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

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

Date: September 21, 2000

Subject: Occupational and Residential Risk Assessment to Support Request for a Section 3 Registration of Azoxystrobin on Barley, Bulb Vegetables, Cilantro, Citrus Fruits, Corn, Cotton, Leafy Vegetables, Root and Tuber Vegetables, Peanuts, and Soybeans

DP Barcode:	PC Code:	Trade Name:	EPA Reg#	MRID#	PRAT Case	Class	Caswell#	40 CFR
D269111	128810	Heritage [®]	10182-408	N/A	292287	Fungicide	N/A	N/A
		Abound [®]	10182-415					

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Introduction

The registrant, Zeneca Ag Products, requests the establishment of tolerances for residues of the fungicide azoxystrobin on barley, bulb vegetables, citrus fruits, field corn, sweet corn, cotton, root and tuber vegetables and tops, leafy vegetables and cilantro, peanuts, soybeans, and

wild rice. Wild rice will not be included in this assessment because residue chemistry data were not adequate to support the proposed tolerance. This memorandum addresses risk from occupational and residential exposure only. An aggregate human risk assessment for azoxystrobin will be included as a separate HED memorandum.

1.0 Executive Summary

Azoxystrobin is currently registered on bananas, canola, cucurbits, stone fruits, grapes, various nuts, peanuts, potatoes, rice, tomatoes, wheat, and turfgrass/ornamentals. The formulated end use products evaluated in this assessment are labeled under the trade names Heritage[®] and Abound[®]. In this memorandum, the name azoxystrobin will be used for the active ingredient(ai) in these products.

Azoxystrobin is a broad spectrum fungicide for the control of plant diseases on agricultural crops, turf, and ornamentals. The formulations of azoxystrobin evaluated in this assessment are the flowable concentrate (i.e., Abound[®] 77.1% ai) and water-dispersible granule (i.e., Heritage[®] 50% ai). The registrant proposes multiple foliar sprays, banded, or in-furrow applications using ground, aerial, or chemigation equipment. Applications are proposed to begin prior to, or in the early stages of, disease development and continue throughout the season up to, and often including, the day of harvest. Proposed use rates are in the range of 0.1-0.4 lb ai/A/application, with a seasonal maximum of 1.5-2.0 lbs ai/A. Many of the target crops may receive up to 6-8 applications during a season, at intervals of 7 to 14 days. For cotton, the use is limited to a single, soil-directed spray at-planting. There are no non-agricultural use sites associated with the proposed uses. However, there are registered non-agricultural uses; e.g., outdoor residential (lawns and ornamentals) and recreational (e.g., golf courses, parks, and athletic fields) sites.

There is a potential for occupational exposure to azoxystrobin during mixing, loading, application, and post-application activities. The HIARC did not select any dermal endpoints for azoxystrobin, because no toxicity was observed at the limit dose of 1,000 mg/kg/day. Therefore, the occupational risk assessment was based on inhalation exposure only. For handlers, daily inhalation doses were converted to oral equivalent doses, assuming an absorption factor of 100%, and compared to the oral NOAELs of 25 mg/kg/day (prenatal developmental oral study in the rat) and 20 mg/kg/day (90-day feeding study in the rat) to estimate the risk from short- and intermediate-term inhalation exposures, respectively. Chronic exposures are not expected for handlers of azoxystrobin for the proposed use patterns.

No chemical-specific handler exposure data were submitted in support of this Section 3 registration. It is the policy of the HED to use data from the Pesticide Handlers Exposure Database (PHED) Version 1.1 as presented in PHED Surrogate Exposure Guide (8/98) to assess handler exposures for regulatory actions when chemical-specific monitoring data are not available (HED Science Advisory Council for Exposure Draft Policy # 7, dated 1/28/99).

Occupational **handlers' inhalation MOEs range from 3,900** for intermediate-term mixing/loading liquids for aerial application to **190,000** for short-term mixing/loading dry flowables for airblast application. These MOEs are greater than HED's target MOE of 100, and therefore, are not of concern.

