



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

WASHINGTON, D.C. 20460

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

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

Date: September 6, 2000

MEMORANDUM

Subject: **PP#9E06020**: Tolerance Method Validation Request for Iprovalicarb Residues in/on
Grapes and Raisins

DP Barcode: D268624

Submission: S566360

PC Code: 098359

Case: 292131

MRIDs: 44865631, 44865632

From: Michael Doherty, Chemist *Michael A. Doherty*
Registration Action Branch 2
Health Effects Division (7509C)

Through: William Cutchin, Chemist *William Cutchin*
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Through: Richard Loranger, Branch Senior Scientist
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R. Loranger

To: F. D. Griffith, Jr., Chief
Analytical Chemistry Branch
Biological and Economic Analysis Division (7503W)

Following is a tolerance method validation (TMV) request (DP Barcode D268757) for the fungicide iprovalicarb. The request was prepared by the Dynamac Corporation under the supervision of HED, RAB2. The request has undergone review within the branch and has been revised to reflect current HED and OPP policies. If any additional input is needed, please advise.

Iprovalicarb

**PC Code 098359
(DP Barcode D268624)**

**Permanent Tolerance Petition (PP#9E6020)
For Use On Imported Grapes**

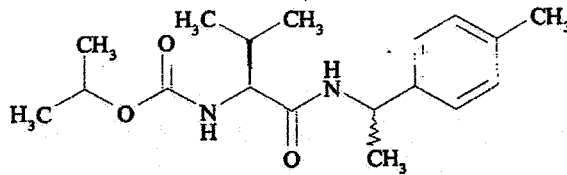
August 7, 2000

Contract No. 68-W-99-053

**Submitted to:
U.S. Environmental Protection Agency
Arlington, VA**

**Submitted by:
Dynamac Corporation
1910 Sedwick Road
Building 100, Suite B
Durham, NC 27713**

IPROVALICARB



PERMANENT TOLERANCE PETITION (PP#9E6020) FOR USE ON IMPORTED GRAPES

PC CODE 098359

(DP BARCODE D268624)

INTRODUCTION

The TM-210 (SZX 0722) Fungicide Task Force, which is comprised of Tomen Agro, Inc. and Bayer Corporation, has submitted a petition for the establishment of permanent tolerances for residues of the fungicide iprovalicarb (SZX 0722) in/on grapes and raisins grown in Europe and imported to the United States. The petitioner has proposed tolerances for residues of iprovalicarb, [(1S)-2-methyl-1-[[[1-(4-methylphenyl)ethyl]amino]carbonyl]propyl]carbamic acid 1-methylethyl ester, in or on:

Grapes	2.0 ppm
Raisins	3.0 ppm

Iprovalicarb belongs to a new class of chemicals derived from natural amino acids and acts both as a contact and systemic fungicide. Iprovalicarb is proposed for multiple foliar applications to grapes for the control of Oomycete fungi, such as downy mildew, and is formulated as 50% water dispersible granule (dry flowable, DF) and marketed under the trade name MELODY® WG 50. No tolerances or Codex Maximum Residue Limits (MRLs) are established for residues of iprovalicarb in/on plant or animal commodities.

In conjunction with the permanent tolerance petition, the petitioner has proposed a LC/MS method, Bayer Method No. 0442, for determining iprovalicarb residues in/on plant commodities. Method validation data and a successful radiovalidation have been provided by the petitioner for this method and the validated limit of quantitation (LOQ) for residues of iprovalicarb is 0.05 ppm in/on plant commodities, except tobacco (LOQ, 0.5 ppm). A method description along with method validation data are appended to this memorandum as Attachment 2.

