



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

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

MEMORANDUM

SUBJECT: Section 18 - Specific Exemptions for Use of Oxyfluorfen (Goal) For Chemical Pruning (Cane Suppression) of Primocanes in Raspberries Grown in Oregon (93-OR-04) and Washington State (93-WA-02).

--ACTION MEMORANDUM --

FROM: Lawrence E. Culleen, Acting Director
Registration Division

TO: Douglas D. Campt, Director
Office of Pesticide Programs

I. APPLICANTS' REQUEST:

APPLICANTS: Oregon Department of Agriculture
Washington State Department of Agriculture

CHEMICAL: Oxyfluorfen

PRODUCT: Goal 1.6E Herbicide, EPA Reg. No. 707-174, manufactured by Rohm and Haas Company.

SITE: Raspberries

PEST: Raspberry primocanes

RATE: At a rate of 1 to 4 pints of product (0.2 to 0.8 lb. a.i.) per broadcast acre per application, with a maximum of 6 pints of product (1.2 lbs. a.i.) per broadcast acre per season.

NO. OF APPL: One or two ground applications made in a minimum of 50 gallons of water/acre, applied to primocanes in a 3-foot band over the row. A 50-day PHI will be observed.



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contains at least 50% recycled fiber

ACREAGE: OR: 3,900 acres in Washington, Multnomah, Clackamas, Linn, Benton, Polk, Lane, Marion, Douglas, and Yamhill counties.

WA: 5,021 acres in counties west of the crest of the Cascade Mountains: Whatcom, Skagit, Snohomish, Clallam, Island, King, Kitsap, Pierce, Thurston, Lewis, Cowlitz, Skamania, and Clark.

POUNDAGE: OR: approximately 878 gallons of product (1,404 lbs. a.i.)
WA: approximately 3,766 gallons of product (6,026 lbs. a.i.)

USE-SEASON: OR: March 1, 1993 through May 15, 1993.
(Oregon issued a crisis exemption for this use on 04/06/93.)
WA: March 1, 1993 to June 1, 1993.
(Washington State issued a crisis exemption for this use on 04/09/93.)

EMERGENCY/REG. ALT.: Chemical pruning of raspberry primocanes with oxyfluorfen is a necessary practice which removes raspberry tree growth at the plant base allowing for the proper operation of harvester catch plates. Also, the pruning of early season vegetative growth diverts nutrients to fruit buds and increases raspberry yields. Since the suspension of dinoseb in 1986, raspberry growers have been searching for alternative, economical methods of primocane suppression. Both Oregon and Washington State have been granted 24(c) registrations for use of monourea sulfuric acid (Enquik) to suppress raspberry primocanes. However, Enquik does not provide adequate cane suppression in the cool, moist pacific northwest climates of Oregon and Washington.

The inability to chemically suppress primocanes may cause a net revenue loss per acre of approximately \$750 for Oregon and Washington State raspberry growers.

II. BACKGROUND:

This is the fourth year this use of oxyfluorfen has been requested under section 18 of FIFRA. Specific exemptions for the use of oxyfluorfen on raspberries were granted to Oregon and Washington State since 1990. Oregon and Washington State both issued crisis exemptions for this use on April 6, 1993 and April 9, 1993, respectively.

Reregistration

- List: B (currently undergoing phase V review by the Agency)
- Registrant: Rohm and Haas
- In Compliance? Yes

- Major Data Gaps: There is an extensive list of studies that will be required in a DCI tentatively scheduled for June of 1993. The contents of the DCI are not final though the list will include residue chemistry and occupational exposure studies. The studies to be requested are necessary in order to replace data previously generated by Craven Laboratories.
- Last Study Due Date: storage stability (12/30/94)
- Expected RED Completion Date: 1996

Progress Toward Registration

IR-4 project #3486 was initiated to generate data in support of a tolerance for residues of oxyfluorfen in or on raspberries. Analyses of the 1989 field trial data from Oregon were completed and IR-4 expects to submit a petition to the Agency by July of 1993.

Section 18 Delaney Policy

Oxyfluorfen is a Group C (possible human) carcinogen, but registration of this use on raspberries would not require a food additive regulation under existing policy; therefore, the Delaney clause does not apply.

Special Review Considerations

A Special Review of oxyfluorfen was completed in January of 1982. The review was initiated due to concerns over contamination of oxyfluorfen with perchloroethylene (PCE), a carcinogen. A decision was made to continue use of the herbicide subject to restriction of the contaminant PCE (not to exceed 200 ppm) in the formulated product.

