

US EPA ARCHIVE DOCUMENT

**FEE**

Date: October 27, 2005

SUBJECT: FEE: 2,4-Dichlorophenoxyacetic Acid

FROM: Debra Rate  
Product Chemistry Team  
Technical Review Branch/RD (7505C)

*Debra Rate*  
*8/20/05 10-27-05-*

TO: Joanne Miller / Tracy White RM 23  
Herbicide Branch / RD (7505C)

DECISION NO: 357159  
DP BARCODE: 317898  
EPA REG. NO.: 2217-455  
PRODUCT: 2,4-Dichlorophenoxyacetic Acid  
PCC: 030001  
REGISTRANT: PBI/Gordon Corp.  
USE: Herbicide

**INTRODUCTION:**

The registrant had originally requested review of an alternate formulation CSF (dated 02/MAR/2005) with a different technical source and site of manufacture for the technical product 2,4-dichlorophenoxyacetic acid. However, through the review process and discussions with the registrant, this alternate formulation has been resubmitted as the basic CSF (dated 24/OCT/2005), and the previously accepted basic CSF (dated 01/OCT/1992) has been resubmitted as an alternate formulation CSF (dated 24/OCT/2005). The following studies were submitted to support the new basic formulation CSF (dated 24/OCT/2005): MRID No. 465482-01, 465482-02, and 465529-01. The new formulation is being submitted for a new manufacturing site in Gujarat, India. Along with the new manufacturing site, new sources for the starting materials are proposed. The technical review branch (TRB) has been asked to review the submitted data and CSFs (dated 24/OCT/2005) for acceptability.

**SUMMARY OF FINDINGS:**

1. The manufacturing site where this product is to be produced by PBI/Gordon Corp. is located at Atul Limited, Agrochemicals Division, Gujarat, India. The 5 batch analysis was performed by Midwest Research Institute (MRI) on test substances (Supplied by Atul Limited.) of the subject product produced by PBI/Gordon Corp.
2. The registrant has submitted a basic formulation CSF 5 (dated 24/OCT/2005) for 2,4-dichlorophenoxyacetic acid to replace the previously accepted basic CSF (dated 01/OCT/1992). The nominal concentration (98.2%) of the AI (2,4-dichlorophenoxyacetic acid) concurs with the product label claim nominal concentration of 98.2%. 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 158.175, respectively.
3. The registrant has submitted an alternate CSF (dated 24/OCT/2005) identical to the previously accepted basic CSF (dated 01/OCT/1992), because the newly submitted basic CSF (dated 24/OCT/2005) would supersede it as the basic CSF.
4. The subject product is produced in an integrated system. The description submitted in MRID No. 465482-01 detailing the production and manufacturing processes corresponding to guidelines 830.1600 and 830.1620, satisfy the requirements for 40CFR§158.160 and 158.162.
5. The registrant has provided an adequate explanation of the impurities that are known to be associated with the subject product and potential impurities of the subject product. This submitted data corresponding to guideline 830.1670 (discussion on the formation of impurities) satisfy the data requirements of 40CFR§158.167. The preliminary 5-batch analysis provided by the registrant concurs with the data the registrant presented on the impurities. [MRID No. 465482-01]
6. The product chemistry data submitted corresponding to the guideline reference 830.1700 (preliminary analysis) satisfy the data requirements for 40CFR§158.170. The % AI and the impurities were determined

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for the test substance. Although a discussion is presented on toxic impurities that could theoretically be present, no toxic impurities are reported present in the 5 batch analysis or on the newly submitted basic formulation CSF (dated 24/OCT/2005). See the Confidential Appendix for details. [MRID No. 465482-02 and 465529-01]

7. The registrant has chosen to cite a previously submitted study (MRID No. 445435-02) to support reference guideline 830.1800 (Enforcement Analytical Method). This cited study satisfies the data requirements of 40CFR§158.180. The method of analysis of the active ingredient (AI) is high-performance liquid chromatography (HPLC) with UV detection (280 nm).

