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

OFFICE OF
PESTICIDES AND TOXIC
SUBSTANCES

SEP 2 1992

**MEMORANDUM**

SUBJECT: RESPONSE TO REGISTRANT'S REQUEST FOR DATA WAIVERS OF REREGISTRATION REQUIREMENTS FOR OXYFLUORFEN (REREG. CASE NO. 2490)

FROM: Laura E. Morris, Environmental Scientist Laura E. Morris 6/12/92

TO: Mark Wilhite
Accelerated Reregistration Branch
Special Review and Reregistration Division (H7508W)

THRU: Alan P. Nielsen, Section Head
Reregistration Section
Larry C. Dorsey, Acting Chief
Occupational and Residential Exposure Branch
Health Effects Division (H7509C)

Please find below, the OREB review of:

DP Barcode: 171845

Pesticide Chemical Code: 111601

EPA Reg. No.: N/A

EPA MRID Nos.: 420983-01; 420983-02

Review Time: 4 days

PHED: NO

(1)

## I. INTRODUCTION

### A. Background:

Oxyfluorfen is a herbicide applied preplant and postemergence to tree fruit (including citrus), cotton, corn, mints, onions, soybeans, artichokes, nuts, ornamental trees and shrubs, conifers, fallow land and rights-of-way/fencerows. Oxyfluorfen (trade name Goal) is formulated as an emulsifiable concentrate, liquid-ready-to-use, or granular to control annual broadleaf weeds and grasses. With regard to the toxicological concerns, oxyfluorfen is considered a quantifiable carcinogen, Group C (HED's "List of Chemicals Evaluated for Carcinogenic Potential", memorandum dated 2/27/92 from R. Engler/HED). According to the data currently available, there are no acute toxicity concerns (i.e., acute dermal category 3 using only 2% a.i. and category 3 dermal for the formulated product--Goal 25W).

During Phase 4 of the Reregistration Process, it was noted that oxyflurofen met the criteria for requiring reentry exposure data, and as a result the Agency issued a Data Call-In Notice requesting the data. In response to the Agency's notice, the registrant, Rohm & Haas Company, has requested a waiver of the following reentry data requirements:

132-1(a) foliar residue dissipation;
132-1(b) soil residue dissipation;
133-3 dermal exposure;
133-4 inhalation exposure.

### B. Purpose:

This memorandum is in response to the data waivers request submitted by Rohm & Haas Company in support of FIFRA '88 reregistration data requirements for List B Chemical, Oxyfluorfen.

## II. DETAILED CONSIDERATIONS

The rationale for the request as stated in the correspondence submitted by Rohm & Haas Co. is as follows:

1) oxyfluorfen is virtually always applied as a directed spray to the soil and the base of the plant, and is phytotoxic to most plant foliage; therefore, foliar residues are rare (exception-- the chemical is applied over very small onion plants which the workers are not likely to come in direct contact with);

2) reentry activities after application are not of the type which would result in "substantial human contact with soil"; and

3) because the chemical is a barrier herbicide active on the soil surface, growers minimize reentry activity to avoid disturbing the soil and inactivating the chemical.

The registrant has noted that reentry activities are more frequent for the tree nursery and ornamental plant uses.

Oxyflurofen was one of several pesticides used in a study sponsored by U.S. Department of Agriculture which measured the persistence of foliar and soil residues of pesticides and exposure of workers under tree nursery conditions. The registrant included in its submission (as Attachments 5 and 6) the studies sponsored by U.S. Department of Agriculture entitled, "Persistence of Dislodgeable Residues Under Tree Nursery Conditions" and "Pesticide Exposure Assessment of Nursery Workers", MRID Numbers 420983-01 and 420983-02, respectively. The data results obtained from the study relative to oxyflurofen were highlighted in the registrant's correspondence (see Attachment). The studies, performed over a one year period, measured foliar dislodgeable residues, soil residue dissipation, worker dermal exposure (using passive dosimetry and hand rinses to measure hand exposure). The results of studies previously conducted by the author indicated inhalation exposure was negligible; therefore, this route of exposure was not measured.

With regard to current re-entry and worker protection standards, the existing approved labels state, "Do not enter treated area without protective clothing until sprays have dried. Because certain states may require more restrictive re-entry intervals for various crops treated with this product, consult your State Department of Agriculture for further information. Do no apply this product in such a manner as to directly or through drift, expose workers or other persons. The area being treated must be vacated by unprotected persons..."

## III. CONCLUSIONS

Based on the use patterns (i.e., applied postemergent to onions as a spray using ground equipment, applied using ground equipment to ornamental trees after transplant) the potential for worker exposure to foliage and soil exists; therefore, data are required for such uses. Foliar dislodgeable residue data are not required for uses which do not involve human contact with the foliage (i.e. applied preplant, fallow land use, etc.) Soil residue dissipation data are not required for use patterns which do not involve substantial contact with the soil such as the directed spray application to soil for the citrus (non-bearing) use.

