

5/25/95

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MEMORANDUM

Subject: PP# 3F4268 - QUIZALOFOP-P ETHYL ESTER (ASSURE® II) IN LEGUME VEGETABLES (SUCCULENT OR DRIED) AND FOLIAGE OF LEGUME VEGETABLES CROP GROUPS, COTTONSEED, SUGARBEET TOPS AND ROOTS, AND MOLASSES. Tolerance Method Validation Request. (MRID #s 433140-01 and 429275-09)[CBTS # 15593]{DP Barcode D215499}

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: E. Zager, Acting Branch Chief
Chemistry Branch I - Tolerance Support
Health Effect Division (7509C)

INTRODUCTION

E.I. duPont de Nemours and Company, Agricultural Products proposes tolerances for the combined residues of its herbicide quizalofop-p ethyl ester, trade named Assure® II (ethyl (R)-2-[4-((6-chloroquinoxalin-2-yl)oxy)phenoxy] propionate) and the S enantiomers of the ester and the acid, all expressed as quizalofop-p ethyl ester in or on the raw agricultural commodities: legume vegetables (succulent or dried) crop group at 0.3 ppm, forage of legume vegetables (except soybean and bean hay) crop group at 0.7 ppm, sugarbeet tops at 0.5 ppm, sugarbeet roots at 0.1 ppm, cottonseed at 0.1 ppm, and sugarbeet molasses at 0.2 ppm.

A TMV is requested for the revised method so that it can replace or supplement the existing enforcement residue analytical method in PAM II. The method was submitted in response to concerns raised by ACL in the initial TMV report and concerns noted by CBTS in our March 4, 1992, memorandum in PP# 1F3951 (quizalofop-p on cottonseed). The specific concerns addressed were that the enzymatic hydrolysis time is reduced from 24 hours to 2 hours, recovery data from radiolabeled studies were presented to show that the extraction step will recover bound residues, and copies of the test methods for the enzymes were presented. The TMV is for the method designated as LAN-1 for the parent and the acid metabolite in cottonseeds at 0.05 ppm and 0.2 ppm.

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Two copies of the LAN-1 HPLC-UV method (duPont method AMR 1853-90, MRID # 433140-01) along with the validation data (recoveries and supporting chromatograms) are attached. Copies of the LAN-3 GC/MS method for the phenolic metabolites are included with the ILV data for LAN-1. The registrant has provided the results of the ILV for both methods LAN-1 and LAN-3 conducted by Enviro-Test Laboratories of Edmonton, Alberta, Canada using cottonseeds as well as recovery data from bean forage, dry/snap beans, peas, canola seed, and sugarbeets for the same 4 compounds (MRID # 429275-09).

CBTS has completed its review of the LAN-1 method. We feel the method has been significantly revised to warrant a new TMV. Our concerns are that the method is suitable to be used by FDA and the State enforcement labs, it can be completed in the time frame reported by the registrant and the ILV lab, and the LD and LOQ can be confirmed.

Please neither use control values for recovery corrections nor report control values as 0.0 ppm. Please run at least one raw cottonseed control sample along with the recoveries. We request you determine and report the time it takes ACL to run a set of samples. Please confirm if there are convenient overnight stopping points in the method.

The data provided by the petitioner suggests that 0.01-0.02 ppm is the MDL/LD. Once the TMV is completed we request your concurrence that 0.01 ppm is a reasonable LD, or provide us with your best estimate of the LD. The LD is essential for the reliability of our data when we prepare our dietary exposure estimate in risk assessment. We also request your concurrence that 0.04-0.05 ppm is the LOQ.

A major reason for conducting TMVs is to assure that all necessary instructions are included in the method write up and the method can be completed in a reasonable time to serve as an enforcement procedure. We expect there will be company contacts to clarify points in the LAN-1 method. CBTS suggests ACL keep a log of all DuPont contacts on the TMV and include a copy of it in the final report to CBTS.

Please obtain the necessary analytical reference standards from the EPA Repository. If any of the analytical reference standards of quizalofop-p ethyl ester and the acid quizalofop are not available from the Repository, then please contact the Registration Specialist at DuPont directly requesting several hundred milligrams of each standard not available along with the required MSDS be provided directly to ACL to start the TMVs. In your final report please note that all standards are or are not available from the Repository as of (date). Also confirm the Repository ordering codes for quizalofop-p ethyl ester and its acid quizalofop metabolites.

The review is not in expedite status. The Registration Division Product Manager for quizalofop-p ethyl ester is Robert Taylor. 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 Forms 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 quizalofop-p residue analytical method supplied directly to you by DuPont for the TMV should be returned to CBTS with your final report.

Please address your written report to:

Robert S. Quick, Section Head
Tolerance Petition Section I
Chemistry Branch I - Tolerance Support
Health Effects Division (7509C)

ATTACHMENTS (2 copies each):

- 1) Method Report Forms.
- 2) DuPont method AMR 1853-90, "Determination of DPX-79376, DPX-79376 Acid and Conjugates as DPX-79376 Acid in Cottonseed and fractions Treated with Assure II Herbicide," 49 pages, MRID # 433140-01.
- 3) "Validation of Quizalofop p-Ethyl (DPX-79376), Quizalofop acid (YE-945), Phenol 2 (IN-A6208), Phenol 3 (IN-G7057), and Phenol 4 (IN-H8515) in Cottonseed, Beans, Peas, Canola, and Sugarbeets" (DuPont study no. AMR 1854-90), Enviro-Test Laboratories, 233 pages, MRID # 429275-09.

cc (w/ attachments 2 and 3 only): M. Clower (FDA, HFS-335).

cc (w/ attachment 1 only): Reviewer/PAM-IIFile(FDG), PP#3F4268, QuizalofopSub.File, . R.F., Circu., R.F. Taylor (PM25), H. Hundley (ACB, Beltsville), P. Bayer (EPAREpository, RTP-NC).

7509C:CBTS:Reviewer (FDG):CM#2:Rm804Q:305-5826:FDG:5/18/95:edit:fdg:5/25/95.
RDI:SecHd:RSQuick:5/23/95:BrSrSci:RALoranger:5/24/95:ActBrCh:EZager:5/25/95.

ATTACHMENT I

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LAN-1

"Analytical Method for the Quantification of Quizalofop (YE-945) and Quizalofop ethyl (DPX-79376) in Raw and Processed Agricultural Commodities," G. Burns, August 26, 1993, p 49-68, MRID # 429275-09.

"Determination of DPX-79376, DPX-79376 Acid and Conjugates as DPX-79376 Acid in Cottonseed and Fractions Treated with Assure II Herbicide," J.S. Amoo, June 27, 1994, 49 pages, MRID# 433140-01.

<u>COMMODITY</u>	<u>CHEMICALS ADDED</u>	<u>PPM ADDED</u>	<u>PPM FOUND</u>	<u>% RECOVERY</u>
Raw	None	0.0		
Cottonseed	(Control)			
	Quizalofop-p Ethyl	0.05		
	(Assure II®)		0.2	
	YE-945	0.05		
	(Quizalofop Acid)		0.2	