Review of AH Marks
Data in support of alt. CSF
for PBI Gordon's product
Do not send
to PBI/Gordon.

DATE OUT: 09 Aug 2000

SUBJECT: **EP [ ] MP [x] PRODUCT CHEMISTRY REVIEW**
DP BARCODE No.: D267474
REG./File Symbol No.: 2217-455
PRODUCT NAME: 2,4-Dichlorophenoxy Acetic Acid
COMPANY: PBI/Gordon Corporation

TO: PM # 23, Joanne Miller/Susan Stanton
Herbicide Branch
Registration Division (7505C)

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

Bruce F. Kitchens
09 Aug 2000

INTRODUCTION:

The registrant, PBI/Gordon Corporation, is submitting a revised alternate formulation for the registered manufacturing use product, 2,4-dichlorophenoxy acetic acid (2,4-D). The manufacturer of this product, A.H. Marks and Company, Ltd., is submitting a new 5-batch analysis as a result of an improved manufacturing process. The active ingredient has a stated purity of 98.5% and is intended for use as a manufacturing use product. In support of this request, the following study has been submitted:

> "Preliminary Analysis of 5 Batches of 2,4-Dichlorophenoxyacetic Acid Technical Grade Active Ingredient (and Confidential Appendix), A.H. Marks Study No. 98/o57, Hutchinson, N.D., March 9, 1999, OPPTS Guideline 830.1700, 188 pages."

This study report is contained in MRID# 449327-01. 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. Methods presented for the determination of the active ingredient, impurities, water, ash, free phenol, and triethanolamine insolubles were validated for linearity, precision, and selectivity and were found to be acceptable methods.

2. Five randomly selected batch samples were analyzed in this study. Upon analysis of the data by the registrant, one batch was rejected and replaced by another randomly selected batch. This deviation did not affect the outcome of the study.

3. Study data indicate that the methods gave consistent results for each batch analyzed. The active ingredient concentration ranged from 97.7 to 99.0% with a mean of 98.3%.

4. The certified limits as proposed on the CSF are acceptable.

5. The nominal concentration listed on the proposed alternate CSF is not the same as the label ingredient statement.

CONCLUSIONS:

TRB has reviewed this submission and concludes the following:

1. This submission meets the data requirements as specified in 40 CFR 158.155, 158.167, 158.175, and 158.180 with respect to product identity and composition, discussion of formation impurities, certified limits, and enforcement analytical method.

2. The proposed alternate CSF dated 23 Sept 1999 is acceptable.

3. This submission meets the criteria as specified in 40 CFR 152.43 with respect to alternate formulations.

4. The five batch analysis shows that the mean active ingredient concentration was 98.3%. The label ingredient statement lists 98.2% as the nominal concentration, while the proposed CSF lists 98.5% as the nominal concentration. The registrant needs to declare a consistent nominal concentration on the CSF and the label ingredient statement.

Note: Discussed the Basic and 3 Alt. CSFs with Shyam Mathur. All have slightly different nominal concentrations. Only Alt. #1 has nom conc. of 98.2% (label claim). Per Shyam, all are OK since all are within standard certified limits of the Basic formulation. S.L. Stanton 2/18/00