residential Exposure were used to assess oral, and dermal post-application exposure to recreational swimmers
- 100 percent (100%) of the application concentration is available in the water for dermal contact and oral ingestion. For purposes of this assessment the maximum concentration is 150 ppb in accordance with label restrictions.
- Assumed surface area is 20,900 cm^2 for adults and 9,000 cm^2 for children (age 6 years)
- Duration of exposure is assumed to be 5 hours a day for both adults (18-64 years) and children (6 years). This duration is based on the 90th percentile value for time spent at home in a swimming pool from the 1996 Exposure Factors Handbook.
- Mean ingestion rate for adult and children swimmers is 0.05 L/hour
- Average body weight is 70 kg for adult male and 22 kg for 6 year old child
- Penoxsulam permeability coefficient is 8×10^{-7}cm/hr
-
- Galleon ™ SC may be applied either directly to water using hoses or as a foliar application to post-emerged vegetation. For **"in water"** applications, the maximum sum of all applications is 150 ppb per annual growth cycle or a single maximum application rate of 150 ppb. For each ppb of penoxsulam, the label indicates that 0.174 fluid ounces of active ingredient should be applied per acre foot of treated water results in a concentration of 1 ppb, or:

$$1 \text{ ppb penoxsulam} = \frac{0.174 \text{ fl oz Galleon}}{\text{A/ ft}}$$

Therefore, using that ratio, a concentration of 150 ppb would require 26.1 fluid ounces of product, or:

$$150 \text{ ppb penoxsulam} = \frac{26.1 \text{ fl oz Galleon}}{\text{A/ft}}$$

The Galleon ™ SC label features instructions for depths of up to 10 feet, which is a typical depth most of the water bodies to be targeted for treatment with this EUP. The maximum application rate (in lb a.i./acre units) to reach a concentration of 150 ppb in a 10 foot body of water would be:

$$\frac{26.1 \text{ fl oz Galleon}}{\text{A-ft}} \times \frac{1 \text{ gal. Galleon.}}{128 \text{ fl oz Galleon}} \times \frac{2 \text{ lb ai}}{\text{gal Galleon}} \times 10 \text{ ft} = 4.1 \text{ lb ai/acre}$$

- For "**foliar applications post emergent**", Galleon ™ SC is applied at the rate of 2.0 to 5.6 fl oz per acre (0.03125 to 0.0875 lb ai/acre).
- For purposes of assessing residential exposure "in water" application was determined to be the worst case scenario (i.e. greatest application rate), and was therefore used to estimate exposure to swimmers.

Calculations:

The following calculations and equations were used to determine oral and dermal exposure as a result of swimming in aquatic areas treated with penoxsulam.

$$\textbf{Incidental Ingestion Dose} = \frac{\textbf{Cw x IgR x ET}}{\textbf{BW}}$$

Where:

Cw = concentration in water (150 ppb = 0.15 mg/L)
IgR = ingestion rate of water (0.05 L/hr)
ET = =exposure time (5 hr/day)
BW = body weight (kg)

$$\textbf{Dermal Dose} = \frac{\textbf{C}_w \textbf{ x SA X ET x K}_p \textbf{ x CF}}{\textbf{BW}}$$

Where:

Cw = concentration in water (150 ppb = 0.15 mg/L)
SA = surface area exposed (cm^2)
ET = =exposure time (5 hr/day)
Kp = permeability coefficient (8×10^{-7}cm/hr)
CF = unit conversion factor (L/1000 cm^3)
BW = body weight (kg)

Permeability coefficient (Kp) is chemical specific estimated using the following equation:

$$\text{Log Kp} = -2.72 + 0.71 \log k_{ow} - 0.0061 \text{ MW}$$

Where:

Kp = permeability coefficient (1.5×10^{-6} x 50% DA = 8.0×10^{-7} cm/hr)
Log k_{ow} = octanol-water partition coefficient (-0.6 at pH of 7), and
MW = molecular weight (438.38)

$$\textbf{Margin of Exposure} = \frac{\textbf{NOAEL (17.8 mg/kg/day)}}{\textbf{Dose (mg/kg/day)}}$$

4.2.1.2. Exposure and Risk Estimates for Swimmers

The above factors were used in the SWIMODEL formulas for dermal and ingestion exposure. The SWIMODEL formulas for the other dermal pathways (aural,

buccal/sublingual and orbital/nasal) were not used because these formulas are based upon recreational swimmers in swimming pools who swim with their heads partially immersed. It is anticipated that recreational swimmers in weed infested areas would be less likely to swim with their heads immersed than recreational swimmers in weed-free swimming pools. In addition, the formulas for the buccal/sublingual and orbital/nasal pathways contain a default absorption factor of 0.01 which is based upon the absorption of nitroglycerin. This factor would greatly overestimate the risk of penoxsulam exposure because penoxsulam is absorbed at a much lower rate.

Since the short-term postapplication assessment needs to address only oral exposure which results in the same estimated dose for intermediate-term exposure, a short-term aggregate exposure was not required. The intermediate-term postapplication exposure assessment combined oral and dermal exposures and is protective for short-term exposure. Short- and intermediate-term postapplication exposures resulted in MOEs > 100 and were therefore not of concern to HED. A summary of the short- and intermediate-term postapplication exposures for adults and children is provided in Table 4.2.1.2.

Characterization of Risk and Exposure

Duration of exposure is assumed to be 5 hours a day for competitive swimmers both adult (18-64 years) and children (6 years) in swimming pools. This duration is based on the 90th percentile value for time spent at home in a swimming pool from the 1996 Exposure Factors Handbook. HED considers this exposure period very conservative for recreational swimmers in weed infested ponds and lakes. Furthermore, the oral route of exposure is the main driver. A mean ingestion rate of 0.05 L/hour for adults and children was used to assess oral margins of exposure. This ingestion rate is based on HED's swimmer model typically used to assess competitive swimmers in pools who tend to swim with their heads partially immersed in the water and can ingest larger amounts of water. It is anticipated that recreational swimmers in weed infested waters would not immerse their heads as often and therefore would ingest smaller amounts of water. Therefore HED concludes that the dermal and oral margins of exposure are over estimates of the actual risk.

