Shaughnessy No.: 128201

Date Out of EAB: 17 SEP 1984

To: Robert Taylor
Product Manager 25
Registration Division (TS-767)

From: Samuel Creeger, Chief
Review Section #1
Exposure Assessment Branch
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Attached, please find the EAB review of...

Reg./File # : 352-EUP-114 and -115

Chemical Name: DPX Y6202

Type Product : Herbicide

Product Name : Assure

Company Name : DuPont

Purpose : Data to support modification of rotational crop restriction

ZBB Code : other

EAB #(s) : 4483-4

Action Code(s): 714

TAIS Code: 52

Date Received: 8/1/84

Total Reviewing Time: 2.0 days

Date Completed: 9/14/84

Deferrals to:

_____ Ecological Effects Branch

_____ Residue Chemistry Branch

_____ Toxicology Branch

1.0 INTRODUCTION

DuPont has submitted data in accession #253781 to support a requested modification of the existing 18 month rotational crop restriction for their Assure herbicide (DPX Y6202) under the two current EUPs (352-EUP-114 and -115)

2.0 STRUCTURE

See previous reviews.

3.0 DIRECTIONS FOR USE

A copy of the proposed label is appended to this review. Briefly, the label content appears virtually identical to that reviewed earlier. There is still no rotational statement of any kind, and no crop-destruct clause.

4.0 REVIEW OF SUBMITTED DATA

Koeppe, Mary K. 1984. Crop Rotation Study with ^{14}C-DPX-Y6202 in the Greenhouse. Document No. AMR-218-84 (company confidential) E.I. DuPont de Nemours and Company, Inc. Agricultural Chemicals Department, Research Division, Experimental Station, Wilmington, DE. (undated) 12 pages, 6 tables, 5 figures, 2 references.

4.1.1 Introduction

The rate of uptake of DPX-Y6202 (as well as level of radioresidues) in various crops was evaluated in a sandy loam soil in the laboratory.

4.1.2 Experimental

The DPX-Y6202 used in this study, labeled in the quinoxaline portion of the molecule was found to have a specific activity of 13.9 uCi/mg with a radiochemical purity of about 97% (method of evaluation unspecified). Structures for parent and possible degradates are summarized in report figure 1, appended to this review.

Characteristics of the Sassafras Sandy Loam soil used in this study are summarized in report a table 1, appended to this review. The method of processing this soil from the field (screening, measurement of water-holding capacity, etc.) was not discussed in the report. Aliquots of the soil were added to each of 4- 16" diameter red clay flower pots. The computed surface area (1.216 ft^2), apparently based on a diameter of 14.9", is equivalent to 2.8×10^{-5} acres.

A stock solution was prepared by dissolving 11.8 mg of the analyte in 20 ml acetone, then making it QS to 200 ml with distilled water. Fifty ml aliquots of this solution were evenly distributed over the surface of each of the four pots. The equivalent application rate was computed to be 3.6 oz. ai/A, as follows:

$$\frac{11.8 \text{ mg} \times .97 \text{ (purity)} \times 50 \text{ ml/pot}}{200 \text{ ml}} = \underline{2.86 \text{ mg/pot}}$$

$$\frac{2.86 \text{ mg ai/pot} \times 1 \text{ gm}/1000 \text{ mg} \times 1 \text{ lb}/454 \text{ gms}}{2.8 \times 10^{-5} \text{ Acres/pot}} = \underline{0.225 \text{ lb ai/A}}$$

$$0.225 \text{ lb ai/A} \times 16 \text{ oz/lb} = \underline{3.6 \text{ oz ai/A}}$$

The pots were reportedly maintained in large plastic "saucers" to "prevent escape of the radioactivity from the test system," and hand watered during the 120 day aging period to maintain moisture content (method of determination of moisture content, if any, was not reported). How the saucers prevented escape of radioactivity was not specified.

At the end of the 120 day aging period, pots were seeded with barley, cotton, beets and peanuts, respectively. Soil cores were taken at planting and at crop maturity. No soil samples were taken on the day of application. Plant samples were taken at 15-day intervals. Crops were harvested on days 45, 165, 186 and 231 (all days +120 days aging), respectively.

