

US EPA ARCHIVE DOCUMENT

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DATE OUT: 18 June 2006

SUBJECT: **PRODUCT CHEMISTRY REVIEW** **MP [X] EP []**
DP BARCODE No.: D327283
Reg. File Symbol No.: 62719-25
PRODUCT NAME: 2,4-Dichlorophenoxy Acetic Acid Flake
COMPANY: Dow AgroSciences LLC
Decision No.: 364376 **PC CODE:** 030001
FOOD USE: [] **Integrated Formulation** []

FROM: Bruce F. Kitchens, Chemist
Technical Review Branch
Registration Division (7505C)

Bruce F. Kitchens
15 June 2006
S/Bom C/22/06

TO: RM#23, Joanne Miller/Eugene Wilson
Herbicide Branch (7505C)
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INTRODUCTION:

The registrant, Dow AgroSciences LLC, is submitting a request for an alternate formulation for the manufacturing use product 2,4-Dichlorophenoxy Acetic Acid Flake. This request is the result of an alternate manufacturing site. The active ingredient in this product is 2,4-D at a label nominal concentration of 97% a.i. This product is intended for use in the manufacture of herbicide end use products. With this package, the registrant has submitted product chemistry data to satisfy the Group A: Product Identity and Composition contained in MRID# 467500-01 and 467500-02. The registrant also submitted a Confidential Statement of Formula (CSF) dated 23 Feb 2006. The Technical Review Branch (TRB) has been asked to review this submission.

SUMMARY OF FINDINGS

TRB has reviewed this submission and reports the following findings:

1. The registrant has submitted the following studies:

Crouse, C., Group A- Product Identity and Composition, Description of Materials Used to Produce the Product, Description of the Production Process, Discussion of Formation of Impurities, Preliminary Analysis, and Certified Limits of 2,4-Dichlorophenoxyacetic Acid Technical – Supplemental Information for MRID#s 410558-01, 410558-02, 410558-04, and 410558-05, Performing Laboratory: Dow AgroSciences LLC, Report No. NAFST-05-181, 27 Jan 2006, MRID# 467500-01.

Comb, A.L., 2,4-D Acid: Batch Analysis (Samples from Polaquimia, Mexico), Performing Laboratory: Huntingdon Life Sciences Limited, Project Number: DOS/424, Sponsor: Dow AgroSciences, Project Number: NAFST-04-892, 07 Dec 2005, MRID# 467500-02

2. The registrant states that the first study does not include results of experimental research, therefore, it is not subject to the requirements of 40 CFR §160 Good Laboratory Practices (GLP). However, the registrant does state that the preliminary analysis was conducted in conformance with 40 CFR §160 Good Laboratory Practice Standards.

3. The following is a brief synopsis of the studies:

The study contained in MRID# 467500-01 presented data intended to satisfy the Group A product chemistry data requirements. The study contained in MRID# 467500-02 presented the results of the preliminary analysis. In that analysis, six representative batches of the proposed product produced at an alternate location were analyzed for active and impurity content. High performance liquid chromatography (HPLC) with UV detection was used to determine the active content. Impurity content was determined by the method specified in the confidential appendix of this report.

4. Comparison of the current basic and the proposed alternate CSF are discussed in the confidential appendix. Both CSFs list the same active ingredient, the same active ingredient nominal concentration, and both have [REDACTED] common impurities and [REDACTED] dissimilar non-toxic impurities. This determination is made based on discussion provided with the basic formula. See the confidential appendix for details.

CONCLUSIONS:

TRB has reviewed this submission and concludes the following:

1. The proposed alternate formula CSF for the manufacturing use product 2,4-Dichlorophenoxy Acetic Acid Flake dated 23 Feb 2006 is acceptable.
2. This submission meets the criteria specified in 40 CFR 152.43 with respect to alternate formulations.
3. At this time, the product chemistry team has determined that changes in the impurity profile do not pose additional risks with the proposed registration.

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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.

* 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.
