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FileU. S. ENVIRONMENTAL PROTECTION AGENCY
Washington, D.C. 20460OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

January 27, 2000

TRANSMITTAL MEMO

SUBJECT: New Chemical: Clodinafop 2E Herbicide (HORIZON)
Chemical: 125203/ Company: 000100 Novartis Crop Protection
DP Barcode: D244333/D246816

FROM: John Jordan, Ph.D. (7507C) *John Jordan*
Microbiologist
Environmental Risk Branch III/EFED

Stephen Carey (7507C) *Stephen Carey 1/27/00*
Biologist
Environmental Risk Branch III/EFED

THRU: Daniel Rieder, Chief (7507C) *Daniel Rieder*
Environmental Risk Branch III/EFED

TO: Susan Stanton (7505C)
PM-23 Team Reviewer
Herbicide Branch/RD

The Environmental Risk Branch III has completed the risk assessment review for clodinafop 2E Herbicide. The environmental risk assessment and characterization for the active ingredient and safener science chapters are attached. The herbicide review is placed in order, starting with: cover memo; environmental risk conclusions; introduction; and integrated environmental risk characterization. Also, included are the active ingredient and safener science chapter, each with its appendices.

The cover memo identifies the outstanding data needs and the precautionary label statement recommendations. Note that while the data and information needs, identified, are important there was adequate data for EFED to complete an assessment of the potential environmental and ecological risks and to support a regulatory decision.



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EFED needs additional information from the registrant on the structural similarity of clodinafop propargyl to other acetyl-coenzyme A carboxylase inhibitors, specifically the aryloxyphenoxy propionate chemical class. The structural similarity information could provide information on the potential for untested degradates, e.g., CGA-193469, to be phytotoxic.

There is some other information that the registrant may be able to provide that would be of value to EFED. For example, what is the mechanism of action for the "inert" safener? We need to know if the safener provides some measure of protection to plant species other than wheat. If the safener does provide protection to other species, the toxicity studies would underestimate the toxicity of Horizon that could be expected from sheet and channel runoff.

DATA REQUIREMENTS

Environmental Fate: The five new studies listed below are needed for a complete risk assessment of Horizon.

Clodinafop propargyl

Some new studies are required; the value added is high, because these studies are basic data requirements for the parent. The registrant should be informed that in order to produce acceptable studies, the analytical methods should be improved to be able to quantify the parent and degradates in support of the low use rates.

161-1 - Hydrolysis: MRID: 443991-69 - a new study is required because the present one was conducted at elevated temperatures and too short a duration to determine whether degradation would occur.

161-2 - Photolysis in Water: MRID: 443991-70 - a new study using sunlight or a xenon lamp is required- the present study used a mercury light source which is unacceptable.

162-2 - Anaerobic Soil Metabolism: 443991-76 - a new study with an initial aerobic incubation period of approximately 4 - 5 days is required. The present study used an initial aerobic incubation period of 28 days and most of the parent dissipated before the anaerobic phase was initiated.

163-1 - Adsorption/Desorption: MRID:443991-81- a new study is required using a U.S. wheat belt soil of < 1% organic matter (O.M.), because the current studies were conducted on soils with higher organic matter contents.

164-1 - Field Dissipation: MRID:443991-84- a new study is required for the parent (ai), and the two degradates CGA-193469, and CGA-302371. The present study was conducted on a foreign soil, and, also, the analytical method detection and quantification levels were too high to detect and quantify the parent and degradates. The study must be conducted in the U.S. wheat belt on a typical "wheat" soil either in Montana, North Dakota, South Dakota, or Minnesota.

Upgradable studies

162-1 - Aerobic Soil Metabolism: MRID:443991-72,73,74 and 76. These studies were conducted with foreign soils with an organic matter content greater than some US wheat growing soils. Furthermore, due to the use of exaggerated application rates to enable detection and quantification these studies are supplemental, because the use of exaggerated application rates may significantly distort the DT_{50} . However, the registrant may be able to upgrade the studies by reanalyzing the data using a non-first order model and making some comparisons with US soils. If MRID: 443991-72 and 73 are upgraded then the two together will satisfy the data requirement; if not, a new study is required.

Degradates of Clodinafop propargyl CGA-193469 and CGA-302371

New studies are required for both degradates. The value added is high, because the parent degrades rapidly in metabolism studies to form the (above) degradates at greater than 10%.

162-1 - Aerobic Soil Metabolism

162-2 - Anaerobic Soil Metabolism

163-1 - Adsorption\Desorption: MRID-888888-01 (CGA-193469) and MRID-888888-01 (CGA-302371). An additional study is required using a U.S. wheat belt soil of < 1% O.M., because the current studies were conducted on soils with higher organic matter contents. The guidance regulations specify that one of the four ads\des studies must be conducted on a soil with <1 % OM.

Cloquintocet Mexyl

The following studies did not fulfill the data requirements, however, the value added of submitting new studies is low.

162-1- Aerobic Soil Metabolism: MRID:443874-45, 46. There was inadequate sampling during the first seven days of the study.

162-3 - Anaerobic Soil Metabolism: MRID:443874-47. The aerobic incubation period of 28 days was too long; only 3.8 and 6.6 % of the applied radioactivity was present as c. mexyl and CGA-153433 at the initiation of the anaerobic study after 28 days of aerobic incubation.

164-1- Field Dissipation: MRID:443991-84. Detection and quantification limits are too high to

accurately determine the dissipation of low application chemicals.

Ecological Effects: Data gaps exist for the following guidelines:

Clodinafop propargyl

71-4 Avian reproduction: Subdivision E requires two avian reproduction studies for a complete risk characterization of the active ingredient, but the requirement is only partially fulfilled due to the unacceptable mallard study (MRID# 443991-11). The total numbers of eggs laid and eggs laid per hen were reduced in the control group and that the possibility of determining statistically significant effects in the treatment levels were not likely. The value of repeating the mallard study in order to completely assess adverse effects to avian reproduction is "low", because the results of the three acute studies suggest that the bobwhite quail may be more sensitive than the mallard and the low peak exposure concentrations -- even on short grass (15 ppm). If the application rates are raised to 2.0 lbs ai/A or greater (resulting in peak short grass residues of 480 ppm), the value added would be "high".

Degradate of Clodinafop propargyl (CGA-193469)

123-1(a)Seedling Emergence/122-1(b) Vegetative Vigor: The parent degrades rapidly in the soil and yet weed control is presumed to be required for longer duration than the initial application. Since the degradate is persistent in the environment and presumed to control the active weeds because of the longer duration, the full battery of species (ten) must be conducted on the degradate of active ingredient without the safener. The value added is high since during or after application the safener may not be present to protect non target plants. Furthermore, EFED wishes to know whether future uses will require different amounts of safener.

LABELING RECOMMENDATIONS

EFED recommends that the Environmental Hazard labeling for clodinafop 2E Herbicide include the following:

End Use Product: Do not apply directly to water or to areas where surface water is present or to intertidal areas below the mean high water mark. Do not contaminate water when disposing of equipment washwater or rinsate.

Manufacturing Use Products: Do not discharge effluent containing this product into lakes, streams, ponds, estuaries oceans or other waters unless in accordance with the requirements of a National Pollutant Discharge Elimination System (NPDES) permit and the permitting authority has been notified in writing prior to discharge. Do not discharge effluent containing this product to sewer systems without previously notifying the local sewage treatment plant authority. For guidance contact your State Water Board or Regional Office of the EPA.