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WASHINGTON, D.C. 20460

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

MEMORANDUM

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SUBJECT: Occupational and Residential Exposure Risk Assessment for Proposed Uses of Aminopyralid

PC Code: 005100 Class: Herbicide
DP Barcode: D305672 Product: GF-871

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A Section 3 registration action has been requested as a joint review by Pest Management Regulatory Agency (PMRA) and the EPA for the proposed use of GF-871. GF-871 is a herbicide for control of annual and perennial broadleaf weeds in wheat, on rangeland, premanent grass pastures, non-cropland areas (rights-of-ways, roadsides, and banks) and natural recreation areas (such as campgrounds and trailheads and trails). It is formulated as a liquid and contains 40.6% of the active ingredient aminopyralid in the form of its triisopropanolammonium salt or 21.1% aminopyralid acid equivalent (a.e..) Based on the proposed uses specified in the label, occupational exposure is expected to be short- and intermediate-term in duration. Residential exposure is expected to be short-term only. No long-term (chronic) exposure is expected.

Hazard Characterization

A developmental rabbit study (GF-871) was used to select a dose and endpoint for short- and intermediate-term incidental oral and inhalation exposure. The NOAEL of 104 mg/kg/day and the LOAEL of 260 was based on a severe inanition (loss of vitality due to lack of food) and body weight loss, decreased fecal output, and mild incoordinated gait. Since long-term inhalation exposure is not expected, a corresponding dose and endpoint were not selected.

No dermal absorption study is available for aminopyralid. However, a 28-day dermal toxicity study in rats was submitted. In this study, no systemic toxicity occurred at the limit dose and the primary toxic effects of concern were adequately assessed in the study. Therefore, it is concluded that aminopyralid is not absorbed or is poorly absorbed through the skin. A quantitative risk assessment for this route is not necessary based on the lack of effects in the 28-day dermal toxicity study.

There is no evidence of increased qualitative or quantitative susceptibility of the fetuses in developmental toxicity studies (rat and rabbit) or in a 2-generation reproduction study (rat) after exposure to aminopyralid. Therefore, there is no need for a degree of concern analysis, and the overall uncertainty factor applied to aminopyralid is based on the FQPA safety factor of 1X along with the 100X applied for inter-species extrapolation and intra-species sensitivity. **For occupational and residential exposure, short-term and intermediate-term oral and inhalation exposure risk assessments, a MOE of 100 is required** to not be of concern to HED.

Residential Exposure

Handlers

The herbicide GF-871 is not applied by homeowners to residential or recreational settings; therefore, a residential handler exposure assessment is not required for purposes of this assessment.

Postapplication

GF-871(Reg # 62719-LRI) may be applied to natural recreation areas (such as wildlife management areas, campgrounds, trailheads and trails) to control weeds. It can be applied by groundboom or aerial equipment for broadcast treatment or by hand spray for spot treatment at an application rate of 0.11 lb acid equivalent (a.e.) per acre. For purposes of this assessment, a grass covered camp ground will serve as the worst case scenario in assessing postapplication exposure.

A dermal endpoint was not selected for aminopyralid and therefore no dermal postapplication exposure assessment is required. Furthermore, since there are no indoor residential uses and only outdoor turf uses associated with this product, inhalation exposure is expected to be negligible. Therefore, a postapplication inhalation exposure assessment was not required. Although there are no concerns for postapplication dermal or inhalation exposure associated with the residential uses for aminopyralid, there are concerns for risk resulting from incidental non-dietary ingestion of pesticide residues from hand-to-mouth transfer, ingestion of treated turf grass and ingestion of soil.

The hand-to-mouth transfer, incidental ingestion of pesticide-treated turf grass and soil scenarios were 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).

For purposes of this assessment, all residential uses are considered short-term in duration. A target MOE of 100 is required for all residential uses to not be of concern. A Tier 1 hand-to-mouth transfer short-term postapplication exposure assessment for turf broadcast uses resulted in a MOE of 61,000 The short-term oral MOEs for pesticide ingestion of treated turfgrass and soil by children were 250,000 and 19,000,000 respectively. All postapplication oral exposures greater than the target MOE of 100 are not of concern to HED.