Occupational **postapplication dermal exposure** is possible following treatment of crops with azoxystrobin. However, because no appropriate dermal endpoints were identified for this exposure potential, **a risk assessment is not required**. Postapplication inhalation exposure is expected to be negligible; therefore, a risk assessment for this route is also not required.

The azoxystrobin technical material has been classified in Toxicity Category III for acute dermal and primary eye irritation, and Toxicity Category IV for primary skin irritation. Per the Worker Protection Standard (WPS), a 12-hr restricted entry interval (REI) is required for chemicals classified under Toxicity Category III or IV, which is the shortest waiting period permitted under the WPS. However, per Pesticide Regulation Notice 95-3 (6/7/95), REIs may be further reduced from 12 hours if certain criteria are met. In a previous risk assessment (Memo, D. Dotson, D248888, 1/28/99), HED determined that the criteria established by Pesticide Regulation Notice 95-3 have been met for azoxystrobin formulated as a water-dispersible granule, and that a 4-hour REI is acceptable on the Heritage[®] label. However, it is not clear whether the criteria have subsequently been met for the flowable concentrate formulation. This needs to be addressed by the Registration Division (e.g., obtain acute toxicity data for the end-use product) to determine whether the Abound[®] label may indicate a reduction in REI to 4 hours.

Azoxystrobin is currently registered for use on residential turfgrass and ornamentals. Short-term exposures may occur during adult residential handling activities. Short- and intermediate-term exposures may occur during postapplication activities for adults and children. Because the HIARC did not select applicable dermal endpoints, **a risk assessment for dermal exposure during handling and postapplication activities is not required**. Inhalation exposure and risk estimates for adult residential handlers were assessed using the same short-term inhalation endpoint described previously for occupational exposure. HED's Draft Standard Operating Procedures (SOPs) for Residential Exposure Assessments were used as the basis for all residential handler exposure calculations.

Toddlers may receive short- and intermediate-term exposure from incidental non-dietary ingestion (i.e., hand-to-mouth, turfgrass transfer, and soil ingestion) during post-application activities on treated turf. The post-application risk assessment is based on generic assumptions as specified by the newly proposed Residential SOPs and recommended approaches by HED's Exposure Science Advisory Committee (ExpoSAC). Revisions to the Residential SOPs have been proposed that alter the residential post-application scenario assumptions. The proposed assumptions are expected to better represent residential exposure and are still considered to be high-end, screening level assumptions. HED management has authorized the use of the revised residential SOPs that were presented to the FIFRA SAP in September 1999. Therefore, HED has deviated from the current Residential SOP assumptions and uses the proposed assumptions to

calculate exposure estimates. All calculated non-occupational postapplication MOEs are greater than the target of 100.

2.0 Hazard Profile

On August 15, 2000, the Health Effects Division's Hazard Identification Assessment Review Committee (HIARC) evaluated the toxicology data base on azoxystrobin, established Reference Doses (RfDs) and selected the toxicological endpoints for occupational/residential exposure and risk assessments. The Committee's conclusions are summarized in Tables 1 and 2. The potential enhanced sensitivity of infants and children from exposure to azoxystrobin as required by the Food Quality Protection Act of 1996 was previously addressed by HED's FQPA Safety Factor Committee (08/24/98).

Table 1. Acute Toxicity Data on Azoxystrobin Technical				
Guideline No.	Study Type	MRID #	Results	Toxicity Category
870.1100	Acute Oral - Rat	43678122	LD ₅₀ > 5000 mg/kg (Limit Test) in Males & Females	IV
870.1200	Acute Dermal - Rat	43678124	LD ₅₀ > 2000 mg/kg (Limit Test) in Males & Females	III
870.1300	Acute Inhalation - Rat	43678126	LC ₅₀ Males = 0.962 mg/L (95% C.I. = 0.674, *) Females = 0.698 mg/L (95% C.I. = 0.509, 2.425) The combined LC50 was not calculated due to mortality pattern	III
870.2400	Primary Eye Irritation - Rabbit	43678128	Slight to moderate erythema and slight chemosis in all rabbits within one hour, but effects resolved within 48 hours of treatment.	III
870.2500	Primary Skin Irritation - Rabbit	43678130	Very slight erythema and edema that persisted for three days on one rabbit and for one hour on another.	IV
870.2600	Dermal Sensitization - Guinea Pig	43678132	No erythema or edema were found 38 or 48 hrs after challenge with test material.	Not a dermal sensitizer

