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

NOV 16 1994

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

DECISION MEMORANDUM

SUBJECT: Registration of Flumiclorac Pentyl (Resource Herbicide)

FROM: Stephen L. Johnson, Director
Registration Division (7505C)

TO: Daniel M. Barolo, Director
Office of Pesticide Programs (7501C)

REGISTRANT: Valent U.S.A. Corporation

CHEMICAL: Flumiclorac pentyl (pentyl[2-chloro-4-fluoro-5-(1,3,4,5,6,7-hexahydro-1,3-dioxo-2H-isoindol-2-yl)phenoxy]acetate)

PRODUCTS: Flumiclorac Pentyl (EPA File Symbol 59639-IR)
Resource Herbicide (EPA File Symbol 59639-IE)

USES: Field Corn, Soybeans

TYPE OF REGISTRATION: Conditional

BENEFITS FINDING:

- Flumiclorac Pentyl is an effective postemergence herbicide used at very low rates in corn and soybeans to control a selected group of broadleaf weeds.
- A conditional registration of flumiclorac pentyl would:
  - lead to an overall reduction in pounds of herbicide applied per year in corn because of the much lower use rate of flumiclorac pentyl than the alternatives.
  - likely lead to the reduction of use, to some degree, of dicamba, 2,4-D, bromoxynil, atrazine, and cyanazine in corn.
  - likely lead to a reduction in use, to some degree, of imazethapyr, chlorimuron ethyl, thifensulfuron methyl, bentazon, acifluorfen, lactofen, imazaquin, fomesafen, and 2,4-DB in soybeans.

- Flumiclorac pentyl has a unique ability to control velvetleaf, which is one of the most prevalent and troublesome weeds to control in corn and soybeans throughout the country, at much later growth stages than the currently available alternatives. Users will benefit from the wider time window of application of flumiclorac pentyl for velvetleaf control. In some cases, users who are prevented from applying alternative herbicides during the period when those herbicides are effective may also see some increase in yield.

- Flumiclorac pentyl will fit into Integrated Pest Management (IPM) programs since its use will be in areas where velvetleaf and common lambsquarters are specifically being targeted as pests. It will also serve as a valuable tool for triazine, sulfonylurea, and imidazolinone weed resistance management in corn and soybeans.

MISSING DATA: Data gaps currently exist for the following:

Soybean Forage Residue Data
Soybean Hay Residue Data

NOTE: The residue data for soybean forage and hay are new requirements that result from the recently published Table II of the Pesticide Assessment Guidelines, Subdivision O, Residue Chemistry. We believe that we have adequate data to make a regulatory decision for a conditional registration.

HIGHLIGHTS OF SCIENCE REVIEWS:

TOXICOLOGY:

- CHRONIC TOXICITY/ONCOGENICITY: A one-year chronic study in dogs resulted in a No-Observed-Effect-Level (NOEL) of 100 mg/kg/day for systemic toxicity. A 79-week oncogenicity study in mice resulted in a NOEL of 300 ppm for systemic toxicity in males and 7000 ppm in females. A combined chronic toxicity/carcinogenicity study in rats resulted in a NOEL of 1000 ppm for systemic toxicity in males and 20,000 ppm in females. There was no evidence of carcinogenicity in these studies.

- TERATOLOGY/REPRODUCTIVE TOXICITY: Developmental toxicity studies were performed on rabbits and rats, and a two-generation reproduction study was performed on rats. There was no evidence of major developmental or reproductive toxicity in any of the studies.

- MUTAGENICITY: In a micronucleus study in mice, no significant differences in the frequency of micronucleated cells were noted in the bone marrow cells of the treated animals. In an in vitro unscheduled DNA synthesis assay performed on rats to examine other genotoxic effects, unscheduled DNA synthesis was not elicited in primary cultures of rat hepatocytes.

- METABOLISM: Metabolism studies in rats resulted in essentially all of the administered dose being eliminated within two days of dosing.

- CARCINOGENIC CLASSIFICATION: This chemical has been classified as a Group E carcinogen (no evidence of carcinogenicity).

- DIETARY EXPOSURE: The Reference Dose (RfD) has been established at 0.35 mg/kg/day. The Theoretical Maximum Residue Concentration (TMRC) for the general population is estimated to be 0.001005 mg/kg body weight/day, which is less than 1% of the RfD. The TMRC for the most exposed subgroups are 0.000012 mg/kg body weight/day for non-nursing infants (less than one year old) and 0.000009 mg/kg body weight/day for children (one to six years old). Therefore, minimal risk is expected from chronic dietary intake since the RfD is not exceeded for either the general population or any subgroup.

RESIDUE CHEMISTRY:

- Tolerance levels are proposed as follows:

Corn, field, grain	0.01 ppm
Corn, field, fodder	0.01 ppm
Corn, field, forage	0.01 ppm
Soybean, seed	0.01 ppm

  The tolerance level for each commodity is expressed in terms of the parent only which serves as an indicator of the use of flumiclorac pentyl on these raw agricultural commodities.

- Analytical method - gas chromatography with a thermionic-specific detector

ENVIRONMENTAL FATE:

Flumiclorac pentyl is not expected to contaminate groundwater. Acceptable data show that parent flumiclorac pentyl is not persistent or mobile. It hydrolyzes and metabolizes within hours or days into a number of degradates. Although the major degradates can

be characterized as mobile, their relative instability greatly reduces the likelihood of their movement to groundwater.

ECOLOGICAL EFFECTS:

- Practically non-toxic to birds, mice, rats, and honey bees
- Slightly toxic to fish
- Highly toxic to shrimp - Labeling will be required in connection with Environmental Hazards to prohibit aquatic applications and to state that "This product/pesticide is toxic to shrimp."
- Minimal risk is expected from the parent material or from the degradates to nontarget plant species.

RECOMMENDATION:

Available data provide adequate information to support the conditional registrations of Flumiclorac Pentyl Technical and Resource Herbicide for use on field corn and soybeans.

I recommend that you concur with the conditional registration of this new chemical herbicide under Section 3(c)(7)(C) of the Act.