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OFFICE OF PREVENTION, PESTICIDES AND TOXIC SUBSTANCES

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

MEMORANDUM

DATE: March 30, 2007

SUBJECT: Occupational and Residential Exposure Assessment for Experimental Use Permit Request for Use of Penoxsulam to Control Aquatic Vegetation Management in Lakes, Reservoirs, Ponds, and Canals.

PC Code:	119031	Barcode:	322533
Chemical Class:	Herbicide	Trade Name:	GF-443 SC SF
Registration No.:	62719-EUP-XX		

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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.

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1.0 EXECUTIVE SUMMARY

This document provides an occupational and residential exposure assessment for the proposed use of penoxsulam in aquatic areas to control weeds and various other vegetations. The proposed formulation is Galleon ™ SC, which contains 21.7% penoxsulam (EPA Reg. No. 62719-499) and is formulated as a suspension concentrate equivalent to 2 lb active ingredient per gallon. Penoxsulam is in the triazolopyrimidine class of chemicals. Penoxsulam products are currently registered for weed control in dry- and water-seeded rice and there are also granular and liquid formulation products being proposed for use on turf. It is proposed that swimming will be allowed at any time in treated sites under the use conditions for this program. Site use for fishing would be conducted under the auspices of catch-and-release.

Hazard Characterization:

The toxicology database for penoxsulam is considered complete for the purpose of this assessment. Technical grade penoxsulam (XDE-638), an off-white powder of 97.5% purity, exhibited minimal acute toxicity in the available studies. The acute oral LD_{50} in male and female rats was >5000 mg/kg (Toxicity Category IV) and the acute dermal LD_{50} in male and female rabbits was >5000 mg/kg (Toxicity Category IV). In primary eye and skin irritation studies in rabbits, it produced only minimal irritation (Toxicity Category IV) and in a dermal sensitization study in guinea pigs (maximization method), it 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 intermediate-term 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.

FQPA and Uncertainty Factors

HED has concluded that there is not a concern for pre- and/or postnatal toxicity resulting from exposure to penoxsulam, therefore, the FQPA Safety Factor has been removed (i.e. reduced to 1X).

Residential (Non-Occupational) Exposure

The proposed use of penoxsulam is for control of weeds and vegetation in lakes, reservoirs, ponds and canals which could result in potential oral, inhalation, and dermal exposure to recreational swimmers using these treated areas.

Handler

Since penoxsulam will be applied by commercial applicators and not by homeowners, a residential handler exposure assessment is not required.

Postapplication

Since the short-term postapplication assessment needs to address only oral exposure which results in the same dose estimated for intermediate-term exposure, a short-term aggregate exposure assessment 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 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.

The duration of exposure is assumed to be 5 hours a day for competitive swimmers both adult (18-54 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.

Aggregate Exposure

As per FQPA, 1996, when there are potential residential exposures to the pesticide, aggregate risk assessment must consider exposures from three major sources: oral, dermal and inhalation exposures. The toxicity endpoints selected for these routes of exposure may be aggregated as follows:

Since short-term exposure needs to address only oral exposure which results in the same dose for intermediate-term exposure, a short-term aggregate exposure assessment was not required. The intermediate-term aggregate exposure assessment combined oral and dermal exposures and is protective for short-term exposure. The short- and intermediate-term aggregate MOEs for recreational swimmers were greater than the level of concern (Total MOE > 100).

Occupational Exposure

Handler

Since a short-term dermal endpoint was not selected, the only short-term route of exposure which needs to be assessed is inhalation. However, for intermediate-term handler exposure, the dermal and inhalation endpoints were the same and could therefore be combined to determine a total margin of exposure. All short- and intermediate-term handler scenarios resulted in MOEs and Total MOEs greater than HED's level of concern (MOE > 100) provided occupational handlers wear single layer of clothing plus gloves.

Postapplication

For purposes of this assessment, postapplication exposure is expected to occur to only non-occupational individuals swimming in treated areas. Therefore an occupational postapplication exposure assessment is not required.