Table 4.2.1.2: Short and Intermediate-Term Postapplication Exposure for Adults and Children Swimmers to Penoxsulam

Exposure Scenarios	Cw [a] (mg/L)	IgR [b] (L/hr)	ET [c] (hr/day)	SA [d] (cm2)	Kp [e] (cm/hr)	CF [f] (L/cm3)	BW [g] (kg)	Oral Dose [h] (mg/kg/day)	Dermal Dose [i] (mg/kg/day)	Adult Total Dose [j]	Adult Total MOE [k]	Child Total Dose [l]	Child Total MOE [m]
Oral	0.15	0.05	5	NA	NA	NA	70	5.4 x 10-4	NA	5.4E-4	33,000	1.7E-3	10,000
							22	1.7 x 10-3					
Dermal		NA		20,900	8E-7	L/1000	70	NA	1.8 x 10-7				
				9,000			22		2.5 x 10-7				

a. Cw = concentration in water (150 ppm = 0.15 mg/L)
b. IgR = ingestion rate of water (0.05 L/hr)
c. ET =exposure time (5 hr/day)
d. SA= surface area exposed (cm^2)
e. Kp = permeability coefficient (8×10^{-7}cm/hr)
f. CF = unit conversion factor ($L/1000\ cm^3$)
g. BW = body weight = 70 kg for adults and 22 kg for children
h. Oral Dose = $\frac{Cw \times IgR \times ET}{BW}$
i. Dermal Dose. = $\frac{C_w \times SA \times ET \times K_p \times CF}{BW}$
j. Adult Total Dose (mg/kg/day) = Adult oral dose + Adult dermal dose
k. Adult Total MOE = NOAEL (17.8 mg/kg/day)/Adult Total Dose (mg/kg/day)
l. Child Total Dose (mg/kg/day) = Child oral dose + Child dermal dose
m. Child Total MOE = NOAEL (17.8 mg/kg/day)/Child Total Dose (mg/kg/day)

4.3 Residential Handler Exposure to Turf

The Agency uses the term "Handlers" to describe those individuals who are involved in the pesticide application process. Four penoxsulam turf products (i.e., Penoxsulam GR 0.04%, Penoxsulam GR 0.014%, Penoxsulam FERT 0.04% granule, and Penoxsulam FERT 0.014% granule) can be applied by home owners. These granular products are to be applied using a hand held or drop/push rotary-type spreader, whirlybirds, cyclones and/or shaker type applicators. The following use scenarios were used to assess handler exposure:

1. mixer/loader/applicator for push-type granular spreader using PHED
2. mixer/loader/applicator for low pressure hand wand and backpack sprayer using PHED
3. mixer/loader applicator for ORETF Granular Push Spreader

4.3.1 Turf Data and Assumptions:

Unit Exposures: No chemical specific unit exposure data was provided in support of this submission; therefore, Pesticide Handlers Exposure Database (PHED) Surrogate Exposure Guide and the Outdoor Residential Exposure Task Force (OREFT) study (MRID 44972201) unit exposures were used to estimate handler exposure.

Acres Treated: Information regarding area treated for the various use scenarios was provided by the registrant

- 1000 ft^2 per day by low pressure hand wand or back pack sprayer for spot treatment of lawns,
- 0.5 acres per day by push-type granular spreader for broadcast treatment of lawns

Application Rate and Amount Handled:

- 0.06 lb ai per acre for broadcast treatment
- 0.0000014 lbs ai per ft^2 (0.0014 lb ai/1000 ft^2) for spot treatment

Exposure Duration: Based on information provided in the proposed labels handler exposure is anticipated to be short-term in duration. The proposed labels indicate that, "additional applications should not be made within four weeks of a previous application". Therefore, neither intermediate- nor long-term exposure to turf handlers is expected and was not assessed.

Body Weight: The average male body weight of 70 kilograms was used to assess handler exposure.

4.3.2 Turf Handler Exposure and Risk

HED's level of concern for non-cancer risks (i.e., Margins of Exposure (MOE)) for penoxsulam is 100 for residential exposure. Since a short-term dermal point was not

selected, the only route of exposure to be addressed is inhalation. Handler inhalation MOEs were significantly greater than 100 and therefore not of concern to HED. Short-term inhalation exposure for residential handlers is summarized in Table 4.3.2.

Table 4.3.2: Short-term Residential Turf Handler Exposure and Risk

Turf Exposure Scenarios	Use Site	Mitigation Level	Inhalation Unit Exposure (mg/lb)[a]	Application Rate[b] (lb ai/acre)	Area Treated (A/day)	Inhalation Dose[c] (mg/kg/day)	MOE[d]
Mixer/loader/Applicator							
ORETF Resident-applicator Granular Push Spreader	lawns		0.00078	0.06 lb ai/A	0.5	0.00000033	54,000,000
PHED Low Pressure handwand and Backpack			0.03	0.0014 lb ai/1000 ft^2	1000 ft^2	0.0000006	30,000,000
PHED "Push-type" Granular Spreader			0.0063	0.06 lb ai/A	0.5	0.0000027	6,600,000

a. Inhalation Unit Exposure derived from PHED Version 1.1 and ORETF Handler Exposure Study MRID 44972201
b. Application Rate based on proposed labels
c. Inhalation Dose = Unit Exposure (mg/lb) x Application Rate (lb ai/day) x Area Treated/BW
d. Inhalation MOE = = NOAEL (17.8 mg/kg/day) / Inhalation Dose

4.4 Postapplication Dermal Exposure on Treated Turf

Postapplication dermal exposure resulting from contact with treated turf was assessed using a chemical specific turf transfer residue (TTR) study (MRID 46703508).

4.4.1 Data and Assumptions

Data:

Determination of Transferable Residue on Turf Treated with Penoxsulam; Robert, D.W. and G.E. Schelle; 2005; MRID 45013501.

This study was designed to characterize dissipation of penoxsulam transferable turf residues when applied to turf at 2 test sites in Georgia and Florida. GF-443 SC, formulated as a suspension concentrate containing 21.4% penoxsulam as the active ingredient, was applied once to each site using a tractor-mounted boom sprayer. (Note: The Study Report states the percent active ingredient is 21.4%; however, on the product label the percent active ingredient is stated to be 21.7%). Each application was made at a target application rate of 100 g a.i./hectare (0.09 lb ai/acre). The application method and application rate were relevant to the use pattern proposed; however, the application rate used in the study was higher than the maximum recommended application rate in the proposed label (0.06 lb ai/acre). Transferable turf residues (TTR) were collected using

the modified California Roller Technique. All untreated control samples were collected at each site prior to application of the test product. Each field site consisted of three replicate plots, each containing subplots for sampling.

