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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

FEB - 3 1992

MEMORANDUM

SUBJECT: Update of the Status of Registration of the New Chemical Facet (Quinclorac)

FROM: Anne E. Lindsay, Director
Registration Division (H7505C)

TO: Douglas D. Campt, Director
Office of Pesticide Programs (H7501C)

This is a follow-up to our previous memos on registration of quinclorac. An update of the status of this registration follows:

1. BASF submitted a revised label on January 9, 1992 bearing a restriction pertaining to aquaculture. All residue chemistry requirements are satisfied.

2. All product chemistry requirements have been satisfied except a revised Confidential Statement of Formula based upon analysis of actual production lots. The company has been notified of this requirement. The Agency is awaiting submission of these data.

3. The review of the data submitted to the Toxicology Branch in support of the developmental toxicity study in rabbits, two generation rat reproduction study and mutagenicity studies have been completed. These data are acceptable and satisfy data requirements.

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4. The data requested by the Toxicology Branch for the 2-year chronic/oncogenicity study in rats have been submitted. These data included the microslides of the pancreas of the rats in the study, BASF's pathologist report of the evaluation of the pancreas from all animals in the intermediate dose groups, and a report summarizing the complete evaluation of the pancreas. On December 18, 1991, the chemical Facet (quinclorac) was reviewed by the HED Peer Review Committee. Quinclorac has been tentatively categorized by the Peer Review Committee as a Group C carcinogen without quantification based on an increase in pancreatic tumors. The dietary risk assessment will be based on the RFD. Finalization of the Peer Review Document awaits sign-off by those outside HED. Since this is a new food use pesticide, normally SAP reviews the toxicological data. The registration of quinclorac requires a food additive tolerance (409) of 15 ppm because quinclorac concentrates in rice Bran. Since this is a Group C carcinogen without quantification a decision will have to be made on how our de minimis risk policy applies.

5. The Ecological Effects review was completed on October 15, 1991. A previous review dated July 16, 1989 stated that all data requirements except Tier II Nontarget Plant Testing were satisfied. The results of the Tier II nontarget plant testing have triggered the requirement for testing terrestrial species at the Tier III level. Because the Agency has no protocols developed for Tier III testing this requirement will be reserved until the protocols are developed. The company has been notified of this requirement.

6. The Environmental Fate and Groundwater review was completed November 7, 1991. In summary, this review concludes the following:

   a. The following data requirements are satisfied:

      1) Hydrolysis (161-1)

      2) Photodegradation in Water (161-2)

      3) Photodegradation in Soil (161-3)

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4) Aerobic Soil Metabolism (162-1)

5) Leaching and Adsorption/Desorption (163-1)

6) Accumulation in Fish (165-4)

b. The following data requirements are not satisfied and remain as data gaps:

1) Anaerobic Aquatic Metabolism (162-3)

2) Aerobic Aquatic Metabolism (162-4)

3) Aquatic Field Dissipation (164-2)

4) Confined Accumulation in Rotational Crops (165-1)

5) Accumulation In Irrigated Crops (165-2)

6) Droplet Size Spectrum (201-1)

7) Drift Field Evaluation (202-1)

The company has been notified of these deficiencies and given a copy of the review discussing them. The PM has met with the Environmental Fate and Groundwater Branch and discussed the deficiencies stated in the review.

During the meeting between the PM and the EFGWB the possibility of a conditional registration was discussed. The product "Facet" is an aquatic herbicide for use in rice. The Anaerobic Aquatic Metabolism, Aerobic Aquatic Metabolism, Aquatic Field Dissipation, and Accumulation in Irrigated Crops studies are pivotal data in the evaluation of the soil chemistry for this active ingredient. Therefore, these studies must be submitted and evaluated prior to the registration of this aquatic herbicide.

The Agency has issued conditional registrations, previously, on a case-by-case basis, for the confined accumulation in rotational crops, the droplet size spectrum, and drift field evaluation studies.

On December 10, 1991 BASF representatives met with the Environmental Fate and Groundwater Branch. During this meeting BASF outlined the time schedule for the completion and submission of the required data.

On December 23, 1991 the Agency met with BASF representatives to discuss the present status of the Facet registration. BASF was requested to submit to EPA in writing, the reasons they believed their data supports a conditional registration and any additional data that could have an impact on our decision. Pursuant to our meeting BASF submitted their written response to the Agency in their letter of January 9, 1992. This response contained no additional data. Data previously submitted on a non-aquatic site indicate that the chemical can persist for a long period of time. In data submitted on an aquatic site, the EFGWB and BASF agree that those residues of the parent solubilized in the floodwater are degraded through photolysis. No data has been submitted to date that addresses the fate and transport of other residues of the parent and its degradates in the soil profile. If Facet or its degradates are not bound to the soil matrix, they may in fact be dissipating by leaching through the soil and may contaminate ground water. The available data does not shed any light on the fate and transport of the chemical in the soil under aquatic conditions (i.e., a flooded rice paddy). Until additional data are submitted the environmental fate and transport of Facet in the environment can not be fully accessed. The company is being notified of these findings.

7. BASF submitted a public interest statement in support of the conditional registration of Facet. BASF stated that Facet is effective in controlling grass weeds such as barnyardgrass, crabgrass, broadleaf signalgrass and junglerice and economically important broadleaf weeds such as eight morningglory species, sesbania, northern jointvetch and eclipta. BASF also stated that Facet's residual efficacy of preemergence or preplant incorporated applications allow rice producers to use ground equipment (versus aerial) and reduce multiple applications. This decreases application costs and lessens the potential for off-target movement (drift) of herbicides. They also stated that Facet can be applied to dry soil without loss from volatility.

The public interest statement submitted by BASF was reviewed by the Biological and Economic Analysis Division (BEAD). BEAD found quinclorac to have a broader weed spectrum, more flexibility in application timing, and both contact and residual weed control when compared to the currently registered herbicides in rice.

The total amount of active ingredient and number of required applications would also be decreased with the use of quinclorac. In order to maintain control of the full weed spectrum and recurring weeds, current rice herbicide application frequencies range from 2 to 6 times per season, and the rates range from 4 to 10 lbs. a.i./A. This is in contrast to quinclorac rates of 0.25 to 0.75 lb. a.i./A per season. This combination of reduced rates and fewer passes over the fields results in a cost savings for the grower.

Quinclorac is likely to partially displace both propanil and molinate, the standard herbicides in rice, both of which have grower and Agency concerns. Propanil resistant barnyardgrass has been documented in Arkansas and is the basis for their 1991 Section 18 request for quinclorac. Barnyardgrass is the number one weed problem in rice and propanil has been the preferred control. Molinate is currently being considered for Special Review due to worker exposure concerns over cholinesterase inhibition. No viable alternatives exist for its mid-season control of barnyardgrass.

The southern rice producing states have been granted Section 18's for either bromoxynil and/or triclopyr, since the late 1980's. The availability of quinclorac (via either conditional registration or Section 18) will likely eliminate the need for one or the other of the two aforementioned Section 18 chemicals. Four of the five southern rice producing states have notified the Agency of their intent to apply for Section 18's for quinclorac on rice. Some states are applying for quinclorac instead of bromoxynil; it can control the resistant barnyardgrass along with some of the broadleaf weeds. Some states will apply for all three chemicals due to unique weed pressure on different acreage.

8. In summary, once all environmental fate and groundwater questions are resolved, a decision on the registrability of this chemical in accordance with the Delaney Clause, will be required, based on its tentative Group C carcinogenic classification.

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