Aggregate Exposure from Residential Uses

In accordance with the requirements of the FQPA (1996), when the potential for residential exposure to the pesticide product exists, aggregate risk assessment(s) must be performed to consider potential exposure from the major sources: oral, dermal, and inhalation. As indicated previously, in the 28-day dermal toxicity study in rats, no systemic toxicity occurred at the limit dose. Therefore, it is concluded that aminopyralid is not absorbed or is poorly absorbed through the skin so a dermal endpoint was not selected. Although the same developmental study and respective common toxicity was used to assess both inhalation and oral routes of exposure, the residential use does not include indoor uses. Therefore, both handler and postapplication inhalation exposures are expected to be negligible and an inhalation exposure assessment was not required nor performed. Since the only source of residential exposure would result from oral

exposure, an aggregate residential exposure assessment was not performed.

Occupational Exposure

Margins of Exposure (MOEs) of 100 are required for handlers of agricultural crops in order for risks not to be of concern to HED. All handler short- and intermediate-term MOEs were greater than the target MOE of 100 and therefore risks did not exceed HED's level of concern.

HED has determined that there are potential dermal exposures to persons entering treated sites (e.g. harvesters) after application of pesticide is complete. However since no dermal endpoints were selected, a postapplication risk assessment for agricultural uses was not possible nor required.

Restricted Entry Interval

GF-871 contains aminopyralid technical and the triisopropanolammonium salt or acid equivalent (a.e.). Agricultural workers are exposed to residues from both aminopyralid and the acid equivalent. Therefore, the restricted entry interval (REI) for agricultural occupational exposure resulting from treated wheat, is based on the acute toxicity of aminopyralid technical and the triisopropanolammonium salt or acid equivalent (a.e.). Aminopyralid is classified as Category IV for acute dermal and dermal irritation and Category I for eye irritation. Chemicals identified as toxicity Category I require a 48-hour REI. Furthermore, chemicals classified as toxicity Category I for eye irritation requires the use of protective eyewear. Therefore, **HED does not concur with the 12-hour REI on the proposed GF-871 Herbicide label**, and recommends that the Registration Division ensure that the proper REI and personal protective equipment (PPE) is included on the label.

Although there may be exposure for transfer of residues from grass treated with GF-871, according to Worker Protection Standard Subpart B of the 40 CFR, an REI is not applicable or required for sites of control of vegetation along rights-of-ways, pasture and rangeland. However, the proposed label does specify that entry restrictions for non-worker protection standard uses (pastures, rangeland, and non-cropland) areas should not allow workers entry into treated areas until sprays have dried.

3. HAZARD CHARACTERIZATION

2.1 Hazard Profile

The toxicology database for aminopyralid is complete and there are no data gaps. The scientific quality of the database for aminopyralid is relatively high and the toxicity profile can be characterized for all effects, including potential developmental, reproductive and neurotoxic effects.

The acute toxicity data indicate that aminopyralid (XDE-750) has low toxicity (Category IV) via oral, dermal, and inhalation routes of exposure. It is not irritating to the skin: however, it is severely irritating to the eye. An acute eye irritation study in rabbits demonstrated corneal opacity (1/3) that was unresolved through day 35. Aminopyralid is not a sensitizer under the conditions of the study. Aminopyralid Triisopropanolamine salt (GF-871) is not toxic via oral, dermal, and inhalation routes of exposure. It is neither irritating to the eye nor the skin. It is not a sensitizer under the conditions of this study. Summaries of the acute toxicity profile for the technical aminopyralid and the acid equivalent (triisopropanol ammonium salt) are provided in **Tables 1a and b**.

