

DP BARCODE No.: D33565 File Symbol No.: 81824-RN PRODUCT NAME: Borathor MAX

DATE OUT: 26 / JAN / 2007

SUBJECT: FEE.PRODUCT CHEMISTRY REVIEW OF MP [ ] EP [X]  
DP BARCODE No.: D335565 File Symbol No.: 81824-RN  
PRODUCT NAME: Borathor MAX  
COMPANY: Ensystem II, Incorporation  
FOOD USE [ ] INTEGRATED FORMULATION [ ]  
PCC: 011103; Decision No. 372680

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*01-26-07*  
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**INTRODUCTION:**

The registrant has submitted product chemistry data in support of the registration application for the proposed end-use product Borathor MAX. The submitted product chemistry data were assigned MRID Nos. 469720-01 and 469720-02. The registrant has submitted CSF's for basic and alternate formulations (both dated 10/30/06) and the product label. The registrant has claimed that the proposed product is substantially similar to the registered product with Reg. No. 64405-01. The TRB has been asked to determine whether the product chemistry data submitted support the registration of the proposed product and determine its similarity to the registered product.

**SUMMARY OF FINDINGS**

1. The proposed end use product contains Disodium octaborate tetrahydrate [REDACTED] as the active ingredient with the product label claim of 40.0%.
2. The CSF's for basic & alternate formulations (both dated 10-30-06) are filled out correctly & completely. The nominal concentration of the active ingredient concurs with the product label claim nominal concentration. The CSF's are in compliance with PR Notice 91-2. The CSF for alternate formulation is in compliance with 40CFR§152.43. The proposed certified limits for the AI and the inert ingredients are in compliance with standard certified limit table set-forth in 40CFR§158.175(b)(2). All the inert ingredients used in the formulation are cleared by the Agency. The data submitted corresponding to guidelines 830.1550 (product identity & composition) and 830.1750 (certified limits) satisfy the product chemistry data requirements of 40CFR§158.150 & 158.175 respectively [MRID No. 469720-01].
3. The data submitted corresponding to guideline 830.1600 (description of materials used to produce the product), 830.1650 (description of formulation process), and 830.1670 (discussion on the formation of impurity) satisfy the data requirements of 40CFR§158.160, §158.165 & §158.167 respectively [MRID No. 469720-01].
4. The data submitted corresponding to guideline 830.1800 (enforcement analytical method) satisfy the data requirements of 40CFR§158.180. The active ingredient (borate) in the sample was titrated with 1N HCl to an inflection point end point, using a combination pH electrode [MRID No. 469720-01].

5. The data submitted corresponding to guideline 830 series subgroup B (physical-chemical properties) corresponding to guidelines 830.6303 (color), 830.6303 (physical state), 830.6304 (odor), 830.6314 (oxidation-reduction), 830.7000 (pH), and 830.7300 (density) and 830.7100 (viscosity) satisfy the data requirements of 40CFR158.190 [MRID Nos. 469720-02].
6. The registrant has stated that the studies corresponding to guidelines 830.6317 (storage stability) and 830.6320 (corrosion characteristics) are in progress. It is recommended that the observations must be made at 0, 3, 6, 9, & 12 month intervals [MRID No. 469720-03].
7. The registrant has requested waivers for the following guidelines: 830.6302, -04, -6313, -6316, -6319, -6321, -7050, -7200, -7220, -7370, -7550, -7570, -7840, -7860, -7950.
8. The product label of the proposed product has the following Physical and Chemical Hazard warning, which does appear on the registered product.

Physical-Chemical Hazards: "Do not apply solutions of this product around electrical equipment, such as electrical conduits, motor housing, junction boxes, switch boxes, etc., due to the possibility of shock hazard".

#### **CONCLUSIONS:**

The TRB has reviewed the product chemistry data submitted for the proposed end use product and has concluded that:

1. The product chemistry data submitted corresponding to guidelines 830 Series Subgroup A and Subgroup B are acceptable, except for the guidelines 830.6317 (one year storage stability) & 830.6320 (corrosion characteristics).
2. The proposed CSF's for basic & alternate formulations (both dated 10-30-06) are acceptable.
3. The registrant should develop studies for the guidelines 830.6317(one year storage stability) & 830.6320 (corrosion characteristics). It is recommended that the observations must be made at 0, 3, 6, 9, & 12 month intervals. The results must be submitted in a hard copy and an electronic format is also requested.
4. The proposed product with File Symbol No. 81824-RN was determined to be substantially similar to the registered product with Reg. No. 64405-1 from product chemistry point of view.

PRODUCT CHEMISTRY DATA (SERIES 830 Subgroup A)

| Subgroup A  | <u>Data Required Fulfilled</u> | <u>MRID No.</u> |
|---|--------------------------------|-----------------|
| 830.1550. Chemical Identity (Basic & Alternate CSF's) | A                              | 10-30-06        |
| 830.1600. Beginning Materials                         | A                              | 469720-01       |
| 830.1650. Formulation Process                         | A                              | " " "           |
| 830.1670. Discussion of Impurities                    | A                              | " " "           |
| 830.1700. Preliminary Analysis                        | NA                             |                 |
| 830.1750. Certified Limits (Basic CSF)                | A                              | 10-30-06        |
| 830.1800. Enforcement Analytical Method               | A                              | 469720-01       |