DATE OUT: 28 Feb 2001

SUBJECT: **EP [ ] MP [x] PRODUCT CHEMISTRY REVIEW**
DP BARCODE No.: D272195
REG./File Symbol No.: 59639-2
PRODUCT NAME: Clethodim Technical
COMPANY: Valent U.S.A. Corp.

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

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Technical Review Branch
Registration Division (7505C)

Bruce F. Kitchens
28 Feb 2001

INTRODUCTION:

The registrant, Valent U.S.A. Corporation, is submitting a revised basic formulation for the registered manufacturing use product, Clethodim Technical. This revision is the result of quantification of a previously identified impurity. The impurity had been identified but not quantified. The active ingredient in this product is Clethodim at 93.4% a.i. and is intended for use as a manufacturing use product. In support of this request, the registrant has submitted a revised basic Confidential Statement of Formula (CSF) dated 07 Dec 2000. 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 Product Chemistry Team notes the addition to the CSF and the nominal concentration level of the newly quantitated impurity. However, no upper certified limit was supplied on the CSF for this impurity. It is also noted that the analysis was conducted on preliminary plant test samples.

2. The registrant notes that a final manufacturing process description and updated CSF will be submitted to the Agency when completed.

3. The analytical method used to quantitate the impurity in question was not submitted.

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4. The active ingredient nominal concentration listed on the label and the revised CSF are the same.

CONCLUSIONS:

TRB has reviewed this submission and concludes the following:

1. The revised basic formulation CSF dated 07 Dec 2000 is not acceptable. The newly quantitated impurity does not have an upper certified limit as specified by 40 CFR 158.167. A revised CSF must be submitted which lists the upper certified limit of the impurity. See confidential appendix for details.

2. In addition to the revised CSF and the finalized manufacturing process description, the registrant must supply the analytical method used to quantify the impurity.

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Page 216 is not included in this copy.

Pages ___ through ___ 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.

__✓__ 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.