A developmental rabbit study (GF-871) was used to select a dose and endpoint for short- and intermediate-term incidental oral and inhalation exposure. The NOAEL of 104 mg/kg/day and the LOAEL of 260 was based on a severe inanition (loss of vitality due to lack of food) and body weight loss, decreased fecal output, and mild incoordinated gait. Since long-term inhalation exposure is not expected, a corresponding dose and endpoint were not selected.

No dermal absorption study is available for aminopyralid. However, a 28-day dermal toxicity study in rats was submitted. In this study, no systemic toxicity occurred at the limit dose and the primary toxic effects of concern were adequately assessed in the study. Therefore, it is concluded that aminopyralid is not absorbed or is poorly absorbed through the skin. A quantitative risk assessment for this route is not necessary based on the lack of effects in the 28-day dermal toxicity study. A summary of the oral, dermal and inhalation doses and endpoints is presented in **Table 2**.

2.2 FQPA and Uncertainty Factor Concerns

There is no evidence of increased qualitative or quantitative susceptibility of the fetuses in developmental toxicity studies (rat and rabbit) or in a 2-generation reproduction study (rat) after exposure to aminopyralid. Therefore, there is no need for a degree of concern analysis. Based on this conclusion, the occupational and residential exposure, short-term and intermediate-term oral and inhalation MOEs are based on the conventional uncertainty factor of 100X (10X for intraspecies variation and 10X for interspecies extrapolation). Therefore, the oral and inhalation exposure risk assessments, require a MOE of 100 to not be considered a concern.

Table 1a. Acute Toxicity Profile - Aminopyralid Technical (XDE-750)				
Guideline No.	**Study Type**	**MRID(s)**	**Results**	**Toxicity Category**
870.1100	Acute oral-rat	46235603	LD_{50} = >5000 mg/kg/bw (both sexes)	IV
870.1200	Acute dermal-rabbit	46235605	LD_{50} = >5000 mg/kg/bw (both sexes)	IV
870.1300	Acute inhalation-rat	46235607	LC_{50} = >5.5 mg/L (both sexes)	IV
870.2400	Acute eye irritation-rabbit	46235609	Corneal opacity in 1/3 unresolved through day 35	I
870.2500	Acute dermal irritation -rabbit	46235611	non-irritant	IV
870.2600	Skin sensitization-guinea pig	46235613	Not a sensitizer	N/A

Table 1b. Acute Toxicity Profile - Aminopyralid Triisopropanolamine salt (GF-871)				
Guideline No.	**Study Type**	**MRID(s)**	**Results**	**Toxicity Category**
870.1100	Acute oral-rat	46235604	LD_{50} = >5000 mg/kg/bw (both sexes)	IV
870.1200	Acute dermal-rabbit	46235606	LD_{50} = >5000 mg/kg/bw (both sexes)	IV
870.1300	Acute inhalation-rat	46235608	LC_{50} = >5.79 mg/L (both sexes)	IV
870.2400	Acute eye irritation-rabbit	46235610	No positive signs of corneal opacity, iritis or conjunctivitis observed	IV
870.2500	Acute dermal irritation -rabbit	46235612	Slight erythema observed at 24 hours and 72 hours, resolving by study day 7	IV

870.2600	Skin sensitization-guinea pig	46235614	Not a sensitizer	N/A

Table 2 Summary of Toxicological Doses and Endpoints for Chemical for Use in Human Risk Assessments

Exposure Scenario	Dose Used in Risk Assessment, UF	Special 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=104 mg ae/kg/day	Residential LOC for MOE = 100 Occupational LOC for MOE = 100	Developmental rabbit study (GF-871) LOAEL=260 mg/kg/day based on severe inanition (loss of vitality due to lack of food) and body weight loss, decreased fecal output, and mild incoordinated gait.
Dermal (All Durations)	N/A	N/A	No endpoint identified for this group. No systemic toxicity was observed in a 28-day dermal toxicity study; no absorption study available.
Inhalation Short-Term (1 - 30 days) and Intermediate-Term (1 - 6 months)	NOAEL=104 mg ae/kg/day	Residential LOC for MOE = 100 Occupational LOC for MOE = 100	Developmental rabbit study (GF-871) LOAEL=260 mg/kg/day based on severe inanition (loss of vitality due to lack of food) and body weight loss, decreased fecal output, and mild incoordinated gait.
Inhalation Long-Term (> 6 months)	N/A	N/A	N/A
Cancer (oral, dermal, inhalation)	**Classification:** Pending		

