

PC 125501

R-18-95  
R.F.



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

DEC 18

MEMORANDUM

OFFICE OF  
PREVENTION, PESTICIDES AND  
TOXIC SUBSTANCES  
IN/ON APPLES.

**Subject:** PP# 3F3392/ FAP# 6H5500 - CLOFENTEZINE (APOLLO®)  
Tolerance Method Validation Request.  
(MRID #s 4380085-01) [CBTS # 16609] {DP Barcode D221645}

**From:** Francis D. Griffith, Jr., Chemist  
Chemistry Branch I - Tolerance Support  
Health Effects Division (7509C)

**To:** Donald A. Marlow, Chief  
Analytical Chemistry Branch  
Biological and Economic Analysis Division (7503W)

**Thru:** Michael S. Metzger, Branch Chief  
Chemistry Branch I - Tolerance Support  
Health Effect Division (7509C)

INTRODUCTION

AgrEvo USA Company proposes a tolerance for its insecticide clofentezine, trade named Apollo® (3,6-bis(2-chlorophenyl)-1,2,4,5-tetrazine in or on the raw agricultural commodity apples at 0.01 ppm.

The TMV request is for the new/revised method, J-95R-02, to determine if the petitioner has revised the method as previously suggested and this revision with its revised clean-up step meets the Agency requirements for an enforcement method. The TMV is for 1 chemical, parent only, on raw apples at 0.01 ppm. Considering the problems encountered in the last TMV, ACB may wish to test the method not only with red delicious apples, but also with yellow apples, Romes, etc.

Two copies of the new/revised method, J-95R-02 (MRID # 438008-01) along with the company's validation data (recoveries and supporting chromatograms) are attached. Per telcon on Dec. 11, 1995, between D. Griffith and H. Hundley no new ILV data are required.

CBTS has completed its review of the method. We note that the extraction, partitioning, concentration, and determination step are the same as in the previous TMV. The cleanup step is significantly different. A copy of our review which has the CBTS suggested revisions has been forwarded to ACB on Dec. 15, 1995. We note that revisions suggested in the February and March reports from ACB to method RAM J/02/92 were not made, and they are germane to this method. If possible please estimate the LD and LOQ for method J-95R-02.

CBTS requests ACL run the TMV for the HPLC-UV method, J-95R-02, in duplicate at 0.01 ppm, the proposed tolerance on apples. Please neither use control values for recovery corrections nor report control values as 0.0 ppm. Please run at least one raw apple control sample along with the recoveries. We request you determine and report the time it takes ACL to run a set of samples.

The data provided by the petitioner suggests that 0.01 ppm is the LD of the new method. Once the TMV is completed we request your concurrence that 0.01 ppm is a reasonable LOQ, or provide us with your best estimate of the LD and the LOQ for the method. The LD is essential for the reliability of our data when we prepare our dietary exposure estimate in risk assessment.

A major reason for conducting TMVs is to assure that all necessary instructions are included in the revised method write up and the method can be completed as written in a reasonable time to serve as an enforcement procedure. We expect there will be company contacts to clarify points in the method. CBTS suggests ACL keep a log of all AgrEvo contacts on the TMV and include a copy of them in the final report.

Please obtain the necessary analytical reference standard from the EPA Repository. If the analytical reference standard of clofentazine is not available from the Repository, then please contact the Registration Specialist, L. P. Czocho, at AgrEvo in Wilmington, Delaware directly requesting several hundred milligrams of standard along with the required MSDS be provided directly to ACL to start the TMV. In your final report please note that the standard is or is not available from the repository as of (date). Also please confirm the Repository ordering code for the clofentazine standard obtained from the Repository.

The review is in priority status. The Registration Division Product Manager for clofentazine is Dennis H. Edwards, Jr. He should be contacted directly concerning the priority for completion of the TMV.

Please return all of the requested information on the attached Method Report Form and all other pertinent information concerning the TMV that are generated according to your SOP on TMVs including source of control sample, fortification of samples, standard curves, modifications/deviations to the methods, and examples of sample calculations. A copy of any clofentazine residue analytical method supplied directly to you by AgrEvo for the TMV should be returned to CBTS with your final report.

Please address your written report to:

Francis D. Griffith, Jr.  
Tolerance Petition Section I  
Chemistry Branch I - Tolerance Support  
Health Effects Division (7509C)

**ATTACHMENTS (2 copies each):**

1) Method Report Forms.

2) AgrEvo method J-95R-02, "Validation of Analytical Method of Clofentezine in Fruit (Western Red Delicious Apples), USA, 1995," 28 pages, MRID # 438008-01.

cc (w/ attachment 2 only): M. Clower (FDA, HFS-335).

cc (w/ attachment 1 only): Reviewer/PAM-IIFile(FDG), PP#6F3392, ClofentezineSub.File, R.F., Circu., D.H. Edwards, Jr. (PM19), H. Hundley (ACB, Beltsville), P. Bayer (EPAREpository, RTP-NC).

7509C:CBTS:Reviewer(FDG):CM#2:Rm804Q:305-5826:FDG:12/12/95:edit:fdg:12/18/95.  
RDI:SecHd:RSQuick:12/14/95:BrSrSci:RALoranger:12/14/95:BrCh:MSMetzger:12/18/95.

AgrEvo METHOD J-95R-02

"Validation of an Analytical Method for Residues of Clofentezine in Fruit (Western Red Delicious Apples), USA, 1995," J.L. Neal, September 27, 1995, 28 pages, MRID # 438008-01.

<u>COMMODITY</u>	<u>CHEMICALS ADDED</u>	<u>PPM ADDED</u>	<u>PPM FOUND</u>	<u>% RECOVERY</u>
Raw Apples	None (Control)	0.0		
	Clofentezine (Apollo®)	0.01		