

3-27-03

MEMORANDUM

SUBJECT: Benfluralin. List B Reregistration Case 2030. PC Code 084301. **Product Chemistry Chapter for the Reregistration Eligibility Decision [RED] Document.** DP Barcode D267993.

FROM: K. Dockter, Chemist
Reregistration Branch 2
Health Effects Division [7509C]

THRU: Alan Nielsen, Branch Senior Scientist
Reregistration Branch 2
Health Effects Division [7509C]

TO: Richard Griffin, Risk Assessor
Reregistration Branch 2
Health Effects Division [7509C]

Attached is the RED product chemistry chapter for benfluralin [N-butyl-N-ethyl-2,6-dinitro-4-(trifluoromethyl)benzenamine; a.k.a. benefin]; a pre-emergence w/ soil incorporation herbicide registered for use on many crops & turf. This chapter was assembled by Dynamac Corporation under supervision of RRB2. The data assessment has undergone secondary and tertiary review in the Branch and has been revised to reflect Agency policies. One product chemistry data requirement remains outstanding, namely, UV/Visible absorption; 830.7050.

Attachment: Reregistration Eligibility Decision: Product Chemistry Considerations

cc: List B file, SF, RF, Dockter, R. Griffin, S. Kinard, D. Anderson.
RDI Benfluralin RED Team.
7509C:RRB2:Rm712N:57886:KD/kd
Benfluralin.RED [965] = D267993.mem.

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BENFLURALIN
Case 2030; PC Code 084301

Reregistration Eligibility Decision:
Product Chemistry Considerations

October 25, 2000

Contract No. 68-W-99-053

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

Submitted by:
Dynamac Corporation
The Dynamac Building
2275 Research Boulevard
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BENFLURALIN

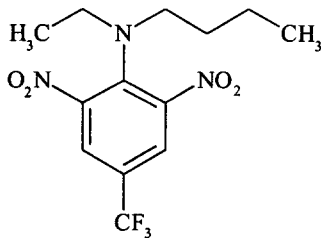
REREGISTRATION ELIGIBILITY DECISION:

PRODUCT CHEMISTRY CONSIDERATIONS

Case 2030; PC Code 084301

DESCRIPTION OF CHEMICAL

Benfluralin (also known as benefin; N-butyl-N-ethyl- α,α,α -trifluoro-2,6-dinitro-p-toluidine) is an herbicide registered for use on alfalfa, birdsfoot trefoil, clover, and lettuce. Benfluralin formulations are also registered for use on ornamental plants, forest trees, turf and established turfgrasses, nonbearing fruit and nut trees, nonbearing vineyards, and nonbearing berries.



Empirical Formula:	C ₁₃ H ₁₆ F ₃ N ₃ O ₄
Molecular Weight:	335.3
CAS Registry No.:	1861-40-1
PC Code:	084301

IDENTIFICATION OF ACTIVE INGREDIENT

Benfluralin is a yellowish-orange crystalline solid with a melting point of 65-68 C, density of 78 lb/cu ft (packed), octanol/water partition coefficient (log P_{ow}) of 5.29, and vapor pressure of 6.57 x 10⁻⁵ mm/Hg at 25 C. Benfluralin is practically insoluble in water (0.1 ppm at pH 7 and 25 C), but is readily soluble in organic solvents such as acetone (>500 mg/mL), chloroform (>500 mg/mL), and xylene (450 mg/mL), and less soluble in solvents such as methanol (40 mg/mL).

MANUFACTURING-USE PRODUCTS

A search of the Reference Files System (REFS) conducted 2/6/03 identified five benfluralin manufacturing-use products (MPs) registered under PC Code 084301. Two 96.6% technical products (Ts) are registered to Dow Agrosciences LLC (EPA Reg. No. 62719-100) and Dintec Agrichemicals (EPA Reg. No. 68156-1); three formulation intermediates (FIs) are registered to Dow Agrosciences

LLC (50%, 19.4%, and 16.3% FIs; EPA Reg. Nos. 62719-103, 62719-102, and 62719-117, respectively). The Dow Agrosiences products were transferred from DowElanco (EPA Reg. No. 1471) in 1989. Because benfluralin is a List B chemical, only the Dow Agrosiences and Dintec Agrichemicals 96.6% T/TGAIs are subject to a reregistration eligibility decision.