The maximum average penoxsulam residues occurred immediately following the application at each site. At the Georgia site, the maximum average penoxsulam residue was 0.043 µg/cm^2, or 4.3% of the applied active ingredient. At the Florida site, the maximum average penoxsulam residue was 0.0068 µg/cm^2, or 0.7% of the applied active ingredient. A linear regression analysis using the natural logarithm of the individual TTR values was conducted. Residue data was collected after the application through the first day where all the TTR values were <LOQ (DAT 7 for both sites). The raw TTR values for field recoveries were not corrected, since the overall field recoveries were >90% for both sites. For values > LOD and <LOQ, HED used a value of ½ the LOQ. For values < LOD, HED used a value of ½ the LOD. It appears that the Registrant used the average residue data from only the sampling times when residues were greater than the LOD (DAT 7 for the Georgia site and DAT 4 for the Florida site). The Registrant corrected the raw TTR values using the average analytical set recovery values, all of which were >90%. It is not known if the Registrant used the LOQ value or ½ LOQ in their calculations. The estimated half-life values were 1.3 days (R^2= 0.8217) and 1.5 days (R^2 = 0.9403) for penoxsulam residues at the Georgia and Florida site, respectively.

The Registrant provided the residues in µg/cm^2 for the triplicate cloth dosimeter samples collected at each sampling interval. The cloth dosimeter penoxsulam residue levels and corresponding statistical summaries are shown in Tables 1 and 2. At the Georgia site, the average penoxsulam residues immediately following the application were 0.043 µg/cm^2, or 4.3% and at the Florida site, the average penoxsulam residues immediately following the application were 0.007 µg/cm^2, or 0.68% of the applied active ingredient (maximum average).

Table 4.1.1a: Penoxsulam Residues from Cloth Dosimeters - Georgia Site

Sampling Interval (Days After Last Treatment)	Residue (µg /sample)	Residue (µg/cm^2)	Arithmetic Mean (µg/cm^2)	Standard Deviation (µg/cm^2)	Coefficient of Variance (%)	Geometric Mean (µg/cm^2)	% of Original Application Rate Transferred
0	337.7667	0.0606	0.0427	0.0157	36.8	0.0410	4.2995
	203.7761	0.0366					
	173.1338	0.0311					
	<LOQ	<LOQ					
	ND	ND					

LOD = 0.00036 µg/cm^2
LOQ = 0.00108 µg/cm^2
Actual Application Rate = 0.994 µg/cm^2

Table 4.1.1b: Penoxsulam Residues from Cloth Dosimeters – Florida Site							
Sampling Interval (Days After Last Treatment)	Residue (µg /sample)	Residue ($\mu g/cm^2$)	Arithmetic Mean ($\mu g/cm^2$)	Standard Deviation ($\mu g/cm^2$)	Coefficient of Variance (%)	Geometric Mean ($\mu g/cm^2$)	% of Original Application Rate Transferred
0	42.2745	0.0076	0.0068	0.0007	10.7	0.0068	0.6818
	34.3044	0.0062					
	36.9867	0.0066					

LOD = 0.00036 $\mu g/cm^2$
LOQ = 0.00108 $\mu g/cm^2$
Actual Application Rate = 0.996 $\mu g/cm^2$

- Postapplication must be assessed on the same day the pesticide is applied since it is assumed that homeowner could be exposed to turfgrass immediately after application. Therefore, exposures are based on day 0.
- The application rate used in the study (0.09 lb ai/acre) was higher than the maximum recommended application rate in the proposed label (0.06 lb a.i./acre).

4.4.2 Dermal and Inhalation Postapplication Exposure and Risk Estimates to Turf

Residential postapplication exposure is generally considered short-term. Since penoxsulam is applied outdoors inhalation postapplication exposure is expected to be negligible. HED does anticipate short-term dermal exposure to individuals entering turf areas treated with penoxsulam. However, a short-term dermal exposure endpoint was not determined since no dermal, systemic, neurological or developmental toxicity concerns were identified at the highest dose tested. An intermediate-term dermal exposure NOAEL of 17.8 mg/kg/day was selected based on multifocal hyperplasia of the pelvic epithelium of the kidney from a 1-year chronic feeding study in the dog.

Based on the following information: (1) proposed turf labels state that additional applications should not be made within four weeks of a previous application; (2) the average penoxsulam residues dropped below the limit of quantitation (LOQ) by DAT 7 (7 days after treatment) at both sites (Georgia and Florida) in the chemical specific TTR study; and (3) the estimated half-life values for penoxsulam residues at the Georgia and Florida sites ranged from 1.3 to 1.5 days, respectively; HED considers intermediate-term dermal exposure to be negligible. Therefore, a dermal postapplication exposure assessment was not performed.

4.5 Oral Postapplication Exposure

4.5.1 Non-dietary Ingestion (Hand-to-Mouth) Exposure from Treated Turf

Postapplication hand-to-mouth exposure was assessed using the SOP for Residential Exposure: 1.3.2. This SOP provides a method for estimating potential dose among

$$PDR = \frac{TTR_0 \times SA \times FQ \times ET \times SE \times CF1}{BW}$$

PDR	=	potential dose rate on day "0" (mg/day)
DFR0	=	dislodgeable foliar residue on day 0 (ug/cm^2 turf)
SA	=	surface area of the hands (cm^2/event)
FQ	=	frequency of hand-to-mouth activity (20 events/hr for short-term and 9.5 events/hr for intermediate-term), Reed et al 1999
ET	=	exposure time (hr/day)
CF1	=	weight unit conversion factor to convert ug units in the DFR value to mg for the daily exposure (0.001 mg/ug for turf)
SE	=	Saliva Extraction Factor (50%)
BW	=	15 kg

Short-term Oral MOE = ***NOAEL (17.8 mg/kg/day) ÷ PDD***

4.5.1.2 Hand-To-Mouth Risk and Exposure

A total UF of 100 has been applied to all residential risk assessments HED's level of concern for risks (i.e., Margins of Exposure (MOE)) for penoxsulam is 100 for residential exposure. All hand-to-mouth MOEs were greater than 100. Residential exposure and risk resulting in MOEs greater than or equal to 100 are not of concern to HED. Table 4.5.1.2 summarizes the short-term MOEs for hand-to-mouth transfer of pesticide residues from broadcast lawn use.

