DATE OUT: DEC 27 1993

DP BARCODE No.: D195714 **SUBMISSION No.:** S445126 **CASE No.:** 4024
CHEMICAL NAME: 021801 Citric Acid 20%, 076001 Phosphoric acid 23.8%, Octanoic acid 6%, and Decanoic acid 2%
PRODUCT NAME: Mandate CIP Acid Sanitizer **Reg. No.** 1677-90

REGISTRATION DIVISION/REGISTRATION SUPPORT BRANCH/PRODUCT CHEMISTRY REVIEW SECTION/TRANSMITTAL/REREGISTRATION OF A MANUFACTURING [ ]/END-USE PRODUCT [X]/8 MONTH RESPONSE TO RED

DATA SUBMITTER: 001677-90 ECOLAB, INC. **RECEIVED DATE:** 07/23/93
MRID #'s: 427276-00, 428557-01, 245476 & 245479
RD PM #/NAME: 32 Ruth Douglas **PHONE #:** 305-7964
RD CRM NAME: Wallace Powell **PHONE #:** 305-6938

MANUFACTURING PROCESS INFORMATION IS NOT INCLUDED

CONCLUSIONS

1. A Reregistration Eligibility Document for Citric Acid was published on June, 1992. EPA has waived all additional generic data requirements for citric acid (Citric Acid RED Facts, 6/92).

2. The submitted product chemistry data in support of reregistration of this end-use product, Mandate CIP Acid Sanitizer Reg. No. 1677-90, is acceptable. No additional data is needed.

3. Product label included with this submission for Mandate CIP Acid Sanitizer, Reg. No. 1677-90 EPA received 7/23/93 is acceptable.

4. Product CSF, Reg.No. 1677-90, dated 3/16/93, is unacceptable. The concentration of each active ingredient appearing in Column 13(b) of the CSF should be equal to the nominal concentration as reported in the submitted data, also expressed correctly on product label. Specifically, phosphoric acid should be listed on the CSF at 23.8% based on pure active ingredient of [redacted] and not on the basis of [redacted] Chemical purity of [redacted] was correctly stated next to the active ingredient's name of phosphoric acid. Please note that the nominal concentration should fall between the upper and lower limits. ← It already does. -wt Therefore, reported limits will need to be revised. Further, material balance should be 100%. ← It already is. -wt

5. At present, the remaining three active ingredients in the product: Phosphoric acid, octanoic acid, and decanoic acid are undergoing reregistration. The eligibility of these ingredients for reregistration must be ascertained prior to a recommendation for reregistration of this end-use products, Mandate CIP Acid Sanitizer Reg. No. 1677-90.

6. With the exception of the deficiencies cited in Conclusion #4 and 5 above, no additional product chemistry data is needed for reregistration of this end-use product, Mandate CIP Acid Sanitizer, Reg. No. 1677-90.

RECOMMENDATIONS

After resolving Conclusions #4 and 5 above, we can recommend for reregistration of this end-use product, Mandate CIP Acid Sanitizer, Reg. No. 1677-90. No additional information is needed. **NOTE TO PM:** Information presented on pages 4 & 5 is **Confidential**.

REVIEWER:	Sami Malak (signature) **Sami Malak, Chemist**	12/27/93 **Date**
SECTION HEAD:	Harold Podall (signature) **Harold Podall, Ph.D.**	12/27/93 **Date**

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DP BARCODE No.: D195714 **SUBMISSION No.:** S445126 **CASE No.:** 4024
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Detailed Considerations

NOTES:

1. Confidentiality of some of the data submitted on the basis of its falling within the scope of FIFRA§10(d)(1)(A), (B), or (C) is reviewed in Confidential Appendix A.

2. The studies included with this submission were subjected to Ecolab's Quality Assurance audits and signed by the director on 6/9/93.

