Isoxa F.

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

WASHINGTON, DC 20460

OFFICE OF
PESTICIDES AND
TOXIC SUBSTANCES

14 MAR 1989

MEMORANDUM

SUBJECT: ISOXABEN EXPOSURE ESTIMATE FOR CHILDREN PLAYING ON TREATED LAWNS (NO HED PROJECT NUMBER)

TO: Richard F. Mountfort
Product Manager 23
Registration Division (H7509C)

FROM: Michael P. Firestone, Ph.D., Chief
Review Section 1
Non-Dietary Exposure Branch/HED (H7509C)

THRU: Charles L. Trichilo, Ph.D., Chief
Non-Dietary Exposure Branch/HED (H7509C)

DEFERRAL TO: TB-HFAS X

I. INTRODUCTION

NDEB has been requested by TB-HFAS to provide exposure estimates for children who may be exposed to isoxaben postapplication via contact with treated home lawns, despite the lack of any chemical specific data. It should be noted that NDEB previously concluded that using foliar dislodgeable residue (FDR) data for a surrogate chemical is not acceptable assessing exposure to isoxaben; also, data should be generated to delineate the relationship between home lawn FDR and human exposure (see M. Firestone memorandum of February 28, 1989).

Despite the lack of any actual data, this assessment will provide a very rough estimate of dermal and ingestion exposure utilizing modified versions of two unsubstantiated methodologies used previously by the Agency. The specific use in question involves the application of a dry flowable formulation of isoxaben (GALLERY 75 DF; 75% ai) to home lawns. Both daily and annual exposures have been estimated.

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II. DETAILED CONSIDERATIONS

The degree of conservativeness of the assumptions utilized in this exposure estimation can not be determined without further research. Previous exposure estimates provided for children playing on home lawns treated with other pesticides have been estimated using data showing the pattern of decline of dislodgeable residues on turf grass. Upon receipt of acceptable chemical specific turf foliar dissipation data (reflecting different grass varieties at several geographically diverse sites), NDEB can refine the exposure estimates provided in this report to more closely represent the actual exposure level (note: a protocol for such a study should be submitted for Agency approval prior to its conduct).

The following assumptions were used in this exposure assessment:

1. Respiratory exposure is insignificant compared to dermal or ingestion exposure.

2. Isoxaben is applied to home lawns twice per year at the maximum application rate of 1 lb ai/A.

3. Exposure is assumed to occur daily for 21 days after each application. In the absence of foliar residue data, NDEB will assume both that uniform coverage of the home lawn will occur and that foliar residues will not dissipate during this exposure period; after 21 days, residue levels will dissipate to a level approaching zero due to watering-in (note: according to the registrant, a worst-case half-life of 87 days has been determined, thus, residue levels would not be expected to significantly decline during the first 21 days after application; however, according to the label, "Gallery must be activated within 21-days of application to be fully effective").

4. Lifetime exposure will encompass 10 years (ages 2 through 12) as assumed by the registrant.

5. Dermal exposure to the child will occur as a result of contact with the treated grass through such activities as crawling and rolling.

   Dermal exposure can be estimated by utilizing either of two unsubstantiated methodologies used previously by the Agency.

   a) In the first method, contact will occur over the entire body surface area. Any dermal contact will result in a quantitative transfer of residues from the foliage to the surface of the skin. This method may not be conservative since a child could be exposed to much higher levels if dermal absorption is rapid as he/she contacts different areas of the treated lawn.

b) The second method of estimating dermal exposure is to use a modification (corrected for the relative child:adult body surface area ratio) of the relationship between dermal exposure by fruit harvesters and FDR developed by Zweig, et al. (Journal of Environmental Science and Health, Volume B20, pp. 27-59, 1985), where:

dermal exposure mg/hr = antilog [(log FDR ug/cm^2) + 0.603]

A child is assumed to play outdoors 4 hours per day.

6. As referenced by the registrant (ICRP 1984), for ages 2 to 6, assumptions include: total body surface area of 7,000 cm^2, hand surface area of 140 cm^2,and body weight of 17 kg; for ages 6 to 12, assumptions include total body surface area of 9,000 cm^2, hand surface area of 180 cm^2, and body weight of 31 kg.

7. All dermal exposure values correspond to the amount of chemical impinging on the skin surface corrected for a dermal penetration factor of 11% (see below).

8. We assume that during the course of an exposure episode, the child will lick an area of his body equal to the surface area of both hands and will lick the surface area of a 3-inch diameter ball. Licking is assumed to quantitatively remove residues from each respective surface. The surface residues on the ball are assumed to be equal to the surface residues on the grass. Possible oral exposure resulting from the ingestion of contaminated soil has not been considered.

II. EXPOSURE CALCULATIONS

A. Dermal Exposure - Method 1: Quantitative Transfer

1. If isoxaben is applied at 1 lb ai/A, the surface residues, assuming uniform coverage, is:

$$\frac{1\ \text{lb ai}}{\text{acre}} \times \frac{1\ \text{acre}}{4047\ m^2} \times \frac{454\ g}{\text{lb}} \times \frac{10^3\ \text{mg}}{g} = 112\ \text{mg}/m^2$$

The daily dermal exposure to a 2 to 6 year old child is:

$$\frac{112\ \text{mg}}{m^2} \times \frac{0.70\ m^2}{\text{child}} \times \frac{1}{17\ \text{kg}} = 4.6\ \text{mg/kg/day}$$

The annual dermal exposure to a 2 to 6 year old child is:

194 mg/kg/year (4.6 mg/kg/day x 21 days/ treatment x 2 treatments/year)