Table 4.5.1.2: Post Application Oral Exposure from Hand-to-Mouth Activity on Penoxsulam Treated Turf

Data Source	Turf Transfer Residue [1] (ug/cm^2)	Application Rate [2] (lb ai/acre)	Percent ai dislodgeable	Surface Area (cm^2)	Hand to Mouth (events/hr)	Extraction by Saliva	Exposure Time (hours)	Body Weight (kg)	Daily Dose [3] (mg/kg/day)	MOE [4]
HED Default	3.33E-2 [1a]	0.06	5%	20	20	50%	2	15	8.88E-4	2,000
Georgia TTR	2.8EE-2 [1c]		NA						7.4E-4	24,000
Florida TTR	4.7E-3 [1c]								1.25E-4	140,000

1a. Turf Transfer Residue (ug/cm^2) = AR x F x (1-D)^0 x 4.54E^8 ug/lb x 2.47E^{-8} acre/cm^2

1b. Determination of Transferable Residue on Turf Treated with Penoxsulam; Robert, D.W. and G.E. Schelle; 2005; MRID 45013501

1c. Georgia TTR = 4E-2 corrected for difference in application rate = 0.06/0.09 = 0.66 x 0.0427 = 2.8E-2; Florida TTR = 6.8E-3 corrected for difference in application rate = 0.06/0.09 = 0.66 x 0.0068 = 4.7E-3

2. Maximum application rate for turf use in accordance with proposed label

3. Oral Dose = $\frac{\text{TTR (ug/cm}^2\text{) x SA (cm}^2\text{) x FQ(events/hr) x SA (cm}^2\text{/event) x ET(hrs/day) x 0.001mg/ug)}}{\text{BW (15kg)}}$

4. Oral MOE = NOAEL (17.8 mg/kg/day) / Oral Dose (mg/kg/day)

4.5.2 Ingestion of Pesticide-Treated Turfgrass (Object-to-Mouth)

This scenario was assessed using the HED Draft Standard Operating Procedures (SOP's) for Residential Exposure Assessments (12/18/97), and the Revisions to the Standard Operating Procedures (SOP's) for Residential Exposure Assessment (Science Advisory Council for Exposure Policy 12, Revised February 22, 2001). The SOP 2.3.3, Postapplication Potential Dose Among Toddlers from the Ingestion of Pesticide-Treated Turfgrass, estimates doses among toddlers from incidental ingestion of residential

toddlers from incidental ingestion of pesticide residues from previously treated turf. This scenario assumes that pesticide residues are transferred to the skin of toddlers playing on treated yards and subsequently ingested as a result of hand-to-mouth transfer.

Penoxsulam turf products formulated as both liquid and granules are applied as broadcast and spot treatment. For purposes of this assessment, broadcast application rates were considered to represent the worst case scenarios and therefore used in assessing oral exposure.

4.5.1.1 Data and Assumptions

Assumptions:

- On the day of application, it may be assumed that 5% of the application rate is available on turfgrass.
- Postapplication activities must be assessed on the same day that the pesticide is applied.
- The median surface area of both hands is 20 cm^2 for children. This value is based on the February 1999 recommendation from the Scientific Advisory Panel (SAP).
- It is assumed that there is a one-to-one relationship between the transferable residues on the turf and on the surface area of the skin after contact.
- The mean rate of hand-to-mouth activity is 20 times/hour for short-term exposure scenarios. This value was provided by the 1999 SAP.
- Duration of exposure for children is assumed to be 2 hours per day for turf and 4 to 8 hours for indoor surfaces.
- The saliva extraction factor is 50%.
- Children are assumed to weigh 15 kg.

Equations, Calculations, and Risks:

$$TTR_0 = AR \times F \times (1-D)^0 \times CF2 \times CF3$$

AR	=	application rate (lb ai/ft^2 or lb ai/acre or mg ai)
F	=	fraction of ai available on turf (unitless)
D	=	fraction of resude that dissipates daily (unitless)
0	=	postapplication day on which exposure is being assessed
CF2	=	weight unit conversion factor to convert the lbs ai in the application rate to ug for DFR value ($4.54E^8$ ug/lb)
CF3	=	area unit conversion factor to convert the surface area units (ft^2) in the application rate to cm^2 for the DFR value ($1.08E^{-3}$ ft^2 /cm^2 or $2.47E^{-8}$ acre/cm^2)
DFR	=	Dislodgeable Foliar Residue

turfgrass that has been previously treated with pesticides. This scenario assumes that turf is ingested by toddlers who play on treated areas.

4.5.2.1 Data and Assumptions

Assumptions and Factors

- on the day of application it may be assumed that 20% of the application rate are available to be ingested
- postapplication exposure is assessed on the same day pesticide is applied
- assumed ingestion rate for grass for children (3 years old) is 25 cm2/day
- children are assumed to weigh 15 kg

Equations and Calculations

$$GR_0 = AR \times F \times (1-D)^0 \times CF2 \times CF3$$

GR_0	=	grass residue on day 0 (ug/cm^2)
AR	=	application rate (lb ai/A)
I	=	fraction of ai available on the grass (unitless)
D	=	fraction of residue that dissipates daily (unitless)
0	=	postapplication day on which exposure is being assessed
CF2	=	weight unit conversion factor to convert the lbs ai in the application rate to µg for grass residue value (4.54E8 µg/lb)
CF3	=	area unit conversion factor to convert surface area units (A) in the application rate to cm^2 for grass residue value (2.47E-8 A/cm^2)

$$PDD = GR_0 \times IgR \times CF1$$

PDD	=	potential daily dose on day 0
GR_0	=	grass residue on day 0 (ug/cm^2)
IgR	=	ingestion rate of grass (cm2/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)

$$\textit{Short-term Oral MOE} = NOAEL\ (17.8\ mg/kg/day) \div PDD$$

4.5.2.2 Risk and Exposure

HED's level of concern for risks (i.e., Margins of Exposure (MOE)) for penoxsulam is 100 for residential exposure. The short and intermediate term object-to-mouth MOEs are greater than 100 and therefore are not of concern to HED. Table 4.5.2.2 summarizes the short-term object-to-mouth MOE for pesticide ingestion of treated turf grass.

