

Fluopicolide

Summary of Analytical Chemistry and Residue Data

Barcode: 339157

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## UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

WASHINGTON, D.C. 20460

OFFICE OF  
PREVENTION, PESTICIDES  
AND TOXIC SUBSTANCES

### MEMORANDUM

OPP OFFICE OF PESTICIDES  
HEALTH EFFECTS DIVISION  
SCIENTIFIC DATA REVIEWS  
EPA SERIES 001

Date: 6/01/07

Subject: PP#5E6903. Fluopicolide. Amendment to Address the Requirements to Establish Tolerances on Imported Grapes and Raisins.

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### Executive Summary

Bayer CropScience AG had proposed, in PP#5E6903, the establishment of permanent tolerances for residues of the new fungicide fluopicolide [2,6-dichloro-N-[[3-chloro-5-(trifluoromethyl)-2-pyridinyl]methyl]benzamide] in/on grapes and raisins which are to be imported into the U.S.

In the previous review (DP Number 321209, 1/23/2007, A. Acierto), HED concluded that additional data and/or information were required: representative labels or a revised Section B to indicate the types of formulations to be used on imported grapes, a proposed confirmatory method or an interference study; a revised Section F; storage stability data for fluopicolide in juice or must and raisins; and storage information for the processed commodities. In addition, HED required that the proposed enforcement method must be validated by the Agency's Analytical Chemistry Branch (ACB). ACB recommended that the petitioner provide information for a second ion transition to provide confirmation of analyte identities, or provide an alternate chromatographic column and/or mobile phase combination to add an additional degree of specificity (DP Number 329578, C. Stafford, 3/1/2007).

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The petitioner has addressed the deficiencies (letter to PM, 2/23/2007). In addition, an adequate confirmatory method was submitted in a separate report (Report No. C20070031) which satisfies the enforcement method requirements for this petition (DP Number 329578 and DP Number 329670, C. Stafford, 3/14/2007).

### **Regulatory Recommendations and Residue Chemistry Deficiencies:**

HED has examined the data submitted by the petitioner to satisfy the deficiencies for fluopicolide use on imported grapes and raisins. HED concludes that all the deficiencies have been resolved.

### **The original residue chemistry deficiencies, the petitioner's responses and HED's conclusions are listed below:**

#### **Deficiency # 1a.**

Residue data were submitted which reflected use of a 4.44% WDG formulation (WG71) and a 95 g/L suspo-emulsion formulation (SE10), which is similar to an emulsifiable concentrate (EC) formulation. The petitioner should submit representative labels or a revised Section B to indicate the types of formulations to be used on imported grapes.

#### **Petitioner's Response to Deficiency # 1a.**

Please find attached to this document an up-to-date label for the product *PROFILER*® (Attachment 1) and a revised Section B (Attachment 2) describing this use pattern. *PROFILER*® is described as a WG formulation, granules dispersible in water.

#### **HED's Conclusion # 1a.**

A representative label was submitted and found adequate. The product name is *PROFILER*®, formulated as a water dispersible granule (WG) with 4.4% fluopicolide and 66.7% fosetyl-Al.

#### **Deficiency # 1b.**

A Section B was submitted which provided some information regarding the proposed use pattern on imported grapes, including the maximum number of applications per season (3), the maximum seasonal application rate (0.36 lb ai/A), the minimum preharvest interval (PHI; 21 days), and retreatment intervals (10-14 days). The petitioner should submit a representative label or a revised Section B to more fully describe the use pattern(s) to be applied to grapes and raisins to be exported to the USA. The additional information to be provided to the Agency should include the maximum single application rate, application timing (as it relates to the plant growth stage), names and quantities of stickers, spreaders, and other adjuvants (if any) to be added to the spray solution, application tank-mix preparation, volume of spray mix per unit area (hectare or acre), and type of application equipment.