Table 2. Summary of Toxicological Doses and Endpoints for Azoxystrobin for Use in Human Risk Assessment

Exposure Scenario	Dose Used in Risk Assessment, UF	FQPA SF and Level of Concern for Risk Assessment	Study and Toxicological Effects
Acute Dietary <u>general population</u> including infants and children	NOAEL < 200 mg/kg/day UF = 300 Acute RfD = 0.67 mg/kg/day	FQPA SF = 1X aPAD = acute RfD FQPA SF = 0.67 mg/kg/day	Acute Neurotoxicity - Rat (MRID 43678134) LOAEL = 200 mg/kg based on diarrhea at two-hours post dose at all dose levels up to and including the LOAEL.
Chronic Dietary <u>all populations</u>	NOAEL= 18 mg/kg/day UF = 100 Chronic RfD = 0.18 mg/kg/day	FQPA SF = 1X cPAD = chronic RfD FQPA SF = 0.18 mg/kg/day	Combined Chronic Toxicity/Carcinogenicity Feeding study - Rat (MRID 43678139) LOAEL in males/females = 34/117 mg/kg/day based on reduced body weights in both sexes and bile duct lesions in males.
Short-Term (1-7 days) Incidental Oral (Residential)	NOAEL= 25 mg/kg/day UF = 100	FQPA SF = 1X	Prenatal Developmental Oral Toxicity - Rat (MRID 43678142) LOAEL = 100 mg/kg/day based on increased maternal diarrhea, urinary incontinence, and salivation.
Intermediate-Term (1 week to several months) Incidental Oral (Residential)	NOAEL= 20 mg/kg/day UF = 100	FQPA SF = 1X	90-Day Feeding - Rat (MRID 43678135) LOAEL = 211/223 mg/kg/day in males/females based on decreased body weight gain in both sexes and clinical signs indicative of reduced nutrition.
Short-, Intermediate-, and Long-Term Dermal (Occupational/ Residential)	none	No dermal or systemic toxicity was seen at the limit dose (1000 mg/kg/day). This risk assessment is not required.	21-Day Repeated Dose Dermal - Rat (MRID 43678137)
Short-Term (1-7 days) Inhalation (Occupational/ Residential)	oral NOAEL= 25 mg/kg/day Use route-to-route extrapolation (inhalation absorption rate = 100%)	LOC for MOE = 100 (Occupational/ Residential)	Prenatal Developmental Oral Toxicity - Rat (MRID 43678142) LOAEL = 100 mg/kg/day based on increased maternal diarrhea, urinary incontinence, and salivation.
Intermediate-Term (1 week to several months) Inhalation (Occupational/ Residential)	oral NOAEL= 20 mg/kg/day Use route-to-route extrapolation (inhalation absorption rate = 100%)	LOC for MOE = 100 (Occupational/ Residential)	90-Day Feeding - Rat (MRID 43678135) LOAEL = 211/223 mg/kg/day in males/females based on decreased body weight gain in both sexes and clinical signs indicative of reduced nutrition.
Long-Term (> 180 days) Inhalation	NOAEL = N/A	This risk assessment is not applicable to the use scenario.	

UF = uncertainty factor, FQPA SF = 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.

3.0 Use Profile

Currently, azoxystrobin is registered on bananas, canola, cucurbits, stone fruits, grapes, various nuts, peanuts, potatoes, rice, tomatoes, wheat, and turfgrass/ornamentals. The proposed uses for this Section 3 petition are summarized in Table 3.