2.0 HAZARD CHARACTERIZATION

2.1 Hazard Profile

The toxicology database for penoxsulam is considered complete for this assessment. Technical grade penoxsulam (XDE-638), an off-white powder of 97.5% purity, exhibited minimal acute toxicity in the available studies. The acute oral LD_{50} in male and female rats was >5000 mg/kg (Toxicity Category IV) and the acute dermal LD_{50} in male and female rabbits was >5000 mg/kg (Toxicity Category IV). In primary eye and skin irritation studies in rabbits, it produced only minimal irritation (Toxicity Category IV) and in a dermal sensitization study in guinea pigs (maximization method), it 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 intermediate-term 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.

2.2 FQPA and Uncertainty Factor Considerations

HED has concluded that there is not a concern for pre- and/or postnatal toxicity resulting from exposure to penoxsulam. Therefore the FQPA Safety Factor has been removed (i.e. reduced to 1X).

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 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 use 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-EUP	Lakes, reservoirs, ponds and canals	**In water treatment**: 0.174 fl oz per acre-foot of water for each part per billion of final concentration of a.i. **Foliar application**: 2 to 11.2 fl oz/acre	Maximum target concentration in any treated area is 150 ppb a.i. per growth cycle for in water treatment

4.0 NON-OCCUPATIONAL/RESIDNETIAL EXPOSURE

4.1 Residential (Homeowner) Handler

The Agency uses the term "Handlers" to describe those individuals who are involved in the pesticide application process. Since penoxsulam will be applied by commercial applicators and not by homeowners, a residential handler exposure assessment is not required.

4.2 Residential (Homeowner) Postapplication

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

4.2.1 Data and Assumptions for Postapplication Exposure Scenario

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:

- Standard Operating Procedures (SOPs) for Residential Exposure were used to assess oral, inhalation, 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 x 10^{-7}cm/hr
- Since penoxsulam is to be applied outdoors and its vapor pressure is very low (7.2 x 10^{-16} mmHg) inhalation exposure is expected to be negligible. Therefore inhalation exposure is not of concern.
- 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 11.2 fl oz per acre (0.175 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.

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)

Dermal Dose = $\frac{C_w \times SA \times ET \times K_p \times CF}{BW}$

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

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

4.2.2 Residential Postapplication Exposure and Risk Estimates

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 (6 years old) is provided in Table 4.2.2a.

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 4.2.2a: Short and Intermediate-Term Postapplication Exposure for Adults and Children 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 Aggregate Margins of Exposures for Aquatic Use (Recreational Swimming)

Since the short-term postapplication assessment needs to address only oral exposure which results in the same dose as for intermediate-term, a short-term aggregate exposure was not required. 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 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 aggregate exposure and risk is provided in Table 4.3a.

Table 4.3a: Short and Intermediate-term Aggregate Exposure and Risk

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

5. OCCUPATIONAL EXPOSURE

This section of the risk assessment estimates occupational exposure and risk resulting from the use of Galleon ™ SC applied either directly into aquatic sites or as a foliar spray on emergent or floating foliage of aquatic vegetation. Foliar spray applications to aquatic vegetation may be made using a variety of equipment, including helicopter-mounted boom, boat-mounted boom and right-of-way handheld equipment from a truck along side a canal. Galleon ™ SC may be applied on a seasonal basis at a maximum single application rate or several applications per annual growth cycle. Based on use rate, exposure is expected to be short- and intermediate-term in duration.

5.1 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

5.2 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.

5.3 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 handler exposure is summarized in Table 5.3a. 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 5.3b. All short- and intermediate-term handler scenarios resulted in MOEs and Total MOEs greater than HED's level of concern (MOE > 100).

Table 5.3a: 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

a. Inhalation Unit Exposure derived from PHED Version 1.1

b. 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)

References

1. "Human Health Risk Assessment for Aquatic Uses of Penoxsulam: Occupational, Dietary, Residential and Aggregate Assessment", J. E. Johnston, MRID 46703510, November 8, 2005

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