Table 4.5.2.2: Postapplication Exposure and Risk Ingestion of Pesticide-Treated Turfgrass (Object-to-Mouth)

Scenario	AR (lb ai/A)	F	CF2 (ug/lb)	CF3 (A/cm2)	GR_0 [a] (ug/cm2)	lgR (cm^2/day)	CF1 (mg/ug)	PDD [b] (mg/kg/day)	MOE [c]
GF-443 SC EPA Reg No. 62719-LUA HED Default TTR	0.06	0.2	4.54E8	2.47E-8	1.33E-1	25	0.001	2.22E-4	80,000
Georgia TTR		NA			2.8E-2			4.6E-5	3,900,000
Florida TTR					4.7E-3			7.8E-6	2,300,000

a. GR_0 = grass residue on day 0 = AR x F x $(1\text{-}D)^0$ x CF2 x CF3
b. PDD = potential dose on day 0 = GR_0 x lgR x CF1 ÷BW
c. MOE = NOAEL (17.8 mg/kg/day)/PDD

4.5.3 Incidental Ingestion of Soil

This scenario was assessed using the HED Draft Standard Operating Procedures (SOP's) for Residential Exposure Assessments (12/18/97), and the Revisions to the Standard Operating Procedures (SOP's) for Residential Exposure Assessment (Science Advisory Council for Exposure Policy 12, Revised February 22, 2001). The SOP 2.3.4, Postapplication Potential Dose Among Toddlers from Incidental Ingestion of Soil from Pesticide-Treated Residential Areas, estimates doses among toddlers from incidental ingestion of soil containing pesticide residues. This scenario assumes pesticide residues in soil are ingested by toddlers who play on treated areas as a result of normal mouthing activities.

4.5.3.1 Data and Assumptions

Assumptions and Factors

- on the day of application, it is assumed that 100% of the application rate are located within the soil's uppermost 1 cm
- postapplication must be assessed on the same day the pesticide is applied
- assumed soil ingestion rate for children is 100 mg/day
- children are assumed to weigh 15 kg

Equations, Calculations and Risks

$$SR_0 = AR \times F \times (1\text{-}D)^0 \times CF2 \times CF3 \times CF4$$

SR_0	=	soil residue on day 0 (ug/g)
AR	=	application rate (lb ai/A)
F	=	fraction of ai available in uppermost cm of soil (1 cm)
D	=	fraction of residue that dissipates daily (unitless)
0	=	postapplication day on which exposure is being assessed
CF2	=	weight unit conversion factor to convert the lbs ai in the application rate to µg for soil residue value (4.54E8 µg/lb)
CF3	=	area unit conversion factor to convert surface area units (A) in the application rate to cm^2 for soil residue value (2.47E-8 A/cm^2)
CF4	=	volume to weight unit conversion factor to convert the volume units (cm3) to weight units for the SR value (0.67 cm3/g soil)

$$PDD = SR_0 \times IgR \times CF1$$

PDD	=	potential daily dose on day 0
SR_0	=	soil residue on day 0 (ug/g)
IgR	=	ingestion rate of soil (mg/day)
CF1	=	weight unit conversion factor to convert the µg of residues on the soil to mg to provide units of mg/day (1E-6 g/µg)

$$Short\text{-}term\ Oral\ MOE = NOAEL\ (17.8\ mg/kg/day) \div PDD$$

4.5.3.2 Exposure and Risk

HED's level of concern for non-cancer risks (i.e., Margins of Exposure (MOE)) for penoxsulam is 100 for residential exposure. The short and intermediate term oral MOEs are greater than 100 and therefore is not of concern. Table 4.2.3.3.2 summarizes the short-term MOEs for incidental ingestion of soil by children.

Table 4.2.3.3.2: Postapplication Exposure and Risk Ingestion of Pesticide-Treated Soil

Scenario	AR (lb ai/A)	F (cm)	CF2 (ug/lb)	CF3 (A/cm^2)	CF4 (cm^3/g)	SR_0 [a] (ug/g)	IgR (mg/day)	CF1 (g/ug)	PDD [b] (mg/kg/day)	MOE
GF-443 SC EPA Reg No. 62719-LCA HED Default TTR	0.06	1	4.54E8	2.47E-8	0.67	4.51E-1	100	1.00E-6	3.01E-6	5.92E
Georgia TTR						2.8E-2			1.8E-7	9.8E7
Florida TTR						4.7E-3			3.1E-8	5.7E8

a. $SR_0 = AR \times F \times (1\text{-}D)^0 \times CF2 \times CF3 \times CF4$
b. $PDD = SR_0 \times IgR \times CF1 \div BW$
c. MOE = NOAEL (17.8 mg/kg/day)/ PPD

4.5.4 Episodic Incidental Ingestion of Granules

There are four proposed penoxsulam turf products formulated as granules (Penoxsulam FERT 0.04%, Penoxsulam FERT 0.014%, Penoxsulam GR 0.014% and Penoxsulam GR 0.04%). These products are applied using a drop or rotary-type spreader designed to apply granular herbicides turfgrass, lawns, recreational areas and golf courses. Although HED believes there is potential for incidental ingestion of pesticide applied to lawns no acute dietary endpoint attributable to a single exposure was identified in the available toxicology studies on penoxsulam. Therefore, an episodic incidental ingestion of granules assessment could not be performed.

4.6 Residential Aggregate Margins of Exposures for Aquatic and Turf Use

4.6.1 Short- and Intermediate term Aggregate Exposure for Swimmer

Since no short-term dermal endpoint was selected, and inhalation postapplication exposure is expected to be negligible, the only route of exposure is oral. The aggregate

intermediate-term exposure assessment combined oral and dermal exposures and is protective for short-term exposure. The aggregate margins of exposure for adults and children swimmers were greater than the level of concern (Total MOE > 100) and therefore were not of concern to HED. A summary of the short- and intermediate-term swimmer aggregate exposure and risk is provided in Table 4.3.1.