REGULATORY BACKGROUND

Benfluralin was the subject of the Product Chemistry Chapter of the Benefin Reregistration Standard dated 11/17/88. In addition, the Benfluralin Phase 4 Reviews were issued on 12/18/90 (L. Cheng). The Phase 4 Reviews determined that the available product chemistry submissions for the DowElanco T/TGAI concerning color, physical state, odor, melting point, density, and solubility (OPPTS 830.6302, 6303, 6304, 7200, 7300, and 7840) were acceptable for Phase 5 review; for the remaining product chemistry requirements, the Phase 4 Reviews indicated that the registrant had committed to generate new studies. The Dintec Agrichemicals T was registered subsequent (6/94) to the Benfluralin Phase 4 Review.

The current status of the product chemistry data requirements for the benfluralin T/TGAIs is presented in the attached data summary tables. Refer to these tables for a listing of the outstanding product chemistry data requirements.

CONCLUSIONS

All pertinent product chemistry data requirements are satisfied for the Dow Agrosiences 96.6% T/TGAI, except that additional data are required concerning UV/visible absorption (OPPTS 830.7050). Because the Dintec Agrichemicals 96.6% T is repackaged from an EPA-registered product, [REDACTED] all product chemistry data requirements will be satisfied by data for the source product. Provided that the registrants submit the data required in the attached data summary tables for the 96.6% T/TGAIs, and either certify that the suppliers of beginning materials and the manufacturing process for the technical products have not changed since the last comprehensive product chemistry review or submit complete updated product chemistry data packages, the Agency has no objections to the reregistration of benfluralin with respect to product chemistry data requirements.

PROCEED WITH REREGERISTRATION OF BENFLURALIN

7/10/94

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Case No. 2030
PC Code 084301

Case Name: Benfluralin
Registrant: Dow Agrosiences LLC
Product(s): 96.6% T (EPA Reg. No. 62719-100)

PRODUCT CHEMISTRY DATA SUMMARY

Guideline Number	Requirement	Are Data Requirements Fulfilled? ¹	MRID Number ²
830.1550	Product identity and composition	Y	42039401 ³ , 42340801 ⁴ , 44258001 ⁵ , CSF 2/13/97 ⁵
830.1600	Description of materials used to produce the product	Y	42039401 ³ , 42779101 ⁶ , 44258001 ⁵
830.1620	Description of production process	Y	42039401 ³ , 44258001 ⁵
830.1670	Discussion of formation of impurities	Y	42039401 ³ , 44258001 ⁵
830.1700	Preliminary analysis	Y	42340801 ⁴ , 43548701 ⁷ , 43548702 ⁷ , 44258002 ⁵
830.1750	Certified limits	Y	42340801 ⁴ , 44258001 ⁵ , CSF 2/13/97 ⁵
830.1800	Enforcement analytical method	Y	42340801 ⁴ , 43548702 ⁷ , 44258003 ⁵ , 44258004 ⁵
830.6302	Color	Y	00160844
830.6303	Physical state	Y	00160844
830.6304	Odor	Y	00160844
830.6313	Stability to normal and elevated temperatures, metals, and metal ions	Y	42066201 ³
830.7000	pH	N/A ⁸	
830.7050	UV/Visible absorption	N ⁹	
830.7200	Melting point/melting range	Y	00160844
830.7220	Boiling point/boiling range	N/A ¹⁰	
830.7300	Density/relative density/bulk density	Y	00160844
830.7370	Dissociation constants in water	N/A ¹¹	
830.7550	Partition coefficient (n-octanol/water), shake flask method	Y	42039402 ³
830.7840	Water solubility: column elution method; shake flask method	Y	00160844
830.7950	Vapor pressure	Y	42785301 ¹²

¹ Y = Yes; N = No; N/A = Not Applicable.