8. The data corresponding to 830 Series Subgroup B (physical-chemical properties) are not required to be submitted for alternate formulation to fulfill the data requirements for 40CFR§158.190. Data submitted for the previously accepted basic formulation CSF (dated 01/OCT/1992) is acceptable for the newly submitted basic formulation CSF (dated 24/OCT/2005).

9 Label requirements for ingredient statement, physical and chemistry (i.e. flammability) and storage and disposal fulfill the label requirements from a product chemistry point of view.

#### **CONCLUSIONS:**

TRB has reviewed the product chemistry data submitted for 2,4-Dichlorophenoxyacetic Acid, and has concluded that:

1. All of the product chemistry data submitted corresponding to 830 Series Subgroup A are acceptable and satisfy the data requirements of 40CFR§158.155.

2. The data submitted corresponding to reference guidelines 830 Series Subgroup B data are acceptable, and satisfy the data requirements of 40CFR§158.190.

3. The newly submitted CSF for basic formulation (dated 24/OCT/2005) is acceptable and supersedes the previously accepted basic CSF (dated 01/OCT/2005).

4. The alternate formulation CSF (dated 24/OCT/2005) submitted with the identical formulation to replace the previously accepted basic CSF (dated 01/OCT/1992) (now superseded, see Conclusion #3) is acceptable.

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Common Name: 2,4-D Acid

Chemical name: 2,4-Dichlorophenoxyacetic Acid

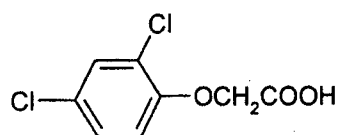
CAS No.: 94-75-7

PC Code No.: 030001

Empirical formula:  $C_8H_6Cl_2O_3$

Molecular Weight: 221.0

Structural formula:



## ATTACHMENT II

## REVIEW OF PRODUCT CHEMISTRY, OPPTS 830 SERIES

Chemical Name (IUPAC, CAS)	2,4-Dichlorophenoxyacetic Acid	
Chemical Number (CAS; PC Code)	CAS No. 94-75-7	PC Code: 030001
Registration/Symbol No.	2217-455	
Type of Product (T, MP, EP)	98.2% TGAI	
DP Barcode	317898	
Reviewer	Debra Rate	
Branch Chief	Deborah McCall	

GLN	Requirement	MRID	Status <sup>1</sup>	Details and/or Deficiency <sup>2</sup>
830.1550	Product Identity & Disclosure of Ingredients	465482-01 CSF (dated 02/MAR/2005)	Y	The nominal concentration of the AI (98.2%) is within the certified limits of the basic CSF (dated ) and is supported by the 5 batch analyses to be with in the certified limits.
830.1600 830.1620	Starting Materials & Manufacturing Process	465482-01	Y	Registrant has submitted to the reviewer the MSDS of the starting materials. The registrant has provided a detailed description of the manufacturing process as well as the quality control measures in place to ensure a 98.5% min. for the TGAI.
830.1670	Discussion of Impurities	465482-01	Y	The registrant discussed the impurities that are found in this product, and the potentially formed impurities of toxicological concern. Although these impurities were not identified in the Preliminary analysis, the Agency should be aware of the possibility of their presence.
830.1700	Preliminary Analysis	465482-02, 465529-01	Y	A 5 batch analysis has been completed on the proposed product which supports the basic CSF submitted with the studies.
830.1750	Certification of Limits	465482-01 CSF (dated 02/MAR/2005)	Y	The registrant based the upper certified limits on the results obtained from the 5 batch analyses, the manufacturing history, and the standards set forth in 40CFR§158.175(b)(2).
830.1800	Analytical Methods	445435-02	U	An appropriate Method of Enforcement has been cited from a previously reviewed MRID study.

<sup>1</sup> A = Acceptable; N = Unacceptable (see Deficiency); U = Upgradable data; N/A = Not Applicable.

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Pages   5   through   11   are not included in this copy.

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The material not included contains the following type of information:

- Identity of product inert ingredients.
- Identity of product impurities.
- 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.
- Proprietary information pertaining to the chemical composition of an inert ingredient provided by the source of the ingredient.
- Attorney-Client Privilege.
- Claimed Confidential by submitter upon submission to the Agency.
- Internal Deliberative Information.

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\* 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.

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