



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

S.F.
Alert

OPP OFFICIAL RECORD
HEALTH EFFECTS DIVISION
SCIENTIFIC DATA REVIEWS
EPA SERIES 361

JUL 18 1995

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

MEMORANDUM

SUBJECT: PP# 5G04507. Alert in or on Oranges and Lemons. Request for Petition Method Validation. MRID# 436221-02. Barcode D217271. Chemical No 129093. CBTS# 15867.

FROM: G.F. Kramer, Ph.D., Chemist
Tolerance Petition Section III
Chemistry Branch I, Tolerance Support
Health Effects Division (7509C)

THRU: M.S. Metzger, Branch Chief
Chemistry Branch I, Tolerance Support
Health Effects Division (7509C)

TO: Donald A. Marlow, Chief
Analytical Chemistry Branch
Biological and Economics Analysis Division (7503C)

American Cyanamid Company has petitioned for an experimental use permit (EUP) and temporary tolerances for residues of the insecticide/miticide Alert [4-bromo-2-(chlorophenyl)-1-(ethoxymethyl)-5-(trifluoromethyl)-1H-pyrrole-3-carbonitrile] as follows: Oranges -- 0.5 ppm; Lemons -- 0.5 ppm. Alert is also known as Pirate, CL 303,630 or AC 303630. CBTS has conducted a preliminary review of the citrus processing study. Based on these data, it appears that Section 701 Maximum Residue Limits will be required for citrus oil and dried citrus pulp. We are thus requesting that the method validation also be performed with citrus oil.

The registrant has submitted a copy of method M 2284 and an Independent Laboratory Validation (ILV) in the following two volumes which are appended to this memorandum as Attachments 2 & 3:

Pirate (CL 303,630) GC Determinative and GC/MS Confirmatory Method for the Determination of CL 303,630 Residues in Whole Oranges, Wet Pulp, Juice, Dried Pulp, Molasses and Oil. Appendix A of Exhibit 1 of MRID# 436221-02.



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CL 303,630: Independent Laboratory Validation of GC Method M 2284 for the Determination of CL 303,630 Residues in Whole Oranges by Huntingdon Analytical Services. Exhibit 2 of MRID# 436221-02.

CBTS has conducted a preliminary review of the ILV. Acceptable recoveries were obtained by the laboratory. A summary of the laboratory's findings may be found on page 82 of the ILV report.

CBTS requests that ACL review the method for acceptability as a tolerance enforcement method. The ILV should also be reviewed to determine if the method has been adequately validated. If the method and the ILV are satisfactory, CBTS requests that ACL conduct a Petition Method Validation (PMV) on the submitted analytical method.

Samples should be run in duplicate per the experimental design specified in Attachment 1. Please complete and return this attachment as part of your report. Also, please include with your report, copies of the standard curves, sample calculations, and representative chromatograms for controls and fortified samples. Any deficiencies in the method, as written, should also be noted and reported. Please comment on the length of time necessary to complete a set of samples.

One of the purposes of conducting a PMV is to determine whether all necessary instructions are included in the submitted method. For this reason, we are requesting that laboratory staff scientists have minimal contact with the registrant during this PMV. Any problems encountered should be documented and included in your report. The registrant will be informed of any deficiencies in the method and asked to resolve them.

Please obtain the necessary analytical reference standards from the EPA Repository. If the analytical reference standard of Alert is not available from the Repository, then please contact the Registration Specialist at American Cyanamid directly requesting several hundred milligrams of each standard not available along with the required MSDS be provided directly to ACL to start the PMV. 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 Alert.

The review is not in expedite status. The Registration Division Product Manager for Alert is Dennis Edwards. He should be contacted directly concerning the priority for completion of the PMV.

Please address your written reports to: F.D. Griffith, Jr., Acting Section Head, Tolerance Petition Section III, Chemistry Branch I, Tolerance Support, Health Effects Division (7509C).

Attachment 1- Experimental Design for PMV

Attachment 2- Proposed Enforcement Method, Exhibit 1 of MRID# 436221-02

Attachment 3- ILV, Exhibit 2 of MRID# 436221-02

cc (with Attachment 1 and 2): M. Clower (FDA, HFS-335)
cc (with Attachment 1 only): PP#5G04507, S.F., Kramer, Circ., R.F.,
H. Hundley (ACB/BEAD), D. Edwards (PM19/RD)/M. Johnson
RDI: F.D. Griffith (7/17/95), M.S. Metzger (7/18/95). M.J. Nelson
for R.A. Loranger (7/18/95)
G.F. Kramer:804V:CM#2:(703)305-5079:7509C:CBTS

ATTACHMENT 1

METHOD: Pirate (CL 303,630) GC Determinative and GC/MS Confirmatory Method for the Determination of CL 303,630 Residues in Whole Oranges, Wet Pulp, Juice, Dried Pulp, Molasses and Oil. Exhibit 1 of MRID# 436221-02.

Please: (i) Indicate the limit of detection and quantitation; (ii) Do not use control values for recovery calculations; and (iii) Do not report control values as zero; if less than the limit of detection, report as such.

Commodity	Chemical Added	ppm Added	ppm Found	Percent Recovery
Whole Oranges	Alert	0.00		
		0.05		
		0.25		
		0.50		
Citrus Oil	Alert	0.00		
		0.05		
		1.00		
		2.00		