UF = uncertainty factor, FQPA SF = Special FQPA safety factor, NOAEL = no observed adverse effect level, LOAEL = lowest observed adverse effect level, PAD = population adjusted dose (a = acute, c = chronic) RfD = reference dose, MOE = margin of exposure, LOC = level of concern, N/A = Not Applicable
* Special FQPA Safety Factor removed (i.e., reduced to 1x)

4. PROPOSED USE PATTERNS AND FORMULATIONS

Table 3 summarizes the proposed product and corresponding scenarios for the agricultural and recreational site uses of aminopyralid.

Table 3: Use Patterns and Formulations for the Proposed Aminopyralid Products

Formulation	Method of Application	Use Sites	Application Rate (lb ae/A)	Timing of Application
GF-871 Reg # 62719-LRI (21.1 % ae = acid equivalent = 2 lb/gal)	ground, aerial and handspray	wheat	broadcast - 0.0089 spot treatment- 0.0092	one application; PHI = 50 days
	groundboom and aerial spot treatment- hand sprayer	rangeland, permanent grass pastures, non-crop land areas, natural recreation areas	broadcast - 0.11	one application

* Application rates represent the maximum rate derived from the product label.

4.0 NON-OCCUPATIONAL/RESIDENTIAL AND RECREATIONAL EXPOSURE AND RISK

Since GF 871 will not be used by homeowners, there is no potential for exposure in residential/recreational settings during the application process for homeowners. However, there is potential for short-term exposure to adults and children from entering areas previously treated with aminopyralid.

4.1. Handler Exposure

The Agency uses the term "Handlers" to describe those individuals who are involved in the pesticide application process. The Agency believes that there are distinct tasks related to applications and that exposures can vary depending on the specifics of each task. Residential handlers (homeowners) are assumed to complete all elements of an application with little use of any protective equipment.

The herbicide GF-871 is not applied by homeowners to residential or recreational settings; therefore, a residential handler exposure assessment is not required for purposes of this assessment.

4.2 Residential (Homeowner)Postapplication Exposure

GF-871(Reg # 62719-LRI) may be applied to natural recreation areas (such as wildlife management areas, campgrounds, trailheads and trails) to control weeds. It can be applied by groundboom or aerial equipment for broadcast treatment or by hand spray for spot treatment at an application rate of 0.11 lb acid equivalent (a.e.) per acre. For purposes of this assessment, a grass covered camp ground will serve as the worst case scenario in assessing postapplication exposure.

4.2.1 Dermal Exposure

A dermal endpoint was not selected for aminopyralid and therefore no dermal postapplication exposure assessment is required.

4.2.2 Inhalation Exposure

Since there are no indoor residential uses and only outdoor turf uses associated with this product, inhalation exposure is expected to be negligible. Therefore, a postapplication inhalation exposure assessment was not required.

4.2.3 Oral Exposure

Although there are no concerns for postapplication dermal or inhalation exposure associated with the residential uses for aminopyralid, there are concerns for risk resulting from incidental non-dietary ingestion of pesticide residues from hand-to-mouth transfer, ingestion of treated turf grass and ingestion of soil.

4.2.3.1 Incidental Nondietary Ingestion of Pesticide Residues from Hand-to-Mouth Transfer

Children may be exposed by incidential non-dietary ingestion of residues on turf. The hand-to-mouth transfer scenarios were 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 following assumptions, factors, equations and calculations were used to estimate hand-to-mouth transfer exposure.

