Read

3-4-94

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

MAR 4 1994

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

MEMORANDUM

SUBJECT: Thidiazuron. Storage Stability in Cottonseed. List D Chemical No. 120301. Case No. 4092. MRID No. 42847601. CBRS No. 12921. DPBarcode D195636.

FROM: Felecia A. Fort, Chemist
Reregistration Section II
Chemistry Branch II: Reregistration Support
Health Effects Division (H7509C)

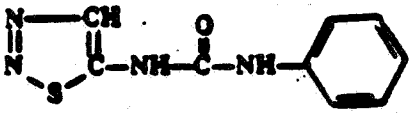
THRU: William J. Hazel, Ph.D., Section Head
Reregistration Section II
Chemistry Branch II: Reregistration Support
Health Effects Division (H7509C)

TO: Bill Wooge/Kathryn Davis PM-52
Accelerated Reregistration Branch
Special Review/Reregistration Division (H7508W)

NOR-AM Chemical Company has submitted storage stability studies for residues of thidiazuron in or on cottonseed. Storage stability studies were required in the Thidiazuron Phase 4 review dated 2/2/93 and the subsequent Data Call-In.

Thidiazuron (N-phenyl-N'-1,2,3-thiadiazol-5-ylurea) has one registered use as a cotton defoliant. In Phase 3 the registrant committed to conduct additional studies to fulfill requirements of nature of the residue-animals, residue analytical methods-animals, storage stability, and magnitude of the residue in meat and milk. On 9/22/93, CBRS (Greybeard Committee) denied a waiver of the requirement of magnitude of the residue in poultry and eggs.

The structure of thidiazuron is shown below.



Background

Currently, the combined residues of thidiazuron and its aniline containing metabolites are regulated. Tolerances ranging from 0.05 ppm to 0.4 ppm are established at 40 CFR 180.403 for residues in or on the fat, meat and meat by-products of cattle, goats, hogs, horses, poultry and sheep; cottonseed; eggs; and milk.

No storage stability data were previously submitted by the registrant. Cottonseed samples from field trials used to support reregistration were stored for up to 5 months at ambient temperatures and then stored frozen for up to 11 months.

Conclusions

1. The nature of the residue in plants has not been subjected to a full Phase 5 review. The residue of concern is tentatively, the parent, thidiazuron (Phase 4 review).

2. The storage stability of thidiazuron residues in/on cottonseed has not been adequately determined because of the nonspecificity of the method, high background levels of thidiazuron and because the conditions and duration of the cotton field trials (all of which must be repeated) are not yet known.

3. The analytical method used in this study is not adequate for data collection or enforcement because of the nonspecificity of the method (i.e. it will detect any aniline-containing moiety) and because background levels of aniline-containing compounds are quite variable and may exceed the residues contributed by thidiazuron.

Recommendations

This study is not acceptable because of the reasons stated in Conclusions 2 and 3 (above). The registrant must submit data collection and regulatory analytical method(s) for the determination of thidiazuron and its metabolites in/on plant matrices and then new storage stability studies must be conducted. We reiterate the conclusions reached in Phase 4, i.e. that cotton field trial data were unacceptable because of the method (nonspecific and high background) and other reasons. Therefore, we recommend that storage stability studies be conducted concurrently with the new field trials (reflecting analysis via a validated specific method) and that use of cottonseed bearing field-weathered residues be used.

Detailed Considerations

Cottonseed control samples were fortified with thidiazuron at 0.45 ppm and stored frozen for up to 4 years. No zero day analyses were conducted. A GC-ECD method was used which converts thidiazuron and its aniline containing metabolites to aniline. Any aniline containing moiety can be detected with this method. In Phase 4, it was concluded that this method was not adequate for data collection because of its nonspecificity and the high background levels of aniline. Control samples in the field trials reviewed during Phase 4 bore residues of 0.01 - 4.3 ppm. As a result, field trials were deemed inadequate as was the existing residue analytical methods-plants. Residues in control samples in the subject storage stability study ranged from 0.007 ppm to 0.079 ppm, i.e. significant residues. The table below shows the recoveries (storage stability) found at intervals up to four years.

Stability of Thidiazuron Under Frozen Conditions

Storage Interval (days)	Fortification (ppm)	% Recovery (Stored Fortification)[1]	% Recovery (Fresh Fortification)	Residues in Control Samples
61	0.45 ppm	93.8 98.9	98.0 95.7	0.020 ppm
95	0.45 ppm	77.3 70.2	60.3 72.4	0.079 ppm
125	0.45 ppm	92.9	95.1 96.9	0.076 ppm
153	0.45 ppm	96.7 100.4	88.5 88.9	0.007 ppm
1460	0.45 ppm	83.7 85.5 68.7	79.0 75.5	0.038 ppm

1. Sample recoveries were corrected for apparent residues in control samples and for recovery of check samples fortified on the day of analysis in the same analytical set.

cc: Reviewer(F. Fort), List D File, RF, SF, Circ.
RDI:WJHazel:2/15/94:MMetzger:3/2/94:EZager: 3/2/94
H7509C:CBRS:CM#2:Rm805B:305-7478:FAFort/FF:12/17/93
Disk4:thidiazu.sto