The daily dermal exposure to a 7 to 12 year old child is:

$$\frac{112 \text{ mg}}{\text{m}^2} \times \frac{0.90 \text{ m}^2}{\text{child}} \times \frac{1}{31 \text{ kg}} = 3.3 \text{ mg/kg/day}$$

The annual dermal exposure to a 7 to 12 year old child is:

137 mg/kg/year (3.3 mg/kg/day x 21 days/ treatment x 2 treatments/year)

2. Average lifetime dermal exposure:

[(194 mg/kg/year x 6 years) + (137 mg/kg/year x 6 years)] / 70 years = 28 mg/kg/yr or 7.8×10^{-2} mg/kg/day

Assuming (as per the registrant's January 25, 1989 submission) a dermal penetration factor of 11% (note: NDEB defers the adequacy of this value to TB-HFAS), lifetime average daily exposure would be 8.6×10^{-3} mg/kg/day.

B. Dermal Exposure - Method 2:
Zweig-Leffingwell-Popendorf Correlation

1. As in II-A(1) above, uniform coverage results in a FDR level of 112 mg/m^2 (11.2 ug/cm^2).

The daily dermal exposure to a 2 to 6 year old child is:

4 hours x 1/17 kg x antilog [(log 11.2) + 0.603] mg/hr

x 0.7 m^2/2.1 m^2 child:adult surface area ratio

= 3.5 mg/kg/day

The annual dermal exposure to a 2 to 6 year old child is:

147 mg/kg/yr (3.5 mg/kg/day x 21 days/ treatment x 2 treatments/year)

The daily dermal exposure to a 7 to 12 year old child is:

4 hours x 1/31 kg x antilog [(log 11.2) + 0.603] mg/hr

x 0.9 m^2/2.1 m^2 child:adult surface area ratio

= 2.5 mg/kg/day

The annual dermal exposure to a 7 to 12 year old child is:

105 mg/kg/yr (2.5 mg/kg/day x 21 days/ treatment x 2 treatments/year)

2. Average lifetime dermal exposure:

[(147 mg/kg/year x 6 years) + (105 mg/kg/year x 6 years)] / 70 years = 22 mg/kg/yr

Since methods 1 (28 mg/kg/yr) and 2 (22 mg/kg/yr) give similar results, the results from method 1 will be used throughout the rest of this exposure estimation.

C. Ingestion Exposure

1. The daily ingestion exposure from licking a 3-inch diameter (7.6 cm) ball is:

$$4\ \text{pi}\ (7.6\ \text{cm}/2)^2 \times \frac{10^{-4}\ \text{m}^2}{\text{cm}^2} \times \frac{112\ \text{mg}}{\text{m}^2} \times \frac{1}{17\ \text{or}\ 31\ \text{kg}} =$$

0.12 mg/kg/day for a 2 to 6 year old; or

0.07 mg/kg/day for a 7 to 12 year old

The annual ingestion exposure from licking the ball is:

daily exposure x 21 days/treatment x 2 treatments/year =

5.0 mg/kg/year for a 2 to 6 year old; or

2.9 mg/kg/year for a 6 to 12 year old

2. The daily ingestion exposure from licking a body surface area equivalent to that of both hands is:

$$\frac{140\ \text{or}\ 180\ \text{cm}^2}{10{,}000\ \text{cm}^2/\text{m}^2} \times 112\ \text{mg}/\text{m}^2 \times \frac{1}{17\ \text{or}\ 31\ \text{kg}} =$$

0.09 mg/kg/day for a 2 to 6 year old; or

0.07 mg/kg/day for a 7 to 12 year old

Annual ingestion exposure from licking both hands is:

3.8 mg/kg/year for a 2 to 6 year old; or

2.7 mg/kg/year for a 7 to 12 year old

3. Average lifetime ingestion exposure =

$$\frac{[(5.0 + 3.8 \text{ mg/kg/yr} \times 6 \text{ years}) + (2.9 + 2.7 \text{ mg/kg/yr} \times 6 \text{ years})]}{70 \text{ years}}$$

$= 1.23$ mg/kg/year or 3.4×10^{-3} mg/kg/day

C. Average Daily Total (Dermal plus Oral) Exposure

Total average daily exposure summing the values for dermal exposure (corrected for dermal penetration) and oral exposure would be:

8.6×10^{-3} mg/kg/day (dermal) + 3.4×10^{-3} mg/kg/day (oral) =

1.2×10^{-2} mg/kg/day

III. CANCER RISK ASSESSMENT

Assuming the registrant's derived value for the cancer potency of 2.1×10^{-3} $(\text{mg/kg/day})^{-1}$ (note: NDEB defers the adequacy of this value to TB-HFAS), incremental lifetime risk would be 3×10^{-5} (1.2×10^{-2} mg/kg/day exposure x 2.1×10^{-3} per mg/kg/day).

IV. CONCLUSIONS

1. The estimate derived above regarding exposure is considered conservative. As stated previously, NDEB will be able to refine these exposure estimates upon receipt of actual isoxaben residue data. Additionally, the extrapolation from foliar residue levels to estimated dermal contact cannot be revised without further research in the areas of residue transfer and child behavioral patterns.

2. NDEB defers to TB-HFAS the adequacy/accuracy of both the registrant-derived dermal penetration factor of 11% and cancer potency factor of 2.1×10^{-3}.

Note to the PM: Since DEB/HED now considers pesticides used on turf grass as a food use, RD should ensure that DEB reviews this action including any label restrictions designed to prevent use on grass grown for seed (see Attachment from DEB dated January 26, 1989).

Attachment

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