Formulation Type (% ai)	Application Method	Use Site	Application Rate (lb ai/A)	Frequency of Application (interval)	Comments
Flowable Concentrate (77.1 % ai) and Water-Dispersible Granule (50% ai)	Aerial, Chemigation, Groundboom	barley	0.10 - 0.2	2 apps (not specified)	
	Aerial, airblast	citrus	0.20 - 0.25	6 apps (7 - 21 days)	
	Aerial, Chemigation, Groundboom	corn	0.10 - 0.25	8 apps (7 - 14 days)	
	Groundboom	cotton	0.10 - 0.23	1 app (N/A)	in-furrow
	Aerial, Chemigation, Groundboom	leafy vegetables	0.10 - 0.25	6 apps (5 - 14 days)	
	Aerial, Chemigation, Groundboom	onion	0.10 - 0.25	6 apps (5 - 14 days)	
	Aerial, Chemigation, Groundboom	peanuts	0.10 - 0.40	2 apps (30 days)	
	Aerial, Chemigation, Groundboom	root & tuber vegetables	0.10 - 0.33	6 apps (5 - 14 days)	
	Aerial, Chemigation, Groundboom	soybeans	0.15 - 0.25	2 apps (not specified)	

4.0 Occupational Exposure

4.1 Handler Exposure and Risk

There is a potential for exposure to azoxystrobin during mixing, loading, and application activities. An exposure/risk assessment using applicable endpoints selected by the HIARC was performed. Handler's exposure and risk were estimated for the following scenarios: (1) mixing/loading liquids for aerial/chemigation application, (2) mixing/loading liquids for groundboom application, (3) mixing/loading liquids for airblast sprayer, (4) mixing/loading dry flowable for aerial/chemigation application, (5) mixing/loading dry flowable for groundboom application, (6) mixing/loading dry flowable for airblast sprayer, (7) applying sprays with fixed-wing aircraft, (8) applying sprays with a groundboom sprayer, (9) applying sprays with an

airblast sprayer, and (10) flagging sprays for aerial operations. Flaggers for aerial application are assessed for 350 acres per day application, because a larger number of acres treated would likely require pilot-activated mechanical flagging or Global Positioning Systems, and not human flaggers.

The minimum level of PPE for handlers is based on acute toxicity for the end-use products. The Registration Division (RD) is responsible for ensuring that PPE listed on the label is in compliance with the Worker Protection Standard (WPS).

No chemical-specific handler exposure data were submitted in support of this Section 3 registration. In accordance with HED's Exposure Science Advisory Council (SAC) policy, exposure data from the Pesticide Handlers Exposure Database (PHED) Version 1.1 as presented in PHED Surrogate Exposure Guide (8/98) were used with other HED default values for acres treated per day, body weight, and the level of personal protective equipment to assess handler exposures. The water-dispersible granular formulation is also known as a dry flowable formulation. The flowable concentrate is considered the same as an emulsifiable concentrate (i.e., liquid) for exposure assessment purposes.

As mentioned previously, no dermal endpoint was selected for azoxystrobin by the HIARC, because no toxicity was observed at the limit dose of 1,000 mg/kg/day. Therefore, the occupational risk assessment was based on inhalation exposure only. The daily inhalation doses were converted to oral equivalent doses, assuming an absorption factor of 100%, and compared to the oral NOAELs of 25 mg/kg/day (prenatal developmental oral study in the rat) and 20 mg/kg/day (90-day feeding study in the rat) to estimate the risk from short- and intermediate-term inhalation exposures, respectively.

The MOEs range from 3,900 for intermediate-term mixing/loading liquids for aerial application to 190,000 for short-term mixing/loading dry flowables for airblast application. **These MOEs exceed HED's target of 100, and therefore, are not of concern.** Exposure assumptions and estimates for occupational handlers are summarized in Table 4.