3. Data waiver are: 62-1, 63-14, 63-16, 63-17, 63-19, 63-20, and 63-21.

PRODUCT CHEMISTRY DATA REQUIREMENTS

Series 61 Product Identity and Composition, MRID #428557-01

The submitted data, entitled "MANDATE - CHEMICAL CHARACTERIZATION, EPA REGISTRATION No. 1677-90". The study, sponsored by Sander L. Bull, was directed by Leanne J. Adkins, performed by Ecolab, Inc., dated 3/31/93, 14 plus 83 pages.

61-1 Product Identity & Disclosure of Ingredients

Product Name: Citric Acid, Rereg Case #4024.

Trade Name: Mandate CIP Acid Sanitizer.

Reg. No. 1677-90

Active Ingredients in the Product are:

021801 Citric Acid 20%, 076001 Phosphoric acid 23.8%, Octanoic acid 6%, and Decanoic acid 2% .

61-2 Description of Beginning Materials & Manufacturing Process
See Confidential Appendix A.

61-3 Discussion of Formation of Impurities
See Confidential Appendix A.

Series 62 Analysis and Certification of Product Ingredients

62-1 Preliminary Analysis of Product Samples
See Confidential Appendix A.

62-2 Certification of Ingredient Limits
See Confidential Appendix A.

62-3 Analytical Methods to Verify Certified Limits MRID #428557-01

The submitted data, entitled "MANDATE - CHEMICAL CHARACTERIZATION, EPA REGISTRATION No. 1677-90". The study, sponsored by Sander L. Bull, was directed by Leanne J. Adkins, performed by Ecolab, Inc., dated 3/31/93, 14 plus 83 pages.

Method for Citric Acid:

The submitted method is entitled: "A & P Test Method No. 9200200, Determination of Citric Acid". The method was written by W. J. Feil, dated 12/1/92.

An HPLC method was described for the determination of the amount of Citric acid in Mandate. The method, a reversed phase liquid chromatography, utilizes Diode Array UV detection. The peaks are then compared using an internal standard. Method precision for each acid was reported at 0.95%.

Method for Octanoic and Decanoic Acids:

The submitted method is entitled: "A & P Test Method No. 9200100, Determination of Octanoic and Decanoic Acids". The method was written by W. J. Feil, dated 11/30/92.

A GC method was described for the determination of the amount of octanoic and decanoic acids in Mandate. The method utilizes a capillary column and a flame ionization detector with an internal standard integration technique. Method precision for each acid was reported at 0.99%.

Method for Phosphoric Acid:

The submitted method is entitled: "A & P Test Method No. 9200400, Determination of Phosphoric Acid". The method was written by K. A. Grandprey, dated 11/30/92.

An anion liquid chromatography method was described for the determination of the amount of phosphoric acid in Mandate. Determination is accomplished by conductivity detection and comparison of peak heights using an external standard. Method precision for each acid was reported at 1.2%.

Series 63 Physical and Chemical Characteristics MRID #428557-01

The submitted data, entitled "MANDATE - CHEMICAL CHARACTERIZATION, EPA REGISTRATION No. 1677-90". The study, sponsored by Sander L. Bull, was directed by Leanne J. Adkins, performed by Ecolab, Inc., dated 3/31/93, 14 plus 83 pages.

63-3	Physical State:	Liquid.
63-7	Density, Bulk Density, or Specific Gravity:	10.58 pounds/gallon
63-12	pH:	8.6
63-14	Oxidizing or Reducing Action:	Waived
63-15	Flammability:	<200°F
63-16	Explodability:	Waived
63-17	Storage Stability:	Not needed.
63-18	Viscosity:	N/A
63-19	Miscibility:	Waived
63-20	Corrosion Characteristics:	Waived
63-21	Dielectric Breakdown Voltage:	Waived

Attachment: Confidential Appendix A (pages 5 & 6)

cc With Attachment: Sami Malak and Central File (Reg. No.1677-90).
H7505W:RD:RSB:PCRS:CS-1:Rm650:S.Malak:s.m.:12/27/93:308-8392: 1677-90.

Page_____ is not included in this copy.

Pages 5 through 6 are not included.

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.

I Confidential Appendix

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.