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

JUL 5 1994

OFFICE OF  
PREVENTION, PESTICIDES AND  
TOXIC SUBSTANCES

MEMORANDUM

SUBJECT: Sodium Acifluorfen. Request for Time Extension. Reregistration Case  
No. 2605. Chemical No. 114402 No MRID # DP Barcode D204442  
CBRS #13925

FROM: Steven A. Knizner, Chemist   
Special Review Section I  
Chemistry Branch II - Reregistration Support  
Health Effects Division (7509C)

THRU: Andrew Rathman, Section Head   
Special Review Section I  
Chemistry Branch II - Reregistration Support  
Health Effects Division (7509C)

TO: Thomas Luminello, Jr., PM Team 52  
Special Review and Reregistration Division (7508W)

In the Phase 4 Review of sodium acifluorfen, the Agency required storage stability data for rice. BASF, the registrant, initiated a study in early 1992 to address this data gap. In the course of analyzing samples from this study, the registrant encountered difficulties with the analytical method and had to develop a new analytical method.

The registrant has submitted a proposed schedule for resubmission of rice magnitude of the residue study results (with samples analyzed by the new analytical method) and corresponding storage stability data. A time extension has been requested for completion of these studies (see page 3 for a timetable of events).

Recommendation

The registrant has requested a time extension for completion of rice magnitude of the residue studies and corresponding storage stability data. CBRS has no objections to granting the requested time extension. The proposed schedule for submission of data is acceptable. CBRS acknowledges that the granting of time extensions is under the purview of SRRD.



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### Detailed Considerations

On 5/17/94 representatives of BASF (Karen Blundell, Nancy Cargile, Thomas Nelson, and Jeffery Burkey) met with Thomas Luminello (SRRD), Andrew Rathman (HED, CBRS) and Steven Knizner (HED, CBRS) to discuss preliminary results for a storage stability study and analytical method development for sodium acifluorfen in rice and its processed commodities (see S.Knizner memo to Files dated 5/26/94).

The registrant provided a brief history concerning the companies (Rohm and Haas and Rhone-Poulenc) which produced sodium acifluorfen prior to BASF acquiring the product. The analytical methods developed for sodium acifluorfen and regulated metabolites (acifluorfen methyl ester, acifluorfen amine, and acifluorfen amine methyl ester) by the previous registrants were described, as well as a method developed by BASF for use on rice and its processed commodities. The BASF method was used to generate the data reported in MRIDs #42330604 and 42330605 (magnitude of the residue in rice and its processed fractions).

A review of the data in MRIDs #42330604 and 42330605 (S.Knizner, 12/9/93, CBRS #9996) concluded that pending receipt of storage stability data, the data provided support established tolerances for acifluorfen in/on rice grain and straw. The storage stability data for rice grain and straw must depict recoveries from grain and straw stored frozen for 268 days.

At the meeting, the registrant presented preliminary data from a rice grain storage stability study. In this study, percent recovery from samples fortified with acifluorfen and its methyl ester (designated ACI-NO<sub>2</sub>) and acifluorfen amine and its methyl ester (designated ACI-NH<sub>2</sub>) were not adequate ( $\geq 58\%$  recovery) following 5.5 months of frozen storage. The registrant was uncertain whether the low percent recoveries were due to instability of the compounds in frozen storage or analytical method problems.

The registrant modified the analytical method used to generate the data in the rice magnitude of the residue study. An additional step, consisting of soaking samples in 0.1 N NaOH prior to extraction, was added. This modification resulted in adequate recoveries for ACI-NO<sub>2</sub> in samples stored for up to 9 months, but recoveries for ACI-NH<sub>2</sub> were still not adequate. When the extraction scheme was further modified to include refluxing samples in 0.5 N NaOH prior to extraction, recoveries for ACI-NH<sub>2</sub> in samples stored frozen for 14 months were adequate.

BASF proposed using two extraction schemes to analyze rice and its processed fractions. The first, incorporating the soaking of samples in 0.1 N NaOH prior to extraction, would be used for analysis of samples for ACI-NO<sub>2</sub>. The second, using reflux of samples in 0.5 N NaOH prior to extraction, would be used for analysis of samples for ACI-NH<sub>2</sub>. CBRS agreed that this approach seems feasible.

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In their letter dated 5/20/94, the registrant proposed a schedule for resubmission of rice magnitude of the residue study results and corresponding storage stability data. This schedule is presented below.

CBRS has no objections to granting the requested time extension. CBRS notes that the granting of time extensions is under the purview of SRRD.

Completion Date

6/94	Initiation of Reanalysis of 1991 Rice and Processed Fractions Samples (samples are 32 to 34 months old)
9/94	Completion of reanalysis of 1991 Rice and PF Samples
11/94	Interim Storage Stability Data available (15, 17, 21 months) from On-Going Study
12/94	Meet with Agency to Discuss Results of Interim Storage Stability Data
2/95	Submission of Interim Storage Stability Report and RAC and PF Reports
3/96	Submission of Final Storage Stability Report to Agency

cc: S.F., circ., R.F., List B File, S.Knizner  
RDI: A. Rathman, 7/1/94 M.Metzger, 7/1/94 E.Zager, 7/1/94  
7509C:CBRS:CM#2:305-6903:SAK:sak:Acifluor:7/1/94