III. EPA EVALUATION:

BEAD Review

BEAD previously reviewed requests from Oregon and Washington State and determined that an urgent, non-routine situation would exist due to the loss of dinoseb for chemically pruning primocanes. BEAD also concluded that substantial yield and harvesting losses are expected to occur without an adequate alternative. There are no registered alternatives for this use, except Enquik, which is registered under section 24(c) for use in Oregon and Washington State. BEAD agreed with the applicants' assertion that Enquik is not an effective alternative to dinoseb, due to its temperature sensitivity. Enquik is only effective when the weather is unusually warm at the time of first treatment. Applications of Enquik when the weather is too cold may actually be counterproductive. BEAD also agreed with the applicants' assertion that hand-pruning of primocanes was not an economically feasible alternative to chemical control.

The 1993 crop loss estimates of 32% by Oregon and up to 45% by Washington State would cause a loss in revenue of approximately \$750 per acre for both states. BEAD's previous analysis of the situation indicated that losses in production of this magnitude would be outside the "normal" range of profitability for growers.

Residue Chemistry

Tolerance Support - Chemistry Branch reviewed Oregon's 1991 section 18 request and concluded that residues of oxyfluorfen and its metabolites containing the diphenyl ether linkage are not expected to exceed 0.05 ppm in or on raspberries as a result of the proposed use. Residues in meat, milk, poultry, and eggs are not expected to result, since no animal feed items are involved. Adequate methodology for enforcement purposes may be found in PAM II, and reference standards are available from the Pesticides and Industrial Chemicals Repository at RTP, N.C.

Toxicological Review

Toxicology Branch I (TOX) reviewed this request in 1991 for use of oxyfluorfen on raspberries and concluded that data are adequate to support the proposed use under an emergency exemption.

HED has established an RfD for oxyfluorfen of 0.003 mg/kg/day, based on the NOEL of 0.3 mg/kg/day from a 20-month mouse feeding study with an uncertainty factor of 100. Existing uses of oxyfluorfen result in a TMRC (Theoretical Maximum Residue Contribution) of 0.000897 mg/kg/day for the overall U.S. population, which utilizes approximately 30% of the RfD. The

proposed use on raspberries would increase the TMRC by 0.00000014 mg/kg/day and result in a small increase in RfD utilization. The only DRES population subgroup with a TMRC in excess of the RfD is non-nursing infants, less than 1 year old. The TMRC for this group is 0.004538 mg/kg/day, which utilizes 151% of the RfD. A DRES analysis incorporating available anticipated residue and percent crop treated data estimated an ARC (Anticipated Residue Contribution) for this subgroup of 0.000028 mg/kg/day, which utilizes only 0.9% of the RfD. The proposed use on raspberries is not expected to measurably increase dietary exposure to oxyfluorfen for infants, since infant consumption of raspberries is low.

HED's Peer Review Committee has classified oxyfluorfen as a Group C (possible human) carcinogen with an upper bound potency estimate (Q_1^*), in human equivalents, of 1.28×10^{-1} (mg/kg/day)⁻¹. TOX deferred to the Science Analysis Branch (SAB) and the Occupational and Residential Exposure Branch (OREB) for dietary and non-dietary exposure analyses, respectively. The results of these analyses are discussed below.

I. Dietary Risk Assessment:

The estimated lifetime dietary risk from existing uses of oxyfluorfen is 1.2×10^{-4} , based on tolerance level residues and assuming 100 percent of the registered crops are treated. The upper-bound estimate of carcinogenic risk for the general population is 1.8×10^{-6} when anticipated residues and percents of crop treated are used. Assuming a residue level of 0.05 ppm in raspberries, the proposed use would result in an additional lifetime dietary carcinogenic risk of 1.8×10^{-8} .

II. Occupational Exposure Assessment:

OREB confirmed that the occupational exposure situation for these workers (mixers, loaders, and applicators) should be similar to the exposure situation derived from surrogate data for the use of oxyfluorfen on grass grown for seed in Oregon previously authorized under section 18. Based on OREB's exposure estimates, TOX Branch I calculated the total (dermal and inhalation) occupational carcinogenic risk to workers who mix/load and apply oxyfluorfen under that exemption to be on the order of 10^{-7} provided protective clothing (long-sleeve shirts, hats, long pants, work footwear, and chemical resistant gloves) are worn by workers involved in the mixing and loading of oxyfluorfen. Occupational carcinogenic risk estimates for this use would be on the same order of magnitude. The mailgrams authorizing this use will require mixers and loaders to use protective clothing.

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A rat teratology study for oxyfluorfen submitted under 6 (a)(2) has reduced the NOEL for developmental effects from the previous 30 mg/kg/day to a NOEL of 15 mg/kg/day. TOX Branch I calculated the margins of exposure (MOE) for developmental effects for a 70 kg woman involved in the use of oxyfluorfen on grasses to be 2080. The MOE for this use would be similar.

OREB emphasized that a data gap would remain due to the lack of precise exposure data for this use and recommended that Rohm and Haas provide exposure data in support of the pending section 3 registration for this use.

