DATE OUT: 17/ APR / 2003

SUBJECT: PRODUCT CHEMISTRY REVIEW OF TGAI / MP [X] EP [ ]
DP BARCODE No.: D287643 File Symbol No.: 74530-G PRODUCT NAME: Glyphosate Technical
COMPANY: Helm AG PCC: 417300

FOOD USE [ ] INTEGRATED FORMULATION [X]

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4-17-03

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INTRODUCTION:

The product chemistry data on the proposed glyphosate technical was reviewed previously (PCR dated 09-17-02, D23790). The registrant was informed of the following issues regarding the proposed technical: the proposed CSF and the product label must be revised, upper certified limit for a toxic impurity must be submitted, and data on few physical-properties (830.6313, 830.6320, and 830.7840) must be provided. The substantial similarity issue was pending, since one of the critical information was not available at the time when previous product chemistry report was written.

The registrant responded on November 22, 2002, submitted the revised CSF for basic formulation (dated 11-12-02) and the revised product label. The registrant also provided additional information on the toxic impurity and the required data on some physical-chemical properties. The product chemistry data has been submitted under MRID No. 458098-01. The TRB has been asked to evaluate the product chemistry data submitted by the registrant.

SUMMARY OF FINDINGS:

1. The registrant has submitted a revised and corrected Confidential Statement of Formula for basic formulation (dated 11-12-02). The nominal concentration of the active ingredient (97%) concurs with the product label claim nominal concentration. The CSF is in compliance with PR Notice 91-2. The data submitted corresponding to GRN 830.1550(Product identity & Composition), and 830.1750 (certified limits) satisfy the data requirements of 40CFR158.155 and 158.175 respectively.

2. The product chemistry data submitted corresponding to GRN 830.6313 (stability to normal & elevated temperatures, metal & metal ions), 830.6320 (Corrosion characteristics), and 830.7840 (solubility in water & organic solvents) satisfy the data requirements of 40CFR158.190.

3. The registrant has provided the upper certified limit for one toxic impurity (N-nitrosamine) present in the proposed technical.

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CONCLUSIONS:

The TRB has reviewed the product chemistry data submitted for the proposed technical and has concluded the followings:

1. The CSF for basic formulation (dated 11-12-02) is acceptable.

2. The data submitted corresponding to GUN 830.6313 (stability to normal & elevated temperatures, metal & metal ions), 830.6320 (Corrosion characteristics), and 830.7840 (solubility in water & organic solvents) are acceptable.

3. The proposed technical (74530-G) was determined not to be substantially similar to the registered technical product (Reg. No. 33660-37), since the amount of the toxic impurity present in proposed product is higher than the registered technical product. Also the density and pH for the two products are different. For details, please refer to Confidential Appendix.

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830.6313. Stability to normal & elevated temperatures, and metal & metal ions: [MRID No. 458098-01]

The TS was found to stable at 54°C for 14 days and up to 3 years under warehouse conditions.

The glyphosate technical is reactive towards metals. The reaction with alkali metal ions, such as sodium or potassium , forms the respective salt with glyphosate. Reactions with iron, mild steel and zinc result in glyphosate decomposing with the liberation of hydrogen gas.

[Note: The necessary warning has been put on the product label]

830.6320. Corrosion characteristics: [MRID No. 458098-01]

Glyphosate is corrosive to iron, mild steel, zinc and aluminum. Glyphosate technical is compatible with stainless steel, glass, and plastic.

830. 7840. Solubility in water & organic solvents: [MRID No. 458098-01]

The registrant provided the following information:

Solvent	Temperature (°C)	Solubility (mg/ml)
Water	25	15,700 (pH=7); 11,600 (pH=2.5)
Acetone	20	780
Dichloromethane	20	2,330
Ethyl acetate	20	120
Hexane	20	260
Methanol	20	2,310
n-octanol	20	200
2-propanol	20	200
Toluene	20	360

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.