4.2 Post-Application Exposure and Risk

This Section 3 action on azoxystrobin involves foliar applications. Therefore, there is a potential for postapplication exposure to scouts, harvesters and other field workers. However, because no appropriate dermal endpoints were identified for this exposure potential, a **risk assessment is not required**. Postapplication inhalation exposure is expected to be negligible; therefore, a risk assessment for this route is also not required. Non-occupational postapplication risk in residential settings is covered in Section 5.2

The azoxystrobin technical material has been classified in Toxicity Category III for acute dermal and primary eye irritation, and Toxicity Category IV for primary skin irritation. Per the Worker Protection Standard (WPS), a 12-hr restricted entry interval (REI) is required for

chemicals classified under Toxicity Category III or IV, which is the shortest waiting period permitted under the WPS. However, per Pesticide Regulation Notice 95-3 (6/7/95), REIs may be further reduced from 12 hours if certain criteria are met. In a previous risk assessment (Memo, D. Dotson, D248888, 1/28/99), HED determined that the criteria established by Pesticide Regulation Notice 95-3 have been met for azoxystrobin formulated as a water-dispersible granule, and that a 4-hour REI is acceptable on the Heritage® label. However, it is not clear whether the criteria have subsequently been met for the flowable concentrate formulation. This needs to be addressed by the Registration Division (e.g., obtain acute toxicity data for the end-use product) to determine whether the Abound® label may indicate a reduction in REI to 4 hours.

Table 4. Inhalation Exposure and Risk Assessment for Occupational Handlers

PHED Scenario Selected from PSEG (8/98)	PHED Unit Exposure ¹ (mg/lb ai)	Application Rate ² (lb ai/A)	Area Treated ³ (A/day)	Short-term Daily Dose ⁴ (mg/kg/day)	Int.-term Daily Dose ⁴ (mg/kg/day)	Short-Term Inhalation MOE ⁵	Intermed-Term Inhalation MOE ⁵	
1. Mixing/Loading Liquids for Aerial/Chemigation Application	0.0012	0.25	1,200	0.0060	0.0051	4,200	3,900	
		0.40	350	0.0028	0.0024	8,900	8,300	
2. Mixing/Loading Liquids for Groundboom Application		0.25	200	0.0010	0.00086	25,000	23,000	
		0.40	80	0.00064	0.00055	39,000	36,000	
3. Mixing/Loading Liquids for Airblast Sprayer		0.25	40	0.00020	0.00017	130,000	120,000	
4. Mixing/Loading Dry Flowable for Aerial/Chemigation Application		0.00077	0.25	1,200	0.0039	0.0033	6,500	6,100
			0.40	350	0.0018	0.0015	14,000	13,000
5. Mixing/Loading Dry Flowable for Groundboom Application			0.25	200	0.00064	0.00055	39,000	36,000
			0.40	80	0.00041	0.00035	61,000	57,000
6. Mixing/Loading Dry Flowable for Airblast Sprayer			0.25	40	0.00013	0.00011	190,000	180,000
7. Applying Sprays with Fixed-wing Aircraft (enclosed cockpit)	0.000068		0.25	1,200	0.00034	0.00029	74,000	69,000
			0.40	350	0.00016	0.00014	160,000	150,000
8. Applying Sprays with a Groundboom Sprayer (open cab)			0.25	200	0.00062	0.00053	41,000	38,000
			0.40	80	0.00039	0.00034	63,000	59,000
9. Applying Sprays with an Airblast Sprayer (open cab)			0.0045	0.25	40	0.00075	0.00064	33,000
10. Flagging (Sprays) for Aerial Operations		0.00035	0.40	350	0.00082	0.00070	31,000	29,000

¹Unit Exposure values are based on exposure without a respirator. There is high confidence in all values except for that of aerial application with an enclosed-cockpit aircraft, for which there is medium confidence.

² Maximum application rate of 0.4 lb ai/acre (from peanuts) was used as a screening value, except for: airblast scenarios, which are for citrus only (Max app. rate of 0.25 lb ai/A); and higher acreage scenarios for corn, soybeans, and cotton (i.e., 1,200 acres for aerial and 200 acres for groundboom) which have a max app. rate of 0.25 lb ai/A.