Assumptions:

- The SOP's for Residential Exposure Assessment scenarios assume that pesticide residues are transferred to the skin of children playing on treated areas and are subsequently ingested

as a result of hand-to-mouth transfer.

- 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). The SAP characterized the hand-to-mouth event as involving 1 to 3 fingers per event (5.7 cm^2 to 17.1 cm^2). For screening purposes, a value of 20 cm^2 was selected to account for 3 fingers.
- It is assumed that there is a one-to-one relationship between the dislodgeable 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.
- Duration of exposure for children is assumed to be 2 hours per day for turf.
- The saliva extraction factor is 50%.
- Children are assumed to weigh 15 kg.

Equations, Calculations, and Risks:

$$DFR_0 = AR \times F \times (1-D)^0 \times CF2 \times CF3$$

AR	=	application rate (lb ai/ft^2 or lb ai/acre or mg ai)
F	=	fraction of ai available on turf, indoor surfaces and pets (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 ug for DFR value ($4.54E^8$ ug/lb)
CF3	=	area unit conversion factor to convert the surface area units (ft^2 or acre) 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	=	Dislodge able Foliar Residue

$$PDD = \frac{DFR_0 \times SA \times FQ \times ET \times SE \times CF1}{BW}$$

PDD	=	potential daily dose on day "0" (mg/day)
DFR_0	=	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), 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)
SE	=	Saliva Extraction Factor (50%)
BW	=	15 kg

Short-term Oral MOE = NOAEL (104 ae mg/kg/day) ÷ PDD

4.2.3.2 Hand-To-Mouth Risk and Exposure

Table 4 summarizes the short-term MOEs for hand-to-mouth transfer of pesticide residues from broadcast turf use. All postapplication oral MOEs greater than the target MOE of 100 are not of concern to HED. A Tier 1 hand-to-mouth transfer short-term postapplication exposure assessment for turf broadcast uses resulted in a MOE of 61,000 and therefore is not of concern.

4.2.3.3 Ingestion of Pesticide-Treated Turfgrass

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 turfgrass that has been previously treated with pesticides. This scenario assumes that turf is ingested by toddlers who play on treated areas. The following assumptions, factors and calculations were used to assess exposure.

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 cm^2/day
- children are assumed to weigh 15 kg

Equations, Calculations and Risk

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

GR_0	=	grass residue on day 0 (ug/cm^2)
AR	=	application rate (lb ai/A)
F	=	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)

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

PDD	=	potential daily dose on day 0
GR_0	=	grass residue on day 0 (ug/cm^2)
IgR	=	ingestion rate of grass (cm^2/day)
CF1	=	weight unit conversion factor to convert the µg of residues on the grass to mg to provide units of mg/day (1E-3 mg/µg)
BW	=	15 kg

Short-term Oral MOE = NOAEL (104 ae mg/kg/day) ÷ PDD

Table 5 summarizes the short-term oral MOE for pesticide ingestion of treated turfgrass by children. A target MOE of 100 is required for all residential uses. The short term oral MOE is 250,000 and therefore does not exceed HED's level of concern.

4.2.2.4 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. The following assumptions, factors and calculations were used to estimate incidental ingestion of soil exposure.

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

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

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 (cm^3) to weight units for the SR value (0.67 cm^3/g soil)

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

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)
BW = 15 kg

$$\textit{Short-term Oral MOE} = \textit{NOAEL (104 ae mg/kg/day)} \div PDD$$

Table 6 summarizes the short-term oral MOE for incidental ingestion of soil by children. A target MOE of 100 is required for all residential uses. The short term oral MOE is 19,000,000 and therefore not of concern to HED.