Table 4.6.1: Short and Intermediate-term Aggregate Exposure and Risk for Swimmers

Population	Oral Dose	Dermal Dose	Total MOE [a]
Adults	5.4E-4	1.8E-7	33,000
Children (6 yrs old)	1.7E-3	2.5E-7	10,000

a. Total MOE = $\frac{\text{NOAEL (17.8 g/kg/day)}}{\text{Dose}_{\text{Oral}} + \text{Dose}_{\text{Dermal}}}$

HED considers the swimmer dermal and oral margins of exposure to be over estimates of the actual risk (see characterization below) **and therefore does not recommend that these MOEs be used when aggregating risk.**

Characterization

Duration of exposure is assumed to be 5 hours a day for competitive swimmers both adult (18-64 years) and children (6 years) in swimming pools. This duration is based on the 90th percentile value for time spent at home in a swimming pool from the 1996 Exposure Factors Handbook. HED considers this exposure period very conservative for recreational swimmers in weed infested ponds and lakes. Furthermore, the oral route of exposure is the main driver. A mean ingestion rate of 0.05 L/hour for adults and children was used to assess oral margins of exposure. This ingestion rate is based on HED's swimmer model typically used to assess competitive swimmers in pools who tend to swim with their heads partially immersed in the water and can ingest larger amounts of water. It is anticipated that recreational swimmers in weed infested waters would not immerse their heads as often and therefore would ingest smaller amounts of water. Therefore HED concludes that the dermal and oral margins of exposure are over estimates of the actual risk.

4.6.2 Short-term Aggregate Exposure to Turf

The only route of exposure to handlers (adults) is via inhalation, which results in minimal (MOE≥6,600,000) exposure. Postapplication inhalation exposure is also anticipated to be minimal, and not of concern. No short-term dermal endpoint was selected. Based on information provide in the penoxsulam TTR study which indicates that the amount of residues remaining on the turf after 30 days would be negligible, HED does not expect intermediate-term dermal exposure to result from application of penoxsulam to turf. As a result, the only route of postapplication exposure for turf to be aggregated is oral (hand-to-mouth, object–to-mouth, and ingestions of soil). A summary of the turf residential aggregate oral exposure is provided in Table 4.3.2. The aggregate margins of exposure for children were greater than the level of concern (Total MOE > 100) and therefore were not of concern to HED.

Table 4.6.2: Short -term Aggregate Exposure and Risk to Turf					
Population & Data Source	Hand-to-Mouth (mg/kg/day)	Object-to-mouth (mg/kg/day)	Soil Ingestion (mg/kg/day)	Total Dose (mg/kg/day)	Total MOE [a]
Children - HED Default	8.88E-4	2.22E-4	3.01E-6	0.0011	16,000
Children - Georgia TTR	2.79E-4	1.74E-5	7.0E-8	0.00029	61,000
Children - Florida TTR	1.36E-4	8.5E-6	3.4E-8	0.000145	120,000

a.Total MOE = $\frac{\text{NOAEL (17.8 g/kg/day)}}{\text{Dose}_{\text{hand-to-mouth}} + \text{Dose}_{\text{object-to-mouth}} + \text{Dose}_{\text{soil ingestion}}}$

5. OCCUPATIONAL EXPOSURE

This section of the risk assessment estimates occupational exposure and risk resulting from the use of six different penoxsulam herbicide products formulated as liquids and granules. These proposed products are for selective control of emergent, floating and submersed aquatic weeds in and around slow-moving and quiescent bodies of water; and for postemergence control of annual and perennial broadleaf weeds in established turfgrass, residential lawns, golf course, sport fields, sod farms and around commercial buildings. Based on use rate, exposure is expected to be short- and intermediate-term in duration

5.1 Handler Aquatic Use Scenarios:

Penoxsulam may be applied either directly into the water through submerged hoses trailing behind boats or as a foliar application to emergent or floating foliage of aquatic vegetation. For in-water uses (i.e. boat-mounted trailing hose), handler exposure is limited to the mixer/loader scenario only. Since the active ingredient is automatically applied to the water through hoses, there is no direct contact between the active ingredient and the applicator. However, foliar applications made from a helicopter or boat will result in exposure to mixer/loaders and applicators. Handheld equipment (i.e. right-of-way) generally involves one person mixing/loading and applying a dilute spray mixture into canals made from a truck. To achieve desired concentrations, trucks travel at 2 to 5 miles per hour. The following use scenarios were used to assess handler exposure:

1. mixer/loader of liquid formulation for helicopter-mounted boom
2. applicator of liquid formulation for helicopter-mounted boom
3. mixer/loader of liquid formulation for boat-mounted trailing hose
4. mixer/loader of liquid formulation for airboat-mounted boom
5. applicator of liquid formulation for airboat-mounted boom
6. mixer/loader/applicator of liquid formulation for right-of-way handheld equipment for foliar applications made from a truck

5.1.1 Data and Assumptions:

Unit Exposures: No chemical specific unit exposure data was provided in support of this submission; therefore, Pesticide Handlers Exposure Database (PHED) Surrogate Exposure Guide unit exposures were used to estimate handler exposure. Since there are

no unit exposure values specific to applying foliar sprays from a boat, unit exposure for open cab groundboom application was used as a surrogate scenario to assess handler exposure.

There are three basic risk mitigation approaches considered appropriate for controlling occupational exposure. These include administrative controls, use of personal protective equipment (PPE), and the use of engineering controls. For the present scenarios occupational handler exposure assessments were completed by HED using baseline and PPE.

The baseline clothing level for occupational exposure scenarios is generally an individual wearing long pants, a long-sleeved shirt, shoes, socks, no chemical-resistant gloves, and no respirator. The first level of mitigation generally applied is PPE which include addition of chemical resistant-gloves, additional layer of clothing and a respirator. The next layer of mitigation considered in the risk assessment process is the use of appropriate engineering controls, which, by design, attempt to eliminate the possibility of human exposure. Examples of commonly used engineering controls include closed tractor cabs, closed mixing/loading transfer systems, and water-soluble packets.

Acres Treated: Information regarding area treated for the various use scenarios was provided by the registrant.