"Method for Determination of Residues of the Fungicide SZX 0722 in/on Various Raw Agricultural and Processed Commodities by Liquid Chromatography using Mass Spectroscopic Detection," Bayer Method No. 0442, R. Brennecke, 8/21/97, Bayer AG. (MRID 44865631)

An ILV of the proposed enforcement method was conducted by ABC Laboratories, using grapes and tobacco (dried leaves). Bayer Method No. 0442 was successfully validated to a lower limit of 0.05 and 0.5 ppm for residues of iprovalicarb in grapes and tobacco, respectively. The results of the ILV trial are contained in the following volume, which is appended to this memorandum as **Attachment 3**:

"Independent Laboratory Validation of Method for Determination of Residues of the Fungicide SZX 0722 in/on Various Raw Agricultural and Processed Commodities by Liquid Chromatography using Mass Spectroscopic Detection According to PR Notice 96-1 and European Guidelines," H. Anderson, 12/5/97, ABC Laboratories. (MRID 44865632)

RAB2 requests that ACB/BEAD conduct a TMV of Bayer's proposed LC/MS tolerance enforcement method (MRID 44865631) per the experimental design specified in **Attachment 1**. All samples should be run in duplicate. Please complete and return this attachment as part of your report. Also, please include in your report all relevant information and supporting documentation concerning the method validation, including modifications which were made, and indicate the suitability of the analytical method for enforcement purposes. Please include the Repository ordering code(s) for the reference standards.

Should you find that the necessary analytical reference standards and/or MSDSs are not available to you, please contact directly Dr. James L. Platt (Project Manager/Senior Scientist, Tomen Agro, Inc., San Francisco, CA, 415-536-3482) to request they be provided.

Since one of the purposes of conducting an in-house TMV is to determine whether all necessary instructions are included in the submitted proposed enforcement method, your laboratory staff scientists should have minimal contact with the petitioner during the conduct of this trial. Any problems encountered in the method as written should be documented and included in your report. The petitioner will be informed of any deficiencies in the method and asked to resolve them.

The RD Product Manager for iprovalicarb is Mary Waller, and she should be contacted directly (703-305-9354) if you require guidance concerning the priority for initiation/completion of this TMV.

Please address and send your report to Michael Doherty, Chemist, RAB2/HED, 7509C. If you need any further information from me my telephone number is 703-305-1031.

Attachments:

1. Experimental Design for TMV
2. Proposed LC/MS Enforcement Method, Bayer Method No. 0442 (MRID# 44865631)
3. ILV by ABC Laboratories. (MRID# 44865632)

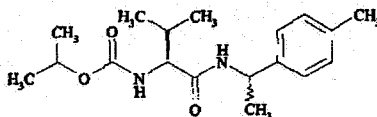
cc (with Attachment 1 only): M. Doherty, RAB2 Reading File, T. Ellwanger (FB/RD/7505C).

cc (with Attachment 3 only): M. Clower [Division of Pesticides and Industrial Chemicals, HFS-335, FDA]

ATTACHMENT 1

METHOD: "Method for Determination of Residues of the Fungicide SZX 0722 in/on Various Raw Agricultural and Processed Commodities by Liquid Chromatography using Mass Spectroscopic Detection," Bayer Method No. 0442, R. Brennecke, 8/21/97, Bayer AG. (MRID 44865631)

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.

Matrix	Chemical Added	ppm Added	ppm Found	% Recoveries
Grapes	 Iprovalicarb	Control		N/A
		0.05		
		1.0		
		2.0		

N/A = Not Applicable

Modifications to Method (Major or Minor):

Special Precautions to be Taken:

Source of Analytical Standards:

If Derivatized Standard Used, Give Source:

Instrumentation for Quantitation:

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ATTACHMENT 1

Instrumentation for Confirmation:

If Instrumentation Parameters Differ from Given in Method, List Parameters Used:

Commercial Source for any Special Chemicals or Apparatus:

Comments:

Page _____ is not included in this copy.

Pages 8 through 21 are not included in this copy.

The material not included contains the following type of information:

Identity of product inert ingredients.

_____ Identity of product inert impurities.

_____ Description of the product manufacturing process.

_____ Description of quality control procedures.

_____ Identity of the source of product ingredients.

_____ Sales or other commercial/financial information.

_____ A draft product label.

_____ The product confidential statement of formula.

_____ Information about a pending registration action.

☒ FIFRA registration data.

_____ The document is a duplicate of page(s)

_____ The document is not responsive to the request.

The information not included is generally considered confidential by product registrants. If you have any questions, please contact the individual who prepared the response to your request.
