U. S. ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

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

MEMORANDUM

DATE: November 8, 2000

SUBJECT: PP# 0F06139. Pyraclostrobin (BAS 500F) in or on Various Crops. Request for Tolerance Method Validation (TMV) Trial.

DP Barcode:	D269850	Chemical#:	099100
PRAT Case#:	292946	Class:	Fungicide
Submission#:	S583112	Trade Name:	Headline™, Cabrio™
EPA Reg#:	7969-XXX		
MRID#:	45118505 (D9904)	45118504 (D9808)	
	45118509 (D9902)	45118510 (446/1)	
	45118501 (ILV of D 9904)		
	45118503 (ILV of D 9908)		
	45118507 (ILV of 446/1)		
	45118514 (ILV of 439/0)		

FROM: Leung Cheng, Chemist
Registration Action Branch 3
HED (7509C)

THRU: Stephen Dapson, Branch Senior Scientist
Registration Action Branch 3
HED (7509C)

TO: F. D. Griffith, Jr., Chief
Analytical Chemistry Branch
Biological and Economics Analysis Division (7503C)

BASF Corporation has submitted a petition for the establishment of permanent tolerances for residues of the new chemical fungicide pyraclostrobin (BAS 500F, methyl-N-[[[1-(4-chlorophenyl)pyrazol-3-yl]oxy]-o-tolyl]-N-methoxycarbamate) and its desmethoxy metabolite methyl-N-[[[1-(4-chlorophenyl)pyrazol-3-yl]oxy]-o-tolyl] carbamate, expressed as parent

compound, in/on the following commodities:

Banana	0.04 ppm
Barley (grain)	0.4 ppm
Barley (hay)	25 ppm
Barley (straw)	6.0 ppm
Berries (crop group)	1.0 ppm
Bulb vegetables (crop group)	0.7 ppm
Citrus (crop group)	0.7 ppm
Cucurbit vegetables (crop group)	0.5 ppm
Fruiting vegetables (crop group)	1.0 ppm
Grapes	2.0 ppm
Grass (seed screenings)	27.0 ppm
Grass (straw)	14.0 ppm
Grass (forage)	10.0 ppm
Grass (hay)	4.5 ppm
Lentil	0.5 ppm
Peanut (nutmeat)	0.05 ppm
Pea (dry seed)	0.4 ppm
Pistachio	0.5 ppm
Root vegetables (crop subgroup 1-B)	0.4 ppm
Radish (tops)	16.0 ppm
Rye (grain)	0.04 ppm
Rye (straw)	0.5 ppm
Stone fruits (crop group)	0.7 ppm
Strawberry	0.4 ppm
Sugar beet (root)	0.2 ppm
Sugar beet (top)	8.0 ppm
Tuberous and corm vegetables (crop subgroup 1-C)	0.04 ppm
Tree nuts (crop group)	0.04 ppm
Almond hulls	1.6 ppm
Wheat (grain)	0.20 ppm
Wheat (hay)	6.0 ppm
Wheat (straw)	6.0 ppm
Wheat (aspirated grain fractions)	0.5 ppm
Orange pulp (dry)	6.3 ppm
Orange oil	4.2 ppm
Tomato paste	2.0 ppm
Raisin	6.0 ppm
Peanut oil	0.1 ppm
Sugar beet pulp (dry)	1.6 ppm
Milk	0.03 ppm
Cattle muscle	0.1 ppm

Cattle liver	0.6 ppm
Cattle kidney	0.1 ppm
Cattle fat	0.1 ppm
Eggs	0.1 ppm
Poultry muscle	0.1 ppm
Poultry liver	0.1 ppm
Poultry fat	0.1 ppm

The petitioner has submitted BASF Method D9904 and Method D9808 (USA) for determining pyraclostrobin residues in plant commodities, and Method 439/0 and Method 446/1 for animal commodities.

For the two plant methods (D9904 and D9808), the reported LOQs for pyraclostrobin and its desmethoxy metabolite are 0.02 ppm each in plant commodities. For Method 439/0, the reported LOQ is 0.01 ppm pyraclostrobin in milk and 0.05 ppm in tissues. For Method 446/1, the reported LOQs are 0.01 ppm in milk and 0.05 ppm in tissues each for parent and its desmethoxy metabolite.

For the plant methods, an independent laboratory validation (ILV) of Method D9904 (MRID 45118501) was conducted at BASF APC, RTP, NC using grape and wheat straw and is entitled:

> "Independent Laboratory Validation of BASF Analytical Method D9904 Entitled "Method for the Determination of BAS 500 F and Its Metabolite BF 500-3 Residues in Plant Matrices Using HPLC-UV"", J. Jordan (2000): BASF Study No.: 64058.

An ILV of Method D9808 (MRID 45118503) was conducted by ADPEN Laboratories, Inc, Jacksonville, FL. using grape and wheat straw, and is entitled:

> "Independent Laboratory Validation of BASF Method Numbers D9808 (USA) and 421/0 (Germany) Entitled "Method for Determination of BAS 500 F and its Metabolite BF 500-3 Residues in Plant Matrices Using LC/MS/MS"", R. Perez and S. Perez (2000): BASF Study No.: 63832.

For the animal methods, an ILV of Method 439/0 (MRID 45118514) was conducted at Fraunhofer Institute of Toxicology, Hannover, Germany using muscle and milk, and is entitled:

> "Independent Validation of BASF Method 439/0 for the Determination of BAS 500 F (as Parent Compound) in Matrices of Animal Origin", Dr. J. Kruppa (1999): Laboratory Project Identification No.: 15 G 99015.