- 100-150 acres treated per day by helicopter for foliar application
- 50-100 acres treated per day by boat-mounted trailing hose application
- 10-12 acres per day by airboat-mounted boom for foliar application
- 6-8 acres per day by handheld equipment (i.e. right-of-way spray) made from trucks for foliar application

Application Rate and Amount Handled: According to the Galleon ™ SC, the maximum sum of all applications is 150 ppb per annual growth cycle or a single maximum application rate of 150 ppb. For **"in water"** applications, the maximum sum of all applications is 150 ppb per annual growth cycle or a single maximum application rate of 150 ppb. For each ppb of penoxsulam, the label indicates that 0.174 fluid ounces of product applied per acre foot of treated water results in a concentration of 1 ppb, or:

$$1 \text{ ppb penoxsulam} = \frac{0.174 \text{ fl oz Galleon}}{\text{A/ ft}}$$

Therefore, using that ratio, a concentration of 150 ppb would require 26.1 fluid ounces of product, or :

$$150 \text{ ppb penoxsulam} = \frac{26.1 \text{ fl oz Galleon}}{\text{A/ft}}$$

The Galleon ™ SC label features instructions for depths of up to 10 feet, which is a typical depth for most of the water bodies to be targeted for treatment with this EUP.

The maximum application rate (in lb a.i./acre units) to reach a concentration of 150 ppb in a 10 foot body of water would be:

$$\frac{26.1 \text{ fl oz Galleon}}{\text{A-ft}} \times \frac{1 \text{ gal. Galleon.}}{128 \text{ fl oz Galleon}} \times \frac{2 \text{ lb ai}}{\text{gal Galleon}} \times 10 \text{ ft} = 4.1 \text{ lb ai/acre}$$

For "**foliar applications post emergent**", Galleon ™ SC is applied at the rate of 2 to 11.2 fl oz per acre (11.2 fl oz/acre x 2 lb a.i./gal x 1 gal/128 oz = 0.175 lb a.i./acre).

Dermal Absorption Factor: Since the intermediate-term dermal endpoint was based on an oral study, a 50% dermal absorption factor was used to determine dermal exposure.

Exposure Duration: Periodic repeat applications of penoxsulam are anticipated in order to maintain efficacious concentrations in treated bodies of water over a minimum period of 45 days. The half-life of penoxsulam in water is about 21 days, which limits the frequency at which applications are made. Therefore, duration of exposure is expected to be both short- and intermediate-term in nature.

Body Weight: The average male body weight of 70 kilograms was used to assess handler exposure.

5.1.2 Aquatic Handler Exposure and Risk

Since a short-term dermal point was not selected, the only route of exposure to be addressed is inhalation. Short-term inhalation exposure is summarized in Table 5.1.2a. All short-term inhalation MOE were greater than 100 and therefore not of concern to HED. Dermal and inhalation endpoints were selected for intermediate-term exposure. Since both endpoints were derived from the same study, toxicological effects were the same and therefore exposures could be combined to determine a total margin of exposure. Intermediate-term handler exposure is summarized in Table 5.1.2b. All short- and intermediate-term handler scenarios resulted in MOEs and Total MOEs greater than HED's level of concern (MOE > 100).

Table 5.1.2a: Short-term Handler Exposure for Penoxsulam						
Exposure Scenario	**Mitigation Level**	**Inhalation Unit Exposure (mg/lb)[a]**	**Application Rate [b] (lb ai/acre)**	**Area Treated (A/day)**	**Inhalation Dose [c] (mg/kg/day)**	**MOE [d]**
Mixer/loader						
Helicopter	Baseline	0.0012	0.175	150	0.00045	40,000
Boat trailing hose			4.1	100	0.007	2500
Boat-boom			0.175	12	0.000036	500,000
Applicator						
Helicopter	Baseline	0.0000018	0.175	150	0.00000067	26,000,000
Boatboom		0.00074		12	0.000022	800,000
Mixer/loader/Applicator						
Right of Way Sprayer	Single layer & gloves	0.0039	0.175	8	0.000078	230,000

b. Inhalation Unit Exposure derived from PHED Version 1.1

c. Application Rate = 10ft x 150 ppb x $\frac{0.174 \text{ fl oz product}}{\text{A-ft-ppb}}$ x $\frac{1 \text{ gal.}}{128 \text{ oz}}$ x $\frac{2 \text{ lb ai}}{\text{gal prod}}$ 4.1 lb ai/acre

c. Inhalation Dose = Unit Exposure (mg/lb) x Application Rate (lb ai/day) x Area Treated/BW

d. MOE = NOAEL $\frac{(17.8 \text{ mg/kg/day})}{\text{Inhalation Dose}}$

Table 5.3b: Intermediate-term Handler Exposure for Penoxsulam									
Exposure Scenario	**Mitigation Level**	**Dermal Unit Exposure (mg/lb) [a]**	**Inhalation Unit Exposure (mg/lb) [a]**	**Application Rate [b] (lb ai/acre)**	**Amount Handled [c] (acres/day)**	**Dermal Dose [d] (mg/kg/day)**	**Inhalation Dose [e] (mg/kg/day)**	**Total Dose [f] (mg/kg/day)**	**Total MOE [g]**
Mixer/loader									
Helicopter	Single layer and gloves	0.023	0.0012	0.175	150	0.0086	0.00045	0.00475	3700
Boat-trailing hose				4.1	100	0.135	0.007	0.075	240
Boatboom				0.175	12	0.00069	0.000036	0.00038	47,000
Applicator									
Helicopter	Single layer & gloves	0.0019	0.0000018	0.175	150	0.00071	0.00000067	0.000356	50,000
Boat-boom		0.014	0.00074		12	0.00042	0.000022	0.00023	77,000
Mixer/loader/Applicator									
Right of Way Sprayer	Single layer & gloves	0.39	0.0039	0.175	8	0.0078	0.000078	0.004	4500

a. Unit Exposures provided by PHED Version 1.1
b. Application Rate provided by proposed label
c. Amount handled provided by Registrant
d. Dermal Dose (mg/kg/day) = Dermal unit exposure (mg/lb) x Application Rate (lb ai/day) x Amount Handled (acres/day)
e. Inhalation Dose (mg/kg/day) = Inhalation unit exposure (mg/lb) x Application Rate (lb ai/day) x Amount Handled (acres/day)
f. Total Dose (mg/kg/day) = [Dermal Dose (mg/kg/day) x 50% Dermal Absorption] + Inhalation Dose (mg/kg/day)
g. Total MOE = NOAEL (17.8 mg/kg/day)/ Total Dose (mg/kg/day)

