Shaughnessy No.: 128201

Date Out of EAB: AUG 23 1985

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

From: John H. Jordan, Chief (acting)
Review Section #3
Exposure Assessment Branch
Hazard Evaluation Division (TS-769)

Attached, please find the EAB review of...

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

Chemical Name: DPX Y6202

Type Product : Herbicide

Product Name : Assure

Company Name : DuPont

Purpose : EUP: Use on Cotton and Soybeans (resubmission)

Action Code(s): 715

EAB #(s) : 5391, 5392

Date Received: 2/20/85

TAIS Code: 51

Date Completed: 8/2/85

Total Reviewing Time: 1.2 days

Deferrals to: Ecological Effects Branch

Residue Chemistry Branch

Toxicology Branch

1. CHEMICAL: DPX Y6202, Ethyl 2-[4[(6-chloroquinoxalin-2-yloxy-phenoxy] propanoate, DuPont Assure (R) Herbicide

2. TEST MATERIAL: [Quinoxaline-phenyl-^{14}C(U)]-DPX-Y6202

3. STUDY/ACTION TYPE: Response to EAB review of 9/17/84.

4. STUDY IDENTIFICATION: Koeppe, Mary K. 1984. Crop Rotation Study With ^{14}C-DPX-Y6202 in the Greenhouse. Document No. AMR-218-84, Revision 1, Experimental Station, Research Division Agricultural Chemicals Department, E. I. DuPont. (company confidential). January 4, 1985.

5. REVIEWED BY:

Emil Regelman
Chemist
EAB/HED/OPP

Signature: Emil Regelman

Date: 8/2/85

6. APPROVED BY:

John H. Jordan
Chief (acting)
Review Section #3, EAB/HED/OPP

Signature: John H. Jordan

Date: 8/12/85

7. CONCLUSIONS:

The registrants response to the deficiencies cited in the EAB review of 9/17/84 was inadequate to resolve all issues. It seems unlikely to EAB that further responses based on this study will be fruitful, considering the unavailability of day-zero soil sampling and low initial application rate.

8. RECOMMENDATIONS:

The registrant notes that another study is currently under way at the maximum rate of application which should satisfactorily address EAB's concerns with respect to all issues raised.

EAB awaits this additional study for its consideration.

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9. BACKGROUND:

A. Introduction

On 9/17/84, EAB completed its review of the study noted in section 4, above and drew the following conclusions with respect to that study:

> 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 level 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 (R) may be applied at up to 7.0 oz ai/acre which is nearly <u>twice</u> the rate tested.
>
> In addition neither raw data nor sample chromatograms were submitted for EAB evaluation.

EAB's conclusions with respect to the confined accumulation data requirement were as follows:

> This study cannot be accepted in support of the rotational crop data requirement until the deficiencies noted in (section) 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.

The current submission (Accession # 256477) is DuPont's response to the above conclusions.

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B. Directions for Use

See review of 9/17/84.

10. DISCUSSION OF INDIVIDUAL TESTS OR STUDIES:

A. Study Identification:

Koeppe, Mary K. 1984. Crop Rotation Study With ^{14}C-DPX-Y6202 in the Greenhouse. Document No. AMR-218-84, Revision 1, Experimental Station, Research Division Agricultural Chemicals Department, E. I. DuPont. (company confidential). January 4, 1985.

B. Response to Previous Review:

ISSUE: Characterization of day 0 Soil Sampling

DuPont: No day zero sampling done. Day 0 sampling from another ongoing study at 8 oz. ai/A submitted which demonstrate excellent recovery.

EAB Response: We were concerned about the day 0 sampling in the original study to confirm the original application rate, not the efficiency of recovery. The lack of this data from the original study, especially in light of the very low residues found in the crops which were monitored, strongly contributed to our doubts about the validity of the remaining submitted data. Therefore, DuPont's response does not satisfactorily address our concerns with respect to this issue.

ISSUE: Absence of Representative Raw Data

DuPont: Sample combustion data may be found in report table III.

EAB Response: The sample raw combustion data representing quadruplicate analyses appears to be adequate. EAB considers this issue to be resolved.

ISSUE: Absence of Sample Chromatograms

DuPont: Sample radiochromatogram may be found in report figure 6.

EAB Response: The radiochromatogram submitted in report figure 6 appears to be excessively noisy. We do not understand how data on parent compound or major degradates can be derived from such a tracing.

This issue remains unresolved.

E. Reviewer's Discussion and Interpretation of Study Results

Due to the low original application rate and failure to monitor soil residues on day zero, this submitted study remains unacceptable in support of the confined accumulation in rotated crops data requirement.

11. COMPLETION OF ONE-LINER:

No additional data have been added to the ongoing one-line data summary.

12. CBI APPENDIX:

There is no CBI appendix.

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