An ILVof Method 446/1 (MRID 45118507) was conducted at BASF, RTP, NC using milk and liver, and is entitled:

"Independent Laboratory Validation of BASF Analytical Method 446/1 Entitled "LC/MS/MS Method for the Determination of REG No. 304428 (BAS 500 F) and Its Metabolites BF 500-10 in Matrices of Animal Origin"", J. Jordan (2000): BASF Study No.: 62681.

RAB3 requests that ACB/BEAD conduct a TMV of BASF Analytical Methods D9904, D9808, and 446/1 per the experimental design specified in Attachment 1. This matrix was developed in consultation between F. D. Griffith, Jr., BEAD, and L. Cheng, HED, telecon, 10/30/2000. All samples should be run in duplicate. Please complete and return Attachment 1 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.

The petition makes no reference to submission of analytical reference standards to EPA. Should you find that the necessary analytical reference standards and/or Material Safety Data Sheets (MSDSs) are not available to you, please contact BASF directly for submission of these standards (Charlotte Sanson, 919-547-2983).

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.

RD has assigned pyraclostrobin a PRATS Priority Classification Ranking of "20". The DDL for completion of data reviews by EPA is 6/2001. The RD Product Manager for pyraclostrobin is Cynthia Giles-Parker (703) 305-7740 and the PM Team reviewer John Bazuin (703) 305-7381. They may be contacted directly if you require guidance concerning the priority for initiation/completion of this TMV.

Please address and send your report to Leung Cheng, Chemist, RAB3/HED, 7509C. If you need further information from me my telephone number is (703) 305-5926. The DP barcodes assigned by HED for conducting this TMV are D269851, 269852, and D269853.

Attachments:

1. TMV Experimental design
2. Proposed enforcement method D9904
3. Proposed enforcement method D9808
4. Proposed enforcement method D9902
5. Proposed enforcement method 446/1

6. ILV of method D9904
7. ILV of method D9808
8. ILV of method 446/1
9. ILV of method 439/0

cc (with Attachment 1 only): L. Cheng, RAB3 Reading File, Giles-Parker (RD/7505C).
RD/I:ChemTeam:11/1/2000:SDapson:11/6/2000
7509C:CM#2:Rm810A:LCheng:10/30/2000:pyraclostrobin/tmv

ATTACHMENT 1

Experimental Design for Pyraclostrobin TMV

METHOD D9904 - "Method for the Determination of BAS 500 F and Its Metabolite BF 500-3 Residues in Plant Matrices Using HPLC-UV", J. Jordan (2000): BASF Study No.: 64058. Unpublished study prepared by BASF Corporation. (MRID 45118505).

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	Pyraclostrobin			BF 500-3		
	ppm Added	**ppm Found**	**% Recovered**	**ppm Added**	**ppm Found**	**% Recovered**
Whole orange	control		NA	control		NA
	0.02			0.02		
	0.5			0.5		
	1.0			1.0		
Peanut nutmeat	control		NA	control		NA
	0.02			0.02		
	0.05			0.05		
Tomato	control		NA	control		NA
	0.02			0.02		
	0.5			0.5		
	1.0			1.0		
Wheat straw	control		NA	control		NA
	0.02			0.05		
	3.0			3.0		
	6.0			6.0		

NA = Not Applicable

METHOD D9808 - "Method for Determination of BAS 500 F and its Metabolite BF 500-3 Residues in Plant Matrices Using LC/MS/MS"", R. Perez and S. Perez (2000): BASF Study No.: 63832. Unpublished study prepared by BASF Corporation. (MRID 45118504).

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	Pyraclostrobin			BF 500-3		
	ppm Added	ppm Found	% Recovered	ppm Added	ppm Found	% Recovered
Whole orange	control		NA	control		NA
	0.02			0.02		
	0.5			0.5		
	1.0			1.0		
Peanut nutmeat	control		NA	control		NA
	0.02			0.02		
	0.05			0.05		
Tomato	control		NA	control		NA
	0.02			0.02		
	0.5			0.5		
	1.0			1.0		
Wheat straw	control		NA	control		NA
	0.02			0.05		
	3.0			3.0		
	6.0			6.0		

NA = Not Applicable

METHOD 446/1 - "LC/MS/MS Method for the Determination of REG No. 304428 (BAS 500 F) and Its Metabolites BF 500-10 in Matrices of Animal Origin", J. Jordan (2000): BASF Study No.: 62681. Unpublished study prepared by BASF Corporation. (MRID 45118510).

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	Pyraclostrobin			BF 500-10		
	ppm Added	**ppm Found**	**% Recovered**	**ppm Added**	**ppm Found**	**% Recovered**
Whole milk	control		NA	control		NA
	0.01			0.01		
	0.03			0.03		
Beef liver	control		NA	control		NA
	0.05			0.05		
	0.3			0.3		
	0.6			0.6		
Egg	control		NA	control		NA
	0.05			0.05		
	0.1			0.1		
Poultry muscle	control		NA	control		NA
	0.05			0.05		
	0.1			0.1		

NA = 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:

Instrumentation for Confirmation:

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

Commercial Source for any Special Chemicals or Apparatus:

Comments:

Chromatograms:

13544

010035

Chemical:	**Invalid PC Code**
PC Code:	**099100**
HED File Code	**11000 Chemistry Reviews**
Memo Date:	**11/08/2000**
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