³Standard values for acres treated in a day were used. The higher acreage of 1,200 and 200 for aerial and groundboom application, respectively, are for corn, soybeans, and cotton only.

⁴ Daily Dose = [Unit Exposure (mg/lb ai handled) x Application Rate (lb ai/A) x Acres Treated (A/day)] / Body Weight (60kg for Short-term; 70 kg for intermediate-term)

⁵ MOE = NOAEL/ Daily Inhalation Dose. Short-term Inhalation NOAEL = 25 mg/kg/day. Intermediate-term Inhalation NOAEL = 20 mg/kg/day.

5.0 Non-Occupational/Residential Exposure

Products containing azoxystrobin are registered for application to turf and ornamentals. They may be applied to turf at rates up to 0.95 lb active ingredient (ai) per acre 5 times per year (i.e., not to exceed 5 lb ai/A/yr) and to ornamentals at rates up to 0.75 lb ai per acre every 7 to 14 days, but not to exceed 5 lb ai/A/yr. The currently registered labels do not prohibit homeowners from mixing/loading/applying either the flowable concentrate or the water-dispersible granule formulations. This residential exposure and risk assessment was conducted using the application rate for turf because it is the highest use rate.

Residential handlers may receive short-term dermal and inhalation exposure to azoxystrobin when mixing, loading and applying the formulations. Adults and children may be exposed to azoxystrobin residues from dermal contact with foliage during post-application activities. Toddlers may receive short- and intermediate-term oral exposure from hand-to-mouth ingestion during post-application activities.

As no dermal endpoint was selected by the HIARC, a dermal exposure and risk assessment was not required for residential handlers or post-application activities. NOAELs of 25 mg/kg/day and 20 mg/kg/day were selected by the HIARC for assessing the risk from short- and intermediate-term incidental oral exposures, respectively. These same NOAELs were selected by the HIARC for assessing the risks from short- and intermediate-term inhalation exposures. The HED FQPA Safety Factor Committee met on August 24, 1998 and decided to remove the safety factor (i.e., reduce to 1x) for the U.S. population and all population subgroups and for all exposure scenarios. Thus, the target MOE for risk assessment purposes is 100.

No chemical-specific exposure or residue dissipation data for handler or post-application activities were submitted to HED in support of the registered lawn uses. Therefore, HED's Draft Standard Operating Procedures for Residential Exposure Assessments were used as the basis for all handler exposure calculations. The post-application risk assessment is based on generic assumptions as specified by the newly proposed Residential SOPs and approaches recommended by HED's Exposure Science Advisory Committee (ExpoSAC). Changes to the Residential SOPs have been proposed that alter the residential post-application scenario assumptions. The proposed assumptions are expected to better represent residential exposure and are still considered to be high-end, screening level assumptions. HED management has authorized the use of the revised residential SOPs that were presented to the FIFRA SAP in September 1999. Therefore, HED has deviated from the current Residential SOP assumptions and used the proposed assumptions to calculate exposure estimates.

5.1 Residential Handler Exposure and Risk

Inhalation daily doses for residential handlers were calculated for the flowable concentrate formulation using data for mixing/loading/applying a liquid; appropriate data are not available for handling the water-dispersible granule formulation for this use, however, based on PHED unit exposure values from other handler scenarios with these formulation types, the

exposure is expected to be less than that of handling a liquid. The following handler scenarios were evaluated:

1. mix/load and spot application of liquid formulation (low-pressure hand sprayer), and
2. mix/load and broadcast application of liquid formulation (garden hose-end sprayer)

The following assumptions (which include *current* HED standard values) were used to calculate inhalation exposures.

