

DATE OUT: 27/FEB/2002

SUBJECT: PRODUCT CHEMISTRY REVIEW OF MP [] EP [X]
DP BARCODE No.: D278322 REG./File Symbol No.: 7969-ROO
PRODUCT NAME: BAS 516 02F Crop Fungicide

FROM: Shyam Mathur, Chemist
Product Chemistry Team
Technical Review Branch/RD (7505C)

Shyam Mathur
02-27-02

TO: Cynthia Giles-Parker, PM 22
Fungicide Branch/RD(7505C)

INTRODUCTION:

The registrant has submitted product chemistry data to support the registration of the subject end-use product. The product chemistry data were submitted under MRID Nos. 454053-09, 454053-11 and 454053-12. The subject product contains two active ingredients which are under process of registration with the Agency. For some inert ingredients, the registrant has proposed wider certified limits and are different than the standard limits as per 40CFR§158.175.(b)(2). The registrant has provided proper justifications for proposing those limits.

SUMMARY OF FINDINGS

1. The subject product contains BAS 510 F technical (File symbol. No. 7969-ROI, 99.0%) and Pyraclostrobin (98%) as the active ingredients with product label claims of 25.2% and 12.8% respectively.
2. The CSF for the basic formulation (undated and unsigned) is filled out correctly and completely. It is in compliance with PR Notice 91-2 and agree with the label claim nominal concentration. The data submitted corresponding to the guideline reference 830.1550 (Product Identity) and 830.1750 (Certified limits) do not satisfy the data requirements of 40CFR§158.155 and 158.175 respectively, since four inert ingredient used in the formulation are not cleared by the Agency.
3. The data submitted corresponding to the guideline reference 830.1650 (Description of formulation process) and 830.1670 (Discussion on the formation of impurities) satisfy the data requirements of 40CFR§158.165 and 158.167 respectively.
4. The data submitted corresponding to the guideline reference 830.1800 (Enforcement of analytical method) satisfy the data requirements of 40CFR§158.180.

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5. The data submitted corresponding to guideline reference color (830.6302), odor (830.6304), Physical state (830.6303), density (830.7300), pH (830.7000), Oxidation/Reduction (830.6314), Flammability (830.6315), Explodability (830.6316), Viscosity (830.7100), Miscibility (830.6319), and Dielectric breakdown voltage (830.6321) satisfy the data requirements of 40CFR§158.190. The TS acts as a mild reducing agent and should not be stored near strong oxidizing agents, such as KMnO₄.

CONCLUSIONS:

The TRB has reviewed the product chemistry data submitted for the subject end-use product and has concluded that:

1. The product chemistry data submitted corresponding to guideline reference 830 Series Subgroup A and Subgroup B (Physical/Chemical properties) satisfy the data requirements of 40CFR§158.150 to 158.190 and are acceptable, except for the CSF for the basic formulation.

2. The CSF for basic formulation (undated) is not acceptable for the following reasons:

a. Four inert ingredients used in the formulation are not cleared by the Agency. The registrant must provide complete chemical composition with chemical names, CAS numbers, and percentages of each component of these inert ingredients. For the names of the inert ingredients please refer to Confidential Appendix.

b. The CSF has not been signed and not dated.

c. The values for density, & pH provided in the CSF do not match with those submitted under Subgroup B (MRID No. 454053-11).

d. The names of the AIs in the CSF do not match with the names on the product label.

The registrant must correct the errors as indicated in items a through d and submit the CSF to the Agency.

3. The proposed wider certified limits for few inert ingredients are acceptable, based on the justifications provided by the registrant.

4. The results of corrosion characteristics (830.6320) and one year storage stability (830.6317) studies must be submitted to the Agency for evaluation.

5. The registration of this end-use product (7969-ROO) is subject to the registration of the two unregistered active ingredients, which are pending the decision from the Agency.

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1. Reviewer: S.B.Mathur 2. Company: BASF Corporation
3. Type of Submission: Registration ☒ Reregistration ☐
 New ☒ Resubmission ☒ Amendment ☐ "ME-TOO" ☐
 Alternate Formulation ☐ Experimental Use Permit ☐
 Other (Specify) _____
4. If "Me-TOO" Registration, this product is ☐ is not ☐
 similar or substantially similar to EPA's Reg. No.: _____

If not, comment in Confidential Appendix A on the differences between the registered and the new source where significant

