UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

WASHINGTON, D.C. 20460

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

MEMORANDUM

DATE: February 6, 2007

SUBJECT: Secondary review of application for registration of Helena Phosphorous Acid Technical Fungicide, EPA File Symbol 5905-LAG. Active Ingredient: 99 % Phosphorous Acid (PC Code 076002, CAS RN 10294-56-1). Decision #: 370955. DP #: (334743). Draft CSF dated 09/26/ 2006. Draft label dated 09/20/2006.

REVIEWER: Nina Simeonova, Chemist
Biopesticides and Pollution Prevention Division (7511P)
Biochemical Pesticides Branch

TO: Driss Benmhend, RAL
Biopesticides and Pollution Prevention Division (7511P)
Biochemical Pesticides Branch

Action requested

On behalf of Helena Chemical Company, SynTech Global LLC requests registration of Helena Phosphorous Acid Technical Fungicide, EPA File Symbol 5905-LAG. The product is TGAI/MP, containing nominally 99 % Phosphorous Acid. It is produced in China by manufacturer not registered with EPA. The proposed product will be used to formulate agricultural fungicides. According to a statement in the cover letter, Helena Phosphorous Acid Technical Fungicide is similar to Agtrol AgriFos, EPA Reg. No. 55146-82.

In support of the request the applicant submitted the studies MRID 469650-01, 469465-02, 469465-03, 469465-04, 469465-05, 469465-06, draft CSF dated 09/26/06, certification with respect to citation of data, data matrix and draft label from 09/27/2006.

Conclusions and Recommendations

1. Some deficiencies identified in the submitted Product Chemistry studies need resolution, as follows:

- It is necessary to provide additional information about the production process, required under 40CFR158.162 (b) (1),(4) and (6) in order to better identify the starting materials [redacted] by the name and the address of the supplier. percentage purity, essential physical and chemical characteristics. This information must replace MSDSs from the foreign producer. The conditions (temperature, pressure) at different stages of the production are also required;

- It is necessary to provide additional data in support of the accuracy for the determination [redacted] It is known that this method is not recommended for samples, containing reducing or oxidizing agents;

- It is necessary to readdress the characteristics Chemical Incompatibility and Stability to Normal and Elevated Temperatures, Metal and Metal Ions in order to characterize better the product as acid, corrosive to metals, moderate reducing agent which can be oxidized to Phosphoric Acid and decomposes at 180 °C (the product is incompatible with bases, metals and oxidizers);

- In the CSF it is recommended not to identify the small amounts of [redacted] %) as Solvent and to set up the nominal concentrations and the certified limits according to the analytical results.

2. The waiver requests for acute toxicity studies, based on the acidity of Phosphorous Acid are acceptable according to 40CFR180.690(c) (II), as pH of 1 % water solution is determined to be 1.76.

3. The waiver requests for Nontarget. Organisms, Ecological Fate and Expression are not acceptable on the base of RED "Mineral Acids", EPA 738-F-93-025 from 12/1993. The document includes Phosphoric, Sulfuric, Hydrochloric Acid and Sodium Bisulfate, but not Phosphorous Acid. The cited 71FR49368 only establishes maximum application rates for Phosphorous Acid on stored potatoes. Acceptable rationale for waivers of ecotoxicity studies is that the acidity, corrosion properties and acute toxicity of Phosphorous Acid are similar to those of the reregistered Phosphoric Acid and it will be used only for formulation purposes.

4. The application for registration of Helena Phosphorous Acid Technical Fungicide, EPA File Symbol 5905-LAG is unacceptable, but upgradeable, provided the deficiencies, mentioned above, are resolved.

Studies Summary

MRID 469650-01. Preliminary Analysis of Phosphorous Acid Technical. The study contains the results from analyses of 5 batches of the product, each identified by Lot # and number, assigned by the performing laboratory. The percentage of the active ingredient is determined by two different methods – iodometric titration and determination of acidity. The iodometric titration provides slightly higher results. The

quantities of the manufacturing impurities [redacted] The study contains also a protocol for the tests and copies of SOPs for the applied analytical methods

MRID 469485-02. Product Identity and Composition. Description of Materials, used to produce the Product. Description of the Production Process. Discussion of Formation of Impurities. The study contains identification of the active ingredient by chemical name, CAS #, molecular formula and molecular weight. It contains in Confidential Attachment identification of the stating materials by chemical name, CAS # and percent purity, description of the continuous manufacturing process and discussion of formation of impurities

MRID 469465-03. Volumetric Determination of Phosphite. The study contains a copy of the SOP for determination of water soluble phosphites by iodometric titration. The precision of the method is determined in previous study with test material 70 % Phosphorous Acid. It was determined that the standard deviation for determination of Phosphorous Acid is 0.13 %.

MRID 46945-04. Physical and Chemical Characteristics of Phosphorous Acid Technical. The study contains results from visual determination of Color and Physical State. pH of 1 % solution in water (w/w) is determined to be 1.76. UV/VIS Absorption is studied at acidic, neutral and alkaline conditions. Melting Point, Bulk Density, Dissociation Constants, Water Solubility, Oxidation/Reduction and Chemical Incompatibility are addressed by data for the pure compound, found in the public literature – Lange's Handbook of Chemistry, CRC Handbook of Chemistry and Physics, the Merck Index. The remaining characteristics, required for TGAI/MP are listed as not applicable for the product.

MRID 469465-05. Helena Phosphorous Acid Technical Fungicide Acute Toxicity Data Requirements. The study contains waiver requests for Acute Oral, Acute Dermal and Acute Inhalation Toxicity, Primary Eye Irritation, Primary Skin Irritation and Skin Sensitization. The rationales for the waivers are the acidity and the corrosive properties of Phosphorous Acid.

MRID 469465-06. Helena Phosphorous Acid Technical Fungicide. Rationale and request for data waivers. The study contains waiver requests for Tier I Ecotoxicity studies based on RED "Mineral Acids" and 71FR49370.

cc: N. Simeonova to D. Benmhend, BPPD Subject File, IHAD Database.
N. Simeonova, PY1, 703-308-0291. 02/06/2007.

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HED Records Reference Center
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