Ecological Effects Review/Environmental Fate Review

EEB previously reviewed requests from Oregon and Washington State and concluded that the proposed use is not expected to pose an unreasonable risk of adverse effects on birds, mammals, or aquatic organisms, but does pose a risk to non-target plant species. Although there are no endangered plant species in Washington State, one endangered plant, Bradshaw's lomatium, occurs in the Willamette Valley of Oregon. EEB recommended that applications of oxyfluorfen be prohibited within 100 yards of "all lowland prairie communities, all wetlands, and all other aquatic habitats including drainage courses, and other water ways" in Benton, Lane, Linn, Marion, and Polk counties to minimize risk of exposure of this endangered plant. This restriction was imposed as a condition of Oregon's previous specific exemptions for the use of oxyfluorfen on raspberries.

The Portland office of the United States Fish and Wildlife Service (USFWS) reviewed a similar use of oxyfluorfen on grasses grown for seed in Oregon and concluded that the existing environmental hazards statements on the Goal 1.6E label should be adequate to protect Bradshaw's lomatium without the need to impose buffer zones in the counties where it is present. However, USFWS noted that, while wet prairie plant communities have become rare in the Willamette Valley due to agriculture and development, small remnant patches persist along fence rows, roadsides, and drainage courses. These communities contain not only the endangered plant, Bradshaw's lomatium, but also other plants (Aster curtis, Erigeron decumbens, etc.) which, although they are not federally listed endangered plants at this time, share the same problems and threats as the lomatium and would also be susceptible to Goal. USFWS, therefore, recommended that a label statement such as the one below be included on Oregon's section 18 labels as a discretionary conservation measure:

Due to the close proximity of native prairie remnants to agricultural areas and the potential for these areas to be adversely affected by herbicides through drift or possible runoff/soil movement, it is recommended that Goal 1.6E herbicide not be applied directly to native prairie habitats

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in Benton, Clackamas, Lane, Linn, Marion, Polk, and Yamhill counties of Oregon.

The mailgram authorizing this use in Oregon will require this statement to appear on the section 18 label.

Oxyfluorfen does not appear on EFGWB's list of chemicals with ground water concerns.

IV. RECOMMENDATION:

I recommend that the Oregon Department of Agriculture and Washington State Department of Agriculture be granted specific exemptions for use of oxyfluorfen for chemical pruning of raspberry primocanes. This recommendation is based on the following:

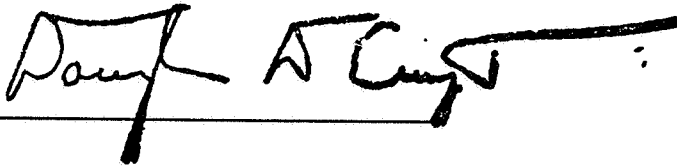
1. An urgent, non-routine situation would exist for Oregon and Washington State raspberry growers if they are unable to use oxyfluorfen to suppress primocane growth. Since the suspension of Dinoseb in 1986 there have been no other registered alternatives available to growers.
2. Residues of oxyfluorfen are not expected to exceed 0.05 ppm in or on raspberries as a result of the proposed use. This level can be toxicologically supported. Existing uses of oxyfluorfen utilize approximately 30% of the RfD for the overall U.S. population and 151% (or 0.9% based on available anticipated residue and percent crop treated information) of the RfD for non-nursing infants. The proposed use on raspberries would result in a small increase in dietary exposure for the U.S. population and all of the DRES population subgroups. The estimated lifetime dietary risk from existing uses of oxyfluorfen is 1.2×10^{-4} , based on tolerance level residues and assuming 100 percent of the registered crops are treated. The upper-bound estimate of carcinogenic risk for the general population is 1.8×10^{-6} when anticipated residues and percents of crop treated are used. The proposed use on raspberries would result in an additional lifetime dietary carcinogenic risk of 1.8×10^{-8} .

The total occupational carcinogenic risk to workers who mix/load and apply oxyfluorfen under this specific exemption is estimated to be on the order of 10^{-7} , provided protective clothing (long-sleeve shirts, hats, long pants, work footwear, and chemical resistant gloves) are worn by workers involved in the mixing and loading of oxyfluorfen.

TOX Branch I calculated the margins of exposure (MOE) for developmental effects of oxyfluorfen on grasses for a 70 kg woman involved in the use of oxyfluorfen to be 2080. MOE for this use would be similar.

3. The proposed use should not pose an unreasonable risk of adverse effects on non-target birds, mammals, or aquatic organisms. The use does pose a risk of adverse effects on the endangered plant, Bradshaw's lomatium, found in certain counties in Oregon. Existing Goal label statements and the inclusion of a precautionary statement recommended by the Oregon office of the USFWS should be adequate to protect this species.
4. Progress toward registration of oxyfluorfen on raspberries appears to have been made. IR-4 expects to submit a petition to the Agency for this use by July of 1993.

Approve: _____



Disapprove: _____

Date: _____

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