² **Bolded** references were determined to be acceptable for Phase 5 review in the Benfluralin Phase 4 Reviews dated 12/18/90 (L. Cheng). All other references were reviewed as noted.

³ DP Barcodes D170322 and D170699, 4/17/92, K. Dockter

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⁴ DP Barcode D180911, 2/25/93, K. Dockter.

⁵ Registration Division (RD), D235555, 5/7/97, S. Mathur.

⁶ DP Barcode D192168, 7/12/93, F. Toghrol.

⁷ DP Barcode D212293, 5/8/95, K. Dockter; nitrosamine analysis and method validation.

⁸ Not required because the T/TGAI is not dispersible in water.

⁹ The OPPTS Series 830, Product Properties Test Guidelines require data pertaining to UV/visible absorption for the PAI.

¹⁰ Data are not required because the TGAI is a solid at room temperature.

¹¹ Data were not required in the Benfluralin Phase 4 Review (12/18/90, L. Cheng).

¹² DP Barcode D192007, 7/12/93, F. Toghrol.

Case No. 2030
PC Code 084301

Case Name: Benfluralin
Registrant: Dintec Agrichemicals
Product(s): 96.6% T (EPA Reg. No. 68156-1)

PRODUCT CHEMISTRY DATA SUMMARY

Guideline Number	Requirement	Are Data Requirements Fulfilled? ¹	MRID Number
830.1550	Product identity and composition	Y	CSF 5/19/94 ²
830.1600	Description of materials used to produce the product	N/A	
830.1620	Description of production process	N/A	
830.1670	Discussion of formation of impurities	N/A	
830.1700	Preliminary analysis	N/A	
830.1750	Certified limits	Y	CSF 5/19/94 ²
830.1800	Enforcement analytical method	N/A	
830.6302	Color	N/A	
830.6303	Physical state	N/A	
830.6304	Odor	N/A	
830.6313	Stability to normal and elevated temperatures, metals, and metal ions	N/A	
830.7000	pH	N/A	
830.7050	UV/Visible absorption	N/A	
830.7200	Melting point/melting range	N/A	
830.7220	Boiling point/boiling range	N/A	
830.7300	Density/relative density/bulk density	N/A	
830.7370	Dissociation constants in water	N/A	
830.7550	Partition coefficient (n-octanol/water), shake flask method	N/A	
830.7840	Water solubility- column elution method, shake flask method	N/A	
830.7950	Vapor pressure	N/A	

¹ Y = Yes; N = No; N/A = Not Applicable. This product is repackaged from an EPA-registered technical product; all product chemistry data requirements will be satisfied by data for the source product.

² The CSF was obtained from the product jacket. We note that, although the product is 100% repackaged from an EPA-registered product; the nominal concentration and certified limits listed on the CSF should reflect the actual levels of the active ingredient in the product.

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AGENCY MEMORANDA CITED IN THIS DOCUMENT

DP Barcode(s): D170322 and D170699
Subject: Reregistration of Benfluralin. DowElanco Product Chemistry Considerations.
Rereg. Case #2030; Chemical #84301.
From: K. Dockter
To: L. DeLuise/T. Myers
Dated: 4/17/92
MRID(s): 42066201, 42039401, and 42039402

DP Barcode(s): D180911
Subject: Reregistration of Benfluralin. DowElanco Product Chemistry [mainly Nitrosamine data] responses to L. Cheng 12/18/90 and K. Dockter 4/17/92 reviews.
From: K. Dockter
To: T. Myers
Dated: 2/25/93
MRID(s): 42340801

DP Barcode(s): D192168
Subject: Benfluralin Reregistration: List B Chemical (Chemical No. 084301; Case No. 2030) DowElanco Response to the Product Chemistry Data Requirement Regarding Beginning Materials and Manufacturing Process (GLN 61-2(a)).
From: F. Toghrol
To: V. Dietrich/T. Myers
Dated: 7/12/93
MRID(s): 42779101

