DATE OUT: 18 Jan 2001

SUBJECT: **EP [x] MP [ ] PRODUCT CHEMISTRY REVIEW**
DP BARCODE No.: D271324
REG./File Symbol No.: 70829-G
PRODUCT NAME: ClearOut 41 Plus
COMPANY: Chemical Product Technologies

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

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

Bruce F. Kitchens
18 Jan 2001

INTRODUCTION:

This submission is a resubmission. The registrant, Chemical Product Technologies, is responding to a previous product chemistry review in which additional product chemistry data was requested. With this submission, the registrant is submitting data to satisfy Product Identity and Composition (830.1550), Description of Production Process (830.1620), and Discussion of the Formation of Impurities (830.1670) all with regard to the source of the active ingredient. The registrant also provides the identity of the source (Manufacturing Facility) of the sample that was used in the preliminary analysis. The registrant has submitted waiver requests for the following data requirements:

- Dissociation Constant (830.7370)
- Octanol/Water Partition Coefficient (830.7550)
- Water Solubility (830.7840)
- Vapor Pressure (830.7950)

The registrant indicates that two studies (MRID#s 451929-02 and -03) were intended to support the determination of nitrosamines, storage stability and corrosion characteristics in ClearOut 41 Plus even though the studies address nitrosamine content and storage stability in another product, ClearOut 62. ClearOut 41 Plus contains 41% glyphosate, while ClearOut 62 contains 61% glyphosate. The registrant reasons that since ClearOut 41 Plus is manufactured from ClearOut 62, it would be appropriate to use these studies to evaluate nitrosamine content and storage stability in ClearOut 41 Plus. The registrant also states that the same would hold true for the corrosion characteristics study. The active ingredient in this product is glyphosate isopropylamine salt at 41% a.i. and is intended for use as an herbicide.

Finally, the PM Team requests that a substantially similar determination for the unregistered source be made with EPA Reg. No. 524-420. In support of this request, the registrant has submitted a basic Confidential Statement of Formula dated 24 Jan 2000, a draft label, and product chemistry data contained in MRID# 452798-01. 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. All inert ingredients are cleared for use in formulated products. In addition, all inert ingredients are exempt from the requirement of a food tolerance.

2. Two ingredients are listed incorrectly on the CSF. See confidential appendix for details. corrected

3. The nominal concentration listed on the draft label and the CSF are the same. The percentage of the inert ingredients listed on the label ingredient statement does not agree with inert ingredient percentages on the CSF.

4. The draft label contains the appropriate storage and disposal statements. In addition, the draft label contains the appropriate physical and chemical hazards statements.

5. The active ingredient certified limits as proposed on the CSF are acceptable. Lower certified limits are missing for the intentionally added inert ingredients.

6. The unregistered source contained in the proposed product differs in composition such that it is not substantially similar to 524-420. subsequent rev

CONCLUSIONS:

TRB has reviewed this submission and concludes the following:

1. The basic formulation CSF dated 24 Jan 2000 is not acceptable and must be revised and resubmitted. Several ingredients are listed incorrectly on the CSF. Also the intentionally added inert ingredients do not list a lower certified limit. See confidential appendix for details.

2. This submission (MRID# 452798-01) meets the data requirements as specified in 40 CFR 158.155, 158.160, 158.162, and 158.167 with respect to product identity and composition, description of materials used to produce the product, description of production process, and discussion of formation impurities in regard to the unregistered technical source.

3. The registrant's request for waiver from submission of the following studies is not granted at this time.

   - Dissociation Constant (830.7370)
   - Octanol/Water Partition Coefficient (830.7550)
   - Water Solubility (830.7840)
   - Vapor Pressure (830.7950)

   The Agency agrees that new studies would not provide any new information since it is conducted on the pure active ingredient (PAI). However, under the Cite-All provisions, the registrant is required to cite study references such as Master Record Identification Number (MRID Number) and date of submission for the cited studies. When the registrant supplies this information the Agency will reconsider the waiver requests. Advise the registrant to consult 40 CFR 152.86 <u>The Cite-All Method</u> and 40 CFR 152.93 <u>Citation of a Previously Submitted Valid Study</u>.

4. This submission (MRID#s 451929-02 and 451929-03) satisfies the data requirements as specified in 830.1670, 830.6317, 830.6320 with respect to the Discussion of the Formation of Impurities (nitrosamine content), Storage Stability, and Corrosion Characteristics.

5. The unregistered source contained in the proposed product has been found not to be substantially similar to EPA Reg. No. 524-420 from a product chemistry standpoint only. See confidential appendix for details.

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Page 4 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.