

Date: February 19, 2002

SUBJECT: Product Chemistry Review of BAS 510 F(Nicobifen) Manufacturing Use Product

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02-19-02

TO: Cynthia Giles-Parker, PM 22
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DP BARCODE: D278298
EPA REG. NO.: 7969-ROI
REGISTRANT: BASF Corporation
USE: Fungicide

INTRODUCTION:

The registrant has submitted Product chemistry data to support the registration of BAS 510 F(MUP)I. The product chemistry data has been submitted under MRIDs 454048-01 to 454048-13 and 454053-10. The manufacturing-use product BAS 510 F is a new reduced risk fungicide and the registrant is seeking petition for tolerances in/on several crops. Forty seven crop and livestock tolerances are being requested for this fungicide. The BAS 510 F fungicide is being used as an active ingredient in the following end-use products:

- (a). end-use product BAS 510 02 F Turf fungicide is a 70% WG Formulation and is intended for use in golf course turf only.
- (b). end-use product BAS 510 02 F Crop fungicide is also a 70% WG and includes the terrestrial food crop uses of berries crop group, grapes, lettuce, peanuts, potatoes, strawberries, stone fruit, tree nut crop group and pistachio.
- (c). end-use product BAS 516 02 F Crop Fungicide is a 38% WG mixture of BAS 510 F and pyraclostrobin.

SUMMARY OF FINDINGS:

1. The registrant has submitted the Confidential Statement of formula(unsigned & not dated) for the proposed manufacturing-use product. The nominal concentration of the AI agrees with the product label claim. The product chemistry data submitted corresponding to guideline reference 830.1550 (Product identity & Composition), and 830.1750 (Certified limits) satisfy the data requirements of 40CFR§158.155 and 158.75 respectively.
2. The product chemistry data submitted corresponding to guideline reference 830.1600 (Description of material used to produce the product) satisfy the data requirements of 40CFR§ 158.160. The registrant has provided the product specifications data on all the starting materials used for the production of this fungicide.
3. The product chemistry data submitted corresponding to guideline reference 830.1620 (Description of production process) satisfy the data requirements for 40CFR§158.162.
4. The product chemistry data submitted corresponding to guideline reference 830.1670 (Discussion on the formation of impurities)satisfy the data requirements for 40CFR§158.167.
5. The product chemistry data submitted corresponding the guideline reference 830.1700 (Preliminary analysis) satisfy the data requirements of 40CFR§158.170.
6. The data submitted corresponding to guideline reference 830.1800(Enforcement analytical method) satisfy the data requirements of 40CFR§158.180.
7. The data submitted corresponding to 830 Series Subgroup B(Physical/Chemical Properties) satisfy the data requirements of 40CFR§158.190.

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CONCLUSION:

1. The product chemistry data submitted corresponding to guideline reference 830.1550 (Product identity & Composition), and 830.1750 (Certified limits) satisfy the data requirements of 40CFR§158.155 and 158.75 respectively. The nominal concentration of the AI concurs with the product label claim of 99%. The CSF for basic formulation is acceptable with comments.

Comments:

- a. The CSF is not dated. The registrant is required to sign and put the date in Block # 21.
- b. The name of one of the impurity on the CSF must be corrected. For the name of the impurity refer to Confidential Appendix (Last page of the review).

The corrected CSF must be submitted to the Agency.

2. The product chemistry data submitted corresponding to guideline reference 830.1600 (Description of material used to produce the product) satisfy the data requirements of 40CFR§ 158.160 and are acceptable.

3. The product chemistry data submitted corresponding to guideline reference 830.1620 (Description of production process) satisfy the data requirements for 40CFR§158.162 and are acceptable.

4. The product chemistry data submitted corresponding the guideline reference 830.1700 (Preliminary analysis) satisfy the data requirements of 40CFR§158.170. The data submitted are acceptable.

5. The data submitted corresponding to guideline reference 830.1800(Enforcement analytical method) satisfy the data requirements of 40CFR§158.180. The data submitted are acceptable.

6. The product chemistry data submitted corresponding to guideline reference 830 Series Subgroup B (Physical/Chemical Properties) for the technical satisfy the data requirements of 40CFR§158.190 and are acceptable.

7. No N-nitrosamines polar and non-polar were detected in BAS 510 F(MUP). No nitrosamines were detected at or above the detection limit of 0.1 ppm for the non-polar and 1 ppm for the polar nitrosamines

8. The TRB has no knowledge on the toxicity of the impurities present in the technical. The PM is advised to contact HED regarding this issue.

BARCODE: D278298; **Reg. No. :** 7969-ROI **PRODUCT:** BAS 510 F (MUP)

830.1550. Product Identity: (MRID No. 454048-01)

Common Name: BAS 510 F (proposed common name: Nicobifen)

Chemical Name (CAS): 3-Pyridinecarboxamide, 2-chloro-N-(4'-chloro[1,1'-biphenyl]-2-yl)
(IUPAC): 2-chloro-N-(4'-chlorobiphenyl-2-yl)nicotinamide

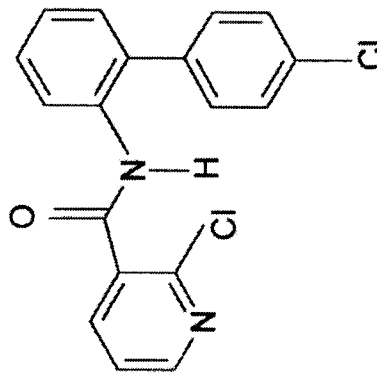
CAS No.: 188425-85-6

PC Code No.: 128008

Empirical formula: C₁₈ H₁₂ Cl₂ N₂ O

Molecular Weight: 343.21 g/mol

Structural formula:



ATTACHMENT II
REVIEW OF PRODUCT CHEMISTRY, OPPTS 830 SERIES

Chemical Name (IUPAC, ANSI, etc.)	(IUPAC): 2-chloro-N-(4'-chlorobiphenyl-2-yl)nicotinamide	
Chemical Number (CAS; PC Code)	CAS No. 188425-85-6	
	PC Code <u>128008</u>	
Registration/Symbol No.	<u>7969-ROI</u>	
Type of Product (T, MP, EP)	99.0 TGAI / MP	
DP Barcode	D278298	
Reviewer	Shyam B. Mathur	
Branch Chief	John Redden, Acting	

Table 1: Manufacturing and Impurity Data for the BAS 510 F 99.0% T/TGA1.				
GLN	Requirement	MRID	Status ¹	Details and/or Deficiency ²
830.1550	Product identity and composition	454048-01	Y	The product label claim is 99.0% which concurs with the nominal concentration in the CSF(updated)
830.1600	Description of materials used to produce product	454048-01	Y	The product specification sheets(MSDS) for all the starting materials have been provided
830.1620	Description of production process	454048-01	Y	The registrant has provided detailed information about the synthesis of the technical. the amounts of each starting material and conditions under which the reaction were performed are provided.
830.1670	Discussion of formation of impurities	454048-01	Y	The registrant has provided required information on the formation of impurities.
830.1700	Preliminary analysis	454048-01	Y	The HPLC in reversed phase mode was used to identify the AI and the impurities in the MUP. The analytical method was validated for accuracy, linearity, and precision.
830.1750	Certified limits	454048-01	Y	certified limits were established on the basis of the results of the analysis of 5 representative batches of BAS 510.
830.1800	Enforcement analytical method	454048-01	Y	HPLC in reversed phase method was used for the AI with UV detector and acetonitrile-water gradient. The HPLC method used for the AI was validated for precision, linearity, and accuracy.
¹ A = Acceptable; N = Unacceptable (see Deficiency); N/A = Not Applicable. ² Refer to CBI Appendix A for details.				

Table 2: Physical and Chemical Properties for the BAS 510 F technical. *See Note for acceptance condition				
GLN	Requirement	MRID	Status ¹	Result ² or Deficiency
830.6302	Color	454048-03	A	White
830.6303	Physical state	" "	A	Solid Powder
830.6304	Odor	" "	A	Faint smoky
830.6313	Stability to normal and elevated temperatures, metals, and metal ions	454048-10	A	The test substance was found to be stable at RT and 54C for 14 days. The TS was also found to be stable when exposed to metals like Al, & Fe, and to corresponding acetate ions.
830.6314	Oxidation/reduction: chemical incompatibility	454048-11	A	with KMnO4 weak exothermic reaction. No reaction with water, Fe, with MAP (fire extinguisher agent)
830.6315	Flammability		NA	
830.6316	Explosibility		Y	non-explosive
830.6317	Storage stability	454048-03	I	The registrant reported that the TS is stable for 14 days at 54C. One year study under warehouse conditions in commercial containers is required.
830.6319	Miscibility	" "	NA	
830.6320	Corrosion characteristics	454048-13	Y	The TS is not expected to be corrosive to the commercial storage container
830.7000	pH	454048-03	A	5.5 at 23C (1% solution)
830.7050	UV/Visible absorption	454048-08	A	207, 228, 290, and 300 nm, with $\epsilon = 31534$, 19834, 1529 and 531 respectively
830.7100	Viscosity	" "	NA	
830.7200	Melting point/ Melting range	454048-02, -03	A	143.5C
830.7220	Boiling point/ Boiling range	" "	NA	
830.7300	Density/ relative density/ bulk density	454048-03	A	702 g / l @ 20C
830.7370	Dissociation constants in water	454048-07	A	TS does not dissociate
830.7550	Partition coefficient (n-octanol/water), shake flask method	454048-09	A	log P o/w = 2.96 ; P o/w = 915 @ 21C
830.7840	Water solubility: column elution method; shake flask method	454048-04 454048-05	A	solubility (in g/l), Water = 4.64 mg / l at 20C; organic solvents g / 100 ml; acetone, 16; acetonitrile, 4; dichloromethane, 20; N,N-DMF, >25; ethylacetate, 6.7; n-heptane, <1.0; methanol, 4; 1-octanol, <1; olive oil, <1.0; 2-propanol, 1; toluene, 2.0
830.7950	Vapor pressure	454048-06	A	7 x 10 ⁻⁹ at 20C ; 2 x 10 ⁻⁸ at 25C [mbar/h Pa]
¹ A = Acceptable; N = Unacceptable (see Deficiency); N/A = Not applicable. ² For example, "brown" for 830.6302; "155° C" for 830.7200. A* = The data are acceptable only if the registrant will provide information on the methods used to determine these properties.				

Attachments: Confidential Appendix A

Review for MRID Nos.45404801 to 45404813

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Pages 7 through 18 are not included in this copy.

The material not included contains the following type of information:

- Identity of product inert ingredients.
- Identity of product impurities.
- X 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.