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

AUG 2 1996
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OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

MEMORANDUM

SUBJECT: Butylate. Storage Stability Data. Case No. 0071. Chemical I.D. No. 041405. CBRS No. 13412. DP Barcode D200681. 43093401

FROM: Felecia A. Fort, Chemist
Chemistry Pilot Review Team *F Fort*
Chemistry Branch II: Reregistration Support
Health Effects Division (7509C)

THRU: Randolph Perfetti, Ph.D., Acting Branch Chief *R Perfetti*
Chemistry Branch II: Reregistration Support
Health Effects Division (7509C)

TO: Paula Deschamp
Risk Characterization and Analysis Branch
Health Effects Division (7509C)

Attached is a review of storage stability data for butylate. The HED Chapter of the RED for Butylate was completed 8/5/93. This information was reviewed by Dynamac Corporation under the supervision of CBRS/HED. The data assessment has undergone secondary review in the Branch and has been revised to reflect Agency policies.

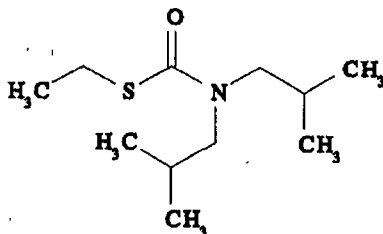
CBRS makes the following conclusions with respect to the submitted study:

- The data indicate that residues of butylate are stable in/on fortified milled corn grain under frozen (-20 ± 5 C) storage conditions for up to ~33 months (988 days). No additional storage stability data are required.
- These data confirm that the established tolerance level of 0.1 ppm for butylate residue in/on corn grain (field and pop) is appropriate.
- Although, no confirmatory storage stability data were submitted for corn forage and fodder, we believe that the reassessed tolerance levels of 0.1 ppm for these corn commodities are also appropriate based on available storage stability data for alfalfa. Guideline 171-4(e) is satisfied.

If you need additional information, please advise.

cc: Reviewer(F. Fort), (SRRD), Reg. Std. File, RF, SF, Circ.
RDI:Pilot Team:8/2/96:RPerfetti:8/2/96
7509C:CBRS:CM#2:Rm804S:305-7478:FAFort/FF:8/2/96
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BUTYLATE

ADDENDUM TO THE REREGISTRATION ELIGIBILITY DECISION:RESIDUE CHEMISTRY CONSIDERATIONS

Shaughnessy No. 041405; Case 0071

(CBRS No. 13412; DP Barcode D200681)

Task 2BBACKGROUND

The Residue Chemistry Science Chapter for the Butylate RED (CBRS No. 10957, DP Barcode D185286, P. Deschamp, 2/1/93) concluded that residues of butylate are stable in/on corn grain stored frozen for up to 1 year. Residues in corn grain stored for 2 and 3 years declined by ca. 50%. A portion of the samples of corn grain used to provide data supporting the established tolerances were stored for intervals in excess of 1 year. Reassessment of the 0.1 ppm tolerance includes the assumption that residues of butylate have declined 50% during storage. The registrant has been required (DCI dated 10/24/90) to submit the sample storage conditions and intervals for those samples deemed to be useful for tolerance reassessment. CBRS regards these data as necessary to confirm the adequacy of the 0.1 ppm tolerance for residues of butylate in/on corn.

In response to the DCI dated 10/24/90, Zeneca, Inc. submitted additional storage stability data (1993; MRID 43093401) depicting the stability of residues of butylate under frozen storage conditions for up to 3 years. These additional storage stability data are evaluated in this document.

The qualitative nature of the residue in corn is adequately understood; the parent butylate is the residue of concern. Corn is the only food/feed crop for which butylate is presently registered. The qualitative nature of the residue in animals is adequately understood based on studies with rats. Data for ruminant and poultry metabolism studies have not been required because of the limited potential exposure to residues of butylate in livestock feed items, and lack of evidence that terminal residues of butylate exist in laboratory animals. There is no reasonable expectation of finite residues of butylate in meat, milk, poultry, and eggs.

Tolerances for residues in/on corn commodities are expressed in terms of butylate *per se* [40 CFR §180.232]. No tolerances have been established for residues of butylate in animal commodities. Adequate enforcement methods are available for determination of residues of butylate in/on corn grain, forage, and fodder. The enforcement method (Method A of PAM Vol. II; Sec. 120.232) is a GLC method with microcoulometric detection for sulfur and a limit of detection of 0.04 ppm. There are no established or proposed Codex MRLs for residues of butylate; therefore, compatibility with respect to U.S. tolerances and Codex MRLs is not an issue.

CONCLUSIONS AND RECOMMENDATIONS

1. The submitted storage stability data indicate that residues of butylate are fairly stable in/on fortified milled corn grain under frozen (-20 ± 5 C) storage conditions for up to ~33 months (988 days). Acceptable recoveries (76.4-106.1%) were obtained from all storage intervals except at the 227-day interval (~8 month-interval) where recoveries ranged from 51.8% to 75.1%.
2. These data validate the frozen storage conditions and the 3-year maximum interval of samples from previously reported magnitude of the residue studies for corn commodities. Although the Residue Chemistry Science Chapter for the Butylate RED assumed a 50% residue decline in samples of corn grain, forage, and fodder stored for periods longer than 1 year, residues were not expected to exceed the established tolerance. These data confirm that the established tolerance level of 0.1 ppm for butylate residue in/on corn grain (field and pop) is appropriate.
3. Although no confirmatory storage stability data were submitted for corn forage and fodder, we believe that the reassessed tolerance levels of 0.1 ppm for these corn commodities are also appropriate based on available storage stability data for alfalfa. It had been reported (DP Barcode D165171, CBRS No. 8114, B. Cropp-Kohlligian, 9/18/91) that butylate is stable in/on alfalfa matrices under frozen storage conditions for up to 3 years. No additional storage stability data are required. Guideline 171-4(e) is satisfied.

