



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

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

12/18/01

MEMORANDUM

SUBJECT: **Sodium Acifluorfen.** Response to Registrant Comments Regarding the Product and Residue Chemistry Chapters of the Reregistration Eligibility Decision (Chemical I.D. No. 114402; DP Barcodes D278494)

FROM: Felecia A. Fort, Chemist
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The comments presented below by BASF Corporation are in response to the Health Effects Division's preliminary Human Health Risk Assessment and Disciplinary Chapters for the Reregistration Eligibility Decision (RED) Document for sodium acifluorfen. The following are the responses to the comments and errors noted in the Product and Residue Chemistry chapters (W. Hazel, 5/5/00, D252560) only.

Product Chemistry

- Registrant Comment.*** On page 3, EPA discusses the regulatory history of sodium acifluorfen as it pertains to the product chemistry which supports currently registered sodium acifluorfen products. The discussion is slightly in error. In actuality, Rohm and Haas Company was the first registrant of sodium acifluorfen. This first registration was granted for the Rohm and Haas product Blazer herbicide

in 1980. In 1987, BASF purchased the registration and data that supported that product. BASF contracted for the toll manufacture of the active ingredient at the Rohm and Haas facility in Bayport, Texas. Rohm and Haas has continued to toll manufacture the active ingredient for BASF under the Rohm and Haas process since the purchase and continues to produce sodium acifluorfen using that original manufacturing process. Under the requirements of PR Notice 87-7, BASF registered the sodium acifluorfen MUP that was produced at the Rohm and Haas facility so that product could be moved from Bayport, Texas to various BASF formulating facilities.

In 1984, Rhone-Poulenc registered its own sodium acifluorfen product, Tackle. Rhone-Poulenc used a slightly different manufacturing process; material was produced in a separate facility in Tennessee. In 1992, Rhone-Poulenc relinquished its sodium acifluorfen business and sold its database for sodium acifluorfen to BASF. Rhone-Poulenc no longer maintains any registrations for Tackle.

The product chemistry data base that BASF has submitted to EPA under the requirements of FIFRA '88, and that EPA has found to be acceptable, has been generated for material produced in the Rohm and Haas production facility.

HED Response. The regulatory history has been corrected based on the comments. [page 4]

2. **Registrant Comment** Bulk density packed should be 32.08 lb/ft³ (packed).

HED Response. The bulk density has been changed from 32.8 lb/ft³ to 32.08 lb/ft³ [page 3]

3. **Registrant Comment** 830.1750 Certified Limits. This study is required for a TGAI. The submitted study has been assigned MRID 41891203.

HED Response. Since the TGAI is also a manufacturing use product (MUP), the study is required. The requirements for certified limits, previously noted as being not applicable, are satisfied. [page 7]

4. **Registrant Comment** 830.1800 Enforcement Analytical Method. This study is required for a TGAI. The submitted study has been assigned MRID 41891202.

HED Response. Since the TGAI is also a manufacturing use product (MUP), the study is required. The requirements for the enforcement analytical method, previously noted as being not applicable, are satisfied. [page 7]

Residue chemistry

1. **Registrant Comment** BASF currently maintains registration for 6 end use sodium acifluorfen products. A sixth product, Conclude Xact (EPA Reg. NO. 7969-179), was registered by EPA on March 29, 2000.

HED Response. The list of end use products was changed to include Conclude Xact(EPA Reg. No. 7969-179) which was registered on March 29, 2000. It was erroneously omitted. [page 12]

2. **Registrant Comment** Under “Residue Analytical Methods,” the Agency suggests that the diazomethane used in the analytical method be replaced with an alternative methylating reagent. BASF has investigated numerous other methylating reagents (e.g., methanolic HCl) in this analytical procedure. However, only the diazomethane method produced satisfactory and reproducible results. In addition, the diazomethane is used as a dilute, ethereal solution. BASF recommends using the ethereal diazomethane method while employing standard safety practices to prevent safety incidents.

HED Response. Since the registrant has found no other methylating reagents to replace diazomethane, HED will no longer require a substitution. [page 18]

3. **Registrant Comment** Under “Method for determination of residues...”, the Agency states that no radiovalidation data have been submitted for the enforcement method (PAM II), and that these remain outstanding. BASF believes that the radiovalidation experiments are of little value based on the low residue situation that exists for sodium acifluorfen in seeds or grains. Residues of concern in the metabolism studies are at or below the limits of quantitation for the final analytes. BASF believes that the nature of the extraction scheme in the enforcement method is chemically reasonable for releasing any residues of concern. The metabolism studies have shown good extractability of the residues of concern in organic solvents such as methanol. The acetonitrile/aqueous acidic extraction techniques involved in the enforcement method are expected to be at least as efficient if not more so, compared to the metabolism extraction scheme. BASF believes radiovalidation would produce at best marginal data because of the low residue levels.

HED Response. HED concurs with the registrant that the requirement for radiovalidation of the analytical methods be waived based on the low residues found in metabolism and field trial studies.[page 18]

4. **Registrant Comment** In the paragraph that continues from page 16, the Agency states that the validated limit of quantitation of 2.05 ppm for rice straw (0.05 ppm for acifluorfen and acifluorfen methyl ester and 2.0 ppm for acifluorfen amine and its methyl ester). The Agency in addition states that this LOQ is above the level determined in the rice straw (<0.124 ppm). BASF disagrees with the claim of 2.0 ppm as the LOQ for acifluorfen amine and its methyl ester. In the method validation

report (MRID 44153801), it was shown that recoveries for acifluorfen, its methyl ester, acifluorfen amine, and its methyl ester were acceptable at the 0.05 ppm level. The recoveries for the amine metabolite were lower than the other compounds at $55 \pm 9\%$ (n=8), but the precision was good with a standard deviation below 10%. In addition, during the analyses of the crop field trial straw samples (MRID 43584502), concurrent recoveries of the amine metabolite at levels of 0.05 and 0.2 ppm ranged from 70-80% (five recovery samples run in total). BASF believes the limit of quantitation of 0.05 ppm for each analyte is appropriate.