- * The maximum application rate from ABOUND Flowable (EPA Reg No 10182-415) of 1.35 fluid ounces per 1,000 square feet or **0.95 lb ai per acre** was assumed.
- * Handlers were assumed to be using a low-pressure hand sprayer for spot treatments to 1,000 ft² areas or a garden hose-end sprayer for broadcast to a 0.5 acre lawn.
- * The inhalation unit exposures for the low-pressure hand sprayer, and garden hose-end sprayer are 30 µg/lb ai handled, and 9.5 µg/lb ai handled, respectively (from Appendix B of the 1997 Draft SOPs for Residential Exposure Assessments).
- * Residential handlers' body weight is 60 kg for calculation of short-term inhalation doses because this endpoint is based on a developmental study (i.e., applicable to females 13+).
- * The overall estimate of inhalation exposure represents a central to high-end value.

As shown in Table 5, the inhalation MOEs for residential handlers are well above the target MOE of 100.

Table 5. Handler Exposure and Risk Estimates for Residential Lawn Applicators					
Handler Scenario	Rate (lb ai/acre)	Acres Treated (acres/day)	PHED Unit Exposure ¹ (mg/lb ai)	Short-term Daily Inh. Dose ² (mg/kg/day)	Short-term Inhalation MOE ³
1. mix/load and spot application of liquid formulation (low-pressure hand sprayer)	0.95	0.023	0.030	1.1E-05	2.7E+06
2. mix/load and broadcast application of liquid formulation (garden hose-end sprayer)	0.95	0.5	0.0095	7.5E-05	3.9E+05

¹ Data Confidence for inhalation unit exposures:

low-pressure hand sprayer: 80 replicates, ABC grade, medium confidence run

garden hose-end sprayer: 8 replicates, ABC grade, low confidence run due to inadequate replicate

² Daily Dose = [Rate (lb ai/A) x Acres Treated (A/day) x Unit Exposure(mg/lb ai handled)] / Body Weight (60 kg for Short-term because endpoint based on a developmental study)

³ MOE = NOAEL (25 mg/kg/day) / Daily Inhalation Dose (mg/kg/day)

5.2 Residential Postapplication Exposure and Risk

As noted previously, a dermal risk assessment for postapplication exposure is not required because no dermal endpoint was selected by the HIARC. Therefore, only the following postapplication exposure scenarios resulting from lawn treatment were assessed: (1) incidental non-dietary ingestion of pesticide residues on lawns from hand-to-mouth transfer, (2) incidental non-dietary ingestion of pesticide-treated turfgrass, and (3) incidental non-dietary ingestion of soil from pesticide-treated residential areas. Postapplication exposures from various activities following lawn treatment are considered to be the most common and significant in residential settings. The exposure via incidental non-dietary ingestion of other plant material may occur but is considered negligible.

The exposure and risk estimates for the residential exposure scenarios are assessed for the day of application (day "0") because it is assumed that toddlers could contact the lawn immediately after application. On the day of application, it was assumed that 5 percent of the application rate is available from the turfgrass as transferrable residue. Both short- and intermediate-term exposure is expected. Risk from short- and intermediate-term incidental ingestion by toddlers is assessed by comparing these exposures to the NOAELs of 25 mg/kg/day and 20 mg/kg/day, respectively. The equations used for the exposure calculations are presented below and the results are presented in Table 6.

$$\begin{aligned} \text{PDR}_t \text{ for hand-to-mouth} &= \text{TTR}_t * \text{SA} * \text{EX} * \text{FQ} * \text{ET} * \text{CF1} \\ \text{PDR}_t \text{ for eating turfgrass} &= \text{GR}_t * \text{Igr1} * \text{CF1} \\ \text{PDR}_t \text{ for soil ingestion} &= \text{SR}_t * \text{Igr2} * \text{CF1} \end{aligned}$$

Where:

$$\begin{aligned} \text{PDR}_t &= \text{potential dose rate on day "t" (mg/day)} \\ \text{TTR}_t &= \text{AR} * \text{F} * (1-\text{D})^t * \text{CF2} * \text{CF3} \\ \text{GR}_t &= \text{AR} * \text{F} * (1-\text{D})^t * \text{CF2} * \text{CF3} \\ \text{SR}_t &= \text{AR} * \text{F} * (1-\text{D})^t * \text{CF2} * \text{CF3} * \text{CF4} \end{aligned}$$