DETAILED CONSIDERATIONS

Residue Analytical Methods

Samples from the storage stability study were analyzed for residues of butylate by Zeneca Ag Products (Richmond, CA) using capillary GC with nitrogen/phosphorous selective thermionic detector (STD). Briefly, samples of fortified and unfortified milled corn grain were slurried with water and extracted with toluene by blending in a tissue homogenizer. The extracts were centrifuged and the supernatant filtered through and collected in anhydrous sodium

sulfate. Aliquots were analyzed by capillary GC/STD. The GC was equipped with a fused silica capillary column bonded with methylsilicone with 6% cyanopropylphenyl stationary phase. It should be noted that this method is capable of detecting and quantifying residues of EPTC; however, only butylate residues will be reported in the present review. The limit of detection was 0.05 ppm.

The registrant provided concurrent method recoveries for corn grain by fortifying untreated control samples with butylate at 0.5 ppm. The concurrent method recoveries from corn grain samples are presented in Table 1. Raw data, sample calculations, and representative chromatograms were submitted. These recoveries indicate that the GC/STD method is adequate for quantitation of butylate residues in corn grain samples.

Storage Stability Data

Zeneca Inc. submitted data (1993; MRID 43093401) depicting the frozen storage stability of butylate residues in/on corn grain. Samples of corn grain were locally purchased and then milled, homogenized, and filtered through a 2-mm screen. The milled corn grain was composited and placed in glass jars with foil-lined lids; subsamples were fortified with butylate at 0.5 ppm. The fortified and non-fortified (control) samples were stored frozen at -20 ± 5 C for up to 3 years. Triplicate samples were extracted and analyzed in duplicate immediately after fortification, and after 6 days and 3, 8, 15, and 33 months of frozen storage.

Concurrent method recoveries of butylate from untreated samples fortified at the same levels as the storage stability samples were conducted at the time of analysis. Apparent residues of butylate in/on six control samples each were nondetectable (<0.05 ppm). The results of the storage stability study are presented below in Table 1.

Table 1. Storage stability and concurrent method recovery of butylate residues in/on corn grain fortified with butylate at 0.5 ppm and stored frozen at -20 ± 5 C.

Storage Interval (Days)	Residues in (ppm) ^a	Storage Stability Recovery (%) ^b	Concurrent Method Recovery (Average)
0	0.399, 0.402, 0.408, 0.410, 0.416, 0.429	--	79.9, 80.5, 81.6, 82.0, 83.2, 85.7, 87.8 (83.0; n=7)
6	0.406, 0.419, 0.425	101.4, 104.5, 106.1	80.2 (80.2; n=1)
112	0.357, 0.375, 0.376	77.0, 80.8, 81.1	92.4, 93.2 (92.8; n=2)
227	0.233, 0.281, 0.338	51.8, 62.6, 75.1	83.8, 88.1, 97.9 (89.9; n=3)
458	0.339, 0.347, 0.369	76.4, 78.3, 83.3	86.7, 88.4, 90.7 (88.6; n=3)
988	0.343, 0.344, 0.358	78.0, 78.2, 81.3	87.7, 88.5 (88.1; n=2)

^a Residues were not corrected for concurrent method recovery.

^b Storage stability recoveries were corrected by reviewer for average concurrent method recovery.

The submitted storage stability data indicate that residues of butylate are stable in/on fortified milled corn grain under frozen (-20 ± 5 C) storage conditions for up to ~33 months (988 days). Acceptable recoveries (76.4-106.1%) were obtained from all storage intervals except at the 227-day interval (~8 month-interval) where recoveries ranged from 51.8% to 75.1%.

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EPA MEMORANDA CITED IN THIS REVIEW

CBRS: 8114
 DP Barcode: D165171
 Subject: Review of Storage Stability Data for Butylate on Various RACs. MRID No. 418122-05. CBRS No. 8114; DP Barcode D165171.
 From: B. Cropp-Kohlligian
 To: L. Schnaubelt
 Date: 9/18/91
 MRID(s): 41812205

CBRS: 10957
 DP Barcode: D185286
 Subject: Butylate: List A Reregistration Case No. 0071. Product and Residue Chemistry Chapters for the Reregistration Eligibility Document (RED). CBRS No. 10957; DP BARCODE D185286.
 From: P. Deschamp
 To: E. Saito and L. Rossi/J. Loranger
 Date: 2/1/93
 MRID(s): None

MASTER RECORD IDENTIFICATION NUMBERS

The citation for the MRID document referred to in this review is presented below.

43093401 Herman, R.S. (1993) EPTC and Butylate: Storage Stability in Field Corn. Study No. EPTA-90-SS-01. Report No. RR 93-013B. Unpublished study conducted by Zeneca Ag Products (Richmond, CA) and submitted by Zeneca, Inc. (Wilmington, DE). 35 p.