Total radioresidues were determined as follows. Soil samples were air-dried, pulverized and combusted in an Oximat Oxidizer. Evolved CO_2 was trapped in Oxifluor and counted by LSC. Vegetative samples were freeze dried, combusted, radio CO_2 trapped in Oxyprep-2, and quantified by LSC counting.

Characterization of plant radioresidues (for those plants whose total radioresidues exceeded 0.01 ppm as DPX-Y6202 equivalents) involved multiple methylene chloride:acetone (1:1, v:v) and acetone:ethanol:water (1:1:1, v:v:v) extractions, centrifugation and filtration. Pooled extracts were counted by LSC in 10 ml of Formula-947. Remaining (extracted) plant tissue was combusted and evolved/trapped CO_2 counted by LSC to determine total unextractable residues.

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Aliquots of the pooled extracts were concentrated in a rotary evaporator, spotted on fluorescent TLC plates and chromatographed against known standards (figure 1) with toluene:acetone:methanol: acetic acid (150:50:5:1, v:v:v:v). Spots were quantified using a Berthold TLC Linear Analyzer. Unlabeled spots were visualized by UV light. TLC analysis of peanut meat could not be performed due to the abundant oils present.

Soil residues were similarly processed, and component radioresidues TLC isolated and quantified.

Neither copies of TLC plates nor raw counting data were submitted with this study for EAB evaluation.

Results and Discussion

Total radioresidues are summarized in report table II, appended to this review. Residues, computed on a fresh weight basis did not exceed 0.01 ppm at any time during the growth period for barley (straw and grain), beets (foliage and roots) and cotton (foliage, fiber and seeds). Residues in mature peanuts were 0.031, 0.054 and 0.017 ppm for the foliage, shell and meat, respectively.

Soil radioresidue data are summarized in report table IV, appended. It is unclear how this data can be related to plant uptake in the absence of day-of-application data.

Due to the low level of total radioresidues, no identification of specific components was apparently possible.

4.1.3 Conclusions

This study appears to be scientifically valid, but incomplete.

Total radioresidues resulting from an application of 3.6 oz ai/a under confined conditions did not exceed 0.01 ppm in any plant component of barley (straw and grain), beets (foliage and roots) and cotton (foliage, fiber and seeds). In mature peanuts, radioresidues were detected at a very low levels in the foliage, shell and meat, at 0.031, 0.054 and 0.017 ppm, respectively. Due to the low level of total radioresidues, no identification of specific components was apparently possible.

Soil radioresidues for samples taken at day 120 and thereafter at the time of crop harvest were reported but could not be evaluated due to the lack of day 0 sampling.

This study was not conducted under conditions of maximal usage. Based on the label-recommended application rate for perennial grasses (quackgrass --- 70 fl. oz. in applications of 40 and 30 fl.oz.), Assure® may be applied at up to 7.0 oz ai/acre which is nearly twice the rate tested.

$$\frac{70 \text{ fl.oz.}}{\text{Acre}} \times \frac{1 \text{ gallon}}{128 \text{ fl.oz.}} \times \frac{0.8 \text{ lb ai}}{\text{gallon}} \times \frac{16 \text{ oz}}{\text{pound}} = 7.0 \text{ oz ai/acre}$$

In addition neither raw data nor sample chromatograms were submitted for EAB evaluation.

5.0 CONCLUSIONS

This study cannot be accepted in support of the rotational crop data requirement until the deficiencies noted in §4.1.3 have been satisfactorally addressed.

Assuming that the study is rerun at the higher application rate, then residues in plant material should be high enough for identification of specific components, which is an important part of this data requirement.

6.0 RECOMMENDATION

6.1 The registrant should be requested to respond to the deficiencies noted in §4.1.3 of this review.

6.2 Based on a review of the EAB files, we note that the registrant has not yet responded to the deficiencies found in the aerobic soil metabolism studies (AMR-126-83 and AMR-146-83) reviewed on 7/19/83 and 1/26/84, respectively. They should be requested to provide an appropriate response before requesting any additional modification to the EUP labelling.

Emil Regelman
Chemist
EAB/HED
September 14, 1984