Where:

$$\begin{aligned} \text{TTR}_t &= \text{turf transferrable residue on day "t" (ug/cm}^2 \text{ turf)} \\ \text{SA} &= \text{surface area of the hands (cm}^2 \text{/event); use palmar surface area of 3 fingers; 20 cm}^2 \\ \text{EX} &= \text{extraction from the hand by saliva = 50\%} \\ \text{FQ} &= \text{frequency of hand-to-mouth activity (events/hr); 20 events/hr} \\ \text{ET} &= \text{exposure time (hr/day); 2 hrs/day} \\ \text{CF1} &= \text{conversion factor (0.001 mg/ug for the TTR or GR equation, or 1E-6 g/ug in the SR equation)} \\ \text{GR}_t &= \text{grass (and plant matter) residue on day "t" (ug/cm}^2 \text{)} \\ \text{Igr1} &= \text{ingestion rate of grass (cm}^2 \text{/day); 25 cm}^2 \text{/day} \end{aligned}$$

- SR_t = soil residue on day "t" (ug/g)
 $IgR2$ = ingestion rate of soil (mg/day); 100 mg/day
 AR = application rate (lb ai/acre); 0.95 lb ai/acre
 F = fraction of ai available on turf/grass or in uppermost cm of soil (unitless); 5% on turf/grass, 100% in uppermost 1 cm of soil
 D = fraction of residue that dissipates daily (unitless); 10%
 t = postapplication day on which exposure is being assessed
 $CF2$ = conversion factor (4.54E8 ug/lb)
 $CF3$ = conversion factor (2.47E-8 acre/cm²)
 $CF4$ = conversion factor (0.67 cm³/g soil)

and

$$PDR_{t-norm} = PDR_t / BW$$

$$MOE = NOAEL / PDR_{t-norm}$$

Where:

- PDR_{t-norm} = potential dose rate, normalized to body weight, on day "t" (mg/kg/day)
 BW = body weight (kg); 15 kg
 $NOAEL_{oral}$ = 25 mg/kg/day (short-term), 20 mg/kg/day (intermediate-term)

Table 6. Short- and Intermediate-Term Incidental Ingestion Exposure and Risk				
Scenarios	TTR/GR/SR ₀ (ug/cm ² or g)	PDR _{0-norm} (mg/kg/day)	Short-Term MOE	Intermediate-term MOE
(1) Hand-to-Mouth	0.53	0.014	1,800	1,400
(2) Grass Ingestion	0.53	0.00089	28,000	23,000
(3) Soil Ingestion	7.1	0.000048	530,000	420,000
Total	N/A	0.015	1,700	1,300

Both short-term and intermediate-term MOEs for each scenario, and the combined MOE resulting from all three exposures, are above the target of 100, and therefore, are not of concern.

The exposure estimates generated above are based on some upper-percentile (i.e., maximum application rate, initial amount of transferrable residue and duration of exposure) and some central tendency (i.e., surface area, hand-to-mouth activity, and body weight) assumptions and are considered to be representative of high-end exposures. The uncertainties associated with this assessment stem from the use of an assumed amount of pesticide available from turf, and assumptions regarding transfer of chemical residues and hand-to mouth activity. The estimated exposures are believed to be reasonable high-end estimates based on observations from chemical-specific field studies and professional judgement.

5.3 Recreational Postapplication Exposure and Risk

Recreational exposures to turf are expected to be similar to those evaluated in section 5.2 Residential Postapplication Exposure and Risk. Although azoxystrobin may be applied to golf courses, a risk assessment for the golfing scenario is not required because no dermal endpoint was selected by the HIARC.

5.4 Off Target Non-Occupational Exposure

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 azoxystrobin. 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 data base 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.

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