**Petitioner's Response to Deficiency # 1b.**

Please see the attached label for the product PROFILER. This is the currently pending EU label for grapes. Key parameters contained on this label are:

1. *PROFILER*® is described as a WG formulation, granules dispersible in water.
2. The maximum single application rate is 3 kg/ha of formulated material which is equivalent to 0.12 lb. ai/A. There are a maximum of 3 applications per season.
3. Application timing is around flowering for the first application. The application interval is 14 days.
4. Stickers, spreaders, and adjuvants are not recommended.
5. Label directions for tank-mix preparation are described as "If there is an association with other products, put the products into the tank in the following order: concentrated suspensions (CS), *PROFILER*, wettable powders, emulsifiable concentrates, and water-based emulsions".
6. As all sprayed types may be used, in France, the normal spray volume is 200-1000L/ha for normal sprayers, 150-500L/ha for air-pressured spraying, and 100-300 L/ha for low-volume mist blowers.
7. The preharvest interval is stated as 28 days.

**HED's Conclusion # 1b.**

The petitioner's response is adequate. No further information is required.

**Deficiency # 1c.**

No spray adjuvants were used in the crop field trials submitted to support this petition. If the petitioner intends to recommend use of spray adjuvants, residue data reflecting use of spray adjuvants should be submitted.

**Petitioner's Response to Deficiency # 1c.**

The use of adjuvants is not recommended when using *PROFILER*.

**HED's Conclusion # 1c.**

The petitioner clarified that an adjuvant is not recommended for this product. No further information is required.

**Deficiency # 1d.**

The submitted residue data reflect use of WDG and EC types of formulations. If other types of formulations are to be used on grapes to be imported, additional residue data would be needed to reflect use of those other types of formulations.

**Petitioner's Response to Deficiency # 1d.**

Additional data will be submitted if the proposed use pattern is changed.

**HED's Conclusion # 1d.**

No further information is required.

**Deficiency # 1e**

There are currently no U.S. tolerances for fosetyl-Al on grapes. Therefore, imported grapes or grape products with fosetyl-Al residues would be considered adulterated until a petition for use of fosetyl-Al on imported grapes is submitted and U.S. tolerances are established.

**Petitioner's Response to Deficiency # 1e.**

A 10 ppm tolerance for fosetyl-aluminum [aluminum tris(*O*-ethylphosphonate)] on grapes is contained in 40 CFR 180.415(c).

**HED's Conclusion # 1e.**

The petitioner's response is correct in citing the regional tolerance for fosetyl-aluminum on grapes. Based on a substantially lower use rate and comparable preharvest interval for imported grapes as compared to the registered fosetyl-aluminum use, residues of fosetyl-aluminum on imported grapes are not likely to exceed the established 10 ppm tolerance. The established 10 ppm tolerance is adequate.

**Deficiency # 2.**

The petitioner must propose confirmatory procedures for the proposed enforcement method, or submit an interference study for *fluopicolide*.

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**Deficiency # 3.**

The proposed enforcement method, Method 00782/M002, must be validated as an adequate enforcement method by ACB/BEAD.

**Petitioner's Responses to Deficiencies #s 2 and 3.**

A revised method was submitted: Valent Report Number C20070031. Study title: Tolerance Enforcement Method for the Analysis of Residues of Fluopicolide in/on Crops Method RM-43C-2. Author: Thomas Schreier. Study Completed: March 7, 2007. Performing Laboratory: Valent U.S.A. Corporation, Walnut Creek, CA. Laboratory Project Identification: Method RM-43C-2.

**HED's Conclusions #s 2 and 3.**

ACB has reviewed the revised method and found that the method incorporates not only the original primary analytical column, but also an alternative liquid chromatography column

to be used for confirmation of residues (DP Numbers 329578 and 329670, C. Stafford, 3/14/2007). Comments from ACB were as follows:

- 1) The analytical procedure described in revised method RM-43C-2 is essentially identical to the analytical procedure described in Method 00782, Revision M002.
- 2) Method RM-43C-2 describes analytical parameters for recovering parent fluopicolide only, and does not discuss metabolites.
- 3) The primary analytical column is a reversed-phase C18 packing while the alternative column is a mixed phase of C18 plus a strong cation exchange packing material. The difference in column polarity between the primary and alternate columns provides an additional degree of method selectivity which satisfies the guideline requirement for a confirmatory method.