4.3 Aggregate Exposure from Residential Uses

In accordance with the requirements of the FQPA (1996), when the potential for residential exposure to the pesticide product exists, aggregate risk assessment(s) must be performed to consider potential exposure from the major sources: oral, dermal, and inhalation. As indicated previously, in the 28-day dermal toxicity study in rats, no systemic toxicity occurred at the limit dose. Therefore, it is concluded that aminopyralid is not absorbed or is poorly absorbed through the skin so a dermal endpoint was not selected. Although the same developmental study and respective common toxicity was used to assess both inhalation and oral routes of exposure, the residential use does not include indoor uses. Therefore, both handler and postapplication inhalation exposures are expected to be negligible and an inhalation exposure assessment was not required nor performed. Since the only source of residential exposure would result from oral exposure, an aggregate residential exposure assessment was not performed.

4.4 Other (Spray Drift)

Spray drift is always a potential source of exposure to residents nearby to spraying operations. This is particularly the case with aerial application, but, to a lesser extent, could also be a potential source of exposure from the ground application method employed for aminopyralid. The Agency has been working with the Spray Drift Task Force, EPA Regional Offices and State Lead Agencies for pesticide regulation and other parties to develop the best spray drift management practices. The Agency is now requiring interim mitigation measures for aerial applications that must be placed on product labels/labeling. The Agency has completed its evaluation of the new database submitted by the Spray Drift Task Force, a membership of U.S. pesticide registrants, and is developing a policy on how to appropriately apply the data and the AgDRIFT computer model to its risk assessments for pesticides applied by air, orchard airblast and ground hydraulic methods. After the policy is in

place, the Agency may impose further refinements in spray drift management practices to reduce off-target drift and risks associated with aerial as well as other application types where appropriate.

Table 4: Postapplication Exposure and Risk for Hand-to-Mouth Transfer of Pesticide Residues Using Residential SOP for Broadcast Use

Scenario	AR [a]	F [b]	CF2 (ug/lb)	CF3 (A/cm^2)	DFR [c] (ug/cm^2)	SA (cm^2/event)	FQ (events/hr)	ET (hr/day)	CF1 (mg/ug)	SE	PDD [d] (mg/kg/day)	MOE [e]
GF-871 (21.1 % ae)	0.11 lb ae/A	0.05	4.54E8	2.47E-8	6.2E-2	20	20	2	0.001	0.5	0.0017	61,000

Notes:

a. AR = Application Rate (lb ae/A) = in accordance with product label
b. F = transferable residue for turfs;.
c. DFR = Dislodgeable foliar residue = AR x F x $(1\text{-}D)^0$ x CF2 x CF3
d. Short-term PDD = DFR_0 x SA x FQ x ET x SE x CF1/BW
e. Short-term MOE = NOAEL (104 ae mg/kg/day)/Short-term PDR

Table 5: Postapplication Exposure and Risk From Ingestion of Pesticide-Treated Turfgrass

Scenario	AR (lb ae/A)	F	CF2 (ug/lb)	CF3 (A/cm^2)	GR_0 [a] (ug/cm^2)	IgR (cm^2/day)	CF1 (mg/ug)	PDD [b] (mg/kg/day)	MOE [c]
GF-871 (21.1 % ae)	0.11	0.2	4.54E8	2.47E-8	0.25	25	0.001	0.00041	250,000

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 IgR x CF1 ÷BW
c. Short-term MOE = NOAEL (104 ae mg/kg/day)/PDD

Table 6: Postapplication Exposure and Risk From Ingestion of Pesticide-Treated Soil

Scenario	AR (lb ae/A)	F (cm^{-1})	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 [c]
GF-871 (21.1 % ae)	0.11	1	4.54E8	2.47E-8	0.67	0.83	100	0.000001	5.5E-6	19,000,000

a. SR_0 = AR x F x $(1\text{-}D)^0$ x CF2 x CF3 x CF4
b. PDD = SR_0 x IgR x CF1÷ BW
c. Short-term MOE = NOAEL (104 ae mg/kg/day)/ PPD

5.0 OCCUPATIONAL EXPOSURE

GF-871 is a herbicide for control of annual and perennial broadleaf weeds in wheat, on rangeland, premanent grass pastures, non-cropland areas (rights-of-ways, roadsides, and banks) and natural recreation areas (such as campgrounds and trail heads and trails). It is formulated as a liquid and contains 40.6% of the active ingredient aminopyralid in the form of its triisopropanolammonium salt or 21.1% aminopyralid acid equivalent (a.e..). Based on the proposed uses specified in the label, occupational exposure is expected to be short- and intermediate-term in duration. Residential exposure is expected to be short-term only. No long-term (chronic) exposure is expected.

