



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY


WASHINGTON, DC 20460

28 FEB 1989


OFFICE OF
PESTICIDES AND
TOXIC SUBSTANCES

MEMORANDUM

SUBJECT: ISOXABEN (GALLERY[™]) RISK ASSESSMENT FOR CHILDREN
PLAYING ON TREATED LAWNS - HED Project No. 9-0750

FROM: Michael Firestone, Ph.D., Chief 
Review Section 1
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Health Effects Division (H7509C)

TO: Richard F. Mountfort, PM 23
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THRU: Charles L. Trichilo, Ph.D., Chief 
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Please find below the NDEB review of

RD Record #: 239 002

Caswell #: 419F

Date Received: 2/1/89

Review Time: 2 days

Deferral to: Toxicology Branch - HFAS

Elanco submitted a hypothetical exposure and risk assessment for the use of their new selective preemergent herbicide isoxaben (Gallery[™]) on home lawns. Elanco is seeking registration of isoxaben for use on the following:

- Established turf
- Landscape ornamentals
- Container grown ornamentals
- Ground covers
- Nursery stock
- Nonbearing fruit and nut crops
- Nonbearing vineyards
- Noncropland

The specific formulation is Gallery 75 dry flowable containing 0.75 pound (lb) active ingredient (ai) per lb. The proposed label states that isoxaben should be applied by low pressure sprayer "in late summer to early fall or in early spring, prior to germination of target weeds, or immediately after cultivation." Further, the label specifies application rates from 0.66 to 1.33 lb formulation/A (0.5 to 1.0 lb ai/A).

This memorandum will only address the issue of postapplication exposure to children playing on home lawns treated twice per year (Note: the question of handler, i.e., mixer/loader and applicator, exposure may be considered in a separate memorandum).

Detailed Considerations

A. Exposure

The exposure/risk assessment for isoxaben use on home lawns developed by Environ Corporation for the registrant is based on extrapolating foliar dislodgeable residue (FDR) data for flurprimidol assuming:

1. FDR levels are directly proportional to application rate; and
2. The relationship between initial total residue and resulting FDR for flurprimidol (wetable powder formulation) is the same as that for isoxaben (dry flowable formulation).

Non-Dietary Exposure Branch (NDEB) considers the above assumptions to be unsubstantiated, and therefore unacceptable for use in exposure assessment.

Specifically, the Agency should require FDR studies at a minimum of three sites as well as additional work at delineating the relationship between home lawn FDR and human exposure (Note: NACA is chairing a joint industry--CDFA--HWC--EPA task force on indoor occupant exposure assessment; many of the issues involved in assessing indoor exposure are relevant to the area of assessing home lawn exposure).

The FDR studies should evaluate the effectiveness of watering-in as a means of reducing residues and, thus, potential for exposure.

NDEB recommends that the registrant develop a protocol for Agency evaluation--the protocol should encompass the set of comprehensive studies necessary to quantitatively evaluate exposure.

B. Risk

NDEB defers evaluation of the cancer potency derivation [$Q_1^* = 2.1 \times 10^{-3} \text{ (mg/kg/d)}^{-1}$] and dermal absorption/penetration value (11%) to Toxicology Branch - Herbicide, Fungicide, and Antimicrobial Support (TB-HFAS).

cc: Sue Rathman
Correspondance File
Isoxaben File
Circulation
TB-HFAS
SACB