

US EPA ARCHIVE DOCUMENT



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

JUL 26 1989

OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

MEMORANDUM

SUBJECT: Clomazone (Command® 4EC and Command® Technical).
EPA Registration Nos. 279-3052 and 279-3053.
Review of FMC's Position Document on Adequacy of
Existing Clomazone Metabolism Studies to Support a Use
and Tolerance on Corn.
(No MRID No.) [DEB #5505] {HED Project #9-1667}

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THRU: Andrew R. Rathman, Section Head
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TO: R. Taylor/J. Yowell, PM Team 25
Herbicide-Fungicide
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RD has requested DEB review and comment on FMC's position document concerning the adequacy of existing clomazone metabolism data to support a use and tolerance on corn.

CONCLUSIONS

1. The nature of the residue in ruminants has been reviewed and discussed. It is adequately understood and the residue of concern is the parent herbicide clomazone.
2. DEB will not substitute a rat metabolism study for any livestock metabolism study.
3. The registrant may need to conduct a poultry clomazone metabolism study, depending on residue levels in the field trial data.
4. DEB cannot concur there are no toxicologically significant levels of the parent herbicide or any clomazone metabolite until the registrant submits the results of the clomazone in corn metabolism study.

5. The registrant also needs to complete a clomazone in corn processing study. Based on levels discussed in the April 10, 1989 EPA-FMC meeting, DEB suggests use of ¹⁴C-clomazone treated corn for this processing study.
6. Judgement is deferred on the adequacy of the existing analytical residue method to enforce a clomazone tolerance in corn. The registrant needs to present a method that corrects the difficulties encountered in the clomazone in soybean PMV. A new PMV may be necessary.
7. Conventional feeding studies (ruminant and poultry) may be necessary for any use where there are residues on a major livestock feed item, such as corn.

RECOMMENDATION

DEB recommends against FMC's position that the present clomazone soybean metabolism studies are adequate for corn. DEB recommends FMC conduct clomazone in corn metabolism studies, corn processing studies using ¹⁴C-clomazone, and conduct, if necessary poultry clomazone metabolism studies and livestock clomazone feeding studies.

DETAILED CONSIDERATIONS

FMC submitted a document titled "Clomazone - Corn, Position Document Addressing the Adequacy of Existing Metabolism Data to Support a Tolerance for the Use of Clomazone on Corn" by Charles Ferraro under the supervision of R. A. Robinson dated June 15, 1989 and coded project no. G164.

DEB Comment

This document was submitted as a follow-up to the FMC-EPA April 10, 1989 meeting. FMC feels registration of clomazone on corn follows a similar pattern demonstrated for registration of clomazone on soybeans.

In the cover letter the registrant requests a formal review of the goat metabolism study submitted in 1986 under MRID #400700-01. DEB (a.k.a. RCB) did receive and review this study (see memo by Lynn M. Bradley dated May 11, 1987 in PP#4F3128). After reconsideration DEB concludes this study has been adequately reviewed. From feeding/dosing of 10 mg or 5 ppm (100 X tolerance) the Total Radioactive Residue (TTR) in milk ranges from 2 to 9 ppb (parts per billion), levels in fat and tissues are <7 ppb, and only in kidney at 20 ppb and liver at 50 ppb were any radiolabeled components detected. The nature of clomazone in ruminants is adequately understood. The residue of concern is the parent herbicide clomazone. At this time no further ruminant clomazone metabolism data are required to support a tolerance of clomazone in corn.

DEB reiterates we do not substitute a rat metabolism study for any livestock metabolism study. The existing clomazone on rats metabolism study is supplementary data only.

FMC contends that since the metabolism of clomazone in soybeans is qualitatively similar in corn and quantitative less (about 20 X less) then additional livestock metabolism studies are not necessary.

We cannot agree with the registrant's conclusion 1. DEB has no basis at this time for assuming toxicologically insignificant levels of the parent or any metabolite are present in corn or corn processing products. The registrant needs to submit a clomazone in corn metabolism study for review. A corn processing should also be submitted. Considering the clomazone levels discussed in the April 10 EPA-FMC meeting, DEB suggests the corn processing study be conducted using ¹⁴C-clomazone treated corn.

Based on the levels discussed in the April meeting DEB suggests the registrant may need to conduct a poultry clomazone metabolism study at levels equal (or higher) to those used in the goat metabolism study. We note that in both the goat and rat metabolism a low but not negligible potential for accumulation exists. Thus a poultry metabolism study may be warranted for a proposed use on a major livestock feed item, depending on the residue levels in the field trials. If the TTR in poultry is on the same order of magnitude as in the goat then fractionation of the TTR at the low ppb level (<10 ppb) is not required.

DEB defers judgement on Conclusion 2, i.e., the adequacy of the existing residue method to enforce clomazone tolerances in corn. The registrant is referred to our review by L. Bradley, of May 3, 1985 of the method tryout results. We pointed out there were a number of problems encountered and the results of the PMV, at best, were only marginal. The clomazone residue in corn method should reflect a correction of the problems encountered. DEB may initiate a request for another petition method validation if we feel there are significant differences between the methods.

If the registrant wishes to register clomazone use on corn, then DEB cannot accept animal feeding restrictions. The registrant may need to conduct and present the results of conventional livestock (ruminant and poultry) in any use where there are residues on a major livestock feed item.

cc: R.F., Circu. (7), PP#4F3128, Reviewer (FDG), Clomazone S.F., PMSD/ISB (Eldredge).
H7509C:DEB:Reviewer(FDG):CM#2:Rm814B:557-0826:mb:7/10/89:
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