5.1 Agricultural Handlers

GF-871 may be applied as a broadcast treatment by ground and aerial equipment to wheat at rates ranging from of 0.0089 to 0.0092 lb ae/acre. It may also be applied by ground, aerial and hand spray as a broadcast and spot treatment to rangeland, grass pastures, non-crop land areas, and natural areas (such as wildlife management areas, natural recreation areas, campgrounds, trailheads and trails) at an application rate of 0.11 lb a.e. per acre.

5.1.1 Data and Assumptions for Proposed Handler Exposure Scenarios

Workers may be exposed to aminopyralid during mixing, loading and applying activities associated with agricultural crops. Based on the proposed use patterns short- and intermediate-term dermal and inhalation exposure are expected to occur. However, since no dermal endpoint was selected, a dermal risk assessment was not required nor performed.

The following exposure scenarios will be assessed for aminopyralid:

- Mixing/loading liquid sprays for groundboom
- Applying liquid sprays for groundboom
- Mixing/loading liquid sprays for aerial fixed wing
- Applying liquid sprays for aerial fixed wing
- Mixing/loading liquid sprays for high pressure hand spray
- Applying liquid sprays for high pressure hand spray
- Flagging (Sprays) for assorted agricultural crops

Unit Exposures

Chemical-specific data for assessing human exposures during pesticide handling activities were not submitted to the Agency in support of this Section 3 application. It is the policy of the HED to use data from the PHED Version 1.1 to assess handler exposures for regulatory actions when chemical-specific monitoring data are not available (HED Science Advisory Council for Exposure, Policy 007,

"Use of Values from the Pesticide Programs," January 1999).

Area Treated

Based on HED's Exposure Science Advisory Committee Policy Number 9.1, the following acres per day treated were assumed :

- 200 acres/day for mixing/loading and applying liquids for groundboom for wheat, rangeland, permanent grass pastures, non-crop land areas, natural recreation areas (campgrounds)
- 1200 acres/day for mixing/loading and applying liquids for fixed wing for wheat, rangeland, permanent grass pastures, non-crop land areas, natural recreation areas (campgrounds)
- 1200 acres/day for sprays (flaggers)

Body Weight

The average body weight of an adult female (60 kg) was used for non-cancer assessments since the endpoint was based on a developmental study.

Equations and Calculations:

$$PDD = \frac{UE \times AR \times A}{BW}$$

PDD	=	Potential Daily Dose (mg/kg/day)
UE	=	Unit Exposure (mg/lb ai)
AR	=	Maximum Application Rate (lb ai/acre or lb ai/gal)
A	=	maximum area treated (acres/day) or (gal/day)
BW	=	Body weight

$$\textit{Inhalation MOE (All Durations)} = \frac{\textit{Inhalation NOAEL (104 ae mg/kg/day)}}{\textit{Dose (mg/kg/day)}}$$

5.1.2 Handler Risk and Exposure

A summary of the inhalation short- and intermediate-term risks for handlers at the baseline level are included in **Table 7.** Margins of Exposure (MOEs) of 100 are required for handlers of agricultural crops in order for risks not to be of concern to HED. All handler short- and intermediate-term MOEs were greater than the target MOE of 100 and therefore risks did not exceed HED's level of concern.

5.2 Postapplication Exposure

HED has determined that there are potential exposures to persons entering treated sites (e.g. harvesters) after application of pesticide is complete. However since no dermal endpoints were selected, a postapplication risk assessment for agricultural uses was not possible nor required.