HED Response. HED concurs that the limit of quantitation is likely less than 2.0 ppm for the acifluorfen amine and its methyl ester; however, the data does not support an LOQ of 0.05 ppm for the analyte. It is more likely somewhere between 0.05 and 0.1 ppm. No additional data will be required if this method will not be used as an enforcement method.[page 19]

5. ***Registrant Comment*** In a discussion of independent laboratory validation, the Agency states that radiovalidation data must be submitted before the method (D9205) can be considered acceptable for tolerance enforcement purposes. BASF is satisfied with having the current PAM II method used as the enforcement method. BASF also considers the extraction procedure in D9205 to be more exhaustive than the enforcement method, and thus has not confirmed the method by radiovalidation. The enforcement method uses an acetonitrile/acidic aqueous solvent for extraction. The data collection method first uses an aqueous basic soak followed by an acetonitrile/acidic aqueous solvent.

HED Response. Since the method will not be used as an enforcement method, an independent laboratory validation is no longer required.[page 19]

6. ***Registrant Comment*** In the discussion of the confined rotational crop study, EPA states that 14C-residues >0.1 ppm accumulated in/on all rotational crop commodities of chard, turnip, sorghum, wheat, and radish planted 39, 103, 145, 313, and/or 370 days following application. BASF believes that a typographical error was made, that the value should be 0.01 ppm, and that the statement should read “that 14C-residues >0.01 ppm accumulated in/on all rotational crop commodities of chard, turnip, sorghum, wheat, and radish planted 39, 103, 145, 313 and/or 370 days following application.

HED Response. The typographical error has been corrected.[page 21]

7. ***Registrant Comment*** The conclusion of this section states that based on the results of the confined rotational crop study (MRID 42785601), the labels for sodium acifluorfen should be amended to specify a 12-month plant back interval (PBI) for rotated crops, while a 6-month PBI would be acceptable for small grain crops. BASF does not agree that the labels should be amended to specify a 12-month plant back interval for rotated crops with a 6-month PBI allowed for small grain crops. BASF's opinion is based on the following considerations. Although total radioactive residues were found to be greater than 0.01 ppm for most of the samples, the individual residues of concern appear at a much lower concentration and would not be detectable with the current analytical methodology. In both the enforcement and data collection methodologies, residues of sodium acifluorfen, which include the acid and salt version of acifluorfen, the methyl ester of acifluorfen, the amine metabolite and

its methyl ester, are determined as a combination of two final analytes. In the enforcement method, all residues of concern are converted to either the methyl ester of acifluorfen or the heptafluorobutyric amide equivalent of the amine metabolite. In the data collection method, all residues of concern are converted to either the methyl ester of acifluorfen or the amine metabolite. The collective limit of quantitation (LOQ) for the final analytes sums to 0.1 ppm, 0.05 ppm per analyte. Because no quantifiable residues of acifluorfen are seen in most crop matrices (rice grain, peanut nutmeat, and soybeans), tolerances have been set at the 0.1 ppm LOQ value. Based on either the enforcement method or the residue data generation methods, residues of acifluorfen would not be measurable. The only residue of concern identified in the confined study was acifluorfen, and this component never exceed 0.024 ppm, even at the 39 day emergency plant back interval. This value is well below the 0.1 ppm tolerance, which is based on the methodology LOQ. Based on this information, BASF feels that no plant back restrictions based on the residue situation should exist for sodium acifluorfen. [page 22]

HED Response The available confined rotational crop data indicate that ¹⁴C-residues >0.01 ppm accumulated in/on all rotational crop commodities of chard, turnip, sorghum, wheat, and radish that were planted at 39, 103, 145, 313, and/or 370 days after [¹⁴C]sodium acifluorfen was applied to sandy soil at 0.5 lb ai/A (1x the maximum registered rate). Residue accumulation declined from the shorter rotation intervals to the longer rotation intervals.

Residues of acifluorfen were detected at levels of >0.01 ppm in/on commodities of 39 DAT sorghum, 103 DAT chard, and 103 DAT radish (see Table 5). At 1 year, residues of acifluorfen were <0.01 ppm in/on sorghum, chard, and radish commodities; no other plant back intervals (PBIs) were assayed for these crops. Residues of acifluorfen were <0.01 ppm in/on 145 DAT wheat commodities; no other PBIs were assayed for wheat.

Based on the available data, HED agrees that the registrant's argument is reasonable but since no limited field studies are available, a plant back restriction is still necessary for acifluorfen. HED will, however, waive the requirement for limited field studies, which would generally be necessary for a shorter PBI, because the residues of concern in the confined study are greater than or equal to 0.01 ppm but less than the limit of quantitation (LOQ) of the analytical method to be used on field trial samples. HED will revise the PBI requirement to 40 days for small grains and 100 days for other crops.

cc: List B Rereg. File,
RDI: WPhang 12/18/01
7509C:FFort:RRB1:CM2:Rm 722H:703 305-7478:12/07/2001