5.2 Handler Turf Use Scenarios

Penoxsulam turf herbicide products are formulated as liquids and granules. These proposed products are for postemergence control of annual and perennial broadleaf weeds in established turfgrass, residential lawns, golf course, sport fields, sod farms and around commercial buildings. Penoxsulam may be applied as a ground broadcast or spot treatment. Spot treatment using liquid formulations my be applied by hand-held or back sprayers. Granular applications are to be applied using a drop or push rotary-type spreader, whirlybirds, cyclones and or shaker type applicators. The following use scenarios were used to assess handler exposure:

1. mixer/loader of liquid formulation for groundboom using PHED
2. applicator using groundboom using PHED
3. mixer/loader/applicator for push-type granular spreader using PHED
4. mixer/loader/applicator for low pressure hand wand and backpack sprayer using PHED
5. mixer/loader applicator for ORETF LCO Handgun Spray –Liquid Flowable
6. mixer/loader applicator for ORETF LCO Push Cyclone Granular Spreader

5.2.1 Turf Data and Assumptions:

Unit Exposures: No chemical specific unit exposure data was provided in support of this submission; therefore, Pesticide Handlers Exposure Database (PHED) Surrogate Exposure Guide and the Outdoor Residential Exposure Task Force (OREFT) study (MRID 44972201) unit exposures were used to estimate handler exposure.

Acres Treated: Information regarding area treated for the various use scenarios was provided by the registrant.

- 40 acres treated per day by groundboom of turf, lawns, golf courses and sports fields
- 80 acres treated per day by groundboom of sod farms
- 1000 ft^2 per day by low pressure hand wand or back pack sprayer for spot treatment of turf, lawns, golf courses and sports fields
- 0.5 acres per day by push-type (cyclone) granular spreader for broadcast treatment of turf, lawns, golf courses and sports fields

Application Rate and Amount Handled:

- 0.06 lb ai per acre for broadcast treatment
- 0.0014 lbs ai per 1000 ft^2 (0.0000014 lb ai/ ft2)for spot treatment

Exposure Duration: Based on information provided in the proposed labels handler exposure is anticipated to be short-term in duration. The proposed labels indicate that, "additional applications should not be made within four weeks of a previous application." Therefore, neither intermediate- nor long-term exposure to turf handlers is expected and was not assessed.

Body Weight: The average male body weight of 70 kilograms was used to assess handler exposure.

5.1.2 Turf Handler Exposure and Risk

HED's level of concern for non-cancer risks (i.e., Margins of Exposure (MOE)) for penoxsulam is 100 for occupational exposure. Since a short-term dermal point was not selected, the only route of exposure to be addressed is inhalation. Handler inhalation MOEs were significantly greater than 100 and therefore not of concern to HED. Short-term inhalation handler exposure is summarized in Table 5.1.2.

Table 5.1.2: Short-term Turf Handler Exposure and Risk

Turf Exposure Scenarios	Use Site	Mitigation Level	Inhalation Unit Exposure (mg/lb)[a]	Application Rate[b] (lb ai/acre)	Area Treated (A/day)	Inhalation Dose[c] (mg/kg/day)	MOE[d]
Mixer/loader							
groundboom – liquid	lawns, turf grass areas, sport fields and golf courses	Baseline	0.0012	0.06	40	0.000041	430,000
groundboom - liquid	sod farm				80	0.0000823	220,000
Applicator							
groundboom - liquid	lawns, turf grass areas, sport fields and golf courses	Baseline	0.00074	0.06	40	0.0000254	700,000
groundboom - liquid	sod farm		0.00074		80	0.000051	350,000
Mixer/loader/Applicator							
ORETF LCO Handgun Spray - Liquid Flowable	lawns, turf grass areas, sport fields and golf courses	Baseline	0.0018	0.0014 lb ai/1000ft^2	1000ft^2	3.6E-8	4.9E8
ORETF LCO Push Cyclone Granular Spreader			0.0075	0.06 lb ai/A	0.5	0.0000032	5,600,000
PHED Low Pressure handwand and Backpack			0.03	0.0014 lb ai/ 1000ft^2	1000ft^2	6.0E-7	2.9E7
PHED "Push-type" Granular Spreader			0.0063	0.06 lb ai/A	0.5	0.0000027	6,600,000

a. Inhalation Unit Exposure derived from PHED Version 1.1 and ORETF Handler Exposure Study MRID 44972201

b Application Rate based on proposed labels

c. Inhalation Dose = Unit Exposure (mg/lb) x Application Rate (lb ai/day) x Area Treated/BW

d Inhalation MOE = = NOAEL (17.8 mg/kg/day) / Inhalation Dose

5.3 Turf Postapplication Exposure

No short-term dermal endpoint was determined since no dermal, systemic, neurological or developmental toxicity concerns were identified at the highest dose tested. An intermediate-term dermal exposure NOAEL of 17.8 mg/kg/day was selected based on multifocal hyperplasia of the pelvic epithelium of the kidney from a 1-year chronic feeding study in the dog. The LOAEL was 46.2 mg/kg/day.

Based on the following information: (1) in accordance with proposed label, additional applications should not be made within four weeks of a previous application; (2) the average penoxsulam residues dropped below the limit of quantitation (LOQ) by DAT 7 (7 days after treatment) at both sites (Georgia and Florida) in the chemical specific TTR study summarized above; and (3) the estimated half-life values for penoxsulam residues at the Georgia and Florida site were 1.3 days (R^2= 0.8217) and 1.5 days (R^2= 0.9403), respectively; HED does believe that an intermediate-term dermal postapplication exposure assessment is required. Based on information provide in the penoxsulam TTR study, the amount of residues remaining on the turf after 30 days would be negligible based on half life data. Therefore, a dermal postapplication exposure assessment was not performed and postapplication dermal exposure is not of concern to adults or children.

5.4 Restricted Entry Internal (REI)

The restricted entry interval is based on the acute toxicity of penoxsulam technical material which is classified as Categories IV. Acute toxicity Category IV chemicals require a 12 hour REI. Therefore, the 12-hour REI which appears on the product labels is adequate and in accordance with worker standard protection guidelines.

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R149995

Chemical: Penoxsulam

PC Code: 119031
HED File Code: 12000 Exposure Reviews
Memo Date: 5/23/2007
File ID: DPD339488
Accession #: 412-07-0208

HED Records Reference Center
7/26/2007