Restricted Entry Interval

GF-871 contains aminopyralid technical and the triisopropanolammonium salt or acid equivalent (a.e.). Agricultural workers are exposed to residues from both aminopyralid and the acid equivalent. Therefore, the restricted entry interval (REI) for **agricultural occupational exposure resulting from treated wheat** is based on the acute toxicity of aminopyralid technical and the triisopropanolammonium salt or acid equivalent (a.e.). Aminopyralid is classified as Category IV for acute dermal and dermal irritation and Category I for eye irritation. **Chemicals identified as toxicity Category I require a 48-hour REI.** Furthermore, chemicals classified as toxicity Category I for eye irritation requires the use of protective eyewear. Therefore, **HED does not concur with the 12-hour REI on the proposed GF-871 Herbicide label**, and recommends that the Registration Division ensure that the proper REI and personal protective equipment (PPE) is included on the label.

Although there may be exposure for transfer of residues from grass treated with GF-871, according to Worker Protection Standard Subpart B of the 40 CFR, an REI is not applicable or required for sites of control of vegetation along rights-of-ways, pasture and rangeland. However, the proposed label does specify that entry restrictions for non-worker protection standard uses (pastures, rangeland, and non-cropland) areas should not allow workers entry into treated areas until sprays have dried.

Table 7: Occupational Handler Short- and Intermediate-term Exposure and Risk

Scenario	Use Site	Unit Exposure [1] (mg/lb ai)	Application Rate [2]	Amount Treated [3] A or ft^2	Daily Dose [4] (mg/kg/day)	Inhalation MOE [5]
Mixer/loader						
GF-871 Liquid (21.1 % ae) Groundboom	wheat	0.0012	broadcast - 0.0089 lb ae/A	200	0.000036	3,000,000
			spot treatment- 0.0092 lb ae/A or 0.00000021 lb ae/ft^2	1000 ft^2	4.2E-9	2.5E10
GF-871 Liquid (21.16 % ae) Aerial			broadcast - 0.0089 lb ae/A	1200	0.00021	500,000
GF-871 (21.1 % ae) Groundboom	rangeland, permanent grass pastures, non-crop land areas, natural recreation	0.0012	0.11 lb a.e/A	200	0.00044	240,000
GF-871				1200	0.00264	40,000

(21.1 % ae) Aerial	areas (campgrounds)					
GF-871 (21.1 % ae) Handgun				< 1	< 0.0000022	> 47,000,000
Applicator						
GF-871 Liquid (21.1 % ai) Groundboom	wheat	0.00074	broadcast - 0.0089 lb ae/A	200	0.000022	5,000,000
			spot treatment- 0.0092 lb ae/A or 0.00000021 lb ae/ft^2	1000 ft^2	2.6E-9	4E10
GF-871 Liquid (21.1 % ai) Aerial		0.000068	broadcast - 0.0089 lb ae/A	1200	0.000012	8,700,000
GF-871 (21.1 % ae) Groundboom	rangeland, permanent grass pastures, non-crop land areas, natural recreation areas (campgrounds)	0.00074	0.11 lb a.e/A	200	0.00027	400,000
GF-871 (21.1 % ae) Aerial		0.000068		1200	0.00015	700,000
GF-871 (21.1 % ae) Handgun		0.079		< 1	< 0.00015	>700,000
Flagger						
GF-871 21.1% a.e.	Wheat, rangeland, permanent grass pastures, non-crop land areas, natural recreation areas (campgrounds)	0.011	0.0089 lb ae/A	1200	0.00196	54,000
			0.11 lb ae/A		0.0242	4,300

1. Unit exposures where derived from PHED
2. Application Rate based on proposed labels
3. HED(Science Advisory Council Exposure Policy 9.1, September 25, 2001
4. Daily Dose = $\frac{\text{Unit Exposure x application rate x Amount treated}}{\text{Body Weight (60 kg)}}$
5. Short- and Intermediate-term Inhalation MOE = $\frac{\text{NOAEL (104 ae mg/kg/day)}}{\text{Daily Dose}}$

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