CONFIDENTIAL STATEMENT OF FORMULA

5. Type of formulation and the sources of active ingredients:
 - Non-integrated formulation system..... ☒
 - Are all technical grade active ingredients used registered?
 - yes ☐ • no ☒ If no, specify Both the Ais are pending registration with the Agency.
 - Integrated formulation system..... ☐
6. Clearance of intentionally added ingredients in the formulation for the intended use (indicate in the Confidential Appendix those that are not cleared; the PC Codes should be provided by the chemist on the CSF for those that are cleared):
- 6(a) Formulation intended for food use under 40CFR§180.1001:
 - yes ☒ • no ☐ • Some are cleared, others are not ☐
 - Cleared under list: • c ☒ • d ☒ • e ☒
 - Are there any limitations for use as an inert under 40CFR§180.1001?
 - yes ☐ • no ☐ If yes, specify _____
- 6(b) Formulation intended for non-food use:
 - yes ☐ • no ☒ • Some are cleared, others are not ☐
- 6(c) Clearance by the FDA of certain formulations under 21CFR§170 to 199. Examples: (a) indirect food additives, such as food contact surface sanitizers; adhesives, coatings, paper and paperboard products that may contact food in packaging or holding; and (b) substances generally recognized as safe (GRAS).
 - yes ☐ • no ☐ • Some are cleared, others are not ☐
 - If yes, the entire formulation is cleared under 21CFR§_____

7. The density, pH, and flammability values given on the CSF are identical with those of GRN 830.7300 (density), 830.7000 (pH), and 830.6315 (Flammability), respectively:
- yes ☐ • no ☒

Note: the values provided for pH and density in the subgroup B data do not concur with those indicated in the CSF.

8. The nominal concentrations (NC) of the active ingredients and the upper and lower certified limits (UCL & LCL) are as follows:

Active ingredient(s)	% by weight		
	NC	UCL	LCL
BAS 510 F TGAI/MUP (99%) 7969-ROI	25.5		
	(25.2)	(26.0)	(24.4)
Pyraclostrobin (98%) technical	13.1		
	(12.8)	(13.2)	(12.4)

9. The calculated NCs, based on the pure active ingredients (PAI), are identical to those on the label:
- yes ☒ • no ☐
10. The certified limits are within the standard limits as per 40CFR§158.175 or are adequately explained if different:
- yes ☒ • no ☐

PRODUCT LABEL

11. The chemical names of the active ingredients on the label are identical to those on the CSF: • yes ☒ • no ☐
12. The appropriate physical and chemical hazards statement regarding flammability or explosive characteristics of the product are given on the label:
- yes ☐ • no ☐ • not applicable ☒
13. The storage and disposal instructions for the pesticide and container are in compliance with PR Notice 84-1 for household use products or PR Notice 83-3 for all other uses:
- yes ☒ • no ☐

PRODUCT CHEMISTRY DATA (SERIES 830 Subgroup A & Subgroup B)

14. <u>Chemical IDs/Manufacture/ Analytical Information</u> New Guideline:830.---	<u>Data Required Fulfilled</u>	<u>MRID No.</u>
1550. Chemical Identity(CSF)	U	undated
1600. Beginning Materials 1650. Formulation Process	Y	454053-09
1670. Discussion of Impurities	Y	" "
1700. Preliminary Analysis	NA	
1750. Certified Limits(CSF)	U	undated
1800. Enforcmnt. of Anal.Method	Y	454053-09

15. <u>Physical/Chemical Properties</u> New Guideline No. 830.---	<u>Data Required Fulfilled</u>	<u>Value or Qualitat. Descrip.</u>	<u>MRID No.</u>
6303. Physical State	Y	extruded granules	454053-11
7300. Density/Bulk Den.	Y	0.464 gm/ml	" "
7000. pH	Y	5.81	" "
6314. Oxid/Red Action	Y	Note 1	454053-12
6315. Flamm.-Flsh Pt.	NA		
6315. Flame Exten.	NA		
6316. Explodability	NA		
6317. Storage Stablty.	PR 92-5		
7100. Viscosity	NA		
6319. Miscibility	NA		
6320. Corrosion Charac	G		
6321. Dielec.Bkd.Vltg	NA		

Explanations: Y = The Requirements Were Fulfilled; N = The Requirements Were Not Fulfilled; NA = Not Applicable; G = Data Gap; U = Requires Upgrading; I = Incomplete or In Progress; W = Waived.

Note1. 830.6314. Oxi/Red.: The TS does not react with water, iron and fire extinguisher agent like MAP. When mixed with KMnO4 there was mild exothermic reaction and therefore can be considered as mild reducing agent and should not be mixed with or stored in close proximity to strong oxidizing agents such as KMnO4.

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CONFIDENTIAL APPENDIX

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1. The names of the inert ingredients not cleared by the Agency:



7/10/03 LF

OK Kletter 7/18/03

The registrant must provide the complete chemical composition with Chemical names, CAS numbers, and percentages of each components of these inert ingredients. The MSDS provided for these inert ingredients do not provide that information.

CSF - Prod. Chem. Rev.