HED concludes that the revised Method RM-43C-2 satisfies the requirements for a confirmatory method for the parent fluopicolide only. An adequate enforcement method (Method RM-43C-2) is available for fluopicolide (parent) on grapes. No further information is required for this petition on imported grapes and raisins.

#### **Deficiency # 4.**

The petitioner must submit data demonstrating the stability of residues of fluopicolide in grape juice (or must) and raisins stored frozen for 29 months or the maximum storage interval for each of these commodities.

#### **Petitioner's Response to Deficiency # 4.**

Valent USA requests a waiver of the requirement for storage stability data for the processed commodities of grape juice and raisins. Storage stability studies are generally necessary to validate the stability or rate of decomposition of pesticide residues to address potential loss by processes such as hydrolysis or reaction with enzymes. The US EPA Guideline for storage stability, OPPTS 860.1380, recommends that storage stability data be generated for five representative crop groups (oilseed, non-oily grain, leafy vegetable, root crop, and fruit or fruiting vegetable) if applicable to a submission. The stability of fluopicolide has been demonstrated for each of these groups except for oil seeds.

For the group fruit or fruiting vegetable, data has been previously submitted demonstrating the stability of fluopicolide and its metabolites in/on grapes for a period of 30 months (Zietz, E., MRID 46474037). Grapes, grape juice, and grape must are primarily slightly acidic, high moisture commodities. As stability has been demonstrated in grapes for 30 months, it is reasonable to assume that a similar period of stability exists for fluopicolide in the commodities of grape juice and grape must. Likewise, the stability of fluopicolide in grapes should also be representative of the stability of fluopicolide in raisins. Grapes are processed into raisins simply through the removal of water. There is no other substantial change to produce this commodity.

Based on the wide variety of crops for which the stability of fluopicolide residues has been demonstrated and the similarity of the proposed commodities of grape juice and raisins to grape fruits, Valent requests that the requirement to produce additional storage stability

data for grape juice and raisins be waived.

**HED's Conclusion # 4.**

HED concludes that this deficiency has been satisfied. No additional storage stability data are required

**Deficiency # 5.**

The petitioner should submit the actual dates of collection, extraction, and analysis for each sample of grape juice (or must) and raisins from the processing studies to determine the storage interval required for the storage stability study.

**Petitioner's Response to Deficiency # 5.**

Actual dates of collection, extraction, and analysis, for each sample are not required at this time as the maximum length of storage may be determined to be less than or equal to the time period from the initiation of processing to the completion of analysis of samples.

For white grapes (MRID 46474105), processing was initiated on 06 October 2000. The analytical phase of this study was terminated on 23 December, 2002. The maximum interval from the initiation of processing to termination of analysis is 808 days or about 27 months.

For red grapes (MRID 46474103), processing was initiated on 01 August 2000. The analytical phase of this study was terminated on 23 December, 2002. The maximum interval from the initiation of processing to termination of analysis is 874 days or about 29 months.

As the maximum length of time from the initiation of processing to the completion of analysis is less than or equal to 29 months, the current stability data of 30 months is sufficient to support these processed grape commodities.

**HED's Conclusion # 5.**

Adequate information regarding the length of storage of grape juice (or must) and raisins have been provided. The interval from initiation to termination of analysis were  $\leq$  29 months.

**Deficiency # 6.**

The proposed tolerances should be revised to reflect the recommended tolerance levels and correct commodity definitions as specified in Table 6.

**Petitioner's Response to Deficiency # 6.**

A revised Section F is attached.

**HED's Conclusion # 6.**

A revised Section F is attached. No further information is required.



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**R149023**

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