In reference to the studies submitted by the registrant, they can not be used **to support the recommendation of granting a data waiver request**, because the studies must be evaluated to determine if the data are acceptable and if the studies were done in accordance with the worker exposure Pesticide Assessment Guidelines. If the registrant wishes to use the studies to provide data concerning dislodgeable residues and worker reentry exposure to oxyflurofen under tree nursery conditions, then it should be indicated that the studies are submitted to **fulfill the Subdivision K reentry data requirements not as data waiver**

**request.** The registrant should review the studies to determine if they were conducted according to Agency standards (Pesticide Assessment Guidelines--Subdivision K) before resubmitting the studies. If study modifications are not required then the registrant may submit correspondence (not necessary to resubmit studies) to the Agency indicating its desire to use to studies to support reregistration exposure data requirements. In the correspondence the registrant should include the study MRID numbers and the guidelines supported by the studies.

In conclusion, the information provided by the registrant does not adequately justify negating the need for worker reentry data. Therefore, OREB recommends that the request for the following data waivers be denied-- 132-1(a) foliar dislodgeable residues, 132-1(b) soil residue dissipation, 133-3 dermal exposure and 133-4 inhalation exposure.

Attachment

cc: Laura E. Morris, OREB
Esther Saito, SACB
Correspondence File
Chemical File (Oxyflurofen)
Circulation

induced by the test article. To overcome the technical limitations presented by this species, Rohm and Haas chose to administer GOAL® technical to the rabbits in this developmental toxicity study as a formulated product of the technical material with inert ingredients that were compatible with an aqueous dosing media. This study should not be rejected because it was technically not feasible to conduct the study with technical grade material dissolved or suspended in more commonly used vehicles.

Copies of current labels for products containing oxyfluorfen are in Attachment 4. Copies of Confidential Statements of Formula for oxyfluorfen products are on file at the Agency and are current.

| | | |
|---|---|---|
| 132-1(a) | Foliar residue dissipation | A waiver is requested for these requirements to develop data to set reentry intervals for oxyfluorfen (132-1(a), (b), 133-3, 133-4) because of the way in which oxyfluorfen products are applied and the nature of the activities performed in fields after application. Oxyfluorfen is a contact herbicide and is phytotoxic to most plant foliage. Oxyfluorfen is virtually always applied as a directed spray to the soil and the base of the plant. As a result, there rarely are foliar residues. Oxyfluorfen is applied over onions but these are very small plants that workers are not likely to brush against. Also, reentry activities following oxyfluorfen application are not of the type which would result in the "substantial human contact with soil" required by the testing guidelines as a precondition for studying soil dissipation or dermal and inhalation exposure to soils. Oxyfluorfen is a barrier herbicide that is active on the soil surface. Reentry activity is |
| 132-1(b) | Soil residue dissipation | |
| 133-3 | Dermal Passive dosimetry expo | |
| 133-4 | Inhal. passive dosimetry expo | |

minimized by growers to avoid disturbing the soil and inactivating oxyfluorfen.

Exceptions to this might be uses in tree nurseries and on ornamental plants where reentry operations are more frequent. A study sponsored by the United States Department of Agriculture measured the persistence of foliar and soil dislodgeable residue of pesticides under tree nursery conditions (Attachment 5) and exposure of nursery workers to pesticides while normal functions were carried out at four different sites over a one year period (Attachment 6). Oxyfluorfen was included in the study. The following results were obtained for oxyfluorfen:

Foliar Dissipation - Maximum foliar residues at two sites were 0.04 and 0.11 $\mu g/cm^2$. Only 10-15% of the residue was present 24 hours after application and half-lives of 7.5 and 12.5 hours were calculated.

Dislodgeable Foliar Residues - Dislodgeable residues of oxyfluorfen were present on only 3 of 295 samples analyzed. Amounts dislodged (shaking in water for 45 seconds) from 50-75 g seedling samples were 9, 18, and 82 µg.

Soil Dissipation - Residue of 0.08 to 0.11 ppm were found in three soil samples analyzed and a half-life of 35 days was calculated.

Dislodgeable Soil Residues - No oxyfluorfen (sensitivity of 0.005 ppm) was removed from soil samples that were shaken in water for 2 hours and then let stand overnight before analysis indicating that <5% of the soil residue was dislodged.

6

Worker Exposure - Patches were placed at several locations on applicators, weeders, scouts, and packers at various times when they performed their activities. The following table summarizes findings with oxyfluorfen.

| Function | No. Workers Examined | No. Patches Examined | No. Patches with Residue | Range of Residue (µg/patch) |
|---|---|---|---|---|
| Applicators | 2 | 11 | 9 | 8-1,533 |
| Weeders | 9 | 52 | 2 | 2.8; 6.0 |
| Scouts | 2 | 10 | 2 | 1.0; 2.5 |
| Packers | 2 | 2 | 0 | -- |

Is is clear from these results that exposure to oxyfluorfen was infrequent and of low magnitude during reentry procedures.

Hand rinses were also analyzed for residues of oxyfluorfen with the following results.

| Function | No. Workers Examined | No. Rinses Examined | No. Rinses with Residue | Residue (µg/Rinse) |
|---|---|---|---|---|
| Applicators | 2 | 9 | 2 | 26; 220 |
| Weeders | 8 | 71 | 0 | -- |
| Scouts | 2 | 3 | 0 | -- |
| Packers | 4 | 15 | 0 | -- |

These results confirm the findings with patches.

Inhalation exposure was not measured in the study since previous studies conducted by the author have shown that exposure by this route is negligible. (See p. 141 in Attachment 5 and discussion below under 163.2.)

7