DP Barcode(s): D192007
Subject: Benfluralin Reregistration (List B; Case No. 2030; Chemical No. 084301) DowElanco Response to the Data Requirement Regarding Vapor Pressure (GLN 63-9) of Benfluralin 96% T/MP (EPA Reg. No. 62719-100).
From: F. Toghrol
To: V. Dietrich/T. Myers
Dated: 7/12/93
MRID(s): 42785301

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DP Barcode(s): D201619
Subject: Benfluralin. DowElanco 3/25/94 Fax Response [62-1 - Nitrosamine Analysis -
GLP Waiver Request for the 96% technical; 62719-100] to Agency 4/23/93 Letter,
RE: K. Dockter 2/25/93 Review; Rereg. Case 2030.
From: K. Dockter
To: D. Canales
Dated: 6/17/94
MRID(s): None

DP Barcode(s): D212293
Subject: Benfluralin. DowElanco 2/14/95 Response [62-1 & 62-3 Nitrosamine Analysis &
Method Validation for the technical] Rereg. Case 2030.
From: K. Dockter
To: R. Kendall/M. Wilhite
Dated: 5/8/95
MRID(s): 43548701 and 43548702

DP Barcode(s): RD Memorandum; D235555
Subject: Product Chemistry Review of Technical; Reg. No.: 62719-100; Product Name:
Balan Technical; Company: DowElanco
From: S. Mathur
To: P. Errico
Dated: 5/7/97
MRID(s): 44258001-44258004

PRODUCT CHEMISTRY CITATIONS

Bibliographic citations include only MRIDs containing data which fulfill data requirements.

References (cited):

00160844 West, S.; Cassell, R. (1985) Physical and Chemical Properties of Technical Benfenin:
EWD8514. Unpublished study prepared by Lilly Research Laboratories. 7 p.

42039401 Handy, P.; Reinhart, R. (1991) Product Composition of Technical Benfenin: Lab Project

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Number: PRH9103. Unpublished study prepared by DowElanco. 20 p.

42039402 Day, E.; Saunders, D.; Loh, A. (1983) Octanol/Water Partition Coefficient of Benefin: Lab Project Number: IOEWD-93-29. Unpublished study prepared by Lilly Research Labs. 9 p.

42066201 Handy, P. (1991) Stability of Technical Benefin to Metals and Metal Ions: Lab Project Number: FOR91062. Unpublished study prepared by DowElanco, Formulation and Environ. Chem. Lab. 13 p.

42340801 DowElanco (1992) Analysis and Certification of Benefin Technical Grade Active Ingredient (T2A CHEPHY US 89-139). 20 p.

42779101 Linscott, D. (1993) Technical Benefin--Beginning Materials Specification Sheets: Lab Project Number: DJL040793. Unpublished study prepared by DowElanco. 34 p.

42785301 Decker, O. (1987) Vapor Pressure of Benefin: Lab Project Number: ODD8720. Unpublished study prepared by Lilly Research Labs. 13 p.

43548701 Hamilton, T. (1995) Series 62-1: Preliminary Analysis of Product Sample of Benefin Technical for Nitrosamines: Lab Project Number: FOR93097. Unpublished study prepared by DowElanco. 22 p.

43548702 Hamilton, T. (1995) Validation of an Analytical Method for the Determination of N-Nitroso Compounds in Benefin Technical Grade Active Ingredient: Lab Project Number: FOR93120.01. Unpublished study prepared by DowElanco. 35 p.

44258001 Linscott, D.; Owen, J.; Cook, J. (1997) Series 61: Product Identity and Composition of Balan Technical: Lab Project Number: GH-C 4268. Unpublished study prepared by DowElanco. 123 p. (Relates to L0000159).

44258002 Hanselman, D.; Yeh, L. (1997) Preliminary Analysis of Product Samples for Active Ingredient and Impurities in Technical Grade Benefin: (Final Report): Lab Project Number: FOR96137. Unpublished study prepared by DowElanco. 77 p.

44258003 Hanselman, D.; Yeh, L. (1997) Analytical Method and Validation for the Determination of Benefin in Benefin Technical by Gas Chromatography with Flame Ionization Detection: Lab Project Number: NA-AM-96-006. Unpublished study prepared by DowElanco. 22 p.