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

JAN 22 1992

OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

MEMORANDUM

SUBJECT: Sodium Acifluorfen. List B Case No. 2605. BASF Corporation Response to Phase 4 Review of the Magnitude of the Residue in Meat/Milk/Poultry/Eggs. CBRS No. 8477. DP Barcode D168104.

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: Thomas Luminello/Linda Deluise, Acting PM-52
Accelerated Reregistration Branch
Special Review and Reregistration Division (H7508W)

BASF Corporation is requesting that the Agency reconsider its position in regard to a data gap for the requirement of Guidelines 171-4(j): Magnitude of the Residue in Meat, Milk, Poultry, and Eggs and 171-4(e) Storage Stability (livestock tissue portion only). Waivers of these same requirements were requested in a BASF Phase 4 DCI 90-day response reviewed by S. Funk (12/5/91).

The Phase 4 Review of sodium acifluorfen concluded the following in reference to the magnitude of the residue in meat, milk, poultry and eggs:

> This study (reformat of hen and cattle feeding studies) is inadequate. Parent and individual metabolites were not determined. Storage stability data were not included. New animal feeding studies are required. Sodium acifluorfen must be fed to dairy cattle (ruminant) and poultry. Livestock are to be treated for a minimum of 28 days or longer (until residues plateau in the milk or eggs). Following oral treatment, test animals must be sacrificed within 24 hours of the final dose. Feeding levels must be determined based on the latest crop residue data available or to be generated and should represent the 1x, 3x, and 10x anticipated dietary burden based on Table II , Subdivision O - Residue Chemistry

Guidelines. Parent and any regulated metabolites are to be determined in milk, eggs, poultry tissue (fat, muscle, liver) and cattle tissue (fat, muscle, liver, kidney). Storage stability studies are needed for both the poultry and ruminant studies.

Registrant's Response

The registrant stated that data submitted indicate that feeding studies generated at 1x, 3x, and 10x the anticipated dietary burden would result in residues below the limit of sensitivity of the residue analytical method (0.05 ppm) and that parent and individual metabolites could not be determined. Storage stability data would not be needed since the data generated was total C-14 data which would account for parent plus metabolites and their potential degradates.

Conclusions

1. An adequate residue method is available to detect the residues of sodium acifluorfen in animal commodities and is listed in PAM Vol. II as Method II.

2. As noted in the 12/5/91 S. Funk memorandum, there may exist a potential for bioaccumulation, but CBRS will reserve the requirement for magnitude of the residue in meat, milk, poultry, and eggs pending an evaluation of the results of the natue of the residue studies (171-4(a), (b)).

3. As noted in the 12/5/91 S. Funk memorandum, the storage stability study will need to be conducted simultaneously with the feeding study, per the registrant's proposed schedule, if the reserved feeding study is found to be necessary.

Recommendations

CBRS reiterates its decisions made in the 12/5/91 S. Funk memorandum, i. e. that magnitude of the residue and storage stability studies on poultry and ruminants be reserved pending the outcome of the outstanding livestock metabolism studies.

NOTE: We strongly urge the registrant to avoid requesting the Agency's response to the same questions/waiver requests in more than one submission, as duplication and delay may occur as a result.

cc: Reviewer(F. Fort), C. Furlow(PIB/FOD), Phase 4 Review file, RF, SF, Circ.
RDI: WJHazel:1/17/92:EZager:1/21/92
H7509C:CBRS:CM#2:Rm800-E:FAFort/FF:10/7/91

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DP BARCODE: D168104 REREG CASE # 260

CASE: 816452 DATA PACKAGE RECORD DATE: 08/28/9
SUBMISSION: S401682 BEAN SHEET Page 1 of 1

* * * CASE/SUBMISSION INFORMATION * * *

CASE TYPE: REREGISTRATION ACTION: 604 PHASE 4 RESPONSE SUBMIS
CHEMICALS: 114402 Sodium acifluorfen (5-(2-chloro-4-(trifluoro-meth

ID#: 114402-007969
COMPANY: 007969 BASF CORPORATION
PRODUCT MANAGER: 52 CHRISTINE RICE 703-308-8177 ROOM: CS1 3F3
PM TEAM REVIEWER: THOMAS JR LUMINELLO 703-308-8075 ROOM: CS1 4M1
RECEIVED DATE: 08/28/91 DUE OUT DATE: 12/26/91

* * * DATA PACKAGE INFORMATION * * *

DP BARCODE: 168104 EXPEDITE: N DATE SENT: 08/28/91 DATE RET.: / /
CHEMICAL: 114402 Sodium acifluorfen (5-(2-chloro-4-(trifluoro-methyl)phenox
DP TYPE: 999 Miscellaneous Data Package
ADMIN DUE DATE: 09/18/91 CSF: N LABEL: N

ASSIGNED TO	DATE IN	DATE OUT
DIV : HED	/ /	/ /
BRAN: RSCB	/ /	/ /
SECT: IO	/ /	/ /
REVR :	/ /	/ /
CONTR:	/ /	/ /

8477

* * * DATA REVIEW INSTRUCTIONS * * *

For this List B reregistration case, please determine if adaquate data has been submitted in the attached letter that would affect our conclusion that the Magnitude of the Residue data, MRID 107479 and 107488, were inadequate and that storage stability studies will be required.

* * * ADDITIONAL DATA PACKAGES FOR THIS SUBMISSION * * *

DP BC	BRANCH/SECTION	DATE OUT	DUE BACK	INS	CSF	LABEL